Annex 14 – PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
Exenatide (Byetta)	Eli Lilly and Company	Endocrinology-gynaecology-fertility-metabolism	PM EMEA-000689-PIP01-09-M01	• 23/12/2009 • 15/01/2010	P/12/2010
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)	Sanofi Pasteur MSD SNC	Vaccines	PM EMEA-000375-PIP01-08-M02	• 23/12/2009 • 15/01/2010	P/13/2010
Denosumab (Prolia, Amgiva)	Amgen Europe B.V.	Oncology Endocrinology-Gynaecology-Fertility-Metabolism Immunology–Rheumatology-Transplantation	PM EMEA-000145-PIP01-07-M02	• 19/11/2009 • 15/01/2010	P/14/2010
13 valent pneumococcal polysaccharide conjugate vaccine (Prevenar 13)	Wyeth Lederle Vaccines S.A.	Vaccines	PM EMEA-000036-PIP01-07-M03	• 19/11/2009 • 15/01/2010	P/15/2010
Saxagliptin	Bristol-Myers Squibb/AstraZeneca EEIG	Endocrinology-gynaecology-fertility-metabolism	PM EMEA-000200-PIP01-08-M01	• 23/12/2009 • 15/01/2010	P/16/2010
N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4-oxoquinoline-3-carboxamide	Vertex Pharmaceuticals Incorporated	Pneumology - Allergology	PM EMEA-000335-PIP01-08-M02	• 19/11/2009 • 15/01/2010	P/17/2010
Tenofovir disoproxil (as fumarate) (Viread)	Gilead Sciences International Limited	Infectious diseases	P EMEA-000533-PIP01-08	• 28/05/2009 • 15/01/2010	P/18/2010
Ecallantide (Recombinant Inhibitor of Human Plasma Kallikrein)	Dyax S.A.	Other / dermatology / pneumology – allergology	P EMEA-000688-PIP01-09	• 20/08/2009 • 15/01/2010	P/19/2010
Expanded human autologous mesenchymal adult stem cells extracted from adipose tissue (CX-401)	Cellerix, S.A.	Gastroenterology -hepatology	P EMEA-000635-PIP01-09	• 23/07/2009 • 15/01/2010	P/20/2010

* PIP (P) / PIP Modification (PM) / Full Waiver (W) / RP (PIP Refusal) / RW (Waiver Refusal) / C (Full Compliance Check)

