

## HEALTH FOR ALL: TOWARDS EFFECTIVE GLOBAL GOVERNANCE FOR MEDICAL INNOVATION AFTER COVID-19

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### THE PROBLEM: MYTHS AND SYSTEM FAILURES

We could read or hear it almost daily in various media that the rapid development of COVID-19 vaccines was made possible by private venture capital and that we owe it to courageous investors that at some point an end to the pandemic is in sight through sufficient vaccines. Such narratives contribute to the myth that the pharmaceutical industry is not only the sole driver of innovation, but also entitled to high profits because of its high and risky spending on research and development (R&D) (Mazzucato 2015). However, myths do not become truer with permanent repetition; they can only be deconstructed disenchanting through solid evidence. The call for an enlightening demystification of this myth has been voiced for a long time, especially from civil society groups.

COVID-19 has made the dramatic aberration of selling out academic research results all too obvious: mRNA technology has been researched for decades at public academic institutions with the help of large public research expenditures. It was only because this technology platform had already been researched that mRNA vaccines (BioNTech/Pfizer, Moderna) could be developed and brought into real use against COVID-19 at such a rapid pace. The research was conducted primarily at US universities (University of Pennsylvania), funded with money from the US National Institute of Health (NIH) and sold to the biotech company Cellscript, which resold it to BioNTech and Moderna for USD 75 million each (Scientific American 2020).

Within the last months Pfizer, BioNTech and Moderna have sold the majority of doses to high-income countries and have earned billions with it, while only a small percentage of their total vaccine supplies went to low-income countries. Despite receiving public funding of over USD 8 billion (Policy Cures Research 2020), the three corporations have refused calls to transfer vaccine technology and know-how. In the Corona pandemic, as

rich countries had secured practically the entire vaccine production with advance purchasing contracts, in poorer countries hardly any vaccine was available for months to protect e.g. health workers, nurses or physicians (Oxfam 2021).

Only in June 2022, after increasing pressure by many countries (e.g. South-Africa and India with established vaccine manufacturing facilities), non-governmental groups (NGOs such as Médecins Sans Frontières/MSF, the European Consumer Organisation/BEUC, European Alliance for Responsible R&D and Affordable Medicines, Public Eye, Public Citizen, Health Action International/HIA, Attac and Oxfam), but also international institutions (WHO, United Nations agencies such as UNAIDS) and protracted negotiations, the 164 members of the World Trade Organisation (WTO) agreed on a temporary lifting of patents for corona vaccines in order to expand production in developing countries – the so-called “TRIPS-waiver”. The agreement on trade-related aspects of intellectual property rights (TRIPS) regulates intellectual property rights (IPR). The agreement already allows individual governments to use “compulsory licences” for the production of COVID-19 vaccines against the will of pharmaceutical companies without calling into question the protection of intellectual property in general (Correa 2020). The „TRIPS waiver“ goes one step further in the temporary lifting of patents for corona vaccines without the need for individual governments’ actions (Deutsches Ärzteblatt 2022). The policy experts from Medicines Law & Policy (2022) call it “a hollow diplomatic compromise with little practical impact”.

By way of criticizing the agreement, in July 2022 the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has presented a proposal – the „Berlin Declaration“ – for a future distribution of vaccines and medicines in the event of a new pandemic. In such a case, the companies shall offer to reserve part of the vaccine or drug production for the supply of the poorest countries from the beginning (International Federa-

tion of Pharmaceutical Manufacturer and Associations 2022), but not to share the respective IPR. Oxfam reacted immediately with writing “this declaration is yet another shameless blame-shifting exercise from an industry that has chosen to prioritize obscene profits over human life throughout the pandemic” (Oxfam 2022).

