← Good manufacturing practice

Mutual recognition agreements (MRA)

The European Union (EU) has signed mutual recognition agreements (MRAs) with third-country authorities concerning the conformity assessment of regulated products. Such agreements contain a sectoral annex on the mutual recognition of good manufacturing practice (GMP) inspections and batch certification of human and veterinary medicines.

Human | Veterinary | Compliance and inspections

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This content applies to human and veterinary medicines.

MRAs allow EU authorities and their counterparts to:

- rely on each other's GMP inspection system;
- share information on inspections and quality defects;
- waive batch testing of products on import into their territories;

Each agreement has a different scope.

MRAs are trade agreements that aim to facilitate **market access** and encourage greater **international harmonisation** of compliance standards while protecting consumer safety.

These agreements benefit regulatory authorities by reducing duplication of **inspections on each other territory**, allowing for greater focus on sites that could have a higher risk and broadening the inspection coverage of the global supply chain.

They also facilitate trade in pharmaceuticals because they **reduce costs for manufacturers** by reducing the number of inspections taking place at facilities and waiving re-testing of their products upon importation.

EMA role

The European Commission is responsible to negotiate MRAs with partner countries on behalf of the EU. The European Commission may consult EMA on **regulatory and scientific questions** as part of this process.

EMA is involved in **operational activities** once the MRAs are in place, including:

- facilitating cooperation on inspections, including joint inspections and exchange of information on inspections;
- facilitating exchange of information and being the relevant contact point between the EU GMP inspectorates and partner authorities;
- operating the EudraGMDP database and connecting partners countries to it;
- responding to queries on the implementation of the MRA;
- involving partners countries in relevant EMA working groups, such as the GMP/Good-distribution-practice Inspectors Working Group;
- coordinating MRA maintenance activities.

Overview of specific MRAs

Australia

Status	In operation since: • 1 January 1999 for human medicines; • 1 June 2001 for veterinary medicines.

Products covered	• human chemical pharmaceuticals • medicinal gases • human biologicals, including vaccines, immunologicals and biotherapeutics • human radiopharmaceuticals • stable medicinal products derived from human blood or human plasma • homeopathic medicines, if classified as medicinal product • vitamins, minerals and herbal medicines if classified as medicinal products • products intended for use in clinical trials, investigational medicinal products (IMPs), except those used in phase I clinical trials • intermediate products and bulk pharmaceuticals • active pharmaceutical ingredients, only for human medicinal products • veterinary chemical pharmaceuticals • premixes for preparation of veterinary medicated feedstuff • veterinary immunologicals, including vaccines, immunologicals and biotherapeutics
Products excluded	• advanced therapy medicinal products
Territorial applicability	Products manufactured in the territories of the EU and Australia.
Exchange of information	Exchange of certificates of GMP compliance for manufacturers and batch certificates. A two-way alert system is in operation.
Agreement	• EU adoption decision • Amendment to the MRA (inclusion of active pharmaceutical ingredients in the operational scope)

	• Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia - Final Act
Related content	Partners and networks: Australia

Canada

Status	In operation since 1 February 2003. In 2017, the MRA was suspended and incorporated into the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada, which applies provisionally as of September 2017. The suspended MRA will be terminated when CETA fully enters into force, pending ratification by EU Member States. The first Joint Sectoral Group on Pharmaceuticals under CETA met in November 2018 and agreed a number of Administrative Arrangements. More information is available from the European Commission.
Products covered	• human pharmaceuticals including prescription and non-prescription medicinal products or drugs and medicinal gases • human biologicals including immunologicals and biotherapeutics • human radiopharmaceuticals • veterinary pharmaceuticals, including prescription and non-prescription medicinal products or drugs, and pre-mixes for the preparation of veterinary medicated feeds

	• intermediate products and bulk pharmaceuticals • products intended for use in clinical trials or investigational medicinal products; manufactured by the manufacturers holding a manufacturing authorisation or establishment licence • vitamins, minerals and herbal remedies, homeopathic medicinal products (known in Canada as natural health products) manufactured by manufacturers holding a manufacturing authorisation or establishment licence in the case of Canada
Products excluded	• stable medicinal products derived from human blood or blood plasma • advanced therapy medicinal products • active pharmaceutical ingredients • veterinary biologicals
Territorial applicability	Products manufactured in the territories of the EU and Canada. GMP inspections of manufacturing facilities in third countries by a regulatory authority of either party may be accepted. This provision is applicable from 15 April 2021.
Agreement	• Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products
Related content	• Partners and networks: Canada • Regulatory cooperation forum

