include potentially increasing the proportion of variations subject to less stringent requirements, and thus less oversight (2).

In Prescrire's opinion, it would appear logical and inevitable for the workload associated with post-authorisation management of drugs to increase year on year, because new drugs are authorised every year, while existing drugs are rarely withdrawn from the market.

In order to ensure an acceptable level of patient protection, Prescrire called on the Commission to allocate sufficient resources (both human and financial) to the European Medicines Agency (EMA) to enable it to fulfil its obligations regarding the oversight of an ever-increasing number of authorised drugs.

In Prescrire's view, there is nothing inherently wrong with simplifying and rationalising administrative tasks, provided that this does not have a negative impact on the surveillance of drug efficacy and patient safety. Prescrire called on the Commission to set stricter standards for the clinical evaluation of drugs prior to authorisation (in order to reduce the number of drugs to be monitored that are not useful to patients), and to strengthen the requirements for post-authorisation evaluation.

Prescrire also urged the EMA to reduce its workload by reviewing the need to keep drugs on the market that have no real clinical utility or that are more dangerous than beneficial.

Finally, Prescrire also stressed the urgent need for more transparency about variations concerning efficacy and adverse effects, and to make more post-authorisation evaluation documents systematically available to the public (1).

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References 1- Prescrire Editorial Staff "Prescrire's response on a call for evidence of the European Commission on the Revision of the variation framework for medicines" 20 September 2023: 2 pages. **2-** European Commission "Call for evidence: Pharmaceuticals – changes to marketing authorizations (revision of the variation framework for medicines)" 29 August 2023: 4 pages.

Non-comparative trials for marketing authorisations: EMA consultation

● Prescrire has contributed to a consultation on the use of non-comparative clinical trials to obtain marketing authorisation.

In September 2023, Prescrire submitted its response to a public consultation organised by the European Medicines Agency (EMA) on the use of non-comparative clinical trials as the main ("pivotal") evidence of efficacy in marketing authorisation applications (1,2).

Prescrire considers that the reflection paper rightly highlighted the methodological weaknesses of non-comparative trials in evaluating the potential efficacy of a drug. It is because of these weaknesses that, with a few rare and substantiated exceptions, marketing authorisations should not be based on such trials. Prescrire felt it was regrettable that the EMA's preparatory document:
– Does not clearly spell out what these trials can do (generate hypotheses) and what they cannot do (demonstrate a causal relationship between the treatment and the outcomes observed);
– And does not define, from the outset, the handful of exceptional situations in which the use of a non-comparative trial might be considered an acceptable basis for marketing authorisation.

Drawing on concrete examples, Prescrire expressed its concern about the fact that, despite the known weaknesses of non-comparative trials, the EMA is increasingly accepting them as the sole basis for marketing authorisations (2).

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References 1- EMA "Reflection paper on establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation" 17 April 2023: 15 pages. **2-** Prescrire Editorial Staff "Final Prescrire response to EMA consultation guideline single arm trials" 20 September 2023: 9 pages.

Drug shortages: Prescrire calls for transparency

In October 2023, ahead of the publication of a Communication from the European Commission on addressing medicine shortages in the European Union (EU), a joint letter was sent to the Commission by Prescrire, the European Public Health Alliance (EPHA) and the patient rights umbrella organisation France Assos Santé (1,2).

The Commission is in favour of introducing a "Voluntary Solidarity Mechanism" across EU member states to address drug shortages. The cosignatories of the letter emphasised that transparency about drug stocks will be needed if such a mechanism is to work. They urged the Commission to call for the introduction of requirements for manufacturers and wholesalers that provide information on stock levels to the EU's national drug regulatory agencies.

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References 1- European Commission "Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions": 19 pages. **2-** EPHA-FAS-Prescrire "Lettre conjointe" 17 October 2023: 1 page.

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