IJBPAS, May, 2025, 14(5): 2440-2448

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

EXAMINING DRUG PRODUCT MARKETING APPROVAL PROCEDURES IN THE MENA REGION

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Received 15th Jan. 2024; Revised 19th Feb. 2024; Accepted 1st July 2024; Available online 1st May 2025

https://doi.org/10.31032/IJBPAS/2025/14.5.8929

ABSTRACT

Drug products approval process in MENA as per the respective country regulatory requirements. The MENA region is one of the world's leading pharmaceutical market places. This thesis provides some common information to get a good understanding about the pharmaceutical market is organized, and marketing permits must be maintained in the MIDDLE EAST AND NORTH AFRICA region. Once the applicant acquires Marketing permission for the drug items. in any of the MENA region, then they can apply for the Marketing authorization of drug products in other MENA countries by using the previous MENA regions marketing authorization data. The process applies to all those who seek a Marketing authorization of drug products and each countries has their own application forms in their own language. This comprises information regarding user fee requirements, data to be submitted by the applicant as per the respective countries submission format by using CTD and eCTD submission techniques.

Keywords: MENA, Marketing authorization, CTD, eCTD, Drug products

INTRODUCTION

MENA is a short form of MIDDLE EAST AND NORTH AFRICA

M – Middle

E – East

N – North

A - Africa

Mentioning the countries between Iran in the East, Tunisia and Morocco in the West. **The MENA countries**. Algeria, Egypt, Iran, Iraq, Israel, Jordan, Lebanon, Qatar, Saudi

Arabia, Syria and Yemen. Sudan and Turkey are sometimes included in MENA **[1]**.

Understanding Regulatory Affairs in the MENA Pharmaceutical Sector"

The Middle East and North Africa region is a "emerging" market for pharmaceuticals globally. The MENA part is mostly an unmarked market, which is momentum for possibility development and gainful growth in the pharmaceutical market. The MENA countries, a spectrum of **22 countries, constitute about 2% of the world's pharmaceutical zone**. Out of which **Saudi Arabia**, a country which has tendency towards unfamiliar and exorbitant branded products, accounts for the largest market share **[2, 3]**.

Middle East:

GCC countries: Saudi Arabia, UAE, Bahrain, Oman, Qatar, Kuwait, Yemen. Levant countries: Iran, Iraq, Syria, Lebanon, West Bank, Jordan, Israel, Egypt, Libya

North-Africa:

Maghreb- States: The countries Morocco, Algeria and Tunisia belong to Maghreb countries **[4]**.

COMPETENT AUTHORITIES IN LEVANT COUNTRIES:

Egypt

EDA is "an initiative for" an administration with in the MOH is accountable for defending persons fitness by synchronising protection and standard of treatment, medical instrument, beauty products, dietarium ingredients, insecticides, herbicides & rodenticides.

The Egyptian Drug Authority has subordinate administration that perform collaboratively to secure the attainment of the Egyptian Drug Authority commission, Central Administration of Pharmaceutical Affairs, NODCAR & NORCB

CAPA is a government authority that includes four amenity providing departments which are:

- Registration Division
- Licensing & Pharmacists services Division
- Inspection & Control Division
- Importation & Exportation Division

The term "NODCAR" refers to a component of MOH that was established in 1976 by presidential decree. It comprised two establishments formerly known as the "Drug Research and Control Centre and the Analytical Drug Administration"

For biological, National Organization for Research and Control of Biologics is the central division of administration, ship in & quality interconnected for Biological **[5]**.

Iran

FDD of the Ministry of Health and Medical Education is in charge for all problems interconnected to the administration, perpetuation, merchandise of medicinal products **[5]**.

Iraq

The Iraq Directorate of Technical Affairs, which is part of the Ministry of Health, is in charge of all drug-related issues such as enrollment, examination, and quality control for medicinal commodities in the Iraqi trade. Since 1992 the Ministry of Health in the Kurdish self-governing zone accustomed Kurdistan Medical Control Agency. This competent body is in charge of the enrolment, quality control, dispensation, and quality control of pharmaceutical products in Kurdistan **[5]**.

