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Market Authorization Process for Medicinal Products in Eurasian Economic Union Council

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Abstract:-

The study aims to discuss about history and structure of the Eurasian Economic Union (EAEU) has been shaped by numerous agreements and treaties aimed at promoting economic cooperation among member states. The EAEU is an international organization comprising the countries of the Eurasian region. Its major treaties and agreements, such as the Partnership and Cooperation Agreement (PCA) of 1997, passed the way for further integration. The Treaty establishing the Eurasian Economic Union, signed on May 29, 2014, marked an important step forward. This treaty established the framework for the EAEU, with its provisions entering into force on 1 January 2015. The treaty covers several key aspects, including the creation of four common spaces: Economy and environment, freedom, security and justice, foreign security, research and education, including cultural cooperation among Member States. The main objective of the EAEU is to facilitate the movement of goods, services, capital and labor within its borders, and to coordinate policies in specific economic sectors as defined by the EAEU. It aims to promote sustainable economic development, improve living standards, create a single market and enhance competitiveness in the global economy. The structure of the EAEU includes key agencies responsible for decision-making and implementation. The Supreme Eurasian Economic Council, composed of the heads of member states, is the highest governing body. The executive functions are performed by the Eurasian Economic Commission, which is responsible for the practical aspects of the EAEU's operations. One notable aspect is the agreement on the general principles and rules of drug marketing within the EAEU. This agreement underscores the EAEU's commitment to ensuring access to safe, high-quality medicines, with an emphasis on distribution coordination and consumer protection. The agreement defines the principles of drug regulation in the member states. The EAEU drug registration procedure includes several routes: mutual recognition, decentralized procedure and national procedure. These procedures are designed to harmonize registration requirements and streamline the delivery process in compliance with EAEU standards. The mutual recognition procedure includes the selection of a Reference Member State (RM) and a Member State of Concern (EMC) for the assessment of the application. Decentralized process allows RMS and CMS to evaluate simultaneously. The national procedure is available to those who wish to register in only one country. Adaptation of old records to EAEU requirements related to RMS selection, followed by assessment and feasibility testing. Successful compliance leads to a harmonized registration certificate and, if eligible, the registration certificate is valid indefinitely.

Keywords: Eurasian Economic Union, economic integration, Treaty on Eurasian Economic Union, healthcare accessibility, registration procedures, international cooperation.

1. Introduction

The Eurasian Economic Union (EAEU) demonstrates the power of international cooperation in promoting economic integration and development. Shaped by a series of treaties and agreements, the EAEU has evolved to facilitate the smooth flow of goods, services, capital and labor between member states. At the heart of this integration is the treaty establishing the Eurasian Economic Union, signed in 2014, which sets the framework for common policies and economic cooperation. An important aspect of the EAEU program is the agreement on common principles and rules for drug marketing within the EAEU, underscoring the alliance's commitment to improving access to health care and ensuring quality assurance of pharmaceutical products. Addressing the complexities of drug registration and compliance, the EEU has established streamlined procedures that demonstrate the organization's commitment to harmonizing cross-border standards. This document delves into the history, structure and key agreements of UEE, focusing on the drug registration process, shedding light on how the alliance has successfully navigated economic integration and health care, health on the Eurasian continent [1-2].

2. History of EAEU:- EAEU treaty & agreement:-

- Partnership & Cooperation Agreement (PCA) - 1997
- Treaty on Eurasian Economic Union for medicinal products for human use was signed on 29 may 2014.

- This treaty came into force on 1st January 2015.
- In this agreement four common spaces are open

i.Economy and Environment
ii.Freedom, Security and justice
iii.External security
iv.Research and Education, including culture of member states.

All member states combine to establish the Eurasian Economic Union ensuring free movement of goods, service, capital and labor within its borders, as well as coordinated and agreed the common policy in the economic sectors determined under the Treaty and international treaties within the Union.

The main objectives of the Union are as follows:

- To create proper conditions which is sustainable for the economic development of the Member States in order to improve the living standards of their population.
- To seek the creation of a common market for goods, services, capital and labor within the Union.
- To ensure comprehensive modernization, cooperation and competitiveness of national economies within the global economy [3].

3. Eurasian Economic Union (Different Bodies)

1. The supreme body of the Union is the Supreme Eurasian Economic Council.
2. This body consists of Heads of Member States.
3. Eurasian Economic Commission is the executive body of the Union. It is responsible for the functioning of the EAEU [4].

