Monitoring of medicines originating from Japan

European regulatory authorities are continuing to work with international regulatory partners to ensure that appropriate measures are taken to monitor medicines manufactured or partially manufactured in Japan following the radiation leak from the Fukushima Daiichi nuclear power plant.

To date, no risks from radioactive contamination have been identified in any medicines imported to the European Union (EU) and the likelihood of such contamination occurring is considered to be minimal. However in the interest of patient safety, a precautionary approach has been introduced that takes into account the measures put in place in the EU for food and animal feed.

Since early May 2011, Marketing Authorisation Holders (MAHs) of medicines partially or totally manufactured in the specific Japanese prefectures to which the food measures apply have been asked to test their products to determine the level of radionuclides prior to export from Japan to the EU and to prepare declarations for submission to the authorities. All test results received to-date have demonstrated the absence of any radioactivity concerns.

The EU food regulations were updated in November 2017 (Commission Implementing Regulation (EU) 2017/2058) and by analogy European regulatory authorities have agreed that the approach for medicines should also be adapted.

The following measures apply to all medicines manufactured, partially manufactured, transited or stored in Japan with the exclusion of products which have been manufactured before 11th March 2011 and exported before 28th March 2011:

- For medicines manufactured, partially manufactured, transited or stored in the prefecture of Fukushima, testing for the presence of radioactivity is still required.
- For medicines manufactured, partially manufactured, transited or stored in the prefectures of Gunma, Ibaraki, Tochigi, Miyagi, Iwate and Chiba, testing is only required for medicinal products containing raw materials of fish or vegetal origin sourced from these prefectures.
- For medicines manufactured, partially manufactured, transited or stored in other Japanese prefectures, no additional testing for the presence of radioactivity is required.
- Testing of cytotoxic products irrespective of origin is not requested in view of the potential risks to the operators and the minimal likelihood of radioactive contamination as confirmed by the data available to date.
European Regulatory Authorities have, in addition, decided that medicines coming from manufacturing sites in any of the listed prefectures where satisfactory test results have been recorded are no longer requested to be tested.

Where testing is still required, MAHs are required to test their products to determine the levels of the radionuclides caesium-134 and caesium-137 prior to export from Japan to the EU.

Since the situation with regard to radioactivity is constantly evolving, a request to re-launch testing may be made if the situation changes. MAHs are reminded that they are responsible for ensuring the continued quality and safety of their products and are encouraged to regularly check this webpage for further updates.

It is stressed that for a series of reasons, it is very unlikely that medicines imported from Japan will be subject to radioactive contamination. Nevertheless, European Regulatory Authorities remain vigilant and active in ensuring that medicines entering the EU from Japan are safe.

The approach is expected to be reviewed again after the next update of the relevant Food Regulation.

**Link to relevant EC food Regulation:**
Commission Implementing Regulation (EU) 2017/2058 of 10th November 2017 amending Implementing Regulation (EU) 2016/6 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R2058