## PRE-COVID-19: INDICATORS OF A POLITICAL WILL FOR CHANGE

This pattern of publicly funding risky basic research in the first place and then selling the findings without conditions and thus privatising the profits without hesitation, only to buy back the same drugs at inflated prices at a later point is a common thread running through other innovative drug developments of recent years, be it hepatitis C drugs (Barenie et al. 2021; Roy 2017) or costly cancer medicines (Schmidt et al. 2022). These serious systemic errors as well as potential remedies have been discussed since years at academic conferences or in policy circles such as during the Austrian EU presidency 2018 (Employment Social Policy Health and Consumer Affairs Council 2018). Now, in the COVID-19 pandemic the problems with monopolistic production of life-saving medicines have become all too obvious.

The pandemic could serve as a catalyst to usher in a paradigm shift that has been discussed for a long time. The transformation of a „rotten“ research, development and marketing system could succeed, provided politicians finally have the courage to act. In the European Commission’s „Pharmaceutical Strategy“ on the triple A (A+++ ) problem areas „Affordability, Availability and Access“, the numerous system errors are only indirectly addressed, but the expert analyses (European Parliament – Directorate-General for Internal Policies (Policy Department – Economic and Scientific Policy) 2016; European Parliament – Report of the ENVI Committee 2017; Expert Panel on Effective Ways of Investing in Health 2018; Medicines Law & Policy 2019; Technopolis 2019) on which the strategy is based, for example on the relaxation of patent protection and the corresponding roadmap for regulatory implementation, show that a certain problem awareness has also reached the highest EU levels.

Until a few years ago, the term „access to medicines“ was associated with the discussion about cheaper, partly generic and essential medicines for developing coun-

tries. For some time now, European and US-institutions have also been addressing „access to medicines“ in numerous analyses and reports (Medicines Law & Policy 2019; National Academy of Sciences 2018; Organisation for Economic Co-operation and Development 2018; United Nations 2016) and have accordingly been questioning the prevailing governance system. The common goal of these initiatives is to react to the excessive prices of medicines with future-oriented solutions. Various models of implementation have been on the table for a long time and have already been tested in individual projects by, for instance, the Drugs for Neglected Diseases Initiative (DNDi) (2014) and by Médecins Sans Frontières.

## POST-COVID-19: SHOW-CASING SOLUTIONS

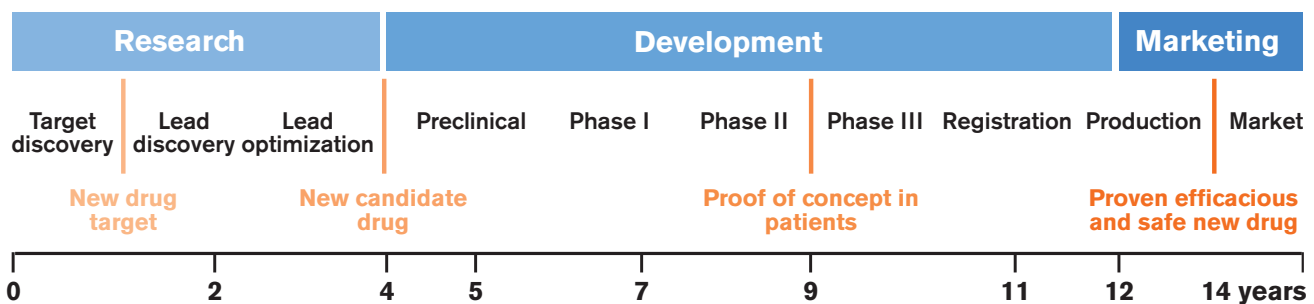
The COVID-19 pandemic and the research funding publicly launched by the WHO and the EU donor conference in May 2020 were accompanied by NGO demands, but also market-oriented institutions (such as the Organisation for Economic Co-operation and Development 2018; 2020) on alternative models of drug research, development and production. The demands and proposals include that any public research and development funding must from the outset include conditions as an integral part of any contract. These conditions range from legal requirements for public research funding (sharing research results: open science practices and principles and public platforms for open access to data), timely access to innovations through open patent pools and royalty-free availability such as non-exclusive licences to prevent supply bottlenecks. Other regulatory approaches include a re-regulation and flexibilization of patent protection and intellectual property rights, as they often serve as a justification for excessive pricing policies; however, it is by no means always conducive to innovation (Perehudoff et al. 2022). New models for the development of medicines (Belgium Health Care Knowledge Center 2016) with defined goals and milestone payments during development – such as new, urgently needed antibiotics – and pre-defined conditions for market access, as well as a complete unbundling of work steps and their compensation in the value chain – as has long been practised in other industries – are being debated worldwide (Netherlands Council for Public Health and Society 2017).

