EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 July 2018
EMA/252360/2018
Media and Public Relations

Press release

EU and Japan reinforce their collaboration on inspections of medicine manufacturers

Update of 2004 mutual recognition agreement extends scope to sterile products, active pharmaceutical ingredients and biologicals including vaccines

The European Union (EU) and Japan have agreed to broaden the range of medicines for which they will recognise each other's inspections of manufacturing sites.

The current mutual recognition agreement (MRA) between the EU and Japan has been operational since 29 May 2004. It allows regulators to rely on Good Manufacturing Practice (GMP) inspections in each other's territories, to waive batch testing of medicines that enter Japan from EU countries and vice versa and to share information on inspections and quality defects. Thanks to this agreement, regulatory authorities in the EU and Japan can make better use of their inspections resources by reducing duplication of inspections in each other's territory.

The scope of this agreement has now been extended to include sterile medicines, certain biological medicines including vaccines and immunologicals, and active pharmaceutical ingredients (APIs) of any medicine covered in the agreement. This means that authorities from the EU and Japan have agreed that they have equivalent regulatory and procedural frameworks for inspections of manufacturers for these products and can therefore rely on each other's inspections.

The full scope of the MRA now covers chemical pharmaceuticals, homeopathic medicinal products (as long as treated as medicinal products and subject to the GMP requirements in Japan), vitamins, minerals and herbal medicines (if considered as medicinal products in both parties); certain biological pharmaceuticals including immunologicals and vaccines, APIs for any of the above categories and sterile products belonging to any of the above categories.

In the EU, inspections of manufacturing sites are carried out by national competent authorities from EU Member States. In Japan, GMP inspections are conducted by the Pharmaceuticals and Medical Devices Agency (PMDA) and the 47 inspectorates of the prefectures.

This is the first update of the original MRA agreement. As part of the product scope expansion project, Japan also evaluated and recognised as equivalent all EU competent authorities for human medicines inspection.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The biological pharmaceuticals, including immunologicals and vaccines, in the scope of the agreement are: medicinal products produced by cell culture utilising natural microorganisms or established cell lines; medicinal products produced by cell culture utilising recombinant microorganisms or established cell lines; and medicinal products derived from non-transgenic plants and non-transgenic animals.
3. More information on the interactions between EMA and Japan are available on the EMA website. More information on the scope of the MRA agreement is available here.
4. The update of applicable legislation and recognition of the equivalence of all EU Member States was formalised through an exchange of Diplomatic Notes with Japan published in the Official Journal of the EU.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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