



KOSOVO MEDICINES AGENCY



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Chief Executive Officer

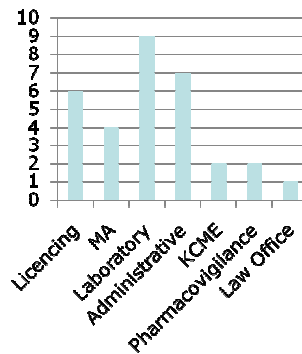
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Organisation

- Agency was established in 2000 under the name KDRA.
- In 2002 with an Administrative Instruction the name is changed into Kosovo Medicines Agency

Departments





The Agency is in charge of

- Issuing of Wholesale/Pharmacy/Manufacturer Licenses
- Issuing import licence for medicinal product and medical devices
- Issuing MA for medicinal products and medical devices,
- Variation/Renewal/approval of maintenance of existing MA
- Quality assurance and control of medicinal products placed in Kosovo;
- Monitoring adverse reactions of medicinal products



Pharmaceuticals Industry

- There are two manufacturers in Kosovo;
- Products registered until 2009 are 775.
- 1127 products that have Authorization for import



Level of implementation of the *acquis communautaire*

harmonisation with the ***acquis communautaire***

- Law No. 2003/26 on Medicinal Products and Medical devices.
- Administrative Instruction No.2008/04 on MA of Medicinal products placed in Kosovo.
- Administrative Instruction No.2006/08 on Pharmacovigilance



Areas of interest

- Centralised procedure-Human;
- Authorisation of generic products in EU;
- Special areas: Pediatrics, Orphan drugs, scientific advice.
- Preparatory steps before accession in the EU;
- Pharmacovigilance