Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

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MONITORING OF VETERINARY MEDICINES ORIGINATING FROM JAPAN

1. 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.

2. 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.

3. 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 information received to-date has demonstrated the absence of any radioactivity concerns.

4. The EU food regulations have recently been updated in May 2013 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 11 March 2011 and exported before 28 March 2011:

   a. For medicines manufactured, partially manufactured, transited or stored in the prefecture of Fukushima, testing for the presence of radioactivity is still required.

   b. For medicines manufactured, partially manufactured, transited or stored in the prefectures of Gunma, Ibaraki, Tochigi, Miyagi, Saitama, Tokyo, Iwate, Chiba and Kanagawa, testing is only required for medicinal products containing raw materials of fish, animal or vegetal origin sourced from these prefectures.

   c. For medicines manufactured, partially manufactured, transited or stored in other Japanese prefectures, no additional testing for the presence of radioactivity is required.

   d. 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.

   e. 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.

5. 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.

6. On the human side, the EMA has asked the Japanese pharmaceutical industry associations to compile the testing results in order to facilitate communication & review of the information and to periodically send a summary of the results to the EMA.

7. 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.

8. 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.

9. As with the food measures, the approach is expected to be applicable until 31 March 2014 and will be reviewed again at that time.

10. European Commission webpage on accident at Fukushima nuclear power plant, including Implementing Regulations: link