

Position Paper 2023/150

Affordable access to pharmaceuticals for all and good jobs in the European pharmaceutical industry

On 26 April 2023, the European Commission published its Pharmaceutical Package: a [Communication](#) setting out the reasons for and aims of the new legislative initiatives, proposals for a [directive](#) and a [regulation](#) that cover the authorisation and supervision of medicinal products for human use and establish rules for the European Medicines Agency. The proposed [Council Recommendations on battling antimicrobial resistance](#) were adopted by the Member States on 12 June 2023.

Patents and supplementary protection certificates are a subject of the Intellectual Property Package and are therefore not part of this position, although the two legislative proposals have relevant overlaps in the area of pharmaceuticals.¹

Introduction

In 2020, the European Commission published the Pharmaceutical Strategy for Europe, addressing both the shortcomings of the (legislative) pharmaceutical system that had been observed for years and the newly identified needs for action shown by the COVID-19 pandemic. The current initiative therefore aims to tackle:

- The need for affordable pharmaceuticals throughout the EU
- The unequal access to medicines for patients in different EU countries
- The lack of pharmaceuticals available for rare diseases
- The growing antimicrobial resistance
- The environmental impact of medicines
- The need to safeguard against shortages
- The objective to retain a competitive pharmaceutical industry that invests in research, development, innovation and production in Europe

Striking the balance: A competitive industry with strong R&D portfolios and equal access to affordable medicine

According to the European Commission, the pharmaceutical industry in the EU directly employs 840 000 people and three times more indirectly in upstream and downstream employment.¹ The strength of the sector depends on a stable legal framework, capital, infrastructure and a skilled workforce. This applies both to the big and known players with strong research, development and innovation (R&D&I) activities and to the – often equally innovative – producers of generics² and biosimilars³.

The current EU pharmaceutical legislation provides innovative medicines with 10 years of regulatory protection (8 years of data protection plus two years of market protection). One extra year is granted in case of a new therapeutic indication. Innovative medicines for rare diseases (orphan medicines) are granted 10 years of market exclusivity. Even considering the long pipeline and massive investments for R&D, this is a strong incentive. The challenge is: how to balance such incentives with the need for more competition on the medicines market and hence more availability and affordability?

The proposal for a new pharmaceutical legislation in Europe broadly addresses relevant issues to ensure a safe and supportive supply for patients and to create a sustainable European pharmaceutical industry. Although the present proposal formulates the blueprint of industrial framework conditions necessary for a successful European pharmaceutical sector, it does not yet sufficiently meet the ambition to create an attractive environment that is conducive to innovation and to the competition for the research, development and manufacturing of medicines in Europe.

A stronger commitment is needed to support the industrial health sector and pharmaceutical industry as the core of value creation. Industry and research need incentives, plannable framework conditions and sufficient reimbursement conditions for industries to decide to opt for the European sector – for research, development, innovation and good working conditions in industry.

Under the proposed reform, medicines will be granted a slightly shorter standard period of regulatory protection, enabling an earlier entry of generics and biosimilars (increasing availability and decreasing prices). Adequately financed innovations at the beginning of the product life cycle will create the necessary conditions for the subsequent emergence of mass markets for generic medicines, from which patients will benefit on a large scale.

This can, however, be extended if, for example, a product addresses an unmet medical need or is launched in all Member States at the same time. The maximum period of regulatory protection that can be granted will be even higher than today: 12 years for innovative medicines (today the

¹ Communication, p.7

² A generic medicinal product has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product; directive, p.50

³ A biological medicinal product's active substance is produced by or extracted from a biological source, a biosimilar is a biologic medical product that is almost an identical copy of an original product.

maximum is 11 years). For orphan medicines that address a high, unmet medical need, regulatory protection periods can add up to 13 years, while today the maximum is 10 years.

Clear, transparent and comprehensible criteria are necessary to determine the protection period for a medication in order to guarantee predictability and legal certainty. The European Commission should examine the possibility of linking market exclusivity with clearly formulated social criteria, such as collective agreements and participation in decision-making. Rapid and fair access to innovation is rightly one of the priorities of European health policy. We would encourage the European Commission to continue down this road.

We know of over 6000 rare diseases with hardly any treatment today. This is especially pronounced when it comes to medicines that are suitable for children. IndustriAll Europe recalls that this lack can be due to limited commercial interest (i.e. too few patients) or scientific obstacles. In addition to regulatory incentives, Europe needs stronger cooperation between the scientific community and industry. It is a disgrace that such treatments are not available in wealthy societies with declared strong social values.

IndustriAll Europe asks the European Commission to regularly review and assess if the regulatory changes and non-regulatory incentives of the proposed reform deliver on the goals. We insist that such an assessment includes an overview of employment in the sector, covering both number and types of jobs.

IndustriAll Europe calls on Member States to make use of the regulatory tools that allow them to engage in joint procurement of medicines.

