From: Belsky, Kimberly
Subject: Regarding: PCIM/11/01 - Public Consultation on implementing measures for pharmacovigilance

To Whom It May Concern:

Reference is made to the Concept Paper released for consultation on 8 September 2011 entitled, "Implementing Measures in Order to Harmonise the Performance of the Pharmacovigilance Activities Provided for in Directive 2001/83/EC and Regulation (EC) No 726/2004. http://ec.europa.eu/health/files/pharmacovigilance/2011-09_concept-paper.pdf

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We appreciate the opportunity to provide comments on this concept paper. We support the Commission in its efforts to create guidance that is robust and appropriately addresses all different implementing measures to supplement the Directive 2001/83/EC and Regulation (EC) No 726/2004 as it pertains to the performance of pharmacovigilance activities from July 2012 onwards, when the new rules are applicable. In that respect, we offer the following comments.

Section 7. Audit/Consultation item no. 4 "Should a copy of the audit report be retained in the master file? Would it be appropriate to require documentation of audit schedules?"

The concept paper states, "Immediately after an audit report has been received that requires corrective or preventative action, the marketing authorisation holder shall place a note concerning the main findings of the audit on the pharmacovigilance master file." While we agree with this statement as written for official audits conducted by Health Authorities, we are concerned that this may be inadvertently extended to internal audits conducted by the sponsor. Audits conducted in accordance with a firm's written quality program should remain outside the scope of the master file. We believe this is critical to encourage firms to conduct assessments that are candid and meaningful. We recommend that the guidance developed specify inclusion of audit information from 'official audits conducted by Health Authorities'.

Section 8. Inspection/Consultation item no. 5: "Overall, do you agree with the requirements as regards the content and maintenance of the pharmacovigilance master file?"

With regard to submission of the pharmacovigilance system master file, the concept paper states, "The marketing authorisation holder shall submit the copy at the latest seven days after receipt of the request…." To allow sufficient time for a firm's internal review and to ensure information being provided is up-to-date (e.g., newly received information has been incorporated), we request that the period of time to submit be reflected as 15 days after receipt of the request. We believe that a time period of 15 days is supported by and consistent with the reporting timeframe defined for suspected serious unexpected adverse reactions in Volume 9A Pharmacovigilance Guidelines.

We trust this feedback will support the Commission's goal to address all different implementing measures to supplement the Directive 2001/83/EC and Regulation (EC) No 726/2004 as it pertains to the performance of pharmacovigilance activities.

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