

# Službeni list

## Europske unije

C 250



Hrvatsko izdanje

### Informacije i objave

Svezak 56.

30. kolovoza 2013.

Obavijest br.	Sadržaj	Stranica
IV. Obavijesti		

#### OBAVIJESTI INSTITUCIJA, TIJELA, UREDA I AGENCIJA EUROPSKE UNIJE

##### Europska komisija

2013/C 250/01	Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. veljače 2013. do 28. veljače 2013. (Odluke donesene u skladu s člankom 34. Direktive 2001/83/EZ ili člankom 38. Direktive 2001/82/EZ) .....	1
2013/C 250/02	Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. lipnja 2013. do 31. srpnja 2013. (Objavljeno u skladu s člankom 13. ili člankom 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća) .....	30
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 Cijena:  
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## IV.

(Obavijesti)

OBAVIJESTI INSTITUCIJA, TIJELA, UREDA I AGENCIJA EUROPSKE UNIJE

## EUROPSKA KOMISIJA

**Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. veljače 2013. do 28. veljače 2013.**

(Odluke donesene u skladu s člankom 34. Direktive 2001/83/EZ <sup>(1)</sup> ili člankom 38. Direktive 2001/82/EZ <sup>(2)</sup>) (\*)  
(2013/C 250/01)

## — Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
28.2.2013	Monovalent and multivalent measles, mumps, rubella and varicella vaccines (live)	See Annex I	See Annex I	1.3.2013

<sup>(1)</sup> SL L 311, 28.11.2001., str. 67.

<sup>(2)</sup> SL L 311, 28.11.2001., str. 1.

(\*) Hrvatski prijevod ovog dokumenta nije dostupan, dokument je objavljen na engleskom jeziku.

## 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 1 000 CCID50	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 1 000 CCID50	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 1 000 CCID50	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 1 000 CCID50	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	Measles virus (live, attenuated) - not less than 1 000 TCID50	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) - 5 000 CCID50	Powder and solvent for solution for injection	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	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 5 000 CCID50	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	Mumps virus (Strain Jeryl Lynn - B level) - not less than 20 000 TCID50	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	live, attenuated rubella virus (strain Wistar RA 27/3) - at least 1 000 CCID50	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) - 1 000 CCID50	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) - 1 000 CCID50	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) - 1 000 CCID50	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	Rubella virus live attenuated (Strain Wistar RA 27/3M) - not less than 1 000 TCID50	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	Rubella virus live attenuated (Strain RA 27/3) - not less than 1 000 TCID <sub>50</sub>	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 1 000 TCID <sub>50</sub>	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	After resuspension, one dose (0,5 ml) contains attenuated varicella zoster virus (OKA strain) - not less than 103,3 PFU (Plaque forming units)	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	After reconstitution, one dose (0,5 ml) contains: Varicella virus** strain Oka/Merck (live, attenuated) ≥ 1.350 PFU*** ** produced in MRC-5 human diploid cells. *** PFU = Plaque forming units	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	Each 0,5 ml dose of the reconstituted vaccine contains: Varicella virus - not less than 103,3 UFP	Powder and solvent for solution for injection	Subcutaneous use
Belgium	Sanofi Pasteur MSD Avenue Jules Bordetlaan 13 B-1140 Brussels Belgium	Provarivax	After reconstitution, one dose (0,5 mL) contains: Varicella virus** Oka/Merck strain (live, attenuated) <sup>3</sup> 1 350 PFU*** * Produced in human diploid cells (MRC-5) ***PFU = Plaque-forming units	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Cyprus	Merck Sharp & Dohme B.V. Waardeweg 39, 2031 BN Haarlem The Netherlands	Varivax powder and solvent for suspension for injection 1 350 PFU	After reconstitution, one dose (0,5 ml) contains: Varicella virus** Oka/Merck strain (live, attenuated)1 350 PFU***	Powder and solvent for suspension for injection	Subcutaneous use
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 (Oka strain) virus* 103,3 plaque forming units (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 virus - not less than 10 <sup>3,3</sup> 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	After reconstitution, one dose (0,5 ml) contains: minimum 103,3 PFU Varicella zoster-virus	Powder and solvent for solution for injection	Subcutaneous use
Estonia	Merck Sharp & Dohme OÜ A.H. Tammsaare tee 47 Tallinn 11316 Estonia	VARIVAX	After reconstitution, one dose (0,5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) ≥ 1 350 PFU	Powder and solvent for suspension for injection	Subcutaneous use
Finland	Sanofi Pasteur MSD Avenue Jules Bordetlaan 13 B-1140 Brussels Belgium	VARIVAX	per 0,5 ml: Varicella virus (Oka/Merck): not less than: 1 350 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	per 0,5 ml: Varicella virus (Oka): not less than: 103,3 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: Varicella virus** Oka/Merck strain (live, attenuated) 103,7 PFU*** ** Produced in human diploid cells (MRC-5) ***PFU = Plaque-forming units	Powder and solvent for solution for injection	Subcutaneous use

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	VARIVAX, poudre et solvant pour suspension injectable. Vaccin varicelleux vivant	one dose (0.5 ml) contains: Varicella virus** Oka/Merck strain (live, attenuated) $\geq 1\ 350$ PFU*** ** Produced in human diploid cells (MRC-5) ***PFU = Plaque-forming units	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) $\geq 1\ 350$ PFU*** ** Produced in human diploid cells (MRC-5) ***PFU = Plaque-forming units	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: Varicella virus** OKA strain (live, attenuated) 103,7 PFU*** ***Produced in human diploid cells (MRC-5) ***PFU = Plaque-forming units	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) $\geq 1\ 350$ PFU*** ** Produced in human diploid cells (MRC-5) ***PFU = Plaque-forming units	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: Varicella virus** OKA strain (live, attenuated)103,7 PFU*** ** Produced in human diploid cells (MRC-5) ***PFU = Plaque-forming units	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Greece	GlaxoSmithKline A.E.B.E Kifissias Avenue 266 Halandri 15232, Athens Greece	VARILRIX	per 0,5 ml dose: Live Attenuated Varicella Virus OKA Strain not less than 103,3 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
Greece	VIANEX S.A Tatoiou Str. 18th km National Road Athens-Lamia New Erythraia P.C. 14671 Athens Greece	VARIVAX	per 0,5 ml dose: Varicella Virus OKA/Merck Strain - not less than 1 350 PFU	Powder and solution for injection	Intramuscular use, subcutaneous use
Hungary	GlaxoSmithKline Kft. 1124 Budapest Csörsz u 43 Hungary	Varilrix	After reconstitution, 1 dose (0,5 ml) contains:Varicella virus OKA strain (live, attenuated) not less than 103,3 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	After reconstitution, 1 dose (0,5 ml) contains:Varicella virus OKA/Merck strain (live, attenuated) not less than 1 350 PFU	Powder and solution for injection	Intramuscular use, subcutaneous use
Iceland	GlaxoSmithkline ehf. Þverholti 14 105 Reykjavík Iceland	Varilrix	1 dose (0,5 ml) contains: ≥ 10 <sup>3,3</sup> PFU (Plaque forming units) of Varicella-Zoster Virus OKA strain	Powder and solvent for solution for injection	Subcutaneous use
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.	Each 0.5 ml dose of reconstituted vaccine contains:Live attenuated varicella virus (Oka/Merck strain) not less than 1 350 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	After reconstitution, 1 dose (0,5 ml) contains: Live, attenuated Varicella virus (OKA strain) not less than 2 000 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	After reconstitution, 1 dose (0,5 ml) contains: Live, attenuated Varicella virus (OKA/Merck strain) not less than 1 350 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
Latvia	SIA „Merck Sharp & Dohme Latvija”, Skanstes iela 50A LV - 1013 Riga Latvia	Varivax powder and solvent for suspension for injection	After reconstitution, one dose (0,5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) $\geq 1\,350$ 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 (Oka strain) virus 103,3 plaque forming units (PFU)	Powder and solvent for solution for injection	Subcutaneous use
Lithuania	UAB „GlaxoSmithKline Lietuva” Goštauto 40A LT-01112 Vilnius Lithuania	Varilrix	After reconstitution, 1 dose (0,5 ml) contains: Live attenuated varicella zoster virus (Oka strain) - not less than 103,3 PFU	Powder and solvent for solution for injection	Subcutaneous use
Lithuania	Merck Sharp & Dohme UAB Kestucio str. 59/27 LT-08124 Vilnius Lithuania	VARIVAX	per dose (0,5 ml): Varicella, live attenuated (Oka/Merck strain) - 1 350 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	1 dose (0,5 ml) contains: Live attenuated Varicella virus - 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	1 dose (0,5 ml) contains: Live attenuated varicella-zoster (Oka/Merck strain) virus not less than 1 350 PFU	Powder for suspension for injection	Subcutaneous use
Malta	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Varilrix	Each 0,5 ml dose of the reconstituted vaccine contains: NLT 103,3 PFU of the live attenuated varicella-zoster virus (OKA strain)	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Malta	Merck Sharp & Dohme Ltd. Hertford Road Hoddesdon Hertfordshire EN 11 9BU United Kingdom	Varivax	Each 0,5 ml dose of the reconstituted vaccine contains: NLT 1 350 PFU of the live attenuated varicella virus (produced in human diploid (MRC-5) cells (OKA.Merck strain)	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Norway	GlaxoSmithKline AS Forskingsveien 2a Postboks 180 Vinderen 0319 Oslo Norway	Varilrix	After reconstitution, 1 dose (0,5 ml) contains: Live attenuated varicella zoster virus (Oka strain) - not less than 10 <sup>3,3</sup> PFU	Powder and solvent for solution for injection	Subcutaneous use
Norway	Sanofi Pasteur MSD Avenue Jules Bordetlaan 13 B-1140 Brussels Belgium	Varivax	After reconstitution, one dose (0,5 ml) contains: Varicella virus, live attenuated, Oka/Merck strain $\geq 1\ 350$ 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	per 0,5 ml of reconstituted vaccine: Not less than 2 000 PFU of the varicella-zoster virus (oka strain)	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	varicella virus (zoster vivo) - 3,3 log <sub>10</sub> PFU/0,5 ml	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	varicella virus (zoster vivo) - 1 350 FPU/0,5 ml	Powder and solvent for suspension for injection	Subcutaneous use
Romania	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	VARILRIX	Varicella virus (Oka strain): $\geq 103,3$ 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
Slovak Republic	Merck Sharp & Dohme B.V Waarderweg 39 2031 BN Haarlem The Netherlands	Varivax	Varicella virus** (Oka/Merck strain) <sup>3</sup> 1 350 PFU*** ** Produced on human diploid cells (MRC-5) ***PFU = Plaque-forming units	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Slovenia	Merck Sharp & Dohme inovativna zdravila d.o.o., Smartinska cesta 140 1000 Ljubljana Slovenia	Varivax prasek in vehikel za suspenzijo za injiciranje	per dose (0,5 ml): Varicella virus (strain Oka/Merck) (live, attenuated) - not less than 1 350,00 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	Live attenuated varicella-zoster virus (Strain OKA) - not less than 103,3 UFP	Powder and solvent for solution for injection	Subcutaneous use
Spain	Aventis Pasteur MSD, S.A. P <sup>o</sup> Castellana, 141 28046 Madrid Spain	VARIVAX POLVO Y DISOLVENTE PARA SUSPENSIÓN INYECTABLE	Live attenuated varicella virus (Strain OKA/Merk) - <sup>3</sup> 1 350 UFP	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Sweden	GlaxoSmithKline AB Box 516 169 29 Solna Sweden	Varilrix®	Varicella virus, strain Oka/Merck live attenuated - 10 <sup>3,3</sup> pfu	Powder and solvent for solution for injection	Subcutaneous use
Sweden	Sanofi Pasteur MSD Avenue Jules Bordetlaan 13 B-1140 Brussels Belgium	Varivax®	Varicella virus, strain Oka/Merck live attenuated - 1 350 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	per 0,5 ml Varicella virus Oka/Merck strain (live, attenuated) > 1 350 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	Live Attenuated Varicella Virus OKA Strain - 10 000 PFU/0,5 ml	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	Varicella Virus OKA/Merck Strain - 1 350 PFU	Powder for suspension for injection	Subcutaneous use

