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Rethinking R&D for Pharmaceutical Products After the Novel Coronavirus COVID-19 Shock*

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The unprecedented global health crisis caused by the coronavirus –COVID-19–pandemic, during the first quarter of 2020, brings back with particular urgency the discussion about the research and development (R&D) model for pharmaceuticals and other technologies necessary to respond to the health problems of both developed and developing countries.

This paper argues that the current R&D model for pharmaceutical products is fragmented, inefficient, expensive, and full of overlaps and waste of resources, and that it will not be able to provide the global solution that the COVID-19 crisis requires. A new R&D model based on health rather than commercial interests –generally supported on patents and other intellectual property rights– can be designed and implemented under the auspices of the World Health Organization (WHO) based on article 19 of the WHO Constitution.

Section 1 of this paper refers to the background of the debate on the R&D model for pharmaceutical products and other health technologies. Section 2 addresses some of the problems of the current R&D model. Section 3 briefly summarizes what could be the objectives and principles of a binding convention on R&D. Section 4 argues that there is a need to move fast and discusses some recent initiatives. Finally, what would be the way forward is briefly considered.

Introduction

We were warned…

Was the current health crisis foreseeable? Was there any indication that a phenomenon of this nature could happen?

In May 2011, a WHO document on pandemic influenza preparedness alerted countries about the "continuing risk

Abstract

The unprecedented global health crisis caused by the coronavirus –COVID-19– pandemic, during the first quarter of 2020, brings back with particular urgency the discussion about the research and development (R&D) model for pharmaceuticals and other health technologies. The COVID-19 crisis shows that there is an urgent need to re-design the global public health governance for health R&D. The adoption of a binding instrument –as allowed by Article 19 of the WHO Constitution– on this matter was proposed many years ago. This brief argues that it is time to revive and materialize this initiative.

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La crisis sanitaria mundial sin precedentes provocada por la pandemia de coronavirus –COVID-19–, durante el primer trimestre de 2020, hace que vuelva a ser especialmente urgente el debate sobre el modelo de investigación y desarrollo (I+D) de productos farmacéuticos y otras tecnologías sanitarias. La crisis de COVID-19 muestra que existe una necesidad urgente de rediseñar la gobernanza mundial de la salud pública para la I+D en materia de salud. La adopción de un instrumento vinculante –como permite el artículo 19 de la Constitución de la OMS– en esta materia fue propuesta hace muchos años. Este documento sostiene que es hora de revivir y materializar esta iniciativa.

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La crise sanitaire mondiale sans précédent provoquée par la pandémie de coronavirus –COVID-19–, au cours du premier trimestre 2020, ramène avec une urgence particulière la discussion sur le modèle de recherche et développement (R&D) pour les produits pharmaceutiques et autres technologies de la santé. La crise COVID-19 montre qu'il est urgent de repenser la gouvernance mondiale de la santé publique pour la R&D en matière de santé. L'adoption d'un instrument contraignant – comme le permet l'article 19 de la Constitution de l'OMS – sur cette question a été proposée il y a de nombreuses années. Ce document soutient qu'il est temps de relancer et de concrétiser cette initiative.

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of an influenza pandemic with potentially devastating health, economic and social consequences, particularly for developing countries, which have a higher disease burden and are more vulnerable."[1] The 2019 Annual Report on Global Preparedness for Health Emergencies, prepared by the World Bank's Global Preparedness Monitoring Board, referred to "a very real threat of a rapidly evolving, highly lethal respiratory pathogen pandemic that could wipe out 5% of the world economy".[2] This indicates that experts[3] have been anticipating the risk of a pandemic like the one we are experiencing now. Why were these warnings not heeded?

Noam Chomsky recently said about the outbreak of COVID-19: "The neoliberal assault has left hospitals unprepared. One example among many: hospital beds have been suppressed in the name of efficiency (...). This crisis is the umpteenth example of market failure, just as the threat of environmental catastrophe is. The governments and the pharmaceutical multinationals companies have known for years that there is a high probability of a serious pandemic, but since it is not good for the profits to prepare for it, nothing has been done".[4]

Recent data on the Italian situation confirms well Chomsky's statement, in Italy, one of the most affected countries by the coronavirus crisis, "in less than ten years, from 2010 to 2016, 70,000 hospital beds disappeared, 175 hospital units were closed, and local autonomous health offices were reduced from 642 in the 1980s to only 101 in 2017. All of this is for the benefit of the private health and insurance industries, which offer no protection against pandemics."[5]

If the imminent arrival of "an influenza pandemic with potentially devastating health, economic and social consequences" was already mentioned in OMS documents since 2011, why ten years after the arrival of the current crisis, there was no complete mapping of what the R&D situation was in terms of vaccines and treatments? The "**Solidarity**" clinical trial for COVID-19 treatments was launched by the WHO Director General on 18 March 2020,[6] almost three months after the start of the problem, but too late to provide a fast response to the already devastating effects of the coronavirus.

