Annex 2 to the joint declaration FAMHP - NIHDI – BeMVO

Agreed guidelines concerning design of packaging – within the frame of FMD.

1. FOLDING BOX OF WHICH THE SUM OF THE TWO LARGEST DIMENSIONS IS > 10 CM

1.1   General Rule
- The 2 D matrix must be printed on the box
- The Product code and Serial Number must be printed in human readable format on the box.

1.2   **Abbreviation and language**
- "PC" is the only correct abbreviation for Product Code – valid for the three languages: NL/FR/GERM
- "SN" is the only correct abbreviation for Serial Number – valid for the three languages: NL/FR/GERM

1.3   Format of human readable PC and SN
- "PC" followed by product code number (GTIN) and "SN" followed by serial number is compulsory,
- Regarding the application identifiers:
   It is recommended <u>not</u> to integrate the application identifiers (01, 17, 10, 21) in the human readable mentions.
   However, if a manufacturer decides to do so (but highly recommended not to do); the application identifiers must be placed between the headers "PC, Lot, EXP, SN" and the corresponding number/date, and must be placed between brackets.
   i.e.:

Recommended	NOT recommended
PC: 05400571000471 SN: A1B23C567D EXP 03.2019 Lot 1AB1245	PC: (01)05400571000471 EXP (17)03.2019 Lot (10)1AB1245 SN: (21)A1B23C567D

1.4   Place of 2 D matrix with UI
- The manufacturer has the freedom to decide on which panel and where on the panel to put the 2D matrix
- The 2 D Matrix with UI is not part of the Blue Box

1.5   Place of human readable PC and SN

If the dimensions of the pack allow it…
- PC and SN human readable mentions should be printed adjacent to the 2D-Matrix, if the dimensions of the pack allow it.
  The manufacturer should doe the fair judgement.
- 'Adjacent' means: just above / left / right / under the 2D matrix

- PC (Gtin) can be treated as variable or as fixed data
        - Variable data : printed "on-line"
        - Fixed data : included in approved artwork
   This means that PC and SN should not be printed in a perfectly "aligned" way – but both adjacent to the 2D matrix.

If the dimensions of the pack does not allow it…
- If the dimension of the pack does not allow to put PC and SN adjacent to the 2D matrix , the manufacturer can choose freely the position of
  the PC and the SN human readable code :
        - PC and SN on same panel as 2D matrix; but not adjacent to 2D matrix
        - PC and SN together on another panel than 2D matrix
        - PC and SN on two different panels than the 2D matrix.
Of course last examples are possible but should be avoided for evident reasons of readability.

1.6   Batch number and expiry date - (cfr QRD template – EMA guidelines - appendix IV)
   - Expiry date should be abbreviated by EXP: valid for the three languages: NL/FR/GERM
   - Batch number should be abbreviated by LOT: valid for the three languages: NL/FR/GERM

1.7   Batch number and expiry date – position
   - The manufacturer can decide on the place of the EXP and LOT
        - can be printed on same panel as 2D matrix
        - can be printed on different panels

2. FOLDING BOX OF WHICH THE SUM OF THE TWO LARGEST DIMENSIONS IS < or = 10 CM

2.1 General Rule
- The 2 D matrix must be printed on the box
- The Human Readable Product code and Serial Number can be put on the box; but are not compulsory

2.2 Batch number and expiry date – position
- The manufacturer can decide on the place of the EXP and LOT (see QRD template)
  - can be printed on same panel as 2D matrix
  - can be printed on different panels

3. CNK ON FOLDING BOX

3.1 General Rule
- For products subject to FMD, CNK code is not mandatory, but can still be put on the box - only in the human readable format.
  Except: during pilot phase serial barcode (with CNK and serial number) will be needed, in parallel with the 2D Matrix

- For products not subject to FMD (out of scope) it is recommended to evolve from serial bar code and CNK to 2D matrix and GTIN for harmonisation in the market and because of the legal obligation of electronic traceability for wholesalers and pharmacists

-- The content of the 2D matrix will than be:
  - Product Code: PC
  - Lot
  - EXP
- No unique serial number (SN) is allowed for exempted products

3.2 Position of the (voluntary) CNK code (only human readable format)
- In case the voluntary CNK code is printed on the box – it should be printed in the Blue Box where applicable
- For a question of convenience, the code should be preceded by "CNK" (i.e.: CNK 1234-567)