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 Medicines in Europe Forum, the International Society of Drug Bulletins (ISDB) and Health Action International (HAI) Europe (three networks of which Prescrire is an active member), and the Cochrane Collaboration submitted joint responses to these consultations. This article summarises the key points of these responses (a)(5,6).

The final versions of the documents released for consultation were still not available as of late June 2015.

Pharmacovigilance hearings: industry influence and uncertain transparency. Several of the provisions proposed by the EMA concerning the organisation of public hearings are counterproductive (3,5).

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 (b).

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 (c)(3).

The joint response to which Prescrire contributed urged the EMA to systematically broadcast live videos of public hearings on its website. And to 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 (5).

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 ADReports interface (www.adreports.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 (d)(1,6). In practice, these data are too limited (6,7). 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 (e)(1,6).

In the draft revision of its policy on access to pharmacovigilance data, the EMA proposed granting greater access to Eudravigilance data to researchers, on request (4). In exchange, however, the EMA would require them to sign confidentiality agreements. It also has the option of censoring scientific debate by demanding “the right to view any publication resulting from Eudravigilance data before submission” and that “any issues raised by the Agency (…) must be addressed to the satisfaction of the Agency before submission for publication (…)” (4,6). These proposals speak volumes about the EMA’s commitment to transparency.

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-
tate technical and organisational mea-
sures 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 pharma-
caceutical industry’s willingness to con-
trol these data and their dissemina-
tion (6,8,9).

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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 ac-
cording 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-
grame “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
a reduction in the proportion of persons
aged over 65 years taking long half-life benzodiazepines from 13.7% in late
2011 to 10.8% in late 2014 (5). How-
ever, the programme failed to reduce the proportion of patients newly
 treated with benzodiazepines who contin-
ted 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
gt years, who were prescribed short
half-life benzodiazepines continued
treatment for more than 12 weeks compared with those who were pre-
scribed long half-life benzodiazepines. This seems “counterproductive”.

This pay-for-performance pro-
grame 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 meeting mea-
surable performance targets.