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
		metabolism / gastroenterology -hepatology		(R)	
Doripenem monohydrate (Doribax)	Janssen-Cilag International N.V.	Infectious disease	PM EMEA-000015-PIP01-07-M02	• 15/07/2010 • 10/09/2010	P/192/2010
Meningococcal group A oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenA-CRM) Meningococcal group C oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenC-CRM) Meningococcal group W-135 oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenW-CRM) Meningococcal group Y oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenY-CRM) (Menveo)	Novartis Vaccines and Diagnostics S.r.L	Vaccines	PM EMEA-000032-PIP01-07-M02	• 15/07/2010 • 10/09/2010	P/193/2010
Tiotropium bromide (monohydrate) (Spiriva Respimat and associated names)	Boehringer Ingelheim International GmbH	Pneumology-allergology	PM EMEA-000035-PIP01-07-M02	• 15/07/2010 • 10/09/2010	P/194/2010
Brivaracetam	UCB Pharma SA	Neurology	PM EMEA-000332-PIP01-08-M02	• 15/07/2010 • 10/09/2010	P/195/2010
Riociguat	Bayer Schering Pharma AG	Cardiovascular diseases	P EMEA-000718-PIP01-09	• 23/12/2009 • 10/09/2010	P/196/2010
Lidocaine hydrochloride Phenylephrine hydrochloride Tropicamide	Laboratoires THEA	Ophthalmology	W EMEA-000991-PIP01-10	• 15/07/2010 • 10/09/2010	P/197/2010
Voriconazole (Vfend)	Pfizer Limited	Infectious diseases	PM EMEA-000191-PIP01-08-M01	• 15/07/2010 • 10/09/2010	P/198/2010
Motavizumab	Abbott	Intramuscular	PM	• 12/08/2010	P/199/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
	Laboratories Limited	use	EMEA-000352-PIP01-08-M01	• 10/09/2010	
Sodium-X-5-Hydroxy-X-6,10-dioxo-3,4,5,6,9,9a,10-hexahydro-2H-1-oxa-4a,8a-diaza-anthracene-7-carboxylic acid-X-benzylamide (GSK1349572)	ViiV Healthcare UK Ltd.	Infectious diseases	PM EMEA-000409-PIP01-08-M01	• 15/07/2010 • 10/09/2010	P/200/2010
Anidulafungin (Ecalta)	Pfizer Limited	Infectious diseases	PM EMEA-000469-PIP01-08-M01	• 15/07/2010 • 10/09/2010	P/201/2010
Propranolol hydrochloride	Pierre Fabre Dermatologie	Dermatology	PM EMEA-000511-PIP01-08-M02	• 15/07/2010 •	P/202/2010
Dermatophagoides pteronyssinus and Dermatophagoides farinae extracts (50 %/50 %)	Allergy Therapeutics (UK) Ltd	Pneumology-allergology	P EMEA-000807-PIP01-09	• 23/03/2010 • 10/09/2010	P/203/2010
Birch, Hazel and Alder Pollen Extracts	Allergy Therapeutics (UK) Ltd	Pneumology-allergology	P EMEA-000808-PIP01-09	• 23/03/2010 • 10/09/2010	P/204/2010
Dermatophagoides pteronyssinus and Dermatophagoides farinae extracts (50 %/50 %)	Allergy Therapeutics (UK) Ltd	Pneumology-allergology	P EMEA-000815-PIP01-0	• 23/03/2010 • 10/09/2010	P/205/2010
Ingenol mebutate	LEO Pharma A/S	Dermatology Oncology	W EMEA-000894-PIP01-10	• 15/07/2010 • 10/09/2010	P/206/2010
Everolimus (Certican, Afinitor and associated names)	Novartis Europharm Limited	Immunology-rheumatology-transplantation	P EMEA-000019-PIP06-09	• 15/10/2009 • 10/09/2010	P/207/2010
Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H1N1/Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H3N2/Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Fluad and associated names)	Novartis Vaccines and Diagnostics S.r.l.	Vaccines	PM EMEA-000149-PIP01-07-M02	• 15/07/2010 • 10/09/2010	P/208/2010
L-asparaginase encapsulated in	ERYtech Pharma	Oncology	P EMEA-000341-	• 23/12/2009 • 10/09/2010	P/209/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
erythrocytes			PIP02-09		
Prucalopride succinate (Resolor)	Shire-Movetis NV	Gastroenterology -hepatology	P EMEA-000459-PIP01-08	• 15/10/2009 • 10/09/2010	P/210/2010
Influenza virus surface antigens (H5N1) Influenza virus surface antigens (H1N1) (Focetria and associated names Aflunov and associated names Foclivia and associated names)	Novartis Vaccines and Diagnostics S.r.l.	Vaccines	PM EMEA-000599-PIP01-09-M0	• 15/10/2009 • 10/09/2010	P/211/2010
Pagibaximab	Biosynexus, Incorporated	Infectious diseases Neonatology-paediatric intensive care	P EMEA-000608-PIP01-09	• 17/09/2009 • 10/09/2010	P/212/2010
Fampridine	Acorda Therapeutics, Inc.	Neurology	PM EMEA-000614-PIP01-10-M01	• 15/07/2010 • 10/09/2010	P/213/2010
Dronabinol	Bionorica AG	Pain	W EMEA-000643-PIP01-09	• 20/08/2009 • 10/09/2010	P/214/2010
Derivative of 4,4'-(1-methylene)-bisbenzonitrile	Novartis Europharm Limited	Endocrinology-gynaecology-fertility-metabolism	W EMEA-000758-PIP01-09	• 23/12/2009 • 10/09/2010	P/215/2010
12 Grass Pollen Extract and Cultivated Rye Pollen Extract	Allergy Therapeutics (UK) Ltd	Pneumology-allergology	P EMEA-000806-PIP01-09	• 23/03/2010 • 10/09/2010	P/216/2010
Birch Pollen Extract	Allergy Therapeutics (UK) Ltd.	Pneumology-allergology	P EMEA-000809-PIP01-09	• 18/02/2010 • 10/09/2010	P/217/2010
12 grass pollen extract, cultivated rye pollen extract and birch pollen extract	Allergy Therapeutics (UK) Ltd.	Pneumology-allergology	P EMEA-000810-PIP01-09	• 18/02/2010 • 10/09/2010	P/218/2010
12 grass pollen extract, cultivated rye pollen extract and mugwort pollen extract	Allergy Therapeutics (UK) Ltd.	Pneumology-allergology	P EMEA-000811-PIP01-09	• 18/02/2010 • 10/09/2010	P/219/2010
12 grass pollen extract, cultivated rye pollen extract and birch/alder/hazel pollen extract	Allergy Therapeutics (UK) Ltd.	Pneumology-allergology	P EMEA-000812-PIP01-09	• 18/02/2010 • 10/09/2010	P/220/2010
12 Grass Pollen	Allergy	Pneumology-	P	• 18/02/2010	P/221/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
Extract and Cultivated Rye Pollen Extract	Therapeutics (UK) Ltd.	allergology	EMEA-000813-PIP01-09	• 10/09/2010	
Birch/Alder/Hazel Pollen Extract	Allergy Therapeutics (UK) Ltd.	Pneumology-allergology	P EMEA-000814-PIP01-09	• 18/02/2010 • 10/09/2010	P/222/2010
Phentermine / topiramate	Vivus BV	Endocrinology-gynaecology-fertility-metabolism	P EMEA-000826-PIP01-09	• 15/04/2010 • 10/09/2010	P/223/2010
Eculizumab (Soliris)	Alexion Europe SAS	Immunology-rheumatology-transplantation	P EMEA-000876-PIP01-10	• 15/04/2010 • 10/09/2010	P/224/2010
1H-Indole-6-carboxylic acid, 2,3-dihydro-3-[[[4-[methyl[(4-methyl-1-piperazinyl)acetyl]amino]phenyl]amino]phenylmethylene]-2-oxo-, methyl ester, (3Z)-, monoethanesulfonate	Boehringer Ingelheim International GmbH	Pneumology-allergology	W EMEA-001006-PIP01-10	• 15/07/2010 • 10/09/2010	P/225/2010
Atazanavir sulphate (Reyataz)	Bristol-Myers Squibb Pharma EEIG	Infectious diseases	P EMA-000804-PIP01-09	• 18/02/2010 • 08/10/2010	P/226/2010
Partially purified bromelain	Teva Pharma GmbH	Dermatology Othe	P EMEA-000142-PIP02-09	• 20/05/2010 • 08/10/2010	P/227/2010
Aztreonam (Cayston)	Gilead Sciences International Limited	Infectious diseases	P EMEA-000827-PIP01-09	• 15/04/2010 • 08/10/2010	P/228/2010
Rosuvastatin calcium (Crestor and associated names)	AstraZeneca AB	Cardiovascular diseases	PM EMEA-000022-PIP01-07-M04	• 15/09/2010 • 08/10/2010	P/229/2010
Moxifloxacin hydrochloride (Avalox and associated names; Octegra and associated names; Actimax and associated names; Actira and associated names)	Bayer Schering Pharma AG	Infectious diseases	PM EMEA-000288-PIP01-08-M02	• 12/08/2010 • 08/10/2010	P/230/2010
Fentanyl citrate	EPMC Pharma SPRL	Neonatology – paediatric intensive care Pain	P EMEA-000712-PIP01-09	• 19/11/2009 • 08/10/2010	P/231/2010
4-hydroxy-n-(2-hydroxyethyl)-	Dr. Franz Köhler Chemie GmbH	Anaesthesiology Neurology	RW EMEA-000764-	• 23/03/2010 • 08/10/2010	P/232/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
butyramide			PIP01-09		
Clopidogrel (Plavix)	Sanofi Pharma Bristol-Myers Squibb SNC	Cardiovascular diseases	PM EMEA-000049-PIP01-07-M03	• 12/08/2010 • 08/10/2010	P/233/2010
Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains: A/Solomon Islands/3/2006 (H1N1) like strain (A/Solomon Islands/3/2006, IVR-145) A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005, NYMC X161B) B/Malaysia/2506/2004 like strain (B/Malaysia/2506/2004) (Optaflu)	Novartis Vaccines & Diagnostics GmbH & Co. KG	Vaccines	PM EMEA-000124-PIP01-07-M01	• 12/08/2010 • 08/10/2010	P/234/2010
Eptacog alfa pegol (activated)	Novo Nordisk A/S	Haematology - Hemostaseology	PM EMEA-000189-PIP01-08-M01	• 12/08/2010 • 08/10/2010	P/235/2010
Etanercept (Enbrel)	Wyeth Europa Limited	Dermatology Immunology-rheumatology-transplantation	PM EMEA-000299-PIP01-08-M02	• 15/09/2010 • 08/10/2010	P/236/2010
Recombinant human monoclonal antibody to human Interleukin 17A (AIN457)	Novartis Europharm Limited	Ophthalmology	P EMEA-000380-PIP04-10	• 15/04/2010 • 08/10/2010	P/237/2010
Teduglutide	Nycomed Danmark ApS	Gastroenterology –hepatology	P EMEA-000482-PIP01-08	• 20/08/2009 •	P/238/2010
Infliximab (Remicade)	Centocor B.V.	Gastroenterology –hepatology Dermatology Immunology-rheumatology-transplantation	PM EMEA-000549-PIP01-09-M01	• 20/08/2009 • 08/10/2010	P/239/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract from the pollen of Betula alba	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000630-PIP02-09	• 21/01/2010 • 08/10/2010	P/240/2010
Aluminium hydroxide	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000662-	• 21/01/2010	P/241/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
adsorbed, depigmented glutaraldehyde polymerised, allergen extract of equal amounts of birch, alder and hazel pollen (1/3 each)			PIP02-09	• 08/10/2010	
Pixantrone	CTI Life Sciences, Ltd	Oncology	P EMEA-000713-PIP02-10	• 12/08/2010 • 08/10/2010	P/242/2010
[(3S)-6-({2',6'-Dimethyl-4'-[3-(methylsulfonyl) propoxy] biphenyl-3-yl}methoxy)-2,3-dihydro-1-benzofuran-3-yl]acetic acid hydrate (TAK-875)	Takeda Global Research and Development Centre (Europe) Ltd.	Endocrinology-gynaecology–fertility-metabolism	P EMEA-000734-PIP01-09	• 19/11/2009 • 08/10/2010	P/243/2010
Recombinant Bet v1 folding variant (rBet v1-FV)	Allergopharma J. Ganzer KG	Endocrinology-gynaecology–fertility-metabolism	P EMEA-000742-PIP01-09	• 21/01/2010 • 08/10/2010	P/244/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of phleum pratense, dactylis glomerata, festuca elatior, lolium perenne and poa pratensis pollen (grasses-mix) and birch, alder and hazel pollen (tree-mix) (50/50)	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000789-PIP01-09	• 21/01/2010 • 08/10/2010	P/245/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of phleum pratense, dactylis glomerata, festuca elatior, lolium perenne and poa pratensis pollen (grasses-mix) and birch pollen (50/50)	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000790-PIP01-09	• 21/01/2010 • 08/10/2010	P/246/2010
Aluminium hydroxide adsorbed,	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000791-PIP01-09	• 21/01/2010 • 08/10/2010	P/247/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
depigmented glutaraldehyde polymerised, allergic extract of equal amounts of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis pollen (Grasses-Mix) and Secale cereale (Cultivated Rye) pollen (75/25)					
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis pollen (Grasses-Mix) and Secale cereale (Cultivated Rye) pollen (50/50)	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000792-PIP01-09	• 21/01/2010 • 08/10/2010	P/248/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of Phleum pratense pollen and Secale cereale (Cultivated Rye) pollen (50/50)	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000793-PIP01-09	• 21/01/2010 • 08/10/2010	P/249/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis pollen (Grasses-Mix) (1/5) each	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000794-PIP01-09	• 21/01/2010 • 08/10/2010	P/250/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000794-PIP01-09	• 21/01/2010 • 08/10/2010	P/251/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
polymerised, allergic extract of Phleum pratense pollen					
Anti-BAFF monoclonal antibody (LY2127399)	Eli Lilly & Company Limited	Oncology Neurology Immunology-rheumatology-transplantation	P EMEA-000802-PIP01-09	• 18/02/2010 • 08/10/2010	P/252/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch pollen	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000837-PIP01-10	• 15/04/2010 • 08/10/2010	P/253/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch, alder and hazel pollen	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000838-PIP01-10	• 15/04/2010 • 08/10/2010	P/254/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of Phleum pratense pollen	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000839-PIP01-10	• 15/04/2010 • 08/10/2010	P/255/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extracts of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis pollen (Grasses-Mix)	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000840-PIP01-10	• 15/04/2010 • 08/10/2010	P/256/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extracts of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis pollen (Grasses-Mix) and	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000841-PIP01-10	• 15/04/2010 • 08/10/2010	P/257/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
Secale cereale (Cultivated Rye) pollen (50/50)					
Mixture of Birch, Hazel and Alder allergen extracts	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000918-PIP01-10	• 20/05/2010 • 08/10/2010	P/258/2010
Betula alba allergen extract	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000919-PIP01-10	• 20/05/2010 • 08/10/2010	P/259/2010
Dermatophagoides pteronyssinus allergen extract	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000920-PIP01-10	• 20/05/2010 • 08/10/2010	P/260/2010
Mixture of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis allergen extracts	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000921-PIP01-10	• 20/05/2010 • 08/10/2010	P/261/2010
Mixture of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis (Grasses-Mix) and Secale cereale (50/50) allergen extracts	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000922-PIP01-10	• 06/10/2010 • 08/10/2010	P/262/2010
Mixture of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis (Grasses-Mix) and Secale cereale (75/25) allergen extracts	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000923-PIP01-10	• 06/10/2010 • 08/10/2010	P/263/2010
Phleum pratense allergen extract	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000924-PIP01-10	• 20/05/2010 • 08/10/2010	P/264/2010
Mixture of Phleum pratense and Secale cereale allergen extracts	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000925-PIP02-10	• 06/10/2010 • 08/10/2010	P/265/2010
Mixture of Dermatophagoides pteronyssinus and Dermatophagoides farinae allergen extracts	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000926-PIP01-10	• 20/05/2010 • 08/10/2010	P/266/2010
Ocriplasmin	ThromboGenics	Ophtalmology	W EMEA-000986-PIP01-10	• 12/08/2010 • 08/10/2010	P/267/2010
Duloxetine hydrochloride (Cymbalta/Xeristar/ Yentreve/Ariclaim/Duloxetine	Eli Lilly & Company	Psychiatry Pain	W EMEA-000420-PIP01-08	• 10/11/2010 • 12/11/2010	P/268/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
Boehringer Ingelheim)					
Insulin detemir (Levemir)	Novo Nordisk A/S	Endocrinology-gynaecology-fertitily-metabolism	P EMEA-000412-PIP01-08	• 11/12/2008 • 12/11/2010	P/269/2010
Pralatrexate	Allos Therapeutics Limited	Oncology	P EMEA-000619-PIP02-10	• 20/05/2010 • 12/11/2010	P/270/2010
Allergens of birch pollen (betula alba/pendula/verrucosa)	Allergopharma Joachim Ganzer KG	Pneumology-allergology	P EMEA-000888-PIP01-10	• 20/05/2010 • 12/11/2010	P/271/2010
Eritoran	Eisai Limited	Infectious diseases Other	PM EMEA-000509-PIP02-09-M02	• 13/10/2010 • 12/11/2010	P/272/2010
Catridecacog	Novo Nordisk A/S	Haematology-haemostaseology	PM EMEA-000185-PIP01-08-M03	• 15/09/2010 • 12/11/2010	P/273/2010
Adsorbed modified allergen extract of a mixture of 50% dermatophagoides pteronyssinus and 50% dermatophagoides farinae	HAL Allergy BV	Pneumology-allergology	P EMEA-000902-PIP01-10	• 20/05/2010 • 12/11/2010	P/274/2010
Allergen extract of betula verrucosa pollen	HAL Allergy BV	Pneumology-allergology	P EMEA-000903-PIP01-10	• 20/05/2010 • 12/11/2010	P/275/2010
Allergen extract of equal parts of lolium perenne, phleum pratense and poa pratensis pollen	HAL Allergy BV	Pneumology-allergology	P EMEA-000904-PIP01-10	• 20/05/2010 • 12/11/2010	P/276/2010
Allergen extract of 50% grass (equal parts of lolium perenne pollen, phleum pratense and poa pratensis) and 50% secale cereale pollen	HAL Allergy BV	Pneumology-allergology	P EMEA-000905-PIP01-10	• 20/05/2010 • 12/11/2010	P/277/2010
Allergen extract of alnus glutinosa pollen	HAL Allergy BV	Pneumology-allergology	P EMEA-000906-PIP01-10	• 20/05/2010 • 12/11/2010	P/278/2010
Allergen extract of a mixture of 50% dermatophagoides pteronyssinus and 50% dermatophagoides farinae	HAL Allergy BV	Pneumology-allergology	P EMEA-000907-PIP01-10	• 20/05/2010 • 12/11/2010	P/279/2010
Allergen extract of corylus avellana	HAL Allergy BV	Pneumology-allergology	P EMEA-000908-	• 20/05/2010 • 12/11/2010	P/280/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
pollen			PIP01-10		
Allergen extract of phleum pratense pollen	HAL Allergy BV	Pneumology-allergology	P EMEA-000909-PIP01-10	• 20/05/2010 • 12/11/2010	P/281/2010
Allergen extract of secale cereale pollen	HAL Allergy BV	Pneumology-allergology	P EMEA-000910-PIP01-10	• 20/05/2010 • 12/11/2010	P/282/2010
Allergen extract of equal parts of betula verrucosa, corylus avellana and alnus glutinosa pollen	HAL Allergy BV	Pneumology-allergology	P EMEA-000911-PIP01-10	• 20/05/2010 • 12/11/2010	P/283/2010
Lanthanum carbonate hydrate (Fosrenol and associated names)	Shire Pharmaceutical Contracts Ltd	Uro-nephrology	P EMEA-000637-PIP02-10	• 15/04/2010 • 12/11/2010	P/284/2010
Dermatophagoides farinae extracts 100 %	Allergopharma Joachim Ganzer KG	Pneumology-allergology	P EMEA-000834-PIP01-10	• 20/05/2010 • 12/11/2010	P/285/2010
Dermatophagoides pteronyssinus extracts 100 %	Allergopharma Joachim Ganzer KG	Pneumology-allergology	P EMEA-000835-PIP01-10	• 20/05/2010 • 12/11/2010	P/286/2010
Dermatophagoides pteronyssinus and Dermatophagoides farinae extracts (50 %/50 %)	Allergopharma Joachim Ganzer KG	Pneumology-allergology	P EMEA-000836-PIP01-10	• 20/05/2010 • 12/11/2010	P/287/2010
Liraglutide (Victoza)	Novo Nordisk A/S	Endocrinology-gynaecology-fertility-metabolism	PM EMEA-000128-PIP01-07-M02	• 13/10/2010 • 12/11/2010	P/288/2010
Aqueous allergen extract of dermatophagoides pteronyssinus and dermatophagoides farinae	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000961-PIP01-10	• 20/05/2010 • 12/11/2010	P/289/2010
Entecavir (Baraclude)	Bristol-Myers Squibb Pharma EEIG	Infectious diseases	PM EMEA-000339-PIP02-09-M01	• 13/10/2010 • 12/11/2010	P/290/2010
Ranibizumab (Lucentis)	Novartis Europharm Limited	Ophthalmology	W EMEA-000527-PIP02-10	• 15/07/2010 • 12/11/2011	P/291/2010
40K pegylated recombinant blood coagulation factor IX	Novo Nordisk A/S	Haematology-hemostaseology	P EMEA-000731-PIP01-09	• 21/01/2010 • 12/11/2011	P/292/2010
Nalmefene hydrochloride dihydrate	H. Lundbeck A/S	Psychiatry	W EMEA-000824-PIP01-09	• 23/03/2010 • 12/11/2011	P/293/2010
Pollen from Dactylis glomerata, Lolium	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000845-	• 15/04/2010	P/294/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
perenne, Phleum pratense, Festuca pratensis, Secale cereale			PIP01-10	• 12/11/2011	
Pollen from betula verrucosa	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000846-PIP01-10	• 15/04/2010 • 12/11/2011	P/295/2010
Pollen from Phleum pratense	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000847-PIP01-10	• 15/04/2010 • 12/11/2011	P/296/2010
Pollen from dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis, secale cereale, betula verrucosa, corylus avellana and alnus glutinosa	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000850-PIP01-10	• 15/04/2010 • 12/11/2011	P/297/2010
Pollen from dactylis glomerata, festuca pratensis, lolium perenne, phleum pratense, poa pratensis, secale cereale and artemisia vulgaris	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000851-PIP01-10	• 15/04/2010 • 12/11/2011	P/298/2010
Pollen from Dactylis glomarata, Lolium perenne, Phleum pratense, Poa pratensis and Anthoxhantum odoratum (20 % each)	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000856-PIP01-10	• 15/04/2010 • 12/11/2011	P/299/2010
Pollen from Dactylis glomarata (16%), Lolium perenne (16%), Phleum pratense (16%), Poa pratensis (16%), Anthoxhantum odoratum (16 %) and Secale cereale (20%)	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000857-PIP01-10	• 15/04/2010 • 12/11/2011	P/300/2010
Pollen from dactylis glomarata (8%), lolium perenne (8%), phleum pratense (8%), poa pratensis (8%), anthoxhantum odoratum (8%), secale cereale (10%), betula pendula (16,7%), corylus avellana (16,6%) and alnus	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000859-PIP01-10	• 15/04/2010 • 12/11/2011	P/301/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
glutinosa (16,6%)					
Pollen from Dactylis glomerata, Festuca pratensis, Lolium perenne, Phleum pratense, Secale cereale (20% each)	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000864-PIP01-10	• 15/04/2010 • 12/11/2011	P/302/2010
Pollen from betula verrucosa	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000865-PIP01-10	• 15/04/2010 • 12/11/2011	P/303/2010
Pollen from Phleum pratense	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000867-PIP01-10	• 15/04/2010 • 12/11/2011	P/304/2010
Pollen from dactylis glomarata (16%), festuca pratensis (16%), lolium perenne (16%), phleum pratense (16%), poa pratensis (16%), secale cereale (20%)	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000869-PIP01-10	• 15/04/2010 • 12/11/2011	P/305/2010
Human normal immunoglobulin / recombinant human hyaluronidase	Baxter Innovations GmbH	Immunology-rheumatology-transplantation	P EMEA-000872-PIP01-10	• 15/04/2010 • 12/11/2011	P/306/2010
Modified allergen extract of grass and mugwort pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000929-PIP01-10	• 20/05/2010 • 12/11/2011	P/307/2010
Modified allergen extract of birch, alder and hazel pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000930-PIP01-10	• 20/05/2010 • 12/11/2011	P/308/2010
Modified allergen extract of birch and hazel pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000931-PIP01-10	• 20/05/2010 • 12/11/2011	P/309/2010
Modified allergen extract of birch pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000932-PIP01-10	• 20/05/2010 • 12/11/2011	P/310/2010
Modified allergen extract of grass and birch pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000936-PIP01-10	• 20/05/2010 • 12/11/2011	P/311/2010
Modified allergen extract of grass and cereal pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000937-PIP01-10	• 20/05/2010 • 12/11/2011	P/312/2010
Modified allergen extract of grass and rye pollen (60/40)	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000938-PIP01-10	• 20/05/2010 • 12/11/2011	P/313/2010
Modified allergen extract of grass and rye pollen (50/50)	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000939-PIP01-10	• 20/05/2010 • 12/11/2011	P/314/2010
Modified allergen extract of grass pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000940-PIP01-10	• 20/05/2010 • 12/11/2011	P/315/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
Modified allergen extract of hazel pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000941-PIP01-10	• 20/05/2010 • 12/11/2011	P/316/2010
Modified allergen extract of pollen from Phleum pratense	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000942-PIP01-10	• 20/05/2010 • 12/11/2011	P/317/2010
Modified allergen extract of rye pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000943-PIP01-10	• 20/05/2010 • 12/11/2011	P/318/2010
Modified allergen extract of birch, alder and hazel pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000944-PIP01-10	• 20/05/2010 • 12/11/2011	P/319/2010
Modified allergen extract of birch and hazel pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000945-PIP01-10	• 20/05/2010 • 12/11/2011	P/320/2010
Modified allergen extract of birch pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000946-PIP01-10	• 20/05/2010 • 12/11/2011	P/321/2010
Modified allergen extract of grass and birch pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000950-PIP01-10	• 20/05/2010 • 12/11/2011	P/322/2010
Modified allergen extract of grass and cereal pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000951-PIP01-10	• 20/05/2010 • 12/11/2011	P/323/2010
Modified allergen extract of grass and rye pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000953-PIP01-10	• 20/05/2010 • 12/11/2011	P/324/2010
Modified allergen extract of grass pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000954-PIP01-10	• 20/05/2010 • 12/11/2011	P/325/2010
Modified allergen extract of hazel pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000955-PIP01-10	• 20/05/2010 • 12/11/2011	P/326/2010
Modified allergen extract of pollen from Phleum pratense	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000956-PIP01-10	• 20/05/2010 • 12/11/2011	P/327/2010
Modified allergen extract of rye pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000957-PIP01-10	• 20/05/2010 • 12/11/2011	P/328/2010
Aqueous allergen extract of birch, alder and hazel pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000958-PIP01-10	• 20/05/2010 • 12/11/2011	P/329/2010
Aqueous allergen extract of birch	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000959-PIP01-10	• 20/05/2010 • 12/11/2011	P/330/2010
Aqueous allergen extract of grass pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000962-PIP01-10	• 20/05/2010 • 12/11/2011	P/331/2010
Aqueous allergen extract of grass and birch pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000963-PIP01-10	• 20/05/2010 • 12/11/2011	P/332/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
Aqueous allergen extract of grass and cereal pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000964-PIP01-10	• 20/05/2010 • 12/11/2011	P/333/2010
Aqueous allergen extract of grass and rye pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000965-PIP01-10	• 20/05/2010 • 12/11/2011	P/334/2010
Aqueous allergen extract of pollen from phleum pratense	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000966-PIP01-10	• 20/05/2010 • 12/11/2011	P/335/2010
Interferon alpha 2b	Helix BioPharma Corp	Endocrinology-gynaecology-fertility-metabolism	W EMEA-001036-PIP01-10	• 15/09/2010 • 12/11/2011	P/336/2010
Coagulation Factor IX (Recombinant)	Inspiration Biopharmaceuticals EU, Ltd.	Haematology-hemostaseology	PM EMEA-000661-PIP01-09-M01	• 15/09/2010 • 12/11/2011	P/337/2010
Modified allergen extract of dermatophagoides farinae	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000933-PIP01-10	• 20/05/2010 • 12/11/2011	P/338/2010
Modified allergen extract of Dermatophagoides pteronyssinus and Dermatophagoides farinae	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000934-PIP01-10	• 20/05/2010 • 12/11/2011	P/339/2010
Modified allergen extract of Dermatophagoides pteronyssinus	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000935-PIP01-10	• 20/05/2010 • 12/11/2011	P/340/2010
Modified allergen extract of dermatophagoides farinae	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000947-PIP01-10	• 20/05/2010 • 12/11/2011	P/341/2010
Modified allergen extract of dermatophagoides pteronyssinus and dermatophagoides farinae	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000948-PIP01-10	• 20/05/2010 • 12/11/2011	P/342/2010
Modified allergen extract of dermatophagoides pteronyssinus	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000949-PIP01-10	• 20/05/2010 • 12/11/2011	P/343/2010
Aqueous allergen extract of dermatophagoides pteronyssinus	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000960-PIP01-10	• 20/05/2010 • 12/11/2011	P/344/2010
Opinion of the Paediatric Committee on a class waiver on condition (s)	**N/A**	**N/A**	**Class Waiver**	• 10/12/2010	P/345/2010
Paliperidone Paliperidone	Janssen-Cilag International NV	Psychiatry	PM EMEA-000014-	• 16/12/2010 • 20/12/2010	P/346/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
palmitate (Invega)			PIP01-07-M05		
Adalimumab (Humira)	Abbott Laboratories Ltd	Dermatology Gastroenterology -hepatology Immunology-rheumatology-transpla ntation	PM EMEA-000366-PIP01-08-M03	• 08/10/2010 • 12/11/2010	P/1/2011
Imatinib mesilate	Novartis Europharm Limited	Oncology	PM EMA-000463-PIP01-08-M01	• 15/09/2010 • 12/11/2010	P/2/2011
Tazarotene	Orfagen	Dermatology	P EMEA-000510-PIP02-10	• 15/09/2010 • 12/11/2010	P/3/2011
Pazopanib (Votrient)	Glaxo Group Limited	Oncology	P EMEA-000601-PIP01-09	• 15/10/2009 • 12/11/2010	P/4/2011
Ecallantide (Recombinant Inhibitor of Human Plasma Kallikrein)	Dyax s.a.	Dermatology Pneumology-allergology Other	PM EMEA-000688-PIP01-09-M01	• 13/10/2010 • 12/11/2010	P/5/2011
Midostaurin	Novartis Europharm Ltd	Oncology	P EMEA-000780-PIP01-09	• 21/01/2010 • 12/11/2010	P/6/2011
Allergens from Dermatophagoides pteronyssinus and Dermatophagoides farinae	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000847-PIP01-10	• 15/04/2010 • 12/11/2010	P/7/2011
Pollen from alnus glutinosa, betula verrucosa and corylus avellana	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000849-PIP01-10	• 15/04/2010 • 12/11/2010	P/8/2011
Pollen from betula pendula (33%), corylus avellana (33%) and alnus glutinosa (33%)	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000852-PIP01-10	• 15/04/2010 • 12/11/2010	P/9/2011
Pollen from betula pendula	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000853-PIP01-10	• 15/04/2010 • 12/11/2010	P/10/2011
Allergen extracts of dermatophagoides farinae and dermatophagoides pteronyssinus (each 50%)	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000860-PIP01-10	• 15/04/2010 • 12/11/2010	P/11/2011
Pollen from alnus glutinosa (33%), betula verrucosa (33%) and corylus avellana (33%)	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000863-PIP01-10	• 15/04/2010 • 12/11/2010	P/12/2011
Allergen extracts of dermatophagoides farinae and dermatophagoides	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000866-PIP01-10	• 15/04/2010 • 12/11/2010	P/13/2011

