



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 June 2011
EMA/457721/2011
Office of the Executive Director

Annexes of the annual report 2010

The main body of this report is available on the Agency's website [here](#).



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Annex 1 – Members of the Management Board

Chair: Pat O'MAHONY

EMA contact: Nerimantas Steikunas

Members

European Parliament	Guiseppa NISTICÓ, Björn LEMMER (<i>Substitute: Jozef HOLOMÁN</i>)
European Commission	Paola TESTORI COGGI ¹ , Pedro ORTUN SILVAN ² (<i>Alternates: Andzej RYS³, Giulia del BRENNIA⁴</i>)
Belgium	Xavier DE CUYPER (<i>Alternate: Greet MUSCH⁵</i>)
Bulgaria	Jasmina MIRCHEVA (<i>Alternate: Alexander YANKOV⁶</i>)
Czech Republic	Jiří DEML ⁷ (<i>Alternate: Jiří BUREŠ</i>)
Denmark	Jytte LYNGVIG (<i>Alternate: Dorthe EBERHRDT SØNDERGAARD⁸</i>)
Germany	Walter SCHWERDTFEGER (<i>Alternate: Hans-Peter HOFMANN</i>)
Estonia	Kristin RAUDSEPP (<i>Alternate: Alar IRS</i>)
Ireland	Pat O'MAHONY (<i>Alternate: Rita PURCELL</i>)
Greece	Ioannis TOUNTAS ⁹ (<i>Alternate: Maria SKOUROLIAKOU¹⁰</i>)
Spain	Belén CRESPO SÁNCHEZ-EZNARRIAGA ¹¹ (<i>Alternate: Laura Franqueza GARCÍA</i>)
France	Jean MARIMBERT (<i>Alternate: Marc MORTUREUX</i>)
Italy	Guido RASI (<i>Alternate: Silvia FABIANI</i>)
Cyprus	Panayiota KOKKINOY (<i>Alternate: George ANTONIOU</i>)
Latvia	Inguna ADOVICA (<i>Alternate: Dace ŽIKUTE</i>)
Lithuania	Gintautas BARCYS ¹² (<i>Alternate: Jonas MILIUS</i>)
Luxembourg	Claude A HEMMER ¹³ (<i>Alternate: Mariette BACKES-LIES¹⁴</i>)
Hungary	Tamás L PAÁL (<i>Alternate: Beatrix HORVÁTH</i>)
Malta	Patricia VELLA BONANNO (<i>Alternate: Gavril FLORES¹⁵</i>)

1 Replaced Heinz ZOUREK as of the December 2010 meeting

2 Replaced Isabel de la MATA as of December 2010 meeting

3 Replaced Georgette LALIS as of December 2010 meeting

4 Replaced Bernard MERKEL as of December 2010 meeting

5 Replaced André LHOIR as of June 2010 meeting

6 Replaced Meri Borislavova Peytcheva as of March 2010 meeting

7 Replaced Lenka Balážová as of October 2010 meeting

8 Replaced Paul SCHÜDER as of March 2010 meeting

9 Joined the Board as of June 2010 meeting

10 Replaced Dimitra Patargia as of June 2010 meeting

11 Replaced Cristina Avendaño-Solà as of December 2010 meeting

12 Replaced Mindaugas BŪTA as of March 2010 meeting

13 Replaced Mariette BACKES-LIES as of June 2010 meeting

14 Replaced Claude A HEMMER as of June 2010 meeting

15 Replaced Kenneth MIFSUD as of June 2010 meeting

Netherlands	Aginus A W KALIS (<i>Alternate: Rob DE HAAN</i>)
Austria	Marcus MÜLLNER (<i>Alternate: Christian KALCHER</i>)
Poland	Grzegorz CESSAK ¹⁶ (<i>Alternate: Artur FALLEK¹⁷</i>)
Portugal	Jorge TORGAL ¹⁸ (<i>Alternate: Miguel OLIVEIRA CARDO¹⁹</i>)
Romania	Daniel Boda (<i>Alternate: Rodica BADESCU</i>)
Slovenia	Martina CVELBAR (<i>Alternate: Vesna KOBLAR</i>)
Slovakia	Ján MAZÁG (<i>Alternate: Dagmar STARÁ</i>)
Finland	Sinikka RAJANIEMI (<i>Alternate: Pekka JÄRVINEN</i>)
Sweden	Christina ÅKERMAN (<i>Alternate: Johan LINDBERG</i>)
United Kingdom	Kent WOODS (<i>Alternate: Steve DEAN</i>)
Representatives of patients' organisations	Mary BAKER, Mike O'DONOVAN
Representative of doctors' organisations	Lisette TIDDENS-ENGWIRDA
Representative of veterinarians' organisations	Henk VAARKAMP

Observers

Iceland	Einar MAGNÚSSON ²⁰ (<i>Alternate: Rannveig GUNNARSDÓTTIR²¹</i>)
Liechtenstein	Brigitte BATLINER (<i>Alternate: Sabine ERNE</i>)
Norway	Gro Ramsten WESENBERG (<i>Alternate: Ivar VOLLSET²²</i>)

16 Replaced Wojceich Matusevicz as of October 2010 meeting

17 Replaced Grzegorz CESSAK as of October 2010 meeting who replaced Jacek SPLAWINSKI as of March 2010 meeting

18 Replaced Vasco A J MARIA as of June 2010 meeting

19 Replaced Fernando d'ALMEIDA BERNARDO as of October 2010 meeting

20 Replaced Rannveig GUNNARSDÓTTIR as of June 2010 meeting

21 Replaced Ingolf J PETERSEN as of June 2010 meeting

22 Replaced Hans HALSE as of June 2010 meeting

Annex 2 – Members of the Committee for Medicinal Products for Human Use

Chair: Eric ABADIE

EMA contact: Anthony HUMPHREYS

Members

- George AISLAITNER (Greece) *Alternate: Catherine MORAITI*
- John Joseph BORG (Malta) *Alternate: Patricia VELLA BONANNO*
- Gonzalo CALVO ROJAS (Spain) *Alternate: Concepcion PRIETO YERRO*
- Pierre DEMOLIS (France) *Alternate: Philippe LECHAT*
- Harald ENZMANN (Germany) *Alternate: Martina Weise*
- Piotr FIEDOR (Poland)²³ *Alternate: Kinga BOROWICZ²⁴*
- Jacqueline GENOUX-HAMES (Luxembourg) *Alternate: Carine DE BEAUFORT²⁵*
- Agnes GYURASICS (Hungary)²⁶ *Alternate: János BORVENDÉG²⁷*
- Jens HEISTERBERG²⁸(Denmark) *Alternate: Jens ERSBØLL²⁹*
- Ian HUDSON (United Kingdom) *Alternate: Rafe SUVARNA*
- Arthur ISSEYEGH (Cyprus) *Alternate: Emilia MAVROKORDATOU³⁰*
- Alar IRS (Estonia) *Alternate: Irja LUTSAR*
- Jaana KALLIO (Finland) *Alternate: Kristiina AIROLA*
- Andrea LASLOP (Austria) *Alternate: Milena STAIN³¹*
- Metoda LIPNIK-STANGELJ (Slovenia) *Alternate: Nevenka TRSINAR*
- David LYONS (Ireland) *Alternate: Patrick SALMON*
- Romaldas MAČIULAITIS (Lithuania) *Alternate: Rugile PILVINIENE*
- Ján MAZÁG (Slovakia) *Alternate: Vlasta Kákošová³²*
- Daniela MELCHIORRI³³(Italy) *Alternate: Luca PANI³⁴*
- Pieter NEELS (Belgium) *Alternate: Jean-François BAURAIN*
- Sif ORMARSDÓTTIR (Iceland) *Alternate: Kolbeinn GUDMUNDSSON*

23 Replaced Michał PIROŻYŃSKI as per June meeting

24 Replaced Piotr SIEDLECKI as per June meeting

25 New CHMP alternate from Luxembourg as per September meeting

26 Replaced János Borvendeg as per June meeting

27 Replaced Agnes Gyurasics as per June meeting

28 Replaced Jens Ersbøll as per September meeting

29 Replaced Jens HEISTERBERG as per September meeting who in turn replaced Mark AINSWORTH as per April meeting who in turn replaced Jens Ersbøll as per January meeting

30 Replaced Panayiota Kokkinou as per May meeting

31 Replaced Hans WINKLER as per February meeting

32 New CHMP alternate from Slovakia as per July meeting

33 Replaced Giuseppe Nisticò as per May meeting

34 Replaced Daniela MELCHIORRI as per May meeting

- Juris POKROTNIEKS (Latvia) *Alternate: Natalja KARPOVA*
- Tomas SALMONSON (Sweden) (*vice-chair*) *Alternate: Kristina DUNDER* ³⁵
- Beatriz SILVA LIMA (Portugal) *Alternate: Cristina SAMPAIO*
- Eva SKOVLUND (Norway) *Alternate: Karsten BRUINS SLOT*³⁶
- Ondřej SLANAŘ (Czech Republic)³⁷ *Alternate: Kateřina KUBÁCKOVÁ*³⁸
- Barbara VAN ZWIETEN-BOOT (Netherlands) *Alternate: Pieter DE GRAEFF*
- Mila VLASKOVSKA (Bulgaria) *Alternate: Awaiting nomination* ³⁹
- *Awaiting nomination* (Romania) *Alternate: Nela VILCEANU* ⁴⁰

Co-opted members

- Robert James HEMMINGS (United Kingdom)
- Hubert G.M. LEUFKENS (Netherlands)
- Jean-Louis ROBERT (Luxembourg)
- Sol RUIZ (Spain)
- Christian SCHNEIDER (Germany)

Working parties, ad hoc groups and scientific advisory groups

Standing working parties

Biologics Working Party

Chair: Jean-Hugues TROUVIN

EMA contact: Nick GATE

EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations

Chair: Lise MURPHY/Isabelle MOULON

EMA contact: Juan GARCIA BURGOS

Pharmacovigilance Working Party

Chair: June RAINE

EMA contact: Roberto DE LISA/Geraldine PORTIER

Joint CHMP/CVMP Quality Working Party

Chair: Jean-Louis ROBERT

EMA contact: Riccardo LUIGETTI

Safety Working Party

Chair: Beatriz SILVA LIMA

EMA contact: Maria NIETO GUTIERREZ

Scientific Advice Working Party

Chair: Robert James HEMMINGS

EMA contact: Spiros VAMVAKAS

³⁵ Replaced Bengt LJUNGBERG as per April meeting

³⁶ Replaced Liv MATHIESEN as per May meeting

³⁷ Replaced Martin VOTOVA as per May meeting

³⁸ Replaced Ondřej Slanař as per September meeting

³⁹ Elena MASSEVA left the Committee as per October meeting

⁴⁰ Replaced Roxana MUSTATA as per September meeting, who in turn replaced Raluca CIRSTEANU as per February meeting

Temporary working parties

Biosimilar Medicinal Products Working Party⁴¹

Chair: Christian SCHNEIDER

EMA contact: Falk EHMANN

Biostatistics Working Party⁴²

Chair: Robert James HEMMINGS⁴³

EMA contact: Martin POSCH

Blood Products Working Party⁴⁴

Chair: *To be elected*

EMA contact: Glenda SILVESTER

Cardiovascular Working Party⁴⁵

Chair: Gonzalo CALVO ROJAS

EMA contact: Anna Maria BACZYNSKA

Working Party on Cell-based Products⁴⁶

Chair: Paula SALMIKANGAS

EMA contact: Peter RICHARDSON

Central Nervous System Working Party⁴⁷

Chair: Barbara VAN ZWIETEN-BOOT

EMA contact: Manuel HAAS

Efficacy Working Party⁴⁸

Chair: Barbara VAN ZWIETEN-BOOT

EMA contact: Maria NIETO GUTIERREZ

Gene Therapy Working Party⁴⁹

Chair: Maria Cristina GALLI

EMA contact: Caroline VOLTZ

Infectious Diseases Working Party⁵⁰

Chair: Mair POWELL

EMA contact: Rachel TURNER

Oncology Working Party⁵¹

Chair: Bertil JONSSON

EMA contact: Irene PAPADOULI

Pharmacogenomics Working Party

Chair: Eric ABADIE

EMA contact: Marisa PAPALUCA AMATI

Pharmacokinetics Working Party⁵²

Chair: Tomas SALMONSON

EMA contact: Michael BERNTGEN

Rheumatology/Immunology Working Party⁵³

Chair: Bridget HEELAN

EMA contact: Radhouane CHERIF

Vaccine Working Party⁵⁴

Chair: Michael PFLEIDERER

EMA contact: Robin RUEPP

41 Established as a temporary working party in 2010 and name changed from Ad Hoc Working Party on Similar Biological (Biosimilar) medicinal Products.

42 New temporary working party (previously Efficacy Working Party drafting group).

43 Replaced by Eva SKOVLUND.

44 Due to public interest it has been decided that BPWP will keep its mandate based on member states representation.

45 New temporary working party (previously part of the Efficacy Working Party).

46 The Committee for Advanced Therapies (CAT) established a temporary working party on cell-based therapy in May 2010, following the discontinuation of the existing Cell-based Products Working Party of the Committee for Medicinal Products for Human Use (CHMP).

47 New temporary working party (previously part of the Efficacy Working Party).

48 As of September 2010 the Efficacy Working Party was disbanded and converted into several temporary working parties.

49 Discontinued under CHMP and established as a temporary working party under the Committee for Advanced Therapies (CAT).

50 New temporary working party (previously part of the Efficacy Working Party).

51 New temporary working party (previously part of the Efficacy Working Party).

52 New temporary working party (previously Efficacy Working Party drafting group).

53 New temporary working party (previously part of the Efficacy Working Party).

54 Robin Ruepp replaced Peter Richardson in December 2010.

Temporary drafting groups

Gastroenterology Drafting Group⁵⁵

Chair: Elmer SCHABEL⁵⁶ EMA contact: Thomas CASTELNOVO

Respiratory Drafting Group⁵⁷

Chair: Gonzalo CALVO ROJAS EMA contact: Jaume GONZALEZ NOGUERAS

Urology Drafting Group⁵⁸

Chair: Kerstin CLAESSION EMA contact: Michael BERNTGEN

Radiopharmaceuticals Drafting Group⁵⁹

Chair: Patrick SALMON EMA contact: Silvy DA ROCHA DIAS

Scientific advisory groups

Scientific Advisory Group on Anti-infectives

Chair: Barbara BANNISTER EMA contact: Eric PELFRENE

Scientific Advisory Group on Cardiovascular Issues

Chair: *To be elected* EMA contact: Daniel GUSTAFSSON

Scientific Advisory Group on Central Nervous System⁶⁰

Chair: Michael DONAGHY EMA contact: Björn ARVIDSON

Scientific Advisory Group on Diabetes/ Endocrinology

Chair: Edwin GALE EMA contact: Eberhard BLIND

Scientific Advisory Group on Diagnostics

Chair: Jean-Noël TALBOT EMA contact: Silvy DA ROCHA DIAS

Scientific Advisory Group on HIV/Viral Diseases

Chair: Ian WELLER EMA contact: Margot MARTIN

Scientific Advisory Group on Neurology⁶¹

Chair: Michael DONAGHY EMA contact: Björn ARVIDSON

Scientific Advisory Group on Oncology

Chair: Michel MARTY EMA contact: Francesco PIGNATTI

Scientific Advisory Group on Psychiatry⁶²

Chair: *To be elected* EMA contact: Florence BUTLEN-DUCUING

55 New temporary drafting group previously part of the Efficacy Working Party).

56 Replaced Sif Ormarsdóttir as of February 2010.

57 New temporary drafting group previously part of the Efficacy Working Party).

58 New temporary drafting group previously part of the Efficacy Working Party).

59 New temporary drafting group previously part of the Efficacy Working Party). Camille Vleminckx replaced Silvy da Rocha Dias for her maternity leave late September 2010 only.

60 Disbanded in September 2010.

61 New Scientific Advisory Group established in September 2010.

62 New Scientific Advisory Group established in September 2010.

Other CHMP-associated groups

EMA/CHMP Working Group with Healthcare Professionals' Organisations

Chair: Noël WATHION EMA contact: Juan GARCIA BURGOS

Invented Name Review Group

Chair: Isabelle MOULON EMA contact: Monica BUCH GARCIA

Working Group on Quality Review of Documents

Chair: Isabelle MOULON EMA contact: Isabelle MOULON

Annex 3 – Members of the Committee for Medicinal Products for Veterinary Use

Chair: Anja Holm⁶³ (Vice-Chair: G. Johan Schefferlie⁶⁴
European Medicines Agency contact: David MACKAY

Members

- Ewa AUGUSTYNOWICZ (Poland) *Alternate: Anna LUTYŃSKA⁶⁵*
- Jean-Pierre BINDER⁶⁶ (Austria) *Alternate: Barbara ZEMANN⁶⁷*
- Jiří BUREŠ (Czech Republic) *Alternate: Alfred HERA*
- João Pedro DUARTE DA SILVA (Portugal) *Alternate: Maria Inês Flor DIAS⁶⁸*
- Judita HEDEROVÁ (Slovakia) *Alternate: Eva CHOBOTOVÁ*
- Tonje HØY (Norway) *Alternate: Hanne BERGENDAHL*
- Damyan ILIEV (Bulgaria) *Alternate: Lubomir LASHEV⁶⁹*
- Ruth KEARSLEY (United Kingdom) *Alternate: Anna-Maria BRADY*
- Petras MAČIULSKIS (Lithuania) *Alternate: Zilvinas Ilevicius*
- Ioannis MALEMIS (Greece) *Alternate: Angeliki TSIGOURI⁷⁰*
- Manfred MOOS (Germany) *Alternate: Cornelia IBRAHIM*
- Cristina MUÑOZ MADERO⁷¹ (Spain) *Alternate: Consuelo RUBIO MONTEJANO⁷²*
- David MURPHY (Ireland) *Alternate: Gabriel BEECHINOR*
- Jean-Claude ROUBY (France) *Alternate: Michael HOLZHAUSER-ALBERTI*
- Halldór RUNÓLFSSON (Iceland) *Alternate: Johann LENHARDSSON*
- G. Johan SCHEFFERLIE (Netherlands) (Vice-Chair) *Alternate: Peter HEKMAN*
- Valda SEJANE (Latvia) *Alternate: Awaiting nomination*
- Tibor SOÓS (Hungary) *Alternate: Gábor KULCSÁR*
- Stane SRČIČ (Slovenia) *Alternate: Katarina STRAUS*
- Lollita Sanda Camelia TABAN (Romania) *Alternate: Simona STURZU*
- Maria TOLLIS (Italy) *Alternate: Virgilio DONINI*
- Ave-Ly TOOMVAP⁷³ (Estonia) *Alternate: Helen MAHLA*

63 Replaced Gerard MOULIN

64 Replaced Anja HOLM

65 Replaced Anna GZYL

66 Replaced Eugen Obermayr

67 Replaced Jean-Pierre BINDER

68 Replaced Berta SAO BRAZ

69 Replaced Ilian GETCHEV

70 Replaced Georgios BATZIAS

71 Replaced Consuelo RUBIO MONTEJANO

72 Replaced Gema CORTÉS

73 Replaced Paul Mõtsküla

- Pavlos TOUMAZOS⁷⁴ (Cyprus) *Alternate: Ioanna TALIOTI*
- Karolina TÖRNEKE (Sweden) *Alternate: Henrik HOLST*
- Bruno URBAIN (Belgium) *Alternate: Awaiting nomination*
- Ellen-Margrethe VESTERGAARD⁷⁵ (Denmark) *Alternate: Lotte WINTHER⁷⁶*
- Fia WESTERHOLM⁷⁷ (Finland) *Alternate: Kristina LEHMANN*
- Marc WIRTOR (Luxembourg) *Alternate: Awaiting nomination*
- *Awaiting nomination* (Malta) *Alternate: Awaiting nomination*

Co-opted

- Rory BREATHNACH (Ireland) *(co-opted)*
- Peter EKSTRÖM (Sweden) *(co-opted)*
- Christian FRIIS (Denmark) *(co-opted)*
- Boris KOLAR (Slovenia) *(co-opted)*
- Wilhelm SCHLUMBOHM (Germany) *(co-opted)*

Working parties, ad hoc groups and scientific advisory groups

Efficacy Working Party

Chair: Michael HOLZHAUSER-ALBERTI EMA contact: Jill KIEFFER

Safety Working Party

Chair: G. Johan SCHEFFERLIE EMA contact: Isaura DUARTE

Immunologicals Working Party

Chair: Jean-Claude ROUBY EMA contact: Jill KIEFFER

Scientific Advice Working Party

Chair: Rory BREATHNACH EMA contact: Jill KIEFFER

Pharmacovigilance Working Party

Chair: Peter EKSTRÖM⁷⁸ EMA contact: Isaura DUARTE

Scientific Advisory Group on Antimicrobials

Chair: Karolina TÖRNEKE EMA contact: Isaura DUARTE

Joint CHMP/CVMP Quality Working Party

Vice-Chair: Piet-Hein OVERHAUS EMA contact: David COCKBURN

Environmental Risk Assessment (temporary working party)

