Federal Agency for Medicines and Health Products
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DG POST authorisation - Marketing Authorisation Division
(Variations & Renewals)

Safety features for medicinal products for human use

Questions and answers about the implementation of the safety features for medicinal products for human use on the packaging of the medicinal products concerned

1. **Formerly, an update of the Quality Review of Documents or QRD template could not be made via type IA variations, but only via type IB variations. Will the FAMHP now accept such modifications within the framework of type IA variations?**
   By definition, a type IA variation does not demand a substantive evaluation for the requested change. The safety features are implemented by implementing the new QRD template. This can therefore be done via each type IA variation that has an impact on the product information (a change that implies the submission of the QRD template) and whereby no substantive evaluation of the submitted document is necessary.
   The implementation of the safety features can therefore be done via a type IA variation on the condition that submitting the QRD template is a requirement for the variation concerned and that no other changes will be implemented that require an evaluation. If the implementation has an impact on the mock-up (= flat design, in colour with the final font and the final font size, providing a clear representation of the three-dimensional presentation of the packaging), the proposal for the new mock-up cannot form a part of the type IA variation, considering an evaluation is necessary here. This will subsequently have to be submitted via a separate notification art. 34 § 4 of the royal decree of 14.12.2006.

2. **In which cases can the FAMHP allow grouping?**
   The existing principles of grouping continue to apply. For medicinal products authorised via the national procedure and for which the implementation of the safety features has no impact on the legibility of the mock-ups of the medicinal products concerned, the FAMHP allows the implementation of the safety features via the submission of one (grouped) dossier for the different medicinal products concerned. Consequently, such a dossier contains the modified QRD templates per medicinal product concerned. The fee corresponds with a grouping of a type IA variation.

3. **If a variation dossier is no longer planned for 2019, and if the addition of the 2D matrix barcode has no impact on the legibility of the outer packaging, should the company then send a notification to the FAMHP? Should the company pay for the notification in such cases? Is it sufficient to send an ordinary letter (cover letter) mentioning that the replacement of the CNK code by the 2D matrix barcode will have no impact on the legibility?**
   The implementation plans of the European Medicines Agency (EMA) and of the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) clearly indicate that notifying the implementation of the safety features is to be done via the submission of the modified QRD template. For the medicinal products concerned, this new QRD template must therefore be submitted via the options indicated in the implementation plan. For medicinal products authorised via the national procedure, the grouping principle can be used (see question 2).

4. **What should be done with ongoing procedures of medicinal products that have already been authorised? Until when can the company provide the FAMHP with a QRD template should a change still occur during the process?**
   - For medicinal products authorised via the Mutual Recognition Procedure (MRP), the FAMHP follows the QRD templates that have been approved by the Reference Member State (RMS).

- For medicinal products authorised via the national procedure, the implementation of the safety features can be added for as long as the documents concerned have not been approved.
  As far as mock-ups are concerned, a new proposal for the implementation of the safety features can be submitted for as long as the evaluation of the submitted mock-up has not yet been initiated, even if the QRD template has not yet been modified.

  The modification of the labelling text in line with the correct version of QRD template and the mock-up may not involve any additional evaluation.