Human and veterinary pharmaceuticals regulation

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

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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

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance Vet. and Pharmacovigilance of vet. Medicinal products in Serbia

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Ministry of Agriculture, Forestry and Water Managment,
Veterinary Directorate, Serbia

Objectives

PhV in Serbia- beginnings

Established system and achieved results

Regulatory PhV requirements

Changes by new legislation

Goals and constraints

Republic of Serbia

1993 –Veterinary faculty- Pharmacology Department, (adverse drugs reactions)

2005 – Agency of Medicines and Medical Devices of Serbia (ALIMS)

Legal basis
Serbian PhV System

Law on Medicines and Medical Devices (O.G. 30/10)

Bylaw defining the manner for reporting, collecting data and monitoring adverse reactions of medicinal products (2006 – under revision)

VOLUME 9B (EU) (Directive2001/82/EC, Regulation EC 726/2004)

Established pharmacovigilance system for the collection and evaluation of information relevant to the risk-benefit balance of medicinal products.

EudraVigilance veterinary(EVVet) Definition

- EudraVigilance is a data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing autorisation of the medicinal products.
- In EU, from 2008. submission of adverse events by MAH to NCA is only accepted via electronic means.
- A major update of EVVet will be initiated to improve data input, to harmonise it with international standards and to include a tracking system for surveillance.

Serbian PhV System
Roles and Responsibilities

Regulatory authority (ALIMS; Ministry of Agriculture, Forestry and Water Management- Veterinary Directorate)

Marketing Authorization Holder (MAH)- Qualified Person for PharmacoVigilance (QPPV)

Health Care Professionals – HCP(veterinary practitioners)

ALIMS rools of organisation VET. PhV

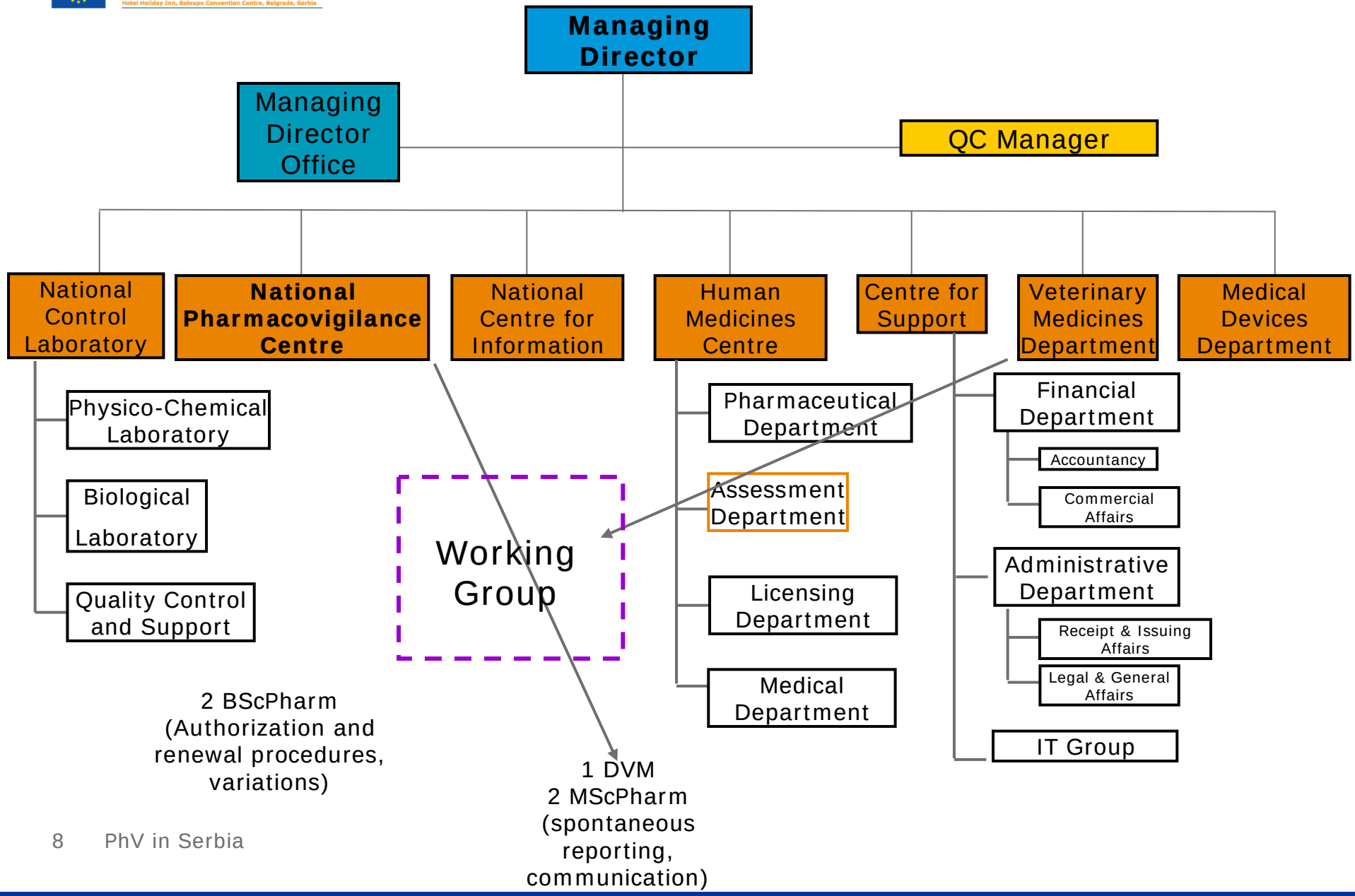
- ALIMS attend sistem of:

