

Table of Contents

Asia-Pacific	3
AUSTRALIA	4
CHINA	9
HONG KONG	13
INDONESIA	15
JAPAN	18
KOREA	24
NEW ZEALAND	32
PHILIPPINES	43
SINGAPORE	49
TAIWAN	51
THAILAND	64
VIETNAM	71
 Europe	 82
BELGIUM	83
CZECH REPUBLIC	87
ESTONIA	90
EUROPEAN UNION	91
FRANCE	94
GERMANY	97
HUNGARY	98
LITHUANIA	102
POLAND	104
RUSSIA	111
SLOVENIA	113
UNITED KINGDOM	117

Middle East/Africa/South Asia	120
EGYPT.....	121
GULF COOPERATION COUNCIL	124
INDIA.....	129
ISRAEL.....	135
MOROCCO.....	138
PAKISTAN.....	141
SAUDI ARABIA	147
SOUTH AFRICA.....	150
TURKEY.....	153
UNITED ARAB EMIRATES	157

The Western Hemisphere	160
ANDEAN COMMUNITY (BOLIVIA, COLOMBIA, ECUADOR, PERU, VENEZUELA).....	161
ARGENTINA	167
BRAZIL	171
CANADA.....	174
CENTRAL AMERICA	180
CHILE	183
DOMINICAN REPUBLIC	185
MEXICO.....	187
URUGUAY.....	189

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA
(PhRMA)**

**FOR THE
NATIONAL TRADE ESTIMATE REPORT
ON FOREIGN TRADE BARRIERS (NTE)**

2001

November 27, 2000

Asia-Pacific

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

AUSTRALIA

Intellectual Property Protection

Patent Term Length

PhRMA considers it essential for an adequate patent life to be afforded to pharmaceuticals in Australia, as in the rest of the world. Many members of PhRMA's International Section maintain affiliates in Australia, and consider Australia an important country in their overall global business and investment planning. PhRMA welcomes recognition by the Australian Government of the importance of patent protection to the pharmaceutical industry, particularly to encourage research, development and investment in Australia.

In 1998, the Australian Government enacted patent term extension for pharmaceuticals by up to five years, in order to bring Australia into line with international practice. The new policy applies to patents that were still viable as of July 1, 1999. The five year extension makes possible an effective patent life of 15 years. Where patent extensions are granted, "springboarding" or Bolar-type provisions will apply, so that generic manufacturers are able to do all necessary testing of their products before the expiration of the innovator's patent rights.

The Australian Government long has viewed any extension for *existing* patents as a "windfall" for the industry, as several companies could benefit from the immediate extension of the patent life for their products. It therefore made the commitment to offer generic firms a "springboarding" benefit in exchange for the "benefit" to the research-based industry of patent term extension. However, the Australian Government overlooked at least two issues in this regard:

- (1) that the market launch of pharmaceuticals in Australia is delayed by the complex and lengthy requirements in a strict cost containment environment, which includes the submission of "cost effectiveness" data; and
- (2) that economic returns from currently marketed products in Australia provide the funding

for future research and development (R&D), so patent term restoration applied to current products on the market in Australia will provide the foundation for investment to support future R&D in that country.

PhRMA does not agree with the necessity of maintaining a “springboarding” provision that basically undercuts the current value of intellectual property protection in Australia, and certainly does not agree that a “springboarding” provision is needed to “compensate” for the value of patent term restoration.

Protection of Proprietary Data

PhRMA applauds the recent enactment by the Australian Government of a law governing data protection that commits Australia to abide by the WTO TRIPS Agreement. PhRMA hopes that the Australian Government would provide protection for confidential data to all chemical entities, to the extent a particular use for which approval is sought has not been granted approval for that particular entity. This should include new indications for entities already approved, in addition to the first approved usage.

Furthermore, while the Australian Government has moved to provide five years of data protection for new chemical entities in the first instance, PhRMA believes that this period of protection should be ***ten years from the date of marketing approval***, to allow for the additional time that it takes for a product to be listed on Australia’s Pharmaceutical Benefits Scheme (PBS), which is the list of products eligible for reimbursement by the Australian Government. If the period of data protection begins before this date, the effectiveness of such protection would be eroded through the lengthy time needed for listing approval.

Pricing and Cost Containment Policies’ Impact on IPR and Market Access

The Australian Government operates effectively as a monopsony purchaser of prescription pharmaceuticals through its operation of the Pharmaceutical Benefits Scheme (PBS). The PBS system accounts for approximately 80% of total prescription drug sales. The PBS aims to provide reliable and affordable access to medicines for the Australian community. Under the PBS, capped co-payments and safety net provisions limit the cost of pharmaceuticals to consumers, with the Government paying the remainder.

The Industry Commission Inquiry into the Pharmaceutical Industry (May 1996) found that “the Government’s use of market power saves taxpayers up to \$A860 million a year.” In effect, the industry thus subsidizes taxpayers to this extent.

In recognition of this price suppression, in April 1997, the Australian Government announced the Pharmaceutical Industry Investment Program (PIIP), under which the Government will allocate A\$300 million over the next 5 years to eligible companies in return for activity.

One month later, in May 1997, the Australian Government announced its intention to introduce Therapeutic Group Premiums (TGP) (reference pricing) from February 1, 1998, for certain classes of drugs which have “similar clinical activity.” For each of these classes, a base or benchmark price was established. The Government reimburses drugs in the class to the level of the base/benchmark price product. For other drugs in the class, patients have to pay any additional premium.

Originally, six classes of drugs were proposed for the TGP; however, strong opposition by industry and medical groups to the inclusion of beta-blockers and SSRIs resulted in their exemption from the TGP. The four remaining classes affected by the TGP include: ACE inhibitors and calcium channel blockers used to treat high blood pressure and heart disease; the HMG class of drugs for treating high cholesterol; and H2 receptor antagonists for the treatment of ulcers.

The Government hopes to achieve PBS savings of A\$460 million over 4 years, through the introduction of TGPs. The TGP proposal is expected to return to Government revenue almost double the average A\$60 million per year foreshadowed in the PIIP.

The TGP proposal should be considered in the context of Australia’s mandatory cost effectiveness criteria, under which manufacturers must already justify the price of their drug through economic and therapeutic evidence, in order to gain reimbursement.

The research-based pharmaceutical industry maintains the position that there are several reasons why TGPs are not appropriate in the Australian reimbursement system. More specifically, TGPs:

- contradict the principle of evidence-based medicine;
- do not recognize that some products are not interchangeable, and that individuals do not necessarily respond in an average or predictable way;
- shift costs to other arms of the healthcare system;
- tend to create a two-tier system of drug access;
- send a negative message to industry because prices in the Australian market are already low;
- discourage R&D and marketing of the latest products;
- result in loss of investment and employment;
- undermine the principles of patent protection.

Impact on intellectual property

The TGP system effectively negates the economic value of the entire remaining patent life of a patented medicine in the affected classes. This occurs through a combination of the way in which the proposal operates and the culture of the Australian health care system. The system involves the grouping of newer patent-protected products with generic versions of older molecules within a therapeutic class (e.g. generic captopril is

grouped with patented enalapril; generic Cimetidine is grouped with patented famotidine).

The benchmark product/price for each class is likely to be set by a generic product – in effect, this generic product becomes the ‘*de facto*’ generic for all other patented products in the class, regardless of patent life. The Government will reduce the level of reimbursement it currently provides to all products in the class to that of the benchmark product. The Government claims that the TGP system allows manufacturers to charge whatever price they wish – a claim that is theoretically correct.

However, the PBS, which has operated for over 50 years, has created a climate *in which free medicine (apart from the co-payment to Government) is seen as the norm*. Market experience has shown that consumers are unwilling to pay more than a A\$2 premium for any medicine (in addition to any co-payment).

Given this environment, manufacturers have the choice of maintaining their current prices and losing substantial volume, or reducing their price and revenue. In either case, the economic return is substantially less than would otherwise have occurred in the absence of TGPs. The reduced return is sustained throughout the remaining life of any patent, devaluing the value of the intellectual property.

Impact on market access

In the Australian context, market access effectively equates to reimbursement. This is because the PBS system accounts for approximately 80% of total prescription drug sales.

The 1996 Australian Industry Commission inquiry found evidence that community access to some drugs was adversely affected by the PBS; and that while Australia has not suffered too much in this area, the position is unlikely to be sustainable because when low prices are taken into account, the overall impact of the PBS has been to reduce sales revenues of some companies, increasing the risk of non-supply.

The introduction to TGPs inevitably will lead to increased risk of non-supply. As Paul Gross, a consultant to the research-based industry, concludes in his report, “There is serious concern amongst pharmaceutical manufacturers that a second stage of TGP pricing in Australia might attempt to use the price relativities established in prior economic appraisals of different drugs (cost effectiveness analysis) to readjust the first year relative prices between reference priced and non reference priced drugs. Such an adjustment would debase both future and past economic appraisals of drugs on the PBS and places manufacturers in double jeopardy when an arbitrary price control scheme (i.e., TGP) is superimposed on the more objective world recognized economic appraisal guidelines.”

A concise example of Gross’s conclusion is where a new proton pump inhibitor would have to prove cost effectiveness against generic Cimetidine. Given the low price of

Cimetidine, it will be hard to justify cost effectiveness to a level sufficient to make it economically worthwhile for a manufacturer to gain reimbursement of the PPI. The likely outcome is that the PPI will not be reimbursed because the subsidy offered by the Government is too low, and the product will not be made widely available to the Australian community. Market access is effectively denied.

Conclusion

Australia's offer because this is particularly
undermining

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

CHINA

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies in China continue to face significant challenges and problems in China as that country finalizes its negotiations with World Trade Organization (WTO) member countries to prepare the way for its accession to the WTO. The major challenges may be found in the broad areas of intellectual property protection, the pricing and reimbursement of medicines and the technical regulation governing the approval of medicines for human use. Some improvements have been made in the operating environment for PhRMA member companies in China since China enacted intellectual property laws in 1993, but significant problems remain. In particular, inadequate intellectual property laws and the poor implementation of China's "Administrative Protection" program (i.e., pipeline protection) for pharmaceuticals pose a serious public health risk, and serve to undermine the competitive advantage that innovative companies gain from their substantial investments in research and development.

Intellectual Property Protection

Administrative Protection

In 1993, the United States and China signed a Memorandum of Understanding (MOU) to allow Administrative Protection (AP) in China for American pharmaceutical patents granted between 1986 and 1992. The Chinese government then extended this MOU to include the European Union (EU) countries and Japan.

The MOU provides seven and one-half years market exclusivity, or AP rights, in China for pharmaceutical patents that:

- were not subject to protection by exclusive rights prior to the amendment of current Chinese laws;
- were patent protected between January 1, 1986 and before January 1, 1993 in an MOU signatory country; and
- were not previously marketed in China.

Due to a number of policy initiatives put forward by the Chinese government, industry has realized few of the benefits intended under the MOU. These include:

- Notice 72: this regulation, not intended under the MOU, allows local companies to submit and gain registration during the evaluation period to market products free of punishment for infringement. In addition to the prolonged delays companies experience during the application process, Notice 72 has caused member companies to lose significant revenue and market share to local generic companies, and has frequently resulted in the outright denial of AP rights by the State Drug Administration (SDA).
- One Drug, One Indication: a new policy interpretation recently advocated by the Office of Administrative Protection within the SDA that would limit the scope of AP to the original utility listed in the pharmaceutical patent. This policy has never appeared in written form and conflicts both with the 1992 MOU and general patent law principles which allow exclusive rights to the invention so as to encourage new and innovative uses for the product during the patent life.

Recommendations

PhRMA Member Companies have lost significant revenue and market share in China from inadequate AP rights. Because of the harm incurred by industry, we urge the United States Trade Representative (USTR) to continue to make Administrative Protection rights a high priority trade issue with the Chinese government.

Policies such as Notice 72 and the “one drug, one indication” policy, are inconsistent with the 1992 MOU and should be repealed immediately.

Counterfeit Pharmaceutical Products

A growing concern of foreign companies operating in China is the significant increase in counterfeit pharmaceutical products. While it is difficult to gain a clear understanding of the extent of the counterfeit pharmaceuticals in China, it is believed that the innovative pharmaceutical industry loses roughly 10 to 15% of annual revenue in China due to counterfeit products. In addition to lost revenue for industry, this issue has very serious implications in the area of public health and safety.

PhRMA has taken an aggressive and cooperative approach in trying to reduce counterfeit pharmaceuticals in China. A number of companies have formed an *Anti-Counterfeiting Coalition* in which participant companies jointly conduct proactive market sampling and surveillance, as well as raids on suspected counterfeit manufacturers and distributors. Detection and enforcement, however, are expensive and difficult, and cannot be accomplished by industry alone. We would like to work as a partner with the Chinese Government to eliminate counterfeit pharmaceuticals, and urge the Chinese Government to make this a high priority issue.

Apart from posing a serious threat to public health, the proliferation of counterfeit medicines could lead to further downward pressure on the prices of innovative U.S. and European medicines, particularly if China adopts some form of reference pricing.

Recommendations

While the State Drug Administration has promulgated an administrative sanctions law and established a small anti-counterfeiting office, few resources have been allocated for anti-counterfeiting efforts. We urge the Chinese government to:

- allocate more resources to anti-counterfeit pharmaceutical initiatives;
- as the licensing authority of pharmaceutical manufacturers, the SDA should commit to random, unannounced searches of pharmaceutical operations; and
- enact mandatory criminal prosecution and jail time for convicted counterfeiters.

Patents

After a foreign company receives patent protection on a pharmaceutical compound in China, it is all too common to find that the SDA has allowed local companies to conduct clinical trials on the patented compound. These clinical trials are conducted without the permission of the patent holder, and thus constitute patent infringement.

Recommendations

When a patent is issued in China, it should be the responsibility of all ministries and agencies in the Chinese government to uphold and enforce the rights of the patent holder. With regard to pharmaceuticals, clinical trial authority should be denied if the compound is under patent and the applicant to conduct clinical trials has not first obtained the express written permission of the patent holder.

Barriers To Market Access For Patented Pharmaceutical Products

Price and Profit Controls/Protectionism

Pharmaceutical products are considered special commodities in China and thus subject to price controls. In 1997, pharmaceutical price jurisdiction was vested in the State Development and Planning Commission (SDPC). Since that time, the SDPC policy or guidelines for establishing pharmaceutical prices have been in a continuous state of change and this has therefore become an area of great concern and unpredictability for pharmaceutical companies. Experience has proven that pharmaceutical price controls discourage innovation and high quality manufacturing, and often result in unintended consequences such as discouraging the timely introduction of innovative products in the marketplace, and maintaining artificially high prices in the generic pharmaceutical sector.

SDPC pricing policy has changed significantly in the past two years and reflects some of the recommendations advocated by the international industry. While the SDPC originally intended to set rigid margin controls at each stage of the distribution chain, a policy change implemented last year focused on the *end retail price* while continuing to monitor margins at the distributor and hospital level. In the event that the SDPC found distributor and hospital margins to be excessive, it reserved the right to cut the product's retail price.

In July 2000, the SDPC promulgated the *Guidelines for Drug Price Administration*. This new policy is encouraging as it immediately allows free market pricing for some products and implies that use of the free market will be gradually expanded. This policy raises new concerns, however, as the SDPC has abrogated a substantial share of its pricing authority to the provincial and local governments. Further, these new regulations set forth the following principles for consideration in establishing pharmaceutical prices:

- Innovative v. Generic; GMP v. non-GMP; and Brand v. non-Brand;
- Imported drug prices should be referenced to locally manufactured drug prices or to the prices in countries at roughly the same level of economic development as China.

This new policy will result in a number of unanticipated and unintended consequences, not least of which are higher operating costs for companies as new pricing departments and personnel are added in order to negotiate with the many regional government-pricing authorities. Additionally, as the SDPC reserves the right to order a price cut, a company may be discouraged from offering higher volume discounts as this could result in an across-the-board price cut for the company's product nationwide. Finally, this new policy theoretically allows provincial and local governments to maintain higher government-established prices for locally produced products. This could exacerbate provincial and local protectionism, which would contradict one of the key policy goals of the central government as China pursues entry into the World Trade Organization (WTO).

Conclusion

PhRMA and its member companies in China continue to face challenges in China with regard to Intellectual Property Rights protection, the pricing and reimbursement of pharmaceuticals and the technical regulation governing the approval of medicines for human use.

Potential sales/Foreign exports

PhRMA is currently studying methodology for estimating damages caused by the aforementioned trade barriers in China. Current estimates of losses in China approximate \$800 million.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

HONG KONG

Intellectual Property Protection

PhRMA is concerned that the Hong Kong Department of Health recently approved 14 generic compounds which the research-based industry in Hong Kong believes infringes the patents of the originators, including Proton Pump and HMG CoAg Reductase Inhibitors. Some of these products, as we understand, were approved partly on the basis of information in the originator's regulatory dossier, which is allowed within certain limits through existing regulations of the Department of Health (DoH).

The research-based industry in Hong Kong is pressing for legislative amendments to close what we believe is an unacceptable loophole in this regard. PhRMA believes that the Hong Kong DoH should review the patent life of any product that comes up for approval in the Special Administrative Region (S.A.R.) of Hong Kong. The Hong Kong DoH should not approve products which infringe the patent of the originator of the product in Hong Kong, and should limit the use of the originator's dossier in seeking such approval.

PhRMA also is concerned that some pharmaceutical products, imported from various countries, including Malaysia, Indonesia and Greece, have not received official regulatory approval in Hong Kong. Although the imports are recorded upon entry, if they are officially designated for re-export (i.e., often to China), there is no requirement that they be approved in Hong Kong, or for the presentation of records on whether, and in what quantity, the shipments have left the S.A.R. This, we believe, has led to the diversion of substantial quantities of non-approved products to the local market in Hong Kong. This, in turn, has eroded the market exclusivity of the patented medicines of PhRMA member companies in Hong Kong.

Market Access Barriers to Patented Pharmaceutical Products

Regulatory Delays

PhRMA is concerned that new procedures for the approval of prescription drugs will delay access to innovative medicines from PhRMA member companies for patients in

Hong Kong. Under recent changes in drug approval regulations, prescription product approvals, rather than marketing being allowed immediately after approval by the Pharmacy and Poisons Board, will not be granted until the forensic classification by the Legislative Council is cleared and officially gazetted. The research-based industry in Hong Kong believes that the requirement could double approval times to eight months. PhRMA is concerned that further approval delays will shorten effective patent life, reduce returns on research investment and delay patient access to new therapies.

Potential Sales/Foreign Exports

PhRMA is studying methodology for estimating damages caused by the aforementioned trade barriers in Hong Kong. It is not possible at this time to estimate the financial impact of the aforementioned barriers on the research-based pharmaceutical industry in Hong Kong.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

INDONESIA

The economic and political turbulence has continued into 2000 despite changes in the political arena under President Wahid. There seems to be little will to make the necessary adjustments to encourage investment, repatriation of funds or elimination of corruption in government and business circles. The currency began the year stronger at Rp7000 to U.S. Dollar but weakened as the year progressed to Rp8500/U.S. Dollar by August. The key issues affecting the U.S. Research Based Pharmaceutical Industry more or less remain the same with some progress being made in certain areas.

The key issues are:

- A. New Chemical Entities (NCE) or Pharmaceutical product registration by the Indonesian Food and Drug Administration (Dir.Jen POM) has been modified under a new regulation. However, no real progress has been seen yet as the old “crash program” remains incomplete. Discrimination against imported products in the product registration process also continues to be a problem for PhRMA member companies.
- B. Intellectual Property Rights (IPR); A new Patent Law amendment is drafted and is before parliament. The new amendment is not fully TRIPS compliant but goes further to strengthen the industry position.
- C. Marketing practices of foreign/domestic industry remain an issue limiting the U.S. companies' ability to compete fairly. Government has recently voiced concerns and is discussing legislation in this area.
- D. Counterfeiting and Smuggling are still rampant and not controlled by the relevant authorities.
- E. Other issues: There are also problems in connection with the protection of trade secrets and with taxation.

NCE and Pharmaceutical Product Registration

It has taken 18 months to persuade the Director General of POM Drs Sampoerno that a new, more efficient system of New Drug Registration was necessary. Following consistent pressure from the International Pharmaceutical Manufacturers Group (IPMG) and Foreign Embassies a new system was announced in July 2000. It looks very similar to the one proposed by IPMG with cosmetic adjustments. However, three major issues are yet to be clarified and resolved:

1. The timetable of the approval process (Number of working days for completion).
2. The cost of the applications (NDA Tariff system).
3. The documentation required to determine the pathway. (Summary basis of approval/EPAR or Independent Assessment Reports).

With approvals now taking over 2 years under the old system it is hoped that this new process will be implemented before too long.

PhRMA also objects to the discrimination against imported products in the process of registration. In principle, the Indonesian FDA grants registration only to locally manufactured products. Import licenses can be obtained for the following 'categories': (i) life saving, (ii) cannot technically be produced locally, (iii) extremely low volumes, (iv) export of locally manufactured product larger than imported volume. Licenses are issued for 2-year periods after which extensions can be obtained but only after a full re-review of the case.

Many years ago, only companies that specifically invested in Indonesia in Manufacturing Units could hold product/marketing licenses and therefore be a "Market Company." No investment in manufacturing meant that the company concerned had to appoint a local or foreign licensee (who had a factory). Many companies still do this today through a local distributor.

PhRMA believes that the Indonesian local manufacturing requirement may be a violation of the WTO. In general, the WTO (GATT Article III) flatly prohibits local manufacturing/local content requirements. This prohibition includes measures that condition import licenses or investment approvals on local manufacturing or local content plans/commitments.

Intellectual Property Rights

The new Patent Law amendment of 1999/2000 is presently before Parliament but is not expected to be approved in the immediate future. The modifications to the existing law are positive although there are sections that remain non-compliant with TRIPS. IPMG, however, now recommends that all research-based companies file for Product and Process patents for NCEs in Indonesia within one year of the country of origin/discovery

application. IPMG is also working on proposals to modify the present amendment to make it more TRIPS compliant. Implementation of all IPR laws will remain the major hurdle for foreign companies operating in Indonesia.

Marketing Practices

During 2000, the official GP Farmasi congress, held in Bali, approved the 1999 Code of Pharmaceutical Marketing Practices. It was, however, not made compulsory and therefore is only IPMG members implemented it. The Ministry of Health (MOH) have been critical recently of the Pharmaceutical Industry, in general, for high prices and unethical business practices and they have requested the Dir.Jen POM to draft new regulations on these issues. IPMG are monitoring the situation carefully and will continue their dialogue with POM. We do not expect any dramatic improvement in business and marketing practices in the short-term.

Counterfeiting and Smuggling

These practices continue unabated and in fact have probably become more commonplace with the deterioration in the economic and political arenas in Indonesia. No quick fix seen in the near future.

Other Issues

Trade Secrets

The lack of protection of trade secrets remains an issue for the pharmaceutical the industry.

Taxation

There is no change from last year, although there are fewer taxation problems with respect to exporters. Expatriate/Foreigner taxation is a possible future issue.

Conclusion

PhRMA and its member companies in Indonesia face difficulties with New Chemical Entities, Intellectual Property Rights, marketing practices, and with counterfeiting and smuggling.

Potential Sales/Foreign Exports

PhRMA is studying methodology for estimating damages caused by the aforementioned trade barriers in Indonesia. The current estimate of losses to the U.S. pharmaceutical industry is approximately \$87 million.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

JAPAN

Deregulation Initiative

Japan is the second largest single market for pharmaceuticals worldwide. Over the past decade, significant regulatory barriers to new product approval developed, leading to an extensive drug lag in which 120 global products launched worldwide since 1985 remain unavailable in Japan.¹ In 1996, an industry survey revealed that on average, new drug approvals in Japan (JNDAs) were taking 26 months for review, compared to 18 months in the United States, the UK and Germany. Average review times further decreased to 12 months in the U.S. in 1997.

As a result, in 1997, the U.S. Government agreed to include the pharmaceutical sector in the U.S. - Japan Enhanced Initiative for Deregulation and Competition. The Government of Japan has taken a series of deregulatory measures, the latest and the most significant being the adoption on March 31, 2000 of the final revisions to its Three-Year Programme for Promoting Deregulation. The salient deregulatory and other measures that relate to the dialogue under the Enhanced Initiative include the following issues:

1. **Recognition of Innovation:** Reaffirm the value of innovation of pharmaceuticals and medical devices, so as not to impede the introduction of innovative products which bring more effective and more cost-effective treatment to patients.
2. **Approval Process:** The speed of the New Drug Application (NDA) approval process has been improved recently and review times are decreasing. The Ministry of Health and Welfare (MHW) has shortened the standard processing period for NDAs to 12 months since April 1, 2000. MHW will allow for the submission and review of an NDA for an additional indication, and for partial change, as well as for the continuance of clinical work, while the NDA for the molecule's initial indication is still pending. MHW abolished the Sub-Committees of the Central Pharmaceutical

¹ Draft Study by L.G. Thomas III, *The New Drug Lag: Barriers to the Japanese Pharmaceutical Market*, 1998.

Affairs Council in November 1999 and strengthened a team-review system in the Pharmaceutical and Medical Devices Evaluation Center. MHW will continue to offer opportunities, as appropriate, for applicants to discuss their NDA's with senior MHW officials. MHW has divided the Special Committee on Drugs of the Central Pharmaceutical Affairs Council into two bodies that will meet for up to 16 times-a-year. MHW has established a Special Committee to review In-vitro Diagnostics (IVD). MHW will maintain dialogue with applicants so that they may have some sense as to how long it will take to process an individual medical device or new drug application.

3. **Acceptance of Foreign Clinical Data:** the Government of Japan provides opportunities for consultation with the Organization for Pharmaceutical Safety and Research (OSR) to promote the facilitation of acceptance of foreign clinical data based on International Conference on Harmonization (ICH) E5 guidelines. MHW notification issued in November 1999 clearly provides protection of rights of individuals and companies, including protection of business proprietary information, when the data as well as patient records are made public after product approval. MHW affirms that on a case-by-case basis, it is possible to submit a bridging data package, as defined by ICH E5 Guidelines, without a new bridging study in order to obtain product approval, if ICH and Good Clinical Practices (GCP) - consistent data for extrapolation are available to confirm comparability. MHW notification issued in August 1998, based on ICH guidelines, resulted in the expanded acceptance of foreign clinical test data for the approval of new pharmaceuticals. The Government of Japan has accepted clinical test data for the approval of new medical devices and pharmaceuticals that meet GCPs, regardless of origin, whether domestic or foreign.
4. **The Reimbursement Process:** An appeals process for medical device and pharmaceutical pricing decisions was implemented in October 2000. Judgments will be based on the appropriate and accurate application of pricing rules, which are set out in writing. MHW will ensure that members serving on the Drug Pricing Organization (DPO) and the Special Organization for Insurance-covered Medical Materials have objective scientific expertise and no conflicts of interest, and that they take into account the opinions of related parties.
5. **Transparency:** To ensure transparency in the consideration of health care policies, foreign pharmaceutical and medical device manufacturers will continue to be provided, upon request, with opportunities to state their opinions in the relevant Councils and relevant study groups on an equal basis with Japanese manufacturers, including foreign manufacturers, and MHW will make maximum efforts so that such opportunities will be meaningful.

These commitments made in 2000 are evidence of the Japanese Government's good faith efforts to engage in positive reform; they were built upon earlier commitments in the Enhanced Initiative negotiations, beginning at the Birmingham Summit of G-8 countries

in May 1998. There, Japan's Government made significant commitments to facilitate market access and deregulation on four specific points related to pharmaceuticals sector regulatory and pricing mechanisms:

1. **Recognition of the value of innovation of pharmaceuticals and medical devices**, so as not to impede the introduction of innovative products which can bring more effective, safer and cost-effective treatments to patients.
2. **Transparency in the consideration of health care policies**: The Government of Japan committed to allowing foreign pharmaceutical and medical device manufacturers meaningful opportunities to state their opinions in the relevant councils on an equal basis with Japanese manufacturers (*"yuigi-na iken hyomei-no kikai"*), and providing them on their request with opportunities to exchange views with MHW officials at all levels.
3. **Shortening of the approval processing period for new drug applications** to 12 months by April 2000, with steady and continuous improvement between now and then, and to further speed the introduction of innovative new pharmaceuticals, significantly shorten review times, particularly for priority drugs.
4. **Expansion of the acceptance of foreign clinical test data for pharmaceuticals** through the incorporation of International Conference on Harmonization guidelines into Japanese regulations by August 1998, and adoption of an acceptance process that is transparent and avoids inappropriate delays.

In June 1999, the Japanese Government further committed to deregulation and valuation of innovation in the Enhanced Initiative with amended language stating that:

"recognizes the value of innovation of pharmaceuticals so as not to impede or prevent the introduction of innovative pharmaceuticals which bring more effective and more cost-effective treatments to patients, and continues to study the pharmaceutical pricing system with related parties, including the U.S. industry, recognizing the role of the market."

Again, these changes are evidence of the Japanese Government's good faith efforts to meet commitments in the Enhanced Initiative. There are still, however, a number of areas where continued engagement is needed to resolve issues both in regulatory and on reimbursement pricing. The following provides a review of Japan's status on regulatory and reimbursement pricing deregulation to date.

Regulatory Barriers

Industry is actively working with MHW as it progresses to ensure reform of

regulatory framework. Areas of current focus and interest are the acceptance of foreign clinical data (issues surrounding the implementation of the ICH E5 guideline on Ethnic Factors in the Acceptability of Foreign Clinical Data), implementation of the a 12 month review time for New Chemical Entities (NCEs) through the introduction of a new New Drug Application (NDA) review process, and a new Post Marketing Safety Surveillance System (PMS System) that MHW has recently proposed.

The implementation of the ICH E5 guideline by MHW in August 1998 paved the way for NDAs to be filed with MHW supported by foreign (non-Asian) clinical data. Until the implementation of this guideline, companies were required to repeat costly and time consuming Phase III clinical trials in order to obtain drug approval in Japan. However, the implementation process has not been smooth, and industry has many concerns regarding the interpretation and practical implementation of this guideline by MHW. Experience to date suggests that MHW still require small, specific studies ('bridging studies') to be carried out in support of an application containing foreign clinical data, rather than accepting the data already generated by the company (the 'bridging package'). Furthermore, industry is concerned that MHW appears to require clinical data from Japanese patients, and will not accept 'Asian' data (ICH considers only three ethnic populations of clinical significance – Asians, Blacks and Caucasians; further country population stratification of these groups is not scientifically justified). Until these issues are resolved companies will continue to experience additional costs and delays entering the Japanese market.

MHW has recently made public a detailed description of its new NDA review process which will allow it to achieve the 12 month review period targeted from April 2000. The implementation of this process will need to be closely monitored, particularly with regard to what is, and is not, included by MHW when counting the 12 month period. This monitoring requires the introduction of clearly defined metrics, agreed to by both industry and MHW, and compiled by an independent third party.

A notification from October 1999 concerning the public disclosure of sections of the NDA via the MHW website remains a significant concern for the industry. While MHW has verbally assured PhRMA that disclosure will only be with prior consent of the application, this should be clearly stated in the regulations. Companies must be assured that MHW will adequately protect their intellectual property that is provided as part of the NDA submission. This is of heightened concern with the recent completion of the Common Technical Document (CTD) by ICH. This will allow a common technical data set to be submitted in the US, EU and Japan for an NDA, and hence disclosure in one region would compromise IP across the three regions.

MHW has recently announced an initiative in the area of Post Marketing Surveillance (PMS). PMS is a broad term that describes many activates (both mandated and non-mandated) undertaken by both government and industry to monitor drugs in the general population once approved by the authorities. The primary objective of such studies is to monitor the occurrence of adverse events (side effects etc) caused by the drug when a

large population is exposed, and hence protect public health. The exact nature of MHW's initiative in this area is unclear. The initial paper MHW published detailed a system of considerable concern to industry, and one that would place a far greater burden on non-Japanese industry than on local industry. Through a dialogue with MHW PhRMA presented alternative systems which MHW seemed to support, although the latest description of the system, published in Japanese, is still not acceptable to industry. This situation needs to be monitored. Industry fully supports PMS, but any system introduced must be consistent with international standards, and not unfairly burden any part of the sector.

Pricing and Reimbursement Barriers

A good portion of the early years of the MOSS discussions targeted trade barriers within the drug approval process; however, market access barriers by means of the reimbursement pricing system have increased significantly over the past several years, and as a result, are now a major portion of the MOSS agenda. Under the Enhanced Initiative, the commitments related to reimbursement pricing include recognition of the value of innovation and the role of the market, transparency and access to all relevant councils and officials involved in policy reform.

To date, most of the reforms proposed by MHW have involved significant price cuts to innovative medicines, compromising the ability of the industry to obtain rewards for investment in innovation and market access for new medicines.

PhRMA currently is making a concerted effort to articulate its views on various measures that are needed in Japan to effect a meaningful drug benefit and health care reform that the Government of Japan has announced it is intending to achieve by April 2002.

In this effort, PhRMA has articulated the view that the current NHI drug pricing system was originally intended to achieve optimal drug pricing in a regulated environment, including providing rewards and incentives for innovation. As often occurs in controlled systems, however, many of the regulations have led to results that are entirely unintended by the original regulation. Notable examples are the biennial and other price revisions, the new product comparator pricing method and the price premium rules. Together, they form a vicious cycle of unintended consequences that undermine the economic incentive to create and introduce innovative pharmaceuticals in the Japanese market, particularly by comparison to pro-innovation policies in the US and Europe.

PhRMA believes that, in particular, the following principles should govern comparator selection and premiums in Japan's reimbursement system. The system should:

1. **Ensure objective, global scientific standards:** A comparator for a newly approved drug should be from the same pharmaceutical class i.e. from a class with the same anatomic, therapeutic, pharmacological and chemical properties as

determined by objective, global scientific standards.

2. **Recognize innovation:** Products with new anatomic, therapeutic, pharmacological, and chemical properties should not be compared with existing therapeutic approaches.
3. **Provide Transparent Process and Predictable Outcomes:** Predictable rewards for innovative drugs are essential to manage and help offset the high risk involved with drug discovery and development. An unpredictable and non-transparent pricing system that does not consistently recognize and reward innovative products creates an unattractive environment for the development and introduction of valuable new drugs.
4. **Reward Innovation:** Innovative therapeutic approaches should be rewarded with prices sufficient to preserve incentives for future drug discovery. As observed in a market system, the distribution of premiums for NCEs should reflect the underlying clinical value created for patients and health care professionals.

Products without a suitable comparator should be priced using an Alternative Pricing Method, in which the manufacturer proposes the new product launch price, through a comprehensive pricing application, consisting of data, both Japanese and foreign, deemed relevant and voluntarily supplied by the company to support the proposed price. Furthermore, all products with a suitable comparator should be considered for premiums, regardless of order of entry into their pharmaceutical class. Finally, PhRMA believes that those who determine reimbursement premiums in Japan should take full cognizance of the very high cost of doing business in Japan compared with other advanced industrialized nations.

Potential Exports/Foreign Sales

Recognition of foreign clinical data would result in significant cost savings and reduced development time. Combined with shortened NDA review times, these changes could result in new drugs reaching the market sooner. Depending on the product, this could mean increased sales on the order of \$75 million to \$125 million per product, in addition to savings in development costs. MHW may be able to approve 30 new, innovative products in an average year (including European and Japanese innovative drugs); this value change could range between \$3 billion and \$4 billion per year.

The adoption of a deregulated reimbursement pricing system would further increase opportunities for trade and investment by the U.S. research-based pharmaceutical industry in Japan.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

KOREA

Korea is the 12th largest pharmaceutical market globally with 1999 sales approaching approximately US\$ 4.9 billion. Healthcare expenditure is approximately 6.0% of GDP (1997 stats). Pharmaceutical products account for about 30% of this amount. International pharmaceutical companies own about 20% market share, with the share of U.S. companies being 7.2%. Local companies dominate 80% of the market in Korea, which is unusually high by standards in other comparable markets, save Japan. Even in Japan, which severely limits access to innovative medicines, the U.S. industry share of the total market is twice that of Korea. The market is characterized by a relatively high number of medicine items dispensed per individual prescription.

During 1999, the market enjoyed moderate growth of approximately 10%. Prospects for future market growth are positive, and hinge on resolution of pricing, prescribing and dispensing, Intellectual Property Rights, and regulatory issues.

Over the past year, through close and constant communication and positive engagement with the Government of Korea, some significant progress has been made in various areas. There remain certain key issues to be resolved through mutual discussion and cooperation, particularly relating to Intellectual Property Protection, and new drug registration. Resolution of these issues would substantially enhance access to medicine and patient welfare in Korea.

Key Issues: Barriers To Market Access For Patented Pharmaceutical Products

For many years the pharmaceutical regulatory and pricing systems under the control of the Ministry of Health and Welfare (MoHW) have been in serious need of deregulation, trade liberalization and harmonization with the international community. Some important steps, such as the listing of imported pharmaceuticals on the national reimbursement schedule, and elimination of illegal hospital dispensing margins related to reimbursement pricing, were made in 1999. However, any moderate progress on market access, non-discrimination and transparency is being targeted for reversal by local interest groups set on causing derailment of important reforms. In addition, new problems continue to develop, and barriers to market access for innovative pharmaceuticals remain in place.

Discriminatory, non-transparent reimbursement pricing methodologies and protectionism in favor of the local industry make Korea an exceptionally difficult market for the industry compared to other major pharmaceutical markets worldwide.

Industry has been working collaboratively with the American Chamber of Commerce (AmCham), the Korean Research-based Pharmaceutical Industry Association (KRPIA), and the U.S. Embassy and USTR, in efforts to resolve Industry issues. In addition, a WTO level trade action has been initiated by the European Commission, and the U.S. industry is now requesting the initiation of a Super 301 investigation of Korea's policies, practices and acts related to the pharmaceutical sector.

The barriers to market access for patented pharmaceutical products include:

1. Pricing and Reimbursement Issues – Actual Transaction Pricing (ATP)
2. Separation of Prescribing and Dispensing/National Treatment-Pharmacy
3. Discriminatory Requirements for New Drug Registration
4. Local Testing of Pharmaceuticals, Biologics and Vaccines
5. Free Sales Certificate (FSC) requirements
6. Intellectual Property Protection Issues

1. Pricing And Reimbursement Issues – Actual Transaction Price (ATP)

In November 1999, the Korean Government eliminated discriminatory hospital dispensing margins (“kickbacks”) applied on pharmaceuticals, through the implementation of a system for reimbursement at Actual Transaction Price (ATP).² Under the ATP system, the reimbursement price would be the same as the ex-manufacturer price to medical institutions (hospitals, pharmacies and clinics).

Implementation of ATP would require documentation (receipts) for all transactions related to the dispensing of medicines, either through hospitals, pharmacies or clinics.

Shortly after the Korean Government implemented ATP, local interest groups stepped up their opposition to full application and enforcement of ATP. At this point, PhRMA's major concern with ATP is enforcement, and the need for additional measures to prevent corrupt practices that translate into market advantages for companies that engage in illegal discounting. Also, the ATP system should include a mechanism to address foreign exchange fluctuation, thus countering the negative effects of major currency devaluation.

