

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 as part of the safety features (i.e unique identifier) introduced under the Falsified Medicines Directive and do not contain information about the medicinal product, are considered out of the scope of this paper. For information, when the medicinal product is required to bear the unique identifier and the applicant wishes to provide additional information about the medicinal product through the 2D data matrix code, please see section 2D-Barcode/Datamatrix ADDITIONAL INFORMATION.

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.

NOTE: The CMDh has also agreed on the possibility of including only the URL without including the correspondent QR code. The information to be linked via this URL should comply exactly with the same conditions established for the QR codes as detailed in this document (content, application procedure, etc).

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 >>

In the case that only the URL is mentioned in the PI (information not linked via QR code, see note on page 2), the following sentence should be included:

<Detailed and updated information on this product is available on the following URL: [URL to be included] <and the <NCA> website >>

The above mentioned sentences should be included at the end of the package leaflet (last sentence), when applicable.

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:

- **NCA’s 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):
 - Comply with the requirements stated by the CMDh (positive list and location);
 - 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 (just for pre-defined MSs);
 - The informing sentence (as defined in section 1.1) 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.
- 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 MSs during the national phase, if applicable.

Should the Applicant, at a later stage, wish to include the QR code in the packages of more Member States than originally stated in the declaration form submitted in the European procedure where the QR code was approved, this can be managed nationally with the Member State(s) concerned.

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.

2D-Barcode/Datamatrix ADDITIONAL INFORMATION

The provisions detailed in this CMDh paper to provide additional information about the medicinal product through a QR code, are also applicable in case the applicant wishes to provide this information through the 2D-barcode/data matrix code described in Commission Delegated Regulation (EU) 2016/161 of 2 October 2015¹ which has been published pursuant to the Falsified Medicines Directive 2011/62/EU.

The regulation does not prohibit the placing of a QR code on the packaging of a medicinal product bearing the safety features as far as it is not used for the purposes of identification and authentication of medicinal products. Those applicants who are required to include the safety features on their products (as set out in the regulation) also wishing to provide additional information about the medicinal product, are however encouraged, wherever technically feasible, to exploit the residual storage capacity of the data matrix to include the information they would otherwise include in the QR code. This would minimise the number of visible barcodes on the packaging and reduce the risk of confusion as regard the barcode to be scanned for verifying the authenticity of the medicinal product².

¹ COMMISSION DELEGATED REGULATION (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use http://ec.europa.eu/health/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf

² SAFETY FEATURES FOR MEDICINAL PRODUCTS FOR HUMAN USE. QUESTIONS AND ANSWERS. Version 4.1. Question No. 22 http://ec.europa.eu/health/files/falsified_medicines/qa_safetyfeature.pdf

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 ¹	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 ²	X	X			X ^{1,2}	X	X ²	X ^{1,2}	X ¹	X	X					X		X	X	X ²	X	X ³	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