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Office of the Executive Director

Annexes of the annual report 2011

The main body of this report is available on the website of the European Medicines Agency (EMA) here.

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An agency of the European Union

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Annex 1 – Members of the Management Board

Chair: Kent WOODS[1]
EMA contact: Nerimantas STEIKUNAS

Members

European Parliament	Guiseppe NISTICÓ, Björn LEMMER (Substitute: Jozef HOLOMÁŇ)
European Commission	Paola TESTORI COGGI, Pedro ORTUN SILVAN (Alternates: Andzej RYS , Giulia del BRENNA)
Belgium	Xavier DE CUYPER (Alternate: Greet MUSCH)
Bulgaria	Jasmina MIRCHEVA (Alternate: Alexander YANKOV)
Czech Republic	Jiří DEML (Alternate: Jiří BUREŠ)
Denmark	Jytte LYNGVIG (Alternate: Dorthe EBERHRDT SØNDERGAARD)
Germany	Walter SCHWERDTFEGER (Alternate: Klaus CICHUTEK[2])
Estonia	Kristin RAUDSEPP (Alternate: Alar IRS)
Ireland	Pat O'MAHONY (Alternate: Rita PURCELL)
Greece	Ioannis TOUNTAS (Alternate: Maria SKOUROLIAKOU)
Spain	Belén CRESPO SÁNCHEZ-EZNARRIAGA (Alternate: Laura Franqueza GARCÍA)
France	Dominique MARANINCHI[3] (Alternate: Marc MORTUREUX)
Italy	Luca PANI[4] (Alternate: Paolo SIVIERO[5])
Cyprus	Panayiota KOKKINOU (Alternate: George ANTONIOU)
Latvia	Inguna ADOVICA (Alternate: Dace ĶIKUTE)
Lithuania	Gintautas BARCYS (Alternate: Jonas MILIUS)
Luxembourg	Claude A HEMMER (Alternate: Mariette BACKES-LIES)
Hungary	Tamás L PAÁL (Alternate: Beatrix HORVÁTH)
Malta	Patricia VELLA BONANNO (Alternate: Gavril FLORES)
Netherlands	Aginus A W KALIS (Alternate: Rob DE HAAN)
Austria	Marcus MÜLLNER (Alternate: Christian KALCHER)
Poland	Grzegorz CESSAK (Alternate: Artur FALLEK)

[1] Replaced Pat O'MAHONY as of as of June 2011.
[2] Replaced Hans-Peter HOFMANN as of March 2011.
[3] Replaced Jean MARIMBERT as of April 2011.
[4] Replaced Guido RASI as of October 2011.
[5] Replaced Silvia FABIANI as of September 2011.

Portugal	Jorge TORGAL (Alternate: Miguel OLIVEIRA CARDO)
Romania	Daniel Boda (Alternate: Simona BĂDOI[6])
Slovenia	Martina CVELBAR (Alternate: Vesna KOBLAR)
Slovakia	Ján MAZÁG (Alternate: Michaela GAJDOŠOVÁ[7])
Finland	Sinikka RAJANIEMI (Alternate: Pekka KURKI[8])
Sweden	Christina ÅKERMAN (Alternate: Johan LINDBERG)
United Kingdom	Kent WOODS (Alternate: Jonathan MOGFORD[9])
Representatives of patients' organisations	Awaiting nomination
Representative of doctors' organisations	Awaiting nomination
Representative of veterinarians' organisations	Awaiting nomination

Observers

Iceland	Einar MAGNÚSSON (Alternate: Rannveig GUNNARSDÓTTIR)
Liechtenstein	Brigitte BATLINER (Alternate: Sabine ERNE)
Norway	Gro Ramsten WESENBERG (Alternate: Ivar VOLLSET)

[6] Replaced Rodica BADESCU as of February 2011.
[7] Replaced Dagmar STARÁ as of August 2011.
[8] Replaced Pekka JÄRVINEN as of January 2011.
[9] Replaced Steve DEAN as of July 2011.

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
• Karsten BRUINS SLOT (Norway)[10]	*Alternate: Awaiting nomination*
• Pierre DEMOLIS (France)	*Alternate:* Philipe LECHAT
• Harald ENZMANN (Germany)	*Alternate:* Martina Weise
• Piotr FIEDOR (Poland)	*Alternate:* Kinga BOROWICZ
• Jacqueline GENOUX-HAMES (Luxembourg)	*Alternate:* Carine DE BEAUFORT
• Agnes GYURASICS (Hungary)	*Alternate:* János BORVENDÉG
• Jens HEISTERBERG (Denmark)	*Alternate:* Jens ERSBØLL
• Ian HUDSON (United Kingdom)	*Alternate:* Rafe SUVARNA
• Arthur ISSEYEGH (Cyprus)	*Alternate:* Emilia MAVROKORDATOU
• Alar IRS (Estonia)	*Alternate:* Irja LUTSAR
• Andrea LASLOP (Austria)	*Alternate:* Milena STAIN
• Metoda LIPNIK-STANGELJ (Slovenia)	Alternate: Nevenka TRSINAR
• David LYONS (Ireland)	Alternate: Patrick SALMON
• Romaldas MAČIULAITIS (Lithuania)	Alternate: Rugile PILVINIENE
• Ján MAZÁG (Slovakia)	Alternate: Vlasta Kákošová
• Daniela MELCHIORRI (Italy)	*Alternate:* Luca PANI
• Pieter NEELS (Belgium)	Alternate: Michel TOUNGOUZ NEVESSIGNSKY[11]
• Kolbeinn GUDMUNDSSON (Iceland)[12]	*Alternate:* Reynir ARNGRIMSSON[13]
• Juris POKROTNIEKS (Latvia)	*Alternate:* Natalja KARPOVA
• Concepcion PRIETO YERRO (Spain)[14]	*Alternate:* Arantxa SANCHO-LOPEZ
• Tomas SALMONSON (Sweden) *(vice-chair)*	*Alternate:* Kristina DUNDER
• Beatriz SILVA LIMA (Portugal)	*Alternate:* Helder MOTA-FILIPE[15]

[10] Replaced Eva SKOVLUND as of November 2011 meeting.
[11] Replaced Jean-Francois BAURAIN as of September 2011 meeting.
[12] Replaced Sif ORMARSDÓTTIR as of February 2011 meeting.
[13] Replaced Kolbeinn GUDMUNDSSON as of March 2011 meeting.
[14] Replaced Gonzalo CALVO ROJAS as of March 2011 meeting.
[15] Replaced Cristina SAMPAIO as of June 2011 meeting.

- Dalivor VALÍK (Czech Republic)[16] *Alternate:* Miloslav SALAVEC[17]
- Barbara VAN ZWIETEN-BOOT (Netherlands) *Alternate:* Pieter DE GRAEFF
- Nela VILCEANU (Romania) *Alternate:* Dana MARIN
- Mila VLASKOVSKA (Bulgaria) *Alternate:* Lyubina TODOROVA[18]
- Awaiting nomination (Finland)[19] *Alternate:* Janne KOMI[20]

Co-opted members

- Robert James HEMMINGS (United Kingdom)
- Hubert G.M. LEUFKENS (Netherlands)
- Jean-Louis ROBERT (Luxembourg)
- Sol RUIZ (Spain)
- Jan MUELLER-BERGHAUS (Germany)[21]

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

[16] Replaced Ondřej SLANAŘ as of January 2011 meeting.
[17] Replaced Kateřina KUBÁCKOVÁ as of February 2011 meeting.
[18] Replaced Elena MASSEVA as of March 2011 meeting.
[19] Jaana KALLIO left in June 2011.
[20] Replaced Kristiina AIROLA as of July 2011 meeting.
[21] Replaced Christian SCHNEIDER as of November 2011 meeting.

Temporary working parties

Biosimilar Medicinal Products Working Party
Chair: Christian SCHNEIDER — EMA contact: Falk EHMANN

Biostatistics Working Party
Chair: Robert James HEMMINGS — EMA contact: Martin POSCH

Blood Products Working Party
Chair: Anneliese HILGER — EMA contact: Glenda SILVESTER

Cardiovascular Working Party
Chair: Gonzalo CALVO ROJAS — EMA contact: Anna Maria BACZYNSKA

Central Nervous System Working Party
Chair: Barbara VAN ZWIETEN-BOOT — EMA contact: Manuel HAAS/Malgorzata Zienowicz

Efficacy Working Party
Chair: Barbara VAN ZWIETEN-BOOT — EMA contact: Maria NIETO GUTIERREZ

Infectious Diseases Working Party
Chair: Mair POWELL — EMA contact: Rachel TURNER/Radu Botgros

Oncology Working Party
Chair: Bertil JONSSON — EMA contact: Irene PAPADOULI

Pharmacogenomics Working Party
Chair: Eric ABADIE — EMA contact: Marisa PAPALUCA AMATI

Pharmacokinetics Working Party
Chair: Tomas SALMONSON — EMA contact: Michael BERNTGEN

Rheumatology/Immunology Working Party
Chair: Bridget HEELAN — EMA contact: Radhouane CHERIF

Vaccine Working Party
Chair: Michael PFLEIDERER — EMA contact: Robin RUEPP

Temporary drafting groups

Gastroenterology Drafting Group
Chair: Elmer SCHABEL — EMA contact: Thomas CASTELNOVO/Joachim MUSAUS

Respiratory Drafting Group
Chair: Gonzalo CALVO ROJAS — EMA contact: Jaume GONZALEZ NOGUERAS

Urology Drafting Group
Chair: Kerstin CLAESSON — EMA contact: Michael BERNTGEN/Joachim MUSAUS

Radiopharmaceuticals Drafting Group
Chair: Patrick SALMON — EMA contact: Silvy DA ROCHA DIAS

Sientific 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 System
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 Neurology
Chair: Michael DONAGHY EMA contact: Björn ARVIDSON

Scientific Advisory Group on Oncology
Chair: Michel MARTY EMA contact: Francesco PIGNATTI

Scientific Advisory Group on Psychiatry
Chair: To be elected EMA contact: Florence BUTLEN-DUCUING

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 Holm (Vice-chair: G. Johan Schefferlie)
European Medicines Agency contact: David MACKAY

Members

- Ewa AUGUSTYNOWICZ (Poland) Alternate: Anna LUTYŃSKA
- Jean-Pierre BINDER (Austria) Alternate: Barbara ZEMANN
- Jiří BUREŠ (Czech Republic) Alternate: Alfred HERA
- João Pedro DUARTE DA SILVA (Portugal) Alternate: Maria Inês Flor DIAS
- Irmeli HAPPONEN[22] (Finland) Alternate: Kristina LEHMANN
- Judita HEDEROVÁ (Slovakia) Alternate: Eva CHOBOTOVÁ
- Tonje HØY (Norway) Alternate: Hanne BERGENDAHL
- Cornelia IBRAHIM[23] (Germany) Alternate: Esther WERNER[24]
- Damyan ILIEV (Bulgaria) Alternate: Lubomir LASHEV
- Helen JUKES[25] (United Kingdom) Alternate: Anna-Maria BRADY
- Johann LENHARDSSON[26] (Iceland) Alternate: Halldór RUNÓLFSSON[27]
- Petras MAČIULSKIS (Lithuania) Alternate: Awaiting nomination[28]
- Ioannis MALEMIS (Greece) Alternate: Angeliki TSIGOURI
- Cristina MUÑOZ MADERO (Spain) Alternate: Consuelo RUBIO MONTEJANO
- David MURPHY (Ireland) Alternate: Gabriel BEECHINOR
- Jean-Claude ROUBY (France) Alternate: Michael HOLZHAUSER-ALBERTI
- 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 TOOMVAP (Estonia) Alternate: Helen MAHLA
- Ioanna TALIOTI[29] (Cyprus) Alternate: Alia MICHAELIDOU-PATSIA[30]

[22] Replaced Fia WESTERHOLM as of November 2011 meeting.
[23] Replaced Manfred MOOS as of December 2011 meeting.
[24] Replaced Cornelia IBRAHIM as of January 2012 meeting.
[25] Replaced Ruth KEARSLEY as of February 2011 meeting.
[26] Replaced Halldór RUNÓLFSSON as of March 2011 meeting.
[27] Replaced Johann LENHARDSSON as of March 2011 meeting.
[28] Resigned in September 2011, new nomination pending.

- Karolina TÖRNEKE (Sweden) — Alternate: Henrik HOLST
- Bruno URBAIN (Belgium) — Alternate: Frédéric KLEIN[31]
- Ellen-Margrethe VESTERGAARD (Denmark) — Alternate: [32]Merete BLIXENKRONE-MØLLER
- Marc WIRTOR (Luxembourg) — Alternate: Jean BIEL[33]
- Awaiting nomination (Malta) — Alternate: Awaiting nomination

Co-opted

- Rory BREATHNACH (Ireland) (co-opted)
- Claire CHAUVIN[34] (France) (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 EKSTRÖM — 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

[29] Replaced Pavlos TOUMAZOS as of September 2011 meeting.
[30] Replaced Ioanna TALIOTI as of December 2011 meeting.
[31] As of November 2011 meeting.
[32] Replaced Lotte WINTHER as of January 2012 meeting.
[33] As of April 2011 meeting.
[34] Replaced Peter EKSTRÕM as of February 2011 meeting.

Annex 4 – Members of the Committee for 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 DEMLOVÁ (Czech Republic)
- Judit EGGENHOFER (Hungary)
- Rembert ELBERS (Germany)
- Marie Pauline EVERS (patients' organisation representative)
- 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)
- Katerina MORAITI[35] (Greece)
- Martin MOŽINA (Slovenia)
- Geraldine O'DEA[36] (Ireland)
- Daniel O'CONNOR (United Kingdom)
- Veijo SAANO (Finland)

[35] Replaced Miranda SIOUTI as of October 2011 meeting.
[36] Replaced Patrick SALMON as of September 2011 meeting.

- Flavia SALEH (Romania)
- Bruno SEPODES (EMA representative)
- Sigurður B. THORSTEINSSON (Iceland)
- Vallo TILLMANN (Estonia)
- Josep TORRENT-FARNELL (Spain)
- Albertha VOORDOUW (the Netherlands)
- *Awaiting nomination*[37] (Bulgaria)
- *Awaiting nomination*[38] (Slovak Republic)

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

[37] Mariana TODOROVA resigned in March 2011.
[38] Tatiana FOLTÁNOVÁ resigned in September 2011.

Annex 5 – Members of the Committee on Herbal Medicinal Products

Chair: Werner KNÖSS
EMA contact: Anthony HUMPHREYS

Members

• Linda ANDERSON (United Kingdom)	Alternate: Sue HARRIS
• Everaldo ATTARD (Malta)	Alternate: Andre MANGANI[39]
• Mariette BACKES-LIES (Luxembourg)	Alternate: Jacqueline GENOUX-HAMES
• Steffen BAGER (Denmark)	Alternate: Nina DÜRR
• Zsuzsanna BIRÓ-SÁNDOR (Hungary)	Alternate: Dezső CSUPOR
• Ioanna CHINOU (Greece) *(Vice-chair)*	Alternate: Eleni SKALTSA
• Per CLAESON (Sweden)	Alternate: Ubonwan CLAESON
• Marisa DELBÒ (Italy)	Alternate: *Awaiting nomination*
• Wojciech DYMOWSKI (Poland)	Alternate: Ewa BACKHAUS
• Nadia GRIGORAS (Romania)	Alternate: Carmen PURDEL
• Sinead HARRINGTON (Ireland)	Alternate: Niamh CURRAN
• Marie HEROUTOVÁ (Czech Republic)	Alternate: Pavla MUZIKÁŘOVÁ[40]
• Dace KALKE (Latvia)	Alternate: Baiba JANSONE[41]
• Artūras KAŽEMEKAITIS (Lithuania)	Alternate: Audronis LUKOŠIUS
• Samo KREFT (Slovenia)	Alternate: Barbara RAZINGER
• Reinhard LÄNGER (Austria)	Alternate: Martine SERNETZ
• Steinar MADSEN (Norway)	Alternate: Gro FOSSUM
• Ana Paula MARTINS (Portugal)	Alternate: Eva MENDES
• Elena MUSTAKEROVA (Bulgaria)	Alternate: Irina NIKOLOVA
• Heidi NEEF (Belgium)	Alternate: Arnold J. VLIETINCK
• Adela NÚÑEZ VELÁZQUEZ (Spain)	Alternate: *Awaiting nomination*
• Evelin SAAR (Estonia)	Alternate: Marje ZERNANT
• Ján SLÚKA (Slovakia)[42]	Alternate: Milan NAGY
• Antoine SAWAYA (France)	Alternate: Jacqueline VIGUET POUPELLOZ
• Eeva Sofia LEINONEN (Finland)[43]	Alternate: Sari KOSKI

[39] Replaced Gabriel MICALLEF as of September 2011.
[40] Replaced Helena LÁTALOVÁ as of July 2011.
[41] Replaced Vita GULEVSKA as of June 2011.
[42] Replaced Lucia SEVCEKOVA as of October 2011.
[43] Replaced Anneli TÖRRÖNEN as of November 2011.

- Panayiotis TRIANTAFYLLIS (Cyprus) Alternate: Maria STAVROU
- Emiel VAN GALEN (Netherlands) Alternate: Burt H. KROES
- Jacqueline WIESNER (Germany)[44] Alternate: Birgit MERZ[45]
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*

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

- Elton MYFTARI (Albania)
- Saša PILIPOVIĆ (Bosnia and Herzegovina)
- Melanie BALD (Council of Europe, EDQM)
- Michael WIERER (Council of Europe, EDQM)
- Josipa CVEK (Croatia)
- Ivan KOSALEC (Croatia)
- Albana DIDA (Kosovo under UNSC Resolution 1244/99)
- Merjem HADJIHAMZA (Macedonia, The Former Yugoslav Republic of)
- Dimche ZAFIROV (Macedonia, The Former Yugoslav Republic of)
- Maja VUJOVIĆ (Montenegro)
- Milena ADZIC (Montenegro)
- Dragan DJUROVIC (Serbia)
- Marija JOVANOVIĆ (Serbia)
- Asli CAN AGCA (Turkey)

[44] Replaced Werner KNÖSS as of January 2011.
[45] Replaced Jacqueline WIESNER as of January 2011.

