EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends revaccination for some travellers in need of protection with Ixiaro

Batch JEV09L37 of Ixiaro to be recalled

The European Medicines Agency Committee for Medicinal Products for Human Use (CHMP) was informed that a specific batch of the Japanese encephalitis vaccine Ixiaro (batch JEV09L37), manufactured by Intercell AG, may be less potent than expected and may not induce a full protective immune response in vaccinees. Therefore, as a precautionary measure, Intercell AG is recalling batch JEV09L37 of Ixiaro throughout the EU. For individuals who have already received one or two doses of Ixiaro from this batch and who are planning to travel soon to regions of exposure to Japanese encephalitis, the CHMP is recommending that revaccination with a different batch should be considered.

Within the EU, batch JEV09L37 has been used in France, Italy, Spain and the United Kingdom. The CHMP recommended that revaccination of individuals, who have received one or two doses of batch JEV09L37 should be considered if the vaccinee envisages travelling to an affected country in the near future.

Ixiaro is a highly purified vaccine and information from clinical trials, though limited, does not indicate any specific safety concern for vaccinees receiving more than two doses within a short period of time.

The CHMP reviewed results of two separate potency tests in experimental models at the 11-month stability time point for batch JEV09L37. The CHMP noted that batch JEV09L37 met all quality specifications including potency at time of release. At 11 month shelf life, all other quality assuring parameters for this batch were within the authorised specifications with the exception of the potency test.

As an additional precaution, the CHMP agreed that further potency testing of other batches should be conducted, in particular of those in the middle and at the end of their shelf lives. This testing has not yet been concluded.

The European Medicines Agency will provide further updates as appropriate.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The European Public Assessment report on Ixiaro is available on the Agency's website.
3. 20000 syringes of batch JEV09L37 Ixiaro have been distributed in the United Kingdom and Spain together, 3000 in Italy and 3000 in France.
4. The Agency has been informed that Health Canada has decided to recall the batch in question from the market in Canada and is also recommending revaccination.
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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