

# Assessing implementation mechanisms for an international agreement on research and development for health products

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**Abstract** The Member States of the World Health Organization (WHO) are currently debating the substance and form of an international agreement to improve the financing and coordination of research and development (R&D) for health products that meet the needs of developing countries. In addition to considering the content of any possible legal or political agreement, Member States may find it helpful to reflect on the full range of implementation mechanisms available to bring any agreement into effect. These include mechanisms for states to make commitments, administer activities, manage financial contributions, make subsequent decisions, monitor each other's performance and promote compliance. States can make binding or non-binding commitments through conventions, contracts, declarations or institutional reforms. States can administer activities to implement their agreements through international organizations, sub-agencies, joint ventures or self-organizing processes. Finances can be managed through specialized multilateral funds, financial institutions, membership organizations or coordinated self-management. Decisions can be made through unanimity, consensus, equal voting, modified voting or delegation. Oversight can be provided by peer review, expert review, self-reports or civil society. Together, states should select their preferred options across categories of implementation mechanisms, each of which has advantages and disadvantages. The challenge lies in choosing the most effective combinations of mechanisms for supporting an international agreement (or set of agreements) that achieves collective aspirations in a way and at a cost that are both sustainable and acceptable to those involved. In making these decisions, WHO's Member States can benefit from years of experience with these different mechanisms in health and its related sectors.

Abstracts in **عربي**, **中文**, **Français**, **Русский** and **Español** at the end of each article.

## Introduction

The challenge of fostering innovation while facilitating access to health products has long stood as one of the greatest barriers to improving global health, especially among the world's poorest people.<sup>1</sup> Patents incentivize private sector research and development (R&D) on products for which companies can expect a return on investment by selling them to people who can afford high prices or benefit from health insurance schemes.<sup>2</sup> While much progress has been made over the past twenty years, investment in R&D remains inadequately low for diseases that predominantly affect developing countries.<sup>3</sup>

To address this challenge, in May 2010 the 63rd World Health Assembly established the Consultative Expert Working Group on Research and Development: Financing and Coordination (henceforth CEWG), whose task was to "examine current financing and coordination of R&D, as well as proposals for new and innovative sources of funding to stimulate R&D" related to the health needs of developing countries.<sup>4</sup> The creation of this group was motivated by the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and built on previous efforts of a similar World Health Organization (WHO) expert working group.<sup>5,6</sup> Ultimately, after assessing current R&D trends, consulting widely and evaluating 15 categories of reform proposals (Box 1), the CEWG concluded with a set of recommendations on financing and coordination.<sup>7,8</sup> To secure implementation, the CEWG advised WHO's Member States to adopt a legally binding agreement pursuant to Article 19 of WHO's constitution that would provide for effective and sustainable financing and coordination of R&D at both the national and

international levels. The CEWG's recommendations were considered by the 65th World Health Assembly in May 2012. Member States were not ready to engage in negotiating a convention but agreed to have national and regional discussions followed by an "open-ended Member States meeting in order to analyse thoroughly the report and the feasibility of the recommendations proposed by the CEWG, taking into account, as appropriate, related studies".<sup>9</sup>

If WHO's Member States choose to pursue an international agreement on these matters, they may naturally first consider the content of any possible binding or non-binding agreement. This may include the principles, norms and rules to which countries will adhere, the goals they will pursue, the functions they will establish, the financial obligations they will have at both the national and international levels and the size of any multilateral pooled fund. But equally important to consider is the full range of implementation mechanisms available for bringing the content of any concerted R&D reform into effect. This includes the reform proposals suggested by WHO's earlier expert working group, which recommended establishing an institutional R&D coordination and funding mechanism with an annual budget of \$3 to 15 billion United States dollars (US\$).<sup>6</sup>

Assessing the range of implementation mechanisms that could support an international agreement on the financing and coordination of R&D for health products obviously requires an evaluation of commitment devices. However, it also calls for an assessment of the range of possibilities available for administration, financial management, decision-making, oversight and promoting compliance. International agreements can be as formal as treaties or as informal as a declaration of

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**Box 1. Categories of research and development (R&D) reform proposals considered by WHO's Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG), 2012**

**Proposals that best met CEWG criteria<sup>a</sup>**

- Global framework on R&D
- Open approaches to R&D and innovation
- Pooled funds
- Direct grants to companies
- Milestone prizes and end prizes
- Patent pools

**Proposals that partially met CEWG criteria**

- Tax breaks for companies
- Orphan drug legislation
- Green intellectual property
- Priority review voucher
- Transferable intellectual property rights
- Health Impact Fund
- Purchase or procurement agreements

**Proposals that did not principally address R&D**

- Regulatory harmonization
- Removal of data exclusivity

WHO, World Health Organization.