Working parties and drafting groups

Working party on Community Monographs and Community List

Chair: Ioanna CHINOU EMA contact: Anthony HUMPHREYS

Organisational Matters Drafting Group

Chair: Emiel VAN GALEN EMA contact: Anthony HUMPHREYS

Quality Drafting Group

Chair: Burt H. KROES EMA contact: 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: Awaiting nomination*
- Carine de BEAUFORT (CHMP Luxembourg) *Alternate:* Jacqueline GENOUX-HAMES
- John Joseph BORG (Malta) *Alternate:* Herbert LENICKER
- Kevin CONNOLLY (Ireland) *Alternate:* Brian AYLWARD
- Helena FONSECA (Portugal) *Alternate:* Hugo TAVARES
- Marta GRANSTRÖM (Sweden) *Alternate:* Viveca Lena ODLIND
- Agnes GYURASICS (CHMP, Hungary) *Alternate:* János BORVENDÉG
- Janez JAZBEC (Slovenia) *Alternate: Awaiting nomination*
- Vlasta KÁKOŠOVÁ (Slovakia) *Alternate:* Jan MAZAG
- Dobrin KONSTANTINOV (Bulgaria) *Alternate:* Margarita GUIZOVA
- Pirjo LAITINEN-PARKKONEN (Finland) *Alternate:* Anne PAAVOLA[46]
- Irja LUTSAR (Estonia) *Alternate:* Alar IRS
- Romaldas MAČIULAITIS (CHMP, Lithuania) *Alternate:* Rugile PILVINIENE
- Christoph MALE (Austria) *Alternate:* Karl-Heinz HUEMER
- Stefanos MANTAGOS[47] (Greece) *Alternate: Awaiting nomination*
- Dirk MENTZER (Germany) *Alternate:* Birka LEHMANN
- Marek MIGDAL (Poland) *Alternate:* Jolanta WITKOWSKA-OŻOGOWSKA
- Hubert MOTTL (Czech Republic) *Alternate:* Peter SZITANYI
- Koenraad NORGA (Belgium) *Alternate:* Jacqueline CARLEER
- Marianne ORHOLM (Denmark) *Alternate:* Dorthe MEYER[48]
- Gylfi OSKARSSON (Iceland) *Alternate:* Kolbeinn GUDMUNDSSON
- Gérard PONS (France) *Vice-chair* *Alternate:* Sylvie BENCHETRIT
- Paolo ROSSI (Italy) *Alternate:* Francesca ROCCHI
- Johannes TAMINIAU (The Netherlands) *Alternate:* Hendrik van den BERG
- Andreas TELOUDES (Cyprus) *Alternate:* Stefanos CHRISTODOULOU
- Matthew THATCHER (United Kingdom) *Alternate:* Timothy CHAMBERS

[46] Replaced Ann Marie KAUKONEN as of March 2011.
[47] Replaced Lida KALANTZI as of December 2011.
[48] Replaced Karen TORNØE as of August 2011.

- Nela VILCEANU (CHMP, Romania) *Alternate:* Dana Gabriela MARIN
- Siri WANG (Norway) *Alternate:* Ine BLANKENBERG SKOTTHEIM

Representatives of patients' and healthcare professionals' organisations

- Matthias Keller[49] (Patient organisation) *Alternate: Pending*
- Michal ODERMARSKY (Patient organisation) *Alternate:* Milena STEVANOVIC
- Tsveta SCHYNS-LIHARSKA (Patient organisation) *Alternate:* Gerard Nguyen
- Jean-Pierre ABOULKER (Health professional) *Alternate:* Alexandra COMPAGNUCCI
- Adriana CECI (Health professional) *Alternate:* Paolo PAOLUCCI
- Anthony NUNN (Health professional) *Alternate: Pending*

[49] Replaced Annagrazia ALTAVILLA as of July 2011.

Annex 7 – Members of the Committee for Advanced Therapies

Chair: Christian SCHNEIDER
EMA contact: Patrick CELIS and Lucia D'APOTE

Members

Members nominated from within the CHMP

- Jens HEISTERBERG — *Alternate:* Henrik TANG VESTERGAAR[50]
- Romaldas MAČIULAITIS — *Alternate:* Jolanta GULBINOVIC
- Jean-Louis ROBERT — *Alternate:* Guy BERCHEM
- Sol RUIZ — *Alternate:* Marcos TIMÓN
- Beatriz SILVA LIMA — *Alternate:* Margarida MENEZES FERREIRA

Members nominated by Member States

- Lennart ÅKERBLOM (Sweden) — *Alternate: Björn CARLSSON*[51]
- Jānis ANCĀNS (Latvia) — *Alternate:* Ajine LINE
- Reynir ARNGRIMSSON[52] (Iceland)
- Claire BEUNEU (Belgium) — *Alternate:* BELAÏD SEKKALI
- Andrzej FAL[53] (Poland) — *Alternate:* Mariusz FRACZEK
- Egbert FLORY (Germany) — *Alternate:* Martina SCHÜSSLER LENZ
- Ivana HAUNEROVÁ (Check Republic) — *Alternate:* Tomás BORÁŇ
- Marit HYSTAD (Norway) — *Alternate:* Rune KJEKEN
- Toivo MAIMETS (Estonia) — *Alternate:* Pille HARRISON
- Giovanni MIGLIACCIO (Italy) — *Alternate:* Maria Cristina GALLI
- Golapan NARAYANAN (UK) — *Alternate:* Andrew CROSBIE
- Monica NEAGU (Romania) — *Alternate:* Gianina-Nicoleta ANDREI[54]
- Maura O'DONOVAN (Ireland) — *Alternate:* Niall MacALEENAN
- Hans OVELGÖNNE (The Netherlands)
- Anna PAFITOU (Cyprus) — *Alternate: Maria VASILIOU*
- Ilona REISCHL[55] (Austria) — *Alternate:* Martin BRUNNER[56]
- Paula SALMIKANGAS (Finland) — *Alternate:* Taina Methuen

[50] Replaced Mette CLAUSEN as of September 2011.
[51] Replaced Wing CHENG as of June 2011.
[52] Replaced Kolbein GUDMUNDSSON as of November 2011.
[53] Andrzej FAL resigned in September 2011.
[54] Replaced Nela Vilceanu as of November 2011.
[55] Replaced Bernd JILMA as of September 2011.
[56] Replaced Ilona REISCHL as of November 2011.

- Anthony SAMUEL (Malta) *Alternate:* Andrew BORG
- Balázs SARKADI (Hungary) *Alternate:* Zsuzsana BUZÁS
- Lyubina TODOROVA (Bulgaria) *Alternate:* Rosen GEORGIEV
- Jean-Hugues TROUVIN (France) *Alternate:* Sophie LUCAS SAMUEL
- Asterios TSIFTSOGLOU (Greece) *Alternate:* Vasilios KOKKAS
- Peter TURČÁNI (Slovakia) *Alternate:* Mikulás HRUBIŠKO
- Robert ZOREC (Slovania) *Alternate:* Borut ŠTRUKELJ

Members representing patients' organisations

- Fabrizia BIGNAMI[57] (EURORDIS) *Alternate:* Michele LIPUCCI DI PAOLA
- Alistair KENT[58] (EGAN *Alternate:* Nicholas MEADE[59]

Members representing clinicians

- George DICKSON (ESGCT) *Alternate:* Thierry VANDENDRIESSCHE
- Dietger NIEDERWIESER[60] (EGBMT) *Alternate:* Per LJUNGMAN

Working parties

Temporary working parties

Gene Therapy Working Party
Chair: Maria Cristina GALLI EMA contact: Caroline VOLTZ-GIROLT

Working Party on Cell-based Products
Chair: Paula SALMIKANGAS EMA contact: Veronika JEKERLE

[57] Fabrizia BIGNAMI resigned in November 2011.
[58] Alistair KENT resigned in September 2011.
[59] Nicholas MEADE resigned in September 2011.
[60] Dietger NIEDERWIESER resigned in July 2011.

Annex 8 – 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 9 – Budget summaries 2010–2011

The summarised comparative budget statements for 2010 and 2011 are as follows:

		2010 (final)[1]		2011 (budget)[2]		2011 (final)[3]	
		€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
	Revenue						
1+5	Fees and charges	160,566	*76.7%*	168,639	*80.7%*	159,641	*80.1%*
200	General EU contribution	24,533	*11.7%*	28,042	*13.4%*	28,042	*14.1%*
200	Surplus of previous year	14,532	*6.9%*	5,477	*2.6%*	5,477	*2.7%*
201	Special EU contribution for orphan medicinal products	7,988	*3.8%*	4,901	*2.3%*	4,720	*2.4%*
300	Contribution from EEA	826	*0.4%*	784	*0.4%*	784	*0.4%*
600	Community programmes	580	*0.3%*	560	*0.3%*	389	*0.2%*
5+9	Other	436	*0.2%*	460	*0.2%*	294	*0.1%*
	TOTAL REVENUE	**209,460**	*100.0%*	**208,863**	*100.0%*	**199,347**	*100.0%*
	Expenditure						
	Staff						
11	Staff in active employment	61,986	*30.6%*	67,845	*32.5%*	66,845	*33.1%*
13	Mission expenses	597	*0.3%*	570	*0.3%*	502	*0.2%*
14	Socio-medical infrastructure	521	*0.3%*	612	*0.3%*	572	*0.3%*
15	Exchange of civil servants and experts	2,329	*1.1%*	2,466	*1.2%*	2,274	*1.1%*
16	Social welfare	132	*0.1%*	245	*0.1%*	205	*0.1%*
17	Entertainment and representation expenses	93	*0.0%*	32	*0.0%*	22	*0.0%*
18	Staff insurances	2,038	*1.0%*	2,141	*1.0%*	2,120	*1.0%*
	Total Title 1	**67,695**	*33.4%*	**73,911**	*35.4%*	**72,539**	*35.9%*
	Building / equipment						
20	Investment in immovable property, renting of building and associated costs	19,065	*9.4%*	20,888	*10.0%*	20,069	*9.9%*
21	Expenditure on administrative data processing	30,789	*15.2%*	8,864	*4.2%*	8,659	*4.3%*
22	Movable property [..]	1,404	*0.7%*	1,573	*0.8%*	1,474	*0.7%*
23	Other administrative expenditure	914	*0.5%*	848	*0.4%*	826	*0.4%*
24	Postage and communications	621	*0.3%*	514	*0.2%*	499	*0.2%*
25	Expenditure on other meetings	90	*0.0%*	121	*0.1%*	87	*0.0%*
	Total Title 2	**52,883**	*26.1%*	**32,808**	*15.7%*	**31,613**	*15.6%*
	Operational expenditure						
300	Meetings	7,425	*3.7%*	8,414	*4.0%*	7,431	*3.7%*
301	Evaluation of medicines	70,561	*34.8%*	71,903	*34.4%*	69,461	*34.4%*
302	Translations	3,580	*1.8%*	4,396	*2.1%*	3,912	*1.9%*
303	Studies and consultants	58	*0.0%*	180	*0.1%*	76	*0.0%*
304	Publications	131	*0.1%*	175	*0.1%*	99	*0.0%*
305	Community programmes	480	*0.2%*	550	*0.3%*	444	*0.2%*
310	Expenditure on data processing related to product lifecycle	0	*0.0%*	5,674	*2.7%*	5,654	*2.8%*
311	Expenditure on data processing for special programmes	0	*0.0%*	10,852	*5.2%*	10,836	*5.4%*
	Total Title 3	**82,234**	*40.5%*	**102,144**	*48.9%*	**97,912**	*48.5%*
	TOTAL EXPENDITURE	**202,813**	*100.0%*	**208,863**	*100.0%*	**202,063**	*100.0%*

[1] Financial Year 2010: as per final accounts

[2] Financial Year 2011: as per final budget

[3] Financial Year 2011: as per provisional accounts

Annex 10 – Establishment plan

Category and grade	TEMPORARY POSTS					
	POSTS 2011				POSTS 2012	
	Authorised		Actual as per 31.12.2011		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	-	6
AD 13	-	7	-	7	-	7
AD 12	-	37	-	36	-	38
AD 11	-	36	-	35	-	38
AD 10	-	32	-	30	-	34
AD 9	-	38	-	37	-	39
AD 8	-	43	-	43	-	47
AD 7	-	42	-	39	-	45
AD 6	-	37	-	35	-	37
AD 5	-	33	-	32	-	33
Total AD	**0**	**315**	**0**	**304**	**0**	**329**
AST 11	-	2	-	2	-	2
AST 10	-	4	-	4	-	5
AST 9	-	8	-	8	-	7
AST 8	-	13	-	13	-	13
AST 7	-	19	-	19	-	20
AST 6	-	34	-	34	-	33
AST 5	-	35	-	34	-	35
AST 4	-	49	-	48	-	51
AST 3	-	32	-	32	-	37
AST 2	-	40	-	37	-	40
AST 1	-	16	-	16	-	18
Total AST	**0**	**252**	**0**	**247**	**0**	**261**
Grand Total	**0**	**567**	**0**	**551**	**0**	**590**

Other staff	Planned (FTE[61]) 2011	Actual (FTE) 2011	Actual as per 31.12.2011	Planned (FTE) 2012
Contract agents	150	105.3	118	132
National experts	20	13.3	19	15

[61] FTE = full-time equivalent.

Annex 11 – CHMP opinions in 2011 on medicinal products for human use

CHMP positive opinions in 2011 on non-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
• Yellox • bromfenac	Croma-Pharma GmbH	• S01BC11 • treatment of postoperative ocular inflammation	• 21/07/2009 • 17/03/2011 • 210 • 393	• 07/04/2011 • 18/05/2011 • 23/5/2011 • C250
• Eurartesim • dihydroartemisinin / piperaquine phosphate	Sigma Tau Industrie Farmaceutiche Riunite S.p.A.	• P01BF05 • treatment of Plasmodium falciparum malaria	• 21/07/2009 • 21/07/2011 • 209 • 492	• 13/07/2011 • 27/10/2011 • 02/11/2011 • C383
• Cinryze • c1 inhibitor, human	ViroPharma SPRL	• B06AC01 • treatment and prevention of angioedema attacks in patients with hereditary angioedema (HAE)	• 23/03/2010 • 17/03/2011 • 201 • 157	• 23/03/2011 • 15/06/2011 • 20/6/2011 • C250
• Zoely • omegestrol/estradiol	Theramex S.r.l.	• G03AA14 • oral contraception	• 18/08/2009 • 22/03/2011 • 210 • 365	• 23/03/2011 • 27/07/2011 • 31/8/2011 • C316
• Colobreathe • colistimethate sodium (rinn)	Forest Laboratories UK Ltd.	• R07AX • treatment of Pseudomonas aeruginosa pulmonary infection	• 25/05/2010 • 22/09/2011 • 210 • 211	• 08/12/2011 • 17/02/2012 • - - • - -
• Vibativ • telavancin	Astellas Pharma Europe B.V.	• J01XA03 • treatment of skin and soft tissue infections and nosocomial pneumonia	• 17/11/2009 • 19/05/2011 • 210 • 337	• 08/06/2011 • 02/09/2011 • 06/9/2011 • C383
• Pravafenix • fenofibrate / pravastatin	Laboratoires SMB S.A.	• C10BA03 • treatment of mixed dyslipidaemia	• 17/11/2009 • 20/01/2011 • 210 • 218	• 01/02/2011 • 14/04/2011 • 19/4/2011 • C184
• Trobalt • retigabine	Glaxo Group Ltd.	• N03AX21 • adjunctive treatment of partial onset seizures	• 17/11/2009 • 20/01/2011 • 210 • 218	• 09/02/2011 • 28/03/2011 • 31/3/2011 • C184
• Benlysta • belimumab	Glaxo Group Ltd.	• L04AA26 • treatment of active, autoantibody-positive systemic lupus erythematosus (SLE)	• 22/06/2010 • 19/05/2011 • 210 • 120	• 26/05/2011 • 13/07/2011 • 31/8/2011 • C316

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
• Rasitrio • aliskiren / amlodipine / hydrochlorothiazide	Novartis Europharm Ltd.	• C09XA54 • treatment of essential hypertension	• 25/05/2010 • 22/09/2011 • 210 • 274	• 10/10/2011 • 22/11/2011 • 14/11/2011 • C56
• Jevtana • cabazitaxel	SANOFI	• L01CD • treatment of prostate cancer	• 25/05/2010 • 20/01/2011 • 208 • 31	• 31/01/2011 • 17/03/2011 • 31/8/2011 • C316
• Bydureon • exenatide	Eli Lilly Nederland B.V.	• A10BX04 • treatment of type 2 diabetes mellitus	• 23/03/2010 • 14/04/2011 • 183 • 203	• 03/05/2011 • 17/06/2011 • 23/6/2011 • C250
• Esmya • ulipristal	PregLem France SAS	• G03AD02 • treatment of uterine fibroids	• 15/12/2010 • 15/12/2011 • 233 • 132	• 15/12/2011 • 23/02/2012 • 14/11/2011 • C56
• Komboglyze • saxagliptin / metformin hydrochloride	Bristol-Myers Squibb / AstraZeneca EEIG	• A10BD10 • treatment of type 2 diabetes mellitus	• 17/08/2010 • 22/09/2011 • 210 • 190	• 10/10/2011 • 24/11/2011 • 14/11/2011 • C56
• Ioa • nomegestrol acetate/estradiol	N.V. Organon	• G03AA14 • oral contraception	• 18/08/2009 • 22/03/2011 • 210 • 239	• 23/03/2011 • 16/11/2011 • 14/11/2011 • C56
• Rasilamlo • aliskiren / amlodipine	Novartis Europharm Ltd.	• C09XA53 • treatment of hypertension	• 22/12/2009 • 17/02/2011 • 208 • 213	• 04/03/2011 • 14/04/2011 • 18/4/2011 • C184
• Halaven • eribulin	Eisai Europe Ltd.	• L01XX41 • treatment of breast cancer	• 25/05/2010 • 20/01/2011 • 180 • 59	• 31/01/2011 • 17/03/2011 • 22/3/2011 • C184
• Dificlir • fidaxomicin	Astellas Pharma Europe BV	• A07AA12 • treatment of Clostridium difficile infections (CDI) also known as C. difficile-associated disease (CDAD)	• 17/08/2010 • 22/09/2011 • 210 • 190	• 04/10/2011 • 05/12/2011 • 14/11/2011 • C56