Israel

Status	The MRA with Israel is an agreement on conformity assessment and acceptance of industrial products (ACAA). This is a **specific type of MRA** based on the alignment of the legislative system and infrastructure of the country concerned with those of the EU. In operation since 19 January 2013 (after Israel had implemented the relevant EU legislation and aligned its GMP standards, inspection procedures and forms to those used in the EU)
Products covered	• human chemical and biological pharmaceuticals • human immunologicals • radiopharmaceuticals • vitamins, minerals and herbal medicines if classified as medicinal products • intermediate products and bulk pharmaceuticals • active pharmaceutical ingredients • excipients • veterinary chemical pharmaceuticals • premixes and preparation of veterinary medicated feedstuff • veterinary biologicals except immunologicals Israel and the EU recognise official batch releases carried out by each other's authorities.
Products excluded	• medicinal gases • homeopathic medicines • products intended to be used in clinical trials, investigational medicinal products (IMP) • medicinal products derived from human blood or human plasma • veterinary immunologicals

	• advanced therapy medicinal products
Territorial applicability	Products manufactured in the territories of the EU and Israel and manufacturers in third countries inspected by the regulatory authority of either party if the product also undergoes re-control in one of the parties.
Exchange of information	Exchange of certificates of GMP compliance for manufacturers and batch certificates. A two-way alert system is in operation.
Agreement	• EU adoption decision OJ L1/1 of 4.1.2013 • ACAA text OJ L1/1 of 4.1.2013
More information	• Implementation of ACAA - Information sheet • Agreement between Israel and the EU on conformity assessment and acceptance of industrial products: Questions and answers
Related content	Partners and networks: Israel

Japan

Status	In operation since 29 May 2004 with limited scope. Updated in July 2018 to to include sterile and biological products and active pharmaceutical ingredients. This scope extension is **effective as of 17 July 2018**.

Products covered	Human medicines only, including:
	• chemical pharmaceuticals;
	• homeopathic medicinal products if classified as medicinal products and subject to GMP requirements in Japan;
	• vitamins, minerals and herbal medicines if classified as medicines in the both parties;
	• biological pharmaceuticals, including immunologicals and vaccines, that are:
	  ◦ produced by cell culture utilising natural or recombinant microorganisms or established cell lines;
	  ◦ derived from non-transgenic plants and non-transgenic animals;
	• active pharmaceutical ingredients of any medicine covered in the agreement;
	• sterile medicines that belong to any of the above categories.

Products excluded	• veterinary medicines • stable medicines derived from human blood or blood plasma • advanced therapy medicinal products • medicinal gases • products intended to be used in clinical trials, investigational medicinal products (IMP)
Territorial applicability	Products manufactured in the territories of the EU and Japan.
Exchange of information	Exchange of certificates of GMP compliance for manufacturers through the EudraGMDP database and batch certificates. A two-way alert system is in operation. For more information, see:

	• Utilisation of EudraGMDP database in regulatory procedures in the context of the mutual recognition agreement between Japan and the European Union - impact on good-manufacturing-practice certificates • Japanese Pharmaceuticals and Medical Devices Agency (PMDA): GMP • PMDA: Application procedure for GMP Certification between the European Union and Japan
Agreement	• Agreement on mutual recognition between the European Union and Japan • Agreement on mutual recognition in order to amend Part B of the Sectoral Annex on GMP • Joint Committee Decision No 2/JP/2018 of 17 July 2018
Related content	• Partners and networks: Japan • PMDA Pharmaceuticals and Medical Devices Agency

New Zealand

Status	In operation since: • 1 January 1999 for human medicines; • 1 June 2001 for veterinary medicines.
Products covered	• human chemical pharmaceuticals • medicinal gases • human biologicals, including vaccines, immunologicals and biotherapeutics • human radiopharmaceuticals • stable medicinal products derived from human blood or human plasma • homeopathic medicines, if classified as medicinal product

	• vitamins, minerals and herbal medicines if classified as medicinal products • products intended for use in clinical trials, investigational medicinal products (IMPs) • intermediate products and bulk pharmaceuticals • veterinary chemical pharmaceuticals • premixes for preparation of veterinary medicated feedstuff • veterinary immunologicals, including vaccines, immunologicals and biotherapeutics
Products excluded	• advanced therapy medicinal products • active pharmaceutical ingredients
Territorial applicability	Products manufactured in the territories of the EU and New Zealand, except Tokelau.
Exchange of information	Exchange of certificates of GMP compliance for manufacturers and batch certificates. A two-way alert system is in operation.
Agreement	Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand
Related content	Partners and networks: New Zealand

Switzerland

Status	In operation since 1 June 2002.

Products covered	• human chemical pharmaceuticals • medicinal gases • human biologicals, including vaccines, immunologicals and biotherapeutics • human radiopharmaceuticals • stable medicinal products derived from human blood or human plasma • advanced therapy medicinal products • homeopathic medicines, if classified as medicinal product • vitamins, minerals and herbal medicines if classified as medicinal products • products intended for use in clinical trials (investigational medicinal products - IMPs) • active pharmaceutical ingredients • intermediate products and bulk pharmaceuticals • veterinary chemical pharmaceuticals • premixes for preparation of veterinary medicated feedstuff • veterinary immunologicals, including vaccines, immunologicals and biotherapeutics Switzerland and the EU recognise official batch releases carried out by each other's authorities.
Territorial applicability	Products manufactured in the territories of the EU and Switzerland and manufacturers in third countries inspected by the regulatory authority of either party if the product also undergoes re-control in one of the parties.
Exchange of information	Exchange of information on manufacturing/import authorisations and GMP compliance and non-compliance including through the EudraGMDP database.

