Guidance on importation of investigational medicinal products from approved countries

How the management and oversight of the import of investigational medicinal products from listed countries will work in a no-deal Brexit.

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Medicines and Healthcare products Regulatory Agency

Documents

Importing Investigational Medicinal Products (IMP) from EEA to UK

HTML

List of approved countries for clinical trials and investigational medicinal products if the UK leaves the EU without a deal

HTML

Details

Sponsors of UK clinical trials that source investigational medicinal products (IMPs) from an EEA State will need to review their existing supply chains.

Action for sponsors of UK clinical trails using IMPs imported from countries on an ‘approved country for import’ list

You will require a UK Manufacturing and Import Authorisation (MIA(IMP)) holder to put in place an assurance system to check these IMPs have been certified by a Qualified Person (QP) in a listed country, before release to the trial. This list is initially, all EU and EEA countries.

IMPs that have been QP certified in a listed country will not require recertification in the UK.

The purpose of this guidance is to describe the principles for the management and oversight of the import of IMPs to the UK from listed countries.

There will be a one-year transition period following the date of the UK’s exit from the EU to implement this guidance.

This guidance will apply from exit day in line with the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019.