

# Consultation strategy for the evaluation and revision of the general pharmaceutical acts under the Pharmaceutical Strategy for Europe

## Directive 2001/83/EC on the Community code relating to medicinal products for human use and Regulation (EC) No 726/2004 laying down procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

### 1) Background information

Patients need safe, efficacious and high quality medicines that are available at an affordable price. At the same time, Europe is home to a strong and competitive pharmaceutical industry. Together with other public and private actors, it serves public health and acts as a driver of job creation, trade and science. Medicine producers made the biggest contribution to research investment in 2019, with over €37 billion. The sector provides 800 000 direct jobs and a €109.4 billion trade surplus. Despite its robustness, the EU pharmaceuticals system faces major challenges. Patients across Europe do not have the same access to medicines, health systems and people paying out of pocket have budgetary difficulties, and some medicines are in shortage. Regulators see the limits of the legislation when it comes to keeping up with the rapidly changing technological environment and businesses need to operate in a system that fosters innovation. The COVID-19 pandemic has raised the vulnerabilities of the EU pharmaceutical system in sharp relief but has also given the opportunity to adapt and learn in order to correct any misgivings.

The European Commission is building a stronger [European Health Union](#), in which all EU countries prepare and respond together to health crises, innovative, safe and effective medicines are available at an affordable cost. On 25 November 2020, the Commission published a [Communication on a Pharmaceutical Strategy for Europe](#)<sup>1</sup>. The strategy is an ambitious, long-term project in the area of health, intended to make the European pharmaceutical system more patient-centred, future-proof and crisis-resistant.

The Pharmaceutical Strategy includes flagship initiatives and other actions to ensure the delivery of tangible results. As a part of the implementation of the strategy, the Commission is evaluating the current general pharmaceutical legislation<sup>2</sup> and assessing the impacts of changes intended to address the following objectives:

- Ensure access to affordable medicines for patients, and address unmet medical needs;
- Enable innovation for the development of high quality, safe, effective medicines, harnessing the benefits of digital and emerging science and technology while reducing the environmental footprint;
- Enhance the security of supply of medicines and address shortages;

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<sup>1</sup> COM(2020) 761 final.

<sup>2</sup> References to the 'pharmaceutical legislation' are to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67) and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

- Reduce regulatory burden and provide a flexible regulatory framework.

This revision will be informed by a 'back to back' evaluation and impact assessment. A study conducted by an external contractor will be carried out. The study will run roughly from Q2 2021 to Q1 2022.

To ensure that all possible views are well reflected and to ensure transparency and accountability, consultations with various categories of stakeholders will be held. The consultation process does not start from zero; the Commission will base its work on the consultations that took place in 2020 in the inception phase of the strategy which provided useful information on the mapping, priorities and views of all major interested parties. More information on all aspects of the strategy, the initial consultation activities and their results can be found in the Pharmaceutical Strategy [dedicated webpage](#).

## 2) Objectives of the consultation

The consultation activities aim at capturing evidence and views from a broad range of interested stakeholders all levels of the value chain and the public, allowing them to provide relevant information on the problems presented and on potential ways forward. The Commission wishes thus to ensure appropriate involvement of all affected actors and to better understand the implications of the possible policy options. It also aims to receive views and evidence on the functioning of the legislation and the impact on the different stakeholders of the potential options.

The consultation activities related to the revision of the general pharmaceutical acts will inform the evaluation of the legislation, which will assess to what extent the general pharmaceutical legislation has delivered against its initial objectives and will also inform the possible options for EU action to be considered in the impact assessment.

The consultations (both public and targeted) should identify areas where there is broad agreement among stakeholders as well as areas where significant differences of views exist. In the latter case, the consultation should allow the identification of the group of stakeholders to which the different views refer and the causes of contention.