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
• Vepacel • whole virion non-adjuvanted influenza virus, propagated in vero cells (continuous cell line of mammalian origin), inactivated, containing antigen of alvietnamII203 12004 (h5nl)	Baxter Innovations GmbH	• J07BBOI • prophylaxis of H5N1 subtype of influenza A	• 17/11/2010 • 15/12/2011 • 210 • 183	• 06/01/2012 • 17/02/2012 • 14/11/2011 • C56
• Fampyra • fampridine	Biogen Idec Ltd.	• N07XX07 • treatment of Multiple Sclerosis	• 20/01/2010 • 19/05/2011 • 209 • 155	• 01/02/2011 • 20/07/2011 • 31/8/2011 • C316
• Nulojix • belatacept	Bristol-Myers Squibb Pharma EEIG	• L04AA28 • indicated for prophylaxis of graft rejection in adults receiving a renal transplant	• 23/02/2010 • 14/04/2011 • 210 • 204	• 20/04/2011 • 17/06/2011 • 23/6/2011 • C250
• Trajenta • linagliptin	Boehringer Ingelheim International GmbH	• A10BH05 • treatment of type 2 diabetes mellitus	• 20/07/2010 • 23/06/2011 • 210 • 127	• 27/06/2011 • 24/08/2011 • 31/8/2011 • C316
• Hizentra • human normal immunoglobuli n	CSL Behring GmbH	• J06BA01 • Replacement therapy (primary immunodeficiency syndromes and secondary hypogammaglobuline mia).	• 23/03/2010 • 17/02/2011 • 210 • 120	• 04/03/2011 • 14/04/2011 • 18/4/2011 • C184
• Eliquis • apixaban	Bristol-Myers Squibb / Pfizer EEIG	• B01A • prevention of venous thromboembolic events (VTE)	• 23/03/2010 • 17/03/2011 • 210 • 148	• 23/03/2011 • 18/05/2011 • 20/5/2011 • C250
• XGEVA • denosumab	Amgen Europe B.V.	• M05BX04 • prevention of skeletal related events with advanced malignancies	• 22/06/2010 • 19/05/2011 • 210 • 120	• 26/05/2011 • 13/07/2011 • 31/8/2011 • C316
• Gilenya • fingolimod	Novartis Europharm Ltd.	• L04AA27 • treatment of multiple sclerosis	• 20/01/2010 • 20/01/2011 • 181 • 183	• 31/01/2011 • 17/03/2011 • 22/3/2011 • C184

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
• Ameluz • 5-aminolevulinic acid hydrochloride	Biofrontera Bioscience GmbH	• L01XD04 • treatment of actinic keratosis	• 21/09/2010 • 20/10/2011 • 210 • 183	• 27/10/2011 • 14/12/2011 • 14/11/2011 • C56
• Yervoy • ipilimumab	Bristol-Myers Squibb Pharma EEIG	• L01XC11 • treatment of advanced melanoma	• 25/05/2010 • 19/05/2011 • 210 • 148	• 25/05/2011 • 13/07/2011 • 31/8/2011 • C316
• Edurant • rilpivirine	Janssen-Cilag International N V	• J05AG05 • treatment of HIV-1 infection	• 21/09/2010 • 22/09/2011 • 210 • 155	• 05/10/2011 • 28/11/2011 • 14/11/2011 • C56
• Dexdor • dexmedetomidine	Orion Corporation	• N05CM18 • light to moderate sedation	• 19/10/2010 • 21/07/2011 • 201 • 73	• 02/08/2011 • 16/09/2011 • 21/9/2011 • C383
• Edarbi • azilsartan medoxomil	Takeda Global Research and Development Centre (Europe) Ltd.	• C09CA09 • treatment of essential hypertension	• 19/10/2010 • 22/09/2011 • 210 • 127	• 26/09/2011 • 07/12/2011 • 14/11/2011 • C56
• Eviplera • emtricitabine / rilpivirine / tenofovir disoproxil	Gilead Sciences International Ltd.	• J05AR08 • treatment of HIV-1 infection	• 21/09/2010 • 22/09/2011 • 210 • 155	• 10/10/2011 • 28/11/2011 • 14/11/2011 • C56
• INCIVO • telaprevir	Janssen-Cilag International N V	• J05AE • treatment of genotype 1 chronic hepatitis C	• 18/01/2011 • 21/07/2011 • 150 • 33	• 03/08/2011 • 19/09/2011 • 22/9/2011 • C383
• Caprelsa • vandetanib	AstraZeneca AB	• L01XE • treatment of thyroid cancer	• 22/09/2010 • 17/11/2011 • 210 • 211	• 07/12/2011 • 17/02/2012 • 14/11/2011 • C56
• Zytiga • abiraterone	Janssen-Cilag International N V	• L02BX03 • treatment of metastatic castration resistant prostate cancer	• 18/01/2011 • 21/07/2011 • 150 • 33	• 02/08/2011 • 05/09/2011 • 07/9/2011 • C383
• Victrelis • boceprevir	Merck Sharp & Dohme Ltd.	• J05AE12 • treatment of chronic hepatitis C (HCV)	• 14/12/2010 • 19/05/2011 • 145 • 10	• 08/06/2011 • 18/07/2011 • 31/8/2011 • C316
• Zelboraf • vemurafenib	Roche Registration Ltd.	• L01XE15 • treatment of BRAF V600 mutation-positive	• 24/05/2011 • 15/12/2011 • 180 • 23	• 19/12/2011 • 17/02/2012 • - - • - -
• Ipreziv • azilsartan medoxomil	Takeda Global Research and Development Centre (Europe) Ltd.	• C09CA09 • treatment of essential hypertension	• 21/06/2011 • 22/09/2011 • 60 • 32	• 26/09/2011 • 07/12/2011 • 14/11/2011 • C56

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
• Aflunov • prepandemic influenza vaccine (h5n1) (surface antigen, inactivated, adjuvanted)	Novartis Vaccines and Diagnostics S.r.l.	• J07BB02 • immunisation against H5N1 subtype of Influenza A virus	• 22/12/2009 • 23/09/2010 • 210 days • 64 days	• 23/09/2010 • 29/11/2010 • 03/12/2010 • C61 of 25/02/2011
• Arepanrix • pandemic influenza vaccine (h1n1) (split virion, inactivated, adjuvanted)	GlaxoSmithKline Biologicals S.A.	• J07BB02 • pandemic influenza vaccine	• 19/01/2010 • 21/01/2010 • 1 day • 0 days	• 01/03/2010 • 23/03/2010 • 25/03/2010 • C258 of 24/09/2010
• Brilique • ticagrelor	AstraZeneca AB	• B01AC24 • prevention of atherothrombotic events	• 17/11/2009 • 23/09/2010 • 206 days • 103 days	• 23/09/2010 • 03/12/2010 • 07/12/2010 • C61 of 25/02/2011
• Brinavess • vernakalant hydrochloride	Merck Sharp & Dohme Ltd.	• C01BG11 • conversion of atrial fibrillation to sinus rhythm	• 18/08/2009 • 24/06/2010 • 209days • 100 days	• 01/09/2010 • 01/09/2010 • 06/09/2010 • C359 of • 31/12/2010
• Daxas • roflumilast	Altana Pharma AG	• R03DX07 • treatment of Chronic Obstructive Pulmonary Disease (COPD) and asthma	• 26/05/2009 • 22/04/2010 • 210 days • 120 days	• 01/07/2010 • 05/07/2010 • 08/07/2010 • C295 of • 29/10/2010
• FLUENZ • influenza vaccine (live attenuated, nasal)	MedImmune LLC	• J07BB03 • prevention of influenza	• 23/12/2008 • 21/10/2010 • 210 days • 454 days	• 21/10/2010 • 27/01/2011 • 01/02/2011 • C128 of 19/04/2011
• Humenza • pandemic influenza vaccine (h1n1) (split virion, inactivated, adjuvanted)	Sanofi Pasteur S.A.	• J07BB02 • prophylaxis of influenza	• 14/01/2010 • 18/02/2010 • 34 days • 0 days	• 01/06/2010 • 08/06/2010 • 10/06/2010 • C258 of 24/09/2010
• Ozurdex • dexamethasone	Allergan Pharmaceuticals Ireland	• S01BA01 • treatment of macular oedema	• 24/03/2009 • 20/05/2010 • 210 days • 211 days	• 20/05/2010 • 27/07/2010 • 01/08/2010 • C295 of 29/10/2010
• Possia • ticagrelor	AstraZeneca AB	• B01AC24 • prevention of atherothrombotic events	• 25/05/2010 • 23/09/2010 • 87 days • 33 days	• 23/09/2010 • 03/12/2010 • 07/12/2010 • C61 of 25/02/2011

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
• 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.	• J07BB02 • immunisation against H5N1 subtype of Influenza A virus	• 22/12/2009 • 23/09/2010 • 210 days • 64 days	• 23/09/2010 • 29/11/2010 • 03/12/2010 • C61 of 25/02/2011
• Pumarix • pandemic influenza vaccine (h5n1) (split virion, inactivated, adjuvanted)	GlaxoSmithKline Biologicals S.A.	• J07BB02 • prophilaxis of influenza in an officially declared pandemic situation	• 05/08/2009 • 18/11/2010 • 91 days • 365 days	• 18/11/2010 • 04/03/2011
• Rapiscan • regadenoson	Rapidscan Pharma Solutions EU Ltd.	• C01EB21 • pharmacological stress agent for radionuclide myocardial perfusion imaging (MPI)	• 26/05/2009 • 24/06/2010 • 209 days • 184 days	• 24/06/2010 • 06/09/2010 • 08/09/2010 • C359 of • 31/12/2010
• Ruconest • conestat alfa	Pharming Group N.V.	• B05 • treatment of angioedema	• 22/09/2009 • 24/06/2010 • 210 days • 64 days	• 24/06/2010 • 28/10/2010 • 04/11/2010 • C359 of • 31/12/2010
• Sycrest • asenapine maleate	N.V. Organon	• N05AH05 • treatment of manic episodes associated with bipolar I disorder	• 26/05/2009 • 24/06/2010 • 210days • 183 days	• 01/09/2010 • 01/09/2010 • 06/09/2010 • C359 of • 31/12/2010
• Teysuno • tegafur / gimeracil / oteracil	Taiho Pharma Europe Ltd.	• L01BC53 • treatment of gastric cancer	• 17/11/2009 • 16/12/2010 • 210 days • 183days	• 16/12/2010 • 14/03/2011 • -- • --
• TOBI Podhaler • tobramycin	Novartis Europharm Ltd.	• J01GB01 • long-term management of chronic pulmonary infection due to Pseudomonas aeruginosa	• 22/12/2009 • 23/09/2010 • 210 days • 64 days	• -- • -- • -- • --

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
• 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 2011 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
• Xaluprine • 6-mercaptopurine monohydrate	Nova Laboratories Ltd.	• L01BB02 • treatment of acute lymphoblastic leukaemia (ALL)	• 20/07/2010 • 21/07/2011 • 200 • 165	• 18/08/2011 • 09/03/2012 • 13/3/2012 • C124
• Plenadren • hydrocortisone	ViroPharma SPRL	• H02AB09 • Treatment of adrenal insufficiency	• 22/06/2010 • 21/07/2011 • 210 • 183	• 03/08/2011 • 03/11/2011 • 14/11/2011 • C56
• Vyndaqel • tafamidis	Pfizer Specialty UK Ltd.	• N07XX08 • treatment of transthyretin amyloidosis in patients with symptomatic polyneuropathy	• 17/08/2010 • 21/07/2011 • 210 • 127	• 02/08/2011 • 16/11/2011 • 14/11/2011 • C56
• Votubia • everolimus	Novartis Europharm Ltd.	• L01XE10 • treatment of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)	• 17/08/2010 • 23/06/2011 • 210 • 99	• 08/07/2011 • 02/09/2011 • 06/9/2011 • C383

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
• 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 2011 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
• Sepioglin • pioglitazone	Vaia S.A.	• A10BG03 • treatment of type 2 diabetes mellitus	• 16/11/2010 • 22/09/2011 • 210 • 99	• 26/09/2011 09/03/2012 13/3/2012 C124
• Matever • levetiracetam	Pharmathen S.A.	• N03AX14 • treatment of partial onset seizures	• 19/10/2010 • 21/07/2011 • 206 • 68	• 29/07/2011 03/10/2011 02/11/2011 C383
• Rivastigmine Actavis • rivastigmine	Actavis Group PTC ehf	• N06DA03 • treatment of dementia	• 25/05/2010 • 14/04/2011 • 210 • 113	• 19/04/2011 16/06/2011 21/6/2011 C250
• Levetiracetam SUN • boceprevir	Merck Sharp & Dohme Ltd.	• N03AX14 • treatment of epilepsy	• 19/10/2010 • 20/10/2011 • 201 • 164	• 27/10/2011 14/12/2011 14/11/2011 C56

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
• Methylthioninium chloride Proveblue • methylthioninium chloride	Provepharm S.A.S.	• V03AB17 • treatment of methaemoglobinaemia	• 19/01/2010 • 17/02/2011 • 210 • 182	• 01/03/2011 06/05/2011 12/5/2011 C250
• Onduarp • telmisartan / amlodipine	Boehringer Ingelheim International GmbH	• C09DB04 • treatment of essential hypertension	• 28/07/2011 • 22/09/2011 • 55 • 0	• 05/10/2011 24/11/2011 14/11/2011 C56
• Temozolomide SUN • temozolomide	Sun Pharmaceutical Industries Europe B.V.	• L01AX03 • treatment of glioblastoma multiforme and malignant glioma	• 20/07/2010 • 19/05/2011 • 210 • 92	• 25/05/2011 13/07/2011 31/8/2011 C316
• Levetiracetam ratiopharm • levetiracetam	ratiopharm GmbH	• N03AX14 • treatment of partial onset seizures	• 19/10/2010 • 19/05/2011 • 180 • 31	• 26/05/2011 26/08/2011 31/8/2011 C316
• Pioglitazone ratiopharm • pioglitazone	ratiopharm GmbH	• A10BG03 • treatment of type 2 diabetes mellitus	• 16/11/2010 • 21/07/2011 • 200 • 46	• 26/05/2011 - - - - - -
• Topotecan Eagle • topotecan	Eagle Laboratories Ltd.	• L01XX17 • treatment of small cell lung cancer	• 20/07/2010 • 20/10/2011 • 182 • 274	• 14/11/2011 22/12/2011 14/11/2011 C56
• Buccolam • midazolam	ViroPharma SPRL	• N05CD08 • treatment of prolonged, acute, convulsive seizures	• 21/09/2010 • 23/06/2011 • 210 • 64	• 04/07/2011 05/09/2011 - - - -
• Pioglitazone Accord • pioglitazone hydrochloride	Accord Healthcare Ltd	• A10BG03 • treatment of type 2 diabetes mellitus	• 16/11/2010 • 21/07/2011 • 200 • 46	• 29/07/2011 21/03/2012 27/3/2012 C124
• Levetiracetam Accord • levetiracetam	Accord Healthcare Ltd	• N03AX14 • reatment of partial onset seizures	• 16/11/2010 • 21/07/2011 • 200 • 46	• 29/07/2011 03/10/2011 - - - -
• Pramipexole Accord • pramipexole	Accord Healthcare Ltd	• N04BC05 • treatment of idiopathic Parkinson's disease and treatment of idiopathic Restless Legs Syndrome.	• 16/11/2010 • 21/07/2011 • 200 • 46	• 22/08/2011 30/09/2011 02/11/2011 C383
• Pioglitazone Teva • pioglitazone	Teva Pharma B.V.	• A10BG03 • treatment of type 2 diabetes mellitus	• 16/11/2010 • 22/09/2011 • 210 • 99	• 23/01/2012 26/03/2012 29/3/2012 C124

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
• Levetiracetam Actavis Group • levetiracetam	Eisai Ltd.	• N03AX14 • treatment of epilepsy	• 14/12/2010 • 22/09/2011 • 210 • 71	• 17/10/2011 05/12/2011 14/11/2011 C56
• Paglitaz • pioglitazone	Krka, d.d., Novo mesto	• A10BG03 treatment of type 2 diabetes mellitus	• 16/11/2010 • 21/07/2011 • 200 • 46	• 29/07/2011 21/03/2012 26/3/2012 C124
• Dasselta • desloratadine	Krka, d.d., Novo mesto	• R06AX27 • relief of symptoms of allergic rhinitis and urticaria	• 22/02/2011 • 22/09/2011 • 180 • 31	• 26/09/2011 28/11/2011 14/11/2011 C56
• Levetiracetam Teva • levetiracetam	Teva Pharma B.V.	• N03AX14 • treatment of epilepsy	• 19/10/2010 • 19/05/2011 • 180 • 31	• 26/05/2011 26/08/2011 31/8/2011 C316
• Docetaxel Mylan • docetaxel	Mylan S.A.S.	• L01CD02 • treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer	• 18/08/2010 • 17/11/2011 • 210 • 246	• 05/12/2011 31/01/2012 14/11/2011 C56
• Repaglinide Accord • repaglinide	Accord Healthcare Ltd.	• A10BX02 • treatment of type 2 diabetes mellitus	• 14/12/2010 • 20/10/2011 • 180 • 129	• 08/11/2011 22/12/2011 14/11/2011 C56
• Pioglitazone Actavis • pioglitazone	Actavis Group PTC ehf	• A10BG03 • treatment of type 2 diabetes mellitus	• 16/11/2010 • 22/09/2011 • 210 • 99	• 26/01/2012 15/03/2012 20/3/2012 C124
• Efavirenz Teva • efavirenz	Teva Pharma B.V.	• J05AG03 • treatment of HIV-1 infection	• 14/12/2010 • 20/10/2011 • 201 • 108	• 04/11/2011 09/01/2012 14/11/2011 C56
• Levetiracetam Actavis • levetiracetam	Actavis Group PTC ehf	• N03AX14 • treatment of partial onset seizures	• 19/10/2010 • 21/07/2011 • 210 • 64	• 29/07/2011 03/10/2011 02/11/2011 C383
• Ibandronic Acid Hexal • ibandronic acid	Hexal AG	• M05BA06 • prevention of skeletal events	• 18/12/2010 • 17/02/2011 • 60 • 0	• 02/03/2011 - - - - - -
• Ibandronic acid Sandoz • ibandronic acid	Sandoz Pharmaceuticals GmbH	• M05BA06 • prevention of skeletal events	• 18/12/2010 • 17/02/2011 • 60 • 0	• 04/03/2011 26/07/2011 31/8/2011 C316