And how the global production and distribution of the vaccine will be organized when it arrives? Will the detainment of products in transit, trade restrictions, the enforcement of intellectual property rights be allowed to prevail over global public health interests? Who is going to make the rules to ensure that the vaccine reaches everybody, in all places at the same time? Who is going to enforce them? Who will protect the world's public interest?

It is time to develop multilateral rules and empower WHO so that it can exercise a real global coordination on health matters: "COVID-19 comes to reveal the inadequacies of global governance in public health. State cooperation and coordination are essential to meet the challenges and ensure equitable access to medicines everywhere."[7]

1. Background of the Debate on the R&D Model

In May 2012, WHO Member States meeting at the World Health Assembly in Geneva, adopted resolution WHA 65.22 endorsing the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). For many of the World Health Assembly (WHA) participants and observers those recommendations provided a roadmap for a first step towards a change in the current pharmaceutical R&D model for pharmaceutical products. In particular, on the premise that the market cannot be the only driver of R&D, the CEWG recommended the negotiation of an international convention in which all countries would commit to promote R&D: "formal intergovernmental negotiation should begin for a binding global instrument for R&D and innovation for health."[8]

In fact, in order to ensure a sustainable long-term R&D and subsequent affordable access to pharmaceuticals in developing as well as developed countries, rather than adopt voluntary guidelines or recommendations, WHO should use its capacity to legislate. Negotiating and adopting a R&D convention is one the paths to follow. If it were in place now, there would have been a much greater capacity and better tools to address the current health crisis.

It is time to develop and better use international health law to effectively address the global health problems. According to Article 19 of the WHO Constitution:

> *The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes.*

The protection of health in times of global health crisis risks reflects a pressing social need that should now be translated into the vocabulary of international law. While enormous challenges lie ahead, especially in terms of the use and strengthening the existing instruments, as noted by one commentator, "[t]here is an urgent need for counterbalancing interests such as international trade, global commerce and the welfare interests of the protection of the health of both individuals and populations worldwide."[9]

Article 19 of the WHO Constitution is the best example of existing international health law, which has already been successfully tested in the case of the WHO Framework Convention on Tobacco Control (FCTC). Tobacco is the first killer in the world. The FCTC is the most efficient

global instrument negotiated in WHO: it has become the "vaccine" against cancer and cardio-vascular diseases.[10]

Despite the regulatory powers conferred by its constitution under article 19, "WHO has paid but scarce attention to law — especially the **hard law** — as a tool to protect and promote health. On the contrary, the Organization has shown itself to be more in favor of seeking a political agreement, and has excused itself in its medico-sanitary profile in order to take on more of a health care than a legal role."[11] The FCTC is the only case in which said article has been used in the history of WHO.

In the present international context of the COVID-19 pandemic, WHO may recover its leadership through the use of article 19 of its constitution by negotiating and adopting global treaties and conventions to help Members States to realize the right to access to health, including in situations of global emergencies, and to achieve the Universal Health Coverage (UHC).[12]

The directives and technical recommendations of the WHO, which are relevant and appropriate in most cases, often are not heeded or followed because they are only recommendations of a voluntary nature. The countries of the European Union, for instance, were unable to agree on the common strategy recommended by the WHO against the coronavirus pandemic. In cases of global health crises, it is essential that necessary measures can be made binding and enforceable. Pandemics have no borders. While WHO could not take compulsory measures, many countries did, and it would have been more consistent if solid WHO guidelines had been mandatory via Article 19 of the WHO Constitution, or the International Health Regulations.

