EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Implementation plan for the introduction of the new pharmacovigilance legislation requirements into the product information of centrally approved medicinal products

The European Medicines Agency and the Quality Review of Documents (QRD) Group have revised the Human Product Information templates as a result of the introduction of the new pharmacovigilance legislation.

Certain aspects of the implementation of the new pharmacovigilance (PhV) legislation impact on the product information:

1) Additional monitoring of medicines: a black symbol followed by the statement "*This medicinal product is subject to additional monitoring*" and a standardised explanatory sentence shall be included in the summary of the product characteristics (SmPC) and in the package leaflet (PL) for medicinal products subject to additional monitoring. (Art. 11 and 59 of Directive 2001/83/EC and Art. 23(4) of Regulation (EC) No 726/2004). The black symbol is identified in the Commission Implementing Regulation (EU) No 198/2013 of 7 March 2013 on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring.

2) Encouragement to report adverse reactions:

- A standard text shall be included in the summary of product characteristics expressly asking healthcare professionals to report any suspected adverse reaction in accordance with the national spontaneous reporting system referred to in Article 107a(1) (Art. 11 of Directive 2001/83/EC).
- A standardised text shall be included in the package leaflet, expressly asking patients to communicate any suspected adverse reaction to his/her doctor, pharmacist, healthcare professional or directly to the national spontaneous reporting system referred to in Article 107a (1), and specifying the different ways of reporting available (electronic reporting, postal address and/or others) (Art. 59 of Directive 2001/83/EC).

This revision is the result of various rounds of consultation with a variety of stakeholders, i.e. members of the Patients' and Consumers' Working Party (PCWP), members of the Healthcare Professionals' Working Group (HCP WG), National Competent Authorities (NCAs), Pharmaceutical industry associations, CROs specialised in user testing/communication experts and academia.

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In addition, the revised QRD template has now introduced additional guidance on how to complete section 10 of the SmPC, further information about the presentation of multipack pack-sizes in Annex IIIA and some clarifications on the presentation of side effects in section 4 of the package leaflet. Lastly, improvements have been introduced in certain linguistic versions, as necessary.

Implementation timelines

1) Products under additional monitoring

For new marketing authorisation applications with a CHMP opinion in April & May 2013 (i.e. EC decision expected before 01/09/13):

Applicants are advised to comply with the revised QRD template, i.e. implement the black symbol + additional monitoring statement + encouragement to report ADRs statement + other QRD changes.

For new marketing authorisations applications with a CHMP opinion as of June 2013 (i.e. EC decision expected on or after 01/09/13):

Applicants shall implement the black symbol + additional monitoring statement + encouragement to report ADRs statement by complying with the revised QRD template.

For existing marketing authorisations granted via the centralised procedure before the publication of the revised QRD template:

Marketing authorisation holders (MAHs) are encouraged to use the first upcoming regulatory procedure affecting Product Information Annexes (e.g. Renewal, Line Extension, Variation II, Variation IB) to implement the black symbol + additional monitoring statement + encouragement to report ADRs statement by complying with the revised QRD template. The CHMP opinion or EMA notification for the above procedures should fall within the 9 months period* following the publication of the revised QRD template and shall occur no later than 31/12/13.

**9 months following publication of the revised QRD template (i.e. April – December 2013)*

In the latter category, if no regulatory procedure (with CHMP opinion or EMA notification) affecting the Annexes occurs within this timeframe, then MAHs will have to submit a Variation Type IA^{IN}** (within 9 months of the template's publication and no later than 31/12/2013) to implement the black symbol + additional monitoring statement + encouragement to report ADRs statement.

***QRD changes other than the inclusion of the black symbol, additional monitoring statement and encouragement to report ADRs statement that require a linguistic review will not be implemented as part of this Variation Type IA^{IN}.*

2) All other medicinal products not subject to additional monitoring

Marketing Authorisation Holders are encouraged to use the first upcoming regulatory procedure affecting Product Information Annexes (e.g. Renewal, Line Extension, Variation II, Variation IB) to comply with the revised QRD template, i.e. encouragement to report adverse reactions + other QRD template changes. Article 61(3) notifications and Type IA Variations cannot be used for this purpose.

In the case of the standardised text related to the encouragement to report adverse reactions only, MAHs may use any upcoming regulatory procedure affecting Product Information Annexes, including any Variation Type IA affecting Product Information Annexes, to include this change.

Applicants/MAHs are advised to discuss the consequences for their product(s) with their Product Team Leader.

User testing

According to the readability guideline "If user consultation has been performed and on a package leaflet in the old QRD template and found successful, there is no need to be retested when updating according to the new QRD template."

Therefore, applicants will not be asked to perform any additional user testing when switching to the new template.