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
• Pioglitazone ratiopharm GmbH • pioglitazone	ratiopharm GmbH	• A10BG03 • treatment of type 2 diabetes mellitus	• 23/04/2011 • 21/07/2011 • 80 • 8	• 29/07/2011 - - - - - -
• Pioglitazone ratio • pioglitazone	ratiopharm GmbH	• A10BG03 • treatment of type 2 diabetes mellitus	• 23/04/2011 • 21/07/2011 • 80 • 8	• 29/07/2011 - - - - - -
• Leganto • rotigotine	UCB Manufacturing Ireland Ltd.	• N04BC09 • treatment of Restless Legs Syndrom; treatment of Parkinson´s disease	• 12/02/2011 • 14/04/2011 • 60 • 0	• 29/04/2011 16/06/2011 22/6/2011 C250
• Desloratadine ratiopharm • desloratadine	ratiopharm GmbH	• R06AX27 • relief of symptoms of allergic rhinitis and urticaria	• 23/02/2011 • 17/11/2011 • 201 • 66	• 24/11/2011 13/01/2012 14/11/2011 C56
• Pioglitazone Teva Pharma • pioglitazone	Teva Pharma B.V.	• A10BG03 • treatment of type 2 diabetes mellitus	• 23/04/2011 • 22/09/2011 • 92 • 59	• 23/01/2012 26/03/2012 14/11/2011 C56
• Desloratadine Teva • desloratadine	Teva Pharma B.V.	• R06AX27 • for the relief of symptoms allergic rhinitis and urticaria	• 22/02/2011 • 22/09/2011 • 180 • 31	• 26/09/2011 24/11/2011 14/11/2011 C56
• Riprazo HCT • aliskiren hemifumarate / hydrochlorothiazide	Novartis Europharm Ltd.	• C09XA52 • treatment of essential hypertension	• 20/11/2010 • 20/01/2011 • 60 • 0	• 26/01/2011 13/04/2011 15/4/2011 C184
• Sprimeo HCT • aliskiren / hydrochlorothiazide	Novartis Europharm Ltd.	• C09XA52 • treatment of hypertension	• 18/12/2010 • 17/02/2011 • 60 • 0	• 28/02/2011 23/06/2011 28/6/2011 C250
• Desloratadine Actavis • desloratadine	Actavis Group PTC ehf	• R06AX27 • treatment of allergic rhinitis and urticaria	• 23/02/2011 • 17/11/2011 • 201 • 66	• 24/11/2011 • 13/01/2012 • 14/11/2011 • C56
• Entacapone Orion • entacapone	Orion Corporation	• N04BX02 • Treatment of adult patients with Parkinson's disease and end-of-dose motor fluctuations	• 23/04/2011 • 23/06/2011 • 60 • 0	• 24/06/2011 • 18/08/2011 • 31/8/2011 • C316
• Levodopa/Carbidopa/Entacapone Orion • levodopa / carbidopa / entacapone	Orion Corporation	• N04BA03 • Treatment of platients with Parkinson's disease and end-of-dose motor fluctuations	• 23/04/2011 • 23/06/2011 • 60 • 0	• 01/07/2011 • 24/08/2011 • 31/8/2011 • C316

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
• Pioglitazone Teva Generics • pioglitazone	TEVA Generics B.V.	• A10BG03 • treatment of type 2 diabetes mellitus	• 23/04/2011 • 22/09/2011 • 92 • 59	• 27/09/2011 • - - • - - • - -
• Pioglitazone Krka • pioglitazone	Krka, d.d., Novo mesto	• A10BG03 • treatment of type 2 diabetes mellitus	• 16/11/2010 • 21/07/2011 • 200 • 46	• 29/07/2011 • 21/03/2012 • - - • - -
• Desloratadine Krka • desloratadine	Krka, d.d., Novo mesto	• R06AX27 • relief of symptoms of allergic rhinitis and urticaria	• 22/02/2011 • 2/09/2011 • 180 • 31	• 26/09/2011 • - - • - - • - -
• Telmisartan Teva Pharma • telmisartan	Teva Pharma B.V.	• C09CA07 • treatment of essential hypertension	• 21/05/2011 • 21/07/2011 • 60 • 0	• 08/08/2011 • 03/10/2011 • 02/11/2011 • C383
• Glidipion • pioglitazone	Actavis Group PTC ehf	• A10BG03 • treatment of type 2 diabetes mellitus	• 21/06/2011 • 22/09/2011 • 60 • 32	• 26/01/2012 • 15/03/2012 • 20/3/2012 • C124

CHMP negative opinions in 2011 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
• Bronchitol • mannitol	Pharmaxis Pharmaceuticals Limited	• R05CB16 • treatment of cystic fibrosis (CF)	• 17/11/2009 • 23/06/2011 • 210 • 372	• 25/10/2011 • 13/04/2012 • - - • - -
• Luveniq • voclosporin	Lux Biosciences GmbH	• L04AD03 • treatment of chronic non-infectious uveitis	• 23/02/2010 • 23/06/2011 • 210 • 274	• 08/07/2011 • - - • - - • - -
• Sumatriptan Galpharm • sumatriptan	Galpharm Healthcare Ltd.	• N02CX04 • treatment of migraine attacks	• 22/06/2010 • 26/07/2011 • 209 • 184	• 04/08/2011 • 17/11/2011 • - - • - -
• Glybera • alipogene tiparvovec	Amsterdam Molecular Therapeutics (AMT) B.V.	• C10 AX10 • treatment lipoprotein lipase deficiency	• 20/01/2010 • 23/06/2011 • 204 • 316	• 06/07/2011 • - - • - - • - -

Annex 12 – CVMP opinions in 2011 on medicinal products for veterinary use

Positive Opinions

Product • Invented name • INN	**Marketing authorisation holder**	**Therapeutic area** • Target species • Summary of indication	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Date of decision • Notification • Official Journal
• CaniLeish	Virbac S.A.	• Dogs • Vaccine against Leishmania infection	• 17/03/2010 • 12/01/2011 • 210 • 91	• 13/01/2011 • 14/03/2011 • 17/03/2011 • OJ C 184/15
• ZULVAC 1 + 8 Ovis	Pfizer Limited	• Sheep • Vaccine for prevention of viraemia caused by Bluetongue Virus serotypes 1 and 8	• 18/03/2010 • 12/01/2011 • 180 • 119	• 13/01/2011 • 14/03/2011 • 17/03/2011 • OJ C 184/15
• BLUEVAC BTV8	CZ Veterinaria S.A	• Cattle, sheep • Vaccine for active immunisation against bluetongue disease	• 17/01/2009 • 09/02/2011 • 210 • 543	• 10/02/2011 • 14/04/2011 • 18/04/2011 • OJ C 184/15
• Procox • Emodepside and toltrazuril	Bayer Animal Health GmbH	• Dogs • Treatment of dogs when mixed parasitic infections, caused by certain specific roundworms and coccidia are suspected or demonstrated	• 16/02/2010 • 09/02/2011 • 210 • 148	• 11/02/2011 • 20/04/2011 • 28/04/2011 • OJ C 184/15
• Veraflox • Pradofloxacin	Bayer Animal Health GmbH	• Dogs, cats • Treatment for dogs and cats with particular infections caused by certain specific and susceptible pathogens	• 19/05/2009 • 14/07/2010 • 205 • 217 • 09/02/2011 (re-consideration)	• 11/02/2011 • 12/04/2011 • 14/04/2011 • OJ C 184/15
• Zuprevo • Tildipirosin	Intervet International BV	• Pigs, cattle • Treatment of bacterial infections in the respiratory tract in pigs and cattle	• 16/02/2010 • 08/03/2011 • 210 • 177	• 10/03/2011 • 06/05/2011 • 06/05/2011 • OJ C 250/16
• CERTIFECT • Fipronil, (S)-methoprene, amitraz	MERIAL SAS	• Dogs • Treatment and prevention of infestations with ticks, alone or in association with fleas and/or chewing lice	• 16/03/2010 • 09/03/2011 • 210 • 148	• 10/03/2011 • 06/05/2011 • 06/05/2011 • OJ C 250/16
• MS-H Vaccine • *Mycoplasma synoviae* strain MS-H	Pharmsure Ltd	• Chickens • Vaccine to reduce air sac lesions and reduce the number of eggs with abnormal shell formation caused by *Mycoplasma synoviae*	• 15/12/2009 • 07/04/2011 • 206 • 271	• 08/04/2011 • 14/06/2011 • 14/06/2011 • OJ C 250/16

Product • Invented name • INN	**Marketing authorisation holder**	**Therapeutic area** • Target species • Summary of indication	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Date of decision • Notification • Official Journal
• Recuvyra • Fentanyl	Nexcyon Pharmaceuticals Ltd	• Dogs • Control of post-operative pain associated with major orthopaedic and soft tissue surgery	• 16/12/2009 • 04/05/2011 • 210 • 294	• 05/05/2011
• Emdocam • Meloxicam	Emdoka bvba	• Cattle, pigs, horses • For treatment in respiratory infections, diarrhoea and mastitis in cattle. For treatment in non-infectious locomotor disorders and in puerperal septicaemia and toxaemia in pigs. In horses for treatment in musculo-skeletal disorders as well for the relief of pain in equine colic.	• 18/05/2010 • 09/06/2011 • 175 • 211	• 09/06/2011 • 18/08/2011 • 22/08/2011 • OJ C 316/15
• Proteq West Nile • West Nile recombinant canarypox virus (vCP2017 virus)	MERIAL	• Horses • Vaccine for the active immunisation of horses against West Nile disease	• 18/05/2010 • 09/06/2011 • 196 • 190	• 09/06/2011 • 05/08/2011 • 10/08/2011 • OJ C 316/15
• Zulvac 1 Bovis • Inactivated Bluetongue virus, serotype 1, strain BTV-1	Pfizer Limited	• Cattle • Active immunisation of cattle for the prevention of viraemia caused by Bluetongue Virus, serotype 1	• 12/08/2010 • 09/06/2011 • 180 • 120	• 06/07/2011 • 05/08/2011 • 10/08/2011 • OJ C 316/15
• Zulvac 1 Ovis • Inactivated Bluetongue Virus, serotype 1, strain BTV-1	Pfizer Limited	• Sheep • Active immunisation of sheep for the prevention of viraemia caused by Bluetongue Virus, serotype 1	• 15/07/2010 • 09/06/2011 • 179 • 148	• 06/07/2011 • 05/08/2011 • 10/08/2011 • OJ C 316/15
• Nobivac Myxo-RHD • Live myxoma vectored RHD virus strain 009	Intervet International BV,	• Rabbits • Active immunisation of rabbits to reduce mortality and clinical signs of myxomatosis and to prevent mortality due to rabbit haemorrhagic disease	• 16/02/2010 • 14/07/2011 • 210 • 302	• 15/07/2011 • 07/09/2011

Product • Invented name • INN	**Marketing authorisation holder**	**Therapeutic area** • Target species • Summary of indication	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Date of decision • Notification • Official Journal
• Recocam • Meloxicam	CF Pharma	• Cattle, pigs, horses • For treatment in respiratory infections, diarrhoea and mastitis in cattle. For treatment in non-infectious locomotor disorders and in puerperal septicaemia and toxaemia in pigs. In horses for treatment in musculo-skeletal disorders as well for the relief of pain in equine colic.	• 16/03/2010 • 14/07/2011 • 210 • 274	• 14/07/2011 • 13/09/2011
• TruScient • Dibotermin-alfa	Pfizer Limited	• Dogs • For the treatment of diaphyseal fractures as an adjunct to standard surgical care using open fracture reduction	• 15/06/2010 • 13/10/2011 • 205 • 279	• 14/10/2011 • 14/12/2011
• Panacur AquaSol • Fenbendazole	Intervet International B.V.	• Pigs • For the treatment and control of gastro-intestinal nematodes in pigs infected with Ascaris suum and Oesophagostomum spp.	• 12/10/2010 • 13/10/2011 • 202 • 163	• 13/10/2011
• Inflacam • Meloxicam	Chanelle Pharmaceuticals Manufacturing Limited	• Dogs, horses, cattle, pigs • For the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.	• 15/06/2011 • 13/10/2011 • 120 • 0	• 13/10/2011
• Activyl Tick Plus • Indoxacarb, permethrin	Intervet International B.V.	• Dogs • Treatment of flea and tick infestations	• 07/12/2010 • 10/11/2011 • 210 • 128	• 11/11/2011
• RevitaCAM 5mg/ml	Abbott Laboratories Limited	• Dogs • For the alleviation of inflammation and pain in acute and chronic musculo-skeletal disorders	• 05/01/2011 • 08/12/2011 • 210 • 128	• 08/12/2011

CVMP Opinions in 2011 on establishment of MRLs for new substances

Name • Substance • INN	**Target species**	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Date of regulation • Official Journal
• Methylpredni –solone (after provisional MRLs)	Bovine	• n/a • 12/01/2011 • 90 • 0	• 27/01/2011
• Octenidine dihydrochloride	All mammalian food producing species	• 11/08/2009 • 08/02/2011 • 210 • 246	• 21/02/2011
• Monepantel (after provisional MRLs)	Caprine	• n/a • 09/03/2011 • 90 • 0	• 25/03/2011
• Azamethiphos	Fin fish	• 21/02/2011 • 07/04/2011 • 45 • 0	• 08/04/2011
• Pegylated bovine granulocyte colony stimulating factor	Bovine	• 16/03/2010 • 05/05/2011 • 210 • 205	• 18/05/2011
• Lasalocid	Bovine	• 10/08/2010 • 05/05/2011 • 210 • 58	• 18/05/2011
• Ivermectin	All mammalian food producing species	• n/a • 09/06/2011 • 176 • 0	• 20/06/2011
• Phenoxymethyl-penicillin	Poultry eggs	• 12/10/2010 • 14/07/2011 • 210 • 65	• 22/07/2011
• Tildipirosin (after provisional MRLs)	Bovine, porcine and caprine	• n/a • 15/09/2011 • 90 • n/a	• 29/09/2011
• Altrenogest	Porcine, *equidae*	• n/a • 13/10/2011 • 129 • n/a	• 18/10/2011
• Neomycin	All food producing species	• 14/09/2010 • 10/11/2011 • 210 • 212	• 16/11/2011
• Closantel	Bovine and ovine milk	• n/a • 10/11/2011 • 83 • 0	• 16/11/2011
• Nitroxinil	Bovine and ovine milk	• n/a • 10/11/2011 • 72 • 0	• 16/11/2011
• Triclabendazole	All ruminants	• n/a • 10/11/2011 • 83 • 0	• 16/11/2011

Name • Substance • INN	**Target species**	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Date of regulation • Official Journal
• Fenbendazole	Chicken and all food producing species except fish.	• 13/07/2011 • 08/12/2011 • 148 • 0	• 14/12/2011
• Clorsulon	Bovine milk	• n/a • 08/12/2011 • 111 • 0	• 14/12/2011

Annex 13 – COMP opinions in 2011 on designation of orphan medicinal products

Positive COMP designation opinions

Product INN	**Sponsor**	**Summary of indication**	**EMA/COMP** • Submission • Start date • Opinion • Active time	**European Commission** • Opinion received • Date of decision
Recombinant thymidine phosphorylase encapsulated in autologous erythrocytes	St George's University of London - UK	Treatment of mitochondrial neurogastrointestinal encephalomyopathy (MNGIE) due to thymidine phosphorylase deficiency	• 19/10/2010 • 12/11/2010 • 12/01/2011 • (61 days/66 days)	• 08/02/2011 • 15/04/2011
Recombinant fusion protein linking human coagulation factor VIIa with human albumin (rVIIa-FP)	CSL Behring GmbH - Germany	Treatment of haemophilia A	• 29/09/2010 • 12/11/2010 • 12/01/2011 • (61 days/66 days)	• 08/02/2011 • 15/04/2011
R-baclofen	Lakeside Regulatory Consulting Services Ltd - UK	Treatment of fragile X syndrome	• 26/10/2010 • 12/11/2010 • 12/01/2011 • (61 days/66 days)	• 08/02/2011 • 15/04/2011
Human anthrax monoclonal antibody	Emergent Sales and Marketing Germany GmbH - Germany	Treatment of inhalation anthrax disease	• 25/10/2010 • 12/11/2010 • 12/01/2011 • (61 days/66 days)	• 08/02/2011 • 15/04/2011
Vorinostat	Merck Sharp & Dohme Limited - UK	Treatment of multiple myeloma	• 22/10/2010 • 12/11/2010 • 12/01/2011 • (61 days/66 days)	• 08/02/2011 • 15/04/2011
Synthetic double-stranded siRNA oligonucleotide directed against transthyretin mRNA	Voisin Consulting S.A.R.L. - France	Treatment of familial amyloid polyneuropathy	• 25/10/2010 • 12/11/2010 • 12/01/2011 • (61 days/66 days)	• 08/02/2011 • 15/04/2011
Ombrabulin	Sanofi Aventis - France	Treatment of soft tissue sarcoma	• 25/10/2010 • 12/11/2010 • 12/01/2011 • (61 days/66 days)	• 08/02/2011 • 15/04/2011
(S)-{8-fluoro-2-2[4-(3-methoxyphenyl)-1-piperazinyl]-3-[2-methoxy-5-(trifluoromethyl)-phenyl]-3,4-dihydro-4-quinazolinyl} acetic acid	AiCuris GmbH & Co. KG - Germany	Prevention of cytomegalovirus disease in patients with impaired cell-mediated immunity deemed at risk	• 02/07/2010 • 12/11/2010 • 12/01/2011 • (61 days/66 days)	• 08/02/2011 • 15/04/2011

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Darinaparsin	Ziopharm Oncology Limited - UK	Treatment of peripheral T-cell lymphoma (nodal, other extranodal and leukaemic/disseminated)	• 09/08/2010 • 15/10/2010 • 12/01/2011 • (89 days/66 days)	• 08/02/2011 • 15/04/2011
Glufosfamide	Theradex (Europe) Ltd. - UK	Treatment of pancreatic cancer	• 01/10/2010 • 15/10/2010 • 12/01/2011 • (89 days/66 days)	• 08/02/2011 • 15/04/2011
S-Nitrosoglutathione	Salupont Consulting Ltd - UK	Treatment of pre-eclampsia	• 26/10/2010 • 12/11/2010 • 09/02/2011/ • (89 days/60 days)	• 14/03/2011 • 13/05/2011
Lisuride hydrogen maleate	Sinoxa Pharma UG - Germany	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension	• 22/10/2010 • 12/11/2010 • 09/02/2011/ • (89 days/60 days)	• 14/03/2011 • 13/05/2011
Lenalidomide	Celgene Europe Limited - UK	Treatment of diffuse large B-cell lymphoma	• 25/11/2010 • 10/12/2010 • 09/02/2011/ • (61 days/60 days)	• 14/03/2011 • 13/05/2011
Recombinant fusion protein linking human coagulation factor VIIa with human albumin	CSL Behring GmbH - Germany	Treatment of haemophilia B	• 29/09/2010 • 10/12/2010 • 09/02/2011/ • (61 days/60 days)	• 14/03/2011 • 13/05/2011
9-cis-Retinyl acetate	QLT Ophthalmics (UK), Ltd - UK	Treatment of retinitis pigmentosa	• 26/11/2010 • 10/12/2010 • 09/02/2011/ • (61 days/60 days)	• 14/03/2011 • 13/05/2011
9-cis-Retinyl acetate	QLT Ophthalmics (UK), Ltd - UK	Treatment of Leber's congenital amaurosis	• 26/11/2010 • 10/12/2010 • 09/02/2011/ • (61 days/60 days)	• 14/03/2011 • 13/05/2011
Allogeneic bone marrow stem cells treated ex vivo with 16,16-dimethyl prostaglandin E2	Fate Therapeutics, LTD - UK	treatment of acute myeloid leukaemia	• 25/11/2010 • 10/12/2010 • 09/02/2011/ • 13/05/2011 (61 days/60 days)	• 14/03/2011 • 13/05/2011
Adeno-associated viral vector containing the human NADH dehydrogenase 4 gene	Institut de la Vision - France	Treatment of Leber's hereditary optic neuropathy	• 26/11/2010 • 10/12/2010 • 09/02/2011/ • (61 days/60 days)	• 14/03/2011 • 13/05/2011
Adeno-associated viral vector containing the human ARSB gene	Fondazione Telethon - Italy	Treatment of mucopolysaccharidosis type VI (Maroteux-Lamy syndrome)	• 27/10/2010 • 10/12/2010 • 09/02/2011 • (61 days/60 days)	• 14/03/2011 • 13/05/2011

