

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states

Measles vaccines (live) with Marketing Authorisation in the European Union

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
France	Sanofi Pasteur S.A. 2 avenue Pont Pasteur 69007 Lyon France	ROUVAX, poudre et solvant pour suspension injectable en flacon multidose, vaccin vivant hyperatténué contre la rougeole	one dose (0.5 ml) contains: Measles virus Schwartz strain (live, attenuated) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
France	Sanofi Pasteur S.A. 2 avenue Pont Pasteur 69007 Lyon France	ROUVAX, poudre et solvant pour suspension injectable, vaccin vivant hyperatténué contre la rougeole	one dose (0.5 ml) contains: Measles virus Schwartz strain (live, attenuated) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Germany	Sanofi Pasteur MSD GmbH Paul-Ehrlich-Str. 1 69181 Leimen Germany	Masern-Impfstoff Merieux	one dose (0.5 ml) contains: Measles virus Schwartz strain (live, attenuated) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Germany	Sanofi Pasteur MSD GmbH Paul-Ehrlich-Str. 1 69181 Leimen Germany	Masern-Impfstoff Merieux	one dose (0.5 ml) contains: Measles virus Schwartz strain (live, attenuated) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Spain	Aventis Pasteur MSD S.A. Pº Castellana, 141 28046 Madrid Spain	AMUNOVAX VIAL	one dose (0.5 ml) contains: Measles virus (live, attenuated) - not less than $10^{3.0}$ TCID ₅₀	Powder and solvent for solution for injection	Subcutaneous use

Mumps vaccines (live) with Marketing Authorisation in the European Union

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
France	Sanofi Pasteur MSD S.N.C., 8, Rue Jonas Salk FR-69007 Lyon France	VACCIN OREILLONS AVENTIS PASTEUR MSD, poudre et solvant pour suspension injectable en seringue préremplie vaccin des oreillons, atténué	one dose (0.5 ml) contains: Mumps virus Jeryl Lynn strain (live, attenuated) – $5 \times 10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Subcutaneous use
France	Sanofi Pasteur S.A. 2 avenue Pont Pasteur 69007 Lyon France	IMOVAX OREILLONS, poudre et solvant pour préparation injectable. vaccin à virus vivants atténués contre les oreillons	one dose (0.5 ml) contains: Mumps virus URABE AM-9 strain (live, attenuated) - not less than $5 \times 10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Spain	Aventis Pasteur MSD S.A. Pº Castellana, 141 28046 Madrid Spain	VACUNA MSD ANTI-PAROTIDITIS	one dose (0.5 ml) contains: Mumps virus (Strain Jeryl Lynn - B level) - not less than $20 \times 10^{3.0}$ TCID ₅₀	Powder and solvent for solution for injection	Subcutaneous use

Rubella vaccines (live) with Marketing Authorisation in the European Union

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Sanofi Pasteur S.A. 2 avenue Pont Pasteur 69007 Lyon France	Rudixax	one dose (0.5 ml) contains: live, attenuated rubella virus (strain Wistar RA 27/3) - at least $10^{3.0}$ CCID ₅₀	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
France	Sanofi Pasteur S.A. 2 avenue Pont Pasteur 69007 Lyon France	RUDIVAX, poudre et solvant pour suspension injectable. Vaccin rubéoleux atténué.	one dose (0.5 ml) contains: Rubella virus Wistar RA 27/3 strain (live, attenuated) - $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Germany	Sanofi Pasteur MSD GmbH Paul-Ehrlich-Str. 1 69181 Leimen Germany	Röteln-Impfstoff HDC Merieux	one dose (0.5 ml) contains: Rubella virus Wistar RA 27/3 strain (live, attenuated) - $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Germany	Sanofi Pasteur MSD GmbH Paul-Ehrlich-Str. 1 69181 Leimen Germany	Röteln-Impfstoff HDC Merieux	one dose (0.5 ml) contains: Rubella virus Wistar RA 27/3 strain (live, attenuated) - $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Spain	Aventis Pasteur MSD S.A. Pº Castellana, 141 28046 Madrid Spain	VACUNA ANTIRRUBEOLA MERIEUX	one dose (0.5 ml) contains: Rubella virus live attenuated (Strain Wistar RA 27/3M) - not less than $10^{3.0}$ TCID ₅₀	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	GLAXOSMITHKLINE, S.A. C/ Severo Ochoa, 2 Tres Cantos 28760 Madrid Spain	VACUNA ANTIRRUBEOLA GSK	one dose (0.5 ml) contains: Live attenuated rubella virus (Strain RA 27/3) - not less than $10^{3.0}$ TCID ₅₀	Powder and solvent for solution for injection	Subcutaneous use
Spain	INSTITUTO BERNA DE ESPAÑA, S.A. Pº de la Castellana, 163 28046 MADRID Spain	RUBEATEN BERNA	Rubella virus live (Strain Wistar RA 27/3) - not less than $10^{3.0}$ TCID ₅₀	Powder and solvent for solution for injection	Subcutaneous use

