

<u>EMA Number</u>	<u>(Invented) name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of Administration</u>	<u>Immediate Packaging</u>	<u>Content (concentration)</u>	<u>Pack size</u>
EU/1/24/1807/001 -- <sup>1</sup>	Incellipan	-- <sup>1</sup>	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes

One dose (0.5 ml) contains:

Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of strain\*: A/turkey/Turkey/1/2005 (H5N1)-like strain (NIBRG-23) 7.5 micrograms\*\*

\* propagated in Madin Darby Canine Kidney (MDCK) cells

\*\* expressed in micrograms haemagglutinin.

Adjuvant MF59C.1 containing:

squalene 9.75 milligrams

polysorbate 80 1.175 milligrams

sorbitan trioleate 1.175 milligrams

sodium citrate 0.66 milligrams

citric acid 0.04 milligrams

#### **Annex IV**

**Conclusions on the granting of the conditional marketing authorisation presented by the  
European Medicines Agency**

**Conclusions presented by the European Medicines Agency on:**

**• Conditional marketing authorisation**

The CHMP having considered the application is of the opinion that the risk-benefit balance is favourable to recommend the granting of the conditional marketing authorisation as further explained in the European Public Assessment Report.