Chair: Joop DE KNECHT EMA contact: Isaura DUARTE

CMD-v

Chair: Esther WERNER EMA contact: Melanie LEIVERS

74 Replaced Charalambos KAKOYIANNIS

75 Replaced Anja HOLM

76 Replaced Ellen-Margrethe VESTERGAARD

77 Replaced Irmeli HAPPONEN

78 Replaced Cornelia IBRAHIM

Annex 4 – Members of the Committee on Orphan Medicinal Products

Chair: Kerstin WESTERMARK

EMA contact: Jordi LLINARES GARCIA

Members

- Björn BEERMANN (Sweden)
- Brigitte BLÖCHL-DAUM (Austria)
- János BORVENDÉG (EMA representative)
- Heidrun BOSCH-TRABERG (Denmark)
- Birthe BYSKOV HOLM (patients' organisation representative) (*vice-chair*)
- Maurizio CLEMENTI (Italy)
- Ana CORRÊA NUNES (Portugal)
- Bożenna DEMBOWSKA-BAGIŃSKA (Poland)
- Regina DEMLOVÁ⁷⁹ (Czech Republic)
- Judit EGGENHOFER (Hungary)
- Rembert ELBERS (Germany)
- Marie Pauline EVERS (patients' organisation representative)
- Tatiana FOLTÁNOVÁ (Slovak Republic)
- Lars GRAMSTAD (Norway)
- Lesley GREENE (patients' organisation representative)
- Emmanuel HÉRON (France)
- Ioannis KKOLOS (Cyprus)
- Dainis KRIEVINS (Latvia)
- André LHOIR (Belgium)
- David LYONS (EMA representative)
- Aušra MATULEVIČIENĖ (Lithuania)
- Henri METZ (Luxembourg)
- Martin MOŽINA (Slovenia)
- Daniel O'CONNOR⁸⁰ (United Kingdom)
- Veijo SAANO (Finland)
- Flavia SALEH (Romania)

⁷⁹ Replaced Kateřina KUBÁČKOVÁ as of October 2010 meeting

⁸⁰ Replaced Segundo MARIZ as of July 2010 meeting

- Patrick SALMON (Ireland)
- Miranda SIOUTI (Greece)
- Bruno SEPODES (EMA representative)
- Sigurður B. THORSTEINSSON (Iceland)
- Vallo TILLMANN (Estonia)
- Mariana TODOROVA (Bulgaria)
- Josep TORRENT-FARNELL (Spain)
- Albertha VOORDOUW (the Netherlands)

Ad hoc groups

Ad hoc group on efficiency improvement

Chair: Lesley GREENE

EMA contact: Jordi LLINARES GARCIA

Ad hoc group on biomarkers project

Chair: Albertha VOORDOUW

EMA contact: Stylianos TSIGKOS

Annex 5 – Members of the Committee on Herbal Medicinal Products

Chair: Werner KNÖSS⁸¹

EMA contact: Anthony HUMPHREYS

Members

- | | |
|---|---|
| • Linda ANDERSON (United Kingdom) | Alternate: Sue HARRIS |
| • Everaldo ATTARD (Malta) | Alternate: Gabriel MICALLEF |
| • Mariette BACKES-LIES (Luxembourg) | Alternate: Jacqueline GENOUX-HAMES |
| • Steffen BAGER (Denmark) | Alternate: Nina DÜRR ⁸² |
| • Zsuzsanna BIRÓ-SÁNDOR (Hungary) | Alternate: Dezsó CSUPOR ⁸³ |
| • Ioanna CHINOI (Greece) ⁸⁴ | Alternate: Eleni SKAL TSA |
| • Per CLAESON (Sweden) | Alternate: Ubonwan CLAESON |
| • Marisa DELBÒ (Italy) | Alternate: <i>Awaiting nomination</i> ⁸⁵ |
| • Wojciech DYMOWSKI (Poland) | Alternate: Ewa BACKHAUS ⁸⁶ |
| • Nadia GRIGORAS (Romania) | Alternate: Carmen PURDEL ⁸⁷ |
| • Vilborg HALLDORS DOTTIR (Iceland) ⁸⁸ | Alternate: <i>Awaiting nomination</i> ⁸⁹ |
| • Sinead HARRINGTON (Ireland) | Alternate: Niamh CURRAN ⁹⁰ |
| • Marie HEROUTOVÁ (Czech Republic) | Alternate: Helena Lá talová |
| • Dace KALKE (Latvia) | Alternate: Vita GULEVSKA |
| • Artūras KAŽEMEKAITIS (Lithuania) | Alternate: Audronis LUKOŠIUS ⁹¹ |
| • Samo KREFT (Slovenia) | Alternate: Barbara RAZINGER |
| • Reinhard LÄNGER (Austria) ⁹² | Alternate: Martine SERNETZ ⁹³ |
| • Steinar MADSEN (Norway) | Alternate: Gro FOSSUM |
| • Ana Paula MARTINS (Portugal) | Alternate: Eva MENDES |
| • Elena MUSTAKEROVA (Bulgaria) ⁹⁴ | Alternate: Irina NIKOLOVA ⁹⁵ |

⁸¹ replaced Konstantin KELLER as of November 2010

⁸² replacing Kristine HVOLBY as of September 2010

⁸³ as of April 2010

⁸⁴ Vice-chair, re-elected in November 2010

⁸⁵ mandate of Monica CAPASSO ended in September 2010

⁸⁶ as of February 2010

⁸⁷ replacing Robert Ancuceanu as of December 2010

⁸⁸ replacing Thorbjörg Kjartandsdóttir as of September 2010

⁸⁹ as of September 2010 after appointment of Vilborg HALLDORS DOTTIR as member of HMPC

⁹⁰ replacing Cathal GALLAGHER as of October 2010

⁹¹ replacing Kristina Ramanauskienė as of January 2010

⁹² replacing Heribert PITTNER as of September 2010

⁹³ replacing Reinhard LÄNGER as of September 2010

⁹⁴ replacing Stefan NIKOLOV as of October 2010

⁹⁵ replacing Elena MUSTAKEROVA as of October 2010

- Heidi NEEF (Belgium) Alternate: Arnold J. VLIETINCK
- Adela NÚÑEZ VELÁZQUEZ (Spain)⁹⁶ Alternate: *Awaiting nomination*⁹⁷
- Evelin SAAR (Estonia)⁹⁸ Alternate: Marje ZERNANT⁹⁹
- Lucia SEVCEKOVA (Slovakia)¹⁰⁰ Alternate: Milan NAGY
- Antoine SAWAYA (France) Alternate: Jacqueline VIGUET POUPELLOZ
- Anneli TÖRRÖNEN (Finland) Alternate: Sari KOSKI
- Panayiotis TRIANTAFYLLIS (Cyprus) Alternate: Maria STAVROU
- Emiel VAN GALEN (Netherlands) Alternate: Burt H. KROES
- *Awaiting nomination*¹⁰¹ Alternate: Jacqueline WIESNER

Co-opted members

- Gioacchino CALAPAI (Clinical pharmacology)
- Silvia GIROTTO (Paediatric medicine)
- Gert LAEKEMAN (Experimental/non-clinical pharmacology)
- Olavi PELKONEN (Toxicology)
- Maria Helena PINTO FERREIRA (General and family medicine)

Observers

- Melanie BALD (EDQM)
- Michael WIERER (EDQM)
- Tamara Bosnic (Bosnia and Herzegovina)
- Josipa Cvek (Croatia)
- Ivan Kosalec (Croatia)
- Maja VUJOVIĆ (Montenegro)
- Milena adzic (Montenegro)
- Ivana drobnjak (Montenegro)
- Dimche ZAFIROV (The Former Yugoslav Republic of Macedonia)
- Merjem Hadjihamza (The Former Yugoslav Republic of Macedonia)
- Rajna Kostoska (The Former Yugoslav Republic of Macedonia)
- Nikola LABACEVSKI (The Former Yugoslav Republic of Macedonia)
- Dragan DJUROVIC (Serbia)

96 replacing Gloria García Lorente as of August 2010

97 as of August 2010 after appointment of Adela NÚÑEZ VELÁZQUEZ as member of HMPC

98 replacing Marje ZERNANT as of September 2010

99 replacing Evelin SAAR as of September 2010

100 replacing Peter Potůček as of December 2010

101 awaiting nomination following the election for Werner KNÖSS to Chair

- Marija Jovanović (Serbia)
- Asli CAN AGCA (Turkey)

Working parties and drafting groups

Working party on Community Monographs and Community List

Chair: Ioanna CHINOÜ

EMA contact: Anthony HUMPHREYS

Organisational Matters Drafting Group

Chair: Emiel VAN GALEN

EMA contact: Anthony HUMPHREYS

Quality Drafting Group

Chair: Burt H. KROES

EMA: Anthony HUMPHREYS

Annex 6 – Members of the Paediatric Committee

Chair: Daniel BRASSEUR

EMA contact: Paolo TOMASI

Members

- Fernando de ANDRÉS TRELLES (Spain) *Alternate:* Maria Jesús FERNÁNDES CORTIZO
- Dina APELE-FREIMANE (Latvia) *Alternate:* Ilze BĀRENE
- Carine de BEAUFORT (CHMP Luxembourg) *Alternate:* Jacqueline GENOUX-HAMES
- John Joseph BORG (Malta) *Alternate:* Herbert LENICKER
- Kevin CONNOLLY (Ireland) *Alternate:* Brian AYLWARD¹⁰²
- Helena FONSECA (Portugal) *Alternate:* Hugo TAVARES
- Marta GRANSTRÖM (Sweden) *Alternate:* Viveca Lena ODLIND
- Agnes GYURASICS (CHMP, Hungary) *Alternate:* János BORVENDÉG¹⁰³
- Janez JAZBEC (Slovenia) *Alternate:* *Awaiting nomination*
- Vlasta KÁKOŠOVÁ (Slovakia) *Alternate:* Jan MAZAG
- Lida KALANTZI (Greece) *Alternate:* Alexandra SOLDATOU
- Dobrin KONSTANTINOV (Bulgaria) *Alternate:* Margarita GUIZOVA
- Pirjo LAITINEN-PARKKONEN (Finland) *Alternate:* Ann Marie KAUKONEN
- Irja LUTSAR (Estonia) *Alternate:* Alar IRS
- Romaldas MAČIULAITIS (CHMP, Lithuania) *Alternate:* Rugile PILVINIENE
- Christoph MALE (Austria) *Alternate:* Karl-Heinz HUEMER
- Dirk MENTZER (Germany) *Alternate:* Birka LEHMANN
- Marek MIGDAL (Poland) *Alternate:* Jolanta WITKOWSKA-OŻOGOWSKA
- Hubert MOTTL (Czech Republic) *Alternate:* Peter SZITANYI
- Koenraad NORGA¹⁰⁴ (Belgium) *Alternate:* Jacqueline CARLEER
- Marianne ORHOLM (Denmark) *Alternate:* Karen TORNØE
- Gylfi OSKARSSON (Iceland) *Alternate:* Kolbeinn GUDMUNDSSON
- Gérard PONS (France) *Vice Chair* *Alternate:* Sylvie BENCHETRIT¹⁰⁵
- Paolo ROSSI (Italy) *Alternate:* Francesca ROCCHI
- Johannes TAMINIAU (The Netherlands) *Alternate:* Hendrik van den BERG
- Andreas TELOUDES (Cyprus) *Alternate:* Stefanos CHRISTODOULOU

102 Yvonne LOONEY (July 2007 – June 2010)

103 Tamas MACHAY (October 2008 – July 2010)

104 Hugo DEVLIEGER (October 2007 – August 2010)

105 Sophie FORNAIRON (July 2007 – October 2010)

- Matthew THATCHER (United Kingdom) *Alternate:* Timothy CHAMBERS
- Nela VILCEANU¹⁰⁶ (CHMP, Romania) *Alternate:* Dana Gabriela MARIN¹⁰⁷
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Representatives of patients' and healthcare professionals' organisations

- Annagrazia ALTAVILLA (Patient organisation) *Alternate:* Pending
- Michal ODERMARSKY (Patient organisation) *Alternate:* Milena STEVANOVIC
- Tsveta SCHYNS-LIHARSKA (Patient organisation) *Alternate:* pending¹⁰⁸
- Jean-Pierre ABOULKER (Health professional) *Alternate:* Alexandra COMPAGNUCCI
- Adriana CECI (Health professional) *Alternate:* Paolo PAOLUCCI
- Pending (Health professional) *Alternate:* Pending

106 Robert ANCUCEANU (July 2007 – November 2010)

107 Roxana MUSTATĂ (August 2009 – July 2010)

108 Karen AIACH (September 2009 – April 2010)

Annex 7 – National competent authority partners

Further information on the national competent authorities is also available on the national authorities' Internet sites: http://www.hma.eu/human_heads.html and http://www.hma.eu/veterinary_heads.html

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Annex 8 – Budget summaries 2009–2010

The summarised comparative budget statements for 2009 and 2010 are as follows:

		2009 (final) ¹⁰⁹		2010 (budget) ¹¹⁰		2010 (final) ¹¹¹	
		€ '000	%	€ '000	%	€ '000	%
Revenue							
100	Fees	141,023	71.9	152,780	73.3	153,681	73.4
200	General EU contribution including surplus from previous year (reserve)	41,220	21.0	42,812	20.5	39,065	18.7
201	Special EU contribution for orphan medicinal products	5,632	2.9	4,500	2.2	7,988	3.8
300	Contribution from EEA	873	0.4	935	0.4	826	0.4
600	Community programmes	103	0.1	460	0.2	580	0.3
500+900	Other	7,283	3.7	6,900	3.3	7,320	3.5
TOTAL REVENUE		196,135	100.0	208,387	100.0	209,460	100.0
Expenditure							
Staff							
11	Staff in active employment	51,988	27.8	63,039	30.3	61,986	30.6
13	Mission expenses	663	0.4	789	0.4	597	0.3
14	Socio-medical infrastructure	535	0.3	615	0.3	521	0.3
15	Exchange of civil servants and experts	2,636	1.4	2,332	1.1	2,329	1.1
16	Social welfare	97	0.1	145	0.1	132	0.1
17	Entertainment and representation expenses	37	0.0	95	0.0	93	0.0
18	Staff insurances	1,786	1.0	2,078	1.0	2,038	1.0
	<i>Total Title 1</i>	<i>57,742</i>	<i>31.0</i>	<i>69,093</i>	<i>33.2</i>	<i>67,695</i>	<i>33.4</i>
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	16,056	8.6	19,066	9.1	19,065	9.4
21	Expenditure on data processing	29,589	15.9	30,802	14.8	30,789	15.2
22	Movable property and associated costs	2,598	1.4	1,486	0.7	1,404	0.7
23	Other administrative expenditure	1,128	0.6	1,103	0.5	914	0.5
24	Postage and communications	818	0.4	694	0.3	621	0.3
25	Expenditure on formal and other meetings	92	0.1	153	0.1	90	0.0
	<i>Total Title 2</i>	<i>50,281</i>	<i>26.9</i>	<i>53,304</i>	<i>25.6</i>	<i>52,883</i>	<i>26.1</i>
Operational expenditure							
300	Meetings	7,660	4.1	8,820	4.2	7,425	3.7
301	Evaluations	66,487	35.6	71,106	34.1	70,561	34.8
302	Translation	3,991	2.1	4,329	2.1	3,580	1.8
303	Studies and consultants	63	0.0	80	0.0	58	0.0
304	Publications	197	0.1	206	0.1	131	0.1
305	Community programmes	272	0.2	480	0.2	480	0.2
	<i>Total Title 3</i>	<i>78,670</i>	<i>42.1</i>	<i>85,021</i>	<i>40.8</i>	<i>82,234</i>	<i>40.5</i>
Provisional appropriation							
900	Provisional appropriation	0	0.0	969	0.4	0	0.0
	<i>Total Title 9</i>	<i>0</i>	<i>0.0</i>	<i>969</i>	<i>0.4</i>	<i>0</i>	<i>0.0</i>
TOTAL EXPENDITURE		186,693	100.0	208,387	100.0	202,813	100.0

109 Financial Year 2009: as per final accounts

110 Financial Year 2010: as per final budget including Amending Budget 01-2010

111 Financial Year 2010: as per provisional accounts

Annex 9 – European Medicines Agency Establishment Plan

Category and grade	TEMPORARY POSTS					
	POSTS 2010				POSTS 2011	
	Authorised		Actual as per 31.12.2010		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	1	-	1	-	1
AD 15	-	4	-	4	-	4
AD 14	-	5	-	5	-	5
AD 13	-	6	-	6	-	7
AD 12	-	37	-	35	-	37
AD 11	-	36	-	34	-	36
AD 10	-	32	-	32	-	32
AD 9	-	35	-	32	-	38
AD 8	-	43	-	42	-	43
AD 7	-	38	-	36	-	42
AD 6	-	39	-	35	-	32
AD 5	-	34	-	34	-	33
Total AD	0	310	0	296	0	310
AST 11	-	2	-	2	-	2
AST 10	-	4	-	4	-	4
AST 9	-	8	-	8	-	8
AST 8	-	13	-	13	-	13
AST 7	-	18	-	18	-	19
AST 6	-	35	-	33	-	35
AST 5	-	35	-	35	-	35
AST 4	-	46	-	45	-	49
AST 3	-	36	-	34	-	36
AST 2	-	40	-	38	-	40
AST 1	-	20	-	20	-	16
Total AST	0	257	0	250	0	257
Grand Total	0	567	0	546	0	567

CONTRACT AGENTS	Planned (FTE ¹¹²)	Actual (FTE) 2010	Actual as per 31.12.2010	Planned (FTE) 2011
Total	125	96.9	94	150

NATIONAL EXPERTS	Planned (FTE)	Actual (FTE) 2010	Actual as per 31.12.2010	Planned (FTE) 2011
Total	19	14.2	16	20

112 FTE=Full Time Equivalent

Annex 10 – CHMP opinions in 2009 on medicinal products for human use

CHMP positive opinions in 2010 on non-orphan medicinal products for human use

Product <ul style="list-style-type: none"> • Brandname • INN 	Marketing authorisation holder	Therapeutic Area <ul style="list-style-type: none"> • ATC Code • Summary of indication 	EMA/CHMP <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • Aflunov • pre-pandemic influenza vaccine (h5n1) (surface antigen, inactivated, adjuvanted) 	Novartis Vaccines and Diagnostics S.r.l.	<ul style="list-style-type: none"> • J07BB02 • immunisation against H5N1 subtype of Influenza A virus 	<ul style="list-style-type: none"> • 22/12/2009 • 23/09/2010 • 210 days • 64 days 	<ul style="list-style-type: none"> • 23/09/2010 • 29/11/2010 • 03/12/2010 • C61 of 25/02/2011
<ul style="list-style-type: none"> • Arepanrix • pandemic influenza vaccine (h1n1) (split virion, inactivated, adjuvanted) 	GlaxoSmithKline Biologicals S.A.	<ul style="list-style-type: none"> • J07BB02 • pandemic influenza vaccine 	<ul style="list-style-type: none"> • 19/01/2010 • 21/01/2010 • 1 day • 0 days 	<ul style="list-style-type: none"> • 01/03/2010 • 23/03/2010 • 25/03/2010 • C258 of 24/09/2010
<ul style="list-style-type: none"> • Brilique • ticagrelor 	AstraZeneca AB	<ul style="list-style-type: none"> • B01AC24 • prevention of atherothrombotic events 	<ul style="list-style-type: none"> • 17/11/2009 • 23/09/2010 • 206 days • 103 days 	<ul style="list-style-type: none"> • 23/09/2010 • 03/12/2010 • 07/12/2010 • C61 of 25/02/2011
<ul style="list-style-type: none"> • Brinavess • vernakalant hydrochloride 	Merck Sharp & Dohme Ltd.	<ul style="list-style-type: none"> • C01BG11 • conversion of atrial fibrillation to sinus rhythm 	<ul style="list-style-type: none"> • 18/08/2009 • 24/06/2010 • 209days • 100 days 	<ul style="list-style-type: none"> • 01/09/2010 • 01/09/2010 • 06/09/2010 • C359 of 31/12/2010
<ul style="list-style-type: none"> • Daxas • roflumilast 	Altana Pharma AG	<ul style="list-style-type: none"> • R03DX07 • treatment of Chronic Obstructive Pulmonary Disease (COPD) and asthma 	<ul style="list-style-type: none"> • 26/05/2009 • 22/04/2010 • 210 days • 120 days 	<ul style="list-style-type: none"> • 01/07/2010 • 05/07/2010 • 08/07/2010 • C295 of 29/10/2010
<ul style="list-style-type: none"> • FLUENZ • influenza vaccine (live attenuated, nasal) 	MedImmune LLC	<ul style="list-style-type: none"> • J07BB03 • prevention of influenza 	<ul style="list-style-type: none"> • 23/12/2008 • 21/10/2010 • 210 days • 454 days 	<ul style="list-style-type: none"> • 21/10/2010 • 27/01/2011 • 01/02/2011 • C128 of 19/04/2011
<ul style="list-style-type: none"> • Humenza • pandemic influenza vaccine (h1n1) (split virion, inactivated, adjuvanted) 	Sanofi Pasteur S.A.	<ul style="list-style-type: none"> • J07BB02 • prophylaxis of influenza 	<ul style="list-style-type: none"> • 14/01/2010 • 18/02/2010 • 34 days • 0 days 	<ul style="list-style-type: none"> • 01/06/2010 • 08/06/2010 • 10/06/2010 • C258 of 24/09/2010

