



REPUBLIC OF MACEDONIA

Bureau for Medicinal products Organization, scope of work

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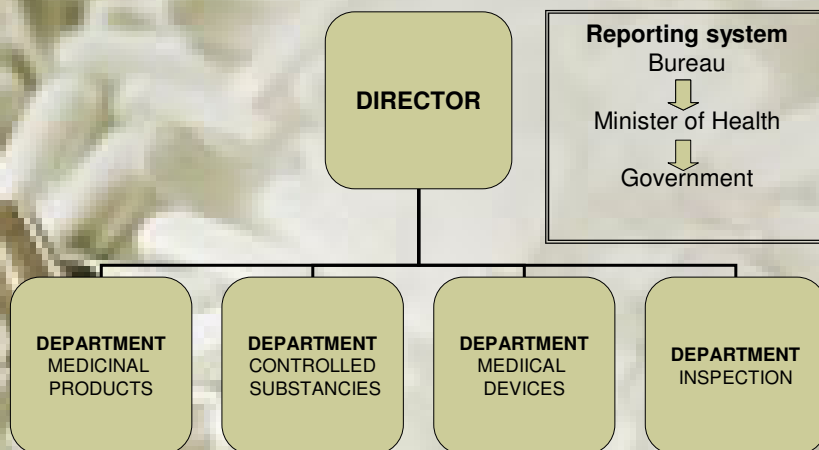
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Organization Chart



Total of 25 employees + 35 external experts



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Organization

□ Pharmacovigilance system

- Rulebook
- Healthcare providers



- National Pharmacovigilance Center



- Sub-Department, Bureau

□ Inspection

- GMP inspection
- GCP inspection
- Inspections of wholesalers and pharmacies



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Organization

□ Marketing Authorization

- National procedure, CP, DP, MRP
- authorized QC laboratories
- Institute for preclinical and clinical pharmacology and toxicology

- **Rulebook: Marketing authorization of medicinal products, Renewal, Variations**
- **Medicinal Products Committee**



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Pharmaceuticals Industry

□ Domestic manufacturers (5)

- GMP inspection (performed by: MoH-GMP Committee, GMP inspections from EU countries, others)
- Production of generics

□ Foreign Pharmaceutical companies (130)

(Present the biggest well established Companies, world wide excepted)



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Pharmaceuticals Industry

☐ Products licensed

- Total number of products licensed - 3150
- Domestic companies - 27%
- Foreign companies (EU countries, USA, Switzerland, Japan) -70%
- others - 3%



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Implementation of the Acquis Communautaire

- ☐ Law for Medicinal Products and medical devices (OG 106/07)
- ☐ 37 Rulebook (published in OG)
 - ☐ 26 on medicinal products
 - ☐ 11 on medical devices
- ☐ Website of Bureau
- ☐ www.reglek.com.mk
- ☐ Implementation phase



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Challenges, solutions, outcomes

Challenges	Solutions	Outcomes
INTERACTIVITIES	Joint Committees/Working groups Communication	Weaknesses/strengths Established orphan medicines working group
Biro for Ph. ↓ Agency for Medicines	Best EU practices EMA advice	National Agency for Medicines to be established in 2010
Inspection GMP, GSP	Development of human resources Training capacities built	Strengthened Human capacities
Developing Pharmacovigilance System	Development of human resources Training capacities built	Strengthened Human capacities



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THANK YOU

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