MEDICINES: ACCESS, AFFORDABILITY AND FAIR INCENTIVES

Global proposals, to Europe and to the Spanish Medicines Act

SALUD por DERECHO
Right to health foundation

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This document contains all the proposals regarding global health, pharmaceutical public policy and R&D in health technologies drafted by Salud por Derecho individually or collectively with other national and/or global organisations for national, European and global level. This was the fruit of a series of reflections for the most part during the campaigns of *No es Sano* and the *European Alliance for Responsible R&D and Affordable Medicines*.

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Contents

0. INTRODUCTION

This document: *"MEDICINES: ACCESS, AFFORDABILITY AND FAIR INCENTIVES* Global proposals, to Europe and to the Spanish Medicines Act" aims to gather

recommendations and proposals in different aspects regarding global, European and domestic medicine policies. We are putting forward these proposals which are the result of extensive reflection with European civil society. We want this document to reach citizens, health professionals and political decisionmakers in Spain and Europe to ultimately ensure that medicines and other health technology be affordable and accessible in and out of Europe.

The aim of this document is to bring concrete proposals on global health and policies for accessing medicines, vaccines and diagnoses to the Government, Congress and Senate in preparation for the different processes that will be introduced in 2022 and 2023, and in some cases extended until 2024. Spain needs to take international leadership, especially next year with its presidency of the European Union, proposing initiatives that ensure fair and equal principles and prioritising the general interest and needs of the people before business and commercial needs.

The proposals should be presented in the various negotiations involving Spain and, where appropriate, should influence the European Union's position. In this sense, the pandemic made it very clear that the European Commission's policies were conservative and favoured the interests of the industry. This is what happened with India and South Africa's proposal at the WTO in 2020 when they requested a "waiver from certain articles of the TRIPS Agreement" to ensure timely, affordable access to vaccines, treatments and diagnoses. The blatant inequality in access and the attitude of richer countries in purchasing and stockpiling vaccines have meant that many low-income countries have vaccinated barely 20%[1] of their population.

Spain has its own challenges in domestic policy on top of the ongoing international processes. Pharmaceutical spending is on the rise, with co-payments increasing and other resources being taken away from the health system because they cannot cover their high budget costs. An example of this is mental health and prevention policies which have been losing fundamental services for years. Given that health budgets are finite, investment has always had an opportunity cost and urgent measures must be promoted so that today and tomorrow's patients get the answers they need from the Spanish health system.

This document has three sections. The first relates to current global initiatives, suggesting concrete proposals to political decisionmakers and within the different international forums such as the International Pandemic Treaty. The second discusses European action, which comes together in the Pharmaceutical Strategy for Europe and the Global Health Strategy, and the final section discusses initiatives in Spain relating to the reform of the Medicines Act.

1. GLOBAL ACTION: INTERNATIONAL TREATY ON PANDEMIC PREVENTION

[1] Coronavirus (COVID-19) Vaccinations - Our World in Data

The recent pandemic shone a light on the enormous risks to health systems if prevention and preparedness for public health crises are not decisively incorporated into countries' public policies and health systems, their human resources and infrastructures strengthened and provided with the necessary financial resources. International coordination and joint action is fundamental, in addition to national preparation.

While previous experiences with the HIV, Ebola and Zika epidemics warned us of the cracks in the R&D system, COVID-19 really highlighted the weaknesses of an innovative system directly or indirectly funded by the public sector's economic resources, which privatises the results and therefore access to life-saving vaccines and medicines. The consequences of an unfair, abusive model that, with the pandemic, has made the inequality gap even deeper between rich countries which stock up products and countries with less resources.

In December 2021, the World Health Assembly approved a resolution to establish a dialogue process between its member states and negotiate a new legal instrument to effectively and fairly prepare the world for future global health crises. This instrument, known as the "Pandemic Treaty", is a key opportunity to discuss these challenges and adopt effective measures to improve R&D and fair access to health technology which is being developed to address these situations.

The Intergovernmental Negotiating Body (INB) was created with the aim of negotiating and drafting the text of the instrument which is to be negotiated between now and 2023 and approved in 2024.

The debates regarding this instrument should be focused on human rights and, more specifically, the right to health and access to health technologies which cure and prevent illnesses, ultimately making this right effective. The people and public interest should be at the heart of the instrument, and as such, equity and social justice in both the decision-making process of the text should be a fundamental value underpinning response measures to crises.

The specific elements of this instrument must include measures that guarantee access and affordability of these health technologies which will help overcome the pandemic everywhere in time and the health benefits of which will help everyone. These recommendations are fundamental, as experience has shown that leaving the solution to a public health crisis in the hands of the market makes those in the depths of the inequality gap even more vulnerable. The measures presented herein cover the full cycle, ensuring accessible R&D, shared production and transferring production to companies with capacity, including Global South countries and countries where intellectual property isn't an issue.

Safeguarding the public interest

This instrument should oblige governments and biomedical R&D financers to incorporate conditions, including in potential early procurement, ensuring: 1) the fair distribution of medicines and vaccines; 2) affordable prices and transparency in

prices, R&D costs and public and private investments; 3) shared knowledge and intellectual property, including the promotion of collaborative pools, such as C-TAP or the MPP which facilitate access to medicines and vaccines, and initiatives that promote innovative knowledge transfer, such as the mRNA vaccine technology transfer hub for Africa.

Ensure the transfer of technology and shared intellectual propriety

The treaty should ensure that governments: 1) promote collaborative innovation between scientists in the north and south with the support of financing and public policies; 3) ensure the exchange of relevant medical technology to prevent and respond to pathogens with pandemic potential and drive mechanisms to do so, as mentioned in the previous section; 4) ensure the necessary public financing to transfer the technology; 5) make full use of the flexibility of the TRIPS Agreement, such as compulsory licencing to share IP in order to increase the offer and fair product allocation, while reducing the price with the competition of generic and biosimilar medicines; 6) within the WTO, approve an automatic waiver on intellectual property regulations regarding pandemic medical technologies as soon as the WHO declares a public health emergency of international concern (PHEIC); 7) adapt national laws to ensure these transfer processes run smoothly and IP rights are shared.

Increase financing in biomedical R&D.

It is essential to increase contributions to biomedical R&D to ensure a gradual increase in national budgets and in international contributions to institutions and mechanisms that drive coordinated innovation between different research centres and respond to emerging needs (HUB messenger ARN). Secondly, we need to finance alternative R&D models that separate R&D financing from the price of products such as prize funds, public procurement, tax incentives and lastly invest in neglected and endemic diseases in southern countries. As mentioned in point 1, fund allocations need to take into account the conditions and rights of shared IP.

