

Médecins Sans Frontières Position on the European Commission's Roadmap for Pharmaceutical Strategy

General Considerations:

Médecins Sans Frontières (MSF) welcomes the European Commission's proposed roadmap "Pharmaceutical Strategy: Timely patient access to affordable medicines".¹ People's lack of access to highly needed medical tools is a global problem well known to MSF. With this briefing document, MSF wishes to share some considerations and recommendations for the pharmaceutical strategy roadmap, based on MSF's 20 years of experience in addressing the access barriers between people and the medical tools they require.

The roadmap correctly identifies a number of barriers that can negatively impact access to essential medicines, diagnostics, and vaccines:

- **Affordability:** products are priced out of reach for individual patients or health care systems, or threaten the fiscal sustainability of specific health care programs over the long term
- **Availability:** lack of sufficient quantities to cover needs
- **Adapted tools:** lack of medical tools appropriately adapted for the needs of people or settings in which they live.

While for each of these barriers an extensive analysis and their own set of recommendations is possible, in MSF's experience they are highly interconnected and largely result from conflicting public and private interests in the current research and development (R&D) model for medical tools.

The current biomedical innovation system is overwhelmingly driven by financial interests: pharmaceutical companies choose to develop drugs based on the projected profit that a product will offer. As such, the current profit-driven R&D model concentrates resources and investments in products that will sell well, but may not be the top priorities from a public health perspective.² While this reality has long been recognised for neglected tropical diseases (NTDs), and similar areas where market volumes are small or the affected communities are poor, in recent years this problem has shown to be far more general and systematic across multiple disease and health areas.

A strategy to stimulate R&D with reinforced or longer market monopolies in the form of evergreening patents, supplementary protection certificates, market exclusivity, data exclusivity, and designation of commercial confidential information in the European Union (EU) has not served the public interest. The pharmaceutical system has disinvested or not significantly invested in R&D for some of the most pressing medical needs of our time, such as antibiotics, or vaccines for pandemic diseases like Ebola and past coronaviruses.³ Stronger and longer monopolies on health products have allowed pharmaceutical companies to price health products at any price the market can bear, at the expense of people's access. MSF has witnessed first-hand how monopolies granted to pharmaceutical corporations result in high prices negatively impacting patient access in different countries.⁴ Research has shown that granting more exclusive rights does not lead to more innovation⁵ but unambiguously discourages it.⁶

An effective EU pharmaceutical strategy that aims to improve access and develop products for unmet health needs should therefore start with an acknowledgment of the drawbacks and flaws of the current R&D model that treats medical innovations as market commodities. A strengthening of safeguards protecting public health interests is needed. The global COVID-19 pandemic has highlighted the need for effective and affordable health products accessible to everyone. We present here five

recommendations for the EU pharmaceutical strategy that can help enable timely access to affordable health products in the EU and beyond.

Recommendations:

1. Review and revise the Supplementary Protection Certificate (SPC) mechanism

Prolonged market monopolies on medical tools through patent evergreening undermine the fiscal sustainability of national health care systems. The impact of Supplementary Protection Certificates (SPCs) has been a major concern of the EU Council regarding access to medicines and the fiscal sustainability of health care systems. Our analysis has shown that SPCs upset the balance between commercial and public interests.⁷ Pharmaceutical corporations do not need SPCs to recoup investments on R&D as repeatedly claimed. We have shown that companies recouped their R&D investments in less than 4 years after market approval,⁷ findings consistent with a study on cancer medicine approvals in the US between 2005 and 2016.⁸ The 4-year duration occurred within the standard patent term of the primary patent. After companies recouped their R&D investments, more than 10 years of market monopoly from the primary patent remained. The companies were nevertheless granted several additional months and years of exclusivity after the primary patent expiry.⁶ In this regard, the 20-year patent monopoly granted to pharmaceutical companies by countries following their obligations under the TRIPS Agreement was already an extended protection that took into account the time taken for patent examination and regulatory approval.⁹