<sup>a</sup> These criteria included: potential public health impact in developing countries; rational and equitable use of resources and efficiency considerations; cost-effectiveness; technical feasibility, potential, for scale-up, replicability and speed of implementation; financial feasibility and sustainability; additionality; intellectual property management issues; potential for de-linking R&D costs and price of products; equity/distributive effect, including on availability and affordability of products and impact on access and delivery; accountability/participation in governance and decision-making; impact on capacity-building in, and transfer of technology to, developing countries; and potential synergy with other mechanisms/potential for combining with others.

principles. Multilateral funds or research institutions can be set up by means of resolutions, decisions, conventions or other agreements, and financial obligations can be either legally, politically or morally binding, regardless of the nature of the instrument itself. Implementation can be led by existing institutions or by newly-established entities in the form of foundations, associations or inter-governmental organizations; decisions can be made by consensus or by various voting mechanisms; oversight can be achieved through state or non-state processes; and compliance can be promoted through carrots or sticks.

The implementation mechanisms used to bring agreements into effect are as important for achieving Member States' goals as the substantive commitments for which they were created. In international law and relations, the so-called "implementation gap" is an important challenge that needs to be overcome.<sup>10,11</sup> If an international agreement is sought to better and more equitably finance and coordinate R&D for health products that meet the needs

of developing countries, its success will depend on its being brought into effect through appropriate implementation mechanisms.

## Commitment mechanisms

In the pursuit of mutually shared goals, states can commit themselves to obligations vis-à-vis other states through a variety of mechanisms. One option is a convention, also known as a treaty, covenant, protocol, exchange of notes, or regulation and by at least 30 other names.<sup>12</sup> A convention is defined by the 1969 Vienna Convention on the Law of Treaties as "an international agreement concluded between states in written form and governed by international law". Conventions are binding instruments and often called "hard law", whereas non-binding instruments like political declarations are often called "soft law", although the distinction is not always straightforward. For example, a hard law convention may contain clauses that solely express aspirations, whereas a soft law declaration may contain very

precise commitments that are universally followed.

Conventions can be adopted through enabling provisions of existing international laws or in the constitutive instruments of existing international organizations – an example is Article 19 of WHO's constitution, which enabled the adoption of the Framework Convention on Tobacco Control (2003) – or through independent state negotiations, such as those that resulted in the Convention on Biological Diversity (1992). Contracts, also legal instruments, involve fewer formalities but can equivalently commit states to legally-binding agreements with other states. Contracts are used every day by governments to procure services, purchase equipment, trade goods and transfer money. However, such contracts are binding under applicable domestic laws and can be enforced in domestic courts, contrary to conventions, which operate in the international legal system and, as discussed further on, often lack compliance mechanisms.

States can also commit themselves to comply with certain requirements or activities using soft law instruments like political declarations, guidelines and codes of practice, which are all public expressions of commitment or intention that do not directly become part of international law. Such declarations can be issued through existing forums, such as the General Assembly of the United Nations (UN), or separately, such as the Paris Declaration on Aid Effectiveness (2005).<sup>13,14</sup>

Finally, state commitments can be achieved through institutional reforms, such as changes to international organizations, or by judicial decisions on existing laws by the International Court of Justice. For example, WHO budget allocations bind Member States to indirectly finance included programmes, just as the non-binding International Court of Justice advisory opinion limiting WHO's involvement in nuclear weapons disarmament practically commits states to pursue this issue through other forums.<sup>15</sup>

The advantages of legal commitment mechanisms like conventions and contracts include the clarity in which commitments are expressed as binding obligations and the domestic and international legal systems to which they become part. But along with clarity comes concern; highly formal legal instruments tend to take longer to

negotiate than political declarations and are often determinedly watered down during consensus-building negotiations. In exercising their sovereignty by committing to international law, states may also feel that they are limiting the future exercise of their sovereign rights. Declarations, on the other hand, can be very influential, just as they can be ignored. The Universal Declaration of Human Rights has come to be seen as part of customary international law, whereas the 1970 UN General Assembly resolution committing economically advanced countries to allocate 0.7% of their gross national product to official development assistance remains unfulfilled, even after it was confirmed in other soft law instruments like the Monterrey Consensus (2002), a resolution of the European Union (2005), the G8's Gleneagles Communiqué (2005) and the Doha Declaration on Financing for Development (2008).<sup>16-21</sup>

## Administrative mechanisms

Regardless of their form, international agreements can rely on various mechanisms for their administration. These include new or existing international organizations like The World Bank and autonomous sub-agencies associated with other entities, like WHO's International Agency for Research on Cancer (IARC). International organizations are public or private entities with independent legal personality. The public variety are often called "intergovernmental organizations" (IGOs), whereas private entities are often called either "non-governmental organizations" (NGOs) or "multinational corporations" (MNCs). New IGOs technically include the various "conferences of parties" (COPs) that are established to govern conventions<sup>22</sup> – including the one governing WHO's Framework Convention on Tobacco Control – although the secretariats serving these COPs are often based at existing IGOs. Mixed organizations are often called "public-private partnerships", although this term is used variously for organizations with and without independent legal personality.

