

The Essential List of Regulatory Authorities in Europe

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Regulatory Tracker

To ease the process of finding drug and medical device regulators in Europe, *Focus* has updated its list of the website(s) for each country's ministry of health and regulatory authority. The list is organized by regional affiliation with the European Union (EU), European Free Trade Association (EFTA) and other European countries.

For countries that do not list a regulatory authority, regulatory functions are either performed by the ministry of health, or the information available online was unclear. Additionally, some of the agencies listed do not appear to have websites, or the websites are not functioning as of this publication.

If you notice an issue with this page or wish to submit a correction please email Focus at news@raps.org.

Country	Drug Regulatory Authority	Medical Devices Regulatory Authority	Ministry of Health
European Union (EU)			
Austria	Federal Office for Safety in Health Care (BASG)	Federal Office for Safety in Health Care (BASG)	Federal Ministry of Labour, Social Affairs, Health and Consumer Protection
Belgium	Federal Agency for Medicines and Health Products (FAMHP)	Federal Agency for Medicines and Health Products (FAMHP)	Federal Public Service (FPS) Health, Food Chain Safety and Environment
Bulgaria	Bulgarian Drug Agency (BDA)	Bulgarian Drug Agency (BDA)	Ministry of Health
Croatia	Agency for medicinal products and medical	Agency for medicinal products and medical	Ministry of Health

	devices of Croatia (HALMED)	devices of Croatia (HALMED)	
Cyprus	Ministry of Health – Pharmaceutical Services	Ministry of Health – Medical & Public Health Services, Cyprus Medical Devices Competent Authority	Ministry of Health
Czech Republic	State Institute for Drug Control (SUKL)	State Institute for Drug Control (SUKL)	Ministry of Health of the Czech Republic
Denmark	Danish Medicines Agency	Danish Medicines Agency	Ministry of Health
Estonia	Agency of Medicines	Health Board, Medical Devices	Ministry of Social Affairs
Finland	Finnish Medicines Agency (FIMEA)	Finnish Medicines Agency (FIMEA)	Ministry of Social Affairs and Health
France	National Agency for Medicines and Health Products Safety (ANSM)	National Agency for Medicines and Health Products Safety (ANSM)	Ministry for Solidarity and Health
Germany	Federal Institute for Drugs and Medical Devices (BfArM), Paul-Ehrlich-Institut (PEI)	Federal Institute for Drugs and Medical Devices (BfArM)	Federal Ministry of Health
Greece	National Organization for Medicines	National Organization for Medicines	Ministry of Health
Hungary	National Institute of Pharmacy and Nutrition	Department for Medical Devices, National Institute of Pharmacy	Ministry of Human Capacities
Ireland	Health Products Regulatory Authority (HPRA)	Health Products Regulatory Authority (HPRA)	Department of Health
Italy	Italian Medicines Agency (AIFA)	Directorate-General for Medical Devices and Pharmaceutical Service	Ministry of Health

Latvia	State Agency of Medicines	State Agency of Medicines	Ministry of Health of the Republic of Latvia
Lithuania	State Medicines Control Agency	State Health Care Accreditation Agency	Ministry of Health of the Republic of Lithuania
Luxembourg	Ministry of Health	Ministry of Health	Ministry of Health
Malta	Medicines Authority	Malta Competition and Consumer Affairs Authority	Ministry for Health
Netherlands	Medicines Evaluation Board, Farmatec	Farmatec	Ministry of Health, Welfare and Sport
Poland	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	Ministry of Health
Portugal	Infarmed	Infarmed	Ministry of Health
Romania	The National Agency for Medicines and Medical Devices (NAMMD)	The National Agency for Medicines and Medical Devices (NAMMD)	Ministry of Health
Slovakia	State Institute for Drug Control (SUKL)	State Institute for Drug Control (SUKL)	Ministry of Health of the Slovak Republic
Slovenia	Agency for Medicines and Medical Devices (JAZMP)	Agency for Medicines and Medical Devices (JAZMP)	Ministry of Health
Spain	Spanish Agency of Medicines and Medical Products (AEMPS)	Spanish Agency of Medicines and Medical Products (AEMPS)	Ministry of Health, Consumer Affairs and Social Welfare
Sweden	Medical Products Agency	Medical Products Agency	Ministry of Health and Social Affairs
United Kingdom	Medicines and Healthcare products Regulatory Agency (MHRA)	Medicines and Healthcare products Regulatory Agency (MHRA)	Department of Health and Social Care
European Free Trade Association (EFTA)			

Iceland	Icelandic Medicines Agency	Icelandic Medicines Agency	Ministry of Health
Liechtenstein	Office of Health	Office of Health	Office of Health
Norway	Norwegian Medicines Agency	Norwegian Medicines Agency	Ministry of Health and Care Services
Switzerland	Swissmedic	Swissmedic	Federal Office of Public Health (FOPH)
Other Countries			
Albania			Ministry of Health
Andorra			Ministry of Health
Belarus	Center for Expertise and Testing in Healthcare	Center for Expertise and Testing in Healthcare	Ministry of Health
Bosnia and Herzegovina	The Agency for Medicinal Product and Medical Devices	The Agency for Medicinal Product and Medical Devices	Federal Ministry of Health
Macedonia	Agency for Medicinal Products and Medical Devices	Agency for Medicinal Products and Medical Devices	Ministry of Health
Moldova	Medicines and Medical Devices Agency	Medicines and Medical Devices Agency	Ministry of Health, Labour and Social Protection
Montenegro	Agency for Medicines and Medical Devices of Montenegro	Agency for Medicines and Medical Devices of Montenegro	Ministry of Health
San Marino			Ministry of Health and Social Security
Serbia	Medicines and Medical Devices Agency of Serbia	Medicines and Medical Devices Agency of Serbia	Ministry of Health
Ukraine	State Service of Ukraine on Medicines and Drug Control	State Service of Ukraine on Medicines and Drug Control	Ministry of Health