Update on eSubmissions in Balkans

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Disclaimer

I am an employee of Bionika Pharmaceuticals

I have about 20 years regulatory affairs & pharmacovigilance practice

Previously, I spent 5 years in chemical business

This presentation represents my personal view and is not necessarily the position of Bionika Pharmaceuticals

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Global aspects – the future

- In EU eSubmissions of medicinal products are mandatory for all types of Applications
- Some regional National Agencies have developed customized softwares for electronic submissions, but also documents in NeeS and eCTD format can be used
- It is expected that all countries will develop similar network and management system in the near future
- Dynamic Submission Management – evolution of pharmaceutical regulation

Conclusion

- Regional aspects are moving towards Global aspects - Harmonisation
- In “near” future eCTD format is expected to be mandatory for all submissions
- Benefits: data quality, structured content, reusability, faster access, more office space
- 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

THANK YOU FOR YOUR ATTENTION !

QUESTIONS ?

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