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| Subject | Response to the consultation on the "Strategy to better protect public health by strengthening and rationalising EU pharmacovigilance: public consultation on legislative proposals" |
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| To | European Commission |

**The European Association of Hospital Pharmacists (EAHP) represents over 21,000 hospital pharmacists and aims to promote and uphold the interest of European hospital pharmacy policies, standards and vision. It is our role to work for the advancement of the position and role of the pharmacists in hospitals and to promote co-operation with other professional bodies.**

## 1. Introduction

The EAHP welcomes the initiative from the European Commission to consult the public on the revision of the European texts related to pharmacovigilance, based on the comments and suggestions collected through its consultation on the same topic in 2006.

EAHP will always support all efforts made towards a robust and user friendly European pharmacovigilance system. However, patient safety should always come first, and simplification procedures for tracking and registering adverse drug reactions (ADR) not implemented at the detriment of the former, or with the risk of introducing a lack of confidence in medicines on the part of the patient. This strategy paper is very much oriented towards the benefits of the industry and medication safety comes second, to the great regret of EAHP. In addition, the proposal to replace title IX of Directive 2001/83/CE with a full set of articles gives in essence a much bigger role and responsibility to the pharmaceutical industry to the detriment of national competent authorities.

Hereby we comment areas where we feel the proposed changes are going beyond the needs related to Patient Safety and underline aspects where we feel improvement and caution are needed.

EAHP regrets that despite the EC general policy to allow at least eight weeks to respond to its consultation, that policy was not respected by DG Enterprise & Industry that launched the above mentioned consultation early December with a due date of 1st of February which does not take into account the Christmas & New Year break that is generally observed in the EU Member States.

**2. Rationalising the existing EU referral procedures and reinforcing the committee structure**

We welcome the creation of a Committee on Pharmacovigilance in the EMEA and see it as beneficial to the strength of European pharmacovigilance.

Overall, EAHP supports the simplification of procedures as long as these will ensure that pharmaceutical companies do communicate of ADR, assess the quality and efficacy of their products, and are not predominant in the pharmacovigilance system.

We question the simplification of information to the authorities of company pharmacovigilance systems: if the products, when entering the market are not strictly monitored (only by request), the marketing authorisation holder may take this as an opportunity to post-pone the development of its pharmacovigilance system.

Regarding the creation of automatic pharmacovigilance referral, EAHP underlines the need for it to reach, at the same time, other Member States, the Agency (EMEA) and the Commission – the report done by a Member State of an incident should be notified simultaneously to the other Member States, the EMEA and the Commission.

**3. Clarify/codify role and responsibilities and codify standards for industry and regulators.**

EAHP regrets that a large emphasis is given to saving costs and time for the pharmaceutical companies (the "market authorisation holder") and to put an end to their administrative burden rather than on the role of healthcare professionals in pharmacovigilance, no-where are the pharmacists, nurses and other dedicated to patient safety professionals mentioned as instrumental to the success of any form of pharmacovigilance. It is of immense importance that all healthcare professionals involved in the medication procedures, be it by prescribing drugs or by distributing and dispensing them are considered as the corner stone of an efficient pharmacovigilance.

The roles and responsibilities of all these agents should be taken into consideration, as only that of the industry and of regulators are developed in this strategy paper. But in case of the withdrawal of a medicine or of a medical device for instance, the pharmacists, doctors and nurses are the ones that are the most exposed to the general public inquiries regarding

safety measures – not the Member State dedicated to patient safety administration. They are also the first ones to be reacting and informing the concerned authorities and market authorisation holders and therefore should be included in the legislative proposal.

We wish to also highlight here the role of the hospital pharmacist which goes beyond monitoring medicinal products and reporting ADRs and other drug-related problems. The hospital pharmacist is also reviewing older medicines versus the new ones put on the market, blood products, biological, medical devices and vaccines. He is also the one informing the doctors (and in some countries, the patient directly) of the risk-benefits of the medicines and medical devices.

The fact that the "Communication" part of this strategy completely ignores the communication between healthcare professionals, patients and the public at large is of deep concern to EAHP.

