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EDITORIAL

Public health policies for the common interest: rethinking EU states' incentives strategies when a pandemic reshuffles all interests

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Introduction: diminishing returns, increasing costs and a reliability crisis

The paper "Should governments buy the drug patents?" published 13 years ago in this same journal [1] reflected on aspects that have become relevant again, both for good and bad reasons. The last 60 years have seen huge advances in many of the scientific, technological, and managerial factors that raises the efficiency of commercial medicines research and development (R&D). Yet the number of new medicines approved per US billion dollars spent on R&D has halved roughly every nine years since 1950, falling around 80-fold in inflation-adjusted terms [2].

Until the mid-1990s, countries like Germany and France exceeded the U.S. in per-capita medicine spending; since then, spending growth in the U.S. has dramatically outpaced other advanced nations and expenditure per person (over US$1000 a year) is about twice than Germany's or France's. At least two reasons could explain this discrepancy. First, higher prices, as Americans use fewer prescription medicines. However, many U.S. consumers bear the full brunt of the expensive development work that goes into new medicines, plus marketing expenditures and profit-seeking by all entities within the pharmaceutical supply chain, including the so-called pharmacy benefit.

Second, additional demand thanks to U.S.' coverage expansions, including the Children's Health Insurance Program, Medicare Part D, and the Affordable Care Act. For many of the newly covered, this meant access to prescription medicines for the first time. However, it also encouraged pharmaceutical companies to take advantage of the newfound payers for their medicines [3]. Nevertheless, even with potentially some signs of reduced R&D spending efficiency, it seems the return for pharmaceutical companies has been in the upper range.

Regarding prices of new and innovative medicines, debates have become increasingly dominated by instances of excessively high prices that challenge the sustainability of the publicly funded healthcare systems. Importantly, it seems prices in many cases are not related to the benefit promised by the treatment, while the costs of R&D seem to be shrouded in a cloud of mystery.

The clinical payoff from molecular reductionism has been overrated. We can take a look at the failure, so far, of the Human Genome Project to be translated into improved therapies for inherited illnesses, or knowledge about neurotransmitters to produce better psychiatric medications [4]. There is a tendency to conceptualize the human body as a sum of relatively independent and clearly defined biological systems, while ignoring the wider reality of how they interact with one another as well as with the medium. As a consequence, medicine discovery is becoming slower over time, despite improvements in technology, and while scientists are generating an unmanageable amount of knowledge, most of it is "contestable, unreliable, unusable, or flat-out wrong" [4].

It is at this crossroads where a public–private understanding is needed to promote sustainable technological developments and therapies. For instance, regulators may have to become more risk tolerant and provide clearer, internationally homogenous paths to marketing authorization and stop approving products with little to no additional clinical value when compared to what is already on the market. R + D managers should strive to look for more efficient trials, adopting more diagnostic technology such as biomarkers and move away from traditional designs which are often costly, involve unreasonable amounts of paperwork and fail to provide meaningful information on clinical benefit. Indeed, the EMA has recently stated its will to revise intellectual

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property laws, facilitate the competitiveness of healthcare markets and R + D that address unmet medical needs, both with public funding and by revising the legal framework [5].

Nevertheless, the pandemic has once again highlighted the life-sciences industry's ability to innovate and provide medicines and vaccines on a large scale. It seems that we are living in a new gold rush for 'big pharma'. However, the pandemic has also created new ethical and political dilemmas. Vaccine nationalism spread as governments panicked that others might get crucial medicines first. For example, the French pharmaceutical Sanofi announced its prioritization in the US market sparking public outrage from the French government. But it can also be seen as an example of rapid collaboration, like the Sanofi & GSK vaccine development collaboration [6].

There is mounting pressure to suspend elements of the patent system. WHO urges medicines firms to pool patents rights [7]. Several dozens of current and former world leaders released an open letter demanding that any successful COVID-19 vaccine should be made available patent free [8].