However, transparency on costs, expenses and benefits is key to enforcement of new models of drug de-

velopment. The work steps with decreasing risk are (see Figure A below): Basic research to discover new compounds or technology platforms (such as mRNA platform), (royalty-free) patenting of the new compound or technology, preclinical development and optimisation, human clinical trials for dose finding and efficacy testing, approval and marketing. Each of these phases could be decoupled and compensated once with milestone payments, so that the acting companies have revenues, but the result can be used licence-free and at real costs.

There is no need for cost-intensive marketing for essential medicines. De facto, individual steps are already carried out by different institutions: resource-intensive and high-risk basic research predominantly takes place in the public sector, at universities and the corresponding publicly funded research institutions, closely observed by “patent scouts”, that identify valuable patents through technology & patent landscape analysis. The Gilead case of Sovaldi shows the business model in an unconcealed way (United States Senate Committee of Finance 2015).

**Figure A: Phases of the development of a drug as basis for unbundling the value chain**



Source: Netherlands Council for Public Health and Society 2017

A compulsory disclosure of money flows and costs along the value chain – from cost-intensive academic basic research to patents, to costs for preclinical and clinical approval studies – is the first clarifying step to deconstruct the myth. But this step is also necessary to recognise the place of the pharmaceutical industry in the value chain: in late-stage clinical development and in the production of medicines. These investments do need appropriate remuneration, but not necessarily via patents.

### PUBLIC RESEARCH & DEVELOPMENT EFFORTS: A SOLID EVIDENCE BASE

Several research initiatives have started to lay the evidence base for the new models of drug development as public-private partnerships aiming at a fair return of (public) investments. Since high R&D expenditure is often used as a justification for high prices and the investment risks as justification for the need of monopolistic patents, the evidence of actual public investments in drug research, including failed investments (also called risk capital) is essential. Whether patent protection actually leads to the promotion of innovations or whether this legal protection is only used to obtain excessive prices has been discussed for some years. Supplementary Pro-

tection Certificates (SPC), Data Exclusivity and Orphan (for rare diseases) Medicinal Product Legislation are ever more often being questioned as being the sole drivers for true innovations (Medicines Law & Policy 2019).

A recent study investigated the proportion of „funding“ by the US National Institute of Health (Cleary et al. 2018): the funding of all 210 drugs approved by the FDA between 2010 and 2016 was examined. The authors found that more than USD 100 billion of NIH research funds were spent on basic research for the 210 new molecular entities (NMEs) that were subsequently approved. This was about 20 % of NIH research spending. The basic research for 84 of the 210 „first-in-class“ drugs alone was funded with USD 64 billion of NIH research funds; i.e. an average of USD 760 million per drug. Various other recent analyses also show that a large proportion of new drugs are developed through public funding. Profit-oriented companies then usually only skim off the most profitable innovations (so-called „cream skimming“) and tend to focus on development, marketing, sales and at the same time reduce in-house research departments. Instead of „research & development“, the strategy is „search & development“ (SOMO 2019). In fact, pharmaceutical companies spend twice as much on marketing and sales as on R&D.