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
pteronyssinus (each 50%)					
Influenza virus type A, H3N2, influenza virus type A, H1N1, influenza virus type B	MedImmune, LLC	Vaccines	P EMEA-000249-PIP01-08	• 10/11/2010 • 12/11/2010	P/14/2011
Ezetimibe (Ezetrol and associated names)	MSD-SP Limited	Cardiovascular diseases	PM EMEA-000007-PIP01-07-M01	• 13/10/2010 • 10/12/2010	P/15/2011
Nepafenac (Nevanac)	Alcon Laboratories (UK) Ltd.	Ophthalmology	W EMEA-000913-PIP01-10	• 13/10/2010 • 10/12/2010	P/16/2011
Perindopril arginine / indapamide amlodipine besilate	Les Laboratoires Servier	Cardiovascular diseases	W EMEA-001048-PIP01-10	• 13/10/2010 • 10/12/2010	P/17/2011
Lixisenatide	Sanofi-Aventis R&D	Endocrinology-gynaecology-fertility-metabolism	P EMEA-000916-PIP01-10	• 20/05/2010 • 10/12/2010	P/18/2011
Sitagliptin (phosphate monohydrate) (Januvia)	Merck Sharp and Dohme (Europe), Inc.	Endocrinology-gynaecology-fertility-metabolism	PM EMEA-000470-PIP01-08-M03	• 13/10/2010 • 10/12/2010	P/19/2011
Alogliptin benzoate	Takeda Global Research and Development Centre (Europe) Ltd.	Endocrinology-gynaecology-fertility-metabolism	PM EMEA-000496-PIP01-08-M01	• 13/10/2010 • 10/12/2010	P/20/2011
Exenatide (Byetta)	Eli Lilly and Company	Endocrinology-gynaecology-fertility-metabolism	PM EMEA-000689-PIP01-09-M02	• 13/10/2010 • 10/12/2010	P/21/2011
Grass pollen allergen extract from Dactylis glomerata L., Anthoxanthum odoratum L., Lolium perenne L., Poa prantensis L. and Phleum pratense L.	Stallergenes S.A.	Pneumology-allergology	P EMEA-000976-PIP01-10	• 15/07/2010 • 10/12/2010	P/22/2011
Tesamorelin	Theratechnologies Inc	Endocrinology-gynaecology-fertility-metabolism	W EMEA-001029-PIP01-10	• 13/10/2010 • 10/12/2010	P/23/2011
Sotrastaurin acetate	Novartis Europharm Ltd	Immunology-rheumatology-transplantation	P EMEA-000093-PIP02-10	• 13/10/2010 • 10/12/2010	P/24/2011
Briakinumab	Abbott Laboratories Ltd.	Dermatology	PM EMEA-000552-PIP01-09-M01	• 13/10/2010 • 10/12/2010	P/25/2011
Meropenem	NeoMero Consortium	Infectious diseases	P EMEA-000898-PIP01-10	• 10/06/2010 • 10/12/2010	P/26/2011

