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.

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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 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.

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.

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. 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 (...).” 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 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 pharma-
caceutical industry’s willingness to
control these data and their dissemina-
tion (6,8,9).

In summary: erosion of transpar-
cency. These two consultations reveal
that the EMA’s approach to transparen-
cy over pharmacovigilance data is even
more timid than its approach to clinical
transparency. Yet, the EMA’s approach to transparen-
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cy over pharmacovigilance data is even
time than its approach to clinical
transparency.

We will continue to monitor the
situation.

Selected references from Prescrire’s literature
search.
1- Prescrire Editorial Staff “European pharmacov-
igi 1999; dvigor 1999; EMA 2010; 624089/1
100% quality drug expenditure: the result of
Prescrire 2010: 30 (326): 932-935.

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 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-
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 meeting mea-
surable performance targets.

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Pay for performance: financial rewards

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 accord-
ing 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
a reduction in the proportion of persons
aged over 65 years taking long half-life
benzodiazepines from 13.7% in
2011 to 10.8% in late 2014 (5). How-
ever, the programme failed to reduce
the proportion of patients newly treated
with benzodiazepines who con-
tinued treatment for more than 12 weeks;
this proportion remained unchanged in
2014, at about 15%.

Selected references from Prescrire’s literature
search.
1- Prescrire Rédaction “Contrats d’amélioration
des pratiques individuelles (CAPI) (suite et fin): un
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2010; 30 (326): 932-935.
2- “Health Policy Brief: Pay-for-Performance”
Health Affairs, October 11, 2012: 6 pages.
3- Cashin C et al. “Paying for performance in health
care. Implications for health system performance
and accountability” European Observatory on
4- Prescrire Rédaction “CAPI - Objectif n° 4” Rev
Prescrire 2010: 30 (325): 862.
5- “La rémunération sur objectifs de santé pub-
lics: une amélioration encore en faveur de la
6- Prescrire Rédaction “Rémunération sur résul-
tations subjectives de soins et de coûts (n° 14 à n° 24)” Rev
7- Rat C et al. “Did the new French pay-for-
performance system modify benzodiazepine
prescribing practices?” BMC Health services research