PHARMACEUTICAL STRATEGY

cep**PolicyBrief**

Centres for European Policy Network
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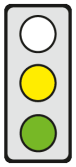
KEY ISSUES

Background: The strategy serves to strengthen the EU Commission's vision of building a stronger European Health Union – especially considering the experiences of the COVID-19 pandemic. In general, it aims to ensure the quality and safety of medicines while boosting the sector's global competitiveness.

Objective of the Communication: The Commission suggests measures to foster patient access to medicines, support the competitiveness of the EU's pharmaceutical industry, develop the EU's open strategic autonomy and ensure both robust supply chains and a strong EU voice on the global stage.

Affected parties: All patients and undertakings in the European health systems.



Pro: (1) The Pharmaceutical Strategy rightly aims to lay the foundation for a more pro-active European health policy.

(2) The threat of antimicrobial resistance (AMR) requires novel antimicrobials as well as incentives for restricting and optimising the use of existing antimicrobials, as they also in fact make an important contribution to containing AMR.

(3) The Commission is right to focus on further harmonisation of the application of supplementary protection certificates and the Bolar exemption.

Contra: The Commission still needs to address "evergreening" as it potentially suppresses competition from generic pharmaceuticals.

The most important passages in the text are indicated by a line in the margin.

CONTENT

Title

Communication COM(2020) 761 of 25 November 2020 on a **Pharmaceutical Strategy for Europe**

Brief Summary

- **Background and Objectives**
  - The EU sees a need for a new approach to ensure a strong, fair, competitive and green industry which especially draws on the potential of the digital transformation of health and care. A well performing single market is needed through an approach that covers the entire lifecycle of pharmaceuticals. [p. 1 et seq.]
  - The COVID-19 pandemic has, and continues to have, a profoundly serious impact on Europe. Existing vulnerabilities have been revealed, including those related to data availability, the supply of medicines and the availability of manufacturing capacities to adapt and support the production of medicines. [p. 1]
  - The Pharmaceutical Strategy aims to ensure the quality and safety of medicines, while boosting the sector's global competitiveness [p. 2].
  - The Pharmaceutical Strategy has four different objectives [p. 2]:
    - fostering patient access to innovative and affordable medicines;
    - supporting the competitiveness and innovative capacity of the EU's pharmaceutical industry;
    - developing the "EU's open strategic autonomy" and ensuring robust supply chains;
    - ensuring "a strong EU voice" on the global stage.
  - As part of these objectives, the EU Commission wants to:
    - address unmet medical needs and antimicrobial resistance (AMR) [p. 3 to 6];
    - ensure access to and affordability of medicines [p. 6 to 9];
    - establish an interoperable EU health data space to foster European pharmaceutical research [p. 10 et seq.];
    - create a European Health Emergency Response Authority [p. 21 et seq.].
- **Addressing "Unmet Medical Needs" and Antimicrobial Resistance**
  - Currently, investment does not necessarily focus on the greatest "unmet needs", due to the absence of commercial interest or limitations of science [p. 4].
  - The Commission wants to stimulate innovation, particularly in areas of "unmet needs", e.g.: [p. 4]
    - novel antimicrobials, given the lack of therapeutic options to address antimicrobial resistance (AMR);

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- neurodegenerative diseases and pediatric cancers;
- other known rare diseases which still have no treatment options.

– The Commission wants to
- introduce measures to restrict and optimise the use of antimicrobial medicines and explore "new types of incentives" for innovative antimicrobials [p. 5];
- revise the legislation on medicines for children and rare diseases to improve the therapeutic landscape and address "unmet needs" through more tailored incentives [p. 6];
- work with the European Parliament and the Council towards the adoption of the Regulation on Health Technology Assessment ["HTA"] [p. 6].

► **Ensuring Access to and Affordability of Medicines**
– Innovative and promising therapies do not always reach the patient in the EU; access to medicines differs among the Member States. There is no obligation to market a medicine in all EU countries. [p. 6]
– The affordability of medicines has implications for both public and household finances. It poses a growing challenge for most Member States. [p. 8]
– There is a lack of:
- transparency regarding the costs of research and development (R&D) and the return on investment which can influence decisions that impact affordability and ultimately access for patients [p. 6].
- transparency and consensus on costing principles, since pricing and reimbursement of medicines are the purview of Member States [p. 8 et seq.].

– Generics and biosimilars, in particular, may provide many patients with accessible and affordable treatments [p. 7].
– The Commission wants to
- revise the system of legal incentives and obligations to support innovation, access and affordability of medicines across the EU taking account of the relationship with intellectual property rights [p. 8];
- review the legislation to improve access to generic and biosimilar medicines [p. 8], including
  - interchangeability, i.e. the possibility of exchanging one medicine for another with the same clinical effect, and
  - the "Bolar" exemption, which is the provision for the conduct of trials on patented products to support generic and biosimilar marketing authorisation applications [Art. 10 (6) Community Code relating to medicinal products for human use [Directive (EC) 2001/83]];
- develop cooperation and exchange among national competent authorities on pricing and payment policies to improve the affordability and cost-effectiveness of medicines as well as the health system's sustainability [p. 9];
- engage with Member States in implementing non-legislative measures to improve transparency, such as guidelines on principles and costing methods for establishing the R&D costs of medicines [p. 9].

► **Establishing an EU Health Data Space to Foster European Pharmaceutical Research**
– Access to health data for the industry and regulators is needed to support innovation [p. 10].
– An interlinked system with access to comparable and interoperable health data will support cross-border analysis, policymaking and regulation as well as health care delivery [p. 10].
– The Commission wants to [p. 11]
- present, in 2021, a legislative proposal on the European health data space;
- establish, by 2025, an interoperable data access infrastructure;
- conduct, in 2021, a pilot project on an interoperable data access infrastructure involving the European Medicines Agency (EMA) and national authorities.

► **Creating a European Health Emergency Response Authority**
– The nature and speed of the EU response to COVID-19 illustrates the need to systematically prepare for future health threats [p. 21].
– The Commission wants to establish a European Health Emergency Response Authority (HERA) in order to improve the EU's crisis preparedness and response infrastructure to cross-border health threats [p. 21].
– HERA will be entrusted with various tasks, which include [p. 22]:
- anticipating specific health threats;
- identifying and addressing investment gaps in key areas, such as the development of antimicrobials;
- monitoring and pooling production capacity, raw materials requirements and availability;
- supporting the development of crosscutting technological solutions, e.g., vaccine platform technologies.

Statement on Subsidiarity by the Commission

No statement on subsidiarity is given by the EU Commission.

Policy Context

The strategy serves to strengthen the EU Commission's vision of building a stronger European Health Union, which President von der Leyen set out in her 2020 State of the Union speech and which was initiated by a Communication on "Building a European Health Union" in November 2020. In the wider sense, the "EU Health Union" is the overarching term for the current reorientation of European health policy [see also cep**Input** Three Steps Towards a European Health Union]. In the narrower sense, it encompasses three legislative proposals: one on the competences of the European Medicines Agency, one on the European Centre for Disease Prevention and Control, as well as a proposal for a Regulation on serious cross-border threats to health. The Pharmaceutical Strategy forms part of this new approach and also stands alongside other health policy strategies such as "Europe's Beating Cancer Plan" and the "European Action Plan to Combat Antimicrobial Resistance" (see cep**PolicyBrief** 2018-01). In addition, it complements, among others, the "Green Deal" and the "Zero Pollution Target", especially regarding the impact of pharmaceutical substances on the environment (for this see also cep**PolicyBrief** No. 02/2020).

Options for Influencing the Political Process

Directorates General:	Health and Food Safety
Committees of the European Parliament:	Environment, Public Health and Food Safety (leading); Rapporteur: N.N.

ASSESSMENT

Economic Impact Assessment

The Pharmaceutical Strategy rightly aims to lay the foundation for a more pro-active European health policy. It primarily addresses issues in need of transnational solutions.

The potential and ever-growing **threat of antimicrobial resistance (AMR) requires novel antimicrobials**. There is a widespread reluctance on the part of pharmaceutical companies to invest in corresponding research and development due to unfavorable economic conditions. Funds can be more profitably invested elsewhere. Furthermore, existing antimicrobials are often not subject to additional innovation because of their comparatively low price, usually locked in through internal reference pricing. Therefore, research incentives must be fundamentally improved**.**

Unfortunately, the Commission does not specify what it means by "new types of incentives". One option could be public-private partnerships. These could play a decisive role in the long term, especially by fostering a build-up of AMR research and development (R&D) capacities to ease the readiness to commercialise products. European and national action may be essential to build up these new capacities and avoid losing precious knowledge and methods in this domain.

Nevertheless, the Commission is right to focus on **incentives for restricting and optimising the use of existing antimicrobials**, especially in livestock farming, as currently they also in fact **make an important contribution to containing AMR.** The use of antimicrobials can also be reduced by broadening the testing of the type of infection (bacterial or viral) thus preventing prescriptions based simply on suspicion. The Commission should organise public campaigns to raise awareness regarding the appropriate use of antimicrobials. Additionally, the Commission should focus on "end-of-pipe" controls, e.g., improved purification technologies in water treatment plants.

