List of external documents- Regulations -10 Nov 2021

Title
DECISION No. 24 / 03.07.2015 approving the amendment of the Annex to HCS no.2 / 22.04.2014 regarding the approval of Regulations for the authorization of units which may conduct clinical trials in the field of drugs for human use
DECISION for the modification of the Government Decision no. 734/2010 on the organization and functioning of the National Agency for Medicines and Medical Devices
Order approving the Principles and Guidelines for Good Manufacturing Practice for Medicinal Products for Human Use, including those for clinical investigation
Law no. 185/2017 on quality assurance in health system
DECISION Nr. 2 / 22.04.2014 on the approval of the Regulations for the authorization of units that may perform clinical trials in the field of medicinal products for human use
ANNEX 1 to HCS No. 2 / 22.04.2014 Authorization for conducting clinical trials in the field of drugs
ANNEX 3 to HCS No. 2 / 22.04.2014 MINIMUM EMERGENCY EQUIPMENT for the emergency services of the centers that conduct phase I clinical trials and bioequivalence
DECISION No. 15 / 23.05.2008 on the approval of the Guide on the requirements regarding the chemical-pharmaceutical documentation of medicinal products for clinical investigation
DECISION No. 20 / 06.07.2011 on the approval of the Guide on the use in clinical trials of drugs for clinical investigation and non-investigational medicines
DECISION No. 22 / 03.09.2010 on the approval of the Detailed Guide on the application for authorization of a clinical trial with a drug product for human use, addressed to the competent authority, notification of important amendments and declaration of closure of a clinical trial
DECISION No. 23 / 03.07.2015 on the adoption of the Guide on good manufacturing practice for medicinal products for human use
DECISION No. 32 / 18.11.2010 approving the amendment of the Decision of the Scientific Council no. 22 / 03.09.2010 regarding the approval of the guide detailed information on the application for authorization of a clinical trial with a drug product for human use to the competent authority, notification of important amendments and declaration of closure of a clinical trial
HCS NR.13 / 13.03.2006 on the approval of the Principles and detailed guidelines on good practice in clinical trials for medicinal products for human use for clinical investigation, as well as on the requirements for the manufacture and import of these medicinal products

PHARMACEUTICAL TRIALS	HCS NR.14 / 13.03.2006 regarding the approval of the Norms for the implementation of the rules of good practice in conducting clinical trials performed with drugs for human use
	HCS NO. 21 / 22.05.2006 regarding the approval of the Guide for the elaboration of the evaluation report regarding the clinical documentation
	DECISION No. 39 / 27.10.2006 regarding the approval of the Guide on good practice in clinical trials
	HCS NO. 47 / 15.12.2006 on the approval of the Guide on inspection procedures for verifying compliance with good practice in clinical trials
	HCS NO. 48 / 15.12.2006 regarding the approval of the Guide on the qualification of inspectors who verify the conformity of clinical trials with good practice in clinical trials
	HCS NR.49 / 15.12.2006 on the approval of the Guide on the application for authorization of a clinical trial with a drug product for human use, addressed to the competent authority, notification of important amendments and declaration of closure of a clinical trial in Romania
	DECISION No. 40 / 27.10.2006 regarding the approval of the Guide on general considerations for clinical trials
	DECISION No. 41 / 27.10.2006 regarding the approval of the Guide on the clinical investigation of medicinal products in the pediatric population
	DECISION No. 50 / 15.12.2006 regarding the approval of the Guide regarding the application form and the documentation that must be sent to the ethics commission in order to obtain its opinion on the development of a clinical study with medicines for human use in Romania
	DECISION No. 51 / 15.12.2006 regarding the approval of the Guide regarding the basic file of the clinical study and its archiving.
	REGULATION (EU) NO. 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on interventional clinical trials with medicinal products for human use and repealing Directive 2001/20 / EC.
	ORDER 903/2006 for the approval of the Principles and detailed guidelines regarding the good practice in the clinical study for medicines for human use for clinical investigation, as well as the requirements for the manufacture and import of these medicines.
	ORDER no. 904 of July 25, 2006 for the approval of the Norms regarding the implementation of the rules of good practice in conducting clinical trials performed with drugs for human use.
	ORDER NO. 912 of July 25, 2006 on the approval of the Regulations for the authorization of units that may perform clinical trials in the field of medicinal products for human use

	DECISION No. 6 / 05.06.2014 approving the Regulations on the authorization by the National Agency of Medicines and Medical Devices of clinical trials / notification to the National Agency of Medicines and Medical Devices of non-interventional studies performed with drugs for human use in Romania
	ORDER No. 287 of March 12, 2014 for the abrogation of the Order of the Minister of Health no. 912/2006 on the approval of the Regulations for the authorization of units that may perform clinical trials in the field of medicines for human use
	DECISION No. 40 / 27.10.2006 regarding the approval of the Guide on general considerations about clinical trials
	DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 April 2001on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials onmedicinal products for human use
	REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance)
	DECISION No. 54 of January 29, 2009 on the conditions for the placing on the market of medical devices
	Law no. 176 of 18/10/2000 Published in the Official Gazette, Part I no. 544 of 02/11/2000 regarding medical devices
	ORDER No. 372 of March 26, 2015 on the registration of medical devices
	DECISION No. 315 of April 23, 2014 for the modification and completion of the Government Decision no. 734/2010 on the organization and functioning of the National Agency for Medicines and Medical Devices
	ORDER No. 44 of January 23, 2013 on the control by periodic verification of medical devices put into operation and in use
	European Directive 93/42 of 14.06.1993 on medical devices
	ORDER No. 1356 of November 13, 2013 on the approval of the tariffs charged by the National Agency for Medicines and Medical Devices for the activities carried out in the field of medical devices
	ORDER No. 792 of June 29, 2006 on the conduct of the clinical investigation procedure and the performance evaluation procedure for medical devices

Medical Devices	LAW No. 132 of October 9, 2014 on the approval of the Government Emergency Ordinance no. 2/2014 for the amendment and completion of Law no. 95/2006 regarding the reform in the field of health, as well as for the modification and completion of some normative acts
	DECISION No. 55 of January 29, 2009 on active implantable medical devices
	DECISION no. 911 of 11 August 2005 laying down the conditions for the placing on the market and putting into service of medical devices
	Regulation no. 745/2017 regarding the devices amending Directive 2001/83 / EC, Regulation (EC) no. 178/2002 and the Regulation (EC) no. 1223/2009 and repealing the Directives 90/385 / EEC and 93/42 / EEC of the Council EEA relevance) Celex number: 32017R0745
	Regulation no. 746/2017 regarding the devices for in vitro diagnosis and repeal of Directive 98/79 / EC and Decision 2010/227 / EU a Commission (Text with EEA relevance) Celex number: 32017R0746
	Law no. 178 (r1) of 18/10/2000 (form republished and consolidated 01/06/2010) on cosmetics Published in the Official Gazette no. 91 of 27/01/2005
	Order no. 966/2017 regarding the amendment of the annex to Order of the Minister of Health, interim, no. 1,446 / 2009 for the establishment of the National Bioethics Commission a Medicines and Medical Devices and for approval of its composition