

Annex A

EU (MA) number	Invented name	Strength	Pharmaceutical form	Target species	Route of administration	Packaging	Content	Package size	Withdrawal period
EU/2/17/207/001	Zulvac BTV	BTV 1 ⁰⁰¹	Suspension for injection	Sheep Cattle	Subcutaneous use (sheep) Intramuscular use (cattle)	Vial (HDPE)	20 ml (10 doses)	1 vial	Zero days
EU/2/17/207/002	Zulvac BTV	BTV 1 ⁰⁰²	Suspension for injection	Sheep Cattle	Subcutaneous use (sheep) Intramuscular use (cattle)	Vial (HDPE)	100 ml (50 doses)	1 vial	Zero days
EU/2/17/207/003	Zulvac BTV	BTV 1 ⁰⁰³	Suspension for injection	Sheep Cattle	Subcutaneous use (sheep) Intramuscular use (cattle)	Vial (HDPE)	240 ml (120 doses)	1 vial	Zero days
EU/2/17/207/004	Zulvac BTV	BTV 4 ⁰⁰⁴	Suspension for injection	Sheep	Subcutaneous use	Vial (HDPE)	20 ml (10 doses)	1 vial	Zero days
EU/2/17/207/005	Zulvac BTV	BTV 4 ⁰⁰⁵	Suspension for injection	Sheep	Subcutaneous use	Vial (HDPE)	100 ml (50 doses)	1 vial	Zero days
EU/2/17/207/006	Zulvac BTV	BTV 4 ⁰⁰⁶	Suspension for injection	Sheep	Subcutaneous use	Vial (HDPE)	240 ml (120 doses)	1 vial	Zero days
EU/2/17/207/007	Zulvac BTV	BTV 8 ⁰⁰⁷	Suspension for injection	Sheep Cattle	Subcutaneous use (sheep) Intramuscular use (cattle)	Vial (HDPE)	20 ml (10 doses)	1 vial	Zero days
EU/2/17/207/008	Zulvac BTV	BTV 8 ⁰⁰⁸	Suspension for injection	Sheep Cattle	Subcutaneous use (sheep) Intramuscular use (cattle)	Vial (HDPE)	100 ml (50 doses)	1 vial	Zero days
EU/2/17/207/009	Zulvac BTV	BTV 8 ⁰⁰⁹	Suspension for injection	Sheep Cattle	Subcutaneous use (sheep) Intramuscular use (cattle)	Vial (HDPE)	240 ml (120 doses)	1 vial	Zero days

- 1 Each dose of 2 ml of vaccine contains one of the following inactivated bluetongue virus strains:
- Inactivated bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1 $RP^* \geq 1$
 - Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02 $RP^* \geq 1$
 - Inactivated bluetongue virus, serotype 4, strain SPA-1/2004 $RP^{**} \geq 0.8$

*Relative Potency by a mice potency test compared to a reference vaccine efficacious in sheep and cattle

**Relative potency by a mice potency test compared to a reference vaccine efficacious in sheep.