117th Session EB117.R13

Agenda item 4.10 27 January 2006

[Global framework on]essential health research and development

The Executive Board,

Having considered current developments regarding access to medicines and the need to develop urgently new medicines and other health care technologies;

Submits to the Fifty-ninth World Health Assembly for its consideration the following draft resolution:

The Fifty-ninth World Health Assembly,

[1] Recalling resolutions WHA52.19, WHA53.14, WHA54.10, WHA56.27, and WHA57.14;

no changes

[2] Considering the need to develop safe and affordable new medicines for such communicable diseases as AIDS, malaria and tuberculosis, and for other diseases or illnesses that primarily affect the world's poorest people;

Agree with text, although it would be preferable to amend it to read, „∑need to further develop‰. This additional change would underscore that products are being developed already; without the word „further‰, it would give the impression that these drugs were not being developed.

[3] Recognizing the importance of providing support for the development of treatments for diseases that have small client populations;

no changes

[4] Recognizing the importance of making global health and medicines a strategic sector;

Can accept wording, although it is unclear what making medicines a „strategic sector‰ actually means.

[5] Concerned about the need for appropriate, effective and safe health tools for patients living in resource-poor settings;

It would be preferable to amend it to read, „∑need to further develop‰. This additional change would underscore that products are being developed already; without the word „further‰, it would give the impression that these drugs were not being developed.

[6] [Mindful that more than 70% of new drug approvals are for medicines that do not provide incremental benefits over existing ones[1]]

This paragraph should be deleted. It is based on a methodologically flawed study done by a front organization of the US insurance industry (NIHCM,s board is made up almost entirely by current or past top executives from the US Blue Cross/Blue Shield companies and is not a US government agency). The flaw in the methodology lies in a misunderstanding of the US FDA,s classification of drugs as „NCEs‰ (other similar drugs, which were developed in parallel to the „NCE‰ but which came onto the market afterwards, are just as innovative and can offer health benefits additional to the NCE,s effects). Also, the „priority review‰ designation by the FDA is an administrative tool, not a judgment regarding the utility of the drug. The apparent purpose behind the NIHCM report was to advocate against using newer, innovative drugs for budget reasons.

[7] Considering the urgency of developing new medicines to address emerging health threats such as multidrug-resistant tuberculosis, and other infectious diseases of relevance to developing countries;

The text should be revised to say at the end „∑ tuberculosis, and other infectious diseases which particularly affect developing countries‰, not „of relevance to developing countries.‰ The amended text is important to keep the focus of further activities on tropical diseases, not to have „mission creep‰ into non-communicable diseases which are already being addressed effectively through the market mechanism. (p.2)

[8] Aware of the need for additional funding for research and development for new vaccines, diagnostics, and pharmaceuticals, including microbicides, for illnesses, including AIDS, that disproportionately affect developing countries;

This paragraph is acceptable.

[9] [Recognizing the importance of global public undertakings such as the Human Genome Project, and the increasing relevance of open and accessible public research in advancing science and the transfer of technology;

[10] [Further aware of the promise of new, open models for the development of medical science, enhanced participation in, and access to, scientific advances, and increased knowledge;

These two paragraphs are overlapping and furthermore over-exaggerate the importance of „open source‰ models of research. Such „open source‰ models are not appropriate for actual drug development, for example, as experience has shown that companies (including generic companies) will only invest in further development of a drug if they can obtain IP protection on it. (For example, CIPLA,s patenting of its „triomune‰ fixed-dose ARV combination product in 18 African states ^ as CIPLA,s South African spokesperson said, „we want to protect our innovation.‰) It would be preferable to note the possible relevance of „open source‰ regarding communications about discoveries relevant to health research (such as the human and other genomes), but then (to give the proper balance) to specifically cite the proven and important incentives which IPRs give to drug development. An alternative text could thus be: „Aware of the possibilities for disseminating discoveries relevant to public health via open and accessible public research and recognizing the important incentives which intellectual property rights give to drug research and development;‰

[11] [Recognizing the importance of public/private partnerships devoted to the development of new essential drugs and research tools, but concerned about the need for governments to set a needs-based priority agenda for health, and to provide political support and sustainable sources of funding for such initiatives;

Acceptable, except that the phrase „to set a needs based priority agenda for health‰ give the impression that current research does not meet public health needs and would support the idea of promoting government-directed research via „R&D guidelines‰. This phrase should thus be deleted and the relevant sentence should read: „∑ but concerned about the need for governments to provide political support and sustainable sources of funding for such initiatives.‰

[12] [Recognizing the importance of public and private investment in the development of new medical technologies;]

OK to include 13th Paragraph: Starting with „Recommending the importance of public and private investment∑)

[13] Considering that a number of developing countries have been strengthening their research and development capacity in new health technologies, and that their role will be increasingly critical, and recognizing the need for continued support for research in and by developing countries;

no comments?