Sub-agencies operate autonomously but derive their legal personality as an extension of another entity. They are created through formal channels. IARC, for example, was established through Article 18(k) of WHO's constitution, which allows WHO to establish its own

institutions to promote research.<sup>23</sup> Joint ventures, consortia or coordinating vehicles are other types of entities, usually established through a political agreement or a contract, such as a funding agreement. These joint ventures would include the many "partnerships" hosted by WHO that have their own governing boards but that rely on WHO's legal personality to contract. The extent to which sub-agencies and joint ventures are controlled by or subject to the influence of the parental legal entity depends on the particular hosting and governance arrangements.

International agreements, of course, can also be implemented without any administrative mechanism. Under this self-organizing model, parties to the agreement are expected to fulfil their obligations individually and have no institutional processes or activities to jointly finance or coordinate.

## Financial mechanisms

WHO's Member States similarly have several options for managing the funds that international agreements may require for implementation. For example, a specialized multilateral fund could be created specifically to support the agreement. The Multilateral Fund for the Implementation of the Montreal Protocol is such an entity. It was established in 1991 to finance activities in developing countries that help reverse deterioration of the Earth's ozone layer and embraces technical assistance, training, capacity-building and industrial conversion. Alternatively, money can be managed by existing financial institutions like The World Bank. This is how funds earmarked for the GAVI Alliance and Global Fund to Fight AIDS, Tuberculosis and Malaria are managed. International organizations of all types can also manage the funds that they collect through membership fees and other sources. Finally, money can be managed separately by each donor but spent in a coordinated way.

The most appropriate financial mechanism for any international R&D agreement will be the one that maximizes impact and feasibility. Although all four models described in the preceding paragraph have been successful in different contexts, the real-world effectiveness of the last model, coordinated self-management, has recently been questioned.<sup>24</sup> Such a model has not

seemed to work for R&D despite decades of discussions of the need to better coordinate health R&D investments.<sup>7,25,26</sup> Feasibility may vary widely depending on financial requirements. If significant long-term financial commitments are required, as expert working groups and the Commission on Macroeconomics and Health have recommended,<sup>4,6,7</sup> then some governments may be limited insofar as to whom and how they make such commitments. For example, governments of the 32 WHO Member States that follow the United Kingdom of Great Britain and Northern Ireland's Westminster parliamentary system – including Australia, Canada, India, New Zealand, Pakistan, Singapore and Thailand – may not have the constitutional authority to financially bind themselves for more than a few years at a time except in certain cases, such as those involving contributions to financial institutions and membership fees for intergovernmental organizations. States can, however, get around this challenge, as they do for the Montreal Protocol's Multilateral Fund, by formally recommitting themselves every few years to renew their contributions. This replenishment model is also used for the GAVI Alliance and Global Fund in addition to reliance on The World Bank to manage their funds.

## Decision-making mechanisms

Depending on the form of a particular international agreement, WHO's Member States may need to choose a way to make collective decisions on activities, budgets, priorities and disputes. This technically involves two dimensions – decision-making bodies (i.e. who decides) and decision-making procedures (i.e. how and when decisions are made) – which will be considered here together for purposes of simplicity.

There are at least four types of decision-making mechanisms available, which themselves can be and often are further combined to create a continuum of decision-making procedures. First, WHO's Member States can opt for a unanimous or consensus model of decision-making whereby deviations from the status quo are only pursued if all parties agree to them (i.e. unanimity) or at least do not disagree with them (i.e. consensus). Unanimity was infamously used by the former League of Nations

and consensus is widely used by various specialized agencies of the UN and the World Trade Organization. Second, decisions can be made by majority or supermajority voting with equal influence among all parties, as seen in the UN General Assembly and other plenary governing bodies. Third, a modified voting system can be used, such as voting weighted according to past financial contributions (e.g. The World Bank and International Monetary Fund) or priority voting (e.g. veto power for the UN Security Council's five permanent members). Fourth, decisions can be delegated either to another entity, a smaller group or an individual expert. WHO's Member States, for example, delegate much of their decision-making about WHO to an Executive Board, whereas UNITAID has a 12-member board with seats reserved for different national, civil society and intergovernmental constituencies (although both organizations often make decisions through consensus).

