Consultation strategy for the Commission's Communication on a "Pharmaceutical Strategy for Europe"

1) Background information

The Commission will launch a Pharmaceutical Strategy for Europe to continue ensuring the quality, safety and efficacy of medicines and reinforcing the sector's global competitiveness. Europe should also make sure that all patients can benefit from innovation while resisting the pressure of increasing costs of medicines.

The EU is a frontrunner in ensuring universal health coverage. People across the EU expect to benefit from equal access to safe, state-of-the-art and affordable new and established therapies. Medicines play an important role in this regard as they offer therapeutic options for diagnosis, treatment and prevention of diseases. At the same time, the pharmaceutical sector is a major contributor to the EU economy as a knowledge-intensive sector with 842,000 direct jobs and an €91 billion trade surplus in 2018. Innovative technologies such as artificial intelligence (AI) and analysis of data collected from clinical experience (real world data) may change the way products are developed and have the potential to transform therapeutic approaches and current business models.

In the past years, companies have offshored their production and increasingly depend on active ingredients originating outside the EU, with more than 80% of ingredients coming from Asia. This has implications, including as regards environmental issues and the security of the supply chain. Shortages of medicines essential for public health, such as cancer treatments, vaccines and antimicrobials affect the continuity of patient care and threaten health security in the EU. The reasons range from disruptions in the supply chain to marketing strategies and procurement practices. The challenges of availability and shortages of medicines, both for new developed and old products, once an issue affecting primarily smaller and less resourced countries, are now a widespread and growing problem throughout the EU and beyond. At the same time, the EU has an ageing population and a rising burden of diseases, this leads to increased spending on pharmaceutical products. To ensure the sustainability of Member States' health systems, the new therapies need to be clinically better than existing alternatives as well as cost effective.

There is a need to build a holistic, patient-centred, forward-looking Pharmaceutical Strategy which covers the whole life-cycle of pharmaceutical products and that creates synergies with general health and other policy considerations, for example regarding medical devices, chemicals, environment, the sound functioning of the internal market and the rationalisation of public expenditure etc.

The strategy will build on evidence gathered so far and on contributions from a diverse set of stakeholders involved in all levels of the value chain, from R&D to authorisation and access of patients to medicines. Consultation with a wide range of stakeholders and citizens will take place in the context of the individual initiatives that will shape the strategy.

In order to ensure that all possible views are well reflected in the design of the future Pharmaceutical strategy and to ensure transparency and accountability, consultations on the Strategy itself will be held.

2) Objectives of the consultation

The consultation activities will inform the problem definition, development of potential areas, tools as well as options for EU action.

The consultations (both open and targeted) should identify both areas where there is broad agreement among stakeholders and areas where significant differences of views exist, and in the latter case, the consultation should allow the identification to which group of stakeholders the different views refer. More specifically, the objectives of the consultation on the Strategy itself are:

- To collect, whenever possible, additional relevant facts and data on the situation in EU Member States beyond those already available;
- To identify the main challenges and gaps faced by actors in all levels of the value chain;
- To identify the main (policy) areas and implementation tools, where the EU can have a real added value;
- To detect neglected areas in addressing those challenges, with EU added value;
- To receive feedback on potential areas for action proposed by the Commission;
- To identify the key policy needs at EU-level and opportunities for closer cooperation between Member States and the EU, including potential investment needs.

It is important to note that this consultation process only relates to the planned Commission Communication and that the subsequent evaluation of the relevant legislative instruments will be informed by a separate consultation strategy and process.

3) Stakeholder mapping

Stakeholder groups concerned by the Pharmaceutical Strategy for Europe are those impacted or potentially impacted by actions proposed under the strategy. As the proposed actions encompass different aspects related to the entire pharmaceutical value chain and the sustainability of health systems as such, thereby including also a social, economic, industrial and technological dimension, the strategy has implications for a broad range of stakeholders.

The main interest groups identified for this consultation are:

Citizens – 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 daily 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 in regards to scientific developments and in making available to patients new innovative therapies.

Environmental organisations – The Communication will also pursue environmental objectives, therefore contributions will be sought from environmental organisations, especially with respect of environmentally friendly production, use and disposal of medicines.

Businesses and their associations
The pharmaceutical industry is the main actor in the development and production of medicines. Contributions will be sought from SMEs as well as from large companies, from originators to generics developers and producers including also clinical research organisations and industries beyond pharma (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.