It is important to note that, as stated above, this consultation process will build on the [results](#) of the consultation on the Commission's Communication on a Pharmaceutical Strategy for Europe. The present consultation will also be informed, where relevant, by consultation processes on other deliverables included in the strategy, such as the revision of the legislation on medicines for children and rare diseases.

## 3) Stakeholder mapping

Stakeholder groups concerned by the revision of the general pharmaceutical legislation are those impacted or potentially impacted by actions proposed under the strategy. As the revision encompasses different aspects related to the entire pharmaceutical value chain, the strategy has implications for a broad range of stakeholders.

The main interest groups identified for this consultation are:

**General public** – This is the largest group. They have a general interest in the availability, affordability and efficacy of medicines and treatment options.

**Organisations representing patients, consumers, civil society, active in public health and social issues** – In addition to the general interests described above, they are specifically concerned about the increasing problem of shortages of medicines and patient unequal access to medicines across the EU and the challenges of affordability and sustainability of health systems, and their socio-economic consequences. Their contributions are particularly important to inform the Commission’s reflection in relation to ‘unmet medical needs’ and value for money/affordability.

**Healthcare professionals and healthcare providers** – They have a pivotal role in identifying and delivering care and treatments for individual patients, and are confronted specifically with challenges of shortages of medicines and access to medicines but also to the costs of care and the budgetary pressure. They are interested in exploiting new technologies and digitalisation of products and processes when they bring value for money and address unmet medical needs.

**Researchers, academia and learned societies** – Many new therapies are developed by these organisations. The regulatory environment influences the uptake of this research. Their contributions are particularly important regarding scientific developments and in making available to patients new innovative therapies.

**Environmental organisations** – The revision will also pursue environmental objectives, therefore contributions will be sought from environmental organisations and stakeholders, especially with respect to the environmental risk assessment, the environmentally friendly production, use and disposal of medicines, including the links between pharmaceuticals in the environment and AMR.

#### **Businesses and their associations**

The pharmaceutical industry is the main actor in the development and production of medicines. Contributions will be sought from small and medium-sized (SMEs) as well as from large companies, from originators to generics, developers and producers including also clinical research organisations and industries beyond the pharmaceutical companies (e.g. medical devices manufacturers, digital companies, healthcare service providers, hospital and care deliverers, health insurances etc.). This category also includes stakeholders in the supply chain of medicines providing raw materials for the production of active ingredients for the manufacturing of medicines, their distribution, supply and subsequent disposal. These include primarily pharmaceutical chemicals importers and producers, active pharmaceutical ingredient (API) producers, parallel traders and wholesalers.

The Commission works closely with the partners listed below. The Commission’s collaboration with these actors is part of the internal policy work process supporting the revision of the legislation. Their input to the general consultation process is also highly welcome:

**European Medicines Agency / National Medicines Agencies** – Both play a pivotal role in the implementation of pharmaceutical legislation in pre- and post-authorisation phases. The existence of centralised and national authorisation routes puts the European Medicines Agency (EMA) and national agencies on the front line of pharmaceutical policy implementation. EMA / Heads of Medicines Agencies (HMA) have developed a [European medicines agencies network strategy to 2025](#), covering both human and veterinary medicines. Their work will contribute to informing the initiative.

**Member States (incl. EEA countries) and public authorities** – Member State Health Ministries and national competent authorities responsible for pharmaceutical policy are a major partner of the Commission. Public authorities such as Health Technology Assessment (HTA) bodies, pricing and reimbursement authorities, payers (public health insurances, public procurement bodies, sickness funds, public payers, etc.) or competition authorities, etc. will be able to contribute on issues in the national policy making that have an EU relevance, notably with regard to affordability and health system sustainability. Ethics Committees and national competent authorities are responsible for the assessment and oversight of clinical trials.

Exchanges with Member States representatives will take place in the framework of the [Pharmaceutical Committee](#), and its Working Groups. The Commission may also use its [Safe and Timely Access to Medicines for Patients \(STAMP\) expert group](#) for more technical issues. Other national authorities are consulted to receive the point of view of payers or pricing and reimbursement authorities in the national authorities on Pricing, Reimbursement and Public Healthcare payers meetings.