Each decision-making mechanism has its advantages and disadvantages. Although models based on unanimity, consensus and equal voting may be relatively more inclusive, they can also be slower and less efficient in arriving at final decisions than delegation to a small group or individual. Unanimity in particular can paralyze decision-making, and consensus can lack transparency since there is no formal voting. Modified voting with vetoes or weighting is often considered unequal or undemocratic, yet giving veto power to the most powerful states can secure their participation. Similarly, giving donors more decision-making influence with each additional contribution can encourage more substantial financial commitments. In spite of this, even the most egalitarian models can be inherently unequal, and the most efficient models incredibly ineffective.<sup>27</sup>

## Oversight mechanisms

Members States also have many options as to how they collectively oversee and monitor their own implementation of any agreement. One option is peer review like that used by the UN Human Rights Council. As part of this process, the state under review participates in an interactive dialogue with members of the Council to discuss the fulfilment of its human rights obligations based on information gathered from previous summaries, self-reports and civil

society documents. The World Trade Organization also uses a form of peer review whereby states have incentives to monitor each other so they can submit formal complaints when other states' alleged non-compliance is believed to negatively affect them. Another option is oversight by independent technical experts. This is what states chose to do when setting up the Human Rights Committee to evaluate adherence to the International Covenant on Civil and Political Rights (1966).<sup>28</sup> Self-reporting is also possible. Every two years parties to the Framework Convention on Tobacco Control submit national implementation reports that involve filling out a standard questionnaire.

When agreements do not contain oversight mechanisms, civil society, academia and unaffiliated individuals may choose to assume this responsibility. The university-based G8 Research Group, for example, systematically tracks commitments made by G8 member states in their annual communiqués, evaluates compliance and sometimes will even assign a letter or numerical grade.<sup>29,30</sup>

The United Nations Economic Commission for Europe's Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (1998), known as the Aarhus Convention, innovatively uses a combination of these oversight mechanisms. Parties to this agreement are expected to submit self-reports and peer reviews of implementation efforts, and quite remarkably both the convention secretariat and regular citizens can submit formal communications to the convention's Compliance Committee concerning parties.

Oversight mechanisms are ultimately about promoting transparency, mitigating informational asymmetries, facilitating reciprocity and encouraging compliance. The ideal oversight mechanism for any agreement will balance information accuracy and due process with cost and available financial resources. Peer review may be the most procedurally legitimate mechanism, but expert review may be more accurate. Civil society oversight can be superb for galvanizing public pressure – harnessing information unavailable or politically unacceptable to state parties or independent experts – but it can also be focused on particular issues that are prioritized by those who fund NGOs.<sup>27</sup> Self-reports, meanwhile, are only as

good as they are accurately presented, both in terms of what states choose to report and of the precision in which the organizing secretariat disseminates this information. On one hand, states have an incentive to inflate their performance and hide non-compliance to improve their reputation or avoid sanctions and shaming. On the other hand, when incapacity can be claimed, states have an incentive to report non-compliance to attract financial and technical assistance. As for the public dissemination of self-reports, even the most reputable IGOs can make mistakes. For example, a July 2012 audit found 32.7% of data points in WHO's Framework Convention on Tobacco Control Implementation Database to be either inconsistent, missing or misinterpreted with reference to the first cycle of self-reports that countries had submitted.<sup>31</sup>

## Compliance mechanisms

Finally, in bringing agreements into effect, states can draw on a range of compliance mechanisms that promote adherence to commitments. Legal processes are possible and include giving states the right to contest non-compliance through the International Court of Justice, the UN Security Council, a specialized adjudicative tribunal or a mandatory alternative dispute resolution process. Agreements can also call for the withdrawal of institutional privileges for non-compliant parties. Article 19 of the UN Charter, for example, prevents UN member states from voting in the UN General Assembly if arrears on membership fees equal or exceed the amount of contributions the state owes for the preceding two years.

