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PUBLIC HEALTH POLICIES FOR THE COMMON INTEREST: *RETHINKING EU STATES´INCENTIVES STRATEGIES WHEN A PANDEMIC RESHUFFLES ALL INTERESTS.*

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Abstract
The current pandemic has reorganised government priorities, putting the health sector in the first place. Historicly large research and development funds have been earmarked for preventive and therapeutic research. Furthermore, labor, state aid and other laws have also been urgently amended to minimize the negative economic impact. We are facing a situation where the globalization status quo and the welfare state have been compromised. However, this may present an opportunity to improve upon some crucial issues regarding the relationship between the different stakeholders in the health sector. In this paper, we discuss two main challenges:

First, the eternal tightrope walks on getting 'fair' medicines prices without compromising the industry´s innovation incentives. Pharmaceutical pricing needs to balance ensuring access to patients and encouraging continuous innovation while not overburdening health care systems

Second, regulation. The COVID-19 pandemic has forced countries to intervene in the approval of new treatments and especially vaccines. Law must not be static especially in times of urgency, but rather facilitate the needs of society.

In a context where the pharmaceutical industry has consistently beat the market in terms of Return On Investment since the 1950s, here we propose some guidelines on how the public-private collaboration could develop in the next few years.

Keywords
Pricing, legislation, pandemic, public-private cooperation

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Introduction: Diminishing returns, increasing costs and a reliability crisis

The paper "*Should governments buy the drug patents?"* published in the *Discussion point* of the European Journal of Health Economics thirteen years ago [1] reflected on aspects that are becoming relevant again, both for good and bad reasons. In the last 60 years, we have seen huge advances in many of the scientific, technological and managerial factors that should tend to raise the efficiency of research and development (R&D) of commercial medicines. Yet the number of new drugs 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. per-capita medicine spending. However, since then, spending growth in the U.S. has dramatically outpaced other advanced nations. While per capita spending in the U.S. today exceeds US$1,000 a year, the Germans and French spend about half of it. USA citizens use fewer prescription medicines, and when they do, they are more likely to use cheaper generic versions. Instead, the discrepancy can attributed to one main issue: prices. Lacking even rudimentary price controls, U.S. consumers bore the full brunt of the expensive development work that goes into new medicines. These costs were further increased by marketing expenditures and profit-seeking practices by all entities within the pharmaceutical supply chain. Moreover, the so-called pharmacy benefit managers add further complexity since they are driven by profit maximization.

Finally, the U.S. has undergone a series of coverage expansions, including the prominent creation of 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 and pent-up demand was released. However, it also encouraged pharmaceutical companies to take advantage of the newfound payers for their drugs[3]. In fact, despite the loss of efficiency in R&D spending, pharmaceutical companies have routinely overperformed the market in terms of return on investment and become an almost risk-free investment option.

The controversy argues from two extremes. On the one hand, debates over pricing and reimbursement of new and innovative medicines have become increasingly dominated by excessively high prices that challenge the sustainability of the publicly funded healthcare systems. In many cases, the price is not related to the benefit expected by the treatment while the costs of R&D seem to be shrouded in a cloud of mystery. On the other hand, 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[4]. As Sarewitz, D. (2016) states, scientists are

generating an unmanageable amount of knowledge, but most of it is “contestable, unreliable, unusable, or flat-out wrong”.

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 European Medical Agency, EMA, has recently stated its will to revise intellectual property laws, facilitate the competitiveness of healthcare markets and promote R+D that address unmet medical needs, both by 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, as seen in the collaboration of the Sanofi & GSK on vaccine development [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 abolish intellectual property. Governments should seek to authorize new medicines faster but more cautiously, as the best way to balance innovation and prices. This may be done through properly measuring value and introducing economic evaluation as the fourth hurdle.