There are, however, alternatives to nationalism and intellectual property abolishment. Governments should seek to authorize new medicines faster more cautiously, as the best way to balance innovation and prices, maybe through properly measuring value, and introducing economic evaluation as the fourth hurdle (at least in those without it).

In a context where regulatory organisms are less risk averse and more internationally homogenous, but also more demanding in terms of clinical value, established pharmaceutical companies may be more incentivized to look for innovative mechanisms of action, and smaller start-up companies that cannot afford to generate the large amount of required paperwork might have a higher chance of competing.

How to price value?

Setting prices at the national level. Sharing the "surplus" between society/consumer and the producer

The discussion on how to set the price of treatments and vaccines for COVID-19 has raised issues that have been debated in policy for decades. At national level, there could be, at least, two options (or extremes) to determine their price: either based on costs or value. Both methods have their pros and cons, as well as complexities, but the choice could reflect the country's strategic priorities on the appropriate share of the (economic) surplus between the society and the manufacturer. When prices are set to the marginal cost of production, all the surplus goes to the buyer (society); alternatively, when priced at the maximum willingness to pay, the surplus is for the manufacturer. The Institute for Clinical and Economic Review (ICER) review of the first treatment for COVID-19 patients illustrates nicely the implications of using either method: the value-based price can be up to 3000 times higher than the minimum price required to cover just minimal marginal costs, or up to nine times higher relative to the resulting price when minimal marginal cost and 2020 projected manufacturer R&D costs are covered [9–11].

In practice, there are many models available to control or regulate medicines' prices, and countries will determine which options they implement depending on their country's perspectives and situation. Mestre-Ferrandiz et al. [12] offer nine (country-specific) objectives of price controls for pharmaceuticals (generally), which could be taken into account when defining and shaping pricing models for vaccines and treatments for COVID-19. These objectives are:

1. Ensure timely, equitable, affordable, and sustainable access to (cost-) effective medicines.
2. Ensure (relative) prices reflect (relative) value, increasing value for money and competition.
3. Help control (public and private) pharmaceutical expenditure/budget, and balance payer's affordability issues.
4. Promote a dynamic pricing system, to encourage monitoring and evaluation of results, allowing flexible pricing over time.
5. Encourage appropriate/rational use and avert under and/or inappropriate use of medicines.
6. Reward valuable research and development (R&D) and innovation (in the future) and share any surplus appropriately between manufacturers and payers.
7. Ensure transparent process, and reduce complexity, bureaucracy, and duplication.
8. Limit the negative impact of one country's pricing and reimbursement system on the access and prices of medicines in other countries.
9. Other industrial objectives.

And why is it important to regulate prices appropriately? A recent paper [13] has revisited the (old) question of whether price regulation affect R&D investment (by companies). Theoretically, price regulation can affect R&D via intermediate variables, such as cash flow and profitability, if on the one hand, price regulation affects cash flow and profitability, and on the other, cash flow/profitability affects R&D expenditure. Their results show, for the top 10 pharmaceutical companies between 2000 and 2017, that price regulation might affect R&D expenditure, although there is a strong company effect. This implies, as argued by the authors, that (the difficult to measure) firm-specific competencies could be important determinants of R&D investment, rather than just price regulation.

Setting prices globally: affordable pricing to ensure access

Given the global need for treatments and vaccines for COVID-19, it is important to consider global pricing issues when thinking about how to define appropriate pricing strategies/models at the country level. Under Ramsey pricing. which was originally explored as a pricing approach for public utilities with large fixed costs, prices should be higher in markets with a lower price elasticity of demand and lower in markets with a higher elasticity of demand, assuring a specified target profit level for the manufacturer, e.g., a firm's target internal rate of return [14]. However, one challenge to apply directly this rule to pharmaceuticals is: who has elasticity, the patients' or third-party payer? It would be difficult, or even impossible, to estimate a true elasticity of demand to determine prices. Moreover, it could be unfair to set higher prices where elasticity of demand is low, if this low elasticity is due to higher need.

