Central Administration for Pharmaceutical Care
General Administration of Pharmaceutical References and Leaflets
Central Administration of Biological and Innovative Products and Clinical Trials
General Administration of Biological Products

Guideline on E-Labelling of Medical Leaflets of Medicinal and Biological Products for Human Use

Year 2024

Code: EDREX: GL.BIOINN /CAP.Care. 001
Version No: 2
Issue Date: 01/05/2024
Effective date:05/2024

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1. Scope

The guidance in this document applies to E-Labelling of Medical Leaflets of Medicinal Products and Biological products for human use.

2. Legal Basis

The legal basis includes the Technical committee decision dated 8/9/2022 and 16/11/2023 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

- **Applicant:** The entity that submits (applies for) an E-Labelling request.
- **Electronic Product Information (ePI):** The product information document that complies with all regulatory requirements, prepared in an electronic form that meets the required specifications.
- **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.
- **The Expanded Programme on Immunization (EPI):** essential programme on immunization aims to strengthen vaccine programmes, supply & delivery to ensure universal access to all relevant vaccines for all populations across the life course.
- **E-labelling submission form link (for human medicinal products):** https://forms.gle/aoPuUN5aeYHfiwg36
- **E-labelling submission form link (for biological products):** https://forms.gle/SB5eeW5tg264NLYS6

4. Abbreviations

- **EDA:** Egyptian Drug Authority.
- **MAH: Marketing Authorization Holder**
- **QR code:** Quick Response code
- **URL:** Uniform Resource Locator.
- **HCP:** Health Care Professional/Provider**.**
- **PDF:** Portable document format.
- **PAC:** Post Approval Changes.
- **QR code:** Quick Response code.
- **HL7:** Health Level 7
- **FHIR:** Fast Healthcare Interoperability Resources

5. Background

Electronic Labelling (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 and tablets.

It aims at the dissemination of updated approved product information in an electronic format, facilitating better sharing of information between manufacturers, healthcare providers, and patients allover Egypt.

E-labelling in Egypt can be briefly described as the provision of approved product medical information, including the Patient Information Leaflet (PIL) and/or Summary of Product Characteristics (SmPC), electronically via a machine-readable Quick Response (QR) code on the outer cartons and/or inner labels of the products that is linked to the EDA systems.

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

Paper leaflets 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.

6. 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 text, audio or video formats and in the language of choice. The built-in search function allows pinpointing the required information in a few seconds, be it safety information or otherwise.

6.1 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 illiterate users or users with vision impairment.

6.2 E-labelling and environment

Billions of sheets of paper are wasted in physical labels, thus significantly impacting 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.

6.3 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 diminished 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 online access - using different kinds of electronic devices - for medicine related information, yet through authorized channels with adaptable font size, improving readability.

Moreover, enabling the option to search the content to easily find information allows rapid pinpointing of required information and is especially beneficial for the partially sighted or patients with any sort of visual impairment.

7. E-labelling Worldwide

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

8. Electronic Labelling for Human Medicinal products: Egypt Perspective

Emerging from Egypt's tendency towards digital transformation of all services provided to the citizens, and 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, EDA pioneered to launch the E-labelling project for Human medicinal products in 2022 to boost the utilization of health information technology solutions in Egypt, being the leading authority in the Middle East, Africa and the Arab World and the first medicines regulatory authority in the region to do so. The 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).

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

With higher efficiency, lower cost and being environmentally friendly, the electronic leaflet is superior to its paper counterpart. 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. Upon scanning the QR code, the ePI can be accessed by handheld devices (e.g. smart phones and tablets) for the convenience of Healthcare providers & patients.

