Drug shortages: proposed European legislation

● Prescrire has suggested improvements to the European Commission's Critical Medicines Act.

In February 2025, as part of the European Commission's public consultation on its plan to introduce legislation to prevent shortages of key drugs (the Critical Medicines Act), Prescrire made a series of recommendations for improving the Commission's proposals:

– Implement a transparency framework on the supply chain and the manufacturing process (including aspects such as raw materials, active pharmaceutical ingredients, intermediate and finished products, stock levels, number of suppliers and producers, and market size) to enable public authorities and manufacturers to identify vulnerabilities and dependence on a limited number of producers, so as to anticipate potential shortages and ultimately strengthen the supply chain;

– Require pharmaceutical companies to hold contingency stocks, and back this up with penalties on those that fail to comply;

– Support the creation of public-sector or not-for-profit production facilities;

– Maintain environmental standards for the production of critical drugs (1).

In July 2025, Prescrire reiterated these recommendations in its response to the Commission's public consultation on its proposal for a Critical Medicines Act. We also submitted a number of proposed amendments to members of the European Parliament closely involved with health-related topics (2,3).

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References 1- Prescrire Editorial Staff "Prescrire's response to public consultation - Call for evidence on a 'Proposal for a Critical Medicines Act'" 19 February 2025: 3 pages. **2-** "Feedback on Commission's proposal of 11.03.2025 for a regulation (...) and amending Regulation (EU) 2024/795 - Prescrire's response" 2 July 2025: 3 pages. **3-** "Critical Medicines Act - Proposal of amendments by Prescrire" 30 July 2025: 8 pages.

EMA: electronic product information

● Prescrire contributed to a consultation by the European Medicines Agency on the content, delivery, publication and use of electronic product information (ePI).

In May 2025, Prescrire responded to a consultation by the European Medicines Agency (EMA) on the provision of information about drugs in electronic format (electronic product information, or ePI). In its comments, Prescrire made clear its view that the introduction of ePI must not lead to the removal or replacement of the paper package leaflet that forms part of the packaging of each medicine (1).

Prescrire also asked the EMA to clearly define what it means by "ePI". To protect patients and maintain public trust, Prescrire called for the scope of ePI to include only information that has been authorised and validated by the appropriate regulatory authority (1).

It is essential that information about drugs is obtained from trustworthy sources and sites. ePI should therefore be hosted on the websites of the national competent authorities and/or the EMA. Prescrire supports the creation of an EMA-hosted web portal as a central point of access to ePI for all centrally and nationally authorised medicines (1).

The EMA and other competent authorities must ensure that ePI does not become a backdoor for deregulation or promotional activities (1).

The technological solutions developed to deliver ePI must be user-friendly, free and easy to access, and must undergo patient and user testing before going live. They should be assessed and monitored by the competent authorities (1).

The EMA must protect the personal data of patients and other users by ensuring that the digital tools and devices used to deliver ePI do not collect any personal data (1).

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References 1- Prescrire Editorial Staff "Submission of comments on EMA 'Reflection paper on linking to electronic product information (ePI) from EU medicine packages' - Prescrire's response" 12 June 2025: 11 pages.

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