Product	Marketing authorisation holder	Therapeutic Area	EMA/CHMP	European Commission
<ul style="list-style-type: none"> • Brandname • INN 		<ul style="list-style-type: none"> • ATC Code • Summary of indication 	<ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop 	<ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • Ozurdex • dexamethasone 	Allergan Pharmaceuticals Ireland	<ul style="list-style-type: none"> • S01BA01 • treatment of macular oedema 	<ul style="list-style-type: none"> • 24/03/2009 • 20/05/2010 • 210 days • 211 days 	<ul style="list-style-type: none"> • 20/05/2010 • 27/07/2010 • 01/08/2010 • C295 of 29/10/2010
<ul style="list-style-type: none"> • Possia • ticagrelor 	AstraZeneca AB	<ul style="list-style-type: none"> • B01AC24 • prevention of atherothrombotic events 	<ul style="list-style-type: none"> • 25/05/2010 • 23/09/2010 • 87 days • 33 days 	<ul style="list-style-type: none"> • 23/09/2010 • 03/12/2010 • 07/12/2010 • C61 of 25/02/2011
<ul style="list-style-type: none"> • Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostic • influenza virus surface antigens (haemagglutinin and neuraminidase) h5n1 (a/vietnam/1194/2004) 	Novartis Vaccines and Diagnostics S.r.l.	<ul style="list-style-type: none"> • J07BB02 • immunisation against H5N1 subtype of Influenza A virus 	<ul style="list-style-type: none"> • 22/12/2009 • 23/09/2010 • 210 days • 64 days 	<ul style="list-style-type: none"> • 23/09/2010 • 29/11/2010 • 03/12/2010 • C61 of 25/02/2011
<ul style="list-style-type: none"> • Pumarix • pandemic influenza vaccine (h5n1) (split virion, inactivated, adjuvanted) 	GlaxoSmithKline Biologicals S.A.	<ul style="list-style-type: none"> • J07BB02 • prophylaxis of influenza in an officially declared pandemic situation 	<ul style="list-style-type: none"> • 05/08/2009 • 18/11/2010 • 91 days • 365 days 	<ul style="list-style-type: none"> • 18/11/2010 • 04/03/2011
<ul style="list-style-type: none"> • Rapiscan • regadenoson 	Rapidscan Pharma Solutions EU Ltd.	<ul style="list-style-type: none"> • C01EB21 • pharmacological stress agent for radionuclide myocardial perfusion imaging (MPI) 	<ul style="list-style-type: none"> • 26/05/2009 • 24/06/2010 • 209 days • 184 days 	<ul style="list-style-type: none"> • 24/06/2010 • 06/09/2010 • 08/09/2010 • C359 of 31/12/2010
<ul style="list-style-type: none"> • Ruconest • conestat alfa 	Pharming Group N.V.	<ul style="list-style-type: none"> • B05 • treatment of angioedema 	<ul style="list-style-type: none"> • 22/09/2009 • 24/06/2010 • 210 days • 64 days 	<ul style="list-style-type: none"> • 24/06/2010 • 28/10/2010 • 04/11/2010 • C359 of 31/12/2010
<ul style="list-style-type: none"> • Sycrest • asenapine maleate 	N.V. Organon	<ul style="list-style-type: none"> • N05AH05 • treatment of manic episodes associated with bipolar I disorder 	<ul style="list-style-type: none"> • 26/05/2009 • 24/06/2010 • 210days • 183 days 	<ul style="list-style-type: none"> • 01/09/2010 • 01/09/2010 • 06/09/2010 • C359 of 31/12/2010
<ul style="list-style-type: none"> • Teysuno • tegafur / gimeracil / oteracil 	Taiho Pharma Europe Ltd.	<ul style="list-style-type: none"> • L01BC53 • treatment of gastric cancer 	<ul style="list-style-type: none"> • 17/11/2009 • 16/12/2010 • 210 days • 183days 	<ul style="list-style-type: none"> • 16/12/2010 • 14/03/2011 • -- • --

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Opinion • Active Time • Clock stop	European Commission • Opinion received • Date of decision • Notification • Official Journal
• TOBI Podhaler • tobramycin	Novartis Europharm Ltd.	• J01GB01 • long-term management of chronic pulmonary infection due to <i>Pseudomonas aeruginosa</i>	• 22/12/2009 • 23/09/2010 • 210 days • 64 days	• -- • -- • -- • --
• TWYNSTA • telmisartan / amlodipine	Boehringer Ingelheim International GmbH	• C09DB04 • treatment of essential hypertension	• 22/09/2009 • 22/07/2010 • 210 days • 92 days	• 22/07/2010 • 07/10/2010 • 11/10/2010 • C359 of • 31/12/2010
• Votrient • pazopanib	Glaxo Group Ltd.	• L01XE11 • treatment of advanced renal cell carcinoma (RCC)	• 24/03/2009 • 22/04/2010 • 210 days • 183 days	• 22/04/2010 • 14/06/2010 • 16/06/2010 • C258 of • 24/09/2010
• Xeplion • paliperidone	Janssen-Cilag International N.V.	• N05AX13 • treatment of schizophrenia	• 22/12/2009 • 16/12/2010 • 180 days • 178 days	• 16/12/2010 • 04/03/2011
• Xiapex • collagenase clostridium histolyticum	Pfizer Ltd.	• M09AB02 • treatment of Dupuytren's contracture in adult patients with a palpable cord	• 20/01/2010 • 16/12/2010 • 210 days • 119 days	• 01/02/2011 • 28/02/2011 • 02/03/2011 • C128 of • 19/04/2011

CHMP positive opinions in 2010 on orphan medicinal products for human use

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Opinion • Active Time • Clock stop	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Arzerra • ofatumumab	Glaxo Group Ltd.	• L01XC10 • treatment of chronic lymphocytic leukemia (CLL or B-CLL), follicular non-Hodgkin's lymphoma (FL), diffuse large B-cell lymphoma	• 24/02/2009 • 21/01/2010 • 188 • 142	• 01/04/2010 • 19/04/2010 • 21/04/2010 • C258 of • 24/09/2010
• Esbriet • pirfenidone	InterMune UK Ltd	• L04AX05 • treatment of Idiopathic Pulmonary Fibrosis (IPF)	• 23/03/2010 • 16/12/2010 • 180 • 87	• 01/02/2011 • 28/02/2011 • 02/03/2011 • C128 of • 19/04/2011

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Opinion • Active Time • Clock stop	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Orphacol • cholic acid	Laboratoires CTRS	• L04AX05 • treatment of inborn errors in primary bile acid synthesis	• 17/11/2009 • 16/12/2010 • 210 • 183	• -- • -- • -- • --
• VPRIV • velaglucerase alfa	Shire Pharmaceuticals Ireland Ltd.	• A16AB10 • treatment of type 1 Gaucher disease	• 22/12/2009 • 24/06/2010 • 150 • 33	• 24/06/2010 • 26/08/2010 • 30/08/2010 • C295 of 29/10/2010

CHMP positive opinions in 2010 on generic medicinal products for human use (including hybrid, informed consent and well-established use applications)

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Opinion • Active Time • Clock stop	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Clopidogrel HCS • clopidogrel	• HCS bvba	• B01AC04 • prevention of atherothrombotic events	• 25/05/2010 • 22/07/2010 • 60 days • 0 days	• 22/07/2010 • 28/10/2010 • 02/11/2010 • C359 of 31/12/2010
• Clopidogrel Teva Generics B.V. • clopidogrel	• Teva Pharma B.V.	• B01AC04 • prevention of atherothrombotic events	• 25/05/2010 • 22/07/2010 • 60 days • 0 days	• 22/07/2010 • 28/10/2010 • 04/11/2010 • C359 of 31/12/2010
• Clopidogrel Teva Pharma B.V. • clopidogrel	• Teva Pharma B.V.	• B01AC04 • prevention of atherothrombotic events	• 22/09/2009 • 22/07/2010 • 210 days • 92 days	• -- • -- • -- • --
• Daliresp • roflumilast	• Nycomed GmbH	• R03DX07 • treatment of chronic obstructive pulmonary disease (COPD)	• 16/10/2010 • 16/12/2010 • 60 days • 0 days	• 01/02/2011 • 28/02/2011 • 02/03/2011 • C128 of 19/04/2011
• Docefrez • docetaxel	• Sun Pharmaceutical Industries Europe B.V.	• L01CD02 • treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer	• 21/10/2008 • 18/02/2010 • 240 days • 244 days	• 01/05/2010 • 10/05/2010 • 12/05/2010 • C258 of 24/09/2010

Product	Marketing authorisation holder	Therapeutic Area	EMA/CHMP	European Commission
<ul style="list-style-type: none"> • Brandname • INN 		<ul style="list-style-type: none"> • ATC Code • Summary of indication 	<ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop 	<ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • Docetaxel Teva Pharma • docetaxel 	<ul style="list-style-type: none"> • Teva Pharma B.V. 	<ul style="list-style-type: none"> • L01CD02 • treatment of locally advanced or metastatic breast cancer, non-small cell lung cancer and prostate cancer 	<ul style="list-style-type: none"> • 21/08/2010 • 21/10/2010 • 60 days • 0 days 	<ul style="list-style-type: none"> • 21/10/2010 • 21/01/2011 • 26/01/2011 • C128 of 19/04/2011
<ul style="list-style-type: none"> • Entacapone Teva • entacapone 	<ul style="list-style-type: none"> • Teva Pharma B.V. 	<ul style="list-style-type: none"> • N04BX02 • treatment of Parkinson's disease 	<ul style="list-style-type: none"> • 25/05/2010 • 18/11/2010 • 152 days • 24 days 	<ul style="list-style-type: none"> • 18/11/2010 • 18/02/2011 • 22/02/2011 • C128 of 19/04/2011
<ul style="list-style-type: none"> • Iasibon • ibandronic acid 	<ul style="list-style-type: none"> • Pharmathen S.A. 	<ul style="list-style-type: none"> • M05BA06 • prevention of skeletal events 	<ul style="list-style-type: none"> • 20/01/2010 • 21/10/2010 • 205 days • 68 days 	<ul style="list-style-type: none"> • 21/10/2010 • 21/01/2011 • 25/01/2011 • C128 of 19/04/2011
<ul style="list-style-type: none"> • Ibandronic Acid Teva • ibandronic acid 	<ul style="list-style-type: none"> • Teva Pharma B.V. 	<ul style="list-style-type: none"> • M05BA06 • prevention of skeletal events in patients with breast cancer and bone metastases 	<ul style="list-style-type: none"> • 23/02/2010 • 24/06/2010 • 120 days • 0 days 	<ul style="list-style-type: none"> • 24/06/2010 • 17/09/2010 • 21/09/2010 • C359 of 31/12/2010
<ul style="list-style-type: none"> • Ifirmacombi • irbesartan / hydrochlorothiazide 	<ul style="list-style-type: none"> • Krka, d.d., Novo mesto 	<ul style="list-style-type: none"> • C09DA04 • treatment of hypertension 	<ul style="list-style-type: none"> • 25/05/2010 • 16/12/2010 • 180 days • 24 days 	<ul style="list-style-type: none"> • 16/12/2010 • 04/03/2011
<ul style="list-style-type: none"> • Lamivudine / Zidovudine Teva • lamivudine / zidovudine 	<ul style="list-style-type: none"> • Teva Pharma B.V. 	<ul style="list-style-type: none"> • J05AR01 • treatment of HIV infection 	<ul style="list-style-type: none"> • 20/10/2009 • 18/11/2010 • 210 days • 183 days 	<ul style="list-style-type: none"> • 01/02/2011 • 28/02/2011 • 02/03/2011 • C128 of 19/04/2011
<ul style="list-style-type: none"> • Leflunomide medac • leflunomide 	<ul style="list-style-type: none"> • medac Gesellschaft für klinische Spezialpräparate mbH 	<ul style="list-style-type: none"> • L04AA13 • treatment of active rheumatoid arthritis 	<ul style="list-style-type: none"> • 22/09/2009 • 20/05/2010 • 180 days • 59 days 	<ul style="list-style-type: none"> • 20/05/2010 • 27/07/2010 • 30/07/2010 • C295 of 29/10/2010
<ul style="list-style-type: none"> • Leflunomide ratiopharm • leflunomide 	<ul style="list-style-type: none"> • ratiopharm GmbH 	<ul style="list-style-type: none"> • L04AA13 • treatment of active rheumatoid arthritis 	<ul style="list-style-type: none"> • 25/05/2010 • 23/09/2010 • 120 days • 0 days 	<ul style="list-style-type: none"> • 23/09/2010 • 29/11/2010 • 06/12/2010 • C61 of 25/02/2011
<ul style="list-style-type: none"> • Leflunomide Teva • leflunomide 	<ul style="list-style-type: none"> • Teva Pharma B.V. 	<ul style="list-style-type: none"> • L04AA13 • treatment of active rheumatoid arthritis 	<ul style="list-style-type: none"> • 21/09/2010 • 16/12/2010 • 55 days • 30 days 	<ul style="list-style-type: none"> • 16/12/2010 • 10/03/2011
<ul style="list-style-type: none"> • Libertek • roflumilast 	<ul style="list-style-type: none"> • Nycomed GmbH 	<ul style="list-style-type: none"> • R03DX07 • treatment of chronic obstructive pulmonary disease (COPD) 	<ul style="list-style-type: none"> • 16/10/2010 • 16/12/2010 • 60 days • 0 days 	<ul style="list-style-type: none"> • 01/02/2011 • 28/02/2011 • 02/03/2011 • C128 of 19/04/2011

Product	Marketing authorisation holder	Therapeutic Area	EMA/CHMP	European Commission
<ul style="list-style-type: none"> • Brandname • INN 		<ul style="list-style-type: none"> • ATC Code • Summary of indication 	<ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop 	<ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • Myclausen • mycophenolate mofetil 	<ul style="list-style-type: none"> • Herbert J. Passauer GmbH & Co. KG 	<ul style="list-style-type: none"> • L04AA06 • prophylaxis of acute transplant rejection 	<ul style="list-style-type: none"> • 22/09/2009 • 22/07/2010 • 180 days • 122 days 	<ul style="list-style-type: none"> • 22/07/2010 • 07/10/2010 • 11/10/2010 • C359 of • 31/12/2010
<ul style="list-style-type: none"> • Olanzapine • Apotex • olanzapine 	<ul style="list-style-type: none"> • Apotex Europe B.V. 	<ul style="list-style-type: none"> • N05AH03 • treatment of schizophrenia 	<ul style="list-style-type: none"> • 26/05/2009 • 18/03/2010 • 199 days • 96 days 	<ul style="list-style-type: none"> • 18/03/2010 • 10/06/2010 • 14/06/2010 • C258 of • 24/09/2010
<ul style="list-style-type: none"> • PecFent • fentanyl 	<ul style="list-style-type: none"> • Archimedes Development Ltd. 	<ul style="list-style-type: none"> • N02AB03 • treatment of breakthrough cancer pain (BTCP) 	<ul style="list-style-type: none"> • 26/05/2009 • 24/06/2010 • 203 days • 190 days 	<ul style="list-style-type: none"> • 01/08/2010 • 31/08/2010 • 06/09/2010 • C295 of • 29/10/2010
<ul style="list-style-type: none"> • Potactasol • topotecan hydrochloride 	<ul style="list-style-type: none"> • Actavis Group PTC ehf 	<ul style="list-style-type: none"> • L01XX17 • treatment of metastatic carcinoma of the ovary or small cell lung cancer [SCLC] and carcinoma of the cervix 	<ul style="list-style-type: none"> • 17/08/2010 • 21/10/2010 • 60 days • 0 days 	<ul style="list-style-type: none"> • 21/10/2010 • 06/01/2011 • 10/01/2011 • C128 of • 19/04/2011
<ul style="list-style-type: none"> • Raloxifene Teva • raloxifene 	<ul style="list-style-type: none"> • Teva Pharma B.V. 	<ul style="list-style-type: none"> • G03XC01 • treatment and prevention of osteoporosis 	<ul style="list-style-type: none"> • 21/10/2008 • 18/02/2010 • 201 days • 283 days 	<ul style="list-style-type: none"> • 01/04/2010 • 29/04/2010 • 03/05/2010 • C258 of • 24/09/2010
<ul style="list-style-type: none"> • Repso • leflunomide 	<ul style="list-style-type: none"> • Teva Pharma B.V. 	<ul style="list-style-type: none"> • L04AA13 • treatment of active rheumatoid and active psoriatic arthritis 	<ul style="list-style-type: none"> • 22/09/2009 • 16/12/2010 • 210 days • 239 days 	<ul style="list-style-type: none"> • 16/12/2010 • 14/03/2011
<ul style="list-style-type: none"> • Ribavirin BioPartners • ribavirin 	<ul style="list-style-type: none"> • BioPartners GmbH 	<ul style="list-style-type: none"> • J05AB04 • treatment of hepatitis C 	<ul style="list-style-type: none"> • 26/05/2009 • 21/01/2010 • 180 days • 59 days 	<ul style="list-style-type: none"> • 21/01/2010 • 06/04/2010 • 09/04/2010 • C258 of • 24/09/2010
<ul style="list-style-type: none"> • Ribavirin Mylan • ribavirin 	<ul style="list-style-type: none"> • Generics [UK] Ltd. 	<ul style="list-style-type: none"> • J05AB04 • treatment of chronic hepatitis C 	<ul style="list-style-type: none"> • 26/05/2009 • 18/03/2010 • 198 days • 97 days 	<ul style="list-style-type: none"> • 18/03/2010 • 10/06/2010 • 14/06/2010 • C258 of • 24/09/2010
<ul style="list-style-type: none"> • Telmisartan Actavis • telmisartan 	<ul style="list-style-type: none"> • Actavis Group PTC ehf 	<ul style="list-style-type: none"> • C09CA07 • treatment of essential hypertension and reduction of cardiovascular morbidity 	<ul style="list-style-type: none"> • 23/06/2009 • 24/06/2010 • 209 days • 156 days 	<ul style="list-style-type: none"> • 24/06/2010 • 30/09/2010 • 05/10/2010 • C359 of • 31/12/2010

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Opinion • Active Time • Clock stop	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Tolura • telmisartan	• Krka, d.d., Novo mesto	• C09CA07 • treatment of hypertension and cardiovascular prevention	• 21/07/2009 • 18/03/2010 • 199 days • 40 days	• 18/03/2010 • 04/06/2010 • 08/06/2010 • C258 of 24/09/2010
• Topotecan Hospira • topotecan	• Hospira UK Ltd.	• L01XX17 • treatment of carcinoma of the cervix and lung cancer	• 23/06/2009 • 18/03/2010 • 210 days • 57 days	• 18/03/2010 • 10/06/2010 • 14/06/2010 • C258 of 24/09/2010

CHMP positive opinions in 2010 on similar biological medicinal products for human use

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Opinion • Active Time • Clock stop	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Product • Brandname • INN	Marketing authorisation holder	• Therapeutic Area • ATC Code • Summary of indication	• EMA/CHMP • Validation • Opinion • Active Time • Clock stop	• European Commission • Opinion received • Date of decision • Notification • Official Journal
• Nivestim • filgrastim	Hospira UK Ltd.	• L03AA02 • treatment of neutropenia	• 24/03/2009 • 18/03/2010 • 210 • 148	• 01/06/2010 • 08/06/2010 • 10/06/2010 • C258 of 24/09/2010

CHMP negative opinions in 2010 on medicinal products for human use

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Opinion • Active Time • Clock stop	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Movectro • cladribine	• Merck Serono Europe Ltd.	• L01BB04 • treatment of multiple sclerosis (MS)	• 21/07/2009 • 23/09/2010 • 210 • 218	• Withdrawn prior to Commission Decision
• Zeftera • ceftobiprole medocartil	• Janssen-Cilag International N.V.	• J01DI01 • treatment of skin and soft tissue infections	• 17/07/2007 • 24/06/2010 (revised) • n/a • n/a	• 16/09/2010 • 20/09/2010

Annex 11 - CVMP opinions in 2009 on medicinal products for veterinary use

Positive Opinions

Product	Marketing authorisation holder	Therapeutic area	EMA/CVMP	European Commission
<ul style="list-style-type: none"> Invented name INN 		<ul style="list-style-type: none"> Target species Summary of indication 	<ul style="list-style-type: none"> Validation Opinion Active time Clock stop 	<ul style="list-style-type: none"> Opinion received Date of decision Notification Official Journal
<ul style="list-style-type: none"> Bovilis BTV 8 	<ul style="list-style-type: none"> Intervet International BV 	<ul style="list-style-type: none"> Cattle, sheep Inactivated vaccine against Bluetongue virus serotype 8 	<ul style="list-style-type: none"> 22/04/2008 16/06/2010 197 589 	<ul style="list-style-type: none"> 17/06/2010 06/09/2010
<ul style="list-style-type: none"> BTVPUR AISap 2-4 	<ul style="list-style-type: none"> Merial S.A.S. 	<ul style="list-style-type: none"> Sheep Inactivated vaccine against Bluetongue virus serotypes 2 and 4 	<ul style="list-style-type: none"> 18/12/2007 14/07/2010 209 728 	<ul style="list-style-type: none"> 15/07/2010 05/11/2010
<ul style="list-style-type: none"> Veraflox 	<ul style="list-style-type: none"> Bayer Animal Health GmbH 	<ul style="list-style-type: none"> Dogs, cats Infections caused by certain specified and susceptible pathogens 	<ul style="list-style-type: none"> 19/05/2009 14/07/2010 202 218 	<ul style="list-style-type: none"> 15/07/2010
<ul style="list-style-type: none"> RHINISENG 	<ul style="list-style-type: none"> Laboratorios Hipra S.A. 	<ul style="list-style-type: none"> Pigs Inactivated vaccine to prevent non-progressive atropic rhinitis in pigs 	<ul style="list-style-type: none"> 16/06/2009 14/07/2010 209 181 	<ul style="list-style-type: none"> 15/07/2010 16/09/2010
<ul style="list-style-type: none"> COXEVAC 	<ul style="list-style-type: none"> Ceva Sante Animale 	<ul style="list-style-type: none"> Cattle, goats Inactivated coxiella burnetti vaccine 	<ul style="list-style-type: none"> 17/12/2008 14/07/2010 203 370 	<ul style="list-style-type: none"> 15/07/2010 30/09/2010
<ul style="list-style-type: none"> Meloxoral Meloxicam 	<ul style="list-style-type: none"> LeVet B.V. 	<ul style="list-style-type: none"> Dogs, cats Alleviation of inflammation and pain 	<ul style="list-style-type: none"> 17/06/2008 14/09/2010 210 609 	<ul style="list-style-type: none"> 16/09/2010 19/11/2010
<ul style="list-style-type: none"> BTVPUR AISAP 1 	<ul style="list-style-type: none"> Merial 	<ul style="list-style-type: none"> Sheep, cattle Inactivated vaccine against Bluetongue virus serotypes 1 	<ul style="list-style-type: none"> 10/12/2009 13/10/2010 180 126 	<ul style="list-style-type: none"> 14/10/2010
<ul style="list-style-type: none"> BTVPUR AISAP 1-8 	<ul style="list-style-type: none"> Merial 	<ul style="list-style-type: none"> Sheep, cattle Inactivated vaccine against Bluetongue virus serotypes 1 and 8 	<ul style="list-style-type: none"> 10/12/2009 13/10/2010 180 126 	<ul style="list-style-type: none"> 14/10/2010
<ul style="list-style-type: none"> Hiprabovis IBR Marker Live 	<ul style="list-style-type: none"> Laboratorios Hipra S.A. 	<ul style="list-style-type: none"> Cattle A live vaccine against infectious bovine rhinotracheitis (IBR) 	<ul style="list-style-type: none"> 17/03/2009 10/11/2010 204 398 	<ul style="list-style-type: none"> 11/11/2010
<ul style="list-style-type: none"> Cimalgex Cimicoxib 	<ul style="list-style-type: none"> Vétoquinol SA 	<ul style="list-style-type: none"> Dogs Alleviation of inflammation and pain 	<ul style="list-style-type: none"> 10/11/2009 07/12/2010 210 180 	<ul style="list-style-type: none"> 09/12/2010

