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1. PDCO opinions on compliance

Summary:

- The PDCO adopted opinions confirming the compliance of the completed studies with 29 agreed PIPs (excluding duplicates).
- Number of PDCO compliance opinions per year: 3 (2008), 9 (2009), 9 (2010) and 8(2011).
- There was 1 adopted PDCO opinions that did not confirm compliance. Compliance could later be confirmed after a modification of the agreed PIP.
- The opinions on compliance are mentioned and summarised in the PDCO monthly reports (http://bit.ly/xGFZEw).
- No Member State reported to have issue an opinion on compliance with an agreed PIP.

Table 1: Opinions on compliance adopted by the PDCO until 31 December 2011

No.	Active substance(s)	Trade name if available	Condition(s) for paediatric use	Date of PDCO compliance opinion	Further outcome / section
1	Abatacept	Orencia		29/05/2009	

No.	Active substance(s)	Trade name if available	Condition(s) for paediatric use	Date of PDCO compliance opinion	Further outcome / section
2	Alanine, Arginine, Aspartic acid, Cysteine/Cystine, Glutamic acid, Glycine, Histidine, Isoleucine, Leucine, Lysine monohydrate, Methionine, Ornithine hydrochloride, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophan, Tyrosine, Valine, Sodium chloride, Potassium acetate, Magnesium acetate, tetrahydrate, Calcium chloride, Sodium glycerophosphate, Glucose, Olive oil, refined, Soya-bean oil, refined	Numeta		16/10/2009	
3	Anastrozole	Arimidex and associated names		03/04/2009	
4	Atorvastatin calcium (trihydrate)	Sortis and associated names		13/11/2009	
5	Azelastine hydrochloride / fluticasone propionate			17/06/2011	
6	Caspofungin acetate	Cancidas		04/06/2008	
7	Clopidogrel	Plavix and associated names		10/12/2010	Failed indication
8	Colesevelam hydrochloride	Cholestagel		24/07/2009	
9	Darunavir (as ethanolate)	Prezista		09/12/2011	
10	Esomeprazole sodium / Esomeprazole magnesium trihydrate	Nexium and associated names		16/07/2010	
11	Etanercept	Enbrel		09/12/2011	
12	Human Papillomavirus type 6 L1 protein / Human Papillomavirus type 11 L1 protein / Human Papillomavirus type 16 L1 protein / Human Papillomavirus type 18 L1 protein	Gardasil		16/04/2010	
13	Infliximab	Remicade		09/09/2011	New indication authorised
14	Insulin glargine (EMEA-C-000387-PIP01-08, EMEA-C-000396-PIP01-08)	Optisulin, Lantus		11/11/2011	
15	Latanoprost	Xalatan		19/03/2010	

No.	Active substance(s)	Trade name if available	Condition(s) for paediatric use	Date of PDCO compliance opinion	Further outcome / section
16	Losartan potassium	Cozaar and associated names		06/02/2009	
17	Meningococcal group C oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenC-CRM)/Meningococcal group A oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenA-CRM)/Meningococcal group Y oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenY-CRM)/Meningococcal group W-135 oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenW-CRM)	Menveo		20/05/2011	
18	Midazolam (as hydrochloride)	Buccolam		06/08/2010	
19	Montelukast	Singulair		15/01/2010	Failed indication
20	Nevirapine	Viramune		06/08/2010	
21	Nomegestrol / [17-beta] estradiol	Ioa, Zoely		21/05/2010	
22	Peginterferon alfa-2b (EMEA-C-000071-PIP01-07, EMEA-C-000384-PIP01-08)	Viraferonpeg		17/10/2008	
23	Purified diphtheria toxoid, Purified tetanus toxoid, Five component acellular pertussis [Purified Pertussis Toxoid (PT), Purified Filamentous Haemagglutinin (FHA), Purified Fimbriae Types 2 and 3 (FIM) and Purified Pertactin (PRN)], Inactivated poliomyelitis vaccine (Vero) – Type 1 (Mahoney), Type 2 (MEF-1) and Type 3 (Saukett), Purified polyribosylribitol phosphate capsular polysaccharide of Haemophilus influenzae type b covalently bound to Tetanus protein (PRP-T)	Pediacel		18/09/2009	
24	Ribavirin	Rebetol		17/10/2008	