These implementation and enforcement problems, in turn, cause older, multi-source products (generics), marketed mostly by the local companies, to be priced at an artificially

² ATP refers to a process by which medicines would be reimbursed at their Actual Transfer Price, with some consideration given within a mechanism to take account of changes in currency fluctuations.

high levels compared with like or similar medicines in other world markets. Industry expects that the lack of enforcement of ATP and corresponding practice of extra margins and other incentives to hospitals, may have the ironic effect of encouraging excessive dispensing of older, less effective products, versus new, innovative, more cost-efficient (albeit foreign) research-based medicines. Moreover, the Korean Government is itself providing hospitals with financial incentives to use a list of generic “essential drugs”.

Of key significance and concern is that the Korean Government is considering offering incentives to hospitals when they purchase drugs at discount price, which would result in the significant price erosion over time. Additionally, prescribing for profit continues under such system. Likewise, the prices of innovative pharmaceuticals are, in contrast to generic prices, relatively low compared to world prices, and the revised new pricing system, enacted by the MoHW from 2000, is seriously flawed.

Notwithstanding that the new pricing system (April 2000) allows a “significantly improved new drug” (in terms of therapeutic efficacy or cost-benefit) to obtain the average price of advanced seven countries, there is no transparent guideline on the definition of “significantly improved new drug.” Additionally, the system still contains a mechanism for therapeutic category comparison that can be applied in a discriminatory fashion when a company fails to prove “significant improvement” even if the new product is patented.

PhRMA requests the continued support of the U.S. Government for full implementation and enforcement of the Korean Government’s commitments to fair and equal treatment of foreign products within the reimbursement pricing mechanism.

2. Separation Of Dispensing And Prescribing (SPD) Including National Treatment (Pharmacy)

The Government of Korea now provides WTO-inconsistent preferences for dispensing of local products compared with imported patented products. The Korean National Assembly has passed into law arrangements planned for the separation of prescribing and dispensing (SPD) in Korea. These include permission for pharmacists, within strict certain limits and conditions (i.e., of the same substance, strength and dosage form), to substitute alternate generics for brand-name medicines prescribed by the doctor (consent). PhRMA is concerned that this practice is a clear effort to promote the use of domestic generic drugs over brand-name foreign products in a WTO-inconsistent manner. Furthermore, in the absence of rigorous generic bio-availability testing in Korea, public health issues could ensue.

Citizens groups publicly have demanded the re-testing of all generic substitutes. However, the Korean Food and Drug Administration (KFDA) plans only limited testing of the “B” List from the U.S. Pharmacopoeia Drug Information (PDI) (i.e., 321 products, 31 different ingredients) and considers that there are not enough institutions available to do more extensive testing before the planned separation in July 2000. PhRMA seeks more rigorous and extensive bio-equivalence testing for generics, to help assure a more

equitable situation and fairer competition.

Concern for the lack of proven bio-equivalence of generics is exacerbated by a lack of assured integrity in the Korean regulatory system. A manufacturer can present for review a product that is represented by physical samples and data obtained under special conditions (e.g., laboratory manufacture by highly qualified scientists using specially purified chemicals) or from the public domain (e.g., journal publications relating to the originator's brand). These subjects do not necessarily relate one to the other. Furthermore, the samples may not bear any relation to the final product that the manufacturer will eventually produce on a large scale.

It would seem that these practices do not generally follow internationally accepted Good Manufacturing Practices (GMP) aimed at assuring reliable quality, e.g. process validation. Importantly, there is a concern that KFDA's approval of a product is thus obtained with respect to materials/data that may not be representative of the product made later on a manufacturing scale and distributed generally to the public. Such practices may well offer local generic manufacturers the opportunity for unfair flexibility in pricing and competitiveness.

KFDA asserts that they test 3,000 products every year and that this is the upper limit of their testing capability. They also assert that standards and testing methods for manufactured products are reviewed before approval and after manufacturing samples are collected and retested and failure rate is only 1.2 percent. However, PhRMA believes that, given the Korean Government's current plan with regard to generic products, in the interest of public health, all generic products to be used in place of innovative products need to be able to produce up-to-date bio-equivalence testing data. These generic products should be retested if such data are not available.

As KFDA does not plan comprehensive testing, generics that do not have such data should not be permitted for substitution purposes. In addition, as the current test requirements to demonstrate bio-equivalence for a product are minimal, testing should be upgraded to more internationally acceptable levels. Furthermore, it is an imperative that the prescribing doctor should have the option of ensuring the patients consistency of treatment for medical reasons by checking a box on the prescription indicating "No Substitution." Under such conditions, substitution should not be permitted.

3. Discriminatory Requirements For New Drug Registration

Discriminatory Requirements for New Drug Registration

The biggest single concern with the Korean regulatory framework has been the requirement for duplication in Korea of the clinical trials already completed outside Korea. This has resulted in both increased costs and delays to market entry for foreign firms attempting to enter the Korean market. In 1999, the MoHW indicated that they would fully implement ICH guidelines, replacing the existing KFDA (Korean Food and Drug

Administration) requirements by January 1, 2000. However, the draft regulations are of considerable concern for the industry, particularly with regard to the implementation of the ICH E5 guideline on Ethnic Factors in the Acceptability of Foreign Clinical data.

The ICH E5 guideline describes how a drug may be assessed for ‘ethnic sensitivity’ (reacting differently in one ethnic population from another, where the ethnic populations of significance are described as Asians, Blacks and Caucasians). The concepts in the guideline show that in many instances, a drug can be approved for use in one ethnic population without clinical data from that population. In the minority of cases where this is not possible – i.e. the drug is ethnically sensitive – the guideline describes the type of small study necessary in the population where there is ethnic sensitivity. This type of study is known as a bridging study. While the KFDA has gone some way to accepting the concepts in the ICH E5 guideline, they are still requiring a bridging study in cases where it is not scientifically necessary, and furthermore the KFDA requires clinical data in Koreans – i.e. ‘Asian’ data is not acceptable. The result of this interpretation is unnecessary bridging studies and delays to registration. An important step to resolving these differences in interpretation would be the introduction of early, binding consultations between the KFDA and the sponsor. PhRMA and the KRPIA are seeking a dialogue with KFDA to resolve these differences in interpretation in a timely manner. Improvements in regulatory approval procedures would benefit Korean patients by accelerating access to innovative U.S. and European medicines.

Local Testing of Pharmaceuticals, Vaccines and Biologics

KFDA requires that complete local test data for three lots (manufacturing batches) of imported pharmaceutical, vaccines and biologics be submitted with the dossier for product registration. This requirement is both onerous and unnecessary, requiring the transfer of complex proprietary analytical techniques to local testing facilities, often resulting in delays to product registration. Furthermore, once registered every lot of the drug product imported into Korea for commercial purposes must be tested. This is scientifically unnecessary, leading to both additional costs and delays, and may be regarded as a non-tariff trade barrier. The requirements could easily be fulfilled without compromising public safety, by the company supplying the Certificate of Analysis (CoA) from the releasing manufacturing site, and the KFDA should be pressed to accept this proposal.

Free Sales Certificates (FSCs)

Currently the KFDA requires a Free Sales Certificate to be provided with a New Drug Application (NDA) at the time of submission to the KFDA. The FSC (or Certificate of Pharmaceutical Product – CPP) indicates that the drug has been approved for sale in a country (and hence these are typically first available from markets such as the US, where drugs are typically launched first). This requirement to supply the FSC at the time of submission typically ends up delaying submission in Korea until the drug is approved in another market and the certification available. The KFDA should alter this requirement to require an FSC at time of *approval* in Korea, hence removing the delays to market. The assurance that the KFDA gains by knowing that a drug has been approved by a major

agency such as the FDA could be provided by a simple listing of submission status in other countries, as in many countries, such as the USA and EU, where there is an early review of the dossier to determine acceptability, and hence a continued review would indicate that a dossier is of a high quality. This would give the KFDA the assure it is seeking.

6. Intellectual Property Protection

Data Protection

As a Member of the World Trade Organization, Korea is obligated to protect certain test data in accordance with TRIPS Article 39.3. The Korean Government, however, never enacted a statute or promulgated a regulation that directly provided the level of protection against “unfair commercial use” as required by TRIPS. Instead, it relies on limitations on copying drugs that arose from requirements that the innovator re-examine safety and efficacy of drugs at a specified time after marketing. These re-examination requirements were rendered ineffective in 1997, and the Korean Food and Drug Administration (KFDA) began to approve products of copy products based on the test data submitted by the innovator, a practice that is inconsistent with Article 39.3. Since then, the Korean Government has reinstated the re-examination requirement, but it will not withdraw approvals given to competitors after 1997 despite the fact the approvals were granted inconsistently with the TRIPS Agreement.

The KFDA has a clear obligation to ensure that data provided to it in pursuit of regulatory review are secure from being accessed/misused by third parties. TRIPS prohibits reliance directly or indirectly, on undisclosed test or other confidential protected data. Unfortunately, there are instances in which the originator’s technical data allegedly has been used by local competitors of the file sponsor to gain registration. The KFDA relied indirectly upon the undisclosed confidential test data in the underlying unpublished clinical studies. In their defense, the KFDA claims that the TRIPS protection prevents use of publicly disclosed data for “commercial purposes”, not new drug registrations. PhRMA and its member companies in Korea, however, assert that registration is for a commercial purpose.

Therefore, PhRMA believes that there are various serious ongoing issues that need to be raised with the Korean Government in the area of the implementation of the TRIPS protocol. Enforcement of the KFDA responsibility in this critical area needs strengthening, perhaps by appointment of an independent *ombudsman* to receive confidential complaints and to conduct inquiries.

TRIPS Article 39.3 also requires that Members protect certain test data from disclosure. The KFDA has proposed an amendment to stipulate the protection of data from disclosure by Government officials, other than in public interest. This amendment is pending before the National Assembly. Under the amendment, companies are supposed to request the protection of this data when they submit the data to KFDA. While PhRMA appreciates any measure by KFDA to improve this aspect of data protection, this amendment does not automatically provide data protection against unfair commercial use.

PhRMA believes that further measures to implement that aspect of the TRIPS Agreement are necessary.

Enforcement of TRIPS Obligations

Given past decisions, PhRMA has little faith in the ability of Korean courts to interpret the intellectual property laws accurately, to apply them to the facts in dispute correctly, and to conclude the proceedings in a timely manner. Furthermore, the courts lack the ability to grant injunction relief or provisional measures as required by TRIPS Article 50. This hampers the ability of the courts to provide effective remedies to the patent owner. As such, the injured party is disinclined to pursue legal proceedings against the KFDA since the company must rely on KFDA officials for the issuance of other product licenses.

Lack of Linkage

The absence of any direct linkage between KFDA and Korean Industrial Patent Office (KIPO) is another area of concern. KFDA, while assuming responsibility for safety and efficacy review, apparently has abdicated any responsibility for ensuring that competitors do not market products covered by patents through linkage to KIPO. Thus, instead of taking the opportunity during the marketing approval process to prevent infringement and unnecessary litigation, the Government of Korea forces patent owners – foreign and domestic – to resort to the court system after infringement has occurred. This practice is in sharp contrast to the more effective system in the United States. In the U.S., those seeking marketing approval must certify that products involved do not infringe patents in force, and the health authorities refuse to approve products whose marketing would infringe a patent. The Korean Government is in the process of discussing the possible establishment of such linkage, but remains non-committal to near term implementation of such a system.

Conclusion

- PhRMA would welcome an opportunity for further and ongoing dialogue with the Korean authorities to ensure that pricing and reimbursement policies comply with WTO rules, support innovative research, and enhance access by Korean patients to the world's leading medicines.
- To this end, PhRMA urges the Korean authorities to refrain from any actions that could be construed as an effort to limit the business opportunities of U.S. pharmaceutical companies in Korea. Furthermore, every effort needs to be made to avoid measures that result in unnecessary delays in the introduction of their products onto the market, that violate intellectual property, and that entail restrictive and discriminatory practices and acts that place unnecessary burdens on their operations in Korea.
- PhRMA requests that the U.S. Trade Representative continue to monitor the implementation of commitments made by the Government of Korea to the U.S.

Government as part of Korea's deregulation reforms in the pharmaceutical sector in 2001 and beyond.

Potential Exports/Foreign Sales

PhRMA is currently studying methodologies for estimating damages caused by the aforementioned trade barriers that apply in Korea to PhRMA member company affiliates.

At the present time, PhRMA believes that its member company affiliates in Korea could realistically maintain an additional 25 percent share of the current US\$2 billion Korean ethical pharmaceutical market (i.e., this is the 1999 size and half the total pharmaceutical market of US\$4 Billion), were it not for the current market barriers there. Currently, PhRMA member company affiliates have a 7.2 percent share of the ethical pharmaceuticals market in Korea but the normal range is over 50 percent in developed countries, except Japan, which has its own research-based Industry. Thus, without barriers to market access and the problems in the industrial property regime, the PhRMA member company affiliates in Korea could likely increase their total market share to 32 percent. So, whereas ethical pharmaceutical sales for PhRMA member company affiliates now total around US\$144 million, they could total around US\$644 million, if the aforementioned barriers were removed in Korea.

The above information and facts signify that the market for pharmaceutical products in Korea falls far short of providing conditions for free and fair-trading. Local manufacturers appear to be clearly favored in matters related to trade. Furthermore, the environment is not as yet open and transparent to the degree expected of a trading partner that is a Member of the World Trade Organization. The U.S. pharmaceutical industry has serious concerns about the degree of commitment of the Korean government to implementing (even sometimes agreed upon) reforms.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

NEW ZEALAND

Market Access for Pharmaceuticals: Overview

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies' affiliates in New Zealand believe that the policies of the New Zealand Government agencies that set the reimbursement price of medicines, largely deny market access for the American research-based pharmaceutical industry to the New Zealand market.

Once regulatory approval has been obtained from the New Zealand Ministry of Health, market access is effectively determined by entry to the Government Pharmaceutical Schedule (PS). Access to the PS is determined by the Pharmaceutical Management Agency (PHARMAC) **currently** a wholly owned subsidiary of the Health Funding Authority (HFA).

As part of wider health sector reforms, the New Zealand Government has introduced a bill which will establish PHARMAC as a stand alone crown entity structured as a statutory corporation. PHARMAC will manage the PS alongside twenty-one proposed district health boards, and the Ministry of Health. The Pharmaceutical Schedule (PS) lists the medicines that attract a Government reimbursement for patients and specifies the ex-manufacturer reimbursement level that will be paid for each listed medicine. The PS also defines the supply conditions by restricting prescriptions of a product when it decides to reimburse a product.

Since the New Zealand Government has instituted a socialized health insurance system, PHARMAC functions as a monopsonistic power in the market by controlling the level of and entitlement to reimbursement. PHARMAC's monopsonistic position allows it to control market access for new medicines and exploit the negative impact of reimbursement premiums to control prices for currently reimbursed medicines. PHARMAC also controls supplier or prescriber restrictions which further restrict the true or potential market for pharmaceuticals in New Zealand.

Due to PHARMAC's practices, and the nature of a socialized health insurance system, significant sales of most medicines in New Zealand are not possible unless the medicine is reimbursed on the Pharmaceutical Schedule. Moreover, all private medical insurers in New Zealand reimburse claims only for medicines that are included on the Pharmaceutical Schedule; this means that no one will underwrite a premium or co-payment for the cost of a medicine unless it is "acceptable" to PHARMAC. The absence of a PS listing also severely limits the in-hospital use of some medicines. Hospital doctors often prefer to initiate treatment with medicines that are reimbursed so that the medicine does not have to be changed when the patient is discharged.

PHARMAC's management of the PS creates barriers to market access by denying or conditioning the listing of new medicines on the willingness of manufacturers to accept discriminatory pricing and reimbursement policies. PHARMAC applies its discriminatory policies in the following manner:

1. Grouping together of patented products with generics for reference pricing - PHARMAC's use of reference pricing differs significantly from that used in other countries, by including patented products in therapeutic reference groups with generic products. This policy erodes the value of intellectual property accrued through innovation.
2. Denying a PS listing when PHARMAC subjectively considers that "sufficient" products are available to meet patients' needs;
3. Denying or conditioning PS listing upon the manufacturer's acceptance of a reimbursement level that is less than or equal to the current PHARMAC-imposed reimbursement level of existing medicines. This effectively limits the Government-allowed reimbursement price of new medicines to the price of older medicines;
4. Denying or conditioning PS listing upon the manufacturers' agreement to set the introductory market price at the reimbursement level, in effect, imposing a maximum price control at the time of listing;
5. Denying or conditioning PS listing upon the manufacturer's agreement to Government-mandated cross therapeutic reference pricing which requires a major price reduction on one or more other medicines, often in a completely unrelated therapeutic class;
6. De-listing of medicines based on the award of a single tender or "preferred provider" status. All competing suppliers not awarded, including those currently on the Pharmaceutical Schedule, have had reimbursement denied, restricted, or have had their products removed from the PS;
7. Lack of transparency in reference pricing methodology - methodology is capriciously applied to different therapeutic sub-groups. Clinical evidence and therapeutic differences, as well as the views of physicians are ignored in favor of products with

lower reimbursement levels.

Market Access for Pharmaceuticals: PHARMAC Exemption from Commerce Act

PHARMAC has been able to institute these policies through its statutory exemption from the anti-trust provisions of the New Zealand Commerce Act. Thus, while pharmaceutical companies are bound by normal commercial competition law, a Government agency has the right to act in such a way as to lessen competition significantly in the market without legal redress by affected companies.

The New Zealand Government continues to retain the exemption from Part II of the NZ Commerce Act 1986, dealing with restrictive trade practices in favor of the PHARMAC. This issue is currently before the New Zealand Parliament in the form of clause 46 of the New Zealand Public Health and Disability (NZPHD) Bill. This clause proposes to maintain the broad exemption from Part II of the NZ Commerce Act for any agreement to which PHARMAC is a party that relates to publicly reimbursed pharmaceuticals. The industry has pursued the removal of PHARMAC's exemption with the New Zealand Government and this has been rejected.

PhRMA member company affiliates in New Zealand have openly acknowledged that some limited form of exemption is appropriate to ensure that PHARMAC's centralized purchasing role can continue under the new health system. Indeed, in its submission to the Health Select Committee on the NZPHD Bill, the industry through the Researched Medicines Industry (RMI) Association, drafted an appropriate form of limited exemption that would cover PHARMAC's purchasing role on behalf of the new District Health Boards.

The only exemption that is required for this purpose relates to the dealings between PHARMAC and the proposed District Health Boards. The current form of exemption is much wider than is necessary and immunizes from normal anti-trust scrutiny all supply arrangements entered into by PHARMAC. The effect is to give PHARMAC effective "carte blanche" in its commercial dealings, without the need to comply at all with the NZ Commerce Act, which is part of the true foundation of New Zealand's economic policy.

PhRMA believes, with the RMI of New Zealand, that the whole purpose of the NZ Commerce Act is to avoid inefficiency and maximize the most efficient use of New Zealand's resources, through an appropriate level of competition. However, the continued retention of the broad exemption from Part II of the Act in favor of PHARMAC is quite inconsistent with this, as it entrenches PHARMAC's monopsony power and creates no incentive for PHARMAC to act in a normal commercial manner in its dealings with pharmaceutical suppliers.

At the time of the health reforms in 1993, PHARMAC enjoyed a broad exemption from Part II of the Act. The rationale for this exemption was to enable PHARMAC, as agent for the then four Regional Health Authorities, to manage and operate the Pharmaceutical Schedule and the reimbursement regime for medicines. It was perceived that, in the

absence of such an exemption, the Regional Health Authorities could be indulging in collusive conduct and price fixing in breach of the Act. The point was that by all four Regional Health Authorities agreeing to reimburse and, therefore, purchase medicines at the same price under the reimbursement regime, this would, prima facie, breach provisions in Part II of the Act.

When the four Regional Health Authorities were disbanded in 1998 and replaced by a single Health Funding Authority ("HFA"), there was no further justification for the exemption. However, the NZ Government chose to overlook the significant change in circumstances, where now there was only one monopsony buyer, the HFA, and PHARMAC was acting as its sole agent.

With the current reforms in the New Zealand health sector, there is now no justification for anything more than the limited exemption necessary to enable PHARMAC to continue its centralized purchasing role on behalf of the District Health Boards. Subject to this limited exception, PHARMAC should be required to comply with the Act.

There is also an inherent contradiction in the New Zealand Government's stance. On the one hand, it claims that PHARMAC's practices and objectives are supportive of competition. On the other hand, the Government insists that the exemption must be retained. PhRMA believes that, if the former were true, the latter would be unnecessary.

The reality is that if the broad exemption is retained, PHARMAC will continue to be insulated from quite proper challenges of misuse of market power. This is a crucial point of principle, as through the administration of the reimbursement regime, PHARMAC and the Health Funding Authority can dictate who enjoys market access. They have the ultimate market power in circumstances where they can restrict, deter or eliminate suppliers from the market place, something that would otherwise be in clear breach of s.36 of the New Zealand Commerce Act, if it were not for the exemption. The empirical evidence shows that if pharmaceutical suppliers do not have their medicines listed on the Pharmaceutical Schedule and thus reimbursed, their ability to access the market is extremely limited, if not impossible, in most cases.

The pharmaceutical industry and PhRMA member company affiliates in New Zealand have no countervailing power in the literal sense. In the current context of the reimbursement regime, the necessary balance does not exist, because pharmaceutical suppliers, unlike PHARMAC and the District Health Boards, operate in a competitive market. The effect of competition is to eliminate precisely those unfortunate consequences, if the pharmaceutical suppliers are to challenge PHARMAC and the District Health Boards from positions of strength, by, for example, withdrawing supplies. In the absence of such extreme action by the pharmaceutical industry, PHARMAC and the District Health Boards have little incentive to agree to change, knowing that by refusing to do so, the pharmaceutical industry has no option but to accept the current position.

The exemption is a complete anomaly in the current “light-handed regulatory environment”, where the Government and New Zealand-based economists are promoting the principles of competition and open market access. There is only a need for a limited exemption. PhRMA believes that PHARMAC, in its own capacity, and as agent for the District Health Boards, should be required to comply with New Zealand’s competition laws. If the “owner” of PHARMAC, the Ministry of Health, is expressly subject to the Act in relation to PHARMAC’s activities, as is the Crown or Government when it acts “in trade,” there is really no reason why PHARMAC should be fully exempt as it is.

PhRMA strongly urges a reduction in the current broad exemption from the New Zealand Commerce Act. This will have no prejudice to PHARMAC, as PHARMAC officers reportedly have stated that they are quite prepared to comply with the Act without the protection of the exemption.

Market Access for Pharmaceuticals: Sole Supply Tenders

PHARMAC has expanded its restrictive listing policies in efforts to further reduce Government expenditure on pharmaceuticals. Several options have been enforced including those for expanded national tendering and further restricting indications and/or patient eligibility criteria for which a medicine can be prescribed.

PHARMAC already has successfully implemented a number of tenders during 1998 and 1999 with the most recent invitation to tender for sole supply, which includes a number of products still on patent, to be released in December 2000. The selection of tender winners, for a tender period ending in July 2003 or July 2004, is scheduled for the first and second quarters of 2001. Sole supply arrangements, including the de-listing of products currently on the Pharmaceutical Schedule, will be implemented in the third and fourth quarter 2001. The value of the products in the existing tender is approximately NZ\$200 million.

As with past tenders, PHARMAC intends to reduce reimbursement of products that are not part of the tender process through reference pricing, to the level of the lowest priced sole supply product in the established therapeutic sub-group. At the same time PHARMAC may change existing therapeutic sub-groups or establish additional therapeutic sub-groups before the tender is held. Reference pricing would also apply to products in any new or changed therapeutic sub-groups.

There are a number of potential distortions to the market and restriction upon competition from awarding sole supply arrangements. Likely distortions include: (a) the risk of price increases, or withdrawal, of alternative dosage forms; (b) the risk of the emergence of monopoly suppliers; (c) the risk that there will be a significant increase in the number of medicines with premiums over and above the level of patient reimbursement available and also increases in the amounts of those premiums, and; (d) the risk that companies’ ability to make available modern medicines to the New Zealand market will be further restricted.

Manufacturers that are not successful in the tender process would have their currently reimbursed products de-listed, in cases where a sole supply tender was granted to a competitor. In other cases, where a preferred supply tender was granted, the pharmacists' contracts with the Health Funding Authority compels them to dispense only the "preferred" product on generic prescriptions, or alternatively on brand-name prescriptions from doctors who have given blanket consent (or specific consent) to substitute.

New generic entrants are encouraged to provide low cost tender applications, not only by the attractive sole or preferred status arrangements, but also (in some cases) through offers by PHARMAC that it will pay up front registration fees, should they win the tender. Such successful tendered products are therefore promised sole or preferred status before they are even registered for sale in New Zealand.

As a result of tenders offered and concluded to-date, at least six PhRMA member company affiliates have significantly reduced their staff numbers, as well as withdrawn from clinical research programs and terminated funding for independently run post-graduate education programs. The next round of tenders may affect many more major companies in a similar way.

Industry and U.S. Government Action

Although the U.S. industry has pursued dialogue with New Zealand Government officials to modify the discriminatory aspects of their system, no progress has been made. Moreover, the New Zealand Government has regularly implemented new policies that further prohibit market access for imported products. In 1998, the U.S. industry sought strong engagement by the U.S. Government with the New Zealand Ministry of Foreign Affairs. The New Zealand Government apparently agreed, as a "down-payment," to engage in consultations with the U.S. Government to address U.S. concerns regarding PHARMAC's policies and practices. The New Zealand Government agreed at least to discuss the following proposals in the bilateral consultations:

1. Market Access

- a) Based on presentation of health economic data which supports the cost-efficacy of new drugs, the New Zealand Government would remove the requirement that new drugs must accept a reimbursement level equivalent to or lower than the current reference price in order to gain access to the Pharmaceutical Schedule.
- b) Elimination of Government-mandated cross-therapeutic reference pricing.
- c) Separation of reimbursement price from market price for patented products.
- d) Separation of patented products from generics in therapeutic/ reimbursement groups.

- e) Elimination of national tendering for patented pharmaceuticals.

2. Governance of PHARMAC

- a) Implementation of a dispute resolution process, particularly a formal process that would allow for appeal to PHARMAC's decisions.
- b) Elimination of PHARMAC's exemption from Part II of the New Zealand Commerce Act of 1986 that governs antitrust behavior through legislative remedy or a change in the PHARMAC rules.

3. Transparency and Consultative Mechanism

- a) Inclusion of industry in the policy review process, including the establishment of an industry-Government working group.
- b) Transparency and publication of procedural changes.

In September 1998, the U.S. Trade Representative engaged in the first round of bilateral discussions with the New Zealand Ministry of Foreign Affairs (MOFA) to address the highly restrictive and anti-competitive policies and practices of PHARMAC. Although no formal resolution of the industry's issues was achieved at the meeting, both the U.S. Government and New Zealand Government stated their positions and agreed to continue the consultations and focus future discussions on the development of new near term procedural mechanisms. The proposed procedural measures included:

- a) Reform of the independent scientific experts committee, the Pharmacology and Therapeutic Advisory Committee, that reviews applications submitted to PHARMAC;
- b) Recommendation for Pharmaceutical Schedule listing decisions made within 3 months;
- c) Establishment of 30-day public comment period;
- d) A public hearing of experts;
- e) Final decisions on listing within 6 months;
- f) Establishment of an independent appeal process for listing denials, and public disclosure of analysis of reasons for denial;
- g) Automatic initiation of appeal process for inaction on applications.

Progress on Procedural Measures

The pharmaceutical industry proposed to the Government of New Zealand a series of procedural mechanisms to improve the operating environment. The New Zealand Government rejected all but one of these proposals.

The industry presented to the New Zealand Government detailed views on the more immediately achievable and less difficult procedural mechanisms described at 3(a) - (g), plus:

- The case for quarterly meetings between the Researched Medicines Industry (RMI) Board (local trade industry association) and PHARMAC representatives under the chairmanship of the Minister with an open agenda.
- The appointment of membership of the PHARMAC Board and PHARMACOLOGY AND THERAPEUTIC ADVISORY COMMITTEE to be the responsibility of Ministers.
- The transfer of the administration of PHARMACOLOGY AND THERAPEUTIC ADVISORY COMMITTEE to the Ministry of Health.
- The removal of the exemption from the anti-competitive provisions of the Commerce Act enjoyed by PHARMAC.

More difficult issues, such as the separation of patented and generic products in therapeutic grouping for reference pricing and elimination of the practice of conditioning access to the Pharmaceutical Schedule upon setting price equal to or less than the level of reimbursement or other concessions were deliberately held over.

This was to allow concentration on issues that could be implemented with minimal effort and cost to the taxpayer should there be a willingness on the part of the New Zealand Government and its advisors to improve the harsh environment within which the international pharmaceutical companies operate. These could be seen as potential confidence building steps.

The New Zealand Government rejected all but one of these proposals in 1999. The New Zealand Government's single positive response was for: *"Reform of the independent scientific experts committee (PHARMACOLOGY AND THERAPEUTIC ADVISORY COMMITTEE) that reviews applications submitted to PHARMAC"*.

This has resulted in a largely inconsequential proposal that has done little, if anything, to engender the confidence of the pharmaceutical industry in the appropriate independence and transparency of the operations of PHARMACOLOGY AND THERAPEUTIC ADVISORY COMMITTEE.

Subsequently, as the new Government considered the future structure of PHARMAC, the pharmaceutical industry again promoted procedural changes to the operations and processes of PHARMAC that would deliver greater transparency and improved consultations between PHARMAC and the industry.

The industry notes that one change that has arisen is the appointment of membership of the PHARMAC Board, for a fixed term, to be the responsibility of the Minister of Health. However, this development is inevitable considering that the Health

Funding Authority, from which the members of the PHARMAC Board were largely drawn, is being disestablished. The remaining proposals for procedural changes have not been taken up.

Notwithstanding these efforts to make advances upon procedural matters, PhRMA believes that the many more fundamental issues raised by the industry in its submissions to the New Zealand Government remain outstanding.

Intellectual Property Protection

Of further concern to the industry is the burden of PHARMAC's policies and practices on the value of U.S. companies' intellectual property. The manner in which the pharmaceutical reimbursement system is implemented effectively erodes the value of patents for new, innovative, more-effective medicines. PHARMAC places patented products in therapeutic groups that are referenced for purposes of reimbursement with generic products and allots the same reimbursement price for both.

Without price differentiation between patented products and generics, the increased value of patented products is not recognized. In addition, the lack of access for patented products to the New Zealand Pharmaceutical Schedule, and requirements to subsidize the product cost by lowering the price of another product in a different therapeutic subgroup further devalues patented products to the level of generics.

Through its control of the levels of reimbursement and application of its reference pricing policies and other planned initiatives such as tendering, PHARMAC's actions burden and restrict U.S. trade in pharmaceuticals, and negatively affect the value of the intellectual property on which these innovative medicines depend. This is because:

- The period over which a level of reimbursement is negotiated or denied shortens the effective patent life. In discussing the problem of delayed listing in a 1997 report on the New Zealand pharmaceutical pricing situation, one authoritative article cites the view of the Researched Medicines Industry (RMI) Association that "companies can ill afford further delays to market (entry). (The RMI) estimates that the average effective patent term, already short at 7.72 years in 1995, will fall to 6.9 years by 2000." Indeed, without a known reimbursement level for a specific medicine, the supplier virtually is denied the opportunity to market the medicine.
- Government-mandated cross therapeutic reference pricing by PHARMAC forces price reductions on patent-protected medicines, or can expose the manufacturer to significant volume losses. These, together with practices that effectively deny market access reduce the opportunity to earn an expected return on medicines whose value is inherent within their intellectual property.

In order to achieve or maintain reasonable market share, research-based pharmaceutical companies are forced by PHARMAC to provide these medicines at the

price of off-patent medicines or prices that prevail as a result of trade-offs for unrelated medicines. PhRMA believes that these practices by PHARMAC, which the New Zealand Government allows and encourages, seriously undermine the value of intellectual property and fail to give adequate recognition to the value of innovation.

Potential Exports/Foreign Sales

The current size of the New Zealand pharmaceutical market is NZ\$882 million (US\$354 million), of which U.S. companies enjoy a market share of around US\$106 million or 30%.

It is not possible at the current time to provide a reliable estimate of the increase in sales that would accrue to the research-based companies in New Zealand, were the Government of that country to change its policies regarding reimbursement of medicines. However, despite the fact that New Zealand is one of the smaller markets in the Asia-Pacific region, the costs of New Zealand maintaining its present course are significant.

New Zealand is one of the leading developed economies in the Asia-Pacific region, yet its model of reference pricing provides wholly inadequate credit to the contribution of innovative medicines to health care and, in effect, denies market access to the American research-based pharmaceutical industry. It thus renders the “value” of intellectual property protection in New Zealand, which PhRMA member companies would come to expect under all other circumstances, virtually meaningless in this market. This “New Zealand model” could serve as an unfortunate example for other countries in the region, which are in the primary stages of developing health care and health insurance policies. Indeed, aspects of the New Zealand reference pricing system have been adopted in British Columbia and by the Australian Government.

Secondly, by implementing its current policies regarding reimbursement of medicines, New Zealand, which is an OECD member, plays the role of global “free-rider” by failing to contribute to the necessary efforts to support research and development for new medicines to treat new and yet uncured diseases both within and outside New Zealand.

Third, PhRMA understands that the New Zealand Government has expressed its interest in concluding a Free Trade Agreement with the United States that might or might not include other countries in the Asia-Pacific region. PhRMA cannot and will not support such an arrangement that includes New Zealand until the aforementioned severe problems the industry encounters in New Zealand are rectified.

Lastly, it is one thing if New Zealand wishes to declare itself a net “importer” of medicines, and to declare that it has absolutely no interest in establishing itself as a center for pharmaceutical R&D and manufacturing. It is entirely something else if the New Zealand Government then enacts measures to deny marketing opportunities to one of the most innovative and successful industries in the world. As a supporter of free trade, New

Zealand's apparent support of anti-competitive policies, such as those of PHARMAC, contradicts the country's economic policies by "destroying" the possibility of an entire industry's presence in their country.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

PHILIPPINES

As with other markets, PhRMA seeks compliance by the Philippines with WTO rules and principles, transparency in the issuance and enforcement of regulations affecting its member companies, adequate protection for intellectual property rights and the removal of non-tariff barriers to trade.

Market Access Barriers to Patented Pharmaceutical Products

Over the past 15 months, a series of policy initiatives have been proposed by the Philippines Government, each of which bear on the Philippines' compliance with its international obligations. Among the proposed policy measures are:

- Import reduction measures and local manufacturing requirements
- Conditioning renewal of product registrations on (1) the registration of a comparable generic; and (2) the annual sale of an amount of the generic at least equal to the amount sold of the branded product. As an alternative to the second requirement, manufacturers would be permitted to reduce the price of the branded product by 50 percent.
- Elimination of brand names (trademarks)
- Compulsory licensing

PhRMA has questioned the validity of these actions and their capacity to provide significant improvements to healthcare in the Philippines. To date, none of the measures have been implemented and the Government has confirmed its intention to abide by its international obligations.

Instead the Government created a Pharmaceutical Affairs Consultative Committee ("PACC") to consider issues relating to pharmaceutical pricing. At first the PACC held promise of providing a forum in which the government, pharmaceutical manufacturers, distributors, doctors, and insurance providers would work cooperatively to seek improvements in health care for the Philippines public. However, subsequent actions by

the Government strongly suggest that it intends to use the PACC to introduce the measures described above.

The October 5th 1999 Memorandum of Understanding ("MoU") that established the PACC and was signed by all the stakeholders, gave a broad mandate to "formulate recommendations to serve as inputs in the review and revision of government policies and programs on the pharmaceutical industry." However, at the same time, and without consulting all the signatories to the MoU, the Philippine Government issued an Advisory Opinion (A.O.) requiring the PACC to make recommendations on certain specified proposals, including proposals to (1) initially require that all drugs be made available in generic form; (2) require eventual elimination of branded drugs; (3) require compulsory licensing under conditions not consistent with TRIPS; and (4) authorize parallel imports. Since the issuance of this A.O., the Philippine Government has proposed in PACC meetings that the industry reduce by 50 percent the prices of its 50 top-selling products and the institution of a moratorium on any price increases.

Registration of Products in the Philippines

PhRMA understands that the Philippine Bureau of Food and Drugs (BFAD) has also required the declaration of a suggested retail price ("SRP") by companies seeking product registration in that country. This is now required under Department of Health (DoH) Administrative Order No. 48-C, dated November 21, 1999. We believe that there is no legal basis for either the Department of Health (DoH) or BFAD to require the declaration of the "SRP" of a pharmaceutical as an additional requirement for product registration. There is nothing in the statutes cited in the Administrative Order that requires the disclosure of the SRP. Neither the Philippine Consumer Act nor the Food, Drugs, Devices and Cosmetics Act concerns itself with the suggested retail prices of drugs. In fact the latter statute only pertains to *the safety and purity of drugs* and does not in any way regulate the commercial or economic aspects of the drug industry.

For its part, the Price Act of the Philippines deals with price manipulation and other predatory practices that affect the general public. Nothing in this law expressly authorizes the DoH or the BFAD to require the disclosure of the SRP of pharmaceutical products.

The Administrative Order also in no way implements any provision of the Price Act. Obviously, any price information necessary to implement the aims of the Price Act must pertain to current information. The SRP, in this regard, would be useless since it refers to the price **at the time of registration** and bears no relevance to any future price adjustments. In addition, the SRP does not take into consideration price differentials brought about by extrinsic factors such as additional distribution expenses for drugs sold in the provinces, availability of raw materials, and fluctuations in fixed costs. It is not unusual for drugs to be sold at varying prices in different retail outlets.

PhRMA agrees therefore with the legal opinion that has been forwarded to the Government of the Philippines by attorneys representing the companies in that country that

the Secretary of Health possesses no legal authority to issue the AO in question. The AO is therefore illegal and is assailable on this basis.

PhRMA also understands that the BFAD has announced a “temporary” suspension in acceptance of applications for initial registration of medicines in the Philippines. PhRMA believes that this suspension violates provisions of the GATT WTO agreements that represent international commitments of the Philippines.

The indefinite suspension of registration constitutes a “technical regulation” violation within the meaning of Annex I of the Technical Barriers to Trade Agreement (TBT). The announced suspension violates Art. 2.2 of the TBT, which requires that technical regulations not be prepared with a view to or the effect of creating **unnecessary obstacle** to international trade. It also requires that technical regulations not be more trade restrictive than necessary to fulfill legitimate objectives.

Specifically, Art. 2.2. of the TBT reads as follows:

2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create. Such legitimate objectives are, *inter alia*; national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of such products

The announced restriction is more than an unnecessary trade restriction because it amounts to an effective “embargo” on imports of new (or existing but unregistered) pharmaceutical products since they are effectively barred from being registered and imported in the Philippines. Moreover, under the Philippines Republic Act No. 8203, such unregistered drugs would be considered counterfeit and therefore their importation into the Philippines would constitute a criminal offense. Even assuming that the objective behind the announced restriction is to ensure public health and safety, indefinitely suspending the initial registration of pharmaceutical products is by no definition an optimal means of ensuring compliance with that objective.

