LIST

Legal acts reletad to activities of Good Practice Inspection department in the Scientific Center of Drug and Medical Technology Expertise after academician Emil Gabrielyan

1. *«Law on medicines» of Republic of Armenia (registration number in justice system of RA №HO-86 (signed by Republic of Armenia President on 13 June, 2016) adopted on 17/5/2016.*
2. *«Law on licensing» of Republic of Armenia (registration number in justice system of RA №HO-193, link in legislation system of Republic of Armenia: https://www.arlis.am/DocumentView.aspx?DocID=141312) adopted on 30.05.2001.*
3. *Order of a Minister of the Republic of Armenia №32-N "On adopting the rules of Good Manufacturing Practice for medicinal products, APIs and for investigational medicinal products in the Republic of Armenia" adopted on 14 Jun 2017.*
4. *Order of a Minister of the Republic of Armenia №24-N "On adopting the rules of Good Distribution Practice of medicinal products in the Republic of Armenia" adopted on 24 May 2017.*
5. *The Government decree N867 from 29 June 2002 "On establishing licensing procedures for manufacturing of medicinal products, pharmacy activities, organizations or individual entrepreneurs medical care and maintenance of implementation, and drug wholesale distribution, forms of licenses".*
6. *The Government decree №199-N from 28 Feb 2019 of the Republic of Armenia "On adopting the rules of conducting GMP compliance inspection of manufacturers of medicinal products and active pharmaceutical ingredients, rules of issuance of Good Manufacturing Practice certificate, conducting an expertise on licensing of manufacturers of medicinal products and establishing the list of required documents, and, also, to recognize the loss of power of the Government decrees №1603-N from 15 Nov 2010 and 1089-N from 26 Sep 2013.*
7. *Decree of the Government of the Republic of Armenia N 164-N of February 28, 2019 «On adopting the procedures in the Republic of Armenia related to rapid alert, termination of circulation and recall of nonregistered, non-conforming quality requirements, expired, registration withdrawal or suspended medicinal products, counterfeit medicinal products, active substance, herbal substances, investigational medicinal products and medicinal products imported in violation of the legislation of the Republic of Armenia».*
8. *The order of a Minister of the Republic of Armenia №1613-A from 8 Jul 2014 "On establishing the requirements to GMP inspectors, their qualification and trainings".*
9. *The Decree of the Government of the Republic of Armenia №716-N from 23 Jun 2017 «On establishing of acting pharmacopoeias in the Republic of Armenia".*

10. *The Decree of the Government of the Republic of Armenia №166-N from 28 Feb 2017 "Establishing the fees for expertise within the medicines state regulation in the Republic of Armenia".*

11. *Order of the Minister of Health of the Republic of Armenia N1325-A of July 8, 2011,"On adopting the list of necessary legal acts and program of implementation of the Quality management system required for the activity of the GMP/GDP inspection department of the "Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan" CJSC of the Ministry of Health of the Republic of Armenia".*

12. *Decree of the Government of the Republic of Armenia N162-N of 28 February 2019 «On adopting the rules for state registration, re-registration, extension of the term of the certificate of medicinal product, as well as for refusal of registration, re-registration and of extension of the term of the certificate, for suspension of registration, withdrawal thereof, the rules for carrying out assessments for these purposes, as well as the rule for the submission and assessment of post-registration changes, the list of required documents, the list of changes of registered medicinal product which do not require new registration, the rule for inspection and for recognition of inspection reports of competent authorities of other countries, in the Republic of Armenia, and on repealing the decree of the Government of the Republic of Armenia N347 of 25 April 2001».*
13. *The decree of the Government of the Republic of Armenia №281-N from 18 Mar 2011 «On Establishing of the licensing procedure and forms of licenses of manufacture, exportation, importation or wholesale distribution of narcotics and psychotropic substances or precursor substances defined by the Government Decree of the Republic of Armenia».*
14. *Decree of the Government of the Republic of Armenia №150-N February 28, 2019, «On designation a body responsible for organization and conduction the assessment and inspection in the field of state regulation of medicinal products circulation».*

15. *The order of a Minister of the Republic of Armenia №28-N from 8 Jun 2017 «On establishing the requirements to qualified persons of manufacturer of medicinal products».*

16. *Council of Europe convention on Combating against counterfeiting of medical products and similar crimes (Medicrime) CET 211.*
17. *CIS countries agreement on collaboration against falsified medicines.*
18. *The order of the Minister of Health of the Republic of Armenia №1396-A from 15 Jun 2012 «On providing harmonization between legal acts regulating the Good Manufacturing Practice and Good Distribution Practice activities of the Republic of Armenia and European Union».*

19. *The order of the Minister of Health of the Republic of Armenia №1395-A from 15 Jun 2012 «On collaboration of the Scientific Center of Drug and Medical Technology Expertise with international organizations, sharing of information and conducting joint inspections.*
20. *The order of a minister of health of the Republic of Armenia №1324-A from 8 Jul 2011 «On submitting the application and program for membership and to international relevant organizations (Certificate of Pharmaceutical Product of World Health Organization, Pharmaceutical Inspection Co-operation Scheme and other)».*
21. *The Government decree №202-N from 28 Feb 2019 «On establishing the procedure on importation into territory of the Republic of Armenia and exportation from the territory of the Republic of Armenia medicinal products, active pharmaceutical ingredients, herbal substances and investigational medicinal products, procedure on conducting expertise for importation and exportation and establishing required documents, also, to recognize the loss of power of the Government decree №581-N from 20 Sep 2000».*