Conflicts of interest in European health technology assessments

In June 2024, Prescrire contributed to a public consultation organised by the European Commission on the procedures for managing conflicts of interest in joint health technology assessments. In Prescrire's view, it is essential to prevent conflicts of interest and to provide transparency and public access to information on this issue, in order to build trust in the outcomes of joint procedures (between European member states) carried out to assess health technologies.

According to the regulation proposed by the European Commission, representatives and experts must declare any financial or other interests they have, in an individual capacity, in their declaration of interests. Prescrire fully supports public access to experts' declarations of interests through the joint assessment website. Prescrire asked the European Commission to pay particular attention to the design of this website, so that this crucial information is easily accessible, and to strengthen its management of declared conflicts of interest.

Prescrire pointed out that representatives, experts and patients involved in assessment activities must be free of conflicts of interest. The rules must be clear and should not leave the way open to exceptions that could easily be contested. When no experts or patients without conflicts of interest are available, this should be recorded in the minutes and reports, in order to explain why no such parties were involved in the work.

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Reference 1- Prescrire Editorial Staff "Prescrire's response to consultation on the procedural rules for assessing and managing conflicts of interest in the framework of joint Health Technology Assessment activities" June 2024: 4 pages.

EMA: protecting personal data and commercially confidential information

In June 2024, Prescrire participated in a public consultation organised by the European Medicines Agency (EMA) on the protection of personal data and commercially confidential information in marketing authorisation applications. In its contribution, Prescrire welcomed the fact that any request by a pharmaceutical company to conceal certain information (redaction) in its marketing authorisation applications must be substantiated by the company and assessed by the EMA or the national drug regulatory agencies of the countries concerned.

Prescrire backed the EMA's comments indicating that, in principle, clinical study reports do not contain information and data of a commercial and confidential nature. However, Prescrire would have preferred the EMA to explicitly state that data which help determine a drug's harm-benefit balance, including pharmacovigilance data, should not be considered commercially confidential, even if their disclosure could undermine the company's economic interests.

Prescrire also expressed differing views on a few of the categories of information that the EMA proposes may be considered commercially confidential. In Prescrire's opinion, information about impurities, product degradation and "innovative" study designs or analytical methods should not be considered confidential, and should therefore not be redactable.

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Reference 1- Prescrire Editorial Staff "Response to the Public consultation on the 'HMA/EMA guidance document on the identification of personal data and commercially confidential information within the structure of the marketing authorisation application (MAA) dossier'" June 2024: 32 pages.

EMA: assessing the risks of drugs for human reproduction and lactation

In August 2024, Prescrire participated in a consultation on the revision of the "Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation". In the interests of patients, Prescrire emphasised a few points in its response that are fundamental to the quality and safety of health care, which the European Medicines Agency (EMA) needs to take into account while drafting its forthcoming "Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation":

– Distinguish between teratogenicity (risk of malformations) and fetotoxicity (risk of harmful effects on the fetus's development);
– Specifically report potential adverse effects on the neonate or mother that occur close to birth;
– Specifically address maternal consequences, such as pre-eclampsia or postpartum haemorrhage;
– Provide educational materials and information to patients, prepared through a standardised method with input from some of the women concerned;
– Specifically consider the risks associated with the use of medicinal products while breastfeeding.

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Reference 1- Prescrire Editorial Staff "Submission of comments on 'Concept paper on revision of the guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling'" August 2024: 24 pages.