No.	Active substance(s)	Trade name if available	Condition(s) for paediatric use	Date of PDCO compliance opinion	Further outcome / section
25	Rizatriptan (benzoate)	Maxalt and associated names		09/09/2011	Failed indication
26	Rotavirus type P1A[8]/rotavirus type G3/rotavirus type G1/rotavirus type G4/rotavirus type G2	Rotateq		15/07/2011	
27	Tretinoin/clindamycin phosphate	Ziana		10/12/2010	
28	Valsartan	Diovan		21/08/2009	
29	Zoledronic acid	Zometa		21/08/2009	Failed indication

2. Statements on compliance of studies with agreed PIP included in marketing authorisations

Summary:

- The statement of compliance as mentioned in Article 28 (3) of the Paediatric Regulation allows to identify:
  - that a marketing authorisation (MA) or a variation application complied with all the measures contained in the agreed completed paediatric investigation plan and
  - that the SmPC reflects the results of studies conducted in compliance with that agreed paediatric investigation plan.
- In total, a statement of compliance was included in the initial marketing authorisation of 1 new medicinal product (1 active substance combination) authorised through national / decentral / mutual recognition procedures and in the initial marketing authorisations of 2 medicinal products authorised centrally (2 active substances).
- A statement of compliance was added in a variation of the pre-existing marketing authorisation of medicinal products for 18 active substances.
- For all 3 active substances covered by newly authorised medicines, a paediatric use was authorised at the time initial marketing authorisation.
- Overall 4 medicinal products with a statement of compliance included into their marketing authorisations, the results of the studies conducted as per the completed PIP did not lead to the targeted paediatric indication (see sections 4.7. and 7.7. for the full list of products).

2.1. Centrally authorised medicinal products with compliance statement in MA

Table 2: Inclusion of compliance statement in the European Commission decision granting marketing authorisation

No.	Active substance (INN)	Medicinal product	Marketing authorisation holder	Initial Marketing Authorisation or variation?	Any paediatric use targeted in PIP authorised?	Date of the EC Decision including the compliance statement
1	Caspofungin	Cancidas	Merck Sharp and Dohme	Variation	Yes	26/11/2008
2	Peginterferon alfa-2b	PegIntron, ViraferonPeg	Schering-Plough Europe	Variation	Yes	11/11/2009 12/11/2009
3	Ribavirin	Rebetol	Schering-Plough Europe	Variation	Yes	11/11/2009
4	Abatacept	Orencia	Bristol-Myers Squibb Pharma EEIG	Variation	Yes	20/01/2010
5	Zoledronic acid	Zometa	Novartis Europharm Ltd	Variation	No	25/01/2010
6	Clopidogrel	Plavix and associated names	Sanofi BMS	Variation	No	27/05/2011
7	Colesevelam	Cholestagel	Genzyme	Variation	No	10/08/2011
8	Midazolam	Buccolam	Viropharma SPRL	Initial MA	Yes	05/09/2011
9	Nevirapine	Viramune	Boehringer	Variation	Yes	16/09/2011
10	HPV vaccine	Gardasil	Sanofi Pasteur	Variation	Yes	16/11/2011
11	Nomegestrol / estradiol	Ioa,* Zoely*	N.V. Organon, Merck Serono Europe	Initial MA	Yes	16/11/2011, 27/07/2011

* Marketing authorisations being updated to include the compliance statement. MA = Marketing Authorisation

2.2. Medicinal products authorised through national / decentral / mutual recognition procedures, including those subject to Article 29 of the Paediatric Regulation with compliance statement in MA

Summary:

- For 5 medicinal products out of 10, the compliance statement was added to the MA not as the result of a referral procedure subject to Article 29 of the Paediatric Regulation. Out of these 5 medicinal products, 4 had their compliance statement added in 2011 (see the 10 products in table 3 below).
- Overall, the compliance statement related to Article 36 (1) of the Paediatric Regulation was added for 5 medicinal products (see the 5 products sections 4.7 and 7.7). There were no compliance statements introduced in marketing authorisations in 2009 in the following countries: Latvia, Lithuania, Luxembourg, Malta, Slovakia.