Product	Marketing authorisation holder	Therapeutic area	EMA/CVMP	European Commission
<ul style="list-style-type: none"> Invented name INN 		<ul style="list-style-type: none"> Target species Summary of indication 	<ul style="list-style-type: none"> Validation Opinion Active time Clock stop 	<ul style="list-style-type: none"> Opinion received Date of decision Notification Official Journal
<ul style="list-style-type: none"> Comfortis Spinosad 	<ul style="list-style-type: none"> Eli Lilly and Company Ltd 	<ul style="list-style-type: none"> Dogs Treatment and prevention of flea infestations 	<ul style="list-style-type: none"> 15/12/2009 08/12/2010 210 147 	<ul style="list-style-type: none"> 09/12/2010
<ul style="list-style-type: none"> ACTIVYL Indoxacarb 	<ul style="list-style-type: none"> Intervet International BV 	<ul style="list-style-type: none"> Cats, dogs Treatment and prevention of flea infestations 	<ul style="list-style-type: none"> 10/11/2009 08/12/2010 198 195 	<ul style="list-style-type: none"> 09/12/2010
<ul style="list-style-type: none"> Purevax Rabies 	<ul style="list-style-type: none"> Merial 	<ul style="list-style-type: none"> Cats vaccine containing the recombinant canarypox virus (vCP65) expressing the rabies glycoprotein G 	<ul style="list-style-type: none"> 15/12/2009 08/12/2010 210 147 	<ul style="list-style-type: none"> 10/12/2010
<ul style="list-style-type: none"> Melosus Meloxicam 	<ul style="list-style-type: none"> CP-Pharma Handelsgesellschaft mbH 	<ul style="list-style-type: none"> Cats Alleviation of inflammation and pain 	<ul style="list-style-type: none"> 15/12/2009 08/12/2010 175 183 	<ul style="list-style-type: none"> 09/12/2010

CVMP Opinions in 2010 on establishment of MRLs for new substances

Substance INN	Therapeutic area	EMA/CVMP	European Commission
	<ul style="list-style-type: none"> Target species 	<ul style="list-style-type: none"> Validation Opinion Active time Clock stop 	<ul style="list-style-type: none"> Opinion received Date of regulation Official Journal
<ul style="list-style-type: none"> Derquantel 	<ul style="list-style-type: none"> Ovine 	<ul style="list-style-type: none"> 18/06/2009 19/05/2010 119 206 	<ul style="list-style-type: none"> 07/06/2010
<ul style="list-style-type: none"> Monepantel (extension of provisional MRLs) 	<ul style="list-style-type: none"> Caprine 	<ul style="list-style-type: none"> N/a 15/09/2010 N/a N/a 	<ul style="list-style-type: none"> 29/09/2010
<ul style="list-style-type: none"> Isoeugenol 	<ul style="list-style-type: none"> Fin fish 	<ul style="list-style-type: none"> 17/09/2009 15/09/2010 209 218 	<ul style="list-style-type: none"> 29/09/2010
<ul style="list-style-type: none"> Closantel (Procedure under Article 9(1b) of Regulation 470/2009) 	<ul style="list-style-type: none"> Bovine and ovine milk 	<ul style="list-style-type: none"> N/a 15/09/2010 97 0 	<ul style="list-style-type: none"> 29/09/2010
<ul style="list-style-type: none"> Triclabendazole (Procedure under Article 9(1b) of Regulation 470/2009) 	<ul style="list-style-type: none"> Milk of all ruminants 	<ul style="list-style-type: none"> N/a 10/11/2010 152 0 	<ul style="list-style-type: none"> 16/11/2010

Annex 12 - COMP opinions in 2010 on designation of orphan medicinal products

Positive COMP designation opinions

Product INN	Sponsor	Summary of indication	EMA/COMP <ul style="list-style-type: none"> Submission Start date Opinion Active time 	European Commission <ul style="list-style-type: none"> Opinion received Date of decision
Lentiviral vector containing the human MYO7A gene	Oxford Biomedica (UK) Ltd - UK	Treatment of retinitis pigmentosa in Usher syndrome 1B	<ul style="list-style-type: none"> 21/10/2009 06/11/2009 06/01/2010 61 days 	<ul style="list-style-type: none"> 20/01/2010 23/03/2010
Taliglucerase	Pfizer Limited - UK	Treatment of Gaucher disease	<ul style="list-style-type: none"> 24/09/2009 09/10/2009 06/01/2010 89 days 	<ul style="list-style-type: none"> 20/01/2010 23/03/2010
Davunetide	FGK Representative Service GmbH - Germany	Treatment of progressive supranuclear palsy	<ul style="list-style-type: none"> 07/10/2009 06/11/2009 06/01/2010 61 days 	<ul style="list-style-type: none"> 20/01/2010 23/03/2010
(1S, 2S, 3R, 4R)-3-(5-Fluoro-2-(3-methyl-4-(4-methylpiperazin-1-yl)-phenylamino)-pyrimidin-4-ylamino)-bicyclo[2.2.1]hept-5-ene-2-carboxamide benzoate)	Merck KGaA - Germany	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> 20/10/2009 06/11/2009 06/01/2010 61 days 	<ul style="list-style-type: none"> 20/01/2010 23/03/2010
N-{2-Chloro-4-[(6,7-dimethoxy-4-quinolyl)oxy]phenyl}-N'-(5-methyl-3-isoxazolyl) urea hydrochloride monohydrate	Aveo Pharma Ltd - UK	Treatment of renal cell carcinoma	<ul style="list-style-type: none"> 18/11/2009 04/12/2009 03/03/2010 89 days 	<ul style="list-style-type: none"> 29/03/2010 09/06/2010
Pagibaximab	Omnicare Clinical Research GmbH - Germany	Prevention of sepsis caused by gram positive pathogens in premature infants less than or equal to 34 weeks of gestational age	<ul style="list-style-type: none"> 16/12/2009 11/01/2010 03/03/2010 51 days 	<ul style="list-style-type: none"> 29/03/2010 09/06/2010
Recombinant human anti-interferon gamma monoclonal antibody	NovImmune B.V. - The Netherlands	Treatment of haemophagocytic lymphohistiocytosis	<ul style="list-style-type: none"> 15/12/2009 11/01/2010 03/03/2010 51 days 	<ul style="list-style-type: none"> 29/03/2010 09/06/2010
Velaglucerase alfa	Shire Pharmaceuticals Ireland Limited - Ireland	Treatment of Gaucher disease	<ul style="list-style-type: none"> 29/10/2009 11/01/2010 03/03/2010 51 days 	<ul style="list-style-type: none"> 29/03/2010 09/06/2010
Maytansinoid-conjugated humanised monoclonal antibody against CD56	ImmunoGen Europe Limited - UK	Treatment of Merkel cell carcinoma	<ul style="list-style-type: none"> 16/12/2009 11/01/2010 03/03/2010 51 days 	<ul style="list-style-type: none"> 29/03/2010 09/06/2010
Synthetic double-stranded siRNA oligonucleotide directed against p53 mRNA	Verius Limited - UK	Prophylaxis of delayed graft function after renal transplantation	<ul style="list-style-type: none"> 18/11/2009 04/12/2009 03/03/2010 89 days 	<ul style="list-style-type: none"> 29/03/2010 09/06/2010
Rifapentine	Sanofi Aventis - France	Treatment of tuberculosis	<ul style="list-style-type: none"> 17/11/2009 04/12/2009 03/03/2010 89 days 	<ul style="list-style-type: none"> 29/03/2010 09/06/2010

Product INN	Sponsor	Summary of indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Dexamethasone (40 mg tablet)	Laboratoires CTRS (Cell Therapies Research & Services) - France	Treatment of multiple myeloma	<ul style="list-style-type: none"> • 20/10/2009 • 04/12/2009 • 03/03/2010 • 89 days 	<ul style="list-style-type: none"> • 29/03/2010 • 09/06/2010
Adrenomedullin	Prof. Dr Stefan Hippenstiel - Germany	Treatment of acute lung injury	<ul style="list-style-type: none"> • 28/10/2009 • 11/01/2010 • 03/03/2010 • 51 days 	<ul style="list-style-type: none"> • 29/03/2010 • 09/06/2010
Pravastatin / zoledronic acid	Prenyl BIO SAS - France	Treatment of Hutchinson-Gilford progeria	<ul style="list-style-type: none"> • 15/12/2009 • 11/01/2010 • 03/03/2010 • 51 days 	<ul style="list-style-type: none"> • 29/03/2010 • 09/06/2010
Glyceryl tri-(4-phenylbutyrate)	Hyperion Therapeutics Limited - UK	Treatment of ornithine carbamoyltransferase deficiency	<ul style="list-style-type: none"> • 18/01/2010 • 06/11/2009 • 03/02/2010 • 89 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010
Raloxifene hydrochloride	Consejo Superior de Investigaciones Cientificas (CSIC) - Spain	Treatment of hereditary haemorrhagic telangiectasia	<ul style="list-style-type: none"> • 21/10/2009 • 06/11/2009 • 03/02/2010 • 89 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010
Glyceryl tri-(4-phenylbutyrate)	Hyperion Therapeutics Limited - UK	Treatment of argininosuccinic aciduria	<ul style="list-style-type: none"> • 18/01/2010 • 06/11/2009 • 03/02/2010 • 89 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010
Pralatrexate	Allos Therapeutics Limited - UK	Treatment of cutaneous T-cell lymphoma	<ul style="list-style-type: none"> • 20/10/2009 • 06/11/2009 • 03/02/2010 • 89 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010
Glyceryl tri-(4-phenylbutyrate)	Hyperion Therapeutics Limited - UK	Treatment of ornithine translocase deficiency (hyperornithinaemia-hyperammonaemia homocitrullinuria (HHH) syndrome)	<ul style="list-style-type: none"> • 18/01/2010 • 06/11/2009 • 03/02/2010 • 89 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010
Glyceryl tri-(4-phenylbutyrate)	Hyperion Therapeutics Limited - UK	Treatment of hyperargininaemia	<ul style="list-style-type: none"> • 18/01/2010 • 06/11/2009 • 03/02/2010 • 89 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010
Glyceryl tri-(4-phenylbutyrate)	Hyperion Therapeutics Limited - UK	Treatment of carbamoyl-phosphate synthase-1 deficiency	<ul style="list-style-type: none"> • 24/09/2009 • 06/11/2009 • 03/02/2010 • 89 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010
Bafetinib	Eudax Srl - Italy	Treatment of chronic myeloid leukaemia	<ul style="list-style-type: none"> • 12/11/2009 • 04/12/2009 • 03/02/2010 • 61 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010
Perifosine	Æterna Zentaris GmbH - Germany	Treatment of multiple myeloma	<ul style="list-style-type: none"> • 16/10/2009 • 04/12/2009 • 03/02/2010 • 61 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010
Entinostat	Nexus Oncology Ltd. - United Kingdom	Treatment of Hodgkin's lymphoma	<ul style="list-style-type: none"> • 19/11/2009 • 04/12/2009 • 03/02/2010 • 61 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010

Product INN	Sponsor	Summary of indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
2-methoxymethyl-2-hydroxymethyl-1-azabicyclo[2,2,2]octan-3-one	Aprea AB - Sweden	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> • 17/11/2009 • 04/12/2009 • 03/02/2010 • 61 days 	<ul style="list-style-type: none"> • 23/06/2010 • 10/06/2010
Glyceryl tri-(4-phenylbutyrate)	Hyperion Therapeutics Limited - UK	Treatment of citrullinaemia type 1	<ul style="list-style-type: none"> • 18/01/2010 • 06/11/2009 • 03/02/2010 • 89 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010
Glyceryl tri-(4-phenylbutyrate)	Hyperion Therapeutics Limited - UK	Treatment of citrullinaemia type 2	<ul style="list-style-type: none"> • 18/01/2010 • 06/11/2009 • 03/02/2010 • 89 days 	<ul style="list-style-type: none"> • 23/02/2010 • 10/06/2010
Tranilast	Altacor Ltd - UK	Prevention of scarring following glaucoma filtration surgery	<ul style="list-style-type: none"> • 22/01/2010 • 08/02/2010 • 08/04/2010 • 59 days 	<ul style="list-style-type: none"> • 29/04/2010 • 27/07/2010
Octenidine dihydrochloride	Schülke & Mayr GmbH - Germany	Prevention of late-onset sepsis in premature infants of less than or equal to 32 weeks gestational age	<ul style="list-style-type: none"> • 21/10/2008 • 11/01/2010 • 08/04/2010 • 87 days 	<ul style="list-style-type: none"> • 29/04/2010 • 27/07/2010
Heparin-activated recombinant human fibroblast growth factor 1 (on a biodegradable device made from alpha-calcium sulphate hemihydrate)	Bioarctic Neuroscience AB - Sweden	Treatment of traumatic spinal cord injury	<ul style="list-style-type: none"> • 20/01/2010 • 08/02/2010 • 08/04/2010 • 59 days 	<ul style="list-style-type: none"> • 29/04/2010 • 27/07/2010
Pomalidomide	Celgene Europe Limited - UK	Treatment of post-essential thrombocythaemia myelofibrosis	<ul style="list-style-type: none"> • 25/03/2010 • 11/01/2010 • 08/04/2010 • 87 days 	<ul style="list-style-type: none"> • 29/04/2010 • 27/07/2010
Pomalidomide	Celgene Europe Limited - UK	Treatment of post-polycythaemia vera myelofibrosis	<ul style="list-style-type: none"> • 25/03/2010 • 11/01/2010 • 08/04/2010 • 87 days 	<ul style="list-style-type: none"> • 29/04/2010 • 27/07/2010
Pomalidomide	Celgene Europe Limited - UK	Treatment of primary myelofibrosis	<ul style="list-style-type: none"> • 16/12/2009 • 11/01/2010 • 08/04/2010 • 87 days 	<ul style="list-style-type: none"> • 29/04/2010 • 27/07/2010
6alpha-ethyl-chenodeoxycholic acid	Intercept Italia S.R.L. - Italy	Treatment of primary biliary cirrhosis	<ul style="list-style-type: none"> • 24/06/2009 • 08/02/2010 • 08/04/2010 • 59 days 	<ul style="list-style-type: none"> • 29/04/2010 • 27/07/2010
Midostaurin	Novartis Europharm Limited - UK	Treatment of mastocytosis	<ul style="list-style-type: none"> • 15/02/2010 • 05/03/2010 • 06/05/2010 • 62 days 	<ul style="list-style-type: none"> • 28/05/2010 • 04/08/2010
Bosutinib	Wyeth Europa Limited - UK	Treatment of chronic myeloid leukaemia	<ul style="list-style-type: none"> • 17/12/2009 • 05/03/2010 • 06/05/2010 • 62 days 	<ul style="list-style-type: none"> • 28/05/2010 • 04/08/2010
3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid	Voisin Consulting S.A.R.L. - France	Treatment of cystic fibrosis	<ul style="list-style-type: none"> • 19/02/2010 • 05/03/2010 • 06/05/2010 • 62 days 	<ul style="list-style-type: none"> • 28/05/2010 • 04/08/2010

Product INN	Sponsor	Summary of indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Everolimus	Novartis Europharm Limited - UK	Treatment of tuberous sclerosis	<ul style="list-style-type: none"> • 22/01/2010 • 05/03/2010 • 06/05/2010 • 62 days 	<ul style="list-style-type: none"> • 28/05/2010 • 04/08/2010
(3S)-3-{4-[7-(aminocarbonyl)-2H-indazol-2-yl] phenyl} piperidine tosylate monohydrate salt	Merck Sharp & Dohme Limited - UK	Treatment of ovarian cancer	<ul style="list-style-type: none"> • 08/02/2010 • 05/03/2010 • 06/05/2010 • 62 days 	<ul style="list-style-type: none"> • 28/05/2010 • 04/08/2010
Pyr-His-Trp-Ser-Tyr-D-Lys(doxorubicinylglutarate)-Leu-Arg-Pro-Gly-NH ₂ , acetate salt	Æterna Zentaris GmbH - Germany	Treatment of ovarian cancer	<ul style="list-style-type: none"> • 08/02/2010 • 05/03/2010 • 06/05/2010 • 62 days 	<ul style="list-style-type: none"> • 28/05/2010 • 04/08/2010
11-(2-pyrrolidin-1-yl-ethoxy)-14,19-dioxo-5,7,26-triaza-tetracyclo[19.3.1.1(2,6).1(8,12)] heptacos-1(25),2(26),3,5,8,10,12(27),16,21,23-decaene	Voisin Consulting S.A.R.L. - France	Treatment of post-essential thrombocythaemia myelofibrosis	<ul style="list-style-type: none"> • 19/02/2010 • 05/03/2010 • 02/06/2010 • 89 days 	<ul style="list-style-type: none"> • 30/06/2010 • 25/08/2010
11-(2-pyrrolidin-1-yl-ethoxy)-14,19-dioxo-5,7,26-triaza-tetracyclo[19.3.1.1(2,6).1(8,12)] heptacos-1(25),2(26),3,5,8,10,12(27),16,21,23-decaene	Voisin Consulting S.A.R.L. - France	Treatment of post-polycythaemia vera myelofibrosis	<ul style="list-style-type: none"> • 19/02/2010 • 05/03/2010 • 02/06/2010 • 89 days 	<ul style="list-style-type: none"> • 30/06/2010 • 25/08/2010
11-(2-pyrrolidin-1-yl-ethoxy)-14,19-dioxo-5,7,26-triaza-tetracyclo[19.3.1.1(2,6).1(8,12)] heptacos-1(25),2(26),3,5,8,10,12(27),16,21,23-decaene	Voisin Consulting S.A.R.L. - France	Treatment of primary myelofibrosis	<ul style="list-style-type: none"> • 19/02/2010 • 05/03/2010 • 02/06/2010 • 89 days 	<ul style="list-style-type: none"> • 30/06/2010 • 25/08/2010
Recombinant porcine factor VIII (B domain deleted)	Inspiration Biopharmaceuticals EU Limited	Treatment of haemophilia A	<ul style="list-style-type: none"> • 24/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Adenovirus-associated viral vector serotype 10 carrying the human N-sulfoglucosamine sulfohydrolase and sulfatase modifying factor 1 cDNAs	SANFILIPPO Therapeutics SAS - France	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome)	<ul style="list-style-type: none"> • 24/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Recombinant fusion protein consisting of human coagulation factor VIII attached to the Fc domain of human IgG1	Biogen Idec Limited - UK	Treatment of haemophilia A	<ul style="list-style-type: none"> • 22/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Nafamostat mesilate	Mucokinetica Ltd - UK	Treatment of cystic fibrosis	<ul style="list-style-type: none"> • 23/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Vorinostat	Merck Sharp & Dohme Limited - UK	Treatment of malignant mesothelioma	<ul style="list-style-type: none"> • 19/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010

Product INN	Sponsor	Summary of indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Eflornithine	Cancer Prevention Pharma Ltd - UK	Treatment of familial adenomatous polyposis	<ul style="list-style-type: none"> • 03/11/2009 • 05/03/2010 • 02/06/2010 • 89 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Allogeneic T cells encoding an exogenous TK gene	LTKFarma - France	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> • 24/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Cyclic pyranopterin monophosphate	Orphatec Pharmaceuticals GmbH - Germany	Treatment of molybdenum cofactor deficiency type A	<ul style="list-style-type: none"> • 11/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Allogeneic human dermal fibroblasts	Intercytex Ltd - UK	Treatment of epidermolysis bullosa	<ul style="list-style-type: none"> • 18/05/2009 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Cysteamine bitartrate (gastroresistant)	Raptor Pharmaceuticals Europe BV - The Netherlands	Treatment of cystinosis	<ul style="list-style-type: none"> • 24/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Autologous bone marrow-derived mononuclear cell fraction	t2cure GmbH - Germany	Treatment of thromboangiitis obliterans (Buerger's disease)	<ul style="list-style-type: none"> • 24/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
1-[2-(Benzo[1,2,5]thiadiazol-5-ylamino)-6-(2,6-dichlorophenyl)-pyrido[2,3-d]pyrimidin-7-yl]-3-tert-butyl-urea	Sanofi Aventis - France	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> • 17/02/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Autologous dendritic cells pulsed with recombinant human-fusion protein (mucin 1 - glutathione S transferase) coupled to oxidised polymannose	Prima Biomed Europe Ltd - UK	Treatment of ovarian cancer	<ul style="list-style-type: none"> • 17/02/2010 • 12/04/2010 • 02/06/2010 • 89 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Heat-killed mycobacterium vaccae (whole cell)	Immodulon Therapeutics Ltd - UK	Treatment of tuberculosis	<ul style="list-style-type: none"> • 23/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Glutathione-pegylated liposomal doxorubicin hydrochloride	to-BBB Technologies BV - The Netherlands	Treatment of glioma	<ul style="list-style-type: none"> • 23/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Forodesine	Mundipharma Research Limited - UK	Treatment of chronic lymphocytic leukaemia	<ul style="list-style-type: none"> • 22/03/2010 • 12/04/2010 • 02/06/2010 • 51 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010
Abarelix	Speciality European Pharma Ltd - UK	Treatment of low-flow priapism	<ul style="list-style-type: none"> • 18/02/2010 • 05/03/2010 • 02/06/2010 • 89 days 	<ul style="list-style-type: none"> • 30/06/2010 • 20/09/2010

