17 September 2020
EMA/CHMP/316963/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Flucelvax Tetra

influenza vaccine (surface antigen, inactivated, prepared in cell cultures)

On 17 September 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Flucelvax Tetra. The marketing authorisation holder for this medicinal product is Seqirus Netherlands B.V.

The CHMP adopted an extension to the existing indication as follows:[2]

Prophylaxis of influenza in adults and children from ~~9~~ **2** years of age.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

[2] New text in bold, removed text as strikethrough

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