SPCs consistently prolong market exclusivity and delay the availability of affordable generic medicines in Europe, potentially causing unnecessary suffering or death for patients.⁸ This calls for a fundamental review rather than a consolidation of the SPC system in Europe. Placing evaluation of the SPC system outside the EU pharmaceutical strategy is not acceptable. The European Commission has not delivered the analysis of the impact of the SPC system on access to medicines as requested by the EU Council,¹⁰ which should be made an immediate priority. ***A review of the SPC system from the perspective of access to affordable medicines, with the abolition of the SPC as a possible option, should be at the centre of the EU's pharmaceutical strategy.***

2. Take legal steps to allow compulsory licensing in the EU

Compulsory licensing provides governments the right to produce or import a generic medicine without the consent of the patent holder, out of a public health concern. The COVID-19 pandemic has again brought into light how intellectual property (IP) and other exclusivities pose an impediment to access to treatments, diagnostics, and vaccines. As a consequence, a growing number of EU countries, such as Germany and Hungary, have indicated that they are prepared to address these barriers to overcome monopoly control of medical tools to address the COVID-19 pandemic.

Yet, even in case of a health emergency, the EU has done nothing to provide safeguards in its law to waive data exclusivity and market protections to allow effective use of compulsory licenses.¹¹ EU member states also declared themselves not eligible as importers for TRIPS Article 31*bis*. Due to this ineligibility, EU member states are not able to legally import ingredients or intermediaries needed for local production, thus hampering effective use of compulsory licenses.¹²

The EU should introduce waivers for data and market exclusivity to ensure effective compulsory licensing in the EU¹³ and encourage EU member states to restate the eligibility for import under Article 31*bis* of the TRIPS Agreement.

3. Implement the World Health Assembly (WHA) transparency resolution

We welcome the emphasis on transparency in the European Commission's roadmap. An overall lack of transparency in the pharmaceutical industry leads to information asymmetry impeding negotiations for a fair price of health products. Areas lacking transparency are the costs of R&D; public funding contributions; regulatory dossiers containing the clinical trial data; number and status of patents and patent applications; costs of manufacturing; product prices charged in different countries; supply chains; and active pharmaceutical ingredient (API) sources. This lack of transparency impedes independent analysis to objectively evaluate and improve the effectiveness and desirability of current pharmaceutical policies and practices.

In 2019, the World Health Assembly (WHA) recognised the critical importance of more transparency in the pharmaceutical sector to ensure better access to affordable medical tools. The WHA adopted a resolution, "Improving the transparency of markets for medicines, vaccines, and other health products."¹⁴ The resolution requests public disclosure of net prices, marketing costs, sales revenues, and public funding of R&D, as well as increased transparency on patent landscapes, patent status information, marketing approval status, and clinical trial data.

We recognise the efforts¹⁵ made by the European Medicines Agency (EMA) to increase transparency under its access-to-documents policy providing public access to clinical study reports.¹⁶ However the agency has faced continuous legal challenges from the pharmaceutical industry on this transparency policy. Member states and the European Commission must ensure that the EMA's policies to increase transparency, allowing public scrutiny in support of patient safety and regulatory trust and accountability, are not diluted or undermined.¹⁷

Both the European Commission and EU member states have the needed competencies to fully implement the WHA resolution through coordination and cooperation. In fact, Italy has already taken important steps towards implementation of the WHA resolution, becoming the first country to require companies to disclose the public subsidies they have received for drug R&D, prices charged in other countries, status of patents, sales revenues, and marketing costs.¹⁸ A significant number of EU member states have called on the European Commission to establish a long-term partnership for the implementation of the EU pharmaceutical strategy.¹⁹ ***Full implementation of the WHA transparency resolution should be a cornerstone of the EU pharmaceutical strategy and its implementation embedded in a long-term partnership.***

