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Mobile scanning and other technologies in the labelling and package leaflet of centrally authorised 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/health care professionals may benefit from information on medicinal products provided through electronic formats. In this context, there has been an increased demand by applicants to the centralised procedure to use mobile scanning and other technologies, such as quick response (QR) codes and two-dimensional (2D) barcodes, or Near-field Communication (NFC), amongst others, as an additional way of providing information to patients and health care professionals.

The use of mobile scanning and other technologies (hereinafter referred to as 'mobile technologies') to provide information cannot replace statutory information (e.g. printed PL).

This paper only addresses the use of mobile technologies to access a dedicated platform (as describe in section 4.1) maintained by the Marketing Authorisation Holder (MAH) or a national competent authority (NCA) with information on medicinal products. It provides guidance in relation to the assessment of the content, independently of the technology used. In light of the rapidly evolving technological innovations, this paper does not endeavour to include a comprehensive list of available technologies. The principles included in this document may apply to any type of electronic technology used to provide information in the labelling and PL of centrally authorised medicinal products.

Applicants should inform EMA of their intention to use mobile technologies. The request for use of mobile technologies should be applied for in the context of an evaluation procedure, as appropriate.

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

For Mutual Recognition and Decentralised procedures, specific guidance is available on the CMDh website (<http://www.hma.eu/cmdh.html>)



2. Legal Framework

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.”. Subject to the conditions provided, therein, this provision permits the use of mobile technologies for the purpose of providing information in the outer (and immediate) packaging and the PL.

3. Information in relation to the two-dimensional barcode carrying the unique identifier

Applicants and MAHs may seek to provide the information outlined in this paper by means of the two-dimensional barcode carrying the unique identifier, which is described in the [Commission Delegated Regulation \(EU\) 2016/161](#).

Commission Delegated Regulation (EU) 2016/161 does not prohibit the placing of other mobile technology features on the packaging of a medicinal product as far as it is not used for the purposes of identification and authentication.

Those applicants who are required to include on their products the unique identifier carried by a two-dimensional barcode, as set out in [Directive 2011/62/EU](#) (Falsified Medicines Directive), also wishing to provide additional information about the medicinal product, are however encouraged, wherever technically feasible, to exploit the residual storage capacity of the two-dimensional barcode to include the information they would, otherwise, include in the mobile technology feature. This would minimise the number of visible barcodes on the packaging and reduce the risk of confusion with regards to the barcode to be scanned for verifying the authenticity of the medicinal product.

This paper does not cover 2D-barcodes that are solely used for internal manufacturing processing and stock control or as part of the safety features (i.e. unique identifier), introduced under the Falsified Medicines Directive.

4. Principles for the acceptability of mobile technologies

Applicants should carefully consider the following aspects before submitting proposals for the use of mobile technologies to EMA:

1. Platform hosting the mobile technology content;
2. Information to be provided to patients/users;
3. Location of the mobile technology feature in the labelling and/or PL.

4.1 Platform hosting the mobile technology

A mobile technology feature may link to a website, web page (e.g. standalone PDF document) and/or smartphone applications or any other platform specifically created for that purpose by the applicant. Additionally, it may link to the website of those NCAs willing to host this information.

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

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

1. The mobile technology feature should be included in the labelling and/or PL 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 mobile technology content should allow easy access to country specific information.
2. Patients should be able to access the information either by means of 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 content must always be displayed in the labelling and/or PL along with the mobile technology feature. 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.

4.2 Information to be provided to patients/users

Applicants may use mobile technologies to provide statutory information or additional information that is compliant with Article 62 of Directive 2001/83/EC, as formally approved by the CHMP.

Statutory information: readily available information extracted from the approved PL, the approved summary of products characteristics (SmPC) and/or the approved risk minimisation measures as outlined in the Risk Management Plan (i.e. educational material).

Additional information: any other information or content (e.g. videos) that is not included in the product information annexes, but is useful to the patients/users/health care professionals and is not connected with any promotional elements.

Additional information provided via the mobile technology should be based on the approved product information.

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

Applicants must ensure that information provided through mobile technologies does not contain promotional elements, e.g. information relating to the MAH or links to the corporate websites.

Only elements agreed by CHMP during the assessment of the content can be included. No links to further information or different websites (except NCA websites, where appropriate) can be included.

4.3 Location of the mobile technology feature in the labelling and/or Package Leaflet

A mobile technology feature may be included in the packaging material and/or the PL.

The location of this feature should take into account the overall readability of the labelling, i.e. packaging material and/or PL.

The inclusion of this feature 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 mobile technology features is not recommended.

Reference to the mobile technology used should be made in Annex IIIA and/or IIIB, as appropriate, as ‘*{name of mobile technology}* to be included’ (grey-shaded format) and followed by the corresponding URL:

{name of mobile technology} to be included’ + <URL>

The actual information provided through the mobile technology 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.).

5. Submission and assessment of mobile technology proposals

5.1 Submission procedure

Initial request for the use of mobile technology: The request can be made as part of the initial marketing authorisation application (pre-authorisation) or after the medicinal product is authorised (via a procedure affecting annexes with Rapporteur’s involvement or an Article 61(3) Notification with Rapporteur’s involvement, i.e. not applicable with Type IA variations).

Applicants are required to submit to EMA a completed [request/declaration form](#)¹ 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 mobile technology feature) in Module 1.3.1 of the dossier.

In exceptional cases when the request for the use of mobile technology 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 request (e.g. to allow sufficient time for the comprehensive evaluation of the request).

In case the request is done via a variation affecting the annexes with Rapporteur’s involvement and when additional information is proposed, the MAH is requested to inform the Quality Review of Document (QRD) Group (QRD@ema.europa.eu) at least one month in advance of such submission in order to allow enough time for QRD and European Commission (EC) consultations, where applicable.

Changes to approved content (post-authorisation): Intended changes to the approved content of a mobile technology (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 Article 61.3 notification with Rapporteur’s involvement). Before applying for a modification of the content, the applicant should consider the following:

- For statutory information, 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.
- For additional information, the applicant should liaise with EMA via the Procedure Manager as these changes may trigger an assessment procedure.

¹ Request/declaration form for the provision of information via mobile technologies in the centralised procedure (EMA/493921/2015)

- For country specific changes (e.g. changes that only affect some languages, etc.), the applicant should liaise with the corresponding NCA via the assigned [contact points](#)².

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

5.2 Assessment

The assessment of the information provided through a mobile technology 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 is proposed, the request will be subject to the Rapporteur's assessment and consultation with the QRD Group. Also, consultation with the EC may be considered on a case by case basis.

6. Implementation

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

When additional information is approved by CHMP, the applicant is required to liaise with the corresponding NCAs via the assigned [contact points](#) to ensure endorsement of the national version prior to launch.

The elements agreed by the CHMP should be reflected in all national versions. Specific national requirements should not deviate from the general principles agreed at central level.

As the use of mobile technologies may involve the collection of personal data, applicants and MAHs are reminded of their obligation to observe the applicable data protection legislation, which includes Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

² Member states contact points for review of national versions of the content of mobile scanning and other technologies (EMA/358267/2015)

Figure 1. Process chart

