Sir/Mada

Following my earlier response to the consultation, I have the following additional comments:

I note from the document 'Questions and answers on practical transitional measures for the implementation of the pharmacovigilance legislation' 23 May 2012 EMA/228816/2012 that variations will probably be required for the following two changes:

5.14
If the PSUR cycle of my medicinal product is changed as per the the EURD list, can I submit my PSUR according to the new Data Lock Point (DLP) without submitting a variation?

MAHs should follow the new PSUR cycle as defined in the EURD list when published as final, independently of a higher or lower frequency than the current one. However, in case the PSUR cycle is stated in the marketing authorisation of a medicinal product, a variation will have to be submitted to update the MA in line with EURD list within 6 months of its publication.

7.1.
When will I have to implement in the product information of my medicinal product the new text on reporting mechanisms and, as applicable, the black symbol with the specific statements?

The selected symbol and standard statements will have to be included in the SmPC and PL of the medicinal products subject to additional monitoring. It is expected that the introduction of the black symbol will require the submission of a variation.

Are there categories already included in the draft guideline to allow MAH holders to apply for these changes or will they be handled during the next update of the guideline?

Thank you

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