

# Regulatory Opportunities Investigations -requirements and procedures for medicines registration in the EAEU and opportunities

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## Introduction

The regulatory intelligence (RI) function continues to develop and increase in importance as companies operate globally. While the scope of RI varies by geography, resources and company size, it has become an essential component of maintaining awareness of and remaining compliant with the ever-evolving regulatory landscape.

However, RI often operates in the background of a company, with limited awareness of its value and contribution to the company's success. The ability to determine the return on investment (ROI) of RI remains elusive for many companies, leaving senior leadership still to determine its value (Clarivate, 2021).

Global harmonization has brought steady method in regulatory submission. Asia is predicted to overtake Europe in pharmaceutical marketplace within the next decade and sales are driven by using increase in key rising markets. The term "rising marketplace economy" was first utilized in 1981 by "Antoine W. Van Agtmael" of the International Finance Corporation of the World Bank. Emerging markets are economies of countries that are within the process of becoming a developed country. More than 85 % population lives in the emerging market and so the real financial boom has come from these markets. This promotes many multinational corporations switched to those rising international locations particularly in China, India, Euro Asian Economic Union (EAEU), Korea and Mexico (Singam et al., 2020).

The EAEU consists of Kazakhstan, Russia, Belarus, Armenia, and Kyrgyzstan and has a combined population of more than 185 million people. The EAEU was formed in 2014 and is headed by the Eurasian Economic Commission (EEC). In recent years, the EAEU has taken steps to unify the pharmaceutical market, and in the future might include a single pharmaceutical regulator similar to

the European Medicines Agency (EMA). The EEC has introduced the 'Agreement on common principles and rules of circulation of medicines within the Eurasian Economic Union' at the end of 2014, and the 'Rules of registration and expertise of medicinal products for human use' (EEC Decision No. 78) on November 3<sup>rd</sup>, 2016. The decision describes two pathways of registering medicines in the EAEU, which have become the official procedures at the start of 2021. Medicines registered before December 31<sup>st</sup>, 2020; need to comply with the EAEU requirements by the end of 2025 (Grata International, 2022).

## Materials and methods

The materials of the study were available publications in peer-reviewed journals on thematic queries based on keywords of the selected topic, official websites, regulatory legal acts, regulating the procedure for registering medicinal products in the EU and different countries, in order to investigate the requirements and procedures for registration of medicinal products in EAEU as a potential opportunity for accelerated registration and marketing authorization procedures of medicines.

## Results and discussion

Replek Farm Ltd. Skopje, as an EU GMP certified pharmaceutical manufacturer and Marketing Authorization Holder of numerous Marketing Authorization certificates of medicines in different EAEU countries, has considered new approaches to registration within the framework of the Eurasian Economic Union from the perspective of new opportunities and emerging

problems for foreign manufacturers of generic medicines. A comparative analysis of the mutual recognition procedure and the national procedure for registration of medicinal products revealed a number of advantages for domestic and foreign manufacturers, favoring the introduction of medicinal products into circulation on the whole territory of the EAEU.

The rules for registration and expert appraisal of medicines for medical use within the EAEU were approved by the Decision of the EEC Council No. 78 dated 3 November 2016 (the 'Rules') and entered into force on 6 May 2017. Medicines registered under the Rules can be circulated and offered for sale throughout the EAEU, without undergoing registration procedures in each of these member states (Grata International, 2022).

Pathways for Medicine Registration in the Eurasian Economic Union (EAEU) are:

1. The mutual recognition procedure is carried out by the reference Member State – The MAH first selects a reference state in the mutual recognition procedure and submits the registration dossier to the competent authority (CA) there. The overall process has a maximum duration of 210 calendar days, with an extension possible if a CA requests additional information. After market authorization in the reference state, the MAH provides access to the eCTD and the expert report in the EAEU unified register for the other member states. The recognition process has a maximum duration of 90 calendar days, making the maximum duration of the whole mutual recognition procedure 300 calendar days (Biomapas, 2021; Foteeva et al., 2022).

2. The decentralized marketing authorization procedure is 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. (Grata International, n.d.) The decentralized procedure has a maximum duration of 210 calendar days and is thus faster than the mutual recognition pathway (Biomapas, 2021).

3. Procedure for Previously Approved Medicines in the EAEU: Medicinal products that have received market authorization before December 31<sup>st</sup>, 2020, are required to comply with the new EAEU standards by December 31<sup>st</sup>, 2025. MAHs largely follow 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 (Biomapas, 2021).

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 medicine 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 (Biomapas, 2021).

Furthermore, a maximum of 210 days before the expiry of a registration certificate, a re-registration request can be submitted, after which a certificate without an expiration date can be obtained (Biomapas, 2021).

## Conclusion

A comparison of registration requirements for different pathways for medicine registration in the Eurasian Economic Union has been done to understand the difference in current regulatory requirements, define a clear regulatory strategy for Replek Farm Ltd. Skopje by looking at the target EAEU regions. It was evaluated that the procedure for EAEU registration of previously approved medicines will lead to harmonized and efficient regulatory approval for current registrations, avoiding unnecessary duplication of work and eventually disabling medicines lag. The review of the process of harmonization of the registration practice of medicinal products in the EAEU speaks of regulatory intelligence (RI) possibilities. The future of developing new potential within EAEU for foreign generic medicines manufacturers, as Replek Farm Ltd. Skopje, shows facilitated access and potential benefit regarding the registration export of effective and safe medicines.

## References

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