



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Human Medicines Division

# Mobile scanning and other technologies in the labelling and/or 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 intended users 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, two-dimensional (2D) barcodes, or Near-field Communication (NFC), amongst others, as an additional way of providing information to intended users.

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

This guidance addresses the use of mobile technologies to access a platform dedicated to product information (as described in section 4.2) maintained by the Marketing Authorisation Holder (MAH), a national competent authority (NCA), or a third party on behalf of the MAH or the NCA. 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 guidance 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/or PL of centrally authorised medicinal products.

Applicants/MAHs should inform the EMA as early as possible of their intention to use mobile technology features on the packaging materials and/or PL. The request for use of mobile technologies should be applied for in the context of an evaluation procedure, as appropriate, and applicants/MAHs should make use of the pre-submission phase to present their strategy and address any potential issues before the procedure starts.

The principles outlined in this guidance 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 ([Heads of Medicines Agencies: General Info](#))



## 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 labelling and/or the PL of centrally authorised medicinal products.

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

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

The 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 they are not used for the purposes of identification and authentication.

Those applicants/MAHs that 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), and that also wish to provide additional information about the medicinal product, are 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 regard to the barcode to be scanned for verifying the authenticity of the medicinal product.

This guidance 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/MAHs should carefully consider the following aspects before submitting proposals for the use of mobile technologies to the EMA:

1. Platform hosting the mobile technology content.
2. Information to be provided to intended 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), smartphone applications or any other platform specifically created by the applicant/MAH, or a third

party on its behalf, for the purpose of displaying product information. The mobile technology feature may also 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/MAH should establish the mechanisms to ensure that intended users can benefit from the information provided, in particular:

- 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.
- Intended users 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. The name chosen for the URL should ideally allow proper identification of the medicinal product (e.g. www.productname.eu). However, if that is not feasible, the name should be simple and easy to type (e.g. avoid using symbols), non-promotional, and as concise as possible. Applicants/MAHs are advised to avoid lengthy URLs to minimise the impact on readability.

## **4.2 Information to be provided to intended users**

Applicants/MAHs 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 intended users and is not connected with any promotional elements.

Additional information provided via the mobile technology should be based on the approved product information, and it will be assessed and formally approved on a case-by-case basis.

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

It is the MAH's responsibility to ensure that the information provided electronically is available when the product is launched in a Member State, and it is kept up to date for as long as the medicinal product is placed in the market.

The information provided via the mobile technology should be based on the latest approved product information. However, in cases where batches of the medicinal product with different information co-exist in the market (e.g. differences in excipients, storage conditions or packaging material, co-packaged device, etc.), the MAH should ensure that the information for those batches is available.

### **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). 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 of the product information, 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 Annex 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. For post-authorisation requests, Article 61(3) Notification is considered the most appropriate procedure as it has Rapporteur's involvement and the timelines are flexible enough to accommodate the QRD consultation, if needed, and address any potential issues.

Applicants/MAHs are required to submit to EMA a completed [request/declaration form](#)<sup>1</sup> 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/MAH 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 product information annexes with Rapporteur's involvement and when additional information is proposed, the MAH is requested to inform the Quality Review of Documents (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.

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

### 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 the product information annexes with Rapporteur's involvement [i.e. not applicable to Type IA variations] or an Article 61(3) Notification with Rapporteur's involvement). Before applying for a modification of the content, the applicant/MAH 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/MAH should liaise with EMA via the Procedure Manager as these changes may trigger an assessment procedure.
- For country specific changes (e.g. changes that only affect some languages, etc.), the MAH should liaise with the corresponding NCA via the assigned [contact points](#)<sup>2</sup>.

Requests for the deletion of a mobile technology feature are considered as any other post-authorisation change, and the procedural guidance above applies. However, if the platform/website provided by the mobile technology feature is decommissioned and there are still batches of the product in the market, the MAH is responsible for informing intended users accordingly when they scan the mobile technology feature.

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

## **5.2 Assessment**

The assessment of the information provided through a mobile technology feature 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. Consultation with the EC may also be considered on a case-by-case basis.

## **6. Implementation**

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

When additional information is approved by CHMP, the applicant/MAH 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.

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

As the use of mobile technologies may involve the collection of personal data, applicants/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).

**Figure 1. Process chart**