	A two-way alert system is in operation. For more information, see: • EU and Switzerland to improve information-sharing on good manufacturing practice through use of the EudraGMDP database • Swissmedic: New application procedure for GMP certificates
Agreement	Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment
More information	• Explanatory notes to Chapter 15 (Medicinal products GMP inspection and batch certification) of Annex 1 of EU - Swiss MRA • Mutual recognition agreements EC - Switzerland: Questions and answers covering interpretation of Chapter 15, explanatory notes, Annex 16 and notice to applicants
Related content	Partners and networks: Switzerland

United States

Status	Entered into force on 1 November 2017 for human medicines and 30 May 2023 for veterinary products. Fully operational for human medicines as of 11 July 2019, following a transition phase. The United States Food and Drug Administration (US FDA) is expected to conclude its assessment of the capability of

	all **national competent authorities** responsible for **veterinary products** in EU Member States by mid-2024. To consult the current list of the veterinary authorities of the EU recognised by the US FDA, see: • European Commission: Good Manufacturing and Distribution Practices Transitory provisions apply for veterinary medicines, vaccines for human use and plasma-derived medicines.
Transition phase	During a transition phase, the authorities assess each other's pharmaceutical legislation, guidance documents and regulatory systems as part of the agreement. **Human medicines** The transition phase for human medicines covered by the agreement **ended on 11 July 2019**. As of 11 July 2019, qualified persons in the EU Member States **do not need to batch test** human medicines covered by the MRA, provided that they have verified that these controls have been carried out in the United States for products manufactured in and imported from the United States. **Veterinary products** As of 30 May 2023: • The EU recognises the US FDA as equivalent for GMP inspections of manufacturers of veterinary products. • The US FDA recognises 16 national competent authorities responsible for veterinary products in the EU.

	Countries added to the list of recognised authorities: • Sweden - added on 3 October 2023 • Latvia - added on 28 November 2023 • Lithuania - added on 18 July 2024 • Germany - added on 7 August 2024 • Cyprus - added on 8 October 2024 • Czech Republic - added on 18 October 2024 • Slovakia - added on 10 December 2024 • Italy - was added on 17 December 2024 To consult the current list of the veterinary authorities of the EU recognised by the US FDA, see: • European Commission: Good Manufacturing and Distribution Practices The assessment of the remaining veterinary authorities is ongoing and is expected to conclude by mid-2024. In July 2024 the European Commission and FDA have agreed to extend the timeline for the completion of the assessments till 31 January 2025. The waiver from batch release testing upon importation of veterinary products to the EU will be implemented once the US FDA has recognised all veterinary authorities of the EU Member States.
Products covered	• marketed finished pharmaceuticals for human use in various pharmaceutical dosage forms such as tablets, capsules, ointments, and injectables, including: ◦ medical gases; ◦ radiopharmaceuticals or radioactive biological products; ◦ herbal (botanical) products if classified as medicinal products;

	◦ homeopathic products. • marketed biological products: ◦ therapeutic biotechnology-derived biological products; ◦ allergenic products. • intermediates • active pharmaceutical ingredients or bulk drug substance • veterinary products: ◦ veterinary pharmaceuticals, including prescription and non-prescription drugs, with the exclusion of veterinary immunologicals; ◦ pre-mixes for the preparation of veterinary medicated feeds (EU), Type A medicated articles for the preparation of veterinary medicated feeds (US).
Products excluded	• human blood and plasma • human tissues and organs • veterinary immunologicals • advanced therapy medicinal products
Products currently not included	• vaccines for human use and plasma-derived medicines: postponed due to the COVID-19 pandemic. A new date for a decision on a possible expansion of the scope needs to be agreed between the EU and the US. However, the parties have agreed to start technical cooperation with a view to a future decision on possible expansion of the scope. • products intended for use in clinical trials (investigational medicinal products): discussion at a later stage.
Agreement	• Agreement on mutual recognition between the European Union and the

	United States of America, amending the Sectoral Annex for GMPs
Territorial applicability	Products manufactured in the territories of the EU and US. GMP inspections of manufacturing facilities in third countries by a regulatory authority of either party may be accepted. However, this provision is currently not in operation pending a conclusion of a pilot reliance project.
Exchange of information	• Exchange of official GMPs documents. • A two-way alert system is in operation.
More information	• EMA, the European Commission and the FDA signed a confidentiality arrangement in August 2017 in the area of GMP inspections, allowing for the exchange of full inspection reports, including confidential information. For more information, see Partners & networks: United States. • Questions and answers on the impact of mutual recognition agreement between the European Union and the United States as of 7 August 2024 • Questions and answers on impact of European Union-United States mutual recognition agreement on marketing authorisation applications and relevant variations

Topics

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