Table 3: Inclusion of compliance statement in the marketing authorisations of a newly authorised medicine

No.	Active substance (INN)	Medicinal product	Any paediatric use targeted by PIP authorised?	Marketing authorisation holder	Year of marketing authorisation including the compliance statement
1	Alanine, arginine, aspartic acid, calcium, cysteine, glucose, glutamic acid, glycine, histidine, isoleucine, leucine, lysine, magnesium, methionine, olive oil, ornithine, phenylalanine, potassium, proline, serine, sodium, soybean oil, taurine, threonine, tryptophan, tyrosine, valine	Numeta and associated names	Yes	Baxter	2011

Table 4: Inclusion of compliance statement in marketing authorisations of an already authorised medicinal product

No.	Active substance (INN)	Medicinal product	Marketing authorisation holder	Any paediatric use targeted in PIP authorised?	Member States reporting inclusion	Year of variation including the compliance statement*
1	Anastrazole*	Arimidex	AstraZeneca AB	No	Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Hungary, Ireland, Italy, Portugal, Slovenia, Sweden, The Netherlands, United Kingdom	2009-2010
2	Atorvastatin*	Sortis and associated names	Pfizer	Yes	Austria, Cyprus, Czech Republic, Estonia, Finland, Germany, Greece, Hungary, Italy, Portugal,	2010

No.	Active substance (INN)	Medicinal product	Marketing authorisation holder	Any paediatric use targeted in PIP authorised?	Member States reporting inclusion	Year of variation including the compliance statement*
					Sweden, United Kingdom	
3	DTP Polio HiB vaccine	Pediacel	Sanofi Pasteur	Yes	France	2011
4	Esomeprazole sodium / esomeprazole magnesium	Nexium and associated names	Astra Zeneca AB	Yes	Ireland, Romania, United Kingdom	2011
5	Latanoprost*	Xalatan and associated names	Pfizer	Yes	Austria, Czech Republic, Denmark, Estonia, Finland, Hungary, Malta, Portugal, Romania, Sweden, United Kingdom	2010-2011
6	Losartan	Cosaar and associated names	Merck Sharp and Dohme	Yes	Austria, Denmark, Estonia, Finland, Germany, Ireland, Italy, Romania, Slovenia, Sweden, United Kingdom	2008-2009
7	Montelukast	Singulair	MSD	No	Austria, Cyprus, Czech Republic, Denmark, Finland, Portugal, Sweden, United Kingdom	2010-2011
8	Rizatriptan	Maxalt and associated names	Merck Sharpe and Dohme	No	Austria, Cyprus, Czech Republic, Denmark, Finland, Lithuania, Malta, Poland, Portugal, Slovenia, Sweden, United Kingdom	2011
9	Valsartan*	Diovan and	Novartis	Yes	Austria, Cyprus,	2009-2010

No.	Active substance (INN)	Medicinal product	Marketing authorisation holder	Any paediatric use targeted in PIP authorised?	Member States reporting inclusion	Year of variation including the compliance statement*
		associated names			Czech Republic, Denmark, Estonia, Finland, Hungary, Italy, Latvia, Malta, Portugal, Sweden, United Kingdom	

* Indicates that the compliance statement was included after a procedure subject to Article 29 of the Paediatric Regulation (see section 5)

3. Supplementary protection certificate extension (6 months) granted by National Patent Offices

Overview of 6-month extensions of supplementary protection certificates granted in relation to Article 36(1) of the Paediatric Regulation, by medicinal product and by year of granting of the extension. There were no extensions of supplementary protection certificate (SPC) in relation to Article 36(1) of the Paediatric Regulation before 2009.

Summary:

- For 11 medicinal products, an extension of the SPC of the medicine was granted in different Member States between 2009 and 2011 (See table %). Of note, one extension of SPC was reported for one medicinal product in 2012.
- In 16 Member States, the NPO granted an extension of the SPC of at least one medicine
- Overall, on the period covered, 105 national SPCs were granted an extension.