### **EU institutions**

**Council** – Since 2016<sup>3</sup>, the Council has called for a review of the system of pharmaceutical incentives and reconciling innovation with the need to ensure access. The December 2019 EPSCO<sup>4</sup> reiterated<sup>5</sup> the need for action on these topics and on health system sustainability. A coordinated approach with Council and the EU Member States will help ensure that EU policy acts in synergy with policies in national areas of competence.

**European Parliament** – The European Parliament adopted resolutions on access<sup>6</sup> (2017), reducing anti-microbial resistance<sup>7</sup> (2018) and shortages<sup>8</sup> (2020). Specifically the Committee on the Environment, Public Health and Food Safety (ENVI) will be closely involved in the process.

**Committee of the Regions and the European Economic and Social Committee** National health systems are not organised in a uniform way, some European regional and local authorities have an important role in healthcare policy and budgetary planning. Different social partners can be directly affected by changes in EU pharmaceutical policy. Any policy options must respect the principles of subsidiarity and proportionality. Both institutions can provide useful data to the revision process.

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<sup>3</sup> Council conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its Member States. Link <https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/>.

<sup>4</sup> Employment, Social Policy, Health and Consumer Affairs Council configuration

<sup>5</sup> Employment, Social Policy, Health and Consumer Affairs Council, 9-10 December 2019

Link: <https://www.consilium.europa.eu/en/meetings/epsco/2019/12/09-10/>.

<sup>6</sup> European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)), link: [http://www.europarl.europa.eu/doceo/document/TA-8-2017-0061\\_EN.html](http://www.europarl.europa.eu/doceo/document/TA-8-2017-0061_EN.html)

<sup>7</sup> European Parliament resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance (AMR) (2017/2254(INI)). Link: [http://www.europarl.europa.eu/doceo/document/TA-8-2018-0354\\_EN.html](http://www.europarl.europa.eu/doceo/document/TA-8-2018-0354_EN.html).

<sup>8</sup> European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem (2020/2071(INI)), link: [https://www.europarl.europa.eu/doceo/document/TA-9-2020-0228\\_EN.html](https://www.europarl.europa.eu/doceo/document/TA-9-2020-0228_EN.html)

#### 4) Consultation activities and timing

This section provides an initial summary of the main consultation methods and tools, which will be further refined following discussions with other Commission services. Most of these will be carried out in the second half of 2021.

Depending on the stakeholder group identified, different tools will be used to conduct the consultation activities.

**Feedback on the Roadmap/Inception Impact Assessment (IIA)** - The Roadmap/IIA will be published for feedback of interested individuals and stakeholders for a period of 4 weeks, indicatively planned to start in March 2021. Stakeholders registered for notification through in the EU Health Policy Platform will be made aware of the possibility to submit their feedback. The publication will be available on the [‘Have Your Say’ portal](#) and the Pharmaceutical Strategy webpage.

**Public Consultation** – the Commission will launch a 12-week public consultation during the second half of 2021 (in all EU official languages) to consult the general public and other stakeholders on the key elements of the revision. It will be conducted via a questionnaire (EU Survey) to be published online and accessible via the Commission's [‘Have Your Say’ portal](#).

**Stakeholder consultation activities** will be organised for the purpose of providing feedback and input on the initial policy elements described in the Inception impact assessment of the general pharmaceutical acts providing more detail where needed on technical issues through specific background documents depending on the type of activity or when an interactive discussion requires it for better consultation. These will include thematic stakeholder consultation workshops, where the participation can include stakeholders only or a combination of stakeholders and Member State authorities. These will be announced in due course on the Pharmaceutical Strategy web page. The Commission will be involved in the preparation of online conferences and events of the Council Presidencies. These events are planned in the course of 2021 with the thematic workshops taking place online in the course of the second half of the year.