BEUC The European Consumer Organisation

The Consumer Voice in Europe

EudraVigilance access policy

BEUC response to the EMA public consultation

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BEUC, the European Consumer Organization, welcomes the European Medicines Agency public consultation on the new draft EudraVigilance access policy[1] . However we regret that the consultation was launched during the summer break and was open for only 6 weeks (4 August – 15 September). This is not in line with the European Commission public consultation guidelines that recommend a consultation period of 12 weeks[2] and prevents many interested parties to contribute to it.

1. General remarks

Consumers are those who experience side effects and whose daily life is negatively affected by adverse drug reactions. Eudravigilance, as the central EU database of adverse drug reaction reports, and its public interface www.adrreports.eu, contain vital information about the safety of medicines for consumers, health care professionals, researchers, pharmaceutical companies and public health authorities.
BEUC welcomes that, following the implementation of the new EU Pharmacovigilance Legislation (Directive 2010/84/EC and Regulation n. 1235/2010) the database now contains data based on reports coming not only from health care professionals and marketing authorizations holders, but also based on direct reports from consumers[3].
Pharmacovigilance data are scientific data about the safety of medicines on the market and they should not be considered "commercially confidential information". The draft should make a clear distinction between the protection of personal data and the protection of intellectual property rights. The draft should also clarify that it applies without prejudice the EU Regulation on access to documents n.1049/2001.

2. Response to EMA Question

- **EMA's question:** ***As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection?***

- **BEUC response:**
  Provided that personal data protection is fully ensured, healthcare professionals and the public should obtain access to additional data outputs from the European database of suspected adverse reactions including tabular presentations or outputs presented as individual cases. There is no reason to restrict access of stakeholder group II to several items of Individual Case Safety Reports (ICSR). Some regulators such as the MHRA in the UK and Lareb in the Netherlands already provide public access to this type of information. It would also be interesting to include more information about the method for the evaluation and the results of assessment.

[1] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500170699&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc
[2] http://europa.eu/rapid/press-release_IP-12-1_en.htm?locale=en
[3] BEUC position on Pharmacovigilance, 2009.

3. Specific comments on the draft

3.1 Access for research organizations

- *"The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication."*
  "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must *not be disseminated in any way without the disclaimer*."

  BEUC considers that the Agency should not be entitled to censor the results of independent research and doesn't support the above mentioned principles.

  Moreover we consider that the draft should include a more precise definition of "Research Organizations" to avoid too narrow interpretations.

- *"An ad-hoc EMA panel will review requests for research access to data based on a research request. The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency*."

  BEUC considers that EMA discretion to refuse access is not justified and not in line with the EU Regulation on access to documents n. 1049/2001. The policy should specify who will be the members of the panel and the criteria for its composition. The criteria to refuse access, namely if the Agency is unconvinced of the public health value of the proposed research and if the Agency judges it is in conflict with the public health and legal responsibilities of the Agency, are too vague and are subject to interpretation. The criteria should be more concrete and objective. In order to increase accountability we recommend integrating some transparency provisions, such as the obligation to detail the reasons for a refusal and the publication on the Agency web site of all the requests received and the answers provided.

3.2 Access for health care professionals and the public

The access to information by the general public and health care professionals remains very limited. We therefore recommend making available also to the Group II (Health care professionals and public) the following information:

- Date of most recent information (C.1.5);
- Gestation period (D.2.2.1d);
- Substance name (D.8.r.Eu.r.1);
- Substance strength (D.8.r.Eu.r.3a);
- Scientific name, form, strength (G.K.2.2.EU 1-5);
- Narratives or summaries : narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment;
- Previous prescriptions: the information is necessary to identify possible interactions between treatments.

It would also be useful to disclose to the general public consumption data in order to put the use of the medicine and the associated adverse events into context.

Finally, we recommend to make the public interface of Eudravigilance, www.adrreports.eu more reader friendly and to organize awareness campaigns on the existence of the website in cooperation with stakeholders and with the Member States in the context of the public information campaigns on the importance of reporting side effects foreseen in the EU pharmacovigilance legislation.

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