PROBLEMS OF VETERINARY MEDICINES PRODUCTION

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In this article we demonstrate the necessity to harmonize the Ukrainian legal framework regulating the manufacture and distribution of veterinary medicines with legal documents of the EU. We provide a specific list of regulatory documents which need to be harmonized or rescinded, and analyze the advantages as well as the risks of transition to the legal framework of the EU. The list includes the Law of Ukraine “On veterinary medicine” (Chapter 10, 11, Articles 63-78), Order of State Department of Veterinary Medicine from 04.12.2002 № 70 “On approval of the Instruction on storage, support, issue, import into Ukraine and export of strains of microorganisms …”.

Order of State Department of Veterinary Medicine from 13.08.2002 № 44 “On approval of Rules of transportation and storage of veterinary medicines, substances, complete animal foods, animal food supplements and means of veterinary medicine in veterinary pharmacies and their structural divisions, depots and storehouses etc.”,

Order of State Department of Veterinary Medicine № 39 from 28.05.2003 “On approval of Provisions on conducting state control and supervision of the quality of veterinary medicines, substances, complete animal foods, animal food supplements and means of veterinary medicine used in Ukraine”*, Order of State Department of Veterinary Medicine from 10.03.2005 №21 “On approving the Procedure of conducting certification of Biological Control Departments of the veterinary immunobiologicals manufacturers and the Procedure of conducting certification of the manufacturing of veterinary immunobiologicals”, Order of State Department of Veterinary Medicine from 08.08.2005 № 68 “Guidelines on conducting certification of the manufacturing of veterinary immunobiologicals”,

Decree of the Cabinet of Ministers of Ukraine №1349 from 21.11.2007 “On approval of Provisions on the state registration of veterinary medicines”, Order of the
State Committee of Veterinary Medicine of Ukraine from 14.07.2008 №133 “On approval of forms for applications, list of materials and compilation procedure of the registration dossier”, Decree of the Cabinet of Ministers of Ukraine from 01.07.2009 №652 “On approval of Procedure of issuing the authorization of importation into the territory of Ukraine of animals, products of animal origin, reproductive material, biological products, pathological material, veterinary medicines, substances, animal food supplements, premixes and animal foods”.

It is concluded that the necessity of implementing the European Union standards for the manufacturing and distribution of veterinary medicines (GMP and GDP) is dictated by the current requirements for the development of the manufacturing industry and for the guaranteed quality of veterinary medicines. The development of relations between government institutions on the one hand and manufacturers and distributors on the other is, in current conditions, a painstaking work of elaborating national legal regulations and their harmonization with the legal framework of the EU. This work is no longer possible without an active participation of non-government organizations and society in general.

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