Compliance mechanisms are, however, not limited to legal or institutional processes. Agreements can also be enforced through economic sanctions and political pressure. With the former, states can punish each other through the cancellation of trade preferences or the imposition of tariffs, import duties or export quotas. The World Trade Organization allows for economic sanctions to encourage compliance with its rules if the party at fault fails to comply with the ruling of the organization's Dispute Settlement Body and permission for such sanctions is obtained from it.<sup>32</sup> With political pressure – which is the most popular but weakest compliance mechanism – states impose reputational

**Box 2. Types of implementation mechanisms that could support an international agreement on the financing and coordination of research and development for health products that meet the needs of developing countries, by mechanism category**

**Commitment mechanisms**

- Conventions, governed by international law (e.g. FCCC)
- Contracts, governed by domestic law (e.g. AMC)
- Declarations (e.g. WHA resolutions)
- Institutional reforms (e.g. ICJ decisions)

**Administrative mechanisms**

- International organization (e.g. The World Bank)
- Sub-agencies (e.g. IARC)
- Joint ventures (e.g. Stop TB Partnership)
- Self-organizing (e.g. Breastmilk Code of Practice)

**Financial mechanisms**

- Specialized multilateral funds (e.g. Montreal Protocol<sup>a</sup>)
- Financial institutions (e.g. Global Fund uses The World Bank)
- Membership organizations (e.g. WHO)
- Coordinated self-management (e.g. IHP+)

**Decision-making mechanisms**

- Unanimity or consensus (e.g. WTO)
- Equal voting (e.g. UN General Assembly)
- Modified voting (e.g. UN Security Council)
- Delegated (e.g. UNITAID)

**Oversight mechanisms**

- Peer review (e.g. UN Human Rights Council)
- Expert review (e.g. ICCPR Human Rights Committee)
- Self-reports (e.g. FCTC)
- Civil society (e.g. G8 Gleneagles Communiqué)

**Compliance mechanisms**

- Legal processes (e.g. Kyoto Protocol to the FCCC)
- Institutional consequences (e.g. UN General Assembly)
- Economic sanctions (e.g. WTO)
- Political pressure (e.g. IHR)

AMC, advanced market commitment; FCCC, UN Framework Convention on Climate Change; FCTC, WHO Framework Convention on Tobacco Control; Global Fund, Global Fund to Fight AIDS, Tuberculosis and Malaria; IARC, International Agency for Research on Cancer; ICCPR, International Covenant on Civil and Political Rights; ICJ, International Court of Justice; IHP+, International Health Partnership and Related Initiatives; IHR, International Health Regulations; TB, tuberculosis; UN, United Nations; WHA, World Health Assembly; WHO, World Health Organization; WTO, World Trade Organization.

<sup>a</sup> Montreal Protocol on Substances that Deplete the Ozone Layer (1987), a protocol to the Vienna Convention for the Protection of the Ozone Layer (1985).

costs on each other, affecting their credibility, prestige, influence and ability to effectively bargain in other forums. Such political pressure is often built through a series of rhetorically powerful symbolic gestures. These may include “naming and shaming” by aggrieved states or authoritative multilateral forums, or actions such as cancelling high-level diplomatic missions, withdrawing embassy staff or preventing a country’s participation in sporting events. Efforts to monitor and evaluate state compli-

ance can promote accountability for resources and results, as is being done by the Every Woman Every Child movement in support of the UN Secretary-General’s Global Strategy on Women’s and Children’s Health.<sup>28,33</sup>

## Discussion

A menu of implementation mechanisms is available to WHO’s Member States seeking to bring into effect an international agreement on the financing and coordina-

tion of R&D for health products (Box 2). Together, states should select their preferred options across categories of implementation mechanisms from the range of available choices and assemble them in a coherent way. In so doing, they will be negotiating and choosing how they want to commit and organize themselves, how they want to manage any pooled funding, how subsequent decisions will be made, how implementation will be overseen and how compliance will be achieved.

No single set of implementation mechanisms is optimal for all agreements. In fact, existing agreements and institutions in the health, environment and research sectors highlight the great variety of possible combinations (Table 1). Some mechanisms are more popular than others, and their comparative effectiveness will certainly vary by context, but all are feasible. The challenge facing WHO’s Member States will be to choose the most effective combination for supporting an international agreement (or set of agreements) on the financing and coordination of R&D for health products that meet the needs of developing countries in a way and at a cost that are both sustainable and acceptable to those involved. And if a single combination is not possible, states can trade off benefits and costs by using different combinations of implementation mechanisms for different parts of any agreement. They can, for instance, apply one set of mechanisms for agreeing on norms, principles and domestic obligations, and another set for financing and managing a pooled funding arrangement.