**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 1 000 CCID50 Rubella virus Wistar RA 27/3 strain (live, attenuated) - not less than 1 000 CCID50	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	After reconstitution, one dose (0,5 ml) contains: Measles virus, strain Schwarz1 (live, attenuated) not less than 103,0 CCID503 Mumps virus, strain RIT 43851, derived from strain Jeryl Lynn (live, attenuated) not less than 103,7 CCID503 Rubella virus, strain Wistar RA 27/32 (live, attenuated) not less than 103,0 CCID503 1 produced in chick embryo cells. 2 produced in MRC-5 human diploid cells. 3 CCID50 = 50 % cell culture infectious dose.	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
Austria	GlaxoSmithKline Pharma GmbH Albert - Schweitzer - Gasse 6 AT-1140 Vienna Austria	Priorix Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	After reconstitution, one dose (0,5 ml) contains: Measles virus, strain Schwarz1 (live, attenuated) not less than 103,0 CCID503 Mumps virus, strain RIT 43851, derived from strain Jeryl Lynn (live, attenuated) not less than 103,7 CCID503 Rubella virus, strain Wistar RA 27/32 (live, attenuated) not less than 103,0 CCID503 1 produced in chick embryo cells. 2 produced in MRC-5 human diploid cells. 3 CCID50 = 50% cell culture infectious dose.	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	Each 0,5 ml dose of the reconstituted vaccine contains: — not less than 103,0 CCID50* of the Schwarz measles1 — not less than 103,7 CCID50 of the RIT 4385 mumps1, and — not less than 103,0 CCID50 of the Wistar RA 27/3 rubella2 virus strains. *CCID50 – Cell Culture Infective Dose 50 1 produced in chick embryo cells 2 produced in human diploid (MRC-5) cells	Powder and solvent for solution for injection	Subcutaneous use Intramuscular use, subcutaneous use
Bulgaria	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix	live attenuated measles virus (Schwarz strain) $\geq$ 103,0 CCID50 live attenuated mumps virus (RIT 4385 strain) $\geq$ 103,7 CCID50 live attenuated rubella virus (strain Wistar RA 27/3) $\geq$ 103,0 CCID50	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	Each 0,5 ml dose of the reconstituted vaccine contains: not less than 103,0 CCID50* of the Schwarz measles1 not less than 103,7 CCID50 of the RIT 4385 mumps1 not less than 103,0 CCID50 of the Wistar RA 27/3 rubella2 virus strains.	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
Czech Republic	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX	per 0,5 ml/dose: Live, attenuated measles virus (Schwarz strain) - not less than $10^{3,0}$ CCID <sub>50</sub> <sup>3</sup> Live, attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> <sup>3</sup> Live, attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> <sup>3</sup>	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	Priorix	per 0,5 ml dose: Not less than:103,0 CCID <sub>50</sub> of the Schwarz measles; Not less than:103,7 CCID <sub>50</sub> of the RIT 4385 mumps; Not less than:103,0 CCID <sub>50</sub> of the Wistar RA 27/3 rubella	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	Varilrix	One dose (0,5 ml) contains: Live attenuated varicella-zoster (Oka strain) virus* $10^{3,3}$ plaque forming units (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: Live attenuated varicella-zoster (Oka strain) virus* $10^{3,3}$ plaque forming units (PFU)	Powder and solvent for solution for injection, suspension	Subcutaneous use
Estonia	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX	Measles virus (live, attenuated) NLT 103,0 CCID <sub>50</sub> ; Mumps virus (live, attenuated) NLT 103,7 CCID <sub>50</sub> ; Rubella virus (live, attenuated) NLT 103,0 CCID <sub>50</sub>	Powder and solvent for solution for injection	Subcutaneous use
Finland	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX	per 0,5 ml: Measles virus (Schwarz) - not less than 103,0 CCID <sub>50</sub> Mumps virus (RIT 4385) - not less than 103,7 CCID <sub>50</sub> Rubella virus (Wistar RA27/3) - not less than: 103,0 CCID <sub>50</sub>	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	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	1 dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than 103,0 CCID50 Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than 103,7 CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than 103,0 CCID50	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
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 1 000 CCID50 Mumps virus URABE AM-9 strain (live, attenuated) not less than 5 000 CCID50 Rubella virus Wistar RA 27/3 strain (live, attenuated) not less than 1 000 CCID50	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) - 1 000 CCID50 Mumps virus Jeryl Lynn strain (live, attenuated) - 5 000 CCID50 Rubella virus Wistar RA 27/3 strain (live, attenuated) - 1 000 CCID50	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 80339 München Germany	Priorix	per 0,5 ml dose: Measles virus - not less than 3,0 log <sub>10</sub> CCID50 mumps virus - not less than 3,7 log <sub>10</sub> CCID50 rubella virus - not less than 3,0 log <sub>10</sub> CCID50	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 80339 München Germany	Priorix	per 0,5 ml dose: Measles virus - not less than 3,0 log <sub>10</sub> CCID50 mumps virus - not less than 3,7 log <sub>10</sub> CCID50 rubella virus - not less than 3,0 log <sub>10</sub> CCID50	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	Live attenuated measles virus (Schwarz strain) – 1 000,000 CC Live attenuated mumps virus (RIT 4385 strain) – 1 000,000 CC Live attenuated rubella virus (Wistar RA 27/3 strain) – 1 000,000 CC	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Hungary	GlaxoSmithKline Kft. 1124 Budapest Csörsz u 43 Hungary	Priorix por ésoldószer oldatos injekcióhoz	After reconstitution, 1 dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) not less than 103,0 CCID50 Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) not less than 103,7 CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) not less than 103,0 CCID50	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Iceland	GlaxoSmithkline ehf. Þverholti 14 105 Reykjavík Iceland	Priorix	per 0,5 ml Rubella virus $\geq 10^3$ CCID50 Measles virus $\geq 10^3$ CCID50 Mumps virus $\geq 10^{3,7}$ CCID50	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 37135 Verona Italy	PRIORIX	Live attenuated measles virus1 (Schwarz strain) - not less than 103,0 CCID503 Live attenuated mumps virus1 (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than 103,7 CCID503 Live attenuated rubella virus2 (Wistar RA 27/3 strain) - not less than 103,0 CCID503	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	After reconstitution, 1 dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) not less than 103,0 CCID50 Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) not less than 103,7 CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) not less than 103,0 CCID50	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
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	After reconstitution, 1 dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) not less than 103,0 CCID50 Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) not less than 103,7 CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) not less than 103,0 CCID50	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Lithuania	UAB „GlaxoSmithKline Lietuva” Goštauto 40A LT-01112 Vilnius Lithuania	Priorix	After reconstitution, 1 dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than 103,0 CCID50 Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than 103,7 CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than 103,0 CCID50	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Luxembourg	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX	1 dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than 10 <sup>3</sup> CCID50 Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than 10 <sup>3,7</sup> CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than 10 <sup>3</sup> CCID50	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	Each 0,5 ml dose of the reconstituted vaccine contains; NLT 103,0 CCID50 of the Schwarz measles (produced in chick embryo cells) NLT 103,7 CCID50 of the RIT 4385 mumps (produced in chick embryo cells) NLT 103,0 CCID50 of the Wistar RA 27/3 rubella (produced in human diploid MRC-5 cells) virus strains	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
Norway	GlaxoSmithKline AS Forskingsveien 2a Postboks 180 Vinderen 0319 Oslo Norway	Priorix	Each 0,5 ml dose of the reconstituted vaccine contains:  Live attenuated Schwarz measles virus strain: not less than $10^3$ CCID50  Live attenuated RIT 4385 mumps virus strain: not less than $10^{3.7}$ CCID50  Live attenuated Wistar RA 27/3 rubella virus strain: not less than $10^3$ CCID50.	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	per 0,5 ml dose:  not less than 1 000 CCID50 of the measles virus Enders-Edmonston strain, not less than 12 500 CCID50 of the mumps virus (Jeryl Lynn strain); and not less than 1 000 CCID50 of the Wistar RA 27/3 rubella virus strains	Powder and solvent for solution for injection	Subcutaneous use
Poland	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix	per 0,5 ml dose:  Not less than: $10^{3.0}$ CCID50 of the Schwarz measles virus;  Not less than: $10^{3.7}$ CCID50 of the RIT 4385 mumps virus; Not less than: $10^{3.0}$ CCID50 of the Wistar RA 27/3 rubella virus strains	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Portugal	SmithKline & French Portuguesa - Produtos Farmacéuticos, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque - Miraflores 1495-131 Algés Portugal	Priorix	per 0,5 ml dose:  Measles virus (Schwarz strain) - not less than 3,0 log10 CCID50 mumps virus (RIT 4385 strain) - not less than 3,7 log10 CCID50 rubella virus (Wistar RA 27/3 strain) - not less than 3,0 log10 CCID50	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Portugal	SmithKline & French Portuguesa - Produtos Farmacéuticos, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque - Miraflores 1495-131 Algés Portugal	Priorix	per 0,5 ml dose:  Measles virus (Schwarz strain) - not less than 3,0 log10 CCID50 mumps virus (RIT 4385 strain) - not less than 3,7 log10 CCID50 rubella virus (Wistar RA 27/3 strain) - not less than 3,0 log10 CCID50	Powder and solvent for solution for injection in pre-filled syringe	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Romania	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX	Measles virus (Schwarz strain): $\geq 103,0$ CCID50 Mumps virus (RIT 4385 strain): $\geq 103,7$ CCID50 Rubella virus (Wistar RA 27/3 strain): $\geq 103,0$ CCID50	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Slovak Republic	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Proirix	Measles virus Schwarz strain (live, attenuated) not less than 103,0 CCID503 Mumps virus RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) not less than 103,7 CCID503 Rubella virus (Wistar RA 27/3 strain) (live, attenuated) - not less than 103,0 CCID503	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	per dose (0,5 ml): Measles virus (strain Schwarz) (live, attenuated) - not less than 103,0 CCID50 Mumps virus (strain RIT 4385 - derived from strain Jeryl Lynn) (live, attenuated) - not less than 103,7 CCID50 Rubella virus (strain Wistar RA 27/3) (live, attenuated) - not less than 103,0 CCID50	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	Live attenuated rubella (Strain Wistar RA 27/3) - not less than 103,0 CCID50, measles (Cepa Schwarz) - 103,0 CCID50 mumps (Cepa RIT 4385, derived from Cepa Jeryl Lynn) - 103,7 CCID50	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Sweden	GlaxoSmithKline AB Box 516 169 29 Solna Sweden	Priorix®	After reconstitution, 1 dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) not less than 103,0 CCID50 Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) not less than 103,7 CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) not less than 103,0 CCID50	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	per 0,5 ml: Measles virus Schwarz strain (live, attenuated) not less than 10 CCID50 Mumps virus RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) not less than 10 CCID50 Rubella virus Wistar RA 27/3 strain (live, attenuated) not less than 100 CCID50	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	Mumps (RIT 4385 Derived from Jeryl Lynn): 5 011 CID50 Measles (Schwarz Strain): 1 000 CID50 Rubella (Wistar RA 27/3 Strain): 1 000 CID50	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

**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) of the solved vaccine contains: Measles virus, strain Schwarz1 (live, attenuated) - not less than 103,0 CCID503 Mumps virus, strain RIT 43851, derived from strain Jeryl Lynn (live, attenuated) - not less than 104,4 CCID503 Rubella virus, strain Wistar RA 27/32 (live, attenuated) - not less than 103,0 CCID503 Varicella Virus, strain OKA2 (live, attenuated) - not less than 103,3 PFU4 1 produced in chick embryo cells. 2 produced in MRC-5 human diploid cells. 3 CCID50 = 50 % cell culture infectious dose. 4 PFU = Plaque forming units.	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) of the solved vaccine contains: Measles virus, strain Schwarz1 (live, attenuated) - not less than 103,0 CCID503 Mumps virus, strain RIT 43851, derived from strain Jeryl Lynn (live, attenuated) - not less than 104,4 CCID503	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
			<p>Rubella virus, strain Wistar RA 27/32 (live, attenuated) - not less than 103,0 CCID503</p> <p>Varicella virus, strain OKA2 (live, attenuated) - not less than 103,3 PFU4</p> <p>1 produced in chick embryo cells.</p> <p>2 produced in MRC-5 human diploid cells.</p> <p>3 CCID50 = 50% cell culture infectious dose.</p> <p>4 PFU = Plaque forming units.</p>		
Belgium	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix-Tetra	<p>After reconstitution, 1 dose (0,5 ml) contains:</p> <p>Measles virus Schwarz strain (live, attenuated) not less than 103,0 CCID50</p> <p>Mumps virus RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) not less than 104,4 CCID50</p> <p>Rubella virus (Wistar RA 27/3 strain) (live, attenuated) not less than 103,0 CCID50</p> <p>Varicella virus OKA strain (live, attenuated) not less than 103,3 PFU</p>	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	Each 0,5 ml dose of the reconstituted vaccine contains:- not less than 103,0 CCID50* of the Schwarz measles1 - not less than 104,4 CCID50 of the RIT 4385 mumps1, - not less than 103,0 CCID50 of the Wistar RA 27/3 rubella2 virus strains and - not less than 103,3 plaque forming units (PFU) of live attenuated varicella-zoster (Oka strain) virus	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	Each 0,5 ml dose of the reconstituted vaccine contains:- not less than 103,0 CCID50* of the Schwarz measles1 - not less than 104,4 CCID50 of the RIT 4385 mumps1, - not less than 103,0 CCID50 of the Wistar RA 27/3 rubella2 virus strains and - not less than 103,3 plaque forming units (PFU) of live attenuated varicella-zoster (Oka strain) virus	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	per 0,5 ml/dose: 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 $10^{4,4}$ CCID50 Live, attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID50 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	per 0,5 ml/dose: 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 $10^{4,4}$ CCID50 Live, attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID50 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	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 $10^{4,0}$ CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID50. 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	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 $10^{4,4}$ CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID50. 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
Estonia	GlaxoSmithKline Eesti OÜ Lõõtsa 2 11415 Tallinn Estonia	PRIORIX-TETRA	Measles virus (live, attenuated) NLT 103,0 CCID50; Mumps virus (live, attenuated) NLT 104,4 CCID50; Rubella virus (live, attenuated) NLT 103,0 CCID50; Varicella virus (live, attenuated) NLT 103,3 PFU	Powder and solvent for solution for injection	Subcutaneous use
Estonia	GlaxoSmithKline Eesti OÜ Lõõtsa 2 11415 Tallinn Estonia	PRIORIX-TETRA	Measles virus (live, attenuated) NLT 103,0 CCID50; Mumps virus (live, attenuated) NLT 104,4 CCID50; Rubella virus (live, attenuated) NLT 103,0 CCID50; Varicella virus (live, attenuated) NLT 103,3 PFU	Powder and solvent for solution for injection	Subcutaneous use
Finland	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	PRIORIX TETRA	per 0,5 ml: Measles virus (Schwarz) - not less than 103,0 CCID50 Mumps virus (RIT 4385) - not less than 104,4 CCID50 Rubella virus (Wistar RA27/3) - not less than: 103,0 CCID50 Varicella virus (Oka) - not less than: 103,3 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)	1 dose (0,5 ml) contains: Measles virus1 Schwarz strain (live, attenuated) not less than 103,0 CCID503 Mumps virus1 RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) not less than 104,4 CCID503 Rubella virus2 Wistar RA 27/3 strain (live, attenuated) not less than 103,0 CCID503 Varicella virus2 OKA strain (live, attenuated) not less than 103,3 PFU4	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)	1 dose (0,5 ml) contains: Measles virus1 Schwarz strain (live, attenuated) - not less than 103,0 CCID503 Mumps virus1 RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) - not less than 104,4 CCID503 Rubella virus2 Wistar RA 27/3 strain (live, attenuated) - not less than 103,0 CCID503 Varicella virus2 OKA strain (live, attenuated) - not less than 103,3 PFU4	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	per 0,5 ml dose: Measles virus - not less than 3,0 log <sub>10</sub> CCID <sub>50</sub> mumps virus - not less than 4.4 log <sub>10</sub> CCID <sub>50</sub> ; rubella virus - not less than 3,0 log <sub>10</sub> CCID <sub>50</sub> ; varicella virus - not less than 3,3 log <sub>10</sub> PFU	Powder and solvent for solution for injection	Subcutaneous use
Germany	GlaxoSmithKline GmbH & Co. KG Theresienhöhe 11 80339 München Germany	Priorix-Tetra	per 0,5 ml dose: Measles virus - not less than 3,0 log <sub>10</sub> CCID <sub>50</sub> ; mumps virus - not less than 4.4 log <sub>10</sub> CCID <sub>50</sub> ; rubella virus - not less than 3,0 log <sub>10</sub> CCID <sub>50</sub> ; varicella virus - not less than 3,3log <sub>10</sub> 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	Measles virus live attenuated (Schwarz strain) – 1 000,000 CC Mumps virus live attenuated (RIT 4385 strain) – 1 000,000 CC Rubella virus live attenuated (WISTAR RA 27/3 strain) – 1 000,000 CC	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,	per 0,5 ml dose: not less than 1 000 CCID <sub>50</sub> of the measles virus Enders-Edmonston strain not less than 5 000 CCID <sub>50</sub> of the mumps virus (Jeryl Lynn strain) not less than 1 000 CCID <sub>50</sub> of the rubella virus strain	Powder and solvent for solution for injection	Intramuscular use
Hungary	GlaxoSmithKline Kft. 1124 Budapest Csörsz u 43 Hungary	Priorix Tetra por és oldószer oldatos injekcióhoz	After reconstitution, 1 dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than 103,0 CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) not less than 103,7 104,4 CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) not less than 103,0 CCID <sub>50</sub> Varicella virus OKA strain (live, attenuated) not less than 103,3 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
Hungary	GlaxoSmithKline Kft. 1124 Budapest Csörsz u 43 Hungary	Priorix Tetra por és oldószer oldatos injekcióhoz előretöltött fecskendőben	After reconstitution, 1 dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than 103,0 CCID50 Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) not less than 104,4 CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) not less than 103,0 CCID50 Varicella virus OKA strain (live, attenuated) not less than 103,3 PFU	Powder and solvent for solution for injection in pre-filled syringe	Subcutaneous use
Iceland	GlaxoSmithkline ehf. Þverholti 14 105 Reykjavík Iceland	Priorix Tetra	per 0,5 ml Live attenuated measles virus $\geq 10^3$ CCID50 - Live attenuated mumps virus $\geq 10^{4,4}$ CCID50 - Live attenuated rubella virus $\geq 10^3$ CCID50 - Live attenuated varicella virus $\geq 10^{3,3}$ CCID50	Powder and solvent for solution for injection	Subcutaneous use
Iceland	GlaxoSmithkline ehf. Þverholti 14 105 Reykjavík Iceland	Priorix Tetra	per 0,5 ml Live attenuated measles virus $\geq 10^3$ CCID50 - Live attenuated mumps virus $\geq 10^{4,4}$ CCID50 - Live attenuated rubella virus $\geq 10^3$ CCID50 - Live attenuated varicella virus $\geq 10^{3,3}$ CCID50	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)	per 0.5 mg: Live attenuated measles virus (Schwarz strain) not less than 103,0 CCID50 Live attenuated mumps virus (RIT 4385 strain) not less than 104,4 CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) not less than 103,0 CCID50 Live attenuated varicella virus (OKA strain) not less than 103,3 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)	per 0,5 ml: Live attenuated measles virus (Schwarz strain) -not less than 103,0 CCID50 Live attenuated mumps virus (RIT 4385 strain) - not less than 104,4 CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than 103,0 CCID50 Live attenuated varicella virus (OKA strain) - not less than 103,3 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)	per 0,5 ml: Live attenuated measles virus (Schwarz strain) - not less than 103,0 CCID50 Live attenuated mumps virus (RIT 4385 in) - not less than 104,4 CCID50 Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than 103,0 CCID50 Live attenuated varicella virus (OKA strain) - not less than 103,3 PFU	Powder and solvent for solution for injection	Subcutaneous use
Italy	GlaxoSmithKline S.p.A. Via A. Fleming, 2 37135 Verona Italy	PRIRIX TETRA	Measles virus1 Schwarz strain (live, attenuated) - not less than 103,0 CCID503 Mumps virus1 RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) - not less than 104,4CCID503 Rubella virus2 Wistar RA 27/3 strain (live, attenuated) - not less than 103,0 CCID503 Varicella virus2 OKA strain (live, attenuated) - not less than 103,3 PFU4	Powder and solvent for solution for injection	Subcutaneous use
Latvia	GlaxoSmithKline Latvia SIA Bruninieku iela 5 Riga LV-1001 Latvia	Priorix-Tetra powder and solvent for solution for injection	After reconstitution, 1 dose (0,5 ml) contains: Measles virus1 Schwarz strain (live, attenuated) not less than 103,0 CCID503 Mumps virus1 RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) not less than 104,4 CCID503 Rubella virus2 Wistar RA 27/3 strain (live, attenuated) not less than 103,0 CCID503 Varicella virus2 OKA strain (live, attenuated) not less than 103,3 PFU4	Powder and solvent for solution for injection	Subcutaneous use
Latvia	GlaxoSmithKline Latvia SIA Bruninieku iela 5 Riga LV-1001 Latvia	Priorix-Tetra powder and solvent for solution for injection in pre-filled syringe	After reconstitution, 1 dose (0,5 ml) contains: Measles virus1 Schwarz strain (live, attenuated) not less than 103,0 CCID503 Mumps virus1 RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) - not less than 104,4 CCID503 Rubella virus2 Wistar RA 27/3 strain (live, attenuated) - not less than 103,0 CCID503 Varicella virus2 OKA strain (live, attenuated) - not less than 103,3 PFU4	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	UAB „GlaxoSmithKline Lietuva” Goštauto 40A LT-01112 Vilnius Lithuania	Priorix-Tetra	After reconstitution, 1 dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than 10 <sup>3,0</sup> CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than 10 <sup>4,4</sup> CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than 10 <sup>3,0</sup> CCID <sub>50</sub> Live, attenuated varicella virus - not less than 10 <sup>3,3</sup> PFU 4	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	1 dose (0,5 ml) contains: Live attenuated Measles virus (Schwarz strain) - not less than 10 <sup>3</sup> CCID <sub>50</sub> Live attenuated Mumps virus (RIT 4385 strain derived from Jeryl Lynn strain) -not less than 10 <sup>4.4</sup> CCID <sub>50</sub> Live attenuated Rubella virus (Wistar RA 27/3 strain) - not less than 10 <sup>3</sup> CCID <sub>50</sub> Live attenuated Varicella virus (OKA strain) - not less than 10 <sup>3.3</sup> PFU	Powder and solvent for solution for injection	Subcutaneous use
Poland	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix-Tetra	per 0,5 ml dose: Not less than 10 <sup>3,0</sup> CCID <sub>50</sub> of the live, attenuated measles virus (Schwarz strain), not less than 10 <sup>4.4</sup> CCID <sub>50</sub> of the live, attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain), not less than 10 <sup>3,0</sup> CCID <sub>50</sub> of the live, attenuated rubella virus (Wistar RA 27/3 strain), not less than 10 <sup>3.3</sup> PFU of the live, attenuated varicella virus (Oka strain)	Powder and solvent for solution for injection	Subcutaneous use
Poland	GlaxoSmithKline Biologicals S.A. Rue de l'Institut 89 B-1330 Rixensart Belgium	Priorix-Tetra	Not less than 10 <sup>3,0</sup> CCID <sub>50</sub> of the live, attenuated measles virus (Schwarz strain) not less than 10 <sup>4.4</sup> CCID <sub>50</sub> of the live, attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) not less than 10 <sup>3,0</sup> CCID <sub>50</sub> of the live, attenuated rubella virus (Wistar RA 27/3 strain) not less than 10 <sup>3.3</sup> PFU of the live, attenuated varicella virus (Oka strain) per 0,5 ml dose	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	SmithKline & French Portuguesa - Produtos Farmacêuticos, Lda. Rua Dr. António Loureiro Borges, 3 Arquiparque - Miraflores 1495-131 Algés Portugal	Priorix-Tetra	per 0,5 ml dose: Measles virus (Schwarz strain) - not less than 3,0 log <sub>10</sub> CCID <sub>50</sub> mumps virus (RIT 4385 strain) - not less than 3,7 log <sub>10</sub> CCID <sub>50</sub> rubella virus (Wistar RA 27/3 strain) - not less than 3,0 log <sub>10</sub> CCID <sub>50</sub> varicella virus (zoster vivo - OKA strain) - not less than 3,3log <sub>10</sub> 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	per 0,5 ml dose: Measles virus (Schwarz strain) - not less than 3,0 log <sub>10</sub> CCID <sub>50</sub> mumps virus (RIT 4385 strain) - not less than 3,7 log <sub>10</sub> CCID <sub>50</sub> rubella virus (Wistar RA 27/3 strain) - not less than 3,0 log <sub>10</sub> CCID <sub>50</sub> varicella virus (zoster vivo - OKA strain) - not less than 3,3 log <sub>10</sub> PFU	Powder and solvent for solution for injection in pre-filled syringe	Subcutaneous use
Romania	GLAXOSMITHKLINE (GSK) SRL - ROMANIA Costache Negri Street, No. 1-5 Opera Center 1 Etaj 3, sector 5 050552 Bucharest Romania	PRIORIX-TETRA	Measles virus (Schwarz strain): ≥ 103,0 CCID <sub>50</sub> Mumps virus (RIT 4385 strain): ≥ 104,4 CCID <sub>50</sub> Rubella virus (Wistar RA 27/3 strain): ≥ 103,0 CCID <sub>50</sub> Varicella virus (Oka strain): ≥ 103,3 PFU	Powder and solvent for solution for injection	Subcutaneous use
Romania	GLAXOSMITHKLINE (GSK) SRL - ROMANIA Costache Negri Street, No. 1-5 Opera Center 1 Etaj 3, sector 5 050552 Bucharest Romania	PRIORIX-TETRA	Measles virus (Schwarz strain): ≥ 103,0 CCID <sub>50</sub> Mumps virus (RIT4385 strain): ≥ 104,4 CCID <sub>50</sub> Rubella virus (Wistar RA 27/3 strain): ≥ 103,0 CCID <sub>50</sub> Varicella virus (Oka strain): ≥ 103,3 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	Measles virus Schwarz strain (live, attenuated) not less than 103,0 CCID <sub>50</sub> Mumps virus RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) not less than 104,4 CCID <sub>50</sub> Varicella virus OKA strain (live, attenuated) not less than 103,3 PFU <sub>4</sub>	Powder and solvent for solution for injection	Subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	GlaxoSmithKline Slovakia s.r.o., Galvaniho 7/A Bratislava 2, 821 04 Slovak Republic	Priorix-Tetra lag	Measles virus Schwarz strain (live, attenuated) not less than 103,0 CCID503 Mumps virus RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) not less than 104,4 CCID503 Rubella virus (Wistar RA 27/3 strain) (live, attenuated) not less than 103,0 CCID503 Varicella virus OKA strain (live, attenuated) not less than 103,3 PFU4	Powder and solvent for solution for injection	Subcutaneous use
Slovenia	GSK d.o.o Cvetkova ulica 29 1000 Ljubljana Slovenia	Priorix-Tetra prašek in vehikel za raztopino za injiciranje v napolnjeni injekcijski brizgi	per dose (0,5 ml): Measles virus (strain Schwarz) (live, attenuated) - not less than 103,0 CCID50 Mumps virus (strain RIT 4385 - derived from strain Jeryl Lynn) (live, attenuated) - not less than 104,4 CCID50 Rubella virus (strain Wistar RA 27/3) (live, attenuated) - not less than 103,0 CCID50 Varicella virus (strain OKA) (live, attenuated) - not less than 103,3 PFU	Powder and solvent for solution for injection	Subcutaneous use
Sweden	GlaxoSmithKline AB Box 516 169 29 Solna Sweden	Priorix Tetra	Measles virus, live attenuated strain Schwarz 10 <sup>3,0</sup> CCID50; Mumps virus, live attenuated strain RIT 438510 <sup>4,4</sup> CCID50 Rubella virus, live attenuated strain Wistar RA 27/3 - 10 <sup>3,0</sup> CCID50 Varicella virus, strain OKA, live attenuated 10 <sup>3.3</sup> pfu	Powder and solvent for solution for injection	Subcutaneous use
Sweden	GlaxoSmithKline AB Box 516 169 29 Solna Sweden	Priorix Tetra	Measles virus, live attenuated strain Schwarz 10 <sup>3,0</sup> CCID50; Mumps virus, live attenuated strain RIT 438510 <sup>4,4</sup> CCID50 Rubella virus, live attenuated strain Wistar RA 27/3 10 <sup>3,0</sup> CCID50 Varicella virus, strain OKA, live attenuated 10 <sup>3.3</sup> 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	per 0,5 ml: Measles virus Schwarz strain (live, attenuated) not less than 10 CCID50 Mumps virus RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) not less than 10 CCID50 Rubella virus Wistar RA 27/3 strain (live, attenuated) not less than 100 CCID50 Varicella virus OKA strain (live, attenuated) not less than 10 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	per 0,5 ml: Measles virus Schwarz strain (live, attenuated) not less than 10 CCID50 Mumps virus RIT 4385 strain, derived from Jeryl Lynn strain (live, attenuated) not less than 10 CCID50 Rubella virus Wistar RA 27/3 strain (live, attenuated) not less than 100 CCID50 Varicella virus OKA strain (live, attenuated) not less than 10 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	Live Attenuated Mumps Virus RT 4385: 4,4 CID50 Live Attenuated Measles Virus (Schwarz Strain): 3 CID50 Live Attenuated Rubella (Wistar RA 27/3 Strain): 3 CID50 Varicella Virus OKA Strain: 3,3 CID50	Powder and solution for injection	Subcutaneous use

**Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. lipnja 2013. do 31. srpnja 2013.**

*(Objavljeno u skladu s člankom 13. ili člankom 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća <sup>(1)</sup>)*

(2013/C 250/02)

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<sup>(1)</sup> SL L 136, 30.4.2004., str. 1.



— Izdavanje odobrenja za stavljanje u promet (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): Prihvaćeno

Datum odluke	Naziv lijeka	INN (međunarodni nezaštićeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
13.6.2013	Memantine ratiopharm	memantin	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/13/836	Filmom obložena tableta	N06DX01	17.6.2013
14.6.2013	Votrient	Pazopanibklorida	Glaxo Group Limited 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/10/628	Filmom obložena tableta	L01XE11	18.6.2013
21.6.2013	Capecitabine SUN	Kapecitabin	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, NL-2132 JH Hoofddorp, Nederland	EU/1/13/831	Filmom obložena tableta	L01BC06	25.6.2013
21.6.2013	Spedra	avanafil	VIVUS B.V. Prins Bernhardplein 200, NL-1097 JB Amsterdam, Nederland	EU/1/13/841	Tableta	G04BE	25.6.2013
21.6.2013	Xtandi	enzalutamid	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/13/846	Kapsula, meka	Pending	25.6.2013
24.6.2013	Nuedexta	dekstrometorfan/kinidin	Jenson Pharmaceutical Services Ltd Carradine House 237 Regents Park Road, London N3 3LF, United Kingdom	EU/1/13/833	Kapsula, tvrda	N07XX	26.6.2013
24.6.2013	Stayveer		Marklas Nederland B.V. Beneluxlaan 2b, NL-3446 GR Woerden, Nederland	EU/1/13/832	Filmom obložena tableta	C02KX01	25.6.2013
27.6.2013	MACI	kultivirani karakterizirani autoložni hondrociti aplicirani na matriks	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/13/847	Matrica za implantaciju	M09AX02	1.7.2013

Datum odluke	Naziv lijeka	INN (međunarodni nezaštićeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
1.7.2013	Iclusig	ponatiniba	ARIAD Pharma Ltd 2 Temple Back East, Temple Quay, Bristol, BS1 6EG, United Kingdom	EU/1/13/839	Filmom obložena tableta	L01XE24	3.7.2013
1.7.2013	Imatinib Accord	Imatinib	Accord Healthcare Limited Sage house, 319 Pinner road, North Harrow, Middlesex HA1 4HF, United Kingdom	EU/1/13/845	Filmom obložena tableta	L01XE01	3.7.2013
12.7.2013	Erivedge	vismodegib	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/13/848	Kapsula, tvrda	L01XX43	17.7.2013
25.7.2013	Lonquex	lipegfilgrastim	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/13/856	Otopina za injekciju	L03AA14	29.7.2013
31.7.2013	Atosiban SUN	atosiban	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, NL-2132 JH Hoofddorp, Nederland	EU/1/13/852	Koncentrat za otopinu za infuziju Otopina za injekciju	G02CX01	2.8.2013
31.7.2013	Imvanex	modificirani virus vakcine ankara	Bavarian Nordic A/S Hejreskovvej 10a, DK-3490 Kvistgaard, Danmark	EU/1/13/855	Suspencija za injekciju	J07BX	5.8.2013
31.7.2013	Lojuxta	Lomitapid	Aegerion Pharmaceuticals 37/39 avenue Ledru Rollin, F-75012 Paris, France	EU/1/13/851	Kapsula, tvrda	C10AX12	5.8.2013
31.7.2013	PHEBURANE	natrijev fenilbutirat	Lucane Pharma 172 rue de Charonne, 75011 Paris, France	EU/1/13/822/	Zrnice	A16AX03	5.8.2013

— Izmjena odobrenja za stavljanje u promet (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): Prihvaćeno

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
11.6.2013	IOA	Organon N.V. Kloosterstraat 6, NL-5349 AB Oss, Nederland	EU/1/11/689	13.6.2013
11.6.2013	Rienso	Takeda Pharma A/S PO Box 88, Langebjerg 1, DK-4000 Roskilde, Danmark	EU/1/12/774	13.6.2013
11.6.2013	Zoely	Theramex S.r.l. Via Messina 38, 20154 Milano, Italia	EU/1/11/690	18.6.2013
13.6.2013	Abilify	Otsuka Pharmaceutical Europe Ltd Hunton House, Highbridge Estate, Oxford Road, Uxbridge, Middlesex UB8 1LX, United Kingdom.	EU/1/04/276	17.6.2013
13.6.2013	Atripla	Bristol-Myers Squibb and Gilead Sciences Limited IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland	EU/1/07/430	17.6.2013
13.6.2013	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/07/391	17.6.2013
13.6.2013	Tysabri	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/06/346	17.6.2013
21.6.2013	Bridion	Organon N.V. Kloosterstraat 6, NL-5349 AB Oss, Nederland	EU/1/08/466	25.6.2013
21.6.2013	Brinavess	Cardiome UK Limited Sherborne House, 119-121 Cannon Street, 3rd Floor, London EC4N 5AT, United Kingdom	EU/1/10/645	25.6.2013
21.6.2013	EDURANT	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/736	25.6.2013

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
21.6.2013	Eviplera	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/11/737	25.6.2013
21.6.2013	Intelligence	Janssen-Cilag International NV Turnhouseweg 30, B-2340 Beerse, België	EU/1/08/468	25.6.2013
21.6.2013	Javlor	Pierre Fabre Médicament 45, place Abel Gance, F-92100 Boulogne, France	EU/1/09/550	25.6.2013
21.6.2013	Osseor	Les Laboratoires Servier 50 rue Carnot, F-92284 Suresnes CEDEX, France	EU/1/04/287	25.6.2013
21.6.2013	Protelos	Les Laboratoires Servier 50 rue Carnot, F-92284 Suresnes CEDEX, France	EU/1/04/288	25.6.2013
21.6.2013	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/03/267	25.6.2013
21.6.2013	Xenical	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/98/071	25.6.2013
21.6.2013	Zerit	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/96/009	25.6.2013
27.6.2013	Glivec	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/01/198	1.7.2013
27.6.2013	Levodopa/Carbidopa/Entacapone Orion	Orion Corporation Orionintie 1, FI-02200 Espoo, Suomi	EU/1/11/706	1.7.2013
27.6.2013	Rasilamlo	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/686	1.7.2013

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
27.6.2013	Rasilez	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/405	1.7.2013
27.6.2013	Vivanza	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/03/249	1.7.2013
1.7.2013	Ariclaim	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/283	3.7.2013
1.7.2013	Emtriva	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/03/261	3.7.2013
1.7.2013	Fampyra	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/11/699	3.7.2013
1.7.2013	Intelence	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/08/468	3.7.2013
1.7.2013	PREZISTA	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/06/380	3.7.2013
1.7.2013	Rasilez HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/491	3.7.2013
1.7.2013	Replagal	Shire Human Genetic Therapies AB Svärdvägen 11D, SE-182 33 Danderyd, Sverige	EU/1/01/189	3.7.2013
1.7.2013	Stocrin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/99/111	3.7.2013
1.7.2013	Sustiva	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/99/110	3.7.2013

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
1.7.2013	Trobalt	Glaxo Group Limited 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/11/681	3.7.2013
1.7.2013	Truvada	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/04/305	3.7.2013
1.7.2013	Viread	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/01/200	3.7.2013
1.7.2013	Votrient	Glaxo Group Limited 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/10/628	3.7.2013
1.7.2013	Yentreve	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/280	3.7.2013
4.7.2013	Cymbalta	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/296	8.7.2013
4.7.2013	Lucentis	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/374	8.7.2013
4.7.2013	Rasitrio	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/730	8.7.2013
4.7.2013	Xeristar	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA Houten, Nederland	EU/1/04/297	8.7.2013
9.7.2013	Prevenar 13	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/09/590	11.7.2013
9.7.2013	Tysabri	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/06/346	11.7.2013

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
15.7.2013	Benlysta	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/11/700	17.7.2013
15.7.2013	Onduarp	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/11/729	17.7.2013
15.7.2013	Pradaxa	Boehringer Ingelheim International GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/442	17.7.2013
15.7.2013	Votubia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/710	17.7.2013
17.7.2013	Iscover	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/98/070	19.7.2013
17.7.2013	Plavix	Sanofi Pharma Bristol-Myers Squibb SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/98/069	19.7.2013
17.7.2013	Votubia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/710	19.7.2013
19.7.2013	Clopidogrel Zentiva	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/08/465	23.7.2013
19.7.2013	DuoPlavin	Sanofi Pharma Bristol-Myers Squibb SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/10/619	23.7.2013
19.7.2013	Ratiograstim	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/444	23.7.2013
19.7.2013	Tevagrastim	Teva GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/445	23.7.2013
19.7.2013	Thalidomide Celgene	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/08/443	23.7.2013

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
25.7.2013	Aranesp	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/01/185	29.7.2013
25.7.2013	Biograstim	CT Arzneimittel GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/08/450	29.7.2013
25.7.2013	Leflunomide medac	medac Gesellschaft für klinische Spezial- präparate mbH Fehlandtstraße 3, D-20354 Hamburg, Deutschland	EU/1/10/637	29.7.2013
25.7.2013	Remicade	Janssen Biologics B.V. Einsteinweg 101, NL-2333 CB Leiden, Nederland	EU/1/99/116	29.7.2013
25.7.2013	Tyverb	Glaxo Group Limited 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/07/440	29.7.2013
25.7.2013	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423	29.7.2013
25.7.2013	Zytiga	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/714	29.7.2013
26.7.2013	BYDUREON	Bristol-Myers Squibb/AstraZeneca EEIG Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom	EU/1/11/696	31.7.2013
26.7.2013	DuoCover	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/10/623	31.7.2013
26.7.2013	Eucreas	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/425	30.7.2013
26.7.2013	Evicel	Omrix Biopharmaceuticals N.V. Leonardo Da Vincilaan 15, B-1831 Diegem, België	EU/1/08/473	30.7.2013
26.7.2013	Iscover	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/98/070	31.7.2013



Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
26.7.2013	Onglyza	Bristol-Myers Squibb/AstraZeneca EEIG Bristol Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, United Kingdom	EU/1/09/545	30.7.2013
26.7.2013	Plavix	Sanofi Pharma Bristol-Myers Squibb SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/98/069	30.7.2013
26.7.2013	Rasilez	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/405	31.7.2013
26.7.2013	Rasitrio	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/11/730	30.7.2013
26.7.2013	Teysuno	Nordic Group B.V. Siriusdreef 22, NL-2132 WT Hoofddorp, Nederland	EU/1/11/669	31.7.2013
31.7.2013	Aprovel	Sanofi Pharma Bristol-Myers Squibb SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/97/046	5.8.2013
31.7.2013	CoAprovel	Sanofi Pharma Bristol-Myers Squibb SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/98/086	5.8.2013
31.7.2013	Copalia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/372	2.8.2013
31.7.2013	Copalia HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/575	5.8.2013
31.7.2013	Dafiro	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/371	5.8.2013
31.7.2013	Dafiro HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/574	2.8.2013

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
31.7.2013	Exforge	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/370	5.8.2013
31.7.2013	Exforge HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/569	2.8.2013
31.7.2013	Galvus	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/414	5.8.2013
31.7.2013	Icandra	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/484	5.8.2013
31.7.2013	Imprida	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/373	5.8.2013
31.7.2013	Irbesartan HCT Zentiva	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/06/377	2.8.2013
31.7.2013	Irbesartan Zentiva	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/06/376	5.8.2013
31.7.2013	Jalra	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/485	5.8.2013
31.7.2013	Karvea	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/97/049	2.8.2013
31.7.2013	Karvezide	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/98/085	2.8.2013
31.7.2013	Leganto	UCB Manufacturing Ireland Ltd. Shannon Industrial Estate, Co, Clare, Ireland	EU/1/11/695	2.8.2013
31.7.2013	Neupro	UCB Manufacturing Ireland Ltd. Shannon Industrial Estate, Co, Clare, Ireland	EU/1/05/331	2.8.2013

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
31.7.2013	ProQuad	Sanofi Pasteur MSD, SNC 8 rue Jonas Salk, F-69007 Lyon, France	EU/1/05/323	2.8.2013
31.7.2013	VELCADE	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, Belgijë	EU/1/04/274	5.8.2013
31.7.2013	Vimpat	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, Belgijë	EU/1/08/470	5.8.2013
31.7.2013	Xiliarx	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/486	5.8.2013
31.7.2013	Zomarist	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/483	2.8.2013

— **Povlačenje odobrenja za stavljanje u promet (članak 13. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća)**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
6.6.2013	Sepioglin	Vaia S.A. 1, 28 Octovriou str., Ag. Varvara 123 51, Athens, Ελλάδα	EU/1/12/754	10.6.2013

— **Prekid obustave odobrenja za stavljanje u promet (članak 20. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća)**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
17.7.2013	Ribavirin Teva	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/509	19.7.2013
17.7.2013	Ribavirin Teva Pharma BV	Teva Pharma B.V. Computerweg 10, NL-3542 DR Utrecht, Nederland	EU/1/09/527	19.7.2013

— Izdavanje odobrenja za stavljanje u promet (članak 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća <sup>(1)</sup>): Prihvaćeno

Datum odluke	Naziv lijeka	INN (međunarodni nezaštićeni naziv lijeka)	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Farmaceutski oblik	Oznaka ATC (Anatomsko-terapijsko-kemijska klasifikacija lijekova)	Datum obavijesti
6.6.2013	Equilis West Nile	Inaktivirani kimerni flavivirus soj YF-WN	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/13/151	Suspencija za injekciju	QI05AA10	10.6.2013
12.7.2013	ProZinc	Ljudski inzulin	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173, D-55216 Ingelheim am Rhein, Deutschland	EU/2/13/152	Suspencija za injekciju	QA10AC01	16.7.2013
15.7.2013	Aftovaxpur Doe	pročišćeni, inaktivirani sojeva virusa koji uzrokuje bolest slinavke i šapa O1 Manisa, O1 BFS, O Taiwan 3/97, A22 Iraq, A24 Cruzeiro, A Turkey 14/98, Asia 1 Shamir	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/13/153	Emulzija za injekciju	QI02AA04	17.7.2013

<sup>(1)</sup> SL L 136, 30.4.2004., str. 1.