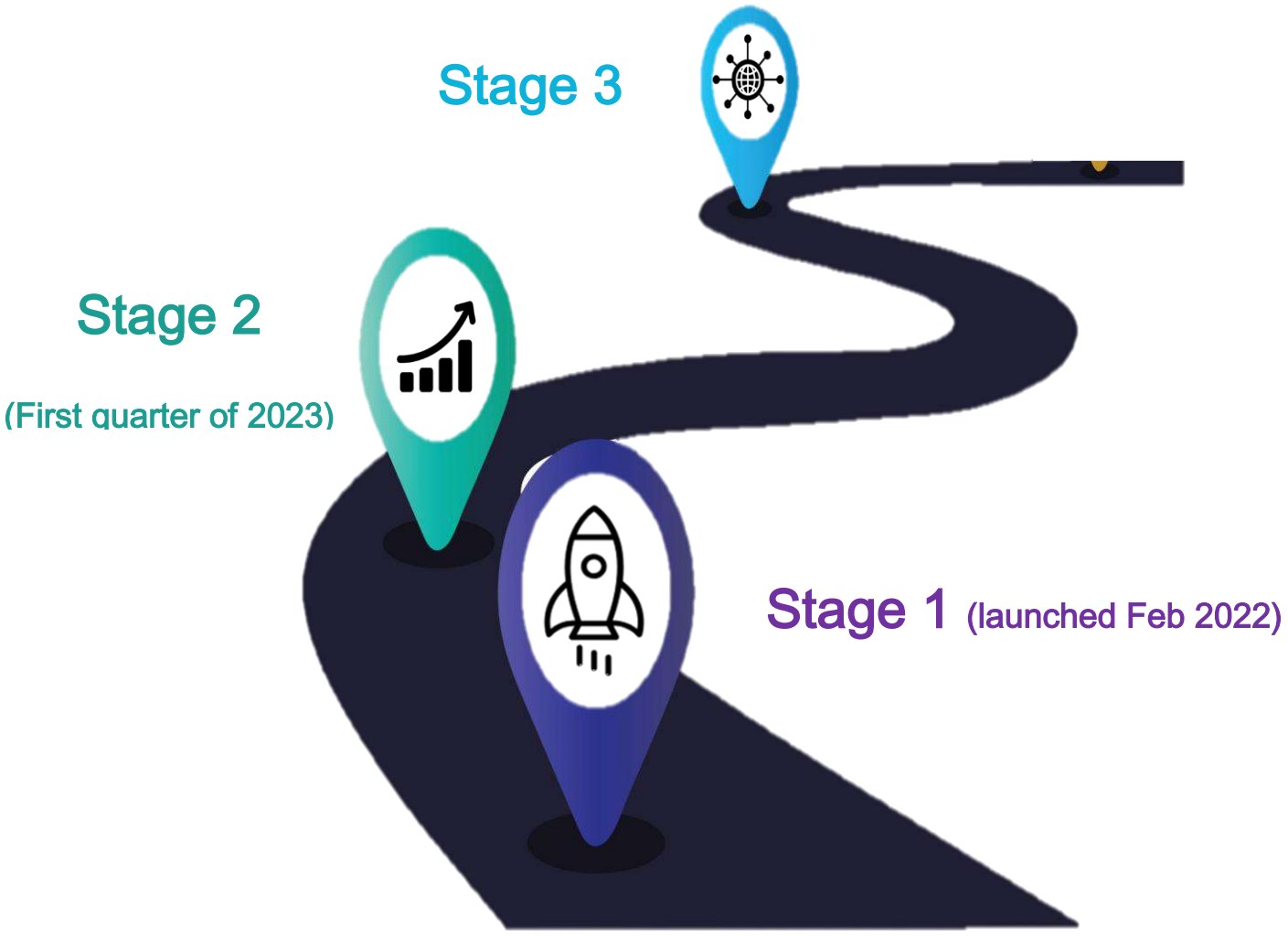
The applicants can submit their E-labelling requests on the following form: https://forms.gle/aoPuUN5aeYHfiwg36

The E-labelling project for Medicinal Products 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. The statement "For the most updated approved leaflet, please scan the QR code". is required to be added on the medicine packs by MAHs to ensure that the main purpose of the QR code is clear to the users.

Stage 2 (current stage) of the project is planned to start in the first quarter of 2023. This is planned to consider a gradual removal of paper leaflets 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 begin after the widespread implementation and thorough evaluation of stage 2 outcomes. It will involve removal of paper leaflets and replacing them with an ePI for a wider spectrum of other products as well as restructuring and more extensive standardization and gradual transition to structured documents and structured content formats of ePIs for interoperability with electronic health records and other digital health initiatives following common terminology and messaging standards, mainly HL7 and FHIR standards to promote foundational, structural, syntactic and semantic interoperability.


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 leaflets 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 leaflet or concurrent use of paper and electronic forms).
- The applicants need to explicitly declare in their applications that they intend to remove the paper leaflets and agree to follow and comply with the requirements.
- The applicants are required to devise and present an awareness campaign plan to educate the intended end users on the service and the efficient utilization of the E-Labelling features.
- 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 replacing the paper pamphlet with QR codes from shipments intended for the healthcare institutions mentioned in their plan provided that they successfully complete the approved awareness plan then they can remove the paper leaflet.
- Failure to comply with any of the requirements or any deviation in the implementation of the plans 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 leaflets included in the packs.
- In case of updates after obtaining QR code, MAH should submit for leaflets 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 leaflet then submit for E-labelling with updated leaflet.

