CMDh clarifications on questions received on the implementation of the Falsified Medicines Directive

1. **Does the CMDh guideline apply also to purely national MAs? Can we interpret the publication of the EC Q24 that the procedure of alignment with the QRDv10 in 3 years’ time is an option by default for all MAs, including purely national MAs?**

   Yes

2. **If purely national MAs are not aligned via QRDv10, a notification under 61.3, but not a variation for purely national MAs should be submitted?**

   In general this understanding is agreed. However we do not have an oversight on how MS have transposed the wording of the Directive 2001/83/EC with regard to Article 61(3) into national legislation which is applicable for pure national MA.

3. **The practical implementation of the inclusion of the safety feature is only in 2019, however, the adaptation to QRDv10/4 is possible already now. In case this adaptation including section 17 and 18 is done already today but there is the need for additional inclusion of information on the outer carton or in P.7 in 2018/2019, how should this be handled?**

   It is possible to implement the new QRD template (including section 17 and 18) and the anti-tampering device separately, using the appropriate regulatory procedures as described in the implementation plan. In case it is necessary to add text to the packaging or update module P.7 related to addition of the anti-tampering device the respective variation should be submitted.

4. **If new mock-ups (with PC, SN, NN, 2D, new dimensions) are approved now, the practical implementation will be later, e.g. in 2018/2019. In this transitional period, we will have discrepancy between approved mock-ups and packaging on the market. How will this be handled?**
The differences between approved labelling in QRD template (or approved mock ups) and packaging on the market are not considered as a discrepancy with regards to implementation of 2D bare code and PC, SN, NN.

5. **Some countries explicitly made an exception not requesting mockups for FMD implementation, others still require the mock ups. How will Member States doing this in practice and how is it going to be visible to the MAH?**

Those Member States that are requesting mock-ups will address this on their national websites including advice how and when to submit the mock-ups.

6. **Can the safety feature already be implemented before approval of the respective variation?**

The notification of the implementation of safety features is regarded as a confirmation that they will be implemented in the legal timeframe. The CMDh therefore agreed that the implementation can take place before approval (independent of the procedure with which it is notified) in line with the process for type IA variations, provided that no other changes are made on the mock-ups at the same time and it has no impact on the overall readability of the mock-up. The MAHs still have to notify the relevant NCAs within the legal timeframe. CMDh recommends submitting the respective variations as early as possible. (see CMDh minutes of January 2017). Please read also question 5 for specific national recommendations.

7. **If no regulatory procedures occur within this timeframe, then MAHs are requested to submit a Notification pursuant to article 61(3) of Directive 2001/83/EC, providing an updated version of the QRD template confirming implementation of the safety features on the packaging, well in advance of the 9th of February 2019. What is meant by “well in advance”?**

An Article 61(3) procedure takes up to a maximum of 90 days excluding the time of preparation for the submission. It is recommended to submit these notifications at least 6 months in advance to be on the safe side. However, MS can process these procedures in an accelerated manner, if no other changes are submitted than this update of the QRD template with regard to sections 17/18. To expedite such assessment it should be confirmed in the cover letter that the only change is to sections 17 and 18 of the template and no other changes to the content of the template have been made.

8. **Would it be possible to use any regulatory procedure (not only the regulatory procedure affecting the Product Information) to align with the V10/4 of QRD template?**

No, only regulatory procedures affecting the product information may be used. Otherwise, an Art. 61(3) notification has to be chosen.

9. **Can the unique identifier and the anti-tampering device during transitional period be implemented in two steps? Meaning that first we implement unique identifier and later on also anti-tampering device? However, we are aware that both features must be on the packaging after Feb 2019.**

Yes it can be done in two steps, but everything has to be in place on 9th February 2019.
10. We have understood that there should only be one code on the box. We have also understood that the Indian supplier is not willing to remove their code. How is it going to be handled?

It is not recommended (also before the FML) to have numerous barcodes on the box. As addressed in the Q&A from the European Commission only one 2D-Matrix Code with the purpose to identify the product is allowed.

11. Is it possible to submit within a procedure mock-ups that show the position of the free area where the serialisation code will appear, in order to update the regulatory dossier ready for implementation of the safety features?

This is acceptable.