Table 5: List of medicinal products and companies that have benefitted from the 6-month extension of the supplementary protection certificate (SPC)

No.	INN of medicine to which patent applies	Marketing authorisation holder	Member State's NPO granting SPC extension (year)	Member State with SPC extension pending (in year)	No application for SPC extension (yet) in Member State (if not confidential)	Member State in which product has no SPC or patent qualifying for an SPC (if not confidential)
1	Abatacept (Orencia)	Bristol-Myers Squibb Pharma	Austria (year not reported possibly 2011) Denmark (21	Bulgaria (2011) Greece (2010) Lithuania	Hungary Italy (SPC granted)	Romania (no SPC) Slovak Republic

No.	INN of medicine to which patent applies	Marketing authorisation holder	Member State's NPO granting SPC extension (year)	Member State with SPC extension pending (in year)	No application for SPC extension (yet) in Member State (if not confidential)	Member State in which product has no SPC or patent qualifying for an SPC (if not confidential)
		EEIG	June 2010) Estonia (17 October 2011) Finland (13 September 2011) France (10 December 2010) Germany (16 August 2010) Ireland (30 June 2010) Luxembourg (23 December 2010) The Netherlands (31 August 2010) Portugal (2 November 2010) Slovenia (16 November 2011) Sweden (21 November 2011) United Kingdom (6 January 2011)	(2011) Luxembourg (2011) Romania (2011) Spain (2010)		
2	Anastrazole (Arimidex and associated names)	AstraZeneca AB	Austria (2010) Belgium (2010) Denmark (2010 Finland (2 March 2010)	Romania (2010, 2011; *SPC granted after appeal*)	Greece Portugal Spain	Bulgaria Greece Hungary Portugal Slovak Republic Slovenia *(no*

No.	INN of medicine to which patent applies	Marketing authorisation holder	Member State's NPO granting SPC extension (year)	Member State with SPC extension pending (in year)	No application for SPC extension (yet) in Member State (if not confidential)	Member State in which product has no SPC or patent qualifying for an SPC (if not confidential)
			France (11 June 2010) Germany (19 July 2010) Ireland (29 June 2010) Italy (16 March 2010) Luxembourg (27 July 2010) The Netherlands (1 April 2010) Sweden (27 April 2010) United Kingdom (10 June 2010)			*SPC)*
3	Atorvastatin (Sortis and associated names)	Pfizer	Austria (year not reported, possibly 2011) Denmark (02 May 2011) Germany (11 August 2011) Ireland (28 June 2011) Italy (17 May 2011) Luxembourg (27 June 2011) Sweden (14 April 2011) The Netherlands (12 April 2011) United	France (2010)	Denmark Finland Greece Ireland Portugal Romania	Bulgaria *(appeal procedure after decision for termination of the procedure for SPC granting)* Germany Greece Hungary Luxembourg Portugal Romania *(no SPC)* Slovak Republic Slovenia *(no SPC)* Spain *(SPC denied)*

No.	INN of medicine to which patent applies	Marketing authorisation holder	Member State's NPO granting SPC extension (year)	Member State with SPC extension pending (in year)	No application for SPC extension (yet) in Member State (if not confidential)	Member State in which product has no SPC or patent qualifying for an SPC (if not confidential)
			Kingdom (23 June 2011)			
4	Caspofungin (Cancidas)	Merck Sharp and Dohme	Austria (31 May 2010) Belgium (21 December 2010) Finland (14 September 2011) Greece (24 November 2010) Italy (13 July 2010) Portugal (12 March 2010) Slovenia (18 May 2010) Denmark (2009) France (2009) Germany (2009) Ireland (2009) The Netherlands (2009) Sweden (2009) United Kingdom (24 August 2009)	Bulgaria (2010) Czech Republic (2010, 2011) Hungary (2010, 2011) Poland (2011) Romania (2010, 2011) Slovak Republic (2010, 2011) Spain (2010)		Luxembourg
5	Clopidogrel (Plavix and associated names)	Sanofi BMS	Denmark (23 January 2012) Finland (9 November 2011)	Ireland (2011) Italy (2011) The Netherlands (2011)		

No.	INN of medicine to which patent applies	Marketing authorisation holder	Member State's NPO granting SPC extension (year)	Member State with SPC extension pending (in year)	No application for SPC extension (yet) in Member State (if not confidential)	Member State in which product has no SPC or patent qualifying for an SPC (if not confidential)
			Germany (30 November 2011) Portugal (8 November 2011) Sweden (13 October 2011)	United Kingdom (2011)		
6	Latanoprost (Xalatan and associated names)	Pfizer	Austria (year not reported, possibly 2011) Denmark (07 March 2011) Finland (12 May 2011) Germany (30 March 2011) Ireland (1 March 2011) Italy (20 February 2011) Luxembourg (15 July 2011) Portugal (21 January 2011) Sweden (17 March 2011) The Netherlands (27 January 2011) United Kingdom (10 May 2011)	Spain (2010)	France Finland Greece Ireland Romania	Bulgaria *(SPC refused)* Germany Greece Hungary Romania *(no SPC)* Slovak Republic Slovenia *(no SPC)*
7	Losartan (Cozaar and associated	Merck Sharp & Dohme BV	Austria (12 February 2010) The	Cyprus (2010)	Greece Portugal Romania Spain	Bulgaria Greece Hungary Portugal

