# Medical Research and Development Treaty (MRDT)

Discussion draft 4[1]

**Table of Contents**



[1] February 7, 2005

# 1 Preamble.

The State Parties to this Treaty (hereinafter referred to as the "Parties") seek to create a new global framework for supporting medical research and development that is based upon equitable sharing of the costs of research and development, incentives to invest in useful research and development in the areas of need and public interest, and which recognizes human rights and the goal of all sharing in the benefits of scientific advancement.

# 2 General Provisions And Basic Principles

## *2.1 Objectives of the Treaty*

Members seek to promote a sustainable system of medical innovation that will:

i. *ensure* adequate and predictable sources of finance for medical research and development,
ii. *allocate* fairly the costs of supporting medical research and development,
iii. *identify* priority areas of research and development,
iv. *encourage* the broad dissemination of information and sharing of knowledge, and access to useful medical inventions,
v. *enable* medical researchers to build upon the work of others,
vi. *support* diversity and competition,
vii. *utilize* cost effective incentives to invest in promising and successful research projects that address health care needs,
viii. *enhance* the transfer of technological knowledge and capacity in a manner conducive to social and economic welfare and development, and
ix. *promote* equitable access to new medical technologies, so that all share in the benefits of scientific advancement.

## *2.2 Mechanisms to Support Research and Development*

The treaty will provide:

i. *Obligations* for minimum levels of investment in medical research and development,
ii. *Processes* for priority setting,
iii. *Obligations and Incentives* to support
    a. Medical research and development, including priority research and development,
    b. broader dissemination of scientific information and knowledge,
    c. enhanced transfer of technology and capacity for research and development in developing countries, and
iv. *Obligations and standards* for transparency, including mechanisms to report, measure and understand the nature of the scientific, economic and

social dimensions of investment flows in medical research and development.

### 2.3 Relations to other agreements

Members agree that in creating a global framework for minimum levels of investment in medical research and development it is possible and appropriate to rely less upon other, indirect mechanisms. Members thus agree to forgo certain WTO TRIPS dispute resolution cases, or bilateral or regional trade sanctions, in areas where compliance with the terms of the Treaty provides an alternative and superior framework for supporting innovation.

## 3 Governance

### 3.1 Assembly for Medial Research and Development (AMRD)

An Assembly for Medical Research and Development (AMRD) is hereby established. Every Party entering the treaty is a voting member of the AMRD. The first session of the AMRD shall be convened [by the World Health Organization] not later than one year after the entry into force of this Agreement.

### 3.2 Council for Medical Innovation (CMI)

The AMRD shall establish a Council on Medical Innovation (CMI), serving fixed terms.

#### 3.2.1 Elected Members

The CMI shall have [18] elected members.

ALTERNATIVE 1

> Half of the members of the CMI will be elected among member nations classified as high income by the World Bank. Half will be elected among member nations classified as middle or low income by the World Bank.

ALTERNATIVE 2

> One third of the members of the CMI will be elected among member nations classified as high income by the World Bank. One third will be elected among member nations classified as high middle income by the World Bank. One third will be elected among member nations classified as low middle income or low income by the World Bank.

No country will have more than one representative.

[

### 3.2.2 Civil Society Members

The elected members of the CMI will appoint [ten] addition non-voting members representing civil society. ]

## *3.3 Secretariat*

The AMRD shall designate a permanent secretariat and make arrangements for its functioning. [Until such time as a permanent secretariat is designated and established, secretariat functions under this Treaty shall be provided by the World Health Organization.]

Secretariat functions shall:

i. make arrangements for sessions of the AMRD, the CMI and subsidiary bodies and provide services as required;
ii. transmit reports received by it pursuant to the Treaty;
iii. provide support to Members, particularly developing country Members and Members with economies in transition, on request, in the compilation and communication of information required in accordance with the provisions of the Treaty;
iv. prepare reports on its activities under the Treaty;
v. ensure the necessary coordination with the competent international and regional intergovernmental organizations and other bodies;
vi. enter into such administrative or contractual arrangements as may be required for the effective discharge of its functions; and
vii. perform other secretariat functions specified by the Treaty and by any of its protocols and such other functions as may be determined by the AMRD or the CMI.

