Pre-accession Regulatory Challenges – Industry view

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Pre-accession challenges

- Upgrading of documentation
- Legal basis for upgrading of "old" medicines
- Amended EU Directive 2001/83/EC (pharmacovigilance, falsified medicines) and implementation of new Croatian Law on Medicinal Product and Medical Devices
  - impact on already registered products
  - impact on pending registrations

Upgrading

- Registration documentation that proves quality, safety and efficacy should be in line with Directive 2001/83/EC
- Transitional period of 4 years is approved for products listed in Annex V (2008)
- Croatian Medicinal Act 2007 and Ordinance in 2008 (registered products considered to be upgraded) except for user testing and Braille

Upgrading

Products not listed in Annex V

- User testing- transitional period until January, 2016
- BRAILLE - transitional period until January, 2015.

Products listed in Annex V

- UT and Braille can be processed simultaneously with upgrading
- The MAH shall ensure that the PIL is made available on request from patients organisations in formats appropriate for the blind and partially-sighted

Upgrading

- Legal basis should be chosen (generic, WEU, hybrid)
- Supported by prepared documentation
- Development (3.2.P.2) for "old" medicines
- No bibliographic data available / no reference products available
- 10, 20 ,30 or even 40 years of clinical use as evidence
  - for WEU when bibliographic data not available
  - for substances belonging to BCS class II or IV - referent product withdrawn
  - hybrid application

Impact of Croatian Medicinal Act / Directive on Pharmacovigilance

- PVMS should be in force / summary to be prepared for dossier
- Changed PSUR concept in favour of risk assessment
- EURD list since April 1, 2013 – no routine PSUR
- PSUR still necessary for third countries
- EVMPD data base should be filled with data for all products authorised in Croatia

Impact of Croatian Medicinal Act / Directive on Falsified Medicines

Import of API in EU

- Accompanied by written confirmation issued from the competent authority of the exporting country
- Listed third countries as equivalent in EU GMP standards
- Exemption granted by EU importing country
- Shortage of medicines

Directive on Falsified Medicines

Import of API in EU

- Extension of the provision implementation / public health is not at risk as current GMP rules suffice:
- Use of API that has been manufactured in accordance to EU GMP
- API can be imported only if manufactured in line to EU GMP standard
- Obligation of EU manufacturers to audit API manufacturers
- API manufacturer possesses valid EU GMP certificate

Directive on Falsified Medicines

Import of API in EU

- Bulk or finished products do not fall under the provision 46(b)2
- Written confirmation could be based on EU GMP inspection
- Generics are considered not to be of interest for falsification – risk assessment based approach

Impact of Croatian Medicinal Act and Directive 2001/83/EC

- Implementation of Article 17 and 18 Directive 2001/83/EC on day of accession
- Withdrawal of application / new procedure MRP or DCP
- Implementation of data exclusivity 8+2+1
- MAs and products withdrawal

Thank you very much for your attention !