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Implementation of electronic product information (ePI) in the European Region: The use of Codes to enable easy access to Electronic package leaflet

Scope

To fulfill the key principle of making the most up-to-date electronic version of the product Information (ePI) of an approved medicinal product easily available, as stated by EMA-HMA-EC[1], it is recognized that several technical solutions and applications could be used. Using the Data Matrix Code (DMC), created to fulfill the requirements from the Falsified Medicines Directive[2], can be explored for this purpose considering that such code is effectively in place for many authorized medicinal products in the European Union (EU).

This position paper describes EFPIA's recommendation on how to approach packaging codes in a common and aligned way, supporting discussions with stakeholders to accelerate the establishment of a universal solution facilitating a faster and effective ePI implementation via the use of one code only in the secondary package of medicinal products.

Background

Providing authorised, statutory product information in a semi-structured format (ePI) for medicines to HCPs, patients, and consumers (the ultimate end-users) is a public health priority as described in the EMA-HMA-EC key principles document on electronic product information[1].

Easy access to the ePI, from a trusted source, with the latest scientific and patient friendly information approved by Health Authorities is critical to ensure correct use of medicines, promoting the understanding of its safety and benefits, helping patients to adhere to their treatment and thus promoting better outcomes.

Taking into account this need and considering current and evolving technologies and standards and, at the same time, anticipating how future needs could be accommodated, there is a value to approach packaging coding linking to ePI in a harmonised way within the industry.

Even if current activities at EMA level are focusing on the upstream process as defined in the EMA-HMA-EC key principles document[1], there are increasing activities at country level focussing on downstream processes looking to ensure that ePI is easily available to end-users. For example, in Germany the DMC ('serialization code')[2] is being used on the medicines packaging to enable the easy access and link to an electronic version of the PI. This not only makes it easier for end users to access the latest product information, but also nudges users towards reading the most up to date benefit/risk information about a medicine whether an HCP or patient. Many other countries have also started discussions related to this matter. Spain has included this element on the primary packaging in their hospital products paperless pilot recently announced.

EFPIA position on packaging codes (QR codes, DMC, and no codes)

It should be pointed out that although the ultimate objective is to make available all the approved product information documents, and beyond regulators approved educational materials, a stepwise approach might facilitate an early implementation of the ePI focusing first on the Package Leaflet.

EFPIA supports that the single and already implemented DMC could be used for easy access to the most up to date regulator approved ePI. The 'serialization' code is already implemented on packaging in the frame of the Falsified Medicines Directive[2] within EU (excluding OTC medicines) and could additionally be used for linking to the ePI. This allows a single code approach to ensure clarity to patients, consumers, HCPs and pharmacists and to avoid the risk of confusion, mistakes and/or misunderstanding[4].

The DMC is recommended as the preferred code, once current technical hurdles related to the need for an app/device to read the embedded information, are solved and thereby easy accessibility to ePI could be realized. Discussions on solving this technical hurdle have started and are expected to evolve. Stakeholders should be encouraged to develop respective technologies so that the various benefits which DMC offers could be achieved. This technology should be common and applicable to all products in order to avoid confusion for patients and consumers.

In the short term, the electronic version of the PI could be made available to users by a quick response (QR) code. Although this implicates an additional code on the box it does not require an app for linking to the PI. While it is recognized that a QR code allows access to PI, the use of the DMC once technical hurdles are solved should be the ultimate goal based on the technology available today. This would minimise the number of visible codes on the outer packaging while ensuring clarity, ease of use and accessibility for patients. Where a QR code is used it might be considered to place it on the inside of the carton but could be difficult to find by the user/patient.

We recommend to provide an additional statement on the secondary packaging to guide the patients/users on how to get the electronic information, i.e. scanning of the respective code or how to access the ePI online (e.g. a url).

Rationale

The DMC is already available on the secondary packaging for almost all Rx medicines (excluding in Greece and Italy) as introduced via the Falsified Medicines Directive[2] for EU market. This online printed serialization code is carrying the unique information about the product with a product identifier (GTIN), serial number, batch number and expiry date of the medicine. The embedded identifier (product code/GTIN) can be used for linking to the ePI. This has successfully been shown in the German (GI 4.0®), Swedish, Norwegian and Danish ePI projects. Thus, one code could be used for both purposes: verification of the medicine and referring to ePI. This approach will therefore be possible without any changes to the current packs. However, a reference is preferred on the pack as indicated above.

Using the DMC offers further benefits related to the additionally embedded information like batch number and expiry date. In future approaches, extended services for patients and users might be developed and implemented, e.g. batch-related information (might be important for change of excipients and possible recalls), reminders related to expiry date (patients might be warned about expiry of shelf life), for stock management in hospitals or supporting adverse event reporting (e.g. including batch data).

