List of WHO-Listed Authorities (WLA)
(in alphabetical order) as of December 2025

Country	Regulatory Authority (RA)	Link to the RA and contact point	Listed product stream(s)	Listed function(s)	Date of first listing	Date of renewal	Link to the listing summary
Australia	Therapeutic Goods Administration (TGA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point:	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Laboratory testing	16 December 2025	January 2031	TGA-listing summary
Australia	Therapeutic Goods Administration (TGA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: tga.international@health.gov.au	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Laboratory testing 4. Regulatory Authority (RA) lot release	16 December 2025	January 2031	TGA-listing summary
Austria[1]	Austrian Federal Office for Safety in Health Care (BASG)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: basg_anfragen@basg.gv.at	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Austria[1]	Austrian Federal Office for Safety in Health Care (BASG)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: basg_anfragen@basg.gv.at	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing	13 May 2024	June 2029	EMRN-listing-summary

				7. Clinical trials oversight 8. Regulatory Authority (RA) lot release			
Belgium[1]	Federal Agency for Medicines and Health Products (FAMHP)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: management@fagg-afmps.be	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Belgium[1]	Federal Agency for Medicines and Health Products (FAMHP)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: management@fagg-afmps.be	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Bulgaria[1]	Bulgarian Drug Agency (BDA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: bda@bda.bg	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Bulgaria[1]	Bulgarian Drug Agency (BDA)	▪ Please click HERE to access the site of the regulatory authority	**Vaccines**	1. Registration and marketing authorization 2. Vigilance	13 May 2024	June 2029	EMRN-listing-summary

		▪ Contact point: bda@bda.bg		3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release			
Canada	Health Canada	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: brddinternational-dmbr@hc-sc.gc.ca	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	21 July 2025	August 2030	HC-listing-summary
Canada	Health Canada	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: brddinternational-dmbr@hc-sc.gc.ca	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	21 July 2025	August 2030	HC-listing-summary
Croatia[1]	Agency for Medicinal Products and Medical Devices of Croatia (HALMED)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: BEMA.Secretariat@halmed.hr ▪ halmed@halmed.hr	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing	13 May 2024	June 2029	EMRN-listing-summary

				7. Clinical trials oversight			
Croatia[1]	Agency for Medicinal Products and Medical Devices of Croatia (HALMED)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: BEMA.Secretariat@halmed.hr ▪ halmed@halmed.hr	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Cyprus[1]	Pharmaceutical Services, Ministry of Health (PHS-MoH)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: zkanther@phs.moh.gov.cy	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Cyprus[1]	Pharmaceutical Services, Ministry of Health (PHS-MoH)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: zkanther@phs.moh.gov.cy	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Czechia[1]	State Institute for Drug Control (SUKL)	▪ Please click HERE to access the site of the regulatory authority	**Medicines** (including multisource [generics], and new medicines [new chemical entities],	1. Registration and marketing authorization 2. Vigilance	13 May 2024	June 2029	EMRN-listing-summary

		▪ Contact point: posta@sukl.cz	biotherapeutics and similar biotherapeutic products)	3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight			
Czechia[1]	State Institute for Drug Control (SUKL)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: posta@sukl.cz	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Denmark[1]	Danish Medicines Agency (DKMA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: dkma@dkma.dk	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Denmark[1]	Danish Medicines Agency (DKMA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: dkma@dkma.dk	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary

				8. Regulatory Authority (RA) lot release			
Estonia[1]	State Agency of Medicines (SAM)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@ravimiamet.ee	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Estonia[1]	State Agency of Medicines (SAM)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@ravimiamet.ee	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Finland[1]	Finnish Medicines Agency (FIMEA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: kirjaamo@fimea.fi ▪ registry@fimea.fi	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Finland[1]	Finnish Medicines Agency (FIMEA)	▪ Please click HERE to access the site of the regulatory authority	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control	13 May 2024	June 2029	EMRN-listing-summary

		▪ Contact point: kirjaamo@fimea.fi ▪ registry@fimea.fi		4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release			
France[1]	The French National Agency for Medicines and Health Products Safety (ANSM)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: communication.ANSM@ansm.sante.fr	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
France[1]	The French National Agency for Medicines and Health Products Safety (ANSM)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: communication.ANSM@ansm.sante.fr	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Germany[1]	Federal Institute for Drugs and Medical Devices (BfARM) Paul-Ehrlich Institut - Federal Institute for	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: leitung@bfarm.de	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary

	Vaccines and Biomedicines (PEI)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: pei@pei.de					
Germany[1]	Federal Institute for Drugs and Medical Devices (BfARM) Paul-Ehrlich Institut - Federal Institute for Vaccines and Biomedicines (PEI)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: leitung@bfarm.de ▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: pei@pei.de	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Greece[1]	National Organization for Medicines (EOF)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: relation@eof.gr	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Greece[1]	National Organization for Medicines (EOF)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: relation@eof.gr	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments	13 May 2024	June 2029	EMRN-listing-summary

