PROPOSALS
TO ENSURE THE RIGHT TO
vaccines, medicines and medical devices

NO ES SANO

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INTRODUCTION

The pandemic caused by COVID-19 has marked a before and after on both a national and international level. In Spain, the National Health System (SNS) has been placed under pressure, stretching to a maximum its attributes in infrastructure, professional resources, and the availability of treatments, among other aspects. In many regions (CCAA), an already weakened health system caused by cuts made during the years of economic recession was brought to its limit. Nevertheless, the pandemic has also demonstrated the importance of having a strong and robust national health system that is universal in its social and healthcare cover, to have the capacity to respond to the needs that emerge in times like today and resilience for future health crises.

During weeks, we have suffered the heartbreaking data showing an increasing trend of persons dying, and we have seen the increase of persons infected that, in thousands of cases, required hospital-level care. However, resources as essential as ventilators were not available to meet demand, and the available beds in the ICU required an extraordinary intervention exceeding on occasion a hospital's capacity, causing a collapse in various regions. Additionally, healthcare professionals working without adequate personal protection cannot be allowed to happen again. The market responded with abusive over-charges for masks, ventilators, tests, and personal protective equipment (PPE), which were prohibitive for States. The ferocious demand of all countries and the scarcity, especially in the first weeks, converted these products in an impossibility for frontline professionals who could not work effectively and safely without them. In addition, there was a lack of a strategic reserve and inexistence of contingency plans for crises like that generated by the pandemic

However, the shortage did not only affect healthcare material. During the crisis, the shortage of medicines for COVID-19 has been one of the main issues for managers, doctors, and patients. On the one hand, given the urgency to respond to the needs of the patients with treatments that until now have been used for other pathologies and that, in clinical practices showed promising results in the control of COVID-19, these treatments have been tested by thousands of professionals in different countries; many are now pending validation in controlled clinical trials. On the other hand during the last years, the shortages that have been occurred on occasions for many medicines, has caused the EU authorities to draw up contingency plans to face non-compliance with availability.

Lastly, clinical, and social science, as well as humanities has also responded to the crisis. A solution is expected from science owing to the discovery of vaccines, treatments, and devices that will put an end to this virus also increasing the knowledge we have about it. A race against time, in which the same strategies as always cannot continue and this apply to production, funding, and patents of medicines, if we want the vaccine to be available to the whole world and not leave anyone behind.

In economic, social, cultural terms, the medium- and long-term consequences are yet to come. The economic impact in 2020 is unprecedented with loss of employment, closed businesses, and thousands of families in situations of vulnerability and social risk that need an immediate response. Therefore, the social and economic reconstruction of a country aggressively hit by the pandemic as well as the inequities generated during these last months, are urgent and should be face them firmly and without delay.

This crisis has brought the healthcare system, which was already stressed, to its limit. The healthcare professionals have gone out daily to fight COVID-19 with suboptimal infrastructures and resources. That is why, we organizations that form part of the No es Sano campaign want to deliver to the authorities and political decision-makers a package of proposals that were becoming urgent, but now cannot wait any longer.

In the following months, we should prepare ourselves to face possible new outbreaks of COVID-19 and equip the healthcare system to be prepared, not only to face this pandemic, but also other global public health problems. The national health system should be strengthened, both in primary care and hospital-level services, as well as in public health for all aspects of detection, planning, and prevention of epidemics and other chronic diseases. Therefore, the State, in its obligation to ensure the right to health and guarantee its implementation, should spearhead concrete measures, such as adequate budget funds, sufficient infrastructures and human resources, and contingency plans. A universal health system that does not exclude anyone, that guarantees cohesion, and equity in the whole territory.

In this process, health policies and more concretely pharmaceutical policy and biomedical innovation are fundamental pillars that will contribute to the objectives to improve the healthcare system and, therefore, the recommendations presented below can be a guide to achieve them. All these recommendations are measures that respond not only to the pandemic, but also to a system that in its new configuration should do things differently if we want public interest first and access to medicines, vaccines, and diagnostics to be universal, affordable, safe, adequate, effective, and quality.

PROPOSALS

1/ Universal access to medicines, vaccines, and diagnostics.

2/ Strategies to counter shortages
and internal production of health technologies.

3/ Applying TRIPS flexibilities in moments of need.

