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Predicaments during a period of health emergency: Waiving patent protections or innovative public procurement? The example of advance purchase agreements (APA) for COVID-19 vaccines

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Abstract.
BACKGROUND: The health emergency provoked by the worldwide pandemic requires immediate action to achieve the immunization of the population and to stop further contagion. The systems of public procurement needed to adapt in a very short time to reach agreements with the pharmaceutical industry.
OBJECTIVE: Proposing options between the waiving of patent protections and innovative public procurement, principally the European Advance Purchase Agreements (APA).
METHODS: A description of the actual situation and the necessary regulatory reforms. The sources are scientific articles, legislative compendiums and opinion pieces and the current press.
RESULTS: The debate over the waiving of patent protections at this time is both misleading and ineffective due to the economic and legal problems involved. The path of the APA has proven to be very effective, although some deficits should be corrected, principally regarding questions of transparency and confidentiality.
CONCLUSIONS: Among the possible options for the acquisition of the COVID-19 vaccine and its universal access, agreements and cooperation between States and innovative industry are desirable. One successful path is that of the advance purchase agreements utilized by the European Union, another could be that of voluntary licensing. We propose following these routes as opposed to the waiving of patent protections.

Keywords: Vaccines, patent protections, advance purchase agreements (APA), COVID-19

1. The context: The competitive improvisation of the States to the European centralization of procurement, with respect to the COVID-19 vaccine as a "global public good"

The declaration by the World Health Organization on March 11, 2020 of an international pandemic provoked by COVID-19 made necessary the adoption of urgent measures to mitigate the impact of an unprecedented crisis with enormous human and economic costs. Our legal and health care systems were not prepared for public procurement in a pandemic crisis [1].

The containment of the epidemic required a massive process of immunization, to limit, but especially to prevent, the rapid spreading of the virus, all in the context of scientific uncertainty. These two elements precipitated an international strategy of collaboration previously unheard of. The challenge, of global dimensions, recommended bolstering research and development in the pharmaceutical sector and reducing bureaucracy, to facilitate the most rapid approval and marketing of the distinct vaccinations which had been authorized. This challenge also led to absolutely novel actions in the field of public health, with the European Union leading, since the onset of the epidemic, the global effort for treatment and universal vaccination. In June of 2020, the European Union, under the legal umbrella of art. 168 TFUE[1] adopted, for the first time in its history, the decision to "centralize" the negotiation and acquisition of vaccines in the name of all of the States, through the mechanism of advance procurement agreements. The process would continue for each State through the common and sole authorization of the European Medicines Agency, proceeding in a centralized form with the massive acquisition of the distinct vaccines. The management of the process of acquisition, prioritization of groups, or the logistics of vaccination are questions which would be left to the distinct States. These agreements include European financing, as a down payment, to the pharmaceutical companies, in exchange for the right or obligation of the States to buy a determined number of doses at a fixed price within a certain timeframe. In this context the conditional authorization of marketing, valid during one renewable year, obliges the holder of the authorization to complete studies confirming that the risk/benefit relationship continues to be favorable.

It is necessary to know that the development of vaccines is a highly complex process which generally takes about ten years, but the pandemic has required greater speed. The process of advance acquisition, anticipated legally but not utilized at the European level, would be the impetus for accelerating the process of acquisition, inasmuch as it implies complete collaboration between public institutions and pharmaceutical companies within the framework—at least theoretically—of transparency and fairness. Even though the legal framework existed it became necessary to adapt EU regulations to the current urgent situation.