## *3.4 Meetings*

The AMRD will determine the venue and timing of subsequent regular sessions at its first session.

Extraordinary sessions of the AMRD shall be held at such other times as may be deemed necessary by the AMRD, or by request of the CMI, or at the written request of any Member, provided that, within six months of the request being communicated to the Secretariat of the Treaty, it is supported by at least one-third of the Parties.

The CMI will meet at least once every year.

### 3.5 Finances

The AMRD shall adopt financial rules for itself as well as governing the funding of any subsidiary bodies it may establish as well as financial provisions governing the functioning of the Secretariat. At each ordinary session, it shall adopt a budget for the financial period until the next ordinary session.

### 3.6 Observers

The AMRD shall establish the criteria for the participation of observers at its proceedings.

## 4 General Obligations

### 4.1 Qualified medical research and development

Members agree to support certain medical research and development. Qualified medical research and development (QMRD) includes:

i. Basic biomedical research,
ii. Development of biomedical databases and research tools,
iii. Development of pharmaceutical drugs, vaccines, medical diagnostic tools,
iv. Medical evaluations of these products, and
v. The preservation and dissemination of traditional medical knowledge.

### 4.2 Minimum levels of investment in medical research and development

The minimum support for QMRD will depend upon the capacity of each country. Minimum levels of support shall depend upon national income. Higher income countries will contribute more in both absolute and relative terms.

ALTERNATIVE 1

Depending upon the classification of the country, using the World Bank definition of income groups, the minimum support for QMRD, as a share of GDP, are as follows:

i. High Income, 15 basis points (.0015)
ii. High Middle Income, 10 basis points (.001)
iii. Lower Middle Income, 5 basis points (.0005)
iv. Low Income, 0 basis points of GDP (0)

ALTERNATIVE 2

The obligation of each party to support QMRD will increase with per capita income. The relevant rates as a share of national income are as follows:

i. 1 basis point of GDP for the per capita income from $300 to $999,
ii. 5 basis points of GDP for the per capita income between $1,000 and $4,999,
iii. 10 basis points of GDP for the per capita income between $5,000 and $9,999,
iv. 15 basis points of GPD for the per capita income between $10,000 and $19,999, and
v. 20 basis points of GDP for the per capita income of $20,000 or more.

The CMI will review the minimum levels every two years. Minimum levels can be changed by consensus, or with support of two-thirds majorities of the high-income members and two-thirds majority of the developing country members.

# 5 Priority Medical Research

## *5.1 Committee on Priority Medical Research and Development*

The CMI will appoint a Committee on Priority Medical Research and Development (CPMRD).

The CPMRD will meet at least once a year to evaluate targets for priority research, and to make recommendations to enhance priority health care research, and improve access to knowledge, technology and products.

## *5.2 Identification of priority medical research targets*

Every two years the CPMRD will adopt global targets for priority medical research and development (PMRD) in the following areas:

a. Vaccine development
b. Neglected diseases
c. Global infectious diseases
d. Databases, research tools and other public goods
e. Health systems and appropriate technology
f. Preservation and dissemination of traditional medical knowledge
g. Other appropriate priority research

## *5.3 Minimum support for priority medical research*

Depending upon the classification of the members by income (using World Bank definitions), the initial minimum share of GDP devoted to PMRD is the following:

ALTERNATIVE 1

a. High Income, 2 basis points, at least half for neglected diseases,
b. High Middle Income, 1 basis point
c. Lower Middle Income, .5 basis points
d. Low Income, 0 basis points of GDP

ALTERNATIVE 2

The obligation of each party to support PMRD will increase with per capita income. The relevant rates as a share of national income are as follows:

i. .2 basis point for GDP for the per capita income between $300 and $999,
ii. .5 basis points of GDP for the per capita income between $1,000 and $4,999,
iii. 1 basis points of GDP for the per capita income between $5,000 and $9,999,
iv. 2 basis points of GDP for the per capita income between $10,000 and $19,999,
v. 3 basis points of GDP for the per capita income of $20,000 or more.

The CMI will review the minimum levels every two years. Minimum levels can be changed by consensus, or with support of two-thirds majorities the high-income members and two-thirds majority of the developing country members.