Criteria for selecting pharmaceutical products for Stage 2:

Eligible products for stage 2 (removal of paper leaflets) include products that are exclusively supplied to healthcare institutions, prescribed by physicians and are administered inside the healthcare institutions by a healthcare provider.

For example; these include 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 leaflets:

• Oral dosage forms

• Topical dosage forms

• Nasal dosage forms

Note: OTC (over the counter products) and non-eligible products can apply to participate in and implement the E-labelling service by adding a QR code on packs without removing the paper leaflets from pack (similar to Stage 1)

Stage 2 Evaluation Criteria:

- There is questionnaire (Survey) announced and published by the General Administration of Pharmaceutical References and leaflets. A link to this survey is included in all published E-Labels, and companies are obliged to include the survey in their awareness campaigns.
- The results of the questionnaire embedded in the electronic leaflets are continuously received and analyzed upon filling the survey by users after scanning the QR code.
- Any complaints or suggestions will be received via this survey link.
- It is advisable to utilize A usage analytics system to provide real-time usage statistics such as the number of times QR codes are scanned, average times spent by the users searching for required information, most searched keywords, most read label sections and other relevant metrics.
- The impact and efficiency of the awareness campaigns will be measured and monitored to ensure effectiveness.

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

- It must include all healthcare institutions that will be supplied with products participating in the Stage 2 of E-Labelling (without paper insert leaflets).

- 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 institution 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 various relevant metrics detailed in the plans.

Refer to The Notice to applicant entitled **"E-Labelling for Human Medicinal Products Stage 2 awareness plan outline"** which is published on EDA Website, in the following link:

https://edaegypt.gov.eg/media/2j3jmjwi/notice-to-applicant-e-labelling-awareness.pdf

Percentage of the paper leaflets.

- A number of paper leaflets is supplied (separately) to the healthcare institutions that receive the packs without a paper leaflet at a rate of 1% of the product quantity that is supplied to the institution to ensure that the leaflet is available in case of poor internet connectivity or power cuts, in coordination with the Pharmaceutical companies, and relevant departments and authorities.
- 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 outages, in coordination with the companies and Relevant department and authorities.

9. Electronic Labelling for Biological products: Egypt Perspective

1.Introduction

Coping with the digitalization era and putting the Egyptian patient as a priority, EDA has taken the lead in the Middle East & North Africa to launch E-labelling for the biological products. One of the most important advantages is the guaranteed accessibility to the most updated product information approved and validated locally by EDA in a timely manner.

Biological Products General administration including Registration Administration as a part of the Central administration of Biological and Innovative products and Clinical Trials in EDA aspires to create an electronic product information service for the availability of updated and officially approved electronic version of product information (EPI), including but not limited to vaccine, monoclonal antibodies, and plasma derived medicinal products.

2. General Guidance and Conditions For E-Labelling of Biological products:

2.1 Biological products eligible for e-labelling

The implementation of e-labelling is voluntary for products that meet the following criteria:

Hospital use products under supervision of HCP include, for example but are not limited to:

- Products that are given intravenously and in large volume parenteral,
- Immunosuppressant (injection dosage form),
- Oncological products (injection dosage form).
- EPI vaccines in Egypt.

2.2 Acceptable e-labelling formats

E-labelling shall be presented in a QR code on the outer carton or the inner label of the product which displays the product information in a pdf format. The format would allow optimized viewing on any electronic devices such as smartphones, laptops, tablets, …etc.

2.3 Stages of implementation

Stage 1 (current stage) of the project it is the use of biological products with the package that contains the electronic leaflet in addition to the paper leaflet, for hospital use only products and vaccines used in EPI that meet the defined criteria only. This comes in parallel with the awareness campaigns carried out by MAHs for citizens and healthcare providers to educate them about the service under the supervision of EDA.

Evaluation of the current stage is planned to include the effectiveness of awareness campaign, user's feedback and analysis of received complaints and suggestions.

Stage 2 is planned to consider a gradual removal of paper leaflet and replacing them with an ePI for hospital use only products and vaccines used in EPI.