— **Izmjena odobrenja za stavljanje u promet (članak 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća): Prihvaćeno**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
6.6.2013	Equioxx	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/08/083	11.6.2013
13.6.2013	Contacera	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain- La-Neuve, Belgique	EU/2/12/144	17.6.2013
9.7.2013	Suvaxyn Aujeszky 783 +O/W	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain- La-Neuve, Belgique	EU/2/98/009	11.7.2013
15.7.2013	Reconcile	Eli Lilly and Company Ltd Priestley Road, Basingstoke, Hampshire RG24 9NL, United Kingdom	EU/2/08/080	19.7.2013
15.7.2013	Zactran	Merial 29 avenue Tony Garnier, F-69007 Lyon, France	EU/2/08/082	17.7.2013
26.7.2013	Zulvac 1+8 Ovis	Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain- La-Neuve, Belgique	EU/2/11/120	30.7.2013

— **Povlačenje odobrenja za stavljanje u promet (članak 38. Uredbe (EZ) br. 726/2004 Europskog parlamenta i Vijeća)**

Datum odluke	Naziv lijeka	Nositelj odobrenja za stavljanje u promet	Broj upisa u registar Zajednice	Datum obavijesti
21.6.2013	Ibafin	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/00/022	25.6.2013

Zainteresirane osobe koje žele na uvid dobiti javno izvješće o procjeni predmetnih lijekova i odluka koje se na njih odnose trebale bi se obratiti:

The European Medicines Agency  
7, Westferry Circus, Canary Wharf  
UK-LONDON E14 4H

**Sažetak odluka Europske unije o odobrenjima za stavljanje u promet lijekova od 1. lipnja 2013. do 31. srpnja 2013.**

(Odluke donesene u skladu s člankom 34. Direktive 2001/83/EZ <sup>(1)</sup> ili člankom 38. Direktive 2001/82/EZ <sup>(2)</sup>)  
(2013/C 250/03)

**— Izdavanje, zadržavanje ili izmjena nacionalnog odobrenja za stavljanje u promet**

Datum odluke	Naziv(i) lijeka	Nositelj(i) odobrenja za stavljanje u promet	Država članica na koju se odnosi	Datum obavijesti
24.6.2013.	Cilostazol	Vidi Prilog I. (*)	Vidi Prilog I. (*)	25.6.2013.
25.7.2013.	Cyproterone acetate/ethinylestradiol	Vidi Prilog II.	Vidi Prilog II.	29.7.2013.
27.6.2013.	Monovalent and multivalent measles, mumps, rubella and varicella vaccines	Vidi Prilog III. (*)	Vidi Prilog III. (*)	1.7.2013.

(\*) Hrvatski prijevod ovog dokumenta nije dostupan, dokument je objavljen na engleskom jeziku.

<sup>(1)</sup> SL L 311, 28.11.2001., str. 67.

<sup>(2)</sup> SL L 311, 28.11.2001., str. 1.

## PRILOG I.

POPIS NAZIVA, FARMACEUTSKIH OBLIKA, JAČINA LIJEKOVA, PUTEVA PRIMJENE, NOSITELJA  
ODOBRENJA ZA STAVLJANJE U PROMET U DRŽAVAMA ČLANICAMA

Member State (in EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Otsuka Pharmaceutical Europe Ltd. Hunton House Highbridge Business Park. Oxford Road GB-UB8 1HU MIDDLESEX United Kingdom	PLETAL 100 mg, comprimé	100 mg	tablet	oral use
France	Otsuka Pharmaceutical Europe Ltd. Hunton House Highbridge Business Park Oxford Road GB-UB8 1HU MIDDLESEX United Kingdom	PLETAL 50 mg, comprimé	50 mg	tablet	oral use
Germany	Otsuka Pharmaceutical Europe Ltd. Hunton House Highbridge Business Park Oxford RoadUxbridge GB-UB8 1HU MIDDLESEX United Kingdom	Pletal 50 mg, Tabletten	50 mg	tablet	oral use
Germany	Otsuka Pharmaceutical Europe Ltd. Hunton House Highbridge Business Park Oxford RoadUxbridge GB-UB8 1HU MIDDLESEX United Kingdom	Pletal 100 mg, Tabletten	100 mg	tablet	oral use
Italy	Otsuka Pharmaceutical Europe Ltd. Hunton House, Highbridge Business Park, Oxford Road, Uxbridge, Middlesex, UB8 1LX United Kingdom	PLETAL	50 MG	tablet	oral use
Italy	Otsuka Pharmaceutical Europe Ltd. Hunton House, Highbridge Business Park, Oxford Road, Uxbridge, Middlesex, UB8 1LX United Kingdom	PLETAL	100 MG	tablet	oral use

Member State (in EEA)	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Otsuka Pharmaceutical Europe Ltd. Hunton House, HighbridgeBusinessPark, Oxford Road Middlesex, UB8 1LX United Kingdom	PLETAL 50 mg comprimidos	50 mg	tablet	oral use
Spain	Otsuka Pharmaceutical Europe Ltd.Huton House Highbridge Busines Park, Oxford RoadUxbridge, Middlesex, UB8 1LX United Kingdom	PLETAL 100 mg comprimidos	100 mg	tablet	oral use
Spain	LACER S.A. Sardenya, 350 08025 Barcelona	EKISTOL 50 mg comprimidos	50 mg	tablet	oral use
Spain	LACER S.A. Sardenya, 350 08025 Barcelona	EKISTOL 100 mg comprimidos	100 mg	tablet	oral use
Sweden	Otsuka Pharmaceutical Europe Limited Hunton House Highbridge Business Park Oxford Road Uxbridge Middlesex UB8 1HU GB	PLETAL	50 mg	tablet	oral use
Sweden	Otsuka Pharmaceutical Europe Limited Hunton House Highbridge Business Park Oxford Road Uxbridge Middlesex UB8 1HU GB	PLETAL	100 mg	tablet	oral use
United Kingdom	Otsuka Pharmaceutical Europe Limited, Hunton House, Highbridge Business Park, Oxford Road, Uxbridge, MiddlesexUB8 1HU,UK	Pletal 50 mg Tablets	50 mg	tablet	oral use
United Kingdom	Otsuka Pharmaceutical Europe Limited, Hunton House, Highbridge Business Park, Oxford Road, Uxbridge, MiddlesexUB8 1HU,UK	Pletal 100 mg Tablets	100 mg	tablet	oral use



## PRILOG II.

POPIS NAZIVA, FARMACEUTSKIH OBLIKA, JAČINA LIJEKOVA, PUTEVA PRIMJENE, NOSITELJA  
ODOBRENJA ZA STAVLJANJE U PROMET U DRŽAVAMA ČLANICAMA

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Austrija	Gynial GmbH Gablenzgasse 11/III 1150 Wien Austria	Alisma 2 mg/35 µg Filmtablette	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Austrija	Ratiopharm Arzneimittel Vertriebs-GmbH Albert-Schweitzer-Gasse 3 1140 Wien Austria	Bellgyn „ratiopharm“ 2 mg/0,035 mg - überzogene Tabletten	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Austrija	Dermapharma GmbH, Türkenstraße 25/12 A-1090 Wien, Austria	Cyprotomin 2 mg/0,035 mg Filmtabletten	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Austrija	Bayer Austria GmbH Herbststrasse 6-10 1160 Wien Austria	Diane mite - Dragees	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Austrija	Dermapharm AG Lil-Dagover-Ring 7 82031 Grünwald Germany	Femogyn 2 mg/0,035 mg überzogene Tabletten	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Austrija	Pelpharma Handels GmbH Stammhausstraße 31 1140 Wien Austria	Midane - Dragees	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Austrija	Bayer Austria GmbH Herbststrasse 6-10 1160 Wien Austria	Minerva - Dragees	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Austrija	Sandoz GmbH Biochemiestraser 10 6250 Kundl Austria	Xylia - Dragées	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Belgija	Mithra Pharmaceuticals S.A. Rue Saint Georges 5 4000 Liège Belgium	Chloe	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Belgija	Sandoz N.V. Telecom Gardens Medialaan 40 1800 Vilvoorde Belgium	Claudia-35	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Belgija	Mithra Pharmaceuticals S.A. Rue Saint Georges 5 4000 Liège Belgium	Daphne	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Belgija	Bayer N.V. Jan Emiel Mommaertsiaan 14 1831 Machelen Belgium	Diane-35	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Belgija	Mylan BVBA/SPRL Terhulpesteenweg 6A 1560 Hoeilaart Belgium	Elisamylan	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Belgija	3 DDD Pharma N.V. Diestersteenweg 349 3510 Hasselt Belgium	Gratiella 35	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Bugarska	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Diane 35	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Bugarska	Medico Uno Worldwide Ltd. 2 Grigori Afxentiou Street Larnaca 6023 Cyprus	Melleva	0,035 mg 2,00 mg	Filmom obložena tableta	Kroz usta
Bugarska	Zentiva, k.s. U kabelovny 130 102 37 Praha 10 Dolní Měcholupy Czech Republic	Chloe	0,035 mg 2,00 mg	Filmom obložena tableta	Kroz usta
Češka Republika	Zentiva, k.s. U kabelovny 130 102 37 Praha 10 Dolní Měcholupy Czech Republic	CHLOE	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Češka Republika	Heaton k.s. Na Pankráci 332/14 14000 Praha 4Czech Republic	VREYA	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Češka Republika	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	MINERVA	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Češka Republika	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	DIANE-35	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Danska	Mithra Pharmaceuticals S.A. Rue Saint Georges 5 4000 Liège Belgium	Chloe	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Danska	Teva Danska A/S Parallelvej 10-12 DK-2800 Kongens Lyngby Denmark	Cypretyl	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Danska	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Diane Mite	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Danska	Alternova A/S Lodshusvej 11 DK-4230 Skælskør Denmark	Dianova Mite	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Danska	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	Feminil mite	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Danska	Stragen Nordic A/S Helsingørsgade 8C DK-3400 Hillerød Denmark	Vreya	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Danska	Orifarm Generics A/S Postbox 69 Energivej 15 DK-5260 Odense S. Denmark	Zyrona	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Estonija	Bayer Pharma AG D-13342 Berlin Germany	Diane	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Estonija	Nycomed Sefa AS Jaama 55B 63308 Põlva Estonia	Femina	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Estonija	Ratiopharm GmbH Graf-Arco-Strasse 3 DE-89079 Ulm Germany	Cypretil	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Finska	Bayer Oy Pansiontie 47 FI-20210 Turku Finland	DIANE NOVA	2,00 mg 0,035 mg	Tableta	Kroz usta
Finska	Ratiopharm GmbH Graf-Arco-Strasse 3 DE-89079 Ulm Germany	CYPRETYL	2,00 mg 0,035 mg	Tableta	Kroz usta
Finska	Sandoz A/S Edvard Thomsens Vej 14 DK-2300 København S Denmark	FEMINIL	2,00 mg 0,035 mg	Tableta	Kroz usta
Finska	Stragen Nordic A/S Helsingørgade 8C DK-3400 Hillerød Denmark	VREYA	2,00 mg 0,035 mg	Tableta	Kroz usta
Francuska	Bayer Santé 220, avenue de la Recherche 59120 Loos France	DIANE 35 µg, coated tablet	2,00 mg 0,035 mg	Obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Francuska	Bayer Santé 220, avenue de la Recherche 59120 Loos France	MINERVA 35 µg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	Bayer Santé 220, avenue de la Recherche 59120 Loos France	CYPROTERONE/ETHINYLESTRADIOL BAYER 35 µg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	Laboratoires Majorelle 80-82 rue Gallieni 92100 Boulogne Billancourt France	CYPROPHARM 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	DCI Pharma 180 Rue Eugene Avinee 59120 Loos France	CYPROTERONE/ETHINYLESTRADIOL DCI PHARMA 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	EG LABO - LABORATOIRES EUROGENERICIS 12 rue Danjou le Quintet bâtiment A 92517 Boulogne Billancourt Cedex France	CYPROTERONE/ETHINYLESTRADIOL EG 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	Ranbaxy Pharmacie Generiques 11-15 quai de Dion Bouton 92800 Puteaux France	CYPROTERONE/ETHINYLESTRADIOL RANBAXY 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	Teva Sante 110 Esplanade du Général de Gaulle 92931 Paris la Defence Francuska	CYPROTERONE/ETHINYLESTRADIOL RATIOPHARM 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	SANDOZ 49 avenue Georges Pompidou 92593 Levallois Perret Cedex France	CYPROTERONE/ETHINYLESTRADIOL SANDOZ 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Francuska	Teva Sante 110 Esplanade du Général de Gaulle 92931 Paris la Defence France	CYPROTERONE/ETHINYLESTRADIOL TEVA 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	Sanofi Aventis Francuska 1-13 Boulevard Romain Rolland 75014 Paris France	CYPROTERONE/ETHINYLESTRADIOL ZENTIVA 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	ZYDUS Francuska Parc d'Activités des Peupliers 25 rue des Peupliers 92000 Nanterre France	CYPROTERONE/ETHINYLESTRADIOL ZYDUS 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	CHEMICAL FARMA 19-23 rue d'Hautpoul 75019 Paris France	ELLEACNELLE 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	MYLAN SAS 117 allée des Parcs 69800 Saint Priest France	EVEPAR 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	EFFIK bâtiment „le Newton” 9-11 rue Jeanne Braconnier 92366 Meudon la Foret France	HOLGYEME 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Francuska	Pierre Fabre Dermatologie 45, place Abel Gance F-92100 Boulogne France	LUMALIA 2 mg/0,035 mg	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Njemačka	Dermapharm AG Lil-Dagover-Ring 7 82031 Grünwald Njemačka	Cyproethinyl acis	0,035 mg 2,00 mg	Filmom obložena tableta	Kroz usta
Njemačka	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Jennifer 35 2 mg/0,035 mg Filmtabletten	0,035 mg 2,00 mg	Filmom obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Njemačka	Bayer Vital GmbH Kaiser-Wilhelm-Allee 51373 Leverkusen Germany	Diane-35 0,035 mg/2 mg überzogene Tablette	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Njemačka	Dermapharm AG Lil-Dagover-Ring 7 82031 Grünwald Germany	Cyproteronacetat/Ethinylestradiol Dermapharm 2 mg/0,035 mg überzogene Tablette	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Njemačka	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Bella HEXAL 35 2 mg/0,035 mg überzogene Tablette	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Njemačka	Mylan dura GmbH Wittichstr. 6 64295 Darmstadt Germany	Juliette	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Njemačka	Ratiopharm GmbH Graf-Arco-Strasse 3 DE-89079 Ulm Germany	Attempta-ratiopharm 35 2 mg/0,035 mg überzogene Tablette	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Njemačka	Taurus Pharma GmbH Benzstr. 11 61352 Bad Homburg Germany	Ergalea 2,00/0,035 mg Filmtabletten	0,035 mg 2,00 mg	Filmom obložena tableta	Kroz usta
Njemačka	UCB Pharma GmbH Alfred-Nobel-Str. 10 40789 Monheim Germany	Moea Sanol 2 mg/0,035 mg überzogene Tabletten	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Grčka	Bayer Hellas ABEE Sorou 18-20 Maroussi Athens GR-15125 Greece	GYNOFEN 35	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Mađarska	Pliva Hungária Kereskedelmi és Szolgáltató Kft. Rákóczi út 70-72 Budapest 1074 Hungary	Bellune Pliva	2,00 mg 0,035 mg	Obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Mađarska	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Diane	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Mađarska	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Minerva	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Island	Bayer Pharma AG D-13342 Berlin Germany	Diane mite	2,00 mg 0,035 mg	Tableta	Kroz usta
Island	Ratiopharm GmbH Graf-Arco-Strasse 3 DE-89079 Ulm Germany	Cypretyl	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Irska	Generics (UK) Limited Station Close Potters Bar Hertfordshire EN6 1TL United Kingdom	Cyproterone Acetate/Ethinylestradiol Tablets 2 mg/0.035 mg	2,00 mg 0,035 mg	Tableta	Kroz usta
Irska	Bayer Limited The Atrium Blackthorn Road Sandyford Dublin 18 Ireland	Dianette 2 mg/35 microgram coated tablets.	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Italija	Bayer S.p.A. Viale Certosa, 130 20156 Milano (MI) Italy	DIANE	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Italija	FIDIA Farmaceutici S.p.A. Via Ponte della Fabbrica 3/A 35031 Abano Terme (PD) Italy	VISOFID	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Latvija	Zentiva, k.s. U kabelovny 130 102 37 Praha 10 Dolní Měcholupy Czech Republic	Chloe 35 micrograms/2 mg film-coated tablets	0,035 mg 2,00 mg	Filmom obložena tableta	Kroz usta



Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Latvija	Takeda Pharma AS Jaama 55B 63308 Põlva Estonia	Femina 2 mg/35 micrograms coated tablets	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Latvija	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Diane 2 000 micrograms/35 micrograms film-coated tablets	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Litva	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Diane	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Litva	Nycomed Sefa AS Jaama 55B 63308 Põlva Estonia	Femina	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Litva	Zentiva, k.s. U kabelovny 130 102 37 Praha 10 Dolní Měcholupy Czech Republic	CHLOE	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Litva	Ratiopharm GmbH Graf-Arco-Strasse 3 DE-89079 Ulm Germany	Cypretil	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Luksemburg	Bayer SA/NV 14 J.E. Mommaertsiaan B-1831 Diegem Belgium	Diane-35	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Luksemburg	Mithra Pharmaceuticals S.A. Rue Saint Georges 5 4000 Liège Belgium	Chloe	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Luksemburg	Mithra Pharmaceuticals S.A. Rue Saint Georges 5 4000 Liège Belgium	Daphne	2,00 mg 0,035 mg	Obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Luksemburg	Pierre Fabre Dermatologie 45, place Abel Gance F-92100 Boulogne France	Lumalia	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Malta	Stragen UK Limited Castle Court 41 London Road Reigate, Surrey RH2 PRJ United Kingdom	Clairette 2000/35 Tablets	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Malta	Sandoz d.d Verovskova 57 1000 Ljubljana Slovenia	Acnocin 2000/35 Tablets	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Norveška	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Diane	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Norveška	Sandoz Edvard Thomsens Vej 14 2300 KØBENHAVN S Denmark	Feminil	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Norveška	Orifarm Generics A/S Postbox 69 Energivej 15 DK-5260 Odense S. Denmark	Zyrona	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Poljska	Acis Arzneimittel GmbH Lil-Dagover-Ring 7 82031 Grünwald Germany	Acnemine	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Poljska	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Diane-35	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Poljska	Zentiva, k.s. U kabelovny 130 102 37 Praha 10 Dolní Měcholupy Czech Republic	Chloe	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Poljska	Pabianickie Zakłady Farmaceutyczne Polfa S.A. ul. Marszałka J. Piłsudskiego 5 95-200 Pabianice Poland	Cyprest	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Poljska	Polfarmex S.A. Józefów 9 99-300 Kutno Poland	OC-35	0,035 mg 2,00 mg	Filmom obložena tableta	Kroz usta
Poljska	SymPhar Sp. z o.o. ul. Włoska 1 00-777 Warszawa Poland	Syndi-35	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Poljska	Sun-Farm Sp. z o.o. Człkówka 75 05-340 Kołbiel Poland	Cyprodiol	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Portugal	Berlifarma - Especialidades Farmaceuticas, Lda. Rua Quinta Pinheiro, 5, Outurela 2794-003 Carnaxide Portugal	Diane 35	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Portugal	Mylan, Lda. Rua Alfredo da Silva, 3 C-4º 1300-040 Lisboa Portugal	Acetato Ciproterona/Etinilestradiol 2 mg/0,035 mg Comprimidos	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Portugal	Generis Farmaceutica, S.A. Rua Joao de Deus, 19 2700-487 Amadora Portugal	Ciproterona + Etinilestradiol Generis	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Portugal	Generis Farmaceutica, S.A. Rua Joao de Deus, 19 2700-487 Amadora Portugal	Ciproterona + Etinilestradiol Inventis	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Rumunjska	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	DIANE- 35	2,00 mg 0,035 mg	Obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Rumunjska	Ladeepharma Pharmaceutical Limited Lajos u. 48-66 E ép. 5. em. H-1036 Budapest Hungary	MELLEVA 2 mg/0,035 mg	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Slovačka Republika	Heaton a.s. Na Pankráci 14 14000 Praha 4 Czech Republic	Vreya	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Slovačka Republika	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Minerva	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Slovačka Republika	Zentiva, k.s. U kabelovny 130 102 37 Praha 10 Dolní Měcholupy Czech Republic	CHLOE	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Slovačka Republika	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Diane-35	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Slovenija	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Diane 0,035 mg/2 mg obložene tablete	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Španjolska	BAYER HISPANIA, S.L. Avda. Baix Llobregat 3 y 5 08970 Sant Joan Despi Barcelona Spain	DIANE 35	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Španjolska	BAYER HISPANIA, S.L. Avda. Baix Llobregat 3 y 5 08970 Sant Joan Despi Barcelona Spain	DIANE 35 DIARIO	2,00 mg 0,035 mg	Obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Španjolska	Laboratorios EFFIK, S.A. San Rafael, 3 28108 Alcobendas Madrid Spain	ETINILESTRADIOL/CIPROTERONA GINESERVICE 0,035 mg/2 mg comprimidos EFG	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Španjolska	Sandoz Farmaceutica, S.A. Avda. Osa Mayor, 4 28023 Aravaca Madrid Spain	ACETATO DE CIPROTERONA/ETINILESTRADIOL SANDOZ 2 mg/0,035 mg comprimidos recubiertos EFG	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Španjolska	Laboratorios EFFIK, S.A. San Rafael, 3 28108 Alcobendas Madrid Spain	GYNEPLEN 0,035 mg/2 mg comprimidos recubiertos	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Španjolska	Farmalider S.A. Calle Aragoneses, 15 28108 Alcobendas Madrid Spain	DIALIDER 2/0,035 mg comprimidos recubiertos con pelicula	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Španjolska	Teva Pharma, SLU Anabel Segura 11 Edificio Albatros B 1 <sup>a</sup> planta 28108 Alcobendas Madrid Spain	CYPRINETTE DIARIO 0,035 mg/2 mg comprimidos recubiertos EFG	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Švedska	Bayer Pharma AG Muellerstrasse 178 D-13353 Berlin Germany	Diane®	2,00 mg 0,035 mg	Tableta	Kroz usta
Švedska	Orifarm Generics A/S Postbox 69 Energivej 15 DK-5260 Odense S. Denmark	Zyrona	2,00 mg 0,035 mg	Obložena tableta	Kroz usta
Nizozemska	Actavis B.V. Baarnsche Dijk 1 3741 LN Baarn The Netherlands	Cyproteronacetaat/ethinylestradiol Actavis 2/0,035 mg, filmomhulde tabletten 2 mg/0,035 mg	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Nizozemska	Apotex Europe B.V. Darwinweg 20 2333 CR Leiden The Netherlands	Cyproteronacetaat/ethinylestradiol Apotex 2/0,035 mg, omhulde tabletten	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Nizozemska	Centrafarm B.V. Nieuwe Donk 3 4879 AC Etten-Leur The Netherlands	Cyproteronacetaat/Ethinylestradiol CF 2/0,035 mg, omhulde tablet	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Nizozemska	Mylan B.V. Dieselweg 25 3752 LB Bunschoten The Netherlands	Cyproteronacetaat/Ethinylestradiol Mylan 2 mg/0,035 mg, omhulde tabletten	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Nizozemska	Mylan B.V. Dieselweg 25 3752 LB Bunschoten The Netherlands	Cyproteronacetaat/Ethinylestradiol Mylan 2 mg/0,035 mg, omhulde tabletten	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Nizozemska	ratiopharm Nederland B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Cyproteronacetaat/ethinylestradiol ratiopharm 2 mg/0,035 mg, omhulde tabletten	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Nizozemska	Sandoz B.V. Veluwezoom 22 1327 AH Almere The Netherlands	Cyproteronacetaat/Ethinylestradiol Sandoz 2/0,035, omhulde tabletten	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Nizozemska	Mylan B.V. Dieselweg 25 3752 LB Bunschoten The Netherlands	Cyproteronacetaat/Ethinylestradiol 2 mg/0,035 mg, omhulde tabletten	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Nizozemska	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Cyproteronacetaat/Ethinylestradiol 2/0,035 PCH, omhulde tabletten 2 mg/0,035 mg	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Nizozemska	Stragen Nordic A/S Helsingørgade 8C DK-3400 Hillerød Denmark	Ethinylestradiol 0,035 mg/Cyproteronacetaat 2 mg, omhulde tabletten	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Nizozemska	Bayer B.V. Energieweg 1 3641 RT Mijdrecht The Netherlands	Diane-35, omhulde tabletten	2,00 mg 0,035 mg	Filmom obložena tableta	Kroz usta
Ujedinjeno Kraljevstvo	Bayer plc Bayer House Strawberry Hill Newbury, Berkshire RG14 1JA, United Kingdom	Dianette Tablets	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Ujedinjeno Kraljevstvo	Teva UK Limited Brampton Road Hampden Park Eastbourne East Sussex BN22 9AG United Kingdom	Co-Cyprindiol Tablets 2000/35	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Ujedinjeno Kraljevstvo	Stragen UK Limited Castle Court 41 London Road Reigate, Surrey RH2 PRJ United Kingdom	Clairette Tablets 2000/35	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Ujedinjeno Kraljevstvo	Chatfield Pharmaceuticals Limited Kramer Mews London SW5 9JL United Kingdom	Camilette Co-Cyprindiol 2000/35 Tablets	0,035 mg 2,00 mg	Tableta	Kroz usta
Ujedinjeno Kraljevstvo	Sandoz Limited Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Acnocrin 2000/35 Tablets	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Ujedinjeno Kraljevstvo	Sandoz Limited Frimley Business Park Frimley, Camberley Surrey GU16 7SR United Kingdom	Cyproterone Acetate 2.0 mg Ethinylestradiol 0.035 mg Tablets	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Ujedinjeno Kraljevstvo	Generics (UK) Limited Station Close Potters Bar Hertfordshire EN6 1TL United Kingdom	Co-Cyprindiol Tablets 2 mg/0.035 mg	0,035 mg 2,00 mg	Obložena tableta	Kroz usta

