EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Evaluation Division

Implementation plan for the introduction of the safety features on the packaging of centrally authorised medicinal products for human use

Certain aspects of the implementation of the Falsified Medicines Directive (Directive 2011/62/EU) and the new delegated act on the safety features (Commission Delegated Regulation (EU) 2016/161 - "the Delegated Regulation") may impact on the product information and the marketing authorisation dossier; in particular the placing of safety features, a unique identifier (UI) carried by a 2-D barcode and an anti-tampering device (ATD), on the packaging of prescription medicines and certain non-prescription medicines for the purposes of authentication and identification.

The European Medicines Agency and the European Commission have prepared this implementation plan to guide applicants and Marketing Authorisation Holders (MAHs) through the regulatory changes necessary to accommodate the new legislative requirements.

The European Medicines Agency and the Quality Review of Documents (QRD) Group have revised the Human Product Information templates. The updated QRD Template will facilitate the implementation of the relevant standard statements on the UI and its carrier under sections 17 and 18 of Annex IIIA, in order for the MAHs to implement the safety features by the 9th of February 2019 as required by the Delegated Regulation.

The inclusion of the safety features standard statements under sections 17 and 18 of Annex IIIA does not indicate that the safety features have been actually implemented on the packaging placed on the market, but rather that the product information has been updated to confirm that the safety features will be implemented on the marketed packaging in line with the provisions of the Delegated Regulation (i.e. by the 9th of February 2019).

The implementation of the ATD is not expected to impact the product information. However, when the ATD is placed on the immediate packaging because there is no outer packaging, certain section(s) of the marketing authorisation dossier may be impacted.

Regulatory requirements and timelines

1. New marketing authorisation applications for medicinal products which have to bear the safety features

For any new marketing authorisation applications submitted from April 2016:

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1. the revised QRD template shall be used;
2. in the case of medicinal products where the ATD is placed on the immediate packaging because there is no outer packaging and the ATD affects the container and its closure system(s), applicants are required to include information on the ATD and how the ATD affects the container and its closure system(s) (sections 3.2.P.2.4 and/or 3.2.P.7 of the Notice to Applicants Volume 2B).

For ongoing marketing authorisation applications:

1. in case of applications with a CHMP opinion in March 2016, applicants are advised to comply with the revised QRD template, i.e. implement the standard statements on the UI and its carrier under sections 17 and 18 of Annex IIIA;
2. in case of applications with a CHMP opinion from April 2016 onwards, applicants shall comply with the revised QRD template, i.e. implement the standard statements on the UI and its carrier under sections 17 and 18 of Annex IIIA;
3. in the case of medicinal products where the ATD is placed on the immediate packaging because there is no outer packaging and the ATD affects the container and its closure system(s), applicants are required to submit information on the ATD and how the ATD affects the container and its closure system(s) (sections 3.2.P.2.4 and/or 3.2.P.7 of the Notice to Applicants Volume 2B). The information has to be submitted at the latest with the replies to the Day 180 list of outstanding issues.

2. For existing marketing authorisations granted via the centralised procedure before the publication of the Delegated Regulation and the revised QRD template

During the 3-year transition period between the entry into force and the application of the Delegated Regulation, MAHs are encouraged to use an upcoming regulatory procedure affecting Product Information Annexes (e.g. Renewal, Line Extension, Variation II, Variation IB, Variation IA[1]) to implement the standard statements on the UI and its carrier by complying with the revised QRD template in order to place the safety features on the packaging. The CHMP opinion or EMA notification for the above procedures should fall within the 3 years period following the publication of the revised QRD template and shall occur no later than 9th of February 2019.

If no regulatory procedure (with CHMP opinion or EMA notification) affecting the Annexes occurs within this timeframe, then MAHs are requested to submit a Notification pursuant to article 61(3) of Directive 2001/83/EC (within 3 years of the template's publication and no later than the 9th of February 2019) to implement the standard statements on the UI and its carrier in order to place the safety features on the packaging.

Concerning the ATD, in the case of medicinal products where the ATD is placed on the immediate packaging because there is no outer packaging and the ATD affects the container and its closure system(s), applicants are required to submit the appropriate variations to include the information on the ATD and how the ATD affects the container and its closure system(s) (see section B.II.e of the Variation Guidelines). The CHMP opinion or EMA notification for the above procedures should fall within

[1] QRD changes, other than the inclusion of the relevant standard statements on the UI and its carrier under sections 17 and 18 of Annex IIIA, that require a linguistic review will not be accepted as part of this type IA variation.

the 3 year period following the publication of the Delegated Regulation and shall occur no later than the 9th of February 2019.

If the ATD does not affect the container and its closure system, or is placed on the outer packaging, no regulatory procedure is necessary. However, if the addition of the ATD has an impact on the readability of the packaging information, MAHs are requested to submit mock-ups as per Checking process of mock-ups and specimens of outer/immediate labelling and package leaflets of human medicinal products in the centralised procedure (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004891.pdf).

3. In case the medicinal product no longer needs to bear the safety features

If the medicinal product no longer needs to bear the safety features (e.g. prescription medicinal products added to Annex I of the Delegated Regulation or non-prescription medicinal products removed from the Annex II of that Regulation), MAHs are encouraged to use an upcoming regulatory procedure affecting Product Information Annexes (e.g. Renewal, Line Extension, Variation II, Variation IB, Variation IA[2]) to remove the standard statements regarding the UI and its carrier.

If no regulatory procedure (with CHMP opinion or EMA notification) affecting the Annexes occurs between the entry into force and the application of the legislative act adding or removing products from Annex I or II of the Delegated Regulation, then MAHs are required to submit a Notification pursuant to Article 61(3) of Directive 2001/83.

Concerning the ATD, if the ATD is to be removed from the immediate packaging, MAHs are required to submit the appropriate variations to delete the information on the ATD and describe any changes affecting the container and its closure system(s) triggered by the removal of the ATD from the immediate packaging (see section B.II.e. of the Variation Guidelines).

If the ATD is to be removed from the outer packaging, no regulatory procedure is necessary.

4. Change of legal status

In case the legal status of a medicinal product changes from non-prescription to prescription following a MAH application for a switch of legal status, MAHs should use that application to comply with the revised QRD template and implement the standard statements on the UI and its carrier, and submit the ATD information, if the ATD is placed on the immediate packaging and affects the container and its closure system(s).

In case the legal status of a medicinal product changes from non-prescription to prescription following a Commission referral or a PSUR assessment, the Commission Decision will cover, inter alia, the regulatory requirements to implement the safety features.

[2] QRD changes, other than the removal of the relevant standard statements on the UI and its carrier under sections 17 and 18 of Annex IIIA, that require a linguistic review will not be accepted as part of this type IA variation.