MINISTRY OF HEALTH OF THE REPUBLIC OF SERBIA

MEDICINES AND MEDICAL DEVICES LEGISLATION AND SURVEILLANCE

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MINISTRY OF HEALTH OF THE REPUBLIC OF SERBIA

Organisation

MINISTRY OF HEALTH: National Health Policy, compilation of Draft Law and other regulations regulating Health care, Health insurance, Medicines and Medical Devices, issuing authorization for manufacture and wholesale distribution, performing surveillance of the implementation of the Law on medicinal products and medical devices as well as regulation passed in order this very law to be implemented (inspection of manufacture and marketing of Medicines and Medical Devices for human use)

MINISTRY OF AGRICULTURE: specific regulations, authorizations and inspection related to veterinary products

MEDICINES AND MEDICAL DEVICES AGENCY: MA, pharmacovigilance, clinical trials, laboratory quality control

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Pharmaceutical Inspectors are authorized:

• to control the implementation of GMP, GLP и GDP;

• to determine the fulfillment of conditions for manufacturing, galenic product, medicines marketing and testing in order of issuing manufacturing authorization and wholesale distribution of medicines and medical devices;

•to place a ban to an enterprise, or the other legal entity if it does not meet the conditions regulated by this law and regulations;

• to order an enterprise, or the other legal entity to harmonize its business; to prohibit, stop marketing, or order withdrawal of medicinal products from the market,

• control of advertising and promotion of medicinal products, pharmacovigilance, sampling

•if an inspector has estimated that there has been made a criminal offence, economic crime or violation by acting or non-acting of the entity, it is obliged to denounce it to the competent authority, i.e. to bring the request for starting the violation proceedings

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Pharmaceuticals Industry

MEDICINES MANUFACTURERS..... **25**

MEDICAL DEVICES MANUFACTURERS..... **70**

WHOLESALERS OF MEDICINES AND MEDICAL DEVICES..... **557**

PHARMACIES

- public/statements..... **593**
- public/private.....**1360**
- hospital.....**85**

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NATIONAL LEGISLATIVE

2004. – Law on Medicinal Products and Medical Devices ("The Official Gazette of the Republic of Serbia", No. 84/04), preparation supported by EU project (EAR)

This Law determines the conditions and the control of the manufacture, marketing and testing of medicinal products and medical devices used in human and veterinary medicines, establishes the Serbian Agency for Medicinal Products and Medical Devices, defines the conditions and the procedure for granting the marketing authorization for medicinal products and medical devices, and regulates other issues relative to this domain.

23 Rulebooks for the implementation of this Law **issued**

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Level of implementation of the acquis communautaire

List of Directives used in harmonizing currant national law:

-The Rules Governing Medical Products in the European Union; Volume 1, Pharmaceutical legislation: Medicinal Products for Human Use;-Directive 2001/83 EC Amended by Directive 2002/98 EC, Amended by Commission Directive 2003/63 EC, Commission Directive 2004/24 EC, Commission Directive 2004/27 EC, The Rules Governing Medical Products in the European Union, Volume 5, Pharmaceutical legislation: Veterinary Medicinal Products, Directive 2001/82 EC, Directive 2004/28 EC

The Law and relevant Regulations are in a certain parts harmonized with EU Directives concerning medical devices: 93/42 EEC (General Medical Devices), 90/385 EEC (Active Implantable Medical Devices), 98/79 EC (In vitro Diagnostics Medical Devices).

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Level of implementation of the acquis communautaire

The Final Draft of new Law on Medicines and Medical devices is in adoption procedure (preparation supported by Twinning project, 2007-2009.), harmonized with:

Directive 2001/83, amended and adopted with Directive 2002/98, 2003/63, 2004/24, 2002/27, 2008/29, 2009/53, 2009/120, and Regulation (EC) 726/2004 and 1394/2007 – for Medicines for human use,

Directive 2001/82, amended and adopted with Directive 2004/28, 2009/9, 2009/53 and Regulation (EC) 726/2004, 2377/90 – for Medicines for veterinary use, Directive EU 90/385. 93/342 and 98/79 – for Medical Devices,

Directive 2003/94 GMP Guideline, Directive EU 2004/94 – for non clinical trials, Directive 2001/20, 2005/28 and GCP Guideline, GDP Guideline 94/C и 63/03

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Level of implementation of the acquis communautaire

Further harmonization of the Law on Medicines and Medical devices with EU legislation, especially regarding:

• New or improved definitions (medicines, advanced therapy medicines, counterfeit medicines, Marketing Authorization Holder completely harmonized with EU terminology regarding rights and obligations, CP for MA, global MA, well established use, fixed combination medicinal products, informed consent applications, QP responsibilities and license, etc)

• Data exclusivity, sun-set clause, GMP and GLP Certificates,

• Medical devices Licensing (new system of CE mark instead of MA system), post marketing surveillance and vigilance of medical devices

• Quality control (laboratory QC of each imported batch of medicines and medical devices)

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Areas of interest

- pharmacovigilance inspection, and GLP inspection are in start up position (PhV WG)
- needs for continuous training in GMP and GDP inspection in order PIC/S application (GMP/GDP WG)
- rulebooks in order new Law on Medicines and Medical Devices to be implemented (QWP)
- evaluation of quality, safety and efficacy data in a purpose of medicines pricing (cost- benefit analysis)
- assessment of healthcare technologies (cost- effectiveness analysis)
- rational pharmacotherapy (pharmacoeconomic evaluation)
- pharmacovigilance monitoring in healthcare system (SWP)

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THANK YOU FOR YOUR ATTENTION