9 November 2023
EMA/818103/2017, rev. 1

Request form for the provision of information via 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

All sections of the form should be completed.

The authorised signatory should sign the form at the end of section 4.

Name of the veterinary medicinal product (including strength and pharmaceutical form)	
Procedure number[1]	
MA number, if available	
Active substance	
Name and address of the applicant	
Name of authorised signatory	

[1] For products authorised via MRP/DCP, please always provide the initial MR/DC procedure number.

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1. Platform hosting the content accessible through a QR code

Type of platform that will host the information provided through a QR code:

Website ☐ Smartphone app ☐ National Agency website ☐ other ☐

What web address (URL) does the QR code link to?

Description of the platform:

(Detailed description of the platform should be given also addressing the mechanisms to ensure that most users can benefit from the information provided)

2. Information provided to users

- **Statutory product information** Yes ☐ No ☐

If applicable, what type of statutory information will be provided?

☐ Text and/or diagrams from the summary of product characteristics (complete text or subsections)

Please specify:

☐ Text and/or diagrams from the package leaflet (complete text or subsections)

Please specify:

☐ Pictures of the national product packaging

- **Additional information** Yes ☐ No ☐

If applicable, what type of additional information will be provided?

[A description of the information provided through the QR code should be provided (e.g. scripts, video clips or animated guides, graphics or schematics, etc.). The URL provided in section 1 should allow the assessor to access the full information; if this is not possible, it is suggested to send the information using standard submission channels, clearly stating the procedure number.]

What are the reasons for providing users with additional information through a QR code and what are the expected benefits?

What is the relation between the additional information proposed and the actual information in the SPC/Package leaflet that supports it?

Purpose of information	**Compliance with SPC [Specify which section(s) of the SPC]**

(Add additional rows as necessary)

3. Location of the QR code

Describe the intended location of the QR code on the printed materials in detail (e.g. panel, inner lid/inner flap or the carton, package leaflet, etc.).

4. Declarations

It is hereby declared that:

☐ **The final design of the platform to be used will reflect the description provided in section 1 of this form, taking into account the outcome of any assessment.**

☐ **The platform hosting the information will not contain any promotional elements.**

☐ **The platform hosting the information and web domain will remain valid as long as the authorisation of the QR code is in place.**

☐ **Statutory product information provided through a QR code will be maintained in compliance with the latest-approved version.**

☐ **The (new or amended) QR code is solely linked to statutory information and will be included in the product information submitted with the next post-authorisation procedure that affects the product information, in accordance with section 4.1.2 or section 4.2 of the QR code guidance document (EMA/364980/2017).**

☐ **The readability of the statutory information provided through a QR code is adequate for the user.**

☐ **The inclusion of the QR code does not compromise the readability of the information on the printed labelling and package leaflet.**

☐ **Prior to placing packaging carrying the QR code on the market, the MAH will contact the corresponding national competent authorities (NCAs) via the assigned contact points to ensure approval of the national versions of the content of the QR code. *[Applicable only when additional information (other than statutory) is provided*]**

☐ **The content provided through the QR code will not be modified without prior authorisation, in accordance with section 4 of the QR code guidance document (EMA/364980/2017), except for updates of the statutory information reflecting the latest approved version.**

Authorised signatory

Print name:

Signature:

Date: