

Active substance (INN)	Medicinal product	Paediatric -only or adult / paediatric use (mixed)?	Marketing authorisation holder	Member State(s)	Year of marketing authorisation
Methylphenidate hydrochloride	Concerta, ritalin	Paediatric	Janssen-Cilag International N.V., Ritalin	Poland, Italy	2007, 2008
Montelukast	SINGULAIR, Montelukast MSD, Montelukast Sandoz 4 mg granulátum, Montelukast Orion 4 mg, rágótabletta, Montelukast Orion 5 mg rágótabletta, Montelukast Orion 10 mg filmtabletta, Montelukast Teva 4 mg granulátum, Monalux rágótabl., Mondeo 10 mg ftbl., Montelukast Accord 4mg-5 mg rágótabletta	Mixed	MSD Polska Sp. z o.o., SANDOZ Hungária Kereskedelmi Kft, Orion Corporation, Teva Magyarország Zrt., Krka, d.d, Actavis Group PTC ehf, Accord Healthcare Limited	Poland, Hungary	2009, 2010, 2011
Moxifloxacin	Vigamox, Vigamox 5 mg/ml eye drops, solution	Mixed	Alcon Polska Sp. z o.o., S.A. Alcon-Couvreur N.V., Rijsksweg 14, Puurs, Belgium	Poland, Slovenia	2009
Mycophenolate mofetil	Mycophenolate mofetil Stada 250 mg kemény kapszula, Mycophenolate mofetil Stada 500 mg filmtabletta, Mycophenolate	Mixed	Stada Arzneimittel AG, Pharm V Solutions Ltd., Actavis Group PTC ehf., Ratiopharm GmbH	Hungary	2011

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	mofetil Pharm V Solutions 500 mg filmtabl, Mycophenolate mofetil Actavis 250 mg kemény kapsz, Mycophenolat Mofetil-ratiopharm 250 mg k. Kapsz, Mycophenolat Mofetil-Ratiopharm 500 mg ftbl.				
Neisseria meningitidis group A Neisseria meningitidis group C Neisseria meningitidis group Y Neisseria meningitidis group W135	Mencevax ACWY powder and solvent for solution for injection in prefilled syringe, Meningitec Meningococca	Mixed	GSK d.o.o., Knezov štradon 90, Ljubljana, Slovenia	Slovenia	2008
Neisseria meningitidis group A Neisseria meningitidis group C Neisseria meningitidis group Y Neisseria meningitidis group W135	Meningitec Meningococca	Not reported	John Wyeth and Brother Limited	Italy	2008
Nitrous oxide	Dinitrogén Oxid Siad cseppfolyósított gáz, Livopan túlnyomásos orvosi gáz, Dinitrogén-Oxid Rad-Med Pharma cseppfoly orvosi	Mixed	SIAD Hungary Gázokat Forgalmazó és Termelő Kft., AGA AB, RAD-MED-PHARMA Gyógyászati, Kereskedelmi és Szolgáltató Kft., AIR	Hungary, Italy	2011

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	gáz, Kalinoxal 50%/50% túlnyomásos orvosi gáz, INALOSSIN		LIQUIDE SANTE INTERNATIONAL, Società Italiana Acetilene e Derivati		
Nutrition	Nutriflex Lipid peri emulziós infúzió, Smoflipid	Mixed, Not available	B. Braun Melsungen AG, FRESENIUS KABI ITALIA S.R.L.	Hungary, Italy	2007, 2011
Octocog alfa	Recombinate 250 iu, recombinate 500 iu, recombinate 1000 iu	Mixed	Baxter Polska Sp. z o.o.	Poland	2011
Omeprazole	Omeprazole pfizer	Mixed	Pfizer Kft.	Hungary	2011
Oxycodone	Codoxy retard tableta	Mixed	G.L. Pharma GmbH	Hungary	2011
Oxygen	Oxigén Vifamed mélyhűtött orvosi gáz, Oxigén Vifamed túlnyomásos orvosi gáz, ARIA AIR LIQUIDE SANITA', ARIA CRIOSALENTO, ARIA MEDICAIR, ARIA OSSIGAS, ARIA RIVOIRA, ARIA SIAD, ARIA SICO, ARIA LINDE MEDICALE, OSSIGENO C.I.O., OSSIGENO	Mixed	Vifamed Bt., AIR LIQUIDE SANTE, CRIOSALENTO s.r.l., MEDICAIR ITALIA s.r.l., OSSIGAS s.r.l., RIVOIRA S.p.A., S.I.A.D. S.p.A, SICO S.p.A., LINDE MEDICALE s.r.l., CONSORZIO ITALIANO OSSIGENO, CRIOSALENTO S.R.L., EUROXAN srl,	Hungary, Italy	2009, 2010, 2011