The aim of an international convention would primarily be to set up an international public fund for pharmaceutical R&D. To ensure sustainability of the fund, the convention would need to provide for a mandatory contribution by signatory countries according to their level of economic development. In return, the products and results financed by this fund would be considered as public goods benefiting all these countries. Hence, the idea is not just to require another financial contribution but rather to put in place an innovative mechanism that better focuses on patients' interests than under the current R&D model. Moreover, the costs of R&D activities financed by this public fund would have to be transparent to guarantee a more efficient and less costly innovation system that meets the real sanitary needs of countries of both the North and the South. Should such mechanism be in place, it would have facilitated to provide a global financial support for the development of products for prevention and treatment of COVID-19 by those capable of undertaking the needed R&D.[13] If an international convention, as proposed, with its financial mechanism, would have been in place, the task would have been easier and accomplished faster.

A binding international convention, negotiated under the auspices of the WHO, could thus serve to sustainably finance R&D on useful and safe pharmaceuticals in order to respond to public health needs, at prices affordable to patients and health systems. Moreover, the adoption of a convention of this nature under article 19 of the WHO Constitution, could be the prelude to a deeper reflection on world health governance.[14]

The negotiation and adoption of an international treaty on health R&D was one of the key elements for the implementation of the *Global Strategy* on Public Health, Innovation and Intellectual Property (*GSPOA*). Indeed, if successful, this could have been the most important achievement of the GSPOA.[15]

2. Problems of the R&D Model for Pharmaceutical Products[16]

The current R&D model for pharmaceutical products is based on the following scheme: **Research (*private or public*) – patents (legal monopoly) – high prices – restricted access.**[17] This model presents several problems that in the long run lead to a disarticulation between innovation and access. These problems include: 1) Lack of transparency of R&D costs; 2) net decrease of pharmacological innovation in the last years.; 3) high prices restricting access.; 4) fragmentation and lack of coordination; 5) waste and overlap.

2.1 Lack of transparency of R&D costs

The cost estimated by a study of Boston Tufts Centre, for the development of a new molecule was of US$ 2.5 billion.[18] This is the figure used since then by the "originator" pharmaceutical industries to argue about the high costs they incur and the need for high prices of medicines to recover them. However, in a study carried out by researchers from the Rwan University, New Jersey, USA,[19] the authors found that the average cost to develop a new product was only US$ 43.4 million. The non-profit foundation Drugs for Neglected Diseases initiative (DNDi) reported in 2019 that the cost for research and development of a sleeping sickness drug was US$ 55 million.[20]

As long as there is no clarity on the real cost of R&D, the problem of prices—and therefore of access to medicines— will continue to go unsolved. The massive difference between the estimates of US$ 55 million or US$ 2.5 billion per molecule clearly indicates that the resulting prices of new medicines, if reasonably based on real R&D costs, would be significantly different.

2.2 Pharmaceutical innovation has significantly decreased

The number of new molecules approved for therapeutic use has declined in the last two decades despite the advancement of science and technology and the availability of financial resources to undertake R&D for the diseases prevailing in developed countries. In addition, the therapeutic value of most of the new medicines has also gone down. According to data published by the French magazine *Prescrire,* for instance, the average of the number of drugs, representing "a major therapeutic advance" intro-

duced on the French market in 10 years (2007-2017) was 4.7 products per year. But these numbers decreased significantly, from 14 products in 2007 to only one product in 2017. "The number of new drugs approved per billion US dollars spent on R&D has halved roughly every 9 years since 1950, falling around 80-fold in inflation-adjusted terms".[21]

In the area of therapeutics for cardiovascular diseases (CVD), for instance, Gail A. Van Norman describes adverse trends towards declining innovation and rising costs of drug development over the last several decades. "Thirty-three percent fewer CVD therapeutics were approved between 2000 and 2009 compared to the previous decade, and the number of CVD drugs starting all clinical trial stages declined in both absolute and relative numbers between 1990 and 2012. In the last 5 years, drugs to treat CVD disease comprised just 6% of all new drug launches".[22]

A recent study by STAT Reports found that "large pharmaceutical companies did not actually invent most of the drugs they sell. Indeed, it appears they have already reduced their investment in the discovery of new medicines".[23]

2.3 High prices restrict access

In 2014, the American firm Gilead Sciences introduced the hepatitis C drug sofosbuvir (brand name SOVALDI®) at the eye-watering price in the USA of US$ 84,000 for a 12-week treatment. In 2015 the American firm Vertex introduced Orkambi®, a medicine used to treat cystic fibrosis in patients aged 2 years and above, at the price of US$ 272.000 per patient per year. A study in the US on 71 anti-cancer medicines approved between 2002 and 2014 by the FDA, found that many of them cost more than US$ 100.000 per treatment per year.[24] In 2018 Novartis introduced the CAR-T leukemia treatment Kymriah® at US$ 350.000. On 27 May 2019 the US FDA gave marketing authorization for "Zolgensma®" a gene therapy, also from Novartis. The price of the drug, administered in a single dose, is US$ 2,125 million, making it the most expensive drug in the history of the pharmaceutical industry.[25]

This escalation of prices over the last five years, especially for products of biological origin, has been recently justified by the industry on the argument that prices should be set on the basis of the "value" of the product for the patient rather than on the cost of R&D, as was previously the case. Neither governments nor WHO have challenged this new concept so far, which is not practiced in any other manufacturing sector, except perhaps in luxury industries.

