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Quality issues get Novartis vaccine in trouble in EU

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Europe halts use of anti-influenza vaccine by Novartis

Singapore: A number of European Union (EU) member states have halted the use, as a precautionary measure, of some anti-influenza vaccines manufactured by Novartis Vaccines, because of a suspected quality defect.

The Italian Medicines Agency (AIFA) was first informed of the suspected quality defect by the manufacturer (Novartis Vaccines) located in Italy. The Italian authorities took prompt precautionary action and AIFA alerted all other member states, the European Commission (EC) and the European Medicines Agency (EMA) using the established mechanisms.

These regulatory actions are precautionary, since so far there is no indication that this suspected quality defect has any impact on the safety or efficacy of the vaccines in question.

The European Medicines Agency has no formal legal role in this case, as the products are nationally authorized, but is taking a supporting role by bringing expertise from the network together to assist AIFA and the authorities in the other Member States.

AIFA is taking the lead on behalf of the EU in investigating the suspected quality defect in order to determine whether it affects the safety and efficacy of these vaccines, and whether the affected batches should be permanently removed from the market. The suspected defect involves the aggregation of proteins that are a normal part of the vaccines.