Our Functions

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HPRA Functions	Human Medicines	Medical Devices for Human Use	Blood, Tissues, Cells and Organs for Transplantation	Veterinary Medicines	Scientific Animal Protection	Controlled Drugs, and Precursor Chemicals	Cosmetics
Advisory	• Development • Classification • Risk communication to healthcare professionals and the public • Drug-device combination products • New manufacturing facilities and upgrades	• Classification • Risk communication to healthcare professionals, users and the public	• New processing facilities and upgrades • Risk communication	• Classification • Risk communication to healthcare professionals and the public • New manufacturing facilities and upgrades • Data on consumption of antibiotics, to the Commission	• Education and training requirements for personnel • Application of the 3R principles • Data on use of animals, to the Commission	• Legal requirements for import, export and possession	• Classification • Risk communication to users
Authorisation	• Clinical trials • Medicinal products • Manufacturers of medicines and investigational medicines • Wholesalers of medicines • Export certification of active substances and medicines • Manufacturers, importers and distributors of active substances (registration) • Exempt medicines (notification) • Contract laboratories	• Medical devices, certain (registration) • Notified Bodies • Clinical investigations • Certificates of free sale for export purposes • Compassionate use	• Blood, tissue and cells and organ establishments	• Clinical field trials • Medicinal products • Manufacturers of veterinary medicines • Export certification of active substances and medicinal products • Contract laboratories	• Establishments that breed, supply or use animals in scientific studies • Projects involving animals used in scientific studies • Individuals involved in use of animals in scientific studies	• Import, export, manufacture and possession of controlled drugs* and precursor chemicals	• Certificates of free sale for export purposes
Inspection and Audit	• Manufacturers, importers, distributors of active substances and wholesalers of medicines • Brokers • Sponsors and investigators carrying out clinical trials • Marketing authorisation holders or firms employed for pharmacovigilance • Contract laboratories	• Manufacturers, including manufacturers of custom-made devices • Notified Bodies	• Blood, tissue and cells establishments, and when required, blood banks • Organ transplant centres and national procurement organisation	• Manufacturers of veterinary medicines • Marketing authorisation holders or firms employed for pharmacovigilance • Contract laboratories	• Establishments that breed, supply or use animals in scientific studies.	• Controlled drugs licence holders and precursor chemical licence or registration holders	• Cosmetic manufacturers and distributors
Surveillance and Market Action	• Adverse reactions • Ongoing benefit:risk • Quality defects and recalls • Advertisements • Analysis of active substances and medicines • Compliance with legislation • Breaches of legislation	• Adverse incidents • Ongoing benefit:risk • Recalls and field safety corrective actions • Compliance with legislation • Breaches of legislation	• Adverse reactions and events associated with tissues, cells and organs for human transplantation. • Compliance with legislation • Breaches of legislation	• Adverse reactions • Ongoing benefit:risk • Quality defects and recalls • Analysis of active substances and medicines • Compliance with legislation • *Breaches of legislation	• Compliance with legislation • Breaches of legislation	• Suspected diversions of controlled drugs or precursor chemicals. • Compliance with legislation • *Breaches of legislation	• Undesirable effects • Product compliance and safety issues. • Compliance with legislation • *Breaches of legislation

*Shared responsibility with other agencies/bodies