Actual R&D costs remain completely intransparent: the Tufts Center, which is closely affiliated with the pharmaceutical industry, calculated R&D costs of USD 2,558 million per drug (DiMasi et al. 2016), including 100 % capital costs. The Open Innovation Initiative of Product Development Partnerships (PDP) for Neglected Diseases reports development costs of USD 50 million for repurposing and combination therapies and up to USD 170 million for the entire R&D (Maxmen 2016) to bring a drug to market. The latter calculations do not include capital costs. Exact figures for public financing have not been available up to now. Similar studies linking European biomedical research expenditure to later drug approvals are not available for Europe. Nevertheless, the call in Europe, as in the US and Canada, for public return on investment is getting increasingly louder (Stieglitz 2017; t’Hoen 2016). The demand is that publicly funded research must result in free use and broad access to affordable medicines (Health Action International 2017). A recent RAND-report, commissioned by the Dutch Ministry of Health, mapped the R&D ecosystem to contribute to this debate (RAND Europe 2022).

Another piece in the evidence puzzle is the long-awaited (and for months withheld) evaluation of the Orphan Drug Regulation (ODR), that finally reached the interested public in August 2019 (Technopolis 2019). This timely publication – appearing during the period of public consultation of the European Commission’s “Pharmaceutical Strategy” – is strategically well placed, as the EC strategy paper discusses policies on access, availability and affordability of new medicines. The evaluation shows one thing above all: the expectations with respect to the ODR were not fulfilled, but the generous incentives granted by the regulation (e.g. extension of market exclusivity and patent protection, administrative simplification of study protocols and fees as well as tax benefits) were used to the maximum: today every third drug approved by the European Medicines Agency (EMA) is an orphan drug sold for “orphan” prices. Between 2007 and 2017, 131 drugs were approved as orphan drugs (OD) for 107 rare diseases; of those (only) 18-24 novel drugs were newly developed. The average effect of the ODR as a contribution to the development of new drugs for rare diseases is therefore about 14 %. Also, in this analysis the trend of large pharmaceutical companies not to conduct research themselves, but buy up late-stage developments from small biomedical companies (often university spin-offs) was confirmed. The authors of the evaluation (Technopolis 2019) conclude that orphan drug legislation has

not been effective in directing R&D to actual „unmet need“ (unmet need is defined by indication areas where there are no therapeutic alternatives), but has only been effective in reducing the „off-label“ use of existing drugs. At the same time as the ODR evaluation, a further study was published on orphan drug revenues: while in 2009 there were 3 ODs with over 1 billion revenues, in 2019 there were already 20 ODs earning that much. The authors of this BMJ publication put it in a nutshell: „lucrative legislation“ (Marselis/Hordijk 2020).

In recent years other evaluations such as the Expert Panel on Effective Ways of Investing in Health (Expert Panel on Effective Ways of Investing in Health 2018) were mandated by the European Commission preparing for a change and indicating that the drug development system is broken and that even the highest layers of policy and regulators are aware of it. It has been widely acknowledged for at least a decade that the current system is not working. The former Dutch Minister of Health Edith Schippers put it this way in 2016: “The system is broken... Patent and intellectual property exclusivities are the only cornerstone of the current model. Companies can ask the price they like. This will no longer do. We need to develop alternative business models...” (Medicines Law & Policy 2019).

## NEXT STEPS: DELINKAGE AND UNBUNDLING AS BUILDING BLOCKS OF AN EFFECTIVE GLOBAL HEALTH GOVERNANCE FOR MEDICINES DEVELOPMENT

As shown, within the existing legal frameworks the established business models of pharmaceutical R&D have led to suboptimal results in some areas such as responding to public needs of patients in low-income countries or to broad distribution of drugs in developing countries. Particularly in recent years, the legal framework has been excessively exploited and rent extraction has been the key driving force in the profit maximization strategies of pharmaceutical companies (SOMO 2020). Publicly funded health systems in high-income countries have been pushed to the limits of financing. Moreover, the instrument of extensive patent protection (see ODR) has partially failed to stimulate necessary innovation.

The UN High Level Panel on Access to Medicines has called for the delinkage of R&D costs from the final price of health technologies in general (United Nations 2016).

