



ADDRESSING THE NEED FOR
GREATER **PUBLIC RETURN** ON
PUBLIC INVESTMENT

Realities and Recommendations for Biomedical R&D

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Acknowledgements

Special thanks to Alex Lawrence and Tim Reed.



Publisher

Health Action International

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Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.

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This paper addresses the need for a greater public return on public investment in biomedical research and development (R&D). In doing so, it provides an update on the paper *Licensing and Access to Health Technologies*¹, and lays out recommendations on the possible next steps and necessary actions by governments and other stakeholders.

BACKGROUND

The R&D of health technologies is a long and costly exercise requiring the collaboration of a number of stakeholders and substantial resources; from early research conducted in public facilities and universities to subsidies and tax breaks, the breadth of public support for R&D is wide.²

The current structure of R&D, centred on intellectual property (IP) related monopolies, allows for a pharmaceutical business model that skews public health needs for more lucrative opportunities. Misuse and abuse of IP in order to extend market exclusivities, excessively high pricing and the risk of shortages of essential medicines are some of the unintended consequences of this.

Attempts at ensuring public return on public investment on R&D have fallen short, either because of difficulties in implementation and/or lack of political will.

CONTEXT

Licensing of IP, know-how and other forms of knowledge and data is one of the most common examples of public-private partnerships. Voluntary licensing remains an effective mechanism for technology transfer

or diversification of manufacturing, as well as scientific cooperation and general dissemination of knowledge, provided that licenses are non-exclusive and of global scope.³

Public institutions still largely favour patenting or other forms of market-oriented exploitation (startups, individual ownership and so on) over licensing when seeking to further develop or bring health goods to patients. This has consequences for the ability of researchers to set conditions on certain aspects (such as pricing, accessibility or technology transfer) of products resulting from their work.

DEVELOPMENTS

Many of the challenges of access to health technologies exposed by the COVID-19 pandemic were not new, but rooted in the structural difficulties that prevent positive societal impact despite public resources being used in the development and production of marketed products.

Several initiatives at national, regional and global levels have attempted to correct the imbalance and improve the inefficiencies of public contributions to biomedical R&D. A non-exhaustive diversity of approaches should be acknowledged: from academia and knowledge governance to supranational support for research or international pooling of patents.

The Netherlands

Between 2018 and 2019, as a reaction to excessive high prices of medicines partially developed at public research institutions, the Dutch association of medical research universities (NFU) engaged in a process to design a set of socially sustainable licensing guidelines, with the goal of guaranteeing societal benefit from publicly generated knowledge. After a lengthy consultation process, it was not possible to achieve consensus and document finally approved was not enforceable.⁴

European Union

Horizon Europe, successor to Horizon 2020, is the main conduit to harness EU-funded research in a number of areas, including health. Civil society and academia made substantial contributions to the discussion, successfully pushing for open science tenets and greater accountability in public-private partnership.⁵ The programme, however, does not include access clauses on end products developed with public participation and does not ensure effective accountability of public-private partnership, such as the Innovative Medicines Initiative 2 (IMI2).⁶

Global

The Medicines Patent Pool (MPP) was created in 2010 with the support of UNITAID. As a public health licensing entity that negotiates voluntary licensing agreements, it makes up part of the World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (WHA61.21). Between 2012 and 2020 it secured deals between patent holders and generic manufacturers in low- and middle-income countries (LMICs) for over 14 products, including antiretrovirals (ARVs) and direct acting antiviral agents (DAAs) for the treatment of hepatitis.⁷ Such agreements contain, in most cases, geographical restrictions on where medicines can be made available, limiting its effectiveness.

The Coalition for Epidemic Preparedness

Innovations (CEPI) was created in 2015-2017 as a public and private partnership, with a focus on the development of new vaccines. This was in part a response to the 2013-2016 outbreak of Ebola in

Central Africa, with a particular focus on Middle East Respiratory Syndrome (MERS), Lassa fever, Nipah virus, Marburg fever and Zika, among other potential infectious diseases to which the market had not given an adequate response. While CEPI's early policy statements on licensing explicitly mentioned the need to ensure equitable access to products manufactured with its support, it was later changed due to opposition by participating pharmaceutical companies.⁸

COVID-19

Early stages of the COVID-19 pandemic showed the consequences of unequal distribution of innovation and the inability of market forces alone to effectively respond to health needs in emergency settings.

Several factors combined seriously hindered access to life-saving health technologies: from the fragility of supply chains of health goods to the lack of solidarity between nations. Once viable vaccines were developed, the concentration of know-how and manufacturing capabilities in the hands of a few companies greatly limited availability.