Measures to ensure transparency

The treaty must demand transparency on: 1) the cost of R&D, including the active ingredients, clinical trials, manufacturing, market launch and other costs; 2) public contribution to R&D costs and production of health technologies; 3) the price in all countries; 4) up-to-date lists of patents and other information relating to the intellectual property in all countries, both those presented and granted; 5) clinical trials, including protocols, details and results, independent of the results of the trial.

Diversified manufacturing

Diversified manufacturing offers many benefits, such as increasing the offer for all countries and ensuring medical technologies are available for all developing countries. This focus will help develop the industrial capacity of many countries and increase competition, therefore bringing down prices. Therefore, the treaty must:

1) ensure that governments invest in their national capacity to absorb, develop and eventually create technology and provide the necessary financing and collaboration with technology creators, financers and international institutions; 2) ensure that governments invest in regional manufacturing capacity and create and economic and scientific environment that attracts local and international investors while maintaining the objectives of public health investment.

2. EUROPEAN ACTION

As stated in the *Pharmaceutical Strategy for Europe*, it will *"Foster patient access to innovative and affordable medicines. It will support the competitiveness and innovative capacity of the EU's pharmaceutical industry. It will develop the EU open strategic autonomy and ensure robust supply chains so that Europe can provide for its needs, including in times of crisis. And it will ensure a strong EU voice on the global stage. The strategy has four work strands which flow from these objectives."*

This work programme proposed by the European Commission marks the start of a new chapter in which the European institutions plan action to bolster the pharmaceutical sector, ensure regional leadership and overcome the barriers that may impede access to medicines for different reasons. The aim of fostering patient access to innovative and affordable medicines offers them an opportunity that civil society cannot let go to waste. We must provide key proposals to ensure the Pharmaceutical Strategy serves the general interest of all and not just the private sector. The following recommendations are briefly presented and some will be discussed in further detail in the forthcoming sections.

Another big challenge for next year is drawing up a *Global Health Strategy*[2] that will serve both the SDGs and future global health challenges. The *Global Gateway* EU initiative has a specific section on health and diversifying its pharmaceutical supply chains and increasing its local production capacities for health technologies[3].

The COVID-19 pandemic proved that the international dimension of the EU's health policy had become a crucial part of its external action. The strategy aims to tackle the following issues: 1) global health systems are not strong or resilient enough to face global threats, including communicable diseases; 2) the global community does not look hard enough to understand, prevent and address health threats. In this last case, there are various problems to be discussed with the European Commission, including: a) the links between the environment, ecosystems and human health; b) new focuses on developing pharmaceutical products to ensure access to safe, high-quality and effective medicines and accessible treatment for all while continuing to innovate; c) the global health architecture needs to address global health threats in an ever-complex geopolitical environment. Health has become a geopolitical topic,

[2] Global health – new EU strategy (europa.eu)
[3] Global Gateway | European Commission (europa.eu)

particularly given the link between health and safety.

With this context of public policy in Europe in mind, we have presented the following recommendations for the European Pharmaceutical Strategy and the Global Health Strategy. The current problems in the innovation system and the pharmaceutical policy are the same in all areas and in general terms, the main goal should be to strengthen the public interest, guarantee the human right to health and thus all principles of global equity and justice.

2.1. The European Global Health Strategy

As we saw, many topics relating to the right to health will be addressed in 2023. At Salud por Derecho, we recognise how important this process is and we will describe the political priorities that we believe should be included in the future European Global Health Strategy below.

General recommendations for the strategy:

1. The final strategy must put the interests and needs of people at the centre of European policies, with a crosscutting approach, and provide a comprehensive solution to all dimensions of health. To achieve this, health systems need to be strengthened, including community and primary healthcare systems and universal healthcare needs to be consolidated for all in terms of equity, justice and guaranteed rights, including for all migrants.
2. Global health R&D policy must support the needs of people with an increased budget that brings together the results of said innovation to global access, affordability, transparency and shared intellectual property with global production capacity. It should be taken into account that the incentives of intellectual property include provisions on access, public return on public investment, fair prices, transparency and mechanisms to overcome the barriers that this property could present. This will involve a trade policy that makes more effective and extensive use of the TRIPS Agreement in national and global health crises.

3. The Pandemic Prevention, Preparedness and Response accord is another fundamental element that should be included in the European Global Health Strategy.

   The structural and systemic flaws in the global response to COVID-19 created a barrier to global access and over time, to services and medical attention, including the vaccines, tests and treatments needed to save people regardless of their place of residence. The pandemic prevention, preparedness and response should be considered as a continuous integrated action. To do so, we need: 1) action that focuses on equitable and fair global governance for all parties; 2) implementation of early warning

systems with effective monitoring mechanisms; 3) coordinated global action that protects all societies; 4) future PPPR plans that include strong solidarity, along with public responsibility to guarantee equitable access to intellectual property financed by public funds for health technology, with transparency and global diversification of its production and widespread sharing of such technologies; 5) future PPPR plans that are governed by principles of transparency and responsibility which extend to manufacturers, so they handle the risks of the health technologies instead of States, as was the case with COVID-19.

4. Including the EU's commitment to ending AIDS by 2030 in the strategy reaffirms the continuous support of the EU to Global Fund, UNAIDS and UNITAID, as does including the focus of HIV in strengthening health systems and developing community systems, with full participation of civil society throughout the whole process. They should also support innovative processes for HIV treatment and prevention while ensuring equitable access to them. These commitments should lead to investments in medium- and low-income countries in particular.

5. Last but not least, the strategy should address climate change and its impact on human health. The main objective is to limit global warming to 1.5ºC/2ºC along with CO_2 emissions with policies to decarbonise the global economy. By not acting, or not acting in a proactive way with adaptive policies and mitigation, we would be doing irreparable damage to ecosystems and human health.

   This is why global health is at the epicentre of climate change. Problems such as: 1) the impact of high levels of air pollution; 2) heatwaves from the high temperatures; 3) extreme weather events such as flooding, droughts and fires; 4) the quality and/or shortage of water and lower crop yields; 5) the impact on vectors and ecology; and 6) social factors such as climate migration, mental health issues from the social and political context, conflicts, violence, etc. They all have a direct impact on people's health causing a range of diseases such as: heat-related diseases; diseases spread by water (cholera); diseases spread by vectors (Chikunguna, dengue, malaria, encephalitis, etc.); environmental allergies; respiratory diseases; cardiovascular diseases; nutritional diseases; maternal and neonatal diseases; trauma and mental health problems.

