BOSNA I HERCEGOVINA
Agencija za lijekove i medicinska sredstva

БОСНА И ХЕРЦЕГОВИНА
Агенција за лијекове и медицинска средства

AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES OF BOSNIA AND HERZEGOVINA

Presented by: Biljana Tubić
Position/Organisational Head of pharmaceutical department

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Agency structure

The Agency was established on May the 1st last year, but before than Bosnia and Herzegovina had two entites institutions for medicines and medical devices (Ministry of healcare Of Republic of Srpska from 1998, and Drug Agency of Republic of Srpska from 2002 year, and for Federation BiH Ministry of healcare and Control laboratory from 1998)

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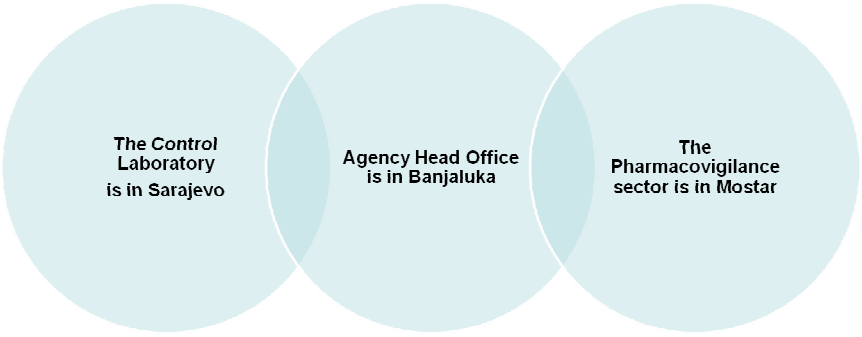

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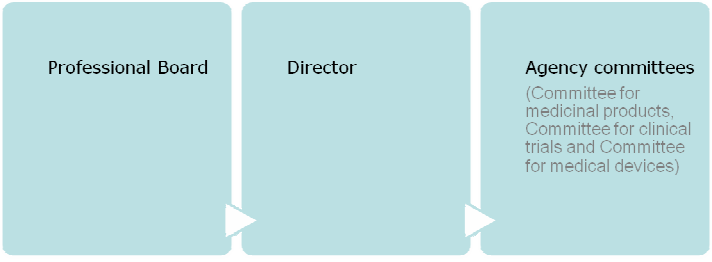
Agency structure

The Agency corporate bodies are:



Agency structure

✓ The number of employees is 96;

✓ The Agency is under the jurisdiction of the Ministry of Civil Affairs of Bosnia and Herzegovina;

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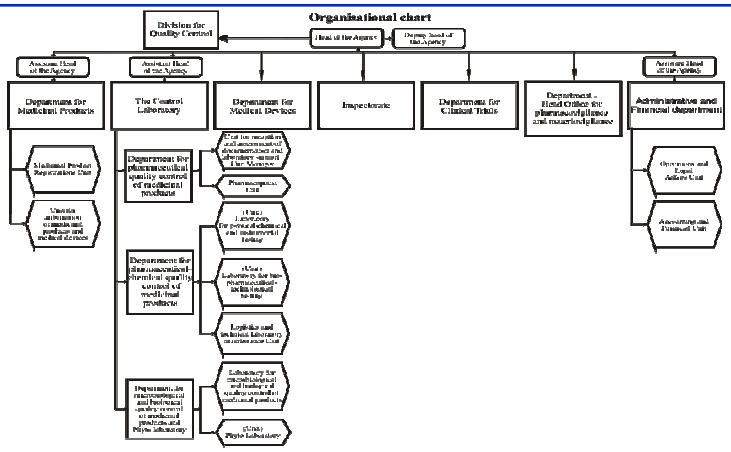

Pharmacovigilance

We are in the stage of forming the Head Office of Pharmacovigilance in Mostar
(the activities of this sector are currently being performed by the Center for medicines of the Institute for pharmacology and toxicology, University of Sarajevo).

By law, the marketin authorisation holder has the duty to inform the Agency of any adverse events or effects of the medicinal products and to periodically submit PSUR.

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Inspection

Within the Agency inspectors from the following areas should work: GMP, GDP, GCP, GLP.

The inspection still has not started with its work, as we are currently awaiting consent to employ inspectors. Until then, based on the decision of the Professional Board, the Director of the Agency has appointed inspectors among the employees.

Authorisation of the medicines

Medicinal products may be marketed, if the following conditions are met:

✓The medicinal product authorisation has been issued,

✓The products are manufactured in accordance with valid documentation, and

✓Each batch of the imported/manufactured medicinal product has been tested for quality.

The procedure lasts 210 days.

Documentation is received in CTD-format (*Common Technical Document*).

The procedure involves assessment of the quality, efficacy and safety of the medicinal product by experts from Agency and involves decision of our Committe for medicines.

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Authorisation of the medicines

The authorisation for marketing medicinal products is not required for: radionuclides in a closed radioactive source, whole blood, blood plasma or blood cells of human origin, except for plasma prepared in the manner which has included industrial processing, medicinal products which are imported emergency treatment of individual patients or if the import has been requested by a public health care facility.

Authorisation of the medicines

In exceptional circumstances (epidemics, etc.) the Director of the Agency may approve marketing authorization without implementation of the whole procedure, and this approval is valid until the special circumstances cease to exist.

The marketing authorisation is issued for a period of 5 years.

The integral part of the marketing authorisation are the approved summary of the main characteristics of the medicinal product (SmPC), the information for patients (PIL) and the packaging of the medicinal product.

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Authorisation of the medicines

Renewal of the marketing of the medicinal product authorisation:

The application is to be submitted 6 months prior to the expiry of the authorisation.

The legal timeframe for renewal of the authorisation is 90 days.

Renewal-administrative act (periodic reports about safety of the medicinal product - PSUR – as a leading document).

Variations) of the marketing authorisation (Type I.A and I.B (“tell and do”) and Type II).

Pharmaceuticals Industry

✓ We have issued approximately 3000 authorisations for marketing medicinal products on the B&H market.

✓ We recognased MA which issued by enttites institucions

✓ The largest number of authorised medicinal products is being imported.

✓ There are 3 domestic manufacturers of medicines:

- ✓ BOSNALIJEK d.d. Sarajevo,
- ✓ HEMOFARM d.o.o. Banjaluka,
- ✓ FARMAVITA, Sarajevo

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Level of implementation of the acquis communautaire

The Medicinal Product and Medical Devices Act of Bosnia and Herzegovina has been drafted in accordance with 2001/EC/83 and with cooperation of a WHO expert.

Regulations (sublegal acts) are also drafted in accordance with the applicable European regulations (valid directives and guidelines), with consultations from the WHO expert.

Our Control Laboratory is in OMCL nettwork.

We are in process of implementation of twininnig project.

We have nominate members in committies of EDQM.

Areas of interest

✓Harmonisation of legal regulations and sublegal acts with valid EU directives and guidelines;

✓Monitoring and adopting the most current standards for testing and assessing quality, safety and efficacy of medicinal products;

✓Monitoring and adopting the most current standards for evaluating registration of documentation;

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Areas of interest

✓Cooperation with all relevant institutions in the area of medicinal products and medical devices in B&H, the region and the EU.

✓Establishment of adequate inspection and supervision of manufacturing and wholesale marketing of medicinal products and medical devices.

✓Inclusion in the EudraVigilance network.
✓Our website: www.alims.gov.ba