Pharmacovigilance Pre-accession Challenges
Industry view

Tatjana Ajhler Đuretek, MD, MSc.
Belupo d.d.

EU28: science, medicines, health – a regulatory system fit for the future
Dubrovnik, 6.-7. 05. 2013.

New EU Pharmacovigilance Legislation

- Challenge for Croatian MAHs as well as for all MAHs within European Union
- Implementation has been starting July 2012 through 2015.
- Pre-accession challenge in Croatia – PhV activities for all products authorised in Croatia should comply with new requirements

MAH responsibilities and expectations - PSUR

Lower workload

- PSUR is no more needed for many generic and well-established use products in EU - we are expecting harmonisation with EURD list by time of accession

Higher workload

- New format - focus on benefit/risk evaluation
- More need from medical input to assess the benefit
- Need to prepare two different PSURs (Europe vs. Non-EU countries)

MAH responsibilities and expectations - RMP

Higher workload

- RMP is required for any new or extended application although some modules may be reduced or omitted for old generics
- It is including more sections and details then last version.
- Summary of RMP to be made public but must be in lay language and level of detail results in a complete new document
- Educational materials and activities should be harmonized across generic MAHs
- Changes to risk minimisation activities require variation submissions and approval.

MAH responsibilities and expectations
Expedited Reporting

- Definition of ADR – additionally include off label use, misuse, abuse, overdose, medication error, occupational exposure
- Non-serious ADR - 90 day time frame
- Consumer reports (already implemented in HR)
- Reporting modality – Interim
  - serious (EU) to CA of country of occurrence
  - non-serious ICSRs (EU) if required, to CA of country of occurrence (in Croatia already required)
  - non-EU serious to EV; if required also to CA in member states in which the medicinal product is authorised

MAH responsibilities and expectations
Expedited Reporting

- ADR should be electronically reported to EV and all competent authorities (including HALMED) by time of accession
- Belupo already registered user of Eudravigilance since 2005
- Implementation of validated electronic database with gateway in order to be complied with these requirements for all authorised products in Croatia and EU
- Reporting to XEVMPD already in place since summer 2012, but with time of accession this requirement should be fulfilled for all products registered in Croatia – higher workload

MAH responsibilities and expectations
Signal Detection

- Focus on signal management related to adverse reactions
- Monitoring data in EudraVigilance – at least once mothly
- Definition of signal detection process for generic products – difficult because of underreporting of ADR for old drugs
- MAH responsible for signal management also from other sources (internet, digital media)
- Perform world wide signal detection activities

MAH responsibilities and expectations PSMF and Quality System

- Quality System - Integral part of the PV system with own structures and processes
- Covers organisational structures, responsibilities, procedures, processes, resources
- Compliance, training, record management in PV
- Important elements:
  - Quality cycle: planning, control, assurance, improvement
  - Key performance indicators
  - Critical PV processes including processes managed outside the Global PV departments

Conclusion

Key concepts

- Better transparency of pharmacovigilance processes
- Better communication of safety information to the public

...with additional workload and responsibilites for MAH

- Many implementation activities at MAHs over the next years
- Many procedural changes
- Many new or additional documentation needed

Thank you!

Tatjana Ajhler Đuretek, MD, MSc.
Head of Medical Affairs and Pharmacovigilance
Business Development & Regulatory Affairs
Belupo d.d, Zagreb, Croatia
tatjana.ajhler-duretek@belupo.hr