No.	INN of medicine to which patent applies	Marketing authorisation holder	Member State's NPO granting SPC extension (year)	Member State with SPC extension pending (in year)	No application for SPC extension (yet) in Member State (if not confidential)	Member State in which product has no SPC or patent qualifying for an SPC (if not confidential)
	names)		Netherlands (2009) Germany(2009) Denmark (2009) Finland (2009) France (2009) Ireland (2009) Italy (2009) Sweden (2009) United Kingdom (2009) Luxembourg (2009)			Slovak Republic Slovenia *(no SPC)*
8	Montelukast (Singulair)	Merck Sharp & Dohme	Denmark (23 January 2012) Ireland (28 November 2011) Slovenia (16 November 2011) Sweden (15 September 2011) The Netherlands (21 September 2011) United Kingdom (03 January 2012)	Germany (2011) Italy (2011) Luxembourg (2011) The Netherlands (2011)		
9	Nevirapine (Viramune)	Boehringer	Denmark (23 January 2012) Portugal (2 December	Italy (2011) Luxembourg (2011)		

No.	INN of medicine to which patent applies	Marketing authorisation holder	Member State's NPO granting SPC extension (year)	Member State with SPC extension pending (in year)	No application for SPC extension (yet) in Member State (if not confidential)	Member State in which product has no SPC or patent qualifying for an SPC (if not confidential)
			2011) Sweden (16 November 2011)			
10	Rizatriptan (benzoate) (Maxalt and associated names)	Merck Sharp & Dohme		Portugal (2012)		
11	Valsartan (Diovan and associated names)	Novartis Pharma AG	Austria (10 December 2010) Denmark (1 November 2010) Finland (22 October 2010) France (10 December 2010) Germany (13 January 2011) Ireland (22 December 2010) Italy (05 November 2010) Luxembourg (23 December 2010) The Netherlands (7 October 2010) Portugal (16 December 2010) Sweden (30	Spain (2010)	Greece Hungary Romania Slovenia	Bulgaria Greece Romania (no SPC) Slovak Republic

No.	INN of medicine to which patent applies	Marketing authorisation holder	Member State's NPO granting SPC extension (year)	Member State with SPC extension pending (in year)	No application for SPC extension (yet) in Member State (if not confidential)	Member State in which product has no SPC or patent qualifying for an SPC (if not confidential)
			September 2010) United Kingdom (11 January 2011)			
12	Zoledronic acid (Zometa and associated names)	Novartis	Austria (year not reported possibly 2011) Denmark (6 April 2010) France (11 June 2010) Finland (14 September 2011) Germany (27 May 2010) Ireland (28 June 2010) Italy (13 July 2010) Luxembourg (22 December 2010) The Netherlands (3 March 2010) Portugal (15 March 2010) Slovenia (19 March 2010) Sweden (27 April 2010) United Kingdom (30 June 2010)	Cyprus (2010) Greece (2010) Hungary (2010, 2011) Romania (2010, 2011) Spain (2010)		Bulgaria Slovak Republic

NPO = National Patent Office

4. Centrally authorised medicinal products

4.1. Initial marketing authorisation (MA) including a paediatric indication

Summary:

- For this section, only medicinal products were considered when a paediatric indication was granted as part of the initial MA.
- Thirty four (34) new medicinal products have been centrally authorised since 26 January 2007 with a paediatric indication at the time of initial MA.
- Out of these 34 medicinal products, 7 were authorised for a use only in the paediatric population, whereas the remaining 27 medicinal products were authorised for use in adults and in children.
- For 10 out of the 34 medicinal products, the requirements of the Paediatric Regulation needed to be fulfilled, meaning the corresponding PIP had not been completed.

