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Questions and answers on the review of Preflucel and associated names (influenza vaccine, purified antigen)

Outcome of a procedure under Article 36 of Directive 2001/83/EC as amended

On 19 July 2012, the European Medicines Agency (EMA) completed a review of the seasonal influenza vaccine Preflucel, following an increase in the number of reported suspected side effects including hypersensitivity (allergic) reactions, which led to a recall of Preflucel batches from the EU market. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the likely cause has been identified and that a number of corrective measures should be integrated into the manufacturing process to resolve the problem.

What is Preflucel?

Preflucel is a vaccine used to prevent seasonal influenza (flu) in adults. It contains fragments of influenza viruses that have been inactivated (killed). It protects against influenza A (sub-types H1N1 and H3N2) and influenza B. The three influenza strains contained in Preflucel are updated each year, based on the official recommendations for the annual flu season.

Preflucel is authorised in the EU under decentralised and mutual recognition procedures, on the basis of an initial authorisation granted in Austria in September 2010. It is currently authorised in Austria, Belgium, Czech Republic, Denmark, Finland, Germany, Ireland, Italy, the Netherlands, Poland, Portugal, Spain, Sweden, the United Kingdom as well as Norway.

Why was Preflucel reviewed?

On 20 October 2011, the Austrian medicines regulatory agency informed the EMA that the company that markets Preflucel, Baxter, had voluntarily recalled the largest batch of the product marketed in the EU following an increase in the number of reported suspected side effects. These involved allergic reactions including cases of anaphylactic (severe allergic) reactions, influenza-like symptoms and eye reactions. Since initial investigations and inspections at the manufacturing sites did not identify process-related issues which could have accounted for the reported reactions, all batches were recalled from the European market as a precautionary measure until the cause had been identified and corrective actions implemented.

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On 9 December 2011, the Austrian medicines agency decided to refer the matter to the CHMP so that the Committee could conduct an EU review of the root cause of the problem, identify appropriate corrective measures, and issue an opinion on whether the marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.

What are the conclusions of the CHMP?

The CHMP concluded that the company has appropriately investigated the root cause of the problem, which related to certain aspects of the manufacturing process. The Committee considered that several corrective measures and additional manufacturing steps had been identified to address the problem, and decided that these should be implemented.

Therefore, the Committee recommended that the terms of the marketing authorisations should be varied to include the necessary changes in the manufacturing process. Before batches of the product produced by the revised process can be released, the company needs to submit an application to implement these changes. It must also carry out a study to show that the vaccine produced by the revised process is as effective at stimulating the production of antibodies against influenza as was seen at the time of initial authorisation and has at least as good a safety profile as other authorised influenza vaccines. The CHMP also decided that the company must carry out a post-marketing study to provide further data on the safety of the revised manufacturing process, and must continue to provide national medicines regulatory authorities with updated monthly information on the reporting of suspected side effects, in particular any cases of severe allergic reactions.

A European Commission decision on this opinion will be issued in due course.