Varicella vaccines (live) with Marketing Authorisation in the European Union

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	GlaxoSmithKline Pharma GmbH Albert-Schweitzer-Gasse 6 AT-1140 Vienna Austria	Varilrix Pulver und Lösungsmittel zur Herstellung einer Injektionssuspension	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for suspension for injection	Subcutaneous use
Austria	Sanofi Pasteur MSD S.N.C., 8, Rue Jonas Salk FR-69007 Lyon France	VARIVAX Pulver und Lösungsmittel zur Herstellung einer Injektionssuspension	one dose (0.5 ml) contains: Varicella virus strain Oka/Merck (live, attenuated) ≥ 1350 PFU*	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Belgium	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Varilrix	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Belgium	Sanofi Pasteur MSD Avenue Jules Bordetlaan 13 B-1140 Brussels Belgium	Provarivax	one dose (0.5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) ≥ 1350 PFU*	Powder and solvent for solution for injection	Subcutaneous use
Cyprus	Merck Sharp & Dohme B.V. Waardeweg 39, 2031 BN Haarlem The Netherlands	Varivax powder and solvent for suspension for injection 1350PFU	one dose (0.5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) 1350 PFU*	Powder and solvent for suspension for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Cyprus	GlaxoSmithKline Biologicals S.A. Rue de l' Institut 89 B-1330 Rixensart Belgium	VARILRIX powder and solvent for solution for injection	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Czech Republic	GlaxoSmithKline Biologicals S.A. Rue de l' Institut 89 B-1330 Rixensart Belgium	VARILRIX	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Estonia	GlaxoSmithKline Biologicals S.A. Rue de l' Institut 89 B-1330 Rixensart Belgium	VARILRIX	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	Varilrix	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) – not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Sanofi Pasteur MSD Avenue Jules Bordetlaan 13 B-1140 Brussels Belgium	Provarivax	one dose (0.5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) ≥ 1350 PFU*	Powder and solvent for solution for injection, suspension	Subcutaneous use
Estonia	Merck Sharp & Dohme OÜ A.H. Tammsaare tee 47 Tallinn 11316 Estonia	VARIVAX	one dose (0.5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) ≥ 1350 PFU*	Powder and solvent for suspension for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Finland	Sanofi Pasteur MSD Avenue Jules Bordetlaan 13 B-1140 Brussels Belgium	VARIVAX	one dose (0,5 ml) contains: Varicella virus (Oka/Merck): not less than 1350 PFU*	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Finland	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	one dose (0,5 ml) contains: Live attenuated varicella-zoster virus (OKa strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
France	Laboratoire GlaxoSmithKline 100 route de Versailles 78163 Marly-le-Roi Cedex France	VARILRIX, poudre et solvant pour solution injectable en seringue préremplie. Vaccin varicelleux vivant	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) – not less than $10^{3.7}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
France	Sanofi Pasteur MSD S.N.C., 8, Rue Jonas Salk FR-69007 Lyon France	VARIVAX, poudre et solvant pour suspension injectable. Vaccin varicelleux vivant	one dose (0.5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) ≥ 1350 PFU*	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Germany	Sanofi Pasteur MSD GmbH Paul-Ehrlich-Str. 1 69181 Leimen Germany	Varivax	one dose (0.5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) ≥ 1350 PFU*	Powder and solvent for solution for injection	Subcutaneous use
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 80339 München Germany	Varilrix	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) – not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Sanofi Pasteur MSD GmbH Paul-Ehrlich-Str. 1 69181 Leimen Germany	Varivax	one dose (0.5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) ≥ 1350 PFU*	Powder and solvent for solution for injection	Subcutaneous use
Greece	GlaxoSmithKline A.E.B.E Kifissias Avenue 266 Halandri 15232, Athens Greece	VARILRIX	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Greece	VIANEX S.A Tatoiou Str. 18th km National Road Athens-Lamia New Erythraia P.C. 14671 Athens Greece	VARIVAX	one dose (0.5 ml) contains: Varicella Virus OKA/Merck Strain - not less than 1350 PFU*	Powder and solution for injection	Intramuscular use, subcutaneous use
Hungary	GlaxoSmithKline Kft. 1124 Budapest Csörsz u 43 Hungary	Varilrix	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Hungary	MSD Pharma Hungary Ltd. 1095 Budapest Lechner Odon fasor 8 Millennium Tower III, 3. em. Hungary	Varivax	one dose (0.5 ml) contains: Varicella virus OKA/Merck strain (live, attenuated) not less than 1350 PFU*	Powder and solution for injection	Intramuscular use, subcutaneous use
Iceland	GlaxoSmithkline ehf. Þverholti 14 105 Reykjavík Iceland	Varilrix	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Ireland	Sanofi Pasteur MSD Limited Block A, Second Floor Cookstown Court Old Belgard Road, Tallaght Dublin 24 Ireland	VARIVAX powder and solvent for suspension for injection.	one dose (0.5 ml) contains: Live attenuated varicella virus (Oka/Merck strain) not less than 1350 PFU*	Powder and solvent for suspension for injection	Subcutaneous use
Italy	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Italy	Sanofi Pasteur MSD S.p.A. Via degli Aldobrandeschi, 15 00163 Rome Italy	VARIVAX	one dose (0.5 ml) contains: Live, attenuated Varicella virus (OKA/Merck strain) not less than 1350 PFU*	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Latvia	SIA „Merck Sharp & Dohme Latvija”, Skanstes iela 50A LV - 1013 Riga Latvia	Varivax powder and solvent for suspension for injection	one dose (0.5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) ≥ 1350 PFU*	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Latvia	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Varilrix powder and solvent for solution for injection	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) – not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Lithuania	UAB „GlaxoSmithKline Lietuva“ Goštauto 40A LT-01112 Vilnius Lithuania	Varilrix	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Lithuania	Merck Sharp & Dohme UAB Kestucio str. 59/27 LT-08124 Vilnius Lithuania	VARIVAX	one dose (0.5 ml) contains: Varicella, live attenuated (Oka/Merck strain) - 1350 PFU*	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Luxembourg	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	one dose (0,5 ml) contains : Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Sanofi Pasteur MSD Avenue Jules Bordetlaan 13 B-1140 Brussels Belgium	PROVARIVAX	one dose (0.5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) ≥ 1350 PFU*	Powder for suspension for injection	Subcutaneous use
