



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Quick Response (QR) codes in the labelling and package leaflet of centrally authorised¹ medicinal products

General principles of acceptability and rules of procedure

1. Introduction

With the availability of new communication technologies it has become apparent that patients/users of medicinal products may benefit from information provided through electronic formats. In this context, there has been an increased demand by applicants to the centralised procedure to include QR codes in the labelling and/or package leaflet (PL) of medicinal products as an additional way of providing information to patients and health care professionals.

According to article 62 of Directive 2001/83/EC, *“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.”* This provision allows the inclusion of QR codes for the purpose of providing information.

Applicants to the centralised procedure should inform EMA of their intention to use QR codes in the labelling and/or package leaflet of centrally authorised medicinal products. The inclusion of QR codes should be applied for in the context of an evaluation procedure, as appropriate.

Measures proposed as part of initiatives/legislation currently in preparation (e.g. delegated act on the safety features) may have an impact on the current recommendations. In case of discrepancy between these recommendations and future legislation, the legislation prevails.

The principles outlined in this document reflect the current policy on the topic and may be subject to modification as more experience is gained in the future.

¹ For MRP and DCP procedures, specific guidance is available in the ‘CMDh position paper on the use of QR codes to provide information about the medicinal product’ (CMDh/313/2014)



2. Principles for the acceptability of QR codes

Applicants should carefully consider the following aspects before submitting proposals for inclusion of QR codes to EMA:

1. Platform hosting the QR code content;
2. Information to be provided to patients/users;
3. Location of the QR code in labelling and/or package leaflet.

2.1. Platform hosting the QR code content

A QR code may link to a website, web page (e.g. standalone PDF document) and/or smartphone applications specifically created for that purpose by the applicant. Additionally, it may link to the website of those National Agencies willing to host this additional information.

The platform hosting the information and web domain rights must remain valid while the authorisation of the QR code is in place.

The applicant should establish the mechanisms to ensure that most patients can benefit from the information provided, in particular:

1/ The QR code should be included in the labelling and/or package leaflet in all the Member States where the medicinal product is marketed and the information should be provided in all the EU official languages of those Member States. The design of the platform hosting the QR code content should allow easy access to country specific information.

2/ Patients should be able to access the information either by scanning the QR code with a smartphone/device or by typing the URL in an internet browser, if they do not have a smartphone/device.

Therefore, the URL of the platform hosting the QR code content must always be displayed in the labelling and/or package leaflet along with the QR code. Applicants are advised to avoid lengthy URLs to prevent readability concerns on the labelling. The name chosen for the URL should be meaningful and allow proper identification of the medicinal product.

2.2. Information to be provided to patients/users

QR codes are considered to be an additional format to provide information to patients/health care professionals and must not replace statutory information (e.g. printed package leaflet).

In principle, applicants may use QR codes to provide statutory information or other information that is compliant with article 62, as formally approved by CHMP.

Statutory information: a QR code may provide patients/users with readily available information extracted from the approved package leaflet, the approved summary of products characteristics (SmPC) and/or the approved additional risk minimisation measures as outlined in the Risk management plan (i.e. educational material).

Additional information: the QR code may also be used to provide any other information or content that is not included in the product information annexes as such, but that it is useful to the patients/users and non-promotional, i.e. compatible with article 62. Additional information provided via the QR code should be based on the product information.

Additional information will be assessed and formally approved on a case by case basis.

Applicants must ensure that information provided through a QR code does not contain promotional elements (e.g. information relating to the marketing authorisation holder (MAH), links to corporate websites, etc.). Only elements agreed by CHMP during the assessment of the QR code content can be included. No link to further information or different website (except NCA websites where appropriate) can be included.

2.3. Location of the QR code in the labelling and/or package leaflet

A QR code may be included in the packaging material and/or the package leaflet.

The location of the QR code should take into account the overall readability of the labelling, i.e. packaging material and/or package leaflet.