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	CRIOSALENTO, OSSIGENO EUROXAN, OSSIGENO IBO, OSSIGENO MEDICAIR, Ossigeno Ossigas, OSSIGENO SON-OX		INDUSTRIA BRESCIANA OSSIGENO S.R.L., MEDICAIR ITALIA S.R.L., OSSIGAS S.r.l., OSSIGENO SOCIETA' OSSIGENO NAPOLI		
Oxymetazoline-hydrochloride	Sinex Wick Eukaliptusz 0,5 mg/ml oldatos orrspray, Ossimetazolina Carlo Erba	Mixed	Wick Pharma Zweigniederlassung der Procter & Gamble GmbH, Carlo Erba OTC	Hungary, Italy	2008, 2011
Pantoprazole	Pantoprazol Krka gyomornedv-ellenálló tabletta, Adozol 20 mg gyomornedv-ellenálló tabletta, Adozol 20 mg gyomornedv-ellenálló tabletta, Pantoprazol Goodwill 40 mg por oldatos injekcióhoz, Acidostop ratiopharm 20 mg gyomornedv-ellenálló tabl	Mixed	Krka, d.d, Plus-Pharma Arzneimittel GmbH, Goodwill Pharma Kft., Ratiopharm GmbH	Hungary	2011
Paracetamol	Paracetamol Actavis 24 mg/ml	Mixed	Actavis Group PTC ehf, Sigillata Ltd.,	Hungary, Italy	2008, 2011

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	belsőleges oldat, Doloramol 1000 mg, 250 mg, 500 mg filmtabletta, Paracetamol Actavis 10 mg/ml old. Inf., Paracetamol Panpharma 10 mg/ml old. Inf., Panadol Rapid 500 mg filmtabletta, Paracetamol Kabi 10 mg/ml oldatos infúzió, symptomed Wick Citrom ízű por belsőleges oldathoz, symptomed Wick Feketeribizli ízű por belsőleges oldathoz, GALAFIN		Panmedica, GSK Consumer Healthcare, Fresenius Kabi Hungary Kft., Wick Pharma Zweigniederlassung der Procter & Gamble GmbH, Marvecspharma Services S.r.l.		
Paracetamol, ascorbic acid, fenilefrin	Coldrex Maxgrip mentol és erdei gyümölcs ízű por, Flumin Béres ftbl., LISOFLU	Mixed	GSK, Béres Házipatika Kft., Sanofi Aventis Spa	Hungary, Italy	2008, 2011
Parenteral nutrition	Periolimel N4E, Olimel N5E, Olimel N7, Olimel N7E, Olimel N9, Olimel N9E emulsion for infusion	Mixed	Baxter d.o.o., Železna cesta 18, Ljubljana, Slovenia	Slovenia	2011
Pelargonium sidoides	Kaloba, keyven,		Dr Willmar	Italy	2007,

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extract	umkan		Schwabe Gmbh, Kedrion SpA, Dr Willmar Schwabe Gmbh & Co Kg		2010, 2011
Phenelzine	Margyl		Dimensione Ricerca Srl	Italy	2007
Piperacillin	Piperan por old. Inj.-hoz, Zytobact por old inj vagy inf	Mixed	Ranbaxy UK Limited, Teva Magyarország Zrt.	Hungary	2011
Potassium chloride, Magnesium chloride hexahydrate, Calcium chloride dihydrate, Sodium acetate trihydrate L-Malic acid	Sterofundin		B. BRAUN MELSUNGEN AG	Italy	2007
Propofol	Propofol Pfizer emulizós injekció vagy infúzió, Curtega emulziós injekció vagy infúzió	Mixed	Pfizer	Hungary	2011
Racecadotril	Hidrasec 10 mg, Hidrasec 30 mg, granules for oral suspension, TIORFAN CHILDREN 30 and 10 mg	Paediatric	Bioprojet Europe Ltd., BIOPROJET FERRER	Poland, Italy	2011, 2007
Remifentanil	Remifentanil Hospira por oldatos injekcióhoz vagy infúzióhoz való koncentrátumhoz, Remifentanil Teva por	Mixed	Hospira UK Limited, Teva Gyógyszergyár Zrt.	Hungary	2011