4/ Limit intellectual property and data exclusivity of innovation.

5/ Transparency, accountability, and good governance
both in pharmaceutic policy and in innovation.

6/ Investment in R&D, safeguarding public interest
and a diverse and independent research agenda
that prioritizes health needs and not business.

7/ Transparent clinical trials and rigorous science.

8/ Information, formation, and training
for safe, effective, and efficient prescription.

9/ International coordination
and commitment to the international initiatives launched
to ensure a response to global health problems.

1/ Universal access to medicines, vaccines and diagnostics

1.1/ Medicines, vaccines, diagnostics should be considered a public good and, therefore, all the necessary initiatives should be implemented so that they are considered as such, within and outside of Spain.

1.2/ Medicines, vaccines, and diagnostics should be safe, effective, quality, and accessible. Likewise, they should be available and at an affordable price. These elements cannot be lacking in the processes in place for R&D and should be a guiding principle adopted by governments, funding entities, and research areas as well as by industry.

1.3/ Therefore, the setting of prices should be based on the real cost of R&D, production, and distribution of each product, to which would be added a fair and reasonable profit margin while also taking into account other elements such as the public investment in each product, fiscal benefits, and incentives.

1.4/ The speed in the development and manufacture on a large scale are key elements in ensuring global access to medicines, vaccines, and diagnostics for COVID-19. We must guarantee the sufficient production and distribution that reaches all persons. Therefore, it will be necessary to implement mechanisms that maximize the transfer of technologies to local and national production and, in this way, eliminate situations of exclusivity in manufacture for only a few companies.

1.5/ In the process of reconstructing the health system, the universal right to healthcare should be reinforced, copayments for medicines should be eliminated, and measures implemented to end pharmaceutical poverty, especially in the most vulnerable sectors.

2/ Strategies to counter shortages and public production of technologies

2.1/ Currently, Spain has a guarantee scheme for supply of medicines until 2022. The impetus for its application is urgent, including specific measures aimed at

businesses that have produced problems in supply; mechanisms to prevent and guarantee the provision of essential and critical medicines without alternatives in the market; as well as the development of a policy for sanctions for those authorization holders that do not comply with supply commitments.

2.2/ Ensure public transparency for the reasons for the shortages of each medicine.

2.3/ Promote public production strategies for essential medicines and priority therapies that cover the needs of the population, leveraging the resources of the national health system and the capacity of other public administration facilities. Spain has experience in the field of advanced therapies that can be used as a reference, and that can be explored for other types of treatments. Companies and public platforms must be in place to manage the authorization and, where appropriate, the marketing of medicines and other health products.

2.4/ Adapt legislative frameworks to increase the possibilities for the preparation of medicines in hospital and community pharmacies, where applicable (prescriptions for specific personalized treatments, following quality and safety regulations, and in specific situations).

2.5/ Develop initiatives directed at national and internal production of medicines, medical devices, and strategic diagnostics, to guarantee production and stocks when facing future pandemics or situations of shortage in essential medicines or resources.

3/ Applying TRIPS flexibilities in moments of need

3.1/ The flexibilities in the Agreement for Trade Related Intellectual Property Rights (TRIPS) exist to provide governments with mechanisms to respond to specific situations that put public health at risk. This agreement awards, among others, the right to grant compulsory licenses and the freedom to determine the terms on which they grant them and what constitutes a national emergency or other circumstances of extreme urgency. Spain should incorporate in its pharmaceutical policies the use of the flexibilities of the TRIPS agreement in all its dimensions.

3.2/ The Spanish government has this instrument included in its current patent law 24/2015 July 24. In scenarios such as that of COVID-19, the government would be more than justified in activating compulsory licenses for specific medicines. Therefore, Spain should actively, effectively, and emphatically plan compulsory licenses as an instrument added to those resources already in place for access to certain medicines in emergency situations.

3.3/ Firmly apply article 66 of the Patent Law insofar as it provides that the exploitation of the object of a patent cannot be done in an abusive manner or clash with public health, and should be well-adapted, in any case, to the prohibitions and limitations, temporary or indefinitely, already established or that will be established using the legal provisions.

3.4/ On the other hand, and under certain circumstances, the governments can suspend patents and exclusivity so that companies share their technologies, data, and knowledge of a specific medicine or health technology.