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Apomorphine hydrochloride	Dr Elkan Raphael Gamzu - UK	Treatment of moderate and severe traumatic brain injury	• 24/08/2010 • 12/11/2010 • 09/02/2011 • (89 days/60 days)	• 14/03/2011 • 13/05/2011
Allogeneic umbilical cord blood cells treated ex vivo with 16,16-dimethyl prostaglandin E2	Fate Therapeutics, LTD - UK	Treatment of acute myeloid leukaemia	• 25/11/2010 • 10/12/2010 • 09/02/2011 • (61 days/60 days)	• 14/03/2011 • 13/05/2011
[N-((2S,3R,3aS,3'R,4a'R,6S,6a'R,6b'S,7aR,12a'S,12b'S,Z)-3,6,11',12b'-tetramethyl-2',3a,3',4,4',4a',5,5',6,6',6a',6b',7,7a,7',8',10',12',12a',12b'-icosahydro-1'H,3H-spiro[furo[3,2-b]pyridine-2,9'-naphtho[2,1-a]azulene]-3'-yl)methanesulfonamide hydrochloride]	Voisin Consulting S.A.R.L. - France	Treatment of chondrosarcoma	• 26/10/2010 • 12/11/2010 • 09/02/2011 • (89 days/60 days)	• 14/03/2011 • 13/05/2011
Metronidazole	FORMAC Pharmaceuticals NV - Belgium	Treatment of pouchitis	• 13/12/2010 • 10/01/2011 • 09/03/2011 • (58 days/82 days)	• 31/03/2011 • 21/06/2011
Genetically modified human adenovirus encoding human PH20 hyaluronidase	VCN Biosciences S.L. - Spain	Treatment of pancreatic cancer	• 21/01/2011 • 07/02/2011 • 07/04/2011 • (59 days/54 days)	• 28/04/2011 • 21/06/2011
Chimeric monoclonal antibody against GD2	United Therapeutics Europe Ltd - UK	Treatment of neuroblastoma	• 18/01/2011 • 07/02/2011 • 07/04/2011 • (59 days/54 days)	• 28/04/2011 • 21/06/2011
Allogeneic T cells encoding an exogenous thymidine kinase gene	LTKFarma - France	Treatment of acute lymphoblastic leukaemia	• 11/01/2011 • 07/02/2011 • 07/04/2011 • (59 days/54 days)	• 28/04/2011 • 21/06/2011
Adeno-associated viral vector serotype 9 containing the human sulfamidase gene	Laboratorios del Dr. Esteve, S.A. - Spain	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome)	• 13/12/2010 • 07/02/2011 • 07/04/2011 • (59 days/54 days)	• 28/04/2011 • 21/06/2011
Viral vector containing DNA encoding the human SMN protein	The University of Sheffield - UK	Treatment of 5q spinal muscular atrophy	• 13/12/2010 • 10/01/2011 • 09/03/2011 • (58 days/82 days)	• 31/03/2011 • 21/06/2011

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Salirasib	TMC Pharma Services Ltd - UK	Treatment of pancreatic cancer	• 18/11/2010 • 10/01/2011 • 09/03/2011 • (58 days/82 days)	• 31/03/2011 • 21/06/2011
Human dermal fibroblasts cultured on a bioresorbable polyglactin mesh	TMC Pharma Services Ltd - UK	Treatment of epidermolysis bullosa	• 13/12/2010 • 10/01/2011 • 09/03/2011 • (58 days/82 days)	• 31/03/2011 • 21/06/2011
Human embryonic stem-cell-derived retinal pigment epithelial cells	TMC Pharma Services Ltd - UK	Treatment of Stargardt's disease	• 13/12/2010 • 10/01/2011 • 09/03/2011 • (58 days/82 days)	• 31/03/2011 • 21/06/2011
Sulfonated monophosphorylated mannose oligosaccharide	S-Cubed Limited - UK	Treatment of hepatocellular carcinoma	• 13/12/2010 • 10/01/2011 • 09/03/2011 • (58 days/82 days)	• 31/03/2011 • 21/06/2011
Fresolimumab	Genzyme Europe BV - The Netherlands	Treatment of focal segmental glomerulosclerosis	• 26/10/2010 • 07/02/2011 • 05/05/2011 • (87 days/60 days)	• 06/06/2011 • 05/08/2011
Human anthrax monoclonal antibody	Emergent Sales and Marketing Germany GmbH - Germany	Post-exposure prophylaxis of inhalation anthrax disease	• 25/10/2010 • 12/11/2010 • 09/02/2011 • (89 days/142 days)	• 16/03/2011 • 05/08/2011
Pegylated recombinant Erwinia chrysanthemi L-asparaginase	Alize Pharma II - France	Treatment of acute lymphoblastic leukaemia	• 13/12/2010 • 07/02/2011 • 05/05/2011 • (87 days/60 days)	• 06/06/2011 • 05/08/2011
Peretinoin	Kowa Pharmaceutical Europe Co. Ltd. - UK	Treatment of hepatocellular carcinoma	• 20/01/2011 • 07/02/2011 • 05/05/2011 • (87 days/60 days)	• 06/06/2011 • 05/08/2011
Acadesine	Advancell - Advanced In Vitro Cell Technologies S.A. - Spain	Treatment of multiple myeloma	• 25/02/2011 • 14/03/2011 • 05/05/2011 • (52 days/60 days)	• 06/06/2011 • 05/08/2011
N-(cyanomethyl)-4-(2-{[4-(morpholin-4-yl)phenyl]amino}pyrimidin-4-yl)benzamide, dihydrochloride salt	Cres Pharmaceuticals Limited - UK	Treatment of post-essential thrombocythaemia myelofibrosis	• 28/02/2011 • 14/03/2011 • 05/05/2011 • (52 days/60 days)	• 06/06/2011 • 05/08/2011

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
N-(cyanomethyl)-4-(2-{[4-(morpholin-4-yl)phenyl]amino}pyrimidin-4-yl)benzamide, dihydrochloride salt	Cres Pharmaceuticals Limited - UK	Treatment of post-polycythaemia vera myelofibrosis	• 28/02/2011 • 14/03/2011 • 05/05/2011 • (52 days/60 days)	• 06/06/2011 • 05/08/2011
N-(cyanomethyl)-4-(2-{[4-(morpholin-4-yl)phenyl]amino}pyrimidin-4-yl)benzamide, dihydrochloride salt	Cres Pharmaceuticals Limited - UK	Treatment of primary myelofibrosis	• 24/11/2010 • 14/03/2011 • 05/05/2011 • (52 days/60 days)	• 06/06/2011 • 05/08/2011
Methyl O-4-O-[2-[2-[2-[2-[[N-[(1R)-1-[[4-(aminoiminomethyl)phenyl]methyl]-2-oxo-2-(1-piperidinyl)ethyl]-N2-	Endotis Pharma - France	Prevention of ischaemia/reperfusion injury associated with solid organ transplantation	• 25/02/2011 • 14/03/2011 • 05/05/2011 • (52 days/60 days)	• 06/06/2011 • 05/08/2011
Low molecular weight dextran sulfate	TikoMed AB - Sweden	Treatment for mobilisation of progenitor cells prior to stem cell transplantation	• 24/02/2011 • 14/03/2011 • 05/05/2011 • (52 days/60 days)	• 06/06/2011 • 05/08/2011
Mixture of seven synthetic fragments consisting of p21 RAS peptides	Targovax AS - Norway	Treatment of pancreatic cancer	• 21/01/2011 • 14/03/2011 • 05/05/2011 • (52 days/60 days)	• 06/06/2011 • 05/08/2011
N-{[(5S)-3-(3-fluoro-4-thiomorpholin-4-ylphenyl)-2-oxo-1,3-oxazolidin-5-yl]methyl}acetamide	Pfizer Limited - UK	Treatment of tuberculosis	• 24/03/2011 • 11/04/2011 • 10/06/2011 • (60 days/61 days)	• 30/06/2011 • 30/08/2011
Sirolimus	Santen Oy - Finland	Treatment of chronic non-infectious uveitis	• 15/03/2011 • 11/04/2011 • 10/06/2011 • (60 days/61 days)	• 30/06/2011 • 30/08/2011
Cardiotrophin-1	Digna Biotech S.L. - Spain	Treatment of acute liver failure	• 25/03/2011 • 11/04/2011 • 10/06/2011 • (60 days/61 days)	• 30/06/2011 • 30/08/2011
Hydroxy-propyl-beta-cyclodextrin	Susan French - UK	Treatment of Niemann-Pick disease, type C	• 25/03/2011 • 11/04/2011 • 10/06/2011 • (60 days/61 days)	• 30/06/2011 • 30/08/2011
Everolimus	Novartis Europharm Limited - UK	Treatment of gastric cancer	• 24/03/2011 • 11/04/201 • 10/06/2011 • (60 days/61 days)	• 30/06/2011 • 30/08/2011

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
5-[1-(2,6-dichlorobenzyl)piperidin-4-ylmethoxy]quinazoline-2,4-diamine dihydrochloride	Repligen Europe Limited - Ireland	Treatment of 5q spinal muscular atrophy	• 31/01/2011 • 14/03/2011 • 10/06/2011 • (88 days/61 days)	• 30/06/2011 • 30/08/2011
Multilamellar microvesicle comprising phosphatidylcholine, sphingomyelin, phosphatidylethanolamine, phosphatidylserine, phospatidylinositol and cholesterol	Lamellar Biomedical Ltd - UK	Treatment of cystic fibrosis	• 28/03/2011 • 11/04/2011 • 10/06/2011 • (60 days/61 days)	• 30/06/2011 • 30/08/2011
Kifunensine	Généthon - France	Treatment of beta-sarcoglycanopathy	• 24/05/2011 • 10/06/2011 • 15/07/2011 • (35 days/60 days)	• 29/07/2011 • 27/09/2011
Macitentan	Actelion Registration Limited - UK	Treatment of pulmonary arterial hypertension	• 23/03/2011 • 11/04/2011 • 08/07/2011 • (88 days/60 days)	• 29/07/2011 • 27/09/2011
Resminostat	4 SC AG - Germany	Treatment of hepatocellular carcinoma	• 20/05/2011 • 10/06/2011 • 15/07/2011 • (35 days/60 days)	• 29/07/2011 • 27/09/2011
Kifunensine	Généthon - France	Treatment alpha-sarcoglycanopathy	• 24/05/2011 • 10/06/2011 • 15/07/2011 • (35 days/60 days)	• 29/07/2011 • 27/09/2011
Kifunensine	Généthon - France	Treatment of gamma-sarcoglycanopathy	• 24/05/2011 • 10/06/2011 • 15/07/2011 • (35 days/60 days)	• 29/07/2011 • 27/09/2011
Kifunensine	Généthon - France	Treatment of delta-sarcoglycanopathy	• 24/05/2011 • 10/06/2011 • 15/07/2011 • (35 days/60 days)	• 29/07/2011 • 27/09/2011
Dinaciclib	Merck Sharp & Dohme Limited - UK	Treatment of chronic lymphocytic leukaemia	• 23/05/2011 • 10/06/2011 • 15/07/2011 • (35 days/60 days)	• 29/07/2011 • 27/09/2011
NH2-Cys-Ser-Ser-Val-Thr-Ala-Trp-Thr-Thr-Gly-Cys-Gly-CONH2	PHARMAXON - France	Treatment of traumatic spinal cord injury	• 24/03/2011 • 11/04/2011 • 08/07/2011 • (88 days/60 days)	• 29/07/2011 • 27/09/2011

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Eflornithine	Cancer Prevention Pharma Limited - UK	Treatment of neuroblastoma	• 15/09/2010 • 11/04/2011 • 08/07/2011 • (88 days/60 days)	• 29/07/2011 • 27/09/2011
Recombinant human galactocerebrosidase	ACE Biosciences A/S - Denmark	Treatment of globoid cell leukodystrophy (Krabbe Disease)	• 20/05/2011 • 10/06/2011 • 08/07/2011 • (28 days/60 days)	• 29/07/2011 • 27/09/2011
Reparixin	Dompé S.p.A. - Italy	Prevention of graft rejection in pancreatic islet transplantation	• 23/05/2011 • 10/06/2011 • 08/07/2011 • (28 days/60 days)	• 29/07/2011 • 27/09/2011
20-pentaerythritol poly (oxy-1,2-ethanediyl)-carboxymethyl-glycinate-7-ethyl-10-hydroxycamptothecine 10-[1,4'-bipiperidine]-1'-carboxylate	Nektar Therapeutics UK Ltd - UK	Treatment of ovarian cancer	• 24/05/2011 • 10/06/2011 • 08/07/2011 • (28 days/60 days)	• 29/07/2011 • 27/09/2011
Genetically modified Lactococcus lactis bacteria containing the human trefoil factor 1 gene	ActoGeniX N.V. - Belgium	Prevention of oral mucositis in head and neck cancer patients undergoing radiation therapy	• 24/03/2011 • 11/04/2011 • 08/07/2011 • (88 days/60 days)	• 29/07/2011 • 27/09/2011
Smilagenin	Phytopharm plc - UK	Treatment of amyotrophic lateral sclerosis	• 20/05/2011 • 10/06/2011 • 15/07/2011 • (35 days/60 days)	• 29/07/2011 • 27/09/2011
2,2'-{2-[(1R)-1-({[(2,5-dichlorobenzoyl)amino]acetyl}amino)-3-methylbutyl]-5-oxo-1,3,2-dioxaborolane-4,4-diyl}diacetic acid	Takeda Global Research and Development Centre (Europe) Ltd - UK	Treatment of multiple myeloma	• 23/05/2011 • 10/06/2011 • 08/07/2011 • (28 days/60 days)	• 29/07/2011 • 27/09/2011
Heterologous human adult liver-derived stem cells	Fresenius Medical Care Deutschland GmbH - Germany	Treatment of ornithine transcarbamylase deficiency	• 24/03/2011 • 11/04/2011 • 08/07/2011 • (88 days/62 days)	• 29/07/2011 • 29/09/2011
Mifepristone	Voisin Consulting S.A.R.L. - France	Treatment of hypercortisolism (Cushing's syndrome) of endogenous origin	• 24/06/2011 • 11/07/2011 • 16/09/2011 • (67 days/23 days)	• 04/10/2011 • 27/10/2011
Gallium (68Ga)-pasireotide tetraxetan	OctreoPharm Sciences GmbH - Germany	Diagnosis of gastro-entero-pancreatic neuroendocrine tumours	• 24/06/2011 • 11/07/2011 • 08/09/2011 • (59 days/23 days)	• 04/10/2011 • 27/10/2011

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Lenalidomide	Celgene Europe Limited - UK	Treatment of mantle cell lymphoma	• 23/06/2011 • 11/07/2011 • 08/09/2011 • (59 days/23 days)	• 04/10/2011 • 27/10/2011
L-cysteine, L-leucyl-L-alpha-glutamyl-L-alpha-glutamyl-L-lysyl-L-lysylglycyl-L-asparaginyl-L-tyrosyl-L-valyl-L-valyl-L-threonyl-L-alpha-aspartyl-L-histidyl-S-[1-[(4-carboxycyclohexyl) methyl]-2,5-dioxo-3-pyrrolidinyl]-complex with keyhole limpet haemocyanin	Orphix Consulting GmbH - Germany	Treatment of glioma	• 27/06/2011 • 11/07/2011 • 08/09/2011 • (59 days/23 days)	• 04/10/2011 • 27/10/2011
Human platelet antigen-1a immunoglobulin	Prophylix Pharma AS - Norway	Prevention of fetal and neonatal alloimmune thrombocytopenia due to human platelet antigen-1a incompatibility	• 23/06/2011 • 11/07/2011 • 08/09/2011 • (59 days/23 days)	• 04/10/2011 • 27/10/2011
Clonidine hydrochloride	Bioalliance Pharma - France	Prevention of oral mucositis in head and neck cancer patients undergoing radiation therapy	• 23/06/2011 • 11/07/2011 • 30/09/2011 • (81 days/23 days)	• 04/10/2011 • 27/10/2011
Sinapultide, dipalmitoylphosphatidylcholine palmitoyl-oleoyl phosphatidylglycerol, sodium salt and palmitic acid	Pharm Research Associates (UK) Limited - UK	Treatment of cystic fibrosis	• 25/03/2011 • 11/07/2011 • 08/09/2011 • (59 days/23 days)	• 04/10/2011 • 27/10/2011
Brivanib alaninate	Bristol-Myers Squibb Pharma EEIG - UK	Treatment of hepatocellular carcinoma	• 23/06/2011 • 11/07/2011 • 08/09/2011 • (59 days/23 days)	• 04/10/2011 • 27/10/2011
Adeno-associated viral vector containing the human alpha-N-acetylglucosaminidase gene	Institut Pasteur - France	Treatment of mucopolysaccharidosis type IIIB (Sanfilippo B syndrome)	• 21/06/2011 • 11/07/2011 • 08/09/2011 • (59 days/23 days)	• 04/10/2011 • 27/10/2011
1-(4-{4-amino-7-[1-(2-hydroxyethyl)-1H-pyrazol-4-yl]thieno[3,2-c]pyridin-3-yl}phenyl)-3-(3-fluorophenyl)urea	Abbott Laboratories - UK	Treatment of acute myeloid leukaemia	• 21/06/2011 • 11/07/2011 • 08/09/2011 • (59 days/23 days)	• 04/10/2011 • 27/10/2011

