Guidance on E-Labelling of Medical Leaflets of Medicinal Products for Human Use

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Preface

Emerging from Egypt's tendency towards digital transformation of all services provided to the citizens, and to be a leading authority in the Middle East and Africa, EDA launched the E-labelling project.

The service includes placing a QR code on the packages for easy display of the latest approved insert by users, which will ensure the speedy provision of the most updated drug information displayed in latest approved inserts overcoming the lag time required in case of updating paper inserts;

With higher efficiency, lower cost and being environmentally friendly, the electronic insert is superior to its paper counterpart.

EDA has the honor to present this Guidance on E-Labelling of Medical Leaflets of Medicinal Products for Human Use, so as to be a guide for Market authorization holders to ensure optimum processing of E-labelling especially in Phase 2.

Special thanks to Dr. Shereen Abdel Gawad, Head of the Central Administration of Pharmaceutical Care for continuous support for this guidance to come to light.

Special acknowledgement for Eng.Sherif Elkhouly, Eng.Kawther Nabil, Dr.Wael el Sisi and his team for their tremendous efforts in this project and continuous cooperation.

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1. Scope

The guidance in this document applies to E-Labelling of Medical Leaflets of Medicinal Products for Human Use nationally.

2. Legal Basis

The legal basis includes the Technical committee decision dated 8/9/2022 and the approval of the respected Legal Counsel of Egyptian Drug Authority in addition to other regulating rules and published guidance issued by EDA.

3. Definitions/ Abbreviations

- **Applicant:** The entity that applies for (submits) an E-Labelling request.
- **EDA:** Egyptian Drug Authority.
- **Electronic Product Information (ePI):** Product Information; The product information document that complies with all regulatory requirements, prepared in an electronic form that meets the required technical specifications.
- **QR code:** Quick Response code.
- **Summary of Product Characteristics (SmPC):** the basis of information on how to use the medicinal product safely and effectively and an integral part of the marketing authorization of all medicines. They should be clear, concise, evidence-based, and relevant to healthcare professionals. They are kept updated throughout the lifecycle of a medicine as new data emerge.
- **Patient Information Leaflet (PIL):** contains information for safe and effective use of medicine directed to the patients/public/end-users.
- **E-labelling submission link:** https://forms.gle/aoPuUN5aeYHfiwg36

4. Background

E-labelling is a modern voluntary alternative to firmly physical labelling which delivers web-based product information on screens of electronic devices such as smartphones.

It includes the dissemination of updated approved product information in an electronic format, allowing for flawless sharing of information between manufacturers, healthcare providers, and patients allover Egypt.

By scanning the approved QR code on product' pack with the smartphone; the user is instantly directed to the most updated and approved product information.

Paper Inserts have some Limitations which may negatively affects the confidence in using the medication such as:

- Poor readability and comprehensibility in conventional physical labels where information may be crammed in a tight space.
- Problems tracking and implementing frequent label updates in order to provide accurate information to the patients and healthcare professionals.
- In case of product recall, it is more problematic to remove paper/physical labels.

5. Benefits and opportunities of E-labelling

Electronic labels allow making informed decisions based on easily accessible, relevant, and updated information. Another advantage of the e-labels is the faster sharing of new information and safety updates while conventional paper labels cannot be easily updated once included in the product's package, they can also deliver personalized user friendly patient information considering patient's medical conditions in video/text and in the language of choice in addition to the search function facilitating easy access to safety information.

5.1 Benefits for public health

- **Improving the access to medicine information**

Provision of the most updated information on a medicine's safety, uses and administration instructions;

Enhanced delivery of medicine information so that the right information is accessible to the right user either HCP and/or patients and their relatives whenever required;

- **Ease of access to users with different abilities**

- E-labelling allows the use of large fonts or high screen contrast for partially sighted users.
- Audible formats may be presented for blind users.

