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

Marketing Authorisation and Quality Control of medicines

Farmacija i zdravstvo
Beograd
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Statistics

Area - 13,812 km²

Population - 684,736 (Estimation 2007)

Currency - Euro (€)

Unemployment rate - 12%

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Pharmaceutical market

- 210 pharmacies

168 privately owned/42 state owned (community pharmacies) - medicines from reimbursement list available on prescription/ no internet pharmacies

- 30 wholesalers
- 2 manufacturers
- 300 pharmacists with licenses in Montenegro
- procurement of medicines for public health institutions/ this year estimated to 23 millions (euro). No relevant statistics for privately owned sector yet

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Agency Establishment

The Administration for Medicines and Medical Devices started in November 2007 in accordance with the Act on medicines, 2004 (Off.Gazette 80/04)

Since 1 January 2009 the Agency has been established by the Government of the Montenegro as independent regulatory authority, in accordance with the Act on medicines, 2008 (Off.Gazette 18/08)

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Competencies

- Agency: Marketing Authorisation of medicines (human and veterinary), Pharmacovigilance, import of medicines without MA, Clinical Trials, Quality Control, Register for Medical Devices

New competence in 2011: reference pricing

- MoH: Inspection

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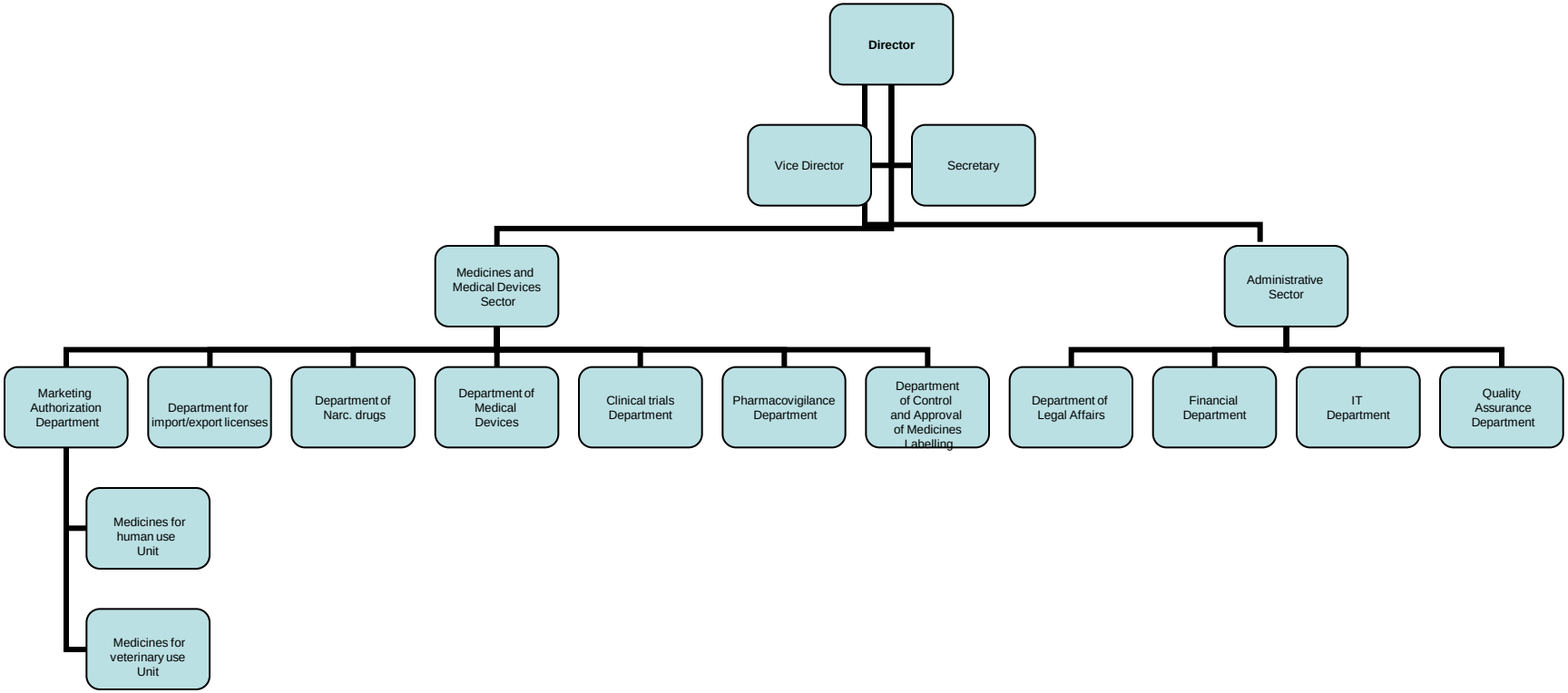
Organization chart