  safety animals;

  safety persons who application vet. medicines

  safety consumers of goods of animal origin

  safety enviromental


Managing Director
Managing Director Office
QC Manager
National Control Laboratory
National Pharmacovigilance Centre
National Centre for Information
Human Medicines Centre
Centre for Support
Veterinary Medicines Department
Medical Devices Department
Physico-Chemical Laboratory
Biological Laboratory
Quality Control and Support
Working Group
Pharmaceutical Department
Assessment Department
Licensing Department
Medical Department
Financial Department
Accountancy
Commercial Affairs
Administrative Department
Receipt & Issuing Affairs
Legal & General Affairs
IT Group
2 BScPharm (Authorization and renewal procedures, variations)
1 DVM
2 MScPharm
(spontaneous reporting, communication)

National Pharmacovigilance Centre - NPC

ADRs reporting (database and signal detection, communication, regulatory measures)

Regulatory procedures (authorizations, renewals, variations)

ADRs reporting

Spontaneous reporting

Mandatory

HCP → MAH

HCP ⇅ ALIMS

MAH ⇅ ALIMS

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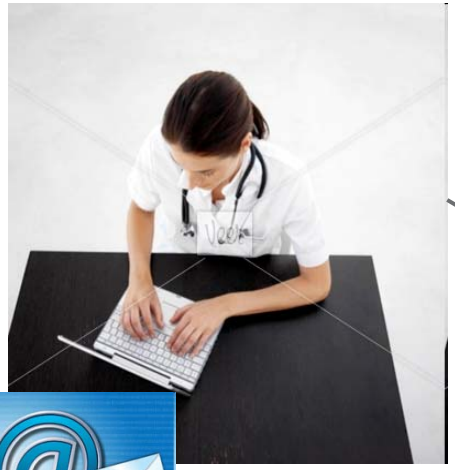
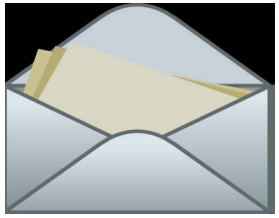
HCP - Health Care Professionals; MAH – Marketing Authorization Holder

ADRs reporting - HCP





Feed-back assessment

Assessment (VICH)

NPC

Inform MAH within 15 days for serious cases

HCP - Health Care Professionals

ADRs reporting - MAH

NPC

Serious case reports from Serbia

Serious unlisted case reports from abroad

} EXPEDITED REPORTING (15 days)

NO gateway for electronic reporting of ICSR

MAH – Marketing Authorization Holder

ESTABLISHMENT OF REGIONAL CENTRES

alims NPC

RC RC RC RC

NPC – National Phv Centre; RC – Regional Centre

REGULATORY PROCEDURES

Authorizations

National procedure

Periodic Safety Update Report (PSUR)