4. Regulation for market authorization & assessment of medicinal products for human use (for innovator &generic drug products only)

In accordance with Article 7 of the Agreement on common principles and rules of medicinal products circulation within the Eurasian Economic Union dated on December 23, 2014, clause 84 to the Regulations of the work of the Eurasian Economic Commission, approved by the Resolution of the Supreme Eurasian Economic Council of December 23, 2014 and the Resolution of the Supreme Eurasian Economic Council of December 23, 2014.

On the implementation of the Agreement on common principles and rules of medicinal products circulation in the Eurasian Economic Union the Council of the Eurasian Economic Commission has solved the following problems:

a) Approve the enclosed Rules of marketing authorization and assessment of medical products for medical use.

b) Establish that: Confirmation or renewal of the marketing authorization, variations to the marketing authorization application dossier and other procedures which are related to the marketing authorization of medicinal products for human use, provided for by the laws of the member states of the Eurasian Economic Union and not completed by the authorized bodies of the Member States before January 1, 2016 shall be completed in accordance with the laws of the Member States.

c) Before December 31,2020, the market authorization of the product can take place if the product is manufactured in accordance with the regulation of a Member State, and MA was only permitted for the territory of a Member State in which it is permitted.

d) The validity of marketing authorizations issued by authorities of the Member States before January 1, 2016 may be extended in accordance with the laws of the Member States, but not longer than until December 31, 2025.

e) At the same time, any variations in the marketing authorization application dossier of medicinal product formed in accordance with the laws of the Member States shall be completed in accordance with the laws of the Member States but not later than December 31, 2025.

f) Certificates of marketing authorization for a medicinal products issued in accordance with the laws of the Member States will be valid until the expiry of their validity but not later than December 31,2025 [5-6].

5. How does the process of aligning old dossiers with the requirements of the Eurasian Economic Union (EAEU) looks like ?

The procedure of bringing a dossier into compliance with the new requirements is similar to other registration procedures, such as initial registration, renewal, and a variation. It is performed similarly as a Mutual Recognition Procedure (MRP), although it differs from it in terms of timelines and scope of assessment. The process involves the selection of a Reference Member State (RMS) – if the medicine is registered in more than one member state of the EAEU before the entry into force of the Agreement1 or before 31 December 2020, the applicant should choose one of the countries to act as the RMS. The documentation flow between the RMS and Concerned Member States (CMS) is

similar to the standard process of an MRP. However at the same time, there is a difference from the MRP: if the drug was registered according to national procedures in at least 3 member states of the Union within 5 years or more, the registration certificate issued after the procedure of bringing the Dossier into Compliance with the EAEU rules will immediately have an indefinite validity. The RMS follows a process for evaluating the completeness of the dossier and its compliance with the application requirements as part of the procedure to bring old dossiers into conformity with EAEU regulations. This is referred to as a "validation procedure" and is completed in 14 business days. The applicant receives a request for the submission of the missing documents and data if there are any concerns about the dossier's completeness during the validation stage[7]. This process can take up to 90 days. It should be reminded that the applicant's deadline for submitting the information and paperwork that are still lacking from the MRP has not been extended. Second, the RMS is required to produce a final evaluation report on the effectiveness, safety, and quality. The report shall become publicly available once the confidential information has been removed and the document has been entered in the Union Register of Medicinal Products. At this point, the work of the RMS is complete and the applicant is granted a registration certificate with the indicated RMS. The modules of the expert reports of the RMS and the modules of the registration dossier of the medicinal product shall be available in the recognition countries chosen by the applicant within 5 working days of the end of the work in the RMS [8].
In the next stage, the evaluators of the Concerned Member State (CMS) evaluate the reports submitted by the RMS and if necessary, request additional information from the applicant. A period of 90 days is given for this action, after which the following 10 days are allowed for the made decision approval. It is important to note that the CMS only reviews Module 1 and the assessment reports of the RMS, however, the CMS may check the compliance of the assessment reports of the RMS with Modules 2-5.
Following the assessment, the registration certificate shall be issued by the CMS under the same number as that issued by the RMS. In a situation where the applicant does not immediately identify all the CMSs, the applicant shall be entitled to list them at any time. In such a case, the MRP will start in the new Member States within 5 working days of the establishment of the updated list. Lastly, in order to carry out the renewal procedure simultaneously in all CMS, the registration certificate for medicinal products authorized in those Member States before 2020 December 31 is issued for the remaining period of validity of the registration certificate [9].

