

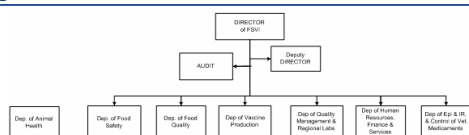


VMP control in Albania

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FSVI Director



Organisation



- FSVI was founded in 1928;
- Staff 147 (Expert/Technicians/Administrative);
- FSVI is depended from MoAFCP and Reports to the Veterinary Directorate in relation of VMP;

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Pharmacovigilance

- Veterinary Directorate
 - Within VD is established the Commission for the control of VMP. The commission have the wrights to register VMP based on reviews of controlled VMP documentation;
- State Lab for VMP Control
 - The lab controls all VMPs imported/localy produced and prepares the technical documentation and submit it to the commission.
- Regional Veterinary Inspectorate
 - Controls the trade of medicinal products, narcotics and other medical substance used in veterinary medicines as well as suspend them if they do not fulfill the legal criteria.

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Pharmaceuticals Industry

•Industry

- State industry is represented by FSVI which is the only Bio-producer in the country;
- Private sector industry for VMPs is represented by only one producer RADOFarma establishment in Shkodra District;
- In general all sort of VMPs are imported/ locally produced and registered. Except cases of VMPs which are forbidden by national law or EU regulations.



Level of implementation of the acquis communautaire

Up to now the Albanian legislation is approximated in regard to the following EU legislation:

- 81/851/EEC
- 81/852/EEC
- 88/320/EEC
- 2309/93/EEC
- The work is ongoing in order to approximate the full EU legislation related to VMPs;



Areas of interest

- Upgrading the national registration to EU levels;
- Technical exchange with EMEA in order to upgrade and ameliorate our working standards;
- Collaboration in practical and scientific activities;