2.4 Accessibility of e-labels

The product information used should be approved by EDA. MAH will display the QR code on the outer packaging (e.g., outer carton) or on the inner label of the products where there is no outer packaging.

2.5 Roles and responsibilities

2.4.1 Scientific file examination unit receives request, revises and evaluates data for approval then issues URL to be sent to the applicant by biological products registration administration.

NB: in case of shared packs, the applicant can submit the request including the URL generated by the company to direct the user to the company website to choose Egypt to direct the user to the EDA website

2.4.2 Applicants are responsible for applying the QR code as approved by EDA.

2.4.3 Applicant can submit proposals for e-labelling in the registration dossier for new product with no change in the process of registration.

2.4.4 Upon approval of any label update, the e-label should be updated immediately through the concerned units in biological products registration administration.

3 Procedure

3.1 For e-labelling during new registration and renewal (if needed):

- Applicant submit request for E-labelling submission through scientific file examination unit link: https://forms.gle/SB5eeW5tg264NLYS6, the applicants will receive an initial acceptance according to related timelines. This acceptance will be granted after reviewing the applications.
- The applicants will select the service required in the application form (New EPI, with or without removal of paper leaflet).
- The assessment timeframe will follow the regular timeframes for assessment registration pathway.

3.2 For submission of e-label in registered products with no update on current insert (add e-label only)

- Applicant submits request through scientific file examination unit link: https://forms.gle/SB5eeW5tg264NLYS6, the applicant will receive an initial acceptance within 3 working days. This acceptance will be granted after reviewing the applications.
- The applicant selects the service required in the application form (New EPI, with or without removal of paper insert).
- The assessment procedure is within 5 working days of receiving the package leaflet file, the decision of the submitted request will be reported to the applicant.

3.3For submission of e-label in registered products inserts updates with/or without an approved one.

- Updates in inserts of approved registered products will be handled by the variation unit as a regular PAC file and follow the same procedures for submission and evaluation (refer to "Guideline on the regulation of Post-approval changes to a registered Biotherapeutic products in Egypt")
- The assessment timeframe will follow the regular timeframes for inserts updates

10. References

- https://www.ema.europa.eu/en/electronic-product-information-human-medicines-european-union-key-principles
- https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-draft-key-principles_en.pdf
- https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf
- https://www.ema.europa.eu/en/news/key-principles-use-electronic-product-information-eu-medicines
- https://www.ifpma.org/publications/position-paper-use-of-electronic-labeling/
- https://www.ifpma.org/wp-content/uploads/2022/02/IFPMA_Position_paper_Electronic-labelling.pdf
- https://www.ifpma.org/resource-centre/position-paper-use-of-electronic-labelling/
- https://environmentalpaper.org/2021/11/pharmaceutical-prescribing-labels-an-enormous-opportunity-to-eliminate-pointless-paper-waste-in-the-united-states/
- https://pubmed.ncbi.nlm.nih.gov/32337707/
- https://www.pmda.go.jp/files/000232161.pdf
- https://npra.gov.my/easyarticles/images/users/1047/Lampiran-A-Guideline-on-E-Labelling-for-Pharmaceutical-Products-in-Malaysia.pdf

11. Document History

Version Number	Issue Date	Summary of Change
1	3/2023	New issue
2	2/2024	The addition of Biological products. Change in the name of guidelines from "Guidance on E-Labelling of Medical Leaflets of Medicinal Products for Human Use" to "Guidance on E-Labelling of Medical Leaflets of Medicinal and Biological Products for Human Use"

Annexes

Annex (1): Medicinal Products Flowchart

Annex (2): Medicinal Products ePI formatting template (Medicinal products)