# 6 Methods of finance

Projects that support QMRD (including PMRD) are selected by Member States. Eligible finance mechanisms include:

i. Public sector support for QMRD
ii. Tax expenditures, such as tax credits for QMRD investments
iii. Philanthropic expenditures on QMRD
iv. QMRD financed by businesses or non-profit organization pursuant to government obligations,
v. National expenditures on relevant medical products, to the degree that such expenditures create incentives for investments in QMRD,
*vi.* Innovation prizes or other innovation incentives, to the degree that such expenditures support QMRD.

# 7 Decentralization and Diversity

Parties are free to decide themselves on specific investments and finance mechanisms for QMRD (including PMRD). Members are free to embrace a diversity of management approaches to support QMRD, including the direct funding of profit or non-profit research projects, market transactions such as purchases of medicine that provide incentives for research and development, payment of royalties to patent owners, tax credits, innovation prizes, investments in competitive research

intermediators, research and development obligations imposed on sellers of medicines or other alternatives that have the practical effect of either directly or indirectly financing QMRD.

Every two years the CMI will publish a report illustrating different mechanisms members have used to directly and indirectly finance QMRD.

# 8 Measurement of QMRD and PMRD

The CMI shall adopt regulations providing for measurement and reporting of investment flows for QMRD and PMRD. These regulations shall be consistent with the following principles:

i. **No double counting**. The mechanisms to finance QMRD (including PMRD) can be complex, involving mixed sources of finance and transnational flows of products and investments. The regulations shall provide that each investment only be counted once.

ii. **Source of finance rather that location of investment**. For purposes of measuring support for QMRD and PMRD, measurement will be based upon the source of finance rather than the location of R&D activity.

    *Explanatory note: For example, if products are purchased in one country, but R&D is performed in another county, the country that paid for the products would be credited with finance of R&D, even though the R&D itself was performed elsewhere.*

iii. **Evidence based estimates.** In cases where measured investments are based upon estimates of the relationship between outlays on products or incentives and actual R&D investments, the estimates shall be based upon the best empirical evidence of such relationships.

The CMI will establish an advisory committee that will adopt and periodically revise "best practices" models for sharing of economic and scientific data.

# 9 Open Public Goods

The CMI shall appoint a committee on open public goods (COPG). The CORG will adopt regulations that identify qualified open public good projects (QOPGP).

# 10 Technology transfer to developing countries

Members agree to report on collaborative research projects that enhance technology transfer and capacity building in developing countries. The CMI shall appoint a committee on technology transfer (CTT). The CTT will establish regulations to define qualifying technology transfer projects (QTTP).

# 11 Exceptionally Productive and Useful Projects

The CMI will appoint a committee on exceptionally productive and useful projects (CEPUP). The CEPUP will establish procedures for the identification of exceptionally productive and useful projects (EPUP), and the assignment of credits for such projects.

# 12 Incentives to support priority research, open research, technology transfer to less developed countries, and exceptionally productive and useful projects

The CMI will provide economic incentives for members to invest in priority research, open research, technology transfer to less developed countries, and exceptionally productive and useful projects.

## *12.1 Special Credits*

Investments in PMRD, QOPGP, QTTP and EPUP qualify for special credits that can be used in funding a members' minimum contribution to QMRD. The initial values of the special credits are:

50 percent of PMRD,
50 percent QOPGP
50 percent of QTTP, and
The credit assigned by the CEPUP for EPUP.

The CMI may periodically revise the weights for PMRD, QOPGP and QTTP. The global total credits for EPUP may not exceed [10] percent of global minimum PMRD obligations.

The PMRD, QOPGP, QTTP and EPUP credits may be traded between countries.

The CMI may periodically revise the weights.

## *12.2 Caps on Special Credits*

No more than [one third] of QMRD can be satisfied by the special credits. The CMI can periodically revise the caps on special credits.

# 13 Access to publicly funded research

## *13.1 Obligations to provide incentives for open access research*

The CMI will appoint a committee on open access research (COAR). The COAR will adopt best a practices model for the support of open access research. Within [5] years, every member will adopt procedures concerning obligations for research supported by the public sector to be made available to the public through open access archives or repositories.

## *13.2 Equitable pricing of government funded inventions,*

Within three years the CMI will adopt regulations that ensure equitable access to government funded inventions.