Product INN	Sponsor	Summary of indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
N-tert-butyl-3-[(5-methyl-2-{[4-(2-pyrrolidin-1-ylethoxy)phenyl]amino}pyrimidin-4-yl)amino]benzenesulfonamide dihydrochloride monohydrate	Sanofi Aventis - France	Treatment of primary myelofibrosis	<ul style="list-style-type: none"> • 20/05/2010 • 05/03/2010 • 16/07/2010 • 35 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010
Ciclosporin	NeuroVive Pharmaceuticals AB - Sweden	Treatment of moderate and severe closed traumatic brain injury	<ul style="list-style-type: none"> • 19/05/2010 • 11/06/2010 • 08/07/2010 • 27 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010
N-(6-(2-aminophenylamino)-6-oxohexyl)-4-methylbenzamide	Repligen Europe Limited - Ireland	Treatment of Friedreich's ataxia	<ul style="list-style-type: none"> • 22/03/2010 • 11/06/2010 • 08/07/2010 • 27 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010
Tecovirimat	SIGA Pharmaceuticals (Europe) Ltd - UK	Treatment of cowpox infection	<ul style="list-style-type: none"> • 23/03/2010 • 12/04/2010 • 16/07/2010 • 95 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010
(3S)-3-{4-[7-(aminocarbonyl)-2H-indazol-2-yl] phenyl} piperidine tosylate monohydrate salt	Merck Sharp & Dohme Limited - UK	Treatment of mantle cell lymphoma	<ul style="list-style-type: none"> • 13/05/2010 • 11/06/2010 • 16/07/2010 • 35 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010
Recombinant humanised anti-human interleukin-1 beta monoclonal antibody	XOMA Ireland Ltd - Ireland	Treatment of Behçet's Disease	<ul style="list-style-type: none"> • 17/05/2010 • 11/06/2010 • 08/07/2010 • 27 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010
16-base single-stranded peptide nucleic acid oligonucleotide linked to a 7-amino acid peptide	Biogenere srl - Italy	Treatment of medulloblastoma	<ul style="list-style-type: none"> • 18/02/2010 • 12/04/2010 • 08/07/2010 • 87 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010
(S)-10-[(dimethylamino)methyl]-4-ethyl-9-hydroxy-4-O-[alpha-(2", 4", 5", 7"-tetranitro-9"-fluorenylideneaminoxy)propionyl]-1H-pyrano[3', 4', 6', 7']indolizino[1,2-beta]-quinoline-3, 14-(4H, 12H)-dione, hydrochloride	TLC Biopharmaceutics B.V. - The Netherlands	Treatment of hepatocellular carcinoma	<ul style="list-style-type: none"> • 20/05/2010 • 11/06/2010 • 08/07/2010 • 27 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010
Ambrisentan	Gilead Sciences International Ltd - UK	Treatment of idiopathic pulmonary fibrosis	<ul style="list-style-type: none"> • 22/03/2010 • 11/06/2010 • 08/07/2010 • 27 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010
Recombinant humanised monoclonal antibody to human Nogo-A protein of the IgG1/kappa class	Glaxo Group Limited - UK	Treatment of amyotrophic lateral sclerosis	<ul style="list-style-type: none"> • 14/05/2010 • 11/06/2010 • 08/07/2010 • 27 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010
Synthetic double-stranded short interfering RNA oligonucleotide directed against proopiomelanocortin	UKR Regulatory Affairs Ltd - UK	Treatment of adrenocorticotropin-dependent Cushing's Syndrome	<ul style="list-style-type: none"> • 23/03/2010 • 12/04/2010 • 08/07/2010 • 87 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010
Maytansinoid-conjugated humanised monoclonal antibody against CD56	ImmunoGen Europe Limited - UK	Treatment of small cell lung cancer	<ul style="list-style-type: none"> • 19/05/2010 • 11/06/2010 • 08/07/2010 • 27 days 	<ul style="list-style-type: none"> • 30/07/2010 • 01/10/2010

Product INN	Sponsor	Summary of indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
2-(2-chlorophenyl)-4-[3-(dimethylamino)phenyl]-5-methyl-1H-pyrazolo[4,3-C]pyridine-3,6(2H,5H)-dione	Fulcrum Pharma (Europe) Ltd. - UK	Treatment of idiopathic pulmonary fibrosis	<ul style="list-style-type: none"> • 25/06/2010 • 12/07/2010 • 09/09/2010 • 59 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
Sildenafil citrate	Pfizer Limited - UK	Treatment of postcardiotomy right ventricular failure	<ul style="list-style-type: none"> • 21/05/2010 • 11/06/2010 • 09/09/2010 • 90 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
Methylthioninium	Dr Hans Moebius - UK	Treatment of progressive supranuclear palsy	<ul style="list-style-type: none"> • 23/06/2010 • 12/07/2010 • 09/09/2010 • 59 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
Murine monoclonal antibody against CD26	ADIENNE S.r.l - Italy	Treatment of graft-versus-host disease	<ul style="list-style-type: none"> • 17/02/2010 • 11/06/2010 • 09/09/2010 • 90 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
Recombinant human arylsulfatase A	Shire Pharmaceuticals Ireland Limited - Ireland	Treatment of metachromatic leukodystrophy	<ul style="list-style-type: none"> • 20/05/2010 • 02/05/2003 • 09/09/2010 • 59 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
N-tert-butyl-3-[(5-methyl-2-{[4-(2-pyrrolidin-1-ylethoxy)phenyl]amino}pyrimidin-4-yl)amino]benzenesulfonamide dihydrochloride monohydrate	Sanofi Aventis - France	Treatment of post-polycythaemia vera myelofibrosis	<ul style="list-style-type: none"> • 25/06/2010 • 12/07/2010 • 09/09/2010 • 59 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
Nanoparticle albumin-bound paclitaxel	Abraxis BioScience Limited - UK	Treatment of pancreatic cancer	<ul style="list-style-type: none"> • 25/06/2010 • 12/07/2010 • 09/09/2010 • 59 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
Recombinant fusion protein consisting of the extracellular portion of human activin receptor IIB linked to the human IgG1 Fc domain	INC Research - UK	Treatment of Duchenne muscular dystrophy	<ul style="list-style-type: none"> • 25/06/2010 • 12/07/2010 • 09/09/2010 • 59 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
N-tert-butyl-3-[(5-methyl-2-{[4-(2-pyrrolidin-1-ylethoxy)phenyl]amino}pyrimidin-4-yl)amino]benzenesulfonamide dihydrochloride monohydrate	Sanofi Aventis - France	Treatment of post-essential thrombocythaemia myelofibrosis	<ul style="list-style-type: none"> • 25/06/2010 • 12/07/2010 • 09/09/2010 • 59 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
Chimeric monoclonal antibody against claudin-18 splice variant 2	GANYMED Pharmaceuticals AG - Germany	Treatment of gastric cancer	<ul style="list-style-type: none"> • 25/06/2010 • 12/07/2010 • 09/09/2010 • 59 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
Recombinant human von Willebrand factor	Baxter Innovations GmbH - Austria	Treatment of von Willebrand disease	<ul style="list-style-type: none"> • 12/05/2010 • 11/06/2010 • 09/09/2010 • 90 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
Methylthioninium	Dr Hans Moebius - UK	Treatment of progressive non-fluent aphasia	<ul style="list-style-type: none"> • 19/05/2010 • 11/06/2010 • 09/09/2010 • 90 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010

Product INN	Sponsor	Summary of indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Methylthioninium	Dr Hans Moebius - UK	Treatment of behavioural variant frontotemporal dementia	<ul style="list-style-type: none"> • 19/05/2010 • 11/06/2010 • 09/09/2010 • 90 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
Methylthioninium	Dr Hans Moebius - UK	Treatment of frontotemporal dementia with parkinsonism-17	<ul style="list-style-type: none"> • 19/05/2010 • 11/06/2010 • 09/09/2010 • 90 days 	<ul style="list-style-type: none"> • 01/10/2010 • 26/11/2010
Tesetaxel	Genta Development Ltd - UK	Treatment of gastric cancer	<ul style="list-style-type: none"> • 22/07/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Human heterologous liver cells (for infusion)	Cytonet GmbH & Co. KG - Germany	Treatment of carbamoyl-phosphate synthetase-1 deficiency	<ul style="list-style-type: none"> • 23/07/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Human heterologous liver cells (for infusion)	Cytonet GmbH & Co. KG - Germany	Treatment of hyperargininaemia	<ul style="list-style-type: none"> • 23/07/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Human heterologous liver cells (for infusion)	Cytonet GmbH & Co. KG - Germany	Treatment of argininosuccinic aciduria	<ul style="list-style-type: none"> • 23/07/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Human heterologous liver cells (for infusion)	Cytonet GmbH & Co. KG - Germany	Treatment of citrullinaemia type 1	<ul style="list-style-type: none"> • 23/07/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Lentiviral vector carrying the Fanconi anaemia-A (FANCA) gene	Center for Biomedical Network Research on Rare Diseases (CIBERER) - Spain	Treatment of Fanconi anaemia type A	<ul style="list-style-type: none"> • 23/07/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
N-[(2S)-2,3-dihydroxypropyl]-3-[(2-fluoro-4-iodophenyl) amino] isonicotinamide hydrochloride	Merck KGaA - Germany	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> • 13/07/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Adeno-associated viral vector containing DNA encoding an RNAi targeting rhodopsin/ adeno-associated viral vector containing a rhodopsin gene	Genable Technologies Ltd - Ireland	Treatment of rhodopsin-linked retinitis pigmentosa	<ul style="list-style-type: none"> • 20/07/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Silibinin-C-2',3-dihydrogensuccinate, disodium salt	Rottapharm S.p.A - Italy	Prevention of recurrent hepatitis C in liver transplant recipients	<ul style="list-style-type: none"> • 22/07/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
7-beta-hydroxycholesteryl-3-beta-oleate	Intsel Chimos SA - France	Treatment of glioma	<ul style="list-style-type: none"> • 29/06/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Veliparib	Abbott Laboratories - UK	Treatment of ovarian cancer	<ul style="list-style-type: none"> • 26/07/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010

Product INN	Sponsor	Summary of indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Lomitapide	Dimensione Ricerca S.r.l - Italy	Treatment of familial chylomicronaemia	<ul style="list-style-type: none"> • 28/06/2010 • 12/07/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Recombinant human lysosomal acid lipase	HungaroTrial Ltd - Hungary	Treatment of lysosomal acid lipase deficiency	<ul style="list-style-type: none"> • 23/07/2010 • 13/08/2010 • 07/10/2010 • 55 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Ovine anti-colchicine polyclonal antibody fragments	Laboratoires SERB - France	Treatment of colchicine poisoning	<ul style="list-style-type: none"> • 24/06/2010 • 12/07/2010 • 07/10/2010 • 87 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Para-aminosalicylic acid	Lucane Pharma SAS - France	Treatment of tuberculosis	<ul style="list-style-type: none"> • 01/06/2010 • 12/07/2010 • 07/10/2010 • 87 days 	<ul style="list-style-type: none"> • 29/10/2010 • 17/12/2010
Tecovirimat	SIGA Pharmaceuticals (Europe) Ltd - UK	Treatment of variola infection	<ul style="list-style-type: none"> • 23/03/2010 • 12/04/2010 • 16/07/2010 	<ul style="list-style-type: none"> • 30/07/2010 • awaited
Tecovirimat	SIGA Pharmaceuticals (Europe) Ltd - UK	Treatment of monkeypox infection	<ul style="list-style-type: none"> • 23/03/2010 • 12/04/2010 • 16/07/2010 	<ul style="list-style-type: none"> • 30/07/2010 • awaited

Negative COMP designation opinions

Product INN	Sponsor	Summary of indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Lentiviral vector containing truncated forms of human tyrosine hydroxylase gene, human aromatic L-amino acid decarboxylase gene and human GTP cyclohydrolase 1 gene	Oxford Biomedica (UK) Ltd - UK	Treatment of 'OFF'-periods in adult patients with advanced Parkinson's disease who are not responding adequately to L-DOPA treatment	<ul style="list-style-type: none"> • 20/05/2010/ • 11/06/2010 • 09/09/2010 	<ul style="list-style-type: none"> • 16/03/2011 • awaited

Annex 13 – HMPC Community herbal monographs and entries into list of herbal substances in 2010

Community herbal monographs

Reference number	Document title	Status
EMA/HMPC/508015/2007	Community herbal monograph on <i>Urticae folium</i>	Adopted January 2010
EMA/HMPC/131901/2009	Community herbal monograph on <i>Thymi aetheroleum</i>	Adopted January 2010 & September 2010
EMA/HMPC/577784/2008	Community herbal monograph on <i>Echinaceae purpureae radix</i>	Adopted March 2010
EMA/HMPC/281496/2009	Community herbal monograph on <i>Orthosiphonis folium</i>	Adopted March 2010
EMA/HMPC/580539/2008	Community herbal monograph on <i>Mate folium</i>	Adopted May 2010
EMA/HMPC/142986/2009	Community herbal monograph on <i>Ribis nigri folium</i>	Adopted May 2010
EMA/HMPC/585558/2007	Community herbal monograph on <i>Valerianae radix/Lupuli flos</i>	Adopted May 2010
EMA/HMPC/235453/2009	Community herbal monograph on <i>Rosmarini aetheroleum</i>	Adopted July 2010
EMA/HMPC/13633/2009	Community herbal monograph on <i>Rosmarini folium</i>	Adopted July 2010
EMA/HMPC/16635/2009	Community herbal monograph on <i>Vitis viniferae folium</i>	Adopted July 2010 Draft rev.1 released for public consultation January 2010
EMA/HMPC/41843/2009	Public statement on <i>Salviae officinalis aetheroleum</i>	Adopted July 2010
EMA/HMPC/246763/2009	Community herbal monograph on <i>Arctii radix</i>	Adopted September 2010 Released for public consultation January 2010
EMA/HMPC/127428/2010	Community herbal monograph on <i>Leonuri cardiaca herba</i>	Adopted September 2010 Released for public consultation May 2010
EMA/HMPC/727465/2009	Public statement on <i>Euphrasiae herba</i>	Adopted September 2010
EMA/HMPC/144006/2009	Community herbal monograph on <i>Agni casti fructus</i>	Adopted November 2010
EMA/HMPC/600717/2007	Community herbal monograph on <i>Cimicifugae racemosae rhizoma</i>	Adopted November 2010
EMA/HMPC/12402/2009	Community herbal monograph on <i>Juniperi aetheroleum</i>	Adopted November 2010 Released for public consultation March 2010
EMA/HMPC/3203/2009	Community herbal monograph on <i>Quercus cortex</i>	Adopted November 2010 Released for public consultation January 2010
EMA/HMPC/587578/2009	Community herbal monograph on <i>Tanacetii parthenii herba</i>	Adopted November 2010 Released for public consultation May 2010
EMA/HMPC/5513/2010	Community herbal monograph on <i>Tormentillae rhizoma</i>	Adopted November 2010 Released for public consultation March 2010

Reference number	Document title	Status
EMA/HMPC/131734/2009	Community herbal monograph on <i>Violae herba cum flora</i>	Adopted November 2010 Released for public consultation March 2010
EMA/HMPC/579663/2009	Public statement on <i>Centellae asiaticae herba</i>	Adopted November 2010
EMA/HMPC/289430/2009	Community herbal monograph on <i>Hederae helicis folium</i>	Released for public consultation January 2010
EMA/HMPC/146221/2010	Community herbal monograph on <i>Trigonellae foenugraeci semen</i>	Released for public consultation May 2010
EMA/HMPC/706229/2009	Community herbal monograph on <i>Cinnamomi corticis aetheroleum</i>	Released for public consultation July 2010
EMA/HMPC/246774/2009	Community herbal monograph on <i>Cinnamomi cortex</i>	Released for public consultation July 2010
EMA/HMPC/573460/2009	Community herbal monograph on <i>Uvae ursi folium</i>	Released for public consultation July 2010
EMA/HMPC/143949/2010	Community herbal monograph on <i>Millefolii flos</i>	Released for public consultation September 2010
EMA/HMPC/290284/2009	Community herbal monograph on <i>Millefolii herba</i>	Released for public consultation September 2010
EMA/HMPC/96911/2010	Community herbal monograph on <i>Myrrha (Commiphora molmol)</i>	Released for public consultation September 2010
EMA/HMPC/262766/2010	Community herbal monograph on <i>Bursae pastoris herba</i>	Released for public consultation November 2010
EMA/HMPC/150218/2009	Community herbal monograph on <i>Cynarae folium</i>	Released for public consultation November 2010
EMA/HMPC/434894/2010	Community herbal monograph on <i>Filipendulae ulmariae flos</i>	Released for public consultation November 2010
EMA/HMPC/434881/2010	Community herbal monograph on <i>Filipendulae ulmariae herba</i>	Released for public consultation November 2010
EMA/HMPC/437858/2010	Community herbal monograph on <i>Plantiginis lanceolatae folium</i>	Released for public consultation November 2010
EMA/HMPC/743927/2010	Public statement on <i>Chelidonii herba</i>	Released for public consultation November 2010

Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products

Reference number	Document title	Status
EMA/HMPC/704562/2009	Community list entry on <i>Hamamelidis folium et cortex aut ramunculus destillatum</i>	Adopted July 2010
EMA/HMPC/5816/2010	Community list entry on <i>Vitis viniferae folium</i>	Adopted July 2010 Released for public consultation January 2010
EMA/HMPC/255527/2009	Community list entry on <i>Thymi aetheroleum</i>	Adopted September 2010 Released for public consultation January 2010

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 <ul style="list-style-type: none"> Start date Opinion (R) Re-examination 	EMA Decision
Exenatide (Byetta)	Eli Lilly and Company	Endocrinology-gynaecology-fertility-metabolism	PM EMEA-000689-PIP01-09-M01	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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
Duloxetine hydrochloride (Cymbalta/Xeristar/Yentreve/Ariclaim/Duloxetine Boehringer Ingelheim)	Eli Lilly & Company	Psychiatry and pain	RP W EMEA-000420-PIP01-08	• 19/11/2009 • 15/01/2010	P/21/2010
Lanthanum carbonate hydrate ("Fosrenol" and associated name "Foznol")	Shire Pharmaceutical Contracts Ltd.	Uro-nephrology	RW EMEA-000637-PIP01-09	• 23/07/2009 • 15/01/2010	P/22/2010
Strontium ranelate (Protelos) (Osseor)	Les Laboratoires Servier	Immunology-rheumatology-transplantation	W EMEA-000732-PIP01-09	• 19/11/2009 • 15/01/2010	P/23/2010
Strontium ranelate (Protelos) (Osseor)	Les Laboratoires Servier	Immunology-rheumatology-transplantation	W EMEA-000733-PIP01-09	• 19/11/2009 • 15/01/2010	P/24/2010
Tiotropium bromide monohydrate (Spiriva, Respimat and associated names)	Boehringer Ingelheim International GmbH	Pneumology	PM EMEA-000035-PIP01-07-M01	• 19/11/2009 • 15/01/2010	P/25/2010
Nevirapine (Viramune)	Boehringer Ingelheim International GmbH	Infectious diseases	PM EMEA-000391-PIP01-08-M01	• 23/12/2009 • 15/01/2010	P/26/2010
Pramipexole dihydrochloride monohydrate (Sifrol)	Boehringer Ingelheim International GmbH	Neurology	PM EMEA-000041-PIP01-07-M01	• 19/11/2009 • 15/01/2010	P/27/2010
Dalcetrapib	Roche Registration Limited	Endocrinology-gynaecology-fertility-metabolism / cardiovascular diseases	P EMEA-000580-PIP01-09	• 28/05/2009 • 15/01/2010	P/28/2010
Rupatadine fumarate (Rupafin and associated names)	J. Uriach y Compañía, S.A	Dermatology / pneumology - allergology / oto-rhinolaryngology	P EMEA-000582-PIP01-09	• 23/07/2009 • 15/01/2010	P/29/2010
Montelukast sodium (Singulair)	Merck-Sharp & Dohme Ltd	Pneumology	C EMEA-000012-PIP01-07-M01	• 23/12/2009 • 15/01/2010	N.A
Fluticasone furoate / triphenylacetic acid - 4-{{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol (1:1)	Glaxo Group Limited	Pneumology - allergology	PM EMEA-000431-PIP01-08-M01	• 19/11/2009 • 15/01/2010 • 19/02/2010 (R)	P/30/2010
Dasatinib (Sprycel)	Bristol-Myers Squibb Pharma EEIG	Oncology	PM EMEA-000567-PIP01-09-M01	• 23/12/2009 • 19/02/2010	P/31/2010