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion*	PDCO • Start date • Opinion (R) Re-examination	EMA Decision
Rizatriptan (Maxalt and associated names)	Merck Sharp & Dohme (Europe) Inc.	Pain	P EMEA-000084-PIP02-10	• 10/06/2010 • 10/12/2010	P/27/2011
Pegloticase	Savient Pharmaceuticals, Inc.	Immunology-rheumatology-transplantation Oncology	P EMEA-000293-PIP02-10	• 20/05/2010 • 10/12/2010	P/28/2011
Oseltamivir (phosphate) (Tamiflu)	Roche Registration Ltd	Infectious diseases	PM EMEA-000365-PIP01-08-M02	• 13/10/2010 • 10/12/2010	P/29/2011
Ticagrelor	AstraZeneca AB	Cardiovascular diseases	PM EMEA-000480-PIP01-08-M01	• 13/10/2010 • 10/12/2010	P/30/2011
Amikacin (sulfate)	Transave, Inc.	Cardiovascular diseases	P EMEA-000525-PIP01-08	• 10/06/2010 • 10/12/2010	P/31/2011
C1 inhibitor	ViroPharma SPRL	Immunology-rheumatology-transplantation	PM EMEA-000568-PIP01-09-M02	• 18/11/2010 • 10/12/2010	P/32/2011
(2S,3R,4R,5S,6R)-2-(4-Chloro-3-{3-[(S)-(tetrahydrofuran-3-yl)oxy]-benzyl}-phenyl)-6-hydroxymethyltetrahydro-pyran-3,4,5-triol (BI 10773)	Boehringer Ingelheim International GmbH	Endocrinology-gynecology-fertility-metabolism	P EMEA-000828-PIP01-09	• 15/04/2010 • 10/12/2010	P/33/2011
House dust mites allergen extract from Dermatophagoides pteronyssinus and Dermatophagoides farinae (50/50)	Stallergenes S.A.	Pneumology-allergology	P EMEA-000977-PIP01-10	• 15/07/2010 • 10/12/2010	P/34/2011
Ozenoxacin	Ferrer Internacional, S.A	Infectious diseases	P EMA-000981-PIP01-10	• 20/05/2010 • 10/12/2010	P/35/2011
Recombinant human granulocyte colony stimulating factor / recombinant human albumin fusion protein	Teva Pharmaceuticals Europe B.V	Oncology	RW EMEA-001042-PIP01-10	• 13/10/2010 • 10/12/2010	P/36/2011
Clopidogrel (Plavix)	Sanofi Pharma Bristol-Myers Squibb SNC	Cardiovascular diseases	C EMEA-000049-PIP01-07-M03	• 18/11/2010 • 10/12/2010	N/A
Clindamycin phosphate / tretinoin	MEDA Pharma GmbH & Co. KG	Dermatology	C EMEA-000892-PIP01-10	• 13/10/2010 • 10/12/2010	N/A