PhRMA considers these measures as presenting a market-access barrier to U.S. products in the Philippines, and believes they are in violation of WTO principles. PhRMA believes that approval of medicines and renewal of registrations should be based on scientific principles. PhRMA is currently unsure as to whether these new measures are being selectively applied to certain categories of foreign medicines, but the new Government measures may not be consistent with the Sanitary and Phyto-Sanitary (SPS) requirements of the WTO.

Intellectual Property Protection

Some of the activities described above, such as the encumbrance of the use of trademarks, or even possible elimination of trademarks, may threaten the Philippines ability to meet minimum international standards under the WTO TRIPS Agreement and to generally provide adequate and effective protection of intellectual property. In addition, the Philippine Government may soon act in direct violation of TRIPS requirements in the areas of data protection (Article 39.3), as well as enforcement and provisional relief measures (TRIPS Articles 42 - 61).

Threat of Parallel Imports

The Government also has threatened to begin parallel importation of medicines from sources outside the Philippines Legitimate generic pharmaceutical products, i.e. products no longer protected by patent or subject to data exclusivity, and produced according to Good Manufacturing Practices (GMP) as regulated by the U.S. Food and Drug Administration (FDA), may be imported through parallel trade consistent with the TRIPS Agreement. The vast majority of products on the WHO list of essential medicines are available generically, consistent with the above. Parallel importation violates intellectual property rights when the exclusive right to the use (including import and export) of a patented and/or trademarked good, provided to the owner of the intellectual property in the country of registration, is infringed.

The WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) includes the right of a patent holder to control importation of a product into third markets (barring parallel import practices). Specifically, TRIPS Article 28 states that "[a] patent shall confer on its owner the following exclusive rights:... to prevent third parties not having his consent from the acts of: making, using, offering for sale, selling, or *importing* for these purposes that product ...". TRIPS Article 27.1 states that "... patent rights (shall be) enjoyable without discrimination as to the place of invention, *the field of technology* and whether the product imported or locally produced" (emphasis added).

Although the agreement does not address explicitly the issue of national or international exhaustion (see TRIPS Article 6), it is generally not possible for a government to permit parallel import of a product under patent protection in that country without recourse to confidential test data or other information protected under TRIPS Article 39(3), or without violating TRIPS enforcement provisions designed to permit a right owner to fast and effective relief for IP infringements.

In order for a pharmaceutical product to be proven to be bio-equivalent to a registered product in a given country, for example, the data relating to the second product would have to be compared to confidential information for the patented product that should be protected under Article 39(3). Accordingly, although a WTO dispute cannot be initiated on the basis of parallel importation itself, there are other TRIPS-related protections that may be violated by the operation of a parallel import regime that permits importation of pharmaceutical products currently under patent in that country. In addition, under

enforcement provisions of the TRIPS Agreement (Articles 41 - 61), WTO members are obligated to provide effective and timely remedies to ensure that products that infringe on a patent holder's rights are kept out of the stream of commerce, including provisional remedies, injunctive relief and border measures. An effective patent system in the Philippines and elsewhere depends on the ability by the patent holder to control the distribution of his or her patented pharmaceuticals—a system that would be greatly undermined in an environment described by unfettered parallel imports.

Administrative Order (A.O.) No. 85 was issued by the Secretary of Health with grave abuse of discretion, amounting to a lack or excess of jurisdiction, rendering same constitutionally infirm. PhRMA believes that A.O. No. 85 violates existing Philippine law. There is no existing law which A.O. No. 85 implements. Furthermore, A.O. No. 85 abandons the long-standing policy and practice of allowing only one registrant per brand per product which was necessary to protect public health.

A.O. No. 85 runs counter to the primary constitutional right of due process. As regards substantive due process, patent rights and contractual rights of exclusive distributors/licensees are violated. With regard to procedural due process, lack of public hearing renders A.O. No. 85 ineffective, if not invalid.

In violating the constitutional right of equal protection, A.O. No. 85 exempts a government agency, to the prejudice and damage of private local run drug companies, from complying with the standard requirements for product registration, and makes this government agency a much favored competitor of private business.

Apart from being null and void, A.O. No. 85 will pave the way for the importation of poor quality, if not counterfeit or adulterated medicines, and their distribution to the public both in the cities and the countryside. This is because said A.O. has authorized the government or any of its agencies to import low priced medicines and sell them to the public, without complying with rigid and strict registration and testing requirements required of pharmaceutical companies in the country before these medicines are distributed to the public. These strict registration requirements are precisely intended to prevent the sale of poor quality, if not outright counterfeit medicines, thus posing a clear and present danger to the health and even the lives of the people who will use them.

Potential Exports/Foreign Sales

The market uncertainty arising from the Government's recent actions could have a chilling effect on PhRMA members' marketing activities. Implementation of the Government's various proposals would severely undermine PhRMA members' access to the Philippine market. PhRMA evaluated the various compulsory licensing proposals placed on the table at the end of last year by the Philippines Department of Health. With the current market valued at approximately US\$1 billion, PhRMA estimates that the proposed compulsory licensing provisions would have reduced the market by about 8 percent or by \$83.3 million in the last 4 months of 1999.

Of this reduction, PhRMA member company affiliates would have incurred around 30 percent of the total loss (i.e., comparable to market share in the Philippines), so this would mean that PhRMA member company affiliates were threatened by around \$25 million in potential losses from the proposed measures in the last 4 months of 1999 alone. The threat of losses over the period of the 12 months of 2000, then, would be around US\$75 million for PhRMA member company affiliates.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

SINGAPORE

Intellectual Property Protection

While Singapore's Government has made significant strides in the last three years to improve its patent law, there remain several vexing problems for the pharmaceutical industry in that country regarding the level of Intellectual Property protection:

Government Licenses

For services of the government, virtually all acts by the government or acts authorized by the government in relation to a patented pharmaceutical invention do not constitute infringement of the patent. Government use, as defined by the Singaporean Government, cannot be prevented by the patentee.

Government Use during Emergencies

Singapore's law treats, in addition to war and other more traditional emergencies, the promotion of the productivity of industry, commerce and agriculture, the fostering of exports and the reduction of imports, and redressing imbalances of trade as emergencies qualifying for the government's use of patented inventions. There appears to be no saving clause in the law that would supersede a government's license or use during an emergency in case of a conflict with an international treaty to which Singapore is a party.

International Patent Exhaustion

The import, use, disposal or offer to dispose of, of any patented invention, which is produced by, or with the consent of, the patentee (conditional or otherwise) does not constitute infringement of the patent in Singapore, regardless of where the patented invention is being produced. This constitutes a broad application of the international patent exhaustion principle. The language "conditional or otherwise" appears to indicate that even resale restrictions imposed on the purchaser of the patented product or territorial limitations in license agreements would not protect the patentee in Singapore.

Potential Exports/Foreign Sales

It is not possible at this time to provide a reliable estimate of the cost of the aforementioned onerous patent law provisions within the Singapore market.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

TAIWAN

Taiwan is the 20th largest pharmaceuticals market internationally, with 1999 sales of approximately US\$2.5 billion. Healthcare spend is 5.3% of GDP; (Government spending is 3.3% and private is 2.0%) pharmaceuticals account for 25% of that amount. International pharmaceutical firms have about 70% market share with U.S. share being around 25%. Prospects for growth in the Government reimbursed market (major portion of market), hinge on resolution of pricing, reimbursement and regulatory issues. Addressing discriminatory barriers to U.S. and European medicines would benefit Taiwanese patients by expanding access to innovative pharmaceuticals and encouraging research into new cures.

1999 enjoyed a moderate market growth of around 9%, and market projections
c423001

and rrfairs, bs hmuig int
D -0.03097 Tc -0.013268 Tc -0m Tw com T
p d ETw (cur9ou) Tj 322.5067 TD -0.13268 Tc -0m Tw com T

of Taiwan currently accords extraordinary and miss-placed incentives to bio-equivalent and (in some cases) questionably effective generic products. Generic companies do not invest significant sums in research & development.

PhRMA believes that the Bureau of National Health Insurance (BNHI) permits overpricing of local generics in general, as part of a national strategy to foster and promote the development of a local biomedicines industry, which does not yet fully exist.

Additionally, there is evidence that the Government of Taiwan recently has implemented a system of *de facto* Reference Pricing, and this is negatively affecting reimbursement pricing in certain categories. PhRMA is deeply concerned by reports that this has been adopted in an inconsistent, discriminatory and non-transparent manner, and in a manner that disproportionately punishes U.S. and European medicines.

A much better path for the Government of Taiwan to follow would be to improve the incentives for the research-based industry through the reimbursement system, thus encouraging greater investment by that industry in R&D in Taiwan. This would, in turn, help to promote partnerships between the local and multinational pharmaceutical sector.

Reimbursement

Article 49 of the National Health Insurance law mandates reimbursement to healthcare providers (hospitals & GPs) at actual transaction costs. In practice, this is not enforced, thus allowing generics producers with little/no R&D costs to recover, the ability to offer significant and highly questionable discounts to the reimbursement rate. This skews the actual reimbursement payments by Government, and creates pressure for continuing price cuts. Industry supports strong enforcement of Article 49 by the Government, so that product bonuses, discounts and other forms of unrecorded promotions, do not misrepresent true reimbursement practices and levels.

In addition, hospitals are permitted to claim the full reimbursement price, after negotiating deep discounts from manufacturers. This results in a “*Black Hole*” (profit for hospitals), which is placing severe pressure on the BNHI healthcare budget, which concurrently is running at serious deficit. The resolution of the “*Black Hole*” in Taiwan should lie at the core of any meaningful attempts to effect real reform of the reimbursement system.

One additional subject, requiring very close monitoring, is the Government’s recently stated intention to implement global budgeting during 2002 as an additional remedy to their healthcare budget deficits. PhRMA believes that a system of global budgeting will further exacerbate, rather than relieve the effects of “*Black Hole*”.

Clinical Trials

Local registration clinical trials are currently required prior to market approval. The resultant delays reduce the period of market exclusivity, as well increasing development costs. While some progress has occurred in eliminating trials for certain classes of drugs, PhRMA supports the Taiwan Department of Health's (DOH) acceptance and implementation of the ICH E5 guideline on Ethnic Factors in the Acceptability of Foreign Clinical Data, which describes how, in this instance, non-Asian data may be used in support of a New Drug Application, and hence local (Taiwanese) data is typically not scientifically necessary.

An early DOH proposal for all registration trials to be waived by July 2000, concurrent with the implementation of the ICH E5 guideline, has not been yet promulgated. This has been due primarily to industry concerns over the DOH's interpretation of the ICH E5 guideline. Industry remains in dialogue with the DOH on this issue, and progress continues to be made. PhRMA strongly contends that the E5 guideline should be not implemented until these discussions have concluded, and industry can support the DOH's interpretation of, and implementation plans for, the ICH E5 guideline.

Plant Master Files

The Taiwan DOH requirements for verification of manufacturing standards for any given pharmaceutical are extremely cumbersome, and require the submission of large quantities of proprietary data (in a file called a 'Plant Master File' – PMF), a process that is especially onerous when a source changes (i.e. there is a new manufacturing site). PhRMA favors Taiwan DOH's acceptance of GMP certification from the source country, with inspection reports, in lieu of PMFs. Taiwan already has a similar arrangement with certain European countries. A similar accord should be struck swiftly with the United States, thereby avoiding differential or discriminatory national practices.

Key Issues Affecting International Pharmaceutical Industry

Taiwanese policies affecting the interests of international pharmaceutical companies fall into three broad categories: pricing and reimbursement; regulatory affairs; and

concern is the negative impact these controls create for the introduction of new products, including novel, breakthrough medicines.

Pricing

Taiwan operates a price setting system based on international comparisons. New products without bioequivalent competition are set at the median price of the product as it is listed in ten developed markets. In practice, new products are often reimbursed near the bottom end of the ten countries' market price spectrum due to the current cost containment measures of the BNHI. For locally manufactured bioequivalent generic products, BNHI allows a price (i.e. reimbursement level – the *de facto* market price) at close to 100% of the originator's brand. For common (i.e. no proven bioequivalent generics), BNHI approves a price near 80% of the originator's price. These discriminatory practices, artificially distort market dynamics, and interfere with free market forces. They also are becoming more prevalent as the BNHI budgetary deficit worsens.

The *de facto* practice of Reference Pricing that appears to have been practiced in recent months, seems to be driven by the BNHI's efforts to achieve immediate, short-term savings by primarily targeting foreign and imported medicines for price restrictions. This results in low reimbursement prices for new products and others in that group. This approach also helps avoid the political complications of fixing the "*Black Hole*", which would be strongly opposed by the local industry, private hospitals who rely on it for revenue, and certain local politicians.

A key difficulty in assessing the new Reference Pricing scheme is its fundamental lack of transparency.

A New Drug Pricing Committee created by BNHI, administers the system without meaningful Industry participation by U.S. and European companies. To date, no rules, regulations, or guidelines have been issued.

There has been little consultation with industry regarding the impact of the new scheme on access to new innovative medicines by Taiwanese patients. As a result, U.S. and European firms have little idea when the new system was adopted or how it really operates. Instead, Reference Pricing has been implemented on an unpredictable case-by-case basis in one-on-one meetings between BNHI officials and managers of individual U.S. and European firms.

Despite its lack of transparency, PhRMA believes the new system being practiced involves (1) therapeutic grouping (comparing new product with existing ones of same category), and (2) generic grouping (comparing all existing off-patent products with generics of same active ingredients), in addition to (3) the original reimbursement guidelines published by the BNHI in 1995.

PhRMA's Concerns Over Pricing Policies

PhRMA maintains that the Taiwan Government's policies are unfair and discriminatory for the following reasons:

- Reference Pricing tends to drive down the prices of innovative medicines, which are primarily produced by research-based U.S. and European pharmaceutical companies, while artificially boosting the prices of local generics. In addition, PhRMA is concerned by reports that the “rules” are being applied arbitrarily and inconsistently. U.S. and European companies have been informed by BNHI officials that their reimbursements will be reduced by a specific percentage, referring to unpublished guidelines. Others have been told that applications for reimbursement of new indications of existing medicines will not be approved unless they agree to arbitrary price reductions for other products.
- Taiwan's Reference Pricing system disproportionately burdens medicines of imported origin. To date, the BNHI apparently has only targeted new products from U.S., European, and Japanese companies. Additionally, BNHI appears to have singled out certain medicines in certain disease categories, e.g. antibiotics, cardiovascular products, hypoglycemics, and hormones, in an effort to cut reimbursement prices for successful international products.
- By fixing originators' prices near the level of domestically produced generics, Taiwan fails to recognize the greater degree of investment in research and development undertaken by the originators (i.e., international R&D-based industry), discouraging research and development into cures that would benefit Taiwanese patients.
- The granting of reimbursement prices to generic producers near the level of originator's gives generic makers considerable commercial freedom in dealing with purchasers, thus skewing competition within many therapeutic classes, distorting prescription patterns on the basis of financial considerations (as opposed to patient welfare), inviting dubious discounting practices, and unfairly promoting local Industry. In recent years, for example, while original manufacturers' reimbursement prices were reduced, local generic reimbursement prices were increased, to levels almost identical to those of original product prices.
- The “*Black Hole*” is the core issue precipitating the need for cost/price interventions by the Taiwan Government. PhRMA believes that the potential introduction of a global budgeting system in the future will not solve the health care funding crisis that Taiwan is experiencing. Conversely, it will further entrench the “*Black Hole*”.
- The time taken to approve new compounds is unnecessarily lengthy, lasting as long as several years in some cases, which currently further reduces the exclusivity period provided by patent protection. This can be due to regulatory delays because of registration clinical trials, or PMF approval and/or BNHI new price reimbursement negotiations. The result is to limit access by Taiwanese patients to innovative

medicines developed abroad, even though such innovations are available in other industrialized nations.

- In summary, PhRMA supports a ratio between originator, bio-equivalent and common generics that provides appropriate recognition of the value of innovative medicines. Effective competition in the current Taiwan structure cannot be stimulated in the market under the conditions by which the Government of Taiwan currently accords extraordinary and misplaced incentives to bio-equivalent and generic products. Greater recognition of innovation is needed, as well as significantly reduced funding for non-BE generics, which are questionably effective medicines (i.e., common generics). This would reduce the burden of generics on the BNHI reimbursement system, and would provide “headroom” for the introduction of innovative, breakthrough medicines.

It is also worth noting that the BNHI reimbursement value of pharmaceuticals for all generics grew from 35% of the total budget in 1995 to around 55% by the close of 1999. This growth is driven not by market competition, but by Government sponsored overpricing support for generics, due to Government attempts to foster development of the local bioscience industry. This support achieves levels higher than would prevail were market forces in place to stimulate greater price differentials between originator and non-originator, off-patent products.

Reimbursement

Virtually all pharmaceuticals (including many OTC's) are reimbursed by BNHI to hospitals and clinics that dispense them. Pharmacy dispensing is not yet fully developed in Taiwan, despite Government intentions to promote it. There are three issues that are of principal concern to PhRMA:

First, Article 49 of the NHI Law states that “drugs, priced medical devices and materials shall be reimbursed at cost.” This law is not enforced, as it should be. Current estimates of the amount between invoices and claimed reimbursements by hospitals are approximately US\$650 million (i.e. this is the value of the “*Black Hole*”), according to the IRPMA, the international pharmaceutical industry group based in Taiwan. The main reason for this difference is that the current reimbursement system allows healthcare providers to profit from the Government's non-enforcement of Article 49.

While the Government has tried to more accurately assess this gap by conducting a price/volume survey, the data have not been fully conclusive, because not all hospitals agree to release full information. Implementation of Article 49 (i.e. elimination of the “*Black Hole*”) is imperative as a pre-requisite for further actions. Otherwise, once reimbursement is cut further, private hospitals will be inclined to demand ongoing free goods and other bonuses from manufacturers to maintain their profit margins currently derived from drug dispensing. What is needed is a more transparent system of reimbursing hospitals that eliminates questionable discounts and provides higher fees for hospitals for the cost of advanced medical care.

Secondly, hospitals (through Government acknowledgement, but not Government mandate) in most cases require a formulary-listing trial to be conducted prior to admission to the hospitals' reimbursement list. These trials are not required for products from generic manufacturers. While it is important that hospital pharmaceutical committees have the authority to review product use, delays to patient access to new and innovative therapies need to be minimized.

Third, there is increasing use restriction placed on new drug reimbursement. Almost all new drugs now have effective reimbursement limitations of one kind or another. In many cases, this burden falls disproportionately on innovative U.S. and European medicines, and means the research-based product is effectively prevented from achieving a reasonable return on investment.

PhRMA recommends that, to correct these reimbursement discrepancies:

- Hospitals should be reimbursed at net actual acquisition cost for pharmaceutical purchases, plus a reasonable management (i.e., dispensing/service) fee, that would be a fixed percentage of the purchase price.
- The price of the products from the fee for the transaction of storage, dispensing and record keeping; such a system would eliminate the non-transparent impact of discounts and free goods on the actual patient cost.

- **Registration Clinical Trials:** Currently registration clinical trials must be conducted prior to marketing approval for a drug. These trials serve no scientific purpose, and result in a 3-4 year delay in launch from first major market.

Some progress has been made in this area to reduce this delay. Parallel submission of the registration dossier and the clinical trial (registration trial) protocol is now possible, so that the review occurs concurrently with the registration trial. therapeutic areas.

In June 1998, the DOH indicated that registration trials would be phased out over the following two years. Over this time, the DOH conducted a review every three months to waive this requirement for certain groups of drugs based on medical indications. In 1999, the DOH announced that it would implement the ICH E5 guideline on Ethnic Differences in the Acceptability of Foreign Clinical Data in June 2000. While the industry is pleased that the DOH would be implementing internationally harmonized standards in this area, the DOH's interpretation of the ICH guideline would require clinical studies to be conducted in Taiwan for the registration of a pharmaceutical, effectively replacing the registration trial with another clinical trial requirement. This was due to become effective in June 2000, but has been postponed due to industry concerns with the DOH's interpretation of the guideline. Industry has been in active dialogue with the DOH on this issue since June 2000. The ICH E5 guideline must not be implemented until the remaining issues on interpretation have been resolved, and an implementation strategy, agreed with industry, is in place.

- **Free Sales Certificates (FSCs):** Taiwan recently has decreased from three to two the number of FSCs it requires for registration, so long as one is from the country of origin within a list of 10 advanced countries (otherwise three are required). However, company manufacturing strategies may result in a product not being sold in the country of origin. In this case, an FSC from the country of origin will not exist, thus preventing the product being launched in Taiwan. Given that the DOH carries out its own review of the dossier for drug approval, the FSC adds no value, and the requirement should be removed.
- **Plant Master Files (PMFs):** PMF is a requisite of a new drug registration in Taiwan, and is a requirement seen in few other countries, justified by the DOH on public health grounds. The PMF contains significant quantities of detailed proprietary information about the drug manufacturing process and the site of manufacture, and its submission is of considerable concern to companies at many levels, not least from an intellectual property perspective. The requirement for submission of the PMF has led to drastically increased review times – 60% of dossiers now take more than 2 years to review, compared to the 3 months claimed by the DOH. Furthermore, if a company changes a manufacturing site for an approved product, this process has to be repeated, at considerable expense and time.

While the DOH is carrying out its mandate in assuring the quality of the products is approved for sale in the Taiwan market, there are other, less onerous, internationally accepted, methods by which it could fulfill this mandate. Taiwan has indicated it will replace the PMF requirement with a GMP (Good Manufacturing Practices) Inspection Report once it becomes a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S). These inspection reports are produced by the regulatory authority in the country to origin, and address all the technical elements of a PMF, without requiring that information to be compiled and submitted to the agency.

As a prelude to this, Taiwan has concluded an accord with Switzerland, Germany, Spain, Italy, Belgium, France to use Site Master Files (a short descriptive document, readily prepared by companies, and non-proprietary) and PIC inspection reports instead of PMFs. However, in the case of the United States, this type of agreement is not possible as the USA is not a member of PIC/S. However, in an analogous fashion the DOH should accept the U.S. FDA issued Certificate of Pharmaceutical Product (CPP), which is the FDA version of the PIC/S report, and waive the PMF requirement. An agreement on this point must be concluded with the DOH as soon as possible, to bring the Taiwan DOH in line with international practices and to reduce the registration time for new pharmaceuticals, as well as new manufacturing sites.

In addition to the PMF issue, in a related area the DOH has recently announced a drug validation scheme which requires companies with imported drugs to provide the same information on drug validation as domestically manufactured drugs. This is an extremely onerous requirement, that is being applied to drugs already registered as well as new drugs. This requirement is unnecessary, is unique to Taiwan, and as with the PMF issue, could be fulfilled by the acceptance of GMP certificate, Site Master File, or PIC/S inspection report of CPP from the country of origin. Failure of a company to comply with this requirement will mean de-listing of the product. It is hence critical that this requirement is lifted, and replaced with a requirement to supply a GMP certificate (or similar) from the country of origin.

- **Re-packaging:** Taiwan maintains restrictions on the ability of companies to import multi-site source products (bulk medicines) for re-packaging in Taiwan pursuant to regulations adopted in April 1998. Taiwan has said it will separate this issue from its accession to the WTO. Taiwan should eliminate this requirement as a good faith sign to eliminate import barriers.

Intellectual Property Rights Enforcement

Taiwan updated its patent laws most recently in 1986 and again in January 1999. Taiwan has opened its Intellectual Property Office signaling a resolve to clamp down on commercial piracy and encourage industrial invention. Taiwan has also been preparing itself for admission to the WTO, via adoption of amendments to its patent law that will enter into force upon WTO membership.

PhRMA's Concerns with Intellectual Property Issues

PhRMA welcomes the anticipated accession of Taiwan to the World Trade Organization (WTO) as an important vehicle for the continued liberalization of that country's international trading regime. In particular, Taiwan's adoption of the TRIPS Agreement will ensure that intellectual property in Taiwan will be subject to internationally recognized standards of protection and enforcement.

PhRMA believes, however, that its member companies in Taiwan will not gain the expected commercial benefits from the stronger intellectual property protection that will flow from the TRIPS Agreement until Taiwan actually enacts national legislation that implements the obligations contained in the Agreement.

In this regard, PhRMA understands that current U.S. policy asks that WTO accession candidates accede to the TRIPS Agreement immediately upon their accession to the WTO.

PhRMA urges the U.S. Government, if it has not already done so, to insist that the report of the Accession Working Group on Taiwan's accession include Taiwan's pledge to apply the provisions of the TRIPS Agreement on the date that it accedes to the WTO.

PhRMA also urges that the U.S. Government take all necessary measures to ensure that Taiwan makes the requisite changes in its Intellectual property laws--especially in its Patent Act--to implement the obligations contained in the TRIPS Agreement. We draw particular attention to Article 70.2 of the TRIPS Agreement that obligates a country to provide TRIPS-level protection to all subject matter existing and protected in that country on the date of the application of TRIPS to that country.

The application of this provision is especially significant with respect to Taiwan, since Taiwan currently provides two different patent terms--only one of which is TRIPS consistent. Under the current patent law, the patent term in Taiwan is twenty years from the filing date in Taiwan. Patents issued under this law meet the obligation contained in TRIPS Article 33 that the term of protection "shall not end before the expiration of a period of twenty years from the filing date".

However, patents issued under the previous Taiwan law received a term of fifteen years from the publication date (which occurs between filing and grant), subject to a cap of eighteen years from the filing date. Many of those fifteen year patents are still in existence and, since these patents were either capped at eighteen years from filing or may have been published less than three years after they were filed, do not receive the term of twenty years from filing that is required by the TRIPS Agreement.

PhRMA urges the U.S. Government to draw Taiwan's attention to this TRIPS obligation, so that it may enact the appropriate legislation in time to ensure that patents that should have received the obligatory additional term of protection, not fall into the public domain on Taiwan's date of accession to the WTO. Other WTO signatories faced with the

similar situation, including the United States, Germany, Austria, New Zealand, Greece and Portugal, have implemented the provision in order to comply with the minimum TRIPS patent term.

Canada also faced the same situation as Taiwan and the other aforementioned countries, but did not make the requisite change in its law. The United States brought a WTO settlement case against Canada. In that case, the WTO panel confirmed the nature of the obligation and found that Canada had not met its TRIPS obligation by not granting additional protection to those “less than twenty year patents” that were in existence on the date that the TRIPS Agreement applied in Canada.

The case against Canada is especially instructive of the commercial impact of a country’s failure to implement this obligation in the frame required by the TRIPS Agreement. To this date, Canada has failed to meet a TRIPS obligation that it had been obliged to meet on January 1, 1996. In the intervening period, many of the old seventeen-year patents, which should have received an additional term of protection, fell into the public domain, costing U.S. patent holders millions of dollars in lost sales.

Taiwan’s failure to provide the additional term of protection required by the TRIPS Agreement will have an adverse impact on the wide range of intellectual property-dependant U.S. industries operating in Taiwan. PhRMA urges the U.S. Government to make this issue a priority in the WTO accession negotiations with Taiwan and in the overall trading relationship with Taiwan.

Other Issues

Two other issues are worth noting.

- **Zero Tariffs:** Taiwan committed to achieve zero tariffs for pharmaceuticals by 2002. Companies currently face on average, a 12.5% import duty on finished products. This level of tariff barrier is hard to justify in a country as internationally competitive as Taiwan. Faster implementation of the zero tariff accord would be a welcome sign of cooperation by Taiwan. Moreover, Taiwan should abolish tariffs on all categories of pharmaceuticals recognized by other nations that have implemented this exercise. There is particular opportunity for this upon Taiwan’s accession to WTO.
- **Relief Fund for Victims of Side Effects:** The Department of Health in 1998 created a relief fund to compensate patients and their families harmed through use of approved medicines. The Fund will initially cover damage caused by Western drugs (as opposed to Traditional Chinese Medicines). Most manufacturers have joined the Fund through a voluntary contribution of 0.1% sales revenue of pharmaceuticals, and companies are represented on the management committee of the Fund. Industry’s major concern remains that Traditional Chinese Medicines and health foods likewise be included in the Fund, in order to eliminate any discriminatory treatment.

Conclusion

- PhRMA would welcome an opportunity for further and ongoing dialogue with the Taiwanese authorities to ensure that pricing and reimbursement policies comply with WTO rules, support innovative research, and enhance access by Taiwanese patients to the world's leading medicines.
- To this end, we urge the Taiwanese authorities to refrain from actions that could be construed as an effort to threaten or intimidate U.S. and European pharmaceutical companies, and avoid measures that result in unnecessary delays to the introduction of their products onto the Taiwan market.
- The world is on the verge of a golden age of pharmaceutical innovation that will shortly bring new cures and hope to millions of people around the world. The human genome project will result in revolutionary new treatments for life-threatening diseases, disability, and the afflictions accompanying old age. Taiwan's Government should avoid measures that would reduce access to such new innovations on the part of Taiwan-based patients.
- PhRMA, above all else is most particularly concerned about the advent of Reference Pricing in Taiwan, as it represents a discriminatory barrier that will thwart access to the best innovative imported medicines, and harm patients. If U.S. and European firms are effectively prevented from bringing their most innovative products to Taiwan through punitive pricing schemes and prolonged regulatory delays, the lives of hundreds of thousands of Taiwanese patients will potentially be put at risk.

Potential Exports/Foreign Sales

PhRMA believes that USTR, supported by the American Institute in Taiwan (AIT), should continue to strongly insist that the Government of Taiwan effect real improvements in its policies, practices and acts that impact the access of quality medicines from the research-based pharmaceutical industry in Taiwan.

The current U.S. - Taiwan Agreement for administrative protection of qualifying pharmaceutical patents, grants seven years of protection for products introduced in Taiwan both before and after June 5, 1992. PhRMA member companies assume that the generic producers in Taiwan would have "dislodged" the original products after the fifth year without this agreement (post-marketing surveillance periods prevented the entry of generics within the first five years for locally manufactured products and within the first three years for imported products).

PhRMA estimates that the total losses or lost income to the industry, due to the aforementioned problems and barriers, will total around US\$450 million by the beginning of

2001. This does not include the as yet un-quantified impact of the emerging practice of reference pricing, which is now being felt by companies operating in Taiwan.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

THAILAND

Intellectual Property Protection

While the Thai patent act changed in 1999 with the abolishment of the Price Review board, there are still many troubling features of the Thai Patent Act which remain:

- Patentable subject matter – Section 9(1) still excludes naturally existing biologicals, which is not in compliance with the requirements of TRIPS. Article 27(3) of TRIPS provides clearly that members may exclude from patentability, plants and animals, other than microorganisms. Therefore, all kinds of microorganisms must be patentable under the Thai Patent Act to comply with TRIPS.
- Compulsory licensing if the patented product is not produced in Thailand is still incorporated in Section 46. However, the Royal Thai Government will now recognize importation as working the patent.
- Section 36(7) of the Patent Act allows importation of patented products if the patentee permits or gives consent to the manufacture or sale of the aforesaid product. This is inconsistent with Thailand's WTO obligations in that TRIPS

Draft Trade Secrets Law

Thailand is preparing a new trade secrets law to comply with TRIPS. Unfortunately, Section 7(2) attempts to exclude disclosure of trade secrets by a government agency to protect any “public interest” not having commercial objectives. This provision may be used to allow the use of registration data for generic regulatory filings. For this use, Section 11(4) is inconsistent with Thailand’s WTO obligations in that TRIPS Article 39.3 specifically recognizes the “protection of undisclosed information” as being a category of intellectual property subject to protection. Article 39.3 provides that:

“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical entities, the submission of undisclosed test or other data, the origination of which involves considerable effort, shall protect such data against unfair commercial use.”

Use of such data to support the regulatory filing of generic products certainly constitutes “unfair commercial use.” Protection of registration data, through the data exclusivity that results from non-reliance on the data, is a governmental function. The authorities may not consider an application for a marketing authorization during the period of data protection. An application relying upon a third party’s data may only be submitted after the period of data protection has expired.

TRIPS Article 39.3 seeks to protect proprietary data submitted to governments for registration purposes. While the provision does not enumerate a minimum period of time, it does require that the data be protected against “unfair commercial use” and “disclosure.”

Subparagraph 3 contains two obligations: protection against disclosure and protection against unfair commercial use. The United States defines these two obligations in the following manner:

With regard to the first requirement, test data must be protected against disclosure to the public (or even within the government) unless such disclosure is necessary for public safety or unless steps are taken to ensure that the data are protected against unfair commercial use.

With regard to the second requirement: TRIPS Agreement negotiators understood it [the term “unfair commercial use”] to mean that the data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data. Any other

definition of this term would be inconsistent with logic and the negotiating history of the provision.³

A similar understanding of the obligation to protect “against unfair commercial use” was contained in a paper presented by New Zealand at the APEC Seminar in 1995:

Defining ‘unfair commercial use’ can only properly be done by reference to the context of the complete provision, i.e. the purpose behind the provision. In the light of this we interpreted Article 39.3 as meaning that there is a restriction on the use which regulatory authorities can make of original data they hold in order to approve subsequent applications for approval of generic medicines, animal remedies or pesticides. In other words, where undisclosed information is provided to a regulatory authority by an applicant so that the authority can approve the applicant’s product, if this information is then used by the authority to approve the product of a second applicant this is, in New Zealand’s view, ‘unfair commercial use.’ In effect, the regulatory authority is giving a commercial advantage to the second applicant in that the applicant does not have to generate the data that was required of the first applicant. This can be a significant economic saving.⁴

These understanding are an integral part of the negotiating history and intent of TRIPS and provide insight into the negotiated intent of Article 39. Accordingly, these understandings form a basis from which to interpret the vague meaning of “public interest” and “unfair commercial use.”

In practice, abbreviated applications for regulatory approval by subsequent applicants cannot be filed in the United States for five years after the originator’s approval. While the EC has not made a similar pronouncement, EC Directive 65/65 provides originators seeking approval of a new chemical entity via the centralized EU-wide approval process with a regulatory exclusivity period of ten years, that is, no subsequent applications seeking approval relying on the originator’s data are allowed for ten years after approval of the originator.⁵ In most European countries, new chemical entities approved by the national regulatory authorities (the alternative approval process to the use of the centralized procedure) receive ten years of data exclusivity.

³ “The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3,” unattributed paper which was drafted by the Office of the General Counsel of USTR for submission in bilateral discussions with Australia, May 1995.

⁴ *Protection of Undisclosed Information and Control of Anti-Competitive Practices*, APEC TRIPS Seminar: 17-19 May 1995, Presentation by New Zealand.

⁵ While “paper applications” (which rely on published scientific literature to demonstrate the efficacy, quality and safety of the competitive drug) are permitted under Directive 65/65, they may only be filed for a drug with an “established medicinal use,” which the European Court of Justice has indicated would normally be met only after “decades” of marketing.

There thus appears to be a United States-EU consensus that Article 39.3 requires WTO Members to protect the data submitted for gaining marketing approval of new chemical entities against “unfair commercial use,” that is, the data may not be relied upon for the marketing of subsequent versions of the drug during the period of exclusivity without the originator’s consent.

Parallel Imports & Counterfeits

The Thai pharmaceutical market suffers a relatively high level of parallel imports and counterfeits from other parts of Asia, yet insufficient progress has been made to rectify the situation, despite the dangers that such imports pose to national health. There is recent evidence the Thai FDA is being more diligent in enforcing restrictions on parallel imports and counterfeits and has offered to work with industry on a guidebook on counterfeit drugs in an effort to prevent proliferation of the problem. The FDA alone, however, cannot end these practices without other government agencies and resources. Police enforcement of anti-counterfeiting laws has increased as well, though the police officials most responsible for this improvement are being targeted for transfer to other duties. PhRMA encourages the government of Thailand to continue and drastically increase its involvement in this important public safety issue.

Restrictive Drug Lists

The original list (NLED or National List of Essential Drugs) has been in place for several years and was an adaptation of the WHO ‘essential drug list’ (designed as a minimal list of drugs that should be available to satisfy basic health care needs in developing countries.) The WHO list maintains some 250 compounds. Thailand expanded its list to about 1,400 compounds, but applied a restrictive pricing scheme to limit reimbursement. Because of the severe price restrictions, companies avoided applying for listing on the National List and sought listing on individual hospital formularies since there were no restrictions on having their products prescribed and reimbursed within the hospital system.

The MOPH recently indicated that the NLED will now become a maximum list for government hospitals and that products with “provisional registration” subject to a “Safety Monitoring Protocol” (SMP)⁶ would be excluded from the list. Non-NLED medicines may be acquired in government hospitals on a case-by-case basis, though this process is unnecessarily burdensome.

The intention of the 1994 Thai FDA Rules on ‘Transitory Provision to Conduct Safety Monitoring and Bioequivalence Study of New Drug’, to provide pipeline protection for pharmaceutical products patented elsewhere in the world between 1 January 1986 and

⁶ The SMP, established in 1992, represents a form of pipeline protection, or the granting of marketing exclusivity, to certain qualifying products in the Kingdom of Thailand.

30 September 1991 is clearly stated. The procedure required companies to report adverse reactions for a two-year period. If requested by the company this could be rolled over for a further “two plus one” year reporting periods during which time the FDA would not accept a registration file for a generic copy. The rules provided up to five years market exclusivity; the only restriction being that sales were restricted to hospitals and clinics (i.e., no drugstore sales).

The treatment of the NLED as a maximum list and the exclusion of the opportunity to have SMP drugs included in the list effectively negates the original intent of the provisions to provide pipeline protection and market exclusivity for new products in Thailand. Innovative products qualifying for the SMP will not be listed or stocked in most hospitals.

PhRMA believes that the Royal Thai Government’s removal of the opportunity to market new products through government hospitals represents a market access barrier to the introduction of new medicines in Thailand.

Import Policies

Drug and raw material imports are subject to duty which currently ranges from 10% to 30%. (In the recent economic stimulation initiative, the duty for certain intermediate hormones was reduced to 1%). The duty rate for drugs where a generic equivalent is not manufactured in Thailand is normally 10%. The duty rate for imported finished goods that compete with locally manufactured product is 20% to 30%. While there are no specific policies which mandate “BUY THAI”, the government hospitals are strongly encouraged to buy locally produced products wherever possible.

Standards, Testing and Labeling Requirements

A new chemical entity can be registered in Thailand, but the filing will not be accepted unless a Free Sales Certificate (FSC) from the country of origin is supplied. Additionally, samples of biological products must be submitted to the Thai Department of Medical Science for analysis prior to acceptance of registration filings. This analysis usually takes 6 months. For all drugs once the file is received, the FDA can take up to 18 months ensuring that it is complete, to its satisfaction, before submitting the clinical work to the Review Committee for consideration. The Committee may ask additional questions or require that a local study be carried out to ensure that Thai national companies under local conditions can duplicate the clinical data in Thailand. Some progress, though, is being made in meeting a 12-month total review time.