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Colistimethate sodium	Forest Laboratories UK Limited	Infectious diseases	PM EMA-000176-PIP01-07-M01	• 21/01/2010 • 19/02/2010	P/32/2010
Rabeprazole sodium (Pariet and associated names)	Eisai Limited	Gastroenterology Hepatology	PM EMA-000055-PIP01-07-M02	• 23/12/2009 • 19/02/2010	P/34/2010
Retigabine	Glaxo Group Limited	Neurology	PM EMA-000116-PIP01-07-M02	• 23/12/2009 • 19/02/2010	P/35/2010
Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), adjuvanted)	Sanofi Pasteur SA	Vaccines	PM EMA-000669-PIP01-09-M01	• 23/12/2009 • 19/02/2010	P/36/2010
Brivaracetam	UCB Pharma SA	Neurology	PM EMA-000332-PIP01-08-M01	• 23/12/2009 • 19/02/2010	P/37/2010
Ferumoxytol	AMAG Pharmaceuticals, Inc.	Haematology-haemostaseology	PM EMA-000373-PIP02-09-M01	• 15/01/2010 • 19/02/2010	P/38/2010
Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), non-adjuvanted	Sanofi Pasteur SA	Vaccines	PM EMA-000670-PIP01-09-M01	• 23/12/2009 • 19/02/2010	P/39/2010
Catridecacog	Novo Nordisk A/S	Haematology-Hemostaseology	PM EMA-000185-PIP01-08-M01	• 23/12/2009 • 19/02/2010	P/40/2010
Tartaric acid	Pneumoflex E.U	Uro-nephrology	W EMA-000772-PIP01-09	• 23/12/2009 • 19/02/2010	P/41/2010
Voriconazole (Vfend)	Pfizer Limited	Infectious diseases	P EMA-000191-PIP01-08	• 10/04/2008 • 19/02/2010	P/42/2010
Rilpivirine (hydrochloride)	Janssen-Cilag International NV	Infectious diseases	PM EMA-000317-PIP01-08-M01	• 23/12/2009 • 19/02/2010	P/43/2010
Insulin degludec	Novo Nordisk A/S	Endocrinology-gynaecology-fertility-metabolism	P EMA-000456-PIP01-08	• 08/01/2009 • 19/02/2010	P/44/2010
Anidulafungin (Ecalta)	Pfizer Limited	Infectious diseases	P EMA-000469-PIP01-08	• 08/01/2009 • 19/02/2010	P/45/2010
Insulin degludec/insulin aspart	Novo Nordisk A/S	Endocrinology-gynaecology-fertility-metabolism	P EMA-000479-PIP01-08	• 08/01/2009 • 19/02/2010	P/46/2010

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Budesonide / salmeterol xinafoate	Laboratoires SMB s.a.	Pneumology-allergology	W EMEA-000623-PIP01-09	<ul style="list-style-type: none"> • 23/07/2009 • 19/02/2010 	P/47/2010
Plerixafor (Mozobil)	Genzyme Europe B.V.	Oncology	PM EMEA-000174-PIP01-07-M02	<ul style="list-style-type: none"> • 23/12/2009 • 19/02/2010 	P/48/2010
Ciclosporin	Novagali Pharma S.A.	Ophthalmology	P EMEA-000575-PIP01-09	<ul style="list-style-type: none"> • 23/07/2009 • 19/02/2010 	P/49/2010
Recombinant Coagulation Factor VIII (N8),	Novo Nordisk A/S	Haematology-haemostaseology	P EMEA-000428-PIP01-08	<ul style="list-style-type: none"> • 05/03/2009 • 19/02/2010 	P/50/2010
Propranolol (hydrochloride)	Pierre Fabre Dermatologie	Dermatology	PM EMEA-000511-PIP01-08-M01	<ul style="list-style-type: none"> • 23/12/2009 • 19/02/2010 	P/51/2010
Lisdexamfetamine dimesylate	Shire Pharmaceutical Contracts Ltd	Psychiatry	P EMEA-000553-PIP01-09	<ul style="list-style-type: none"> • 30/04/2009 • 19/02/2010 	P/52/2010
Decitabine	Janssen-Cilag International NV	Oncology	P EMEA-000555-PIP01-09	<ul style="list-style-type: none"> • 28/05/2009 • 19/02/2010 	P/53/2010
Semuloparin sodium	Sanofi-aventis Recherche & Développement	Haematology-haemostaseology	P EMEA-000562-PIP01-09	<ul style="list-style-type: none"> • 30/04/2009 • 19/02/2010 	P/54/2010
(2R, 3aR, 10Z, 11aS, 12aR, 14aR)-N-(cyclopropylsulfonyl)-2-[[[2-(4-isopropyl-1, 3-thiazol-2-yl)-7-methoxy-8-methyl-4-quinolinyl]oxy]-5-methyl-4, 14-dioxo-2, 3, 3a, 4, 5, 6, 7, 8, 9, 11a, 12, 13, 14, 14a-tetradecahydrocyclopenta [c] cyclopropa [g] [1, 6] diazacyclopentadecine-12a (1H)-carboxamide, (TMC435)	Tibotec BVBA	Infectious diseases	P EMEA-000625-PIP01-09	<ul style="list-style-type: none"> • 23/07/2009 • 19/02/2010 	P/55/2010
Eritoran	Eisai Ltd	Infectious diseases	P EMEA-000509-PIP02-09	<ul style="list-style-type: none"> • 21/01/2010 • 19/03/2010 	P/56/2010
Taliglucerase alfa	Protalix B.V.	Endocrinology-gynaecology-fertility-metabolism	P EMEA-000648-PIP01-09	<ul style="list-style-type: none"> • 20/08/2009 • 19/02/2010 	P/57/2010
Esomeprazole magnesium / acetylsalicylic acid	AstraZeneca AB	Gastroenterology-hepatology	W EMEA-000682-PIP01-09	<ul style="list-style-type: none"> • 20/08/2009 • 15/01/2010 • 19/03/2010 (R) 	P/59/2010
A/California/7/2009 influenza-like virus	Novartis Vaccines &	Vaccines	PM EMEA-000663-	<ul style="list-style-type: none"> • 18/02/2010 • 19/03/2010 	P/60/2010

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strain	Diagnostics GmbH & Co. KG		PIP01-09-M02		
Nomegestrol acetate / 17beta - estradiol	N.V. Organon (part of Schering Plough)	Endocrinology-gynaecology-fertility-metabolism	PM EMEA-000250-PIP01-08-M02	<ul style="list-style-type: none"> • 21/01/2010 • 19/03/2010 	P/61/2010
Infliximab (Remicade)	Centocor B.V	Immunology-rheumatology-transplantation / dermatology / gastroenterology-hepatology	P EMEA-000549-PIP01-09	<ul style="list-style-type: none"> • 23/07/2009 • 19/03/2010 	P/62/2010
Opinion of the Paediatric Committee on a class waiver on condition(s)	N/A	N/A	Class Waiver	<ul style="list-style-type: none"> • 16/04/2010 	P/63/2010
Iron, aqua carbonate hydroxy oxo starch sucrose complex	Novartis Europharm Limited	Uro-nephrology	PM EMEA-000100-PIP01-07-M01	<ul style="list-style-type: none"> • 18/02/2010 • 19/03/2010 	P/64/2010
Octocog alfa (ADVATE)	Baxter AG	Haematology-hemostaseology	W EMEA-000358-PIP02-09	<ul style="list-style-type: none"> • 21/01/2010 • 19/03/2010 	P/65/2010
Avotermin	Renovo Ltd	Dermatology	P EMEA-000634-PIP01-09	<ul style="list-style-type: none"> • 23/07/2009 • 19/03/2010 	P/66/2010
Diamorphine	Azanta A/S	Other (addictology)	W EMEA-000749-PIP01-09	<ul style="list-style-type: none"> • 21/01/2010 • 19/03/2010 	P/67/2010
Sorafenib (as tosylate) (Nexavar)	Bayer Schering Pharma AG	Oncology	W EMEA-000781-PIP01-09	<ul style="list-style-type: none"> • 21/01/2010 • 19/03/2010 	P/68/2010
Forodesine hydrochloride	Mundipharma Research Ltd	Oncology	W EMEA-000785-PIP01-09	<ul style="list-style-type: none"> • 21/01/2010 • 19/03/2010 	P/69/2010
Diamorphine hydrochloride	Genus Pharmaceuticals Limited	Other (addictology)	W EMEA-000799-PIP01-09	<ul style="list-style-type: none"> • 21/01/2010 • 19/03/2010 	P/70/2010
Tocilizumab (RoActemra)	Roche Registration Limited	Immunology-rheumatology-transplantation	PM EMEA-000309-PIP01-08-M02	<ul style="list-style-type: none"> • 18/02/2010 • 19/03/2010 	P/71/2010
Icatibant acetate (Firazyr)	Jerini AG	Immunology-rheumatology-transplantation	PM EMEA-000408-PIP01-08-M01	<ul style="list-style-type: none"> • 18/02/2010 • 19/03/2010 	P/72/2010
Human normal immunoglobulin	Kedrion S.p.A.	Immunology/rheumatology/transplantation	PM EMEA-000454-PIP01-08-M01	<ul style="list-style-type: none"> • 21/01/2010 • 19/03/2010 	P/73/2010
Japanese encephalitis virus, inactivated (attenuated strain SA14-14-2 grown in vero cells) (Ixiaro)	Intercell AG	Vaccines	PM EMEA-000559-PIP01-09-M01	<ul style="list-style-type: none"> • 18/02/2010 • 19/03/2010 	P/74/2010
Levonorgestrel	Bayer Schering Pharma AG	Endocrinology-gynaecology-	P EMEA-000606-	<ul style="list-style-type: none"> • 23/07/2009 • 19/03/2010 	P/75/2010

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		fertility-metabolism	PIP01-09		
Cholic acid	Special Products Ltd	Endocrinology-gynaecology-fertility-metabolism / gastroenterology-hepatology	P EMEA-000651-PIP01-09	<ul style="list-style-type: none"> • 15/10/2009 • 19/03/2010 	P/76/2010
Human normal immunoglobulin	LFB Biotechnologies	Immunology/rheumatology/transplantation	PM EMEA-000167-PIP01-07-M01	<ul style="list-style-type: none"> • 21/01/2010 • 19/03/2010 	P/77/2010
Mometasone furoate (Nasonex and associated names)	Schering-Plough Research Institute, a division of Schering Corporation	Pneumology-allergology	W EMEA-000351-PIP01-08	<ul style="list-style-type: none"> • 23/07/2009 • 19/03/2010 	P/78/2010
Perampanel	Eisai Ltd	Neurology	P EMEA-000467-PIP01-08	<ul style="list-style-type: none"> • 23/07/2009 • 19/03/2010 	P/79/2010
Latanoprost	Pfizer Global Research & Development	Ophthalmology	C EMEA-000011-PIP01-07-M03	<ul style="list-style-type: none"> • 18/02/2010 • 19/03/2010 	N.A
Taspoglutide	Roche Registration Limited	Endocrinology-gynaecology-fertility-metabolism	P EMEA-000649-PIP01-09	<ul style="list-style-type: none"> • 20/08/2009 • 19/03/2010 	P/80/2010
Taspoglutide	Roche Registration Limited	Endocrinology-gynaecology-fertility-metabolism	P EMEA-000665-PIP01-09	<ul style="list-style-type: none"> • 20/08/2009 • 19/03/2010 	P/81/2010
Vorinostat	Merck Sharp & Dohme Ltd.	Oncology	W EMEA-000805-PIP01-09	<ul style="list-style-type: none"> • 18/02/2010 • 16/04/2010 	P/82/2010
Pneumococcal Polysaccharide Serotype 1 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 4 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 5 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate Pneumococcal	Wyeth Lederle Vaccines SA	Vaccines	PM EMEA-000036-PIP01-07-M04	<ul style="list-style-type: none"> • 18/02/2010 • 16/04/2010 	P/83/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion *	PDCO <ul style="list-style-type: none"> • Start date • Opinion (R) Re-examination 	EMA Decision
Polysaccharide Serotype 6B – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 9V – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 14 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 18C – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate (Prevenar 13)					
Golimumab (Simponi)	Centocor B.V.	Immunology-rheumatology-transplantation	PM EMA-000265-PIP01-08-M01	<ul style="list-style-type: none"> • 18/02/2010 • 16/04/2010 	P/84/2010
Adalimumab (Humira)	Abbott Laboratories Limited	Immunology-rheumatology-transplantation / dermatology /gastroenterology-hepatology	P EMA-000366-PIP02-09	<ul style="list-style-type: none"> • 17/09/2009 • 16/04/2010 	P/85/2010
Cediranib	AstraZeneca AB	Oncology	P EMA-000477-PIP01-08	<ul style="list-style-type: none"> • 02/04/2009 • 16/04/2010 	P/86/2010
Clindamycin (phosphate) / bituminosulphonate (sodium)	ICHTHYOL - GESELLSCHAFT Cordes, Hermann & Co. (GmbH & Co.) KG,	Dermatology	P EMA-000532-PIP01-09	<ul style="list-style-type: none"> • 20/08/2009 • 16/04/2010 	P/87/2010
Beclometasone dipropionate / formoterol fumarate dehydrate	Chiesi Farmaceutici S.p.A.	Pneumology – allergology	P EMA-000548-PIP01-09	<ul style="list-style-type: none"> • 30/04/2009 • 16/04/2010 	P/88/2010

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(Foster and associated names, Kantos and associated names, Kantos Master and associated names, Inuvair and associated names)					
Solifenacin succinate (Vesicare and associated names)	Astellas Pharma Europe B.V.	Uro-nephrology	P EMEA-000573-PIP01-09	<ul style="list-style-type: none"> • 30/04/2009 • 16/04/2010 	P/89/2010
Bisotrizole / titanium dioxide	Orfagen	Dermatology	P EMEA-000585-PIP01-09	<ul style="list-style-type: none"> • 23/07/2009 • 16/04/2010 	P/90/2010
Fluocinolone acetonide	Campharm Ltd.	Ophthalmology	W EMEA-000801-PIP01-09	<ul style="list-style-type: none"> • 18/02/2010 • 16/04/2010 	P/91/2010
Ipilimumab	Bristol-Myers Squibb International Corporation	Oncology	PM EMEA-000117-PIP01-07-M01	<ul style="list-style-type: none"> • 23/03/2010 • 16/04/2010 	P/92/2010
Sitagliptin phosphate monohydrate / metformin hydrochloride (Janumet and associated names)	Merck Sharp & Dohme (Europe), Inc.	Endocrinology-gynaecology-fertility-metabolism	W EMEA-000165-PIP02-09	<ul style="list-style-type: none"> • 18/02/2010 • 16/04/2010 	P/93/2010
Peginterferon alfa-2a (Pegasys)	Roche Registration Ltd	Infectious diseases	P EMEA-000298-PIP01-08	<ul style="list-style-type: none"> • 01/07/2008 • 16/04/2010 	P/94/2010
Rivaroxaban (Xarelto)	Bayer Schering Pharma AG	Cardiovascular diseases	PM EMEA-000430-PIP01-08-M01	<ul style="list-style-type: none"> • 18/02/2010 • 16/04/2010 	P/95/2010
Canakinumab	Novartis Europharm Limited	Immunology / rheumatology / transplantation	PM EMEA-000060-PIP01-07-M02	<ul style="list-style-type: none"> • 18/02/2010 • 16/04/2010 	P/96/2010
Boceprevir	SP Europe	Infectious diseases	P EMEA-000583-PIP01-09	<ul style="list-style-type: none"> • 28/05/2009 • 16/04/2010 	P/97/2010
Fidaxomicin	FGK Representative Service GmbH	Infectious diseases	P EMEA-000636-PIP01-09	<ul style="list-style-type: none"> • 23/07/2009 • 16/04/2010 	P/98/2010
Anagrelide hydrochloride monohydrate (Xagrid (0.5 mg hard capsules))	Shire Pharmaceutical Contracts Ltd	Haematology-hemostaseology	P EMEA-000720-PIP01-09	<ul style="list-style-type: none"> • 17/09/2009 • 16/04/2010 	P/99/2010
Human papillomavirus1 Type 6 L1 protein / human papillomavirus1 Type 11 L1 protein / human papillomavirus1 Type 16 L1 protein	Sanofi Pasteur MSD SNC	Vaccines	C EMEA-000375-PIP01-08-M02	<ul style="list-style-type: none"> • 23/03/2010 • 16/04/2010 	N/A

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/ human papillomavirus1 Type 18 L1 protein (Gardasil)					
Dapagliflozin	Bristol Myers Squibb /AstraZeneca EEIG	Endocrinology-gynaecology-fertility-metabolism	P EMEA-000694-PIP01-09	<ul style="list-style-type: none"> • 15/10/2009 • 21/05/2010 	P/100/2010
Rabeprazole (sodium) (Pariet and associated names)	Eisai Limited	Gastroenterology / hepatology	PM EMEA-000055-PIP01-07-M03	<ul style="list-style-type: none"> • 15/04/2010 • 21/05/2010 	P/101/2010
Adalimumab (Humira)	Abbott Laboratories Ltd.	Gastroenterology -hepatology dermatology immunology-rheumatology-transplantation	PM EMEA-000366-PIP01-08-M02	<ul style="list-style-type: none"> • 23/03/2010 • 21/05/2010 	P/102/2010
Papillomavirus Type 6 L1 protein / Human Papillomavirus Type 11 L1 protein / Human Papillomavirus Type 16 L1 protein / Human Papillomavirus Type 18 L1 protein / Human Papillomavirus Type 31 L1 protein / Human Papillomavirus Type 33 L1 protein / Human Papillomavirus Type 45 L1 protein / Human Papillomavirus Type 52 L1 protein / Human Papillomavirus Type 58 L1 protein	Merck Sharp & Dohme (Europe), Inc.	Vaccines	P EMEA-000654-PIP01-09	<ul style="list-style-type: none"> • 15/10/2009 • 21/05/2010 	P/103/2010
Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 4 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein /	GlaxoSmithKline Biologicals S.A.	Vaccines	P EMEA-000673-PIP01-09	<ul style="list-style-type: none"> • 17/09/2009 • 21/05/2010 	P/104/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion *	PDCO <ul style="list-style-type: none"> • Start date • Opinion (R) Re-examination	EMA Decision
<p>pneumococcal polysaccharide serotype 5 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 6B conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 7F conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 9V conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 14 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 18C conjugated to tetanus toxoid / pneumococcal polysaccharide serotype 19F conjugated to diphtheria toxoid / pneumococcal polysaccharide serotype 23F conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein (Synflorix)</p>					

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Everolimus (Afinitor)	Novartis Europharm Limited	Oncology	PM EMEA-000019-PIP02-07-M01	<ul style="list-style-type: none"> • 15/04/2010 • 11/06/2010 	P/105/2010
Azilsartan medoxomil	Takeda Global Research and Development Centre (Europe) Ltd	Cardiovascular diseases	PM EMEA-000237-PIP01-08-M02	<ul style="list-style-type: none"> • 15/04/2010 • 11/06/2010 	P/106/2010
Dabigatran etexilate mesilate (Pradaxa)	Boehringer Ingelheim International GmbH	Haematology-hemostaseology	PM EMEA-000081-PIP01-07-M02	<ul style="list-style-type: none"> • 15/04/2010 • 11/06/2010 	P/107/2010
Liraglutide (Victoza)	Novo Nordisk A/S	Endocrinology/gynaecology/fertility/metabolism	PM EMEA-000128-PIP01-07-M01	<ul style="list-style-type: none"> • 23/03/2010 • 21/05/2010 • 11/06/2010 (R) 	P/108/2010
Paliperidone / paliperidone palmitate (Invega)	Janssen-Cilag International NV	Psychiatry	PM EMEA-000014-PIP01-07-M04	<ul style="list-style-type: none"> • 23/03/2010 • 21/05/2010 	P/109/2010
etravirine (Intelence)	Janssen-Cilag International NV	Infectious diseases	PM EMEA-000222-PIP01-08-M02	<ul style="list-style-type: none"> • 23/03/2010 • 21/05/2010 	P/110/2010
Tulobuterol	CSI GmbH	Pneumology - allergology	W EMEA-000763-PIP01-09	<ul style="list-style-type: none"> • 23/03/2010 • 21/05/2010 	P/111/2010
N.meningitidis Outer Membrane Vesicles (OMV) from NZ 98/254 strain, N.meningitidis 287-953 purified antigen, N.meningitidis 961c purified antigen, N.meningitidis 936-741 purified antigen	Novartis Vaccines and Diagnostics S.r.l.	Vaccines	P EMEA-000139-PIP01-07	<ul style="list-style-type: none"> • 08/05/2008 • 21/05/2010 	P/112/2010
Etanercept (Enbrel)	Wyeth Europa Limited	Immunology-rheumatology-transplantation	PM EMEA-000299-PIP01-08-M01	<ul style="list-style-type: none"> • 20/05/2010 • 21/05/2010 	P/113/2010
C1 inhibitor	ViroPharma SPRL	Immunology-rheumatology-transplantation	PM EMEA-000568-PIP01-09-M01	<ul style="list-style-type: none"> • 15/04/2010 • 21/05/2010 	P/114/2010
Trifluoromethyl-benzoyloxymino-ethyl-carboxylic acid derivative (BAF312)	Novartis Europharm Limited	Immunology-rheumatology-transplantation / neurology	P EMEA-000716-PIP01-09	<ul style="list-style-type: none"> • 15/10/2009 • 21/05/2010 	P/115/2010
sodium sulfate/potassium sulfate/magnesium sulfate heptahydrate	Ipsen Pharma	Gastroenterology-hepatology	RW EMEA-000816-PIP01-09	<ul style="list-style-type: none"> • 21/01/2010 • 21/05/2010 	P/116/2010
Diclofenac sodium/Omeprazole	Temmler Werke GmbH	Immunology-rheumatology-transplantation	W EMEA-000820-PIP01-09	<ul style="list-style-type: none"> • 23/03/2010 • 21/05/2010 	P/117/2010
Mesothelin	Eisai Ltd	Oncology	W	<ul style="list-style-type: none"> • 23/03/2010 	P/118/2010