Malta	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Varilrix	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Malta	Merck Sharp & Dohme Ltd. Hertford Road Hoddesdon Hertfordshire EN 11 9BU United Kingdom	Varivax	one dose (0.5 ml) contains: not less than 1350 PFU* of the live attenuated varicella virus (OKA.Merck strain)	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Norway	GlaxoSmithKline AS Forskningsveien 2a Postboks 180 Vinderen 0319 Oslo Norway	Varilrix	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Norway	Sanofi Pasteur MSD Avenue Jules Bordetlaan 13 B-1140 Brussels Belgium	Varivax	one dose (0.5 ml) contains: Varicella virus, live attenuated, Oka/Merck strain ≥ 1350 PFU*	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Poland	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Varilrix	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Portugal	SmithKline & French Portuguesa - Produtos Farmacêuticos, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque - Miraflores 1495-131 Algés Portugal	Varilrix	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Portugal	Sanofi Pasteur MSD, S.A. Alfrapark - Estrada de Alfragide, 67 Lote F Sul, Piso 2 2610-008 Amadora Portugal	Varivax	one dose (0.5 ml) contains: varicella virus (zoster vivo) - 1350 PFU*	Powder and solvent for suspension for injection	Subcutaneous use
Romania	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Slovak Republic	Merck Sharp & Dohme B.V Waarderweg 39 2031 BN Haarlem The Netherlands	Varivax	one dose (0.5 ml) contains: Varicella virus (Oka/Merck strain) ≥ 1350 PFU*	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Slovenia	Merck Sharp & Dohme inovativna zdravila d.o.o., Smartinska cesta 140 1000 Ljubljana Slovenia	Varivax prasek in vehikel za suspensijo za injiciranje	one dose (0.5 ml) contains: Varicella virus (strain Oka/Merck) (live, attenuated) - not less than 1350.00 PFU*	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Spain	GLAXOSMITHKLINE, S.A. C/ Severo Ochoa, 2 Tres Cantos 28760 Madrid Spain	VARILRIX	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than 10 ^{3.3} PFU*	Powder and solvent for solution for injection	Subcutaneous use
Spain	Aventis Pasteur MSD, S.A. Pº Castellana, 141 28046 Madrid Spain	VARIVAX POLVO Y DISOLVENTE PARA SUSPENSIÓN INYECTABLE	one dose (0.5 ml) contains: Live attenuated varicella virus (Strain OKA/Merk) - ≥1350 PFU*	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Sweden	GlaxoSmithKline AB Box 516 169 29 Solna Sweden	Varilrix®	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than 10 ^{3.3} PFU*	Powder and solvent for solution for injection	Subcutaneous use
Sweden	Sanofi Pasteur MSD Avenue Jules Bordetlaan 13 B-1140 Brussels Belgium	Varivax®	one dose (0.5 ml) contains: Varicella virus, strain Oka/Merck live attenuated - 1350 PFU*	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
The Netherlands	Sanofi Pasteur MSD Avenue Jules Bordetlaan 13 B-1140 Brussels Belgium	Provarivax, poeder en oplosmiddel voor suspensie voor injectie	one dose (0.5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) > 1350 PFU*	Powder and solvent for solution for injection	Parenteral use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
United Kingdom	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	VARILRIX	one dose (0.5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
United Kingdom	Sanofi Pasteur MSD Limited Mallards Reach Bridge Avenue Maidenhead Berkshire SL6 1QP United Kingdom	VARIVAX Powder for Suspension	one dose (0.5 ml) contains: Varicella Virus OKA/Merck Strain - 1350 PFU*	Powder for suspension for injection	Subcutaneous use

*PFU: plaque forming units

Measles and rubella vaccines (live) with Marketing Authorisation in the European Union

Member State (EU/EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical form	Route of administration
France	Sanofi Pasteur S.A. 2 avenue Pont Pasteur 69007 Lyon France	RUDI ROUVAX, poudre et solvant pour solution injectable. vaccin à virus vivants atténués contre la rougeole et la rubéole	one dose (0.5 ml) contains: Measles virus Schwartz strain (live, attenuated) - not less than $10^{3.0}$ CCID ₅₀ Rubella virus Wistar RA 27/3 strain (live, attenuated) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

Measles, mumps and rubella vaccines (live) with Marketing Authorisation in the European Union

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	GlaxoSmithKline Pharma GmbH Albert - Schweitzer - Gasse 6 AT-1140 Vienna Austria	Priorix Pulver in Durchstechflaschen und Lösungsmittel in Fertigspritzen zur Herstellung einer Injektionslösung	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Austria	GlaxoSmithKline Pharma GmbH Albert - Schweitzer - Gasse 6 AT-1140 Vienna Austria	Priorix Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Belgium	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Subcutaneous use Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Bulgaria	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Cyprus	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix injection	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Czech Republic	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Estonia	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Subcutaneous use
Finland	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
France	Laboratoire GlaxoSmithKline 100 route de Versailles 78163 Marly-le-Roi Cedex France	PRIORIX, poudre et solvant pour solution injectable en seringue préremplie. vaccin rougeoleux, des oreillons et rubéoleux vivant	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
France	Sanofi Pasteur S.A. 2 avenue Pont Pasteur 69007 Lyon France	R.O.R., poudre et solvant pour solution injectable. vaccin à virus vivants atténués contre la rougeole, les oreillons et la rubéole	one dose (0.5 ml) contains: Measles virus Schwartz strain (live, attenuated) not less than $10^{3.0}$ CCID ₅₀ Mumps virus URABE AM-9 strain (live, attenuated) not less than $5 \times 10^{3.0}$ CCID ₅₀ Rubella virus Wistar RA 27/3 strain (live, attenuated) not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
France	Sanofi Pasteur MSD S.N.C., 8, Rue Jonas Salk FR-69007 Lyon France	R.O.R. VAX, poudre et solvant pour suspension injectable. Vaccin rougeoleux, des oreillons et rubéoleux atténué.	one dose (0.5 ml) contains: Measles virus Edmonston 749D strain (live, attenuated) - $10^{3.0}$ CCID ₅₀ Mumps virus Jeryl Lynn strain (live, attenuated) – $5 \times 10^{3.0}$ CCID ₅₀ Rubella virus Wistar RA 27/3 strain (live, attenuated) - $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 80339 München Germany	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	GlaxoSmithKline A.E.B.E Kifissias Avenue 266 Halandri 15232, Athens Greece	PRIORIX	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) – not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) – not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) – not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Greece	VIANEX S.A Tatoiou Str. 18th km National Road Athens-Lamia New Erythraia P.C. 14671 Athens Greece	R.O.R.VAX	one dose (0.5 ml) contains: not less than $10^{3.0}$ CCID ₅₀ of the measles virus Enders-Edmonston strain not less than $5 \times 10^{3.0}$ CCID ₅₀ of the mumps virus (Jeryl Lynn strain) not less than $10^{3.0}$ CCID ₅₀ of the rubella virus strain	Powder and solvent for solution for injection	Intramuscular use
Hungary	GlaxoSmithKline Kft. 1124 Budapest Csörsz u 43 Hungary	Priorix por ésoldószer oldatos injekcióhoz	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Iceland	GlaxoSmithkline ehf. Þverholti 14 105 Reykjavík Iceland	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 37135 Verona Italy	PRIORIX	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Latvia	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix powder and solvent for solution for injection	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Latvia	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix powder and solvent for solution for injection in pre-filled syringe	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Lithuania	UAB „GlaxoSmithKline Lietuva“ Goštauto 40A LT-01112 Vilnius Lithuania	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Luxembourg	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Malta	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from strain Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Subcutaneous use , Intramuscular use
Norway	GlaxoSmithKline AS Forskningsveien 2a Postboks 180 Vinderen 0319 Oslo Norway	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Poland	MSD Polska Sp. z o.o. Chlodna st., 51 00-867, Warsaw Poland	M-M-R II	one dose (0.5 ml) contains: not less than $10^{3.0}$ CCID ₅₀ of the measles virus Enders-Edmonston strain, not less than 12500 CCID ₅₀ of the mumps virus (Jeryl Lynn strain); and not less than $10^{3.0}$ CCID ₅₀ of the Wistar RA 27/3 rubella virus strains	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Portugal	SmithKline & French Portuguesa - Produtos Farmacêuticos, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque - Miraflares 1495-131 Algés Portugal	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Portugal	SmithKline & French Portuguesa - Produtos Farmacêuticos, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque - Miraflares 1495-131 Algés Portugal	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection in pre-filled syringe	Intramuscular use, subcutaneous use
Romania	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Slovenia	GSK d.o.o Cvetkova ulica 29 1000 Ljubljana Slovenia	Priorix prašek in vehikel za raztopino za injiciranje	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Spain	GLAXOSMITHKLINE S.A. C/ Severo Ochoa, 2 Tres Cantos 28760 Madrid Spain	PRIORIX, POLVO Y DISOLVENTE EN JERINGA PRECARGADA PARA SOLUCIÓN INYECTABLE	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Sweden	GlaxoSmithKline AB Box 516 169 29 Solna Sweden	Priorix	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	GlaxoSmithKline B.V Huis ter Heideweg 62 3705 LZ ZEIST The Netherlands	Priorix, poeder en oplosmiddel voor suspensie voor injectie	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Parenteral use
United Kingdom	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	PRIORIX powder and solvent for solution for injection	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3.7}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