Table 6: Medicinal Products with initial marketing authorisation including a paediatric indication

Year of European Commission Decision	No. in year	Requirement to fulfil Paediatric Regulation at first authorisation?	Indication is paediatric-only or "mixed" (adult and paediatric)?	Active substance(s)	Trade name
2007	1	No	Mixed	Retapamulin	Altargo
2007	2	No	Mixed	Nelarabine	Atriance
2007	3	No	Mixed	Human papillomavirus vaccine [types 16, 18]	Cervarix
2007	4	No	Mixed	Hydroxocobalamin	Cyanotik
2007	5	No	Mixed	Idursulfase	Elaprase
2007	6	No	Mixed	Gadoversetamide	Optimark
2007	7	No	Mixed	Betaine anhydrous	Cystadane
2007	8	No	Paediatric-only	Stiripentol	Diacomit
2007	9	No	Paediatric-only	Mecasermin	Increlex
2007	10	No	Mixed	Rufinamide	Inovelon
2007	11	No	Mixed	Hydroxycarbamide	Siklos
2007	12	No	Mixed	Human normal immunoglobulin (ivig)	Flebogamma DIF
2008	1	No	Mixed	Fluticasone furoate	Avamys
2008	2	No	Mixed	Human normal immunoglobulin	Privigen
2008	3	No	Mixed	Lacosamide	Vimpat
2008	4	No	Mixed	Micafungin	Mycamine
2008	5	No	Mixed	Sapropterin	Kuvan
2008	6	No	Mixed	Sugammadex	Bridion

Year of European Commission Decision	No. in year	Requirement to fulfil Paediatric Regulation at first authorisation?	Indication is paediatric-only or "mixed" (adult and paediatric)?	Active substance(s)	Trade name
2009	1	No	Paediatric-only	Tocofersonal d-alpha tocopheryl polyethylene glycol succinate	Vedrop
2009	2	No	Mixed	Mifamurtide	Mepact
2009	3	No	Mixed	Rilonacept	Rilonacept Regeneron
2009	4	No	Mixed	Tacrolimus	Modigraf
2009	5	No	Paediatric-only	Pneumoccocal polysaccharide conjugate vaccine (absorbed)	Synflorix
2009	6	Yes	Mixed	Canakinumab	Ilaris (PIP not yet completed)
2009	7	Yes	Paediatric-only	Pneumoccocal polysaccharide conjugate vaccine (13-valent, absorbed)	Prevenar 13 (PIP not yet completed)
2010	1	Yes	Mixed	Meningococcal group a, c, w135 and y conjugate vaccine	Menveo (PIP completed)
2010	2	Yes	Mixed	Velaglucerase alfa	Vpriv (PIP not yet completed)
2011	1	Yes*	Paediatric-only	Influenza vaccine (live attenuated, nasal)	Fluenz (Waiver)
2011	2	Yes	Mixed	C1 inhibitor, human	Cinryze (PIP not yet completed)
2011	3	Yes	Mixed	Dihydroartemisinin / piperaquine phosphate	Eurartesim (PIP not yet completed)
2011	4	Yes (PUMA)	Paediatric-only	Midazolam	Buccolam (PIP completed)
2011	5	Yes**	Mixed	Everolimus	Votubia (PIP not yet

Year of European Commission Decision	No. in year	Requirement to fulfil Paediatric Regulation at first authorisation?	Indication is paediatric-only or "mixed" (adult and paediatric)?	Active substance(s)	Trade name
					completed)
2011	6	Yes**	Mixed	Tobramycin	Tobi Podhaler (PIP not yet completed)
2011	7	Yes	Mixed	Nomegestrol / estradiol	Ioa, Zoely(PIP completed)

* The PDCO opinion had granted a waiver for the full paediatric population. ** This was a new marketing authorisation for an orphan designated condition of a medicinal product that was already authorised in the EU for non-orphan designated condition(s). PUMA = Paediatric use marketing authorisation

4.2. Extension of therapeutic indication to include the paediatric population

- The therapeutic indications of 33 centrally authorised medicinal products was extended or amended to include part or subsets of the paediatric population.
- 38 changes to the authorised indications were adopted to include part or subsets of the paediatric population for these 33 centrally authorised medicinal products (several products had more than 1 change to their indications affecting the paediatric population).

