

Annex A

EU (MA) Number	Invented name	Strength	Pharmaceutical Form	Target Species	Route of administration	Packaging	Content	Package Size	Withdrawal period
EU/2/03/038/005	ProteqFlu-Te	⁻⁻⁻¹	Suspension for injection	Horses	Intramuscular use	vial (glass)	1 ml	10 vials	Zero days

⁻⁻⁻¹ Influenza A/eq/Ohio/03 [H₃N₈] recombinant canarypox virus (vCP2242) ≥ 5.3 log₁₀ FAID₅₀*/ml

Influenza A/eq/Richmond/1/07 [H₃N₈] recombinant canarypox virus (vCP3011) ≥ 5.3 log₁₀ FAID₅₀*/ml

Clostridium tetani toxoid: ≥ 30 IU**/ml

* vCP content checked by global FAID₅₀ (fluorescent assay infectious dose 50%) and qPCR ratio between vCP.

** antitoxic antibody titre induced after repeated vaccination in guinea pig sera according to Ph. Eur.