*PFU: plaque forming units

Measles, mumps, rubella and varicella vaccines (live) with Marketing Authorisation in the European Union

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	GlaxoSmithKline Pharma GmbH Albert - Schweitzer - Gasse 6 AT-1140 Vienna Austria	Priorix - Tetra Pulver in Durchstechflaschen und Lösungsmittel in Fertigspritzen zur Herstellung einer Injektionslösung	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Austria	GlaxoSmithKline Pharma GmbH Albert - Schweitzer - Gasse 6 AT-1140 Vienna Austria	Priorix - Tetra Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	One dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Belgium	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix-Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Cyprus	GlaxoSmithKline (Cyprus) Ltd 12-14 Kennedy Avenue Kennedy Business Centre 4th Floor 1087 Lefkosia Cyprus	Priorix Tetra powder and solvent for solution for injection	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Cyprus	GlaxoSmithKline (Cyprus) Ltd 12-14 Kennedy Avenue Kennedy Business Centre 4th Floor 1087 Lefkosia Cyprus	PRIORIX TETRA POWDER IN VIAL + SOLVENT IN AMPOULE	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Czech Republic	GlaxoSmithKline, s.r.o. Na Pankráci 17/1685 140 21 Prague 4 Czech Republic	PRIORIX-TETRA INJ. STRÍKAČKA	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Czech Republic	GlaxoSmithKline, s.r.o. Na Pankráci 17/1685 140 21 Prague 4 Czech Republic	PRIORIX-TETRA LAHVIČKA/AMPULE	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	Priorix-Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	Priorix-Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Estonia	GlaxoSmithKline Eesti OÜ Lõõtsa 2 11415 Tallinn Estonia	PRIORIX-TETRA	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Estonia	GlaxoSmithKline Eesti OÜ Lõõtsa 2 11415 Tallinn Estonia	PRIORIX-TETRA	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Finland	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX TETRA	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
France	Laboratoire GlaxoSmithKline 100 route de Versailles 78163 Marly-le-Roi Cedex France	PRIORIX-TETRA, poudre et solvant pour solution injectable en seringue préremplie. Vaccin rougeoleux, des oreillons, rubéoleux et varicelleux (vivant)	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
France	Laboratoire GlaxoSmithKline 100 route de Versailles 78163 Marly-le-Roi Cedex France	PRIORIX-TETRA, poudre et solvant pour solution injectable. Vaccin rougeoleux, des oreillons, rubéoleux et varicelleux (vivant)	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 80339 München Germany	Priorix-Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 80339 München Germany	Priorix-Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Greece	GlaxoSmithKline A.E.B.E Kifissias Avenue 266 Halandri 15232, Athens Greece	PRIORIX-TETRA	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Hungary	GlaxoSmithKline Kft. 1124 Budapest Csörsz u 43 Hungary	Priorix Tetra por és oldószer oldatos injekcióhoz	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Hungary	GlaxoSmithKline Kft. 1124 Budapest Csörsz u 43 Hungary	Priorix Tetra por és oldószer oldatos injekcióhoz előretöltött fecskendőben	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection in pre-filled syringe	Subcutaneous use
