GE Healthcare's Comments
Strategy to Better Protect Public Health by Strengthening and Rationalising EU Pharmacovigilance

General
GE Healthcare welcomes the European Commission's initiative to rationalise the European Pharmacovigilance strategy. We would encourage the Commission throughout these activities, to be cognisant of international Pharmacovigilance reporting requirements and to take this opportunity to harmonise requirements wherever possible.

Key proposals for legislative change
1. Fast robust EU decision-making on safety issues by rationalising the existing EU referral procedures and reinforcing the committee structure
GE Healthcare supports this proposal.

2. Clarify/codify roles and responsibilities and codify standards for industry and regulators
The introduction of a legal basis for Good Vigilance Practice is welcomed. We wish to stress that industry and the regulatory authorities would benefit from an international (ICH) definition of Good Vigilance Practice, such that a common standard is applicable and recognised globally.

3. Simplify informing the authorities about the company pharmacovigilance system
The proposals require a Pharmacovigilance System Master File to be established. GE Healthcare proposes that the Pharmacovigilance System Master File should be one document which is accepted by all EU member state national authorities i.e. national variants are not required.

4. Rationalise risk management plans
No comments

5. Codify oversight of non-interventional safety studies
No comments

6. Simplify and make proportional reporting of single serious adverse drug reaction (ADR) case reports
There will be a legal basis for patients to report suspected adverse drug reactions. Will these patient reports be considered causally related on equal terms with healthcare professional reports? Will there be a requirement for confirmation by a healthcare professional? How will authorities treat these reports, i.e. will they have the same status as medically confirmed reports? What are the implications for labeling and what might feasible criteria be? Will the Marketing Authorization Holder be informed of these reports? How will patient reports be addressed in the Periodic Safety Update report? These aspects need further clarification.

It is stated that the EMEA will take on the task of scanning scientific literature and entering case reports from the literature. Does this mean that a Marketing Authorization Holder is relieved from the task of regulatory reporting events

observed from the literature? Will the EMEA inform the Marketing Authorization Holder of literature findings? If so, would this help in light of reporting requirements outside the EU?

The concept of reporting proportional to the known risk has been introduced. It is unclear how the list of medicines under intensive monitoring will be derived, i.e. which criteria for inclusion will be applied. Will the Commission be consulting on the criteria to be applied? Article 101j states that the Agency shall make public a list of medicinal products for human use under intensive monitoring and this list shall include an electronic link to the product information. Is this 'product information' intended to be the authorised Summary of Product Characteristics (SmPC) only? It is feasible that a product under intensive monitoring may be authorised under national (rather than centralised) procedures, would the electronic link include the SmPCs of all countries where the product is approved?

It seems to be unclear whether all EU domestic reports, i.e. serious and non-serious ones, need reporting to EudraVigilance. If non-serious reports need to be reported within 15 days this will lead to very different reporting requirements in the EU compared with the USA. Is this the intention?

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

The concept of "No PSUR needed for old established products" is stated. The definition of 'old established products' is unclear. Is it intended that these should be products for which there is no risk management plan and that the product is not included in the list of products under intensive monitoring? Does the definition relate to 'well established medicinal use' as mentioned in article 10 and annex 1 of Directive 2001/83/EC as amended? It needs to be clarified how this category of products is established and agreed across all Member States.

We request that it is clarified that the Committee on Pharmacovigilance **will** determine the European reference dates and frequency of submission of PSURs for **all** medicinal products for human use authorised in the Community (see article 101f paragraph 4(a). The current draft text of this paragraph states that ' the Committee on Pharmacovigilance referred to in Article 56(a)a of Regulation EC(No) 726/2004 **may** determine the European reference dates and frequency of submission for periodic safety update reports for **certain** medicinal products for human use authorised in the Community.' We are concerned that unless the Committee addresses all authorised products, a number of old established products will default to the schedule listed in article 101f (2c), which is clearly not the intent.

8. Strengthen medicines safety transparency and communication

No comments.

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

No comments