Nevertheless, it could be that in the context of a worldwide pandemic, even these initiatives for multinational response are not sufficient. When dealing with global public good (and bad), collective action is required because it has been demonstrated that neither prejudice nor benefit recognize borders. In the name of solidarity, or even purely as a defense mechanism, the mechanism of COVAX [2] has arisen at the international level, codirected by the Global Alliance for Vaccines and Immunizations (GAVI), with the participation of UNICEF, the Coalition for Epidemic Preparedness Innovations (CEPI) and the World Health Organization (WHO). The European Union joined this initiative with its Vaccines Strategy of the 17th of June, 2020 [3]. It was implemented as a specific mechanism within the so called Accelerator of Access to the Tools against COVID-19 (ACT-A), a worldwide collaborative network created to accelerate

[1] This precept permits the EU, in order to achieve the objectives which at the State level are difficult to accomplish to reach a common action, to promote a policy of coordination while respecting "the responsibility of the Member States with respect to their health policies as well as the organization and provision of health services and medical care".

the development, production and access to diagnostic tests, treatments and vaccines. Its goal is to promote the equitable distribution of vaccines in all of the States, integrating a public/private alliance for the financial support of the urgent distribution of vaccines with the objective of assuring that all of the countries have access to the vaccine without regard to their income levels. Nevertheless, the 80.7 million doses distributed to 129 countries are still far below the commitment to distribute more than 3860 million doses in the coming years [4].

This situation precipitates an intense debate as to whether the provisional suspension of patents is, in the short term, the most effective way to accelerate the vaccination of humanity against COVID-19.

The uncertainties are not only scientific or technological, but also economic, geopolitical and logistical. No less important are the legal problems of a regulatory framework that plays on several sides in the context of supra-national law based on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) and the Doha Declaration of 2001 over the agreements of TRIPs and Public Health.

From there, looking at the present, but especially at the future, the Rome Declaration [5] encourages a non-short-term strategy regarding various aspects of our health systems, but especially with respect to vaccinations. Regarding the former, focusing on "One Health", which is fomenting sustained investment in global health, with a view to achieving Universal Health Coverage, placing primary care at the epicenter, with the idea that preparation and resilience are broad macroeconomic and social investments in the public good, and that the cost of inaction could be even greater. Respect is given to the role of extensive immunization against COVID-19, which is considered the principal of these global public benefits.

This is not the first time that the superior value of vaccines has been mentioned. It was already recognized at the beginning of the European Vaccination Strategy and explicitly crystalized in the Decision of the Commission of the 18th of June, 2020 through which the agreement was approved by the Member States regarding the acquisition of vaccines in the name of those States and the related procedures [Document C(2020) 4192 end], which contains, as an annex, the agreement that Member States signed with the Commission to join in the centralized procurement process. In the case of Spain, the agreement was signed on the 20th of July and published in the BOE (Official State Bulletin) on the 5th of August, 2020 [6]:

> *"In negotiations with the pharmaceutical industry in the framework of the present Agreement, the Commission considers the vaccine against COVID-19 as a global public benefit. Said consideration includes access by low and medium income countries to these vaccines in sufficient quantities and at moderate prices. The Commission intends to promote determined aspects associated with the pharmaceutical industry as they relate to the distribution of intellectual and industrial property, especially when this has been developed with public financing, to achieve these ends. The vaccines available in virtue of the APA which have concluded but which result as unnecessary and which have not been acquired by participating Member States can be added to the efforts of global solidarity."*

The central question, in my judgement, deals with finding a balance point which achieves the significance and universal access of this global public good, in a situation where speed is the key, but doesn't alter the rules of the game in a market where innovation is fundamental. We must prepare, not only for the COVID-19 vaccine, but also for the political, legal and technological anchors that could be required in other global emergencies, which could surpass the deficits and the improvisation which marked the beginning of the pandemic. Because extremes and false dichotomies are not the most expedient, I don't believe that the solution should be seen in the strict terms of "patents yes or no". Toward that end we could forget about intermediate states that are probably more adequate, effective and legally viable. This proposal is what we are going to try to develop here.

2. Lessons learned: To increase global production capacity and promote value based purchasing

It has been pointed out that each year as many as five zoonotic viruses, products of new interactions between man and animal, emerge in the world. SARS-CoV-2 is one of them, but we can be sure it will not be the last [7]. Therefore, the Declaration of Rome insists on the necessity to prepare ourselves for the future, using the lessons we have learned from this pandemic. One of the principal focal points will be how to anticipate future threats through the development of an extensive arsenal of vaccines.

