

## TRANSPARENCY COMMITTEE

### OPINION

### 11 DECEMBER 2019

#### ***Quadrivalent influenza vaccine, inactivated, prepared in cell cultures*** **FLUCELVAX TETRA, suspension for injection in pre-filled syringe**

#### **First assessment**

##### ► **Key points**

Favourable opinion for reimbursement in prophylaxis of influenza in adults and children from 9 years of age for whom influenza vaccination is recommended<sup>1</sup>

##### ► **What therapeutic improvement?**

No clinical added value.

##### ► **Role in the care pathway?**

In France, vaccination against seasonal influenza is recommended in all people aged 65 years and over and in the following special populations (see vaccine schedule):

- pregnant women, regardless of the trimester of pregnancy;
- people, from 6 months of age, with conditions promoting the onset of serious influenza complications;
- obese people;
- people staying in follow-on care facilities and medical-social care home residents;
- families of infants under 6 months of age with serious influenza risk factors, as well as the families of immunocompromised individuals;
- professionals in regular and prolonged contact with individuals with a severe influenza risk, in particular healthcare professionals and flight crews.

<sup>1</sup> For more information, see page 3.

**Role of the medicinal product in the care pathway**

FLUCELVAC TETRA may be used in accordance with its MA in the context of current vaccine recommendations, aimed at preventing serious forms and seasonal influenza-related deaths.

## 01 COMMITTEE'S CONCLUSIONS

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### 01.1 Clinical Benefit

- ▶ Influenza is a highly contagious acute viral disease. Sometimes serious complications develop more readily in subjects already weakened by underlying diseases and/or over 65 years of age.
- ▶ This proprietary medicinal product is a preventive treatment.
- ▶ The immunogenicity/adverse effects ratio of FLUCELVAC TETRA is high.
- ▶ There are alternative vaccines for the prophylaxis of influenza in adults and children from 9 years of age (FLUARIXTETRA, INFLUVAC TETRA and VAXIGRIPTETRA).
- ▶ FLUCELVAC TETRA may be used in accordance with its MA (from 9 years of age) in the context of current vaccine recommendations, aimed at preventing serious forms and seasonal influenza-related deaths.

#### ▶ **Public health impact**

Considering:

- the frequency (2.5 million people affected each year) and potential severity of influenza, which can cause serious complications, particularly in individuals with specific risk factors (almost 3,000 serious cases admitted to intensive care units in the 2017-2018 season),
- the public health objective, aimed at reducing the morbidity and mortality of this infection,
- the fact that vaccination is the most effective tool to prevent influenza and its complications,
- the objective of improving vaccination coverage to reach a minimum of 75% in the populations targeted by vaccination,
- the medical need to expand the offer in order to be able to guarantee seasonal vaccination of all recommended populations in subsequent influenza seasons,
- the immunogenicity and safety of FLUCELVAX TETRA, comparable to those of the OPTAFLU trivalent vaccine produced in cell cultures (assessed by the Transparency Committee in 2013),
- the expected impact of vaccination on the organisation of care,

FLUCELVAX TETRA is likely to have an impact on public health, in the same way as the other vaccines available to prevent influenza. However, this impact remains dependent, firstly, on achievement of an adequate vaccination coverage rate in the targeted populations and, secondly, on the protection provided by the seasonal vaccine against the viral strains circulating.

**Considering all these elements, the Committee deems that the clinical benefit of FLUCELVAX TETRA is substantial in prophylaxis of influenza in adults and children from 9 years of age for whom influenza vaccination is recommended.**

**The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the indication “prophylaxis of influenza in adults and children from 9 years of age” for whom influenza vaccination is recommended.**

## **01.2 Clinical Added Value**

**In the absence of clinical efficacy data, the Transparency Committee considers that FLUCELVAX TETRA provides no clinical added value (CAV V), in adults and children from 9 years of age for whom vaccination is recommended, compared to the other available inactivated vaccines indicated in this population.**