

## **CONTRIBUTION TO THE UNITED NATIONS SECRETARY-GENERAL'S HIGH LEVEL PANEL ON ACCESS TO MEDICINES**

### **THE NEED FOR GLOBAL NEGOTIATIONS ON AGREEMENTS TO FUND R&D WITHIN THE CONTEXT OF A PROGRESSIVE DE-LINKING OF R&D COSTS FROM PRODUCT PRICES**

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**This submission is endorsed by the following organizations and individuals:**

#### **Organizations**

1. Coalition Plus
2. Commons Network
3. European Public Health Alliance (EPHA)
4. Health Action International (HAI)
5. Innovarte, Chile
6. Knowledge Ecology International (KEI) and KEI Europe
7. Misión Salud, Colombia
8. Salud y Fármacos, USA
9. Stop AIDS, UK
10. Treatment Action Campaign (TAC), South Africa
11. Union for Affordable Cancer Treatment (UACT)
12. Young Professionals Chronic Disease Network (YP-CDN)

#### **Individuals**

13. Judit Rius Sanjuan, Médecins Sans Frontières/Doctors Without Borders (MSF)

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- **Section 1: ABSTRACT**

High prices are the disease that kills policy coherence, and de-linkage is the cure. To implement de-linkage globally, there is a need for practical steps to address cross-border obligations to ensure robust and sustainable funding for R&D.

We propose the UN initiate a Member State-led process to negotiate one or more global agreement(s) on the funding, coordination and performance of biomedical research and development (R&D) to promote innovation and access to medicines, vaccines, diagnostics, and medical devices (‘health technologies’) for all health needs.

The agreement(s) would establish mechanisms to ensure sustainable funding of biomedical R&D, including in areas of unmet need, in a manner that is consistent with commitments to the human right to health and the Sustainable Development Goals (SDGs), including the need to provide universal, equitable, and affordable access to medicines for all, and the ambition to achieve universal health coverage.

The goal is to create a pathway for Member States to collectively improve global, regional, and national R&D outcomes by progressively de-linking the cost of R&D from product prices, and not relying on high prices and monopolies to pay for innovation.

This contribution recognizes and complements or builds upon previous recommendations on the need for norms to coordinate and improve the biomedical R&D system, but is flexible on how Member States and other R&D stakeholders fund and conduct biomedical R&D, and the form of the final agreement(s), while fulfilling the objective of implementing progressive reforms to ensure that biomedical R&D outcomes are consistent with the human right to health and SDGs.

This contribution should be considered in combination with other contributions dealing with the need to address existing intellectual property barriers to ensure affordable access to health technologies under the current biomedical R&D system.

## CALL FOR CONTRIBUTIONS – SUBMISSION FORM

- **Section 2: YOUR CONTRIBUTION (limit 3,000 words)**

### **Introduction – The need for change**

The current system, including the use of research grants, subsidies, and intellectual property rights to fund and create incentives to invest in R&D, has had success in bringing a number of health

technologies to market, and many of those innovations are important. However, access to innovations is limited during the period when a monopoly is granted, leading to the rationing of medical care and causing death and suffering for millions of people. Even when access is achieved, the costs of the monopolies created under the current system are high and increasing at an alarming rate, as populations are aging in both the developing and the developed world.

Access and health outcomes are unequal, and mechanisms to induce R&D investments predictably conflict with and violate human rights as well as a plethora of norms regarding universal access and fairness.

It is well known that the grant of temporary monopolies is a poor mechanism to stimulate R&D for some diseases and medical innovations, and also other types of research not easily monetized by the grant of a monopoly. Examples of such market failures include inadequate investment and/or perverse incentives for:

- Research that advances basic knowledge;
- Development of new and rational uses of generic products;
- Identification and reporting of adverse effects of medicines;
- Development of products that are most useful when used sparingly, such as antibiotics;
- Development of products that treat illnesses primarily affecting poor people, such as new drugs for neglected tropical diseases;
- Development of low-cost and interoperable point-of-care diagnostics;
- Sharing the knowledge, materials and technologies necessary for successful product development; and
- Developing vaccines and diagnostics for emerging infections, such as Ebola and Zika.

(The appalling lack of transparency in the current markets for medicines is addressed in more detail in a separate contribution).

The current global trade framework has a laser focus on creating new and expanding existing intellectual property privileges for pharmaceutical companies, and does not provide the tools to support robust funding of the research grants and subsidies critical to the advancement of science or the development of products in many areas.

