Guidance document
Mobile technologies

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1 Terms, definitions, abbreviations

1.1 Terms and definitions

2D code:

A two-dimensional (2D) barcode comprises lines or dots of different widths with varying gaps in between, with the maximum possible contrast between lines/dots and gaps. These codes can be read optoelectronically. The 2D barcodes most frequently used for medicinal products are the data matrix code and the quick response (QR) code.

QR code:

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

Data matrix code:

A data matrix code is a 2D code consisting of black and white cells, generally arranged in a square or rectangular pattern. The number of rows and columns increases with the quantity of information stored in the code, up to a maximum of 2,335 alphanumeric characters. See the *Packaging* guidance document for data matrix specifications.

URL:

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).

Accessibility:

Threshold-free or low-threshold access to the content that ensures full access and unrestricted opportunity of use for all.

Integrity:

Immutability of information, i.e. protection against manipulation or unauthorised modification of the content. Providing information security by ensuring the content is complete and intact.

1.2 Abbreviations

TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22)
EMA	European Medicines Agency
IHP	Information for Healthcare Professionals
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
PL	Package leaflet of veterinary medicinal products
PI	Patient information
PM	Packaging materials (primary and secondary packaging)
RMP	Risk management plan for human medicinal products
TPO	Therapeutic Products Ordinance of 21 September 2018 (SR 812.212.21)
TPLO	Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (SR 812.212.23)
WL	W*egleitung* = guidance document

2 Introduction

Mobile technologies can be used to simplify access to information associated with the use of medicinal products and provide support to people with disabilities in particular.
This guidance document describes the use of mobile technologies using the example of QR codes for human and veterinary medicinal products. It is geared to the requirements of the European Medicines Agency (EMA) (EMA/493897/2015 and EMA/364980/2017_rev.1). Given the rapid pace of technological progress, this guidance document will apply by analogy to other mobile technologies in addition to QR codes.

2.1 Legal framework

The legal framework is provided by TPA, TPO, TPLRO and KPTPO. In particular, the requirements are based on the following legal provisions:

TPA

- **Art. 11 para. 2 let. a, no. 4** Application for a marketing authorisation
- **Art. 67 para. 1bis** Informing the general public

TPO

- **Art. 4** RMP
- **Art. 26** Language
- **Art. 28** Updating the medicinal product information
- **Art. 29** Time of publication of the medicinal product information

TPLRO

- **Art. 5a** RMP documentation
- **Art. 12** Information and text on containers and packaging materials
- **Art. 13** Information for healthcare professionals
- **Art. 14** Package leaflet
- **Art. 16** Exceptions

- **Ann. 1** Information and text on containers and packaging materials
- **Ann. 3** Requirements for the declaration of active substances and pharmaceutical excipients in human medicinal products
- **Ann. 4** Requirements for the Information for healthcare professionals for human medicinal products
- **Ann. 5.1 – 5.3** Requirements for the package leaflet / Patient information
- **Ann. 6** Labelling and medicinal product information for veterinary medicinal products

KPTPO

- **Art. 26** Labelling and medicinal product information

3 Objective

As this is a guidance document aimed at administrative bodies, it does not directly specify the rights and obligations of private individuals. Swissmedic uses this document first and foremost as a resource for applying the legal provisions on authorisation in a uniform and equitable manner. The publication of the guidance document is designed to make it clear to third parties what requirements must be fulfilled according to the practice of Swissmedic.

4 Scope

This guidance document applies to the authorisation of human and veterinary medicinal products and is not applicable to complementary medicinal products without indication and veterinary medicinal products in the notification procedure under Art. 39 TPLO.

5 Assessment principles

5.1 General principles

QR codes must only link to information that does not violate therapeutic products legislation and which is useful, medically necessary, clear and not misleading. QR codes and the information to which they link must not jeopardise medicinal product safety or deceive users. Marketing authorisation holders must ensure integrity and accessibility. Accordingly, they must 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.
QR codes must not impair the legibility of the mandatory information required by TPLRO. QR codes can be requested as part of the new authorisation procedure or for medicinal products that have already been authorised.