Annex 15 – Guidelines and working documents in 2010

Committee for Medicinal Products for Human Use (CHMP)

Working Party/Group	Total number of adopted guidelines/ documents for which working party/group is responsible	Number of concept papers/ guidelines/ documents initiated during 2010	Number of concept papers/ guidelines/ documents in progress during 2010	Number of guidelines/ documents adopted during 2010
CHMP Biologics Working Party	68	4	13	6
CHMP Blood Products Working Party	26	4	9	3
CHMP Efficacy Working Party	18	0	10	9
CHMP Gene Therapy Working Party	2	2	5	2
CHMP Pharmacogenomics Working Party	10	4	4	0
CHMP Pharmacovigilance Working Party	31	3	5	4
CHMP Safety Working Party	44	0	8	4
CHMP Similar Biological (Biosimilar) Medicinal Products Working Party	19	9	5	4
CHMP Vaccine Working Party	13	0	1	1
CHMP Working Party on Cell-based Products	3	5	3	2
CHMP Invented Name Review Group	1	1	1	0
EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)	14	5	3	3
EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)	3	2	0	0
CHMP Ad-Hoc SmPC Group	1	0	0	0

Working Party/Group	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest
CHMP Biologics Working Party	• Quality aspects relating to development of biosimilar medicinal products
CHMP Blood Products Working Party	• Clinical investigation of human normal immunoglobulin for intravenous administration
CHMP Gene Therapy Working Party	• Quality, preclinical and clinical aspects of gene transfer medicinal products • Application of the risk-based approach for advanced therapy medicinal products • Quality, pre-clinical and clinical issues relating to recombinant adeno-associated viral vectors
CHMP Pharmacovigilance Working Party	• ICH-E2C(R) Guideline on Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs – Concept Paper • Guide on the interpretation of case reports of suspected adverse reactions to medicines
CHMP Safety Working Party	• Conduct of single and repeated dose toxicity studies of active substances intended for human use • Non-clinical evaluation of drug-induced liver injury
CHMP Vaccine Working Party	• Quality, non-clinical and clinical aspects of live recombinant vectored vaccines

Working Party/Group	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest
CHMP Working Party on Cell-based Products	• Stem cell-based medicinal products • Risk-based approach for advanced therapy medicinal products
CHMP Invented Name Review Group	• NRG Position Paper - Re-use of invented names of medicinal products - in progress • Overview of nationally approved names for on (radio) diagnostics - initiated
EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)	• Reflection paper on the further involvement of patients and consumers in the agency's activities (EMA/10723/2009) • Report from experience acquired from pilot phase participation of patients/consumers representatives in PHVWP and proposal for participation of patients'/consumers' representatives as observer to the PHVWP (EMA/355206/2009) • Framework on the interaction between the EMEA and patients' and consumers' organisations (EMEA/354515/2005-Final) • Third report on the progress of the interaction with Patients' and Consumers' Organisations involved in EMA activities during 2009 (EMA/MB/117170/2010) • Rules of Involvement of Members of Patients' / Consumers' and Healthcare Professionals' Organisations in Committees related activities (EMEA/483439/2008 rev. 1) • Procedure for review of information on medicinal products by patients and consumers (EMA/174255/2010 Rev. 2) • Information on benefit-risk of medicines: patients', consumers' and healthcare professionals' expectations (EMEA/40926/2009) • Criteria to be fulfilled by patients' and consumers' organisations involved in the European Medicines Agency activities (EMEA/14610/04/Final)
EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)	• HCP WG: Final Recommendations and Proposals for Action (EMEA/185036/2008) • Information on benefit-risk of medicines: patients', consumers' and healthcare professionals' expectations (EMEA/40926/2009) • Rules of Involvement of Members of Patients' / Consumers' and Healthcare Professionals' Organisations in Committees related activities (EMEA/483439/2008 rev. 1) • Framework of interaction between the European Medicines Agency and healthcare professionals (EMA/688885/2010) – in progress • Criteria to be fulfilled by healthcare professionals' organisations involved in the European Medicines Agency activities (EMEA/14610/04/Final) – in progress
CHMP Ad-Hoc SmPC Group	• Revision 2 of the guideline on Summary of Product Characteristics (SmPC) for adoption by the European Commission

Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/EWP/62867/2009	Concept Paper on proposed revision to the guideline for the conduct of efficacy studies for NSAIDs	Adopted for consultation, May 2010 (End of consultation 31 August 2010)
EMA/CVMP/330382/2007-Rev.2	Guideline on the conduct of bioequivalence studies for veterinary medicinal products	Adopted for 2nd consultation, July 2010 (End of consultation 31 October 2010
EMA/CVMP/EWP/459868/2008-CONSULTATION	Guideline on demonstration of target animal safety and efficacy of veterinary medicinal products intended for use in farmed finfish	Consultation period extended, July 2010 (End of consultation 31 October 2010)
EMA/CVMP/EWP/81976/2010	Guideline on statistical principles for veterinary clinical trials	Adopted for consultation, September 2010 (End of consultation 31 March

Reference number	Document title	Status
		2011)
EMA/CVMP/EWP/87114/2010	Concept paper for the revision of the guideline on the Conduct of efficacy studies for intramammary products for use in cattle	Adopted for consultation, September 2010 (End of consultation 31 December 2010)
EMA/CVMP/EWP/62867/2009	Concept paper for the revision to the Guideline for the conduct of efficacy studies for NSAIDs	Adopted for consultation, May 2010 (End of consultation extended until 30 November 2010)
EMA/CVMP/EWP/81987/2010	Concept paper for a guideline on the demonstration of palatability of veterinary medicinal products	Adopted for consultation, November 2010 (End of consultation extended until 28 February 2011)
EMA/CVMP/EWP/459883/2009	Guideline on veterinary medicinal products controlling *Varroa destructor parasitosis* in bees	Adopted, November 2010

CVMP Environmental Risk Assessment (ERA)

Reference number	Document title	Status
EMA/CVMP/ERA/430327/2009-CONSULTATION	Guideline on degradation of veterinary medicinal products in manure	Adopted for consultation, February 2010 (End of consultation, 31 August 2010)
EMA/CVMP/ERAWP/389867/2010	Concept paper on assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicine	Adopted for consultation, July 2010 (End of consultation 1 September 2010
EMEA/CVMP/ERA/172074/2008-Rev.2	Questions and Answers (Q&A) document on the implementation of CVMP guideline on Environmental Impact Assessment for veterinary medicinal products in support of the VICH guidelines GL6 (PHASE I) and GL38 (PHASE II)	Adopted, July 2010