4/ Limit intellectual property and data exclusivity of innovation

4.1/ The innovation directed at COVID-19 relies on an enormous public effort and should be free from the restrictions attached to the protection of intellectual property, safeguarding the public interest. Experience shows how intellectual property rights on knowledge and the confidentiality of research act as a barrier, both for research and for the large-scale production of affordable health technologies and, therefore, its access.

4.2/ Therefore, limiting intellectual property rights is essential. Likewise, the transfer of knowledge and health technologies should opt for non-exclusive licenses on an international level and not limited in time.

4.3/ Avoid the resource of secondary patents and additional regulatory exclusivities, such as supplementary protection certifications, that provide greater shielding of medicines and health technologies and create additional barriers to access.

4.4/ Open sharing of knowledge and research data, especially those that count on public support. R&D is conducted behind closed doors owing principally to commercial confidentially and to avoid that the reporting of negative results. Funding should always necessitate that the results and data are public domain.

4.5/ Launch platforms, repositories, and alliances that facilitate global access and knowledge transparency to facilitate large-scale production, distribution, sale, and use of the technologies.

4.6/ Beyond pandemics and emergency situations, these principals should be a guide to the construction of a new model of global, accessible, and sustainable innovation.

5/ Transparency, accountability and good governance both in pharmaceutical policy and in innovation

5.1/ Transparency is, without a doubt, the best instrument to ensure that decision-making processes are clear in all its aspects. Transparency should be applied both in innovation funding and in the processes of authorization and pricing of medicines, diagnostics, vaccines, and health technologies in general.

5.2/ With regards to public funders, the funding agreements for R&D, use, and technological transfer of the results should be made public. Spain participates with investment in national and international projects. The contributors have the right to know the performance of these public investments in R&D and their results.

5.3/ In terms of pricing and reimbursement of medicines and health technologies, transparency is vital both in governance spaces and in the information used as a basis for decision-making. All these transparent processes should be reinforced by independent audits.

5.4/ Transparency in the relationship between industry and the public sector. For this, it will be necessary to establish binding and compulsory legal mechanisms that monitor and ensure a policy of conflict of interests between professionals and the health industry that guarantees the public interest over and above private interests.

6/ Investment in R&D safeguarding public interest and a diverse and independent research agenda that prioritizes health need and not business

6.1/ The Spanish government and the public funding agencies should introduce conditions and provisions in their funding contracts and technological transfer ensuring public interest and public return of results stemming from those initiatives. The principal objective is to ensure that the medicine, vaccines, and diagnostics that result from the research projects are accessible, affordable in price, are available to all persons, are safe, effective, and good quality.

6.2/ Governments should ensure that the research findings conducted with public funds are available and are publicly accessible on a global level. In addition to fostering open science, it is essential that all data, both the positive and the negative results, generated by research projects, as well as the knowledge derived from these, are accessible and have shared use. This exercise could be undertaken with binding legal measures that are taken care of in the funding agreements and technological transfer.

6.3/ Boost independent research funds that ensure innovation that is free and autonomous from the pharmaceutical industry in all its phases, avoiding in this way the inevitable biases generated by research sponsored by industry, or by companies directly affected by its value in the stock market or its sales influenced by any news related to the development of the product. This public initiative would allow projects, not only in basic science, but also in pre-clinical and clinical phases, and including the more advanced stages. Quality clinical research that can achieve the necessary products for the national health system, avoiding the conflicts of interest suffered by professionals sponsored by industry. This will require the expansion of resources and funding of public R&D initiatives that contribute to strengthen the state public network of research and the public health system.

6.4/ Health research should meet the priorities of the population. It is necessary to rebalance the research agenda and protect public health needs. Until the arrival of COVID-19, certain disease groups, including infectious disease, were especially ignored in clinical research. Priorities need to be urgently revised, and better use of science fostered from a basis of transparency, data sharing, avoiding duplicities, and with a research effort that responds to the real health needs of the population.

7/ Transparent clinical trials and rigorous science

7.1/ Clinical trials are one of the most relevant phases in the innovation process. Transparency should also be applied to these as an instrument to allow understanding of the design and both the negative and positive results of the studies. The publication of results and access to data will allow independent meta-analyses that can demonstrate the comparative efficacy of the medicines, vaccines, and health technologies. National authorities should make decisions on authorization based on solid evidence.