Governments need to continue to develop new approaches to fund R&D that will expand access, address inefficiencies and research gaps, and improve cost effectiveness and affordability of products, including the progressive implementation of policies that de-link R&D costs from product prices. A number of proposals to do so have been made over the past fifteen years, but there has been a lack of leadership in moving such negotiations forward. In some cases, the negotiations have

divided countries or limited ambitions in ways that have delayed the recognition that new approaches to funding R&D are needed globally, leaving a system that leads to huge inequality in achieving the right to health and SDGs.

## **The proposal**

We ask the UN Secretary General to initiate a process for Member States to negotiate one or more global agreement(s) on the funding, coordination, and performance of biomedical research and development (R&D) to promote innovation and access to medicines, vaccines, diagnostics, and medical devices ('health technologies').

The goal is to create a pathway for Member States to improve global, regional, and national R&D outcomes coherent with the principles of access to medicines for all, and with States' and other actors' obligations and responsibilities under human rights law, by progressively de-linking R&D costs from product prices.

Recognizing and complementing or building on previous recommendations on the need for global norms to coordinate and improve the biomedical R&D system, this contribution is flexible on how Member States fund and conduct biomedical R&D and the form of the final agreement, while fulfilling the objective of progressively implementing reforms needed to ensure that the mechanisms to fund R&D are coherent with access to medicine objectives and human rights obligations.

To do so, governments must have the ability to ensure, expand, and introduce sustainable and robust funding of R&D, without relying upon high prices for products. While traditional intellectual property-based incentives may remain through the medium term, the goal is to progressively eliminate the reliance on monopolies and the associated high prices to support funding for R&D.

The process and negotiations can build upon the on-going efforts at the World Health Organization (WHO) and other forums to identify new approaches to fund and coordinate R&D, but can also provide a broader mandate and a fresh context.

For more than fifteen years, the WHO has been engaged in discussions over new approaches to funding and coordinating R&D. Many of those initiatives have focused on research targets that primarily affect low-income persons living in low-income countries, with a particular focus on infectious and tropical neglected diseases. These initiatives are important and laudable, but have not gone far enough and have not addressed the access and affordability challenges for other products that have important societal impact, such as drugs for cancer, rare diseases, and broad categories of non-communicable diseases. Negotiators from high-income countries have unfortunately perceived these initiatives as wealth transfers from high-income to lower income countries with little relevance to their own countries' health needs. Such perceptions limit the ambition and impact of negotiations in ways that are harmful to health, including in developing countries, which are also facing challenges dealing with cancer and non-communicable diseases, and which aspire to provide

treatments for rare diseases. The more comprehensive and universal the research targets, the greater the benefits for all patients, and the higher likelihood such agreements will be perceived as an alternative to the strategy of higher product prices. Indeed, efforts at the WHO and other forums to support new models for the development of products to address antimicrobial resistance illustrate the possibility that coalitions that include governments can in fact embrace new efforts to cooperate on R&D funding, including endorsements of de-linkage.

The suggestions presented in this contribution are an example of a practical approach that can be followed. There are also other variations or approaches that would achieve positive results.

### **A. Core norms for a public health-driven R&D system**

Biomedical R&D efforts and initiatives should be coherent with the right to health and the SDGs. We endorse the following norms and principles, developed jointly with others:

#### 1. R&D Funding

The agreement should ensure sustainable and robust funding for biomedical R&D, including sufficient funding for areas of priority.

#### 2. Priority-setting

The agreement should provide mechanisms for identifying unmet needs and areas of priority for biomedical R&D.

#### 3. Affordability, equity and progressive de-linkage

The agreement should support efforts to make health technologies universally affordable and available. The mechanisms to fund R&D should be progressively de-linked from product prices.

#### 4. Access to knowledge and openness

The agreement should encourage and, when appropriate, require open sharing of data, scientific, and technological knowledge. Openness of data and cooperation and/or collaboration among R&D funders, researchers, and other stakeholders should be promoted to increase rapid progress and efficiency as well as ensure responsible and ethically sound conduct in research activities and outputs.

#### 5. Transparency

The agreement should encourage, facilitate, and progressively mandate transparency of all aspects of the biomedical R&D system and the market for products including, for example, clinical trial costs;

medical outcomes and patient level data sets from clinical trials and reporting of post-approval patient outcomes; patent status information; terms and conditions of licensing agreements; manufacturing costs; product prices and sales; government funding and subsidies (including grants, tax credits, etc.); and other information that is critical for evaluating and designing appropriate policies.

## 6. Governance

Governments and institutions engaged in R&D processes should operate in a transparent manner and provide the means and mechanisms for the public to have meaningful access to information and the ability to participate to ensure full accountability.