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
2-hydroxyoleic acid	Lipopharma Therapeutics SL - Spain	Treatment of glioma	• 23/05/2011 • 10/06/2011 • 08/09/2011 • (90 days/23 days)	• 04/10/2011 • 27/10/2011
Recombinant human minibody against complement component C5	ADIENNE S.r.l. - Italy	Treatment of primary membranoproliferative glomerulonephritis	• 23/05/2011 • 10/06/2011 • 16/09/2011 • (98 days/23 days)	• 04/10/2011 • 27/10/2011
Glycosylation independent lysosomal targeting tagged recombinant human acid alpha glucosidase	BioMarin Europe Ltd. - UK	Treatment of glycogen storage disease type II (Pompe's disease)	• 24/05/2011 • 11/07/2011 • 08/09/2011 • (59 days/23 days)	• 04/10/2011 • 27/10/2011
Plerixafor	Genzyme Europe BV - The Netherlands	Adjunctive treatment to cytotoxic therapy in acute myeloid leukaemia	• 23/06/2011 • 11/07/2011 • 07/10/2011 • (88 days/42 days)	• 28/10/2011 • 09/12/2011
Resminostat	4 SC AG - Germany	Treatment of Hodgkin's lymphoma	• 19/07/2011 • 12/08/2011 • 07/10/2011 • (56 days/42 days)	• 28/10/2011 • 09/12/2011
Nanoliposomal irinotecan	Merrimack Pharmaceuticals UK Limited - UK	Treatment of pancreatic cancer	• 23/05/2011 • 12/08/2011 • 07/10/2011 • (56 days/42 days)	• 28/10/2011 • 09/12/2011
Interferon gamma	Prof. Roberto Testi - Italy	Treatment of Friedreich's ataxia	• 21/07/2011 • 12/08/2011 • 07/10/2011 • (56 days/42 days)	• 28/10/2011 • 09/12/2011
Human haptoglobin	Bio Products Laboratory Ltd - UK	Treatment sickle cell disease	• 22/07/2011 • 12/08/2011 • 07/10/2011 • (56 days/42 days)	• 28/10/2011 • 09/12/2011
Cysteamine	NovaBiotics Ltd - UK	Treatment of cystic fibrosis	• 23/05/2011 • 12/08/2011 • 07/10/2011 • (56 days/42 days)	• 28/10/2011 • 09/12/2011
Adeno-associated viral vector serotype 8 containing the human AIPL1 gene	Fondazione Telethon - Italy	Treatment of Leber's congenital amaurosis type 4	• 01/06/2011 • 12/08/2011 • 07/10/2011 • (56 days/42 days)	• 28/10/2011 • 09/12/2011
Alpha-tocotrienol quinone	Edison Orphan Pharma BV - The Netherlands	Treatment of Leigh syndrome	• 22/06/2011 • 11/07/2011 • 07/10/2011 • (88 days/42 days)	• 28/10/2011 • 09/12/2011

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Pegylated proline-interferon alpha-2b	AOP Orphan Pharmaceuticals AG - Austria	Treatment of polycythaemia vera	• 24/05/2011 • 11/07/2011 • 07/10/2011 • (88 days/42 days)	• 28/10/2011 • 09/12/2011
4-[[9-[(3S)-tetrahydro-3-furanyl]-8-[(2,4,6-trifluorophenyl)amino]-9H-purin-2-yl]amino]-trans-cyclohexanol	Celgene Europe Limited - UK	Treatment of idiopathic pulmonary fibrosis	• 22/07/2011 • 12/08/2011 • 07/10/2011 • (56 days/42 days)	• 28/10/2011 • 09/12/2011
Lipopolysaccharide of Ochrobactrum intermedium	Diomune, S.L. - Spain	Prevention of sepsis in at-risk premature infants of less than or equal to 32 weeks of gestational age	• 21/07/2011 • 09/09/2011 • 09/11/2011 • (61 days/35 days)	• 07/12/2011 • 11/01/2012
Recombinant protein consisting of modified human growth hormone releasing hormone and the translocation and endopeptidase domains of botulinum toxin serotype D	Syntaxin Limited - UK	Treatment of acromegaly	• 26/08/2011 • 09/09/2011 • 09/11/2011 • (61 days/35 days)	• 07/12/2011 • 11/01/2012
Ornithine phenylacetate	Dr Ulrich Granzer - Germany	Treatment of acute liver failure	• 24/08/2011 • 09/09/2011 • 09/11/2011 • (61 days/35 days)	• 07/12/2011 • 11/01/2012
Mogamulizumab	Gregory Fryer Associates Ltd - UK	Treatment of peripheral T-cell lymphoma (nodal, other extranodal and leukaemic/disseminated)	• 24/08/2011 • 09/09/2011 • 09/11/2011 • (61 days/35 days)	• 07/12/2011 • 11/01/2012
Sodium phenylbutyrate	GMP-Orphan SAS - France	Treatment of 5q spinal muscular atrophy	• 22/07/2011 • 12/08/2011 • 09/11/2011 • (89 days/35 days)	• 07/12/2011 • 11/01/2012
Liposomal combination of cytarabine and daunorubicin	Celator UK (Ltd) - UK	Treatment of acute myeloid leukaemia	• 23/06/2011 • 09/09/2011 • 09/11/2011 • (61 days/35 days)	• 07/12/2011 • 11/01/2012
Recombinant homodimer of the human annexin V	Astellas Pharma Europe B.V. - The Netherlands	Prevention of the ischaemia/reperfusion injury associated with solid organ transplantation	• 23/08/2011 • 09/09/2011 • 09/11/2011 • (61 days/35 days)	• 07/12/2011 • 11/01/2012

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Chimeric locked nucleic acid-deoxynucleoside phosphorothioate-linked oligonucleotide directed against microRNA-451	Miragen Therapeutics Europe Ltd - UK	Treatment of polycythaemia vera	• 26/08/2011 • 09/09/2011 • 09/11/2011 • (61 days/369 days)	• 07/12/2011 • 11/01/2012
Brentuximab vedotin	Takeda Global Research and Development Centre (Europe) Ltd - UK	Treatment of cutaneous T-cell lymphoma	• 19/08/2011 • 09/09/2011 • 09/11/2011 • (61 days/35 days)	• 07/12/2011 • 11/01/2012
N,N'-bis(2-mercaptoethyl)isophthalamide	CTI Science Limited - Ireland	Treatment of mercury toxicity	• 25/07/2011 • 12/08/2011 • 09/11/2011 • (89 days/35 days)	• 07/12/2011 • 11/01/2012
Adeno-associated viral vector containing the human factor IX gene	Amsterdam Molecular Therapeutics BV - The Netherlands	Treatment of haemophilia B	• 22/07/2011 • 09/09/2011 • 09/11/2011 • (61 days/35 days)	• 07/12/2011 • 11/01/2012
Vincaleukoblastin-23-oic acid, O4-deacetyl-2-[(2-mercaptoethoxy)carbonyl]hydrazide, disulfide with N-[4-[[(2-amino-3,4-dihydro-4-oxo-6-pteridinyl)methyl]amino]benzoyl]-L-gamma-glutamyl-L-alpha-aspartyl-L-arginyl-L-alpha-aspartyl-L-alpha-aspartyl-L-cysteine	Endocyte Europe B.V. - The Netherlands	Treatment of ovarian cancer	• 22/07/2011 • 12/08/2011 • 07/10/2011 • (56 days/104 days)	• 28/10/2011 • 09/02/2012
N-[4-[[(2-amino-3,4-dihydro-4-oxo-6-pteridinyl)methyl]amino]benzoyl]-D-gamma-glutamyl-(2S)-2-amino-beta-alanyl-L-alpha-aspartyl-L-cysteine and folic acid	Endocyte Europe B.V. - The Netherlands	Diagnosis of positive folate receptor status in ovarian cancer	• 22/07/2011 • 12/08/2011 • 07/10/2011 • (56 days/35 days)	• 05/01/2012 • 09/02/2012
Human monoclonal antibody against Fas ligand	PinCell s.r.l. - Italy	Treatment of pemphigus	• 29/09/2011 • 14/10/2011 • 07/12/2011 • (56 days/35 days)	• 05/01/2012 • 09/02/2012
(1S,3S)-3-amino-4-(difluoromethylene) cyclopentanecarboxylic acid hydrochloride	Catalent Pharma Solutions Limited - UK	Treatment of West syndrome	• 30/08/2011 • 09/09/2011 • 07/12/2011 • 09/02/2012 • (89 days/35 days)	• 05/01/2012 • 09/02/2012

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Nimorazole maleate	Conventia Medical LLP - UK	Treatment of squamous cell carcinoma of the head and neck in patients undergoing radiotherapy	• 19/08/2011 • 09/09/2011 • 07/12/2011 • 09/02/2012 • (89 days/35 days)	• 05/01/2012 • 09/02/2012
S[+] apomorphine	The University of Sheffield - UK	Treatment of amyotrophic lateral sclerosis	• 24/08/2011 • 09/09/2011 • 07/12/2011 • (89 days/35 days)	• 05/01/2012 • 09/02/2012
Sodium phenylbutyrate	Lucane Pharma SA - France	Treatment of citrullinaemia type 1	• 17/08/2011 • 09/09/2011 • 07/12/2011 • (89 days/35 days)	• 05/01/2012 • 09/02/2012
Sodium phenylbutyrate	Lucane Pharma SA - France	Treatment of ornithine transcarbamylase deficiency	• 17/08/2011 • 09/09/2011 • 07/12/2011 • (89 days/35 days)	• 05/01/2012 • 09/02/2012
Sodium phenylbutyrate	Lucane Pharma SA - France	Treatment of carbamoyl-phosphate synthase-1 deficiency	• 17/08/2011 • 09/09/2011 • 07/12/2011 • (89 days/35 days)	• 05/01/2012 • 09/02/2012
Autologous haematopoietic cells, genetically modified with a lentiviral vector containing the human gp91(phox) gene	Généthon - France	Treatment of X-linked chronic granulomatous disease	• 30/09/2011 • 14/10/2011 • 07/12/2011 • (54 days/35 days)	• 05/01/2012 • 09/02/2012
Doxycycline hyclate	Giampaolo Merlini - Italy	Treatment of familial amyloid polyneuropathy	• 30/09/2011 • 14/10/2011 • 07/12/2011	• awaited

Negative COMP designation opinions

Product INN	**Sponsor**	**Summary of indication**	**EMA/COMP** • Submission • Start date • Opinion • Active time	**European Commission** • Opinion received • Date of decision
Nabilone	MRN-Medical Research Network GmbH - Austria	Treatment of amyotrophic lateral sclerosis	• 02/07/2010 • 15/10/2010 • 16/09/2011 • (336 days/51 days)	• 26/09/2011 • 16/11/2011
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	• 20/05/2010 • 11/06/2010 • 07/02/2011 • (241 days/74 days)	• 18/03/2011 • 31/05/2011

Annex 14 – HMPC Community herbal monographs and entries into list of herbal substances in 2011

Community herbal monographs

Reference number	Document title	Status
EMA/HMPC/563408/2010	Community herbal monograph on Agropyri repentis rhizoma	Released for public consultation January 2011 Adopted November 2011
EMA/HMPC/347189/2011	Public statement on Allii cepae bulbus	Released for public consultation July 2011
EMA/HMPC/262766/2010	Community herbal monograph on Bursae pastoris herba	Adopted July 2011
EMA/HMPC/534924/2010	Community herbal monograph on Caryophyllii aetheroleum	Released for public consultation January 2011 Adopted September 2011
EMA/HMPC/112102/2011	Public statement on Caryophyllii flos	Released for public consultation March 2011 Adopted November 2011
EMA/HMPC/560734/2010	Community herbal monograph on Chamomillae romanae flos	Released for public consultation January 2011 Adopted November 2011
EMA/HMPC/743927/2010	Public statement on Chelidonii herba	Adopted September 2011
EMA/HMPC/706229/2009	Community herbal monograph on Cinnamomi corticis aetheroleum	Adopted May 2011
EMA/HMPC/246774/2009	Community herbal monograph on Cinnamomi cortex	Adopted May 2011
EMA/HMPC/56155/2011	Public statement on Citri bergami aetheroleum	Released for public consultation September 2011
EMA/HMPC/722367/2010	Community herbal monograph on Colae semen	Released for public consultation March 2011 Adopted November 2011
EMA/HMPC/136024/2010	Community herbal monograph on Cucurbitae semen	Released for public consultation September 2011
EMA/HMPC/150218/2009	Community herbal monograph on Cynarae folium	Adopted September 2011
EMA/HMPC/688216/2008	Community herbal monograph on Echinaceae angustifoliae radix	Released for public consultation March 2011
EMA/HMPC/434894/2010	Community herbal monograph on Filipendulae ulmariae flos	Adopted July 2011
EMA/HMPC/434881/2010	Community herbal monograph on Filipendulae ulmariae herba	Adopted July 2011
EMA/HMPC/239271/2011	Community herbal monograph on Fraxini folium	Released for public consultation July 2011
EMA/HMPC/574766/2010	Community herbal monograph on Fumariae herba	Released for public consultation January 2011 Adopted September 2011
EMA/HMPC/289430/2009	Community herbal monograph on Hederae helicis folium	Adopted March 2011
EMA/HMPC/354156/2011	Community herbal monograph on Hippocastani cortex	Released for public consultation September 2011
EMA/HMPC/143181/2010	Community herbal monograph on Lavandulae aetheroleum	Released for public consultation January 2011

Reference number	Document title	Status
EMA/HMPC/734125/2010	Community herbal monograph on Lavandulae flos	Released for public consultation January 2011
EMA/HMPC/571119/2010	Community herbal monograph on Liquiritiae radix	Released for public consultation July 2011
EMA/HMPC/290284/2009	Community herbal monograph on Millefolii herba	Adopted July 2011
EMA/HMPC/143949/2010	Community herbal monograph on Millefolii flos	Adopted July 2011
EMA/HMPC/96911/2010	Community herbal monograph on Myrrha (Commiphora molmol)	Adopted July 2011
EMA/HMPC/430507/2009	Community herbal monograph on Oleae folium	Released for public consultation January 2011 Adopted November 2011
EMA/HMPC/277792/2009	Community herbal monograph on Oenotherae biennis oleum	Released for public consultation March 2011 Adopted December 2011
EMA/HMPC/560961/2010	Community herbal monograph on Pelargonii radix	Released for public consultation March 2011
EMA/HMPC/437858/2010	Community herbal monograph on Plantaginis lanceolatae folium	Adopted November 2011
EMA/HMPC/232091/2011	Community herbal monograph on Rhodiolae roseae rhizoma et radix	Released for public consultation July 2011
EMA/HMPC/572846/2009	Community herbal monograph on Symphyti radix	Released for public consultation July 2011
EMA/HMPC/130042/2010	Community herbal monograph on Thymi herba/Primulae radix	Released for public consultation January 2011
EMA/HMPC/337066/2011	Community herbal monograph on Tiliae flos	Released for public consultation September 2011
EMA/HMPC/510064/2011	Public statement on Tiliae tomentosae flos	Released for public consultation September 2011
EMA/HMPC/146221/2010	Community herbal monograph on Trigonellae foenugraeci semen	Adopted January 2011
EMA/HMPC/461160/2008	Community herbal monograph on Urticae radix	Released for public consultation September 2011
EMA/HMPC/573460/2009	Community herbal monograph on Uvae ursi folium	Adopted March 2011
EMA/HMPC/57109/2011	Public statement on Visci albi herba	Released for public consultation September 2011
EMA/HMPC/749154/2010	Community herbal monograph on Zingiberis rhizoma	Released for public consultation July 2011

Annex 15 – PDCO opinions and EMA decisions on paediatric investigation plans and waivers in 2011

Product INN	Invented name – if available	Type of PDCO opinion*	Therapeutic area	Applicant	EMA decision number	Signature date
Adalimumab	Humira	PM	Dermatology Gastroenterology-hepatology Immunology-rheumatology-transplantation	Abbott Laboratories Ltd	P/1/2011	03/01/2011
Imatinib mesilate	Glivec	PM	Oncology	Novartis Europharm Limited	P/2/2011	03/01/2011
Tazarotene	N/A	P	Dermatology	Orfagen	P/3/2011	03/01/2011
Pazopanib	Votrient	P	Oncology	Glaxo Group Limited	P/4/2011	03/01/2011
Ecallantide (Recombinant Inhibitor of Human Plasma Kallikrein)	N/A	PM	Dermatology Pneumology-allergology Other	Dyax s.a.	P/5/2011	03/01/2011
Midostaurin	N/A	P	Oncology	Novartis Europharm Ltd	P/6/2011	03/01/2011
Allergens from Dermatophagoides pteronyssinus and Dermatophagoides farinae	N/A	P	Pneumology-allergology	ALK-Abelló A/S	P/7/2011	03/01/2011
Pollen from alnus glutinosa, betula verrucosa and corylus avellana	N/A	P	Pneumology-allergology	ALK-Abelló A/S	P/8/2011	03/01/2011
Pollen from betula pendula (33%), corylus avellana (33%) and alnus glutinosa (33%)	N/A	P	Pneumology-allergology	ALK-Abelló A/S	P/9/2011	03/01/2011
Pollen from betula pendula	N/A	P	Pneumology-allergology	ALK-Abelló A/S	P/10/2011	03/01/2011
Allergen extracts of dermatophagoides farinae and dermatophagoides pteronyssinus (each 50%)	N/A	P	Pneumology-allergology	ALK-Abelló A/S	P/11/2011	03/01/2011
Pollen from alnus glutinosa (33%), betula verrucosa (33%) and corylus avellana (33%)	N/A	P	Pneumology-allergology	ALK-Abelló A/S	P/12/2011	03/01/2011

* PIP (P) / PIP modification (PM) / Full waiver (W) / RP (PIP Refusal) / RW (Waiver refusal) / Compliance check (C).

