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CMDh position paper on the use of Mobile scanning and other technologies to be included in labelling and PL in order to provide information about the medicinal product

Introduction

Mobile scanning and other technologies, such as QR codes (abbreviated from Quick Response Codes)and other two-dimensional (2D) bar codes or Near-field Communication (NFC), amongst others, are used to provide easy access by patients and/or Health Care Professionals to information through a smartphone/device.

The possibility of using mobile scanning and other technologies (hereinafter referred to as 'mobile technologies') as a way for providing information, in a broad sense, on medicinal products is currently being considered not only by the Pharmaceutical Companies but also the National Competent Authorities (NCAs).

The use of mobile technologies in medicines' packaging have been proposed (1) to access platforms (either maintained by the industry or by NCAs) with information about the medicine, (2) to provide batch number and expiration date to visually handicapped, (3) for manufacturing processing and stock control or (4) as the safety features included in the falsified medicines legislation.

In any case the use of 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 maintained by the Marketing Authorisation Holder (MAH) or national competent authority (NCA) **with information about the 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 in the field of mobile scanning, 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 providing information in the labelling and PL of medicinal products authorised via Mutual Recognition and Decentralised procedures.

Therefore, 2D-barcodes that are solely used for internal manufacturing processing stock control or as part of the safety features (i.e unique identifier) introduced under the Falsified Medicines Directive and does not contain information about the medicinal product, are considered out of the scope of this paper. For information when the medicinal product is required to bear the unique identifier and the

applicant wishes to provide additional information about the medicinal product through the 2D data matrix code please see section 2D-Barcode/Datamatrix ADDITIONAL INFORMATION.

Current legislation

Art. 62 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.

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.

Inclusion of mobile technologies in MRP/DCP procedures: CMDh agreement

The CMDh has agreed on the elements that could be provided through the mobile technologies in Mutual Recognition (MRP) and Decentralized (DCP) procedures.

The inclusion of a mobile technology linking to those elements included in the positive list would be automatically accepted **by all Member States** without any further assessment which is particularly of relevance in the case of MRP/DCP procedures. However, the inclusion of the mobile technology feature on the packaging for all Concerned Member States (CMS) is not mandatory. The Applicant can decide in which Member States packs with the code will be marketed.

It is relevant to clarify that the Coordination Group has only agreed on the 'minimum' information accepted by all Member States. However, there are a number of countries allowing the link to additional information via mobile technology (See Annex I). The inclusion of such additional information (e.g. videos) should be managed and discussed nationally.

The Coordination Group has also established an ad-hoc procedure for the inclusion of the mobile technology features. The proposed criteria and procedure for acceptance is detailed in this document (subsections 1-5) and will be in force after the publication of this paper.

NOTE: The CMDh has also agreed on the possibility of including only the URL without including the correspondent mobile technology feature. The information to be linked via this URL should comply exactly with the same conditions established for the mobile technologies as detailed in this document (content, application procedure, etc.).

1. Content of the mobile technology ('Positive list')

The CMDh has agreed that the following elements can be provided via mobile technology:

- Product information: Statutory information (as approved by competent authorities);
- Additional risk minimisation material for the patient which has been approved by the NCAs (i.e. Educational material as outlined in the Risk Management Plan);

The inclusion of the mobile technology feature cannot replace the inclusion of the statutory information (e.g. printed package leaflet).

The mobile technology could be considered a way for providing updated information on medicinal products (i.e. product information updated to the latest variation(s) approved for the medicinal product still not implemented in the printed version).

However, these discrepancies between the latest approved Product Information (linked via mobile technology) and the printed information for the patients/users (i.e. patient leaflet) could lead to confusion among the patients or even lead to potential misinterpretation of the Product Information for similar products in the case of Health Care Professionals. Therefore, it is recognized that this issue should be advised to the users.

For that reason, it is proposed the inclusion of the following sentence to inform users about the potential discrepancies with the Product Information provided via mobile technology:

<Detailed and updated information on this product is available by scanning [the QR code][other two-dimensional (2D) bar code][Near-field Communication (NFC)] included in the <PL> <outer carton> with a smartphone/device. The same information is also available on the following URL: [URL to be included] <and the <NCA> website >>

In the case that only the URL is mentioned in the PI (information not linked via mobile technology, see note on page 2), the following sentence should be included:

<Latest approved information on this product is available on the following URL: [URL to be included] <and the <NCA> website >>

The above mentioned sentences should be included at the end of the package leaflet (last sentence), when applicable.

If it is intended to use speech technologies to provide a spoken version of the package leaflet, this should be limited to reading aloud the complete PL or the entire content of the individual sections of the PL.

2. Status of the medicinal products that could apply for mobile technology

Considering the **'positive list'** (Product Information and educational material), the CMDh has agreed that the inclusion of the mobile technology feature is acceptable for both OTC and prescription only products.

3. Location of the information to be provided via mobile technology (links)

The elements of the 'positive list' can be provided via:

- NCAs websites: Member States requiring direct link to their websites are detailed in Annex 1.
- Platforms created by the Marketing Authorisation Holder (MAH) specifically for the mobile technology.