Fortunately, in making these decisions, WHO’s Member States can benefit from many years of global health diplomacy and experience with a variety of implementation mechanisms commonly used in health and its related sectors. They can draw on the numerous lessons learnt through negotiation of the Framework Convention on Tobacco Control, including the reports that, as a part of the preparations, assessed different legally binding and non-binding options available to states for bringing agreements on substantive issues into effect.<sup>34,35</sup>

Further analysis of any particular combination of implementation mechanisms favoured by WHO’s Member States for an international R&D agreement will be necessary. For example, Member States will want to consider not

Table 1. **Combinations of implementation mechanisms that have been used to support various international R&D, health and environmental agreements, by type of commitment mechanism**

International agreement	Mechanism category					
	Commitment	Administrative	Financial	Decision-making	Oversight	Compliance
UN Charter [General Assembly] (1945)	Convention	International organization	Membership organization	Equal voting	Expert review and civil society <sup>a</sup>	Institutional consequences
UN Charter [Security Council] (1945)	Convention	International organization	Membership organization	Modified voting	Expert review and civil society <sup>a</sup>	Legal processes and economic sanctions
Constitution of the World Health Organization (1946)	Convention	International organization	Membership organization	Equal voting	Expert review and civil society <sup>a</sup>	Institutional consequences
Convention for the Establishment of a European Organization for Nuclear Research (CERN) (1953)	Convention	International organization	Membership organization	Equal voting	Expert review <sup>a</sup>	Institutional consequences
UN Treaty I-13668: Agreement Establishing the European Molecular Biology Laboratory (1973)	Convention	International organization	Membership organization	Equal voting	Peer review	Institutional consequences
The London Amendment to the Montreal Protocol [Multilateral Fund for the Implementation of the Montreal Protocol] (1990)	Convention	International organization	Specialized multilateral fund and financial institution	Consensus	Expert review	Political pressure <sup>a</sup>
UN Treaty I-30822: United Nations Framework Convention on Climate Change (1992)	Convention	International organization	Coordinated management	Equal voting	Peer review and self-reports	Political pressure <sup>a</sup>
UN Treaty I-33757: Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction [Organization for the Prohibition of Chemical Weapons] (1993)	Convention	International organization	Membership organization and coordinated management	Equal voting	Expert review and self-reports	Institutional consequences and economic sanctions
UN Treaty I-31874: Marrakesh Agreement Establishing the World Trade Organization (1995)	Convention	International organization	Membership organization	Consensus and equal voting	Peer review	Economic sanctions
UN Treaty I-33836: Agreement on the establishment of the International Vaccine Institute (1996)	Convention	International organization	Membership organization	Delegated	Civil society <sup>a</sup>	Political pressure <sup>a</sup>
UN Treaty A-30822: Kyoto Protocol to the UN Framework Convention on Climate Change (1997)	Convention	International organization	Coordinated management	Equal voting	Expert review and self-reports	Legal processes and institutional consequences
UN Treaty I-37770: UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters ("Aarhus Convention") (1998)	Convention	International organization <sup>a</sup>	Coordinated management	Equal voting	Peer review, civil society and self-reports	Political pressure <sup>a</sup>
WHO Framework Convention on Tobacco Control (2003)	Convention	International organization	Membership organization and coordinated management	Equal voting	Self-reports	Political pressure <sup>a</sup>
International Health Regulations (2005)	Convention	International organization	Membership organization and coordinated management	Equal voting	Expert review and self-reports	Political pressure <sup>a</sup>
European Council Resolution 3666/06: establishing the 7th framework programme of the European Community for research and technological development [European Research Council] (2006)	Convention and institutional reform <sup>a</sup>	Sub-agency	Membership organization	Delegated	Expert review and civil society	Legal processes
European Council Regulation 73/2008: setting up the joint undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines (2007)	Convention	Joint venture	Membership organization	Delegated	Civil society <sup>a</sup>	Institutional consequences

