RAPS 2020 Euro Convergence

eSubmissions — regional moving towards global aspects

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Introduction

Obtaining marketing authorization can be a significant barrier to market entrance. A good knowledge of the medicinal products regulation is very important component of a product's marketing strategy, because there are differences in non European Union countries in comparison with EU countries. Development of a regulatory strategy early in the product life cycle can greatly accelerate time of commercial entrance.

The main goal of this study is to make comparative analysis of regulatory submission differences for medicinal products. The choise of countries is based upon where the company Bionika Pharmaceuticals is active.

Materials and Methods

Comparative method is used, as required by the subject of the research. In the study have been analyzed medicinal products regulation and submissions for obtaining marketing authorisation in countries of interest: EU, Macedonia, Serbia, Montenegro, Albania, Kosovo, Bosnia and Herzegovina (figure 1).

Results and Discussion

Case study

- In EU eSubmissions of medicinal products are mandatory for all types of Applications

- "Paper" CTD format is accepted in Montenegro

- "Paper" CTD format is accepted in Albania (evaluation in 2 separate consecutive phases)

- In Serbia partial eSubmissions are accepted from 20.12.2016 (e-appointments, cover letters and application forms, CPPs, advertising of medicinal products, variations*, renewals*), although "paper" CTD format is still in force for medicinal products.
*If the files are too large, they should be submitted in "paper format" (*10 MB max. filedata).

From 02.12.2018 eSubmissions of medical devices are mandatory (first country from the region).

- In Bosnia and Herzegovina *NeeS (non-eCTD format) is mandatory for all types of Applications starting from 01.07.2015 (first country from the region). On the Agency website is uploaded NeeS Checker.

*The company has developed its own in-house software for creation of NeeS format for submissions in Bosnia and Herzegovina and for other countries of interest.

- In Kosovo eSubmissions are mandatory only for new Marketing authorisations from 01.04.2018 (figure 3). For renewals and variations "paper" CTD format is still in force.

- In Macedonia eSubmissions are mandatory for all types of Applications starting from 18.09.2018 (figure 2)

Regional National Agencies have developed customized softwares for electronic submissions, but also documents in NeeS and eCTD format can be used for upload.

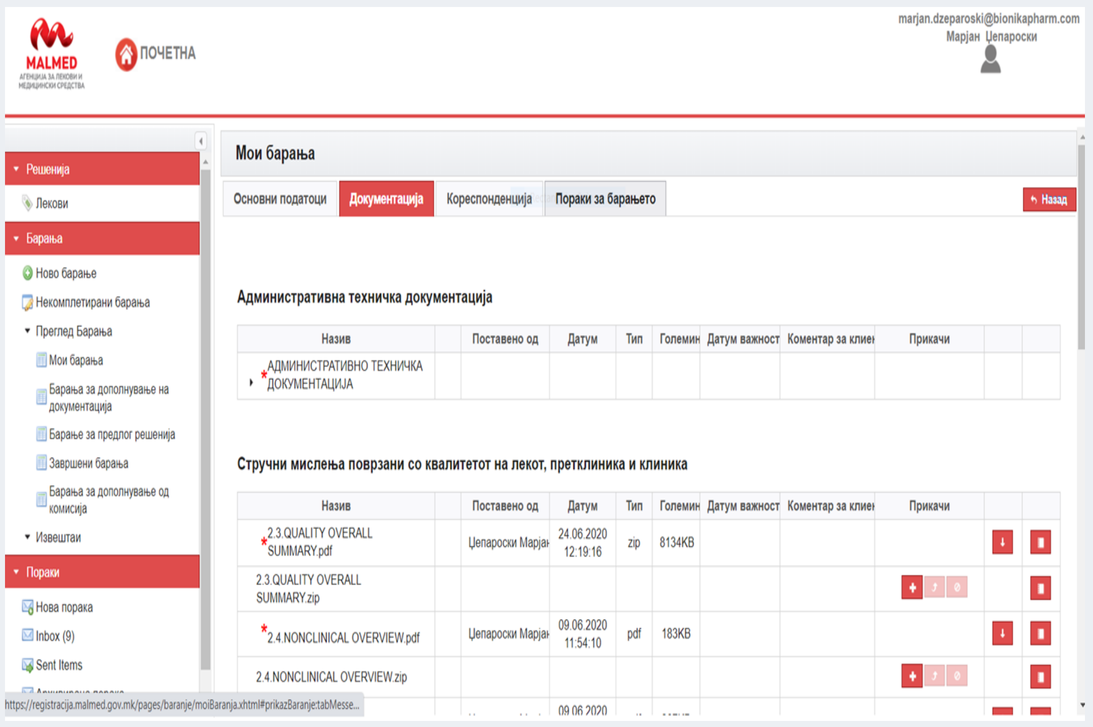
It is expected that all countries will develop similar network and management system in the near future.