6. Agreement on Common Principles and Rules of Circulation of Medicinal Products within the EAEU

The Eurasian Economic Union (EAEU) is committed to advancing economic cooperation, expanding trade, and strengthening financial connections among its Member States, as stated in the EAEU Treaty of May 29, 2014. In line with this goal, the EAEU prioritizes the well-being of its population by ensuring access to safe, effective, and high-quality medicines. Recognizing the social significance of medicinal products, the EAEU emphasizes a coordinated approach to their distribution, taking into account concerns for the protection of human life and health, environmental preservation, animal and plant welfare, and the prevention of deceptive practices that may mislead consumers. These efforts aim to foster optimal conditions for the growth of the pharmaceutical industry, enhance the competitiveness of pharmaceutical goods manufactured within the EAEU Member States, and facilitate their entry into the global market [10].

6.1 Scope of the Agreement

a)This Agreement establishes shared principles and regulations governing the circulation of medicinal products within the EAEU, with the aim of creating a unified market for such products.
b)The provisions of this Agreement apply to legal relations arising from the circulation of medicinal products within the EAEU.

7. Why Was the European Union Created?

The overarching purpose of the European Union, in the years after World War II, was to put an end to the devastating wars that had wracked Europe for centuries. At the same time, it became increasingly clear that a united Europe would have far greater economic and political power than the individual nations in the post-war world.

7.1 Outcomes

- The European Customs Union is the body that regulates imports and exports within the European Union.
- The Union eliminated customs duties and import restrictions among its member nations.
- It established and administers the tariff-free movement of goods among its member countries.
- It also sets regulations for the quality and safety of goods imported into member countries.

- The U.K.'s exit from the European Union and the Customs Union changed the rules for British businesses doing business in Europe and for U.K. consumers buying European goods [11].

7.2 Members of the Board of the Eurasian Economic Commission:

1. From the Republic of **Armenia**
2. From the Republic of **Belarus**
3. From the Republic of **Kazakhstan**
4. From the Republic of **Kyrgyzstan**
5. From the **Russian** Federation.

8. The following products are not subject to marketing authorization in accordance with these Rules in the Union:

a) Medicinal products prepared in pharmacies,
b) Active pharmaceutical ingredients (active substances).
c) Medicinal products for use in non-clinical and clinical studies.
d) Medicinal products imported by individuals for personal use.
e) Radiopharmaceuticals prepared directly in healthcare institutions in accordance with the procedure established by the competent authorities.

9. EAEU – Economy

1. The EAEU is seen as an energy superpower since it produces more than 20% of the world's natural gas.
2. Russia, Belarus, Armenia, and Kazakhstan intend to create a single hydrocarbons market by 2025 and create a common electricity market.
3. EAEU produces 9% of the world's electrical energy.
4. It produces 5.9% of the world's coal.
5. The EAEU is the world's top producer of sunflower and sugar beet.
6. EAEU is responsible for the coordination of agricultural policy-making between member states and ensuring collective food security. Agricultural subsidies are also provided [12].

10. General principles of marketing authorization for medicinal products

- A marketing authorization for medicinal products may be granted at the request of an applicant in several Member States in accordance with the mutual recognition procedure successively or in the several Member States in accordance with the decentralized marketing authorization procedure simultaneously.
- The mutual recognition procedure shall be carried out:

a) By the reference Member State under these Rules in view of granting a marketing authorization for a medicinal product only in this Member State (the national marketing authorization procedure).
b) In the Member States concerned as desired by the applicant after the marketing authorization for the medicinal product has been granted in the reference Member State under the mutual recognition procedure.

- The Decentralized marketing authorization procedure shall be carried out simultaneously by several Member States where the application for the marketing authorization has been submitted and the reference Member State is need to be chosen.
- The applicant may choose the reference Member State and, where necessary, the Member State concerned when submitting the application for granting a marketing authorization for a medicinal product.
- Only one Member State may be designated as a reference Member State.
- The manufacturing of medicinal products shall comply with the requirements of the Good Manufacturing Practice of the Eurasian Economic Union [13].

11. Registration procedure:-

The registration of medicinal product within the countries of the Eurasian Economic Union (EAEU) involve 3 types of market authorization procedures:

i. Mutual Recognition.
ii. Decentralized Procedure.
iii. National Procedure.

The procedures for mutual recognition and decentralized market authorization within the EAEU closely resemble those in the European Union (EU). However, the centralized procedure is not applicable in the EAEU. Initially, the primary registration certificate within the EAEU is issued for a period of 5 years. Upon successful completion of the renewal procedure, the registration becomes indefinite. It is important to establish and approve the market authorization procedures before the common market of pharmaceutical products can commence operation.