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/58879/2010	Reflection paper on data requirements for swine influenza vaccines against pandemic (H1N1) 2009 influenza	Adopted, February 2010
EMA/CVMP/IWP/105506/2007	Guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD)	Adopted, March 2010
EMA/CVMP/IWP/43283/2010	Recommendation on the submission of multi-strain dossier applications for vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD)	Adopted, March 2010
EMA/CVMP/IWP/250147/2008	Guideline on data requirements to support in-use stability claims for veterinary vaccines	Adopted, March 2010
EMA/CVMP/IWP/582970/2009	Reflection paper on control of the active substance in the finished product for immunological veterinary medicinal	Adopted, March 2010

Reference number	Document title	Status
	products (IVMPs)	
EMA/CVMP/IWP/439467/2007	Reflection paper on the demonstration of a possible impact of maternally derived antibodies on vaccine efficacy in young animals	Adopted, March 2010
EMA/CVMP/IWP/123243/2006-Rev.2	Guideline on data requirements for immunological veterinary medicinal products intended for Minor Use or Minor Species/ Limited markets	Adopted, April 2010
EMA/CVMP/IWP/596708/2010	Public statement on the number of tests required to control for complete inactivation in inactivated vaccines	Adopted, November 2010

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/729768/2009	Veterinary Pharmacovigilance 2009 Public Bulletin	Adopted, February 2010
EMA/CVMP/PhVWP/471721/2006	Recommendation for the basic surveillance of Eudravigilance Veterinary data	Adopted for consultation, May 2010 (End of consultation, 30 November 2010)
EMA/CVMP/10418/2009-Rev.2	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted, July 2010
EMA/CVMP/553/03-Rev.5	List of species and breeds for electronic reporting of suspected adverse reactions in veterinary pharmacovigilance	Adopted, July 2010
EMA/CVMP/PhVWP/288284/2007-Rev.3	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted, July 2010
EMA/123352/2004-Rev.5	Revised call for comments on standard lists for EudraVigilance Veterinary	Adopted, July 2010
EMA/CVMP/VICH/647/2001	VICH GL30: Guideline on controlled list of terms	Adopted, September 2010
EMA/CVMP/VICH/123940/2006	VICH GL35: Guideline on pharmacovigilance of veterinary medicinal products: electronic standards for transfer of data	Adopted, September 2010 (End of consultation, 15 March 2011)
EMA/CVMP/VICH/355996/2005	VICH GL42: Data elements for submission of adverse event reports	Adopted, Sptember 2010

Joint CHMP/CVMP Quality

Reference number	Document title	Status
EMA/CHMP/CVMP/QWP/809114/ 2009	Concept paper on the revision of the guideline on process validation	Adopted for consultation, January 2010 (End of consultation, April 2010)
EMA/63033/2010	Concept Paper on the need for revision of the guideline on stability testing for applications for variations to a marketing authorisation	Adopted for consultation, February 2010 (End of consultation, 30 April 2010)
EMEA/CHMP/CVMP/QWP/80386/	Questions and Answers concerning	Adopted, February 2010

Reference number	Document title	Status
2010	stability issues of pharmaceutical bulk products used in the manufacture of drug products	
EMA/CVMP/VICH/502/1999-Rev.1	VICH GL 18 residual solvents in new veterinary medicinal products, active substances and excipients	Adopted for consultation, May 2010 (End of consultation 31 October 2010)
EMA/CVMP/VICH/581467/2007	VICH GL 45 quality: bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products	Adopted, May 2010
EMA/CHMP/CVMP/QWP/300039/ 2010	Question and Answer document on GMP compliance documentation that should be submitted in case of sterilisation of an active substance	Adopted, June 2010
EMA/CHMP/CVMP/QWP/199250/ 2009	Guideline on setting specifications for related impurities in antibiotics	Adopted for consultation, July 2010 (End of consultation 31 January 2011)
EMA/CVMP/QWP/565528/2010	Question and Answer document on the microbiological quality of veterinary premixes containing excipients of natural origin	Adopted, October 2010
EMA/CVMP/QWP/565529/2010	Question and Answer document on rubber stopper testing	Adopted, October 2010
EMA/CVMP/QWP/574579/2010	Question and Answer document on veterinary powders for use in drinking water	Adopted, October 2010
EMA/CVMP/QWP/565531/2010	Question and Answer document which clarifies the regulatory issues concerning whether or not it is permitted to authorise a multi-dose (parenteral) veterinary medicinal product for use both as an intramuscular injection and also an intramammary preparation	Adopted, October 2010
EMA/CHMP/CVMP/QWP/586330/2010	Question and Answers document on post-approval change management protocols	Adopted, October 2010
EMA/CHMP/CVMP/QWP/586385/2010	Question and Answer document on Variation B.II.b.4 (change of batch size of the finished product)	Adopted, October 2010
QP Declaration template	Template for the Qualified Person's declaration concerning GMP compliance of the active substance used as a starting material, and verification of its supply chain	

CVMP Safety

Reference number	Document title	Status
EMA/CVMP/SWP/543/03-Rev.1	Guideline on user safety for pharmaceutical veterinary medicinal products	Adopted, March 2010
EMA/CVMP/516817/2009	Guideline on data to be provided in support of a request to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009	Adopted, November 2010

EMA/CVMP/SWP/736014/2010	Concept paper on revision of the note for guidance for the determination of withdrawal periods for Milk	Adopted for conusltation, December 2010 (End of consultation 31 March 2011)

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMA/CVMP/SAGAM/736964/2009	Reflection paper on meticillin-resistant *Staphylococcus pseudintermedius*	Adopted for consultation, September 2010 (End of consultation 30 November 2010)
EMEA/CVMP/SAGAM/741087/2009	Reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation, November 2010 (End of consultation 28 February 2011)
EMA/CVMP/287420/2010	CVMP Strategy on Antimicrobials 2011-2015	Adopted for consultation, December 2010 (End of consultation 28 February 2011)

General

Reference number	Document title	Status
SOP/EMA/85634/2006-Rev.1	Standard Operating Procedure (SOP) on Evaluation procedure for applications and requests for the establishment of Maximum Residue Limits (MRLs) under Articles 3, 9, 10 and 15 of Regulation (EC) 470/2009	Adopted, February 2010
EMA/CVMP/38660/2010	Analysis of the functioning of the current veterinary legislation and proposals for its evolution to provide clarification on its views and additional areas for consideration by the European Commission	Adopted, July 2010
EMA/CVMP/VICH/463/02	VICH GL34 on mycoplasma contamination	Consultation re-opened, December 2010 (End of consultation 31 March 2011)

Committee for Orphan Medicinal Products (COMP)

Scientific Committee	Total number of adopted guidelines/ documents for which committee is responsible	Number of concept papers/ guidelines/ documents initiated in 2010	Number of concept papers/ guidelines/ documents in progress during 2010	Number of guidelines/ documents adopted in 2010
Committee for Orphan Medicinal Products	0	1	1	0

Scientific Committee	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest
Committee for Orphan Medicinal Products	• Impact and relevance of biomarkers for the designation and evaluation of orphan drugs

*Committee on Herbal Medicinal Products (HMPC) **

Reference number	Document title	Status
EMA/HMPC/85114/2008	Reflection paper on ethanol content in herbal medicinal products and traditional herbal medicinal products used in children	Adopted January 2010
EMA/HMPC/121934/2010	HMPC statement on environmental risk assessment of herbal medicinal products	Adopted March 2010
EMA/HMPC/5829/2010	Glossary on herbal teas	Adopted March 2010 Rev.1 adopted July 2010
EMA/HMPC/833398/2009	Reflection paper on the necessity of initiatives to stimulate the conduct of clinical studies with herbal medicinal products in the paediatric population	Released for public consultation November 2010

* Including documents prepared by the HMPC Working Party on Community monographs and Community list (MLWP)

HMPC Quality Drafting Group

Reference number	Document title	Status
EMA/HMPC/CHMP/CVMP/287539/2005 Rev.1	Revised Guideline on declaration of herbal substances and preparations in herbal medicinal products/traditional herbal medicinal products	Adopted March 2010
EMA/HMPC/3626/2009	Reflection paper on stability testing of herbal medicinal products and traditional herbal medicinal products	Adopted March 2010
EMA/HMPC/186645/2008	Reflection paper on level of purification of extracts to be considered as herbal preparations	Adopted September 2010
EMA/HMPC/41500/2010	Questions & answers on quality of herbal medicinal products	Adopted September 2010

HMPC Organisational Matters Drafting Group

Reference number	Document title	Status
EMA/HMPC/84530/2010	Procedure on the publication of HMPC public statements when Community herbal monographs on herbal substances, preparations and/or combinations thereof are not established	Adopted for release for public consultation July 2010
EMA/HMPC/75972/2010	Template for a public statement when no Community herbal monograph is established	Adopted for release for public consultation July 2010
EMA/HMPC/107436/2005 Rev. 5	Revised Template for a Community herbal monograph	Adopted July 2010
EMA/HMPC/439705/2006 Rev. 4	Revised Template for a Community list entry	Adopted July 2010
EMA/HMPC/126542/2005 Rev. 2	Revised Timelines for the establishment of a Community herbal monograph and/or a Community list entry	Adopted July 2010
EMA/HMPC/326440/2007 Rev.1	Revised Reflection paper on the reasons and timelines for revision of final Community herbal monographs and Community list entries	Adopted July 2010

Committee for Advanced Therapies (CAT)