# 14 Changes in patent laws

## *14.1 Mechanisms to limit patents on inventions which are derived from certain open public goods databases`*

The COPG will adopt procedures whereby persons, organizations or communities that seek to establish certain qualifying open public goods databases (QOPGD) apply for a time limited period during which no patent applications can be submitted that rely upon the data from the QOPGD.

*Explanatory note: For example, when it was first created, the developers of the HapMap database (see licensing terms below) asked that patents not be filed for a period of three years. The license did create problems in terms of the dissemination of the information, and was eventually eliminated, but only after it had served its basic purpose, which was to protect the public good against misappropriation by private patents for a critical period of time.*

**DO NOT translate the text in this box**

**EXCERPTS FROM THE ORIGINAL TERMS AND CONDITIONS FOR ACCESS TO AND USE OF THE GENOTYPE DATABASE**

2. You may access and conduct queries of the Genotype Database and copy, extract, distribute or otherwise use copies of the whole or any part of the Genotype Database's data as you receive it, in any medium and for all (including for commercial) purposes, provided always that:

a. by your actions (whether now or in the future), you shall not restrict

the access to, or the use which may be made by others of, the Genotype Database or the data that it contains;

b. in particular, but without limitation,

i. you shall not file any patent applications that contain claims to any composition of matter of any single nucleotide polymorphism ("SNP"), genotype or haplotype data obtained from the Genotype Database or any SNP, haplotype or haplotype block based on data obtained from the Genotype Database; and

ii. you shall not file any patent applications that contain claims to particular uses of any SNP, genotype or haplotype data obtained from the Genotype Database or any SNP, haplotype or haplotype block based on data obtained from, the Genotype Database, unless such claims do not restrict, or are licensed on such terms that that they do not restrict, the ability of others to use at no cost the Genotype Database or the data that it contains for other purposes; and

### *14.2 Minimum exceptions to patent rights for research purposes*

The CMI will adopt regulations that provide for minimum exceptions to patents rights for research purposes. Members will enact such minimum exceptions within 5 years.

## 15 Exceptions in laws for copyright and related rights to support research

The CMI will adopt a best practices model for exceptions in laws on copyright and related rights, including laws on databases.

## 16 Relationship with Other Agreements

a. In order to better enhance medical innovation, Parties are encouraged to exceed the investment standards required by this Agreement, and nothing in this Agreement shall prevent a Party from exceeding the investment obligations of this Agreement.

b. The purpose of the Agreement is to establish an international system that deals directly with sustainable investment in medical innovation, with the intention of both providing sustainable sources of finance for such innovation and fairly allocating the cost burdens of such innovation.

c. The provisions of the Agreement shall in no way affect the right of Parties to enter into bilateral or multilateral agreements, including regional or sub-regional agreements, on issues of or additional to the Agreement, provided

that such agreements are compatible with their obligations under the Agreement, including (d).

d. Members agree, for products defined as QMRD, to forgo dispute resolution cases on Articles 27 through 34 and Article 39.3 of the WTO TRIPS Agreement, and similar provisions in regional or bilateral trade agreements, or in unilateral trade policies. Members further agree to forgo dispute resolution cases in regional or bilateral trade agreements, or in unilateral trade polices, that concern pricing of medicines. However, members may enter into bilateral or regional agreements to increase investments in medical research and development.

e. The Parties concerned shall communicate any agreements on issues relevant to the Treaty to the Council on Medical Innovation through the Secretariat.

# 17 Transition Arrangements

Members will have [5] years to enact policies consistent with the Treaty.

# 18 Reservations

[There will be no reservations to this agreement]

# 19 Appendix A: Abbreviations

| | |
|---|---|
| AMRD | Assembly for Medical Research and Development |
| CEPUP | Committee on exceptionally productive and useful projects |
| CMI | Council on Medical Innovation |
| COAR | Committee on open access research |
| COPGP | Committee on open public goods projects |
| CPMRD | Committee for Priority Medical R&D |
| CTT | Committee on technology transfer |
| EPUP | Exceptionally productive and useful projects |
| MRDT | The Medical Research and Development Treaty |
| PMRD | Priority medical research and development |
| QMRD | Qualified Medical Research |
| QOPGP | Qualified open public good projects |
| QTTP | Qualifying technology transfer projects |