# CMDh POSITION PAPER ON THE USE OF QR CODES TO PROVIDE INFORMATION ABOUT THE MEDICINAL PRODUCT

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## PROBLEM STATEMENT

The QR code (abbreviated from Quick Response Code) is a two-dimensional bar code that is used to provide easy access by patients and/or Health Care Professionals to information through a smartphone.

The possibility of using these codes as a way for providing information, in a broad sense, on medicinal products is currently being considered not only by the Pharmaceutical Companies but also the National Competent Authorities (NCAs).

QR codes and 2D barcodes in medicines' packaging have been proposed (1) to access web pages (either maintained by the industry or by NCAs) with information about the medicine, (2) to provide batch number and expiration date to visually handicapped, (3) for manufacturing processing and stock control or (4) as the safety features included in the falsified medicines legislation.

**This paper only addresses the use of QR codes to access web pages with information about the medicinal products.** Therefore, 2D barcodes that are solely used for internal manufacturing processing stock control or anti-counterfeit measures and does not contain information on the medicinal product, are considered out of the scope of this paper.

## CURRENT LEGISLATION

Art. 62 Directive 2001/83/CE
The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and 59(1) and other information compatible with the summary of the product characteristics which is useful to the patient, to the exclusion of any element of a promotional nature.

## INCLUSION OF QR CODES IN MRP/DCP PROCEDURES: CMDh AGREEMENT

The CMDh has agreed on the elements that could be provided through the QR code in Mutual Recognition (MRP) and Decentralized (DCP) procedures.

The inclusion of a QR code linking to those elements included in the positive list would be automatically accepted by all Member States without any further assessment which is particularly of relevance in the case of MRP/DCP procedures. However, the inclusion of the QR code on the packaging for all Concerned Member States (CMS) is not mandatory. The Applicant can decide in which Member States packs with the code will be marketed.

It is relevant to clarify that the Coordination Group has only agreed on the 'minimum' information accepted by all Member States. However, there are a number of countries allowing the link to additional information via QR code (See Annex I). The inclusion of such extra information (e.g. videos) should be managed and discussed nationally.

The Coordination Group has also established an ad-hoc procedure for the inclusion of the QR codes. The proposed criteria and procedure for acceptance is detailed in this document (subsections 1-5) and will be in force after the publication of this paper.

### 1. CONTENT OF THE QR CODE ('POSITIVE LIST')

The CMDh has agreed that the following elements can be provided via QR code:

- Product information: Statutory information (as approved by competent authorities)
- Additional risk minimisation material for the patient which has been approved by the NCAs (i.e. Educational material as outlined in the Risk Management Plan)

The inclusion of the QR code cannot replace the inclusion of the statutory information (e.g. printed package leaflet).

The QR code could be considered a way for providing updated information on medicinal products (i.e. product information updated to the latest variation(s) approved for the medicinal product still not implemented in the printed version).

However, these discrepancies between the latest approved Product Information (linked via QR code) and the printed information for the patients/users (i.e. patient leaflet) could lead to confusion among the patients or even lead to potential misinterpretation of the Product Information for similar products in the case of Health Care Professionals. Therefore, it is recognized that this issue should be advised to the users.

For that reason, it is proposed the inclusion of the following sentence to inform users about the potential discrepancies with the Product Information provided via QR Code:

*<Detailed and updated information on this product is available by scanning the QR Code included in the <PIL> <outer carton>* with a smartphone. The same information is also available on the following URL: *[URL to be included] <and the <NCA> website >>*

This sentence should be included at the end of the package leaflet (last sentence).

## 2. STATUS OF THE MEDICINAL PRODUCTS THAT COULD APPLY FOR A QR CODE

Considering the '**positive list'** (Product Information and educational material), the CMDh has agreed that the inclusion of the QR code is acceptable for both OTC and prescription only products.

## 3. LOCATION OF THE INFORMATION TO BE PROVIDED VIA QR CODE (LINKS)

The elements of the **'positive list'** can be provided via:

- **NCAs websites:**
  Member States requiring direct link to their websites are detailed in Annex 1.

- **Website created by the Marketing Authorisation Holder (MAH) specifically for the QR code.**
  For those countries not requiring the direct link to their Agencies or requiring a direct link to their Agencies for product information only, it would be acceptable to link to a website specifically created by the MAH for the QR code.

  Such webpages cannot have neither a link to the MAH webpage nor contain any information or element not specifically described in the positive list (as stated in section 1).

- **Standalone PDF document**
  Alternatively, it would be acceptable to directly link to a standalone PDF document including such information.

## 4. LOCATION OF THE QR CODE IN THE PRODUCT INFORMATION

The QR code could be included in the outer carton and/or the package leaflet if the legibility is not negatively affected by its inclusion.

The inner lid/inner flap of the carton should be preferably considered in case of small size packages (Eye-drops, small size vials, etc), multilingual packs, existence of national barcodes, etc.

The URL linking to the QR code content should be displayed along with the QR code so that patients without smartphone or device can still access the info via web.

Multilingual Packages

In the case of packages containing more than one language, the inclusion of several QR codes is not recommended. Alternatively, it would be desirable that the first page displayed could cover further language specific links.

## 5. PROCEDURE FOR INCLUDING THE QR CODES

In the case of new Marketing Authorisation Applications (MAA), the intention of including a QR code and key elements have to be declared in the MAA in order to be considered during the assessment. The Applicant should notify its intention not later than D106 of the procedure. Inclusion of the QR code will not be acceptable in the national phase.