In a context where regulatory organisms are less risk-averse and more internationally homogenous, but more demanding in terms of clinical value, those 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. For our purposes, it is useful to distinguish between country-level decisions and global pricing interrelations. At a national level, and broadly speaking, there could be, at least, two options (or extremes) to determine the price of a treatment/vaccine: either that based on costs or that based on 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). This is because profits of the manufacturer would be zero, or negative, depending on if there are some fixed or sunk costs, which would not be (re)covered. By increasing prices over marginal cost, we would be transferring surplus to the manufacturer. A critical question arises: how much higher should the price be over production costs? Moreover, should cost-plus prices also incorporate R&D costs and not just production costs? Alternatively, the price of the medicine could be based on its value, measured up to a 'threshold' (with some exceptions), being that threshold based on a country's social willingness and capacity to pay.

The experience in the US with the first treatment authorized for COVID-19 patients, and its subsequent evaluation by the Institute for Clinical and Economic Review (ICER)[9-11], shows the implications of using either a cost-plus or a value-based method, and the complexities and challenges with applying them in practice. For instance, in the case of the ICER's review, under the cost-plus method, the resulting price to cover minimal marginal cost and 2020 projected manufacturer R&D costs is 320 times higher than the price that would just cover minimal marginal cost (out of the R&D costs). Also, under the cost-effectiveness approach, the resulting price would depend on the incremental cost-effectiveness threshold assumed. And when comparing across methods, the value-based price can be upto 3000 times higher than the minimum price required to cover just minimal marginal costs. Or upto 9 times higher relative to the resulting price when minimal marginal cost and 2020 projected manufacturer R&D costs are covered. This example also highlights the challenges of measuring the relevant costs under the cost-plus method. Under the value-based option, it is interesting to note that ICER explained that the public health emergency justified scaling the threshold down, although they did not elaborate further on this.

But price controls for medicines might have many different objectives, depending on the country's perspectives and situation. Mestre-Ferrandiz et al [12] offer nine (country-specific) objectives of price controls for pharmaceuticals 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) that prices reflect (relative) value, increasing value for money and competition.
3. Help to control (public and private) pharmaceutical expenditure/budget and balance the payer's affordability issues.
4. Promote a dynamic pricing system, to encourage monitoring and evaluation of results, allowing flexible pricing over time.
5. Encourage an 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 a 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? Could price regulation affect R&D investment of companies? A recent paper [13] has revisited this old question. Theoretically, price regulation can affect R&D via intermediate variables, such as cash flow and profitability, if (i) price regulation affects cash flow and profitability, and (ii) cash flow/profitability affects R&D expenditure. The authors build on previous research, uses the latest available data from 2000 to 2017 for the top 10 pharmaceutical companies and find that indeed price regulation may affect R&D expenditure, although there is a strong idiosyncratic company effect. This is because once firm fixed effects are included in the regression, while price regulation still continues to relate negatively to cash flow and profitability, there is no significant relationship of price regulation with R&D intensity, where R&D intensity is R&D expenditure divided by sales. Interestingly, and as reported by the authors on the relationship between price regulation and R&D intensity: "Although the point estimate itself remains unchanged (with company-specific effects) … the standard error increases rendering the statistical association insignificant". The paper then concludes that (the difficult to measure) firm-specific attributes may be important determinants of the 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.

We believe the concept of Ramsey pricing provides one possible framework to determine relative price levels across countries of different income levels. Under

Ramsey pricing, which was originally explored as a pricing approach for public utilities with large fixed costs, prices are chosen in each market in inverse relation to the demand elasticities, and subject to assuring a specified target profit level for the manufacturer, e.g. a firm's target internal rate of return [14]. This means prices should be higher in markets with a lower price elasticity of demand and lower in markets with a higher elasticity of demand. However, one challenge to apply directly this rule to pharmaceuticals is: who's elasticity, as mentioned above – 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.

As an alternative, but consistent with Ramsey pricing principles, [15] argue 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, expressed as an incremental cost-effectiveness ratio threshold based on its citizens' willingness-to-pay for health – as argued before, this would represent the 'value-based-approach' to pricing. 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] argue that a strategic system of value-based tiered pricing for low and middle-income countries, wherein each country would pay a price for each health product commensurate with the local value it provides, could improve access, enhance efficiency, and empower countries to negotiate with product manufacturers.

In practice, it is probably fair to say that 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]. Also, to add to the complexities, the use of external reference pricing, whereby prices of medicines in one country can depend on their prices in countries elsewhere, could, at least theoretically, drive to uniform prices. Again, the evidence is mixed as to whether external reference pricing is indeed 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].