An alternative consistent with Ramsey pricing principles [15] argues that income levels could be used to proxy elasticities, and thus higher-income countries would need to pay higher prices. Within countries, the price would be determined on value, but this time expressed as an incremental cost-effectiveness ratio threshold based on its citizens' willingness-to-pay for health. This combination of setting absolute and relative price levels would give rise to value-based differential pricing and would achieve the second-best static and dynamic efficiency. If prices in each country are then set equal to this threshold, then the surplus for the company would be the difference between costs and the threshold. More recently, Chalkidou et al. [14] have argued value-based tiered pricing for low- and middle-income countries (the price reflects with the local value it provides), could improve access, enhance efficiency, and empower countries to negotiate with product manufacturers.

Nevertheless, the empirical evidence is mixed as to whether prices of medicines do differ across countries, and if so, whether such differences can be explained by income levels [16, 17]. The extended use of external reference pricing, whereby prices in one country can depend on prices in countries elsewhere, could, at least theoretically, drive to uniform prices. Again, the evidence is mixed as to whether external reference pricing is causing a convergence in prices, globally, or not [18]. One further challenge to ascertain global price differentiation is the lack of transparency around prices and price systems more generally. With the increase of discounts as part of the managed entry agreements signed between companies and the third-party payers (be them at national, regional, or local level), plus rebates systems at a national level (which entail companies returning funds under certain conditions and which are not product specific) [2], implies it is sometimes difficult to establish the true price of a medicine. Still, there are many unresolved issues that merit further around the issue of price transparency [19].

Moving beyond prices: additional incentives to drive R&D

In addition to prices, other factors drive private R&D, including additional incentives implemented by regulators and policymakers. These are usually defined as "push" or "pull", with different variants, and where a key distinction is whether payment is conditional on the availability of a (successful) technology and thus, how the risks are mitigated. Push-type incentives fund or reward R&D effort ex ante, i.e., irrespective of the outcome, thus reducing research and development costs and failure rates, and reducing scientific risk; pull, however, provides rewards for R&D effort ex-post if the outputs of R&D achieve health gain, thus creating the market and so reducing commercial risk. Examples of incentives reducing (clinical) development costs and risks include the direct funding of research, fiscal/tax incentives, or public–private partnerships while incentives raising profitability include market entry rewards, advanced market commitments, or value-based reimbursement alongside regulatory incentives, such as priority review vouchers, tradable patent extensions, or extended market/data exclusivity. Some, but not all, of these incentives might be relevant for COVID-19 treatments/vaccines.

Over the last few decades, additional incentives have been used with neglected diseases, orphan medicinal products, and pediatric indications, for example, being there a debate on the appropriate balance between them. For COVID-19 treatments and vaccines, Sampat and Shadlen [20], Towse and Firth [21] and Lobo and Fernandez Cano [22] provide a good summaries of current R&D initiatives. It is astonishing the number of initiatives to develop treatments and vaccines for COVID-19, as is indeed the plethora of vaccines in development and companies involved; as of 18 June 2021, 102 candidate vaccines are in clinical evaluation [23], and four had already been authorized by the EMA at the time of writing. However, the vaccines' markets before COVID-19 had been suffering from a continuous decline in the number of manufacturers and developers; an issue already raised more than a decade ago [24, 25].

Law and innovation: time for innovative laws

If patents do not match with pandemics, what are the alternatives?

Patents are a classical instrument (the first patent was awarded in the XV century) within Intellectual Property Rights to incentivize innovation. The patent system works

well as a mechanism that allows the inventor to recover the investment during the (temporary) monopoly granted by the patent. There are advantages and disadvantages of using the patent system, but the key question is: If patents do not match with pandemics, what are their alternatives?

