EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Quick Response (QR) codes in the labelling and/or package leaflet of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised procedures (DCP) and national procedures**

General principles of acceptability and procedure

1. Introduction

With the availability of new communication technologies it has become apparent that users of veterinary medicinal products may benefit from information provided through electronic formats. In this context, there has been an increased demand by applicants to include Quick Response (QR) codes in the product information (PI) of veterinary medicinal products as an additional method of providing information to animal owners and veterinarians (hereafter users).

Applicants should inform the relevant Competent Authority[1] (CA) of their intention to use QR codes in the PI of veterinary medicinal products. The inclusion of QR codes should be applied for as part of a suitable assessment procedure (see section 4).

Other data matrices used solely for purposes other than to provide information through electronic formats to users (e.g. serialisation/traceability/manufacturing purposes) are out of scope of this guidance. However, if a QR code is proposed for serialisation/traceability/manufacturing purposes, this needs to be declared using the request form.

Measures proposed as part of initiatives/legislation currently in preparation may have an impact on the current recommendations. In case of discrepancy between these recommendations and future legislation, the legislation prevails as soon as it is in force.

The principles outlined in this document may be subject to modification as more experience is gained in the future.

[1] EMA for CP; RMS and CMS for MRP/DCP and National Competent Authorities (NCAs) for purely-national procedures.
** Guidance does not apply to national procedures in Croatia, Hungary and the United Kingdom

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2. Definitions

Statutory product information

Product information exactly as approved by the relevant CA and in the official language of the Member States (MS) in which the veterinary medicinal product is marketed.

Statutory PI may be reproduced in electronic format[2].

Pictures of the national product packaging exactly as it appears on the market are also in the scope of statutory PI.

Statutory PI may be reproduced online in alternative formats in order to facilitate access by everyone.

Additional information

Additional information in electronic format is defined as content that is consistent with the approved PI but is not identical, word for word, to the approved text.

Examples of additional information provided to users through QR codes may include:

- video clips or animated guides, graphics or schematics not in the approved PI, showing how to administer/use the veterinary medicinal product;
- links to report side effects

If information in electronic format is a combination of both statutory PI and additional information, assessment criteria for the additional information apply to the entire set of information.

3. Principles for the acceptability of QR codes

The presence of a QR code does not substitute for any of the packaging elements required by Directive 2001/82/EC e.g. the package leaflet.

Applicants should carefully consider the following aspects before submitting proposals for inclusion of a QR code to the CA:

- Platform hosting the content accessible through a QR code,
- Type of information to be provided to users (see 2. Definitions),
- Location of the QR code on the labelling and/or package leaflet

3.1. Platform hosting the QR code content

Applicants may choose any suitable online platform to host their content. Content may be optimised for viewing with standard web browser technology on different devices and/or for use in form of a mobile app (software designed to run on smartphones and other mobile devices). Applicants need to ensure that the platform hosting the information and the web address (URL) which the QR code is linked to remain active, valid and current as long as the QR code is included in the PI.

The applicant should establish a mechanism to ensure that most users can benefit from the information provided.

[2] Electronic format refers to, for example, Portable Document Format (PDF), web pages and web applications

On the printed materials, the full URL which the QR code is linked to must always be displayed next to the QR code. Applicants are advised to avoid lengthy URLs to ensure readability. The name chosen for the URL should be non-promotional.

3.2. Information to be provided to users

Information accessible through QR codes is categorised into **statutory product information** and **additional information** (see section 2. Definitions).

All information provided through a QR code must be approved by the relevant CA. Applicants must ensure that the additional information provided through a QR code does not contain promotional elements (e.g. information not directly relevant to the use of the veterinary medicinal product, hyperlinks to other websites, etc.). Where agreed with the relevant CA a link to their website may be included.

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

A reference to the QR code and its URL should be included in the labelling and/or package leaflet, as appropriate.