Marketing everywhere at the same time

IndustriAll European Trade Union strongly supports the objective to make medicines available in all Member States at the same time. Today, a company's commercial decision may be to only market their products in selected countries (although a central marketing authorisation allows them to do so everywhere at the same time). This does not necessarily depend on the purchasing power of a Member State or its population. The geographical location (distribution logistics) of a country or a rare language (adequate labelling) also play a role. Therefore, some countries are more at risk than others. In addition to the incentive of an extended regulatory protection period, we would also like to see some form of duty to explain the decision against general marketing. This could also help legislators and public health systems for future initiatives.

However, ensuring a rapid and fair access to innovative medicines in Europe is not just the responsibility of the pharmaceutical industry, it also depends on the context.

Transparency

The pharmaceutical package requires pharmaceutical companies to publish information about any public funding that they may have received for their R&D activities. IndustriAll Europe insists that it is high time that this measure is implemented. It is the first step to more fairness – in competition between companies and for negotiations with the competent health authorities about pricing and reimbursements.

Preventing shortages and “Open Strategic Autonomy”

Shortages can result from several factors. In the case of medicines, the main causes that have been identified are a) the dependency on a limited number of supplier countries to provide medicines or (active pharmaceutical) ingredients; b) the increasing specialisation and complexity of supply chains (too many potential bottlenecks); and c) perceived regulatory hurdles.

The European Commission limits its response for the time being to more coordination, earlier notifications of potential shortages and possible stockpiling. The proposed Critical Raw Materials Regulation would have to secure certain relevant ingredients. A list of essential medicines is to allow for the analysis of “supply chain vulnerabilities” and recommendations to mitigate. IndustriAll Europe fears that this is insufficient, will be time consuming and result in recommendations that will be too weak to effectively ensure sufficient availability of medicines for all Europeans.

As set out in [our response to the publication of the Pharmaceutical Strategy](#), IndustriAll Europe urges the European institutions and Member States to foster the reshoring of value chains into the European Union. This could be done through, for example:

- Tender specifications that link the public health spending on medicines to a certain degree of domestic production
- When stockpiling for emergencies, conduct purchases from companies with domestic production
- Tie research funding to a compulsory share of domestic production of the marketed pharmaceutical/active ingredient

We welcome the fact that the Spanish EU Presidency has explicitly named pharmaceutical products among the goods whose supply chain Europe should secure and made the issue a political priority.

The French Government has announced that France is to launch eight reshoring projects, covering in total 25 drugs or molecules, to be supported with €160 million of state aid. France has compiled a list of strategic drugs, containing 450 that it deems “essential drugs”. The aim is to fully reshore or increase domestic production for 50 of them.

IndustriAll Europe welcomes such concrete steps. We call for full transparency and strong social conditionality: all such state aid must be conditional on the protection and guarantee of quality employment.

An EU Critical Medicines Act

Shortly after the publication of the Package, several Member States proposed a Critical Medicines Act for the European Union, modelled on the Critical Raw Materials Act. More and more countries have joined the call, endorsed by a range of industry federations. Although it remains a vague proposal, IndustriAll Europe is in favour of exploring such an initiative further. As stated in the previous paragraph: Any public funding that goes to secure domestic production must be granted with clear and strong social conditions attached.

Addressing pharmaceutical residues in the environment

In recent years, the problem of pharmaceutical residues in the environment, especially in water, has gained attention. They pose a problem for wildlife, but also for (workers engaging in) waste water management.

The proposed pharmaceutical legislation extends the responsibility of the producers in this context: all pharmaceutical products (already on the market and foreseen for the future) must undergo an environmental risk assessment with clear requirements, regular updates, and potentially additional studies. This assessment must include mitigation measures. Failure to provide such an assessment can lead to the withholding of a marketing authorisation. The rules do take into account that environmentally harmful substances stem only partly from the production process. Residues from use (digestion) and disposal of unused medications are just as significant.

IndustriAll Europe welcomes stricter assessment rules with more ambitious mitigation measures. Clear procedures of information dissemination must also be put in place. However, we point out that the very “toxicity” of a pharmaceutical product is the characteristic that makes it a potent medication. This may therefore not be a reason to refuse authorisation. The effectiveness of a medication must be the main consideration.

IndustriAll Europe calls for the greatest possible limitation of the negative environmental impact of medicines for human and veterinary use through, for example:

- Clear labelling of environmental risks of a medicinal product to allow informed choices among equivalent therapeutic options
- Strict disposal rules for unused medicines
- Strict regulation and enforcement of waste products and residues from production processes
- Enhanced wastewater treatment

Antimicrobial Resistance

Antimicrobial⁴ resistance (AMR) is a growing problem and is likely to pose major difficulties to health systems. AMR decreases the capability to treat infectious diseases and threatens the ability to perform even routine surgery. IndustriAll Europe sees the first and most important step in a more prudent use of existing antimicrobials, i.e. better information for patients and restrictions on prescriptions. However, new medicines will be needed. We call on authorities to facilitate cooperation between academia and industry and on researchers for open-mindedness to new or rediscovered sources.