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International agreement	Mechanism category					
	Commitment	Administrative	Financial	Decision-making	Oversight	Compliance
Governing instrument for the Green Climate Fund (2010)	Convention	Sub-agency	Specialized multilateral fund and financial institution	Delegated	Civil society <sup>a</sup>	Political pressure <sup>a</sup>
WHA Resolution 29.71: Special Programme for Research and Training in Tropical Diseases (1975) and Memorandum of Understanding on the Administrative and Technical Structures of the Special Programme for Research and Training in Tropical Diseases (TDR) (1978)	Contract and declaration	Joint venture	Membership organization	Delegated	Self-reports <sup>a</sup>	Institutional Consequences
GAVI Alliance (2000)	Contract <sup>a</sup>	Joint venture	Membership organization	Delegated	Expert review <sup>a</sup> and self-reports	Political pressure <sup>a</sup>
Framework Document of the Global Fund to fight AIDS, Tuberculosis and Malaria (2002)	Contract <sup>a</sup>	Joint venture	Financial institution	Delegated	Expert review	Political pressure <sup>a</sup>
Memorandum of understanding concerning the hosting of the International Drug Purchase Facility [UNITAID] (2006)	Contract <sup>a</sup>	Joint venture	Membership organization	Delegated	Civil society <sup>a</sup>	Political pressure <sup>a</sup>
Global Alliance for Chronic Diseases (2009)	Contract <sup>a</sup>	Joint venture	Coordinated management	Consensus <sup>a</sup>	Civil society <sup>a</sup>	Political pressure <sup>a</sup>
Pneumococcal Advanced Market Commitment (2009)	Contract <sup>a</sup>	Joint venture	Financial institution	Delegated <sup>a</sup>	Expert review	Political pressure <sup>a</sup>
WHA Resolution 18.44: Establishment of an International Agency for Research on Cancer (IARC) (1965)	Declaration	Sub-agency	Membership organization	Equal voting	Expert review	Institutional consequences
WHA Resolution 34.22: International Code of Marketing of Breast-Milk Substitutes (1981)	Declaration	Self-organizing	Coordinated management	Not applicable	Expert review, civil society and self-reports	Political pressure <sup>a</sup>
Instrument for the establishment of the Restructured Global Environment Facility (1994)	Declaration <sup>a</sup>	Sub-agency	Financial institution	Delegated	Expert review <sup>a</sup> and self-reports <sup>a</sup>	Political pressure <sup>a</sup>
ECOSOC Resolution 1994/24: Joint and Co-Sponsored United Nations programme on HIV/AIDS (UNAIDS) (1996)	Declaration	International organization	Membership organization	Delegated	Civil society	Political pressure <sup>a</sup>
Roll Back Malaria Partnership operating framework (1998)	Declaration <sup>a</sup>	Joint venture	Membership organization	Delegated	Expert review <sup>a</sup>	Political pressure <sup>a</sup>
Basic framework for the Global Partnership to Stop TB (2001)	Declaration <sup>a</sup>	Joint venture	Membership organization	Delegated	Civil society <sup>a</sup>	Political pressure <sup>a</sup>
G8 Gleneagles Communiqué (2005)	Declaration	Self-organizing	Coordinated management	Not applicable	Civil society	Political pressure <sup>a</sup>
International Health Partnership and Related Initiatives (IHP+) (2007)	Institutional reform	International organization <sup>a</sup>	Membership organization and coordinated management	Consensus	Civil society <sup>a</sup>	Political pressure
Joint Declaration of the Consultative Group on International Agricultural Research [creating the CGIAR Fund] (2009)	Institutional reform	International organization	Financial institution	Delegated	Peer review <sup>a</sup>	Political pressure
UN Secretary-General's Global Strategy for Women's and Children's Health [creating Every Woman Every Child movement] (2010)	Institutional reform <sup>a</sup>	Joint venture	Coordinated management	Delegated <sup>a</sup>	Expert review and civil society	Political pressure <sup>a</sup>

AIDS, acquired immunodeficiency syndrome; CGIAR, Consultative Group on International Agricultural Research; ECOSOC, Economic and Social Council; GAVI, Global Alliance for Vaccines and Immunization; HIV, human immunodeficiency virus; R&D, research and development; TB, tuberculosis; UN, United Nations, UNECE, United Nations Economic Commission for Europe; WHO, World Health Organization.

<sup>a</sup> Indicates classifications were based on authors' and/or key informants' knowledge, whereas all other classifications were based on written materials found online (available upon request from the corresponding author).

Note: In keeping with the focus of this paper on mechanisms available to states for implementing agreements, the categorization of mechanisms in this table is with respect to the provisions of agreements. When these agreements resulted in the creation of new international organizations or other entities, the mechanisms were categorized according to states' rights, obligations and relationships vis-à-vis these new entities.





contraignants ou non contraignants par le biais de conventions, contrats, déclarations ou réformes institutionnelles. Les États peuvent régir les activités visant à mettre en œuvre leurs accords par l'intermédiaire d'organisations internationales, de sous-agences, de coentreprises ou de processus d'auto-organisation. Le financement peut être géré par des fonds spécialisés, des institutions financières multilatérales, des organisations associatives ou l'autogestion coordonnée. Les décisions peuvent être prises à l'unanimité, par consensus, par vote égal, vote modifié ou délégation. Le contrôle peut être effectué par des pairs, des examens d'experts, des auto-évaluations ou la société civile. Ensemble,

les États doivent choisir les options qu'ils préfèrent parmi toutes les catégories de mécanismes de mise en œuvre, dont chacune présente des avantages et des inconvénients. Le défi réside dans le choix des combinaisons de mécanismes les plus efficaces pour soutenir un accord international (ou un ensemble d'accords) qui réalise les aspirations collectives d'une manière et à un coût qui soient à la fois durables et acceptables pour les parties concernées. En prenant ces décisions, les États membres de l'OMS peuvent bénéficier d'années d'expérience avec ces différents mécanismes dans le domaine de la santé et ses secteurs connexes.