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(MORAB-009)			EMEA-000833-PIP01-10	• 21/05/2010	
Telbivudine (Sebivo)	Novartis Europharm Limited	Gastroenterology / hepatology	PM EMEA-000065-PIP01-07-M01	• 23/03/2010 • 21/05/2010	P/119/2010
Human normal immunoglobulin	Kedrion S.p.A.	Immunology-rheumatology-transplantation /haematology-hemostaseology	P EMEA-000775-PIP01-09	• 23/12/2009 • 21/05/2010	P/120/2010
Nomegestrol acetate and 17beta - estradiol	N.V. Organon	Endocrinology/gynaecology/fertility/metabolism	C EMEA-C-000250-PIP01-08-M02	• 15/04/2010 • 21/05/2010	N/A
Antigen of pre-pandemic strain A/Vietnam/1203/2004 propagated in Vero cells	Baxter Innovations GmbH	Vaccines	PM EMEA-000156-PIP01-07-M01	• 15/04/2010 • 11/06/2010	P/121/2010
Lisdexamfetamine dimesylate	Shire Pharmaceutical Contracts Ltd	Psychiatry	PM EMEA-000553-PIP01-09-M01	• 15/04/2010 • 11/06/2010	P/122/2010
3-[5-(2-fluorophenyl)-[1,2,4]oxadiazole-3-yl]-benzoic acid	Genzyme Europe B.V.	Pneumology	PM EMEA-000115-PIP01-07-M01	• 15/04/2010 • 11/06/2010	P/123/2010
Voclosporin	Lux Biosciences GmbH	Endocrinology-gynaecology-fertility-metabolism	PM EMEA-000132-PIP01-07-M02	• 15/04/2010 • 11/06/2010	P/124/2010
Lidocaine / tetracaine	ZARS Pharma	Anaesthesiology	W EMEA-000168-PIP02-09	• 15/04/2010 • 11/06/2010	P/125/2010
Modified grass pollen extract	Allergy Therapeutics (UK) Ltd	Pneumology/allergy	PM EMEA-000284-PIP01-08-M01	• 15/04/2010 • 11/06/2010	P/126/2010
N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4-oxoquinoline-3-carboxamide	Vertex Pharmaceuticals Incorporated	Pneumology	PM EMEA-000335-PIP01-08-M03	• 15/04/2010 • 11/06/2010	P/127/2010
Bosentan monohydrate (Tracleer)	Actelion Registration Ltd	Cardiovascular diseases	P EMEA-000425-PIP02-10	• 15/04/2010 • 11/06/2010	P/128/2010
4-O-(β-D-galactopiranosyl)-D-xylopyranose	Lactest SL	Diagnostic / gastroenterology-hepatology	W EMEA-000641-PIP01-09	• 20/08/2009 • 11/06/2010	P/129/2010
Synthetic erythropoietin (EPO) receptor agonist	Takeda Global Research & Development Centre (Europe) Ltd	Haematology-hemostaseology	P EMEA-000646-PIP01-09	• 20/08/2009 • 11/06/2010	P/130/2010
Coagulation Factor IX (Recombinant)	Inspiration Biopharmaceuticals EU	Haematology-hemostaseology	P EMEA-000661-PIP01-09	• 20/08/2009 • 11/06/2010	P/131/2010

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Split influenza virus, inactivated, containing antigen: A/California/7/2009 (H1N1)v like strain (X-179A)	GlaxoSmithKline Biologicals S.A.	Vaccines	PM EMA-000725-PIP01-09-M02	• 15/04/2010 • 11/06/2010	P/132/2010
Omalizumab (Xolair)	Novartis Europharm Limited	Pneumology – allergology	W EMA-000735-PIP01-09	• 19/11/2009 • 11/06/2010	P/133/2010
Amlodipine besilate / perindopril tert-butylamine	Gedeon Richter Plc.	Cardiovascular diseases	W EMA-000823-PIP01-10	• 15/04/2010 • 11/06/2010	P/134/2010
Levonorgestrel / ethinylestradiol	Teva Pharma B.V.	Endocrinology-gynaecology-fertility-metabolism	W EMA-000829-PIP01-09	• 15/04/2010 • 11/06/2010	P/135/2010
Amlodipine / ramipril	EGIS Pharmaceuticals PLC	Cardiovascular diseases	W EMA-000887-PIP01-10	• 15/04/2010 • 11/06/2010	P/136/2010
Tapentadol hydrochloride	Grünenthal GmbH	Pain	PM EMA-000018-PIP01-07-M02	• 15/04/2010 • 11/06/2010	P/137/2010
Darunavir (Prezista)	Janssen-Cilag International NV	Infectious diseases	PM EMA-000038-PIP01-07-M03	• 20/05/2010 • 11/06/2010	P/138/2010
Dexamethasone	Allergan Pharmaceuticals Ireland	Ophthalmology	W EMA-000198-PIP04-10	• 15/04/2010 • 11/06/2010	P/139/2010
Human coagulation Factor VIII / Von Willebrand Factor	CSL Behring	Haematology-hemostaseology	PM EMA-000312-PIP01-08-M01	• 15/04/2010 • 11/06/2010	P/140/2010
Recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (AIN457)	Novartis Europharm Limited	Immunology-rheumatology-transplantation	P EMA-000380-PIP02-09	• 19/11/2009 • 11/06/2010	P/141/2010
Tapentadol hydrochloride	Grünenthal GmbH	Pain	PM EMA-000494-PIP01-07-M02	• 15/04/2010 • 11/06/2010	P/142/2010
Tapentadol hydrochloride	Grünenthal GmbH	Pain	PM EMA-000495-PIP01-07-M02	• 15/04/2010 • 11/06/2010	P/143/2010
(3R,4R)-4-methyl-3-(methyl-1H-pyrrolo[2,3-d]pyrimidin-4-ylamino)-β-oxo-1-piperidinepropaneni trile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1) (CP-690,550)	Pfizer Limited	Immunology-rheumatology-transplantation	P EMA-000576-PIP01-09	• 28/05/2009 • 11/06/2010	P/144/2010

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Vedolizumab	Takeda Global Research & Development Centre (Europe) Ltd	Gastroenterology -hepatology	P EMEA-000645-PIP01-09	<ul style="list-style-type: none"> • 17/09/2009 • 11/06/2010 	P/145/2010
A/California/7/2009 influenza-like virus strain	Novartis Vaccines & Diagnostics GmbH	Vaccines	PM EMEA-000663-PIP01-09-M03	<ul style="list-style-type: none"> • 20/05/2010 • 11/06/2010 	P/146/2010
Tafamidis meglumine	FoldRx Pharmaceuticals, Ltd.	Neurology	W EMEA-000884-PIP01-10	<ul style="list-style-type: none"> • 15/04/2010 • 11/06/2010 	P/147/2010
Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted), containing antigen equivalent to Influenza A/California/7/2009 (Produced at Quebec manufacturing site) (Arepanrix)	GlaxoSmithKline Biologicals S.A.	Vaccines	PM EMEA-000687-PIP01-09-M02	<ul style="list-style-type: none"> • 15/04/2010 • 11/06/2010 	P/148/2010
Chlorprocaine hydrochloride	Sintetica Italia S.r.l.	Anaesthesiology	P EMEA-000639-PIP02-09	<ul style="list-style-type: none"> • 21/01/2010 • 16/07/2010 	P/149/2010
Emtricitabine / tenofovir disoproxil fumarate/ rilpivirine hydrochloride	Gilead Sciences International Limited	Infectious diseases	P EMEA-000774-PIP01-09	<ul style="list-style-type: none"> • 21/01/2010 • 16/07/2010 	P/150/2010
Zoledronic acid (Aclasta)	Novartis Europharm Limited	Metabolism	Re-examination (PM) EMEA-000057-PIP01-07-M02	<ul style="list-style-type: none"> • 15/04/2010 • 11/06/2010 • 06/08/2010 (R) 	P/151/2010
Entecavir (Baraclude)	Bristol-Myers Squibb Pharma EEIG	Infectious disease	P EMEA-000339-PIP02-09	<ul style="list-style-type: none"> • 23/12/2009 • 06/08/2010 	P/152/2010
Rufinamide (Inovelon)	Eisai Ltd.	Neurology	P EMEA-000709-PIP01-09	<ul style="list-style-type: none"> • 15/10/2009 • 06/08/2010 	P/153/2010
Boceprevir	Merck Sharp & Dohme Ltd	Infectious diseases	P EMEA-000583-PIP01-09	<ul style="list-style-type: none"> • 15/07/2010 • 06/08/2010 	P/154/2010
Bazedoxifene / conjugated estrogens	Pfizer Ltd	Endocrinology-gynaecology-fertility-metabolism	W EMEA-000998-PIP01-10	<ul style="list-style-type: none"> • 20/05/2010 • 16/07/2010 	P/155/2010
Ivabradine hydrochloride (Corlentor)	Les Laboratoires Servier	Cardiovascular diseases	P EMEA-000627-PIP01-09	<ul style="list-style-type: none"> • 20/08/2009 • 16/07/2010 	P/156/2010
Ivabradine hydrochloride (Procoralan)	Les Laboratoires Servier	Cardiovascular diseases	P EMEA-000628-PIP01-09	<ul style="list-style-type: none"> • 20/08/2009 • 16/07/2010 	P/157/2010
Ceftaroline fosamil	AstraZeneca AB	Infectious	P	<ul style="list-style-type: none"> • 23/12/2009 	P/158/2010

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		diseases	EMA-000769-PIP01-09	<ul style="list-style-type: none"> • 16/07/2010 	
Telmisartan / hydrochlorothiazide (MicardisPlus)	Boehringer Ingelheim International GmbH	Cardiovascular diseases	W EMA-000885-PIP01-10	<ul style="list-style-type: none"> • 20/05/2010 • 16/07/2010 	P/159/2010
Clindamycin phosphate / tretinoin	MEDA Pharma GmbH & Co. KG	Dermatology	P EMA-000892-PIP01-10	<ul style="list-style-type: none"> • 20/05/2010 • 16/07/2010 	P/160/2010
Indapamide / amlodipine besilate	Les Laboratoires Servier	Cardiovascular diseases	W EMA-000896-PIP01-10	<ul style="list-style-type: none"> • 20/05/2010 • 16/07/2010 	P/161/2010
Perindopril erbumine / amlodipine besylate	Krka, d.d., Novo mesto	Cardiovascular diseases	W EMA-000983-PIP01-10	<ul style="list-style-type: none"> • 20/05/2010 • 16/07/2010 	P/162/2010
Valsartan / amlodipine besylate	Krka, d.d., Novo mesto	Cardiovascular diseases	W EMA-001000-PIP01-10	<ul style="list-style-type: none"> • 20/05/2010 • 16/07/2010 	P/163/2010
Mepolizumab	Glaxo Group Limited	Gastroenterology-hepatology / Immunology-rheumatology-transplantation	PM EMA-000069-PIP01-07-M02	<ul style="list-style-type: none"> • 20/05/2010 • 16/07/2010 	P/164/2010
Fluticasone furoate	Glaxo Group Limited	Pneumonology-allergology	PM EMA-000431-PIP01-08-M02	<ul style="list-style-type: none"> • 20/05/2010 • 16/07/2010 	P/165/2010
Cinacalcet (as hydrochloride) (Mimpara)	Amgen Europe B.V.	Endocrinology-gynaecology-fertility-metabolism / Uro-nephrology	PM EMA-000078-PIP01-07-M01	<ul style="list-style-type: none"> • 20/05/2010 • 16/07/2010 	P/166/2010
Recombinant human glutamic acid decarboxylase (rhGAD65)	Diamyd Medical AB	Endocrinology-gynaecology-fertility-metabolism	P EMA-000609-PIP01-09	<ul style="list-style-type: none"> • 24/07/2009 • 16/07/2010 	P/167/2010
Insulin glargine, lixisenatide	Sanofi-Aventis R&D	Endocrinology-gynaecology-fertility-metabolism	W EMA-000915-PIP01-10	<ul style="list-style-type: none"> • 20/05/2010 • 16/07/2010 	P/168/2010
Vildagliptin / metformin hydrochloride (Eucreas)	Novartis Europharm Limited	Endocrinology-gynaecology-fertility-metabolism	W EMA-000703-PIP01-09	<ul style="list-style-type: none"> • 15/10/2009 • 16/07/2010 	P/169/2010
Bosutinib (SKI-606)	Wyeth Europa Limited	Oncology	P EMA-000727-PIP01-09	<ul style="list-style-type: none"> • 19/11/2009 • 16/07/2010 	P/170/2010
Esomeprazole sodium	AstraZeneca AB	Gastroenterology-hepatology	C EMA-C-000331-PIP01-08-M01	<ul style="list-style-type: none"> • 15/07/2010 • 16/07/2010 	N/A
Sitagliptin (phosphate monohydrate) (Januvia)	Merck Sharp and Dohme (Europe), Inc.	Endocrinology-gynaecology-fertility-metabolism	PM EMA-000470-PIP01-08-M02	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/171/2010
Mirabegron	Astellas Pharma Europe B.V.	Uro-nephrology	P EMA-000597-PIP02-10	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/172/2010

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Romiplostim (Nplate)	Amgen Europe B.V	Haematology-haemostaseology	P EMEA-000653-PIP01-09	<ul style="list-style-type: none"> • 16/10/2009 • 06/08/2010 	P/173/2010
Retigabine	Glaxo Group Limited	Neurology	PM EMEA-000116-PIP01-07-M03	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/174/2010
(R)-3(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropane nitrilephosphate	Novartis Europharm Ltd	Oncology	W EMEA-000901-PIP01-10	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/175/2010
(R)-3(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropane nitrilephosphate	Novartis Europharm Ltd	Oncology	W EMEA-000901-PIP02-10	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/176/2010
Artemether / lumefantrine (Riamet)	Novartis Europharm Limited	Infectious diseases	P EMEA-000777-PIP01-09	<ul style="list-style-type: none"> • 21/01/2010 • 06/08/2010 	P/177/2010
Colistimethate sodium	Forest Laboratories UK Limited	Infectious diseases	PM EMEA-000176-PIP01-07-M02	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/178/2010
Catridecacog	Novo Nordisk A/S	Haematology-haemostaseology	PM EMEA-000185-PIP01-08-M02	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/179/2010
Ustekinumab (Stelara)	Janssen-Cilag International NV	Dermatology Immunology-rheumatology-transplantation	PM EMEA-000311-PIP01-08-M01	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/180/2010
Pasireotide	Novartis Europharm Ltd	Endocrinology-gynaecology-fertility-metabolism	W EMEA-000464-PIP02-10	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/181/2010
Diphtheria toxoid / Tetanus toxoid / Bordetella pertussis antigen: Pertussis toxoid / Bordetella pertussis antigen: Filamentous Haemagglutinin / Bordetella pertussis antigen: Pertactin / Inactivated poliovirus: type 1 (Mahoney strain) / Inactivated poliovirus: type 2 (MEF-1 strain) / Inactivated poliovirus: type 3 (Saukett strain) (Boostrix Polio and associated names)	GlaxoSmithKline Biologicals S.A.	Vaccines	PM EMEA-000500-PIP01-08-M01	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/182/2010
(Glycinamide, L-cysteinyl-L-	International Pharma Science	Cardiovascular diseases	P EMEA-000506-	<ul style="list-style-type: none"> • 25/06/2009 • 06/08/2010 	P/183/2010

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phenylalanyl-L- isoleucyl-6-oxo-L- lysyl-L-asparaginy- L-cysteinyl-L-prolyl- N5-(1- methylethyl)-L- ornithyl-, cyclic(1→6)- disulfide acetate) (FE 202158 acetate)	Center, Ferring Pharmaceuticals A/S		PIP01-08		
Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, trivalent	Abbott Biologicals B.V.	Vaccines	P EMEA-000632- PIP01-09	<ul style="list-style-type: none"> • 23/07/2009 • 06/08/2010 	P/184/2010
Afamelanotide	Clinuvel UK Limited	Dermatology	W EMEA-000737- PIP01-09	<ul style="list-style-type: none"> • 19/11/2009 • 06/08/2010 	P/185/2010
Guanfacine hydrochloride	Shire Pharmaceutical Contracts Ltd	Psychiatry	P EMEA-000745- PIP01-09	<ul style="list-style-type: none"> • 19/11/2009 • 06/08/2010 	P/186/2010
Recombinant human monoclonal antibody to human interleukin-13	MedImmune Ltd	Pneumology- allergology	P EMEA-000782- PIP01-09	<ul style="list-style-type: none"> • 21/01/2010 • 06/08/2010 	P/187/2010
Amlodipine camsylate Losartan potassium	Hanmi Europe Limited	Cardiovascular diseases	W EMEA-000886- PIP01-10	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/188/2010
Copper [64 Cu] chloride	Sparkle Srl	Other	W EMEA-001002- PIP01-10	<ul style="list-style-type: none"> • 10/06/2010 • 06/08/2010 	P/189/2010
Eritoran	Eisai Limited	Infectious diseases	PM EMEA-000509- PIP02-09-M01	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/190/2010
Midazolam (as hydrochloride)	ViroPharma SPRL	Neurology	C EMEA-C-000395- PIP01-08	<ul style="list-style-type: none"> • 15/07/2010 • 06/08/2010 	N/A
Nevirapine	Boehringer Ingelheim International GmbH	Infectious diseases	C EMEA-C-000391- PIP01-08-M01	<ul style="list-style-type: none"> • 15/07/2010 • 06/08/2010 	N/A
Nevirapine	Boehringer Ingelheim International GmbH	Infectious diseases	C EMEA-C-000391- PIP01-08-M01	<ul style="list-style-type: none"> • 15/07/2010 • 06/08/2010 	N/A
Midazolam (as hydrochloride)	ViroPharma SPRL	Neurology	C EMEA-C-000395- PIP01-08	<ul style="list-style-type: none"> • 15/07/2010 • 06/08/2010 	N/A
Eritoran	Eisai Limited	Infectious diseases Other	PM EMEA-000509- PIP02-09-M01	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/190/2010
Cholic acid	Special Products Ltd	Endocrinology- gynaecology- fertility-	PM EMEA-000651- PIP01-09-M01	<ul style="list-style-type: none"> • 15/07/2010 • 16/07/2010 • 15/10/2010 	P/191/2010

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		metabolism / gastroenterology -hepatology		(R)	
Doripenem monohydrate (Doribax)	Janssen-Cilag International N.V.	Infectious disease	PM EMA-000015-PIP01-07-M02	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/192/2010
Meningococcal group A oligosaccharide Conjugated to Corynebacterium diptheriae CRM197 protein (MenA-CRM) Meningococcal group C oligosaccharide Conjugated to Corynebacterium diptheriae CRM197 protein (MenC-CRM) Meningococcal group W-135 oligosaccharide Conjugated to Corynebacterium diptheriae CRM197 protein (MenW-CRM) Meningococcal group Y oligosaccharide Conjugated to Corynebacterium diptheriae CRM197 protein (MenY-CRM) (Menveo)	Novartis Vaccines and Diagnostics S.r.L	Vaccines	PM EMA-000032-PIP01-07-M02	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/193/2010
Tiotropium bromide (monohydrate) (Spiriva Respimat and associated names)	Boehringer Ingelheim International GmbH	Pneumology-allergology	PM EMA-000035-PIP01-07-M02	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/194/2010
Brivaracetam	UCB Pharma SA	Neurology	PM EMA-000332-PIP01-08-M02	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/195/2010
Riociguat	Bayer Schering Pharma AG	Cardiovascular diseases	P EMA-000718-PIP01-09	<ul style="list-style-type: none"> • 23/12/2009 • 10/09/2010 	P/196/2010
Lidocaine hydrochloride Phenylephrine hydrochloride Tropicamide	Laboratoires THEA	Ophthalmology	W EMA-000991-PIP01-10	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/197/2010
Voriconazole (Vfend)	Pfizer Limited	Infectious diseases	PM EMA-000191-PIP01-08-M01	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/198/2010
Motavizumab	Abbott	Intramuscular	PM	<ul style="list-style-type: none"> • 12/08/2010 	P/199/2010

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	Laboratories Limited	use	EMEA-000352-PIP01-08-M01	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/200/2010
Anidulafungin (Ecalta)	Pfizer Limited	Infectious diseases	PM EMEA-000469-PIP01-08-M01	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/201/2010
Propranolol hydrochloride	Pierre Fabre Dermatologie	Dermatology	PM EMEA-000511-PIP01-08-M02	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 23/03/2010 • 10/09/2010 	P/205/2010
Ingenol mebutate	LEO Pharma A/S	Dermatology Oncology	W EMEA-000894-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/208/2010
L-asparaginase encapsulated in	ERYtech Pharma	Oncology	P EMEA-000341-	<ul style="list-style-type: none"> • 23/12/2009 • 10/09/2010 	P/209/2010

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erythrocytes			PIP02-09		
Prucalopride succinate (Resolor)	Shire-Movetis NV	Gastroenterology-hepatology	P EMEA-000459-PIP01-08	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 15/10/2009 • 10/09/2010 	P/211/2010
Pagibaximab	Biosynexus, Incorporated	Infectious diseases Neonatology-paediatric intensive care	P EMEA-000608-PIP01-09	<ul style="list-style-type: none"> • 17/09/2009 • 10/09/2010 	P/212/2010
Fampridine	Acorda Therapeutics, Inc.	Neurology	PM EMEA-000614-PIP01-10-M01	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/213/2010
Dronabinol	Bionorica AG	Pain	W EMEA-000643-PIP01-09	<ul style="list-style-type: none"> • 20/08/2009 • 10/09/2010 	P/214/2010
Derivative of 4,4'-(1-methylene)-bisbenzotrile	Novartis Europharm Limited	Endocrinology-gynaecology-fertility-metabolism	W EMEA-000758-PIP01-09	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 23/03/2010 • 10/09/2010 	P/216/2010
Birch Pollen Extract	Allergy Therapeutics (UK) Ltd.	Pneumology-allergology	P EMEA-000809-PIP01-09	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 18/02/2010 • 10/09/2010 	P/220/2010
12 Grass Pollen	Allergy	Pneumology-	P	<ul style="list-style-type: none"> • 18/02/2010 	P/221/2010