Technologically, the speed in the development of COVID-19 vaccines is a consequence of the research and development begun more than a decade ago, driven by the epidemic outbreaks of SARS-Cov-1, MERS and Ebola, and of the previous research efforts for a vaccine against HIV. On the other hand, new tools like CRISP-R (clustered regularly interspaced short palindromic repeats) have accelerated the research into therapies based on DNA and RNA, originally for the treatment of neoplasia. The success of mRNA vaccines in clinical trials highlights the potential of mRNA technology to be the future of medicine. The rapid development and clinical success of COVID-19 mRNA vaccines can be credited to the relationship between inventors and innovators [8]. Therefore, initially we can count on the advantages of the platforms which have successfully overcome the regulatory phases, permitting a considerable saving of time and money.

Nevertheless, vaccinations became an important liability some years ago, due to lack of incentives and poor profitability compared to other medications, to the point that today there are only five companies (GSK, Merck, Pfizer, Sanofi and CFL) that remain dedicated to this essentially European market [9]. The depleted investment in public health (3% of the total spending on health on average) is another of the big perennial problems.

The reasons are varied. One is the uncertainty of the market: it is difficult to anticipate when an epidemic outbreak might become a pandemic, with the eventuality of the insufficiency of cases which go to clinical trial to verify safety and efficacy. Another is the purchasing model, based fundamentally on price, which doesn't value the specificity of vaccines compared to other medications, given the limited production and extended time frames. Thus the need to strengthen the collaboration between health authorities and manufacturers with a stable and strategic model of "value based purchasing" which improves predictability for both, and in particular, the capability of responding flexibly in the case of a public health threat. With these things in mind, it has been pointed out that we should be prepared for a future which requires increasing production capacity and facilitating technological transfers, creating supranational ecosystems with highly qualified human resources, quality control systems, guarantees of supply and adequate equipment, in a stable and predictable regulatory framework, equipped with innovative financing instruments in the form of advance contracts or financing schemes adequate for high risk innovation and extended time frames [10].

The current problem is not so much one of prices as it is of production, supply and distribution. Under the guise of solidarity which is being celebrated, there is evident vaccine nationalism. As much as we are in the COVAX initiative to distribute vaccines to the poorer countries, the rich countries, just 13% of the world population, have hoarded more than half of the vaccines for themselves [11].

Then the relevant issue is how to guarantee that the universal access, that is always, but even more so in times of a pandemic, seen as essential. And as expected, the age old debate over the waiving of patents, voluntary licensing agreements and other exemptions for intellectual property have rearisen like the Phoenix. Is this the way? Or rather, is this the easiest, most populist way out, to hide other underlying problems like the possibility of over vaccination, the defects in prioritizing, or the selfish hoarding of doses in the northern hemisphere?

3. Patents and vaccines: Advantages and inconveniences. Are waivers really the most adequate alternative to guarantee short term universal access?

In May of 2021 in a historic move, the US government announced that it supports waiving patent protections for COVID-19 vaccines, a measure aimed at boosting supplies so that people around the world can get the shots [12]. On the 11th of June, 2021 this debate arrived unresolved at the European Parliament which, in a Resolution approved with 355 votes in favor, 263 against and 71 abstentions, proposes opening negotiations for the temporary suspension of patents on vaccines against COVID-19 [13]. The principal argument is that 11,000 million doses are necessary to vaccinate 70% of the world's population, and that only a part of this percentage has been covered, and even more grave, only 0.3% of the doses have arrived at the 29 poorest countries. The waiving of patent protections would supposedly facilitate the global access to affordable vaccines, with the transfer of necessary knowledge and technology being the key to increasing global production of the vaccines in the long term, calling for the USA and the United Kingdom to lift the veto on the exportation of vaccines and raw materials, as well as to support the COVAX mechanism in global distribution.