Mutual Recognition Procedure:-
In mutual recognition procedure Market Authorization Holder has to file Market Authorization Application in other Member State using a reference Member State as it is also called sequential procedure because this procedure is used for a already registered medicinal product. Within 210 days, the mutual recognition process for a pharmaceutical product is finished. The process of mutual recognition is not a stand-alone procedure, and the Market Authorization Holder (MAH) cannot submit an application if the product is not already registered in one or more EAEU member states.

Decentralized procedure:-
During the decentralized procedure, it is expected that the registration process will be conducted simultaneously by both the reference and concerned member states. In this procedure, regulatory authorities perform the evaluation within 105 days, followed by an additional 105 days for the assessment and resolution of any contentious issues with the applicant. The decentralized procedure should not exceed a total of 210 calendar days, although it can be completed within a shorter timeframe if a consensus is reached. This procedure allows the Market Authorization Holder to submit applications to two or more member states of the Eurasian Economic Union (EAEU). One member state is designated as the reference state, while others are classified as concerned member states. The complete dossier is submitted to the reference state, with only module 1 documents submitted to the concerned member states.

Day 0	Start of the procedure
Day 105	Discussion between RMS and CMS. Issue of request for additional information/Documentation
Clock stop	Applicant has 90 days to answer deficiencies
Day120	RMS provides preliminary Assessment Report, Normative Document, PIL and Labelling
Day149	CMS send remarks and comments to the documentation provided by RMS.
Day150	Procedure may be finalized in case of consensus
Day 180	Start of national procedure to issue Registration certificates
Day 210	Close of procedure

National procedure:-
The national procedure will be available for applicants seeking marketing authorization who are satisfied with access to the pharmaceutical market of a single country. This procedure will remain in effect until 2025, in accordance with the national legislations of the member states within the Eurasian Economic Union (EAEU). More detailed information on the specific requirements for the registration of medicinal products in different EAEU member states is provided on the subsequent pages. Sectors that are not covered by the Agreement on the Uniform Principles and Rules of the Circulation of Medicines within the EAEU will continue to be regulated by the national legislation of each respective state. Examples of such sectors include obtaining licenses for pharmaceutical manufacturing, the operation of drugstores, advertising of medicines, and the formation of lists and price control for drugs listed as vital and essential medicines. These aspects will continue to be governed by the national pharmaceutical legislations of the member states [14].

11.1 Procedure for Previously Approved Drugs In The EAEU
Medicinal products that have received market authorization before December 31st, 2020, are required to comply with the new EAEU standards by December 31st, 2025. Market Authorization holders must follows the mutual recognition procedure: they select a reference state to submit the eCTD and other documents to, harmonized with the new regulations. It is important to note that this harmonization process should not include new information on safety, efficacy, or technical details of the medicinal product; i.e., any variations should first be submitted and processed for the old eCTD. The reference state performs the evaluation and potential inspections and then provides an expert opinion. The other states follow the recognition procedure based on this opinion and the eCTD.

The procedure for bringing a medicinal product in compliance with the new requirements is accelerated and has a maximum duration of 100 calendar days. If the drug was already registered in at least three member states for five years or more, a registration certificate without an expiration date would be issued. In other cases, the authorities grant the standard validity period of five years [15].

11.2 Registration Format for Innovator (New) Medicinal Products.
The registration format used in the Eurasian Economic Union (EAEU) follows the Common Technical Document (CTD), which serves as the standardized registration format for all member states of the EAEU. The CTD format aligns with the guidelines set by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).

The Common Technical Document consists of several modules, each containing specific information for the registration of pharmaceuticals for human use:
Module 1: Administrative Information and Prescribing Information
- Table of Contents of the Submission, including module 1.1 Documents Specific to Each Region
- Summary of Product Characteristics
- GMP (Good Manufacturing Practices) Certificate
- Free Sale Certificate (if required)
- COPP (Certificate of Pharmaceutical Product)

Module 2: Common Technical Document Summaries
- Common Technical Document Table of Contents (Modules 2-5)
- CTD Introduction
- Quality Overall Summary
- Nonclinical Overview
- Clinical Overview
- Nonclinical Written and Tabulated Summaries (Pharmacology, Pharmacokinetics, Toxicology)
- Clinical Summary (Biopharmaceutical Studies and Associated Analytical Methods, Clinical Pharmacology Studies, Clinical Efficacy, Clinical Safety, Literature References, Synopses of Individual Studies)

Module 3: Quality
- Table of Contents of Module 3
- Body of Data
- Literature References

Module 4: Nonclinical Study Reports
- Table of Contents of Module 4
- Study Reports
- Literature References

Module 5: Clinical Study Reports
- Table of Contents of Module 5
- Tabular Listing of All Clinical Studies
- Clinical Study Reports
- Literature References [16]

