**Commission Pharmacovigilance Strategy: Public consultation on draft legislative proposals**

Comments from Infarmed I. P.

Infarmed I. P. welcomes the opportunity to comment the current proposals and congratulates the Commission for the in-depth review of the current pharmacovigilance system.

Excessive complexity and unnecessary duplication of activities and data generation may hamper the effectiveness of pharmacovigilance systems. Generally speaking, the proposals contained in this document address these issues and concerns in very relevant terms. Although supportive of the strategy and guiding principles behind the proposals, from our viewpoint, to achieve the ultimate aim of rationalisation and strengthening of the pharmacovigilance system some aspects need clarification and further elaboration.

3.2.1. Fast robust EU decision-making on safety issues by rationalising the existing EU referral procedures and reinforcing the committee structure

- Referrals to have light procedures and public hearings: establishing compulsory public hearings in a referral procedure will override the objective of making it simple and easily manageable. We would favour the possibility of public hearings only when considered necessary.

3.2.3. Simplify informing the authorities about the company pharmacovigilance system

- At marketing authorisation only key elements of the pharmacovigilance system to be submitted as part of the dossier: identification of these key items should be made clear to make the procedure simple without neglecting important information.

  Pharmacovigilance System Master File: having the master file available on site and upon request is an important step for competent authorities. However, with this comes the possibility of having to request a potentially large number of master files for authorities to complement the information on pharmacovigilance at their disposal.

- For centrally authorised products create a specific supervisory authority for pharmacovigilance which is the Member State where the company Qualified Person resides: a clear definition of the role and responsibilities of the Member State acting as supervisory authority is needed for this concept to be understood.

3.2.4. Rationalise risk management planning

This is of the utmost importance if RMP is to have its intended impact on prospective assurance of the safety of medicines.

3.2.6. Simplify and make proportional reporting of single serious adverse drug reaction (ADR) case reports

- Establish a European list of medicines under intensive monitoring. We fully support the creation of such a list. However, its inclusion and removal criteria must be clearly established.

- The marketing authorisation holder shall accept reports of adverse reactions electronically. It is very important that MAHs are able to receive electronic reports, given the fact that electronic transmission of adverse reactions aims at eliminating paper reports and as such this should happen in both directions (MAH → NCA and NCA → MAH).

- Marketing authorisation holders shall submit electronically to Eudravigilance, no later than 15 -days following the receipt of the report, all adverse reactions that occur in the Community (…). These reports will be made available to the Member State through Eudravigilance. This means that, for local cases, MAHs will no longer send the ADR cases that are brought to their attention by healthcare professionals to the NCA of the Member State where the ADR occurred, and that the NCA will only have access to these cases through Eudravigilance. Although the cases will be in EudraVigilance, we have doubts concerning the capability of the system to cope with the huge number of partners that will use EudraVigilance to perform signal detection once that EV is the only database containing all local cases. Furthermore, at present the cases reported to MAHs by healthcare professionals and sent to Eudravigilance by the NCAs are checked for their quality, which can no longer be guaranteed if NCAs stop receiving these cases.

- Medication errors: a definition should be sought as it would clarify the broad scope of understanding of what is a medication error. On the other hand clarity around this issue is essential to promote the reporting of this type of adverse reactions to competent authorities.

- Reporting to the authorities case reports of adverse reactions from the worldwide medical and scientific literature is currently an obligation on all companies leading to the same literature case report being submitted to multiple authorities by sometimes hundreds of companies (for generic medicinal products). Giving the core task for specific literature to the EMEA will reduce duplication of effort within the system and improve data quality in adverse reaction databases. In order to minimise the burden of this task, the EMEA could set up harmonised literature data search and relevance criteria and distribute the task amongst the member states, each of which could be assigned with a group of medicines/pharmacological groups of which it would be in charge.

- 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. It is our opinion that such these reports should go to the NCA since we feel that patients may be more reluctant to report to the MAH than to the NCA. Moreover, careful consideration should be given to the implementing aspects of this 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. Every effort should be done to have ADR reports from patients validated by a healthcare professional (HP), and as such the contact details of the HP that attends the patient, as well as permission from the patient for the NCA to contact the HP, should be given when the patient fills in the form in the website. In our view, the healthcare professional in charge of this validation should be the patient's medical doctor.

3.2.7 Simplify and make proportional to risk periodic safety update report submission by industry (PSURs)

- No PSURs for old established products: Provision of a legal basis for the existing PSUR assessment work-sharing with a clear coordinating role for the new EMEA pharmacovigilance committee is welcome. Nevertheless, further to the approval of changes to the periodicity of submission from companies and requests for no submission of PSURs, this new committee should be able to redefine a new submission cycle of PSURs whenever safety issues need further monitoring.

3.2.9 Clearer safety warnings in product information to improve the safe use of medicines

- To allow patients to rapidly identify key messages, introduce a new section in the Summary of Product Characteristics and Patient Information Leaflet on 'key safety information': Such a section has a potential to be a major improvement to SPCs and PILs, since prompt identification of key messages in those documents may be a problem on account of the thoroughness and therefore density of information contained therein. Further clarification is needed as to the criteria to include information in this black box. It is also not clear whether it would be the same information already included in another section of the SPC or PIL and simply highlighted in this box or if it is new information not included elsewhere. The latter possibility would risk adding to the complexity of these critical risk communication tools.