The classic debate over the waiving of patent protections has taken on somewhat particular tones in this pandemic. To accelerate the global availability of vaccines we move between two non-exclusive axioms: one ethical, which proposes that no right to protection of intellectual property comes before the right to health and the right to life; the other, tied to the principle of paternalism, employing solidarity and self-interest, which (for egotism or intelligence) encourages action in countries with minimal resources to avoid the propagation of the pandemic [14]. Meanwhile, the undeniable success of the process of authorization and marketing of the vaccine has only been partial, as problems have already manifested themselves with regard to production, either expected or promised. Sufficient private investment in innovation and technology has not been obtained, in spite of the strong, and until now almost unexplored, public investment. Additionally, some of the businesses which produce the marketed vaccines (AZN and Janssen) have explicitly forgone benefits while the pandemic endures.

In light of these peculiar circumstances it is notable (to a point) that the debate over patents has resurfaced with significant force, as if it were the key which would solve the problems of universal accessibility.

We are not going to insist on a discussion over that which is already well known. For the time being, no other instrument exists which is as effective in providing incentive for innovation and fomenting its diffusion. But, additionally, it is important to remember that patents protect rights like intellectual property, freedom of scientific creation and research, or even private property. And that the great benefits that these have provided in the field of health don't only satisfy individual interests but also public interests as inherent to progress, driving a model of shared advantages of the derived benefits [15].

The *Trade Related Aspects of Intellectual Property Rights* (TRIPs) and the World Trade Organization (WTO) have controlled the rules of the game and protected patent rights internationally since 1995.

Most assuredly the solution is not simple. The evolution of the monopoly system linked to patents also has its critical points. This privilege has led to where only those who can pay (effective demand) have at their disposal a product which probably wouldn't exist without this powerful incentive, which on occasion, as in the case of vaccines, has a value far superior to its price. In addition to the barriers to diffusion of knowledge, there are the double cost to society if financing of R+D is public, or the specific added problems when dealing with health patents, such as *pay for delay* (payments to delay the arrival of the first generics to the market when the patent expires), *evergreening* (re-patenting the same product with some slight modification to extend the term of protection) or defensive patents.

Certainly these deviations have fostered an important critical mass against the model, and they don't help to focus the terms of a necessary debate. But, in the current situation, and said in the strictest terms of efficacy in guaranteeing universal immunization, temporary elimination of patent protections betting on coercive licensing, could carry effects adverse to those desired. These compelling reasons have been pointed out [16]:

(a) The limitations on current supply come from the scarcity of raw materials and the demands for quality in the manufacturing process, not from innovation incentives, which there have been, primarily of a public nature and also with the assumption of the risk of failure in the research. Many of these materials are difficult to produce and are subject to their own patents (which may have markets in products distinct from COVID-19 vaccines)[2].
(b) The expansion of the manufacture of vaccines also requires the transfer of very complex technology; it is difficult to complete the production if the local manufacturers don't have special resources and training in innovative vaccines.
(c) There is no experience in the implementation of obligatory licenses, resources, technical and legal requirements. In a process led by the WHO the States should adapt their regulations on intellectual property and surely this will not be an easy or quick question.
(d) Additionally, public financing agreements will be necessary for the payment of obligatory licenses, for the vaccines which are of generic manufacture and for the rest of the licenses tied to production.

Are we really prepared for this process? And above all, will it arrive in time to achieve the group global immunity intended in record time?

According to Ortún et al. there are other less traumatic alternatives that could be tried in the meantime, and which could serve as a test bench against other possible future threats: the acquisition of patents by Governments, at auction and at social value for their transfer to the public domain [17]; substitute patents with "prizes" or "dividends" so as not to impede the transfer of knowledge, discourage the costs of diffusion and anti-competitive behaviors which artificially increase the benefits of monopolies; or finally, advance purchase agreements for vaccines in the research phase, as long as they are well armed legally and do not allow neglect of the most vulnerable collectives.

The latter of these have shown themselves to be, with regard to the COVID-19 vaccine, alternatives capable of reducing risks and costs, promoting research, achieving a reduction in bureaucracy through the centralization of purchasing and research times, without altering the security, quality and efficacy of the final process. This has been the bet of the European Union, and supposedly the first precedent, of great value, that should continue to be explored to correct errors and deficits that have been shown. We refer to this mechanism hereafter.