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Extract and Cultivated Rye Pollen Extract	Therapeutics (UK) Ltd.	allergology	EMEA-000813-PIP01-09	<ul style="list-style-type: none"> • 10/09/2010 	
Birch/Alder/Hazel Pollen Extract	Allergy Therapeutics (UK) Ltd.	Pneumology-allergology	P EMEA-000814-PIP01-09	<ul style="list-style-type: none"> • 18/02/2010 • 10/09/2010 	P/222/2010
Phentermine / topiramate	Vivus BV	Endocrinology-gynaecology-fertility-metabolism	P EMEA-000826-PIP01-09	<ul style="list-style-type: none"> • 15/04/2010 • 10/09/2010 	P/223/2010
Eculizumab (Soliris)	Alexion Europe SAS	Immunology-rheumatology-transplantation	P EMEA-000876-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 15/07/2010 • 10/09/2010 	P/225/2010
Atazanavir sulphate (Reyataz)	Bristol-Myers Squibb Pharma EEIG	Infectious diseases	P EMA-000804-PIP01-09	<ul style="list-style-type: none"> • 18/02/2010 • 08/10/2010 	P/226/2010
Partially purified bromelain	Teva Pharma GmbH	Dermatology Othe	P EMEA-000142-PIP02-09	<ul style="list-style-type: none"> • 20/05/2010 • 08/10/2010 	P/227/2010
Aztreonam (Cayston)	Gilead Sciences International Limited	Infectious diseases	P EMEA-000827-PIP01-09	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 15/09/2010 • 08/10/2010 	P/229/2010
Moxifloxacin hydrochloride (Avalox and associated names; Otegrea and associated names; Actimax and associated names; Actira and associated names)	Bayer Schering Pharma AG	Infectious diseases	PM EMEA-000288-PIP01-08-M02	<ul style="list-style-type: none"> • 12/08/2010 • 08/10/2010 	P/230/2010
Fentanyl citrate	EPMC Pharma SPRL	Neonatology – paediatric intensive care Pain	P EMEA-000712-PIP01-09	<ul style="list-style-type: none"> • 19/11/2009 • 08/10/2010 	P/231/2010
4-hydroxy-n-(2-hydroxyethyl)-	Dr. Franz Köhler Chemie GmbH	Anaesthesiology Neurology	RW EMEA-000764-	<ul style="list-style-type: none"> • 23/03/2010 • 08/10/2010 	P/232/2010

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butyramide			PIP01-09		
Clopidogrel (Plavix)	Sanofi Pharma Bristol-Myers Squibb SNC	Cardiovascular diseases	PM EMEA-000049-PIP01-07-M03	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 12/08/2010 • 08/10/2010 	P/235/2010
Etanercept (Enbrel)	Wyeth Europa Limited	Dermatology Immunology-rheumatology-transplantation	PM EMEA-000299-PIP01-08-M02	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 15/04/2010 • 08/10/2010 	P/237/2010
Teduglutide	Nycomed Danmark ApS	Gastroenterology -hepatology	P EMEA-000482-PIP01-08	<ul style="list-style-type: none"> • 20/08/2009 • 	P/238/2010
Infliximab (Remicade)	Centocor B.V.	Gastroenterology -hepatology Dermatology Immunology-rheumatology-transplantation	PM EMEA-000549-PIP01-09-M01	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 21/01/2010 • 08/10/2010 	P/240/2010
Aluminium hydroxide	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000662-	<ul style="list-style-type: none"> • 21/01/2010 	P/241/2010

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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 EMA-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 EMA-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 EMA-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 EMA-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 EMA-000790-PIP01-09	• 21/01/2010 • 08/10/2010	P/246/2010
Aluminium hydroxide adsorbed,	LETI Pharma GmbH	Pneumology-Allergology	P EMA-000791-PIP01-09	• 21/01/2010 • 08/10/2010	P/247/2010

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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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 21/01/2010 • 08/10/2010 	P/250/2010
Aluminium hydroxide adsorbed, depigmented glutaraldehyde	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000794-PIP01-09	<ul style="list-style-type: none"> • 21/01/2010 • 08/10/2010 	P/251/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion *	PDCO <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 15/04/2010 • 08/10/2010 	P/257/2010

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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	<ul style="list-style-type: none"> • 20/05/2010 • 08/10/2010 	P/258/2010
Betula alba allergen extract	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000919-PIP01-10	<ul style="list-style-type: none"> • 20/05/2010 • 08/10/2010 	P/259/2010
Dermatophagoides pteronyssinus allergen extract	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000920-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 06/10/2010 • 08/10/2010 	P/263/2010
Phleum pratense allergen extract	LETI Pharma GmbH	Pneumology-Allergology	P EMEA-000924-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 20/05/2010 • 08/10/2010 	P/266/2010
Ocriplasmin	ThromboGenics	Ophthalmology	W EMEA-000986-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 10/11/2010 • 12/11/2010 	P/268/2010

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Boehringer Ingelheim)					
Insulin detemir (Levemir)	Novo Nordisk A/S	Endocrinology-gynaecology-fertility-metabolism	P EMEA-000412-PIP01-08	<ul style="list-style-type: none"> • 11/12/2008 • 12/11/2010 	P/269/2010
Pralatrexate	Allos Therapeutics Limited	Oncology	P EMEA-000619-PIP02-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 20/05/2010 • 12/11/2010 	P/271/2010
Eritoran	Eisai Limited	Infectious diseases Other	PM EMEA-000509-PIP02-09-M02	<ul style="list-style-type: none"> • 13/10/2010 • 12/11/2010 	P/272/2010
Catridecacog	Novo Nordisk A/S	Haematology-haemostaseology	PM EMEA-000185-PIP01-08-M03	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 20/05/2010 • 12/11/2010 	P/279/2010
Allergen extract of corylus avellana	HAL Allergy BV	Pneumology-allergology	P EMEA-000908-	<ul style="list-style-type: none"> • 20/05/2010 • 12/11/2010 	P/280/2010

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pollen			PIP01-10		
Allergen extract of phleum pratense pollen	HAL Allergy BV	Pneumology-allergology	P EMEA-000909-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 15/04/2010 • 12/11/2010 	P/284/2010
Dermatophagoides farinae extracts 100 %	Allergopharma Joachim Ganzer KG	Pneumology-allergology	P EMEA-000834-PIP01-10	<ul style="list-style-type: none"> • 20/05/2010 • 12/11/2010 	P/285/2010
Dermatophagoides pteronyssinus extracts 100 %	Allergopharma Joachim Ganzer KG	Pneumology-allergology	P EMEA-000835-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 20/05/2010 • 12/11/2010 	P/289/2010
Entecavir (Baraclude)	Bristol-Myers Squibb Pharma EEIG	Infectious diseases	PM EMEA-000339-PIP02-09-M01	<ul style="list-style-type: none"> • 13/10/2010 • 12/11/2010 	P/290/2010
Ranibizumab (Lucentis)	Novartis Europharm Limited	Ophthalmology	W EMEA-000527-PIP02-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 21/01/2010 • 12/11/2011 	P/292/2010
Nalmefene hydrochloride dihydrate	H. Lundbeck A/S	Psychiatry	W EMEA-000824-PIP01-09	<ul style="list-style-type: none"> • 23/03/2010 • 12/11/2011 	P/293/2010
Pollen from Dactylis glomerata, Lolium	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000845-	<ul style="list-style-type: none"> • 15/04/2010 	P/294/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion *	PDCO <ul style="list-style-type: none"> • Start date • Opinion (R) Re-examination 	EMA Decision
perenne, Phleum pratense, Festuca pratensis, Secale cereale			PIP01-10	<ul style="list-style-type: none"> • 12/11/2011 	
Pollen from betula verrucosa	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000846-PIP01-10	<ul style="list-style-type: none"> • 15/04/2010 • 12/11/2011 	P/295/2010
Pollen from Phleum pratense	ALK-Abelló A/S	Pneumology-allergology	P EMEA-000847-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 glomerata (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 <ul style="list-style-type: none"> • Start date • Opinion (R) Re-examination 	EMA Decision
Modified allergen extract of hazel pollen	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000941-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 20/05/2010 • 12/11/2011 	P/329/2010
Aqueous allergen extract of birch	ROXALL Medizin GmbH	Pneumology-allergology	P EMEA-000959-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 20/05/2010 • 12/11/2011 	P/332/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion *	PDCO <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 20/05/2010 • 12/11/2011 	P/335/2010
Interferon alpha 2b	Helix BioPharma Corp	Endocrinology-gynaecology-fertility-metabolism	W EMEA-001036-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 10/12/2010 	P/345/2010
Paliperidone Paliperidone	Janssen-Cilag International NV	Psychiatry	PM EMEA-000014-	<ul style="list-style-type: none"> • 16/12/2010 • 20/12/2010 	P/346/2010

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion *	PDCO <ul style="list-style-type: none"> • Start date • Opinion (R) Re-examination 	EMA Decision
palmitate (Invega)			PIP01-07-M05		
Adalimumab (Humira)	Abbott Laboratories Ltd	Dermatology Gastroenterology -hepatology Immunology- rheumatology- transplantation	PM EMA-000366- PIP01-08-M03	<ul style="list-style-type: none"> • 08/10/2010 • 12/11/2010 	P/1/2011
Imatinib mesilate	Novartis Europharm Limited	Oncology	PM EMA-000463- PIP01-08-M01	<ul style="list-style-type: none"> • 15/09/2010 • 12/11/2010 	P/2/2011
Tazarotene	Orfagen	Dermatology	P EMA-000510- PIP02-10	<ul style="list-style-type: none"> • 15/09/2010 • 12/11/2010 	P/3/2011
Pazopanib (Votrient)	Glaxo Group Limited	Oncology	P EMA-000601- PIP01-09	<ul style="list-style-type: none"> • 15/10/2009 • 12/11/2010 	P/4/2011
Ecallantide (Recombinant Inhibitor of Human Plasma Kallikrein)	Dyax s.a.	Dermatology Pneumology- allergology Other	PM EMA-000688- PIP01-09-M01	<ul style="list-style-type: none"> • 13/10/2010 • 12/11/2010 	P/5/2011
Midostaurin	Novartis Europharm Ltd	Oncology	P EMA-000780- PIP01-09	<ul style="list-style-type: none"> • 21/01/2010 • 12/11/2010 	P/6/2011
Allergens from Dermatophagoides pteronyssinus and Dermatophagoides farinae	ALK-Abelló A/S	Pneumology- allergology	P EMA-000847- PIP01-10	<ul style="list-style-type: none"> • 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 EMA-000849- PIP01-10	<ul style="list-style-type: none"> • 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 EMA-000852- PIP01-10	<ul style="list-style-type: none"> • 15/04/2010 • 12/11/2010 	P/9/2011
Pollen from betula pendula	ALK-Abelló A/S	Pneumology- allergology	P EMA-000853- PIP01-10	<ul style="list-style-type: none"> • 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 EMA-000860- PIP01-10	<ul style="list-style-type: none"> • 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 EMA-000863- PIP01-10	<ul style="list-style-type: none"> • 15/04/2010 • 12/11/2010 	P/12/2011
Allergen extracts of dermatophagoides farinae and dermatophagoides	ALK-Abelló A/S	Pneumology- allergology	P EMA-000866- PIP01-10	<ul style="list-style-type: none"> • 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 EMA-000249-PIP01-08	• 10/11/2010 • 12/11/2010	P/14/2011
Ezetimibe (Ezetrol and associated names)	MSD-SP Limited	Cardiovascular diseases	PM EMA-000007-PIP01-07-M01	• 13/10/2010 • 10/12/2010	P/15/2011
Nepafenac (Nevanac)	Alcon Laboratories (UK) Ltd.	Ophthalmology	W EMA-000913-PIP01-10	• 13/10/2010 • 10/12/2010	P/16/2011
Perindopril arginine / indapamide amlodipine besilate	Les Laboratoires Servier	Cardiovascular diseases	W EMA-001048-PIP01-10	• 13/10/2010 • 10/12/2010	P/17/2011
Lixisenatide	Sanofi-Aventis R&D	Endocrinology-gynaecology-fertility-metabolism	P EMA-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 EMA-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 EMA-000496-PIP01-08-M01	• 13/10/2010 • 10/12/2010	P/20/2011
Exenatide (Byetta)	Eli Lilly and Company	Endocrinology-gynaecology-fertility-metabolism	PM EMA-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 pratensis L. and Phleum pratense L.	Stallergenes S.A.	Pneumology-allergology	P EMA-000976-PIP01-10	• 15/07/2010 • 10/12/2010	P/22/2011
Tesamorelin	Theratechnologies Inc	Endocrinology-gynaecology-fertility-metabolism	W EMA-001029-PIP01-10	• 13/10/2010 • 10/12/2010	P/23/2011
Sotrastaurin acetate	Novartis Europharm Ltd	Immunology-rheumatology-transplantation	P EMA-000093-PIP02-10	• 13/10/2010 • 10/12/2010	P/24/2011
Briakinumab	Abbott Laboratories Ltd.	Dermatology	PM EMA-000552-PIP01-09-M01	• 13/10/2010 • 10/12/2010	P/25/2011
Meropenem	NeoMero Consortium	Infectious diseases	P EMA-000898-PIP01-10	• 10/06/2010 • 10/12/2010	P/26/2011

Product INN	Applicant	Therapeutic Area	Type of PDCO opinion *	PDCO <ul style="list-style-type: none"> • Start date • Opinion (R) Re-examination 	EMA Decision
Rizatriptan (Maxalt and associated names)	Merck Sharp & Dohme (Europe) Inc.	Pain	P EMEA-000084-PIP02-10	<ul style="list-style-type: none"> • 10/06/2010 • 10/12/2010 	P/27/2011
Pegloticase	Savient Pharmaceuticals, Inc.	Immunology-rheumatology-transplantation Oncology	P EMEA-000293-PIP02-10	<ul style="list-style-type: none"> • 20/05/2010 • 10/12/2010 	P/28/2011
Oseltamivir (phosphate) (Tamiflu)	Roche Registration Ltd	Infectious diseases	PM EMEA-000365-PIP01-08-M02	<ul style="list-style-type: none"> • 13/10/2010 • 10/12/2010 	P/29/2011
Ticagrelor	AstraZeneca AB	Cardiovascular diseases	PM EMEA-000480-PIP01-08-M01	<ul style="list-style-type: none"> • 13/10/2010 • 10/12/2010 	P/30/2011
Amikacin (sulfate)	Transave, Inc.	Cardiovascular diseases	P EMEA-000525-PIP01-08	<ul style="list-style-type: none"> • 10/06/2010 • 10/12/2010 	P/31/2011
C1 inhibitor	ViroPharma SPRL	Immunology-rheumatology-transplantation	PM EMEA-000568-PIP01-09-M02	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 15/07/2010 • 10/12/2010 	P/34/2011
Ozenoxacin	Ferrer Internacional, S.A	Infectious diseases	P EMA-000981-PIP01-10	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 18/11/2010 • 10/12/2010 	N/A
Clindamycin phosphate / tretinoin	MEDA Pharma GmbH & Co. KG	Dermatology	C EMEA-000892-PIP01-10	<ul style="list-style-type: none"> • 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
EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)	14	5	3	3
EMA/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	<ul style="list-style-type: none"> Quality aspects relating to development of biosimilar medicinal products
CHMP Blood Products Working Party	<ul style="list-style-type: none"> Clinical investigation of human normal immunoglobulin for intravenous administration
CHMP Gene Therapy Working Party	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> • Stem cell-based medicinal products • Risk-based approach for advanced therapy medicinal products
CHMP Invented Name Review Group	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 2 nd 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 2011)

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 <i>Varroa destructor parasitosis</i> 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)
EMA/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, September 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)
EMA/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 consultation, December 2010 (End of consultation 31 March 2011)
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CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMA/CVMP/SAGAM/736964/2009	Reflection paper on meticillin-resistant <i>Staphylococcus pseudintermedius</i>	Adopted for consultation, September 2010 (End of consultation 30 November 2010)
EMA/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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> • 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	clopidogrel

Type of referral	Date of CHMP opinion	International non-proprietary name (INN)
Article 29(4) of Directive 2001/83/EC	18/02/2010	clopidogrel
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	<ul style="list-style-type: none"> • Date of clock start • CVMP opinion 	<ul style="list-style-type: none"> • Product name • INN
Referral under Art. 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 11/02/2009 • 10/02/2010 	<ul style="list-style-type: none"> • All strengths of water soluble powders and oral solutions containing doxycycline hyclate • Doxycycline hyclate
Referral under Art. 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 16/04/2009 • 10/02/2010 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 13/05/2009 • 10/03/2010 (after re-examination) 	<ul style="list-style-type: none"> • Veterinary medicinal products containing quinolones or fluoroquinolones for all food-producing species • Quinolones / fluoroquinolones
Referral under Art. 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> • 12/11/2008 • 11/11/2009 (after re-examination) 	<ul style="list-style-type: none"> • Tildren 500 mg • Tiludronic acid (as disodium salt)
Referral under Art. 6(12) of Regulation (EC) No 1084/2003	<ul style="list-style-type: none"> • 14/10/2009 • 19/05/2010 	<ul style="list-style-type: none"> • Porcilis PRRS • Live attenuated PRRS virus strain DV
Referral under Art. 6(12) of Regulation (EC) No 1084/2003	<ul style="list-style-type: none"> • 14/10/2009 • 19/05/2010 	<ul style="list-style-type: none"> • Porcilis M Hyo • Inactivated whole cell concentrate of Mycoplasma hyopneumoniae strain 11
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 11/11/2009 	<ul style="list-style-type: none"> • Fortekor vet and associated names • Benazepril hydrochloride
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 15/10/2008 • 10/03/2010 	<ul style="list-style-type: none"> • Tiamutin premix • Tiamulin fumarate
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 14/04/2010 	<ul style="list-style-type: none"> • Synulox Lactating Cow and associated names • Amoxicillin, clavulanic acid, prednisolone
Procedure under Art. 78 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 19/05/2010 • 14/07/2010 	<ul style="list-style-type: none"> • Pregsure BVD and associated names • Inactivated Bovine Viral Diarrhoea (BVD) type 1 virus
Procedure under Art. 30(3) of Regulation 726/2004	<ul style="list-style-type: none"> • 19/05/2010 • 15/09/2010 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 16/06/2010 • 14/07/2010 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 14/07/2010 	<ul style="list-style-type: none"> • Combimox Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> • 14/07/2010 	<ul style="list-style-type: none"> • Nisamox Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	<ul style="list-style-type: none"> • 14/07/2010 	<ul style="list-style-type: none"> • Combisyn Lactating Cow • Amoxicillin, clavulanic acid, prednisolone

Type of referral	<ul style="list-style-type: none"> • Date of clock start • CVMP opinion 	<ul style="list-style-type: none"> • Product name • INN
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 14/07/2010 	<ul style="list-style-type: none"> • Doxycycline 50% WSP and associated names • Doxycycline hyclate
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 14/07/2010 	<ul style="list-style-type: none"> • Doxyfar 50% WSP and associated names • Doxycycline hyclate
Procedure under Art. 45 of Regulation (EC) No 726/2004	<ul style="list-style-type: none"> • 13/07/2010 • 14/07/2010 	<ul style="list-style-type: none"> • Flexicam 1.5 mg/ml Suspension for Dogs • Meloxicam
Procedure under Art. 45 of Regulation (EC) No 726/2004	<ul style="list-style-type: none"> • 14/09/2010 • 15/09/2010 	<ul style="list-style-type: none"> • Acticam 1.5 mg/ml Oral Suspension for Dogs • Meloxicam
Referral under Art. 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> • 09/11/2010 	<ul style="list-style-type: none"> • Baytril 10% oral solution and associated names • Enrofloxacin

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

Alvarez Y., Hidalgo A., Maignen F., Slattery J.:

Validation of statistical signal detection procedures in eudravigilance post-authorization data: a retrospective evaluation of the potential for earlier signalling. *Drug Safety* 2010; 33 (6): 475-487

Bahri P.:

Public pharmacovigilance communication: a process calling for evidence-based, objective-driven strategies. *Drug Safety* 2010 Dec 1;33(12):1065-79

Blind E., Dunder K., de Graeff PA, Abadie E.:

Rosiglitazone: a European regulatory perspective. *Diabetologia*: 54 (2) 213 – 218

Davies EH., Ollivier CM., Saint Raymond A.:

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.:

New drug approval success rate in Europe in 2009. *Nature Reviews Drug Discovery* 9, 355-356 (May 2010)

Eichler HG., Bloechl-Daum B., Abadie E., Barnett D., König F., Pearson S.:

Relative efficacy of drugs: an emerging issue between regulatory agencies and third-party payers. *Nature Reviews Drug Discovery* 2010 Apr;9(4):277-91

Grave K., Torren-Edo J., Mackay D.:

Comparison of the sales of veterinary antibacterial agents between 10 European countries. *Journal of Antimicrobial Chemotherapy* 2010 Sep;65(9):2037-40

Herold R., Saint Raymond A.:

Preamble May Not Improve Consent and Assent Process. *Pediatric Blood & Cancer* 2011;56:327

Isaac M., Koch A.:

The risk of death among adult participants in trials of antipsychotic drugs in schizophrenia. *Journal of European College of Neuropsychopharmacology* 2010 Mar;20(3):139-45

Liberti L., Breckenridge A., Eichler HG., Peterson R., McAuslane N., Walker S.:

Expediting Patients' Access to Medicines by Improving the Predictability of Drug Development and the Regulatory Approval Process. Workshop on Predictable Outcomes September 30–October 1, 2008 Washington, DC. Workshop on Expediting Patients' Access to Medicines March 30–31, 2009 Surrey, UK. *Clinical Pharmacology & Therapeutics* 87, 27-31 (January 2010)

Mackay D., Kriz N.:

Current challenges in viral safety and extraneous agent testing. *Biologicals* Volume 38, Issue 3, May 2010, Pages 335-337

Regnstrom J., Koenig F., Aronsson B., Reimer T., Svendsen K., Tsigkos S., Flamion B., Eichler HG., Vamvakas S.:

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

Seigneuret N.:

The Paediatric Regulation: Three years on. Regulatory Rapporteur – Vol 7, No 6, June 2010

Silva-Lima B., Due Theilade-Thomsen M., Carleer J., Vidal JM., Tomasi P., Saint-Raymond A.:

Juvenile animal studies for the development of paediatric medicines: a description and conclusions from a European Medicines Agency workshop on juvenile animal testing for nonclinical assessors. Birth defects research. Part B, Developmental and reproductive toxicology. 2010 Dec;89(6):467-73

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

Tomasi P.:

In Search of Safe and Effective Medicines European Pharmaceutical Contractor, Paediatrics: Clinical Development & Regulatory Update: 46-49

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

The current state-of-the-science. Report of a European Medicines Agency Workshop. Cytokine. 2010 Aug;51(2):213-5

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 by the 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