Submission of products for obtaining marketing authorization by companies must be planned early in the product life cycle and in accordance with the current country regulation for specific product category.

Figure 1 – Countries of interest

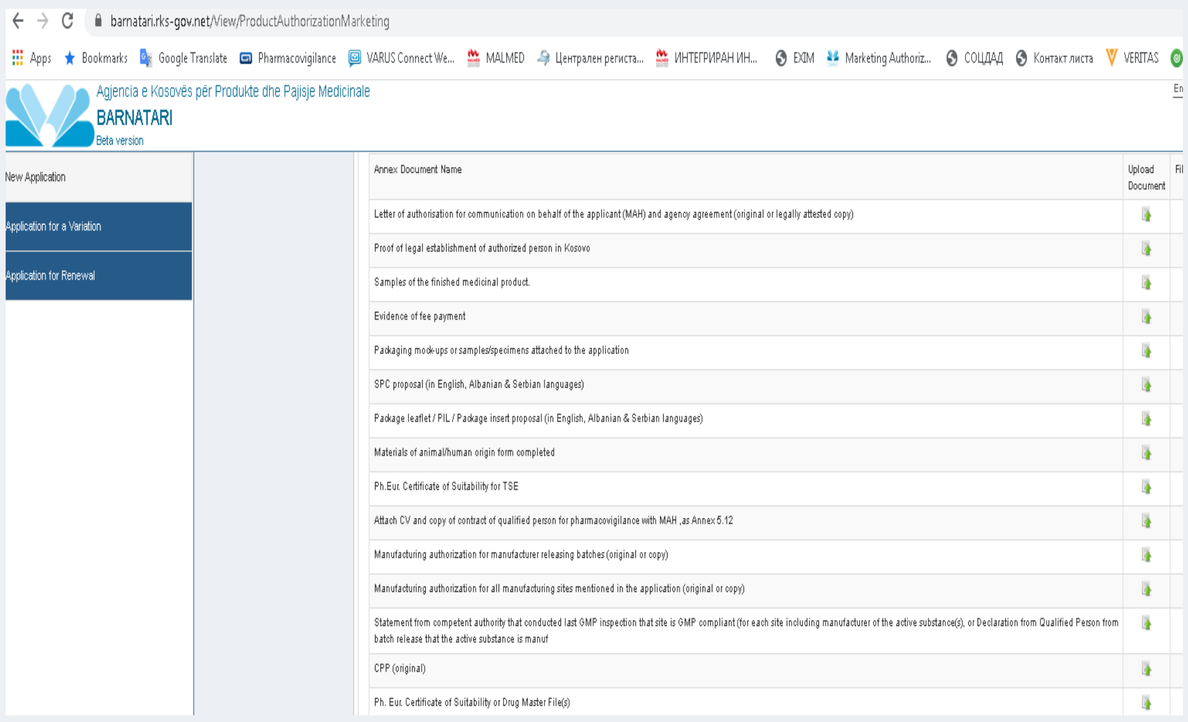
Image source: https://images.app.goo.gl/CfawXSc6rto4wLjH7

Figure 2 – Electronic submission platform in Macedonia



Data source: Macedonian agency for medicinal products and medical devices

Figure 3 – Electronic submission platform in Kosovo



Data source: Kosovo medicines agency

Conclusion

There are differences concerning medicinal products regulation and submissions for obtaining marketing authorization in non European Union countries in comparison with EU countries.

Regional aspects are moving towards Global aspects – Harmonisation.

In "near" future eCTD format is expected to be mandatory for all submissions.

Benefits: data quality, reusability, faster access, more office space.

References

1. Law on medicines and medical devices ("Official Gazette of the Republic of Macedonia" No. 106/07, 88/10, 11/12, 147/13, 27/14, 88/15, 134/15).
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3. Law on Medicines ("Official Gazette of Montenegro" No 80/20).
4. LAW No. 105/2014 ON DRUGS AND PHARMACEUTICAL SERVICE (Promulgated by Decree no. 8680, dated 15.08.2014 of the President of the Republic of Albania, Bujar Nishani).
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