Before moving out from the current patent system, it is important to highlight the flexibilities the system allows for (through the TRIPS—Trade-Related Aspects of Intellectual Property Rights—agreements), voluntary and compulsory licensing. These are not new concepts but have been discussed for new treatments for COVID-19.

A compulsory license allows the "use of a patented innovation without the permission of the patent titleholder" [26]. It has its pros and cons [27]: the patent (and the monopoly that grants) is "an imperfect but effective instrument to promote the development of new products" and the compulsory license is the exception that "sometimes becomes necessary to avoid misuse of monopoly right and to protect the human right to health".

With the voluntary license, the patent holder gives the authorization to a country/generic company to produce the patented medicine as a generic. Already used in the 2005–2006 pandemic flu, where the manufacturer granted a voluntary license to Argentina and Taiwan [26], it was recently used again by Gilead for remdesivir, allowing generic pharmaceutical manufacturers based in Egypt, India, and Pakistan to manufacture for distribution in 127 countries ("nearly all low-income and lower-middle-income countries, as well as several upper-middle- and high-income countries that face significant obstacles to healthcare access)" [28].

Far from these TRIPS flexibilities, some other proposals are being discussed to avoid limiting access to COVID-19 treatments and vaccines due to intellectual property rights. One of the most important characteristics of patents is that it awards the holder a (temporary) monopoly which could generate expensive prices for everyone (and assuming the treatment is ultimately developed successfully), but mainly for developing countries. Without patents, however, the medicine or vaccine will be a public good so everyone can produce it. The question is how can we "transform" an innovative medicine or vaccine into a public good.

During the last years, there have been several proposals, including the well-known "prizes, not patents" by Stiglitz [29]. He proposed an alternative method for funding research, with "a medical prize fund that would reward those who discover cures and vaccines". In the last years, similar approaches (with different names) have been proposed, under the concept of "delinkage". One such initiative is the "Advance Market Commitment", where "country governments and/or foundations […] put aside a pot of money dedicated to purchasing of a potential vaccine meeting a prespecified target product profile (TPP), which does not yet exist and would need to be agreed upon. It could be structured as a market entry prize (lump sum) or a price–volume commitment; either way, the price/prize would be fixed in advance. As a condition of receiving the AMC guarantee, governments could also require the successful innovator(s) to license their vaccines out to local biologic producers at low or zero cost, helping facilitate widespread scale-up" [30].

The more than 10 years' experience with the AMC for pneumococcal vaccines shows the impact of well-designed incentives. According to its latest report, the AMC could be deemed as successful: first, 86% of AMC-eligible countries (63 out of 73) had been approved to introduce pneumococcal vaccines to date, and 60 have included these life-saving vaccines into their routine programs. Second, pneumococcal vaccines are available to Gavi-supported countries at less than 5% of the public price in the USA [31]. A critical issue, also relevant for COVID-19 treatments, is the alternative when countries transit out of this Gavi support program. International bodies, as the European Union, are using some other instruments as Advance Purchase Agreements (APAs), with vaccine producers via the Emergency Support Instrument (ESI) [32] to guarantee the production of the vaccine as soon as it will be (has been) available.

Another proposal has been the COVID-19 Technology Access Pool (C-TAP), proposed by Costa Rica, and launched by WHO and partners in May 2020 to "provide a global one-stop shop for developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to share their intellectual property, knowledge, and data, with quality-assured manufacturers through public health-driven voluntary, non-exclusive and transparent licenses" [33]. When launched, it received significant press coverage; however, in May 2021, the WHO issued a call once again on Member States to actively support C-TAP, as "it remains an underutilized tool" [34].

Still, the issues of pharmaceutical prices, profits, and R&D were actively being discussed before the pandemic. One line of argument was around the request for the nationalization of the pharmaceutical industry under the idea that "Drug companies fail to take account of the public interest and relentlessly focus on short term returns", but with the counterargument that "profits drug companies make are vital for developing new medicines" [35].