7.2/ To guarantee transparency, clinical trials should be correctly added to all registers authorized for this purpose, which includes national and international registers (AEMPS, EMA, and WHO). The included information should be complete, coherent, and accurate, including everything relevant to the clinical trial protocol, the active ingredient, number of patients, funding, conflict of interest declaration, locations and persons responsible for the trial, the results, and, of course, all the relevant information needed to determine in real-time the status of each study. Sanctioning mechanisms should be established against those public and private sponsors that do not comply.

7.3/ Clinical research is at the core of R&D. Many actors participate in it, including public institutions. It is necessary to recognize the role that each plays and place value on the essential participation of hospitals and public health centers in the conducting of clinical trials. This requires the monetization of the public contribution with direct funding, human resources, services, and infrastructures; determine the actual costs of clinical research; and act in favor of transparency, accountability, and good governance of R&D.

7.4/ The need to find treatments and vaccines against COVID-19 has placed health professionals and researchers in a race against time to deliver the response needed by the population. It is fundamental that, in these accelerated processes in research and review in collaboration with the regulatory authorities, patient safety and quality of the results are guaranteed, along with the thoroughness of the scientific evidence and its publication.

8/ Information, formation and training for safe, effective and efficient prescription

8.1/ Keeping in mind the diagnostic and treatment means available at any given moment, the work by health professionals is key in proposing the most adequate course of action for a patient and the patient's decision to take said action (vaccine, antiviral, etc.).

8.2/ In this process of recommendation and agreement, the information available to health professionals is key, along with adequate, ruled, and independent training. It is fundamental to achieve separation in said training with regards to that sponsored by the pharmaceutical industry, as the sponsor may condition the behavior of the professional.

8.3/ It is fundamental to strengthen and coordinate the actual structures of the national health system aimed at the therapeutic selection and positioning of medicines and health technologies. It is essential for the national health system to develop and promote its knowledge-based independent from promotional interests, at all levels, and based on the evaluation of novel therapeutics and diagnostics, with efficient and evidence-based criteria, without conflict of interests.

8.4/ Likewise, the development of health education programs for the whole population is fundamental and would allow citizens to make informed decisions. Similarly, patient associations should be supported by health administrations to not depend on the sponsorship of the pharmaceutic industry.

8.5/ To guarantee training and independent quality information, it would be necessary to have a public fund with sufficient capacity to cover its needs.

9/ International coordination and commitment to the international initiatives launched to ensure a response to global health problems

9.1/ The global health crisis in which we currently find ourselves should be recognized as an opportunity for the public health system to be strengthened. Spain must take on the leadership and coordinated participation and active foster initiatives in international spaces that allow access to affordable, safe, effective, and quality medicines, treatments, and vaccines, that are available for all persons.

9.2/ The EU has to assume leadership and ensure that response measures to COVID-19 guarantee actions that are similar and common to all the countries. Furthermore, it has to ensure independent, transparent, free from conflicts of interest research policies and determined support for alternative models of biomedical innovation.

9.3/ In terms of funding innovation in international spaces, Spain must ensure that the contributions of different international mechanisms incorporate conditions and provisions in terms of both access, availability, and affordability of these, and in terms of intellectual property for shared use and not subject to exclusivities. Medicines, vaccines, and diagnostics should be considered global public goods and, in particular, those that are produced in the battle against COVID-19.

9.4/ In the same way, transparency in agreements in international spaces is crucial, thereby avoiding inequalities and inequities in the negotiation between governments, international organizations, and the private sector.

9.5/ The pandemic caused by SARS-CoV-2 has provoked a health and social crisis worldwide. The need to adopt coordinated measures to research, develop, manufacture, and distribute medicines, vaccines and other health technologies is an opportunity to reflect on the need to change the current model and take firm steps in this direction. The 73rd World Health Assembly celebrated on the 18th and 19th of May has increased international awareness of the need to achieve measures of prevention and treatments that are effective and accessible for all populations. However, intense pressures that oppose these changes continue to exist, for example, to the application of TRIPS flexibilities. Spain could play an important role in these debates, advancing in the proposals of the Report of the High-Level Panel convened by the Secretary-General of the United Nations in September 2016.

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