Relating to price-setting approaches, perhaps for the low-income countries, marginal cost pricing can be used as a ceiling to set prices and acknowledging that in some countries the only feasible solution would be to supply at (basically) free-cost. Moreover, there are alternative and complementary options to widen access to treatments in lower-income countries, as discussed later.

Moving beyond prices: push and pull incentives to drive R&D

Price regulation might be a determinant of private R&D, although other factors play an important role, including additional incentives implemented by regulators and policymakers to encourage R&D. Such incentives can be characterized as "push" or "pull", the distinction being whether payment is conditional on the availability of a (successful) technology and thus how the risks are mitigated. In other words, push 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 push incentives include the direct funding of research, fiscal/tax incentives, or public-private partnerships while pull incentives 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 exclusivity. Some, but not all, of these incentives might be relevant for COVID-19 treatments/vaccines.

Over the last few decades, and since the experience we have had with neglected diseases, orphan medicinal products, and pediatric indications, for example, where the additional push and pull incentives have been implemented, there has been a debate as to the appropriate balance between them. For COVID-19 treatments and vaccines, in particular, Towse and Firth [20] and Lobo and Fernandez Cano [21] provide a good summaries of current R&D initiatives (table 1). 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 29 December 2020, the WHO Draft landscape of COVID-19 vaccines stated there were 60 candidate vaccines in clinical evaluation [22], and one had already been authorized by the EMA at the time of writing. We should not forget that 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 [23, 24].

Table 1: COVID-19 treatments and vaccines: current R&D initiatives (Own elaboration)

Category	Description
Push	Operation Warp Seed in the US, the Coalition for Epidemic Preparedness (CEPI)
Pull	The COVID-19 Vaccine Global Access Facility (COVAX)
BBAMC	Benefit-based advanced market commitment
Mix	The WHO Access to Covid Tools (ACT) Accelerator, Accelerating HT, Gates

Analyzing how incentives and business models for antibiotics have been evolving might be a useful analogy to explore to assess the best options for models for COVD-19 treatments and vaccines. While recent push initiatives have been implemented in part

to give time for governments "to create market conditions that enable sustainable investment in the antibiotic pipeline" (AMR Action Fund [25]), our focus here is on the experience with pull incentives, and in particular, to highlight the concept of "de-linkage". With a de-linkage model, the return to the company is delinked from the traditional 'price * volume' model, as the return is independent of usage and volume. This model has been also referred to as the subscription or the Netflix model [26], and it is also similar to the concept of an advanced market commitment.

What is important to highlight, however, is the difference in the rationale for the use of such a model between antibiotics and treatments/vaccines for COVID. For the former, the market failure comes about because we want a new antibiotic, but we do not want to use it, to mitigate the buildup of resistance; thus, market revenues measured by the traditional model would yield very low volumes. This, in part, makes it unattractive for developers – albeit acknowledging there are many complex issues behind the failure of the current model for antibiotics. For the latter, of course, once there is a treatment/vaccine that works against COVID-19, the objective would be to expand access as much as possible. So, the 'failure' would not arise from low volumes, but rather, because of the potential budget impact. This would make the traditional model unattractive for the payer.

A critical issue, among others, with the de-linkage model, is how to determine the magnitude of the "prize" or reward for the company. There could be two options; first, the payment is related to the "value" of the product. Second, the payment is calculated to ensure an appropriate return to the company. These two options resemble, in spirit, the VBP and 'cost-plus' approaches respectively discussed before for price-setting. However, with these de-linkage models, the notion of 'price per unit' tends to be less relevant (as it would depend on the size of the payment, and not on the units sold).

We have very limited experience with such de-linkage models for antibiotics, as only now are we starting to see some real action. There is encouraging news from the UK and Sweden, however. The former agreed in 2019 to test a pilot "subscription model", and in April 2022, two antibiotics will be funded via this model. The magnitude of the annual reward for the company is capped at GBP10m per year but will be determined based on the product's value. To determine such value, NICE will evaluate the two antibiotics (in 2021) but using an adjusted HTA framework to factor in the characteristics of antibiotics, such as insurance value, diversity value, transmission value, and enablement value [27], which are not included in the usual HTA framework.

