Macedonian pharmaceutical bulletin, 68 (Suppl 1) 473 - 474 (2022)
Online ISSN 1857 - 8969
DOI:10.33320/maced.pharm.bull.2022.68.03.227
Short communication

Comparison of Parallel Import/Trade in North Macedonia and in EU

Bojana Danilovska Brashnarska[1*], Marija Trajchuleski[2], Zorica Naumovska[3]

[1]*Novo Nordisk Pharma dooel, Nikola Kljusev no.11, 1000 Skopje, R.N. Macedonia*
[2]*Agency for medicinal products and devices, Blvd. Ss. Cyril and Methodius 54, 1000 Skopje, R.N. Macedonia*
[3]*Faculty of Pharmacy, Ss. Cyril and Methodius University, Majka Tereza 47, 1000 Skopje, RN Macedonia*

Introduction

Parallel import is based on the principle of free movement of goods between the EU/EEA countries. Parallel import in the European Union is the legal activity under Art. 28-30 EC of buying goods in a low-price country.

Centrally authorized medicinal products ("CAPs") put on the market of one Member State can be marketed in any other Member State by a distributor, independently of the marketing-authorization holder ("parallel distribution"). Parallel distribution (hereinafter also "PD") pertains to all centrally authorized products and is checked by the European Medicines Agency (hereinafter "the Agency").

Centrally authorized products are marketed in all Member States under the same name and must comply with the Community Marketing Authorization. The task of the European Medicines Agency is to check compliance of products distributed in parallel with the conditions laid down in Community legislation on medicinal products and in the marketing authorization of the product. In this case the parallel distributors must send an initial notification for parallel distribution to the Agency.

The obligation of notifying the Agency allows it to check compliance of the medicinal product to be distributed in parallel with the conditions laid down in the EU legislation on medicinal products and in the marketing authorization. The outcome of the check is shared with the parallel distributor. Additionally, the MAH and National Competent Authorities will be notified when a letter of non-compliance is issued, or the product is re-branded.

Article 57(1)(o) of Regulation (EC) No 726/2004 (amended by Article 1(22) (a) (iii) of Regulation (EU) 2019/5) foresees the following task for the Agency:

"Checking that the conditions laid down in Union legislation on medicinal products for human use and on veterinary medicinal products and in the marketing, authorizations are met in the case of parallel distribution of medicinal products for human use and on veterinary medicinal products authorized in accordance with this Regulation or, as applicable, Regulation (EU) 2019/6."[3].

If the medicinal product is distributed in parallel, in the absence of the Agency's check or despite the Agency's letter of non-compliance, the national competent authorities may take regulatory actions regarding the said parallel distributor. Parallel import on the other hand concerns only nationally authorized products and is authorized by the national competent authority of the Member State of import based on the similarity to the product distributed in the Member State of destination by the marketing-authorization holder (hereinafter "MAH") (EMA/297155/2021 Re.2, 2022). In North Macedonia Parallel import was introduced in the Law for medicines and medical devices in 2012 and it was allowed for distributor registered in North Macedonia to import products from EU, Switzerland, Norway, Canada, Japan, Israel or USA. (Official gazette number 11, year 2012). In 2013 was adopted new change of the Law (Official gazette number 147, year 2013). With this change it was allowed for distributor registered in North Macedonia to import products from EU, Switzerland, Norway, Canada, Japan, Israel, USA, Russia and Turkey upon they receive approval letter by Macedonian Agency of Medicinal Products and Devices (MALMED) for products to be imported.

With this Amendment of the Law, parallel import started in North Macedonia.

After the implementation in the Law, several distributors have registered products to be imported with parallel import from Turkey and these products were

*bjdb@novonordisk.com

actively imported. During this period there were several challenges and several potential risks detected and raised by patient organisations, HCP organizations and Pharma industry.

In 2018, the Health Authority directors, experts from the pharmaceutical environment and pharma industry have held meeting in order to discuss the potential challenges and risks from not enough regulated Parallel import, and it was concluded that the documentation that is submitted during registration and import of the products must be in original format (not copy) and an appropriate certificate to prove the quality of the product.

The conducted study aims to underline the problems, challenges and potential risks for public health that befell when the adoption and implementation of parallel import law occurred in the Republic of North Macedonia.

Materials and methods

Relevant EU and Macedonian legislations have been reviewed, in general, as well as PubMed, Medline and other relevant websites with articles evaluating the impact of EU regulatory requirements and activities related to parallel import.

Results and discussion

The obtained results have confirmed that the parallel import/distribution in EU is based on the principle of free movement of goods between the EU/EEA countries and in North Macedonia the parallel import is based on countries that are not in same economic zone and with different regulations. Also, it is evident that the PI in EU was strictly regulated and all responsibilities of the parallel distributors, Health authorities and MAH were clearly defined and in North Macedonia regulation the responsibilities for PV, Quality and maintenance of the product were not clearly defined or not implemented in full.

With the first implementation of the change (introduction of Parallel import) there were issues as several things were not defined clearly in the Law:

- With obtaining approval letter for the parallel imported drugs, distributor becomes “second” MAH, but with limited responsabilities, as the PV and Quality responsibilities of the parallel distributor were not clearly defined
- Parallel distributor had right to apply on tender and to have exclusivity for selling the product in defined timeframe
- Despite that parallel distributor had obligation to inform the MAH for its intention to import products via parallel import, this was never implemented in practice
- When importing the products, the parallel distributor was not obliged to have original documents (for example, CoAs), only copy.
- The awareness of reporting of safety information is low in North Macedonia, and during parallel there were small number of reports in MALMED, even though patients were complaining on the quality and efficacy of the products.
- Repackaging of the imported foreign packs was not in control of the manufacturer or its representative office, which was a hihg risk for the safety of the patients and quality of the product
- Not following the Good Distribution Practice there was a risk of importation of counterfeit/diverted products.

After the joint meeting of all affected stakeholders, organized by Ministry of Health in 2018, the Law for Medicinal Products and Devices, was amended and accepted on 20 Jun 2018 (Official gazette number 113/18). The new updated Law resulted in absence of new submission for registration of parallel imported products, and the existing approval were not renewed.

Conclusion

The performed evaluation and comparison of the EU and North Macedonian legislation have confirmed strictly regulated and implemented Laws is inevitable in order to minimize or even eliminate the potential safety risks for the patients and obtain the quality of the products and protect the opportunity for importing counterfeit/diverted products not following the Good Distribution Practice.

References

Amendment on Macedonian Law for medicines and medical devices, Official gazette number 11, 2012

Amendment on Macedonian Law for medicines and medical devices, Official gazette number 147, 2013

Amendment on Macedonian Law for medicines and medical devices, Official gazette number 113, 2018

Macedonian Law for medicines and medical devices, Official gazette number 107, 2007

Parallel distribution: Regulatory and procedural guidance: https://www.ema.europa.eu/en/human-regulatory/post-authorisation/parallel-distribution/parallel-distribution-regulatory-procedural-guidance#guidance-documents-section (last accessed 14-Jun-2022)