   The climate crisis puts the implementation of universal health coverage (UHC) at serious risk, exacerbating the existing disease burden and broadening existing barriers to accessing health services, often in times when they are most needed.

The future Global Health Strategy should ensure: 1) the achievement of the Paris Agreement; 2) support from adaptive national and regional public policies and mitigation to address the health challenges mentioned above; 3) regional and national budgets that allow them to support such global health policies.

2.2. Opportunities for the European Pharmaceutical Strategy

One of the four pillars of the EU's Pharmaceutical Strategy is to ensure patients' access to affordable medicines and fulfilling unmet medical needs. To achieve these objectives, the EU must undertake to support innovative solutions based on people's needs and access to affordable health technologies.

It must improve transparency in the sector and ensure it sets conditions to access public financing which protect the general interests of the people. By evaluating and reviewing the current system, the European Commission has an opportunity to find the critical balance between public health needs, access, affordability and innovation. It can also tackle some of the flaws and imperfections of the intellectual property and pharmaceutical systems and focus its strategy on public health needs so that ultimately, it is the patients, citizens and healthcare systems that benefit from it. To do so, the EU must take stock of the lessons learnt regarding the effect of the intellectual property incentives in biomedical R&D compared with that of other mechanisms such as public financing, prizes or others, that are also used as incentives.

General recommendations for the strategy:

1. Ensure that the principle of having access to safe, effective, affordable medicines is covered in all areas of the EU's pharmaceutical strategy and not just in one specific section.

2. Ensure transparency[4] in R&D costs, in all stages of the process, as stated in the recent resolutions of the United Nations General Assembly.

3. Remove incentives that impede access to affordable medicines and consider the detrimental effects of those that create obstacles to using the flexibilities of the TRIPS Agreement, which guarantee access to medicines.

4. Do not add new incentives without clear proof and transparent, inclusive debates on the benefits they might offer patients and society**.** For example, new incentives to drive the development of new antibiotics through "transferable exclusivity vouchers" do not seem to be supported by evidence demonstrating that they will be able to address the complexities and

[4] The strategy should be in line with the resolution on transparency adopted by the World Health Organisation General Assembly in 2019. A requirement should be added for companies to reveal in the market authorisation stage their R&D and manufacturing costs, public financing received, as well as other important information for regulatory filings including clinical trial data, sources of main active ingredients, number and status of patents and patent applications, and information on supply chains.

vulnerabilities of R&D for new antibiotics[5].

5. Remove unnecessary obstacles to competition and address abuses and unfair practices in the system. The increase in number, reach and duration of different market monopolies have not had a positive impact on the public interest. At the same time, this trend has caused significant problems, blocking or slowing down access to affordable medicines and threatening the sustainability of national health systems[6]. Competition law and policies should be actively used to rectify abuses and unfair practices in the system. The EU should also strengthen the role of the Competition Authority with the aim of reviewing and monitoring potential abuses of dominant market position, with unjustified prices based on monopolies.

6. Make the system coherent by bringing R&D policies in line with access to affordable medicines. The EU is an important public "financer" of R&D throughout the world and between its Member States, as well as being a major medicines "buyer". Therefore, it should try to align its R&D policies with its aim to promote access to affordable medicines using the following measures: 1) ensure accountability and transparency in R&D agreements throughout the EU; 2) add specific access provisions linked to public financing (conditions and transparency) to ensure the return on public investment is transferred back to society; 3) support global R&D collaboration efforts; 4) adopt the European Health Emergency Preparedness and Response Authority (HERA) initiative, a global agenda with a long-term vision, driven and led by Member States.

7. Drive new, alternative organisation, financing and incentive models for R&D in areas with unmet medical needs. This would help tackle the high – and growing – cost of medicines that treat these kinds of diseases and the persistent lack of development in some of the diseases with the greatest unmet needs.

8. The role of non-profit organisations, such as academic institutions and research institutions, should be strengthened and supported so they can cover therapeutic areas with little commercial interest. They should have access to the results of clinical trials and individual patient data, including unpublished data from unsuccessful trials, to provide high quality evaluations. Specific incentives could be considered for very small businesses, non-profit research institutions and academic institutions that have less medicines on the market to support sustainable manufacturing and production.

[5] Outterson, K. y McDonnell, A. (2016). Funding antibiotic innovation with vouchers: recommendations on how to strengthen a flawed incentive policy. Health Affairs, 35(5), 784-790, https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2015.1139

[6] Fonteijn C, Akker I, Sauter W. Reconciling competition and IP law: the case of patented pharmaceuticals and dominance abuse. ACM Working Paper (The Netherlands Authority for Consumers and Markets). [Online]. 2018 [cited on 22 April 2021]. Available at: https://www.acm.nl/sites/default/files/documents/2018-03/acm-working-paper-reconciling-competition-and-ip-law-2018-03-07.pdf

9. Prioritise and defend the needs of the public health system and patient when introducing changes to the current legal framework, including all those regarding shortages. These actions will ensure that medicines remain available over the long term.

10. In terms of prices, the EU must encourage countries to introduce cost-plus pricing and support price negotiations coordinated to gradually cut down prices. This pricing must be supported by independent audits.

2.2.1. European Initiatives

As the mandate of the Pharmaceutical Strategy is to address incentives, it would be a great opportunity to review existing initiatives and introduce all the measures needed to ensure that medicine development and authorisation be more accessible and affordable. We will present recommendations for each of the incentives below.

a) Orphan medicines

Incentives for orphan medicines aim to spur the development of drugs to treat rare diseases. As less people suffer from these diseases, the pharmaceutical sector believes that the market is too small to invest in developing new medicines.

Based on this reality, the EU decided to establish an incentive system. This included push initiatives offering economic assistance during the initial stages of R&D, with the aim of reducing costs and uncertainty surrounding the development of orphan medicines, and pull initiatives in the later stages as a reward for completing the development, increasing the probability that the medicines will be affordable upon completion[7]. Incentives include assistance in terms of regulations, waivers on fees relating to pre- and post-market authorisation procedures for orphan medicines, 10-year market exclusivity (that can be extended by up to two years for paediatric indications) and other push incentives such as research assistance for small and medium enterprises (SMEs)[8]. However, legislation on orphan medicines has created numerous inconsistencies in the market which need to be reviewed. Firstly, it has led to unequal availability and delays in access, resulting in treatments that are often unaffordable for EU Member State patients[9].

However, the development of orphan medicines has become an extremely attractive business[10]. In 2018, 22 of the 99 new medicines or indications were orphan medicines, according to a study by Prescrire[11]. Nevertheless, only some of the newly developed medicines will bring real benefits to society: out of 22 evaluations, only 11 medicines (or new indications) were classified as having made "progress", but the majority were considered to have made "minimum progress".

