From: Nicolas Tsiakkas
Subject: Concept paper for public consultation_New PV legislation

To whom it may concern,

On behalf of Medwork Pharma Research and Consulting, a CRO company in Greece, I would like to communicate to you our comments on the "Concept Paper submitted for Public Consulation" PCIM/11/01.

- Consultation item no 2

We agree that changes to the content of the master file should no longer be subject to variation obligations. We think it would be important, though, to inform immediately authorities of significant changes/modifications to the master file.
We think that every time that significant changes to the master file take place, the MAH should prepare a report stating those parts of the master file that have been modified. This report should be sent as a notification letter to the authorities, not subject to the variation regulation and fees. Nevertheless, we would like to emphasize here that since the modifications to the master file are not going to be subject to the variation regulation, this should necessarily lead to a modification of the Communication from the Commission 2010/C 17/01 (Guideline on the details of the various categories of variations to the terms of MAs for medicinal products for human use and veterinary medicinal products) and in particular Part C, C.1.8.-C.1.9.that defines variation procedures for these items now included in the master file.

- Consultation item no 2

We agree that the master file should contain a date when it was last reviewed. Moreover, we think that it should contain a version number, the date it becomes effective and the date by which it has to be reviewed. This version number should be utilized for the communications with the authorities concerning modifications to the master file, as stated above.

- Consultation item no 4

We believe that a copy of the audit report should be retained in the master file as well as the suggested CAPAs. Documentation of the audit schedules could be included, unless they are described in MAH's SOPs.

- Consultation item no 9

Our opinion is that small-sized companies with generic products should not be obliged to conduct signal detection for their products. Since the number of ICSRs they receive is usually limited, they should be excluded from this obligation. Signal detection should be enforced to companies with novel products or generic companies with high sales volumes, i.e. market leaders. Within the newly established framework of signal detection from EMA, competent authorities and companies with high sales volumes, the impact of signal detection practices from small generic companies will be minimal if any. Additionally, one of the main driving forces of the new legislation was the will of all stakeholders to minimize unnecessary work and simplify processes. Lifting the obligation of PSUR submissions and global literature search of the most common active substances is an example of such actions that make pharmacovigilance in the EU more efficient and limit dramatically unnecessary work. However, requesting small generic companies to conduct signal detection effectively cancels the community's efforts to reduce redundant work and foster the functioning of small and medium sized companies.

Sincerely,

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