Revision of European pharmaceutical legislation

● The European Parliament is set to vote on a proposed new regulation and directive in spring 2024. Prescrire has proposed a number of amendments.

In April 2023, the European Commission adopted proposals for the revision of European pharmaceutical legislation, consisting of a new directive and a new regulation to replace several existing directives and regulations applying to this sector (1,2).

In September 2023, Prescrire submitted a list of amendments designed to improve the Commission's proposals in several areas of major importance for achieving high-quality care. They include:

– requiring companies to conduct comparative trials versus the standard treatment, where one exists, before marketing authorisation is granted;
– rejecting the idea of shortening the European Medicines Agency (EMA) evaluation period for marketing authorisation applications from 210 days to 180 days, and of abolishing the 5-yearly renewal of marketing authorisations, which would be detrimental to public health;
– requiring greater transparency regarding the scientific advice the EMA provides to companies before they apply for marketing authorisation;
– strengthening the transparency of the EMA regarding variations to marketing authorisations due to pharmacovigilance issues;
– improving the information in patient leaflets and labelling, and maintaining the provision of paper leaflets;
– providing access to anonymised patient data included in marketing authorisation applications;
– enhancing supply chain continuity and combating drug shortages by introducing the obligation to hold contingency stock, coupled with sanctions for companies that do not comply with these requirements;
– and strengthening the role of the EMA in the monitoring of medical devices, especially those resembling drugs.

Prescrire has also proposed removing from the directive the right of member states to restrict or prohibit access to contraceptives or abortifacients.

In the first step of the European legislative process, the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) will vote on the European Commission's proposals, as amended by the Members of the European Parliament (MEPs) and in particular by their rapporteurs. The rapporteurs published their proposed amendments in early October 2023.

The rapporteur for the proposed directive (who belongs to the European People's Party) mainly proposed amendments favourable to the pharmaceutical industry, having met with very many company representatives (and very few representatives of civil society). Her proposals seek in particular to strengthen the protection of clinical data (and, as a result, prolong the period during which companies enjoy a monopoly for their drugs); to relax requirements pertaining to the assessment of the impact of drugs on the environment; to allow pharmaceutical companies to choose not to market their drugs in countries that are of no economic interest to them; and to enable member states to opt for electronic patient leaflets rather than paper leaflets (4).

The rapporteur for the proposed regulation (a member of the Progressive Alliance of Socialists and Democrats) proposed amendments that are more in line with those requested by civil society, and had met with many representatives of this sector. He put forward similar amendments to those proposed by Prescrire and other civil society organisations, in particular: maintaining the requirement to renew marketing authorisations every 5 years; refusing the general roll-out of an assessment method for emergency situations, trialled during the covid-19 pandemic; and refusing the institutionalisation of a very high-level exemption from the legislation, referred to as a regulatory "sandbox", which would allow the EMA to bypass the European legislative process entirely (5). However, a number of important points were not included, in particular the need to conduct comparative trials versus standard treatment, where one exists, in order to obtain marketing authorisation.

In the next step, MEPs will vote on the European Commission's proposals, as amended by the ENVI committee. Prescrire will be monitoring the process every step of the way.

► Translated from *Rev Prescrire* December 2023 Volume 43 N° 482 • Page 946 and January 2024 Volume 44 N° 483 • Page 67

References **1-** European Commission "Proposal for a directive (...) and Directive EC 2009/35/CE" COM (2023) 192 final: 197 pages. **2-** European Commission "Proposal for a regulation (...) and Regulation (EC) N° 1901/2006" COM (2023) 193 final: 194 pages. **3-** Prescrire Editorial Staff "Prescrire's position paper on the (...) pharmaceutical legislation" 13 September 2023: 81 pages. **4-** Weiss P "Draft report on the proposal (...) and directive 2009/35/EC" 03-10-2023: 86 pages. **5-** Wölken T "Draft report on the proposal for a regulation (...)" 20-10-2023: 109 pages.