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	oldatos injekcióhoz vagy infúzióhoz való koncentrátumhoz				
Rifaximin	Flonorm, ximinorm		Alfa Biotech Srl, Alfa Wassermann SpA	Italy	2011
Rocuronium-bromide	Rocuronium-Teva oldatos injekció vagy infúzió	Mixed	Teva Magyarország Zrt.	Hungary	2011
Ropivacaine	Ropivacain B. Braun old. Inj.	Mixed	B. Braun Melsungen AG	Hungary	2011
Rosuvastatin calcium	Crestor	Mixed	Astra Zeneca AB	Poland	2009
Rupatadine	Rupafin 10 mg tablets	Lambda Therapeutics Limited	J. Uriach & Cía., S.A. Av. Camí Reial, 51-57 08184 Palau-solità i Plegamans, Spain	Slovenia	2008
Sodium alginate / Potassium hydrogen carbonate	Gaviscon advance	Mixed	Reckitt Benckiser (Poland) S.A.	Poland	2010
Sodium picosulphate	Pico-salax	Mixed	Ferring Magyarország Gyógyszerkereskedelmi	Hungary	2011
Somatropin	Saizen 5,83 mg/ml oldatos injekció, Saizen 8 mg/ml oldatos injekció	Mixed	Merck Kft	Hungary	2011
Spironolactone	Spitonep 25 mg tabletta, spitonep 50 mg tabletta	Mixed	Extractum Pharma Zrt.	Hungary	2011

Active substance (INN)	Medicinal product	Paediatric -only or adult / paediatric use (mixed)?	Marketing authorisation holder	Member State(s)	Year of marketing authorisation
Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A))	Panenza suspension inyectable en vial multidosis, panenza suspension inyectable en jeringa precargada		Sanofi Pasteur S.A.	Spain	2009
Tacrolimus	Tacrolimus Astron kemény kapszula, Tacrolimus Lambda kemény kapszula, Tacrolimus Mylan kemény kapszula, Tacrolimus Sandoz kemény kapszula, Tacrolimus Intas,	Mixed	Astron Research Limited, Lambda Therapeutics Limited, Mylan S.A.S., Sandoz Hungária Kft, Intas Pharmaceuticals Limited	Hungary	2011
Tetrabenazine	Xenazina		Chiesi Farmaceutici SpA	Italy	2007
Trace minerals	Béres Csepp Extra belsőleges oldatos cseppek	Mixed	Béres Gyógyszergyár Zrt.	Hungary	2011
Tramadol	Noax 50 mg szájban diszp. Tbl.	Mixed	CSC Pharmaceuticals Handels GmbH	Hungary	2011
Tramadol / paracetamol	Zaldiar 37,5 mg/325 mg effervescent tablets, KOLIBRI, Tramadololo e Paracetamololo	Mixed	Grünenthal GmbH, Zieglerstrasse 6, Aachen, Germany, Alfa Wassermann SpA	Slovenia, Italy	2008
Triptorelin	Diphereline SR	Mixed	Ipsen Pharma	Hungary	2011

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	22,5 mg por és oldószer szuszp. Injkc.				
Valsartan	Diovan 3mg/ml, Valmed filmtabletta, Valsartan propharma, Valsartan Arrow filmtabletta	Paediatric, Mixed	Novartis s.r.o., Helm AG, Propharma, Arrow	Czech Republic, Hungary	2010
Vancomycin	Vancomycin Actavis por old. Inf.-hoz, Vancomycin Kabi por oldatos injekcióhoz, Vancomycin Pharmaswiss por old. Inf.-hoz	Mixed	Actavis Group PTC ehf, Freseneus Kabi Hungary Kft., PharmaSwiss Česká republika s.r.o.	Hungary	2011
Ziprasidone hydrochloride	Zeldox	Not reported	Pfizer AB	Italy	2008
Not reported	Rifaximina	Not reported	ALFA WASSERMANN S.P.A	Italy	2011
Not reported	Rivonox	Not reported	Rivoira SPA	Italy	2011
Not reported	Torvast	Not reported	Parke-Davis	Italy	2007

7.2. Extension of therapeutic indication to include the paediatric population

Summary:

- The authorised paediatric indication would be reflected in the sections 4.1 (Table 17) and / or 4.2 (Table 18) of the SmPC.
- In total 11 Member States reported extensions of the authorised indications to the use in the paediatric population for medicinal products corresponding to 33 active substances.

Table 18: Paediatric indication added in SmPC section 4.1 (by year of first completed procedure).

Year	Procedure? (N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member States
2007	MRP	Glaxosmithkline	Malarone	Atovaquone / Proguanile hydrochloride*	Not reported	Italy
2007	MRP	Eli Lilly Italia Spa	Prozac and associated names	Fluoxetine hydrochloride*	Not reported	Italy
2007	MRP, N	Various	Various	Oxybutynin hydrochloride*	Not reported	Italy, United Kingdom
2007	MRP	Recordati Industria Chimica E Farmaceutica S.P.A.	Peptazol	Pantoprazole*	Not reported	Italy
2007 - 2008		Eli Lilly Oy	Humatrope and associated names	Somatropin*	Not reported	Italy, Finland
2008		Gebro Pharma GmbH	Nocutil	Desmopressin *	Nocturnal enuresis (over 6 5 years of age) [...]vasopressin - sensitive cranial diabetes insipidus.	Austria
2008		Teva Pharmaceuticals Ltd	Copaxone	Glatiramer acetate*	well-defined first clinical episode and are determined to be at high risk of developing clinically definite multiple sclerosis (CDMS) [...] limited published data suggest that the safety profile in adolescents from 12 to 18 years of age receiving Copaxone 20 mg subcutaneously every day is similar to that seen in adults	Finland, United Kingdom
2008		Sanofi	Imovax polio	Inactivated	aktiv immunisering	Sweden

Year	Procedure? (N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member States
		Pasteur Msd, Belgium	(n)	poliovirus 1-3	mot polio av spädbarn, barn och vuxna, både för primär immunisering och påföljande booster-doser.	
2008	N	Astrazeneca AB, Sweden	Narop, 2 mg/ml Solution for injection/infusion (N)	Ropivacaine hydrochloride*	"Akut smärtlindring (per- och postoperativ) hos barn	Sweden
2009	MRP	Mylan AB	Ciprofloxacin Merck NM (now Mylan), 100 mg, 250 mg, 500 mg, 750 mg, Film-coated tablets (MRP)	Ciprofloxacin*	Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas aeruginosa, Complicated urinary tract infections and pyelonephritis, Inhalation anthrax (post-exposure prophylaxis and curative treatment)	Sweden, Italy
2009	MRP	Medias International	Smoflipid	dl-alfa-tocopherol, medium chain triglycerides, purified fish oil, purified olive oil, soybean oil*	Not reported	Slovenia
2009		Bayer Schering Pharma Oy	Gadovist	Gadobutrol	Not reported	Finland
2009		Baxter AG	Subcuvia	Human normal immunoglobulin*	Not reported	Finland
2009	MRP	Glaxosmithkline S.P.A.	Priorix	Measles Mumps Rubella vaccine*	Vaccination against measles, mumps, rubella	Italy
2009	MRP	Various	Various	Metformin hydrochloride*	Diabetes mellitus	Italy
2009	DC	Ibigen S.R.L.	Piperacillina e	Piperacillin	Not reported	Italy

Year	Procedure? (N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member States
			tazobactam ibigen (dcp)	sodium / tazobactam sodium*		
2009	MRP	Glaxosmithkline Spa	Relenza	Zanamivir*	Not reported	Italy
2009	MRP	Pfizer AB	Zeldox	Ziprasidone*	Treatment of manic or mixed episodes of moderate severity in bipolar disorder in adults and children and adolescents aged 10-17 years	Italy, Sweden
2009 - 2010	MRP	Merck Sharp & Dohme	Cozaar and associated names	Losartan	Hypertension	Romania, Italy, Finland
2009 - 2011	MRP	Alk-Abelló A/S, Denmark	GRAZAX and associated names	Grass pollen allergen extract	Treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.	Sweden, Italy
2010	N	Pfizer Hellas Ae	Lipitor and associated names	Atorvastatin	Hypercholesterolemia children & adolescents over 10 years of age	Cyprus, Estonia, Romania, Finland
2010	MRP	Merck Sharp & Dohme Romania S.R.L.	Singulair	Montelukast	Asthma	Romania
2010		Astra Zeneca Oy	Crestor 5 mg, 10 mg, 20 mg, 40 mg tabletti, kalvo-päällysteinen	Rosuvastatin calcium	Not reported	Finland
2010		Fresenius	Smoflipid 200	Soiae oleum	Not reported	Finland