Additionally, there is movement in the regulatory environment towards the acceptance of a FSC from a country other than country of manufacture. In such cases, companies are required to show a CPP (certificate of pharmaceutical product) from country of origin as well as the manufacturer’s Good Manufacturing Practices (GMP) certificate. If this process is in fact adopted and followed and depending on specific cases, registration timing is expected to improve by up to two to four months. It is

important to note though that the obtaining of a CPP certificate is often as time consuming and burdensome as that for a FSC. The two documents are essentially the same though the granting authority is different (i.e., the FSC comes from more central authorities and CCP from more local authorities).

The Thai FDA has implemented “user fees” to quicken the registration process and this policy has improved registration timing. However, these user fees are being politically challenged and may be eliminated in the near future. If this occurs, registration timing may fall back to the old two year filing term.

The Ministry of Public Health has eliminated the requirement for sample analysis before filing of registration dossiers. The Ministry still requires an FSC to allow filings for imported products. An FSC is not required for regulatory filings where the product is to be based upon local production. PhRMA believes this is in contravention of WTO principles of national treatment.

Median Pricing Policy

The government of Thailand’s procurement policies include a pricing requirement whereby a product is procured based on the median price of other products in the same therapeutic class, regardless of origin or quality. This policy discriminates against innovative, largely imported medicines due to the price differentials between brand-name and generic products. Such differentials are based on differentials in product quality, the risk inherent in the drug development process for innovative, western medicines, and the investment needed to market such products.

The effect of the policy is to assign a below average price for innovative, imported medicines while subsidizing lower cost local generic medicines. Discrimination against patented medicines reduces the ability of right holders to enjoy the intellectual property rights that come with patents. This policy disproportionately affects imported products, is contrary to the principle of national treatment, and discourages investment in high risk, high cost research and development.

Government Pharmaceutical Organization

This organization, established by the Royal Thai Government to manufacture medicines in the Government’s name, is exempted from registration and Good Manufacturing Practice requirements and has rights to an exclusive position in supplying government hospitals with products on the National List of Essential Drugs. PhRMA believes this also is in contravention of WTO principles regarding national treatment. The GPO may with impunity manufacture any product, even those still under SMP protection. It is hoped that the new Drug Act will end this practice.

Potential Exports/Foreign Sales

From Thai-based sales data and from estimates based on the size and buying power of the Thai population, PhRMA estimates that the potential market for its companies could be US\$70 million, if the aforementioned barriers were removed.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

VIETNAM

PhRMA is pleased that Vietnam has accepted the basic principles of the World Trade Organization (WTO) in the recently concluded U.S.-Vietnam trade agreement. PhRMA hopes for additional transparency in the issuance and enforcement of regulations affecting its companies in Vietnam, national treatment for foreign pharmaceutical companies in Vietnam, the dismantling of tariff and non-tariff barriers to trade, and the elimination of protectionism in all its forms. PhRMA also hopes that an acceptable level of compliance with these principles can be achieved as soon as possible so that Vietnam can be granted U.S. Most-Favored-Nation (MFN) status and admission to the WTO at the earliest possible date. Given the remaining deficiencies in Vietnam's intellectual property regime and barriers to market access for patented pharmaceutical products, PhRMA asks that Vietnam be included in the 2000 "Special 301" Watch List.

Intellectual Property Protection

PhRMA applauds provisions in the new Vietnamese Civil Code and related implementing legislation that extend the term of protection for patents from 15 years to 20 years and provide temporary protection to patent owners during the examination process. PhRMA is also pleased that Vietnam has accepted obligations regarding its patent regime that are reflected in the TRIPS Agreement, and in some cases, exceed the obligations of the TRIPS Agreement.

PhRMA member companies in Vietnam, however, remain concerned about the lack of adequate patent protection in that country today, and are unclear as to the status of implementation of reforms in the patent system consistent with its new obligations under the U.S.-Vietnam trade agreement.

Compulsory Licensing

Under existing law, the National Office of Industrial Property (NOIP) may order a "compulsory license" i) if a patent is not used, or is inadequately used, during the period of protection, ii) if a prospective licensee has attempted to obtain a license for a patent, but the owner has refused "notwithstanding that a reasonable price has been offered", or iii) if the patent is needed for prevention and treatment of disease. Specifically, the legislation provides no guidance as to what constitutes adequate "use" of the patent or how

“reasonable” compensation is to be determined, though PhRMA looks positively on the fact that patent owners will be permitted to rebut another party’s request for a “compulsory license”.

PhRMA believes that patent compulsory licensing systems are counter-productive except in cases of national emergency or other urgent circumstances. Consequently, we believe that the current law should be amended to eliminate the existing grounds for granting non-voluntary licenses, and to include conditions provided in the U.S.-Vietnam Agreement and the WTO TRIPS Agreement. In particular, we believe that the second and third grounds are not likely to be consistent with these obligations, and should be deleted. The working requirement specified in the first paragraph should be scaled back significantly, if it is not eliminated.

In addition, the Vietnamese Government should include in their implementation package measures that specify that importation of a patented product (as opposed to manufacturing the patented product or using the patented process in Vietnam) will be legally equivalent to manufacturing of the product in Vietnam, and as a consequence, be sufficient to block the grant of a compulsory license based on non-use or inadequate use. Such a change is necessary to render the Vietnamese law consistent with obligations of Articles 27 and 31 of the TRIPS Agreement (Articles 27 and 31). The reforms should also specify that licenses based on refusal to license voluntarily should only be issued in extraordinary circumstances. In addition, the patent law should be amended to require “compulsory licensees” to pay a level of compensation commensurate with the patent’s market or “economic” value as provided in the TRIPS Agreement and the U.S.-Vietnam trade agreement, and should meet other conditions required for compulsory licensing outlined in Article 31. This will encourage the transfer of patented technology to Vietnam.

Infringement of Registered Trademarks of Pharmaceutical Products

Although the new Civil Code and associated implementing legislation provide a clear legal basis for protecting registered industrial property rights in Vietnam, infringement of registered trademarks is systematic and widespread in Vietnam, causing substantial financial losses to members of PhRMA. State-owned pharmaceutical companies under the jurisdiction of the Ministry of Health, and manufacturers and distributors from foreign countries figure prominently in infringement of the registered trademarks of PhRMA member companies. The substandard quality of some of these imported infringing products adds a public health dimension to the consumer confusion generated by the acts of infringement. Trademark infringement is also one of the deterrents to investment and technology transfer in the production of pharmaceuticals in Vietnam.

Inadequate Enforcement

In the absence of a legal basis supporting a formal administrative mechanism for enforcing registered intellectual property rights, a mechanism has evolved in practice to which infringement victims primarily turn when they are unable to settle cases through informal discussions with the infringer. This involves petitioning the NOIP for a decision of infringement. While the NOIP has issued decisions of infringement in a responsible and

timely manner, victims of infringement have encountered difficulties enforcing NOIP decisions through the *de facto* administrative mechanism for the following reasons:

- State-owned manufacturers and importers of pharmaceutical products sometimes refuse to comply with the NOIP decisions on the ground that they are subject to the regulatory authority of the MOH only, not the NOIP;
- The administrative enforcement bodies, specifically the Market Management Bureau and the Economic Police, sometimes say they are confused over whether the NOIP has authority to issue instructions to pharmaceutical companies that are primarily regulated by the MOH;
- The administrative enforcement bodies are influenced by the local authorities who claim they have the authority to make an independent decision as to whether an infringement has actually occurred; and
- The MOH does not cooperate closely with the NOIP to resolve cases of trademark infringement by pharmaceutical companies. (In a few cases, the MOH has acted in unison with the NOIP by following up NOIP decisions of infringement with letters of its own instructing the infringing company to change the name of its product. However, this is not being done in all cases and even when there is such follow-up, little is done to compel recalcitrant infringers to comply with the MOH directive).

PhRMA believes that Vietnam is obliged by its acceptance of intellectual property enforcement obligations under the U.S.-Vietnam trade agreement to change its enforcement environment to remove these deficiencies. In particular, PhRMA believes Vietnam must make changes to its legislation governing enforcement of intellectual property rights to comply with its new obligations. In addition PhRMA requests that USTR seek a confirmation from Vietnam that it will issue new guidance, pursuant to Article 65 of Decree No. 63/CP of the Government providing *Detailed Regulations and Guidelines for Implementing the Civil Code Provisions on Industrial Property* dated 24 October 1996 which stipulates that i) all companies operating in Vietnam, including local and foreign manufacturers and distributors of pharmaceutical products, are required to comply with NOIP's decisions concerning infringement of industrial property and ii) the administrative enforcement bodies are required to comply with NOIP decisions irrespective of the opinion of local authorities.

PhRMA also believes that the MOH and NOIP should coordinate more closely to resolve infringement problems in respect of pharmaceutical trademarks, at least until it is made clear that infringers and local enforcement bodies must comply with NOIP instructions. PhRMA welcomes *Decision No. 1203/BYT/QĐ of the Ministry of Health Promulgating Regulations on Medicine Registration* to the extent it requires local and foreign pharmaceutical companies, before registering their products, to present a verification from the NOIP that the name of the product does not infringe the registered trademark of another company. It is hoped that this portends closer cooperation between

the MOH and NOIP on this important issue.

Insufficient Protection for Product Trade Dress

Vietnam is obligated under the U.S.-Vietnam trade agreement to eliminate loopholes in the current legal framework for protection of trade dress. This loophole allows companies to mimic or copy the product packaging of other companies, thereby trading unfairly on the hard-earned goodwill associated with such product “trade dress”. Vietnam must amend its legislation to provide protection for both foreign and local companies from this type of unfair competition. It is hoped Article 9 of the new Commercial Law will provide a basis for legal action against companies that attempt to deceive consumers by imitating the unregistered trade dress of another company’s products.

Market Access Barriers to Patented Pharmaceutical Products

Vietnam’s National Drug Policy

On 20 June 1996, the Vietnamese Government announced a National Drug Policy in conjunction with *Decree No. 37/CP on the Strategic Orientation for the Care and Protection of the People’s Health*. PhRMA believes that several fundamental aspects of Vietnam’s National Drug Policy should be reconsidered in light of WTO standards. These include:

- moves toward reinforcing centralized management of the production and distribution of pharmaceutical products which fetter competition and reduce efficiencies, resulting in higher costs for Vietnamese consumers;
- a pronounced trend toward protectionism in favor of locally-manufactured pharmaceutical products with the apparent goal of replacing imports of a large number of foreign pharmaceutical products; and
- restrictions on the forms in which foreign pharmaceutical companies may invest and do business in Vietnam, which impede the transfer of technology.

These general features of Vietnam’s National Drug Policy have given rise to a number of specific problems for foreign pharmaceutical companies that are addressed as follows:

Restrictions on the Import and Distribution of Products

PhRMA member company affiliates are not permitted to freely import and distribute their products in Vietnam. According to *Decision No. 1523/BYT/QD of the Ministry of Health on Permitting Foreign Companies to Engage in the Trading of Medicines and Medicinal Raw Materials for Humans in Vietnam* dated September 9, 1996, foreign pharmaceutical companies are permitted to import and trade in their products only on the basis of contractual relationships with designated Vietnamese companies authorized to

engage in the import and export of pharmaceuticals and pharmaceutical raw materials. This inefficient and anti-competitive practice of preserving state control over pharmaceutical distribution in Vietnam ultimately leads to higher costs to Vietnamese consumers. It also forces foreign pharmaceutical companies to deal with some State-designated importers who are concurrently importing and/or distributing products that infringe their registered trademarks.

Directive No. 03/BYT/CT of the Ministry of Health Concerning the Supply, Management and Use of Drugs at Hospitals issued on 25 February 1997 and *Official Dispatch No. 110/TCTD/KH/HTQT* issued on 11 March 1997, indicate that steps will soon be taken to further strengthen State control and management of pharmaceutical distribution in Vietnam. The MOH is expected to grant a monopoly on distribution of pharmaceuticals to hospitals under MOH management in favor of three State-owned companies, each with its own regional responsibility. Reacting to this measure, provincial authorities are now implementing a similar scheme for provincial hospitals that can only be supplied by provincial suppliers/distributors. PhRMA is concerned that this portends further steps to centralize state management and restrict the free and efficient distribution of pharmaceutical products to the Vietnamese population at large.

PhRMA requests that USTR seek Vietnam's agreement to decentralize and liberalize distribution of pharmaceuticals. Foreign pharmaceutical companies should be permitted to import and distribute their products freely in cooperation with a Vietnamese company of their choice or by themselves through branch offices. The branch office provisions of the new *Commercial Law* should be applied to allow foreign pharmaceutical companies to establish branches in Vietnam, subject to fair and internationally accepted levels of taxation, licensing requirements and regulations governing the scope of their activities. This will lower pharmaceutical prices and generate additional tax revenues for the State budget.

Import Quotas

Vietnam is one of the few countries that still impose import quotas on pharmaceutical products. The criteria for establishing these quotas are unknown. Currently, all state companies wishing to import foreign pharmaceutical product are required to apply for annual quotas. This introduces instability and uncertainty into the market mechanism. Moreover, it provides fertile ground for corruption related to the circumvention of applicable quotas.

PhRMA requests that USTR seek the gradual elimination of all import quotas so that the market may determine the amount of pharmaceutical products that are imported into Vietnam. During the transitional period, the criteria for establishing quotas should be transparent.

Product Registration

PhRMA considers *Decision No. 1203/BYT/QD of the Ministry of Health Promulgating Regulations on Medicine Registration*, which took effect on August 1996, a

positive step insofar as it i) stipulates specific and clear procedures for registering pharmaceuticals and ii) contains a welcome requirement that the MOH and Ministry of Science, Technology and the Environment ("MoSTE") cooperate in protecting the registered trademarks of Vietnamese and foreign pharmaceutical companies. However, the product registration regime should be reviewed in respect of the following issues:

New Regulations on Product Registration Applications

Until recently, product registration applications could be submitted in English, French or Vietnamese. On 25 April 1997, with no advance notice, the MOH issued a new directive requiring three copies of the application in Vietnamese and one copy in English or in French. At a time when most countries are trying to eliminate superfluous paperwork, this unnecessary requirement introduces another obstacle to the expeditious issuance of product visas for foreign pharmaceutical products in Vietnam and adds to the uncertainty of the commercial environment generally.

Ban on Re-registration and Import of Certain Pharmaceuticals

On 30 May 1996, the MOH issued *Official Dispatch No. 4162/VD* announcing a list of 63 pharmaceutical products (which was subsequently reduced to 62) which may no longer be registered and re-registered by foreign companies and, accordingly, no longer imported after current registrations expire. PhRMA understands that recent pressure on Hanoi by an envoy from the European Union resulted in many European products being removed from this "negative List."⁷ A new negative list was published on May 20th 1999, reducing the number of de-listed products from 62 to 40. While most of the products taken off this "negative list" were European, most of the new additions were U.S. products. PhRMA now understands that at least five of its member companies may be severely affected by the new de-listing decision.

The basis for *Official Dispatch No. 4162/VD* is the MOH's conclusion that Vietnamese companies are now capable of meeting domestic demand for these 62 products. On 21 April 1997, the MOH announced that applications for registrations and re-registrations of the 62 products would continue to be accepted until 30 September 1997. However, registrations for these products, if granted, will only be valid until the end of 1998. (See *Official Dispatch No. 2608/QLD of the Ministry of Health* dated 21 April 1997).

Such protectionism not only conflicts with WTO principles, it ignores the fundamental reality that foreign pharmaceutical companies will be unable to invest in manufacturing facilities or transfer the technology that Vietnam wants and needs unless such investment and technology transfer can be funded by the sale of various products for which there is a significant existing market in Vietnam. Most of these products are on the list currently banned from registration and re-registration.

PhRMA asks that U.S. negotiators urge Hanoi to remove the U.S. products from the

⁷ The European envoy reportedly threatened trade sanctions against Vietnam textile quotas in Europe unless the European medicines were taken off the negative list.

existing “negative list” in order to facilitate the final signing of the pending bilateral trade agreement between the U.S. and Vietnam⁸. The Vietnamese Ministry of Health should understand this message quite clearly.

Inconsistencies in Duration of Product Visas

In most countries, registrations for pharmaceutical products are valid for 5 years. This was the case in Vietnam until 1996, when the MOH began issuing product visas with validity periods of as short as one year. PhRMA is concerned that this reflects an intent on the part of MOH to require certain products to be re-registered annually after considering whether to deny re-registration altogether. This is cumbersome to companies that must prepare applications annually and to the MOH that must review them.

Discriminatory Enforcement of Product Registration Requirements

At the same time the MOH is issuing more stringent product registration requirements, state-owned importers of pharmaceutical products under the jurisdiction of the MOH continue to import and/or distribute products from companies that have not registered their products. This discriminates against foreign pharmaceutical companies that go to the trouble and expense of registering their products in accordance with applicable regulations. Many of the unregistered pharmaceutical products also infringe the registered trademark rights of others or violate applicable quotas.

The objective of product registration, in PhRMA’s view, should be to record necessary information about pharmaceutical products being sold in Vietnam and ensure product quality. Accordingly, PhRMA requests that USTR seek the following remedial measures with regard to the foregoing aspects of the registration process:

- limit paperwork to only what is necessary to achieve the legitimate objectives of registration;
- repeal the list of pharmaceutical products that are currently banned from registration and re-registration, and issue product visas with five-year validity periods for all pharmaceutical products; and
- issue and enforce regulations strictly prohibiting the import of unregistered pharmaceutical products.

Requirements Concerning Shelf Life of Imported Raw Materials:

Under *Official Dispatch No. 5410/VD* dated 6 June 1996, Vietnamese importers of pharmaceutical raw materials with a shelf life of less than three years must obtain special approval from the MOH to import such raw materials. This restriction is unnecessary, as

⁸ The US- Vietnam Bilateral Trade Agreement to establish “Normal Trade Relations” was concluded in Vietnam on July 24th 1999. PhRMA understands that there is still an on-going process for finalizing technical details and language certification. While signing at the APEC Forum in Auckland was anticipated in September 1999, this did not take place.

the shelf life of pharmaceutical raw materials has nothing to do with quality. The uncertainty associated with having to request approval each time they want to import quality raw materials affects production efficiencies of Vietnamese manufacturers and imposes further unnecessary strains on the efficient use of their limited capital resources.

It also pressures Vietnamese manufacturers to turn to disreputable suppliers who are circumventing this restriction by affixing labels to packaging which either lack a date of manufacture and “expiry date”, or which contain fictitious expiry dates or dates of manufacture on the container. Such false labeling practices threaten the health of the Vietnamese population.

PhRMA requests that USTR seek the repeal of Official Dispatch No. 5410/VD. It should be replaced, if necessary, with a rule that requires pharmaceutical raw materials to be imported within six (6) months before the date of expiration of their shelf lives. Confiscation, fines and other penalties should be imposed on companies that place labels on product packaging that fail to list or falsely list the shelf-life of the product based on scientific criteria.

Requirement That Pharmaceutical Raw Materials Be Imported Within Six Months of Manufacture:

In addition to the aforementioned shelf-life requirement, *Official Dispatch No 5410* requires that all pharmaceutical raw materials be imported into Vietnam within six (6) months of the date of manufacture. This requirement, which lacks scientific justification, discriminates against manufacturers who must i) produce buffer stocks of such raw materials at least five months in advance of delivery in order to meet fluctuating demand and ii) produce in large quantities in order to keep unit costs down. This also results in inefficiencies in the production and delivery of pharmaceuticals that in turn raise the cost of such products for Vietnamese consumers.

PhRMA requests that USTR seek extension of the period within which pharmaceutical raw materials must be imported into Vietnam after their manufacture to up to 12 months or no later than six (6) months before the date of expiration of their shelf-lives.

Requirement that Clinical Trials of Vaccines Be Conducted in Vietnam:

Under *Decision No. 2010/BYT/QD of the Ministry of Health Promulgating the Regulations on Registration of Vaccines and Immunization Products* dated October 28, 1996, foreign manufacturers of vaccines are now required to conduct clinical trials in Vietnam before being permitted to register their vaccines for sale in Vietnam. This is unnecessary, as most international pharmaceutical companies that develop and manufacture vaccines will have already carried out safety and efficacy trials in accordance with the very stringent rules and rigorous protocols required by the U.S. Food and Drug Administration and/or other regulatory agencies before introducing their vaccines to Vietnam. Further, resources currently available in Vietnam would need to be upgraded significantly before clinical vaccine trials can be carried out in a manner that would achieve

reliable results.

PhRMA requests that USTR seek agreement from Vietnam that foreign research-based vaccine manufacturers that conduct clinical trials outside of Vietnam in accordance with FDA or other high standards be exempt from the requirement that vaccine trials be conducted in Vietnam. Increased availability of high quality non-plasma based vaccines will help Vietnam reduce the high social cost of serious preventable diseases, including chronic Hepatitis B.

Restrictions on Local Manufacturing:

International research-based pharmaceutical companies want to invest in Vietnam, but economic considerations prohibit them from building or renovating production facilities as a first step. Foreign pharmaceutical manufacturers must already consider a number of risks associated with the current investment environment in Vietnam, including:

- the low manufacturing standards of Vietnamese pharmaceutical companies that require major investments in equipment and technology to meet GMP standards;
- problems protecting their registered trademarks and other intellectual property rights in Vietnam;
- the inability of foreign-invested enterprises in the pharmaceutical field to control their own hospital distribution networks in Vietnam; and
- the high cost of doing business in Vietnam.

Foreign pharmaceutical manufacturers must also consider *Decision No. 7268/VD of the Ministry of Health* dated 29 August 1996 (“Decision No. 7268/VD”). This decision lists 26 products for which registration for local manufacture has been temporarily suspended. This presents a significant additional restriction and risk factor for foreign pharmaceutical companies because:

- the 26 products are products for which there is a market of sufficient size to justify investment;
- it is uncertain as to when the restrictions will be lifted, if at all; and
- the very existence of the list of 26 products presents the possibility of further restrictions in the future.

PhRMA requests that USTR ask Vietnam to repeal Decision No. 7268/VD and allow the market forces and the companies themselves to decide on the range of products to be manufactured. In addition, Vietnam should issue new legislation to ensure long-term stability and predictability of the business and commercial environment for foreign companies and local companies.

Ban on Toll Manufacturing

Toll manufacturing or “third party manufacturing” arrangements between foreign pharmaceutical companies and local Vietnamese companies were previously permitted under *Decision No. 106/BYT of the Ministry of Health Promulgating Regulations on the Processing of Medicine for Disease Prevention and Treatment of Humans* dated 30 January 1991 (“Decision No. 106”). However, MOH *Decision No. 1824* dated 11 November 1996 (“Decision No. 1824”) repealed Decision No. 106, thus prohibiting this option for foreign pharmaceutical companies.

PhRMA requests that USTR ask Vietnam to repeal Decision No. 1824 or issue new legislation authorizing foreign pharmaceutical companies to enter into toll manufacturing arrangements with local manufacturers (including foreign-invested enterprises). Toll Manufacturing arrangements are the beginning of the process by which know-how and GMP standards are transferred and therefore should be encouraged by the Vietnamese Government.

Tariffs

Currently, some pharmaceutical products are subject to tariffs, while others are not. Different tariffs are applied in different provinces for the same product on arbitrary grounds. The tariff rate is often not known until the products are imported. Such subjective and protectionist criteria conflict with the principles of the WTO and regional trade organizations and protocols, including some to which Vietnam belongs.

PhRMA requests that USTR ask Vietnam to reduce tariffs on foreign pharmaceutical products with a view to ultimately eliminating such tariffs in accordance with the Zero-For-Zero Tariff Agreement. As long as there are tariffs, the process by which they are determined should be transparent and tariffs should be applied consistently nationwide.

PhRMA Companies Are Charged Discriminatory Rates for Services in Vietnam:

PhRMA member company affiliates, like other foreign companies in Vietnam, are required to pay higher rates for water, electricity, domestic airline tickets, hotel room, commercial office space, advertising space and other services than are Vietnamese companies. Such discriminatory treatment, which is at odds with the “national treatment” principles of the WTO, raises the already very high cost of doing business in Vietnam and thus is an additional deterrent to foreign investment and technology transfer.

PhRMA requests that USTR work to ensure that Vietnam require foreign companies to pay the same rates as Vietnamese companies for services and products in Vietnam.

Potential Exports/Foreign Sales

PhRMA is currently studying methodology for estimating damages caused by the aforementioned trade barriers in Vietnam. However, Vietnam has made important

progress since initiating Doi Moi reforms in 1986. In many instances over the past 10 years, the Vietnamese Government has shown itself to be open to suggestions from a variety of sources, public and private, as it moves toward integrating the country's economy with the world economy. However, more needs to be done. Even as Vietnam is moving toward gaining membership in the WTO and obtaining MFN status, the Vietnamese Government appears bent on strengthening State monopolies over the import and distribution of pharmaceutical raw materials and finished products, thus discouraging imports. Other protectionist policies conflict with WTO principles and, combined with inadequate protection of intellectual property rights, discourages the kind of investment and technology transfer in the pharmaceutical field which the Vietnamese government says it desires.

PhRMA hopes that the Vietnamese government will address the issues and problems discussed above and move in the direction of early compliance with WTO standards.

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA
(PhRMA)**

**FOR THE
NATIONAL TRADE ESTIMATE REPORT
ON FOREIGN TRADE BARRIERS (NTE)**

2001

November 27, 2000

Europe

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

BELGIUM

PhRMA is increasingly concerned about the deteriorating environment for innovative U.S. pharmaceutical products in Belgium. The situation now ranks as one of the least hospitable in Europe, according to new survey research and reports from individual U.S. and European pharmaceutical companies.

The U.S. represents the largest contributor of Foreign Direct Investment (FDI) in Belgium among non-EU countries. This investment last year totaled US\$ 17.5 billion. At least ten percent of this investment is in the pharmaceutical sector. The pharmaceutical sector directly employs thousands of Belgians, and is an indirect employer of thousands more. For Belgium to offer world-class medicine to its citizens, and continue to attract FDI to its pharmaceutical sector, it is important that the Government foster a business and health care environment that recognizes, supports and rewards pharmaceutical innovation. Unfortunately, as the situation stands today, Belgium falls short of this goal in a number of critical areas.

The Belgian market for pharmaceuticals is characterized by a number of obvious and non-transparent barriers to trade, resulting in lost export sales for U.S. companies and circumscribed choices for consumers. PhRMA supports regulatory systems that put patients first by approving innovative, effective new drugs for critical diseases as rapidly as possible.

Regulatory Approval Barriers

Although Belgium has achieved a noticeable improvement for drugs introduced after 1997, the issuance of a marketing authorization in Belgium still takes, on average, an additional seven months more than the legally allowable European delay of 210 days.

Restrictive Reimbursement Practices

After marketing approvals are granted, U.S. and other companies face tremendous hurdles in making innovative new products available to Belgian consumers. Due to the nature of the health care system, the overwhelming majority of Belgian patients rely on the national health care scheme to provide their medications. According to new survey

research (*European Economics*), it can take at least 600 days after marketing approval before a new drug is made available to patients as a “reimbursed” product. In Belgium there are cases where it has taken 3-5 years to approve new medicines for inclusion in the national health care scheme, two to four years longer than the average length of time in European countries. Norway is the only other exception in this category. This means that patients, who have contributed through taxation to the national health scheme, must either forego access to the latest breakthrough products, or pay out of their disposable income, a form of “double taxation.”

The reasons for these excessive delays are not entirely clear; one explanation is that the Belgian system imposes long delays as an opaque and short-sighted form of “cost containment”, irrespective of the impact this may have on “health improvement,” or savings that may be realized elsewhere (e.g., reduced hospitalizations, surgeries).

The Minister of Social Affairs this year gave a very firm commitment to decrease the approval delays for new products to a maximum of 180 days under the EU 89/105 Transparency Directive. Reforms, however, can only be implemented (as a best-case scenario) in the second quarter of 2001. The current delays continue to put new medicines beyond the reach of Belgian patients long after they are available to citizens in other EU member states. Innovative U.S. companies are disproportionately affected, as many or most of the latest, cutting edge products are of U.S. origin.

Onerous Price Controls

Certainly one reason why new drugs have a hard time making their way into the hands of sick Belgians has to do with the Government's onerous system of price controls. Among the wealthiest countries in Europe, Belgium insists on controlling prices for medicines at slightly or far below European averages. Unlike the United Kingdom, which relies largely on transparent market mechanisms and competition to ensure affordable prices, Belgium pursues a policy of imposing uneconomic and unreasonable price controls on new products, irrespective of the value of the innovation to the patient or health care system. On average, the Belgian authorities try to impose price reductions lower than the lowest European country price, irrespective of differences in purchasing power, GDP, or personal income.

As a monopsony buyer, especially in the area of chronic medicines, Belgium is in a position to unfairly engage in protracted price negotiations with companies, effectively delaying market entry for many years in some cases. In cases where the Ministry of Economic Affairs has approved prices closer to the European average, the Ministry of Social Affairs has subsequently imposed price reductions as a condition of reimbursement. When lower prices are imposed in such a compulsory manner, it merely shifts the cost of new medicines research and development to countries such as Germany, the United Kingdom or United States, which must shoulder the burden of expensive research for the entire world.

In some cases, uneconomic and unreasonable prices granted for U.S. and

European products have led to situations where the technology is not commercialized. When new medical technology is not introduced, it exacerbates the “treatment gap” between Belgian patients and fellow Europeans.

Taxation Harms Innovation

It is a peculiarity of the Belgian system that innovation is especially heavily taxed, at a time when many countries are offering tax incentives to encourage more research and investment.

Under the current taxation arrangement, companies pay 6% sales taxes based on total sales turnover. The Ministry of Social Affairs apparently recognizes the existing penalties as a flawed approach, and has pledged to reduce the sales taxes only gradually (to 4% in 2001, then to 3% in 2002).

To encourage innovation and investment, the Government should abolish this system, and replace it with the kind of tax incentives for research and high technology industries similar to those in neighboring countries.

The pharmaceutical industry faces an additional tax burden. Although the Ministry of Social Affairs has set a slightly higher budget for medicines in 2001, the pharmaceutical industry will be penalized for budgetary “overspending”. One can assume for next year that this will represent at least an additional 3%-5% added to the sales taxes of 4% based on the turnover of the companies.

Even as innovative pharmaceuticals are contributing to a reduction of expenditures in other parts of the health care system, and are increasingly relied upon to deliver superior value and care, the Government continues to under-fund *actual* need. Under the current taxation-budgetary arrangement, companies which offer new and innovative products to patients, and are therefore successful in the market, must pay a greater share of the overspend, based on company turnover. This is a tax on innovation, because newer drugs typically do cost more on a unit basis than products that have been on the market for ten or twenty years or longer, and successful companies are typically growing and larger than companies which do not offer innovative products. Instead of rewarding innovation, the taxes siphon profits that would normally be reinvested by successful companies in new research and investment. U.S. companies are disproportionately impacted, as many of the most effective and successful new drugs are from U.S. firms.

Restrictions on Consumer Information

The situation in Belgium should be contrasted with that which faces Belgian companies operating in free markets such as the United States. There, Belgian companies receive marketing approvals in an efficient and transparent manner, are able to compete at market prices, and have broad access to compete in almost every customer segment within days of obtaining marketing approval from the FDA. Moreover, Belgian companies are free to communicate directly to consumers with information about their products in the form of Direct to Consumer advertising, while in Belgium, antiquated laws and regulations

prohibit almost all forms of communication about prescription medications to consumers. This leads to a situation where some in society may be well informed about breakthrough treatments relating to their illnesses, while others – people who are not literate in a foreign language, unable to travel, or do not have access to the internet, do not have the means to learn about such scientific breakthroughs. In an era where patients enjoy less time in face to face consultations with doctors, patients deserve to come to the physician's office well-equipped to ask about their treatment options.

Impact on Innovation/Competition

While all research based pharmaceutical companies are in some way affected, it is fair to say that U.S. companies face a disproportionate impact. Because U.S. based pharmaceutical companies account for more than 50% of global pharmaceutical innovation, research and new products, the fact that new pharmaceutical products are effectively kept off the market for up to 2-5 years is especially burdensome on U.S. firms.

PhRMA asks that the U.S. Government raise the issue of these obvious and non-obvious trade barriers with Belgian authorities. There is no reason why an advanced European country such as Belgium cannot ensure efficient regulatory approvals and broad access to innovative medicines at prices at or above European averages. Faster approvals, a loosening of arbitrary price controls, and earlier inclusion in the national health scheme will stimulate the kind of competition to ensure affordable prices. It will also stimulate research and development investment in Belgium, and strengthen the research-based pharmaceutical sector there. No one will benefit more than the Belgian patient, who today must rely on information from foreign sources or trips to neighboring countries to ensure full access to needed medicines.

Potential Exports/Foreign Sales

PhRMA is unable at this time to provide any reliable estimates of the increase in our industry's sales that would accompany the removal of the aforementioned trade barriers.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

CZECH REPUBLIC

Intellectual Property Protection

The Czech Republic has made significant steps forward towards ensuring that its intellectual property regime is TRIPS compliant. In April 2000 the Czech Parliament endorsed an amendment to the Patent Law allowing Supplementary Protection Certificates and has rejected a proposed amendment allowing experimental use (Bolar principle).

Pipeline Protection

The Czech Patent Act of 1991 introducing product patent protection was the first of its kind in the Central and Eastern Europe countries. Paragraph 82 of the Patent Act also enabled pipeline protection. However, this was for a very limited time period only. As a consequence the first patent-protected pharmaceutical products will start to appear on the Czech market between 1999 and 2001. Furthermore, pharmaceutical products which were granted product patents in the U.S. and the EU before 1991, and which are enjoying protection there up to 2011 are, and will remain unprotected in the Czech Republic for their entire lifetime. Since 1991, 165 submissions have been made for pipeline protection, of which only 16 have been approved by the Patent Office.

While pipeline protection is not required under the WTO TRIPS Agreement, under the EU Association Agreement, the Czech Republic has promised to achieve a level of protection including appropriate means of enforcement. In addition, the absence of pipeline protection in the Czech Republic has contributed to a situation where there is little effective protection for patented pharmaceutical products. PhRMA believes, therefore, that the Czech Republic should be held to this commitment.

Compulsory Licensing Amendments

The Czech Parliament recently amended its legislation with respect to compulsory licensing in order to bring it into conformity with the TRIPS agreement. The Patent Law has been adapted so as to explicitly consider the importation of a patented product as "working the product" and to consequently exclude the granting of a compulsory license for it.

Enforcement of Patents

The practice of patent rights enforcement in the Czech Republic is sadly lacking. The only mechanism for challenging patent violators is via lengthy and costly court proceedings. There is an urgent need for granting timely temporary injunctions in cases of suspected patent right infringements and for improving civil procedural rules, as required under the TRIPS Agreement (TRIPS Article 50 requires effective provisional measures). The Czech patent enforcement system does not permit effective actions against patent infringements as required under TRIPS Article 41. In the past, Czech courts have refused to consider an infringement action because the defendant did not have sufficient assets in the Czech Republic, even though the defendant sold the allegedly infringing product into the territory of the Czech Republic. In addition, under Czech law, either the court or the patent office can order the reversal of the burden of proof. However, the Czech courts have left requests for reversal of burden of proof unanswered and the patent office has denied its competence to reverse the burden of proof, resulting in a *de facto* denial of the reversal, in violation of TRIPS Article 43.

Barriers to Market Access

Marketing Authorization

The Medicines Act guarantees a final decision within 18 months for the registration for product submissions. The Amendment to the Medicines Act (April 2000) will reduce the registration time to 210 days. Since January, 1998 the State Institute for Drug Control (SUKL) began recognizing EU centralized procedures insuring a maximum of 4 months for the approval of marketing authorization. While PhRMA looks forward to the improved processing of marketing authorization applications, member companies operating in the Czech Republic still face registration delays for filings made before 1998, with older registrations often taking 3-5 years.

Market Pricing

All pharmaceutical products registered for commercial purposes in the Czech Republic are subject to price regulation, but this price regulation is not applied in a transparent, non-discriminatory manner as required by WTO principles. Different criteria are applied for maximum pricing for domestic products versus imported R&D products. Moreover, the criteria are not transparent and leave much room for misinterpretation by the Ministry of Finance. Additionally there are no firm rules in place for appeal of the process.

Reimbursement

The Czech Healthcare insurance reimbursement system also lacks objective and verifiable criteria for the inclusion and setting of reimbursement limits. The Categorization Committee, which reviews pharmaceutical products for reimbursement, generally sets price limits at the price of the least expensive drug in a specific ATC category with no consideration of the innovative/differential nature of a given product. There is no transparent and reliable process for appeal of reimbursement decisions despite ongoing appeals to the Ministry of Health.

Potential Exports/Foreign Sales

PhRMA is currently studying methodology for estimating damages caused by the aforementioned trade barriers in the Czech Republic. Preliminary indications are that consolidated losses for U.S. pharmaceutical companies operating in the Czech Republic are in the US\$ 15-20 million range. However, on a *prima facie* basis, the Czech Republic has an inadequate patent enforcement regime. In addition, transparency with respect to the pricing and reimbursement of pharmaceutical products must be improved.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

ESTONIA

Intellectual Property Protection

The Estonian patent law took effect in 1994 at which time product patent protection for pharmaceutical products became available. Since the law does not provide for pipeline protection, pharmaceutical products will benefit from the law approximately in the year 2006. "Pipeline" protection for marketed pharmaceutical products in Estonia is needed.

Data Exclusivity – Confidentiality

As it takes 10 to 12 years to bring a new medicine to the market, the benefits of the 1994 patent act will not be felt before 2006. Until then, data exclusivity is the only type of protection which may prevent early copying.

Although the protection of undisclosed information is regulated by the Competition Act, which prohibits the misuse of confidential information, there is no provision in Estonian law corresponding directly to Estonia's WTO TRIPS obligations in the area of data exclusivity. Current Estonian Patent law does not include any provisions meeting the requirements of Art. 39.3 of WTO-TRIPS on the use of a previous applicant's documents, and, in particular, does not provide that, in order to refer to documents submitted by a previous applicant, the second applicant has to obtain the consent of the previous applicant. There is therefore a high probability that health authorities in Estonia may provide marketing approval to a product relying on confidential test data of another patented product without approval of the right holder.

Potential Exports/Foreign Sales

PhRMA is not able at this time to provide any reliable estimates of the increase in our industry's sales that would accompany the removal of the aforementioned trade barriers.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

EUROPEAN UNION

Intellectual Property Protection

Single Trademark Policy

The European Commission (EC), supported by the European Medicines Evaluation Agency (EMA), has taken the position that only a single trademark will be approved for use in connection with each product for which marketing authorization is granted under the centralized procedure. Therefore, applicants are being required to submit a trademark that is valid throughout the Community.

As a result, the process of approval under the centralized procedure hinges on the clearance of a single trademark throughout the Community, a factor which has no relationship to the safety, effectiveness or quality of a product. In effect, a fourth hurdle to marketing has been imposed and products undergoing the centralized procedure are being discriminated against, as no equivalent obstacle to approval is being raised under the decentralized or national procedures.

