EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY

EU-US MRA

JOINT SECTORAL COMMITTEE

List of Recognised Authorities

under Article 7 of the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs)

Country	**Regulatory authority for medicinal products for human use***	**Date of Recognition by Other Party**
United States	Food and Drug Administration	1 Nov 2017
Austria	Austrian Agency for Health and Food Safety / *Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH*	1 Nov 2017
Croatia	Agency for Medicinal Products and Medical Devices / *Agencija za lijekove i medicinske proizvode (HALMED)*	1 Nov 2017
France	French National Agency for Medicines and Health Products Safety / *Agence nationale de sécurité du médicament et des produits de santé (ANSM)*	1 Nov 2017
Italy	Italian Medicines Agency / *Agenzia Italiana del Farmaco*	1 Nov 2017
Malta	Malta Medicines Authority (MMA)**	1 Nov 2017
Spain	Spanish Agency of Medicines and Medical Devices / *Agencia Española de Medicamentos y Productos Sanitarios*	1 Nov 2017
Sweden	Swedish Medical Product Agency / *Läkemedelsverket*	1 Nov 2017
Czechia	State Institute for Drug Control / *Státní ústav pro kontrolu léčiv (SÚKL)*	1 Mar 2018
Greece	National Organisation for Medicines / *Ethnikos Organismos Farmakon (EOF) – (Εθνικόσ Οργανισμόσ Φαρμάκων)*	1 Mar 2018

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Country	**Regulatory authority for medicinal products for human use***	**Date of Recognition by Other Party**
Hungary	National Institute of Pharmacy and Nutrition / *Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet*	1 Mar 2018
Romania	National Agency for Medicines and Medical Devices of Romania / *Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale din România*	1 Mar 2018
Ireland	Health Products Regulatory Authority (HPRA)	1 Jun 2018
Lithuania	State Medicines Control Agency / *Valstybinė vaistų kontrolės tarnyba*	1 Jun 2018
Portugal	National Authority of Medicines and Health Products / *INFARMED, I.P Autoridade Nacional do Medicamento e Produtos de Saúde, I.P*	14 Sept 2018
Belgium	Federal agency for medicines and health products – FAMHP / *Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten – FAGG / Agence fédérale des médicaments et produits de santé – AFMPS*	16 Nov 2018
Denmark	Danish Medicines Agency / *Lægemiddelstyrelsen*	16 Nov 2018
Finland	Finnish Medicines Agency / *Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)*	16 Nov 2018
Latvia	State Agency of Medicines / *Zāļu valsts aģentūra*	16 Nov 2018
Estonia	State Agency of Medicines / *Ravimiamet*	28 Nov 2018
Poland	Chief Pharmaceutical Inspectorate / *Główny Inspektorat Farmaceutyczny (GIF)*	7 Feb 2019
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia / *Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)*	7 Feb 2019
Bulgaria	Bulgarian Drug Agency / *Изпълнителна агенция по лекарствата*	29 Apr 2019

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Country	**Regulatory authority for medicinal products for human use***	**Date of Recognition by Other Party**
Cyprus	Ministry of Health – Pharmaceutical Services / *Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας*	29 Apr 2019
Luxembourg	Ministry of Health, Division of Pharmacy and Medicines / *Ministère de la Santé, Division de la Pharmacie et des Médicaments*	10 Jun 2019
Netherlands	Healthcare and Youth Care Inspectorate, Ministry of Health, Welfare and Sport / *Inspectie Gezondheidszorg en Jeugd (IGJ), Ministerie van Volksgezondheid, Welzijn en Sport*	10 Jun 2019
Germany	Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices / *Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)*	26 Jun 2019
Slovakia	State Institute for Drug Control / *Štátny ústav pre kontrolu liečiv (ŠÚKL)****	11 Jul 2019

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Country	**Regulatory authority for veterinary medicinal products***	**Date of Recognition by Other Party**
United States	Food and Drug Administration	30 May 2023
Austria	Austrian Agency for Health and Food Safety / *Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH*	30 May 2023
Belgium	Federal Agency for Medicines and Health Products – FAMHP / *Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten – FAGG / Agence fédérale des médicaments et des produits de santé – AFMPS*	30 May 2023
Bulgaria	Bulgarian Food Safety Agency / *Българска агенция по безопасност на храните*****	30 May 2023
Denmark	Danish Medicines Agency / *Lægemiddelstyrelsen*	30 May 2023
Estonia	State Agency of Medicines / *Ravimiamet*	30 May 2023
Finland	Finnish Medicines Agency / *Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)*	30 May 2023
France	French Agency for Food, Environmental and Occupational Health & Safety – French Agency for Veterinary Medicinal Products / *Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail – Agence nationale du médicament vétérinaire (Anses-ANMV)*	30 May 2023
Greece	National Organisation for Medicines / *Ethnikos Organismos Farmakon (EOF) - (Εθνικόσ Οργανισμόσ Φαρμάκων))*	30 May 2023
Hungary	National Food Chain Safety Office, Directorate of Veterinary Medicinal Products / *Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állatgyógyászati Termékek Igazgatósága (ÁTI)*	30 May 2023
Ireland	Health Products Regulatory Authority (HPRA)	30 May 2023
Luxembourg	Ministry of Health, Division of Pharmacy and Medicines / *Ministère de la Santé, Division de la Pharmacie et des Médicaments*	30 May 2023

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Country	**Regulatory authority for veterinary medicinal products***	**Date of Recognition by Other Party**
Netherlands	Medicines Evaluation Board (MEB) / *College ter Beoordeling van Geneesmiddelen (CBG)* Veterinary Medicinal Products Unit / *Bureau Diergeneesmiddelen*	30 May 2023
Poland	Chief Pharmaceutical Inspectorate / *Główny Inspektorat Farmaceutyczny (GIF)*	30 May 2023
Portugal	General Directorate of Food and Veterinary / *Direção-Geral de Alimentação e Veterinária (DGAV)*	30 May 2023
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) / *Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)*	30 May 2023
Spain	Spanish Agency of Medicines and Medical Devices / *Agencia Española de Medicamentos y Productos Sanitarios*	30 May 2023
Sweden	Swedish Medical Product Agency / *Läkemedelsverket*	26 Sep 2023
Latvia	Food and Veterinary Service / *Pārtikas un veterinārais dienests*	28 Nov 2023
Lithuania	State Food and Veterinary Service / *Valstybinė maisto ir veterinarijos tarnyba*	18 Jul 2024
Germany	Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices / *Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)*	7 Aug 2024

* **Limitations:**

The recognition does not apply temporarily to the following:

- Vaccines for human use
- Plasma derived pharmaceuticals
- Investigational products (clinical trial material)

Excluded from the MRA scope are: Advanced Therapy Medicinal Products (ATMPs), human blood, human plasma, human tissues and organs and veterinary immunologicals.

** Malta – capability for human medicines excludes sterile or aseptically processed drugs and biological products; and non-sterile, highly potent drug products.

*** Slovakia – for human medicines only for inspections of chemically synthesized active pharmaceutical ingredients intended for use in drug products for human oral administration and manufactured in a dedicated, single product facility.

**** Bulgaria – capability for veterinary products excludes sterile veterinary drug products.