Besides DMC, QR codes are available and might be used for linking to the ePI. They are already widely used, and most people are familiar with scanning QR codes, often easily done with a smartphone

camera. A QR code can be printed offline on the packaging materials but will then appear as an additional code on the boxes that already carry the DMC.

Using more than one code on the packaging is potentially confusing for the patient/user and carries the risk of scanning errors in the pharmacy. Moreover, printing an additional code takes up valuable package space, which is already limited and could also lead to impaired readability of the carton. Therefore, EMA and CMDh emphasize in their position papers[5,6] that inclusion of several mobile technology features is not recommended.

However, despite all the described advantages of the DMC the fact that an app is currently required for reading the information remains a hurdle. Specific apps that need to be developed lead to problems related to interoperability, especially when introducing country-specific apps, or asks related to possible options for developing universal health apps. On the other hand, an ideal solution for the end users would be to have easy access to the ePI by scanning a code on the packaging without the need to download any app.

Therefore, EFPIA encourages initiatives working on technical solutions that will ultimately allow reading the content embedded in the DMC about the batch as well as enabling access to the relevant ePI without an app. This is not technically possible at the moment since iOS and Android default camera apps do not support DMC.

In conclusion, EFPIA recognizes a stepwise approach in the short/ medium term for the use of QR codes linking to an electronic version of the product information and thereafter, as soon as mobile phone devices allow, or a universal app is developed, use of the DMC is preferred. This should allow a simpler, harmonized and faster way of implementation across the EU.

It is acknowledged that in some instances, in particular for hospital only products, the patient may never come in contact with the pack and therefore alternative means to access the ePI need to be available that do not require scanning.

Appendix: DMC and QR Codes - Additional technical information

- **Data Matrix code (DMC)**: The DMC is already available on the secondary packaging of prescription medicines as introduced via the Falsified Medicines Directive (Directive 2011/62/EU)[2], i.e. EU legislation requires DMC for serialization purposes. It carries the unique information about the product with a product identifier (GTIN), serial number, batch number and expiry date of the medicine and is used in pharmacies to verify the medicine. Data fields start typically with Application Identifiers (AI) defining exactly the meaning of its content and are world-wide harmonized by GS1, how long the following data element is and what is means. The scans are processed in the European Medicine Verification System which are not directly accessible and readable for patients. For reaching patients an app will be needed to get use of the embedded information and allow linking of the embedded GTIN to the ePI. EFPIA is open to collaborate with GS1 in utilizing the embedded identifier (product code/GTIN) for linking to electronic package leaflets (GS1 digital link). This solution will therefore make use of the already implemented coding without any changes at the manufacturer site. DMC is used also in further countries outside the EU.

- **QR code**: The QR code typically carries a url that links to dedicated webpages when scanned by a capable smart phone embedded camera. QR codes are not foreseen, nor are referred in the EU legislation, to be used for verification purposes. Current usage is company and product specific, e.g. for additional safety information or information for use.

QR code vs. DMC (used for serialization) – pointing out some pro's and con's:

QR code	DMC
Must be printed on the respective packaging material as additional code with possibly space issues and impairment of readability of the carton	Already printed on the packaging material (for almost all Rx medicines as requested by FMD and other regulations world-wide)
Easy implementation (printing) on various artworks (in case of static data e.g. link or product identifier)	Typically, online printing on secondary packaging level containing variable data elements (dynamic data, multiple data using Application Identifies for a systemic data read out as used in the EU today)
Possible confusion for patients and pharmacists by using more than one code on the box	Only one code on the box for both purposes (verification and referring to ePI)
Additional human readable print of the url would need additional space	Human readable GTIN is already included
Code can be read without any specific app offering benefits in terms of accessibility only in case of a simple link or product identifier, for advanced features (e.g. GS1 Digital Link) an app is needed as well	Special app necessary for reading the information (current technical status)
People are very familiar with scanning of QR codes since widely used	Option to use additionally embedded information (batch-related information, expiry date) for possible extended services for patients/users (batch-related PIL, reminder related to expiry date, recall information) and for materials management (e.g. in hospitals)

Experience:	Experience:
Product-specific approaches (e.g. vaccines), ePI initiatives e.g. in Singapore, Australia and EU (EMA). For vaccines, in particular, experience is nearly worldwide capturing in Corona-apps.	e-leaflet initiatives in Germany (GI 4.0®), Sweden, Spain, Singapore, South Africa, Norway.

References

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