[7] Boulet P., Garrison C., Ellen't Hoen E. (2019), cited work, p. 40.
[8] https://ec.europa.eu/health/human-use/orphan-medicines_en
[9] Prescrire report "Orphan drug status: abuse of incentives", Prescrire Int 2016; 25 (171): 138.
[10] Marselis D., Hordijk L. (2020). From Blockbuster to "Nichebuster": How a Flawed Legislation Helped Create a New Profit Model for the Drug Industry. BMJ 370, m2983. 10.1136/bmj.m2983
[11] Prescrire "L'année 2018 du médicament, en bref" ("A summary of medicine in 2018") Rev Prescrire; 2019 ;39 (424) p. 142-144.

Recommendations for orphan medicine legislation

- **Draw up a clear definition of "unmet medical needs" based on transparent, objective criteria.** The incidence, survival rates, existing alternative treatments, mortality rates and seriousness of the disease.

- **Correct problems/legal loopholes that create uncertainty or undermine competition.** Such is the case in Article 8(2) of Commission Regulation 141/2000 where the definitions of "sufficient" and "significant" profit and "sufficient" and "insufficient" profitability (of the investment) must be made clearer. What's more, with no definite limit on the market exclusivity, the capacity of generic pharmaceutical manufacturers to produce these products is affected once the originally intended exclusivity period expires which, in turn, restricts access and availability and may affect prices[12].

- **Remove the prevalence criterion for the designation of a medicine as "orphan".** Instead of being prevalence-based, adopt a "return on investment" criterion for all applications for orphan medicine designation, which should be supported by evidence justifying the incentives offered. It must ensure transparency in R&D costs to justify this criterion.
- **Consider introducing a clause** allowing for the withdrawal of orphan designation when the drug is already sufficiently profitable, irrespective of whether the prevalence or cost-effectiveness criterion has been used.

- **A mechanism similar to the "withdrawal clause" (of the orphan designation), which was already present in the first drafts of the Regulation, should be reintroduced in the current Article 8(2).** The reintroduction of such a mechanism should bring about a significant change in the behaviour of some pharmaceutical companies that work with orphan diseases, in cases where orphan drug exclusivity extends over a longer period than their other intellectual property rights, and where there are other companies able and willing to compete.

- **Ensure that the collection and storage of data falling under the competence of the authorities is carried out properly and that such data are published.** The European portal that will implement the obligations set out in the EU Clinical Trial Regulation, which will enter into force on 31 January 2022 and will give access to all clinical trials - both ongoing and completed - should include results (whether positive or negative) for orphan and paediatric medicines[13]. Whenever possible, randomised clinical trials (RCTs) and comparative trials should be required.

[12] See Teva Pharma BV versus the European Medicines Agency (EMA). (2016) C-138/15P.
[13] https://www.transparimed.org/single-post/european-medicines-regulators-set-to-tackle-missing-clinical-trial- results

- **In the case of paediatric medicines, incentives and rewards should only be granted for those placed on the market whose pharmaceutical format and packaging are adapted for paediatric use. For clinical practice, it is not sufficient to focus only on the unmet medical need.** Paediatric medicines should be in a (pharmaceutical) format that is safe and appropriate for children[14].

b) Supplementary Protection Certificates (SPC)

Supplementary Protection Certificates are rights that serve to extend, up to a maximum of 5 years, the protection of certain patents for medicines. SPCs are part of a group of mechanisms aimed at restoring or extending the patent term in the case of pharmaceutical patents.

SPCs were introduced in the EU under Regulation 1768/92/EEC (now Regulation 469/2009/EC, amended). Its justification is to compensate for the period during which the patent could not be exploited because the pharmaceutical product had not yet received the required authorisation. This mechanism has been in use for over 20 years and it is still not clear that SPCs are justified[15]. This is also because SPCs are not granted based on an assessment of the revenues or profits that the pharmaceutical company has earned for a given product. It is therefore possible that a product that is already highly profitable may be granted an SPC. In such cases, granting such exclusivity is hardly justified and may instead promote opportunistic behaviour by pharmaceutical companies.

There is evidence of the negative impact of SPCs on timely access to affordable medicines. Based on an analysis of three hepatitis C drugs and cancer treatments, Doctors Without Borders highlighted the social cost of the introduction of SPCs, including delayed competition and maintained high medicine prices in European countries[16].

Recommendations concerning SPCs

- **Stricter rules for SPCs.** A number of factors should be taken into account when granting an SPC, including the ability of the applicant to demonstrate that the R&D costs outweigh the benefits obtained during the normal period of patent protection, as well as the damage caused by administrative or bureaucratic delays during the drug authorisation process (by the regulatory authority)[17].

- **Promote transparency on R&D costs.** Since SPCs would only be

[14] https://www.prescrire.org/fr/3/31/61047/0/NewsDetails.aspx
[15] See Thyra de Jongh et al., Final report 'Effects of Supplementary Protection Mechanisms for Pharmaceutical Products' (Technopolis Group, May 2018) 54, which concludes that Supplementary Protection Certificates (SPCs) offer patent holders adequate compensation for their effective loss of patent term. However, they had a less clear effect as a pharmaceutical incentivising measure.
[16] Hu, Y., Eynikel, D., Boulet, P. y Krikorian, G. (2020). Supplementary protection certificates and their impact on access to medicines in Europe: case studies of sofosbuvir, trastuzumab and imatinib. Journal of pharmaceutical policy and practice, 13(1), 1-12.
[17] Health Action International (HAI), Consultation Response, European Commission Intellectual Property (IP) Action Plan, https://haiweb.org/wp-content/uploads/2020/07/HAI-Wemos-contribution-to-EU-IP-Roadmap-consultation.pdf.

justified if it is demonstrated (with evidence) that the patent term is insufficient to cover R&D investments, pharmaceutical companies should submit data on the benefits obtained and do so on a regular basis, or at least before the original expiry date of the patent.

- **Promote transparency as regards the basic patent applied** with its corresponding dates in the different Member States, so that there is no possibility for companies to apply the most favourable option in each case.

- **Facilitate the participation of third parties to challenge SPCs.** These third parties may have useful information, e.g. on whether an SPC should not be granted or whether the benefits have been sufficient to cover R&D costs. The flow of information from third parties should be encouraged in order to either anticipate before granting an SPC or revoke it after it has been granted.

