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EMA Inspections Office

Questions & Answers on the impact of Mutual Recognition Agreement (MRA) between the European Union and the United States as of 1st October 2025

Q1: What is in place since 1 November 2017?

A1: The provisions of the agreement relating to the mutual recognition of good manufacturing practice (GMP) inspections took effect on 1 November 2017. This milestone followed the confirmation, in June 2017, by the European Union (EU) that the United States Food and Drug Administration (US FDA) has the capability, capacity and procedures in place to carry out GMP inspections for certain human medicines at a level equivalent to the EU and on 1 November 2017, the confirmation by the FDA of the capability of Austria, Croatia, France, Italy, Malta, Spain and Sweden.

US FDA confirmed the capability for inspections of human medicinal products of the remaining Member States on:

- 1 March 2018: Czechia, Greece, Hungary and Romania;
- 1 June 2018: Ireland and Lithuania;
- 14 September 2018: Portugal;
- 16 November 2018: Belgium, Denmark, Finland and Latvia;
- 28 November 2018: Estonia;
- 7 February 2019: Poland and Slovenia;
- 29 April 2019: Bulgaria and Cyprus;
- 10 June 2019: Luxembourg and the Netherlands;
- 26 June 2019: Germany;
- 11 July 2019: Slovakia.

Joint Sectoral Committee Decision No 2536/2023 extended the scope of the EU-US MRA Sectoral Annex on Pharmaceutical GMP to veterinary products as these were not in the scope of the Annex from the beginning (Transitory Provision under Article 20(2) of the that Annex).

On 30 May 2023, following an assessment of the US FDA based on similar requirements to the one conducted for human medicines, the EU recognised the US FDA as equivalent for GMP inspections of veterinary products. At the same time the US FDA confirmed the capability of 16 EU Member States – Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Slovenia, Luxembourg, Netherlands, Poland, Portugal, and Spain. With these recognitions, the MRA became operational for veterinary products.
Between June 2023 and September 2025 FDA confirmed the capability of Sweden, Latvia, Lithuania, Germany, Cyprus, Czechia, Slovakia, Italy and Romania. The assessments of the remaining 2 EU Member States (Malta and Croatia) for inspections of manufacturers of veterinary products are on-going.

Q2: Does this Mutual Recognition Agreement mean that from 1 November 2017 for human medicines and from 30 May 2023 for veterinary products EU and US regulators will stop conducting GMP inspections in each other's territories?

A2: As of 1 November 2017, for human medicines and 30 May 2023 for veterinary products, the EU Member States will not duplicate inspections conducted by the FDA. At the same time, it is expected that the FDA will not duplicate inspections conducted by a recognised authority[i].

Exceptionally, both the EU and FDA reserve the right to inspect in each other's territory at any time.

Q3: Does this Mutual Recognition Agreement mean that from 1 November 2017, EU and US regulators can rely on each other's GMP inspections, not only in their territories but also outside the EU and the US?

A3: Following an evaluation through a pilot programme the EU GMP/GDP Inspectors Working Group agreed to enable the voluntary provision of the EU-US MRA foreseen in Article 3(1) of the agreement to rely on the outcome of US FDA inspections conducted outside the US as of 1 October 2025. Following a case-by-case assessment and the application of a risk-based approach EU national competent authorities may decide to apply reliance and to postpone the conduct of an EU inspection that would normally be required during the assessment timelines of a Marketing Authorisation Application (MAA) or variation. A proactive provision of FDA inspection reports by applicants in the pre-submission phase or with the filing of the MAA or variation will facilitate the application of this provision.

Q4: What is the difference between this agreement and the Mutual Recognition Agreement signed in 1998?

A4: The EU and the US signed the agreement on mutual recognition between the European Community and the United States of America in 1998. The agreement included a Pharmaceutical Annex providing reliance on each other's GMP inspections. However, this was never fully implemented. The 2017 amendment to the Sectoral Annex is building on the 1998 MRA. It benefits from the cooperation of the EU and the US in the past years through various pilot initiatives on GMP inspections.

Q5: What products are included in the scope of the Mutual Recognition Agreement?

A5: The indicative scope of the amended Sectoral Annex (see Appendix 3 thereto) covers a broad range of human medicines, marketed biological products as well as veterinary products with specific exclusions for human blood, human plasma, human tissues and organs as well as veterinary immunologicals.
The current operational scope of the agreement includes human and veterinary products. At a later stage, and after thorough assessment, the Joint Sectoral Committee has the option to extend the operational scope gradually to human vaccines and human-plasma-derived products and investigational medicinal products.

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:

  (a) veterinary pharmaceuticals, including prescription and non-prescription drugs, with the exclusion of veterinary immunologicals;

  (b) pre-mixes for the preparation of veterinary medicated feeds (EU), Type A medicated articles for the preparation of veterinary medicated feeds (US).

Please see also the MRA webpage on the EMA website.

Q6: What products are excluded from or are currently not in the scope of the Mutual Recognition Agreement?

A6: Human vaccines and human-plasma-derived products are not immediately included within the operational scope of the agreement. A decision on their possible inclusion will be taken at a later stage.

Human blood, human plasma, human tissues and organs as well as veterinary immunologicals are excluded from the scope. Also, investigational medicinal products (IMPs) and advanced therapy medicinal products (ATMPs) are currently not included.

Q7: Are combination products included in the scope provided they are regulated by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) in the US and registered as a "medicinal product" in the EU?

A7: The applicable product scope is defined by the provisions of Article 4 and Appendix 3 of the Sectoral Annex. Products falling within this scope are covered by the MRA.

Q8: What will happen next?

A8: Following the implementation of the MRA for human medicines and veterinary products, the Joint Sectoral Committee will consider whether to extend the operational scope of the MRA to human vaccines and human-plasma-derived products.

Q9: Where can I find an up-to-date list of recognised authorities?

A9: The EC is publishing the list of recognised authorities[i]. This list will be regularly updated once a Member State authority has been found capable by the FDA for human medicines and/or veterinary product inspections.

Q10: Can I stop import testing for human medicines?

A10: Yes, the provision on batch testing as foreseen in Article 9 of the GMP Sectoral Annex to the MRA came into force on 11 July 2019. The Article 9 waiver was conditional on all EU Member States authorities responsible for human medicines listed in Appendix 2 of the MRA being recognised and therefore currently only applies to human medicines included in the MRA scope (see products in Q5).
From 11 July 2019, qualified persons in the EU Member States are relieved of their responsibility for carrying out the controls on human medicines laid down in Article 51 paragraph 1 of Directive 2001/83/EC provided that they verified that the product was manufactured in the United States and the controls have been carried out in the United States. Each batch/lot should be accompanied by a batch certificate (in alignment with the WHO certification scheme on the quality of medicinal products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

Q11: Can I stop import testing for veterinary products?

A11: No, the provision on batch testing for veterinary products as foreseen in Article 9 of the GMP Sectoral Annex to the MRA will come into force only once FDA has recognised all EU National Competent Authorities responsible for veterinary medicinal products. Currently this is estimated to be by Q1/2025. Further guidance on this topic will be published in due course.

[i] as per Appendix 2 of the Sectoral Annex