4. Conduct a pilot study on leveraging public investments to ensure access

In the EU, the public sector invests an estimated €25 billion each year in biomedical R&D.²⁰ According to our research, this amounts to about one-third of the annual global public investment in all biomedical R&D (estimated annual global total investment of €77 billion: €25 billion in the EU, €39 billion in the US, and €19 billion in Asia-Oceania region; based on publicly available information). This amount does not include additional financial incentives for pharmaceutical corporations such as tax reductions, regulatory fee waivers, and infrastructure investments. Anecdotal evidence shows such financial incentives have a considerable financial cost. In Belgium alone, the pharmaceutical sector was granted €872 million in tax credits on patents and R&D activities in 2016.²¹ Pharmaceutical corporate investments amounted to an estimated €150 billion per year globally,²² though as much as half of the R&D investments by the private sector are estimated to be financing costs (cost of capital) rather than direct investment in R&D activities.²³

A vast majority (76%, €175 billion) of the total annual expenditures on medicines (€231 billion) in the EU goes to originator products.²⁴ While developing a new medicine is expensive, the World Health Organization (WHO) and multiple researchers and academics, have dispelled the myth that high prices of medicines are needed to recoup high R&D costs and spur innovation.²⁵ Since the European public sector is a significant global funder of biomedical R&D and a major spender on originator products, exploring avenues to leverage public funds for more affordable access to products is a sound strategy from both an economic and health perspective.

The European Commission should commission a pilot study, to be made publicly available, to identify how both upstream and downstream R&D investments can be used more effectively to obtain affordable prices for originator products upon market launch. The study should accurately estimate overall EU public funding and contributions for biomedical R&D in its various forms, and make this information transparent and publicly available in line with the WHA transparency resolution (see Recommendation #3). The study should also identify how such information can be used to negotiate more affordable prices for medicines. Finally, the study should identify how the introduction of legal arrangements in funding agreements (licensing agreements, step-in rights, access and affordability conditions) and public-private research collaborations can be leveraged to ensure more accessible and affordable medicines.

5. Refrain from introducing additional harmful financial incentives or exclusive rights

Across the EU, drug stockouts and shortages, due to multifaceted causes, have caused unacceptable disruptions in people receiving the medicines they require.²⁶ More diverse, transparent and stable supply chains for essential health products are desirable in the EU and elsewhere. Yet, proposed ***financial incentives for pharmaceutical corporations to bring manufacturing to Europe in an attempt to increase control over supplies, as proposed by members of the European Parliament,***²⁷ ***may unnecessarily drive up global medicine prices and access in resource-limited settings.*** In addition, there is an inherent risk that companies can request ever-larger incentives to maintain manufacturing capacities in Europe or relocate elsewhere. This could further destabilise the fiscal sustainability of health care systems in the EU and could prioritise global competition over access to scarce medical supplies and manufacturing capacities. Such a dynamic is already witnessed with access to future COVID-19 vaccines and would particularly leave low- and middle-income countries vulnerable to lacking supplies.²⁸

Exclusive rights such as Orphan Drug Designation and SPCs in the form of transferable exclusivity vouchers as incentives for the development and marketing of novel antibiotics have been tabled with the European Commission.²⁹ Yet, the use of exclusive rights has long proven not to be effective to respond to global public health needs and are no different to existing mechanisms that failed to stimulate the development of new antibiotics in the past decades. Such simplistic proposals aimed at inflating the market entry reward have failed to grasp the complexities and vulnerabilities in the R&D pipeline for new antibiotics. In addition, these TRIPS+ mechanisms have a proven negative impact on patient access to affordable medicines.^{30,31} The introduction of ***additional exclusive rights is therefore not a suitable option to address the urgent need for new antibiotics.*** Instead systemic coordination and tailored collaborative support across stakeholders and with stewardship conditions and access provisions built in is a prerequisite to antibiotic therapeutical advancements.³² Such support should be based on a coordinated global mapping of needs to inform R&D activities and funding for new antibiotics.³³

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