Table 7: List of centrally authorised medicinal products for which the therapeutic indication was extended or amended to the paediatric population

Trade name	Active substance (INN)Inn	Date of EU DC	Subject of extension	MAH	Requirement to fulfil Article 8 of Paediatric Regulation Yes/No
Keppra	Levetiracetam	04/01/2007	Extension of the indication to include adjunctive therapy in the treatment of primary generalised tonic-clonic (PGTC) seizures in adults and adolescents from 12 years of age with idiopathic generalized epilep	UCB Pharma SA	No
Prevenar	Pneumococcal saccharide conjugated vaccine, adsorbed	09/03/2007	Extension of the indication to include new information on efficacy against disease caused by Streptococcus pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F and 23F in otitis media.	Wyeth Lederle Vaccines S.A.	No

Trade name	Active substance (INN)Inn	Date of EU DC	Subject of extension	MAH	Requirement to fulfil Article 8 of Paediatric Regulation Yes/No
Prevenar	Pneumococcal saccharide conjugated vaccine, adsorbed	02/04/2007	Extension of indication from active immunisation against bacteraemic pneumonia to active immunisation against pneumonia.	Wyeth Lederle Vaccines S.A.	No
Remicade	Infliximab	30/05/2007	Extension of indication to include treatment of severe active Crohn's disease in children aged 6 to 17 years.	Janssen Biologics B.V.	No
Aranesp	Darbepoetin alfa	30/08/2007	Extension of indication for CRF patients, which currently restricts the use of Nespo to paediatric subjects >/= 11 years of age	Amgen Europe B.V.	No
Telzir	Fosamprenavir	13/09/2007	Extension of indication of Telzir in combination with ritonavir for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults in combination with other antiretroviral medicinal products to include paediatric populations.	ViiV Healthcare UK Limited	No
Combivir	Lamivudine / zidovudine	13/11/2007	Extension of indication to include paediatric patients and replacement of film coated tablets by scored film coated tablets.	ViiV Healthcare UK Limited	No
Aerius	Desloratadine	31/03/2008	Extension of indication from 'chronic idiopathic urticaria' to 'urticaria'.	Merck Sharp & Dohme Ltd.	No
Apidra	Insulin glulisine	20/06/2008	Extension of indication to include 6 years old and older children based on the results of 2 paediatric studies.	Sanofi-aventis Deutschland GmbH	No
Gardasil	Human papilloma virus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)	10/07/2008	Extension of indication to include the prevention of high-grade vaginal dysplastic lesions (VaIN 2/3).	Sanofi Pasteur MSD, SNC	No

Trade name	Active substance (INN)Inn	Date of EU DC	Subject of extension	MAH	Requirement to fulfil Article 8 of Paediatric Regulation Yes/No
Humira	Adalimumab	25/08/2008	Extension of indication to include treatment of active polyarticular juvenile idiopathic arthritis in adolescents from 13 to 17 years of age.	Abbott Laboratories Ltd.	No
Cancidas	Caspofungin	26/11/2008	Extension of the indication to include the paediatric population.	Merck Sharp & Dohme Ltd.	No
Enbrel	Etanercept	22/12/2008	Extension of indication to include the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.	Pfizer Ltd.	No
Zavesca	Miglustat	26/01/2009	Extension of indication to include the treatment of progressive neurological manifestations in adult patients and paediatric patients with Niemann-Pick type C disease.	Actelion Registration Ltd.	No
Protopic	Tacrolimus	26/02/2009	Extension of indication to 'maintenance treatment' further to completion of one study in adult patients and one in paediatric patients.	Astellas Pharma Europe B.V.	No
Aptivus	Tipranavir	23/06/2009	Extension of indication to include the treatment of HIV-1 infection in highly pre-treated adolescents 12 years of age or older with virus resistant to multiple protease inhibitors.	Boehringer Ingelheim International GmbH	No
Xolair	Omalizumab	27/07/2009	Extension of indication to children from 6 to <12 years of age as add-on therapy to improve allergic asthma control.	Novartis Europharm Ltd.	No
Abilify	Aripiprazole	21/08/2009	Extension of indication to include treatment of schizophrenia in adolescents 15 years and older.	Otsuka Pharmaceutical Europe Ltd.	No
Keppra	Levetiracetam	02/09/2009	Extension of indication to include the adjunctive treatment of partial seizures with or without secondary generalisation in children from 1 month to <4 years old.	UCB Pharma SA	No