QRD template

If a QR code is to be included the statement *'QR code to be included'* + <*URL*> should appear:

- in the LABELLING after section 17 of the particulars to appear on the outer package;
- in the PACKAGE LEAFLET in section 15 before the listing of local representatives, if included.

Printed materials

The location of the QR code should take into account the overall readability of the printed materials where the QR code is to be displayed.

The inclusion of a QR code should not compromise the readability of statutory information on the printed materials. National translations of the information provided through the QR code, if applicable, should be accessible through a single QR code on packs.

4. Submission and assessment of QR code proposals

4.1. Request for inclusion of a QR code for the first time

4.1.1. Pre-authorisation

A request for inclusion of a QR code in the labelling and/or package leaflet can be made as part of the initial marketing authorisation application. Applicants are required to include a completed request form accompanied by an appropriate description and, if applicable, visual representation of the information available to users through the QR code. This should be included in Part 1 of the dossier ('1a-admin-info' ~~add-info'~~ folder). The PI submitted within the initial MAA should reflect the proposed inclusion of the QR code in the correct location(s) according to section 3.3 above. Mock-ups should equally reflect the layout of the QR code on the artwork.

4.1.2. Post-authorisation

Any post-authorisation request for initial inclusion of a QR code should be submitted to the relevant CA[3] as a Type IB variation, using classification C.II.6.b. The application should include:

- the QR code request form;
- an appropriate description and, if applicable, visual representation of the information available to users through the QR code;
- PI reflecting the proposed inclusion of the QR code in the correct location(s) according to section 3.3 above;

However, if the proposed QR code solely links to statutory information, a dedicated variation is not required but the MAH should submit the QR code request form to the EMA/respective NCA[3]. Furthermore, in this case, the MAH is reminded to submit updated PI reflecting the inclusion of the QR code in the correct location(s) according to section 3.3 above at the next post-authorisation procedure affecting the PI.

In each of the above scenarios, a formal mock-up check may be needed according to the usual requirements of the EMA/NCA.

4.2. Amendment of information available through a QR code

When only the statutory PI is provided through a QR code, a separate procedure to update the content of information available through the QR code is not required as updates are considered approved with the approval of the updated PI.

[3] If, for a product authorised via MRP/DCP, the proposed inclusion of, or change to, a QR code is only applicable nationally (i.e. rather than in RMS/all CMSs), then the submission should be made on a national basis only to the respective NCA.

In the case of a post-authorisation application that requires consequential changes to the additional information (as defined as section 2 of this document) available through the QR code, no separate, subsequent variation is required if the MAH is in a position to provide within the application:

- the updated QR code request form, outlining the changes in section 2 of the form (subsection 'Additional information');
- an appropriate description and, if applicable, visual representation of the updated additional information available to users through the QR code.

If the MAH is not in a position to provide the updated additional information provided through the QR code at the time of the post-authorisation application, then a stand-alone variation may be required, in which case the requirements of section 4.1.2 above would apply.

If the MAH wishes to amend the additional information provided through the QR code in any other context i.e. not as a consequence of amendment to the terms of the marketing authorisation, then a stand-alone variation is required (Type IB, classification C.II.6.b). In this case the MAH should provide:

- the updated QR code request form, outlining the changes in section 2 of the form (subsection 'Additional information');
- an appropriate description and, if applicable, visual representation of the updated additional information available to users through the QR code.

4.3. Assessment

The assessment of information provided through a QR code will be performed by the relevant CA.

If information provided through a QR code is the statutory PI exactly as approved by the relevant CA, only the QR code request form is reviewed.

When additional information (as defined in section 2 of this document) is provided through a QR code, the request will be subject to assessment and, for centrally authorised products, potential consultation with the Quality Review of Documents (QRD) Working Group.

5. Implementation

The information provided through QR codes should be in compliance with the approved content as declared by the applicant and approved by the CA. For products where additional information (other than statutory PI) has been assessed in English language, applicants are required to liaise with the corresponding NCAs via the assigned contact points prior to launch (e.g. for checking of the national translations of an approved video, etc.).