For those countries not requiring the direct link to their Agencies or requiring a direct link to their Agencies for product information only, it would be acceptable to link to a platform specifically created by the MAH for the mobile technology.

Such platforms can neither have a link to the MAH webpage nor contain any information or element not specifically described in the positive list (as stated in section 1).

- Standalone PDF document

Alternatively, it would be acceptable to directly link to a standalone PDF document including such information.

4. Location of the mobile technology feature in the Product Information

The mobile technology feature could be included in the outer carton and/or the package leaflet if the legibility is not negatively affected by its inclusion.

The inner lid/inner flap of the carton should be preferably considered in case of small size packages (Eye-drops, small size vials, etc), multilingual packs, existence of national barcodes, etc.

The URL linking to the content should be displayed along with the mobile technology feature so that patients without smartphone or device can still access the info via web.

Reference to the mobile scanning technology should be made in the labelling text templates, 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 scanning technology will determine the specific section of the Product information 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.).

Multilingual Packages

In the case of packages containing more than one language, the inclusion of several mobile technologies is not recommended. Alternatively, it would be desirable that the first page displayed could cover further language specific links.

5. Procedure for including the mobile technology feature

In the case of new Marketing Authorisation Applications (MAA), the intention of including a mobile technology feature and key elements have to be declared in the MAA in order to be considered during the assessment. The Applicant should notify its intention not later than D106 of the procedure.

Inclusion of the mobile technology feature will not be acceptable if introduced only within the national phase.

For authorised products, applications could be submitted via European Art 61(3) notification (P-notifications) or may be included in another Type IB, Type II, 'C' category only variation affecting the product information or Renewal.

5.1 Content of the application

The following information should be provided within the dossier, located under *Module 1.3.1*.

1) Declaration of the content + URL and intended location of the mobile technology feature

2) MAH/Applicant certificate confirming that the mobile technology feature content (see Annex 2):

- Comply with the requirements stated by the CMDh (positive list and location);
- Will remain unchanged after approval. Any changes to the content of the materials after approval will be the subject of a new submission excepting for the updates of the product information resulting from the approved modifications

NOTE: Product information and educational materials will be updated after approval/implementation of variations according to the timelines established in the CMDh BPG on variations;

- Will be provided via link to the NCA website when is mandatory (just for pre-defined MSs);
- The informing sentence (as defined in section 1.1) will be included in the PL;
- Any additional elements as listed in Annex 1 comply with Article 62 of Directive 2001/83 EC and will be submitted for further assessment where required by individual member states.

3) Mock ups:

a. New MAAs: To be provided during the national phase;

b. Variations, Notifications & Renewals: Updated version should be provided for those countries requiring artworks.

5.2 Approval of the mobile technology feature

The acceptance of the mobile technology feature will be automatically agreed by the RMS during the evaluation phase based on the declaration provided by the applicant.

Those applications received via European art 61(3) notification (P- notifications) solely used for the inclusion of the mobile technology feature will be resolved according to the standard procedure.

Final details (e.g. mock ups including the mobile technology feature) will be assessed by Member States during the national phase, if applicable.

Should the Applicant, at a later stage, wish to include the mobile technology feature in the packages of more Member States than originally stated in the declaration form submitted in the European procedure where the mobile technology feature was approved, this can be managed nationally with the Member State(s) concerned.

As the implementation 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).

Conclusion

The CMDh has agreed on the elements that could be provided through the mobile technology without further evaluation as well as the criteria and procedure to accept it.

The CMDh will monitor the impact and interest of this decision on the mobile technology Once further experience is gained, further discussion on the inclusion of additional information via mobile technology feature will be maintained by the Coordination Group if needed.

Annex 1- List of elements that could be provided through mobile technology features for individual MS

	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IS	IT	LI	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK (NI)
Product information	X	X	X	X	X	X	X	X	X	X[1]	X	X[1]	X	X[1]	X	X	X	X	X[1]	X	X	X	X	X	X	X	X[1]	X	X	X[1]	X
Additional risk minimisation material for the patient which has been approved by the NCA (as outlined in the RMP)	X	X	X	X	X	X	X	X	X	X[1]	X	X[2]	X	X[1]	X	X	X	X	X[1]	X	X	X	X	X	X	X	X	X	X[1]	X	X
Videos (Instructional, no containing extra info)	X	X[2]			X[2]	X	X	X[2]		X[1, 2]	~~X~~X[2]	X[2]	X[2]	X[1]	X	X	X		X[2]		X	X	X	X	X[2]	X	X[3]	X[2]		X	X[2]
Photos of the packaging and/or the pharmaceutical form					X[2]					X[1]				X[1]																	
Additional risk minimisation material for the Health Care Professionals which has been approved by the NCA (as outlined in the RMP)					X	X		X		X[1]		X[2]	X			X							X						X[1]		X
Any information compatible with art 62	X	X[2]			X[2]		X	X[2]		X[1]													X								X[2]

[1] The Applicant can refer this information exclusively by linking to the NCA website;
[2] Assessment needed to be in line with national legislation;
[3] Videos permitted only if included in RMP as Pharmacovigilance educational material for Patients;