3.4 Israel

For approval, control, merchandise of persons, herb and veterinary things the Ministry of Health in Israel is accountable. The Enrolment Division is answerable for the permit activity.

The Academy for Standardization and Control of Pharmaceuticals is an institute within the Ministry of Health that is responsible for assuring the value of medications.

3.5 Jordan

The JFDA was established in 2003 as a proficient administration for medication safety and efficacy, as well as food safety and quality **[5]**.

Objectives:

Jordan food and Drug Administration is a free-spirited public sector regulatory union whose intention are to ensure that,

- Food is safe, nutritious, and appropriately marked.
- Drugs are safe and effective.

3.6 Lebanon

Ministry of Public Health will supervise for drug interconnected "Service of Pharmacy" as portion of the MOPH has the following activities:

- Issuing certifications for pharmacies and pharmacist practice.
- Price of drugs
- Drug industry management and control
- Trade, distribution, and data for narcotic drugs.
- Medicinal trade
- Managing drug enrolment and control
- Pharmacies and drug stores examination **[5]**.

4. CTD TRAINGLE:

The CTD contains a table of information referred as backbone that conduct all the data for an application.

This backbone is broken down into 5 modules.

Module 1– includes regional information such as forms, cover letters, labels, and investigative brochures.

Module 2 – reviews such as quality, clinical and non -clinical.

Module 3 – quality data

Module 4 – non clinical data

Module 5 – clinical data

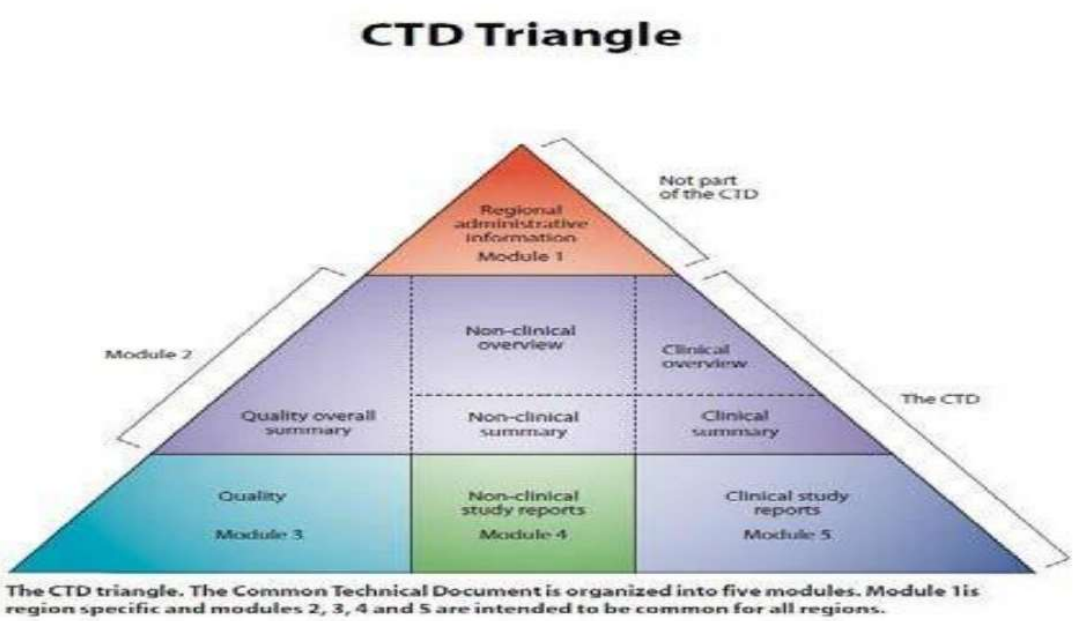

Figure 1: Definition of CTD dossier according to ICH

5. STUDY METHODOLOGY

❖ SOURCES OF DATA

i. Data were collected and analysed the data from sources listed below.
ii. Guidelines published officially by government authorities
iii. Available research papers, articles.
iv. Other internet sources using numerous search engines like- Google, Google Scholar, etc.

❖ METHODS

Digital and printed data / literature were screened to compile the data.