4. Betting on a common vaccination strategy against COVID-19: advance acquisition agreements

With the arrival of the vaccine on the horizon the European Union presents a combined strategy taken from the accurate premise that:

[2]The complexity of the production processes is clear, for example, with the Pfizer vaccine. For its production, around 280 materials come from 86 different suppliers located in 19 countries; between 10–15 raw materials are needed including plasmid DNA, nucleotides, protection agents and lipids-, and more than 40 independent quality control tests are carried out for each finished lot.

"No Member State on its own has the capacity to secure the investment in developing and producing a sufficient number of vaccines. A common strategy allows better hedging of bets, sharing of risks and pooling investments to achieve economies of scale, scope and speed." [18]

The advantages of this bet are obvious. All Member States will be able to benefit from the option to purchase the vaccines through a single public procurement action at the European level. The pharmaceutical businesses would have access to a considerably simplified negotiation process, by way of a single point of contact, which would reduce costs and improve regulatory security for all parties. The European focus also permits the avoidance of "undue" competition for the acquisition of vaccines between Member States, and at the same time favors solidarity between them, independent of the size of their populations and their powers of acquisition.

In short, to the promptness with which the EU has acted, other positive effects of centralized purchasing can be added, like the **collective negotiation** through which tangible benefits have been obtained, the coordinated actions which permit **equitable distribution** of the doses among the European Member States, and the **diversification of purchasing,** as the agreements are not made with a single provider, thereby increasing production and adjusting prices.

The chosen mechanism will be the *Advance Purchase Agreements* (APA)[3] foreseen in the Agreement between the European Commission and the Member States over vaccines against COVID-19, with a regulatory base in the Rules over the provision of urgent health care [19].

4.1. Key questions

In the agreements signed by the Member States with the Commission the essential characteristics of the APA are very succinctly specified, and their negotiation and signing are entrusted to the Commission. Fundamentally, it is stated that, during the negotiations with the companies, the best conditions will be sought, which in the contracts will specify all of the payments to be made, details of the distribution of the vaccines once they have been authorized, price per person immunized, laws applicable to the contracts (which will be the same for all Member States) and the relevant courts.

With these proposals, the European Commission invited the pharmaceutical companies to express their interest in having this type of agreement, giving preference to those which could begin clinical trials of the vaccines in 2020 and which had the proven capacity to produce them on a large scale during 2021[4] [20]. The purpose of holding various contracts was to diversify the purchase of vaccines at a time when it was still unknown which vaccines would be authorized, if all would finally be authorized, the surplus could be turned over to third countries [21]. In short, the efficacy and enforceability of these contracts depend on a suspensory condition, inasmuch as until the vaccines are manufactured successfully and receive the authorization for their going to market, the full legal effects of the contracts will not be seen.

[3]On the 18th of June, 2020 the Decision of the Commission, the agreement among the Member States over the acquisition of vaccines in the name of those States and the related procedures was adopted. [Documento C(2020) 4192 final] contains, as an appendix, the agreement which Member States must sign with the Commission in order to be part of the centralized purchasing procedure. In the case of Spain, the agreement was signed on the 20th of July and published in the BOE on the 5th of August, 2020.

[4]During the last five months of 2020 the Commission signed contracts with distinct pharmaceutical companies and is currently in negotiations with other companies. Specifically, 2,300 million vaccine doses, totaling an estimated 21,000 million euros with the following companies: BioNTech/Pfizer, Moderna and AstraZeneca, Sanofi-GSK; Janssen Pharmaceutica NV, of the Johnson & Johnson group, and CureVac, although the vaccine will only be available when it is licensed. Regarding the negotiations.

4.2. The division of responsibilities in the purchasing model and the negotiable ends

Article 2 of the Agreement indicates that "The procurement of vaccine doses from manufacturers under the APA will be carried out by the participating Member States, and not by the Commission, unless otherwise agreed. Relevant vaccination policies will remain the responsibility of the participating Member States". The legally binding nature of these (art. 5) is an immediate consequence. That is to say, these APA function as a technique of joint or aggregate purchasing.