11.3 Registration Format for Generic Medicinal Products.
The Registration format of EAEU is according to Common Technical Document (CTD) which is common registration format for all the EAEU Member States. According to ICH guidelines Organization of the common technical document for the registration of pharmaceuticals for human use
Module 1: Administrative Information and Prescribing Information
- Table of Contents of the Submission Including Module
- Documents Specific to Each Region (for example, application prescribing information) forms
- Summary of Product Characteristics
- GMP (Good Manufacturing Practices) Certificate.
- Free sale certificate(if required)
- COPP (Certificate of Pharmaceutical product)

Module 2: Common Technical Document Summaries
- Common Technical Document Table of Contents (Modules 2-5)
- CTD Introduction
- Quality Overall Summary
- Nonclinical Overview
- Clinical Overview
- Nonclinical Written and Tabulated Summaries Pharmacology Pharmacokinetics Toxicology

- Clinical Summary Biopharmaceutic Studies and Associated Analytical Methods Clinical Pharmacology Studies Clinical Efficacy Clinical Safety Literature References Synopses of Individual Studies

Module 3: Quality

- Table of Contents of Module
- Body of Data
- Literature References

Module 4: Nonclinical Study Reports

Non clinical studies are not applicable part for generic medicinal products

Module 5: Clinical Study Reports

- Bio-equivalence (if required)
- Bio-waiver (if required) if BE is not required than bio waiver study reports are submittes or Literature references are submitted.
- CDP(Comparative dissolution parameters are submitted CTD Common Technical Document [17].

12. Benefits:-

The Market Authorization Process for medicinal products for medicinal products in Eurasian Economic Union is a very good initiative taken by the regulatory body of Eurasia. After the Implementation of this process it become easier to get approval for the medicinal products in the Member states of Eurasia. [18].

13. Understanding the difference between Eurasian Economic Union, Council & Commission

Eurasian Economic Commission is the permanent regulatory body of the Eurasian Economic Union. The supreme body of the Eurasian Economic Union is the Eurasian Economic Council.

Conclusion:-

The registration process within the Eurasian Economic Union (EAEU) plays a critical role in ensuring the safety and effectiveness of medicines across its member states. The EAEU employs different market authorization procedures, including mutual recognition, decentralized procedures, and national procedures. While there are similarities between the MRP & DCP procedures in the EAEU and those in the European Union (EU), it is important to note that the EAEU does not have a centralized procedure. The registration process places emphasis on the need for member states to modernize their domestic institutions in order to effectively address non-tariff barriers and reap economic benefits. The registration process for medicinal products for human use in Eurasian Economic Union is very simplifying and clearing pathways for pharmaceutical companies to get register the drug in all member states of Eurasia. After adapting the CTD submission process by Europe and many other countries, Eurasia take initiative to start their own registration process by using common technical document format. The DCP & MRP procedures adapted by EAEU has been started from 2014 and all the previous dossier should be in compliance with EAEU guidelines till 30 December 2025. To obtain registration, pharmaceutical companies must submit a detailed dossier containing preclinical and clinical data, along with manufacturing information, to the respective national regulatory authorities of the EAEU member countries they wish to market their product in EAEU. If the product meets all the necessary criteria, it is granted registration, allowing it to be marketed and distributed within the EAEU region, promoting access to essential medicines for the population while upholding the highest standards of patient safety and public health.

Upon receiving the dossier, the regulatory authority initiates the review process. National expert committees carefully assess the data to ensure that the medicinal product meets the required standards. This evaluation covers aspects such as pharmacological properties, safety profiles, clinical efficacy, manufacturing processes, and labeling information. If any additional data or modifications are requested during the evaluation process, companies must provide timely responses and updates to the regulatory authorities. After obtaining registration and product launch, pharmaceutical companies are required to monitor the safety and efficacy of their products through post-marketing surveillance. This involves tracking adverse events and maintaining compliance with any post-approval commitments. All over the registration process for medicinal products in Eurasian Economic Union is a great initiative takes by Regulatory Authority of Eurasia for registering the drug easily.

Abbreviations:

Abbreviations	Full form
EAEU	Eurasian Economic Union
EEC	Eurasian Economic Commission
UNIDO	United Nations Industrial Development Organization
DCP	Decentralized procedure
MRP	Mutual Recognition procedure
CMS	Concerned Member state
RMS	Reference Member State
Pk	Pharmacokinetic
PD	Pharmacodynamics
BE	Bioequivalence
BA	Bioavailability

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Conflict Of Interest Statement

The authors declare that there is no related conflict – academic, financial, or otherwise for publication of this work.

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