

Annex I

List of the names, pharmaceutical forms, strength of the medicinal products, routes of administration, marketing authorisation holders in the Member States

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength*	Pharmaceutical form	Route of administration
Austria	GlaxoSmithKline Pharma GmbH Albert Schweitzer-Gasse 6 A-1140 Wien Austria	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Austria	GlaxoSmithKline Pharma GmbH Albert Schweitzer-Gasse 6 A-1140 Wien Austria	Priorix		Powder in vials and solvent in prefilled-syringes for solution for injection	Subcutaneous use Intramuscular use
Belgium	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Bulgaria	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for suspension for injection	Subcutaneous use Intramuscular use
Cyprus	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength*	Pharmaceutical form	Route of administration
Czech Republic	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Estonia	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Finland	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength*	Pharmaceutical form	Route of administration
France	Laboratoire GlaxoSmithKline 100 route de Versailles 78163 Marly-le-Roi Cedex France	Priorix powder and solvent for solution for injection in a pre-filled syringe Measles, mumps, and rubella vaccine (live)		Powder and solvent for solution for injection	Subcutaneous use
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 D-80339 München Germany	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Greece	GlaxoSmithKline AEBE 266 Kifisias avenue 152 32 Halandri Greece	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Hungary	GlaxoSmithKline Kft. 1124 Budapest Csörsz u 43 Hungary	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Iceland	GlaxoSmithKline ehf. Thverholt 14 105 Reykjavik Iceland	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength*	Pharmaceutical form	Route of administration
Ireland	GlaxoSmithKline (Ireland) Limited Stonemasons Way Rathfarnham Dublin 16 Ireland	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 37135 Verona Italy	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Latvia	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix pulveris un šķīdinātājs injekciju šķīduma pagatavošanai		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Lithuania	UAB „GlaxoSmithKline Lietuva“ Goštauto 40A LT-01112, Vilnius Lithuania	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Luxembourg	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength*	Pharmaceutical form	Route of administration
Malta	SmithKline Beecham plc Great West Road, Brentford, Middlesex TW8 9GS Trading as GlaxoSmithKline UK Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Netherlands	GlaxoSmithKline BV Huis ter Heideweg 62 3705 LZ Zeist The Netherlands	Priorix		Powder and solvent for solution for injection	Subcutaneous use
Norway	GlaxoSmithKline AS Forskningsveien 2a Postboks 180 Vinderen 0319 Oslo Norway	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Poland	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength*	Pharmaceutical form	Route of administration
Portugal	Smith Kline & French Portuguesa, Produtos Farmacêuticos, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque – Miraflores 1495-131 Algés Portugal	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Romania	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Slovak Republic	GlaxoSmithKline Biologicals s.a. Rue de l'Institut, 89 1330 Rixensart Belgium	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Slovenia	GSK d.o.o., Ljubljana, Knezov štridon 90, 1000 Ljubljana Slovenia	Priorix prašek in vehikel za raztopino za injiciranje		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

Member State EU/EEA	Marketing authorisation holder	(Invented) Name	Strength*	Pharmaceutical form	Route of administration
Spain	GlaxoSmithKline, S.A. C/Severo Ochoa, 2 28760 Tres Cantos (Madrid) Spain	Priorix polvo y disolvente en jeringa precargada para solución inyectable		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
Sweden	GlaxoSmithKline AB, Box 516, 169 29 Solna Sweden	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use
United Kingdom	SmithKline Beecham plc 980 Great West Road, Brentford, Middlesex TW8 9GS United Kingdom Trading as GlaxoSmithKline UK Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Priorix		Powder and solvent for solution for injection	Subcutaneous use Intramuscular use

* Strength applicable for all countries

After reconstitution, 1 dose (0.5 ml) contains:

Live attenuated measles virus (Schwarz strain)

not less than $10^{3.0}$ CCID₅₀

Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain)

not less than $10^{3.7}$ CCID₅₀

Live attenuated rubella virus (Wistar RA 27/3 strain)

not less than $10^{3.0}$ CCID₅₀