EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY

U.S. FOOD & DRUG ADMINISTRATION

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**
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 medicament et des produits de santé	1 Nov 2017
Italy	Italian Medicines Agency / Agenzia Italiana del Farmaco	1 Nov 2017
Malta	Medicines Regulatory Authority**	1 Nov 2017
Spain	Spanish Agency of Medicines and Medical Devices/ Agencia Española de Medicamentos y Productos Sanitarios	1 Nov 2017
Sweden	Medical Products Agency / Läkemedelsverket	1 Nov 2017
United Kingdom	Medicines and Healthcare products Regulatory Agency	1 Nov 2017
Czech Republic	State Institute for Drug Control/Státní ústav pro kontrolu léčiv (SÚKL)	1 Mar 2018
Greece	National Organisation for Medicines/Ethnikos Organismos Farmakon (EOF) - (ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ))	1 Mar 2018
Hungary	Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet / National Institute of Pharmacy and Nutrition	1 Mar 2018

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Country	**Regulatory authority for medicinal products for human use***	**Date of Recognition**
Romania	National Agency for Medicines and Medical Devices / Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale	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 / Federaal Agentschap voor geneesmiddelen en gezondheidsproducten/ Agence fédérale des médicaments et produits de santé	16 Nov 2018
Denmark	Danish Medicines Agency / Laegemiddelstyrelsen	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	The Main 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
Cyprus	Ministry of Health - Pharmaceutical Services / Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας	29 Apr 2019

Luxembourg	Minìstere de la Santé, Division de la Pharmacie et des Médicaments	10 Jun 2019
Netherlands	Healthcare Inspectorate / Inspectie voor de Gezondheidszorg (IGZ)	10 Jun 2019
Germany	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

* **Limitations:**

The recognition does not apply temporarily to the following:

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

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

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

*** Slovakia – 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.