Leadership provided by WHO and collaboration between governments was critical to ensure that access to vaccines, therapeutics and diagnostics did not depend on borders or wealth. Taxpayer-funded support, whether financial, administrative or regulatory, was critical for the R&D of medical responses to COVID-19. Without public investment and commitment to advanced procurement, it would not have been possible for companies to develop mRNA technology-based vaccines in such a short time, nor to benefit so greatly from it.⁹

The global response was hindered by the failure to spread innovation at a 'pandemic pace'. Efforts to distribute vaccines (e.g., COVAX) among those countries unable to access pharmaceutical markets, due to prices and hoarding practices, failed to achieve the equitable access goals they set out to accomplish.

A number of initiatives sought to counter the imbalances and shortcomings by fostering technology transfer, sharing of know-how and promotion of local manufacturing.

The mRNA Tech Transfer Hub launched in June 2021 with the support of WHO and the MPP among other institutions, and based in the premises of Afrigen, Cape Town, South Africa. Its goal is to build capacity in LMICs to produce mRNA vaccines through a network of technology recipients, or so-called spokes.¹⁰ The multinational team of scientists gathered at Afrigen were able to replicate the Moderna-patented COVID-19 vaccine without the collaboration of the patent holder. For the second generation of mRNA vaccines, they will keep IP rights and collaborate with MPP to negotiate licensing agreements.¹¹

The Health Emergency Preparedness and Response Authority (HERA) was created in December 2021 as part of the EU response to pandemics and other health emergencies. It is loosely inspired in the US Biomedical Advanced Research and Development Authority (BARDA), with the “development, production, procurement, and equitable distribution of medical countermeasures (MCMs)” as part of its mission. HERA’s operations are divided in two phases: preparedness and emergency. The preparedness phase includes, inter alia, fostering R&D, promoting industrial capacity and improving knowledge and skills. The emergency phase consists mainly, but not exclusively, of ensuring availability of medical countermeasures, engaging in centralised procurement and activating emergency measures for research.¹²

The COVID-19 Technologies Access Pool (C-TAP) was created by WHO after a call to action endorsed by over 40 governments.¹³ C-TAP was supposed to be a conduit for technology transfer and know-how sharing between manufacturers and patent holders and governments in need.

It faced two obstacles: frontal opposition from pharmaceutical industry to participate in the scheme and a lack of political support from WHO senior management and the very same governments that endorsed its creation. Since its inception, C-TAP has secured the rights to the research portfolio of the US National Institute of Health (NIH)¹⁴ and the licence to a diagnostic kit developed by the Consejo Superior de Investigaciones Científicas (CSIC), the main a public research institute in Spain¹⁵ (subsequently sub-licensed to Biotech-Africa). More recently it secured three additional licensing agreements: for a COVID-19 vaccine developed by CSIC¹⁶ and another by Medigen Vaccine Biologics Corp, a Taiwanese private pharmaceutical manufacturer. Lastly, an assay for quantification of neutralising antibodies developed by the University of Chile.¹⁷ All licenses are global, transparent and non-exclusive to all manufacturers.

In relation to improved access and the distribution of biomedical innovation, the global response to COVID-19 contributed to the reinforcement of existing structures including CEPI and MPP and while WHO participated in many initiatives, its most lasting contribution was its support for the Tech Transfer hub.

The EU deployed a massive programme of technology transfer, vaccine donation, promotion of pharmaceutical manufacturing and advanced procurement of medical countermeasures that spread across several departments and units, which has been proven difficult to track and hold accountable.

While several governments and organisations did invest substantially in the development of vaccines and therapeutics against COVID, it appears contracts did not include accessibility clauses regarding price, delivery or, more importantly, technology transfer. Moreover, most contracts remain confidential, and accountability has thus been difficult to uphold.

POST COVID-19

Since the declaration by WHO that the Public Health Emergency of International Concern (PHEIC) was over, the global health agenda has been largely focused in how to better prevent, prepare and respond to the next pandemic.¹⁸ To that effect there are three parallel discussion processes which, while avoiding overlap and ensuring coherence, need to address the issue of generation, distribution and access to innovation. At stake is not only the effectiveness of the response to new pandemics and/or health emergencies but the emergence of a new global health governance structure that heeds the lessons of COVID-19 in terms of equity and inclusion.

The Pandemic Accord is an idea initially put forward by the President of the European Council in December 2020. It was endorsed by a number of governments before being considered at a special session of the World Health Assembly (WHA) in November 2021 that convened the Intergovernmental Negotiating Body (INB).¹⁹ The INB has a mandate to draft a convention, agreement or other international instrument to strengthen pandemic prevention, preparedness and response.

With the 77th WHA as a deadline, it has proved difficult to find consensus on major issues such as IP, public finance support for R&D and Access and Benefit Sharing (ABS), with a growing gap between the Global North and Global South. Participation of public-interest groups, while welcomed by several governments, is limited to non-negotiating sessions, greatly limiting civil society's ability to contribute and influence the outcome of the discussions.