## Резюме

### Оценка механизмов реализации международного соглашения по научно-исследовательским и опытно-конструкторским работам (НИОКР), касающимся изделий медицинского назначения

Государства-члены Всемирной организации здравоохранения (ВОЗ) в настоящее время обсуждают содержание и форму международного соглашения, направленного на улучшение финансирования и координации научно-исследовательских и опытно-конструкторских работ (НИОКР), касающихся изделий медицинского назначения, предназначенных для удовлетворения потребностей развивающихся стран. В дополнение к рассмотрению содержания возможного правового или политического соглашения государства-члены могут посчитать нужным рассмотреть полный спектр доступных механизмов реализации соглашения. В них входят механизмы для государств-членов по принятию обязательств, управлению деятельностью, управлению финансовыми взносами, принятию последующих решений, контролю исполнения обязательств каждой стороной и обеспечению соответствия. Государства могут брать на себя юридические или не имеющие юридической силы обязательства путем заключения договоров, соглашений, принятия деклараций или проведения институциональных реформ. Государства могут управлять деятельностью по реализации своих соглашений через международные организации, субагентства, совместные

предприятия или процессы самоорганизации. Управление финансами может производиться через специализированные многосторонние фонды, финансовые институты, членские организации или скоординированное самоуправление. Решения могут приниматься по принципам единства, единодушия, равного голосования, модифицированного голосования или передачу полномочий. Надзор может осуществляться через экспертные проверки, экспертные оценки, самоотчеты или гражданское общество. Государства должны совместно выбрать свои предпочтительные варианты по категориям механизмов реализации, каждый из которых имеет свои преимущества и недостатки. Задача заключается в выборе наиболее эффективных сочетаний механизмов поддержки международного соглашения (или пакета соглашений), благодаря которому достигаются коллективные стремления путем и ценой, которые будут сбалансированы и приемлемы для государств-участников соглашения. При принятии этих решений государства-члены ВОЗ могут воспользоваться многолетним опытом работы с упомянутыми различными механизмами в здравоохранении и смежных ему секторах.

## Resumen

### Evaluar la puesta en marcha de los mecanismos para adoptar un acuerdo global sobre la investigación y el desarrollo de productos sanitarios

Los Estados miembros de la Organización Mundial de la Salud (OMS) debaten en la actualidad el contenido y la forma de un acuerdo internacional para mejorar la financiación y coordinación de la investigación y el desarrollo (I + D) de productos sanitarios que satisfagan las necesidades de los países en desarrollo. Además de tener en cuenta el contenido de cualquier acuerdo legal o político posible, los Estados miembros consideran que sería útil que repercutiera en toda la gama de mecanismos de puesta en marcha disponibles para llevar a efecto cualquier acuerdo. Esto incluye los mecanismos que los estados pueden emplear para asumir compromisos, administrar actividades, gestionar contribuciones financieras, tomar decisiones posteriores, seguir la actuación de otros estados y fomentar el cumplimiento. Los estados pueden asumir compromisos vinculantes o no a través de convenciones, contratos, declaraciones o reformas institucionales; pueden administrar actividades para poner en práctica sus acuerdos por medio de organizaciones internacionales, sub-agencias, operaciones conjuntas u organizando procesos. Gracias a los fondos multilaterales

especializados, instituciones financieras, organizaciones de afiliados o una autogestión coordinada, es posible gestionar las finanzas. Las decisiones se pueden tomar por unanimidad, consenso, votación con el mismo derecho a voto, votación moderada o delegación. Los exámenes por parte de un grupo de colegas o de expertos, los auto-informes o una sociedad civil son opciones a través de las cuales es posible garantizar una supervisión. Los estados deberían escoger juntos las opciones que prefieren de entre las categorías de mecanismos de puesta en marcha, pues cada una tiene sus ventajas y desventajas. El desafío reside en elegir las combinaciones de mecanismos más eficaces para respaldar un acuerdo (o conjunto de acuerdos) internacional que lleve a cabo las aspiraciones colectivas de un modo y con unos costes que sean tanto sostenibles como aceptables para las partes involucradas. A la hora de tomar esas decisiones, los Estados miembros de la OMS pueden beneficiarse de los años de experiencia que tanto el sector sanitario como los relacionados tienen con los diferentes mecanismos.

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