Year	Procedure? (N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member States
		Kabi Ab	mg/ml infuusioneste, emulsio	raffinatum triglyceride saturate media piscis oleum omega-3-acidis abundans*		
2010	MRP	Apotex Europe Bv	Sumatriptan tablets 50, 100mg	Sumatriptan succinate*	Not reported	United Kingdom
2010	MRP	Novartis Pharmaceuticals UK Ltd	Diovan fctabs 40mg	Valsartan	Hypertension in children & adolescents 6 to 18 years of age	Cyprus, Estonia, Romania, Finland, Sweden
2010 - 2011	MRP	Pfizer Enterprises Sar	Xalatan and associated names	Latanoprost	Glaucoma	Estonia, Finland, Romania, Spain, Sweden
2011	N	Tillomed Laboratories Limited	Ciclofarm and associated names	Acyclovir*	Not reported	United Kingdom
2011	MRP	Astrazeneca UK Limited	Nexium	Esomeprazole	Children 1-11years old, Children over 4 years of age, In combination with antibiotics in treatment of duodenal ulcer caused by Helicobacter pylori	Slovenia, Sweden, Spain
2011	MRP	Merck Sharp & Dohme Bv, Netherlands	Ezetrol tabs	Ezetimibe	Primary non-familial hypercholesterolaemia/ heterozygous familial hypercholesterolaemia, adolescents 10 to 17 years of age	Cyprus
2011	N	Antigen International Limited	Antigen metoclopramide injection bp	Metoclopramide hydrochloride*	Not reported	United Kingdom

Year	Procedure? (N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member States
			10mg/2ml			
2011		Glaxosmithkline AB, Sweden	Zofran	Ondansetron*	Profylax och behandling av illamående och kräkningar inducerade av kemoterapi [...] postoperativt illamående och kräkningar hos barn ? 1 månad.	Sweden
2011	DC	Merck Sharp & Dohme	Maxalt	Rizatriptan	Migraine	Czech Republic

* No agreed PIP for active substance available.

Table 19: Paediatric population added in SmPC section 4.2 (by year of first completed procedure).

Year	Procedure (N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member State
2007	MRP	Glaxosmithkline Spa	Malarone	Atovaquone / Proguanil hydrochloride	Not reported	Italy
2007	MRP	Eli Lilly Italia Spa	Prozac	Fluoxetine hydrochloride	Not reported	Italy
2007	MRP	Janssen Cilag Spa	Lyrinel	Oxybutynin hydrochloride	Not reported	Italy
2007	MRP	Nycomed S.P.A., Recordati Industria Chimica E Farmaceutica S.P.A.	Pantecta (mrp), peptazol (mrp)	Pantoprazole sodium sesquihydrate	Not reported	Italy
2007		Eli Lilly Oy	Humatrope 6 mg, 12 mg, 24 mg injektiokuiva-aine ja liuotin, liuosta varten	Somatropin	Not reported	Finland
2008		Gebro Pharma GmbH	Nocutil 0,1 mg / 0,2 mg - Tabletten	Desmopressin	Nocturnal enuresis (over 6 5 years of age) [...] treatment of vasopressin -	Austria

Year	Procedure (N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member State
					sensitive cranial diabetes insipidus	
2008	MRP	Eli Lilly Italia S.P.A.	Prozac (mrp)	Fluoxetine hydrochloride	Not reported	Italy
2008	MRP in UK	Teva Pharmaceuticals Limited	Copaxone 20 mg/ml injektioneste, liuos, esitäytetty ruisku, COPAXONE® 20MG/ML SOLUTION FOR INJECTION, PREFILLED SYRINGE	Glatiramer acetate	Not reported	Finland, United Kingdom
2008		Sanofi Pasteur Msd, Belgium	Imovax polio (n)	Inactivated poliovirus 1-3	aktiv immunisering mot polio av spädbarn, barn och vuxna, både för primär immunisering och påföljande boosterdos. Imovax polio är också indicerat: - -för immunförsvagade patienter, deras närstående och individer för vilka oralt poliovaccin är kontraindicerat - -som booster till individer som tidigare erhållit oralt poliovaccin	Sweden
2008	N	Astrazeneca AB, Sweden	Narop, 2 mg/ml Solution for injection/infusion (N)	Ropivacaine hydrochloride	Akut smärtlindring (per- och postoperativ) hos barn	Sweden
2008	MRP in Italy	Pfizer Oy, Eli Lilly Italia Spa	Genotropin 5mg, 12mg, injektiokuiva-aine ja liuotin, liuosta varten,	Somatropin	Not reported	Finland, Italy