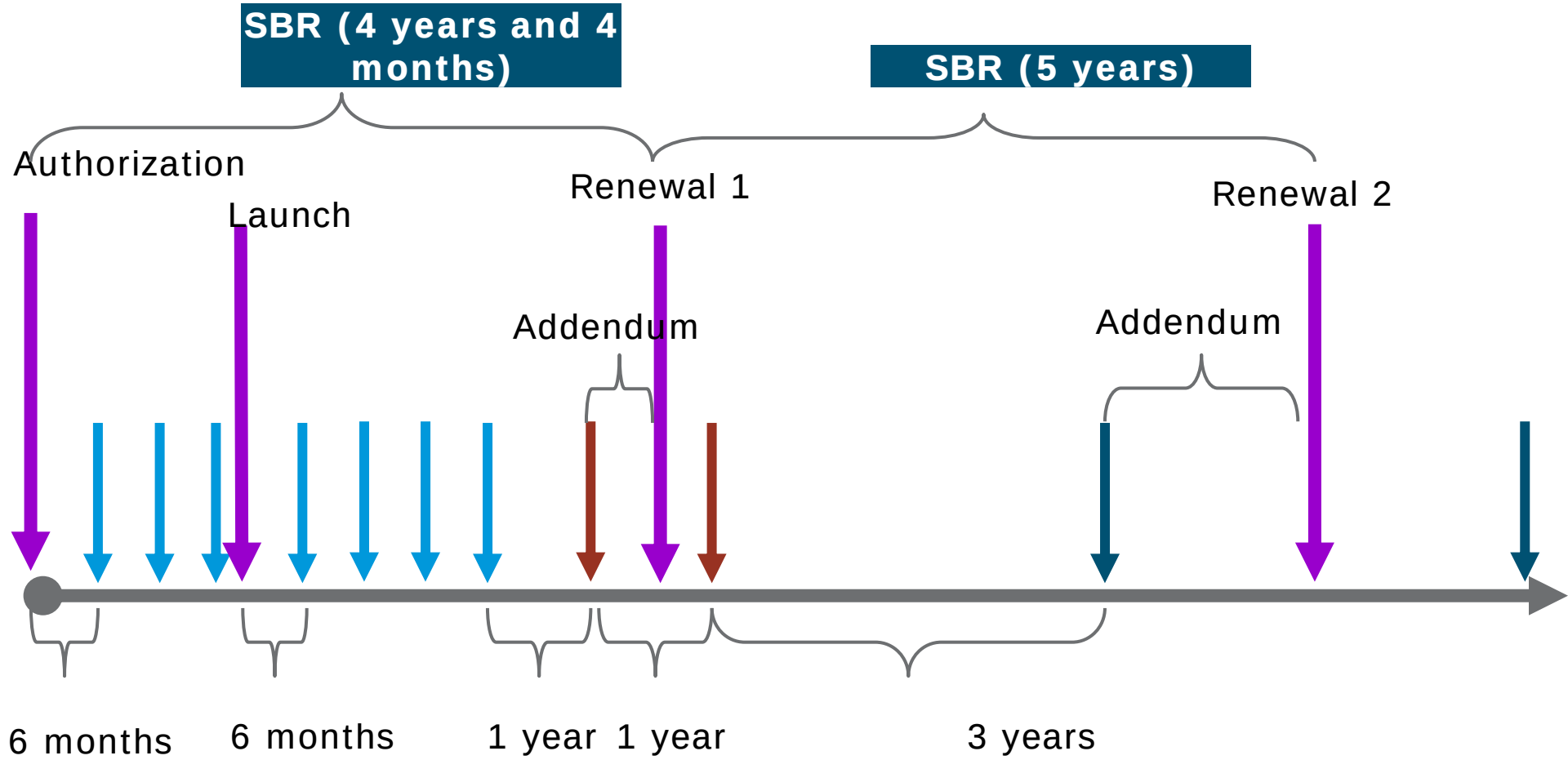
By the Law – full documentation: ...*Postmarketing experience*...

Generic drugs ?

Risk Management Plan (RMP)

Detailed Description of PhV System

PSUR cycle


SBR (4 years and 4 months)
SBR (5 years)
Authorization
Launch
Renewal 1
Renewal 2
Addendum
Addendum
6 months
6 months
1 year
1 year
3 years

Changes of PSUR Cycle

The periodicity of PSUR submission may be amended (lower frequency than once every 3 years is not possible) according to IBD/EU-HBD.

http://www.hma.eu/80.html

Part of application for Marketing Authorization;

Postauthorization phase - variation type II.

Regulatory procedures
Current practice in Serbia

Expedited ADRs reporting (within 15 days - serious ADRs from Serbia and serious, unexpected ADRs from abroad)

PSUR (assessed during authorization and renewal procedure)

Safety variations

Risk Management Plan (RMP) +/-

Revised Serbian regulation defines more requirements in accordance with EU

The applicant for a marketing authorization (MAA) is required to provide a detailed description of PhV system (DDPS);

The risk management system which the MAA will introduce, if necessary;

Updates to the information provided in the DDPS should be made as type II variations.

PhV Inspection in Serbia – M.A.F.W.M.- Veterinary Directorate

To ensure that MAH comply with pharmacovigilance regulatory obligations.

Routine Inspections;

Targeted Inspections – when triggers are identified, e.g. submission of poor quality or incomplete PSURs, inconsistencies between reports and other information sources…

PhV Systems Inspections

Product-Specific Inspections

Instead of CONCLUSION

Problems and Challenges

To improve reporting (quality of reports and annual rate)

PhV Inspection development

Serbia is not part of EU network – Work-sharing assessment reports ?

Crisis Management SOP

Transparency (ALIMS web site)

NPC capacity limits (need to increase number of staff, rationalize processes, keep going with training, QMS)

Challenges in 2010

- Vet PhV was developed with the work programe of the PhVWP and project on work- sharing between NCAs for the assessment of PSURs.
- Further challenges include:
- Finalisation of Volume 9B;
- Development of guidance and concept of Risk management plans for VMP;
- Development of recommendations on the use of data contained in EVVet.

THANK YOU
FOR YOUR ATTENTION