CALIMS
Agencija za lijekove i medicinska sredstva Crne Gore
Agency for Medicines and Medical Devices of Montenegro

AGENCY FOR MEDICINES AND MEDICAL DEVICES OF MONTENEGRO

OVERVIEW, STRATEGY FOR DEVELOPMENT

Presented by: Zeljka Besovic
Head of Marketing Authorisation department

CALIMS
Agencija za lijekove i medicinska sredstva Crne Gore
Agency for Medicines and Medical Devices of Montenegro

MONTENEGRO

- Montenegro is a country of 670 000 inhabitants
- Independent from 2006 (part of Yugoslavia and Serbia and Montenegro previously)
- No institution in charge for QC and MA of medicines before (Institutes for pharmacy in all other republics)
- MA for medicines and medical devices issued on federal level until 2003

Establishment

The Administration for Medicines and Medical Devices started in November 2007 (Law on medicines 2004 (Off. Gazette No 80/04)

Since 1 January 2009 the Agency has been established as an independent regulatory authority, in accordance with the Law on medicines 2008 (Off. Gazette No 18/08)

Competencies in MA/import licences for human and veterinary medicines, CT, PhV, GMP, GCP inspections, MD, narcotic drugs

First Marketing Authorisations for medicine issued on 18.03.2009.

Organisation

- 25 employees in total;

-Administrative Sector: 7 employees

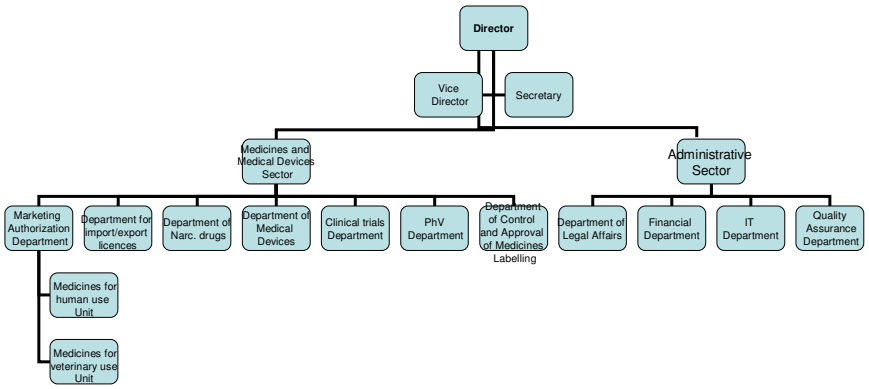
-Medicines and Medical Devices Sector: 18 (pharmacists, MD, DVM, DDM, chemist)

-More than 140 experts (not only from Montenegro)

- Advisory Commitee for MA, Safety issues (first topic – pandemic vaccine)

Agency reports to: MoH, Ministry for agriculture, National Assembley

Organization chart



PhV, inspection, MA

- Department for pharmacovigilance (spontanous reporting-health institutions (appointed co-ordinators), mandatory reporting by MAH
- Inspection in co-ordination with Ministry of health (Ministry in charge of market surveillance)
- Authorisation of the medicines (national procedure in accordance with Law on medicines harmonised with 2001/83 EC)
  - exeptionaly-faster procedure for medicines that have MA in EU

Pharmaceuticals Industry

- Two generic manufacturers in Montenegro –human medicines;
- No manufacturers of veterinary medicines
- Products that are licensed / imported:

MA procedure at the beginning, only 147 issued so far (about 500 in procedure).

Majority of medicines still being imported without MA (based on MA issued in EU and ex Yugoslav republics)

Level of implementation of the acquis communautaire

Legal regulations in field of medicines and medical devices is in main parts harmonized with EC directives

•Law on medicines (Off. Gazette No. 80/04 and 18/08)-

harmonization with consolidated 2001/83/EC,

2001/20/EC, 2001/82/EC)

•Regulations–further harmonization

MA procedure, pharmaceutical testing, QC adopted

(PhV, CT, Labeling in the procedure of adoption)

Areas of interest

- participation in different EMA WG
- getting further regulatory knowledge in order to improve national procedures and further harmonise with *acqui*
- Strengthening collaboration with other CC and PCC also participating in the project
- Access to EMA database

Challenges

Small market (especially for veterinary medicines)

Development of human resources (scientific and regulatory expertise)

Control laboratory (using already limited capacities of contracted laboratories – Agencies in the region)

Further Development of PhV system

Not enough of trained inspectors within the MoH and Agency

Improvement of administrative capacities

Lacking of adequate infrastructure (facilities)


PRECISE MAP OF MONTENEGRO
CALIMS
Agencija za lijekove
i medicinska sredstva Crne Gore
Adriatic Sea