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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Pharmaceutical strategy for Europe and other upcoming initiatives *- Information from the Commission*

Delegations will find in Annex an information note from the Commission on the above mentioned subject to be raised under "Any other business" at the meeting of the EPSCO Council (Health) on 7 December 2021.

ANNEX

Pharmaceutical strategy for Europe and other upcoming initiatives

State of play on the Pharmaceutical Strategy for Europe

The Pharmaceutical Strategy for Europe, adopted in November 2020, sets an ambitious long-term agenda for a new pharmaceutical policy in Europe. It will create a future proof regulatory framework to support European industry to remain a world leader in innovation and to invest in research and development of therapies, that are safe, efficacious and address unmet medical needs, in particular. A key objective of the strategy is to ensure that innovative treatments reach patients and that medicines are available to patients at all times, wherever they are in the EU.

More specifically, the **revision of the pharmaceutical legislation** aims to:

- 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; and
- Reduce regulatory burden and provide a flexible regulatory framework.

The proposal for this revision is planned to be adopted by the Commission in the last quarter of 2022 together with the proposal on medicines for rare diseases and for children. The evaluation and impact assessment are ongoing and the open public consultation is running until 21 December 2021. At the same time, the Commission is working with national authorities in the Pharmaceutical Committee on key issues of the revision. These discussions have also involved stakeholders and authorities responsible for Health Technology Assessment and for pricing and reimbursement.

For the **review of the orphan and paediatric legislation**, the Commission is carrying out an impact assessment which builds on the evaluation that was published last year. The open public and targeted consultations have been completed. The evaluation has shown that:

- The Orphan and the Paediatric Regulations have led to increased development of medicines for patients with rare diseases for children.
- However, the legislation has not been able to stimulate the necessary development of medicines in areas of unmet needs (95% of rare diseases still have no treatment option and there is limited development of medicines for neonates) and to better ensure patients access, independently from the country they live in.

One of the main features of the Orphan Regulation is to provide specific incentives, and their design can influence business decisions and the focus of research and development. It can also impact market competition and influence availability of and access to medicines as well as health systems' sustainability. These elements will be looked at as part of the impact assessment.

State of play of the revision of the EU legislation on blood, tissues and cells

The evaluation of the legislation on blood, tissues and cells, published in October 2019, highlighted a number of gaps that will be addressed to ensure the framework is up-to-date, fit for purpose and future-proof. The initiative therefore aims at:

- Ensuring safety and quality for patients treated with BTC therapies, for donors and for children born from in vitro fertilization, and enforcement of safety and quality requirements.
- Optimising access to, and avoiding shortages of BTC therapies.
- Ensuring the framework is future-proof and facilitates the development of innovative BTC therapies.

The legislation will be updated in the direction of a more flexible alignment with scientific and technological developments and remove from the legislation many outdated technical provisions, which will allow a faster update of standards. It will tackle the (re-)emergence of communicable diseases, including lessons learnt from the COVID-19 pandemic and focus on the increasing commercialisation and globalisation of the sector.

The proposal for the revision is planned to be adopted by the Commission in the first quarter of 2022.

State of play of the revision of the EMA fee legislation

In September 2019, the Commission published the evaluation of the fee system of the European Medicines Agency (EMA). In place since 1995, EMA fees are charged to marketing authorisation holders and applicants for obtaining and maintaining Union-wide marketing authorisations for medicinal products for human and veterinary use.

The evaluation indicates that the fee system of the EMA is generally efficient and effective but that it would benefit from some revisions. The aim of the proposal is to set the fees and remunerations amounts as 'cost based' and ensure that the system is more flexible and allows for updates more easily in the future.

The impact assessment it ongoing. The proposal for the revision is planned to be adopted by the Commission in the second quarter of 2022.

State of play of the legislative proposal for the European Health Data Space

The pandemic has demonstrated the importance and value of health data for the development of policy in response to crisis situations.

The Commission is preparing the legislative proposal for the European Health Data Space and is currently assessing different options and their impacts. The general objective is to:

- Ensure that individuals have access to and control over their own health data and can benefit from a wealth of innovative health products and services based on health data use and reuse; and
- ensure that researchers, innovators, policy makers and regulators can make the most of the available health data for their work, while preserving trust and security.
- Create a genuine single market for digital health products.

The legislative proposal is expected to be adopted in the first quarter of 2022.