Notice to applicant

Guidance for Fifth Year Report submission

Year 2024

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I. SCOPE:

This guidance is applied on Local and Imported pharmaceutical products. It provides a standardized approach to the submission of regulatory information, making it easier for health authorities to review and evaluate the data.

II. Objective:

This guidance presents the documents required to be submitted by applicants to EDA for fifth year report, to ensure comprehensive coverage of quality, safety and efficacy aspects.

III. Procedures:

1- The company shall submit the fifth-year report to the administration of human pharmaceuticals regulatory affairs within the last 3 months from fifth year of MA license, otherwise the marketing shall be suspended based on a report from head of Central administration of pharmaceutical products and head of Central Administration of Operations to be approved by EDA Chairman.
2- The Administration of Human Pharmaceuticals regulatory affairs shall screen the submitted documents in the report within 7 working days.
3- Administration of human pharmaceutical regulatory affairs shall distribute the submitted documents to the concerned administrations for evaluation within 60 working days.
4- In the case that supplementary documents are required to be fulfilled after evaluation by any of the administrations, the company shall be notified. The company shall submit the supplementary documents in a maximum period of 120 days.
5- Upon fulfilling all the requirements of all the concerned administrations, the Administration of Human Pharmaceuticals regulatory affairs issue the approval within a maximum of 10 working days.

VI. Documents to submit:

Module 1

1.1. Administrative requirements

1.1.1. Application form on company letter head signed, stamped and dated. (**Annex 1)**
1.1.2. Latest MA license and prove all conditions and specific obligations in MA license were submitted since granting MA.
1.1.3. Any Technical Committee decisions, relates to the finished product or API corresponding actions taking by the company in alignment with the decision.
1.1.4. List of all variation approvals since granting MA with prove that all condition is fulfilled if any including date of submission, date of approval (if approved), with brief description of the change.

1.1.5. Approved leaflet:
Latest updated leaflet including all updated warnings that has been added to the marketed leaflet.
1.1.6. Latest Approved layout.
1.1.7. Inspection Report for valid and marketed batch.
1.1.8. Certificate of Pharmaceutical Product (CPP) / Electronic Certificate of Pharmaceutical Product (eCPP) issued by Competent Authorities in Country of Origin (In case of imported or under license product).
1.1.9. list of countries in which the product is registered and marketed (In case of imported products).

1.2.Technical studies/approvals
1.2.1. CADC certificate.
1.2.2. Latest stability approval
1.2.3. Latest BE /comparative studies approval (if any)
1.2.4. GMP:
1.2.4.1. Valid GMP certificate for the manufacturer of finished product.
In case of products imported from non- reference country and not marketed in any reference countries: Latest situation of manufacturing site.
1.2.4.2. GMP of Manufacturer/s of API.

1.2.5. Valid and Marketed Reference

Module 2:

2.3. Update to Quality overall summary
2.3.S. Drug Substance
2.3.S.1. General Information
2.3.S.2. Manufacture
2.3.S.3. Characterization
2.3.S.4. Control of Drug Substance
Currently authorized specifications for the active substance (with the date of the latest approval and procedure number)
2.3.S.5. Reference standards or Materials
2.3.S.6. Container/Closure System
2.3.S.7. Stability: Latest stability studies approved
2.3.P. Drug Product (or Finished Pharmaceutical Product (FPP))
2.3.P.1. Description and Composition of the FPP
(Qualitative and Quantitative composition in terms of the active substance and excipients (with date of the latest approval and procedure number)
2.3.P.2. Pharmaceutical Development
2.3.P.3. Manufacture
2.3.P.4. Control of Excipients

2.3.P.5. Control of FPP

Currently authorized specifications for the finished product (with the date of the latest approval and procedure number)

2.3.P.6. Reference Standards or Materials

2.3.P.7. Container/Closure System

2.3.P.8. Stability

2.3.A. Appendices

2.3.A.1. Facilities and Equipment

2.3.A.2. Adventitious Agents Safety Evaluation

2.3.A.3. Excipients

2.3.R. Regional information

2.3.R.1. Production documentation

2.3.R.1.1. Executed production documents

2.3.R.1.2. Master production documents

2.3. R.2.Analytical procedures and validation information

2.4. Update to Non-Clinical Overview

update to non-clinical overview is not required as part of the application.

2.5. Update Clinical Overview

2.5.1. Product Development Rational

2.5.2. Overview of Pharmacokinetics

The latest performed BE or comparative studies (if any)

2.5.3. Overview of Clinical Pharmacology

2.5.4. Overview of Efficacy

2.5.5. Overview of Safety:

Last updated Risk management plan (RMP)

Most updated status of PSMF (standalone letter or confirmation mail)

Addendum of clinical overview (ACO) covering last 5 years

2.5.6. Benefits and Risks Conclusions

2.5.7. References

Annex 1
Application form

السيد الدكتور/ رئيس هيئة الدواء المصرية

تحية طيبة وبعد،،،

نتقدم لسيادتكم بملف التسجيل للحصول على رخصة تسويق المستحضر الآتي:

Trade Name: **English and Arabic**		
Registration number		
Active Ingredient(s) and Strength (s):		
Pharmaceutical dosage form:		
Physical Characters:		
Shelf Life:		
Storage Condition:		
Approved Price Pack:	Note: Kindly Specify No. of Units according to the Pricing Certificate and Packaging Material according to the Stability Approval.	
Price:		
Reference:		
Reference Link		
Therapeutic Group: **ATC Code:**		
Approved Indication		
Applicant:		
Company Profile Username:		
Marketing Authorization Holder/License Holder:		
Manufacturer:		
Manufacturer of Solvent/ Accessories (If Applicable):		

Packager:	
Batch releaser:	
Storage Site and Address:	
Type of registration:	
Market status:	

API Name /Form/ Specs:	
Name of Manufacturer and country of origin + Address as in the manufacturer's GMP":	
Studies that had been performed on each manufacturer of API	

Note: The above box can be repeated according to No. of APIs in Product

Contact person:	
Telephone number:	
E-mail:	

رئيس مجلس إدارة (أو /العضو المنتدب/ المفوض بالإمضاء) شركة .....وأتعهد أنا الموقع أدناه
..... بالآتي:

. بأن كافة البيانات المذكورة أعلاه صحيحة ودقيقة وكاملة

:تم عمل المتغيرات الآتية للمستحضر عن آخر إخطار تسجيل

Type of Variation	From	To	Status (Final /Conditioned)

ختم الشركة

رئيس مجلس الإدارة او المفوض إليه بالإمضاء

:الاسم

:التوقيع

:التاريخ