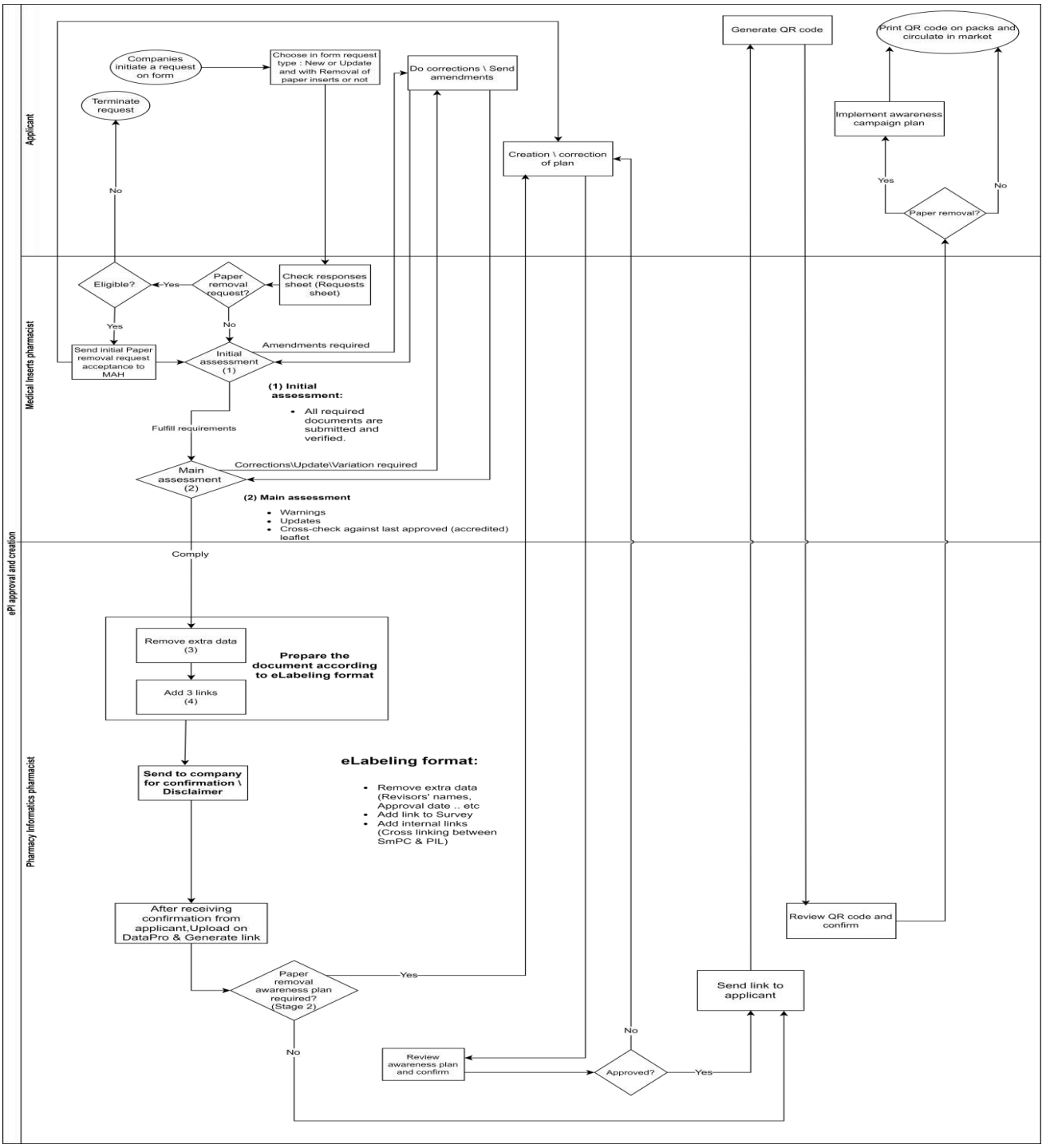
Annex (3): EDA fees for Stage 2 services (Medicinal Products)