PhRMA strongly disagrees with the position taken with respect to a single trademark, and has drawn attention to the fact that there is no basis in Community law to support such a requirement. Instead, there is reason to conclude that such a requirement does, in fact, run counter to Community law and decisions taken by the Council of Ministers and the European Parliament. It may also violate the trademark section of the Trade Related Intellectual Property (TRIPS) provisions of the World Trade Agreement.

The Commission position is also inconsistent with policies on trademarks enunciated by the Council and the European Court of Justice (ECJ). The Community Trademark Regulation does not preclude multiple Community trademarks for the same product, and it preserves the right to seek separate national registrations rather than a Community registration. The ECJ has recognized that producers of medicinal products may have legitimate reasons to use different trademarks for the same product in different Member States. When there is evidence that multiple trademarks have been used to create obstacles to free movement of goods, the Court will permit parallel imports that would otherwise infringe national trademarks.

Parallel Trade – Exhaustion of Rights

In 1981, the ECJ issued a controversial interpretation of the doctrine of exhaustion of patent rights. The ECJ stated that if a product was placed on a market in a Member State where patent protection was not recognized, then the patent holder by that act would exhaust its patent rights with respect to that product in all other Member States. This decision was recognized as inherently unfair in that it penalized the innovator and rewarded the copier in such cases. However, the ECJ upheld the 1981 ruling in the Merck Primecrown case in 1996.

The EU Internal Market Council in its Conclusions on the Single Market in Pharmaceuticals (May 1998) stated that “the development of the single market requires Member States to take account of European Union dimensions ... and that ways need to be found within the Treaty to address the question of the price differentials between Member States and the issue of parallel trade in this sub-sector.”

In keeping with the Council's instructions, the Commission in its *Communication on the Single Market in Pharmaceuticals* [Com (98) 588 final (Nov. 25, 1998)], stated that Member States when controlling their public health expenditures are expected to adopt measures that do not distort the operation of the market leading to a reduction in the competitiveness of this sector in a global context.”

Border Testing

The EU policy of testing for quality at point-of-entry into the EU each batch of pharmaceuticals imported from the U.S. poses a significant non-tariff barrier to trade. No equivalent barrier exists to the import of pharmaceuticals from the EU into the U.S. The testing obligation is costly and time consuming, and this delays market access and increases market costs – and this places U.S.-based pharmaceutical manufacturers at a distinct competitive disadvantage.

Furthermore, other countries are following the EU lead and are adopting similar batch testing at the border requirements for pharmaceutical imports, such as Switzerland.

Border testing poses immediate practical concerns to all U.S.-based drug manufacturers exporting to the EU, and is particularly damaging to U.S.-based vaccine manufacturers. In the case of vaccines, improperly conducted testing and inherent false positive results in mandated testing can prompt a second battery of tests, further adding to cost and further delaying market access.

Despite expectations, the Mutual Recognition Agreement (MRA) with the EU offers no relief to the U.S. pharmaceutical industry. The MRA did not suspend such testing, nor will it in the foreseeable future. The batch testing may cease by December 2002, at the conclusion of the MRA equivalency determination phase – but only if both parties complete and agree to their respective equivalency determination findings. If not, then U.S. pharmaceutical exports will continue to be subjected to this EU barrier to trade well into the next decade or even longer.

Potential Exports/Foreign Sales

Trademark: The immediate impact of the policy is to force companies to pay a registration fee of Ecu 140,000 for each application, including duplicate applications for a second trademark. And these files will require no additional evaluation whatsoever. It is not possible to

provide a reliable estimate of the potential market effect for PhRMA member companies in the European Union if their costly high tech and biotech products are denied approval under the current policy.

Parallel Trade: PhRMA members estimate that parallel exports from Spain alone could be as much as US\$ 800 million. There are no absolute data on the current impact of parallel trade, however.

Border testing: The immediate impact of this practice is to force each U.S. pharmaceutical exporter to pay on the average US\$ 2 million annually for the EU border testing. The testing burden also ensures significant market access delays of up to 4 or more months for a U.S.-based vaccine manufacturer. A typical potency test for vaccines can take up to two months to complete. If re-testing is required due to the inherent likelihood of a technical rejection of a given batch, then a further delay in market entry of an additional 2 or more months must be factored. Finally, the EU testing not only leads to significant costs and delays to market entry, it also substantially reduces shelf life – hence the marketing and patent life – of U.S.-made medicinal products in the EU marketplace. For example, a U.S.-made vaccine can lose nearly a full year of marketing life in the EU due to this unnecessary trade barrier – 4 or more months of testing plus the 4 or more months of shortened shelf life.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

FRANCE

PhRMA members are concerned that the French System will have long lasting detrimental effects on the growth and development of the pharmaceutical industry in France, and substantially erode the quality of health care in France. Specifically, the French system (i) places limits on and thus lowers the efficiency of production of medicinal products, due to a quota imposed on annual sales, and (ii) discourages research and development into new medicinal products, because limits placed on growth will lower the return on investment needed to engage in such activities. This will lead to a loss of employment, substantial reduction of investment in research and development, delay in the introduction of innovative products on the French market, and ultimately harm the long-term competitiveness of the research-based pharmaceutical industry.

Government-Imposed Price and Volume Controls

In recent years, the French Government has expanded the coverage and scope of health services provided within the Social Security system. However, it has simultaneously pursued a strict policy of limiting health expenditures; as a result, the health system faces both unfunded mandates and unrealistic expectations regarding spending, particularly in the area of pharmaceuticals.

As part of a broader plan to reduce the budget deficit, France has adopted several laws and regulations to control Social Security expenditures on pharmaceuticals. These measures, however, control not only overall drug spending, but also individual company sales, therapeutic class sales, and specific product sales. As a result, the government is controlling growth of the pharmaceutical industry and of individual companies, and by extension, is determining market share. Most importantly, these government-imposed pricing measures have a disproportionate impact on innovative firms. Because research-based firms with innovative products are primarily non-French, the impact of this system on foreign firms is much greater than the impact on domestic firms.

First, the government sets an overall target for the annual increase in health spending; for the year 2000, the approved rate was 2%. If spending exceeds this rate, the

government requires a rebate from different sectors of the health system. However, the pharmaceutical industry is required to bear a disproportionate share of “excess” spending, far above the actual proportion of drug spending to health expenditures. Moreover, this rate has always been set at unrealistically low levels. Health spending in France has been growing at approximately 6% per year reflecting additional coverage, an aging population, and improving technologies. Capping growth at unrealistic levels may be politically expedient but fails to recognize the realities of the health and pharmaceutical markets.

Second, in addition to overall growth caps, the French government limits growth of therapeutic categories of pharmaceuticals and also directly controls the prices of individual pharmaceutical products that are reimbursed by the Social Security system (representing 77 percent of the pharmaceutical turnover in France). Prices are either negotiated between the pharmaceutical company and the Comité Economique du Médicament (Economic Committee for Medicines, or “CEM”) or are fixed by decree by the Ministries of Economics, Health, and Social Security. As part of the first process, companies must establish individualized targets and refund obligations for their own products, in agreement with the CEM. If a company’s overall sales, or individual product sales to the French government exceed the amounts agreed to by contract, the company must rebate a proportion of the budget overrun to the government. In other words, the government penalizes those companies that are successful and whose products generate higher-than-expected demand by patients and physicians. This practice in effect limits companies’ growth, the volume of individual product sales, and market share potential. Again, companies facing rapid growth in demand for their products are those with newer and more innovative products, which by and large are non-French companies.

If a pharmaceutical company refuses to voluntarily enter into a CEM agreement, it is nevertheless subject to a statutory “Safeguard clause” which automatically exacts rebates from companies for sales exceeding an established limit. This limit was set at 3% for 1999 sales. Forcing companies to pay back a proportion of their gross margins to the government effectively blocks access to the market. This is a particularly onerous burden for research-based pharmaceutical companies with innovative products.

Fourth, manufacturers must also pay a promotional tax, which disproportionately impacts companies with innovative products that are new to the market. Lastly, the French Social Security Financing Law provides for the imposition of a levy on pharmaceutical companies (1.3% on 1999 sales of reimbursable products) in order to finance social security budget overruns. While this is termed an “exceptional contribution”, it has continued to be in place for several years and thus appears “routine” rather than “exceptional”.

R&D-based companies determine their investments years in advance, based on current projections of the future market environment. Arbitrarily capping the growth of the drug budget to 2% (or other unrealistic levels) has severe competitive consequences that could also nullify and impair the value of the investments committed to by the U.S. industry.

Finally, for all of the reasons described above, the system favors older, less-expensive products, even if they are less effective or create greater public health risks or overall costs. This practice tends to perpetuate the market life for old, less efficacious products. In November 1999, the Transparency Committee recommended that 262 of these older products be delisted from reimbursement as having little or no therapeutic value. However, action on the recommendation has been delayed for months due to political resistance from the manufacturers of these products, despite the argument that the delistings will free resources for reimbursement of newer medicines.

Potential Exports/Foreign Sales

PhRMA estimates that foreign sales would rise by over US\$ 500 million if the aforementioned trade barriers were removed.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

GERMANY

Government Pricing and Reimbursement

Companies may price patent-protected products introduced onto the market after January 1, 1996, to reflect market conditions. A reference price system controls the prices for those patented producers introduced onto the German market before December 31, 1995. The reference price system controls the prices of two-thirds of all prescribed pharmaceuticals.

All drugs prescribed by physicians are eligible for reimbursement as long as they are not included in a negative list. Patients have a modest variable co-payment. However, physicians operate under strict budgetary controls that limit the amounts that they may prescribe. If physicians exceed this limit by more than 15%, they must generally pay the difference. Thus, physicians often are not in a position to prescribe the products that, in their professional opinion, would best suit their patients' needs. The budgets create a bias away from innovative therapies that may be the most appropriate for patients. The end result is that U.S. companies are disproportionately impacted because U.S. industry is the global leader in bringing new drugs to market.

Parallel Trade

German legislation is intended to make parallel imports easier and therefore increase parallel trade into Germany. The law does not significantly reduce public expenditures, but does have a significant negative impact on R&D-based companies. The problem will be further exacerbated as countries in Central and Eastern Europe accede to the EU because of the very low prices in those countries.

Potential Exports/Foreign Sales

PhRMA estimates that foreign sales would increase by between US\$100 million and US\$ 500 million if the aforementioned trade barriers were removed.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

HUNGARY

Intellectual Property Protection

Data Exclusivity – Confidentiality

As it takes 10 to 12 years to bring a new medicine to the market, the benefits of the 1994 patent act will not be felt before 2004-2006. Until then, data exclusivity is the only type of protection which may prevent early copying.

TRIPS Art. 39.3 requires WTO Members to protect against “unfair commercial use” of undisclosed test data and other confidential protected data submitted to governments as a condition for obtaining marketing approval of pharmaceutical products utilizing new chemical entities. In most industrialized countries, a special legal regime provides that no person may, without the permission of the person who generated and originally submitted the costly and confidential data, rely on such undisclosed and proprietary test data in support of an application for product approval, not only while the originator’s marketing application is pending before the regulatory authorities, but also for a specified period from the marketing approval date of the original product. However, current Hungarian law contains no restrictions on its regulatory agency with regard to reliance on the original filing data for any specific time period. In fact, the agency has permitted registration of second filing applications, which rely on the original filing, without the originator’s consent, even in cases where the time between the original filing and the second filing is less than five years and in some instances as little as a few months. The agency has taken the position – stated for example in a recent reply to U.S. companies questioning the process – that in the absence of such restrictions clearly prescribed by legislation, it would not deal with the issue.

The Hungarian government has claimed that its Unfair Competition Law (UCL) of 1994 is sufficient to fulfill Hungary’s obligations under Art. 39.3. However, the Unfair Competition Law is not suited to fulfill these obligations, for several reasons. First, the UCL is not directed at the behavior of governments, which is the intent of this paragraph of TRIPS, but at the actions of private parties. Second, the UCL is designed to allow for a civil action after the breach of confidentiality has occurred; it has no power to prevent the breach, which is the intent of Art. 39.3. Third, confidentiality obligations imposed on

governments, including those of Art. 39.3, would inhibit any data gathering process that would be necessary to pursue a case through the UCL. In other words, there is nothing in the UCL to prevent the government from creating an anti-competitive situation as a result of not protecting the data of the original filer. Since this is the intent of TRIPS Art. 39.3, the UCL is an insufficient means of fulfilling Hungary's obligations under that article. As long as Hungary does not have a specific regime in place to guarantee the protection of original filing data, it is in violation of TRIPS.

A draft data exclusivity law is being discussed and apparently provides for a six-year period of protection. However, the data exclusivity term would begin at the date of the first marketing authorization in the EU. Since Hungarian marketing authorizations are typically issued later than authorizations in the EU with its central and mutual recognition approval procedures, the Hungarian reference to a third country can considerably shorten the data exclusivity period. Furthermore, reference to third country marketing approval dates is not provided for nor is it in the spirit of Art. 39.3 TRIPS. Moreover, despite a formal marketing authorization, a pharmaceutical company may not market the product before the price of the product approved by the government is published in the Official Gazette. This requirement typically takes one year, but recently up to two years, thereby reducing a would-be six-year period correspondingly. In addition, although the period of protection for confidential data is a maximum of six years, the data exclusivity period ends earlier than six years – possibly at zero years – if and when the patent expires earlier. This opens the possibility for unfair commercial use of the originator's data in violation of Art. 39.3 TRIPS which does not provide for a linkage of for unfair commercial use of data.

Enforcement

TRIPS Art. 41 requires that WTO Members ensure that their enforcement procedures permit "effective action" against intellectual property infringement acts and include "expeditious remedies to prevent infringements and remedies, which constitute a deterrent to further infringements." As such, it is not enough for a WTO Member to merely make available in their statutes the remedies that are enumerated in the TRIPS Agreement, such as preliminary injunctions and damages, but it must also ensure that these remedies are effectively and expeditiously applied by their judiciary in relevant cases.

Among the obstacles that U.S. patent holders, especially those holding pharmaceutical patents, are facing with respect to the enforcement in the Hungarian courts of their intellectual property rights, is the difficulty of obtaining preliminary injunctions against infringements of their process patents. This problem is especially exacerbated by the seeming unwillingness of the Hungarian judiciary to reverse the burden of proof in process patent infringement cases involving new products, as required by TRIPS Art. 34. The unwillingness to order the defendant to demonstrate the actual process used in producing an identical product in a process patent infringement case involving a new product makes it very difficult if not impossible, to enforce a process patent in the Hungarian courts. This is particularly true given the difficulty that process patent holders have in determining, through reasonable efforts, the process that was actually used by the

defendant.

In addition, lax civil procedural practices by Hungarian courts unfairly allow a defendant to introduce new defenses at advanced stages of infringement cases – sometimes even during appeals that are pending in the second instance – resulting in protracted litigation from which the alleged infringer unfairly benefits. Furthermore, Hungarian courts fail to revoke the rights of defendants who fail to comply with requests to submit sufficient evidence.

Taken together, these current practices provide less-than-expeditious enforcement of intellectual property rights. As a result, the enforcement of patent rights that is envisaged by the TRIPS Agreement is rendered ineffective in Hungary.

Requirement of Local Working

Current Hungarian patent law does not explicitly recognize the importation of a patented product as meeting the “working the patent” requirements contained in the law. As such, Hungarian law should be amended to guard against the granting of a compulsory license when patented products have been imported. Local manufacture should not be necessary to satisfy the working requirement.

Failure to comply with U.S.-Hungary Bilateral Trade Agreement

Hungary has failed to implement the Agreement properly by improperly defining the filing date of certain “pipeline” patent applications.

Other Market Access Barriers

There is a general lack of objective and verifiable criteria by which medicinal products are admitted to reimbursement lists. This is especially blatant in the case of the positive list for indigent patients (*Közgyógy*) affecting approximately six percent of the population but nearly 20 percent of total pharmaceutical demand. Indigent patients receive all medical care, including pharmaceuticals, free of charge. The list contains all categories on the general positive list, as well as additional categories which are not reimbursed through the general list.

The vast majority of the products on the *Közgyógy* list are locally produced products. Even when an imported product is available at equal or lower price, preference is given to the local one. Additional products – not reimbursed through the general list – are exclusively locally produced. Companies are not informed about the reasons for non-inclusion of their products and no appeal procedure is available.

In June, the Hungarian Government ordered a pricing and reimbursement freeze on pharmaceutical products for 180 days. This freeze was carried out in a non-transparent manner, and will adversely impact U.S. firms which provide a large proportion of innovative pharmaceutical products and which have been denied access to the reimbursement list.

Potential Exports/Foreign Sales

PhRMA conservatively estimates that the industry's sales would increase by between US\$ 50 million and US\$ 100 million if the aforementioned trade barriers were removed

December 4, 1999

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

LITHUANIA

Intellectual Property Protection

Lithuania's patent law took effect on February 1, 1994, and product patent protection for pharmaceutical products became available. The Agreement between the United States and Lithuania on Trade Relations and Intellectual Property Rights Protection was signed on April 26, 1994. According to Article VII, paragraph 5, a contracting party shall provide a transitional protection for pharmaceutical products for which product patents were not available prior to February 1, 1994, if the following conditions are satisfied:

- the U.S. patent has been issued for the product based on application filed 12 months or more before February 1, 1994, but not before February 1, 1984,
- the product has not been marketed in the territory of the Contracting Party providing such transitional protection.

However the Lithuanian government did not ratify this Agreement because of strong opposition of local pharmaceutical companies. Consequently, the products that could qualify for "pipeline" protection have now lost this benefit and now must compete against pirate copies. "Pipeline" protection for marketed pharmaceutical products in Lithuania is needed.

Data Exclusivity – Confidentiality

As it takes 10 to 12 years to bring a new medicine to the market, the benefits of the 1994 patent act will not be felt before 2006 because its "pipeline" provisions are ineffective. Until then, data exclusivity is the only type of protection which may prevent early copying.

However, current Lithuanian law does not include any provisions meeting the requirements of Art. 39.3 of WTO-TRIPS on the use of a previous applicant's documents, and, in particular, does not provide that, in order to refer to documents submitted by a previous applicant, the second applicant has to obtain the consent of the said previous

applicant.

Potential Exports/Foreign Sales

PhRMA is not able at this time to provide any reliable estimates of the increase in our industry's sales that would accompany the removal of the aforementioned trade barriers.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

POLAND

Intellectual Property Protection

The majority of in-line and many new products suffer from inadequate patent protection because they were patented prior to the enactment of a new patent law in 1993 and also because the development and registration process is long (10 - 12 years or more in some cases). Poland's pipeline protection provision, which was enacted in 1993, contains so many limitations that, in practice, it is worthless. In particular, products that had a first marketing authorization anywhere in the world in the six months prior to December 1992 only benefited from market exclusivity if the product was actually manufactured in Poland. In addition, the term for all process patents (new and existing) has not been extended to 20 years.

A new law on Industrial Property Protection has just passed through the legislative process in Parliament. The law is awaiting the President's signature and he has sent it to the Constitutional Tribunal in view of uncertainties with regard to trademark ownership.

TRIPS/EU incompatible provisions in the draft Industrial Property Law include:

- *lack of clarity of patent holders rights so that infringer can invoke the law as a defense*
- *lack of statement that governments can invoke compulsory license only in terms of public safety or order for non-commercial production*
- *Roche-Bolar provision*
- *lack of Supplementary Protection Certificates provision (patent restoration term)*
- *international exhaustion of patents*
- *lack of scope and duration provision for compulsory licensing*
- *non-transparent and undefined use of words "excessively high price" of pharmaceuticals as a reason to grant compulsory license*
- *no reversal of burden of proof*

Data Exclusivity

Data Exclusivity is that period of time during which another company, to obtain marketing authorization for a generic product, may not refer to and the regulatory authorities may not rely on test and clinical trial data provided earlier by the originator company. In order to obtain regulatory approval for a product pharmaceutical companies are required to submit costly pharmacological and toxicological test and clinical trial data to the drug regulatory authorities for them to assess the efficacy and safety of the product. This proprietary information is secret and confidential and typically cannot be patented.

Data protection and data exclusivity remains inadequate In Poland. There is clearly a policy to encourage the production and rapid registration of copies while there is still a “window” before joining the EU and higher IP standards make this impossible. There was a steep increase in the number of generics (true and copy products) registered in 1999. There appear to be two reasons for this attitude. Firstly, the view is still prevalent that health care cost control can be achieved through weak IP protection. Early adoption of copies is an instrument used by the Polish Government to bring down prices and particularly reference prices. The second reason is the protection of manufacture by domestic producers, coupled with the failure to understand the need to adapt to becoming a real generic industry in view of global generic competition and in view of EU accession. In the absence of effective patent protection for in-line products, data protection is the only means to protect R&D products still patent protected in the U.S. and Europe from being exposed to premature copies. Poland has missed deadlines under international agreements (TRIPS, Europe Poland Agreement) to implement data exclusivity.

Article 39.3 TRIPS requires WTO Members to protect against “unfair commercial use” of the costly and confidential test data submitted to governments as a condition for obtaining marketing approval of pharmaceutical products utilizing new chemical entities, although it does not specify a data exclusivity period. The data protection term is 6-10 years in the EU, and 5 years net in the U.S. and New Zealand.

Data protection is not part of the industrial property law and should be regulated through provisions governing drug registration. Currently, Polish law provides for abridged registration dossier if the originator product has been on the market for more than 3 years (Ordinance on Register of Pharmaceuticals and Medical Materials, 15 December 1993, at §5). However, §10 provides that the Registration Committee may in appropriate circumstances at the request of the applicant defer from requesting some of the documents which would normally have to be submitted. By providing a period of three years of data exclusivity, Poland is in clear violation of its TRIPS obligations. It is likely that health authorities in Poland will continue to provide marketing approval to products relying on proprietary test data of patented products without the approval of the right holder.

A new draft pharmaceutical law is currently under development. However, its provisions are inadequate in respect of data exclusivity:

- the law provides for 6 years for original products registered in the EU, with the term counting from the registration in the EU, however given the delay in registration in Poland the effective period of data exclusivity would be significantly reduced
- the law introduces patent linkage for data exclusivity. The data exclusivity period can end even prior to six years if the underlying patent expires earlier, even though data protection provides for a different type of intellectual property protection (non-patentable data) than patents (invention), and even though TRIPS 39.3 does not provide for limitation of data protection due to patent expiration.

The draft law is expected to reach Parliament in November.

Poland maintains that according to the provisions of its 1993 Act on Unfair Competition, Polish ordinary courts would be competent to hear cases involving cases of test data protection and that these courts were bound to apply TRIPS since January 1, 2000. Poland refers owners of data to seek protection of their proprietary information in a court proceeding. However, the Unfair Competition Act (UCA) is not suited to fulfill the TRIPS obligations under Article 39.3 for several reasons. First, the UCA is not directed at the behavior of governments, which is the intent of this paragraph of TRIPS, but at the actions of private parties. Second, the UCA is designed to allow for a civil action after the breach of confidentiality has occurred or data have been used otherwise unfairly; it has no power to prevent the breach, which is the intent of Art. 39.3. The governmental agency to which the data are entrusted by the owner of the data is able to prevent the unfair use if appropriate legislation so directs the agency. Third, confidentiality obligations imposed on governments, including those of Art. 39.3, would inhibit any data gathering process that would be necessary to pursue a case through the UCA. As long as Poland does not have a specific regime in place to guarantee the protection of original filing data, it is in violation of TRIPS.

Weak Enforcement of Existing Patent Rights

TRIPS Article 41 requires Poland to provide for fair and equitable enforcement of intellectual property rights. The current patent law does not provide for preliminary injunctions, without which a patent may lose much of its value to the patent holder due to the time it takes to litigate a patent action. This is a key remedy in patent infringement actions.

The draft law provides for preliminary injunction but this is in terms of a generalized statement. The law states that the patent holder can apply to the *court* (and not the patent office) in cases of infringement. However, it is noteworthy that a patent section has been established in the Supreme Administrative Court. Article 71 of the new law would allow a party who was, in good faith, using an invention at the time of a decision on patent precedence was being taken, to continue to use the invention without charge even when patent precedence by another party is confirmed.

Compulsory Licensing

Article 31 TRIPS sets out a number of requirements that must be satisfied in order to ensure that the use of inventions without consent of the patent owner complies with the

TRIPS Agreement. Although several of these conditions appear to be incorporated into the draft patent law, others do not. In particular:

- Article 82.4 of the new law states that a compulsory license can only be granted if the applicant can prove that he has applied for a license from the right holder in all good faith. This does not comply with the requirement of Art. 31(b) TRIPS that (other than in cases of emergency) the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and that such efforts have not been successful within a reasonable period of time;
- Article 84.2 of the new law requires the Patent Office to define the scope and duration of the compulsory license. It does not, however, comply with the requirement in Art. 31(c) TRIPS that the scope and duration must be limited to the purpose for which the use was authorized;
- Although Art. 86 of the new law provides that in certain circumstances, there is a power to amend compulsory licenses, this does not comply with Art. 31(g) TRIPS which provides that a compulsory license must be terminated if and when the circumstances which led to it being granted cease to exist and are unlikely to recur;
- There is nothing in the new Patent Law indicating that the use permitted under the compulsory license must be predominantly for the supply of the domestic market as is required by Art. 31(f) TRIPS.
- The amount payable in respect of the compulsory license is to be based on “the market value of the license”. This is arguably inconsistent with Art. 31(h) TRIPS which requires the amount payable to be adequate in the circumstances of the case, the economic value of the license being only one factor to be taken into account.
- In addition, the new patent law, at Art. 68, prohibits the enforcement of patent rights in an abusive manner. The draft patent law also provides that the abusive enforcement of a patent right is grounds for a compulsory license. However, Art. 68 does not appear in the Chapter of the law that deals with Compulsory Licenses, suggesting that this article is intended to have further effects. If this is the case, two possibilities arise. The first is that a third party infringer of a patent can invoke Art. 68 as a defense. This would contravene the exclusive rights conferred by a patent under Art. 28 TRIPS, and cannot be justified under Art. 30 TRIPS. Secondly, acts falling within Art. 68 will mean that Poland’s competition laws can be invoked against the patent owner.

Exhaustion

Article 70 of the draft patent law provides for patent exhaustion in countries with which Poland has concluded a free trade agreement. Therefore it exempts from infringement importation into Poland of products that are placed on the market outside Poland by third parties without the consent of the patent owner. In essence Poland is providing for international exhaustion of patent rights, which itself undermines the rights of

the patent owner. It is in direct contravention of the exclusive right to import provided by Article 28 TRIPS and is incompatible with principles of patent law existing in the EU Member States.

Market Access Barriers

Transparency

Registration and reimbursement and pricing systems lack transparency and the framework in which they are conducted undermines competition and penalizes foreign products. In January 1999 an ordinance came into effect which provided at some criteria for grouping similar products for reference price purposes. However, this ordinance is not respected by the authorities and was weakened by substituting the original phrase “the same” with regard to criteria such as mechanism of action and indications for the word “similar”. Furthermore the reference price instrument is applied inconsistently. The ATC/DDD system which was developed as an instrument to measure drug consumption is used inappropriately contrary to the WHO guidelines for its use which that the use of the ATC/DDD classification for reimbursement and pricing decisions is a misuse of the system. The system does not comply with the EU Transparency Directive.

New Pricing and Reimbursement Law

In late March, a new pricing proposal was sent out from the Ministry of Finance. However, representatives of foreign-based firms were not among the list of reviewers. While the current law imposes significant market barriers to the research-based pharmaceutical industry, the new law will make it even more difficult for the U.S. pharmaceutical industry to operate in Poland.

A draft pricing law is beginning the legislative procedure in Parliament. The draft law covers price issues in general but specifically pharmaceuticals. The provisions concern reimbursed drugs but there is a facultative possibility to extend the system to hospital products. The intention is to treat both domestic and foreign products in the same way, instead of the current administrative price fixing for domestic producers operated by the MOF. Prices will be “negotiated by the MOH based upon a recommendation from a drug management advisory team including two representatives from each of Ministry of Health, Ministry of Finance, Ministry of Economy and the Union of Health Insurance Funds”. Recommendations will be based upon five criteria:

- level of prices in countries with a similar per capita GDP
- comparison of prices used by producers and importers
- costs of production and importation
- volume of achieved and declared sales
- results of pharmacoeconomic analysis

The provisions of the law are likely to come into effect in 2001. This proposal will distort free trade and hamper open competition by continuing to impose a non-market-

based approach to the purchase and consumption of pharmaceuticals. Since the U.S. research-based industry is the world leader in the development of new medicines, our members and their innovative products will disproportionately bear the brunt of these measures and will also be denied the opportunity to compete fairly.

The draft law also introduces an amendment of the Health Insurance Law concerning reimbursement. It appears that some of the provisions of the EU Pricing Transparency Directive have been incorporated as a delegation for the Minister of Health to set criteria and procedures. The law states that pricing and reimbursement procedure cannot extend beyond 180 days.

Formularies

In mid 1999 the Office of the Government Plenipotentiary for implementation of Health Insurance produced a formulary for primary care physicians supposedly based upon the “competencies of the primary care physician”, indicating which products could be prescribed directly by them and which only after a specialist initiated therapy. Compared with the reimbursement lists, the formulary was restrictive and left out many innovative products. The individual Health Insurance Funds were to decide on whether to implement the formulary or not.

Recently, very restrictive local formularies have been appearing which discriminate against innovative products and favor copies of products which still enjoy patent protection in the U.S. and EU.

The formularies violate the Polish Constitution (unequal treatment of citizens, restriction by a statutory instrument of a higher legal provision) in the following ways: they are non-transparent; they are discriminatory (unfair competition); and they limit the autonomy of the physician. The Office for Health Insurance Supervision (a regulatory body) has recently stated that these formularies are illegal. However there is evidence that some regional health Insurance Funds have yet not withdrawn their local formularies.

Protectionism

The Polish system discriminates in favor of local companies:

- Registration of original products may take twice as long as the registration of subsequent copy products by local producers for products still under patent in the EU;
- Local manufacturers can count on easy registration for their products. Since 1999, the ratio between product registrations of generic products versus innovative products in Poland has developed to the disadvantage of the latter;
- Prices of locally manufactured products are set by the Ministry of Finance and then serve as reference price limits for reimbursement. Since locally produced products are not innovative products and are often less expensive than those which are imported, this results in high patient co-payment and, therefore, constitutes a trade barrier for U.S.

pharmaceutical exports to Poland;

- Government representatives have publicly announced that tax breaks are being considered for local manufacturers; and,
- Even though current legislation requires the Ministry of Health to update the reimbursement list at least once a year, the last update occurred in 1998. In the last two years, only locally produced generic products have been added to the Basic and Supplementary Drug list, while original products are constantly omitted. In fact, generic products represent approximately 70% of the reimbursement list. Since U.S. manufacturers source a large proportion of innovative pharmaceuticals, this practice impacts U.S. research-based companies more significantly than others.

Potential Exports/Foreign Sales

PhRMA estimates that the potential increase in exports per annum if the trade barriers described were removed is between US\$ 100 – 500 million.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

RUSSIA

Intellectual Property Protection

The Russian Patent Law passed in 1995 considerably improved the situation regarding the defense of intellectual property, including the protection of patents for pharmaceutical products. Companies with new product patents are able to register their patents in Russia and receive full protection. The Government of Russia has also made substantial efforts to improve legislative and enforcement provisions for intellectual property protection towards its prospective WTO TRIPS obligations, despite difficult political and economic conditions.

PhRMA appreciates the continuing efforts undertaken under the auspices of the U.S./Russian bilateral technical cooperation program, which has facilitated discussion of needed legislative and enforcement reforms, and law enforcement training for judges, prosecutors and investigators. Although problems remain in Russian administration and adjudication of patent disputes or violations of registered patents, we recognize that significant progress has been made. PhRMA has learned of two cases in which PhRMA member firms won patent infringement cases in the federal Commercial Court for Moscow and the Moscow Region, in one case for a patented product and in the second for a process patent. Given previous uncertainty in the process patent area, we hope that the most recent case in which the Commercial Court establishes legal protection for process patents will serve as useful precedent. Certainly the courts are gaining in experience in this area, but the degree of protection is dependent on the detail of each specific process patent.

Given the progress noted, we do remain very concerned by the possibility that the Government of Russia may adopt detailed provisions on intellectual property as part of the ongoing work on the Civil Code Part III, which would preempt current patent and enforcement provisions in Russian law and cause confusion for right holders and Russian law enforcement and judicial officers.

Data Exclusivity — Confidentiality

The new Russian Civil Code, which was passed in 1997, contains language which appears to meet the requirements of Article 39.3 of the GATT-TRIPS. Article 139 of the

Civil Code provides for serious penalties if commercial secrecy and confidentiality is violated. Further, the Patent Law provides protection for patents of new molecules and so far PhRMA members have experienced no problems in this regard.

Market Issues

There is a lack of objective and verifiable criteria by which products are included on reimbursement lists. Lists and state purchases are conducted with virtually no transparency and little open or verifiable concern for the interests of quality and safety.

Potential Exports/Foreign Sales

PhRMA is unable at this time to provide any reliable estimates of the increase in our industry's sales that would accompany the removal of the aforementioned trade barriers.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

SLOVENIA

Intellectual Property Protection

Data Exclusivity

After initially showing progress by enacting a data exclusivity law that was to come into effect on December 31, 1999, Slovenia reversed itself and has suspended the implementation of its data exclusivity law until December 31, 2002. Article 39.3 TRIPS requires WTO Members to protect against “unfair commercial use” of the costly and confidential test data submitted to governments as a condition for obtaining marketing approval of pharmaceutical products utilizing new chemical entities. PhRMA believes that this delay in implementing data exclusivity represents a significant step backwards for Slovenia which has been required to have a law protecting proprietary test data since TRIPS became applicable there in 1995.

In addition, the Slovenian data exclusivity provision as written suffers from several other shortcomings. Although the period of protection for confidential data is a maximum of six years, the data exclusivity period ends earlier than six years – possibly at zero years – if and when the patent expires earlier. This opens the possibility for unfair commercial use of the originator’s data in violation of Art. 39.3 TRIPS, which does not provide for a linkage of data exclusivity to a patent. The six-year data exclusivity period under the Slovenian law starts with the marketing authorization either in Slovenia or in any of the EU member states. Since Slovenian marketing authorizations are typically issued later than authorizations in the EU with its central and mutual recognition approval procedures, the Slovenian reference to a third country can considerably shorten the data exclusivity period. Furthermore, reference to third country marketing approval dates is not provided for, nor is it in the spirit of, Art. 39.3 TRIPS.

Weak Enforcement of Existing Patent Rights

Attempts to enforce the existing process patents in the Slovenian courts have been largely unsuccessful. The Slovenian courts have repeatedly denied enforcement measures under TRIPS such as preliminary injunctions and the reversal of the burden of proof. Slovenian courts have held that the burden of proof rests on the plaintiff where the alleged infringing defendant has been granted its own process patent subsequent to the plaintiff’s.

This interpretation is incompatible with TRIPS and with EU law. Several cases on intellectual property against domestic copy producers have been pending in Slovenian courts for more than four and up to six years, due the inaction or inappropriate delays of the courts. This results in a *de facto* denial of a fair and equitable enforcement of intellectual property rights as provided for in Art. 41 TRIPS.

Other TRIPS Inconsistencies

Article 32 of the Slovenian Intellectual Property Act (IPA) permits the interpretation of a patent right only as a positive right of use, whereas U.S. and European patent concepts unanimously provide for a right to restrict others from using the patented invention. Without patent rights predicated on exclusive use of the invention as outlined in TRIPS Art. 28, there is little benefit to patent protection for pharmaceutical products. Furthermore, Art. 121 of the Slovenian Law on Industrial Property discriminates against the patentability of medicines versus products from other industry sectors in violation of Art. 28 TRIPS. The effect of Art. 121 is to prevent those pharmaceutical substances that were protected by a product patent under Yugoslav law with a priority date before January 1, 1993 and subsequently transferred to Slovenia from enjoying continued product patent protection in Slovenia. Such denial results in lower patent protection of pharmaceutical products compared to products from other industrial sectors for which patents were transferred from Yugoslavia to Slovenia. Since the enactment of TRIPS in Slovenia in 1995, Art. 121 should no longer be applied.

Lack of Pipeline Protection

Product patent protection became available in 1993. However, since there is no pipeline protection, the full effect of this law will not be felt until 2013. Patent applications must be filed very early in the research and development process, and it may take up to 8 - 12 years to develop a patented product to meet safety, efficacy and quality standards before regulatory marketing authorization is granted. Therefore, the majority of currently marketed pharmaceutical products, as well as those that will be launched in the next few years, are protected in Slovenia only by a process patent, and are exposed to easy copying by local firms. Unless appropriate pipeline protection is provided, it will not be until 2013-2018 (20 years from introduction of product protection plus up to five years patent term restoration) that the full product portfolio of R&D companies will enjoy the same level of protection available today in the U.S. and most of the EU. This lack of protection has allowed and continues to allow local and other companies to routinely copy pharmaceuticals patented in the U.S. and EU. Although pipeline protection is not a TRIPS obligation, the absence of it in Slovenia has contributed to a situation where there is little effective protection for patented pharmaceutical products.

Contributory infringement

The IPA does not provide for relief against contributory infringements (see Art. 26 of the Community Patent Convention), such as supplying third parties, domestic or foreign, with intermediary products used in the synthesis of a protected substance.

Absence of Provisional Relief

Article 93 of the IPA grants relief only against infringements of a patent, but does not specify that this applies also to threatened infringements as required by TRIPS Arts. 41 and 50.

Protection against equivalents

Article 94(1) of the IPA prohibits the imitation of a protected model, design, trade or service mark, but does not extend this to patents, although the imitation of a protected invention in the way of equivalents is the most common form of infringement.

Additional Barriers to Market Access for Patented Pharmaceutical Products

Sample Products

The Slovenian regulatory authorities continue to require pharmaceutical companies applying for marketing authorization to submit product samples even though Slovenia no longer conducts analytical testing as part of the marketing approval process. This has resulted in a trade barrier for patented pharmaceutical products.

Import Tariffs for U.S. Products

The regimes under which Slovenia is gradually lowering import tariffs from pharmaceuticals produced in the EU in the context of EU accession negotiations is becoming a trade barrier. In certain cases, the difference of tariff between products of EU origin as opposed to U.S. origin can be as high as 15%. Such significant differences in tariffs influence government decisions on whether or not to reimburse the cost of a medicine, and thus put products of U.S. origin at a great disadvantage.

Additional Violation of National Treatment

In January, 1999 the Slovenian government commenced implementation of pricing regulations (sub-law of the Medicines Act) first introduced in April, 1998 which on average represented a price reduction for imported products of 30-40%. The regulations discriminate against imported pharmaceutical products, to the benefit of local producers. There is much evidence to suggest that this was in fact the original intent of the regulations, and not a coincidental result.