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Allergen extracts of dermatophagoides farinae and dermatophagoides pteronyssinus (each 50%)	N/A	P	Pneumology-allergology	ALK-Abelló A/S	P/13/2011	03/01/2011
Influenza virus type A, H3N2, influenza virus type A, H1N1, influenza virus type B	Fluenz	P	Vaccines	MedImmune, LLC	P/14/2011	03/01/2011
Ezetimibe	Ezetrol and associated names	PM	Cardiovascular diseases	MSD-SP Limited	P/15/2011	21/01/2011
Nepafenac	Nevanac	W	Ophthalmology	Alcon Laboratories (UK) Ltd.	P/16/2011	21/01/2011
Perindopril arginine / indapamide amlodipine besilate	N/A	W	Cardiovascular diseases	Les Laboratoires Servier	P/17/2011	21/01/2011
Lixisenatide	N/A	P	Endocrinology - gynaecology-fertility-metabolism	Sanofi-Aventis R&D	P/18/2011	24/01/2011
Sitagliptin (phosphate monohydrate)	Januvia	PM	Endocrinology - gynaecology-fertility-metabolism	Merck Sharp and Dohme (Europe), Inc.	P/19/2011	25/01/2011
Alogliptin benzoate	N/A	PM	Endocrinology - gynaecology-fertility-metabolism	Takeda Global Research and Development Centre (Europe) Ltd.	P/20/2011	25/01/2011
Exenatide	Byetta	PM	Endocrinology - gynaecology-fertility-metabolism	Eli Lilly and Company	P/21/2011	25/01/2011
Grass pollen allergen extract from Dactylis glomerata L., Anthoxanthum odoratum L., Lolium perenne L., Poa prantensis L. and Phleum pratense L.	N/A	P	Pneumology-allergology	Stallergenes S.A.	P/22/2011	25/01/2011
Tesamorelin	N/A	W	Endocrinology - gynaecology-fertility-metabolism	Theratechnologies Inc	P/23/2011	25/01/2011
Sotrastaurin acetate	N/A	P	Immunology-rheumatology - transplantation	Novartis Europharm Ltd	P/24/2011	26/01/2011
Briakinumab	N/A	PM	Dermatology	Abbott Laboratories Ltd.	P/25/2011	26/01/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Meropenem	N/A	P	Infectious diseases	NeoMero Consortium	P/26/2011	26/01/2011
Rizatriptan	Maxalt and associated names	P	Pain	Merck Sharp & Dohme (Europe) Inc.	P/27/2011	28/01/2011
Pegloticase	N/A	P	Immunology-rheumatology-transplantation Oncology	Savient Pharmaceuticals, Inc.	P/28/2011	28/01/2011
Oseltamivir (phosphate)	Tamiflu	PM	Infectious diseases	Roche Registration Ltd	P/29/2011	28/01/2011
Ticagrelor	N/A	PM	Cardiovascular diseases	AstraZeneca AB	P/30/2011	28/01/2011
Amikacin (sulfate)	N/A	P	Cardiovascular diseases	Transave, Inc.	P/31/2011	28/01/2011
C1 inhibitor	N/A	PM	Immunology-rheumatology-transplantation	ViroPharma SPRL	P/32/2011	28/01/2011
(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)	N/A	P	Endocrinology-gynecology-fertility-metabolism	Boehringer Ingelheim International GmbH	P/33/2011	28/01/2011
House dust mites allergen extract from Dermatophagoides pteronyssinus and Dermatophagoides farinae (50/50)	N/A	P	Pneumology-allergology	Stallergenes S.A.	P/34/2011	28/01/2011
Ozenoxacin	N/A	P	Infectious diseases	Ferrer Internacional, S.A	P/35/2011	28/01/2011
Recombinant human granulocyte colony stimulating factor / recombinant human albumin fusion protein	N/A	RW	Oncology	Teva Pharmaceuticals Europe B.V	P/36/2011	28/01/2011
GLP-1 analogue linked to human IgG4 Fc-fragment (LY2189265)	N/A	P	Endocrinology-gynaecology-fertility-metabolism	Eli Lilly & Company	P/37/2011	28/01/2011
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	N/A	PM	Vaccines	Novartis Vaccines and Diagnostics S.r.l.	P/38/2011	17/01/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Azilsartan medoxomil	N/A	PM	Cardiovascular diseases	Takeda Global Research and Development Centre (Europe) Ltd	P/39/2011	04/02/2011
Romidepsin	N/A	W	Oncology	Celgene Europe Limited	P/40/2011	03/02/2011
Mipomersen (sodium)	N/A	P	Endocrinology - gynaecology-fertility-metabolism	Genzyme Europe B.V.	P/41/2011	07/02/2011
Meningococcal group A oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenA-CRM) Meningococcal group C oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenC-CRM) Meningococcal group W-135 oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenW-CRM) Meningococcal group Y oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenY-CRM)	Menveo	PM	Vaccines	Novartis Vaccines and Diagnostics S.r.L	P/42/2011	07/02/2011
Etravirine	Intelence	PM	Infectious diseases	Janssen-Cilag International NV	P/43/2011	11/02/2011
Chimeric monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E (SGN-35)	N/A	P	Oncology	Takeda Global Research and Development Centre (Europe), Ltd	P/59/2011	21/02/2011
Adalimumab	Humira	PM	Immunology-rheumatology - transplatation	Abbott Laboratories Ltd	P/63/2011	18/02/2011
Telcagepant	N/A	PM	Pain	Merck Sharp and Dohme (Europe), Inc.	P/44/2011	03/03/2011
Atorvastatin (L-lysine salt) / amlodipine (besilate)	N/A	W	Cardiovascular diseases	Gedeon Richter Plc.	P/45/2011	03/03/2011
(E)-4-(2-(6-(2-(2-(2-[18F]fluoroethoxy)ethoxy)ethoxy)pyridin-3-yl)vinyl)-N-methylbenzenamine	N/A	W	Diagnostic	Avid Radiopharmaceuticals Ireland Limited	P/46/2011	03/03/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005 (H5N1) Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1)	Prepandrix Prepandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted) Pandemic influenza vaccine (H5N1 Vietnam) (split virion, inactivated, adjuvanted)	PM	Vaccines	GlaxoSmithKline Biologicals S.A.	P/47/2011	04/03/2011
Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05/ (H5N1)	N/A	PM	Vaccines	GlaxoSmithKline Biologicals S.A.	P/48/2011	04/03/2011
Brivaracetam	N/A	PM	Neurology	UCB Pharma S.A.	P/49/2011	04/03/2011
Lenalidomide	Revlimid	W	Oncology	Celgene Europe Ltd.	P/50/2011	04/03/2011
Tenofovir (disoproxil fumarate)	Viread	PM	Infectious diseases	Gilead Sciences International Limited	P/51/2011	04/03/2011
Decitabine	N/A	PM	Oncology	Janssen-Cilag International NV	P/52/2011	04/03/2011
Coagulation Factor IX (Recombinant)	N/A	PM	Haematology-hemostaseology	Inspiration Biopharmaceuticals EU, Ltd.	P/53/2011	04/03/2011
2'-O-methyl-uridylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5' O,Ophosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5' O,O-	N/A	p	Neurology	Glaxo Group Limited	P/54/2011	04/03/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyladenosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5' O,O-phosphorothioyl)-2'-Omethyl-guanosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5' O,Ophosphorothioyl)-2'-O-methyl-uridylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5' O,Ophosphorothioyl)-2'-O-methyl-uridylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5' O,Ophosphorothioyl)-2'-O-methyl-uridine sodium salt Also known as exon 51 specific phosphorothioate oligonucleotide						
(1R,2S)-6-bromo-alpha-[2-(dimethylamino)ethyl]-2-methoxy-alpha-1-naphthalenyl-beta-phenyl-3- quinolineethanol (2E)-2-butenedioate(1:1) (salt) (TMC207)	N/A	P	Infectious disease	Tibotec BVBA	P/55/2011	04/03/2011
Bimatoprost	LUMIGAN 0.1 mg/ml eye drops, solution LUMIGAN 0.3 mg/ml eye drops, solution	P	Ophthalmology	Allergan Pharmaceuticals Ireland	P/56/2011	04/03/2011
Human coagulation factor X	N/A	P	Haematology-hemostaseology	Bio Products Laboratory	P/57/2011	04/03/2011
Laquinimod (sodium)	N/A	P	Neurology	Teva Pharma GmbH	P/58/2011	04/03/2011
Testosterone	N/A	W	Endocrinology-gynaecology-fertility-transplantation	Eli Lilly and Company Limited	P/60/2011	04/03/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Human Papilloma Virus Type 16 E6 071-095 / Human Papilloma Virus Type 16 E7 064-098 / Human Papilloma Virus Type 16 E6 055-080 / Human Papilloma Virus Type 16 E6 001-032 / Human Papilloma Virus Type 16 E6 091-122 / Human Papilloma Virus Type 16 E6 041-065 / Human Papilloma Virus Type 16 E6 019-050 / Human Papilloma Virus Type 16 E7 022-056 / Human Papilloma Virus Type 16 E6 127-158 / Human Papilloma Virus Type 16 E6 085-109 / Human Papilloma Virus Type 16 E7 043-077 / Human Papilloma Virus Type 16 E6 109-140 / Human Papilloma Virus Type 16 E7 001-035	N/A	W	Oncology	ISA Therapeutics BV	P/61/2011	04/03/2011
Bucelipase alfa	N/A	P	Gastroenterology-hepatology	Swedish Orphan Biovitrum AB	P/62/2011	07/03/2011
Abatacept	Orencia	P	Immunology-rheumatology-transplantation	Bristol-Myers Squibb Pharma EEIG	P/64/2011	10/03/2011
Rivastigmine	Exelon Prometax	W	Neurology	Novartis Europharm Ltd.	P/65/2011	11/03/2011
Bevacizumab	Avastin	P	Oncology	Roche Registration Ltd	P/66/2011	11/03/2011
Antigen of pre-pandemic strain A/Vietnam/1203/2004 propagated in Vero cells	N/A	PM	Vaccines	Baxter Innovations GmbH	P/67/2011	11/03/2011
17 Rotavirus type G1/rotavirus type G2/rotavirus type G3/rotavirus type G4/rotavirus type P1A[8] /03/2011	RotaTeq	P	Vaccines	Sanofi Pasteur MSD SNC	P/68/2011	17/03/2011
Saxagliptin	Onglyza	PM	Endocrinology-gynaecology-fertility-transplantation	Bristol Myers Squibb/Astra Zeneca EEIG	P/69/2011	15/03/2011
Amlodipine besilate / perindopril tert-butylamine	N/A	W	Cardiovascular diseases	Gedeon Richter Plc.	P/70/2011	04/04/2011
Iloperidone	N/A	W	Psychiatry	Vanda Pharmaceuticals Ltd.	P/71/2011	04/04/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
[18F]flutemetamol	N/A	W	Diagnostic Neurology Psychiatry	GE Healthcare Ltd	P/72/2011	04/04/2011
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 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	PM	Vaccines	Pfizer Ltd	P/73/2011	05/04/2011
Voriconazole	Vfend	PM	Infectious diseases	Pfizer Limited	P/74/2011	05/04/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Anidulafungin	Ecalta	PM	Infectious diseases	Pfizer Limited	P/75/2011	05/04/2011
Dimethyl fumarate	N/A	P	Neurology	Biogen Idec Ltd.	P/76/2011	05/04/2011
Ciclosporin	N/A	P	Immunology-rheumatology-transplantation	APT Pharmaceuticals Limited	P/77/2011	05/04/2011
Fibrinogen (human plasma-derived)	N/A	P	Haematology-hemostaseology	LFB Biotechnologies	P/78/2011	06/04/2011
Human normal immunoglobulin	N/A	W	Immunology-rheumatology-transplantation	LFB Biotechnologies	P/79/2011	06/04/2011
Ivabradine hydrochloride	Corlentor	PM	Cardiovascular diseases	Les Laboratoires Servier	P/80/2011	06/04/2011
Ivabradine hydrochloride	Procoralan	PM	Cardiovascular diseases	Les Laboratoires Servier	P/81/2011	06/04/2011
Azelastine (hydrochloride) / fluticasone (propionate)	N/A	P	Pneumology-allergology	MEDA Pharma GmbH & Co. KG	P/82/2011	06/04/2011
Aciclovir	N/A	RW	Infectious diseases	BioAlliance Pharma	P/83/2011	06/04/2011
Lubiprostone	N/A	P	Gastroenterology-hepatology	Sucampo Pharma Europe Ltd	P/84/2011	08/04/2011
Imatinib (mesilate)	Glivec	P	Cardiovascular diseases	Novartis Europharm Limited	P/85/2011	08/04/2011
Velaglucerase alfa	N/A	PM	Endocrinology-gynaecology-fertility-metabolism	Shire Pharmaceuticals Ireland Limited	P/86/2011	08/04/2011
Japanese encephalitis virus, inactivated (attenuated strain SA14-14-2 grown in vero cells)	Ixiaro	PM	Vaccines	Intercell AG	P/87/2011	08/04/2011
Boceprevir	N/A	PM	Infectious diseases	Merck Sharp & Dohme Ltd	P/88/2011	08/04/2011
Valganciclovir	Valcyte and associated names	P	Infectious diseases	Roche Registration Ltd	P/89/2011	08/04/2011
Recombinant human N-acetylgalactosamine-6-sulfatase	N/A	P	Endocrinology-gynaecology-fertility-metabolism	BioMarin Europe Limited	P/90/2011	08/04/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Propane-1-sulfonic acid {3-[5-(4-chlorophenyl)-1H-pyrrolo[2,3-b]pyridine-3-carbonyl]-2,4-difluorophenyl}- amide (RO5185426)	N/A	P	Endocrinology - gynaecology-fertility-metabolism	F. Hoffmann La Roche Ltd	P/91/2011	08/04/2011
Human Cell Line recombinant human Factor VIII (human-cl rhFVIII)	N/A	P	Haematology-hemostaseology	Octapharma Pharmazeutika Produktionsges.m.b.H	P/92/2011	08/04/2011
Meningococcal group A oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenA-CRM) Meningococcal group C oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenC-CRM) Meningococcal group W-135 oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenW-CRM) Meningococcal group Y oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenY-CRM)	Menveo	PM	Vaccines	Novartis Vaccines and Diagnostics S.r.L	P/93/2011	01/04/2011
Amlodipine (besylate) / atorvastatin (calcium)	N/A	W	Cardiovascular diseases	Miklich Laboratorios, S.L.	P/94/2011	04/04/2011
Ezetimibe/simvastatin	Inegy and associated names	W	Cardiovascular diseases	MSD-SP Limited	P/95/2011	04/04/2011
Insulin degludec / insulin aspart	N/A	PM	Endocrinology - gynaecology-fertility-metabolism	Novo Nordisk A/S	P/96/2011	08/04/2011
Saxagliptin	Onglyza	PM	Endocrinology - gynaecology-fertility-metabolism	Bristol Myers Squibb/Astra Zeneca EEIG	P/97/2011	08/04/2011
Delafloxacin	N/A	W	Infectious diseases	Rib-X Therapeutics Ltd	P/98/2011	08/04/2011
Aripiprazole	Abilify	P	Psychiatry	Otsuka Pharmaceutical Europe Ltd.	P/99/2011	14/04/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Cinacalcet hydrochloride	Mimpara	PM	Uro-nephrology	Amgen Europe B.V	P/100/2011	11/04/2011
Darbepoetin alfa	Aranesp	P	Cardiovascular diseased Oncology Uro-nephrology	Amgen Europe B.V	P/101/2011	11/04/2011
Rivastigmine	Exelon Prometax	W	Neurology	Novartis Europharm Ltd.	P/113/2011	27/04/2011
Liraglutide	Victoza	PM	Endocrinology-gynaecology-fertility-metabolism	Novo Nordisk A/S	P/102/2011	03/05/2011
Conestat alfa	Ruconest	PM	Immunology-rheumatology-transplantation	Pharming Group N.V.	P/103/2011	03/05/2011
Lisdexamfetamine dimesylate	N/A	PM	Psychiatry	Shire Pharmaceutical Contracts Ltd	P/104/2011	03/05/2011
Everolimus	Certican and associated names Afinitor	PM	Immunology-rheumatology-transplantation	Novartis Europharm Limited	P/105/2011	04/05/2011
Ataluren	N/A	P	Endocrinology-gynaecology-fertility-metabolism Pnuemology-allergology	Genzyme Europe B.V.	P/106/2011	04/05/2011
Von Willebrand Factor	N/A	PM	Haematology-hemostaseology	CSL Behring	P/107/2011	06/05/2011
Tadalafil	Adcirca Cialis	P	Cardiovascular diseases	Eli Lilly and Company Limited	P/108/2011	06/05/2011
Tazarotene	N/A	PM	Dermatology	Orfagen	P/109/2011	06/05/2011
Linaclotide	N/A	P	Gastroenterology – hepatology	Almirall S.A.	P/110/2011	06/05/2011
Autologous cartilage derived cultured chondrocytes	N/A	P	Other	Genzyme Europe BV	P/111/2011	06/05/2011
Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-methoxy-133 ester with granulocyte colony-stimulating factor [methionyl,133-[O-[2-(acetylamino]-6-O-[N-[N-	N/A	P	Oncology	Ratiopharm GmbH	P/112/2011	06/05/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
carboxyglycyl)amino]-alpha neuraminosyl]-2-deoxy-alpha-D-galactopyranosyl]-L-threonine]] (human)						
Sildenafil citrate	Revatio	PM	Cardiovascular disease	Pfizer Limited	P/114/2011	06/05/2011
Canakinumab	N/A	PM	Immunology-rheumatology-transplantation	Novartis Europharm Limited	P/115/2011	06/05/2011
Perflubutane	N/A	P	Cardiovascular diseases Diagnostics	Granzer Regulatory Consulting & Services	P/116/2011	18/05/2011
Aztreonam	Cayston	PM	Infectious diseases	Gilead Sciences International Limited	P/117/2011	20/05/2011
Autologous oral mucosal epithelial cells	N/A	P	Ophthalmology	CellSeed Europe S.A.R.L.	P/118/2011	23/05/2011
Fluticasone furoate / triphenylacetic acid - 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol (1:1)	N/A	PM	Pneumology-allergology	Glaxo Group Limited	P/119/2011	07/06/2011
Ombrabulin	N/A	P	Oncology	Sanofi-aventis recherche & developpement	P/120/2011	07/06/2011
Human normal immunoglobulin	Gammaplex	P	Haematology-hemostaseology Immunology-rheumatology-transplantation	Bio Products Laboratory	P/121/2011	07/06/2011
Treosulfan		W	Immunology-rheumatology-transplantation Oncology	medac Gesellschaft für klinische Spezialpräparate mbH	P/122/2011	07/06/2011
Recombinant fusion protein consisting of human coagulation factor IX attached to the Fc domain of human IgG1 (rFIXFc)	N/A	P	Haematology-hemostaseology	Biogen Idec Ltd.	P/123/2011	07/06/2011
Cobicistat	N/A	P	Infectious diseases	Gilead Sciences International	P/124/2011	07/06/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
				Limited		
Elvitegravir / emtricitabine / tenofovir disoproxil (as fumarate) / cobicistat	N/A	P	Infectious diseases	Gilead Sciences International Limited	P/125/2011	07/06/2011
Octocog alfa		P	Haematology-hemostaseology	Bayer Schering Pharma AG	P/126/2011	07/06/2011
Everolimus	Afinitor	PM	Neurology Oncology Uro-nephrology	Novartis Europharm Ltd	P/127/2011	08/06/2011
Ipilimumab	N/A	P	Oncology	Bristol-Myers Squibb International Corporation	P/128/2011	08/06/2011
Etravirine	Intelence	PM	Infectious diseases	Janssen-Cilag International NV	P/129/2011	08/06/2011
1-[2-(2,4-dimethyl-phenylsulfanyl)phenyl] piperazine (Lu AA21004)	N/A	P	Psychiatry	H. Lumdbeck A/S	P/130/2011	08/06/2011
Imatinib mesilate	Glivec	PM	Oncology	Novartis Europharm Limited	P/131/2011	08/06/2011
Influenza virus surface antigens (H5N1 or H1N1 strains)	Focetria and associated names Aflunov and associated names Foclivia and associated names	PM	Vaccines	Novartis Vaccines and Diagnostics S.r.l.	P/132/2011	08/06/2011
Gallium [68 Ga] Chloride / Germanium [68 Ge] Chloride	N/A	W	Other	Eckert & Ziegler Radiopharma GmbH	P/133/2011	08/06/2011
Sitagliptin (phosphate monohydrate)	Januvia	PM	Endocrinology - gynaecology-fertility-metabolism	Merck Sharp and Dohme (Europe), Inc.	P/134/2011	08/06/2011
Edoxaban (tosylate)	N/A	PM	Cardiovascular diseases	Daiichi Sankyo Development Limited	P/136/2011	10/06/2011
(S)-3'-(OH)-desazadesferrithiocin-polyether, magnesium salt (FBS0701)	N/A	PM	Haematology-hemostaseology	FerroKin BioSciences, Ltd	P/137/2011	10/06/2011
Canagliflozin/Metformin	N/A	W	Endocrinology - gynaecology-fertility-metabolism	Janssen-Cilag International	P/138/2011	10/06/2011
Mipomersen (sodium)	N/A	PM	Endocrinology - gynaecology-	Genzyme Europe B.V.	P/139/2011	01/06/2011

