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.