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Organisation

- 28 employees in total;

-Administrative Sector: 6 employees

-Medicines and Medical Devices Sector: 22 (pharmacists, MD, DVM, DDM)

A list of over 150 experts from Montenegro and region

- Agency reports to:

Ministry of health of Montenegro/ National Assembley

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Marketing Authorization procedures

The Act On Medicinal Products (Off. Gazette 80/04, 18/08 and 34/10), harmonized with 2001/83/EC

Regulation on Granting the MA (2009)

- National procedure 210 days after formal assessment
- Faster procedure for European authorisation introduced

Faster procedure 90 days (Assessment Report from EU procedure required)

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Evaluation in MA procedure

- national legislation (Act and Regulations)

- EMA guidelines

-Assessment reports from Serbian, Bosnian, Croatian and Macedonian Agencies or EU countries

No re-evaluation by CALIMS – faster procedure

-strengthening capacities for internal assessment within the Agency and associate experts from Montenegro trough cooperation with neighbouring countries and EMA IPA project

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Quality Control

Act On Medicinal Products/Regulation on QC

1.QC of the MP before granting of MA and placing on the market of the MP

2.QC of the MP after the granting of MA and placing on the market of the MP

taking random samples/solving identified problems/testing the quality MP with increased risk (vaccines, blood products…)

3.QC of magistral and galenic MP

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Quality Control

Act On Medicinal Products/Regulation on QC

1.Laboratory testing

performed in contract laboratory if required (National Control Laboratory ALIMS)

2.Documentation quality control of the imported MP on the basis of the quality certificate issued by the EU manufacturer or an EU Competent Authority for QC of the MP

lab testing is obligatory for each batch release of vaccines, sera and products from blood

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Quality Control before issuing MA

Laboratory testing not necessary:

Batches already tested in Agencies that CALIMS has Agreement with or EU authority for QC

Batch release by the EU GMP certified manufacturer

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Data and market exclusivity

According to Montenegrian Legislation a generic medicinal product may be authorised 10 years after the first authorisation of the reference medicinal product (aditional 1 year for new indication – in new Low on medicines 2011)

Reference Product needs to be authorised

in Montenegro, in an EU member state or in

any country with the same requirements as

Montenegro based on the full application.

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Products that are licensed / imported:

Marketing authorisation started in 2008
First Marketing Authorisations for human medicine issued in March 2009.

200 MA issued so far

1000 more applications are under evaluation.

No applications for veterinary medicines yet.

Majority of medicines still being imported with import licence

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Latest development

- Law on medicines has been amended in June 2010 (Off. Gazette 34/10).

Art. 110b

After 31st of March 2011, only medicines with CALIMS MA or confirmation of complete application issued can be marketed. All other medicines will have to obtain MA from CALIMS before being placed on the market.

- new guideline for applicants for MA available on http://calims.me/Regulativa-uputstva.html

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Activities

-ISO certification 9001:2008 completed successfully

-bylaw on Clinical Trials and PhV

- further harmonisation with EU regulations trough New Law on medicines in 2011

- preparing for the reference pricing

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Regional initiatives

- Even better cooperation with Agencies in the region trough agreements signed and future projects for CALIMS staff education.
- Further exchange in Assessment Reports between the Agencies

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website

- Our website: http://calims.me
- Low on Medicines and

Low on Medical Devices

available in English language

- Regulations and guidance

in national language only