In the negotiations an agreement should be reached which specifies anticipated payments (such as amount, due dates and financing structures), the details of the delivery of the vaccine, once its efficacy has been demonstrated (such as price per person vaccinated, the quantity and the timetable for delivery following approval) and any other pertinent conditions (such as the capacity for production in the European Union, the availability of production facilities for the manufacture of other vaccines or medications in case of failure, or the provisions for liability issues).

The delivery of the vaccines should be directly to the States, in accordance with previously formalized orders. And, in this regard, it is important that companies are not ultimately obliged to produce and deliver the doses but rather to make their *"best reasonable efforts"*: the activity and level of effort that a business of similar size, with infrastructure of similar size and similar resources, would undertake or utilize in the development and fabrication of a vaccine in a pertinent timeframe for development or marketing, keeping in mind the urgent necessity to have the vaccine available. Additionally, priority must be given to production in the territory of the European Union (and of the United Kingdom)[5].

4.3. The method of financing

The object of this public procurement is advance financing, eliminating the investment risk and increasing the speed and scale of manufacturing. The initial payments are financed through the Instrument of the Provision of Urgent Assistance (ESI) (Emergency Support Instrument) [22]. The Agreements will grant the right, or in certain circumstances, the obligation of the Member States to purchase a concrete number of doses of the vaccine in a determined timeframe at a determined price. And the financing received by the companies will be considered a payment on account of the vaccines which the Member States will actually buy. In this way, the investment risk for the pharmaceutical industry in the process of research and production is diminished and sales are guaranteed.

4.4. Clauses on intellectual property, trade secrets and confidentiality: COVID-19 vaccines as a global public good with reservations? The deficit of transparency

The final item of the Agreement points out that in negotiations with the pharmaceutical industry the COVID-19 vaccines are promoted as global public goods, including for access by low and medium income countries to these vaccines in sufficient quantities and at moderate prices. And, without further explanation

[5] In the contract with CureVac it is anticipated that production will not be possible in third countries without prior consent of the Commission, while it is stipulated in the contract with AstraZeneca that the company should make the maximum effort to assure this. And when not possible, the European Commission should be notified, it being further provided that, if the company cannot fulfill its intention to produce the doses established in the agreement, the Commission or participating Member States can propose to AstraZeneca, other entities (contract manufacturing organizations) inside of the Union capable of producing the doses of the vaccine and that the company will make its "best reasonable effort" to contract them to increase available production.

allude to the intent to "to promote certain aspects associated with the pharmaceutical industry in relation to the sharing of intellectual and industrial property, especially when it has been developed with public financing". Nevertheless, in the end the APA don't compensate public financing with any rights over intellectual property or guarantee non-exclusive licenses, but rather they attribute the patents and the right of exploitation of the vaccines which are ultimately authorized to the proprietary laboratories, and that is how it is explicitly stated in the signed contracts.

Additionally, the contracts are subject to confidentiality clauses, as justified by the Commission itself in the highly competitive character of this global market [23]. Nevertheless, the existence of alleged difficulties by one of the companies (AstraZeneca) in the delivery of one of the agreed on vaccines has placed the focus of public opinion on these contracts and some of the companies (CureVac and AstraZeneca itself) have authorized their publication (although the most sensitive elements are redacted).

But the problem, without a doubt, started at the beginning, as absolute secrecy has existed in the negotiations of the contracts. In the difficult balance between transparency and trade secrets, the latter have clearly won, which leads us directly to the key question. What if the business fails to fulfill that which is stipulated in the contract?

4.5. The exceptional rules over fulfillment of the contract

Another of the key elements of the contracts is that of the information that the pharmaceutical companies should provide to the Commission during their execution, from regulatory questions about the vaccines to data on production capacity, owing immediate communication if difficulties are encountered which put the capacity to produce or sell the agreed upon doses at risk. This provision has already been applied, when AstraZeneca communicated some difficulties in making a contracted delivery [21].