### **B. Basic elements of a global R&D agreement**

There are a variety of potential elements that could be part of a global agreement(s) on biomedical R&D. The basic elements of a biomedical R&D agreement could include:

1. A transparent process to identify medical R&D needs and priorities;
2. Global and country-specific targets for both overall levels and priority R&D spending;
3. Guiding norms for a public-health driven R&D system;
4. Norms and procedures for transparency, reporting obligations, and evaluation procedures;
5. Norms and procedures to address technology transfer and access to know-how, for example, to facilitate more cost-effective procurement of biologic drugs and vaccines, and drugs with small client populations, and open sharing of data and knowledge; and
6. Various incentives for governments to join the agreement.

Governments could also have flexibility in progressively meeting several of the elements of the agreement and being provided with options on how to meet the commitments. For example, the source of funding for R&D can be left to member countries. Governments already pay for R&D through a variety of sources, including high prices on patented drugs, public funding, and subsidies. Some countries may want to implement policies that lower product prices and use the savings to fund R&D through grants and/or innovation inducement prizes. In these cases, there is no need for increased taxes, and on the contrary, there is an opportunity for cost savings. In other cases, a government may have to increase levels of spending on R&D. The government would have the freedom to increase funding through a variety of mechanisms, including through general or special tax revenues or innovative financing mechanisms.

### **C. Progressive implementation of de-linkage**

A key objective of this agreement is for the reform of R&D funding mechanisms to progressively implement the principle of de-linkage so that the costs of research and development of new health technologies are not linked to (i.e. financed by) high product prices.

We can define de-linkage in the negative, by saying that the R&D funding should not be tied to the price of the product.

R&D incentives and funding mechanisms that involve granting or extending a product monopoly to charge high prices are not de-linkage mechanisms.

There are multiple and complementary mechanisms to fund R&D, many of which are already in place, that can meet the de-linkage criteria if appropriately designed. The problem is that currently not only are these mechanisms typically implemented without regard to affordability of products, but on the contrary, high prices are seen as the primary reward and incentive for product development.

Direct grants and contracts (such as NIH or EU Framework grants, for example) and R&D subsidies (such as orphan drug tax credits) can be expanded and reformed so that products are put on the market at lower and eventually affordable generic prices. Incentive mechanisms that now rely on the granting of product monopolies and high prices (patents, test data monopolies, orphan drug exclusivity, etc.), can be progressively replaced with new incentives including, most importantly, cash innovation inducement prizes or prize funds.

There can be confusion or ambiguity about the role of patents and other intellectual property in a de-linkage system. Research grants, contracts, and innovation inducement prizes can be implemented with or without patents, as patents can be managed with or without the subsequent creation of monopolies. For example, patents could be used to establish a claim on prize revenues, when the prize is provided as a substitute for the monopoly, rather than as a complement, an approach proposed by Senator Bernie Sanders in the United States.

Progressive de-linkage means that governments implement reforms over time that sequentially and progressively move prices closer and closer to affordable generic prices, and reform incentives so they no longer rely upon high prices.

#### **D. Form of agreement(s)**

The proposal for one or more global R&D agreement(s) can take a variety of forms, and can evolve over time, with different forms for different elements.

Some have called for a framework agreement, either modelled loosely on the WHO Framework Convention on Tobacco Control, or the proposed Framework Convention on Global Health to achieve universal health coverage. In 2012, the WHO CEWG report recommended for Member States to start negotiating a global R&D convention and provided specific recommendations on the

potential elements, including binding government R&D funding targets. The 2005 Medical Research and Development Treaty proposal provided for specific targets for national obligations to fund R&D, mechanisms to induce funding in areas of priority, greater openness of research, and a mechanism to eliminate relevant TRIPS dispute resolution between members of the treaty when governments satisfied the funding norms. There have been numerous proposals by governments, NGOs, experts, and academics that are mentioned in the bibliography and which will not be described here, due to length constraints.

The UN can consider the merits of building upon existing efforts and proposals, many of which are relevant and reference de-linkage as an objective, make some modification or remix, or propose something completely new, so long as the strategy follows the guiding principles described above. What is important is not only to begin or reinvigorate negotiations on R&D funding, but to be explicit that one objective is to strengthen the mechanisms that can facilitate the progressive de-linkage of R&D funding from product prices, and make it clear that some elements will not only increase innovation and expand access, but will lower and not increase healthcare costs, making it even more compelling for governments to engage.

### **E. Enforceability**

The primary rationale to join and implement such an agreement is to collaboratively reform and eventually replace a dysfunctional set of global norms for funding R&D through high prices with a more flexible and less expensive approach that expands rather than restricts access to medicines. To the extent that global norms on R&D funding through means other than high prices address a more comprehensive set of diseases, conditions and medical research needs, these reforms become even more compelling, particularly as governments everywhere are confronted with uncomfortable tradeoffs between access and innovation under the current system. That said, the negotiations may also want to consider and address other incentives for governments to join and implement the elements of the agreement or agreements. Some proposals for additional incentives have been controversial, such as, for example, preferred access to grants and R&D rewards for researchers and entities located in countries that are members of the agreement, and reduced obligations regarding either product pricing or intellectual property enforcement. It may be important to reflect upon the need for and nature of incentives that are necessary and appropriate to induce participation.

