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Safety and labelling in non-EU Countries

Abstract

Serialization is driving operational value and is adding safety securing distribution chain against counterfeit and adulterated products. Developing countries are much more vulnerable to this worldwide problem. Readers will learn about regulatory requirements in the countries of interest: Macedonia, Serbia, Montenegro, Bosnia & Herzegovina, Albania and Kosovo. Readers will get in-depth look concerning safety & labelling and will be updated with the country specific environments, as well as with serialization main benefits and the future perspectives.

Keywords: safety, labelling, serialization, non-EU countries

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Introduction

Medicinal products are characterized by its efficacy, quality and safety. Pharmaceutical industry is working for a long time to secure the distribution chain, against counterfeit and adulterated products, which is a big problem worldwide. According to WHO 10% from medicinal products are falsified globally, in developed countries about 1%, in developing countries more than 50%, and more than 50% from falsified medicinal products are purchased online. The securing of distribution chain should happen through implementation of serialization process in over 50 countries. In USA is required unit & case serialization without aggregation from November 2017; serialization traceability will be required from November 2023. In EU is regulated with Directive 2011/62/EU[1] (falsified medicines) and Commission Delegated Regulation (EU) 2016/161[2] (safety features), comprising unit level serialization and point of dispense verification. It is applied of 9th February 2019, with implementation period of 3 years. Ireland has prolonged the test phase until 30.09.2019. Greece & Italy will postpone serialization until 2025.

The safety features consist of two elements placed on the packaging of a medicinal product:

a. A unique identifier, a unique sequence carried by a two-dimensional barcode allowing the identification and authentication of the individual pack on which it is printed;

b. A device allowing the verification of whether the packaging of the medicinal product has been tampered with (anti-tampering device).

Serialization is not required in non-EU countries. These countries are using 1-dimensional barcodes, as did all countries before serialization.

Countries of interest

These are the countries where the small generic company Bionika Pharmaceuticals is most active, mainly in the neighbouring countries: Serbia, Montenegro, Bosnia & Herzegovina, Albania and Kosovo. Bionika Pharmaceuticals is manufacturing medicinal products, medical devices, food supplements & medical cosmetics and is located in North Macedonia, in the Balkan Peninsula, Southeast Europe. All countries follow the EU regulation for medicinal products.

Discussion

North Macedonia

In all countries by law is required local language labelling; in North Macedonia Cyrillic letters are used. In almost all countries of interest per year by law is allowed limited import of medicinal products with international labelling (local PIL - patient information leaflet and stamp are added on the outer packaging). Only in this country there is differentiation in maximum allowed quantities for import and they are: 10.000 packs for originator products and 5.000 packs for generic products/year.[3]

Serbia

In Serbia is also required local language labelling; both Cyrillic & Latin letters can be used (as approved). By law is allowed limited import of medicinal products with international labelling: 10.000 packs/year.[4]

Montenegro

Local language labelling is also required; because of the similarity between languages also approved Serbian, BiH (Bosnia and Herzegovina) & Croatian packs with stamps issued by the state Agency CInMED & local PIL can be used. By law is allowed limited import of medicinal products with international labelling: 5.000 packs/year. For serialized medicinal products there is no such limit and this is valid only for this country.[5]

Bosnia & Herzegovina

Local language labelling is required; there are 3 official languages in this country and labelling can be on Bosnian, Croatian or Serbian language. In the 1st year is allowed import of medicinal products with international labelling after obtaining marketing authorization, limited to 3.000 packs (this is the smallest quantity from all countries) and only if there is no parallel medicinal product on the market with the local labelling.[6]

Kosovo*

By law is required local bilingual labelling; there are 2 official languages in this country and labelling must be on both, Albanian and Serbian language. It is allowed limited import of medicinal products with international labelling: 15.000 packs/year (this is the biggest quantity from all countries).[7]

Albania*

Local language labelling is required; also it is possible to be approved English mock-up with Albanian PIL and medicinal products can be imported as approved. Albania is the only country from the region which does not allow import of medicinal products with international labelling.[8]

From all countries of interest, the following is valid only for both countries:

*Marketing Authorization Holder is either the manufacturer or the foreign MAH

*Primary packaging can be international, without obligation to state the MAH

*Braille is not mandatory for medicinal products, so they can be imported without braille label. If the MAH wants to implement braille later, it can be only done through variation submission.

Conclusion

In non-EU countries serialization is not required. Import of serialized packs is possible, but only in limited quantities/year, allowed by law of medicinal products with international labelling, with some exceptions. In Montenegro there is no such limit and Albania does not allow import of medicinal products with international labelling. For manufacturers like Bionika Pharmaceuticals, placed in non-EU countries, for distribution of medicinal products in countries of interest serialization is not required. This is also true for distribution of OTC (over the counter) medicines in EU market and worldwide. For distribution of Rx medicines (prescription medicinal products) in EU, serialization & batch release should be contracted by EU manufacturer, because also batch release in EU must be done by a manufacturer within the EU.

The main benefits of serialization are: prevention of falsified medicines in distribution chain, safe medicines in distribution (not having medicines with already expired dates anymore), much easier and quicker product recalls, returns, optimized reimbursement (by adding country specific additional data on a matrix code), financial reconciliation processes and chargebacks. It should create efficient, safe and demand driven supply chains, which benefit manufacturers, health systems and above all patients. There are different timelines in different countries worldwide and the serialization process is already implemented, or it is planned, or is ongoing.

Serialization implementation is expected also in the non-EU countries, as a global trend, although not in a near future. There are some considerations in the Agencies in Serbia & North Macedonia as accession in EU is expected, but the main obstacles are from financial character. It will most probably happen in a longer time frame. Parts of the research were presented during Drug Safety World Congress Europe held from 10-11th September 2019 in Amsterdam.

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Conflicts of interest

Author declares that there is no conflict of interest.

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