New data after marketing authorisation: European Commission consultation (continued)

In September 2023, Prescrire responded to a consultation organised by the European Commission prior to revising the "Variations Regulation", which sets out the procedures for updating marketing authorisations when new indications are sought, or when new data (on adverse effects, efficacy, use in children, etc.) become available (1).

In February 2024, Prescrire contributed to a consultation on the draft version of this delegated regulation (2). Prescrire's "feedback" included three requested changes to the regulation:

– Provide the possibility of extending the assessment period for major (type II) variations (new or modified indications which have a significant impact on quality, efficacy or safety) to enable robust assessment;
– Increase transparency, in particular by publishing an assessment report on each type II variation;
– Process changes to combination products (composed of a medicinal product and a medical device) or in-vitro diagnostic medical devices through the procedure for major (type II) variations.

Barely two weeks after the deadline for responses to this consultation, the European Commission published the final version of the delegated regulation... None of Prescrire's requests had been taken into account (3).

► Translated from *Rev Prescrire* October 2024 Volume 44 N° 492 • Pages 789-790

References 1- "New data after marketing authorisation: European Commission consultation" *Prescrire Int* 2024; 33 (261): 194-195. **2-** "Prescrire's position paper on the proposed revision of the European Commission delegated regulation related to the examination of marketing authorisation variations" 28 February 2024: 6 pages. **3-** "Commission Delegated Regulation (EU) 2024/1701 of 11 March 2024 amending Regulation (EC) No 1234/2008 as regards the examination of variations to the terms of marketing authorisations (...)" *Official Journal of the European Union*, 17 June 2024.

EMA: two surveys about the patient leaflet

In December 2023, Prescrire responded to a survey organised by the European Medicines Agency (EMA) for the purposes of revising the template that serves as a basis for the patient leaflet (package leaflet) provided with medicinal products. The aim of the revision is to shorten the length of these leaflets, and to make the information they contain more understandable and relevant to patients/users, while still complying with current legislation on their content and the order in which information is presented (1).

The questions mainly concerned the table of contents, the order in which sections are displayed, and the presentation of adverse effects in order of frequency or severity.

In February 2024, Prescrire responded to a second EMA package leaflet survey. The stated aim of this initiative is to improve the content and structure of the package leaflet, in order to make these leaflets more understandable and relevant to patients. The survey focused on two aspects: the inclusion of a "key information" section; and the addition of information on the drug's benefits (2).

Prescrire is in favour of adding a "key information" section, consisting of information about the drug's indications, the main benefits of the treatment and its adverse effects, as well as contraindications. Information about benefits and risks should be presented side by side, to help users assess the drug's harm-benefit balance (2).

With regard to the addition of information about benefits, Prescrire would like the published information to include: the proportion of patients who can expect to benefit from using the drug; the drug's effects on quality of life; the strength of the evidence for the claimed benefits; and the uncertainties that remain, in particular when data (concerning a long-term benefit or adverse effect, for example) are lacking or the level of evidence is too low (2).

► Translated from *Rev Prescrire* October 2024 Volume 44 N° 492 • Page 790

References 1- "Package Leaflet (PL) improvement survey" 6 December 2023: 11 pages. **2-** "Package Leaflet (LP) improvement survey" 26 February 2024: 6 pages.