Launch of international pilot programme on inspection of manufacturers of sterile medicines

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EMA and its European and international partners are launching a [pilot programme to increase their cooperation in the inspection of manufacturers of sterile medicines for human use](https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/international-collaboration-gmp-inspections#manufacturers-of-sterile-medicines-section). This new initiative is built on the success of and experience gained from a similar collaboration, the [international active pharmaceutical ingredients (APIs) inspection programme](https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/international-collaboration-gmp-inspections#active-substance-inspections-section).

This collaboration will allow EMA, EU national authorities (France and the United Kingdom), the United States [Food and Drug Administration (FDA)](https://www.fda.gov/home), Australia's [Therapeutic Goods Administration (TGA)](https://www.tga.gov.au/), [Health Canada](https://www.canada.ca/en/health-canada.html), the Japanese [Pharmaceuticals and Medical Devices Agency (PMDA)](https://www.pmda.go.jp/english/), and the [World Health Organization (WHO)](https://www.who.int/) to share information on[good manufacturing practice (GMP)](https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice) inspections of manufacturers of sterile medicines who are located outside the participating countries, and to organise joint inspections for manufacturing sites of common interest.

International collaboration in inspections has demonstrated its benefits in improving oversight of manufacturers and making best use of inspection resources worldwide, through mutual reliance between participating regulatory bodies, the reduction of duplication of inspections and the increase in the coverage of sites inspected worldwide. The objectives, scope and general principles of this new collaboration are laid out in the [terms of reference for the programme](https://www.ema.europa.eu/documents/other/pilot-programme-international-cooperation-gmp-inspection-manufacturers-sterile-medicinal-products_en.pdf) .

The products in scope are sterile [medicinal products](https://www.ema.europa.eu/en/glossary/medicinal-product) for human use of chemical origin and certain therapeutic [biotechnology](https://www.ema.europa.eu/en/glossary/biotechnology)-derived products (such as monoclonal antibodies and recombinant proteins). Products currently out of scope of this pilot are vaccines, cell and gene therapies and plasma-derived pharmaceuticals.

The pilot will last for a minimum of two years after which the participating authorities will assess the programme and determine the next steps in the collaboration.