UK BioIndustry Association

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European Commission
Directorate-General for Health and Consumers
Unit SANCO/D/3
BE-1049 Brussels

7 November 2011

Dear Sirs,

Response to European Commission Public Consultation on Implementing Measures for Pharmacovigilance

The BioIndustry Association (BIA) welcomes the opportunity to submit these comments and observations on the concept paper describing the implementing measures for the performance of the pharmacovigilance activities provided for in Directive 2001/83/EC and Regulation (EC) No 726/2004.

Established in 1989, the BIA is the trade association for innovative enterprises involved in UK bioscience. Our members are responsible for over 90% of biotechnology-derived medicines currently in clinical development in the UK and are at the forefront of innovative scientific developments targeting areas of unmet medical need. This innovation will lead to better outcomes for patients, to the development of the knowledge-based economy, and economic growth.

We support the new EU pharmacovigilance legislation which aims at strengthening the Community system and better protecting public health.

The BIA broadly endorses the EFPIA (European Federation of Pharmaceutical Industries and Associations) position and their comments on the concept paper.

To the extent that is necessary to efficiently manage and maintain the pharmacovigilance system master file, and consistent with the better regulation principles, the BIA, in consultation with our sister organisations and member companies, would be pleased to provide further input, where necessary, in the detailed implementation of this specific measure.

In addition, we wish to provide on behalf of our members some further comments relating to the monitoring of biological medicinal products, including biosimilar medicines, for consideration by the Commission, regulatory authorities in EU Member States and the European Medicines Agency when finalising these implementing measures.

1. **Pharmacovigilance signal detection methods should be designed to capture the unique characteristics of biological medicinal products** including immunogenicity, potential safety issues linked to changes in product quality and other characteristics of their safety profiles.

2. **Traceability/identification of the biological medicinal product** (see section 15 of the concept paper and Annex I, Para 4 (h)). In accordance with Article 102(e) of Directive 2001/84/EC amending Directive 2001/83/EC, “The Member States shall

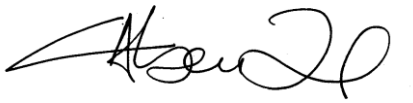
ensure, ..., that all appropriate measures are taken to identify clearly any biological medicinal product prescribed, dispensed, or sold in their territory which is the subject of a suspected adverse reaction report, with due regard to the name of the medicinal product, in accordance with Article 1(20), and the batch number". Thus it should be noted that Member States must ensure identification of biological medicinal products for pharmacovigilance purposes and can impose prescribing by brand name. Adverse drug reaction reports should identify the product by international non-proprietary name, brand name, marketing authorisation holder and batch number.

3. **Changes to a biological manufacturing process.** Biological medicinal products have complex manufacturing processes that must be appropriately controlled to provide a consistent product. Any change to a biological manufacturing process, formulation, container-closure or handling has a potential to impact the prevalence, incidence or severity of adverse drug reactions, including unwanted immune responses. In this regard Recital (17) of Regulation (EU) No 1235/2010 amending Regulation (EC) No 726/2004 requires that significant changes to the manufacturing process of a biotechnology-derived medicinal product are reflected in appropriate risk management plans. Thus marketing authorisation holders should conduct enhanced pharmacovigilance to ensure any safety signals are detected as early as possible.

4. **Immunogenicity-related reactions.** Marketing authorisation holders of biological medicinal products should be accountable to patients and the medical community by providing clinical immunology and analytical support to ensure proper diagnosis and appropriate implementation of risk mitigation measures of a suspected incidence of unwanted anti-therapeutic antibodies for a given patient. The support provided includes: (a) availability of the clinical service to test patient samples in the institutions where patients receive treatment; and (b) availability of standardised test or assay as part of the patient monitoring strategy.

We would be happy to discuss any of the comments in this response. We look forward to continue the dialogue with the Commission and regulatory authorities to facilitate the effective implementation of the new EU pharmacovigilance legislation.

Yours sincerely,



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