International Health Regulations (IHR), approved in 2005, constitute the only binding instrument guiding governments response to pandemics. Under revision after the COVID-19 pandemic, which saw several countries failing to observe regulations, through the Working Group

on Amendments to the International Health Regulations (WGIHR), with the same deadline as the INB.

While there are no specific articles related to innovation or R&D, there has been much discussion around two principles, which may be relevant when addressing dissemination of know-how and technology transfer. First, the Common But Differentiated Responsibilities (CBDR), which would acknowledge, for the sake of equity and fairness, that countries are not in the same position to implement certain obligations. Secondly, ABS in connection to pathogens and/or Genetic Sequence Data (GSD) that links sharing this material with guarantees of having access to the derived benefit (i.e., vaccines).²⁰

The Medical Countermeasures (MCM) platform was presented by WHO in early 2023 after the evaluation of ACT-A. Discussed at G20, G7 and other international forums, the platform will be made up by international and regional organisations, civil society and industry identified as “anchor” partners.

The aim of the MCM platform is to coordinate access to necessary medical goods should a global health threat emerge. It would do so through three pillars (medicines, vaccines and diagnostics), and covering cross-cutting issues including R&D, manufacturing and supply. While it would seek to overcome the underrepresentation of LMICs that affected ACT-A, civil society has expressed concern that issues such as technology transfer, mapping of manufacturing capabilities or use of TRIPS flexibilities are not being mentioned.²¹

Other initiatives are likely to have an impact both in PPPR in general and dissemination of health-related technology in particular. For example, the amendment of the **European Pharmaceutical Strategy**, which will engage HERA in the promotion of R&D for new antibiotics²² or the **World Local Production Forum (WPL)**, mandated by resolution WHA74.6, promoting technology transfer and enhance local production to improve access.²³

GENERAL RECOMMENDATIONS

Better, more equitable and fair distribution of biomedical innovation is a global, shared responsibility. In order to counter imbalances in access to health technologies and shortcomings in manufacture and supply, R&D models must be adapted to current demands and settings.

Effective public return on public investment in biomedical R&D requires a reinforced public stewardship of all stages of research: from the management of resources to the use of installations or the exercise of march-in rights.

Public research institutions should not depend solely on market forces and incentives to further develop or scale up research. Access policies need to be developed and applied from early-stage research in order to guide licensing strategy or other forms of collaboration and partnership.

In order to guarantee public return and societal benefit, specific and enforceable clauses regarding access, pricing and technology transfer must be included in any public private partnerships, with transparency of data and information.

An IP-based model centred around patents and market exclusivities is not suited to adequately respond to health emergencies and pandemics. Development and manufacturing of medical countermeasures should not be bound by stringent IP rights but be considered Global Public Goods from inception.

Entities such as MPP and CEPI, with extended and renewed mandates, must seek out greater and more meaningful input from civil society and recipients of technology transfer. Transparency on their licenses and grants should be upheld, not reduced for expediency's sake.

It is imperative that PPPR focused initiatives interact in a productive way with other public interventions at national, regional and global levels. Health-oriented IP management must be part of this conversation for LMICs to take full advantage of existing TRIPS flexibilities without fear from reprisals and retribution.²⁴

SPECIFIC RECOMMENDATIONS

ACADEMIA

Technology Transfer Offices in public research institutions should be the executioners of access and licensing policies agreed upon by relevant government agencies shaping long-term research agenda, goals and objectives. Outreach should be focused on recipients of technology transfer through non-exclusive licensing agreements.

INDUSTRY

Should disclose relevant data related to the development of health technologies, including financial figures related to R&D investments, mergers and acquisitions (and associated IP) as well as subsidies and tax breaks. In addition, industry must make available for regulatory authorities all clinical trials, regardless the results, involved in the development of a marketed product and accessible for researchers all relevant data necessary to replicate/advance research.

GOVERNMENTS

Discussions on pandemic prevention preparedness and response need to include binding commitments to secure access to government-funded/assisted health technologies in emergency settings. A pandemic accord, whatever form it takes, must reflect the engagement of international community to make life-saving health technologies global public goods.

Public stewardship of research needs to go beyond early stages. Support for development and manufacturing would fulfil a health-oriented industrial policy agenda. Private actors can be invited to invest or collaborate, but IP and know-how will be open to share and replicate.

CIVIL SOCIETY

Public-interest driven civil society needs to engage more closely with research institutions and funders to ensure transparency, accountability and health-driven research agenda. Also, the contribution from civil society in pandemic prevention and preparedness discussions is critical to ensure a more equitable response, based on innovation as global public good.

ENDNOTES

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