Annex (4): QR codes specifications

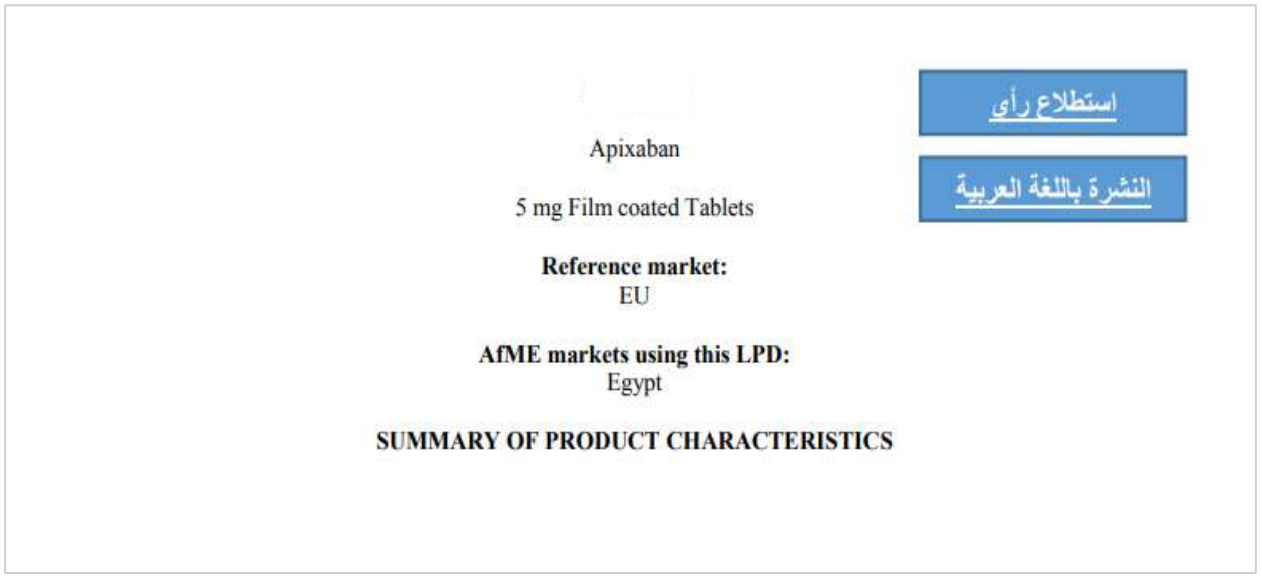
Annex (5): E-labelling application form (Biological Products)

Annex (6): EDA fees (Biological Products)

Annex (1): Medicinal Products Flowchart



Annex (2): Medicinal Products ePI formatting template (Medicinal products)



Annex (3): EDA fees for Stage 2 services (Medicinal Products)

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

- 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 and easily decoded by handheld devices.
- Even though different strengths of the same product may share the same file (The file is identical among the different strengths if they share the same approved leaflet), A unique separate URL is generated for each strength/concentration, 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 and separate QR codes.
- **QR codes** should directly guide the users to the provided ePI URLs (not through a 3rd party interface or an external landing page)
- **In case of products marketed in international or shared packs** (where the same pack is marketed in different countries with no possibility for customization or marketing a country-specific pack), the MAH can print the QR codes complying with the previous specifications on the packs marketed in Egypt using suitable inkjet machines, or can apply Non Removable Adhesive Labels (permanent, no peel labels).
    - The MAH can also, if necessary, use pre-printed QR codes on the packs that point to an initial URL hosted on the company's servers or website, not an external party, which will then redirect users to the appropriate ePIL hosted on **EDA servers** if the user is in Egypt or the user selects Egypt from a list of available countries \ ePIs.

Annex (5): E-labelling application form (Biological Products)

Application For E-Labelling to A Marketing Authorization for Biological Medicinal Products for Human Use.

Name of the product:
Active substance(s):
Concentration:
Dosage form & commercial presentation:
Manufacturer of finished product:
Storage conditions:
New revision date:
Old revision date (if available):
Registration number (if available):
Applicant:
E-mail:

(Tick the appropriate change required)	**Change**	
New E-Labelling submission.		
Update with removal of physical paper inserts.		
Concurrent use of paper and electronic forms.		
DECLARATION OF THE APPLICANT: **I declare that (please tick the appropriate declarations):**		
	Yes	**No**
Had previously applied to E- Labelling for this product.		
Intend to remove the paper inserts.		
Fees have been paid.		
Fees paid Amount:		

Main Signatory: **Print name:** **Status (job title):** **Date:**	**Secondary signatory:** **Print Name:** **Status (job title):** **Date:**

Annex (6): EDA fees (Biological Products)

مقابل خدمات تطبيق النشرات الدوائية الإليكترونية المقدمة من إدارة التسجيل التابعة للإدارة العامة للمستحضرات الحيوية بالإدارة المركزية للمستحضرات الحيوية والمبتكرة والدراسات الاكلينيكية		
م	الخدمة المقدمة	مقابل الخدمة بالجنيه المصري
1	طلب تطبيق النشرة الإليكترونية للمستحضر الحيوي الواحد مع استبدال النشرة الورقية	٥٠٠٠
2	طلب تحديث النشرة الإليكترونية للمستحضر الحيوي الواحد مع استبدال النشرة الورقية	٢٠٠٠
3	طلب تطبيق النشرة الإليكترونية للمستحضر الحيوي الواحد دون استبدال النشرة الورقية	٢٥٠٠
4	طلب تحديث النشرة الإليكترونية للمستحضر الحيوي الواحد دون استبدال النشرة الورقية	١٠٠٠