In Sweden, the "de-linkage" model is intended to secure the availability of supply of antibiotics, whereby the state guarantees a minimum annual revenue to the pharmaceutical company, and in return, the company delivers a certain amount of antibiotics within specified time limits. For the time being, Sweden will start a pilot to investigate whether the model is efficient and effective, which will run until 2022. Thereafter, the project will recommend to the Government whether, and in what way, the model should be implemented in Sweden [28]. It is important to highlight that the focus of both schemes is for antibiotics treating critical pathogens with the highest clinical need.

What is relevant is that some kind of “de-linkage” model could be used for COVID-19 treatments and vaccines. But important to differentiate between higher-income countries, and middle and lower-income countries, as strategies could be different.

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), mainly because the concepts of voluntary and compulsory licensing have been discussed for new treatments for COVID-19.

A compulsory license is a special license that allows the "use of a patented innovation without the permission of the patent titleholder" [29]. As already commented by many authors, the use of compulsory licenses have pros and cons [30]: the patent (and the monopoly that grants) is an "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. In the 2005-6 pandemic flu, for instance, the manufacturer granted a voluntary license to Argentina and Taiwan [29]. More recently, Gilead informed [31] that they "had signed non-exclusive voluntary licensing agreements with generic pharmaceutical manufacturers based in Egypt, India, and Pakistan to further expand the supply of remdesivir. The agreements allow the companies […] to manufacture remdesivir for distribution in 127 countries". The reasons for selecting these countries have not been disclosed, although it is stated that these "countries consist of 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". This distinction between LMIC and HIC might be important for designing optimal pricing and access strategies for COVID-19 treatments and vaccines, as argued later.

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" proposal by the Nobel laureate in economics, Joseph Stiglitz [32]. 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, and as alluded to already, there have been similar approaches (with different names) 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" [33].

It should be noted the pilot AMC for pneumococcal vaccines (PCV), which we understand is the only use of an AMC so far but hopefully not the last, completed its tenth year of implementation in 2018. According to its latest update (AMC Secretariat of GAVI, 2019), the AMC could be deemed as successful. For example, out of the US$ 1.5 billion AMC funds, the two suppliers that offer prequalified PCV have been allocated US$ 1.238 billion, meaning that 17.5% of the total AMC funding remains available. In terms of country demand, 82% of AMC-eligible countries (60 out of 73) had been approved to introduce pneumococcal vaccines to date, and as of 31 December 2018, 59 countries have included these life-saving vaccines into their routine programs. In terms of prices, pneumococcal vaccines are available to Gavi-supported countries at less than 5% of the public price in the USA: for instance, and by early 2019, Gavi had secured the lowest price offer from one of its pneumococcal vaccine suppliers of US$ 2.90 per dose [34]. However, one critical issue, which will be also relevant for treatments for COVID-19, is the alternative when countries enter the pathway to transition 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) (European Commission, 2020) to guarantee the production of the vaccine as soon as it will be (has been) available.

Several proposals have arisen in the last years with a similar objective, but possibly one proposal with significant press coverage and appearing more in the headlines is the Costa Rica proposal to WHO to make the "COVID-19 Intellectual Property Pool" or the "Access to COVID-19 Accelerator"[35]: a "platform for open, collaborative sharing of knowledge, data and intellectual property on existing and new health tools to combat COVID-19".

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"[36].

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); secondly, 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 the alternative scenario, the 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)" [37]. 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. As it was commented by Joseph Stiglitz [32] in his initiative related to the prize fund, this "would not replace patents. It would be part of the portfolio of methods for encouraging and supporting research." 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 incentives) for "for de-risking the market, incentivizing innovation, and scaling a potential vaccine for the COVID-19 crisis"[33]. Still, Silverman et al. identify four key characteristics that define the current market for a vaccine under the global pandemic crisis that 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, 4) Existence of substantial push funding". 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´s 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 European Union 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); 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 central buying with fixed price purchase, and distributing vaccines among member states goes in the right direction.

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