The inclusion of a QR code should not compromise the readability of statutory information and should be located in an area with minimal or no impact on readability (e.g. inner flap of the carton). This aspect should be particularly considered in multilingual packs. Inclusion of several QR codes is not recommended.

Reference to QR code should be made in Annex IIIA and/or IIIB, as appropriate, as 'QR code to be included' (grey-shaded format) and followed by the corresponding URL:

'QR code to be included' + <URL>

The actual information provided through the QR code will determine the specific section of the Annexes IIIA and/or IIIB templates where the reference above should be made (e.g. under 'method of administration' in the case of a video showing how the medicinal product should be administered, etc.).

3. Submission and assessment of QR code proposals

3.1. Submission procedure

Initial request for inclusion of QR code: The request for inclusion of QR codes in the labelling and/or package leaflet of centrally authorised medicinal products can be made as part of the initial marketing authorisation application (pre-authorisation) or after the medicinal product is authorised (via procedure affecting annexes with Rapporteur's involvement or an article 61(3) notification with rapporteur involvement; i.e. not applicable with Type IA variations).

Applicants are required to submit to EMA a completed request/declaration form² accompanied by relevant information (material to be linked (video, etc.) as well as the updated mock-ups and product information annexes describing the intended exact location of the QR code) in Module 1.3.1 of the dossier.

In exceptional cases where the QR code request is submitted after the start of an evaluation procedure, the applicant should liaise with EMA via the assigned procedure manager (PM) to discuss the practicalities of the QR code request (e.g. to allow sufficient time for the comprehensive evaluation of the request).

² Request/declaration form for the provision of information via quick response (QR) codes in the centralised procedure (EMA/493921/2015)

In case the request is done via a variation affecting the annexes with Rapporteur's involvement and when additional information (other than statutory) is proposed via a QR code, the MAH is requested to inform the QRD (QRD@ema.europa.eu) at least one month in advance of such submission in order to allow enough time for QRD and EC consultations, where applicable.

Changes to approved content (post-authorisation): Intended changes to the approved content of a QR code (as reflected in the declaration and CHMP assessment report) will trigger an assessment procedure (i.e. procedure affecting annexes with Rapporteur's involvement (i.e. not applicable with Type IA variations) or an art. 61.3 notification with rapporteur involvement.). Before applying for a modification of QR code content, the applicant should consider the following:

When the package leaflet or SmPC are provided via the QR code, any updates should be automatically implemented in the context of the post-authorisation procedure triggered by those changes in the product information annexes, as appropriate.

When the changes are intended to the English version of information other than statutory (i.e. 'additional information'), the applicant should liaise with EMA via the Procedure Manager as these changes may trigger an assessment procedure.

For country specific changes (e.g. changes that only affect some languages, etc.), the applicant should liaise with the corresponding national competent authority via the assigned contact point.³

See also *Figure 1 – Process chart*, for further details.

3.2. Assessment

The assessment of the information provided through a QR code is to be performed and agreed at CHMP level and reflected in the relevant CHMP assessment reports. The acceptability outcome issued by CHMP should be based on the final English version of the platform hosting the information.

For statutory information, the Rapporteur only reviews the declaration form.

When additional information (other than statutory) is proposed via a QR code, the request will be subject to Rapporteur's assessment and consultation with the Quality Review of Documents (QRD) Group. Also, consultation with the European Commission (EC) may be considered on a case by case basis.

4. Implementation

The information made available to patients/users through QR codes should be in compliance with the approved content as declared by the applicant and confirmed in the corresponding CHMP assessment report.

When additional information (other than statutory) is approved by CHMP to be provided through a QR code, the applicant is required to liaise with the corresponding national competent authorities (NCAs) via the assigned contact points³ prior to launch (e.g. for checking of the translations of an approved video, etc.).

³ Member states contact points for review of national versions of Quick Response (QR) codes (EMA/493930/2015)

Figure 1. Process chart

