Revision of European pharmaceuticals legislation

● Prescrire has responded to a public consultation organised by the European Commission.

The European Commission has organised a public consultation on a planned revision, due in late 2022, of Directive 2001/83 "on the Community code relating to medicinal products" and Regulation 726/2004 "laying down Community procedures for the authorisation and supervision of medicinal products (...) and establishing a European Medicines Agency" (1).

The Commission's stated aims are: to ensure access to affordable medicines and address unmet medical needs; to foster innovation by harnessing the benefits of digital and emerging technologies, while reducing the environmental footprint; to make the supply of medicines more secure and resolve drug shortages; and to reduce red tape and provide a flexible regulatory framework (1).

Prescrire's response to this consultation included a number of proposals. Prescrire reminded the Commission of the need for robust evidence before marketing authorisations are granted, based on double-blind randomised comparative clinical trials. Accelerated assessment procedures are legitimate when there is a real, unmet, health need. However, because they increase the uncertainty regarding the clinical value and safety of the drug in question, accelerated marketing authorisation procedures should only be used in exceptional cases, in serious situations for which no appropriate treatment exists, to avoid unnecessarily exposing patients to avoidable harm. Accelerated procedures require that evidence be gathered after marketing authorisation has been granted. Failure to respect post-marketing commitments and requirements should not be tolerated.

As regards security of supply, Prescrire stressed the need to remind marketing authorisation holders of their precise legal obligations, the need for minimum stock levels, diversification of supply chains and potential alternative production sites, as well as transparency over production sites and production capacity.

Prescrire also encouraged the Commission to examine a number of topics not addressed in the roadmap, especially how to: manage and improve medication safety, including the safety of drugs already on the market; ensure affordability and sustainable access to drugs; and make the European Medicines Agency (EMA) more transparent and independent.

The Commission has a duty to ensure that the EMA has sufficient public funding and human resources to meet its transparency obligations in a sustainable manner (2).

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References 1- European Commission "Revision of the EU general pharmaceuticals legislation". ec.europa.eu accessed 23 August 2021: 1 page. **2-** "Revision of the EU's general pharmaceutical legislation in 2022: Prescrire's remarks on the European Commission Roadmap (April 2021)" https://english.prescrire.org/en/79/207/46302/7822/7773/SubReportDetails.aspx.

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