Governments vs global interest and the need for global public goods

Before the authorization of vaccines for COVID-19, two events caused some concern to public opinion. First, the agreement announced by the (now former) president of the USA, Donald Trump, with a pharmaceutical company to secure almost the full stock of the first approved medicine for COVID-19 (Remdesivir); second, Germany,

"nationalized" a company that is developing a vaccine for COVID-19 (through the investment of 300 million euros in exchange for a 23% stake).

The situation just described is the consequence of having a competition to "win the race" of getting the vaccine/treatment, its patent (monopoly), and the revenues that are associated with it. All the private goods (including medicines, vaccines, etc.) have rights associated with them. This is the traditional scenario; the issue is whether such rights should apply, or not, during the pandemic scenario?

In an alternative scenario, a proposal would be to "convert" the medicines and vaccines (i.e., private goods) that are launched in the market under a pandemic situation to public goods. But the traditional public good is the "knowledge", because it fulfills all the criteria for being a public good: "their benefits are enjoyed by all (non-excludable) and consumption by one individual does not deplete the good and, thus, does not restrict its consumption by others (non-rivalrous)" [36]. Thus, in the case of vaccines and medicines, the proposal is not that the vaccines or medicines will the public good, but the rights (patents) that are around them, so every country can produce them without restrictions. However, this "would not replace patents. It would be part of the portfolio of methods for encouraging and supporting research" [29]. In the past, there have been several initiatives (primarily focusing on research and development funds) also supplementary to the patent system, mainly with the need of targeting disease for low-income countries (as the Global Alliance for Tuberculosis Drug Development).

Several other authors have highlighted the need for more demand (market) side incentives (i.e., pull type) for "for de-risking the market, incentivizing innovation, and scaling a potential vaccine for the COVID-19 crisis" [30]. Four key characteristics need to be taken into account when assessing the appropriate mix of incentives: "(1) Shared burden and demand across high-income, middle-income, and low-income countries, (2) Non-viability of a traditional profit-maximizing sales strategy, (3) Need for massive, rapid scale-up, and (4) Existence of substantial push funding" [30]. These characteristics are different from the 'traditional' medicines or vaccines markets.

The EU has acted as a life guard regarding the distribution of the different vaccines to European markets. Thanks to a centralized acquisition a balance between innovation/gains for the big pharma (Pfizer-BioNtech, Moderna and Oxford-AZ) and a fair price has been (sort of) achieved.

However, it is time to raise awareness about what is the most pertinent model to regulate the entry of vaccines to the market under both a pandemic scenario and regular circumstances.

Conclusion

The current health crisis may be an opportunity to face three challenges that, although they were already relevant, are now essential to guarantee the sustainability of health systems: the lack of advocacy in public health, the difficulty in setting fair prices agreeable to all parties, and the rigidity of medicines regulation.

Perhaps, the solution passes by meeting halfway: medicines and vaccines under global threats (pandemics/global sanitary crises) shall become global common goods (or at least the patent around them). They should be managed through global governance that starts with a strengthening of public–private partnerships. The life-sciences industry should lead the change towards this new era. We are talking about real innovation: another way of doing things. The current situation with an EU agreement where the vaccines prices are similar in all the countries and the distribution of vaccines is related to the population is a good example of cross border collaboration that can be extrapolated to other situations.

In the current pandemic situation, there is hardly any debate about the price of most of the new vaccines. Three are three main reasons for that: (1) part of R&D has been made thanks to public funding; (2) due to the previous situation, the vaccines will arrive to the market with a pre-agreement in price (so, there is no "classical" negotiation process); and (3) most of the countries will cover the vaccines with the national public budget. This give us some ideas about how health priorities could be funding R&D in the future.

Public Health, Regulation and Pricing shall act as one under stronger public–private partnerships. Leadership among main actors—government and life-sciences industry—is compulsive. The EU latest role buying, fixing prices, and distributing vaccines goes in the right direction.

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