European Union (EU) Mutual Recognition Agreement

The U.S.-EU Mutual Recognition Agreement (MRA) Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMP) MRA entered into force on November 1, 2017. Initially the agreement included only pharmaceuticals intended for human use. On May 31, 2023 the U.S. Food and Drug Administration (FDA) and the European Union (EU) announced their decision to expand the scope of the MRA to include inspections of veterinary pharmaceuticals. To date, the FDA has completed capability for all 27 of the EU countries' human drug regulatory authorities, and 18 of the EU countries' veterinary drug regulatory authorities.

FDA also has MRAs in force with Switzerland (/international-programs/international-arrangements/switzerland-mutual-recognition-agreement) and the United Kingdom (/international-programs/international-arrangements/united-kingdom-uk-mutual-recognition-agreement).

Country	Regulatory authority for medicinal products for human and/or veterinary use*	Type	Date Recognized
Austria	Austrian Agency for Health and Food Safety / Österreichische Agentur für Gesundheit und Ernährungssicherheit (GmbH)	Human Drugs Animal Drugs	November 1, 2017 May 30, 2023
Belgium	Federal agency for medical and health products / Fedraal Agentschap voor geneesmiddelen en gezondheidsproducten/ Agence fédérale des médicaments et produits de santé	Human Drugs Animal Drugs	November 16, 2018 May 30, 2023
Bulgaria	Bulgarian Drug Agency ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА	Human Drugs	April 29, 2019
Bulgaria	Bulgarian Food Safety Agency / Българска агенция по безопасност на храните****	Animal Drugs	May 30, 2023
Croatia	Agency for Medicinal Products and Medical Devices / Agencija za lijekove i medicinske proizvode (HALMED)	Human Drugs	November 1, 2017
Cyprus	Ministry of Health – Pharmaceutical Services Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας	Human Drugs	April 29, 2019
Czech Republic	State Institute for Drug Control	Human Drugs	March 1, 2018

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Country	Regulatory authority for medicinal products for human and/or veterinary use*	Type	Date Recognized
Denmark	Danish Medicines Agency / Laegemiddelstyrelsen	Human Drugs Animal Drugs	November 16, 2018 May 30, 2023
Estonia	State Agency of Medicines / Ravimiamet	Human Drugs Animal Drugs	November 28, 2019 May 30, 2023
Finland	Finnish Medicines Agency / Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)	Human Drugs Animal Drugs	November 16, 2018 May 30, 2023
France	French National Agency for Medicines and Health Products Safety / Agence nationale de sécurité du medicament et des produits de santé	Human Drugs	November 1, 2017
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)*	Animal Drugs	May 30, 2023
Germany	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)	Human Drugs	June 26, 2019
Greece	National Organisation for Medicines	Human Drugs Animal Drugs	March 1, 2018 May 30, 2023
Hungary	National Institute of Pharmacy and Nutrition	Human Drugs	March 1, 2018
Hungary	National Food Chain Safety Office, Directorate of Veterinary Medicinal Products / Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állatgyógyászati Termékek Igazgatósága (ÁTI)	Animal Drugs	May 30, 2023
Ireland	Health Products Regulatory Authority (HPRA)	Human Drugs Animal Drugs	June 1, 2018 May 30, 2023
Italy	Italian Medicines Agency / Agenzia Italiana del Farmaco	Human Drugs	November 1, 2017
Lativa	State Agency of Medicines / Zāļu valsts aģentūra	Human Drugs	November 16, 2018
Lativa	Food and Veterinary Service	Animal Drugs	November 28,2023
Lithuania	State Medicines Control Agency / Valstybinė vaistų kontrolės tarnyba	Human Drugs	June 1, 2018
Luxembourg	Minìstere de la Santé, Division de la Pharmacie et des Médicaments	Human Drugs Animal Drugs	June 10, 2019 May 30, 2023
Malta	Medicines Regulatory Authority***	Human Drugs	November 1, 2017
Netherlands	Healthcare Inspectorate / Inspectie voor de Gezondheidszorg (IGZ)	Human Drugs	June 10, 2019
Netherlands	Medicines Evaluation Board (MEB) / College ter Beoordeling van Geneesmiddelen (CBG) Veterinary Medicinal Products Unit / Bureau Diergeneesmiddelen	Animal Drugs	May 30, 2023
Poland	The Main Pharmaceutical Inspectorate/ Główny Inspektorat Farmaceutyczny (GIF)	Human Drugs Animal Drugs	February 7, 2019 May 30, 2023
Portugal	National Authority of Medicines and Health Products / INFARMED, I.P / Autoridade Nacional do Medicamento e Produtos de Saúde, I.P	Human Drugs	September 14, 2018

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Country	Regulatory authority for medicinal products for human and/or veterinary use*	Type	Date Recognized
Portugal	General Directorate of Food and Veterinary / Direção-Geral de Alimentação e Veterinária (DGAV)	Animal Drugs	May 30, 2023
Romania	National Agency for Medicines and Medical Devices	Human Drugs	March 1, 2018
Slovakia	State Institute for Drug Control / Štátny ústav pre kontrolu liečiv (ŠÚKL)**	Human Drugs	July 11, 2019
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)	Human Drugs Animal Drugs	February 7, 2019 May 30, 2023
Spain	Spanish Agency of Medicines and Medical Devices/ Agencia Española de Medicamentos y Productos Sanitarios	Human Drugs Animal Drugs	November 1, 2017 May 30, 2023
Sweden	Medical Products Agency / Läkemedelsverket	Human Drugs Animal Drugs	November 1, 2017 September 26, 2023
United States	Food and Drug Administration	Human Drugs Animal Drugs	November 1, 2017 May 30, 2023

***Limitations:** The capability determinations apply to routine surveillance inspections. In the future the following product and inspection types may be included in the coverage of the agreement, pending further consideration:

- Vaccines for human use
- Plasma derived pharmaceuticals
- Investigational products (clinical trial material), specific to each agreement

The FDA and the EU have considered the issue of expanding the scope of the MRA to include vaccines and plasma-derived pharmaceuticals for human use. FDA has decided to consider the issue again in July 2025 based on further assessment.

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 nonsterile, 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.

Resources

- Frequently Asked Questions - Mutual Recognition Agreement (/media/168700/download?attachment)
- FDA Expands Mutual Recognition Agreement with European Union (/media/168704/download?attachment), OGPS Statement, May 31, 2023
- Ensuring Patient Safety and Drug Manufacturing Quality Through Partnership with European Union Regulators (/news-events/fda-voices/ensuring-patient-safety-and-drug-manufacturing-quality-through-partnership-european-union-regulators)
- U.S.-EU Mutual Recognition Agreement Sectoral Annex for GMPs (https://ustr.gov/sites/default/files/IssueAreas/Manufacturing/20170119%20Pharma%20MRA%20US%20EU%20%28FINAL%29.pdf)

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- Press Release - FDA takes unprecedented step toward more efficient global pharmaceutical manufacturing inspections (/news-events/press-announcements/fda-takes-unprecedented-step-toward-more-efficient-global-pharmaceutical-manufacturing-inspections)
- Press Release- Mutual Recognition promises new framework for pharmaceutical inspections for United States and European Union (/news-events/press-announcements/mutual-recognition-promises-new-framework-pharmaceutical-inspections-united-states-and-european)
- Four more EU Member States benefit from EU-US mutual recognition agreement for inspections (http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/03/news_detail_002915.jsp&mid=WC0b01ac058004d5c1) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

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