Nevertheless, in principle, that didn't automatically imply noncompliance with the contract, safeguarded in this extreme by diverse clauses, the majority of which are of general application on materials of the contractual and extracontractual responsibility of the manufacturers, specifically:

(a) Acts of God: if the company has difficulties in delivering the agreed doses, the terms of the contract indicate that there is no infraction when the delay or noncompliance of the agreement is due to an act of God, which is to say, events which are out of reasonable control on the part which goes unfulfilled.
(b) The contracts typify a clear obligation of means, not of results. This is to say, the business is not obliged to produce "n" doses, but rather to make "*its best reasonable efforts*" to arrive at an agreement to increase production.
(c) Priority of manufacturing in the EU territory (not by third parties without previous agreement with the EU and the United Kingdom) [21]. The dynamic of the process, and to avoid promised doses manufactured in Europe being exported to third States, led the Commission to approve the Performance Regulation (EU) 2021/111, of the 29th of January, which subordinates the exportation of certain products to the presentation of authorization for export.

Finally, and in the face of well-founded suspicions that AstraZeneca was supplying its vaccines to countries which offered a better price, the Commission denounced the company, which was finally sanctioned in the Judgement of the Lower Court of Brussels which ordered the company to deliver 50 million doses [24], basing the decision on AstraZeneca having committed a grave failure to fulfill its obligations and not realizing its reasonable best efforts within the agreed timeframe to guarantee supply.

4.6. The delicate exception to the responsibility of the manufacturer in the case of adverse effects

Finally, the European Commission has made an exception with respect to COVID-19 vaccines of the general principles of the responsibility for medications or health products provided for in the European Directive of Responsibility for Defective Medicines or Health Products [25], for which, on occurrence, are the responsibility of the manufacturing business [26–29]. In this case, the pharmaceutical companies are exempt from the corresponding indemnizations, which then fall on the Member States through the following processes of state liability. The difficult problems which could be raised by this possibility, the analysis of which are beyond the scope of this paper [30], are raising the urgent need for the implementation of a compensation fund for vaccine damages, like those which exist in many other countries that have followed in the wake of the American VAERS model, which avoid the adjudication of the claims and could result in an interesting legal-private collaboration [31].

5. In conclusion: Consolidating strategies of collaborative purchase and investment in public health

The unprecedented achievement of having safe and effective vaccines against COVID-19 in place in less than a year has been possible thanks to global investment in public health and public-private collaboration. The APA have been shown to be an effective tool in motivating and promoting innovation, at reasonable prices, and reducing bureaucracy acting in the sense of "one health" as advocated by the Declaration of Rome. With the shortcomings of beginners, we believe that it is the moment to consolidate this type of public procurement for the supply of vaccines in Europe, through the recognition of the fair value of the vaccines and an intelligent collaboration between buyer and supplier which favors improved management of public spending, converting it, in the case of the vaccines, to the best investment that can be made in health materials.

Forcing a debate, in this context, over the suspension of patents, we neither view as necessary, nor much less, sufficient or efficient for its own sake to obtain universal access and the expansion necessary for the production of vaccines. Much more effective and intelligent would be to consolidate and maintain the investment, assure the necessary production capacity, and reinforce the mechanisms of epidemiological vigilance. To prepare for the future, without removing, at a complicated moment, tools which have not really worked badly for the wellbeing of humanity.

In any case, in line with the Declaration of Rome, it could be the time to explore more flexible avenues, like the development of voluntary licenses with the pharmaceutical industry. The agreements with AstraZeneca and Novavax are already facilitating large scale production in in India, Japan and South Korea. And many of the resulting vaccines are destined for low income countries through COVAX. And in any case, to learn from and correct errors: to identify and take care of bottlenecks in production, while diversifying production capacity; to promote greater efficiency in the use of global capabilities and distribution through collaborative and cooperative mechanisms with the support of and investment in new tools TIC; to correct deficits of transparency that have been seen to be so pernicious, including in the pharmaceutical industry itself, and have generated doubts about vaccination among the population.

Finally, it is advisable to insure that innovation in effective vaccines continues, in light of potential new variants and to assure larger, more robust supply chains of sustainable vaccines in the long term. And for that we need to embark on a journey together, industry and States at the global level, insisting on understanding and negotiation, more than on imposition and populism. We should not let this opportunity pass, for the COVID-19 vaccine, but also for other vaccines, present and yet to come.

Conflict of interest

None to report.

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