Alternative governance models such as delinkage or unbundling or decoupling of individual production stages as effectively implemented in the telecommunications and railway sectors are critically examined with respect to their applicability in the drug industry. A recently published expert report by the European Commission has gone one step further, discussing a complete decoupling of the working steps in the value chain (Expert Panel on Effective Ways of Investing in Health 2018). In reality, such a decoupling of the individual work stages has been implemented by the pharmaceutical industry for a long time already (Wintermantel 2013). Major pharmaceutical companies are sending out drug hunters and patent scouts to buy promising developments. Research partnerships with public research organisations and small biotech start-ups are common in the industry. These are paid according to defined milestones (asset transfer agreements). The commissioning of Contract Research Organisations (CROs) to outsource development and clinical trials is increasingly being implemented in low-cost countries: around 30 % of all clinical trials are conducted in such countries (e.g. India) under questionable circumstances (Public Eye n.d.) where the patients will never have access (outside of trials) to these medicines for high-income countries. The approval and market introduction are then carried out by the global pharmaceutical companies.

## PARADIGM SHIFT: ALTERNATIVE MODELS OF DEVELOPMENT AND APPROVAL

Nobel laureate Joseph Stiglitz warned some time ago that the prevailing excessive pricing policy could lead to an implosion of the entire pharmaceutical system. Both the Belgian HTA Institute KCE (Belgium Health Care Knowledge Center 2016) and the Dutch “Council for Public Health and Society” (2017) proposed alternative models of drug development based on a much more active role for communities of states in drug development and testing. One-off payments for genuine innovations could replace long patent terms. Issuing tenders for conducting clinical trials for new drugs with subsequent “generic” prices is also conceivable. The prices would have to include production costs, marketing expenditure, and profits, but the research effort would no longer be paid tablet by tablet. The first initiatives on patent pools and research platforms have shown that it is also possible to manufacture medicines outside the corporate world (Sunyoto 2020).

It is essential to reconsider the sell-out of research results from public research organisations (universities) in order to ensure that taxpayers’ funds also benefit patients in an appropriate form. Health policy at all levels is called to explicitly express its priorities in research programmes in national institutions and within the European framework of research funding. It would be a worthwhile task for the EU to define concrete research investments in the next budget period. The use of funds, the outcome, as well as the patient benefits would have to be communicated transparently: EU projects must prove directly beneficial to European citizens and taxpayers. Civil society’s call for transparency of the costs incurred in the various phases of drug development is justified, because the funds used for R&D and later for the purchase of medicines have been raised by the public and the welfare state.

## CONCLUSION: STRONG PUBLIC GOVERNANCE NEEDED

The COVID-19 pandemic reminded us of the serious systemic failures that we have allowed to happen over past decades: a drug research and development system that publicly funds the majority of high-risk basic research, but then sells the findings without conditions and privatizes the profits only for the public to buy the same drugs back. The pandemic has lent a new urgency to debates that have been rumbling on for years among legal experts and civil society, pushing regulatory bodies to make long overdue policy changes. With regard to targeted public research funding for the development of therapies and compulsory licensing, we must ensure that the strategies and experience gained during the COVID-19 pandemic are applied across the board. The pandemic could be a catalyst for change, if public institutions recognize the opportunity to transform a highly dysfunctional system.

As a result of the excessive pricing policy, new models for the development of medicines have been proposed for years, and partly applied during the pandemic. Public procurement and advance purchasing agreements have reduced the risk for pharmaceutical companies, while increased the response to public health needs. Those outcome-based pull incentives, coming along with milestone payments have proven to work, while other aspects remained unconsidered: public policy conditions in exchange for extensive public funds have still not been included in contracts, free access for all patients to essential drugs via open patent pools such as the

Medicine Patent Pool, non-exclusive rights, generic pricing policy based on manufacturing costs with a small profit margin have not been secured. Thinking further, it is advisable to specifically initiate public calls for tenders for promising therapeutic approaches that have curative intentions. Strong public governance applying the toolbox for alternative ways to develop truly needed drugs is urgently needed!

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