6. RESULT AND DISCUSSION

6.1 Egypt

Egypt's developing interest for therapeutic items because of segment development and urbanization makes it as major markets in the Middle East and North Africa region.

All medication items are required to be affirmed by the Egyptian Drug Authority (EDA) before circulation or advertising in the nation **[6]**.

To market a drug product in the Egypt, the manufacturer or the marketing authority has to apply for "NEW HUMAN MEDICINAL PRODUCT REQUEST INQUIRY FORM"

Set of Rules and Regulations-Egypt:

- Make note that, the organization summarize ought to be submitted ahead of time of the accommodation of the solicitation request structure, so as to continue with your application.
- You ought to present an examined duplicate of the receipt connected with the structure, the organization ought to determine the nonexclusive name, and quality and dose structure.

- Every structure ought to comply for each character.
- Things ought to be satisfied totally.
- Organization gets the notice mail within fifteen days.

If the case is shut and an activity Letter if the container is opened.

- Answer mail or activity letter expresses the decay of solicitation & decrease of solicitation & request will put away as per the accepting time.

HUMAN DRUG REGISTRATION WORK FLOW OVER VIEW

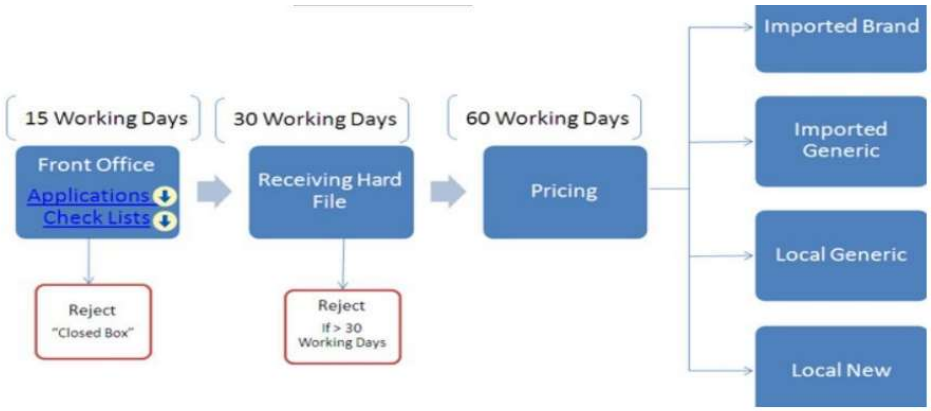

Figure 2: Human drug registration work flow

6.2 Iraq

In Iraq, there is no provision permitted by law organizing the capacity and authority of the MRA **[7]**.

Regulatory Investigation

In Iraq, allocation permitted by law subsist allowing for assignation of government pharmaceutical inspectors. Allocation permitted by law subsist legalizing inspectors to inspect site where pharmaceutical activities are carried out, such investigation are legalized and are a necessary condition for the validating facilities **[7, 8]**

6.3 Iran

Iran has a national drugs list called as IDL which is documented by the Iran Drug Selection Committee. All authorization and Over the Counter drugs retailed in Iran must be named in Iran Drug List to availability for authorization. A cramped proportion of unrecorded drugs are sanctioned to be ship in through EPCs **[9]**.

Documents required for registration of a pharmaceutical product in Iran **[9, 10]**;

1- Document of Pharmaceutical Product by World Health Organisation

2- Document consists of catalogue of the countries where legacy is listed with registration number

3- Document consisting catalogue and of the countries where legacy is marketed and particulars concerning date of foundation in merchandise.

4- Document has a formulating unit and the direction of formulating unit consists catalogue of the countries.

5-Report of bureau for the legacy to an Iranian company

6- Absolute outline for price of legacy

7- Complete Drug ship in petition

8- Specimen of legacy including meticulous evidence and multi - disciplinary folder DMF

6.4 Jordan

MOH oversees medical widget in the premises through JFDA. Though formulators can get report, sanction and merchandise supremacy. Provocations they face is with up-to-date refurbished guidelines of Ministry of Health **[11]**.