- **Ensure that SPCs do not hinder or prevent the use of IP flexibilities.** While IP flexibilities - under the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) - have been considered essential for the promotion of public interest and development objectives, in practice, instruments such as SPCs have hindered the use of flexibilities such as compulsory licensing or the so-called 'Bolar Clause'. SPCs should not prevent the use of these flexibilities; therefore, the possibility of introducing derogations or exemptions for Member States should be included[18].

- Finally, **we propose that it be gradually phased out**, replacing the current model of patents and monopolies with alternative models that separate R&D from the final price of the product.

c) Commercial exclusivity and data exclusivity

According to Regulation (EC) No 726/2004, medicinal products authorised in accordance with the provisions of that Regulation shall benefit from a data protection period of eight years and a marketing protection period of ten years. During the first period, known as "data exclusivity", the marketing authorisation holder enjoys exclusive rights to the results of pre-clinical tests and clinical trials related to the drug. As a result, a generic company cannot rely on or refer to these data when registering a generic drug, even if the drug is needed for compelling public health reasons, for an emergency, or when a compulsory licence or government use order has been issued during that period. Such data from pre-clinical tests and clinical trials cannot be re-generated, not only because of the economic costs involved but also for ethical reasons. EU

[18] Ibid.

pharmaceutical legislation makes no exception to this rule[19].

Recommendations on market exclusivity and data exclusivity

- **Replace the data exclusivity system with a compensatory system.** A compensatory system can recognise the actual investments made to generate the data without granting exclusionary rights that prevent others from using the data.

- **In the protections conferred by data/market exclusivity, include an exception applicable in cases of public health necessity or for compulsory licensing or government use.** Currently, these exclusivities give the producer of the original clinical data (those relating to the drug in question) additional legal protection and prevent a generic manufacturer from registering/marketing a generic drug by using the same data for a period of 8 to 10 years. This may be a considerable obstacle to the practical use of compulsory licences in the EU and should be urgently reconsidered.

- As market and data exclusivities are justified on the grounds that innovators need to be protected or rewarded for their R&D investments, it is crucial that **there is more transparency** to know which entity is behind these investments in relation to other inputs (e.g. public funding).

d) Patents and compulsory licences

Compulsory licensing is an important public health safeguard to ensure access to essential medicines. By granting a compulsory licence, a government allows third parties to produce a patented product (drug) without the consent of the patent holder. This legal instrument can be used to meet public health needs when access to medicines deemed necessary has to be ensured. Unfortunately, there are a number of legal obstacles that can make it difficult to use this mechanism effectively and quickly during a public health emergency, even within the EU.

Under the TRIPS Agreement, and as later ratified by the Doha Declaration, which is also binding on EU countries, compulsory licences can be granted in different circumstances, as determined by each country. Such circumstances may include emergencies, other urgent situations, for non-commercial purposes in the public interest and to remedy unfair competition practices. Countries are therefore free to use compulsory licences for a variety of reasons and not only during an emergency. The argument that compulsory licensing should only be used as a "last resort" is an inaccurate and misleading interpretation of the

[19] FM't Hoen, E., Boulet, P. y Baker, B. K. (2017). Data exclusivity exceptions and compulsory licencing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation. Journal of pharmaceutical policy and practice, 10(1), 1-9, https://joppp.biomedcentral.com/articles/10.1186/s40545-017-0107-9.

TRIPS Agreement.

Spain has compulsory licensing in its patent law, but has never made use of this resource, not even during the pandemic. The EC recognises the need to improve the effective use of compulsory licensing and defended this at the World Trade Organisation (WTO) during discussions on the "TRIPS waiver" requested by India and South Africa to address the COVID-19 crisis.

Recommendations relating to patents and compulsory licensing

- Eliminate data and market exclusivities during the implementation of a compulsory licence, and align national and European legislation to facilitate its administrative implementation.

- Recognise the importance and encourage the EU to use this instrument whenever necessary to address national or international health crises.

- Refrain from 'exporting' EU intellectual property rules, including those on data exclusivity, in bilateral trade agreements with other countries. This increases the barriers to effective use of compulsory licensing worldwide[20].

e) Incentives for new antibiotics

Antibiotic resistance is a serious public health problem, responsible for 4.95 million associated deaths in 2019 alone, of which 1.27 million were attributable to bacterial antibiotic resistance[21]. Addressing this growing problem requires a combination of long-term strategies, where access to innovative antibiotics itself is an increasingly alarming problem.

In an antibiotic innovation ecosystem that is increasingly market-driven and seen as unprofitable for large companies[22], there is a growing need for the development of candidates with the potential to treat pathogens on the WHO's critical threat list[23]. The recommendations that have been put forward revolve around two main strategies: increasing public investment in antibiotic R&D (push mechanisms) and creating incentives to ensure that newly developed antibiotics address established public health needs in a long-term sustainable manner, while ensuring their cost-effectiveness (pull mechanisms)[24].

Concerns about the rise of antimicrobial resistance and the lack of solutions in the European context have been growing in recent years[25], which has prompted the

[20] https://msfaccess.org/analysis-eu-position-compulsory-licensing-and-trips-waiver-covid-19-pandemic
[21] Murray, C. J., Ikuta, K. S., Sharara, F., Swetschinski, L., Robles Aguilar, G., Gray, A., Han, C., Bisignano, C., Rao, P., Wool, E., Johnson, S. C., Browne, A. J., Chipeta, M. G., Fell, F., Hackett, S., Haines-Woodhouse, G., Kashef Hamadani, B. H., Kumaran, E. A. P., McManigal, B., … Naghavi, M. (2022). Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. The Lancet, 399(10325), 629-655.
[22] Klug DM, Idiris FIM, Blaskovich MAT, et al. There is no market for new antibiotics: this allows an open approach to research and development. Wellcome Open Res. 2021;6:146. Published 2021 Jun 11. doi:10.12688/wellcomeopenres.16847.1
[23] https://www.who.int/publications/i/item/WHO-EMP-IAU-2017.12
[24] Årdal, C. et al. (2018) DRIVE-AB - Revitalizing the antibiotic pipeline: Stimulating innovation while driving sustainable use and global access. Available at http://drive-ab.eu/wp-content/uploads/2018/01/ CHHJ5467-Drive-AB-Main-Report-180319-WEB.pdf
[25] https://www.oecd.org/health/Antimicrobial-Resistance-in-the-EU-EEA-A-One-Health-Response-March-2022.pdf

European Commission to address the review of pharmaceutical legislation in Europe. Among the (few) pull-type options considered to introduce incentives for R&D of new antibiotics, **Transferable Exclusivity Extensions (TEEs**) have emerged as a potentially problematic option to be adopted. Spain, whose **National Antibiotic Resistance Plan (PRAN)** included in its first strategy (2014-2018) as Measure IV the action to "Study incentive mechanisms for research projects based on identified needs" and which subsequently in its second strategy (2019-2021) included actions to create public calls to fund research on antibiotics as well as to promote R&D of new antibiotics, considering options with an efficient, coordinated approach and with the public interest at the centre, for which TEEs do not seem to be the best option according to the available evidence, despite the fact that the pharmaceutical industry raises it as a desirable option both at European level[26] and at national level[27].