The regulations fix Slovenian wholesale prices based on the average of the *wholesale* prices in three reference countries in the EU – over which the manufacturers have no control – multiplied by an arbitrary factor of 0.85 (innovative products are, however, exempted from the factor requirement). Four percent for import costs can be added. As a result, foreign companies were forced to lower their prices between 20-30 percent, with more extreme consequences for individual products where pirated copies exist.

However, in reality the foreign companies have to pay a 7 percent wholesale margin, 1 percent import costs and custom duty (EU origin: 0 percent as of January 1, 2000; non-EU origin: 10-15 percent). As long as Slovenia is not a full member of the EU, the MFN clause should remain applicable, and tariffs for products such be reduced to EU levels. Furthermore, Slovenia should be encouraged to follow the Czech example and sign

a zero-for-zero agreement.

The exchange rate in these regulations is the middle exchange rate of the Bank of Slovenia. However, wholesalers have to buy foreign currency at commercial exchange rates which are much higher. Thus, wholesalers are further discouraged from purchasing imported rather than local products.

Conflict of Interest

In Slovenia there are a number of conflict of interest situations which hamper fair decision-making and result in trade barriers. For example, the CEO of a local pharmaceutical company is a president of the Assembly of the State Sick Fund. The Assembly meets four times a year, and decisions of the Reimbursement Committee are reviewed. This has an influence on the choice of products for, and the level of, reimbursement. If a product is excluded from reimbursement, it has virtually no acceptance in the market, because Slovenian patients will not pay out of pocket for medicines. The main criteria considered by the Reimbursement Committee is price, and in general pricing and reimbursement decisions are not transparent and are taken without the involvement of the pharmaceutical companies. No mechanism of appeal exists.

Product Registration

Product registration in Slovenia lacks transparency and discriminates against foreign products. For new product applications under review, the Slovenian MOH requirements for product prescribing information are frequently inconsistent and often require more extensive information from foreign companies than from local firms.

- a) The MOH does not accept foreign clinical data for product registration, but insists upon a local expert report. In addition, the Ministry accepts only original documentation and certificates. These requirements are not based on scientific principles, but are clearly discriminatory and intended to delay the time to market foreign products.
- b) Local testing of foreign products takes up to one year despite the fact that the products are manufactured according to the international standards and are accompanied by the manufacturer's Certification of Quality Assurance. The local trials offer no additional verification of safety, quality and efficacy beyond those already established by the manufacturer's initial clinical trials conducted abroad.
- c) Every batch of imported products must be tested, causing further delays in receiving import documentation and additional costs.

Potential Exports/Foreign Sales

PhRMA estimates that the industry's sales would increase in the range of US\$ 50 million to US\$ 100 million if the aforementioned trade barriers were removed.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

UNITED KINGDOM

The National Institute for Clinical Excellence (NICE) – A Fourth Hurdle to Market Access

The National Institute for Clinical Excellence provides guidance to the National Health Service (NHS) on the cost and clinical effectiveness of medicines and medical technologies. As well as judging cost and clinical effectiveness, NICE is required to have regard to the “effective use of available resources” in the NHS, which brings its work into the arena of cost control. Department of Health officials have admitted that both the Department and ministers themselves discuss with NICE questions of affordability and priorities in relation to certain NICE appraisals. The fact that it is an agency of the Government gives rise to the legitimate suspicion that NICE is an arm of cost-control.

Government has made it clear that it expects NICE guidance to be adhered to and any parts of the NHS found to be disregarding NICE guidance would be required to account for their actions to the Department of Health. A separate agency, the Commission for Health Improvement, has been set up with statutory authority to enforce guidance to the NHS. In effect, therefore, for a medicine to be routinely used and reimbursed in the NHS, a positive NICE guidance is required. Since it is the stated aim of NICE to appraise new medicines, either at or shortly after, their launch, such medicines are faced with a *de facto* fourth hurdle to market access. As well as satisfying the marketing authorization requirements of quality, safety and efficacy, such medicines must prove their cost-effectiveness to NICE.

A further issue emerging is one of NICE “blight”. There is evidence that health authorities are discouraging the use of new medicines that are in the process of being evaluated by NICE, on the grounds that it is necessary to await final guidance before deciding their policy. Since it is usual for the assessment processes to take up to one year, and often longer, to be completed, medicines affected by this blight can be prevented from reaching the market for this significant length of time.

The problem is compounded by the fact that both the Government and NICE itself

assume that it is possible to reach a definitive judgment on the relative therapeutic value of a new product before it is introduced into the marketplace. The proposition that NICE's role is to focus spending on products that offer a real "breakthrough" or significant therapeutic improvement or cost-benefit over existing products founders because it is based upon the fallacy that such attributes can be measured objectively in new products. Repeated submissions from industry bodies to the UK Government on this point have been ignored. The Government persists in arguing that the true economic and therapeutic value of a medicine can be measured at or around the time of launch.

A fourth hurdle, such as is presented by NICE, restricts the access of medicines to the health service where they can be used to improve the quality of care. Even where NICE guidance is ultimately positive, the delay and blight that is associated with the process, means that access is at the very least slowed. Aside from having a damaging impact on the quality of health care for patients, the fourth hurdle impedes the ability of pharmaceutical companies to sell their products, for which they have received legitimate marketing authorization, to the market. Although promoted by the UK Government as a way of securing faster access and better use of medicines, the impact of NICE is likely to be the reverse.

Parallel Trade

It is estimated that parallel trade costs the pharmaceutical industry in the UK over £750 million (translate this into \$) every year. More than one in eight prescriptions in the UK are now filled with a parallel imported product, accounting for more than 10 per cent of sales in 1999. The level of parallel trade into the UK has increased dramatically in recent years.

Parallel trade growth is further driven in the UK by the fact that, indirectly, UK pharmacists have incentives to dispense parallel imports. The "clawback" mechanism presupposes that pharmacists receive discounts on the drug tariff price and so acts as an incentive for the pharmacists to buy the cheapest products – usually from parallel importers.

The use of parallel trade as a further mechanism to control costs in the UK drugs bill is shortsighted. The benefits to the UK taxpayer are, in any case, negligible, since most of the profit available from exploiting the price differential goes to the parallel traders themselves. Parallel trade does have a disproportionately negative impact on U.S. companies because it focuses on new innovative products.

The Pharmaceutical Price Regulation Scheme (PPRS)

The PPRS is the means by which, indirectly, the UK Government controls the price of branded medicines sold to the NHS. Although the PPRS permits the free pricing of new products at launch (this benefit though is eroded by the effect of parallel trade), it does so within a context where the profits that pharmaceutical companies are allowed to make from

sales to the NHS are strictly controlled. Profit is regulated in relation to the return a company is allowed to make on the capital they have invested in research, development and manufacturing for sales to the NHS (or return on sales for smaller companies). Although the PPRS is supposedly a “voluntary” agreement, negotiated between the ABPI and the Department of Health, this is in name only. Since 1999, the Government has possessed legal powers to oblige all companies covered by the Scheme to comply with it. The Health Act 1999 also prescribes financial penalties for non-compliance.

The PPRS is renegotiated every five years. The existing Scheme came into force in October 1999. As a condition of this new agreement, the Department imposed upon the industry an across the board price cut of 4.5 per cent with prices then frozen until January 2001 (apart from cost-neutral modulations). The 4.5 per cent price cut was arbitrary, imposed by the Government without reference to any objective other than its own determined need to control growth in the NHS drugs bill.

The PPRS also creates perverse incentives. It encourages, for example, the "gold-plating" of assets, since a higher capital base means higher prices, regardless of whether the additional capital investment is efficient. There is also a potential export disincentive, since increasing productivity and exports would lead to a lower allowable capital base for home production and hence lower allowed prices.

The PPRS is but one intervention practiced by the Government in the market for prescription medicines in the UK. Such interventions exist on both the supply and demand sides. Deregulation of the PPRS should be part of a wider picture of market reform that permits easier access of medicines to the NHS and a central role for competition in both driving up quality and moderating prices.

Potential Exports/Foreign Sales

PhRMA estimates that our industry's sales would increase by more than US\$ 500 million if the aforementioned trade barriers were removed.

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA
(PhRMA)**

**FOR THE
NATIONAL TRADE ESTIMATE REPORT
ON FOREIGN TRADE BARRIERS (NTE)**

2001

November 27, 2000

Middle East/Africa/South Asia

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

EGYPT

Intellectual Property Protection

Although PhRMA is pleased to note incremental steps taken by Egypt towards meeting its current WTO TRIPS obligations, Egypt has thus far failed to implement needed measures to meet its current (January 1, 2000) obligations, including data exclusivity (Article 39.3), enactment of a patent mailbox (Article 70.8), and exclusive marketing rights (Article 70.9). In addition, Egypt's current draft industrial property legislation falls far short of meeting minimum TRIPS standards. The U.S. Government should not reward Egypt with the initiation of Free Trade Area Agreement (FTAA) negotiations unless and until Egypt demonstrates its ability to meet current WTO obligations, including full TRIPS compliance.

Current TRIPS Obligations

In the past year, Egypt has moved closer to compliance with WTO TRIPS obligations by administratively extending the period of protection for process patents to 20 years. PhRMA also appreciates the constructive steps that the Government of Egypt has taken to date on Exclusive Marketing Rights (EMR), including issuance of Prime Ministerial Decree 547, a Ministerial Decree from the Ministry of Higher Education and Scientific Research, and publication of implementing regulations by the Academy of Scientific Research and Technology. PhRMA members await the final implementation of the EMR decree through the approval of the first EMR application for Eli Lilly's product Zyprexa® (olanzapine). Egypt was required to provide EMRs to products meeting requirements specified in TRIPS Article 70.9, as of January 1, 1995. Lilly's mailbox patent application in 1996 initiated the EMR approval process. Egypt is now more than four years behind in meeting its obligation to implement EMRs.

Both with respect to products that are eligible for EMR approval, and with respect to other eligible products, PhRMA has formally requested that Egypt adopt a Prime Ministerial Decree similar to the EMR decree to provide protection for confidential test and other data from unfair commercial use. In this respect, PhRMA has requested, and the Egyptian Ministry of Health has agreed to provide, a pause in consideration of applications pending as of January 1, 2000. This has resulted in a freeze on product applications for

registration and marketing approval of pharmaceutical products that make reference to, rely directly or indirectly on, or otherwise make use of, protected data.

With respect to the Data Protection Decree, PhRMA remains concerned that critical elements may be lacking in the draft currently under consideration within the Prime Minister's office. An effective data protection system must have a number of key features: Regarding jurisdiction, it is essential that the decree cover products currently being marketed in the U.S. or elsewhere that have not yet entered the Egyptian market. In particular, generic marketing approvals may not be granted on products that had not entered the market as of January 1, 2000, in view of the fact that the TRIPS Agreement became applicable to Egypt on that date. A period of protection of at least 5 years from the time the product was first registered in Egypt is another important feature of an effective data protection regime. (The EU and Japan provide a term of protection more than this, varying from six to ten years). The protection against unfair commercial use must cover both direct and indirect reliance by the relevant ministry on the data package used to support initial marketing approval. This means that the protection should extend to the data itself as well as to conclusions based on that data, so that an application not filed by the innovator will not gain approval for the full term of protection. If not carefully crafted, the decree may allow third parties to unfairly take advantage of the delay in implementing this protection, or could unfairly result in denial of protection to parties entitled to such protection. It is also important that accompanying instructions be issued simultaneously with the decree.

Draft Industrial Property Law

The current Egyptian patent law is based on the "Law on Patents, Designs, and Industrial Models 1949-1955." The current law has specific discriminatory aspects against pharmaceuticals. While the basic patent term available in Egypt is 15 years from date of application (with a possible extension of up to 20 years), pharmaceuticals, medicines and foodstuffs specifically are excluded from product patentability. Furthermore, while manufacturing processes for pharmaceuticals and medicines are patentable, the term for process patents is only 10 years, which poses an additional layer of discrimination. Given the long period of time between the grant of a patent and the commercialization of the product due to regulatory review, a 10-year process patent is virtually meaningless.

The latest draft industrial property law retains a substantial number of inconsistencies with the TRIPS Agreement, and introduces a few new ones. These include but are not limited to: inappropriate restrictions on patentable subject matter, aggressive compulsory licensing provisions (including local working requirements), discrimination against pharmaceutical patents inconsistent with TRIPS Article 27, inadequate protection for trademarks, limited and inconsistent protection of trade secrets and confidential data, inadequate penalties for infringement and generally deficient enforcement provisions. It is important that the U.S. Government deliver a strong message that the Government of Egypt should adopt a patent law that at the very least does not fall below minimum international standards for protection of industrial property contained in the WTO TRIPS Agreement.

Other Barriers

Egypt maintains an onerous price control system that does not allow for price increases to compensate for inflation. Also, many regulations regarding manufacture and registration are opaque and vague. Furthermore, Egypt bans the import of many pharmaceuticals in finished dosage forms, and requires foreign companies to license the manufacture and sale of imported drugs to local companies. All of these requirements appear to violate Egypt's WTO commitments regarding national treatment of foreign investors. Moreover, as the Government has shown considerable progress in divesting and liberalizing large segments of the Egyptian economy, the pharmaceutical sector appears increasingly to be unfairly targeted for control. The sector remains under very tight price controls that distort competition and delay or discourage the introduction of new products.

Potential Exports/Foreign Sales

Egypt is a significant market – indeed one of the largest – in the Middle East/Africa region. Even under current adverse circumstances, U.S. firms hold an estimated 18 percent share of the Egyptian pharmaceutical market, in a market estimated at approximately one billion dollars in 2000. If Egypt were to meet its WTO obligations, the U.S. share of the market would likely increase to at least 25%, and the market itself would likely show substantial expansion. At present, PhRMA member companies are postponing an estimated US\$300 million in planned investments in Egypt's pharmaceutical sector. In addition, given its location and large population, if Egypt were to adopt a modern patent law and market-based pricing, it would enhance its potential as a regional center for multinational pharmaceutical production. Accordingly, PhRMA estimates current losses in Egypt as in excess of US\$100 million.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

GULF COOPERATION COUNCIL

Intellectual Property Protection

The GULF COOPERATION COUNCIL (GCC) secretariat has recently taken actions undermining the ability of its members to remain in compliance with World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) obligations by approving Gulf-wide sale of copycat products through the central procurement process (known as the Secretaries General of Health (SGH) pharmaceutical tender process in Riyadh, or the SGH process). In addition, several GCC members have yet to implement the GCC 1999 patent law and regulations, or have failed to do so in a transparent and TRIPS-consistent manner. These developments, combined with the unwillingness or inability of the United Arab Emirates (UAE) to meet its current TRIPS obligations, have resulted in a significant threat to the American research-based pharmaceutical sector in the Gulf.

The unauthorized production in the UAE of U.S. patented pharmaceuticals by the Ras Al Khaimah firm Julphar, and the subsequent registration of these copycat drugs by the UAE federal government in Abu Dhabi poses a threat far beyond the UAE market. PhRMA members face potential losses of multi-million dollar markets for their leading products throughout the Gulf. PhRMA understands from U.S. Government (USG) reports from Riyadh that pirated pharmaceuticals are also now beginning to be produced in Saudi Arabia. In order to stem the tide, PhRMA has recently filed a petition for a Special 301 out-of-cycle review of the UAE, seeking the UAE's identification as a Priority Foreign Country under the provisions of the Trade Act of 1974, as amended.

GCC Practices Undermine the 1999 Patent Law

Despite the substantial efforts of individual members, the GCC's overall level of patent protection is less than meets the eye. PhRMA remains concerned that recent activities of the GCC secretariat through the SGH Tender Committee undermine existing patent and data protection in GCC member states. For example, the GCC Secretariat has recently approved for sale a number of copycat products produced in the UAE (described above). While industrial property officials in most GCC states take their January 1, 2000 TRIPS obligations seriously, the GCC is now marketing these pirated products to Ministries of Health throughout the Gulf. These Health Ministries appear unaware or

unconcerned that these procurement practices violate the TRIPS Agreement. Although the GCC secretariat has declined to release the list of affected products, PhRMA understands that the list includes cutting-edge products from GlaxoWellcome, Johnson & Johnson (doing business as Janssen-Cilag), Merck, Pfizer, and other leading international innovative pharmaceutical companies. Despite repeated USG and industry communications to the GCC on this subject, the Secretariat is moving forward with its plans to sell these products throughout the Gulf. The Director General of the GCC Patent Office, Mohammed Al-Racheed responded to PhRMA's September correspondence via a letter dated November 19, 2000 wherein he stated that unless a PhRMA member has sought patent protection through the GCC Patent Office, the GCC secretariat bears no responsibility to protect the intellectual property rights in question (correspondence attached).

The GCC's new patent law and regulations were approved by GCC Ministers on November 27, 1999. In theory, they have been implemented by all GCC members. Neither industry nor the USG had the benefit of discussion or review of the proposed patent regime prior to final passage and implementation of the new regime. There are a number of basic problems in the regime, including a lack of data protection, and other WTO-inconsistent provisions.

In late November 1999, U.S. representatives raised the issue of the new patent law and regulations with GCC members, but were unable to obtain definitive responses regarding the important issue of legislative preemption. For example, interlocutors were unable to answer whether the GCC laws take precedence over individual state laws that may be more consistent with TRIPS, and the relationship between GCC institutions and national regulatory or judicial bodies.

GCC Patent Provisions that Conflict with WTO Member TRIPS Obligations

The GCC legislation fails to meet the following WTO TRIPS requirements:

- The GCC patent law requires local working.
 - ◆ TRIPS requires that patents be available and patent rights enjoyable without discrimination as to the field of technology, place of invention, and whether products are imported or locally produced (Article 27.1). Importation must be considered to be equivalent to working the invention locally for purposes of any conditions placed on enforcement or use of patent rights. To the extent that individual GCC states fail to treat importation on the same terms as local manufacture of the patented invention, their patent regime will not rise to the minimum level required by TRIPS.
 - ◆ TRIPS Members cannot condition use of patent rights based on where a product subject to the patent has been manufactured. (Article 27.1) Thus, if a Member requires a patent owner to "work" the patented invention or face the sanction of

a compulsory license, the patent owner must be allowed to satisfy this requirement by importation of the product. Given the experience we have had with so-called "working requirements," it is essential that the law explicitly provide that the "working requirement" can be met not only through local manufacture of the product but also the importation and sale of the product. This is one of the most important provisions of the TRIPS Agreement.

- The GCC Patent Law does not include Data Exclusivity.
 - ◆ In addition to enumerating patent standards, the TRIPS Agreement requires that Members protect undisclosed information. Specifically, it requires Members to permit owners of certain undisclosed information – often called trade secrets – to prevent others from disclosing, acquiring, or using this information without their consent in a manner that is contrary to honest commercial practices. In addition, TRIPS requires Members to protect certain test data from disclosure and “unfair commercial use” if that data is submitted to the Member to obtain permission to market a pharmaceutical or agricultural chemical product. In other words, those who generate this valuable data must be able to prevent competitors from relying on this data to prove that their products are safe and effective for a reasonable period of time, which in most instances will be ten years (Article 39).
- The GCC Law does not provide full patent protection in all areas of technology.
 - ◆ TRIPS requires that patents be available for inventions in all technological areas except for those specifically enumerated in the second and third paragraphs of Article 27. Given developments in communications and information technology, the term “invention” now includes processes executed on computers and processes for conducting business, especially those conducted electronically. As a result, some exceptions related to computer programs and methods of doing business that were often contained in patent laws are often now too broad to be consistent with the TRIPS Agreement.
 - ◆ TRIPS Members can exclude certain inventions on grounds related to public order. This exclusion can only be used if it is necessary to prevent commercialization of the invention within the Member to protect the public order. The mere fact that it is illegal to market a particular type of invention is not sufficient to exclude it from patentable subject matter. (Article 27.2)
 - ◆ TRIPS Members are permitted to exclude plants and animals from patentable subject matter. Such exclusions, however, will deter the development and marketing in the region of new biotechnology products that can provide great benefits in the forms of improved agricultural and medical products to residents of the region. Furthermore, TRIPS Members who fail to provide patent protection for new plants must protect plants under a separate form of

protection, such a system consistent with the 1991 Act of the UPOV Agreement (Article 27.3).

- The GCC Patent Law contains Compulsory Licensing provisions that are not consistent with the TRIPS Agreement.
 - ◆ The TRIPS Agreement enumerates safeguards that Members must apply to protect patent owners if they chose to permit third parties to use patented inventions without the authorization of the patent owner (often called compulsory licenses). (Article 31) For example, there must be some merit or benefit to permitting unauthorized use of the patented invention. Further, the request for the compulsory license must be evaluated and granted on an individual basis. (Article 31(a)).
 - ◆ In instances other than antitrust violations or national emergency situations, those seeking to use the patented invention must request a voluntary license from the patent owner before requesting a compulsory license. (Clause (b))
 - ◆ Any compulsory license granted must allow use of the patented invention that is explicitly limited to the supply of the domestic market. The holder of a compulsory license may not manufacture the patented invention and export it to foreign markets without authorization of the patent owner. (Clause (f))
 - ◆ Third parties must compensate the patent owner for the unauthorized use of the patented invention and the compensation must take into account the “full economic value” of the use. This means that the compensation must be set at market value, not a pre-established royalty rate for a class of inventions. (Clause (h))
 - ◆ Decisions permitting unauthorized use of a patented invention and on establishing compensation levels under the license must be subject to judicial or independent review. (Clauses (i) and (j))
- The GCC Patent Law does not provide for required enforcement mechanisms.
 - ◆ In addition to requiring that the Members’ patent laws meet certain substantive standards, the TRIPS Agreement requires that Members have fair and equitable systems for granting and for enforcing patent rights. These systems must not be unnecessarily complicated or costly and must be expeditious. (Articles 41 and 62)
 - ◆ TRIPS requires all Members to make available provisional remedies (e.g., preliminary injunctions, temporary restraining orders, *ex parte* seizures). Provisional relief is critically important to most enterprises, and a failure to

provide this relief will be viewed as a serious deficiency (Articles 44 and 50).

- ◆ Members are also required to award damages to patent owners to provide full compensation for the economic damage caused by the infringement of the patent. In addition, judicial authorities must be authorized to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity. (Article 45)

Potential Exports/Foreign Sales

It is not possible to provide a reliable current estimate of the potential market size for PhRMA member companies throughout the GCC member states, if current deficiencies were rectified. However, the Saudi pharmaceutical market was estimated at more than US\$1 billion, and the UAE market is valued at US\$200 million annually. If the GCC Secretariat continues to undermine the ability of its member states to provide TRIPS-consistent patent and data protection, the damage to the U.S. research-based pharmaceutical industry will be substantial, amounting to tens of millions of dollars per year.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

INDIA

India's industrial property system was designed to allow local Indian industries to free-ride on the innovations of inventors and companies from developed countries like the United States. Their patent system denies rights for pharmaceutical and other chemical product inventions and makes procurement and enforcement of patent rights virtually impossible. Most U.S. companies do not even attempt to obtain patents in India because of the difficulties they face in obtaining, licensing and enforcing rights.

Unfortunately, the Indian regime has become a "model system" for opponents of strong intellectual property protection systems. Those who cite the "benefits" of the Indian regime tend to be those who support weakening the disciplines of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). In other areas of its trade regime, India continues to resist U.S. requests for improved market access and other needed reforms. Furthermore, India continues to block the international consensus that is needed to continue market access and other trade reforms sought by the United States in new multilateral trade negotiations in the WTO.

Moreover, India has refused to take the difficult steps needed to reform its fundamentally flawed industrial property system. Rather than use the five-year transition period under the TRIPS Agreement to bring about the legislative and regulatory reforms to comply with its obligation, India has chosen to fight the U.S. and European Union on a simple transitional measure it had failed to implement, and has led political attacks on the TRIPS Agreement in the WTO. Now that the transition period is over, and nearly a year after India was obligated to have its reforms in place, the situation in India remains bleak for industrial property reform.

Accordingly, PhRMA urges the U.S. Government to initiate a dispute settlement action in the WTO against the Government of India for its failure to implement its obligations under TRIPS.

The Current Situation

The Indian industrial property system, particularly its patent law, has been designed to punish importers of patented technology into India, and to coerce local production and distribution of products. The current Indian patent regime contains many inconsistencies

with the TRIPS Agreement, many of which were described in PhRMA's Special 301 submission of February 18, 2000.

The Deficient Patent Regime of India

- The Indian patent system curtails or eliminates rights for foreign-originated technology or importers of patented products in a wide variety of ways. Sanctions under the Indian regime include disqualification of standing to obtain patents, special compulsory licensing penalties for those who import patented products and those who do not manufacture patented products in India.
- The Indian patent system also denies eligibility to a wide range of technologies that are within the core of the U.S. industrial base, including not only pharmaceutical and agricultural chemicals, but also other types of chemical products, glass products, and semiconductors.
- The term of protection for pharmaceutical process patents in India is only seven years under the existing Patent Act of 1970. As of January 1, 2000, India has been obligated by TRIPS Article 33 to provide a minimum term of at least twenty years from the filing date of the patent application.
- The Indian compulsory licensing system, with its infamous practice of "licenses of right" and unbridled government use authority, does not contain the safeguards required by TRIPS Article 31 and targets and penalizes U.S. inventors, particularly those that do not manufacture their inventions within India.
- The numerous deficiencies of the Indian patent system have resulted in very weak and ineffective patent protection in India. The experience of PhRMA member companies has been so negative with regard to the Indian system that most companies have abandoned efforts to obtain or enforce patents in India.

The Draft Patent Legislation

The Government of India and its Parliament are currently considering patent reform. We are discouraged that India waited until mid-November of last year, less than two months before the deadline for TRIPS implementation, to *start* the legislative process to amend its patent law. In and of itself, this is evidence of India's overall bad faith with respect to TRIPS obligations. More recently, a Parliamentary Select Committee charged with preparing the legislation has engaged in tactical delays to prevent introduction of the overdue patent reform bill. The most recent example is a six-country visit to ostensibly research the TRIPS implementation efforts of Argentina, Brazil, China, Japan and Korea with a report to follow prior to discussion of the patent law before its formal consideration in the Parliament. PhRMA believes that the date for introduction and substantive debate of the legislation will slide well into the year 2001.

The proposed legislation does improve certain features of the Indian system. These improvements, however, build on a fundamentally flawed regime. Unfortunately, the draft legislation is also regressive in a number of areas. In fact, the legislation introduces several new provisions that are inconsistent with TRIPS and fails to remove many of the most offensive inconsistencies noted above.

- The draft law, if enacted, would continue to discriminate against foreign patent owners who manufacture products outside of India. The new law retains sanctions, including compulsory licenses, for patent owners who do not "work" their patented inventions within India. Local working as a requirement for full enjoyment of patent rights without the recognition that the obligation may be satisfied through importation is prohibited under Article 27.1 of the TRIPS Agreement.
- Some improvements would be made to the existing compulsory licensing regime in Indian law. However, an extensive amount of authority would continue to be available to the Indian Government to use patented technology without the consent of the patent owner and in a manner inconsistent with Articles 27 and 31 of the TRIPS Agreement.
- Competitors would continue to have the right to harass and challenge patent applicants and patent owners. Numerous grounds will continue to be available under the law to oppose, cancel and revoke patents on grounds not permitted under the TRIPS Agreement. For example, the Indian system of pre-grant opposition would be altered to provide two new grounds for opposing patent grants that are not allowed under Article 29 of TRIPS. Combined with the backlog of more than 30,000 applications pending in India and the dearth of qualified examiners, the opposition proceedings would easily allow competitors of patent applicants to delay the issuance of a patent until the expiration of the term. This would effectively eliminate patent protection for important inventions.
- The draft law, in contravention to Article 28.1 of the TRIPS Agreement would exclude product-by-process protection for certain types of products that are now denied full product patent protection under Indian law. This exclusion also violates Article 27.1 of the TRIPS Agreement, which forbids discrimination as to the field of technology of the invention. In addition, the product-by-process protection would only be available to patents issued on applications filed after January 1, 2000, in contravention of the transition provisions contained in Article 70.2.

As noted above, the Indian patent regime currently and will continue to fall far short of India's obligations under the TRIPS Agreement. More troubling is the apparent lack of political will and commitment to the establishment of a modern patent system that delivers the patent exclusivity that is a necessary precondition to significant investments in India by our industry.

We are also disappointed that India's greatest efforts have been reserved for Geneva and Seattle, where, rather than sincerely attempting to meet its own obligations, it has

sought the support of other WTO Members for weakening the industrial property standards now found in the TRIPS Agreement. From this we can only conclude that the Indian Government is fully aware of its obligations under the TRIPS Agreement, but is unprepared to meet its current obligations. Accordingly, PhRMA urges the U.S. Trade Representative not only to strip India of its GSP benefits, but also to initiate a dispute settlement action in the WTO against the Government of India for its failure to properly implement its current TRIPS obligations.

Exclusive Marketing Rights and Absence of Data Exclusivity

India is particularly hostile to intellectual property rights that would interfere with the commercial strength of its domestic pharmaceutical and chemical industries. This explains India's essentially non-functional patent system, and the decision of the Government of India to refuse to grant exclusive marketing rights or rights in data used to obtain marketing approval for pharmaceutical and other chemical products.

India fought against implementing its obligations under Articles 70.8 ("mailbox") and 70.9 (exclusive marketing rights) until the complete WTO dispute settlement process had been completed. It made substantial commitments to the United States to settle the dispute. These commitments were to have resulted in establishment of an efficient process for granting exclusive marketing rights. However, since that settlement, the Indian regulations passed to implement the agreement have been challenged in two courts, and the Indian Government has made no effort to prevent third parties from obtaining marketing approval for covered products. India thus has ignored its obligations to settle the mailbox/EMR disputes to the detriment of U.S. interests.

India has also elected to ignore its obligations under Article 39.3 of the TRIPS Agreement. Neither the Indian Government nor the Indian Parliament has even raised the idea of implementing legislation that would provide protection for test data submitted by innovators to obtain marketing approval for their new products. The absence of such protection renders the Indian IP regime inconsistent with Article 39.3 of the TRIPS Agreement.

In the rare cases where EMR applications have actually been filed, it has been clear from the stand taken by the Patents Office that the system is totally geared towards rejection of such claims. Flimsy technical objections which amount to nit-picking are raised at every step, and the Patents Office refuses to admit judicial evidence in defense. It is thus virtually impossible to obtain and enforce EMRs without taking recourse to a long and tortuous legal process, which may be resolved only years after the claim in question has been rendered completely academic.

Government Drug Pricing Policy

The Indian Government's liberalization and economic reforms have not yet been fully extended to the pharmaceutical industry. The industry is unable to attract fresh investment

and the research-based pharmaceutical industry is either withdrawing from India or not expanding operations. In the area of drug pricing, India imposes some of the most stringent price controls in the world under the rigid provisions of the Drug Price Control Order (DPCO). In the eyes of many research-based company managers in India, this strict pricing regime - combined with the lack of any meaningful patent protection - make India virtually non-viable for research-based companies from a commercial standpoint. This is especially if those companies were to consider placing on the Indian market the latest and best innovative drugs. Foreign companies also experience arbitrary BICP (Bureau of Industrial Cost and Pricing) pricing norms.

The present pricing regime is more than five years old. Recognizing that the pricing regime needs change, the government constituted a committee to propose a new pricing policy. The committee's report was subjected to the review of a special task force, yet no meaningful new price control regimen has been established. There is no system allowing automatic increase of prices to offset cost increases and inflation. Individual research-based firms have held good faith discussions with the Government of India for provision of needed drugs at preferential rates in return for market-based reforms. Our industry would urge any new Government in India to consider seriously abolition of the DPCO. The DPCO is neither in the interest of the Indian economy nor of the Indian pharmaceutical industry, nor – and most importantly – in the interests of the Indian health care consumer.

PhRMA and its member companies desire that:

- The Government of India remove the anomalies in the present Price Control Order.
- The Government of India take measures to adopt a system of market-based pricing in India in the near-term.

Import Policies

PhRMA member companies operating in India also face high 44% effective import duty for active ingredients and 66% for the finished products import and complex import procedures. The Government of India has stated its intention to progressively lower import tariffs on pharmaceuticals. Duty rates, however, remain unacceptably high. In 1996, tariffs were brought down to 85% with plans to further decrease rates to 25% by the end of 1999. Progress has been slow and tariff rates are currently high. PhRMA urges U.S. negotiators to insist that tariffs be brought down to zero, the goal for GATT signatories.

Standards, Testing, Labeling, etc.

There currently are no discriminatory regulations for pharmaceutical multinationals, except for the problem of trademarks and the regulations concerning the size and

placement of the generic name on medicines in India. PhRMA member companies operating in India have reported experiencing arbitrary local FDA decisions.

Potential Exports/Foreign Sales

The damage caused by the inadequate protection of intellectual property rights in India reaches beyond direct losses caused by displaced sales in India. Indian bulk pharmaceutical companies aggressively export their products to third countries where intellectual property laws are similarly lax. The damage caused to U.S. pharmaceutical manufacturers due to the deficiencies of the Indian patent regime thus goes beyond displaced sales in the Indian market, and reaches to the ability of U.S. companies to compete in other significant markets, especially in the Asia-Pacific and Middle East regions. PhRMA estimates the losses attributable to the deficiencies in the Indian intellectual property system to be approximately \$500 million per year.

Accordingly, PhRMA member companies believe it is imperative that the U.S. Government initiate dispute settlement proceedings against the Government of India as the first step towards reforming their fundamentally deficient regime. This would at a minimum preserve the ability of the United States to protect its rights under the WTO

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

ISRAEL

Intellectual Property Protection

In early 1999, the Government of Israel (GOI) passed into law amendments to the Pharmacists' Act that would allow importation by non-right holders of patented pharmaceutical products registered in Israel. Prior to adoption of this amendment, U.S. Government (USG) and PhRMA officials had been assured that the goal of the legislation was to permit parallel import of generic products. In May 2000, Israel's then-Minister of Health signed into effect regulations to implement parallel importation of patented pharmaceutical products as of September 3, 2000.

Ongoing Litigation

In late July 2000, five PhRMA members (Bristol-Myers Squibb, Johnson & Johnson, Eli Lilly, Merck, and Schering-Plough) filed a petition in the Supreme Court of Israel to challenge the recently signed regulations. An additional PhRMA member, Wyeth-Ayerst, has since joined the proceedings. In conjunction with the lawsuit, the petition sought a preliminary injunction to stop the regulations from taking effect, on the belief that as of the September 1 implementation deadline, there could be immediate and harmful parallel importation of patented products without notice to right holders.

In its answer to the Israel Supreme Court filed on August 30, the State stated that the Ministry of Health was not yet prepared to implement the regulations, and accordingly that there was no immediate risk of parallel importation. It appears that the State may be correct in this regard.⁹ First, the Supreme Court petition seems to have had the effect of chilling potential importers. Potential importers may now believe that petitioners will act aggressively to protect their legal rights if patents are infringed. Other PhRMA members have also made statements that they will take infringers to court. The Ministry of Health and Sick Funds appears to be taking a "wait and see" approach, likely waiting for the resolution of the Supreme Court petition before actually conducting parallel importation. The

⁹ The State's response also acknowledged that the parallel importation program would infringe patents held by the research-based pharmaceutical industry in Israel, but argued that civil remedies protect the petitioners, and the State is not obligated to provide data protection. (But note that Ministry of Justice officials are now exploring legislative proposals to add data protection for pharmaceutical test and other data.)

petitioners have requested an expedited hearing on this matter and have received a court date of January 8, 2001. Thus far, the Petition has improved the environment for the pharmaceutical industry in Israel by having the effect of delaying implementation of parallel importation and contributing to an atmosphere in which the Ministry of Justice is now considering legislative proposals for data protection of pharmaceutical tests and other commercially valuable data.

While we are encouraged by Ministry of Justice statements that the GOI may consider legislative proposals to provide data protection, PhRMA believes that unless patented pharmaceutical products are explicitly eliminated from the jurisdiction of the law, the parallel import program will: (1) facilitate patent infringement by importation by non-right holders; and (2) violate Israel's WTO TRIPS obligations, particularly in the area of data exclusivity and effective enforcement measures. PhRMA appreciates the strong USG support that has, coupled with the ongoing litigation, thus far prevented actual parallel importation, and will continue to work closely with all parties to insure that the final result does not weaken patent protection in Israel.

PhRMA also remains concerned that the GOI's TRIPS Omnibus legislation, passed in December 1999, fails to provide adequate provisional and border measures required by TRIPS Articles 50 - 60 in order to deter infringement and counterfeiting activities.

In 1998, the GOI amended the patent law to allow local companies that are not patent owners or licensees to manufacture patented material prior to expiration in order to submit registration data to health authorities in Israel, and other countries which allow similar pre-expiration activities for marketing approval. Implementation of this law allows Israeli manufacturers who do not have any rights to the patent to conduct large-scale manufacturing in Israel during the life of the originator's patent. Although the law is designed to permit the manufacture and export of patented medications for the limited purpose of applying for marketing approval, because the Israeli government has not established any effective enforcement mechanisms to prevent abuse of this provision, companies may manufacture and export large quantities of pharmaceutical products during the period of patent protection.

The law has, in effect, significantly shortened the period of patent protection for pharmaceutical products (which discriminates between technologies and so may violate TRIPS), and so reduces patent protection in Israel. The effective period of patent protection in Israel is now approximately five years, the shortest patent terms in any developed country except Canada. Notably, the European Union has launched a WTO complaint against the Canadian system.

Potential Exports/Foreign Sales

Given that the threat of parallel importation on patented pharmaceutical products is not in place, it is difficult to estimate potential damages. But based on experiences in other markets, parallel importation would have a domino effect on the whole market and

would not be limited to a specific product. Parallel importation could seriously damage the Israeli healthcare system, and the Israeli pharmaceutical and related sectors.

The Israeli pharmaceutical market totals some US\$690 million (1998). Sales of patented imported products were approximately US\$450 million (most sales are by the multinational pharmaceutical companies). Sick funds represent 90% of the market – i.e. US\$ 400 million in patented imported products. Members of the research-based pharmaceutical industry in Israel currently employ 700 people; many may lose their jobs. International research-based firms invest US\$80 million per annum in clinical trials conducted by Israeli medical institutions and physicians. If parallel importation of patented pharmaceutical products were to be implemented, many of these research initiatives could be moved out of Israel.

In sum, parallel importation brings with it the attendant risk of significant job losses in Israeli PhRMA members, curtailed participation by Israeli doctors and scientists in clinical trials, and reduced incentives for new biotech investment by foreign firms. All of the foregoing could have adverse impacts on public health and safety outcomes. Good medicine relies on the availability of skilled personnel and resources.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

MOROCCO

Intellectual Property Protection

In March 16, 2000, Morocco published Law No.17-97 relating to protection of industrial property. This law contains new patent and trademark legislation, which is intended to bring Morocco in compliance with its TRIPS obligations. It should be noted that this legislation has not been made available to industry in English, and that we are not assured that it is fully compliant with the WTO TRIPS Agreement. In particular, we understand that this law has been based on the French patent legislation, which is known not to be fully TRIPS compliant. Additionally, this law does not address the question of data exclusivity protection and does not create any system allowing for the protection of data exclusivity rights. PhRMA would appreciate any information available concerning the new law.

