1 Holders of authorisation for a co-marketing medicinal product are required to notify all variations to the basic product (application type A.101 – Adaptation of a co-marketing medicinal product to ensure alignment with the basic product). Does this apply to variations that should not have been submitted at all?

Variations that can be applied autonomously to the basic product do not have to be notified to Swissmedic for the co-marketing medicinal product. This applies even if the holder of authorisation for the basic product submits applications for variations that should not even have required approval/should not have been notified.

2 We intend to apply for authorisation of a co-marketing medicinal product in the near future and have several questions on the new requirements. The new requirements set out in the TPLRO have not yet been applied to the basic product. Given that the co-marketing product has to be identical to the basic product, we would like to know whether we can now apply for authorisation of the co-marketing product using texts that do not comply with the new requirements, or if we have to wait until the new requirements have been applied to the basic product before we can submit our application for authorisation of the co-marketing product?

You do not have to wait until the basic product is up to date to submit your new application for authorisation of the co-marketing medicinal product. You can submit the co-marketing medicinal product on the basis of the current (not yet updated) texts for the basic product. As soon as the basic product has been updated, Swissmedic must be notified of the variations to the co-marketing product.

3 From when does the Italian Information for healthcare professionals have to be published for the co-marketing product? Is the date determined by the due date for renewal of authorisation?

The Italian Information for healthcare professionals for the co-marketing product should be published after the Information for healthcare professionals for the basic product. This means that timing is not geared to the renewal of authorisation (similarly to modifications under the revised TPLRO).

4 How and when should modifications under the revised TPLRO be made to co-marketing medicinal products? Is the date determined by the due date for renewal of authorisation?

Co-marketing medicinal products are a special case here, i.e. the modifications under the revised TPLRO are not linked to renewal. As soon as the modifications under the revised TPLRO have been implemented for the basic product, the corresponding variations also have to be implemented by means of a type IA variation (application type AE IAIN AI/PE Anpassen an Ref C.I.2 a)).

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