Year	Procedure (N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member State
			HUMATROPE			
2009	MRP	MYLAN S.P.A., Merck NM AB, Sweden (Transferred To Mylan AB, Sweden), Bayer Healthcare AG, Germany	CIPROFLOXACINA MYLAN GENERICS, Ciprofloxacin Merck NM (now Mylan), 100 mg, 250 mg, 500 mg, 750 mg, Film-coated tablets, Ciproxin 50 mg/ml, 100 mg/ml, granulät och vätska till oral suspension	Ciprofloxacin	Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas aeruginosa; Complicated urinary tract infections and pyelonephritis; Inhalation anthrax (post-exposure prophylaxis and curative treatment)	Italy, Sweden
2009	MRP	Medias International D.O.O., Leskoškova Cesta 9D, Ljubljana, Slovenia	Smoflipid 200 mg/ml Emulsion for infusion	Di-alfa-tocopherol medium chain triglycerides purified fish oil purified olive oil soybean oil	Not reported	Slovenia
2009	MRP	Ratiopharm GmbH, Mylan S.P.A.	Fluoxetina ratiopharm, fluoxetina mylan generics	Fluoxetine hydrochloride	Not reported	Italy
2009		Bayer Schering Pharma Oy	Gadovist 1,0 mmol/ml injektioneste, liuos kertaannosuisku Gadovist 1,0 mmol/ml injektioneste, liuos	Gadobutrol	Not reported	Finland
2009	MRP	Alk-Abelló A/S	Grazax(, grazura	Grass pollen allergen extract	Not reported	Italy
2009		Baxter AG	Subcuvia 160 g/l	Human normal	Not reported	Finland

Year	Procedure (N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member State
			injektioneste, liuos	immunoglobulin		
2009	MRP in Italy	Merck Sharp & Dohme B.V., Sigma-Tau Industrie Farmaceutiche Riunite Spa, Msd Italia S.R.L.	Cozaar 2.5 mg/ml jauhe ja liuotin oraalisuspensiot a varten, Cozaar 12.5 mg, 50mg, 100mg, tabletti, kalvopäällysteinen, LOSAPREX, NEO-LOTAN, LORTAAN	Losartan	Not reported	Finland, Italy
2009	MRP	Glaxosmithkline S.P.A.	Priorix	Measles mumps rubella	Not reported	Italy
2009	MRP	Hexal S.P.A., Laboratori Guidotti S.P.A.	Metformina hexal, metforalmille	Metformin hydrochloride	Not reported	Italy
2009	DC	Ibigen S.R.L.	Piperacillina e tazobactam ibigen (dcp)	Piperacillin sodium / tazobactam sodium	Not reported	Italy
2009	MRP	Glaxosmithkline Spa	Relenza	Zanavimir	Not reported	Italy
2009	MRP	Pfizer Italia S.R.L., Pfizer Ab, Sweden	ZELDOX, Zeldox 20 mg 40 mg 60 mg 80 mg capsules, hard ZELDOX 10 mg/ml Oral suspension	Ziprasidone	Treatment of manic or mixed episodes of moderate severity in bipolar disorder in adults and children and adolescents aged 10-17 years (prevention of episodes of bipolar disorder has not been established).	Italy, Sweden
2010	N	Pfizer Hellas Ae, Pfizer Europe Ma Eeig, Pfizer Oy, Pfizer Europe Ma	Lipitor fctabs 10mg, Lipitor fctabs 20mg, Lipitor fctabs 40mg, Sortis, Lipitor 10 mg,	Atorvastatin	hypercholesterolaemia children over 10 years of age	Cyprus, Estonia, Finland, Romania

