From: Calin Lungu
Subject: PCIM/11/01 - Public Consultation on implementing measures for pharmacovigilance

Dear Madam, Dear Sir,

I represent Drug Development Consulting Services S.A. (DDCS), which falls in the category of small and medium size enterprises.

Consultation item no. 1

No comment.

Consultation item no. 2

The PV master file should be version controlled.

Notification of significant changes should be made by letter / fax / email to all concerned NCAs.

Consultation item no. 3

No comment.

Consultation item no. 4

The audit reports should not form part of the PV master file. A list of unresolved findings from the audits is sufficient in the PV master file.

It would be appropriate to include in the PV master file the audit schedules. This may help understand an inspector if the scope, frequency and type of audits adequately cover the Quality Assurence activities in pharmacovigilance.

Consultation item no. 5

Agree. Maybe it would be useful to specify if the deadline of 7 days for the MAH to provide the Agency or the NCA with a copy of the PV master file refers to calendar days or to business days.

Consultation item no. 6

It would be useful to have procedures covering all aspects of electronic submission of individual case safety reports as well as medicinal product information to EudraVigilance, e.g. detection of duplicates, testing electronic submission, quality control aspects etc.

Consultation item no. 7

Agree.

Consultation item no. 8

It would be useful to specify the EMA's activities for literature searches, in particular
a) what substances are covered by the EMA's literature screening
b) what are the criteria for a substance to be added on the list of substances for which the EMA performs literature searches
c) how will the MAHs know if their substance(s) are covered by the EMA's literature searches

d) how will MAHs be informed of new cases identified by the EMA during literature searches and within what timelines.

Consultation item no. 9

No comment.

Consultation item no. 10

Agree. Would suggest to explain how access to EudraVigilance data will be given to MAHs to allow them to perform signal detection activities.

Consultation item no. 11

Agree.

Consultation item no. 12

Agree.

Consultation item no. 13

Annex 1, paragraph 4 (a): suggest to replace "precise date" with fully pecise date (day/month/year)".
Annex 1, paragraph 4 (d): suggest to replace "Member State" with "primary source country", as Member State does not apply to reports originating outside of the EU/EEA
Annex 1, paragraph 4 (j): suggest to add the need tp provide the suspected adverse reaction(s) coded with Low Level Terms in MedDRA.

Consultation item no. 14

Agree.

Consultation item no. 15

Agree.

Consultation item no. 16

Not sure how the PSUR can be assessed in the absence of line listings with respect to the safety reports which are not classified as expedited reports, e.g. non-serious spontaneous reports from outside the EU/EEA.

Consultation item no. 17

Agree.

Kind regards,

Dr Calin LUNGU
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