Obstacles to transparency over pharmacovigilance data within the EMA

Abstract

- In July and August 2014, the European Medicines Agency (EMA) organised two public consultations concerning European pharmacovigilance. These two consultations reveal a number of EMA proposals that are counterproductive to the objective of improving transparency over pharmacovigilance data.

- The EMA’s proposals offer pharmaceutical companies an opportunity to participate in public hearings held by the European Pharmacovigilance Risk Assessment Committee (PRAC), in order to defend their drug. They also provide for the possibility of holding non-public hearings to discuss public data. There is a great risk that the drug industry might use these provisions to influence the debate.

- The strings attached to the access that the EMA proposes to grant researchers to data contained in the centralised European pharmacovigilance database would allow the EMA to censor the publication of their findings. The EMA seems to regard pharmacovigilance data as commercially confidential information.

- Responding to these consultations provided an opportunity to remind the EMA that data about adverse effects are a public good, in the common interest, and that it is unacceptable to keep this information confidential.

The regulations reorganising European pharmacovigilance, adopted in late 2010, included several measures that should increase transparency (1,2). One of these measures was that the new European Pharmacovigilance Risk Assessment Committee (PRAC) would hold public hearings.

In mid-2014, almost four years later, the European Medicines Agency (EMA) finally launched a public consultation on how these public hearings would be organised and conducted (3). And in another consultation, the EMA proposed to revise its policy on access to pharmacovigilance data (4).

The EMA's proposals offer pharmaceutical companies an opportunity to participate in public hearings held by the PRAC. In order to defend their drug, companies can use these consultations to influence the debate. They also provide for the possibility of holding non-public hearings. This is counterproductive to the objective of improving transparency.

The joint response to which Prescrire contributed urged the EMA to systematically broadcast live videos of public hearings on its website. This would prevent hearings from being monopolised by European patient groups that are heavily funded by the pharmaceutical industry. The EMA was also encouraged to ensure that representatives of independent patient groups (victims of adverse effects, consumers, patients and their relatives) are heard, and allowed to testify in their own language.

Access to pharmacovigilance data: too limited. Since 2012, the public has been able to access some quantitative data extracted from the centralised European pharmacovigilance database, EudraVigilance, through the unfortunately rather unwieldy ADRreports interface (www.adrreports.eu). For example, the public can find out how many spontaneous reports were recorded in Eudravigilance in which a specified adverse effect was associated with a given drug. In practice, these data are too limited. In order to interpret spontaneous reports and ensure that individual cases are not stripped of their full clinical significance through the use of inappropriate terms when they are entered in the database, anonymised narrative case summaries must also be made publicly available.

Pharmacovigilance hearings: industry influence and uncertain transparency. Several of the provisions proposed by the EMA concerning the organisation of public hearings are counterproductive.

In its draft document, the EMA proposed giving pharmaceutical companies “the opportunity to present its/their view(s) to the participants of the public hearing”. The EMA would thus offer drug companies an ideal platform from which to downplay concerns over the adverse effect profiles of their drugs, despite the risk of influencing the debate.

The EMA also proposed holding non-public hearings when a company or another person “intending to submit information has confidential data relevant to the subject matter of the procedure”. This provision would undermine the transparency of the debates and the independence of the EMA’s decision-making process. Non-public hearings are only acceptable for protection of the identity of a whistle-blower.

In addition, despite the fact that pharmacovigilance data are a public...
good, in the common interest, state-
ments about the need to protect intel-
lectual property have appeared, such as the responsibility to apply “appropri-
ate technical and organisational measures to protect information and personal data (…) against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss” (4).

This wording, which resembles the title of the proposal for a European directive on “trade secrets” currently under review by the European Parlia-
ment, reveals that the EMA now seems to regard pharmacovigilance data as commercially confidential information or even “trade secrets”, and has taken on board the pharmaceu-
tical industry’s willingness to control these data and their dissemi-
nation (6,8,9).

In summary: erosion of transpar-
cy. These two consultations reveal that the EMA’s approach to transparen-
cy over pharmacovigilance data is even more timid than its approach to clinical trial results (7). The final versions the EMA adopts for its rules of procedure on the organisation and conduct of public hearings and for its policy on access to pharmacovigilance data will need to be examined carefully.

We will continue to monitor the situation.

In Europe, FHI’s proposals for a European drug regulation in 2005 (4) stressed the need to “promote transparency of adverse drug reactions in Europe: Proactive public access to drug regulation” (ref 5).

The full versions of these responses are freely available under review by the European Parlia-

Pay for performance: financial rewards without improving quality of care

Pay-for-performance systems offer healthcare professionals financial incentives intended to support public health initiatives, to reduce health care spending, or to apply “best” practices (1). Yet according to various analyses, pay-for-performance programmes yield mixed and often disappointing results (2,3). The effects of one such programme involving benzodiazepine prescribing in France show that the reality can be complex.

Reduced benzodiazepine use? In 2009, one of the objectives of the French National Health Insurance Fund’s pay-for-performance pro-
gramme “CAPI” (Contracts for Improved Individual Practice) was to reduce the proportion of persons aged over 65 years taking long half-life benzodiazepines to less than 5%. A reduction in the duration of benzodi-
azepine treatment would have been a more relevant measure for patients, however (4). In 2011, the “ROSP” programme (Payment for Public Health Objectives), which replaced the CAPI programme, addressed this issue by encouraging prescribers to limit benzodiazepine treatment to less than 12 weeks (5,6).

In a report on the ROSP programme published in 2015, the National Health Insurance Fund congratulated itself on the programme’s success in reducing long half-life benzodiazepines from 13.7% in late 2011 to 10.8% in late 2014 (5). However, the programme failed to reduce the proportion of patients newly treated with benzodiazepines who continued treatment for more than 12 weeks; this proportion remained unchanged in 2014, at about 15%.

Counterproductive. The results of a study conducted in the Pays de la Loire region of France may explain this phenomenon. The reduction in the proportion of prescriptions for long half-life benzodiazepines between 2011 and 2012 was associated with an increase in prescriptions for short half-life benzodiazepines (7). And a greater proportion of patients over the age of 65 treated with benzodiazepines continued treatment for more than 12 weeks compared with those who were prescribed short half-life benzodiazepines. This seems “counterproductive”.

This pay-for-performance pro-
gramme therefore altered benzodiaz-
epine prescribing patterns without leading to any real improvement in the quality of health care. Protecting patients from adverse effects requires more than payments for measuring measurable performance targets.