Human and veterinary pharmaceuticals regulation
Towards EU accession: Serbia's regulatory challenges, expectations and opportunities
29-30 November 2010
Hotel Holiday Inn, Belexpo Convention Centre, Belgrade, Serbia

Republika Srbija
Ministarstvo zdravlja
Ministarstvo poljoprivrede, šumarstva i vodoprivrede,
Uprava za veterinu

Republic of Serbia
Ministry of Health
Ministry of Agriculture, Forestry and Water Management,
Veterinary Directorate

alims
Agencija za lekove i medicinska sredstva Srbije
Medicines and Medical Devices Agency of Serbia

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Impact of the single market and availability of veterinary medicines

Member state perspectives

Kliknite sem a upravte štýl predlohy podnadpisov.

Conference Belgrade, 29.-30. November 2010

Presented by: Judita Hederová, ISCVBM Slovakia

Single market and availability

EU project (1957) to create ***free trade (or internal market)*** within the EU which implies: free movement of goods, to provide services, capital and people.

In terms of authorisation of VMPs it means:

- harmonised leadership in authorisation of VMPs (EC, EMA, national authorities)
- harmonised procedures in authorisation of VMPs
- regulatory and scientific co-operation between EU member states
- creation of efficient control mechanisms
- animal and human health protection
- co-operation with EU and International Institutions (IFAH EU, Codex Alimentarius, EFSA, JECFA ...)
- guarantee of quality, safety and efficacy of products placed on the EU market
- availability of an adequate range of veterinary medicines to treat the wide variety of animal species within the European Community

EU enlargement activities

- **New** candidates for accession EU: CZ, EE, LV, LT, PL, SK, SL, HU, CY, MT, BG, RO
- **TAIEX** fora (Technical Assistence Information Exchange Office) held in Prague and Brussels in 1998

  TAIEX/CEESA fora: – Regulation of VMPs Brussels Dec.1998, Regulation on VMPs EMEA , June 1999, Veterinary pharmacovigilance in Germany 2002, Forum on the Regulation of Immunologicals, Good manufacturing Practices, in Spain, April 2001

- **TAIEX/EMEA** CEECs Forum on Regulation of VMPs June 1999 (the goals were: to familiarise with the centralised system of authorisation of medicines and the work of CVMP), Veterinary Immunologicals EMEA, March 2002
- It was created **CADREAC** for human side and later **CAVDRI –** Collaboration Agreement between Veterinary Drug Regulatory Authorities of candidate countries. **The aim of CAVDRI was**: smooth acces EU, exchange of information, meetings with other agencies, develop common strategies of accession, facilitate implementation of EU standards, procedures, practices, facilitate the involvement into EU activities.
- EMEA - opportunity to be as observers of CVMP, CVMP WPs, CMDv, QRD and also NtA WG EC.

EU enlargement activities - cont.

PERF I, II, III (Paneuropean regulatory forum on Pharmaceuticals)

- PERF I – the main goals were: Quality issues, Aquis Communautaire, safety of VMPs, establishing of MRLs, validated analytical methods
- Conference in Budapest Hungary, 2000
- PERF II – the main goals were: Implementation of Aquis , CP-pre-submission, assesment process, linquistic check of SPCs, MRP and DCP, PhW reporting, assesment of Part IV.,MRLs, VICH GLs, antimicrobial resistance
- Conference in Tallin, Estonia, 2002
- PERF III – the main goals were: Aquis Communautaire and Pharmacovigilance issues
- Conference in Warsaw, Poland 2003
- **The main goals** of all these activities were:harmonisation of legislation, trainings for regulators in authorisation of VMPs, assessors to follow safety, efficacy and quality of VMPs, understanding of GMP, GCP, GLP standards, pharmacovigilance issues, usage of EU Pharmacopoeia, simplified procedures of MRP and CP.

Important steps before accession

- First voluntary implementation of EU legislation started in Slovakia in 1998

  by implementation of Directives: 81/851/EEC, 81/852/EEC, 87/18/EEC, 90/219/EEC, 90/22/EEC, 91/412/EEC, 90/218/EEC, 90/677/EEC and Reg. 2377/90 to the Law No. 140/98 about Medicaments and Medical Devices
- Update of the old dossiers by MAHs according European pharmaceutical legislation till May 2004
- Implementation of ISO 9001:2000 at the Institute to have in place Quality Management System
- Process of simplified procedures for MRP and CP
- Quality review documents – translation of SPCs and product literature to national language
- Improvement of existing resourses and changing of Institute structure

Main difficulties

- Enhaced workload at the Institute
- Lack of sufficient number of experienced assesors and regulators
- Limited number of external experts
- Appropriate understanding and using of existing legislation,GLs,VICH GLs
- Language difficulties
- Integration to the all EU pharm. structures due to limited staff
- Appropriate functionality of Institute according Quality Management System

Accession advantages

- Faster availability of new products via centralised or mutual recognition procedure - (more active substances, target species, indications, vaccines...)
- Common authorisation of VMPs via MRP, DCP and CP
- Ensurance of common and better quality, safety, efficacy dossier assesment
- Common improvement of European legislation (hard and soft legislation)
- Common solution of goals (MRLs, ERA, antimicrobial resistance, pharmacovigilance, availability of vaccines)
- Permanent trainings of assesors and regulators (CVMP and WPs)
- Scientific advice for manufacturers, SME, MUMS, extrapolation of MRLs
- Possibility to place on the EU market also VMPs from national manufacturers

Availability - national activities

- The publication on webside a list of all authorised VMPs, of all variations, renewals and withdrawn products, list of distributors, manufacturers of VMPs www.uskvbl.sk
- Encourage pharmaceutical companies to maintain old authorisations and authorisation of MUMS products (pigeons, bees, rabitts ...)
- Implementation of exemptions accepted in Directives 2001/82/EC and 2004/28/EEC (cascade, medicines for horses, special import...)
- Regulatory advice to national manufacturers of VMPs
- Advice in clinical trials and approving of CT
- The cooperation with CZ in solution of scientific assesment of VMPs (Q,S,E) and the common procedure in harmonisation of SPCs nationally authorised products between SK and CZ
- National legislation allows to distribute VMPs with labelling exemptions with the limited number of package (limit is max. 1000 packages)
- Special AISLPvet system issued and Vademecum of VMPs issued every two years

Thank you for your attention.

Human and veterinary pharmaceuticals regulation

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

29-30 November 2010

Hotel Holiday Inn, Belexpo Convention Centre, Belgrade, Serbia

Human and veterinary pharmaceuticals regulation

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

29-30 November 2010

Hotel Holiday Inn, Belexpo Convention Centre, Belgrade, Serbia

Human and veterinary pharmaceuticals regulation

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

29-30 November 2010

Hotel Holiday Inn, Belexpo Convention Centre, Belgrade, Serbia

Human and veterinary pharmaceuticals regulation

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

29-30 November 2010

Hotel Holiday Inn, Belexpo Convention Centre, Belgrade, Serbia

Human and veterinary pharmaceuticals regulation

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

29-30 November 2010

Hotel Holiday Inn, Belexpo Convention Centre, Belgrade, Serbia

Human and veterinary pharmaceuticals regulation

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

29-30 November 2010

Hotel Holiday Inn, Belexpo Convention Centre, Belgrade, Serbia