Other Trade Barriers

Local Ownership Requirement

Under Law 1-59-367 of February 19, 1960 (the "Law"), only companies that are controlled by individual pharmacists can be regarded as "pharmaceutical companies" and be allowed to manufacture, stock, and market pharmaceutical products. The Law specifically requires for that purpose that 51% of the share capital of a pharmaceutical company be held by individual pharmacists and that 26% of the share capital be held by pharmacists licensed in Morocco (i.e. Moroccans).

As a result of this local ownership requirement, foreign companies creating a local subsidiary are compelled to make a choice between two evils: either (a) allow a pharmacist licensed in Morocco to own 26% of their local subsidiary in order that their local subsidiary be a "pharmaceutical company" (and may benefit from the rights granted to a pharmaceutical company), or (b) register all their products through a local licensee (or distributor for imports), and allow the local licensee (or distributor) to enjoy quasi-ownership rights over their products in Morocco. Indeed, in the latter case, the local licensee is treated by the Ministry of Health as the sole and true owner of the products registered by this licensee in Morocco. Throughout the life of the product in Morocco, and regardless of

what the License Agreement provides, the local licensee is fully empowered to act as if it was the owner of the licensed products. As a result, the foreign investor cannot:

- import and sell pharmaceutical products in the country;
- be the official contact to the Ministry of Health;
- officially negotiate the price of its products with the Ministry of Health;
- transfer the marketing license to another licensee;
- monitor the pharmaco-vigilance;
- control the continuous supply of the market, as the licensee is to decide when to buy and in what quantities; and
- enforce its rights under the License Agreement with the licensee in case of termination.

Actual ownership of the marketing licenses puts the licensee in a position of extreme strength vis-à-vis the foreign licensor. For example, in case of termination, regardless of the provisions of the License Agreement, the Ministry of Health will refuse to transfer the marketing license of the products without the licensee's prior written approval. The licensee can take unfair advantage of this extremely strong position and is thus able to impose an onerous indemnification payment on the licensor, regardless of the original terms and conditions of the License Agreement.

The health authorities also require that, to become a "pharmaceutical company," a company must own a manufacturing presence. The Law is unclear as to the extent and form of such a presence, but the health authorities generally take the view that only full ownership of a manufacturing facility will meet this requirement. As a result, import licenses are in practice only given to companies who have their own local factory. Those who do not cannot own the registrations for their products and cannot be seen as true pharmaceutical companies. These companies can only be seen as a promotional agency acting for its local pharmaceutical partner. The Law is truly antiquated (1960); in particular as it assumes that the pharmaceutical industry only comprises pharmacists working out of their own shop. It was originally intended to protect pharmacists as a guild. The Law should be amended in order to allow foreign companies to retain full ownership of their local investment and be entitled to register their products under their name in Morocco. The conditions required for pharmaceutical companies to manufacture and market their products should be modernized. Other countries have shown that there are other and better ways to ensure that pharmaceutical products are safely manufactured and marketed in the best interests of the public.

High Customs Tariffs

There are high customs barriers on drugs: approximately 17% on imported raw materials and imported finished products that cannot be manufactured locally; approximately 40% on imported finished products which are deemed to be "locally manufacturable." This type of use of custom tariffs is solely protectionist and intended to safeguard local manufacturing. This also creates over-capacity at the local level. WTO membership should normally lead to a reduction in these tariffs, which adversely impact the

competitiveness of foreign products.

Potential Exports/ Foreign Sales

PhRMA cannot provide a reasonable estimate at this time of potential exports and foreign sales in Morocco, but would be interested in investigating new commercial opportunities in Morocco should the intellectual property and market access conditions improve materially.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

PAKISTAN

Price Controls and Forced Price Reductions

While the Government of Pakistan has committed itself to allowing annual price increases utilizing a formula which considered currency devaluation and local inflation, allowed price increases have been intermittent and inadequate. The last price increase was allowed in June 2000, including an 8% price increase for Controlled Drugs and a 10% increase for Decontrolled Drugs effective from June 19, 2000. These price increases were substantially below the indexed figure which represented the true cost increases that the industry had to bear over the past several years. PhRMA seeks the support of the U.S. Government to ensure that the Government of Pakistan provides appropriate price adjustments on an annual basis, and at a level which will be sufficient to stem the dramatically declining profitability of the research-based pharmaceutical industry during recent years.

This dramatic decline in profitability is driven by:

- A cost increase of 90% over the last five years generated by three factors: an inflation of 76%, a devaluation of Pakistani currency by 85% in relation to the U.S. Dollar, and an introduction of duties of 10% beginning June 1996.
- Insufficient price increases which do not compensate for cost increases:
 - For "Controlled" drugs, the price increase was only 29% in the last seven years.
 - For "Decontrolled" drugs, the price increase was only 39% in the last seven years.
- Government imposed compulsory price reductions on targeted products which were based on an unjustified price comparison with India.

There are three other recent developments that have harmed the industry significantly and have had enormous impact on pricing decisions. These include:

agreed on reductions ranging from 5-28% on 21 packs of 17 products. (Double that number were on the original list). The drive behind this move is political and the reason given is the prices which prevail in India for the same products. Utilization of prices applicable to the Indian market is inappropriate when applied to pricing of pharmaceuticals in the Pakistani market. India has a significantly lower cost base for all materials, utilities and labor. Further, the purchasing power of the average Indian is significantly below a Pakistani citizen. In addition, all prices have, in any case, been approved by the Ministry of Health (MOH). Furthermore, in cases where a product's price is lower in Pakistan than in India, the pricing comparison is ignored.

119 High Price Products

Apparently the MOH has a list of 119 packs of 56 products, including those already targeted, they consider to have high prices (again the rationale is the price of these particular products in India). The likely outcome is that when prices are increased, these 119 presentations will not be allowed any increase.

Alleged Illegal Price Increases

There has been much recent coverage in the Pakistani media alleging that companies have been illegally raising prices. Such claims are untrue because of requirements that all price increases have to be notified to, and authorized by, MOH. MOH has the legal ability and right to take appropriate action to withdraw any increases made illegally. In fact, research-based companies have complied with the Government's controls on prices in good faith during the financial turmoil in Pakistan, only to find that the Government is reneging on its legal obligation to allow for annual price adjustments.

These data clearly demonstrate the serious difficulty facing the pharmaceutical industry. No other industry in Pakistan has been put under such stringent price controls; and no other industry has been forced to reduce prices. Given the significant level of foreign investment and international quality of locally-produced products, it is only fair that the Government of Pakistan seriously consider the negative impacts of the current economic environment upon the industry when making decisions regarding the price increases which are now due.

In order to return to the profitability level of four years ago (i.e. 1993) the Government-allowed price increase should be of over 50% according to the SRO 1038(I)94 formula. However, the industry understands that such a large increase cannot be approved by the government for political reasons. Furthermore, the industry would not wish to burden the people for humanitarian reasons.

In order to return to an acceptable minimum profitability level, PhRMA supports the efforts of the research-based pharmaceutical industry in Pakistan to achieve:

1. Immediate implementation of upward price adjustments for "controlled" products, recognizing that the adjustment made in June, 2000 was no more than a down payment on what is due now (it having been more than two years since the previous price

increase). A figure in excess of 20% will in no way compensate for the historical shortfall, but will allow the industry to maintain supply of quality products.

2. The commitment of the Government to honoring annual price adjustments for controlled products, according to an acceptable formula that will enable the industry to plan for the future with some confidence.
3. Either the removal of the Customs Duty or a compensation in price adjustment. Note that the adjustment must be to maintain margin, not simply to pay the duty. Hence, since approximately 65% of industry cost base is imported material, the extra increase must be 6.5%.
4. Withdrawal of all notions of a high-priced group of products on which no upward adjustments will be allowed.
5. Introduction of the concept of market-driven pricing for the "decontrolled" products (i.e. abolish any control over these prices).

Intellectual Property Barriers

Pakistan has an intellectual property protection law. In Pakistan, patents are registered under the Patents & Designs Act of 1911 (PDA) and trademarks are registered under the Trademarks Act of 1940. Protection for patents is for processes only, and the duration of protection normally is 16 years.

The PDA confers on the patentee exclusive privilege for making, selling and using his invention throughout Pakistan and for authorizing others to do so. The primary purpose of the PDA is to protect new invention and to encourage the growth of industry in the country.

In case the patentee is inadequately remunerated for his patent during currency of the patent period, he may apply to the Federal Government for patent extension at least six months before the expiry of the patent period. The Pakistan Government may refer the application to the High Court which may, after hearing, grant an extension for a period of five years.

The PDA covers "manner of new manufacture" i.e., process patent as registered in Pakistan. In the event the same item is manufactured from another process, it would not be construed as patent infringement. As a consequence there are only few litigations of patent infringements cases registered in Pakistan. Moreover, there is always the chance that someone with a slightly different process can reproduce the same product/formula and market it on an equal footing.

There are several specific problems with the Pakistan law in addition to its lack of product patent protection for pharmaceuticals. These include the following:

- The right of the patentee is not adequately protected in the law, with the result that the infringer continues to freely manufacture counterfeit products.
- Numerous pending cases in High Courts result in delays of justice. Due to court proceeding delays, the patentee cannot immediately obtain injunction orders against an infringer.
- The patent-owner only can file a suit against the infringer. The law does not allow a licensee of a pharmaceutical product to institute a legal proceeding against the infringer.
- There is always a threat of revocation of the patent through compulsory licensing. An application in the High Court can be filed claiming that the patented article in Pakistan is not being met to an adequate extent and on reasonable terms and can thus force a compulsory license to be issued.

In sum, the two basic issues are that: (a) more active legal enforcement should take place, and (b) product patents should be allowed as well. The existing law needs to be amended and clarified in terms of providing clear protection to genuine original patent holders, whose process patents are infringed upon by others who have a slightly different process. The law should provide protection in "letter and spirit" and there should be no lacunae in the law.

In addition, the penalties for infringement should be more severe, and there should be a dedicated Government Office, as well as a separate panel of well-trained judges who fully understand the laws and are competent exclusively to try intellectual property infringement cases. This could result in the formation of an effective deterrent to potential infringers.

PhRMA does applaud the fact that, in 1996, Pakistan's Government moved expeditiously to provide a form of interim protection for certain qualifying pharmaceutical products through a "Mailbox" provision in its law, as per its obligations under TRIPS.

Other Barriers

Product Registration

The regulations to obtain a sales permit for a given pharmaceutical product require that the dossier of supporting data be accompanied by Certificates of Free Sale, confirming the approval for sale of the product in developed countries of the world, such as the U.S., Europe and Japan. The research-based industry has understood and accustomed itself to this requirement.

Now, however, it seems that the Pakistan MOH is unilaterally adopting a discriminatory policy against multinational pharmaceutical companies by insisting that they can only register products which are on sale in the country of incorporation of the respective company. Local companies, however, can register products from any source. This policy discriminates, therefore, against the research-based companies operating in Pakistan, many of which have registered in Pakistan as Pakistani companies.

Moreover, the general experience of many multinational pharmaceutical companies in Pakistan is that the time required for the registration process often is two years and sometimes longer. For the benefit of patients in Pakistan, and in view of increasing costs of pharmaceutical research and development and limited patent life of drugs, it is vital to keep the procedure of registration as brief as possible. PhRMA believes it necessary that the Government of Pakistan enhance the capacity of its equipment and manpower sufficiently to complete a registration process within a maximum period of twelve months.

There is a related issue in this area which also concerns the research-based pharmaceutical industry in Pakistan, and that is the proposed amendments in the form of a revised application for the Renewal of Product Registration Form. There are several proposed amendments that are cumbersome and unnecessary, and, in some cases, irrational. The Technical/Regulatory Affairs Subcommittee of the Pharma Bureau in Pakistan (i.e., the local equivalent of PhRMA) is examining these amendments with a view to filing formal objections to those clauses which they believe are not required, or are discriminatory. However, it is still too early to paint a clear picture of where this issue stands and how far it has progressed.

Drug Labeling Rules

By a Pakistan Government notification dated August 24, 1994, the generic name of the substance has to be printed "with at least equal prominence as that of the brand name." This has now been carried forward as policy by the Pakistan Government.

The addition of the generic name in equal prominence to the trademark constitutes an infringement of the proprietary rights of the originator. This is intended to dilute existing differences in quality, efficacy and safety, and incorrectly implies total interchangeability and equality of two different products. PhRMA asks the U.S. Government to note that these laws also appear to place Pakistan in violation of WTO TRIPS rules protecting trademarks, and therefore should be amended to comply with TRIPS.

Potential Exports/Foreign Sales

Pakistan remains an "Outsider" in the global community of nations providing some form of intellectual property protection for pharmaceutical products. At present, there is no product patent protection in Pakistan, but only protection for processes. It is incumbent upon the patent holder in Pakistan to prove that the "pirate" is using the same process as the inventor, which is practically impossible in the current Pakistan legal environment. One of the most important current issues for our industry in Pakistan is that this piracy continues

to inflict losses on the research-based pharmaceutical industry, now estimated at \$15 million to \$20 million per year. While these "losses" are not as significant as those that we incur in India, they still represent a threat to the industry's ability to utilize its resources for the discovery of new medicines to address problems of morbidity and mortality, and uncured diseases worldwide.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

SAUDI ARABIA

Intellectual Property Protection

Although Saudi Arabia has had a patent law in place providing product patent protection for pharmaceuticals since 1993, to date this has yielded only theoretical protection. In over four years, no patents have actually been granted or issued. The resulting ambiguity in the actual effectiveness of intellectual property protection exacerbates the difficult commercial operating environment in Saudi Arabia. The lack of issuance of any pharmaceutical product patents in the Kingdom represents a serious barrier to American inventors doing business in Saudi Arabia.

More serious concerns are raised by the increasing threat that the Saudi Ministry of Health has initiated purchases of copycat UAE-origin pharmaceutical products. Further, current events appear to have emboldened at least one local Saudi copycat pharmaceutical producer. The company is now reportedly investigating the possibility of obtaining marketing approval for a blockbuster antibiotic produced by a PhRMA member company. Loss of this market for that product would alone cause losses of millions of dollars annually for that PhRMA member company.

Other Market Access Barriers

The following practices in Saudi Arabia are inconsistent with WTO disciplines, and have a substantial and negative impact on the market share in Saudi Arabia for U.S.-patented pharmaceutical products. We continue to bring these issues to the attention of the U.S. Government in the context of Saudi Arabia's WTO accession negotiations:

Price Controls

The Saudi Government imposes a rigid registration and price control system that lacks transparency and delays product introduction. Saudi Arabia uses a very simplistic and burdensome reference price system. The Government requires companies applying for marketing authorization to provide the price of the candidate product in as many as 30

other countries, many of which, e.g., Lebanon or Jordan, are not comparable economically. The authorities will typically choose the lowest of the 30 prices as the Saudi price. Additionally, the Saudi Government is currently proposing a new pricing policy which, again, lacks transparency, is not based on the principle of market-based pricing, and stipulates compulsory price reductions.

Introduction of new medicines is also delayed, mainly due to unnecessary laboratory analysis by the Saudi Ministry of Health. The requirement applies to products approved by leading health regulatory authorities such as the Food and Drug Administration, the Medicines Control Agency or the European Medicines Enforcement Agency. These products are typically available in large, well-regulated markets in North America, Europe or Japan, where they are taken by millions of consumers. Laboratory testing which is inconsistent with International Conference on Harmonization (ICH) requirements or does not take into account the valid certification of these products in these major markets is simply redundant and time consuming, raise costs, and constitutes an unnecessary burden on companies and a barrier to trade.

Protectionism

Saudi Arabia does not allow foreign direct investment; rather, foreign investors are required to partner with local distributors who are the actual legal representatives of the company in the Kingdom. The new Foreign Investment Law did not change the situation for the international pharmaceutical industry, since trade regulations remained the same under this new law. Saudi Arabia still does not allow foreign direct investment in this sector; rather, foreign investors are required. In other words, foreign companies continue to lack legal status in the Kingdom. According to Saudi law, Saudi nationals must control or own 51% of enterprises. The ban on foreign majority ownership is a major impediment to foreign direct investment or technology transfer, and raises the cost of doing business in the Kingdom. It also raises the fundamental issue of reciprocity. Saudi nationals are allowed to freely and wholly own property and enterprises in the United States, but U.S. citizens and corporations are not extended the same rights in the Saudi domestic market.

There is also a lack of national treatment in public procurement with local and GCC-based companies such as Spimaco, Tabuk and Julphar being treated more favorably than international companies.

Government Procurement

Saudi Arabia's public tendering system fails to meet WTO disciplines in terms of national treatment and transparency, among other areas. The system discriminates in favor of local or regional (GCC) companies, providing both faster registration and preferential pricing (a 10% advantage in tenders as compared to multinational companies) for "locally" made products.

Potential Exports/Foreign Sales

It is not possible to provide a reliable current estimate of the potential market size for PhRMA member companies in Saudi Arabia, if current deficiencies were rectified. The Saudi pharmaceutical market was estimated at more than one billion dollars in 1997. If the Government of Saudi Arabia were to adopt a patent regime consistent with WTO TRIPS standards, the U.S. share of this market would likely expand substantially, even if the market itself did not grow significantly.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

SOUTH AFRICA

Intellectual Property Protection

New Developments

At the launch of litigation in February 1998, the South African Government (SAG) voluntarily agreed not to promulgate or bring into effect Section 15C, (or any part of Act 90) pending a ruling by the Constitutional Court. Several attempts to reach a negotiated settlement followed. In June 1999, South Africa held its second free national elections, as a result of which a new Cabinet was appointed. Via the South Africa Pharmaceutical Manufacturers Association (SA PMA), the industry immediately made multiple overtures to the new Government, for the purpose of reaching a mutually acceptable solution to the dispute over the Medicines Act, to no avail. The SA PMA was ultimately forced by the government to file replying papers in July 2000, despite additional confusion being created by the government which had attempted to incorporate Section 15C into the Medicines Act regulatory legislation of 1999. Court appearances on the lawsuit are likely to occur in March, 2001.

In August of 1999, SA PMA voluntarily suspended litigation after Health Minister Manto Tshabalala-Msimang announced that the Medicine Act would be returned to Parliament for extensive amendments. Despite several further public announcements that these amendments would be made during 2000, the law has not been returned to Parliament. Amendments during this year are now unlikely. Notwithstanding the promised amendments, the Minister's legal advisors have insisted that petitioners continue litigation on the existing law – refusing to allow the continued and logical suspension of the case. PhRMA members active in the South African market continue to pursue every possible avenue to reach a negotiated settlement. PhRMA members would ultimately prefer a negotiated settlement and the forging of a partnership that immediately seeks to address the AIDS pandemic in Southern Africa.

In particular, PhRMA members remain committed to assisting the SAG in establishing programs to halt the progress of the HIV pandemic. We remain deeply concerned by the SAG's apparent questioning of the link between HIV and AIDS and the dissemination of unbalanced and inaccurate data concerning HIV drug safety. In addition,

despite several budget allocations for HIV/AIDS spending, dedicated funding for AIDS medicines remains unspent. These funds could be used to reduce suffering and save lives. PhRMA members eagerly await the SAG's formal response to the industry's recent offers of donated medicines and proposals to dramatically reduce the cost of AIDS therapies. To date, the Government has failed to call for any meaningful tenders for HIV/AIDS drugs and thus cannot know what best prices might be for HIV/AIDS treatments. The SAG has also failed to respond to industry's global initiatives to discount and supply HIV/AIDS drugs. As an additional note, at the European Union Summit in September 2000, the Ministry of Health stated the country was not interested in donated medicines (referring to the five company UNAIDS offer) but would like to explore local manufacturing of pharmaceuticals to ensure the country's independence.

Notwithstanding the foregoing, PhRMA member companies presently work closely with a number of South African agencies and ministries to help combat theft of medicines. In South Africa, where at least 50% of all State drugs are stolen or lost through poor management, parallel imports would exacerbate the entry into the market of counterfeit goods. In recent months, police have seized over R100m worth of stolen and counterfeit medicines. Some potentially lethal products have already been found in circulation.

Background

Until November 23, 1997, South Africa had a relatively modern patent regime, providing full product patent protection for pharmaceuticals. Regrettably, on November 23, the Government adopted a new law, the "Medicines and Related Substances Control Act Amendments," that, if implemented, would seriously undermine the terms of intellectual property and patent protection for pharmaceuticals in South Africa. Specifically, Article 15C of the new law states that:

That the Ministry of Health may notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to act in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;

This clause, 15C(a), would appear to allow the Department of Health to revoke all pharmaceutical patents valid in the Republic of South Africa, "notwithstanding anything in the Patents Act," at ministerial discretion. This is a clear violation, we believe, of both domestic South African law and South Africa's WTO TRIPS obligations. Furthermore, the new law, at 15C(b) allows for the parallel importation, a violation of TRIPS Article 28 which while not actionable through WTO dispute settlement procedures, poses a serious threat to the viability of American pharmaceutical investment in South Africa. It may be worth noting that implementation of a parallel import system would likely violate other TRIPS obligations, including data exclusivity (Article 39.3), and the obligation to provide effective remedies to prevent and deter infringement (Article 41 et seq.).

In 1998, over 40 pharmaceutical companies operating in South Africa, and the SA PMA filed a legal challenge to the Medicines Act before the Constitutional Court in South Africa, a new, post-apartheid institution. Both sides have filed briefs before the Court, but the industry has made clear its preference for a negotiated, mutually acceptable solution to the dispute. In June 1999, South Africa held its second free national elections, as a result of which a new Cabinet was appointed. Via the SA PMA, the industry immediately made overtures to the new Government, for the purpose of reaching a mutually acceptable solution to the dispute over the Medicines Act. As a part of the ongoing dialogue between the industry and the Government, both parties to the litigation have agreed to a delay in the schedule of the legal challenge.

Price Controls

The law would also implement, at Section 22G, for the first time in South Africa, a system of price controls. Based on industry analysis not disputed by the Government, prices for pharmaceuticals in South Africa, including patented, new-technology medicines as well as older, multi-source (generic) products, are among the lowest in the world.

Potential Exports/Foreign Sales

The South African market is estimated at approximately R12 billion a year, with research-based pharmaceutical firms accounting for around 80% of the industry and employing around 17,000 highly skilled people. The above-described policies would cause tremendous harm to the South African pharmaceutical sector, a sector where PhRMA members have spent approximately R500 million annually on social projects, clinical trials, and research and development in South Africa, in addition to significant contributions made to maintain high academic standards. SA PMA itself trains around 300 industry employees annually, enabling factory workers with little formal secondary qualifications to qualify as Pharmacists Assistants. In addition to harm to the local market, implementation of the threatened policies would cause untold damage elsewhere in markets in the developing world.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

TURKEY

Intellectual Property Protection

The United States, the European Union and Turkey have been in negotiations over the improvement of Turkey's intellectual property regime for several years. With the conclusion of the Customs Union agreement between Turkey and the EU, Turkey has now implemented a patent law effective January 1, 1999. The patent law issued by Executive decree in June 1995, however, falls well short of TRIPS standards in numerous areas, including:

- Conditions of Patentability: Under Article 6 of the patent law, many important biotechnology inventions could be excluded. We note in particular Article 6(2) which exempts from patentability "plant and animal varieties or biological processes for the production thereof." In addition, there is no provision for the TRIPS-required transitional patent mailbox.
- Obligation to Work: Article 96 of the law requires actual "working" of the patented invention within three years of patent grant, it would appear to exclude pharmaceuticals and agricultural chemicals from patentability since the marketing registration period typically takes far longer than three years after patent grant.
- Local Working Requirement: Article 97 implies that importation does not satisfy working requirements since inspection of "manufacturing" facilities is a condition of patentability.
- Compulsory Licenses: The patent law provides a compulsory licensing section of unparalleled length in Articles 99-120. These provisions facilitate the granting of compulsory licenses in violation of the patent owner's rights. In general, the provisions are far too broad, allowing for compulsory licenses for technical progress if the invention is not of "significant merit" (opening the door to arbitrary government decisions), and for vague and undefined "public interest". There appear to be no provisions for the termination of a compulsory license when the conditions leading

to its grant cease to exist. Lest there is any doubt of the government's intentions to facilitate the issuance of compulsory licenses, Article 120 requires the government to provide publicity and financial incentives for applicants to seek compulsory licenses. This entire section should be deleted and re-written to conform with Article 31 of TRIPS.

- Lack of Protection of Proprietary Data: A principal means by which pharmaceutical intellectual property is pirated in Turkey is the unauthorized use of the originator's proprietary data submitted as part of the registration/marketing authorization process. The material, which includes safety and efficacy information gathered from lengthy and expensive clinical and human testing is often simply photocopied and submitted to the authorities which then approve the copied product without requiring any bioequivalence or bioavailability testing. Turkish provisions on data protection fail to include prohibitions against unfair commercial use. This unsafe practice is also in direct conflict with TRIPS Article 39.3, "Protection of Undisclosed Information". PhRMA urges that the protection of proprietary information also be improved in Turkey. Turkey should be required to implement a system of data exclusivity consistent with TRIPS Article 39, as of the effective date of the new patent law, i.e., January 1999.

In addition to not meeting minimum international standards contained in the TRIPS Agreement, the patent law also lacks other common protections that have been adopted by most industrialized countries in recent years, including patent term extension. Pharmaceuticals and many other products such as agricultural chemicals require a lengthy registration/approval process before they are brought to market but after they are patented. Article 72 of the patent law should be changed to allow for the extension of patent terms for products that require a lengthy pre-marketing approval process.

Market Access Barriers

The Government of Turkey has undertaken a system of price controls that is arbitrary and non-transparent. The system violates the principle of national treatment, does not reward innovation, may endanger public health, and limits current and future pharmaceutical company investment in the country. In addition, new Ministry of Health policies aimed at limiting pharmaceutical import licenses benefit local industry while discriminating against foreign companies by requiring burdensome proof of the "necessity" of importing products in lieu of manufacturing locally.

Pricing

The Government of Turkey has arbitrarily altered its long-standing drug pricing policy, which requires companies to negotiate a product price in U.S. dollars at the time of product approval in Turkey. In order to adjust for currency fluctuations in Turkey's hyperinflationary environment, the government formulates a price for each lot of product imported into the country based on the current exchange rate. In the past, domestically

produced medicines were sold at established prices with increases provided at predictable intervals by the Government of Turkey. The Turkish government and pharmaceutical companies have relied on this legal and transparent system for the last several years.

In June 1999, the Turkish Ministry of Health introduced a reference-pricing scheme that would force companies to immediately lower their negotiated prices to those of the

in-country. The Turkish government has asked these companies to explain the technical justification for importing products instead of producing them locally. In order to renew import licenses, Turkey will schedule a technical site visit to “ensure” that local production is not possible.

This discriminatory process interferes with foreign companies’ ability to conduct business in Turkey. The inspection itself may be intrusive and may violate intellectual property standards by exposing companies’ operating procedures to outside sources. Additionally, any delays in the inspection process that slow the process of obtaining an import license could seriously inhibit the flow of innovative imported products into Turkey. Therefore, this policy is not only a non-tariff trade barrier, it also may present a public health concern if citizens do not have full access to new, efficient medicines.

Potential Exports/Foreign Sales

PhRMA estimates that, were the aforementioned problems to be corrected, the increase in sales that would accrue to American research-based pharmaceutical company affiliates in Turkey would be in the range of \$60 million annually.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

UNITED ARAB EMIRATES

Intellectual Property Protection

Due to express violations by the United Arab Emirates (UAE) of bilateral and multilateral commitments to protect intellectual property rights for patented pharmaceutical products and confidential data, PhRMA has recently asked the U.S. Government to conduct a special, Out-of-Cycle Review of the UAE under the "Special 301" provisions of the Trade Act of 1974. The UAE has failed to live up to written commitments and appears to have abrogated its WTO obligations. Under intense pressure from a local company, the Ministry of Health has registered an undisclosed number of copycat pharmaceutical products that infringe on patented products and unfairly rely on confidential and commercially valuable data. Accordingly, PhRMA has requested an Out-of-Cycle review (OCR) by USTR of the UAE under its "Special 301" authority and the designation of the UAE as a Priority Foreign Country (PFC).

The UAE's last-minute removal from the Watch List during last spring's Special 301 review came only as a result of a Memorandum of Understanding (MOU) reached between PhRMA and the UAE. Under the terms of the MOU, the UAE agreed not to provide marketing approval for unlicensed drugs under valid U.S. patents, and to immediate implementation of data protection (required by TRIPS Article 39.3). The UAE's current actions are a clear violation of the terms of the MOU and their minimum WTO obligations under TRIPS. More specifically, approval of these infringing copies violates both the UAE's WTO obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) Article 39.3 protecting commercially valuable and confidential test and other data, and the UAE's Cabinet Declaration No. 404 issued in May 2000, as well as its April 2000 MOU with PhRMA. Although the U.S. Government was not a party to this MOU, the PhRMA meetings were scheduled at the express request of the U.S. Ambassador, and senior officials of both the Embassy and the consulate in Dubai attended the meetings, serving as witnesses to the UAE's commitments. The Ambassador has taken every possible step to obtain UAE compliance with the MOU and its own undertakings in this regard, but to date, these efforts have not been rewarded

As stated, the UAE has already registered an undisclosed number of copycat products originating from a company in the UAE and has refused to provide an accounting of these registrations to the U.S. Government or to industry. Through its actions, the UAE enabled the sale of these unauthorized copies throughout the Gulf Cooperation Council region and beyond. The UAE has further signaled its intent to authorize for sale dozens of additional infringing copies of patented pharmaceutical products manufactured by a local company, products which rely either directly or indirectly on original data submitted by PhRMA member companies, and therefore infringe their rights.. Finally, the UAE has likely not yet begun serious consideration of a TRIPS-consistent patent law, which was another condition of the April 2000 MOU, a pledge critical to PhRMA's amended Special 301 report recommending the UAE be removed from the Watch List.

In addition to the "Special 301" OCR petition, the pharmaceutical industry may ultimately ask USTR to initiate a formal WTO case against the UAE for failure to implement its TRIPS obligations. The UAE is an excellent candidate for a data protection case; USTR is known to be in search of a so-called "slam dunk" case, and in this case the UAE has reneged on its own commitments on data protection. As a high-income oil-producing state, the UAE is unlikely to draw sympathy either internationally or on the Hill. PhRMA members are currently considering whether to request that the U.S. Government initiate formal consultations with the UAE in Geneva as the first step in a WTO dispute resolution process.

Other Barriers

Research-based companies are concerned about a perceived lack of transparency and possible conflict of interest at the Ministry of Health. According to reports, some health officials may hold financial interests in certain local health and/or pharmaceutical companies. Indeed, on more than one occasion, research industry has observed local health officials—many of whom have responsibility for policies and procedures affecting multinational companies--openly working to promote local companies to other Gulf and Middle East officials.

As is the case with other GCC countries, the UAE allows "local" GCC producers prices up to 20% higher in public sector bidding and procurement, vs. multinational companies. This rule is in place despite ongoing Government cost containment programs, and allows local generics companies to "shadow price" foreign competitors.

Potential Exports/Foreign Sales

The UAE market is estimated at CIF\$220 million, and represents the second largest GCC market after Saudi Arabia. The current problem in the UAE has emerged in the last three months and PhRMA does not have damage estimate methodology specific to the Gulf market and these circumstances. Given the large number of infringing products now authorized to enter the UAE market (estimated by the UAE Government at 90), and

the recent GCC approval for marketing of infringing UAE copies throughout the Gulf, the actual commercial damages are substantial and run into millions of dollars in losses on an annual basis. In addition, the UAE situation threatens to undermine progress elsewhere in the region. In past years, PhRMA has expressed concern that the Ministry of Health would acquiesce to pressure from the local company, Julphar, to register large numbers of new pirate copies in advance of anticipated changes to the patent law. This now appears well underway. Damages fall into three categories: direct losses in the UAE; losses due to GCC sales to Ministries of Health, and potential losses from future private sector sales in the Gulf, and the greater Middle East region, including North Africa. The latter is due to the fact that Julphar will be able to bid on tenders throughout the Middle East and North Africa as long as the UAE Government in Abu Dhabi fails to rescind the infringing registrations.

As a single example, one affected U.S. company stands to lose export sales of US\$1.5 – 2.0 million per year in the UAE alone due to the infringing registration of a pirated anti-histamine product. Beyond the UAE, as both public sector and private sector purchasers move to buy the Julphar products, companies face increasing losses. One PhRMA member estimates that it will lose sales of up to \$10 million per year through the introduction of a single Julphar copycat product for its widely prescribed cardiovascular product in the Gulf-wide tender, nearly 20% of the company's annual sales in the region. A second PhRMA member estimates losses of \$15 million in total from regional losses due to the registration of an infringing copy of a blood product. Other pirated products include the leading anti-depressant and the leading pediatric antibiotic worldwide. Because Julphar has chosen to pirate cutting-edge, block-buster products, almost every infringing product registered in August and September will lead to direct losses in the millions for PhRMA members including among others (not listed above).

PhRMA urges U.S. officials to prioritize the IPR issue on the bilateral agenda. Pending the outcome of the current negotiations, PhRMA members are evaluating whether to formally request that USTR seek bilateral consultations as the first step in a WTO dispute resolution process against UAE. The failure to provide data exclusivity and to meet other WTO obligations contained in the TRIPS Agreement provide a firm basis for a successful case.

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA
(PhRMA)**

**FOR THE
NATIONAL TRADE ESTIMATE REPORT
ON FOREIGN TRADE BARRIERS (NTE)**

2001

November 27, 2000

The Western Hemisphere

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

ANDEAN COMMUNITY (BOLIVIA, COLOMBIA, ECUADOR, PERU, VENEZUELA)

Intellectual Property Protection

On September 14, 2000, the Governments of the Andean Community adopted Decision 486, which replaced Decision 344 (in effect since January 1994). The new Decision will take effect on December 1, 2000. It improves upon Decision 344 in several ways, including expanding the definition of patentability and strengthening data exclusivity. Defining “unfair commercial use” and determining the term for data exclusivity has been left up to each member country to determine individually by December 1, 2000. In our view, the Andean Community should adopt a ten-year period standard against the use of proprietary data submitted for registration purposes, as is the case in several EU countries.

Unfortunately, Decision 486 falls short of adequate pharmaceutical patent protection by placing unjustified restrictions on biotech inventions and by disallowing second use patents. Also, the Andean Tribunal of Justice ruled against Peru in 2000, disallowing second use patents. This represents a serious blow to intellectual property protection, and we hope that the Government of Peru will obtain a reversal of this ruling on appeal.

Several important medical advances would not be available to patients around the world without the availability of second-use patents. These products are subject to the same review process as any other patent application, meaning they must be new, involve an inventive step, and be capable of industrial application. Second use patents are thus no different from any other patent. Patent laws of the U.S. and our major trading partners incorporate these standards, which are also enumerated in the WTO TRIPS Agreement (Article 27). Pharmaceutical research companies apply for patents on new molecules at the earliest possible opportunity. Additional, unforeseen medical indications may be discovered during the lengthy research phase that follows. The results benefit patients and, if they meet the patentability criteria outlined above, deserve patent protection. The Andean Community, by outlawing these patents, is misinterpreting TRIPS and is out of step with most countries in the world.

Pharmaceutical companies have filed product patent applications since Decision 344 took effect in 1994, and products that are the subject of these applications are on the market. However, the risk of patent piracy remains high due to administrative and other delays in the approval process and inadequate enforcement against unfair commercial use of patented products. Moreover, health authorities often fail to coordinate with patent officials and inappropriately issue sanitary registrations for products already under patent, whose patent application is pending, or whose period of data exclusivity has not expired. The adoption of “linkage” regulations (i.e., establishing a formal link between health and patent authorities) would help to ameliorate this situation, requiring that “second applicants” (i.e., generic, or in some cases, “pirate” applicants) demonstrate that the product for which they are requesting market approval is not the subject of a valid patent or pending application. “Linkage” exists in the United States, Europe and Japan, and is crucial to maintaining the integrity of the intellectual property and patent system.

Another way in which the intellectual property environment could be improved in the Andean Community is for these countries to implement and enforce provisions guarding against the unauthorized commercial use of company proprietary data, as per the principles outlined in TRIPS Article 39. Pharmaceutical research and clinical trials represent an enormous investment, making the resulting safety and efficacy data extremely valuable. As is described in several other country sections in this submission, allowing the registration of “generic” products that use, or incorporate by reference, the company proprietary data of the innovator is an unfair trade practice that severely, and at times completely, undercuts intellectual property protection for pharmaceuticals.

Colombia

Intellectual Property

Pharmaceutical companies continue to suffer greater commercial damage due to weak intellectual property protection in Colombia than in any other Andean country. Since the current patent regime went into effect in 1991, only a few patents have been examined and granted, and the process remains extremely slow. At the same time, numerous copy products have inappropriately garnered significant market share. Data exclusivity norms expressly contemplated in both Decision 344 and Decision 486 are ignored by INVIMA (the National Institute of Supervision of Foods and Medicines), which allows copies to be placed on the market the day after the innovative product is approved for commercialization. Although some elements of the Colombian government, specifically the Ministry of Foreign Trade, have provided assurances of Colombia’s commitment to intellectual property rights protection, copying remains rampant. The Government of Colombia needs to take steps to speed the patent process and get copy products off the market. Such steps include:

- improve the operational structure of the patent office;
- improve enforcement mechanisms to handle patent infringement issues;
- create linkage regulations between the regulatory and patent offices;

- implement pertinent judicial training programs.

Price Controls

Even though prices were liberated in February 1999, this was done with one significant caveat, that at least three identical molecules be available in the marketplace. Products that do not have copies in the marketplace (less than three) remain under the price controls, with once a-year-adjustments determined through an unclear methodology. This policy has maintained pharmaceutical prices well below the devaluation rate and several points below the expected level of overall inflation, a trend that jeopardizes industry sustainability.

Legislation on Medicines (*Ley del Medicamento*)

The Colombian Government inappropriately promotes non-branded pharmaceuticals at the expense of those produced by multinational companies. Law 100 establishes that the Colombian population will be covered by either the Social Security or a Health Promoting Entity (EPS), and pharmaceutical products will be supplied based on a list of only 307 generic substances. This law has dramatically affected the private brand name market.

Ecuador

Intellectual Property

As a consequence of a ruling by the Andean Tribunal, Ecuador was forced to deny about 120 pipeline patent applications for the pharmaceutical industry. In addition, third parties have filed petitions or judicial actions requesting the nullification of already-granted pipeline patents.

Third parties continue to profit at the expense of originator companies because the Government of Ecuador continues to allow the registration of copies of PhRMA company products with pending patent applications.

The Andean Community position against second use patents (see above) will affect patent applications in Ecuador and elsewhere in the Andean Community.

Legislation on Medicines

The Ecuadorean Congress recently passed a law aiming to stimulate the production and commercialization of generic drugs. This law also covers price controls, health registration, quality standards, and a wide array of sanctions. There are several disturbing provisions regarding generics:

- When prescribing a branded product, physicians must include the name of the generic equivalent.
- Drugstores must offer their customers the generic equivalent.
- Local manufacturers must produce at least 20% of generics.
- Government institutions must buy generics only.