5.2 E-labelling and environment

Billions sheets of paper are wasted in physical labels, this significantly impacts the environment. Each year, Millions of trees are consumed to produce these paper labels, this as a result leads to worsening the greenhouse effect year after year. In addition to the great amount of water that is consumed to produce these labels. The existence of digital labels would eliminate this unnecessary paper consumption, preserve natural resources and reduce carbon footprint and consequent environmental impact.

5.3 Role of E-labelling in Promoting better patient and HCP understanding

One of the most important advantages is the guaranteed accessibility to the most up-to-date product information approved and validated by the local NRA virtually in real time and in the corresponding local language.

Poor understanding and adherence to product information have been associated with poor health outcomes and increased expenses. E-labelling can be used to overcome that and aid in the best use of the medicinal product.

E-labelling provides the user with the opportunity to search online -using different kinds of electronic devices - for medicine related information, yet through authorized channels with adaptable font size, improving readability.

In addition, enabling the option to search the content to easily find information, is especially relevant for the partially sighted or patients with any sort of visual impairment.

6. E-labelling Worldwide

Worldwide, Electronic labelling projects have initiated in some countries in both healthcare and pharmaceutical fields as part of a broader digital transformation e.g., U.S.A, Australia, Belgium, Canada, Europe, and Singapore.

7. Electronic Labelling: Egypt Perspective

In order to cope with the fast-paced advances in E-Health and rapidly growing implementation of Biomedical and Health informatics, while taking advantage of the global trends to harness the

powers of mobile technology, the E-Labelling or Electronic Product Information project initiative was launched to boost the utilization of Health solutions in Egypt under the support and supervision of Egyptian Drug Authority (EDA).

General Administration of Pharmaceutical References and leaflets as a part of the Central administration of pharmaceutical care in EDA provided a vision for creating an electronic product information service for the availability of up-to-date & officially approved electronic version of product information (ePI),