The Pharmaceutical Package introduces incentives for the development of novel antimicrobials, including research grants and guaranteed revenue.

(A voucher scheme for additional regulatory data protection will be tested.ⁱⁱ⁾)

The Council Recommendations on stepping up EU actions to combat antimicrobial resistance in a One Health approach cover a wide range of activities: monitoring and reporting, information campaigns, prevention in health care settings, manure and sewage sludge management, etc. Most importantly, they ask for National Action Plans with measurable targets.

IndustriAll Europe appeals to the Member States to walk the talk and devise ambitious National Action Plans with clear targets, regular reviews, follow-up actions and sanctions for non-compliance.

Treatments of the Future

Finally, industriAll Europe recalls that the shift from mass medicinal products to personalised medicines is likely to increase in the coming decades. For example, gene and cell therapies may offer treatments that would require new business models for pharmaceutical producers and the preparedness of public health systems to address the shift in cost from chronic to one-time treatment. It is necessary that this trend is monitored and shaped by a dialogue involving all stakeholders. A regulatory response may be required soon.

Other remarks

The package presented includes proposals that are considered to be positive in terms of the regulatory framework, namely the simplification of the European Medicines Agency's procedures, the reduction of approval times and regulatory "sandboxes" which offer innovative therapeutic alternatives more flexibility in the authorisation process. However, these proposals are counterbalanced by a multitude of individual measures which could lead to legal and planning

⁴ An ANTIMICROBIAL is any substance of natural, semisynthetic or synthetic origin that kills or inhibits the growth of microorganisms but causes little or no damage to the host.

uncertainties for the industry. IndustriAll Europe calls for an in-depth dialogue with the policy makers and the industry on the role that the industry can play to address urgent global issues (e.g. the health of an ageing population in industrialised countries, the consequences of climate change on health). It is necessary to adopt a global approach to the role of the pharmaceutical industry in the European health sector, taking into account the workforce and the appropriate framework conditions for the industry.

The European Union defines itself as a community founded on values of solidarity. In order to respect these values of solidarity, the EU must not just supply medicines to its own population, but also ensure that the citizens of financially fragile countries also have access to quality medicines. IndustriAll Europe encourages the creation, development and support of research and production capacities in all regions and across all continents.

IndustriAll Europe calls on the European Commission and the Member States to ensure that the online distribution giants do not take control of this distribution and avoid any dependence on individual distributors. Furthermore, it is necessary to strengthen the means to fight against the counterfeiting of medicines.

IndustriAll Europe's demands:

- Stronger cooperation between the scientific community and industry to battle rare diseases and fulfil unmet needs.
- That the European Commission regularly reviews and assesses if regulatory changes and non-regulatory incentives deliver on the goals of the reform.
- Make medicines available in all Member States at the same time: In addition to the incentive of an extended regulatory protection period, we would also like to see a duty for the producer to explain the decision against general marketing.
- Easily accessible information about any public funding that a pharmaceutical company may have received for their R&D&I activities.
- To foster the reshoring of value chains into the European Union, e.g., through tender specifications and purchasing decisions. In the case of state aid for reshoring projects, we call for full transparency and strong social conditionality: all such aid must be conditional on the protection and guarantee of quality employment.
- Improve the attractiveness of the European sector through digitisation, simplification of authorisations and initial investments through public funds that encourage private capital.

- Strong obligations for environmental risk assessment and mitigation measures without compromising the availability and effectiveness of medicines.
- That Member States devise ambitious National Action Plans to fight Antimicrobial Resistance with clear targets, regular reviews, follow-up actions and sanctions for non-compliance.

ⁱ An example of this is the Bolar exemption: The producers of generic or biosimilar products can start studies for later regulatory approval during the patent protection period of the reference medicine. Newly proposed rules would broaden the scope of this option and harmonise it across Member States.

ⁱⁱ “The voucher will grant an additional year of regulatory data protection to the developer of the antimicrobial, which the developer can either use for one of its own products or sell to another marketing authorisation holder. The eligibility to the scheme will be restricted to game-changing antimicrobials that address antimicrobial resistance and the priority pathogens recognised by the WHO. Strict conditions will govern the use of the voucher, so that the main reward goes to the developer of the innovative antimicrobial. The proposed scheme also includes conditions for the supply of the antimicrobial to ensure its delivery when required.

A voucher scheme creates an attractive business case for the development of innovative antimicrobials for which the current research pipeline is very limited. This scheme will ultimately transfer the costs of the vouchers to the Member States’ health systems, by delaying the market entry of generics of the products covered by the vouchers. To curtail the costs for the health systems, the reform will restrict the number of vouchers reserved for novel antimicrobials to a maximum of 10 vouchers that can be granted over a period of 15 years.” (Communication, p. 15).