

Annex A

EU (MA) Number	Invented Name	Strength	Pharmaceutical form	Target species	Route of administration	Packaging	Content	Package size	Withdrawal period
EU/2/10/114/001	Hiprabovis IBR Marker Live	-- ¹	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: bottle (type I glass); solvent: bottle (type I glass or PET)	Lyophilisate: 5 doses; solvent: 10 ml	Lyophilisate: 1 bottle; solvent: 1 bottle	Zero days
EU/2/10/114/002	Hiprabovis IBR Marker Live	-- ¹	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: bottle (type I glass); solvent: bottle (type II glass or PET)	Lyophilisate: 25 doses; solvent: 50 ml	Lyophilisate: 1 bottle; solvent: 1 bottle	Zero days
EU/2/10/114/003	Hiprabovis IBR Marker Live	-- ¹	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: bottle (type I glass); solvent: bottle (type II glass or PET)	Lyophilisate: 30 doses; solvent: 60 ml	Lyophilisate: 1 bottle Solvent: 1 bottle	Zero days

--¹ Live gE⁻ tk⁻ double-gene deleted Bovine Herpes Virus type 1 (BoHV-1), strain CEDDEL: $10^{6.3} - 10^{7.3}$ CCID₅₀ per 2 ml (gE⁻: deleted glycoprotein E; tk⁻: deleted thymidine kinase; CCID: cell culture infectious dose)