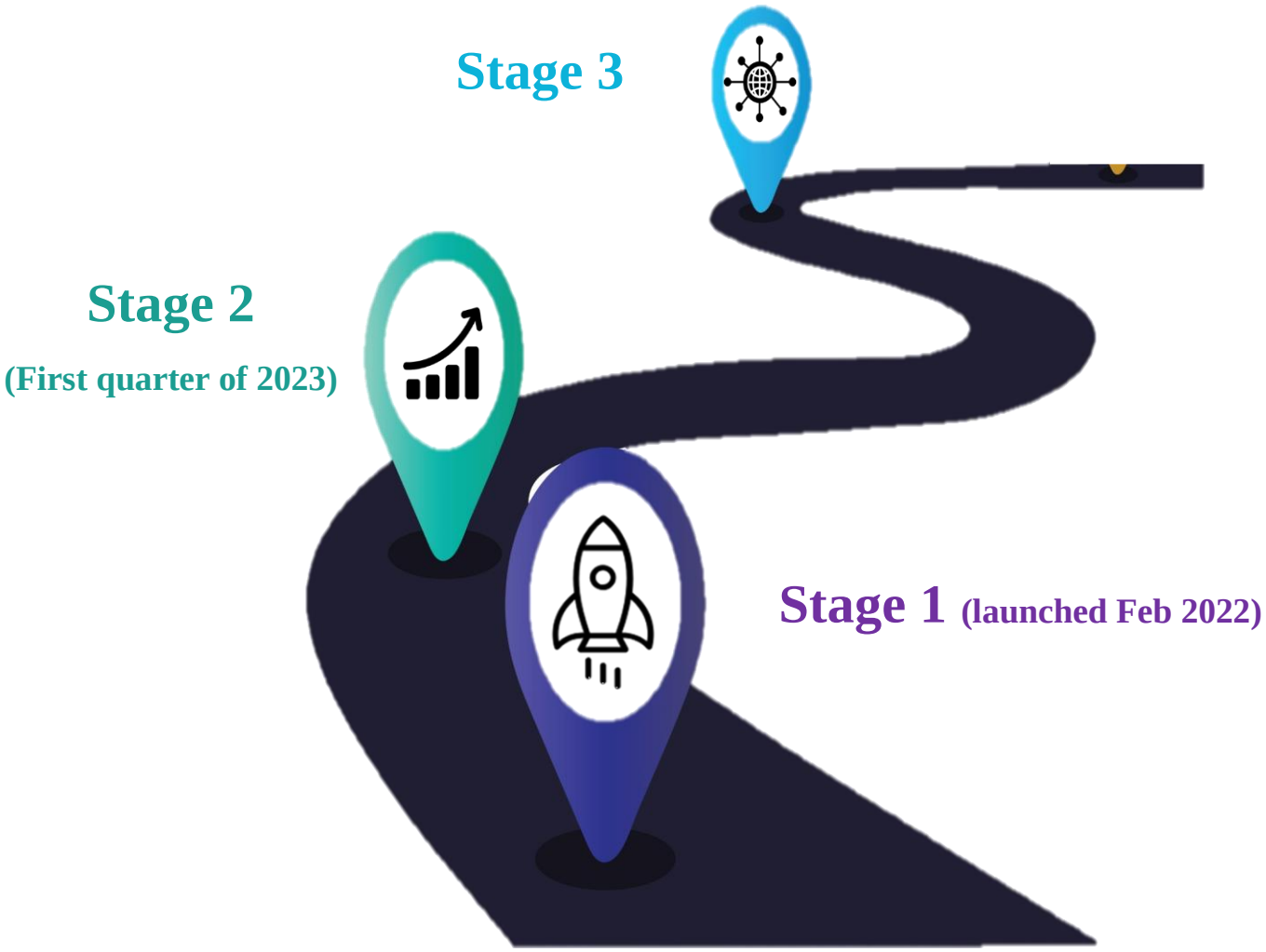
This label digitalization program was officially announced on February 2022 linking the ePI via a QR code printed on the outer packaging of the product which can be accessed by handheld devices (e.g. smart phones and tablets) for the convenience of Healthcare providers & patients.

The E-labelling project in Egypt is planned to be implemented via A multi-step process including principal 3 stages,

Stage 1 began since the launch in February 2022 and is voluntary for interested market authorization holders (MAHs).It involves using the 2 formats (paper and electronic with QR code on the pack) and served as a pilot and introductory phase for the new service, A statement is required to be added on the pack by MAHs "For the most updated approved leaflet, please scan the QR code".

Stage 2 of the project is planned to start in the first quarter of 2023. This is planned to consider a gradual removal of paper inserts and replacing them with an ePI for some products only which are intended for use in hospitals by HCPs with defined criteria by EDA; this comes parallel with awareness campaigns carried out by MAHs for citizens and healthcare providers to educate them about the service under the supervision of EDA.
Stage 2 evaluation is planned to include the effectiveness of awareness campaign, user's feedback and analysis of received complaints and suggestions.

Stage 3 will shortly begin after the consummation and thorough evaluation of stage 2 outcomes. It will involve removal of paper inserts and replacing them with an ePI for a wider spectrum of other products as well as restructuring and more extensive standardization of ePIs for interoperability with electronic health records and other digital health initiatives.


Stage 3
Stage 2
(First quarter of 2023)
Stage 1 (launched Feb 2022)

Road Map

Stage 2 Key points:

- As phase 2 involves gradual removal of paper inserts from eligible products' packs, the applicants will need to receive an initial acceptance to proceed with the additional steps of stage 2. This acceptance will be granted after reviewing the applications and ensuring they meet the specified criteria.
- The applicants will select the service required in the application form (New ePI or Update, with removal of physical paper insert or concurrent use of paper and electronic forms).
- The applicants need to explicitly declare in their applications that they intend to remove the paper inserts and agree to follow and comply with the requirements.
- After MAHs submit their awareness campaign plan and the plan is reviewed and approved by the EDA, the applicants will receive a formal conditional approval letter that they can proceed with removing the paper pamphlet from shipments intended for the healthcare institutions mentioned in their plan provided that they successfully complete the approved plan.
- Failure to comply with any requirements or any deviation in the implementation of the awareness plan from the MAHs' side can result in regulatory actions from the EDA side, including but not limited to cancellation of the approval letter and\or recall of shipments that have no paper inserts included in the packs.
- In case of updates after obtaining QR code, MAH should submit for insert update on pharmacology submission link in which they should answer yes on the following question in the submission form "Have you previously applied to E-Labelling for this product?" and consequently should submit a new E-Labelling request to update their uploaded ePI file.
- This is also the case for raised warnings ratified by pharmacology committee especially for those requiring special calculations; MAHs shall submit on

Pharmacology submission link to update the insert then submit for E-labelling with updated insert.

First: Criteria for selecting pharmaceutical products:

Includes products that are supplied to hospitals, prescribed by physician (OTC (over the counter products) can submit in E-labelling to get QR code without removing the paper inserts from pack) and are given inside the hospital include, for example but are not limited to:

- Products that are given intravenously and large volume parenteral.
- Anesthetics.
- Immunosuppressant (pharmaceutical form: injection)
- Narcotics (pharmaceutical form: injection)
- Oncological products (pharmaceutical form: injection)
- Diagnostic preparations (used in diagnosis by healthcare providers)

Examples of dosage forms which are NOT ELIGIBLE for removal of paper inserts but can submit in E-labelling to get QR code without removing the paper inserts from pack (similar to phase 1):

- Oral dosage forms
- Topical dosage forms
- Nasal dosage forms

Second: Second Stage Evaluation Criteria:

- The results of the questionnaire whose link is listed on the electronic leaflet are continuously received upon scanning the code and analyzing those results.
- Any complaints or suggestions will be received via the relevant link.
- The questionnaire link is announced and published by the General Administration of

Pharmaceutical References and leaflets in coordination with the Unified Purchasing Authority and companies are obliged to add the link in awareness campaigns.

Third: Consideration for the awareness plans that will be proposed by the companies.

- It must include all hospitals that will supply items to which electronic leaflets will be applied in the second phase.
- The awareness campaign should include a workshop in addition to the theoretical part to ensure optimum application.
- Commitment to provide evidence of the completion of the awareness campaign to all members of the medical staff inside each hospital from the signature and stamp of the hospital director or his representative.
- Awareness materials that will be distributed during the campaign must be approved by the relevant department.
- The efficiency of the awareness campaign is evaluated by comparing pre and post questionnaires

Fourth: Percentage of the paper leaflets.

- Number of paper leaflets are supplied (separately) at a rate of 1% of the quantity that is supplied to the hospital to ensure that the leaflet is available in case of difficulty in the Internet or power cuts, in coordination with the companies, the Unified purchasing Authority and the central administration of operations.
- In the case that the item is supplied as a box of 50 or 100 ampoules, this requires the supply of a number of paper leaflets at a rate of 5% of the quantity supplied to the hospital to ensure the presence of the leaflet in case of difficulty in the Internet or power cuts, in coordination with

the companies and Unified purchasing authority and central administration of operations.

