European pharmaceutical legislation: too many opportunities missed

On 10 April 2024, members of the European Parliament (MEPs) held a plenary vote on the European Commission's proposals for the revision of European pharmaceutical legislation (1,2). Overall, despite a number of welcome advances, MEPs failed to take full advantage of this opportunity to strengthen drug evaluation and patient safety (see also "Revision of European legislation: a disappointing vote in the Parliament" p. 278-279).

Prescrire and other civil society representatives had proposed, and hoped to see, several advances that MEPs ultimately did not vote through. They include: requiring comparative trials to be conducted versus standard treatment, where one exists, before marketing authorisation is granted; and rejecting the proposal to shorten the European Medicines Agency (EMA) evaluation period for marketing authorisation applications from 210 days to 180 days, as well as the proposal to abolish the five-yearly renewal of marketing authorisations, two measures that would put patients at risk (1-3).

A proposal by the European Commission, which was supported by civil society representatives, was largely stripped of its substance by the Parliament. It consisted of changes to the clinical data exclusivity period, which would have shortened the period during which companies enjoy a monopoly for their drugs (2,3). Many other amendments favourable to the interests of pharmaceutical companies were approved in the plenary vote (1,2).

A number of welcome advances were adopted, however. Those requested by Prescrire, among others, include: requiring pharmaceutical companies to report the amount of indirect public funding (tax credits) they receive, in addition to direct public funding; barring anyone who provides scientific advice to a pharmaceutical company on behalf of the EMA from subsequent involvement in assessing the marketing authorisation application for the same product; ensuring transparency about the EMA's scientific advice; improving the quality of the information provided in patient leaflets and on packaging; removing the ability of the European Commission to unilaterally scrap the provision of a patient leaflet inside a product's packaging; envisaging a requirement for pharmaceutical companies to hold stocks of critical medicines to prevent shortages; enabling member states to impose sanctions if companies fail to comply with "*obligations related to the availability and supply of medicinal products*"; ensuring the EMA has adequate funding to fulfil its transparency obligations; and removing from the directive the reference to the right (which already exists) of member states to restrict or prohibit access to contraceptive drugs or abortifacients (1-3).

Prescrire and other civil society groups will work with member states to consolidate and further develop the improvements adopted by the European Parliament, and to encourage them to seize the opportunities the MEPs missed to really improve the European Commission's proposals.

Prescrire

References **1-** European Parliament "P9_TA(2024)0220 - Union code relating to medicinal products for human use. European Parliament legislative resolution of 10 April 2024 on the proposal for a directive (...) and repealing Directive 2001/83/EC and Directive 2009/35/EC (...)": 142 pages. **2-** European Parliament "P9_TA(2024)0221 - Union procedures for the authorisation and supervision of medicinal products for human use and rules governing the European Medicines Agency. European Parliament legislative resolution of 10 April 2024 on the proposal for a regulation (...) amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (...)": 160 pages. **3-** Prescrire Editorial Staff "Revision of European pharmaceutical legislation" *Prescrire Int* 2024; 33 (256): 55.