As proposed in the review of this mechanism by the European Public Health Alliance (EPHA) and ReACT[28], TEEs risk becoming the measure adopted in Europe to address the problem of incentives to develop new antibiotics by proving to be an option that does not require any direct investment by the public administration. With TEEs, the company that introduces a new antimicrobial into the market is granted a transferable right, which can be used either to extend the exclusivity period of another product from the same company, or be sold to another company to use in its products. However, in the long run, this measure could potentially cost the public system more than the benefits it could bring. Delaying the entry of generics and biosimilars for companies' blockbuster drugs, onto which these extensions will presumably be transferred, will mean a higher cost for each new antibiotic benefiting from the TEE[29]. In addition to increasing the duration of monopolistic practices, a reward system will be established through this mechanism whereby the profits gained through the potential transfer of exclusivity to blockbuster drugs will disproportionately increase the total cost of the process of bringing a new antibiotic from its initial stage to market.

<u>Recommendations on incentives for new antibiotics</u>

Based on the above, the EU and Spain must address the problem of the lack of innovative candidates in the field of antibiotics in a coordinated manner[30], with comprehensive and effective solutions that incorporate a combination of strategies whose fundamental pillar is to safeguard the public interest, proposing the necessary mechanisms to ensure the return on public investment and an effective and comprehensive governance of the entire process of research, development and commercialisation of new antibiotics that allows for their

[26] https://www.efpia.eu/media/636464/a-new-eu-pull-incentive-to-address-anti-microbial-resistance-amr.pdf
[27] https://www.larazon.es/salud/20220508/uyrcrix3pjhqfc6j7nbfidr3f4.html
[28] https://epha.org/wp-content/uploads/2022/07/antibiotic-incentives-pharma-legislation-joint-paper-2022.pdf
[29] Årdal C., Lacotte Y., Ploy M., (European Union Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections, EU-JAMRAI), Financing Pull Mechanisms for Antibiotic-Related Innovation: Opportunities for Europe, Clinical Infectious Diseases, Volume 71, Issue 8, 15 October 2020, Pages 1994-1999, https://doi.org/10.1093/cid/ciaa153.
[30] https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance

sustainability and rational use.

- Align in a coordinated manner the research priorities of the **National Antibiotic Resistance Plan (NARP)** with the international priorities of the WHO in order to address global needs in accordance with the WHO Priority Pathogens List.

- Provide a sufficient and stable line of funding to the NARP research line for pre-clinical and translational research on new antibiotics carried out by foundations, public research organisations and small and medium-sized companies, including the necessary conditions to safeguard the public interest and guarantee access throughout the R&D chain to new treatments that respond to public health needs.

- Join the WHO DG's call for Spain to join the Global Antibiotic Research and Development Partnership (GARDP), alongside other leading countries, to strengthen the global antibiotic R&D chain, and in particular to achieve the goal of developing 5 new antibiotics by 2025 ("5 in 2025"[31]).

- Promote coordinated mechanisms at national and European level for open sharing of research data and compound libraries to improve coordination and efficiency in innovative antibiotic research. Promote the participation of Spanish public institutions in GARDP to ensure that knowledge gained through public funding in the field of antimicrobial resistance is shared with the global community.

- Promote, in a sustainable manner, a national network of independent clinical trials for innovative antibiotics and those to optimise existing antibiotics, based on the Carlos III Health Institute's SCReN platform and on the experience gained through the Spanish Network for Research in Infectious Diseases (REIPI).

- Promote at European level the adoption of pull-type incentive models that do not favour exclusivity periods, and that focus on sustainability and fair and equitable pricing. To ensure access to innovation, we propose that expected revenues be separated from the volume of sales, safeguarding the public interest at all levels of publicly financed R&D.

2.2.2. Shortages[32]

In addition to high prices, which make medicines unaffordable, shortages are

[31] https://www.gardp.org/who-we-are/5-by-25/

[32] This text is part of a document produced and endorsed by members of the European Alliance for Responsible Research and Affordable Medicines. The organisations are as follows: Public Health Alliance (EPHA); Asociación por un Acceso Justo al Medicamento (Spain); Consumer Association the Quality of Life- EKPIZO (Greece); Médecins du Monde (Spain); Prescrire; AIDS Action Europe (AAE); Organización de Consumidores y Usuarios (Spain); La Ligue contre le cancer (France); TRT-5 CHV (France); AIDES (France); France Assos Santé; Salud por Derecho (Spain); Pharmaceutical Accountability Foundation (The Netherlands).

another critical obstacle to patients' access to medicines and optimal healthcare. It is therefore imperative that the review of pharmaceutical regulations addresses this growing problem and considers it a priority and an essential part of the access to medicines strategy.

Drug shortages have dramatic consequences for patients in terms of worsening symptoms, disease progression, as well as reduced protection against infectious diseases. Such shortages can also lead to sub-optimal medical care, substitution of suitable medication with less effective or more toxic treatments, increased medication errors and the risk of exposure to counterfeit medicines. Indeed, when patients are faced with shortages of the medicines they need, they sometimes resort to unreliable sources of supply, especially with internet shopping[33].

The rapid increase in drug shortages in recent years[34] highlights one of the most glaring shortcomings of current EU pharmaceutical regulations. To try to counteract this trend, several countries have adopted legal and non-legal measures to prevent or cope with such shortages. Some of these measures include: 1) the obligation to notify both actual and potential shortages (risk of shortage) and longer notification periods in the event of commercial withdrawal of a medicine from the market; 2) the obligation for pharmaceutical companies to hold safety stocks of medicines of high therapeutic value; 3) the development of management and prevention plans[35]; 4) the imposition of sanctions in the event of non-compliance with obligations.

Recommendations for the revision of EU pharmaceutical legislation on medicine shortages

Information on medicine shortages

- Strengthen the obligation for pharmaceutical companies to notify both shortages and unforeseen shortage risks as soon as they are detected, in order to enable management and/or prevention measures to be put in place as soon as possible.

- Require a longer notice period (at least one year) for the withdrawal of a medicinal product from the market for commercial reasons.

- Establish harmonised criteria for the notification of shortages and the risk of shortages; such notification should include detailed information on a number of key parameters (product data, reasons for shortages, expected duration and impact, etc.).