8. References

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Annexes

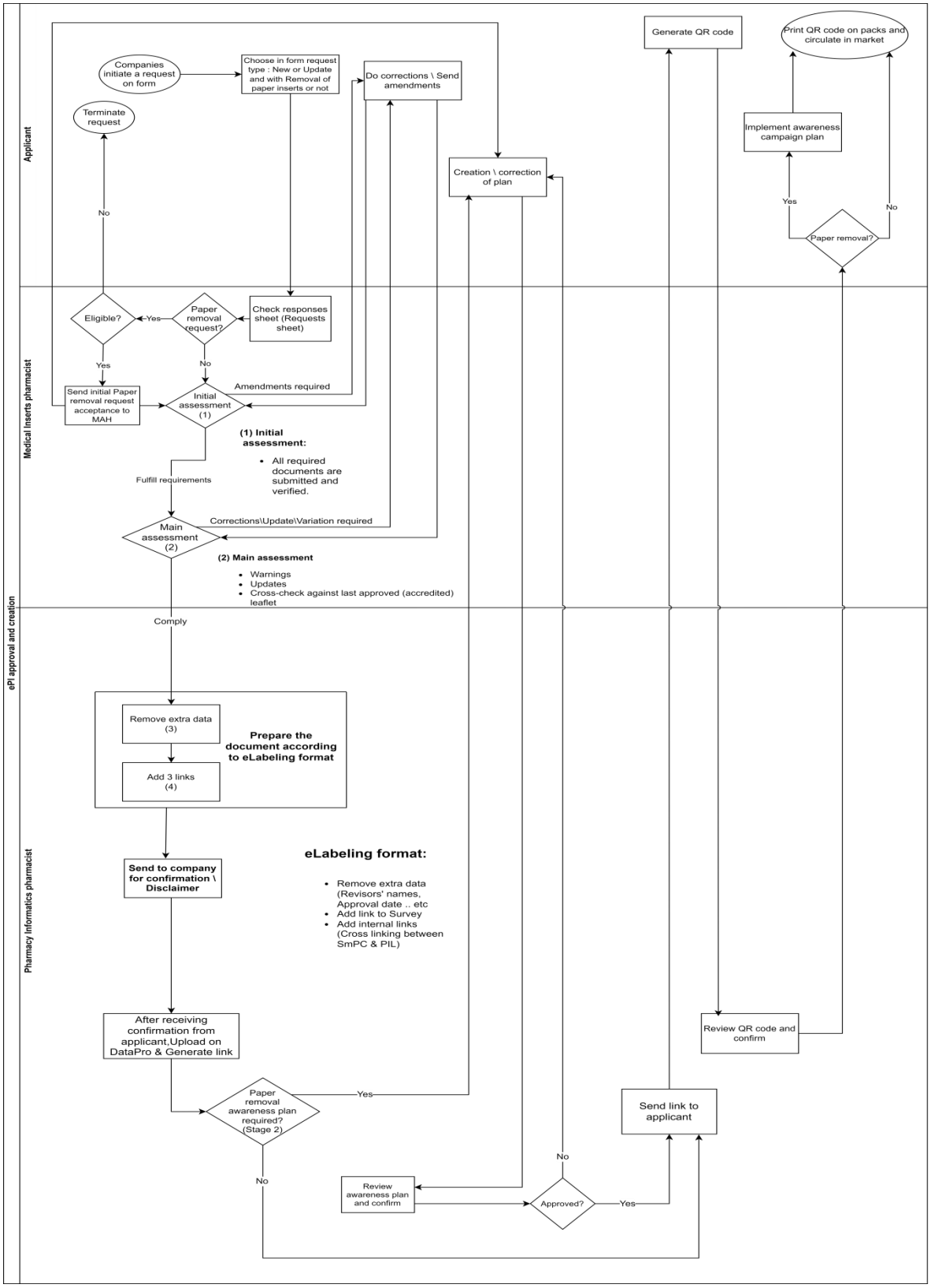
Annex (1): Flowchart

Annex (2): E-formatting template

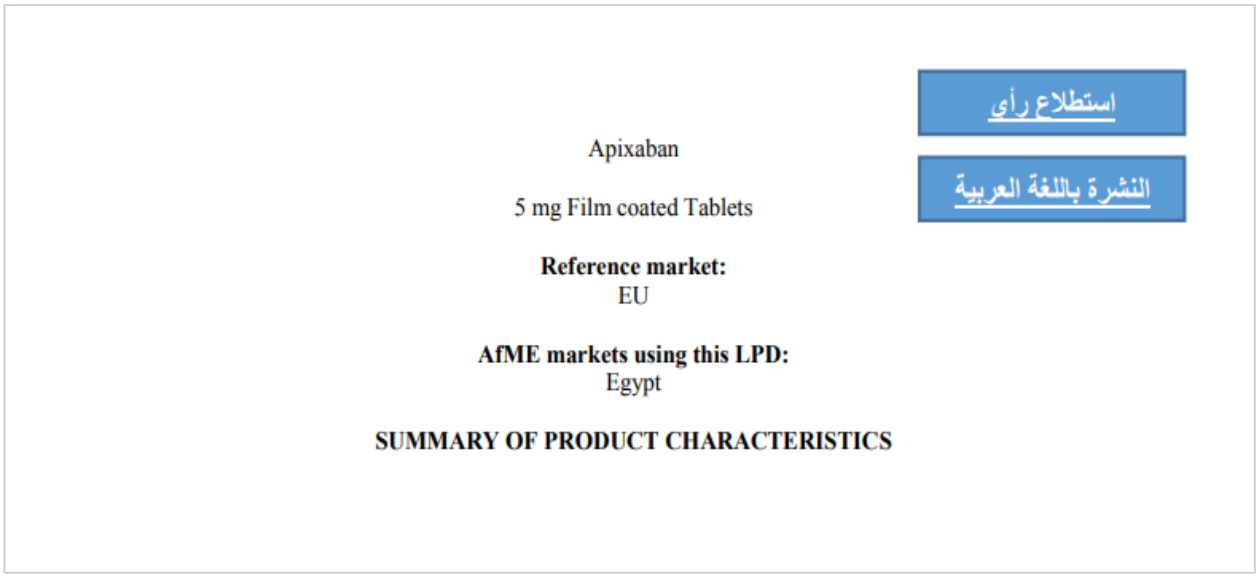
Annex (3): EDA fees for Stage 2 services

Annex (4): QR codes specifications

Annex (1): Flowchart



Annex (3): E-formatting template



Annex (3): EDA fees for Stage 2 services

مقابل خدمات تطبيق النشرات الدوائية الإليكترونية المقدمة من إدارة النشرات التابعة للإدارة العامة للمراجع الصيدلية والنشرات بالإدارة المركزية للرعاية الصيدلية		
م	الخدمة المقدمة	مقابل الخدمة بالجنية المصري
١.	طلب تطبيق النشرة الإليكترونية للمستحضر الطبي الواحد مع إستبدال النشرة الورقية.	٥٠٠٠ جنيه
٢.	طلب تحديث النشرة الإليكترونية للمستحضر الطبي الواحد مع إستبدال النشرة الورقية.	٢٠٠٠ جنيه
٣.	طلب تطبيق النشرة الإليكترونية للمستحضر الطبي الواحد دون إستبدال النشرة الورقية.	٢٥٠٠ جنيه
٤.	طلب تحديث النشرة الإليكترونية للمستحضر الطبي الواحد دون إستبدال النشرة الورقية.	١٠٠٠ جنيه

Annex (4): QR codes specifications

- QR codes should directly guide the users to the provided ePI URLs (not through a 3rd party interface or an external landing page)
- The phrase "لأحدث نشرة معتمدة امسح الكود" must be added in a suitable position around the QR code.
- The size of the printed QR codes on the actual packs should be convenient easily decoded by handheld devices.
- Each strength is considered a separate product with a different registration number and consequently a unique record in EDA database. Each strength has its own e- Label attached to it, even though different strengths may share the same file. A unique separate URL is generated for each strength anyway.
- However, the file is identical among the different strengths if they share the same approved leaflet. The MAHs **can** opt to **use a single URL and generate a single QR code** for all the concentrations **on their own responsibility** since they all reflect identical files with the same information and content, although it's advised to use the separate URLs.