Iceland	GlaxoSmithKline ehf. Þverholti 14 105 Reykjavík Iceland	Priorix Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Iceland	GlaxoSmithKline ehf. Þverholti 14 105 Reykjavík Iceland	Priorix Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Ireland	GlaxoSmithKline (Ireland) Ltd. Stonemasons Way Rathfarnham Dublin 16 Ireland	Priorix-Tetra – powder and solvent for solution for injection in a pre-filled syringe Measles, mumps, rubella and varicella vaccine (live)	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Ireland	GlaxoSmithKline (Ireland) Ltd. Stonemasons Way Rathfarnham Dublin 16 Ireland	Priorix-Tetra – powder and solvent for solution for injection Measles, mumps, rubella and varicella vaccine (live)	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Ireland	GlaxoSmithKline (Ireland) Ltd. Stonemasons Way Rathfarnham Dublin 16 Ireland	Priorix-Tetra – powder and solvent for solution for injection Measles, mumps, rubella and varicella vaccine (live)	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 37135 Verona Italy	PRIRIX TETRA	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Latvia	GlaxoSmithKline Latvia SIA Bruņinieku iela 5 Rīga LV-1001 Latvia	Priorix-Tetra powder and solvent for solution for injection	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Latvia	GlaxoSmithKline Latvia SIA Brūņinieku iela 5 Rīga LV-1001 Latvia	Priorix-Tetra powder and solvent for solution for injection in pre-filled syringe	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Lithuania	UAB „GlaxoSmithKline Lietuva“ Goštauto 40A LT-01112 Vilnius Lithuania	Priorix-Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Luxembourg	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX TETRA	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385 strain derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (OKA strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix-Tetra	one dose (0.5 ml) contains dose: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Portugal	SmithKline & French Portuguesa - Produtos Farmacêuticos, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque - Miraflores 1495-131 Algés Portugal	Priorix-Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Portugal	SmithKline & French Portuguesa - Produtos Farmacêuticos, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque - Miraflores 1495-131 Algés Portugal	Priorix-Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection in pre-filled syringe	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Romania	GLAXOSMITHKLINE (GSK) SRL - ROMANIA Costache Negri Street, No. 1-5 Opera Center 1 Etaj 3, sector 5 050552 Bucharest Romania	PRIORIX-TETRA	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Slovak Republic	GlaxoSmithKline Slovakia s.r.o., Galvaniho 7/A Bratislava 2, 821 04 Slovak Republic	Priorix Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Slovak Republic	GlaxoSmithKline Slovakia s.r.o., Galvaniho 7/A Bratislava 2, 821 04 Slovak Republic	Priorix-Tetra lag	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Slovenia	GSK d.o.o Cvetkova ulica 29 1000 Ljubljana Slovenia	Priorix-Tetra prašek in vehikel za raztopino za injiciranje v napolnjeni injekcijski brizgi	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Sweden	GlaxoSmithKline AB Box 516 169 29 Solna Sweden	Priorix Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use
Sweden	GlaxoSmithKline AB Box 516 169 29 Solna Sweden	Priorix Tetra	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ ZEIST The Netherlands	Priorix-Tetra injectieflacon/ampul, poeder en oplosmiddel voor oplossing voor injectie	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Parenteral use
The Netherlands	GlaxoSmithKline B.V. Huis ter Heideweg 62 3705 LZ ZEIST The Netherlands	Priorix-Tetra, poeder en oplosmiddel in voorgevulde spuit voor oplossing voor injectie	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solvent for solution for injection	Parenteral use
United Kingdom	SmithKline Beecham plc 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	PRIORIX-TETRA powder for solution for injection	one dose (0.5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4.4}$ CCID ₅₀ Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3.0}$ CCID ₅₀ Live attenuated varicella virus (Oka strain) - not less than $10^{3.3}$ PFU*	Powder and solution for injection	Subcutaneous use

*PFU: plaque forming units