From: Tehan Sian - UK
Subject: PCIM/11/01 - Public Consultation on implementing measures for pharmacovigilance

Please find below comments from Sanofi Pasteur MSD Ltd who are responsible for pharmacovigilance for the UK and Republic of Ireland affiliates:

Consultation Item No. 2:

The PV Master File should be dated and version controlled and signed by the QPPV and a representative of the MAH if the QPPV is a consultant to the MAH.

Will there be a minimum period for review of the Master File if no changes have been made e.g. annually?

If the MAHs have to notify the CAs of significant changes clear guidance should be provided as to what will constitute a significant change.

Consultation Item No. 4:

Rather than keeping the audit report in the Master File, the CAPA, showing the finding, corrective action and date the action was completed could be kept on file.

Including the audit schedule in the Master File will highlight to MAHs the importance of the audits and MAHs will be more likely to stick to the schedules.

Section C13

Please ensure that there are clear guidelines as to experience and training required for a QPPV.

Section 14(d)

Why do MAHs have to check web portals on a daily basis? For small departments this is not always practical.

Consultation Item No. 6:

There should be quality procedures for all aspects

It is essential that there are quality procedures in place to detect duplicates when ICSRs are reported to Eudravigilance. Can this be done on receipt of the ICSRs before they are uploaded to Eudravigilance? This will avoid the problems that are apparent with the MHRA system where no duplicate checks are done on receipt of ICSRs resulting in many duplicates on their database. This is a particular problem with literature case reports where many companies may be reporting the same case.

Consultation Item No. 9:

It makes sense for all tasks relating to signal management are dealt with by one Member State as long as this does not result in delays due to lack of resource. However, experience with the PSUR Worksharing scheme has shown that some of the Final Assessment Reports are very confusing and difficult to folloew and in a number of cases the timelines for issuing the FARs are not adhered to so this may be compounded if all signal management for a product is assigned to one Member State.

Consultation item No. 16:

Currently ADRs are included in PSURs with the new format a cumulative summary of AEs will be required but will the cumulative and interval data from spontaneous sources be AEs or ADRs. This needs to be clearly defined.

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