[14] Recognizing that intellectual property rights are one of several important tools to promote innovation, creativity, and the transfer of technology;

OK to include 14th paragraph

[15] [Recognizing at the same time the importance of providing for a proper balance between intellectual property rights and the public domain, and the need to implement intellectual property rules in a manner that is consistent with the fundamental right of every human being to the enjoyment of the highest attainable standard of health and the promotion of follow-on innovation;]

Needs to be re-written as follows: „Recognizing at the same time the important role which intellectual property rights play in bringing knowledge into the public domain and, in doing so, helping to promote follow-on and adaptive innovation to attain the highest attainable standard of health.‰

[16] Taking into account Article 7 of the TRIPS agreement that states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations";

OK to include as it accurately repeats the text of TRIPS Art.7

[17] Stressing that the Universal Declaration of Human Rights provides that "everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits" and that "everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author";

OK

[18] [Considering that it is imperative to reconcile the public interest in accessing the products derived from new knowledge, with the public interest in stimulating invention;]

This paragraph is redundant with the concepts of previous paragraphs, such as para 16, and thus should be deleted.

[19] [Concerned about the impact of high prices of medicines on access to treatment, and the need to implement intellectual property laws in a manner that reconciles incentives for development of new medicines with the need to promote access to all, consistent with paragraphs 4, 5 and 7 of the Doha Declaration on TRIPS and Public Health;] Aware of the need for [a new global framework (mechanism) to provide] adequate and sustainable levels of financial support for public health needs-driven research, including in particular for priority medical research;[including the possibility of exploring a new global framework]

This paragraph should be deleted, as it gives the impression that IPRs and access are antagonistic, which they are not. Also, it implies that high prices are due to IPRs, when in reality (as noted in the CIPIH report), many other factors play a role in determining the final consumer price. (p.3)

[20] [Considering the global appeal on research and development on neglected diseases launched on 8 June 2005 with the support of 18 Nobel Laureates, over 2500 scientists and health experts, academics, nongovernmental organizations, public research institutes, governments officials and members of parliament, calling for [Noting the need for] new policy [rules] [approaches] to stimulate essential research and development in health, especially for the most neglected diseases;]

If this statement should be included, then it should be balanced with a reference to the „Civil Society Report‰ prepared by a group of pro-market NGOs facilitated by the International Policy Network.

[21] Aware of the need to promote new thinking on the mechanisms that support innovation;

acceptable as written

[22] Recognizing the importance of strengthening capacity of local public institutions and businesses in developing countries to contribute to, and participate in, research and development efforts,

acceptable as written

1. URGES Member States:

(1) to make global health and medicines a strategic sector, to take determined action to emphasize priorities in research and development addressed to the needs of patients, especially those in resource-poor settings, and to harness collaborative research and development initiatives involving disease-endemic countries;

acceptable as amended

(2) [taking into account [the results of the Commission on Intellectual Property Rights, Innovation and Public Health and] existing frameworks, to take an active part, in cooperation with WHO and other international actors, [in the establishment of a framework for defining global health priorities] in supporting essential medical research and development [based on the principle of equitable sharing of the costs of research and development by all those who benefit from it] and incentives to invest in useful research and development in the areas of patients' need and public interest;]

Needs rewording as follows: „taking into account existing frameworks, to take an active part, in cooperation with WHO and other international actors, in supporting essential medical research and development through incentives promoting research and development in areas of patients, needs and public interest;‰

(3) to ensure that progress in basic science and biomedicine is translated into improved, safe and affordable health products - drugs, vaccines and diagnostics - to respond to all patients' and clients' needs, especially those living in poverty, taking into account the critical role of gender and to ensure that capacity is strengthened to support rapid delivery of essential medicines to people;

OK as amended

[(4) to encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health;]

Should be eliminated, as bilateral trade agreements do not fall within WHO,s mandate.

[(5) to ensure that the report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health is included on the agendas of WHO's regional committees in 2006;]

OK

2. REQUESTS the Director-General:

Is such a working group, which will cost about US$1.2 million over two years, really the best use of WHO,s limited resources? And, given that an expert panel could not reach consensus over two years of research and analysis, why would a working group of Member States be any more successful?

(1) to establish an open-ended working group of interested Member States to consider proposals to [establish a global framework for supporting][strengthen incentives and mechanisms for] needs-driven research, consistent with appropriate public interest issues [and [taking note of the work][building on the analysis] of the WHO Commission on Intellectual Property Rights, Innovation and Public Health];

Should be amended to read: „To advise Member States on the implementation of proven and effective incentives to promote research&development into diseases which particularly affect developing countries.‰

[(2) to submit an annual progress report on the working group of interested Member States [to] beginning with the [Sixtieth] World Health Assembly [(May 2007), and, if possible], a final report [with concrete proposals] through the Executive Board at its 121st session (January 2008) to the Sixty-first World Health Assembly (May 2008)[and to suggest alternative simplified systems for protection of intellectual property, with a view to enhancing accessibility to health innovations and building capacity for product development, uptake and delivery in developed and developing countries.]]

Should be deleted in any case, especially the part regarding „alternative simplified systems of intellectual property‰ ^ this is definitely not WHO,s mandate!

Reference:

(1) The National Institute for Health Care Management Research and Educational Foundation, Changing patterns of pharmaceutical innovation. Washington, DC, NIHCM Foundation, May 2002.