[33] https://www.france-assos-sante.org/wp-content/uploads/2019/02/Penuries-medicaments-Resultats-BVAdec2018.pdf
[34] In France, the number of high therapeutic value medicines affected by shortages increased from 871 in 2018 to 1,504 in 2019 and 2,446 in 2020; in the Netherlands shortages affected 769 key medicines in 2018 versus 1,492 in 2019, and in the Czech Republic they affected 1,630 in 2018 versus 2,208 in 2019. See https://epha.org/wpcontent/uploads/2020/04/epha-a2m-medicine-shortages-position.pdf
[35] https://ansm.sante.fr/actualites/disponibilite-des-medicaments-lansm-publie-les-lignes-directrices-pourlelaboration-des-plans-de-gestion-des-penuries

- Enable patients to self-report medicine shortages, as this method could provide valuable data on the effects of shortages and contribute to better management of shortages.

- Ensure effective and transparent communication on the shortage of medicines in the EU by creating a complete and comprehensive database accessible to the general public. The database should include information on the causes of the shortage and the expected duration.

Preventive measures

- Establish an independent and proactive system to monitor and control medicine stocks in the EU, in order to anticipate shortage risks as early as possible. Such a system should include a legal obligation for pharmaceutical companies to provide transparent and regular information on their stocks, as well as effective controls by Medicines Agencies.

- Establish a legal obligation for pharmaceutical companies to develop and submit transparent shortage prevention and management plans, which have taken into account input from competent authorities, patients and healthcare professionals.

- Introduce a legal obligation for pharmaceutical companies, for medicines of high therapeutic value, to maintain the necessary safety stocks at EU level.

- Adapt the joint procurement model used for COVID-19 vaccines to purchase medicines with limited availability and distribute them in a fair and equitable manner among Member States, thereby improving the transparency of the negotiation process and contractual conditions.

- Promote public production strategies whenever necessary to ensure the availability of essential medicines and treatments[36].

Mitigating measures and sanctions

- Adapt the regulatory framework so that hospital pharmacists clearly have the authority to prepare and distribute medicines of high therapeutic value in case of shortages (including the withdrawal of a medicine from the market for commercial reasons).

- Ensure that pharmaceutical companies comply with their legal obligations and provide for dissuasive sanctions in case of non-compliance.

3. NATIONAL ACTION

[36] A number of strategies are currently being pursued in the field of advanced therapies that can serve as a reference and could be explored for possible application to other types of treatment.

In a system such as the Spanish one, where public financing of medicines is the exclusive competence of the State and with a constant increase in financed pharmaceutical spending, which reached almost 21,000[37] million euros in 2021, the government has proposed an amendment to RDL 1/2015 approving the revised text of the Law on guarantees and rational use of medicines and health products.

In view of the government's proposed change aimed at addressing pharmaceutical policy needs, prioritising the rationalisation of pharmaceutical spending, there are a number of outstanding challenges that need to be addressed and for which there is now an undeniable opportunity.

Public funding of medicines and pricing.

Due to the high prices of new medicines, the viability of the Spanish National Health System depends to a large extent on the containment and reduction of the prices of new medicines, as well as their incorporation into the portfolio of services with the guarantee of being accessible. In this sense, the modifications made by the government in recent years have not served to contain and significantly reduce high medicine prices because they have been based on different "payment by value" methods driven by the pharmaceutical industry.

The decision on public funding must consider whether the medicine is safe and effective and whether the price proposed by the company is cost-effective compared to current treatments. Therefore, public funding should only be approved if the new medicine is effective, safe and cost-effective (incremental clinical benefit).

On the other hand, cost-effectiveness, value-based pricing or incremental clinical benefit, in whatever form (payment per QALY, etc.), should not be used **for pricing**, as comparators are already using abusive drug prices. Comparison with other similar medicines, which are also priced on a value basis, leads to a never-ending spiral of overpricing that is far removed from the real costs and in many cases from the therapeutic value provided[38]. As long as the price is set based on the value of the medicine to the public system by quantifying the benefit and willingness to pay for it, and not on the actual cost, access to innovative medicines will be increasingly limited by making accessibility dependent on bargaining power and market dynamics[39].

In this respect, the price should be set based on the actual cost of manufacturing and R&D, duly audited. Thus, pricing should make use of other pricing mechanisms, such as cost-plus, to ensure a fair and reasonable profit margin, also taking into account other elements such as public investment in each product, tax benefits and incentives. There are a number of situations where this model could initially be developed, such as those medicines or vaccines that are subject to advance purchase agreements or have received a significant amount of public funding, as

[37] Indicators on Pharmaceutical and Health Expenditure: Ministry of Finance and the Civil Service

[38] Fernando Lamata, Ramón Gálvez, Javier Sánchez Caro, Pedro Pita, Francesc Puigventós. Medicamentos: ¿Derecho Humano o Negocio? Ediciones Diaz de Santos 2017. ISBN. 978-84-9052-050-5

[39] http://noessano.org/es/wp-content/uploads/2021/12/Informe_AltosPreciosMedicamentosEspa%C3%B1a-1.pdf

has been the case for medical countermeasures in the COVID-19 pandemic[40] [41], or that have been developed in the public domain such as academic CAR-Ts. Likewise, this mechanism would be useful for products that are the first in their group and will act as a benchmark for pricing, thus avoiding a progressive spiral of overpricing.

However, if the objective is to ensure the viability of the National Health System, then prices need to be close to the real costs of R&D, production and distribution, plus a reasonable profit margin. The overspending resulting from other pricing methods results in an opportunity cost in a system where people's health needs are not restricted to health technologies, but also to adequate medical care, clinical tests, adequate infrastructure and so on.

Independence of health professionals

Equally, rational use of medicines can only be ensured with independent training of professionals and public sponsorship of clinical guidelines and research. As long as the industry can pay for training, clinical guidelines, sponsorship chairs, congresses, scientific societies, publications, etc., and professionals can receive financial incentives, prescribing will inevitably be biased and will contribute to avoidable adverse effects and an increase in unnecessary and harmful healthcare spending.

In order to safeguard the independence of health professionals and patients' associations, the law should ensure public funding of training and research activities of health professionals, as well as of patients' associations with a social interest. Similarly, all Clinical Guidelines and other Official Protocols that guide the clinical behaviour of professionals in the public sector should be publicly funded.

In the *Draft Conclusions of the Health and Public Health Working Group (159/1)* it was proposed to limit industry funding of these activities and instead to facilitate processes of "public funding of continuous training of health professionals by public administrations, and for independent research, health education/outreach and sponsorship of activities of patient associations"[42].