Scientific Committee	Total number of adopted guidelines/ documents for which committee is responsible	Number of concept papers/ guidelines/ documents initiated in 2009	Number of concept papers/ guidelines/ documents in progress during 2009	Number of guidelines/ documents adopted in 2009
Committee for Advanced Therapies	3	-	-	3
CAT Cell-based Products Working Party	2	1	3	2
CAT Gene Therapy Working Party	2	2	1	3

Scientific Committee	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest
Committee for Advanced Therapies	• Public Statement on Concerns over unregulated medicinal products containing stem cells (EMA/763463/2009) - April 2010 • CHMP/CAT Position Statement on Creutzfeldt-Jacob disease and Advanced therapy medicinal products (EMA/CHMP/CAT/BWP/353632/2010) - June 2010
CAT Cell-based Products Working Party	• Draft Reflection paper on stem cell-based medicinal products (EMA/CAT/CPWP/571134/2009) • Reflection paper on in-vitro cultured chondrocyte containing products for cartilage repair of the knee (EMA/CAT/CPWP/288934/2009) - April 2010 • Concept paper to the Guideline on the risk-based approach according to annex I, part IV of directive 2001/83/EC applied to advanced therapy medicinal products (CHMP/CPWP/708420/09)

Scientific Committee	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest
CAT Gene Therapy Working Party	• Draft Guideline on the quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells (EMA/CHMP/GTWP/671639/2008) – May 2010 • Reflection paper on quality, non-clinical and clinical issues related to the development of recombinant adeno-associated viral vectors (rAAV) (EMA/CHMP/GTWP/587488/2007) – June 2010 • Reflection paper on changes during gene therapy medicinal product development EMA/CAT/GTWP/44236/2009

Annex 16 – Arbitration and Community referrals overview 2010

Referrals made to the CHMP

Procedures started

Type of referral	Date of CHMP start of procedure	International non-proprietary name (INN)
Article 5(3) procedure of Regulation (EC) No 726/2004	22/04/2010	live attenuated vaccines
Article 5(3) procedure of Regulation (EC) No 726/2004	24/06/2010	angiotensin II (type-1) receptor antagonists
Article 5(3) procedure of Regulation (EC) No 726/2004	16/12/2010	Baxter peritoneal dialysis solutions
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	25/03/2010	rotavirus vaccine, live
Article 20 procedure of Regulation (EC) No 726/2004	20/05/2010	rotavirus vaccine, live
Article 20 procedure of Regulation (EC) No 726/2004	24/06/2010	saquinavir
Article 20 procedure of Regulation (EC) No 726/2004	09/07/2010	rosiglitazone
Article 20 procedure of Regulation (EC) No 726/2004	09/07/2010	rosiglitazone/glimepiride
Article 20 procedure of Regulation (EC) No 726/2004	09/07/2010	rosiglitazone/metformin hydrochloride
Article 20 procedure of Regulation (EC) No 726/2004	27/08/2010	influenza vaccine (H1N1)v (split virion, inactivated, adjuvanted)
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	bevacizumab
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	zoledronic acid
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	zoledronic acid

Type of referral	Date of CHMP start of procedure	International non-proprietary name (INN)
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	alendronic acid/colecalciferol
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	alendronic acid/colecalciferol
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	alendronic acid/colecalciferol
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	ibandronic acid
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	ibandronic acid
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	ibandronic acid
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	ibandronic acid
Article 20 procedure of Regulation (EC) No 726/2004	16/12/2010	somatropin
Article 20 procedure of Regulation (EC) No 726/2004	16/12/2010	somatropin
Article 20 procedure of Regulation (EC) No 726/2004	16/12/2010	somatropin
Article 29(4) of Directive 2001/83/EC	22/04/2010	galantamin
Article 29(4) of Directive 2001/83/EC	20/05/2010	risedronate sodium/calcium carbonate plus colecalciferol
Article 29(4) of Directive 2001/83/EC	20/05/2010	risedronate sodium/calcium carbonate plus colecalciferol
Article 29(4) of Directive 2001/83/EC	23/09/2010	isotretinoin
Article 29(4) of Directive 2001/83/EC	23/09/2010	docetaxel
Article 29(4) of Directive 2001/83/EC	16/12/2010	clotrimazole
Article 30 of Directive 2001/83/EC	18/02/2010	fluconazole
Article 30 of Directive 2001/83/EC	22/04/2010	cefuroxime axetil
Article 30 of Directive 2001/83/EC	22/04/2010	cefuroxime sodium
Article 30 of Directive 2001/83/EC	22/04/2010	calcipotriol monohydrate/ betamethasone dipropionate
Article 30 of Directive 2001/83/EC	24/06/2010	granisetron
Article 30 of Directive 2001/83/EC	22/07/2010	anastrozole
Article 30 of Directive 2001/83/EC	23/09/2010	letrozole
Article 30 of Directive 2001/83/EC	21/10/2010	levofloxacin
Article 31 of Directive 2001/83/EC	18/02/2010	nimesulide
Article 31 of Directive 2001/83/EC	18/03/2010	antifibrinolytics (aprotinin/aminocaproic acid/trenexamic acid)
Article 31 of Directive 2001/83/EC	22/07/2010	dexrazoxane
Article 31 of Directive 2001/83/EC	23/09/2010	alendronate, clodronate, etidronate, ibandronate, neridronate, pamidronate, risedronate, tiludronate, zoledronate
Article 31 of Directive 2001/83/EC	21/10/2010	human normal immunoglobulin

Type of referral	Date of CHMP start of procedure	International non-proprietary name (INN)
Article 31 of Directive 2001/83/EC	18/11/2010	terpenic derivatives containing suppositories
Article 107(2) of Directive 2001/83/EC	21/01/2010	bufexamac
Article 107(2) of Directive 2001/83/EC	23/09/2010	human normal immunoglobulin
Article 107(2) of Directive 2001/83/EC	16/12/2010	somatropin
Article 29 of Regulation (EC) No 1901/2006	22/04/2010	latanoprost

Procedures finalised

Type of referral	Date of CHMP opinion	International non-proprietary name (INN)
Article 5(3) procedure of Regulation (EC) No 726/2004	18/11/2010	live attenuated vaccines
Article 20 procedure of Regulation (EC) No 726/2004	21/01/2010	natalizumab
Article 20 procedure of Regulation (EC) No 726/2004	18/02/2010	bercaplermin
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	18/03/2010	clopidogrel
Article 20 procedure of Regulation (EC) No 726/2004	22/07/2010	rotavirus vaccine, live
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	rosiglitazone
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	rosiglitazone/glimepiride
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	rosiglitazone/metformin hydrochloride
Article 20 procedure of Regulation (EC) No 726/2004	23/09/2010	rotavirus vaccine, live
Article 20 procedure of Regulation (EC) No 726/2004	21/10/2010	saquinavir
Article 20 procedure of Regulation (EC) No 726/2004	16/12/2010	bevacizumab
Article 29(4) of Directive 2001/83/EC	18/02/2010	clopidrogrel

Type of referral	Date of CHMP opinion	International non-proprietary name (INN)
Article 29(4) of Directive 2001/83/EC	18/02/2010	clopidrogrel
Article 29(4) of Directive 2001/83/EC	18/03/2010	bendamustin hydrochloride
Article 29(4) of Directive 2001/83/EC	24/06/2010	risedronate sodium/calcium carbonate plus colecalciferol
Article 29(4) of Directive 2001/83/EC	24/06/2010	risedronate sodium/calcium carbonate plus colecalciferol
Article 29(4) of Directive 2001/83/EC	22/07/2010	morphine sulphate
Article 29(4) of Directive 2001/83/EC	23/09/2010	chlorhexidine diacetate
Article 29(4) of Directive 2001/83/EC	23/09/2010	galantamin
Article 29(4) of Directive 2001/83/EC	16/12/2010	isotretinoin
Article 30 of Directive 2001/83/EC	21/01/2010	omeprazole
Article 30 of Directive 2001/83/EC	18/02/2010	escitalopram
Article 30 of Directive 2001/83/EC	18/03/2010	candesartan cilexetil
Article 30 of Directive 2001/83/EC	22/04/2010	famciclovir
Article 30 of Directive 2001/83/EC	22/04/2010	valaciclovir
Article 30 of Directive 2001/83/EC	22/04/2010	cilazapril
Article 30 of Directive 2001/83/EC	24/06/2010	candesartan/hydrochlorothiazide
Article 30 of Directive 2001/83/EC	22/07/2010	calcipotriol monohydrate/ betamethasone dipropionate
Article 30 of Directive 2001/83/EC	23/09/2010	atorvastatin
Article 30 of Directive 2001/83/EC	21/10/2010	ceftazidime
Article 30 of Directive 2001/83/EC	21/10/2010	piperacillin/tazobactam
Article 30 of Directive 2001/83/EC	21/10/2010	cilazapril/hydrochlorothiazide
Article 30 of Directive 2001/83/EC	16/12/2010	imipenem/cilastatin
Article 31 of Directive 2001/83/EC	22/07/2010	modafinil
Article 31 of Directive 2001/83/EC	22/07/2010	morphine, oxycodone, fentanyl, hydromorphone
Article 31 of Directive 2001/83/EC	21/10/2010	fenofibrate, bezafibrate, ciprofibrate, gemfibrozil
Article 107(2) of Directive 2001/83/EC	21/01/2010	sibutramine hydrochloride monohydrate
Article 107(2) of Directive 2001/83/EC	22/04/2010	bufexamac
Article 107(2) of Directive 2001/83/EC	22/07/2010	ketoprofene
Article 107(2) of Directive 2001/83/EC	23/09/2010	human normal immunoglobulin
Article 6(12) of Commission Regulation (EC) No 1084/2003	24/06/2010	somatropin
Article 6(13) Of Commission Regulation (EC) No 1084/2003	22/04/2010	quetiapine
Article 29 of Regulation (EC) No 1901/2006	18/03/2010	atorvastatin calcium
Article 29 of Regulation (EC) No 1901/2006	18/03/2010	atorvastatin calcium

