

QR codes for medicines – new guidance



By **Celine Weber**
MLaw, Attorney at Law
Managing Associate
Phone +41 58 658 56 17
celine.weber@walderwyss.com

On 1 March 2023, Swissmedic published a new guidance document on mobile technologies¹. It contains regulations on the use of mobile technologies, in particular on QR codes on the packaging of medicines and in the medicinal product information.

What is a QR code?

A QR code is a 2D barcode that complies with the ISO/IEC 18004 standard.

How can QR codes be used in connection with medicines?

QR codes may only link to information that:

- does not violate therapeutic products legislation;
- is useful, medically necessary, clear and not misleading;
- does not jeopardise medicinal product safety;
- does not deceive users; and
- is provided in the languages required by therapeutic products legislation (however, additional languages are permissible in principle).

QR codes may link to information required by therapeutic products legislation (i.e. most recently approved medicinal product information/packaging materials) and/or to additional information, such as instructional videos on handling the medicine. Such additional information must relate to the safety, efficacy and/or quality of the medicine and be justified on medical grounds as well as beneficial to users.

Further requirements include, inter alia, compliance with current data protection and pharmaceutical advertising regulations, that the electronic version of the texts provided is identical to the most recently approved texts² and that a URL³ is provided.

Placement, integrity and accessibility

QR codes must not impair the legibility of the mandatory information required by the Ordinance of the Swiss Agency for Therapeutic Products on the Requirements for the Authorisation of Medicinal Products⁴. They can be placed on the medicinal product information⁵ and/or the packaging. The URL should be placed close to the QR code.

Marketing authorisation holders must ensure integrity and accessibility and thus put in place mechanisms to protect against attempted manipulation and use appropriate devices and software to ensure the information to which the code links is fully accessible.

Applications to be submitted to Swissmedic

When a QR code is added as part of a new authorisation procedure, a separate application is not necessary. Regarding authorised medicines, however, adding a QR code will require:

- an application for a type IB A.z. variation "Other regulatory change" if the linked information is required by therapeutic products legislation;
- an application for a type II C.I.z. variation "Other changes relating to safety, efficacy or pharmacovigilance" if the linked information contains (also or only) additional information.

With respect to the modification of a QR code, i.e. changes to the information accessible via the QR code, the following applies:

- information required by therapeutic products legislation: when Swissmedic has approved updates to information required by therapeutic products legislation and which is accessible via a QR code, the authorisation holder must implement the updates itself and make them accessible concurrently with official publication;
- additional information: for changes to additional information, an application for a type II C.I.z. variation "Other change relating to safety, efficacy or pharmacovigilance" must be submitted. Changes to additional information must be implemented promptly after the application has been completed

The removal of a QR code needs to be reported as a type IA/IAIN A.z variation "Other regulatory change".

The form can be found [here](#).

Endnotes

- 1 See www.swissmedic.ch > Services & lists > Documents and Forms > Human medicinal product (last visited on 7 March 2023).
- 2 Information for Healthcare Professionals, patient information, package leaflet of veterinary medicinal products, packaging materials (primary and secondary packaging) and risk management plan for human medicinal products.
- 3 A Uniform Resource Locator (URL) identifies and localises a website by means of the access method to be used (e.g. the appropriate network protocol such as HTTP or HTTPS) and the site address (e.g. www.swissmedic.ch).

4 SR 812.212.22.

5 Information for Healthcare Professionals and/or patient information/package leaflet of veterinary medicinal products.

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