European Parliament

A pharmaceutical strategy for Europe: First steps

On 1 June 2020, the European Commission published a roadmap for a pharmaceutical strategy for Europe. The strategy will have the overall goal of ensuring Europe's supply of safe and affordable medicines and supporting the European pharmaceutical industry's innovation efforts. Two consultations (on the roadmap and the strategy, respectively), are currently under way. Adoption of the strategy is envisaged for the fourth quarter of 2020.

Why a pharmaceutical strategy?

There has been recurrent debate on the two broad thematic strands the strategy targets, and the coronavirus pandemic has brought both into focus. The pharmaceutical sector is a major contributor to the EU economy (EU-28 pharmaceutical production sold reached €26.1 billion in 2018). At the same time, bottlenecks in the supply chain for medicines have increased and are deemed an emerging problem.

A European Commission priority

European Commission President Ursula von der Leyen tasked the Commissioner for Health, Stella Kyriakides, with exploring ways to ensure Europe has supplies of affordable medicines to meet its needs and, in doing so, support the European pharmaceutical industry to ensure that it remains an innovator and world leader. In her answer to the European Parliament questionnaire in preparation of her hearing, Stella Kyriakides committed to supporting Member States in their efforts to ensure affordable, accessible and high quality medicines. She added 'Our dependency on non-EU countries for manufacturing pharmaceutical active substances used in EU medicines is another issue that needs to be addressed'. At her hearing before Parliament, Kyriakides reiterated that '[t]here is a legal obligation on the pharmaceutical industry to ensure that patients have access to and supply of medicines. We need to work closely and try to have a holistic pharmaceutical strategy, so as to be able to deliver what we need for patients'. A pharmaceutical strategy is one of the new initiatives included in the Commission's work programme for 2020, presented in January and adjusted in May.

European Commission roadmap

The strategy will cover all levels of the pharmaceutical value chain, from research and development, to authorisation and patients' access to medicines. It will look at how to put scientific and technological advances into practice and how to fill market gaps. Lessons learned from the pandemic around preparedness and supply chains will also inform the strategy. The roadmap identifies several challenges:

- the major impact a rapidly changing global context can have on access to medicines in the EU, such as the EU's growing dependency on imports of medicines and active pharmaceutical ingredients (APIs) produced outside the EU;
- unequal access to medicines that are not always affordable for patients and national health systems across the EU, such as innovative therapies, including cancer medicines;
- shortages of medicines, which often concern off-patent medicines (on which the patent has expired), such as antibiotics, cancer medicines and vaccines;
- innovation efforts that are not always aligned with public health and health systems' needs, resulting in therapies or medical technologies not being developed because of limitations to the science, or lack of interest from industry to invest;
- challenges for the EU pharmaceuticals innovation 'ecosystem', meaning research done by smaller biotech companies is not always translated into commercially exploited innovation;
- technological and scientific developments that may challenge the regulatory framework and lead to unintended barriers to innovation, such as gene and personalised therapies, smart health applications and artificial intelligence;
- the need to improve the way environmental risks are addressed, such as those resulting from the production, use and disposal of medicines, and in particular, antimicrobial resistance (AMR).

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How might the new strategy look?

Based on the above considerations, the Commission identifies four specific objectives for the strategy:

1. Make sure patients across Europe have new medicines and therapies in their countries quickly and under all circumstances, and that there are fewer shortages of medicines;
2. Help make medicines more affordable, and increase the 'value for money' of medical expenses;
3. Take advantage of digitalisation, and make sure innovation and emerging science and technology cater to patients' therapeutic needs, while reducing the environmental footprint;
4. Reduce direct dependence on raw materials sourced from non-EU countries, influence other countries to harmonise international standards for the quality and safety of medicines, and help European pharmaceutical companies compete globally on an equal footing.

According to the Commission, the strategy is in line with the new industrial strategy for Europe and linked to other priorities, including the European Green Deal and Europe's Beating Cancer plan. It will consider both legislative and non-legislative actions. The former could consist of follow-up to initiatives already in preparation, such as the evaluation of the legislation on medicines for children and rare diseases (the Paediatrics and Orphan Medicines Regulations, respectively), and a targeted evaluation with subsequent review of the basic pharmaceutical legislation (Directive 2001/83/EC and Regulation (EC) 726/2004). EU investment would include programmes such as Horizon Europe, InvestEU and Digital Europe.

The European Parliament has adopted two resolutions on topics related to the pharmaceutical strategy. A 2017 resolution on **improving access to medicines** calls, among other things, for a new Transparency Directive replacing Directive 89/105/EEC, aiming to ensure full transparency on price-setting and reimbursement procedures used for medicines in the Member States. It also calls on the Commission to amend the Paediatric Medicines Regulation and to evaluate the implementation of the regulatory framework for orphan medicines. It encourages the Commission and the Member States to foster research and development (R&D) driven by patients' unmet needs, such as researching new antimicrobials, and to launch a high-level strategic stakeholder dialogue on developments in the EU pharmaceutical system. A 2018 resolution on **antimicrobial resistance** calls on the Commission and the Member States to encourage the development of sustainable medicines with a low impact on the environment and water, and to encourage further innovation in the pharmaceutical industry in this area. It urges the Commission to consider a new legislative framework to stimulate the development of new antimicrobials. It notes that the usual business model for developing medicines is not suitable for antibiotic development, reminds the industry of its corporate and social responsibility in helping tackle AMR, and calls for early and continuous dialogue with stakeholders on developing incentives for R&D in the field of AMR.

Stakeholder views and expectations

Stakeholders welcome the Commission's roadmap, broadly agreeing with its goals. The International Association of Health Mutuals (AIM) believes the strategy needs to guarantee that developments in evidence-generation, such as those coming from real-world data, or AI, deliver meaningful information to decision-makers. According to the Association of the European Self-Care Industry (AESGP), the strategy needs to acknowledge the specificities of different pharmaceutical products and their regulatory pathways. It should seize on the benefits of improved availability of non-prescription medicines. The European Federation of Pharmaceutical Industries and Associations (EFPIA) considers much can and should be done already now within the existing framework, through recognition and efficient implementation of the lessons learned from Covid-19. Regarding access to vaccines and treatments, EFPIA calls on the Commission to create a High-Level Forum on Better Access to Health Innovation, as proposed by the European Health Coalition. Acknowledging the EU's focus on enhancing its strategic autonomy in specific areas, EFPIA notes that Europe's pharmaceutical industry already has a strong in-built resilience, with 76 % of the APIs used in the manufacture of innovative medicines in Europe now being sourced in the EU. The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) sees a need for a strategy that enables research and attracts investments in Europe, alongside a solid regulatory framework that promotes science and development of new medicines. According to the generic, biosimilar and value-added medicines lobby Medicines for Europe, the strategy should build on existing pharmaceutical manufacturing capacity and invest in a globally competitive medicines manufacturing sector. It should improve medicines' availability, recognising that industry and governments have a shared responsibility to improve access to medicines.