Type of referral	Date of CHMP opinion	International non-proprietary name (INN)
Article 29 of Regulation (EC) No 1901/2006	18/03/2010	atorvastatin calcium
Article 29 of Regulation (EC) No 1901/2006	22/07/2010	latanoprost

Referrals made to the CVMP

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
Referral under Art. 35 of Directive 2001/82/EC	• 11/02/2009 • 10/02/2010	• All strengths of water soluble powders and oral solutions containing doxycycline hyclate • Doxycycline hyclate
Referral under Art. 35 of Directive 2001/82/EC	• 16/04/2009 • 10/02/2010	• Veterinary medicinal formulations containing colistin at 2 MIU/ml and intended for administration in drinking water to any food producing species • Colistin sulfate
Referral under Art. 35 of Directive 2001/82/EC	• 13/05/2009 • 10/03/2010 (after re-examination)	• Veterinary medicinal products containing quinolones or fluoroquinolones for all food-producing species • Quinolones / fluoroquinolones
Referral under Art. 33(4) of Directive 2001/82/EC	• 12/11/2008 • 11/11/2009 (after re-examination)	• Tildren 500 mg • Tiludronic acid (as disodium salt)
Referral under Art. 6(12) of Regulation (EC) No 1084/2003	• 14/10/2009 • 19/05/2010	• Porcilis PRRS • Live attenuated PRRS virus strain DV
Referral under Art. 6(12) of Regulation (EC) No 1084/2003	• 14/10/2009 • 19/05/2010	• Porcilis M Hyo • Inactivated whole cell concentrate of Mycoplasma hyopneumoniae strain 11
Referral under Art. 34 of Directive 2001/82/EC	• 11/11/2009	• Fortekor vet and associated names • Benazepril hydrochloride
Referral under Art. 34 of Directive 2001/82/EC	• 15/10/2008 • 10/03/2010	• Tiamutin premix • Tiamulin fumarate
Referral under Art. 34 of Directive 2001/82/EC	• 14/04/2010	• Synulox Lactating Cow and associated names • Amoxicillin, clavulanic acid, prednisolone
Procedure under Art. 78 of Directive 2001/82/EC	• 19/05/2010 • 14/07/2010	• Pregsure BVD and associated names • Inactivated Bovine Viral Diarrhoea (BVD) type 1 virus
Procedure under Art. 30(3) of Regulation 726/2004	• 19/05/2010 • 15/09/2010	• Retrovirus RD114 in relation to live attenuated vaccines for use in dogs and cats • N/a
Procedure under Art. 45 of Regulation (EC) No 726/2004	• 16/06/2010 • 14/07/2010	• Suvaxyn PCV • Inactivated recombinant Porcine Circovirus type 1 expressing the Porcine Circovirus type 2 ORF2 protein
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010	• Combimox Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010	• Nisamox Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010	• Combisyn Lactating Cow • Amoxicillin, clavulanic acid, prednisolone

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
Referral under Art. 34 of Directive 2001/82/EC	• 14/07/2010	• Doxycycline 50% WSP and associated names • Doxycycline hyclate
Referral under Art. 34 of Directive 2001/82/EC	• 14/07/2010	• Doxyfar 50% WSP and associated names • Doxycycline hyclate
Procedure under Art. 45 of Regulation (EC) No 726/2004	• 13/07/2010 • 14/07/2010	• Flexicam 1.5 mg/ml Suspension for Dogs • Meloxicam
Procedure under Art. 45 of Regulation (EC) No 726/2004	• 14/09/2010 • 15/09/2010	• Acticam 1.5 mg/ml Oral Suspension for Dogs • Meloxicam
Referral under Art. 34 of Directive 2001/82/EC	• 09/11/2010	• Baytril 10% oral solution and associated names • Enrofloxacin

Annex 17 – Publications by EMA staff members and experts in 2010

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Paediatric investigation plans for pain: painfully slow! European Journal of Clinical Pharmacology 2010 Nov;66(11):1091-7

Dieterle F. et al.:
Renal biomarker qualification submission: a dialog between the FDA-EMEA and Predictive Safety Testing Consortium. Nature Biotechnology 28, 455–462, (2010)

Eichler HG., Aronsson B., Abadie E., Salmonson T.:
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Eichler HG., Bloechl-Daum B., Abadie E., Barnett D., König F., Pearson S.:
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Factors associated with success of market authorisation applications for pharmaceutical drugs submitted to the European Medicines Agency. Eur J Clin Pharmacol. 2010 Jan;66(1):39-48

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Silva-Lima B., Due Theilade-Thomsen M., Carleer J., Vidal JM., Tomasi P., Saint-Raymond A.:
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Sistare FD. et al.:
Towards consensus practices to qualify safety biomarkers for use in early drug development. Nature Biotechnology 28, 446–454, (2010)

Spina A.:
European networks in the regulation of biotechnologies. European Law Review (2010) 35(2), 197-213

Stoyanova-Beninska VV., Wohlfarth T,. Isaac M., Kalverdijk LJ., van den Berg H., Gispen-de Wied C.:
The EU paediatric regulation. Effects on paediatric psychopharmacology in Europe. Journal of European College of Neuropsychopharmacology 2010 Jul 9

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Vidal JM., Kawabata TT, Thorpe R., Silva-Lima B., Cederbrant K., Poole S., Mueller-Berghaus J., Pallardy M., van der Laan JW.:
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Annex 18 – Agency contact points

Pharmacovigilance and product quality defect reporting

The constant monitoring of the safety of medicines after authorisation ('pharmacovigilance') is an important part of the work of the national competent authorities and the European Medicines Agency. The Agency receives safety reports and product quality defect reports from within the EU and outside concerning centrally authorised medicinal products and coordinates action relating to the safety and quality of medicinal products.

For matters relating to pharmacovigilance for medicinal products for human use

Peter ARLETT
Direct telephone: +44 (0)20 7523 7108
E-mail: pharmacovigilance@ema.europa.eu

For matters relating to pharmacovigilance for medicinal products for veterinary use

Jos OLAERTS
Direct telephone: +44 (0)20 7418 8624
E-mail: vet-phv@ema.europa.eu

For product quality defects and recalls see: www.ema.europa.eu/inspections/defectinstruction.html

For instructions and contact points

E-mail: qdefect@ema.europa.eu
Direct telephone: +44 (0)20 7523 7676 (for use only as stated in the relevant instructions)
Fax: +44 (0)20 7418 8590
Out of hours telephone: +44 (0)7880 550 697

SME Office

The SME office has been set up within the Agency to address the particular needs of smaller companies. The office aims to facilitate communication with SMEs through dedicated personnel within the Agency who will respond to practical or procedural enquiries, monitor applications, and organise workshops and training sessions for SMEs.

SME office contact point:

Melanie CARR
Direct telephone: +44 (0)20 7418 8575/8463
Fax: +44 (0)20 7523 7040
E-mail: smeoffice@ema.europa.eu

Certificates of a medicinal product

The EMA issues certificates of a medicinal product in conformity with the arrangements laid down bythe World Health Organisation. These certify the marketing authorisation and good manufacturing status of medicinal products in the EU and are intended for use in support of marketing authorisation applications in and export to non-EU countries.

For enquiries concerning certificates for centrally authorised medicines for human or veterinary use

E-mail: certificate@ema.europa.eu
Direct telephone: +44 (0)20 7523 7107
Fax: +44 (0)20 7418 8595

PMF/VAMF EMA certificates

The Agency issues plasma master file (PMF) and vaccine antigen master file (VAMF) certificates of a medicinal product in conformity with the arrangements laid down by Community legislation. The Agency PMF/VAMF certification process is an assessment of the PMF/VAMF application dossier. The certificate of compliance is valid throughout the European Community.

For enquiries concerning PMF certificates

Silvia DOMINGO ROIGÉ
Direct telephone: +44 (0)20 7418 8552
Fax: +44 (0)20 7418 8545
E-mail: PMF@ema.europa.eu

For enquiries concerning VAMF certificates

Ragini SHIVJI
Direct telephone: +44 (0)20 7418 8698
Fax: +44 (0)20 7418 8545
E-mail: VAMF@ema.europa.eu

Documentation services

A wide range of documents are published by the Agency, including press releases, general information documents, annual reports and work programmes.

These and other documents are available:

- on the Internet at www.ema.europa.eu
- by email request to info@ema.europa.eu
- by fax to +44 (0)20 7418 8670
- by writing to:

  EMA Documentation service
  European Medicines Agency
  7 Westferry Circus
  Canary Wharf
  London E14 4HB, UK

European experts list

Over 4 000 experts are used by the Agency in its scientific evaluation work. The list of these European experts is available for examination on request at the Agency's offices.

Requests should be sent in writing to the European Medicines Agency or to

E-mail: europeanexperts@ema.europa.eu

Press office

For press enquiries please contact:

Martin HARVEY ALLCHURCH, Monika BENSTETTER or Sabine HAUBENREISSER
Telephone (44-20) 74 18 84 27
E-mail: press@ema.europa.eu