

VMD and FDA Announce Mutual Recognition Agreement

News story

Announcement of Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections of Veterinary Medicines.



The Veterinary Medicines Directorate (VMD) and the U.S. Food and Drug Administration (FDA) today, 27 September, announce their decision to expand the scope of the U.S.- UK Mutual Recognition Agreement (MRA) Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMP) to include inspections of veterinary pharmaceuticals.

This MRA entered into force on 1 January 2021, but initially included only pharmaceuticals intended for human use. Today's action to include veterinary medicines in the MRA is an important step that will enhance efficiencies for the UK and U.S. regulatory systems.

An MRA is an agreement between two or more countries to recognise a specific process or procedure of the other country and this is the first step toward strengthening use of each other's veterinary medicines inspection expertise and resources.

The overall goal of the MRA is to produce greater efficiencies for both regulatory systems and provide a more practical means for both the VMD and the FDA to oversee the facilities that manufacture veterinary medicines in these locations.

By utilising each other's inspection reports and related information, an MRA can ultimately enable the VMD and the FDA to avoid duplication of some inspections and enable regulators to devote more resources to other areas where there may be greater risk.

Over the past several months, the VMD and the FDA have taken numerous steps to prepare for expanding and implementing the MRA's coverage. This has included among other things, sharing information about the oversight of

veterinary medicines manufacturing, observing audits and evaluating regulatory frameworks, which found both countries have the capability, capacity, equivalent standards and procedures to carry out routine GMP surveillance inspections that meet the requirements for veterinary products.

Published 27 September 2021