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Dr Peter Arlett

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Subject : Commission consultation on a strategy to better protect public health by strengthening and rationalising EU pharmacovigilance

Dear Dr Arlett,

In response to the Commission's consultation regarding the above mentioned public consultation on legislative proposals, Eurordis wishes to support the Commission's initiative in its efforts to improve the safe use of medicines and to reinforce the European pharmacovigilance system.

Eurordis is particularly interested in this initiative as orphan drugs are assessed under exceptional circumstances, they often correspond to an unmet medical need, and thus it is of utmost importance to continue data collection on the risk/benefit ratio after their marketing authorisation. Patients and their health care professionals can only benefit of a more rational and efficient process to minimise risks and to increase safety information after marketing authorisation has been granted. In addition, as described by our surveys among marketing authorisation holders for orphan products, SMEs involved and committed to develop and place on the market orphan products should also benefit from a simpler system with less duplication and more focus on products that require an intensive monitoring scheme. Eurordis agrees with the proposed simplifications and the emphasis given to the assessment of the risk / benefit ratio.

Eurordis welcomes the proposal to further coordinate risk management plans for centrally authorised products. The CHMP opinion and the measures proposed by its members and discussed with the Marketing Authorisation Applicant should apply homogeneously in the EU/EEA, with as little variation from one Member State to the other. If safety is a national responsibility, patients, health care professionals and public health do not vary greatly in Europe to such an extent that measures should differ significantly among Member States. Product information for

centrally authorised products is now the same in all EU Member States, as should be the risk management plans. This is the spirit of the single market; moreover, this is the interest of patients.

We also wish to express some more specific comments:

1. Eurordis fully supports the creation of a Pharmacovigilance Committee at EMEA with the involvement of two patient representatives and their alternates. In addition, PSURs relevant to the diseases represented by patient organisations having established working relations with the EMEA could be presented and discussed directly with the concerned organisations. The Pharmacovigilance Committee should be encouraged to communicate directly to these organisations when important findings are identified and important conclusions are drawn, or in case of a crisis. Adequate resources should be allocated to the Committee to organise this process.

   - Page 45, Regulation (EC) No 726/2004 Article 61(1 and 2): "The Pharmacovigilance Committee shall additionally include:

     (a) two members and two alternates appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent health professionals;

     (b) two members and two alternates appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament , in order to represent patient associations".

     - Our proposal: "The Pharmacovigilance Committee shall additionally include:
       (a) two members and two alternates appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent health professionals;
       (b) two members and two alternates appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament , in order to represent patient associations".
       Members representing patient associations shall be remunerated in accordance with a scale of fees to be included in the financial arrangements established by the Management Board."
     - Justification: the current activities of the EMEA Pharmacovigilance working party represent monthly 3-day meetings, with many documents and reports to prepare each meeting. With more activities in the next to be created Pharmacovigilance Committee, the work load would represent an estimated 4 to 6 days commitment monthly. Appropriate remuneration would ensure more sustained representation and active role of patient representatives.

2. Eurordis fully supports the possibility for patients to report themselves adverse reactions: in Member States where pilot but limited experiences have been conducted, the quality, the completeness, and the interest of the information support the development of this innovative approach. The Patients' and Consumers' Working Party at EMEA has recommended this approach to be implemented using various methodologies and to compare their outcomes.

This being said, we have a few remarks:

- Page 7, the proposals stands: "Make clear the legal basis for patients to report suspected adverse drug reactions - Patient adverse reaction reporting forms to be part of the patient information leaflet for intensively monitored drugs, with reports going to the Marketing Authorisation holder".
    - Our proposal: "Make clear the legal basis for patients to report suspected adverse drug reactions - Patient adverse reaction reporting forms to be part of the patient information leaflet for intensively monitored drugs, these forms could be either sent to the national authority in charge of pharmacovigilance, to the prescribing physician or to the dispensing pharmacist, or to the patient's organisation, and those reports communicated to the Marketing Authorisation holder by the national authority".

    - The rationale being that different modalities for the patient to send the form back are possible and these modalities could be defined by Member States. However, a system where the patient would need to end the form to the Marketing Authorisation holder would not seem the most efficient, given the relative lack of trust of the general public into the pharmaceutical industry, particularly in terms of early signal detection and prompt reaction when severe adverse reactions are to be reported.

- On Page 23, article 101e, paragraph 3: "To facilitate the reporting of suspected adverse reactions by healthcare professionals and patients, each Member State shall accept reports of adverse reactions via their websites which shall be linked to the European medicines safety web-portal referred to in Article 101i."
    - Our proposal: "To facilitate the reporting of suspected adverse reactions by healthcare professionals and patients, each Member State shall accept reports of adverse reactions via their websites or via printed forms distributed by pharmacists and collected either by health care professionals or patients' organisations. The role of patients' organisations to encourage patients to report side effects should be acknowledged. The Member States websites shall be linked to the European medicines safety web-portal referred to in Article 101i."

    - Justification: it should appear clearly that electronic submissions of adverse reactions by patients are not the only tool for reporting, as many patients do not use internet daily, e.g. the elderly who are high consumers of medications.

3. To improve communication, Eurordis also fully supports the creation of a dedicated European medicines safety web-portal supervised by the Agency.

    - On page 28, Chapter 5, article 101i: "(c) Information about how to report suspected adverse reactions to medicinal products and forms for their web-based reporting by patients, healthcare professionals and marketing authorisation holders".

- Our proposal: "(c) Information <u>in all EU languages</u> about how to report suspected adverse reactions to medicinal products and forms for their web-based reporting by patients, healthcare professionals and marketing authorisation holders".

- Justification: it is our understanding that the intensive monitoring list referred to in Article 101j will exist in all EU languages. Among all other indents (a) to (i) of this paragraph, it seems important to have the information described in (c) in all EU languages, as a mean to disseminate the information to the largest public possible.

4. To more efficiently regulate medicinal products, Eurordis advocates for the inclusion, in the pharmaceutical legislation, of provisions regarding the withdrawal of a marketed product. Recent examples of unilateral withdrawal decision for safety reasons by the Marketing Authorisation holder, with no dialogue with regulatory agencies, emphasize the need to reinforce this aspect of Directive 183/2001 and of Regulation 726/2004.

   - On page 29, Chapter 6, article 101k: "(h) it is informed by the marketing authorisation holder of its intention to withdraw, or of the fact that it has withdrawn a medicinal product from the market on the basis of safety concerns".
     - Our proposal: "(h) it is informed by the marketing authorisation holder of its intention to withdraw~~, or of the fact that it has withdrawn~~ a medicinal product from the market on the basis of safety concerns".

Sincerely,

François Houÿez
Health Policy Officer
EURORDIS
8/02/2008