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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Revision of Pharmaceutical legislation *- 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 9 December 2022.

ANNEX

Revision of the pharmaceutical legislation

Background

The revision of the general EU pharmaceutical legislation is one of the flagship initiatives under the Pharmaceutical Strategy for Europe adopted on 25 November 2020, which encompasses both legislative and non-legislative actions.[1]

The general EU pharmaceutical legislation consists of two acts (Directive 2001/83/EC and Regulation (EC) No 726/2004), which are the centrepiece in a broader EU regulatory landscape for medicinal products. They include the authorisation and post-authorisation requirements for medicines, pre-authorisation support schemes, the provision of regulatory incentives in terms of data and market protection, the manufacturing, the supply of medicines, and provisions related to the European Medicines Agency (EMA).

The general pharmaceutical legislation is complemented by specific legislation, such as for medicines for rare diseases (Regulation 141/2000/EC) and for medicines for children (Regulation (EC) 1901/2006). These two regulations are currently being revised alongside the general pharmaceutical legislation.

The revision is driven by the following main objectives:

- Promote innovation, in particular for unmet medical needs
- Create a balanced system for pharmaceuticals in the EU that promotes affordability for health systems while rewarding innovation
- Ensure access to innovative and established medicines for patients, with special attention to enhancing security of the supply across the EU
- Reduce the environmental impact of the pharmaceutical product lifecycle
- Reduce the regulatory burden and provide a flexible regulatory framework

[1] Pharmaceutical Strategy for Europe. Communication from the Commission (COM(2020) 761 final)

In order to achieve these objectives, the scope of the revision is broad and encompasses major parts of the legislation. The revision aims to maintain the functional features of the current system but adapt, improve and complement it where necessary.

State of play

In the context of the preparation of impact assessments for the revision of the pharmaceutical legislation, extensive public and stakeholder consultations as well as external studies were carried out. The Commission has consulted extensively Member States at expert level through its Pharmaceutical Committee. Commission Staff Working Documents containing the Evaluation and Impact Assessment Reports are being finalised. The impact assessments present and analyse different policy options for addressing identified shortcomings, in accordance with Better Regulation principles. The Impact Assessment Reports and supporting studies will be published together with the legislative proposals.

The preparation of the Commission legal proposals is currently ongoing. The Commission plans to put forward its proposals for the revision of the general pharmaceutical legislation and of the legislation for medicines for rare diseases and children as a package. Adoption is planned in the first quarter of 2023.