Online Filing Application;

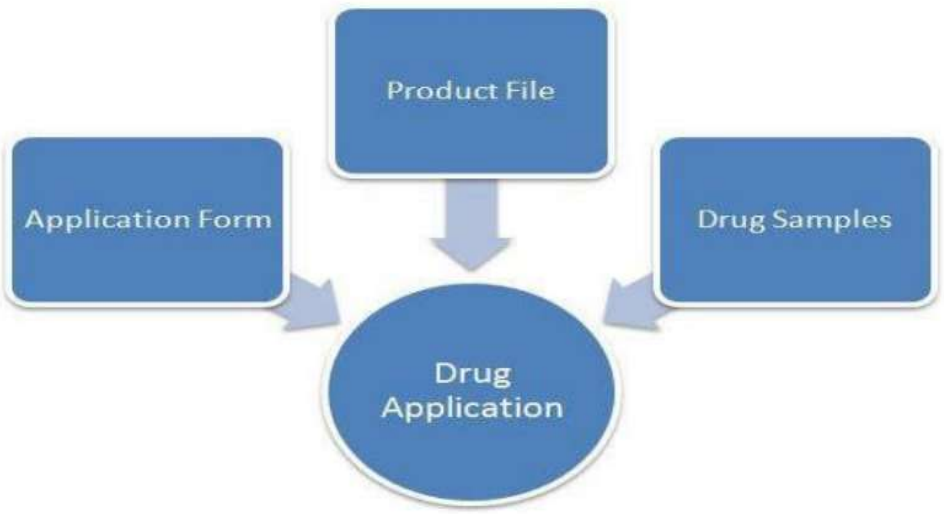

Figure 3: Drug Application process

Acceptance of Drug Application:

Figure 4: Registration Process Flow

6.5 Israel

Registering a drug is a complex process that involves examining and examining the data submitted in the registry file **[12]**.

Details of the process steps [12]

- Filling out forms and attaching documents according to the type of preparation "according to Procedure for Application for Registration of Medicinal Products"
- The forms and documents must be submitted to the pharmacy department's registration department during the reception.
- If all documents are found to be valid, the application reference number will be accepted at the time of application.
- The documents will be handled by the Department of Registration of the Department of Pharmacy and at the same time by the Institute of Audit and (Standards of Medical Materials for the purpose of issuing a quality certificate).
- The application will be discussed by the appropriate committee according to the type of preparation
- At the same time as the committees' discussion, the application is being reviewed at the Institute for Standards and Medical Review for the purpose of issuing a quality certificate.
- Once the quality certificate has been received from the Institute for Review and Standards of Medical Materials, the examination process will continue in the registration department
- If all tests have passed properly, the drug will be registered.
- The registration certificate will be mailed; the original registration certificate and quality certificate will be mailed.

6.5 Lebanon

Drugs inscribe escort link chains that are endured to the control of a Drug catalogue TC at the Ministry of Public Health. Pharmaceutical legacy must be catalogued at the Ministry of Public Health being formulated and shipped in. All shipped in or dispensation of drugs that is not catalogued to control of Ministry of Public Health is reviewed and not permitted by the law and is content to annexation **[13]**.

Registration Condition - Original drug [new molecules];

- Manufacturing Plant: Filled questionnaire and GMP certificate.
- Free sale certificate, Certificate of Pharmaceutical Product (CPP).
- Provide raw material provenance and GMP certificates for all associated manufacturers.

- A Certificate of Analysis detailing raw material amount and purity, as well as analytical methodologies.
- Pharmaceutical studies (disintegration, dissolution, pH) and stability data for 3 different batches. ¬ detailed bioavailability of active ingredients issued by the source which carried out the study.
- Knowledge on drug efficacy (pharmacodynamics data).
- Understanding the drug's toxicity and carcinogenicity.
- Pharmacokinetic studies

7. CONCLUSION:

This comprises the most critical aspects of the marketing authorization of drug products in the MENA countries.

• Each country differs in drug products registration time and approval

• Each country has their own registration requirements data and forms to be submitted.

• Regulatory requirements for each country are discussed and required documents are attached.

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