Year	Procedure(N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member State
		Eeig	20mg, 40mg, 80mg, tabletti, kalvopäällysteinen, Sortis 10 mg film coated tablets Sortis 20 mg film coated tablets Sortis 40 mg film coated tablets Sortis 80 mg film coated tablets			
2010		Fresenius Kabi Ab	Smoflipid 200 mg/ml infuusioneste, emulsio	Di-alfa-tocopherol medium chain triglycerides purified fish oil purified olive oil soybean oil	Not reported	Finland
2010	MRP for Estonia, N for Sweden	Pfizer Enterprises Sar, Pfizer Ab, Sweden	Xalatan, Xalatan, 50 microgram/ml	Latanoprost	Sänkning av det intraokulära trycket hos barn med förhöjt intraokulärt tryck och barnglaukom.	Estonia, Sweden
2010	MRP	Merck Sharp & Dohme Romania S.R.L.	COZAAR 12,5 mg film coated tablets	Losartan	Not reported	Romania
2010	MRP	Merck Sharp & Dohme Romania S.R.L.	Singulair 4 mg/sachet granules	Montelukast	Not reported	Romania
2010		Astra Zeneca Oy	Crestor 5 mg, 10 mg, 20 mg, 40 mg tabletti, kalvopäällysteinen	Rosuvastatin calcium	Not reported	Finland
2010	MUTUAL RECOGNITION	Apotex Europe Bv	Sumatriptan tablets 50,	Sumatriptan succinate	Not reported	United Kingdom

Year	Procedure (N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member State
	ON		100mg			m
2010	MRP	Novartis Pharmaceuticals UK Ltd, Novartis Finland OY, NOVARTIS PHARMA GmbH, Novartis Sverige AB	Diovan fctabs 40mg, 80mg, 160mg, 320mg, Diovan, Diovan 40 mg, 80 mg, 160mg, 320 mg, tabletti, kalvo-päällysteinen, Diovan, 40 mg, 80 mg, 160 mg, 320 mg, Film-coated tablet	Valsartan	Hypertension in children from 6 years to less than 18 years of age	Cyprus, Estonia, Finland, Romania, Sweden
2010		Pfizer Oy	Orbeus 10 mg, 20 mg, 40 mg, 80 mg, tabletti, kalvopäällysteinen		Not reported	Finland
2011	N	Tillomed Laboratories Limited	Aciclovir tablets bp 200, 400, 800mg; aciclovir dispersible tablets 200,400mg, cyclofarm limited aciclovir dispersible tablets/virovir dispersible	Acyclovir	Not reported	United Kingdom
2011	MRP	Astrazeneca UK Limited, 15 Stanhope Gate, London, United Kingdom, Astrazeneca Farmacéutica Spain, S.A., Astrazeneca AB, Sweden	Nexium 10 mg gastro-resistant granules, NEXIUM MUPS 20 mg comprimidos gastrorresistentes, AXIAGO 20 mg comprimidos gastrorresistentes, AXIAGO 10 mg granulado gastrorresistente	Esomeprazole	Adolescents from the age of 12 years Gastroesophageal Reflux Disease (GERD) - treatment of erosive reflux esophagitis - long-term management of patients with healed esophagitis to prevent relapse - symptomatic treatment of	Slovenia, Spain, Sweden

Year	Procedure (N / DC / MRP)	Marketing Authorisation Holder	Invented name	Active substance (INN)	Paediatric indication	Member State
			e para suspensión oral, sobres, NEXIUM 10 mg granulado gastroresistente para suspensión oral, sobres, NEXIUM 20 mg Gastro-resistant tablets, NEXIUM 10 mg Gastro-resistant granules for oral suspension, sachet, NEXIUM 40 mg Powder for solution for injection/infusion		gastroesophageal reflux disease (GERD) In combination with antibiotics in treatment of duodenal ulcer caused by Helicobacter pylori / oral suspension primarily indicated for: Children 1-11 years old Children over 4 years of age In combination with antibiotics in treatment of duodenal ulcer caused by Helicobacter pylori	
2011	MRP	Merck Sharp & Dohme Bv, Netherlands	Ezetrol tabs 10mg	Ezetimibe	Primary non-familial hypercholesterolaemia/ heterozygous familial hypercholesterolaemia, adolescents 10 to 17 years of age	Cyprus
2011	MRP	Alk-Abelló A/S, Denmark	GRAZAX 75,000 SQ-T Oral lyophilisate	Grass pollen allergen extract	Treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.	Sweden
2011		Pfizer Oy, Pfizer Europe Ma Eeig, Pfizer, S.A.	Xalatan 50 mikrog/ml silmätipat, liuos I, XALATAN	Latanoprost	Children from 1 year old to 11 years old Gastro-oesophageal	Finland, Romania, Spain