Independent clinical research funding

In the current architecture of the innovation system, the funding of independent clinical trials is crucial[43]. However, Spain has been discarding this instrument that would generate a large return to the public system. Firstly, by completing a research process that begins and ends within the public space. Secondly, it reinforces the R&D capacities of the current system, which is so necessary for patients and the future of personalised medicine, and finally it would further strengthen the public health infrastructure network.

Finally, it is essential that competent authorities are directly involved in research

[40] https://left.eu/content/uploads/2021/07/Advanced-purchase-agreements-1.pdf
[41] Cross S, Rho Y, Reddy H, et al. Who funded the research behind the Oxford–AstraZeneca COVID-19 vaccine? BMJ Global Health 2021;6:e007321.
[42] https://www.congreso.es/docu/comisiones/reconstruccion/conclusiones/390301_Borrador_GT_Sanidad_Salud_Publica.pdf
[43] Baker D. The benefits and savings from publicly funded clinical trials of prescription drugs. Int J Health Serv. 2008;38(4):731-50

agendas, taking the lead with strategies that respond to R&D based on the needs of the people and not on private interests, creating structures to support this development, such as non-commercial clinical trial networks and platforms for drug development up to the commercialisation phase. Therefore, the recommendations of international, national and European institutions with competence in global health, such as WHA Resolution 72.8 on Improving transparency in the markets for medicines, vaccines and other medical devices, are necessary as a reference[44]. In this way, today's health systems will be prepared to respond to present and future health needs.

Transparency

Transparency is necessary for effective and efficient management, as well as to facilitate democratic participation and the control and monitoring of the decisions of public administrations. Thus, Spain needs to strengthen transparency in all areas related to medicines, such as decision-making bodies; minutes, contents and documents of meetings; manufacturing costs of medicines; R&D costs of medicines; registration of clinical trials; public access to information or disaggregated health expenditure. It is therefore urgent to implement Resolution WHA72.8[45] supported by Spain within the WHO, which calls for the public sharing of information on the net prices of publicly funded health technologies; data on the results and costs of clinical trials; sales revenues, prices, marketing costs, subsidies and incentives; and information on the status of patents and marketing approvals.

Incompatibilities

In order to address this problem, a comprehensive declaration of potentially conflicting interests needs to be in place in Spain. Therefore, the pharmaceutical industry should be prohibited from offering economic incentives to people who have to make decisions on the approval of medicines, pricing, prescribing, etc. This includes experts or professionals who are consulted by the Spanish Agency for Medicines and Health Products or who sit on its committees and panels.

In addition, revolving doors should be prevented by prohibiting public officials involved in medicines from being employed by companies in the sector until several years after leaving office. Likewise, the funding of the Spanish Agency for Medicines and Health Products from the public budget should be guaranteed, avoiding dependence on companies through their payments for reports. Membership of the National Health System's Advisory Committee for the Financing of the Pharmaceutical Provision shall be incompatible with receiving, directly or indirectly, any amounts from the pharmaceutical industry (research projects, advice, consultancy, teaching, participation in courses, publications, etc.).

[44] https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-sp.pdf
[45] https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-sp.pdf

Public interest and valuing the contribution of the National Health System to the development of clinical trials

There is a need in Spain to safeguard the public interest in the entire biomedical research chain, thus making the State's contributions, their social return and traceability visible[46].

All public investments and subsidies should have a public interest clause, according to which the resulting products will be licensed on a non-exclusive basis, will be priced at cost plus a reasonable and limited profit margin, and the public sector will receive a return commensurate with its contribution. In addition, all clinical trials carried out within the public health system network must establish a system for valuing the human and material resources made available to them in such a way that there is clear and transparent information on the costs borne by the system and how they should be reflected in the price in terms of public return and the general interest of society.

User contribution

Co-payments, in general, create a barrier to access. They are also a form of privatisation of public health care, transferring part of the public health expenditure to patients' pockets. The industry is in favour of co-payments, even up to 100%, as it "takes pressure off" public administrations to reduce unnecessary pharmaceutical spending. However, the data show that both co-payments and pharmaceutical spending itself are increasing.

User contributions should be abolished, and this can be done progressively in parallel with the reduction of medicine prices.

Public manufacturing of medicines

The public manufacture of gene therapy drugs, somatic cell therapy drugs and others, which can be developed in hospital institutions, should be encouraged, with the required guarantees.

The industrial manufacture of medicines will be promoted through one or more public companies to ensure strategic supplies of medicines and health products. In the same way, the public undertaking may act by manufacturing or importing products when the usual manufacturer fixes excessive prices by abusing their dominant position. The national public company(ies) may collaborate in strategic agreements with initiatives of other EU countries, the European Commission, the WHO or non-profit organisations.

Shortages

The new regulations should specifically include elements to control and mitigate shortages. To achieve this, we propose the following: a) guarantee the obligation to notify both actual and potential shortages (risk of shortage) and longer notification periods in the event of the commercial withdrawal from the market; b) ensure public

[46] http://noessano.org/es/wp-content/uploads/2020/10/Interes_Publico_Inovacion_Biomedica.pdf

reporting and transparency on the reasons for shortages of each medicine; c) the obligation, for pharmaceutical companies, to hold safety stocks of medicines of high therapeutic value; d) promote strategies for the public production of out of stock medicines to cover the needs of the population; e) adapt regulatory frameworks in order to increase the possibilities for medicines to be prepared in hospital pharmacies and community pharmacies, where appropriate (compounds for certain personalised treatments under quality and safety standards and in specific situations); f) develop management and prevention plans; g) impose sanctions in the event of non-compliance with the obligations.

Environmental and waste management

The financing and pricing system should be adapted to incorporate environmental criteria. To this end, progress is needed in the development of evidence and indicators that allow the measurement of the long-term environmental impact of medicines and medical devices on human health and the ecosystem, in terms of their production, distribution, use, storage and disposal; and the implementation of a system to review medicines that allows the systematic classification and comparison of their environmental impact.

Compulsory Licensing

The review of the current regulation presents a good opportunity to incorporate compulsory licensing, one of the main flexibilities of the TRIPS Agreement, for medicines. This should be done in the public interest and the government should consider this option at any time. At times such as the pandemic, it is more necessary than ever to be able to use these flexibilities to meet the needs of the people. This has been the position of the European Union in the World Trade Organisation, most recently at the 12th WTO Ministerial Conference in June 2022.

Facilitating the implementation of compulsory licensing, both in the decision-making process and in the more technical aspects, is therefore urgent and should be undertaken as soon as possible, taking advantage of the current legislative review process.

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