

Appendix 10. List of laws and bylaws to be amended, replaced, cancelled

LEGAL ACT	TYPE OF CHANGES
Law on Medicinal products	Establish new Agency in the form of central governmental body with special status.
	Introduce specific rules of subordination and accountability for new Agency.
	Determine the status of employees (leadership, administrative staff and experts) of new Agency.
	Introduce higher level of salaries for employees having civil servants status compared to the regular level established by the Law On Civil Service.
	Stipulate detailed provisions on procedure of competitive selection of the head of new Agency.
	Add clear rules regarding criteria for advisory/scientific council of the registration body involvement in the procedure of registration, its composition etc.
	Set up clear individual responsibility of experts for the decisions taken in the sphere of registration.
	Introduce provisions on public access to information through the portal of new Agency for applicants and for general public.
	Add specific requirements on conflict of interest for experts of new Agency.
	Add provisions on transfer to electronic procedures of registration of medicinal products.
	Establish new rates of registration fees.
	Establish that the certain percent of the registration fees payable by the applicants to the state budget, shall be directed to financing the new registration Agency.

	Provide MoH with the right to reduce fees for registration of important medicinal products (e.g. orphan, with pediatric indications etc.), as well as for small and medium enterprises.
Law on Prevention of Corruption, Law on Medicinal Products	Add specific category “experts of new Agency” being subjects to declaration of income.
Fundamentals of the Legislation of Ukraine on Healthcare	Substitute MoH as a governmental body responsible for state registration of medicinal products with new Agency.
Law on Medicinal Products	
Law on Advertising	
Tax Code of Ukraine	Substitute MoH as the governmental body responsible for approval of clinical trials with new Agency.
Criminal Code of Ukraine	The wording of Article 321(2) of the Criminal Code should be amended to provide genuine safeguard for the proper course of medicines registration procedure.
Budget Code of Ukraine	Introduce amendments to the Budget Code of Ukraine in order to allow financing of UMA on the conditions, established in the Plan
Law of Ukraine On Sources of Financing of Governmental Authorities	Amend provisions of the said law in order to allow financing of UMA.
Decree of the Cabinet of Ministers of Ukraine of 26 May 2005 No. 376 “On Procedure of State Registration (re-registration) of Medicines and State Registration (re-registration) Fee”	Align with the provisions of the amended laws.
Decree of the Cabinet of Ministers of Ukraine of 12 August 2015 No. 647 “On Approval of the Regulation on the State Administration of Ukraine on Medicinal Products and Narcotics Control”	Align with the provisions of the amended laws.
Decree of the Cabinet of Ministers of 2 October 2013 No. 753 “On Approval of the Technical Regulations on Medical Products”	Align with the provisions of the amended laws.
Decree of the Cabinet of Ministers of Ukraine of 2 October 2013 No. 754 “On Approval of the Technical Regulations on Medical Products for In-vitro Diagnostics”	Align with the provisions of the amended laws.
Decree of the Cabinet of Ministers of Ukraine of 2 October 2013 No. 755 “On Approval of the Technical Regulations on Implanted Medical Products”	Align with the provisions of the amended laws.
Order of the Ministry of Health of Ukraine of 26	Align with the provisions of the amended laws.

August 2005 "On Procedure for Conducting Expert Evaluation of Registration Information for Medicines Submitted for State Registration (Reregistration) and Expert Evaluation of Information on Changes to Registration Information during Validity of Registration Certificate"	
Order of the Ministry of Health of Ukraine of 23 September 2009 No. 690 "On Approval of the Procedure for Conducting Clinical Trials of Medicinal Products and Expertise of Materials for Clinical Trials and the Model Regulations on the Ethics Committee"	Align with the provisions of the amended laws.
Order of the Ministry of Health of Ukraine of 27 December 2006 No. 898 "On approval of the Pharmacovigilance Procedure"	Align with the provisions of the amended laws.