

Annex A

<u>MA (EU) 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/1/20/1433/001	Fluad Tetra	-- ¹	Suspension for injection	Intramuscular use	pre-filled syringe (glass) with needle	0.5 ml	1 pre-filled syringe
EU/1/20/1433/002	Fluad Tetra	-- ¹	Suspension for injection	Intramuscular use	pre-filled syringe (glass) without needle	0.5 ml	1 pre-filled syringe
EU/1/20/1433/003	Fluad Tetra	-- ¹	Suspension for injection	Intramuscular use	pre-filled syringe (glass) with needle	0.5 ml	10 pre-filled syringes
EU/1/20/1433/004	Fluad Tetra	-- ¹	Suspension for injection	Intramuscular use	pre-filled syringe (glass) without needle	0.5 ml	10 pre-filled syringes

--¹ Each 0.5 ml dose contains:

Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains*:

A/(H1N1) - like virus antigen	15 µg HA**
A/(H3N2) - like virus antigen	15 µg HA**
B/(Victoria Lineage) - like virus antigen	15 µg HA**
B/(Yamagata Lineage) - like virus antigen	15 µg HA** per 0.5 ml dose

* propagated in fertilized hens' eggs from healthy chicken flocks and adjuvanted with MF59C.1

** haemagglutinin