ALIMS

Republic of Serbia
Ministry of Health

Medicines and Medical Devices Agency of Serbia (ALIMS)

Regulatory Performances

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ALIMS

Activities

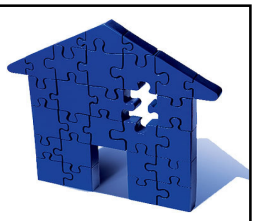
The Serbian Agency (ALIMS) is in charge of:

- Issuing marketing authorisations for medicinal products;
- Performing laboratory quality control;
- Issuing clinical trials authorisations and controlling their conduct;
- Monitoring adverse reactions and decision-making on appropriate regulatory measures due to safety reasons;

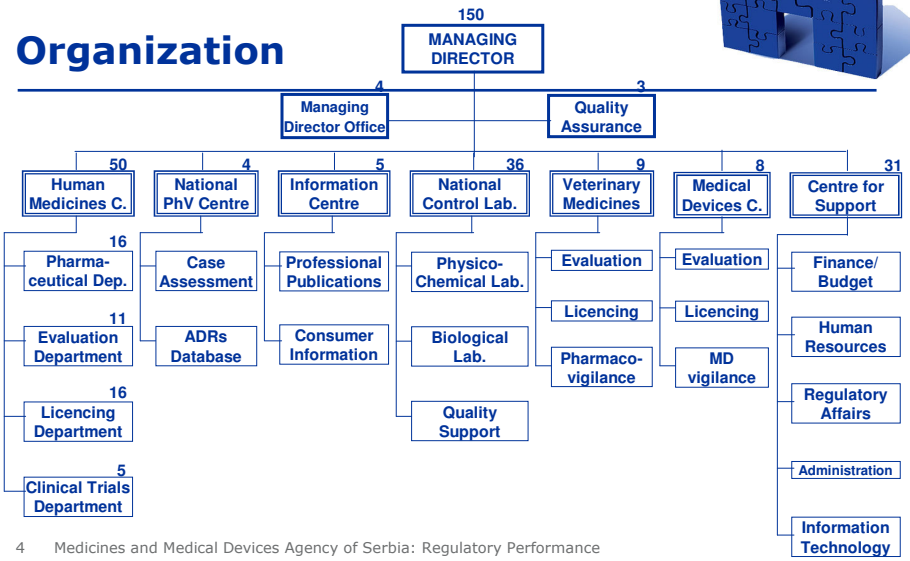
the most important

Activities

- Authorising the imports of non-registered medicinal products;
- Classification of medicinal products;
- Collecting and processing statistical data on medicines consumption;
- Providing information and promotion of rational use of medicines;
- Integration into international networks of medicines information and international agencies associations.



Organization



Human Medicines Authorisation

HUMAN MEDICINES CENTRE (HMC):

Assessment of benefits for patients and potential risks of a medicinal product during its use in clinical practice, in order to grant or not marketing authorisation (MA) is performed within:

1. **PHARMACEUTICAL DEPARTMENT**: quality assessment
2. **EVALUATION DEPARTMENT**: assessment of non-clinical toxicity, clinical efficacy and safety for original medicines, and therapeutic equivalence for generic medicines; postmarketing safety evaluation (PSUR assessment) for original and generic drugs;
3. **LICENCING DEPARTMENT**: formal documentation assessment, SPC/PIL approval and issuing licences to MA holders.

Human Medicines Pharmacovigilance

BEFORE 15th February 2010:

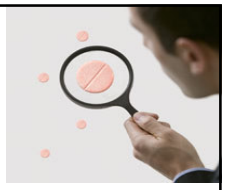
1. Spontaneous reporting and case assessment;
2. Decision-making on regulatory measures;
3. Reporting suspected unexpected serious adverse reactions (SUSARs) from Clinical Trials;
4. PSUR Assessment.

All these activities were performed in the National Pharmacovigilance Centre (NPC).

AFTER 15th February 2010:

1. Spontaneous reporting and case assessment – NPC;
2. Decision-making on regulatory measures – NPC and HMC;
3. Reporting SUSARs from Clinical Trials – CT Department in HMC;
4. PSUR Assessment – Evaluation Department in HMC.

These activities will be performed in the Human Medicines Centre (HMC) and NPC.



Human Medicines Inspection

Medicines and Medical Devices Agency of Serbia and its *Human Medicines Centre* (HMC) with *Clinical Trials Department* is in charge of:

- Clinical Trials Approval and Control (Clinical Trials Inspection)

Veterinary Medicines Authorisation, Pharmacovigilance and Inspection

- **VM Authorisation**
  is performing well within ***Veterinary Medicines Department***, and consists of assessment of formal documentation, quality, efficacy and safety documentation and residues;

- **VM Pharmacovigilance**
  has not been established yet, but as a result of the Twinning Project, draft version of the "Regulations concerning reporting, collecting and monitoring of adverse reactions on veterinary medicines" was prepared;

- **VM Inspection**
  Ministry of Agriculture, Forestry and Water Economy and its *Veterinary Directorate* are in charge of Veterinary Medicines Inspection in Serbia.

Pharmaceuticals Industry

(HUMAN MEDICINES - HM)*

- **Level of domestic industry development**

  ~50% of all marketed HM in Serbia are domestic;
  ~35% of all imported and **65%** of all domestic HM are reimbursed by health-care insurance as essential medicines.

- **Data on products approved by the Agency (ALIMS):**

  in 2008: **695** first licences + **525** renewed licences (**22** refusals)
  in 2009: **681** first licences + **512** renewed licences (**27** refusals)

~25% of all registered HM are original and imported medicines,
~10% of first approvals and **40%** of renewals refer to domestic HM.

*source: ALIMS Database

Pharmaceuticals Industry

(VETERINARY MEDICINES - VM)*

- **Level of domestic industry development is <u>low to moderate</u>:**

2 medium + **4** small size domestic veterinary medicines manufacturers;
~**40%** of all marketed VM and ~**80%** of all sold VM are domestic.

- **Data on products approved by the Agency (ALIMS)**

  in 2008: **37** first licences + **114** renewed licences (**4** refusals)
  in 2009: **81** first licences + **102** renewed licences (**29** refusals)

~35% of all licences (first approvals + renewals) refer to domestic VM.

*source: ALIMS Database

Level of implementation of the acquis communautaire

- **2004 ("Official Gazette RS" No. 84/04).**

  "Law on medicines and medical devices" covers human and veterinary medicines

Areas of interest

HUMAN MEDICINES

- **EWP (Efficacy Working Party)** which provides recommendations on matters relating to the efficacy of HM, as well as preparation, review and update of efficacy guidelines, and support to dossier evaluation;
- **SWP (Safety Working Party)** which provides scientific expertise on all issues regarding the safety of HM, and review of safety guidelines;
- **SAWP (Scientific Advice Working Party)** which provides scientific advice on general and product-specific matters relating to design of

Areas of interest
VETERINARY MEDICINES

List of Meetings for Veterinary Medicinal Products (planned during IPA Project) already covers the most important areas of interest for veterinary medicines, such as Immunologicals Working Party, QWP, EWP, SWP and Pharmacovigilance Inspection.

Therefore, the additional area of our interest is the **Committee for Veterinary Medicinal Products** which provides methodology of the Committee work in issuing final opinion on marketing authorisation granting.