Zemlja članica (u EEA)	Nositelj odobrenja	Naziv lijeka	Jačina	Farmaceutski oblik	Put primjene
Ujedinjeno Kraljevstvo	Generics (UK) Limited Station Close Potters Bar Hertfordshire EN6 1TL United Kingdom	Generics UK Cyproterone Acetate and Ethinylestradiol Tablets	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Ujedinjeno Kraljevstvo	Strandhaven Limited 600 High Road Seven Kings, Ilford Essex IG3 8BS United Kingdom	Strandhaven Co-Cyprindiol 2000/35 Tablets	0,035 mg 2,00 mg	Obložena tableta	Kroz usta
Ujedinjeno Kraljevstvo	Fannin (UK) Limited 42-46 Booth Drive Park Farm South Wellingborough Kent NN8 6GT United Kingdom	Fannin UK Co-Cyprindiol 2000/35 Tablets	0,035 mg 2,00 mg	Filmom obložena tableta	Kroz usta
Ujedinjeno Kraljevstvo	Farmalider SA Calle Aragoneses 15 Alcobendas Madrid E-28108 Spain	Dialider Tablets	0,035 mg 2,00 mg	Filmom obložena tableta	Kroz usta
Ujedinjeno Kraljevstvo	Cipla (EU) Limited Hillbrow House Hillbrow Road Esher Surrey KT10 9NW United Kingdom	Co-Cyprindiol 2000/35 Tablets	0,035 mg 2,00 mg	Filmom obložena tableta	Kroz usta



**POPIS NAZIVA, FARMACEUTSKIH OBLIKA, JAČINA LIJEKOVA, PUTEVA PRIMJENE, NOSITELJA  
ODOBRENJA ZA STAVLJANJE U PROMET U DRŽAVAMA ČLANICAMA**

**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 <sub>50</sub>	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 <sub>50</sub>	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 <sub>50</sub>	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 <sub>50</sub>	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Spain	Aventis Pasteur MSD S.A. P <sup>o</sup> Castellana, 141 28046 Madrid Spain	AMUNOVAX VIAL	one dose (0,5 ml) contains: Measles virus (live, attenuated) - not less than $10^{3,0}$ TCID <sub>50</sub>	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 <sub>50</sub>	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 <sub>50</sub>	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
Spain	Aventis Pasteur MSD S.A. P <sup>o</sup> 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 <sub>50</sub>	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 <sub>50</sub>	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 <sub>50</sub>	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	Röteln-Impfstoff HDC Merieux	one dose (0,5 ml) contains: Rubella virus Wistar RA 27/3 strain (live, attenuated) - $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub>	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 <sub>50</sub>	Powder and solvent for solution for injection	Subcutaneous use
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 <sub>50</sub>	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 <sub>50</sub>	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 <sup>3,3</sup> 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) ≥ 1 350 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 <sup>3,3</sup> 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) ≥ 1 350 PFU (*)	Powder and solvent for solution for injection	Subcutaneous use
Cyprus	Merck Sharp & Dohme B.V. Waardegeweg 39, 2031 BN Haarlem The Netherlands	Varivax powder and solvent for suspension for injection 1 350 PFU	one dose (0,5 ml) contains: Varicella virus Oka/Merck strain (live, attenuated) 1 350 PFU (*)	Powder and solvent for suspension for injection	Subcutaneous use
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 <sup>3,3</sup> 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 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) $\geq 1\ 350$ 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) $\geq 1\ 350$ PFU (*)	Powder and solvent for suspension for injection	Subcutaneous use
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 $1\ 350$ 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

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	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 <sup>3,7</sup> 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) ≥ 1 350 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) ≥ 1 350 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 <sup>3,3</sup> 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) ≥ 1 350 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 <sup>3,3</sup> 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 1 350 PFU (*)	Powder and 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	Varilrix	one dose (0,5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than 10 <sup>3,3</sup> 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 1 350 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 <sup>3,3</sup> PFU (*)	Powder and solvent for solution for injection	Subcutaneous use
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 1 350 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 <sup>3,3</sup> 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 1 350 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
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) $\geq 1\,350$ 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
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) - $1\,350$ 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) $\geq 1\,350$ PFU (*)	Powder for suspension for injection	Subcutaneous use



Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
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 <sup>3,3</sup> 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 1 350 PFU (*) of the live attenuated varicella virus (OKA.Merck strain)	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Norway	GlaxoSmithKline AS Forskingsveien 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 <sup>3,3</sup> PFU (*)	Powder and solvent for solution for injection	Subcutaneous use
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 ≥ 1 350 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 <sup>3,3</sup> 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 <sup>3,3</sup> 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) – 1 350 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
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) $\geq 1\ 350$ PFU (*)	Powder and solvent for suspension for injection	Intramuscular use, subcutaneous use
Slovenia	Merck Sharp & Dohme inovativna zdravila d.o.o., Smartinska cesta 140 1000 Ljubljana Slovenia	Varivax prasek in vehikel za suspenzijo za injiciranje	one dose (0,5 ml) contains: Varicella virus (strain Oka/Merck) (live, attenuated) - not less than 1 350,00 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) - $\geq 1\ 350$ 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

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
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 - 1 350 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) > 1 350 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	VARILRIX	one dose (0,5 ml) contains: Live attenuated varicella-zoster virus (Oka strain) - not less than 103,3 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 - 1 350 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 <sub>50</sub> Rubella virus Wistar RA 27/3 strain (live, attenuated) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	Powder and solvent for solution for injection	Subcutaneous use Intramuscular use, subcutaneous use
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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	one dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
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 Schwarz strain (live, attenuated) not less than $10^{3,0}$ CCID <sub>50</sub> Mumps virus URABE AM-9 strain (live, attenuated) not less than $5 \times 10^{3,0}$ CCID <sub>50</sub> Rubella virus Wistar RA 27/3 strain (live, attenuated) not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Mumps virus Jeryl Lynn strain (live, attenuated) - $5 \times 10^{3,0}$ CCID <sub>50</sub> Rubella virus Wistar RA 27/3 strain (live, attenuated) - $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> of the measles virus Enders-Edmonston strain not less than $5 \times 10^{3,0}$ CCID <sub>50</sub> of the mumps virus (Jeryl Lynn strain) not less than $10^{3,0}$ CCID <sub>50</sub> 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 érsoldószer oldatos injekcióhoz	one dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from strain Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> of the measles virus Enders-Edmonston strain, not less than 12 500 CCID <sub>50</sub> of the mumps virus (Jeryl Lynn strain); and not less than $10^{3,0}$ CCID <sub>50</sub> of the Wistar RA 27/3 rubella virus strains	Powder and solvent for solution for injection	Subcutaneous use
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 - Miraflores 1495-131 Algés Portugal	Priorix	one dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 - Miraflores 1495-131 Algés Portugal	Priorix	one dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	Powder and solvent for solution for injection in pre-filled syringe	Intramuscular use, subcutaneous use

Member State (EU/EEA)	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{3,7}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub>	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use

**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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 INJ. STRÍKAČKA	one dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 LAHVÍČKA/AMPULE	one dose (0,5 ml) contains: Live attenuated measles virus (Schwarz strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> . 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> . 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 Lõdõtsa 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated varicella virus (Oka strain) - not less than $10^{3,3}$ PFU (*)	Powder and solvent for solution for injection	Subcutaneous use
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated varicella virus (Oka strain) - not less than $10^{3,3}$ PFU (*)	Powder and solvent for solution for injection	Intramuscular use, subcutaneous use
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated varicella virus (Oka strain) - not less than $10^{3,3}$ PFU (*)	Powder and solvent for solution for injection	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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sup>3,0</sup> CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than 10 <sup>4,4</sup> CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than 10 <sup>3,0</sup> CCID <sub>50</sub> Live attenuated varicella virus (Oka strain) - not less than 10 <sup>3,3</sup> 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 <sup>3,0</sup> CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than 10 <sup>4,4</sup> CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than 10 <sup>3,0</sup> CCID <sub>50</sub> Live attenuated varicella virus (Oka strain) - not less than 10 <sup>3,3</sup> 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 <sup>3,0</sup> CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than 10 <sup>4,4</sup> CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain ) - not less than 10 <sup>3,0</sup> CCID <sub>50</sub> Live attenuated varicella virus (Oka strain) - not less than 10 <sup>3,3</sup> 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 <sup>3,0</sup> CCID <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than 10 <sup>4,4</sup> CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than 10 <sup>3,0</sup> CCID <sub>50</sub> Live attenuated varicella virus (Oka strain) - not less than 10 <sup>3,3</sup> 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 Bruņinieku 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385 strain derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated varicella virus (OKA strain) - not less than $10^{3,3}$ PFU (*)	Powder and solvent for solution for injection	Subcutaneous use
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain ) - not less than $10^{3,0}$ CCID <sub>50</sub> 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
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated varicella virus (Oka strain) - not less than $10^{3,3}$ PFU (*)	Powder and solvent for solution for injection	Subcutaneous use
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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> 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 <sub>50</sub> Live attenuated mumps virus (RIT 4385, derived from Jeryl Lynn strain) - not less than $10^{4,4}$ CCID <sub>50</sub> Live attenuated rubella virus (Wistar RA 27/3 strain) - not less than $10^{3,0}$ CCID <sub>50</sub> Live attenuated varicella virus (Oka strain) - not less than $10^{3,3}$ PFU (*)	Powder and solution for injection	Subcutaneous use

(\*) PFU: plaque forming units.





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