The enforceability of the agreement will depend upon a variety of factors, including the degree to which the agreement is perceived as useful and welfare-enhancing, and the consequences under the agreement for non-performance in terms of the norms.

There are other options to make adherence to the norms more binding and enforceable. For example, in many cases, there are so-called binding agreements that in practice are weak on enforceability on their own, such as various WIPO or human rights treaties. However, when WIPO treaties are included as an obligation in trade agreements, and made subject to dispute resolution, they become more enforceable.



We further note there is a proposal, described in a separate contribution, to create a schedule for the supply of public goods in the WTO, which could allow commitments in an R&D agreement to become subject to WTO dispute resolution.

We note that international agreements dealing with climate change have been undertaken outside of trade agreement frameworks.

The extent to which agreements are in practice enforceable is not only a legal matter. When there is a consensus among governments that certain policies or norms are collectively in everyone's best interest, the informal pressures to conform can be quite consequential, and, indeed, one can argue that many of the most important outcomes of intellectual property rules are decisions made in response to non-legal expectations rather than the binding legal norms.

### **Impact on policy coherence**

The full implementation of de-linkage to fund and incentivize biomedical innovation is the most straightforward way to bring policy coherence to the areas of law and policy that this high-level panel has been asked to resolve. High prices are the disease that kills policy coherence, and delinkage is the cure. To implement de-linkage globally, there is a need for practical steps to address cross-border obligations to ensure robust and sustainable funding for R&D.

### **Impact on public health**

The two key aspects of the proposal that impact public health are to make R&D funding robust and sustainable, including in areas of priority, and to expand access to products.

De-linkage, which is to be progressively implemented, is the only policy that is consistent with the goal of universal access and the elimination of price-based rationing of drugs. Delinkage is also the best outcome for low-income persons.

### **Impact on human rights**

The Universal Declaration of Human Rights safeguards the human right to health, and has been consistently interpreted to include universal access to medicines. The SDGs encapsulate these commitments under SDG 3, through commitments to universal health coverage, specifically innovation and access to medicines, vaccines and other health technologies.

Current measures to incentivize innovation, which are coupled with higher drug prices, fundamentally obstruct the realization of these basic rights. This is not limited merely to the poorest countries, but especially applies to middle-income countries, where 75 percent of all people living in poverty reside, and to high-income countries, where increasing inequality is both a cause and

consequence of the current innovation system, and where there are increasing access barriers and rationing of high-priced medicine.

States are fundamentally unable to meet core responsibilities to satisfy the human right to health, and are implementing policies, laws and practices that deny enjoyment of the right to health. States also operate within a framework of international trade rules that hinder people's enjoyment of the right to health. Progressive realization of the right to health will require not only re-examining and addressing the shortcomings of existing rules, but also introducing ways to promote R&D and access to health technologies.

## **Implementation**

The need for global and coordinated priority-setting for biomedical R&D, and for some pooling of R&D funding, has growing support, at least for areas where market failure is clear. Incentives that de-link the cost of R&D from prices are being implemented and/or considered not only for neglected diseases, but also to promote innovation for global priorities like antibiotics.

There are several initiatives that are trying to improve the current biomedical R&D system, including ongoing negotiations at the World Health Organization about the implementation of the 2008 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, the recommendations of the 2012 CEWG Report, the proposed WHO Blueprint for R&D to accelerate the development of new vaccines and treatments for emerging infectious diseases with epidemic potential, as well as the different initiatives being considered to globally coordinate and increase biomedical R&D for antibiotics and vaccines.

Yet these initiatives are partial because they mostly address the needs of developing countries, or only address particular issues such as regulatory strategies to accelerate drug approval or because they mostly deal with a specific subset of diseases or a specific health technology. The ongoing WHO discussions are being led by representatives of Health Ministries, not heads of state, and have difficulties generating the financial resources and political commitment needed.

The UN High-Level Panel has the unprecedented opportunity to start THE process to change the global normative framework that underpins the biomedical R&D system, bringing coherence to the different processes and elevating the decision-making process to a Head-of-State level. It can ensure that there is robust and sustainable funding for R&D, irrespective of drug prices, while also ensuring access and affordability of medicines. Ultimately it will require the recognition that the progressive realization of the right to health requires the progressive implementation of delinkage, backed by high-level political leadership.

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