When it comes to the treatment of rare diseases, the smaller the number of patients, the less likely the private development of medicines will be. Early and regular detection of patients is essential in this regard. The Commission should establish programs and incentives to increase the awareness of rare diseases among medical practitioners. R&D funding, to facilitate individualised treatments for patients with e.g. ultra-rare diseases, would also be beneficial. The Commission should also consider bridging legislation to enable a manageable transition of a pharmaceutical from an "orphan drug status" to a regular status. EU countries' reimbursement policies vary hugely in this context, so pharmaceutical companies usually adapt their HTA strategies – i.e. for assessing the efficiency of new pharmaceuticals essential for national reimbursement and pricing policies – to national regulations which in turn shape research incentives. The Commission therefore needs to be more active in promoting the development of treatments for rare diseases by encouraging Member States to harmonise their reimbursement policies for orphan pharmaceuticals.

A first crucial step would be to harmonise the clinical methodologies used in the efficiency assessment. A convergence effort – e.g. within the EUnetHTA, the forum for national HTA agencies – is needed, for instance between France and Germany, which have methodological divergences in their efficiency assessment regarding relevant efficiency submissions.

Given high pharmaceutical R&D costs, pharmaceutical companies need intellectual property (IP) rights – i.e. patents – to achieve profits and keep innovating. However, due to high pharmaceutical costs, patents trigger various issues relating to affordability and even accessibility in many European countries. **The Commission is right to focus on further harmonisation of the** regulatory framework. This could, e.g., lower the costs of inefficiencies linked to the application of different regulations across EU Member States. The **application of supplementary protection certificates** (SPC) – which extend the period of protection (the legal effect) of a patent by up to a maximum of five years – **and the Bolar**

exemption – which allows trials on patented products to support generic and biosimilar marketing authorisation applications – should be further harmonised so that patent lifetime and the possibility for competition remains the same across the EU. **The Commission still needs to address "evergreening"** – i.e. the de facto ability of manufactures to prolong their patent protection by patenting the manufacturing process, a slight difference or a second use – **as it potentially suppresses competition from generic pharmaceuticals.**

The creation of a European Health Data Space will provide access to comparable and interoperable health data, especially for policymakers, researchers and the industry**.** Pharmaceutical companies already share data with the EU and Member States – e.g., as part of an approval procedure. Interoperable health data can be used to gain insights into health policy issues and improve health policy regulations and research. This would, i.a., facilitate access to so-called real-world-evidence (RWE). For a truly interoperable system, data standards need to be put in place. A first step would be to support the Member States in their efforts towards digitalisation, while interoperability should form the basis of the data space. However, early-stage R&D data, in particular, should be protected. In the future, this health data space could be used as a platform for a data market with data-based services, e.g., data-driven artificial intelligence, to assist researchers in R&D processes.

The EU share of global R&D investments in the pharmaceutical industry is receding, a European pharmaceutical strategy could therefore be a "game-changer". The Commission's proposals, however, fail to address one essential challenge: The attractiveness of, e.g., the USA in terms of pharmaceutical R&D is mainly due to a financial environment which encourages more risk-taking by venture capital. There are no comparable conditions in Europe. The Commission should deepen the Capital Market Union and encourage Member States to implement taxation schemes that offer fiscal benefits for risky investments in radical innovation such as pharmaceutical products. Most of the time, radical innovation in the pharmaceutical sector is driven by SMEs ("biotechs"), which are often bought up by large pharmaceutical companies at the development stage of their products. Therefore, by targeting fiscal incentives at such companies, an environment which brings together human and monetary capital should emerge.

Legal Assessment

Legislative Competence of the EU

The EU has only limited competences when it comes to health policy. Whether or not the measures proposed in the strategy are compatible with them will depend on their actual design. The creation of a European Health Emergency Response Authority (HERA) is not per se a violation of Member States competences, as the EU can establish its own EU institutions to support the fight against cross-border diseases and health threats [Art. 168 (5) TFEU]. Whether its establishment will breach the Member States' area of responsibility as protected under primary law [Art. 168 (7) TFEU] will depend on its powers. The same goes for the creation of a European Health Data Space. A data space which allows access to patients' health data in electronic health records does, however, support the exercise of the fundamental freedoms of EU citizens in the area of cross-border healthcare.

Subsidiarity and Proportionality with Respect to Member States

Dependent on the design of the individual legislative measures.

Summary of the Assessment

The Pharmaceutical Strategy rightly aims to lay the foundation for a more pro-active European health policy. The threat of antimicrobial resistance (AMR) requires novel antimicrobials. Incentives for restricting and optimising the use of existing antimicrobials make an important contribution to containing AMR. The Commission is right to focus on further harmonisation of the application of supplementary protection certificates and the Bolar exemption. The Commission still needs to address "evergreening" as it potentially suppresses competition from generic pharmaceuticals.