



**MALMED**

MACEDONIAN AGENCY FOR  
MEDICINES AND MEDICAL DEVICES

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# STEP FORWARD OF MACEDONIAN AGENCY

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Director of MALMED



# Establishment of the Macedonian Agency for Medicines and Medical Devices

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- Founded on 16 September 2014
- Law on Medicines and Medical Devices
- Independent regulatory authority of the state administration





# Establishment of the Macedonian Agency for Medicines and Medical Devices





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# Bureau of drugs





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# OMCL LABORATORY





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# LEGISLATION

- 4 Laws
- 42 Rule books for medicines
- 13 Rule books for medical devices
- 18 Applications for medicines



# COOPERATION

- EMA (IPA project 2008-2014, GMP, GDP)
- EDQM
- Council of Europe (MEDICRIME convention for counterfeit medicines)
- TAIEX
- WHO
- WTO
- EGA (2009 Symposium for generic medicines in Ohrid)
- ISPOR (Internacional Society for Pharmacoeconomics)

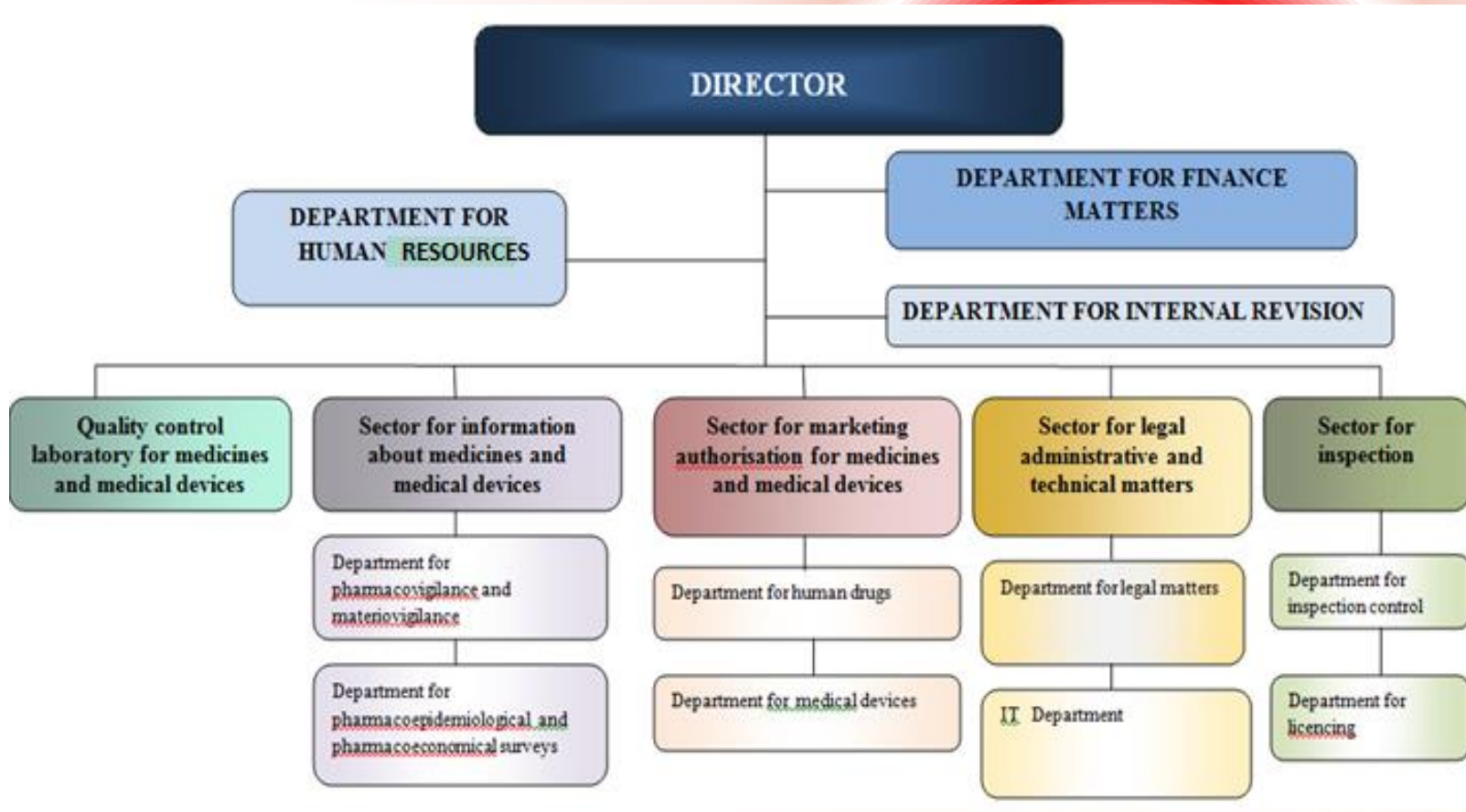




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# Agency for medicines and medical devices



# Agency for medicines and medical devices

- From the date of establishing the Agency, the Bureau for drugs does not exist
- Abbreviated name of the Agency **MALMED**





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# Agency for medicines and medical devices

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# NEWS - Transparency in work

**[lekovi@zdravstvo.gov.mk](mailto:lekovi@zdravstvo.gov.mk)**

- write
- ask
- get information
- submit appointments for consultation and submit documents
- show us
- remind us





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# ACTIVITIES

- **New 15 employees**
- **Revision of the Law on medicines and medical supplies**
- **Project for rational use of medicines**
- **Project for pharmacies / pharmacy stations in settlements up to 3,500 inhabitants**
- **Project for movable pharmacies in settlements up to 1,000 inhabitants**
- **Project for new drugs on the list of drugs that are covered by the FZOM**







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# ACTIVITIES

- **Reviewing the essential list of medicines**
- **Project for Braille letter in coordination with MLSP**
- **Control in pharmacies**
- **Developed a Rulebook for internal organization**
- **Developed a Rulebook for systematization of working posts**
- **Certification according to ISO 9001:2008**





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# ACTIVITIES

- **Project for new drugs on the list of drugs that are covered by the FZOM**
- **Reviewing the essential list of medicines**
- **Project for Brail letter in coordination with MLSP**
- **Control in pharmacies**
- **Development of a strategic plan**
- **Preparation of Action Plan**



# Plan in the near future

**Implementation of the READY!™ (Regulatory Affairs diary) - allows the regulatory agency transparent and organized leadership and management which are all currently in processes at the Agency**



# ROLE OF THE AGENCY

- Quality, safe, efficient and effective (post registration in real life) Medicines and Medical Devices
- In our focus is the health of all residents of RM



# RECOMMENDATION

**RESPECT THE LEGAL ACTS IN  
COMPETENCES OF THE AGENCY**



# Instead of conclusion

**BE A PART OF THE ESTABLISHING  
OF THIS AGENCY**





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**THANK YOU**

