The EMA is withholding too much information

The creation of the European Medicines Agency (EMA) in 1995 constituted a step forward, compared with the practices of France's drug regulatory agency at the time. For example, the EMA's online publication of information on drug evaluations, such as European Public Assessment Reports, was a major advance in transparency as to the data in its possession.

The level of transparency at the EMA has since fluctuated over the years (see "European Medicines Agency: transparency policy marred by too many failings" pp. 130-139). Yet the basic texts on which the European Union is founded guarantee transparency over the activities and decisions of European bodies. The EMA has made progress overall since its inception, thanks to action by the European Ombudsman, the European Parliament, researchers and civil society, including Prescrire. However, in 2022, the Agency is still putting up barriers to transparency. For example, when requesting access to documents held by the EMA, Prescrire has come up against new procedures in recent years that have the effect of withholding information, with response times of several months. And important information, in particular on clinical data, is redacted on the grounds that pharmaceutical companies feel that its disclosure could jeopardise their commercial interests.

It is one thing for pharmaceutical companies to consider that data showing the limitations of their drugs are commercially sensitive. But it is quite another – and utterly unacceptable – for the EMA to actually orchestrate the concealment of these data by pharmaceutical companies.

Transparency is not a fad or an end in itself. In the pharmaceutical field, it is a requirement for better and safer patient care. There is no valid reason to hide information about clinical trials, their methodology or their results, or evaluation data obtained on drugs after their market introduction, particularly data on adverse effects.

Perhaps there are certain individuals within the EMA who are dissatisfied with this situation? Or who are simply resigned to the power relations at play? Or who feel that the way the EMA operates is a necessary compromise, given the varying legislation? If so, these individuals are not speaking up and their opinions are not reflected in the EMA's practices. Whatever the case may be, Prescrire's negative assessment of the level of transparency at the EMA is intended as a wake-up call for policy makers and for legal bodies (such as the Ombudsman) who are in a position to improve the EMA's operational practices.

So that the EMA might at last embrace full transparency, and disclose all the information that is necessary for patient care and safety.

Prescrire