Lack of transparency on the costs of R&D, a diminishing rate of pharmaceutical innovation in recent years and high prices, in conjunction, demonstrate that a structural problem exists in the current R&D model for pharmaceutical products. Several documents discussed in WHO in the last 10 years, as well as a large number of studies and articles produced by scholars[26] point to the shortcomings and incoherence in the current R&D model. At the end of 2015, the Secretary General of the United Nations established a High-Level Panel on Access to Medicines; the panel was constituted by an array of personalities and international experts of demonstrated competence. The terms of reference set for the expert group called for a study on **"the incoherence between the rights of inventors, international human rights legislation, trade rules and public health".**[27] As noted above, although an encouraging path to go to a new direction was opened in 2013 at WHO with the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG),[28] such recommendations have not been implemented so far.

2.4 Fragmentation and lack of coordination

At the time the novel coronavirus started to spread in 2020, it was clear that the stocks or production capacity of masks or alcohol-based hand rub or breathing assistance devices were unknown. Who were the producers and how could they respond to the quantities needed? Prices shot up and some countries imposed export restrictions. The European Union (EU) moved to limit exports of medical equipment outside the EU: "We need to protect our health workers, who are in the first line of defense against the virus," said Ursula von der Leyen on 15 March 2020.[29] What is valid for production and distribution also applies to research and development of vaccines and possible future treatments. WHO has tried to gather information and when it has it (in case private and public actors provide it) what will it do with this information, how will the organization be able to set the rules of the game?

The search for new treatments and health technologies –as well as the production and distribution of products necessary for the protection of life and recovery of health– should be carefully planned and subject to well defined rules. Sharing information is fundamental but it is not enough. The world is interdependent in relation to R&D for and the production of pharmaceuticals. This current crisis has dramatically shown the need for cooperation in the field of research, development and production of pharmaceuticals. Sharing of technologies, and not only information about them, is essential to maintain the supply of vital products. No country is totally self-sufficient. Closing borders and restricting exports may be a palliative, but not a solution. The only solution is a global coordination of all actors. This is a role that WHO could play if the organization is allowed to use the legal instruments available under its constitution.

"The WHO R&D Blueprint is a global strategy and preparedness plan that allows the rapid activation of R&D activities during epidemics. Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crisis." This is an excellent but insufficient initiative in view of what is happening now. If WHO has the information, it is already one step, but the information is only the basis for decision making. Who will make the decisions? And what will be the instruments for their implementation? WHO cannot

be a world health government without laws and instruments to enforce those laws. As noted by Viergever "[o]ne of the most pressing global health problems is that there is a mismatch between the health research and development (R&D) that is needed and that which is undertaken. The dependence of health R&D on market incentives in the for-profit private sector and the lack of coordination by public and philanthropic funders on global R&D priorities have resulted in a global health R&D landscape that neglects certain products and populations and is characterized, more generally, by a distribution that is not 'needs-driven'."[30]

2.5 Waste and overlap

There is waste and overlap in vaccine and treatments research. According to information from WHO Blueprint there is a number of research studies on the vaccine candidates (in China, Australia, UK, Canada, France, Germany, US, etc.) As there is little or no exchange on research progress between the different countries, resources are spent looking for what others have probably already found. According to WHO there are currently clinical trials in animals for 5 vaccine candidates.[31] Research with the same objective is done in different sites and countries. There is no information in the WHO Blueprint on whether progress is shared on different research, in particular among those working with the same platform technologies. Not sharing research results extends the time and costs of the process. In January 2020, RAN Europe wrote in its report on innovating for better healthcare: "A variety of funding schemes support innovation in the health system, but there is a need to improve the coordination, sustainability and stability of funding flows."[32]

According to the WHO Blueprint there are several ongoing research efforts, on existing drugs:

- "In vitro studies of antiviral agents
- Cross-reactivity studies to evaluate monoclonal antibodies (mAbs) developed against SARS
- Clinical trials in China (>85):
    - Remdesivir
    - Lopinavir+Ritonavir
    - Tenofovir, Oseltamivir, Baloxivir marboxil, Umifenovir
    - Novaferon
    - Interferons (IFNs)
    - Chloroquine
    - Traditional Chinese Medicines: Lianhua Qingwen"[33]

WHO should also ensure that all pandemic-related products (existing or to be developed) be treated as **public goods**, that is, they should be available to producers around the world to be able to respond to a massive demand, something that a single or group of producers would not be able to achieve. This should be part of an internationally agreed pandemic declaration. Some antivirals and other existing medications are being tested to see if they could be used for treatment of persons infected with the coronavirus. It is not yet clear whether there will be patents for second uses or new indications. This kind of patents is not required under the TRIPS Agreement and, if granted, they may pose important barriers to access of medicines.[34]

3. A Binding International Convention

As noted earlier, there is only one historical precedent for the use of Article 19 of the WHO Constitution: The Framework Convention on Tobacco Control (FCTC). It was adopted in May 2003 and has now been signed by 168 countries. For the first time, WHO exercised the power to adopt international treaties and agreements in a substantive area and provided a global legal response to a global health threat.

The WHO Framework Convention on Tobacco Control is a framework treaty which, while alluding to many substantive issues, essentially sets out the objectives, principles, institutions, and functioning of what should be a more comprehensive system with the adoption of future additional protocols on technical issues, such as promotion and sponsorship, advertising, illicit trade, and liability.[35]

According to the report of the Eighth Session of the Conference of the Parties 2018 (COP8) to the WHO FCTC, Vera Luiza da Costa e Silva, Head of the WHO FCTC, said: "We are happy to report, based on the information received from the Parties in the 2018 reporting cycle, that progress is evident in implementation of most articles to the Convention, especially the time bound measures concerning smoke-free environments, packaging and labelling and tobacco advertising, promotion and sponsorship ban."[36]

The finding that the current system of incentives through the protection of patents has failed to respond to the global health problems shows the urgency of using efficient mechanisms to ensure and enable universal health coverage. The success of FCTC should serve as inspiration.

As far as sustainable long-term access to medicines for the developing countries and today even for developed countries is not available, WHO should, rather than recommend, use its capacity to legislate: a convention or a treaty on R&D is undoubtedly one the paths to follow. As noted by the report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) "there is a need for an international mechanism to increase global coordination and funding of medical R&D, the sponsors of the medical R&D treaty proposal should undertake further work to develop these ideas so that governments and policy-makers may make an informed decision".[37]

3.1 Objective and scope

The objectives of an international and binding treaty for R&D and innovation for health would be as follows: promote R&D for all diseases, conditions or problems (including pandemic outbreaks), promote R&D capacity in developing countries and with a sustainable and affordable model that prioritizes public interest and health.

3.2 Possible main components

To achieve this goal, an international treaty must include the following:

- The establishment of priorities based on public health needs.
- Coordination of public R&D on pharmaceuticals.
- Develop sustainable financing mechanisms.

Priority setting would aim to ensure that the R&D program in medicines and health technologies is based on the public health needs of the population and not on potential commercial benefits.

A key component of a binding global R&D treaty should be the development of R&D coordination mechanisms in order to achieve clearly identified objectives at the lowest possible cost. All actors (public and private) should be informed and/or guided in the allocation of resources, and R&D efforts can be monitored and evaluated. Mechanisms to be agreed upon may include the creation of networks of existing institutions, particularly in developing countries, and the creation of new programs and facilities.

A binding international R&D treaty should propose the establishment of a funding mechanism, based on the transparency of research and development costs. The source of funding for the fund would come from governments, with contributions according to their level of development.[38]

4. The Need to Act Fast

In the face of the health crisis, Canada, Chile, Ecuador and Germany have taken in March 2020, steps to facilitate their right to issue compulsory licenses for COVID-19 present and future diagnostics, medicines, vaccines and other medical products and technologies.[39] Similarly, the government of Israel issued a compulsory license for patents on a medicine they were investigating for use against COVID-19.[40] On 14 March, Spain issued a decree declaring the state of emergency, giving the government the power to intervene and temporarily occupy factories in the pharmaceutical sector; to enforce the orders necessary to guarantee the supply of medicines and products necessary for the protection of public health, and also to adopt special measures in relation to the manufacture, importation, distribution and dispensation of medicines.[41] Other governments have taken similar measures. These isolated and uncoordinated efforts would be more effective in the context of a global response.