Outreach activities with other institutions and bodies in the development of the Pharmaceutical Strategy for Europe will include:

International actors – One of the themes of the strategy pertains to the global aspect, consulting selected international actors (government and regulatory authorities) can inform the relevant elements of the Communication in areas such as international supply chain, access, protection terms etc.

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 EMA and national agencies on the front line of Pharmaceutical policy implementation. European Medicines Agencies (EMA) / Heads of Medicines Agencies (HMA) are developing a 5-year regulatory science strategy[1], 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 in designing the EU strategy. Public authorities such as HTA bodies, pricing and reimbursement authorities, payers (public health insurances, 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 play an important role in the assessment and management of clinical trials.

[1] https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-2025

Council[2] – Since 2016, the Council has called[3] for a review of the system of pharmaceutical incentives and reconciling innovation with the need to ensure access. The December 2019 EPSCO Council[4] reiterated the need for action on these topics and on health system sustainability, calling for the creation of an EU working agenda for the period 2020-2024. A coordinated approach with Council and the EU MS will help ensure that the EU achieves the objectives of the strategy through mutually conducive actions in the respective area of competence.

European Parliament[5] – The European Parliament adopted resolutions (2017[6] and 2018[7]) on options for improving access to medicines and reducing anti-microbial resistance. Specifically the Environment committee will be closely involved in the development process, notwithstanding an ad hoc possible involvement of other committees: International trade (trade related issues on APIs), Industry, research and energy (industrial/research aspect), Civil liberties, justice and home affairs (issues related to privacy, data and AI).

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 services. Most of these will be carried out in Q2 2020 as consultation activities are expected to be completed by 15 July 2020.

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

Feedback on the roadmap of the Communication - The Roadmap will be published for feedback of interested citizens and stakeholders for a period of 4 weeks, indicatively planned to start on 11 March 2020. Stakeholders registered for notification through in the EU Health Policy Platform will be made aware of the possibility to submit their feedback.

Open public consultation – the Commission will launch a 12-week public consultation in April 2020 (in all EU official languages) to consult the general public and other stakeholders on the key elements of the Communication. It will be conducted via a questionnaire (EU Survey) to be published online and accessible via the Commission's better regulation portal.

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[2] The European Parliament and Council are not consulted in the strict sense of the word as they are co-legislators, however the input from those two actors as regards the main objectives of the Communication is important due to their representative character.

[3] 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/.

[4] 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/.

[5] Cf. fn. 2

[6] 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

[7] 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 .

Stakeholder outreach activities will be organised for the purpose of providing feedback and input on the strategy or its individual pillars where more detail is needed for instance on technical issues or when an interactive discussion allows for better consultation. A stakeholder consultation workshop is planned in 2Q2020 in Brussels.

Other European institutions and bodies will be involved:
EMA/HMA – close and continuous exchanges with EMA will take place throughout the process taking into account the published roadmap of the Communication. The Commission will participate with a presentation in the EMA/HMA regulatory network strategy launch event with stakeholders on 4 May and invite the EMA in its own consultation activities with MS and stakeholder consultation workshop.

Exchanges with Member States representatives will take place in the framework of the Pharmaceutical Committee, an advisory committee to the Commission on issues relating to legislation of pharmaceutical policy. Pharmaceutical Committee meetings are planned for 12 March and 2 July 2020 with the possibility for written consultations on specific issues. Discussions on the Communication will be included on the agenda of those meetings. Other national authorities (e.g. payers or pricing and reimbursement authorities, etc.) will be consulted as needed, either in the relevant existing groups or in specific ad hoc meetings.

Bilateral exchange with the European Parliament – an exchange on the Communication will be held in the European Parliament, possibly in the ENVI Committee.

Informal EPSCO Council – A presentation of the strategy in the informal meeting of Health Ministries will provide the opportunity for a political discussion on the strategy. Possibly for the agenda of the meeting scheduled on 29-30 April.

The Commission will also rely on data and consultations such as the Commission initiative on pharmaceuticals in the environment[8], past EMA stakeholder consultations[9], the consultation activities in the framework of the Commission's evaluation on orphan, paediatrics and EMA fees regulations and the implementation of the Clinical Trials Regulation.

5) Communication strategy

The consultation strategy will provide several opportunities to communicate on the Pharmaceutical Strategy for Europe's aims and proposals. A communication plan will be prepared covering from the start of the consultation to the adoption of the strategy and beyond.

[8] https://ec.europa.eu/info/consultations/public-consultation-pharmaceuticals-environment_en & as referenced in the relevant PIE consultation strategy
[9] https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-2025#public-consultation-section