These provisions violate several Constitutional rights by granting competitive advantages and privileges to generics at the expense of free market principles.

Price Controls

Prices for branded pharmaceutical products are also governed by the recently-issued generic law. A 12-member pricing committee created by this law includes members representing organizations unrelated to pharmaceutical pricing matters, creating the potential for politicized decisions. The committee slows down the pricing approval process and works in a conflictive atmosphere. It recently issued a resolution shrinking the gross profit margin that pharmacies had enjoyed for the past 30 years, contrary to specific provisions in Ecuador's Protocol for WTO Accession. This may in turn jeopardize the pharmaceutical industry's profit margins, which originate from the same legal basis.

Health Registration

The generic drug law allows for homologation of health registrations issued in selected countries through very simplified procedures, only for generic products, thus creating a discriminatory practice against pharmaceutical products.

Peru

Intellectual Property

Peruvian legislation on data exclusivity led the Peruvian Patent Office (INDECOPI) to request that the regulatory agency (DIGEMID) withdraw illegal copy products from the market. Enforcement remains inadequate, however. In a troubling development, sanitary registrations have been issued for copies of products that are patented, have pending patent applications, or whose period of data exclusivity has not yet expired. The Peruvian Government should rescind these registrations.

When patent infringement occurs, the innovator must take steps to file a claim for penalties to be applied to the copier. When a product or process is under patent in the country where it was originated, but is not yet registered in Peru, then Peruvian law allows it to be copied. Pipeline protection is not allowed in Peru, nor in the Andean Community (Decisions 344 and 486).

Communication between INDECOPI and DIGEMID is limited, and no formal linkage mechanism exists to protect products with issued or pending patents or still-current data exclusivity. Members of the Association of Peruvian Pharmaceutical Laboratories (ALAFARPE) have been told to inform DIGEMID directly when they have a patent pending or issued – something INDECOPI should do itself.

Peru does not require supporting scientific information to register a pharmaceutical product. The product simply must be included in a pharmacopoeia or have a certificate issued in the country of origin saying it could be sold without any restrictions. It is unclear whether Peruvian authorities recognize that confidential data were required for sales authorization in the country of origin.

Since 1998, Peru had recognized second use patents. However, as noted above, the Andean Tribunal has ordered Peru to stop issuing second use patents.

Government Tenders/Bidding

Domestic producers who take part in government bids are granted an extra 15 points. This favoritism has a substantial negative affect on foreign bidders attempting to supply the sizable government/Social Security pharmaceutical market.

Prescription Substitution

INDECOPI, in collaboration with the Ministry of Health, has advocated generic substitutions of physicians' prescriptions. However, Peruvian generic and copy products are not required to demonstrate bioequivalency to the innovative products, thus exposing patients to potential risks from poorly made products.

Venezuela

Intellectual Property

Intellectual property rights are protected by law and generally respected in practice in Venezuela despite recent government rhetoric. Pharmaceutical products have received patents since 1992, but with no pipeline protection. Thus, the first medicines protected by patents are just beginning to appear on the Venezuelan market; many more will appear in the next two to four years. A complete evaluation of de facto patent protection is therefore premature. Confidential data is protected in practice; the government has not issued sanitary registrations for copies of innovative products under patent or with pending patent applications. However, there is no clearly defined government policy on this subject.

A draft industrial property law introduced in 1999 unfortunately failed to come to fruition in 2000. This proposal would have created a financially autonomous Institute of Intellectual Property.

Price Controls

Despite drastic market reforms which lifted price controls for most industries, the pharmaceutical industry remains the target of political maneuvering. To date, only the prices of over-the-counter (OTC) medicines and products with more than four alternatives in the market have been liberated, while the prices for products that are most significant for the research-based industry continue to be heavily controlled.

Medicine Law (Ley de Medicamentos)

A new medicine law was passed in 2000 containing provisions of concern to the research-based pharmaceutical industry, including:

- language allowing the government to regulate prices;
- a mandatory National Therapeutic Formulary at public institutions;
- a provision on prescription substitutions at the pharmacy level;
- a requirement that pharmaceutical companies produce individualized doses to meet the exact level required per patient;
- a requirement that all medicine imported into the country must be evaluated by clinical trials in Venezuela.

The new law also may be unconstitutional because it calls for accumulated sanctions.

Potential Exports/Foreign Sales

The value of the Andean pharmaceutical market reached US\$2.9 billion in 1995. If barriers were removed, PhRMA members' sales increase would lie in the range of US\$ 100 million to US\$ 500 million.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

ARGENTINA

Intellectual Property Protection

Argentina remains the worst expropriator of the intellectual property of the research-based pharmaceutical industry in the entire hemisphere, and one of the worst in the world. It intentionally permits the local industry to copy innovative pharmaceutical products immediately, without permission of the innovator and without having to expend resources for research and development to prove safety and efficacy. The government actively facilitates local company appropriation of the core of PhRMA member competitiveness in both the Argentine and the extended regional market. In addition, Argentina has signaled its intent to dilute existing commitments, create onerous compulsory licensing requirements (including for local working), and to unfairly encumber the grant of exclusive marketing rights.

On March 22, 1996, Argentina approved a new patent regime through Decree 260. The law came into force in October 2000. Although the industrial property office (INPI) began issuing pharmaceutical patents – for the first time in Argentine history – on October 24, 2000, the patents issued thus far have not been for commercially significant products. Moreover, due to the lack of protection for medicines in development (pipeline) and other severe deficiencies, effective pharmaceutical product protection cannot be expected to take place even after the year 2001.

Because of its numerous deficiencies, Argentina's patent regime is expected to dilute the incentives for pharmaceutical innovation and to undermine the health of the Argentine population.

Under the current Argentine patent law, pharmaceutical products are not eligible for patent protection unless they are new, inventive, and industrially applicable. However, the law also provides for compulsory licensing of pharmaceutical products in cases of public health emergency, and for the use of patented pharmaceutical products for research and development purposes.

- It does not implement the transitional measures properly, e.g., it does not extend the term of existing patents and does not permit the conversion of process patent applications in some instances.
- It does not provide patent protection for certain biotechnological inventions.
- It does not implement required safeguards on compulsory licensing included in TRIPS Article 31.
- It does not provide for preliminary injunctive relief and/or reversal of burden of proof during trials for patent infringement.

Argentine practices exert a substantial negative impact on the ability of the U.S. research-based pharmaceutical industry to compete in the Argentine market and more generally in the Western Hemisphere. The Argentine regime directly and adversely affects PhRMA members as follows:

- Under Argentine law, an applicant whose application for a process patent was pending on January 1, 2000, is not permitted to amend the application to include product claims. This denies effective product patent protection in Argentina for products that are patentable under the TRIPS Agreement.
- Further, the absence of exclusive rights in products made by patented processes, a loophole closed by the TRIPS Agreement, allows competitors to avoid liability for infringement of patented processes.
- The growing number of products across therapeutic classes that rely on biotech inventions remain unprotected under Argentine law.
- The overly broad definition of anti-competitive practices allows for the issuance of a compulsory license when, for example, the manufacturer prices its product above market prices for legitimate commercial reasons, or when it rationalizes its operations in a way that results in a slowing of marketing of production activities. This is a clear violation of TRIPS Article 31.
- The granting of compulsory licenses to produce products for export markets violates TRIPS requirements that compulsory licenses be limited to allow use predominantly for the supply of the domestic market. The Argentine system allows compulsory licensees to export patented inventions when the license was granted due to a national emergency in Argentina.
- Argentine law dramatically and unjustifiably magnifies the scope of a compulsory license by automatically granting compulsory licenses for patents on any technology that is necessary to work the patent that was the subject of a compulsory license.
- The failure to provide preliminary injunctions in patent cases allows competitors to continue to infringe a patent until the litigation is concluded, which irrevocably erodes

the market share and the reputation of the patent owner. The TRIPS Agreement requires that judicial authorities be given the authority to halt this type of unauthorized exploitation during the litigation.

- TRIPS requires that the defendant bear the burden of proof in an infringement action, even if the product was new prior to January 1, 2000. However, Argentina has reversed this, forcing to bear the impossible burden of proving that a product identical to that which results from a patented process was made by the defendant using an infringing process.

A separate law was enacted to regulate the disclosure and protection of test data used in connection with applications for marketing approval of pharmaceutical and agricultural chemical products. Instead of protecting this data from “unfair commercial use” as required by TRIPS Article 39.3, it permits competitors to rely on the test data prepared at great expense and submitted by the developer of the product. As a consequence, any competitor can begin to market the innovator’s product no later than 120 days after a request to market without having to undertake the expense of proving that the product is safe and effective.

Argentina’s data exclusivity law legitimizes the use by other companies of confidential test data and other commercially valuable data submitted for registration purposes after only four months. The data exclusivity law runs counter to TRIPS Article 39, and to established practice in the U.S., Europe, and many other countries. There is no acceptable remedy to this legislation, other than wholesale changes. However, as noted in the discussion of “linkage” in the Andean Pact section above, requiring that “second applicants” affirmatively demonstrate that their application does not violate either a product or process patent might provide some amelioration of a very poor IP situation.

Argentina has failed repeatedly to respond to efforts by the research-based industry and the U.S. Government to identify specific administrative actions that would serve to at least partially address the deficiencies in its patent regime. The approval by the Argentine Congress of this unacceptable regime is the result of the Argentine domestic laboratories’ pressure to maintain barriers to U.S. trade and investments, and maintain Argentina’s deficient industrial property regime well beyond the time frame stipulated by the WTO. The De la Rúa Administration has not advocated any changes to the current regime. Given its past history, the Argentine Congress is unlikely to enact legislation to enhance the protection of intellectual property rights in Argentina.

Difficulties in effectively implementing a precedent-setting decision by the National Institute of Industrial Property (INPI) and the health agency (ANMAT) to honor exclusive marketing rights (EMR) led the U.S. Government to initiate a WTO dispute settlement case against Argentina in 1999. Argentina, flouting terms of Article 70.9 of TRIPS, has effectively precluded the enjoyment of the rights, delayed new approvals, and more recently, rejected on questionable grounds an application that had earlier received every assurance that it complied with all eligibility requirements. The U.S. government has

continued to pursue these violations in the broader WTO case initiated in mid-2000. The Argentine Congress responded by proposing legislation to force companies to produce patented products locally and mandating compulsory licensing of products with Exclusive Marketing Rights.

Only a decision by the WTO dispute settlement panel will induce change in Argentina and we urge the U.S. Government to proceed expeditiously to the panel phase of its WTO dispute settlement case.

Potential Exports/Foreign Sales

Argentina remains by far the worst expropriator of U.S. pharmaceutical inventions in the Western Hemisphere, as local firms dominate over 50% of the pharmaceutical market currently estimated at almost US\$ 4.1 billion. Substantial and continuing loss of market share in the range of hundreds of millions of dollars is directly attributable to Argentina's defective intellectual property regime.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

BRAZIL

Intellectual Property Protection

Brazil's 1996 industrial property law (No. 9279/96) is quite strong in many respects, providing a 20-year product patent term; pipeline protection for products in the approval process; basic biotechnology protections in accordance with TRIPS; a ban on parallel imports; and a one-year implementation period (TRIPS allows Brazil until 2005). In recognition of the significance of Brazil's expedited adoption of product patent protection, the research-based pharmaceutical industry invested US\$ 2.1 billion in Brazil by 2000.

However, part of the Brazilian law directly conflicts with TRIPS Article 27.1, which allows importation as a means of satisfying the requirement that the patent be "worked" in a country. Article 68 of the Brazilian law requires domestic exploitation of the subject matter of a patent. Importation may only satisfy this requirement if local manufacture is not feasible, which is inconsistent with the terms of TRIPS Article 27. Since passing the law in 1996, Brazil refused to address this TRIPS violation beyond inviting a WTO case to resolve the issue. In May 2000 the U.S. government initiated formal WTO consultations as the first step in a dispute resolution process (DSP) against Brazil. Formal consultations between the parties took place in July and November 2000. The research-based pharmaceutical industry strongly supports the USG's efforts to resolve outstanding TRIPS inconsistencies and urges moving expeditiously to the panel phase of the WTO dispute resolution process.

Another cause for concern is the October 6, 1999 Presidential Decree regulating the implementation of Article 71 of the law, which governs the granting of compulsory licenses in broadly defined situations of national emergency. Beyond any definition-related concerns, this particular decree is troubling because of the absence of any dialogue with industry prior to its publication, the broad discretionary powers given to officials below the presidential level, the apparent inconsistency with TRIPS obligations (and subsequent potential benefit to domestic manufacturers), and the mandatory transfer of technology considered in Article 5. The Brazilian government announced in September 2000 that it will invoke this decree if it is unable to produce 80% of the market for AIDS drugs by the

year 2002.

In addition, “Medidas Provisorias” (Temporary Measures) issued in December 1999 require that, under a revised Article 229-C of the law, the National Sanitary Supervision Agency (ANVS) approve all patent applications related to pharmaceutical products or processes. While our industry has long advocated a formal linkage mechanism between the patent office and ANVS to safeguard confidential data (consistent with Brazil’s TRIPS obligations), this measure poses numerous problems and will potentially delay patent approvals even further. Its consistency with the anti-discrimination clause of TRIPS Article 27.1 is questionable, as products from other industries are not subjected to the same review by relevant regulatory authorities. Also, any review of the applications other than for the patentability criteria set forth in TRIPS Article 27.1 would not be consistent with TRIPS, and any review of patentability criteria is beyond the expertise of ANVS.

Several pieces of draft legislation pending in the Brazilian Congress would severely limit intellectual property protection, including measures that would exclude the patentability of AIDS drugs and increase the issuance of compulsory licenses in violation of patent rights. Health Minister Jose Serra has publicly stated his desire to use loopholes in the patent law to achieve his objective of reducing drug prices. While the research-based pharmaceutical industry shares the goal of improving access to medicine, violating international obligations is the wrong route to attain this goal.

Brazilian legislation also appears inconsistent with TRIPS, particularly Article 27.1, in several areas: various exclusions from patentability, forfeiture of patent rights, term of protection, and the absence of protection of test data and other confidential, valuable information against unfair commercial use.

We remain concerned about continuing delays in processing patents. The National Institute of Industrial Property (INPI) lacks sufficient resources to process applications in a timely fashion, resulting in a substantial backlog (estimated at 10,000 pending patent applications). These delays will seriously hinder our industry’s ability to plan effective product launches. We endorse additional training of INPI staff and a greater allocation of resources for automation and other administrative needs.

Pricing

The Brazilian Congress conducted an investigation (Portuguese acronym: CPI) of pharmaceutical pricing practices, concluding in May 2000 with numerous recommendations that have significant potential to interfere with competition and free market practices. In July 2000, the Brazilian government, by means of a “Protocol of Intentions,” essentially coerced companies to freeze prices to their June 2000 level. A public-private task force was convened to come up with a model for price “regulation.” Its proposals are expected in early 2001. Our industry remains concerned that these proposals will continue the problematic trend of interference in the free market.

Potential Exports/Foreign Sales

Brazil is the largest market for pharmaceuticals in Latin America. It is not possible at this time to determine the impact on sales of PhRMA member company affiliates in Brazil if the aforementioned provisions were strengthened and renewed pricing concerns resolved. As a result of Brazil's devaluation, compounded by some of the measures described, the Brazilian market declined steeply from an estimated value of \$7.2 billion in 1998 to \$5.3 billion in 1999 – a drop of 25%. The 2000 estimate is for \$5.5 billion, a slight improvement over 1999 but still significantly less than 1998, reflecting the lingering effects of Brazil's economic crisis and the prize freeze imposed by the Brazilian government.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

CANADA

Intellectual Property Protection

Canada has made noteworthy progress since 1992 to provide greater patent protection. As a result, several PhRMA member companies have made significant investments in Canada as the protection of our intellectual property has strengthened. However, Canada's industrial property regime was found lacking in two WTO cases in 2000.

Canada's patent law, amended to comply with TRIPS, only provided 20-year patent protection from the date of filing for all patent applications filed on or after October 1, 1989. The United States successfully argued before the WTO Dispute Resolution Body that this did not provide the required 20-year protection to those patents which had been filed before October 1, 1989, and which took less than three years to obtain. Important innovative pharmaceutical products were denied the full length of protection required by TRIPS and would have been prematurely forced off patent.

In addition, Canada lost, in part, a WTO case filed by the European Union challenging the operation of Canada's "Bolar" provisions. The WTO panel found in favor of the EU on the issue of "stockpiling," wherein Canada allowed generic companies to produce and warehouse patented pharmaceuticals for ultimate commercial export immediately upon expiration. Canada has agreed to amend its practices and related regulations in this area.

Despite two WTO losses, in whole or in part, Canada continues to fall short of its TRIPS requirements. PhRMA remains seriously concerned by the failure of Canadian regulatory authorities to provide effective data exclusivity, as required by TRIPS Article 39.3. In many cases, cutting-edge innovative products are not approved for marketing in the U.S. and Canada until just before or even after the expiration of patent protection, so innovators must rely on data protection instead. Although Canada has statutory data protection, recent judicial decisions have rendered those protections meaningless. Canadian authorities allow parties other than the right holder to gain marketing approval in direct reliance of protected confidential data. This violates TRIPS Article 39.3 as it eliminates the TRIPS requirement to prevent "unfair commercial use" of protected data.

We urge the United States to move data protection to the top of the bilateral commercial agenda with Canada.

Other Obligations

Canada is required under both TRIPS and NAFTA to ensure effective enforcement of the standards of patent protection provided for in those Agreements.

Article 28 of TRIPS and Article 1709 of NAFTA require Canada to confer on patent owners the exclusive right to prevent third parties not having the owner's consent from making, using or selling the product or process that is the subject of the patent.

Article 41 and related Articles of TRIPS and Article 1714 and related Articles of NAFTA require Canada to "ensure that enforcement procedures are available under its law so as to permit effective action against any act of infringement of intellectual property rights covered by (these) Agreements, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements."

Enforcement

Systemic inadequacies in Canada's administrative and judicial procedures call into question whether Canada is meeting its TRIPS and NAFTA obligations with respect to pharmaceutical patents.

These inadequacies allow generic versions of patented medicines to be approved by Health Canada, to be listed for use by doctors and use or even mandatory substitution by pharmacists, and to reach or be ready to reach the market in commercial quantities while valid patents are still in force.

This can occur under the *Patented Medicines (Notice of Compliance) Regulations*, the so-called "linkage regulations" administered by Health Canada, and as a result of how patent infringement claims are treated in the Canadian Courts.

The linkage regulations fail to provide for transparent and equitable consideration of the rights of patent owners and prevention of patent infringement.

Under the linkage regulations, generic producers can apply at any time for approval by Health Canada of generic medicines. Such generic medicines are assessed for safety and efficacy against data and clinical trials relating to previously approved patented medicines. These regulations extend significant advantages to generic companies.

The linkage regulations indicate that Health Canada must determine whether there are patents registered that could be infringed if approval, i.e., a Notice of Compliance (NOC), was granted for the generic medicine. If a patent is identified, the generic producer is required, in principle, to issue a Notice of Allegation (that there would be no

infringement) to the brand name company who, if it believes the allegation is not justified, may challenge that allegation in the Court. Thus, the brand name company has access to a judicial procedure to present its claim and seek an order of prohibition to prevent the issuance of an NOC.

This arrangement, in principle, could provide the basis for effective protection of pharmaceutical patent owners' rights as required under TRIPS and NAFTA. Experience shows, however, that the manner in which the procedures are applied fails to extend such protection in a majority of cases where infringement is at issue. Indeed, there is a pattern that reveals clear bias in favor of generic companies.

This is seen in a number of ways:

- The legal burden is on the brand name company to prove that the generic company's allegation of non-infringement is not justified. Access to information on the generic company's product may be restricted, however, because there is not necessarily discovery in such proceedings. The brand name company may therefore be reliant on whatever information the generic company is prepared to supply. This approach is open to abuse to the detriment of the brand name company.
- Health Canada has been inconsistent in its policies and practices relating to the listing of brand name companies' patents and in requiring generic companies to send a Notice of Allegation. In some cases no Notice is provided. This means that the brand name company has no opportunity to present a claim and, in fact, may remain unaware that a generic version of its drug has been submitted for approval until an NOC is issued. This has occurred and could easily occur again in future.
- The linkage regulations do not apply to process patents, notwithstanding the fact that claims to a medicine itself were previously forbidden under Canadian patent law. This means that many brand name companies have only process patents to protect their inventions. This situation will continue for a period of years.

As a result of these inadequacies, there have been dozens of cases since 1993 (when the linkage regulations came into effect) in which patentees had an infringement claim but were unable to prevent the issuance of an NOC and the marketing of a generic version of a patented medicine.

The Canadian courts fail to provide effective recourse in cases where an NOC is issued for an infringing generic medicine.

If a patentee is unsuccessful in preventing the issuance of an NOC by Health Canada, the next step would be to seek relief through an infringement action. In the first

instance, a patentee could apply for an interlocutory injunction to maintain its rights and, in particular, to prevent the marketing of an infringing generic version pending trial.

It is virtually impossible, however, to obtain an interlocutory injunction. It is estimated that less than 10% of requests for such injunctions are granted.

- The Canadian Courts apply a very high standard of “irreparable harm”, the test applied for the granting of an interlocutory injunction. This standard is impossible to meet in practical terms.
- A patentee is required to establish that there will be irreparable harm that cannot be compensated by the eventual award of damages. The Courts do not accept that a monetary damage award may not provide full compensation for loss of market share for the product and related products, lost business, lost investment and research opportunities due to the absence of income from sales, or for loss of reputation and goodwill.
- It generally takes two to five years before an action for patent infringement is tried. After this amount of time, a brand name company’s market share has been severely eroded. Moreover, Canadian Courts may be reluctant to grant the large damage awards that a brand name company would be owed in such cases.

The standards applied by the Canadian Courts are not consistent with the standards provided for in TRIPS and NAFTA.

- The fundamental private right under these Agreements is, of course, the exclusive right to prevent the making, use or sale of a patented product or process that is not authorized by the patentee.
- In terms of the enforcement of that right, Article 50 of TRIPS and Article 1716 of NAFTA call for “prompt and effective” provisional measures, i.e., including interlocutory injunctions, “to prevent an infringement of any intellectual property right, and in particular to prevent the entry into the channels of commerce in their jurisdiction of allegedly infringing goods”. The test under TRIPS and NAFTA for provisional measures is that “any delay in the issuance of such measures is likely to cause irreparable harm to the right holder”, a clearly lower standard than that applied by the Canadian Courts.

The concerns of pharmaceutical patent owners are serious and have important implications beyond economic losses in Canada. If a major developed country such as Canada is failing and continues to fail to comply with the spirit and letter of TRIPS, this will set a negative example for developing countries. Canadian practices that create a dangerous precedent should be addressed before they are adopted in other jurisdictions.

Conclusion

Although Canada has eliminated its former compulsory licensing system for pharmaceuticals as a result of NAFTA and TRIPS, there continues to be a strong bias favoring the early and often infringing entry of generic versions of patented medicines into the marketplace. There are systemic inadequacies in administrative and judicial procedures that allow this to occur, resulting in substantial and on-going economic losses to patent owners and calling into question Canada's compliance with its obligations under both NAFTA and TRIPS.

Moreover, Canada's policies and practices constitute a problematic example that could be followed by others, particularly developing countries.

USTR should attach high priority to remedying this situation.

Price Controls

The Patented Medicine Prices Review Board (PMPRB) continues to work toward revising its overall approach to setting price ceilings. Reports emerging from the Federal/Provincial/Territorial Pharmaceutical Issues Committee suggest the likelihood of increased collaboration among different levels of government toward more stringent, non-market based interventions.

The use of international price comparisons and the establishment of price ceilings on patented medicines are counterproductive to initiatives to provide high quality health care, and thus improve the health of patients, or to help contain health care spending. The following are among the principal concerns regarding such practices.

- **Using international comparisons ignores valid reasons for price differentials across countries.** The prices of pharmaceutical products, as well as all other types of goods and services, differ widely across countries, for many legitimate reasons. These include living standards, income levels, consumer preferences, disease and drug consumption patterns, product volume, exchange rates, product liability, regulatory requirements, as well as the degree of competition in the health services and pharmaceutical markets. Superimposed on these factors are government-mandated reimbursement and price controls, which affect prices throughout the distribution chain. As a result, establishing price ceilings by using prices from other countries ignores prevailing market conditions and impedes biomedical innovation by prohibiting each innovator from establishing prices for its medicines based on market factors.
- **There is little evidence that international price benchmarking leading to price controls actually curbs overall pharmaceutical spending.** Government-set prices preclude the benefits of price competition. In these circumstances, such government interventions in the market have little, if any, positive impact on the rate of growth in

pharmaceutical expenditures over the long term. Under market conditions, however, price competition has proven to be an effective way to hold overall spending down and to provide high quality health care.

- **International price benchmarking threatens patients' health by dampening incentives to improve on today's treatments, thus lowering health care quality.**

In order to fund critical long-term activities to discover and develop potentially life-saving drugs, pharmaceutical companies must be able to fairly and adequately recoup investment in research and development. Price control practices that prevent innovators from covering their costs will thus impede biomedical innovation and can jeopardize high quality health care for future patients.

In deciding how best to allocate health care resources and resolve the tension between controlling health care spending, improving the health of the population, and ensuring that the research-based pharmaceutical industry can continue to deliver cost-effective innovations for patients, the PMPRB's proposed approach of further restricting pricing flexibility has the potential to negatively impact the latter.

Potential Exports/Foreign Sales

It is not possible at this time to determine the impact on sales for PhRMA member company affiliates in Canada if the aforementioned issues were to be resolved. However, the level of pharmaceutical research in Canada is only 5% of the level of total research in the United States, which demonstrates how little incentive the Canadian intellectual property regime provides for pharmaceutical innovation.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

CENTRAL AMERICA

(COSTA RICA, EL SALVADOR, GUATEMALA, HONDURAS, NICARAGUA AND PANAMA)

Intellectual Property Protection

Although some Central American countries made progress in updating their intellectual property legislation, the process remains incomplete, and enforcement is still inadequate. Counterfeit pharmaceuticals also continue to threaten the region's public health.

A proposed Central American Agreement on Inventions and Industrial Designs (*Convenio Centroamericano sobre Invenciones y Diseños Industriales*) never came to fruition. Instead, throughout 1999 and 2000, individual countries adopted legislation in order to meet their obligations to comply with TRIPS. Issues of particular concern remain compulsory licensing, international exhaustion, and the absence of pipeline protection.

Costa Rica

Costa Rica updated its existing patent regime via law 7979, adopted in December 1999. A separate law, law 7978, was adopted to focus specifically on confidential information. Unfortunately, the changes were inadequate, and indeed the law is being reviewed by a local court, because it contains provisions that appear to be unconstitutional. Compulsory licenses and patent exhaustion can occur if a patent is not worked within four years. The patent can also be canceled for non-working. Law 7978 permits government authorities to use confidential data.

El Salvador

El Salvador's patent law (Decree Law No. 604, effective since November 1993) represented an improvement over previous legislation, but several provisions are not consistent with TRIPS. Problems include: only fifteen years patent protection for pharmaceutical products and processes from the date of application; a broad interpretation of patentable material; overly broad compulsory licensing provisions; the

potential for obligatory compulsory licenses; and no protection for products in the pipeline. On the positive side, the law protects against parallel importation and does not require local manufacturing of patented products. As of November 2000, the law had not yet been revised to bring it into full compliance with TRIPS, almost a year after the WTO's January 1, 2000 deadline.

Guatemala

In July 2000, the Guatemalan Congress approved patent legislation by means of Decree No. 46-2000. Because of the law's serious flaws – rendering it non-compliant with TRIPS – the President of Guatemala vetoed it on August 1, 2000. A new law was approved and went into effect on November 1, 2000. It is largely compliant with TRIPS, but enforcement remains a perennial problem.

Honduras

On December 9, 1999, Honduras brought its previous patent regime into compliance with TRIPS via Decree 12-99E. Enforcement remains limited, however.

Nicaragua

Nicaragua's new patent law, Number 354, went into effect on November 24, 2000. It is largely compliant with TRIPS. However, it permits compulsory licenses “for reason of public interest, national emergency, or to remedy any anti-competitive practice.” The latter is defined as “those which unduly affect free competition or which constitute abuse of dominant market position.” In conflict with Article 31(b) of TRIPS, Article 52 of the new Nicaraguan law appears to allow compulsory licenses without previously asking for and being denied a contractual license. Inventions are not defined as “process” or “product” but merely as “problem-technical solution.” The national treatment provision calls for reciprocity, which could lead to restrictive interpretations or onerous requirements to qualify for equal treatment in Nicaragua.

Panama

Panama's patent law, Decree Law No. 35, went into effect in May 1996, and is consistent with TRIPS requirements. The law completely eradicated any provisions for compulsory licensing. Patent exhaustion is local, protecting against parallel importation. Additionally, past expiration based on non-manufacturing was eliminated. Efforts should now be directed towards improving the registration procedures and administration of justice, allowing for an effective and practical application of the legislation.

Other Barriers

Price Controls

Nicaragua and Panama continue to maintain a policy of price controls on

pharmaceutical products. Indeed, the Panamanian Congress approved a law on November 7, 2000 to reduce pharmaceutical prices to their October 1999 level and freeze them for two years. This sends a strong, negative signal to investors regarding Panama's lack of commitment to market principles. Ministry of Health and Presidential Decrees in Costa Rica expressly aim to reduce pharmaceutical prices, allowing parallel imports by wholesalers and promoting the use of generics by explicitly requiring that pharmacists provide consumers options similar or equivalent to what has been prescribed.

Potential Exports/Foreign Sales

If barriers were lifted in Central America, the increase in sales for PhRMA member company affiliates would range between US\$ 100 to US\$ 500 million dollars in potential exports.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

CHILE

Intellectual Property Protection

Chile implemented a flawed patent law (Number 10939) in 1991, which provides limited product patent protection for pharmaceuticals. This law offers an inadequate patent term (15 years from approval) and no transition (i.e., pipeline) protection for pharmaceuticals. Draft legislation designed to bring Chile into compliance with TRIPS obligations has not yet been adopted, almost a year since the WTO-imposed January 1, 2000 deadline. Chile should take prompt steps to bring its legislation into conformity with its international legal obligations.

The draft legislation represents an improvement over the existing law in several ways, including:

- extending the patent term to 20 years;
- providing patent protection for processes and the products obtained by those processes;
- increasing fines for infringement;
- elimination of the burdensome and subjective requirement to prove that an infringer “acted in bad faith” (complainants must simply demonstrate that the infringing activities had a commercial purpose);
- expanded protection for confidential data.

The draft legislation could be improved in a number of ways, however. The research-based pharmaceutical industry advocates greater linkage between health authorities and patent officials. To that end, the new law should require so-called “second applicants” (i.e., applicants seeking to copy existing products) to demonstrate that the product for which they seek approval from health authorities is not the subject of valid patent or pending application. The 1991 law contained no mention of parallel imports; the

new law does, which we regard as a step backward. The language of Article 51, which discusses compulsory licenses, should be modified to avoid ambiguity about when such licenses might be issued.

Another way in which the intellectual property environment could be improved in Chile, until improved, adequate and effective *de jure* patent protection is in place, is for the government to implement and enforce provisions guarding against the unauthorized commercial use of company proprietary data, as per the principles outlined in TRIPS Article 39. As is described in several other country sections in this submission, allowing the registration of “generic” products that use, or incorporate by reference, the company proprietary data of the innovator is an unfair trade practice that severely if not completely undercuts intellectual property protection for pharmaceuticals. Chile should adopt a ten-year period standard against the use of proprietary data submitted for registration purposes, as is the case in several EU countries.

Our industry has welcomed more expeditious patent application processing in recent years and hopes this positive trend will continue.

Other Barriers

The Chilean health registration system (e.g., Sanitary Code/Decree 1836) sets a higher standard for innovative products than for copy products seeking registration in Chile. This process discriminates against the research-based pharmaceutical industry when introducing original products into Chile, whereas it allows the swift introduction of copies in the Chilean market.

Potential Exports/Foreign Sales

At this time it is estimated that if current barriers were removed, sales of PhRMA company affiliates could increase in the range of US\$ 50 million to US\$100 million.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

DOMINICAN REPUBLIC

Intellectual Property Protection

On May 11, 2000, then-President Fernandez signed into law an industrial property bill whose numerous deficiencies make it the worst in the Western Hemisphere. Many of its provisions make it non-compliant with TRIPS, including:

1. The law excludes patenting of second uses, does not include protection for vegetable obtentions, business or economic plans or non-biological methods and processes connected with living materials.
2. Compulsory licensing: The law allows the granting of compulsory licenses on the sole basis of the denial of a contractual license within 210 days after the contractual license is requested. There is no need to prove any fault by the patent holder. The only grounds a patent owner can allege is the impossibility to exploit a patented invention. Additionally, the law allows for issuance of compulsory licenses on patents on raw materials, i.e. the potential licensee would be authorized to finish the product locally, thereby discriminating between imported finished products and those locally produced.
3. The above compulsory license is in addition to compulsory licenses granted in cases of lack of exploitation, abuse due to non-competitive practices, public interest and cases of dependent patents.
3. Article 39 of the law discriminates between imported finished products and locally manufactured products, by requiring both importation and local manufacture, in a clear violation of Article 27.1 of TRIPS. Furthermore, the law discriminates between foreigners and nationals by requiring foreigners to place a bond in an amount sufficient to cover court costs and legal fees in cases where they appear as plaintiffs in a lawsuit (where the patent or trademark was issued prior to the publication of the new law, that is May 11, 2000). This goes against the national treatment stipulated by Article 3 of TRIPS. (Paradoxically, the new Dominican copyright law adopted in 2000 expressly states that such a bond will not be required in any case.)

4. Article 39 of TRIPS contemplates the protection of undisclosed tests or other data filed before sanitary authorities as a precondition of approving the marketing of pharmaceutical, agricultural, or chemical products. Completely contrary to the spirit of this provision, the Dominican law violates data protection principles by authorizing all uses of a patent which are necessary to obtain health registration or approval for commercialization of a product.

Additionally, the Department of Health continues its practice of issuing health registrations (equivalent to a permission to commercialize) to products that violate locally registered patents in spite of legal requests to the contrary.

5. Article 186 (2) only grants issued patents the term granted pursuant to the old law (fifteen years), thereby denying extension to 20 years in view of Article 70.2 of TRIPS.

Other Barriers

Law 173 of 1966 severely limits unilateral termination of distribution agreements. Termination of distribution agreements is only possible by mutual consent or through the award of unreasonable indemnification rights due to the subjective criteria specified by the law. Local distributors have no incentive to pursue aggressive distribution of the goods they represent, since a poor performance on their part does not invalidate the indemnification considered in the law.

Potential Exports/Foreign Sales

PhRMA member companies in the Dominican Republic estimate that, if trade barriers were removed, exports to that country could increase from US\$50 to US\$100 million.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

MEXICO

Intellectual Property Protection

In 1991, Mexico implemented its industrial property law which addressed most of the concerns of the U.S. pharmaceutical industry. In another positive development, the North American Free Trade Agreement (NAFTA) served to strengthen the Mexican patent law and raised it to the level of an international agreement. However, contrary to its NAFTA and WTO TRIPS obligations, the Mexican government fails to protect the rights of patent holders in several key areas.

Data Protection/Linkage

Pharmaceutical companies must submit safety and efficacy data to health authorities before being granted registrations to sell their products. These data are very valuable, representing a huge investment in research and clinical trials. In return, governments are supposed to protect the data from unauthorized use. The Mexican Ministry of Health (SSA) grants health registrations to generic products without verifying with the Mexican Institute of Industrial Property (IMPI) whether a patent already exists. When pressed about this practice, Mexican health authorities have stated that they are not responsible for enforcing patent laws. They see their sole responsibility as ensuring the safety and efficacy of products seeking registration, regardless of whether they infringe patents. The marketing of these copies, based on innovator companies' data, is "unfair commercial use" as defined by NAFTA and TRIPS. Yet innovator companies are forced to take the patent infringers to court – an expensive and time-consuming process, particularly in the absence of preliminary injunctive relief. Several years can elapse before a case is resolved, leading to considerable losses for our member companies because the infringing product remains on the market during litigation.

PhRMA companies also have expressed concern with the enforcement of the law, where "lack of unity" can lead to revocation, in whole or in part, of the patent. That is, the patentee could be penalized for a mistake made by the patent office.

Problems with counterfeit and otherwise illegal products in the border area persist. Mexican authorities have acknowledged (in an agreement signed with the pharmaceutical

industry in August 1999) that “a high percentage of irregularities in the importation, distribution and sale of pharmaceutical products in the cities of Tijuana, Mexicali and neighboring towns along the border area of the State of Baja California, which are in violation of the rules set forth in the General Health law and its regulations...”. The agreement called for ending the issuance of special import permits, since many of the counterfeit and potentially dangerous products sold in these pharmacies originally were manufactured in India, Pakistan, and China. Unfortunately, although import permits are no longer issued, falsified permits are frequently used to import these questionable products, and the problem remains as serious as ever. This situation is illegal and dangerous, and the Mexican government should take prompt, effective steps to remedy it.

Other Barriers

The Mexican Government continues trying to steer some of the business it generates directly to local companies, contrary to the spirit of NAFTA. Recent changes in the requirements for products to be identified as domestically produced signal this as a increasingly entrenched problem of discrimination against the innovator.

NAFTA/Local Content

Under NAFTA, Mexico was granted a transition period extending until 2001 which allows the Government to require that, for those products competing for a public tender, 50% of the content must be manufactured locally. The way the tender bids are timed, the practical implementation actually extends well into 2002. This prejudices PhRMA member products by favoring local manufacturers. This happens because bids are accepted the 4th quarter of every year preceding delivery. Accordingly, the bids for the year 2002 are done in 2001. New bids not constrained by the 50% content rule will not be entertained until well in 2002 for the following year. Mexico is thus able to extend the impact of its domestic content rule for an additional year. This is inconsistent with the spirit of the NAFTA transition period and is contrary to WTO national treatment provisions.

Price Controls

The pharmaceutical industry is still one of the very few in the Mexican economy subject to Government price controls under PROMIF.

Potential Export/Foreign Sales

The removal of current barriers would mean an increase in sales and exports in the range of US\$300 million to US\$500 million dollars for PhRMA members.

November 27, 2000

**SUBMISSION OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE)
2001**

URUGUAY

Intellectual Property Protection

Uruguay updated its 1941 patent law on August 19, 1999 by passing Law 17.164, the Law of Patents of Invention, Utility Models and Industrial Designs. It does not comply with TRIPS in several respects.

- Compulsory licensing is very broadly established;
- Data exclusivity is omitted, contrary to Article 39.3;
- Exclusive marketing rights are not considered;
- Pipeline patent protection is not considered;
- Parallel importation is allowed.

Potential Export/Foreign Sales

The removal of current barriers would mean an increase in sales and exports in the range of US\$ 50 million to US\$ 100 million for PhRMA members.