A WHO declaration of pandemic should include, among other key elements, a recognition of the right of countries not to enforce exclusive rights under patents or other intellectual property rights in relation to all present and future health products (diagnostics, treatment and vaccines) related to the pandemic. In an open letter to the Director Generals of WHO, WIPO, and WTO, the Executive Director of the South Centre stated that "access to affordable medicines, vaccines and diagnostics and to medical equipment, and to the technologies to produce them, is indispensable to treat COVID-19" and that such technologies "should be broadly available to manufacture and supply what is needed to address the disease. Any commercial interest supported by the possession of intellectual property rights on those technologies must not take precedence over saving lives and upholding human rights. This should always be the case, but this premise is often overlooked in times where asymmetries in development and inequality are deemed to be normal facts". The letter also called upon the three organizations, to " support developing and other countries, as they may need, to make use of article 73(b) of the TRIPS Agreement to suspend the enforcement of any intellectual property right (including patents, designs and trade secrets) that may pose an obstacle to the procurement or local manufacturing of the products and devices necessary to protect their populations."[42]

5. Conclusions and Recommendations

- As a starting point, in cases such as the present COVID-19 pandemic, WHO should include in the pandemic declaration a call for all products and technologies related to the pandemic to be treated as public goods.
- The global health crisis caused by the coronavirus COVID-19 pandemic creates an opportunity to rethink and put in place an R&D model for pharmaceutical products and health technologies that is more efficient, less costly and responsive to health needs.
- There is a need for sustainable long-term innovative mechanisms to promote pharmaceutical R&D to address public health needs, particularly in developing countries, in the context of a model that structurally links innovation with access.
- WHO Member States should, based on article 19 of the WHO Constitution, start negotiations for a binding global instrument for R&D and innovation for health, as recommended by the WHO-CEWG and the UN High Level Panel on Access to Medicines.
- A successful binding global instrument for R&D must be able to prioritize R&D in accordance to health needs, to coordinate R&D to avoid unnecessary duplication of efforts and to design sustainable public mechanisms for financing for R&D. The world would

be better prepared for a health crisis as the one created by the COVID-19 pandemic.

- As noted in the open letter mentioned above, "[we] need to have the courage to change course. The resource gap in addressing the health crisis is huge and health inequality is probably the most unbearable of injustices. It will be a matter of rebuilding a world that is viable, the one we are leaving behind, was not."[43]

Annex: Principles and Elements for an International R&D Convention

Principles

The following principles can be considered when developing an international R&D convention:

- The right to health is a universal and inalienable right and it is the duty of governments to ensure the means for its realization.
- The right to health must prevail over commercial interests in R&D for new pharmaceuticals.
- The right to health implies equitable and universal access to medicines and other health products.
- R&D must be carried out in a sustainable manner to address public health priorities.
- The international and binding treaty on R&D must include mechanisms to ensure transparency in terms of planned funding and costs incurred in R&D.
- The binding international R&D treaty should include mechanisms to decouple the cost of R&D from prices. The prices of the medicines and other health products produced should be set on the basis of accessibility by all those in need.
- Strengthening the innovative capacity of developing countries is essential to respond to public health needs.
- The international and binding R&D treaty should include all diseases and pandemic outbreaks.
- The results of R&D undertaken in the context of the international treaty should be regarded as a public goods and remain in the public domain.

Possible elements of a binding international treaty for R&D for health

For methodological purposes, we refer to the "components" (detailed in the previous point) as the substantive part of a convention and the "elements" (addressed here) as the complementary mechanisms that can foster the implementation of the main components of a convention. The elements mentioned here are not exhaustive, and others will be identified during the negotiation, as occurred for example during the negotiation of the Tobacco Convention:

- Ethical criteria and financial mechanisms for conducting clinical trials with full disclosure of test data.
- Mechanisms to build and strengthen research and local capacities in developing countries.
- Mechanisms (attractors and drivers) to decouple the cost of R&D from the price of the product in order to promote access to medicines for all.
- Mechanisms to ensure that the outcome of R&D will be kept in the public domain or otherwise accessible in developing countries.
- Research and policy development based on articles 12 and 15.1.b of the International Covenant on Economic, Social and Cultural Rights: the right to health and the right to enjoy the benefits of scientific progress and its applications.

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