5.2 Language

The information to which QR codes link must be provided in the languages required by therapeutic products legislation. It is also permissible to link to other language versions of the information. However, Swissmedic will only check the versions in the correspondence language; it is the responsibility of the marketing authorisation holder to ensure that translations in all other languages are correct.
If a human medicinal product is intended solely for use in hospitals in accordance with Art. 26 para. 4 TPO and is labelled accordingly, texts accessible via QR code may only be in an official language or English. The authorisation holder must ensure that additional information can be provided in the official language requested by users.

5.3 Requirements for QR codes

The authorisation holder must ensure:

- compliance with current data protection regulations.
- communication between the hosting platform and end user is encrypted to current standards.
- guaranteed legibility and accessibility of the linked data.
- guaranteed integrity and availability of the linked data.
- the hosting platform is valid and accessible from all browsers widely used in Switzerland.
- the electronic version of the texts provided is identical to the most recently approved texts (IHP/PI/PL/PM).
- information on using the medicinal product (e.g. videos) is based on the most recently approved texts (IHP/PI/PL/PM/RMP).
- no legal provisions governing therapeutic products advertising have been violated.
- a URL (e.g. short URL) is provided.
- the printed QR code is legible.

5.4 Information accessible via QR code

The QR code can point to information required by therapeutic products legislation and/or to additional information.

5.4.1 Information required by therapeutic products legislation

The information required by therapeutic products legislation comprises

- the most recently approved medicinal product information (IHP/PI or PL)
- the most recently approved packaging materials
- the officially ordered information materials (defined in the guidance document *RMP ICH E2E Information for submission HMP*)

5.4.2 Additional information

Additional information is information that goes beyond that required by therapeutic products legislation (e.g. an instructional video on handling the medicinal product or other training documents not defined in section 5.4.1) and which relates to the safety, efficacy and/or quality of the medicinal product. This additional information must carry a description (e.g. script of an instructional video) and be consistent with the information in the most recently approved version of the medicinal product information texts. It must be justified on medical grounds and beneficial to users.

5.5 Adding or modifying QR codes

Adding refers to the first-time use of a QR code. Modifying refers to changes to the information accessible via a QR code.
To add, modify or remove a QR code, please submit the *Mobile technologies* form.

5.5.1 Adding QR codes as part of a new authorisation procedure

A separate application is not required if the QR code is added as part of a new authorisation procedure.

5.5.2 Adding QR codes after a new authorisation procedure

To add a QR code that refers solely to information required by therapeutic products legislation, an application for a type IB A.z. variation *Other regulatory change* must be submitted. For veterinary medicinal products, an application for an A.z. variation *Other administrative change that does not require assessment* must be submitted.
To add a QR code that also or only links to additional information, an application for a type II C.I.z. variation *Other changes relating to safety, efficacy or pharmacovigilance* must be submitted. For veterinary medicinal products, an application for a G.I.z.a) variation *Other changes relating to safety, efficacy or pharmacovigilance that requires assessment* must be submitted.

5.5.3 Modifying QR codes

Once 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.
For changes to additional information accessible via a QR code, an application for a type II C.I.z. variation *Other change relating to safety, efficacy or pharmacovigilance* must be submitted. For

veterinary medicinal products, an application for a G.I.z.a) variation *Other change relating to safety, efficacy or pharmacovigilance that requires assessment* must be submitted.
Changes to additional information must be implemented promptly after the application has been completed.
Removal of a QR code must be reported as a type IA/IAIN A.z variation *Other regulatory change*. For veterinary medicinal products, an application for an A.z. variation *Other administrative change that does not require assessment* must be submitted.

5.6 Positioning of QR code and URL

The QR code can be printed on the medicinal product information (IHP and/or PI/PL) and/or the packaging. For reasons of user friendliness, the URL should be placed near to the QR code.

5.7 Timelines

The timelines are set out in the guidance document *Time limits for authorisation applications*.

5.8 Fees

Fees are subject to the Ordinance of 14 September 2018 on the Fees charged by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5)

Change history

Version	Change	sig
1.3	Section 5.4.1 "Training materials" are now known as "officially ordered information materials"	ski, dst
1.2	New therapeutic products information: training material according to RMP	ski, sab
1.1	New layout, no content adjustments to the previous version.	dei
1.0	New document	ski, sab, zsa, ber, lac, iom, jua, er