				5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release			
Hungary[1]	National Center for Public Health and Pharmacy (NNGYK)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: gyszertitkarsag@nngyk.gov.hu ▪ egyedi@nngyk.gov.hu	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Hungary[1]	National Center for Public Health and Pharmacy (NNGYK)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: gyszertitkarsag@nngyk.gov.hu ▪ egyedi@nngyk.gov.hu	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Iceland[1]	Icelandic Medicines Agency (IMA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: lyfjastofnun@lyfjastofnun.is	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary

Iceland[1]	Icelandic Medicines Agency (IMA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: lyfjastofnun@lyfjastofnun.is	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Indonesia	The Indonesian Food and Drug Authority (BPOM)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: halobpom@pom.go.id	**Vaccines**	1. Registration and marketing authorization 2. Licensing establishments 3. Regulatory inspection (GMP, GSDP) 4. Laboratory testing 5. Regulatory Authority (RA) lot release	16 December 2025	January 2031	BPOM-listing-summary
Ireland[1]	Health Products Regulatory Authority (HPRA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@hpra.ie	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Ireland[1]	Health Products Regulatory Authority (HPRA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@hpra.ie	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary

				8. Regulatory Authority (RA) lot release			
Italy[1]	Italian Medicines Agency (AIFA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: protocollo@pec.aifa.gov.it	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Italy[1]	Italian Medicines Agency (AIFA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: protocollo@pec.aifa.gov.it	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Japan	Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency (MHLW/PMDA)	▪ Please click HERE and HERE to access the site of the regulatory authority ▪ Contact point: mhlw-pharm@mhlw.go.jp pmda-multilateral@pmda.go.jp	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance	21 July 2025	August 2030	PMDA-MHLW-listing-summary

Latvia[1]	State Agency of Medicines of Latvia (ZVA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@zva.gov.lv	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Latvia[1]	State Agency of Medicines of Latvia (ZVA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@zva.gov.lv	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Liechtenstein [1]	Office of Health/ Medicinal Products Control Agency (LLV)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: pharminfo@llv.li	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Liechtenstein [1]	Office of Health/ Medicinal Products Control Agency (LLV)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: pharminfo@llv.li	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP)	13 May 2024	June 2029	EMRN-listing-summary

				6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release			
Lithuania[1]	State Medicines Control Agency (VVKT)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: vvkt@vvkt.lt	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Lithuania[1]	State Medicines Control Agency (VVKT)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: vvkt@vvkt.lt	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Luxembourg[1]	Ministry of Health (MoH)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: uxdpm@ms.etat.lu	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Luxembourg[1]	Ministry of Health (MoH)	▪ Please click HERE to access the site	**Vaccines**	1. Registration and marketing authorization 2. Vigilance	13 May 2024	June 2029	EMRN-listing-summary

		of the regulatory authority ▪ Contact point: uxdpm@ms.etat.lu		3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release			
Malta[1]	Malta Medicines Authority (MMA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: annalise.a.attard@gov.mt ▪ danika.camilleri-agius-decelis@gov.mt	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Malta[1]	Malta Medicines Authority (MMA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: annalise.a.attard@gov.mt ▪ danika.camilleri-agius-decelis@gov.mt	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Netherlands (the) [1]	Medicines Evaluation Board (CBG-MEB)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: Contact | Medicines	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP)	13 May 2024	June 2029	EMRN-listing-summary

		Evaluation Board (cbg-meb.nl)		6. Laboratory testing 7. Clinical trials oversight			
Netherlands (the) [1]	Medicines Evaluation Board (CBG-MEB)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: Contact | Medicines Evaluation Board (cbg-meb.nl)	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Norway[1]	Norwegian Medical Products Agency (NOMA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: post@noma.no	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Norway[1]	Norwegian Medical Products Agency (NOMA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: post@noma.no	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Poland[1]	Office for Registration of Medicinal	▪ Please click HERE to access the site	**Medicines** (including multisource [generics], and new medicines	1. Registration and marketing authorization 2. Vigilance	13 May 2024	June 2029	EMRN-listing-summary

	Products, Medical Devices and Biocidal Products (URPL)	of the regulatory authority ▪ Contact point: urpl@urpl.gov.pl	[new chemical entities], biotherapeutics and similar biotherapeutic products)	3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight			
Poland[1]	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: urpl@urpl.gov.pl	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Portugal[1]	National Authority of Medicines and Health Products, IP (INFARMED)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: gpq@infarmed.pt	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Portugal[1]	National Authority of Medicines and Health Products, IP (INFARMED)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: gpq@infarmed.pt	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary

				8. Regulatory Authority (RA) lot release			
Republic of Korea	Ministry of Food and Drug Safety (MFDS)	▪ Please click HERE to access the website of the regulatory authority ▪ Contact point: intlpharm@korea.kr	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	26 October 2023 and 21 July 2025	Novembe r 2028	MFDS-listing-summary
Republic of Korea	Ministry of Food and Drug Safety (MFDS)	▪ Please click HERE to access the website of the regulatory authority ▪ Contact point: intlpharm@korea.kr	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversights 8. Regulatory Authority (RA) lot release	26 October 2023 and 21 July 2025	Novembe r 2028	MFDS-listing-summary
Romania[1]	National Agency for Medicines and Medical Devices of Romania (NAMMDR)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: secretariat@anm.ro	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Romania[1]	National Agency for Medicines and Medical Devices of	▪ Please click HERE to access the site of the regulatory authority	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control	13 May 2024	June 2029	EMRN-listing-summary

	Romania (NAMMDR)	▪ Contact point: secretariat@anm.ro		4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release			
Singapore	Health Sciences Authority (HSA)	▪ Please click HERE to access the website of the regulatory authority ▪ Contact point: hsa_intl_office@hsa.gov.sg	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversights	26 October 2023 and 13 May 2024	Novembe r 2028	HSA-listing-summary
Slovakia[1]	State Institute for Drug Control (SUKL)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@sukl.sk	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Slovakia[1]	State Institute for Drug Control (SUKL)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@sukl.sk	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary

Slovenia[1]	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@jazmp.si	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Slovenia[1]	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@jazmp.si	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Spain[1]	Spanish Agency of Medicines and Medical Devices (AEMPS)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: sdaem@aemps.es	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Spain[1]	Spanish Agency of Medicines and Medical Devices (AEMPS)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: sdaem@aemps.es	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP)	13 May 2024	June 2029	EMRN-listing-summary

				6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release			
Sweden[1]	the Swedish Medical Products Agency (SMPA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: planerings-ochekonomifunktionen@lakemedelsverket.se ▪ eu-koordination@lakemedelsverket.se	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
Sweden[1]	the Swedish Medical Products Agency (SMPA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: planerings-ochekonomifunktionen@lakemedelsverket.se ▪ eu-koordination@lakemedelsverket.se	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	EMRN-listing-summary
Switzerland	Swissmedic	▪ Please click HERE to access the website of the regulatory authority ▪ Contact point: Networking@swissmedic.ch	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	26 October 2023	Novembe r 2028	Swissmedic-listing-summary

Switzerland	Swissmedic	▪ Please click HERE to access the website of the regulatory authority ▪ Contact point: Networking@swissmedic.ch	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	26 October 2023	November 2028	Swissmedic-listing-summary
United Kingdom of Great Britain and Northern Ireland	Medicines & Healthcare products Regulatory Agency (MHRA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@mhra.gov.uk	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Licensing establishments 4. Regulatory inspection (GMP, GSDP and GCP) 5. Laboratory testing 6. Clinical trials oversight	21 July 2025	August 2030	MHRA-listing-summary
United Kingdom of Great Britain and Northern Ireland	Medicines & Healthcare products Regulatory Agency (MHRA)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: info@mhra.gov.uk	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Licensing establishments 4. Regulatory inspection (GMP, GSDP and GCP) 5. Laboratory testing 6. Clinical trials oversight 7. Regulatory Authority (RA) lot release	21 July 2025	August 2030	MHRA-listing-summary
United States of America	US FDA	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: FDA_Global@fda.hhs.gov	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing	13 May 2024	June 2029	US FDA-listing-summary

				7. Clinical trials oversight			
United States of America	USFDA	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: FDA_Global@fda.hhs.gov	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	13 May 2024	June 2029	US FDA-listing-summary

Regional Regulatory Systems	Regulatory Authority (RA)	▪ Link to the RA and contact point	Listed product stream(s)	8. Listed function(s)	Date of first listing	Date of renewal	Link to the listing summary
European Medicines Regulatory Network[2]	European Commission (DG SANTE) European Medicines Agency (EMA) National Regulatory Authorities	▪ Webpage: https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/health-and-food-safety_en ▪ Contact point: SANTE-CONSULT-A4@ec.europa.eu ▪ Webpage: https://www.ema.europa.eu ▪ Contact point: EMAinternational@ema.europa.eu ▪ Contact point: ps@hma.eu	**Medicines** (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary
European Medicines Regulatory Network[2]	European Commission (DG SANTE) European Medicines Agency (EMA) National Regulatory Authorities	▪ Webpage: https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/health-and-food-safety_en ▪ Contact point: SANTE-CONSULT-A4@ec.europa.eu	**Vaccines**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	EMRN-listing-summary

		▪ Webpage: https://www.ema.europa.eu ▪ Contact point: EMAinternational@ema.europa.eu ▪ Contact point: ps@hma.eu		8. Regulatory Authority (RA) lot release			

[1] Evaluated as part of the European Medicines Regulatory Network

[2] The European Medicines Regulatory Network is composed of the European Commission, the European Medicines Agency and the regulatory authorities of the following EU/EEA-EFTA countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden. In addition, the European Directorate for the Quality of Medicines & HealthCare (EDQM) coordinates laboratory testing and lot release related activities for the EMRN.