For authorised products, applications could be submitted via European art 61(3) notification (P- notifications) or may be included in another Type IB, Type II, 'C' category only variation affecting the product information or Renewal.

### 5.1 Content of the application

The following information should be provided within the dossier, it is proposed to locate this request under *Module 1.3.1.*

1) Declaration of the QR code content + URL and intended location of the code

2) MAH/Applicant certificate confirming that the QR code content (see Annex 2):
    a. Comply with the requirements stated by the CMDh (positive list and location)
    b. Will remain unchanged after approval. Any changes to the content of the materials after approval will be the subject of a new submission excepting for the updates of the product information resulting from the approved modifications

        *NOTE: Product information and educational materials will be updated after approval/implementation of variations according to the timelines established in the CMDh BPG on variations*
    c. Will be provided via link to the NCA website when is mandatory (just for pre-defined MSs)
    d. The informing sentence (as defined in section 1.1) will be included in the PIL

e. Any additional elements as listed in Annex 1 comply with Article 62 of Directive 2001/83 EC and will be submitted for further assessment where required by individual member states.

3) Mock ups:
    a. New MAAs: To be provided during the national phase
    b. Variations, Notifications & Renewals: Updated version should be provided for those countries requiring artworks.

5.2 Approval of the QR Code

The acceptance of the QR code will be automatically agreed by the RMS during the evaluation phase based on the declaration provided by the applicant.

Those applications received via European art 61(3) notification (P- notifications) solely used for the inclusion of the QR code will be resolved according to the standard procedure.

Final details (e.g. mock ups including the QR code) will be assessed by MS's during the national phase, if applicable.

## CONCLUSION

The CMDh has agreed on the elements that could be provided through the QR code without further evaluation as well as the criteria and procedure to accept it.

The CMDh will monitor the impact and interest of this decision on the QR Codes. Once further experience is gained, further discussion on the inclusion of additional information via QR code will be maintained by the Coordination Group if needed.

## Annex 1- List of elements that could be provided through QR codes for individual MS

| | AT | BE | BG | CY | CZ | DE | DK | EE | EL | ES | FI | FR | HR | HU | IE | IS | IT | LI | LT | LU | LV | MT | NL | NO | PL | PT | RO | SE | SI | SK | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Product information | X | X | X | X | X | X | X | X[1] | X | X[1] | X | X[1] | X[1] | X[1] | X | X | X | X | X[1] | X | X | X | X | X | X | X | X | X | X | X[1] | X |
| Additional risk minimisation material for the patient which has been approved by the NCA (as outlined in the RMP) | X | X | X | X | X | X | X | X[1] | X | X[1] | X | X[2] | X[1] | X[1] | X | X | X | X | X[1] | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Videos (Instructional, no containing extra info) | X | X[2] | | | X[3] | X | X | | | X[1,2] | X | X[2] | X[1,2] | | X | X | | | | | X | | X | X | X[2] | X | X | X[2] | | X | X[2] |
| Photos of the packaging and/or the pharmaceutical form | | | | | | | | | | | | | | X[1] | | | | | | | | | | | | | | | | | |
| Additional risk minimisation material for the Health Care Professionals which has been approved by the NCA (as outlined in the RMP) | | | | | | | | | | X[1] | | X[2] | X[1] | | | X | | | | | | | | | | | | | | | X |
| Any information compatible with art 62 | X | X[2] | | | | | X | | | | | | | | | | | | | | | | X | | | | | | | | X[2] |

[1] The Applicant can refer this information exclusively by linking to the NCA website
[2] Assessment needed to be in line with national legislation
[3] Videos permitted only if included in RMP as Pharmacovigilance educational material for Patients

## Annex-2 Template for the Applicant declaration

### APPLICATION FOR THE INCLUSION OF QR CODE IN MRP/DCP PROCEDURES

| | |
|---|---|
| Procedure number (s) | |
| Name of the medicinal product in the RMS | |
| Name of the active substance | |
| Applicant | |
| Intended CMS in which the QR code will be included (s) | |

### I. Declaration of the QR content

*The Applicant is requested to*
*1) Specify the information to be linked via QR Code and*
*2) Provide the URL linking such information (not needed when the information is provided via NCA website)*

### II. Intended location of the QR code in the product information

*Applicant should declare the location of the QR code within the Product information (e.g. inner lid/inner flap of the carton, Package Leaflet, etc)*

### III. Location of the information to be provided via QR code (Links)

- NCA websites (MSs requiring link to their websites are detailed in Annex 1) ☐
- Website created by the MAH specifically for the QR code. ☐
- Standalone PDF document ☐

### IV. Applicant's declaration

The undersigned certifies by the present declaration that the proposed QR code and its contents:

- Comply with the requirements stated in the CMDh Position Paper on the use of QR codes to provide information about the medicinal product
- Will remain unchanged after approval. Any changes to the content of the materials after approval will be the subject of a new submission excepting for the updates of the product information resulting from the approved modifications
  *NOTE: Product information and educational materials will be updated after approval/implementation of variations according to the timelines established in the CMDh BPG on variations*
- Will be provided via link to the NCA website when is mandatory
- The informing sentence as stated in the CMDh Position Paper on the use of QR codes will be included in the PIL
- Any additional elements as listed in Annex 1 comply with Article 62 of Directive 2001/83 EC and will be submitted for further assessment where required by individual member states.

On behalf of *<Applicant/MAH name>,*
*Authorised signatory*