Revision of European pharmaceutical legislation: a disappointing vote in the Parliament

● In April 2024, MEPs voted on the European Commission's proposals for the revision of European pharmaceutical legislation.

● Overall, despite a number of welcome advances, MEPs failed to take advantage of the opportunity to strengthen drug evaluation and patient safety.

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, which consist of a directive and a regulation (known as the "pharmaceutical package") (see editorial "European pharmaceutical legislation: too many opportunities missed by MEPs" p. 255) (1,2).

This article looks at how the Parliament voted on the main amendments proposed by Prescrire (and in many cases by other civil society groups). It is not an exhaustive analysis of how MEPs voted.

MEPs often overly favourable to the pharmaceutical industry

In the plenary vote, MEPs largely accepted the amendments proposed by their rapporteurs.

The amendments on the proposed directive submitted by the rapporteur (who is a member of the European People's Party, the largest party in Parliament) mainly defended the interests of pharmaceutical companies. She had met with numerous industry representatives, and very few representatives from civil society (**a**). Her proposals sought, in particular: to strengthen the protection of clinical data (and thus prolong the period during which companies enjoy a monopoly for their drugs); to relax the requirements on companies pertaining to the assessment of the environmental impact of drugs; and to allow companies to choose not to market their drugs in countries that are of no economic interest to them (3). These amendments, along with several others that are favourable to the interests of pharmaceutical companies, were approved by a large majority in the plenary vote (1,2).

The rapporteur for the proposed regulation (who is a member of the Progressive Alliance of Socialists and Democrats) had met with numerous representatives from civil society, and proposed amendments more in line with the demands from this sector. He presented amendments similar to those proposed by Prescrire (and other civil society groups), some of which were voted on in the plenary session (1-3).

Missed opportunities

In September 2023, Prescrire proposed a list of amendments designed to improve the Commission's proposals in several areas of major importance for achieving high-quality health care. They included:
– Requiring comparative trials to be conducted versus standard treatment, where one exists, before marketing authorisation is granted (**b**);
– 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 five-yearly renewal of marketing authorisations, which would put patients at risk (3).

The European Parliament did not vote in favour of any amendments to this effect, and thus not only failed to seize the opportunity to improve the quality of the clinical evaluation of drugs before their market introduction, but in fact agreed to water down the requirements (1,2).

Prescrire had proposed an amendment to the regulation that was taken up by the rapporteur, but not voted through in the plenary session. It was designed to restrict to exceptional circumstances the EMA's use of the "*phased review*" (or rolling review) evaluation process trialled during the covid-19 pandemic, since this experiment proved to be very draining on the Agency's resources.

Another amendment to the regulation proposed by Prescrire and taken up by the rapporteur, but not voted through in the plenary session, was to refuse the institutionalisation of a very high-level exemption from the legislation, referred to as a regulatory "sandbox", which would allow the EMA and European Commission to depart from standard marketing authorisation regulations without going through the European legislative procedure. Prescrire also opposed "*temporary emergency*" marketing authorisations, on the grounds that conditional marketing authorisations already provide an adequate option, but no amendment to that effect was tabled or adopted (2-3).

Along with numerous representatives from civil society, Prescrire opposed the inclusion in the regulation of "transferable exclusivity (or data exclusivity or regulatory protection) vouchers" (TEVs), which are intended to encourage the development of high-priority antimicrobial drugs, but have the potential to substantially increase spending on other medicines by extending the duration of the market monopoly for highly profitable drugs (**c**)(3). No amendment to that effect was adopted (2).

The Commission had proposed a reduction in the basic clinical data exclusivity period, combined with extensions designed to incentivise companies to conduct trials versus standard treatment or to market

drugs across all member states, for example. This proposal, which was supported by Prescrire and many other organisations, was largely stripped of its substance by the Parliament (amendments 196 and 199 to 207 to the proposed directive).

A number of welcome advances, to be maintained or strengthened

The improvements introduced by the MEPs that had been called for by Prescrire, among others, included the following:

– Requiring pharmaceutical companies to report the amount of indirect public funding (tax credits) they receive in addition to direct public funding, specifying the drugs concerned, and centralising these data on the EMA website (amendments 169 to 173 to the proposed directive);

– 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 (amendments 176 and 177 to the proposed regulation); and ensuring transparency about enhanced scientific and regulatory support for priority medicinal products (amendment 180 to the proposed regulation);

– Improving the quality of the information provided in patient leaflets and on packaging (at the single dose level for antimicrobial drugs) (amendments 184 and 186 to the proposed directive);

– Maintaining the provision of patient leaflets in paper form (unless electronic-only patient leaflets have been approved via prior consultation of patients, carers and other relevant stakeholders) (amendment 176 to the proposed directive); and removing the ability of the European Commission to unilaterally scrap the paper leaflet (amendment 180 to the proposed directive);

– Envisaging a European-wide requirement that pharmaceutical companies hold safety stocks of critical medicinal products (considered to be of major therapeutic interest) in order to prevent shortages (amendment 293 to the proposed regulation); and enabling member states to impose sanctions if companies fail to comply with "*obligations related to the availability and supply of medicinal products*" (amendments 347 and 363 to the proposed regulation);

– Ensuring the EMA has adequate funding to fulfil its transparency obligations (amendments 23 and 340 to the proposed regulation);

– Removing from the directive the reference to the right (which already exists) of member states to restrict or prohibit access to contraceptives or abortifacients (amendment 85 to the proposed directive);

– Requiring member states to maintain national transparency registers with information on the benefits offered to persons qualified to prescribe drugs (amendment 298 to the proposed directive) (1,2).

The Council will issue its opinion on the two legislative texts sometime in 2024 or 2025, after which "trilogue" interinstitutional negotiations will be held between the Council, Parliament and Commission.

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a- *The MEP in question was associated with a move to suppress or amend the report on the pharmaceutical research and development system by the European Parliament's Panel for the Future of Science and Technology. This report favoured greater public oversight of the European pharmaceutical sector (ref 4).*

b- *MEPs did vote for one amendment to the proposed directive (number 36) referring to the need to conduct comparative trials versus standard treatment, where one exists, before marketing authorisation is granted, but this only concerns a recital to the directive, and its substance was not included in an article (ref 1).*

c- *Transferable exclusivity vouchers can be used by the holder for another of their drugs, thus extending the duration of their market monopoly. These vouchers can also be sold to another company.*

Selected references from Prescrire's literature search

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.

4- Martuscelli C "Big Pharma lobbied MEP lovers days before drugs study was pulled offline" *Politico* 1 December 2023: 7 pages.

French Senate hearing on drug shortages

On 22 November 2023, Prescrire contributed to a hearing held by the French Senate's Committee for European Affairs as it prepared a resolution on the European Commission's revision of pharmaceutical legislation, with a specific focus on drug shortages.

The priorities emphasised by Prescrire included: strengthening supply chain continuity by introducing the obligation to hold contingency stocks, coupled with penalties for companies that fail to comply with these requirements; ensuring that the European list of "critical medicines" (drugs that are considered to be essential and must therefore be permanently available) is drawn up in an independent and transparent manner; maintaining the provision of patient leaflets in paper form; and supporting the idea of public production of critical drugs.

In mid-2024, senators included these recommendations in their final resolution sent to the French government (1).

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References 1- French Senate "Résolution européenne sur l'action de l'Union européenne contre les pénuries de médicaments" 10 May 2024: 13 pages.