Therefore EAHP strongly recommends the introduction/addition of the mention "healthcare professionals organisations" to Article 101b(1), Article 101b(2), Article 101d(2), Article 101l(2)

**4. Rationalise risk management planning**

EAHP cannot accept that the notion of Risk Management Systems (RMS) justifies the intervention of the pharmaceutical companies at all the steps of the elaboration of this RMS and with the aim to provide marketing authorisation at an earlier stage of development of the products (see section 3.2.1(b)). By doing so, this proposal allows risk assessment not prior to the marketing authorisation, but when there are actual risks, hence trivialising the assessment of adverse drug reactions and reducing pharmacovigilance to administrative management. Moreover, the RMS must take into account the importance of the collaboration with healthcare professionals in order to best communicate benefits and risks of medicines and not stay limited to a communication between health authorities and the pharmaceutical firms.

EAHP is strongly against generalising the possibility to ease and fasten the granting of marketing authorisation as stated in the Article 22 of this strategy, with the removal of the mention "*in exceptional circumstances and following consultation with the applicant*" when we see no medication safety justification for this. Years of experimenting facilitated marketing authorisations in Europe and in the US demonstrate that the pharmaceutical firms do not respect their commitments regarding assessing already marketed medicines[i]. We see the change of this article as a way to support pharmaceutical firms rather than medication safety – which is confirmed by the mention in section 3.2.1 of the Introduction: "*earlier*

*product authorisation provides faster return on investment and by reducing the cost of capital the total cost of product development is reduced*".

The Commission in this strategy proposes to delete, in the new version of Article 26 of the Directive, the mention: "*the marketing authorisation shall be refused if [...] it is clear that its therapeutic efficacy is insufficiently substantiated by the applicant*". Only a demonstrated efficacy can justify exposing the population to the risk of adverse drug reactions (or worse) when putting on the market a new medicine; patients and healthcare professionals do not want to take the risks that were imposed to them with the Thalidomide in the 1960', for instance. It would be a major step-back not to have to demonstrate efficacy of a product prior to the delivery of its marketing authorisation. Therefore, EAHP strongly advises the Commission to keep point 1. (b) in Article 26.

**5. Reporting of ADR**

EAHP welcomes the much needed possibility now offered to the patients to report an ADR themselves, for medicines that are intensively monitored. But it cannot accept that he shall do so directly to the pharmaceutical firm, and not via a healthcare professional, as stated in Article 59 (ba) "*suspected adverse reactions should be reported to < the name and address of the marketing authorisation holder>*". Reporting should always go through the national healthcare authority in charge of pharmacovigilance, not through private parties and should be complemented with a discussion between the patient and his healthcare professional.

We also welcome the forecasted simplification of the Eudravigilance database and underline the necessity to involve more healthcare professionals (by promoting the database for instance) in reporting via this system. We request that pharmacists, as it is the case for doctors are clearly stated in the legislative proposal rather than included in "other health care professionals" (Article 101a).

**6. Strengthen medicines safety transparency and communication**

EAHP welcomes the proposal to centralise the coordination of the communication on a particular ADR or incident at the EMEA, which could make decision making more effective, but maybe not more rapid.

However EAHP would like the healthcare professionals involved in medication safety to be better informed and provided with all necessary information and explanation before an incident with a medicine, a medical device or blood product is made public, so that the healthcare professionals can adequately inform the patients when questioned on the matter.

EAHP does not find it appropriate the suggestion of having to ask for the agreement of the manufacturer for making publicly available an amended abstract of a post-authorisation study (Article 101h(j)) – what happens if the marketing holder does not agree? The abstract is not published? Such a refusal should also be made public. At a time when the European Commission is positioning itself as being more transparent it should not limit publications of studies related to medicines safety.

## 7. Conclusion

It is EAHP opinion that this "Strategy to better protect public health by strengthening and rationalising EU pharmacovigilance" bears some positive aspects but goes too far in many of its suggestions, by highlighting the need to put a new medicine very quickly on the market, to support the pharmaceutical industry. The fact that the role of the pharmacist and more specifically of the hospital pharmacist, is not mentioned at all in this proposal is not acceptable for EAHP, especially when knowing that most ADRs take place in hospitals, or when they do not, then often imply a hospitalisation of the patient. Based on the above mentioned comments, suggestions and opinions, EAHP is not in favour of this strategy.

END - EAHP, 1 February 2008

[i] US Government accountability Office "Drug safety – Improvement needed in FDA's postmarket decision-making" and oversight process" Report GAO-06-402,2006. Internet: www.gao.gov