Questions and answers – Unique identifier

1. Does the unique identifier has to be listed in a particular order?
   Yes. The unique identifier must be listed in the same order as in the QRD template. Product code (PC) is stated first, followed by the serial number (SN).

2. Do we have to include «NN» (national number) in the labelling text?
   No. As we do not require «NN» on Norwegian packages, it is not necessary to include it in the Norwegian labelling text.

3. Is it sufficient to print only the alphanumeric code next to the 2D barcode?
   No. The abbreviations PC and SN must always be stated in front of the appropriate alphanumeric code.

4. Is it required to place the batch number and the shelf life together with the product code and the serial number next to the 2D barcode?
   No. The batch number and the shelf life has to be stated on the pack regardless of the unique identifier. However, they can be stated together with the rest of the unique identifier if desirable, but this is not a requirement.

5. How should the unique identifier be implemented?
   The labelling or mock-ups can be updated in connection with a variation application (IA, IB, II) or a renewal which affects the product information. If there are no planned variations ahead of the implementation date, a 61(3) notification can be used.

6. Do we need to prepare word versions of the Norwegian labelling for all products?
   You do not have to submit Norwegian labelling in word format if you have already submitted updated mock-ups in connection with the application. However, if updated mock-ups are not available, the Norwegian labelling in word format must be prepared in connection with the application.

7. Do we have to fill in the numbers and/or letters behind PC and SN in the labelling?
   No. In the labelling the abbreviations PC and SN should be followed by a blank space, corresponding to the known practice for batch/LOT.

8. Is it possible to submit mock-ups for information only if the labelling has not already been provided in connection with an earlier variation?
   Yes, as long as the requirements regarding submission of a 61(3) notification for information only are met.
   - The existing text on the side panel where the unique identifier is intended can be removed if the text is stated elsewhere on the pack.
   - All the other information on the mock-up is identical with the already approved mock-ups with regard to the placement of text, font size and –type, design, layout and the use of color.

9. Do we have to submit updated mock-ups if the labelling is already approved?

Yes. The mock-ups can be submitted as a 61(3) notification for information only if the implementation of the unique identifier does not lead to layout changes other than the unique identifier itself. Layout changes are defined as changes affecting other panels than the one directly concerned by the unique identifier. You will not receive an approval from NoMA after submitting the mock-ups for information only; hence the approval date equals the submission date.
If the change results in rearranging information from one panel to another on the mock-up, it is considered a layout change and a 61(3) notification with mock-ups for approval is required. You will receive mock-ups with an approval date in return from NoMA.

10. Is it acceptable to send mock-ups for more than one medicinal product in the same 61(3) notification?
    Yes

11. Do we have to prepare updated labelling for parallel imported products?
    No

12. Do we have to submit updated mock-ups for parallel imported products?
    Yes

13. In a transition period, could a pack contain both the current EAN barcode and the future 2D barcode?
    Yes. Until 9 February 2019 packs that contain both the current EAN barcode and the future 2D barcode can be placed on the Norwegian market.