Product INN	Invented	Type of	Therapeutic fertility-metabolism	Applicant	EMA	Signature
Influenza virus type A, H1N1 / influenza virus type A, H3N2 / influenza virus type B, yamagata lineage / influenza virus type B, victoria lineage	N/A	P	Vaccines	MedImmune Limited	P/140/2011	06/06/2011
Adalimumab	Humira	PM	Immunology-rheumatology-transplantation	Abbott Laboratories Ltd,	P/141/2011	06/06/2011
Chemically modified house dust mites allergen extract (dermatophagoides pteronyssinus and dermatophagoides farinae)	N/A	P	Oto-rhino-laryngology Pneumology-allergology	Granzer Regulatory Consulting & Services	P/142/2011	09/06/2011
Chemically modified extract of trees pollen from birch and alder	N/A	P	Oto-rhino-laryngology Pneumology-allergology	Granzer Regulatory Consulting & Services	P/143/2011	09/06/2011
Chemically modified extract of trees pollen from birch and alder	N/A	P	Oto-rhino-laryngology Pneumology-allergology	Granzer Regulatory Consulting & Services	P/144/2011	09/06/2011
Chemically modified house dust mites allergen extract (dermatophagoides pteronyssinus and dermatophagoides farinae)	N/A	P	Oto-rhino-laryngology Pneumology-allergology	Granzer Regulatory Consulting & Services	P/145/2011	09/06/2011
Chemically modified house dust mites allergen extract (dermatophagoides pteronyssinus and dermatophagoides farinae)	N/A	P	Oto-rhino-laryngology Pneumology-allergology	Granzer Regulatory Consulting & Services	P/146/2011	09/06/2011
Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis	N/A	P	Oto-rhino-laryngology Pneumology-allergology	Granzer Regulatory Consulting & Services	P/147/2011	09/06/2011
Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis	N/A	P	Oto-rhino-laryngology Pneumology-allergology	Granzer Regulatory Consulting & Services	P/148/2011	09/06/2011
Rotavirus type G1/rotavirus type G2/rotavirus type G3/rotavirus type G4/rotavirus type P1A[8]	RotaTeq	PM	Vaccines	Sanofi Pasteur MSD SNC	P/149/2011	09/06/2011
Progesterone	N/A	W	Endocrinology-gynaecology-	IBSA Farmaceutici Italia Srl	P/150/2011	10/06/2011

Product INN	Invented	Type of	Therapeutic fertility-metabolism	Applicant	EMA	Signature
Ipilimumab	N/A	PM	Oncology	Bristol-Myers Squibb International Corporation	P/151/2011	10/06/2011
(3aR,4S,7aR)-Octahydro-4-hydroxy-4-[(3-methylphenyl)ethynyl]-1H-indole-1-carboxylic acid methyl ester (AFQ056)	N/A	P	Neurology	Novartis Europharm Ltd	P/152/2011	30/06/2011
Benzamide, 4-[4-[[2-(4-chlorophenyl)-5,5-dimethyl-1-cyclohexen-1-yl]methyl]-1-piperazinyl]-N-[[4-[[(1R)-3-(4-morpholinyl)-1-[(phenylthio)methyl] propyl]amino]-3-[(trifluoromethyl)sulfonyl]phenyl] sulfonyl] (ABT-263)	N/A	PM	Oncology	Abbott Laboratories	P/135/2011	10/06/2011
Colistimethate sodium	N/A	PM	Infectious diseases	Forest Laboratories UK Limited	P/153/2011	04/07/2011
Paliperidone / paliperidone palmitate	Invega	PM	Psychiatry	Janssen-Cilag International NV	P/154/2011	04/07/2011
Sotrastaurin (acetate)	N/A	PM	Dermatology	Novartis Europharm Ltd.	P/155/2011	04/07/2011
Retigabine	N/A	PM	Neurology	Glaxo Group Limited	P/156/2011	04/07/2011
Fluticasone propionate / formoterol fumarate dihydrate	N/A	PM	Pneumology-allergology	Mundipharma Research Ltd	P/157/2011	04/07/2011
Ocrelizumab	N/A	P	Neurology	Roche Registration Limited	P/159/2011	04/07/2011
House dust mites allergen extracts	N/A	PM	Pneumology-allergology	Stallergenes S.A.	P/160/2011	04/07/2011
Ciclosporin	N/A	PM	Ophthalmology	Novagali Pharma S.A.	P/161/2011	04/07/2011
(3R,4R)-4-methyl-3-(methyl-7H-pyrrolo[2,3-d]pyrimidin-4-ylamino)-β-oxo-1-piperidinepropanenitrile , 2-hydroxy-1,2,3-propanetricarboxylate (1:1) (CP-690,550-10)	N/A	PM	Immunology-rheumatology-transplantation	Pfizer Limited	P/162/2011	04/07/2011
Chlorhexidine gluconate / isopropyl alcohol	N/A	P	Other	3M Health Care Limited	P/163/2011	04/07/2011
Canagliflozin	N/A	P	Endocrinology-	Janssen-Cilag International	P/164/2011	04/07/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
			gynaecology-fertility-metabolism	N.V.		
Alogliptin (benzoate) / metformin (hydrochloride)	N/A	W	Endocrinology - gynaecology-fertility-metabolism	Takeda Global Research and Development Centre (Europe) Ltd	P/165/2011	04/07/2011
Ciclosporin	N/A	W	Ophthalmology	Allergan Pharmaceuticals Ireland	P/166/2011	06/07/2011
Risperidone	Risperdal and associated names	P	Psychiatry	Wockhardt UK Ltd	P/167/2011	06/07/2011
Aprepitant	Emend	PM	Oncology	Merck Sharp & Dohme Ltd.	P/168/2011	08/07/2011
Peginterferon alfa-2a	Pegasys	PM	Infectious diseases	Roche Registration Ltd	P/169/2011	08/07/2011
Fosaprepitant	Ivemend	PM	Oncology	Merck Sharp & Dohme Ltd.	P/170/2011	08/07/2011
Coagulation Factor IX (recombinant)	N/A	PM	Haematology-hemostaseology	Inspiration Biopharmaceuticals EU, Ltd.	P/172/2011	01/07/2011
Recombinant fusion protein consisting of Human Coagulation Factor VIII attached to the Fc domain of Human IgG1 (rFVIIIFc)	N/A	P	Haematology-hemostaseology	Biogen Idec Ltd.	P/173/2011	08/07/2011
Pravastatin (sodium) / acetylsalicylic acid	N/A	W	Cardiovascular diseases	TEVA Pharma B.V.	P/174/2011	08/07/2011
Dabigatran etexilate mesilate	Pradaxa	PM	Haematology-hemostaseology	Boehringer Ingelheim International GmbH	P/175/2011	04/07/2011
Gadobutrol	Gadovist	P	Diagnostic	Bayer Schering Pharma AG	P/176/2011	08/07/2011
Perindopril (erbumine) / amlodipine (besylate)	N/A	W	Cardiovascular diseases	KBM Pharma OÜ	P/187/2011	29/07/2011
Denosumab	Xgeva (previously Amgiva) Prolia	PM	Endocrinology - gynaecology-fertility-metabolism Immunology-rheumatology - transplantation Oncology	Amgen Europe B.V.	P/158/2011	04/07/2011
Rivaroxaban	Xarelto	PM	Cardiovascular diseases Haematology-hemostaseolo	Bayer Schering Pharma AG	P/171/2011	08/07/2011

Product INN	Invented	Type of	Therapeutic gy	Applicant	EMA	Signature
Anagrelide	Xagrid	PM	Haematology-hemostaseology	Shire Pharmaceutical Contracts Limited	P/179/2011	01/08/2011
Tenofovir (disoproxil fumarate)	Viread	PM	Infectious diseases	Gilead Sciences International Limited	P/180/2011	28/07/2011
Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeablehaemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 4 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / 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 nontypeable 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	Synflorix	PM	Vaccines	GlaxoSmithKline Biologicals S.A.	P/181/2011	28/07/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
polysaccharide serotype 23F conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein						
Corifollitropin alfa	Elonva	PM	Endocrinology - gynaecology-fertility-metabolism	N.V. Organon	P/182/2011	03/08/2011
Tapentadol (hydrochloride)	Palexia	PM	Pain	Grünenthal GmbH	P/183/2011	04/08/2011
Tapentadol (hydrochloride)	Palexia	PM	Pain	Grünenthal GmbH	P/184/2011	04/08/2011
Tapentadol (hydrochloride)	Palexia	PM	Pain	Grünenthal GmbH	P/185/2011	04/08/2011
Aflibercept	N/A	W	Opthamology	Bayer Schering Pharma AG	P/186/2011	02/08/2011
Strontium (ranelate) / colecalciferol	N/A	W	Immunology-rheumatology - transplantation	Les Laboratoires Servier	P/188/2011	02/08/2011
Teriparatide	Forsteo	W	Endocrinology - gynaecology-fertility-metabolism	Eli Lilly & Company Limited	P/189/2011	02/08/2011
Amlodipine (besilate) / valsartan	N/A	W	Cardiovascular diseases	Gedeon Richter Plc.	P/190/2011	02/08/2011
N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4-oxoquinoline-3-carboxamide	N/A	PM	Pneumology-allergology	Vertex Pharmaceuticals Incorporated	P/191/2011	03/08/2011
Beclometasone dipropionate / formoterol fumarate dihydrate	Foster and associated names Kantos and associated names Inuvair and associated names Kantos Master and associated names	PM	Pneumology-allergology	Chiesi Farmaceutici S.p.A.	P/192/2011	03/08/2011
Florbetaben	N/A	W	Diagnostic	Bayer Schering Pharma AG	P/193/2011	03/08/2011
Recombinant salmon calcitonin	N/A	W	Endocrinology - gynaecology-fertility-metabolism	Novartis Europharm Ltd	P/194/2011	03/08/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Human normal immunoglobulin	N/A	PM	Immunology-rheumatology-transplantation	LBF Biotechnologies	P/195/2011	29/07/2011
Lopinavir / ritonavir	Kaletra	P	Infectious diseases	Abbott Laboratories Limited	P/199/2011	04/08/2011
Dasatinib	Sprycel	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	P/200/2011	05/08/2011
Vildagliptin	Galvus	W	Endocrinology-gynaecology-fertility-metabolism	Novartis Europharm Limited	P/177/2011	26/08/2011
Asenapine (maleate)	Sycrest	PM	Psychiatry	N.V. Organon	P/178/2011	26/08/2011
Bilastine	Bilaxten and associated names	PM	Dermatology Oto-rhino laryngology Pneumology-allergology	Faes Farma S.A.	P/196/2011	26/08/2011
Modified Grass Pollen Extract	N/A	PM	Pneumology-allergology	Allergy Therapeutics (UK) Ltd.	P/202/2011	26/08/2011
Riociguat	N/A	PM	Cardiovascular diseases	Bayer Schering Pharma AG	P/204/2011	26/08/2011
Artemether / lumefantrine	Riamet	PM	Infectious diseases	Novartis Europharm Limited	P/205/2011	26/08/2011
Golimumab	Simponi	PM	Immunology-rheumatology-transplantation	Janssen Biologics B.V.	P/197/2011	30/08/2011
Ulipristal acetate	EllaOne	PM	Endocrinology-gynaecology-fertility-metabolism	Laboratoire HRA Pharma	P/198/2011	30/08/2011
Cilengitide	N/A	P	Oncology	Merck KGaA	P/201/2011	30/08/2011
Teriflunomide	N/A	P	Neurology	sanofi-aventis recherche & développement	P/209/2011	30/08/2011
Telbivudine	Sebivo	PM	Gastroenterology-hepatology	Novartis Europharm Limited	P/203/2011	31/08/2011
Cholic acid	N/A	PM	Endocrinology-gynaecology-fertility-metabolism Gastroenterology-hepatology	Special Products Ltd	P/206/2011	31/08/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Colestilan	N/A	P	Uro-nephrology	Mitsubishi Pharma Europe Ltd	P/207/2011	01/09/2011
Canakinumab	Ilaris	PM	Immunology-rheumatology-transplantation	Novartis Europharm Limited	P/208/2011	02/09/2011
Apixaban	Eliquis	PM	Cardiovascular diseases	Bristol- Myers Squibb International Corporation	P/210/2011	02/09/2011
Brivaracetam	N/A	PM	Neurology	UCB Pharma SA	P/211/2011	02/09/2011
Veliparib	N/A	P	Oncology	Abbott Laboratories Ltd	P/212/2011	02/09/2011
Eslicarbazepine (acetate)	Zebinix Exalief	P	Neurology	BIAL - Portela & Ca, SA	P/213/2011	02/09/2011
Sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate	N/A	P	Gastroenterology-hepatology	Ipsen Pharma	P/214/2011	02/09/2011
Split influenza virus, inactivated containing antigen equivalent to A/California/7/2009 (H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), non-adjuvanted	Panenza	PM	Vaccines	Sanofi Pasteur SA	P/215/2011	09/09/2011
Deferasirox	Exjade	P	Haematology-Hemostaseology	Novartis Europharm Limited	P/216/2011	09/09/2011
Prednicarbate / octenidine dihydrochloride	N/A	P	Dermatology	Almirall Hermal GmbH	P/217/2011	16/09/2011
Canakinumab	Ilaris	PM	Immunology-rheumatology-transplantation	Novartis Europharm Limited	P/218/2011	26/09/2011
Mepolizumab		P	Pneumology-allergology	Glaxo Group Limited	P/219/2011	26/09/2011
Loxapine	N/A	P	Psychiatry	Alexza UK Limited	P/220/2011	30/09/2011
Dapagliflozin / metformin hydrochloride		P	Endocrinology-gynaecology-fertility-metabolism	Bristol-Myers Squibb / AstraZeneca EEIG	P/221/2011	26/09/2011
Rabeprazole (sodium)	Pariet and associated names	PM	Gastroenterology-hepatology	Eisai Limited	P/222/2011	27/09/2011
Fingolimod (hydrochloride)	Gilenya	PM	Neurology	Novartis Europharm Limited	P/223/2011	27/09/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Exenatide	Byetta	PM	Endocrinology - gynaecology-fertility-metabolism	Eli Lilly and Company	P/224/2011	27/09/2011
Lixisenatide	N/A	PM	Endocrinology - gynaecology-fertility-metabolism	sanofi-aventis R&D	P/225/2011	27/09/2011
Antithrombin alfa	ATryn	RW	Haematology-hemostaseology	GTC Biotherapeutics UK Limited	P/226/2011	27/09/2011
Dihydroartemisinin / piperaquine phosphate anhydride	Eurartesim	PM	Infectious diseases	Sigma-Tau SpA	P/227/2011	28/09/2011
Split Influenza virus, inactivated, containing antigen: A/California/7/2009 (H1N1)v like strain (X-179A)	Pandemrix	PM	Vaccines	GlaxoSmithKline Biologicals S.A.	P/228/2011	28/09/2011
Ozenoxacin	N/A	PM	Infectious diseases	Ferrer Internacional, S.A.	P/229/2011	28/09/2011
Progesterone	N/A	P	Endocrinology - gynaecology-fertility-metabolism	Teva Pharmaceuticals Europe B.V.	P/230/2011	28/09/2011
Coagulation Factor IX (Recombinant)	N/A	PM	Haematology-Hemostaseology	Inspiration Biopharmaceuticals EU, Ltd.	P/231/2011	20/09/2011
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 / 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 nontypeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 7F conjugated	Synflorix	PM	Vaccines	GlaxoSmithKline Biologicals S.A.	P/232/2011	26/09/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
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						
Aciclovir	N/A	P	Infectious diseases	BioAlliance Pharma	P/233/2011	26/09/2011
Eltrombopag	Revolade	P	Haematology-hemostaseology Oncology	GlaxoSmithKline Trading Services Limited	P/234/2011	30/09/2011
Rituximab	Mabthera	PM	Immunology-rheumatology-transplantation Oncology	Roche Products Ltd	P/235/2011	30/09/2011
Vatreptacog alfa (activated)	N/A	P	Haematology-hemostaseology	Novo Nordisk A/S	P/236/2011	30/09/2011
Aliskiren	Rasilez and associated names	PM	Cardiovascular diseases	Novartis Europharm Limted	P/237/2011	30/09/2011
Icatibant acetate	Firazyr	PM	Other	Jerini AG	P/238/2011	30/09/2011
Ticagrelor	Brilique Possia	PM	Cardiovascular diseases	AstraZeneca AB	P/239/2011	30/09/2011
Dextromethorphan (hydrobromide) / Quinidine sulfate	N/A	P	Neurology	Avanir Pharmaceuticals, Incorporated	P/240/2011	30/09/2011
Etanercept	Enbrel	PM	Dermatology Immunology-rheumatology-	Pfizer Limited	P/241/2011	29/09/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
			transplantation			
Rilpivirine (as hydrochloride)	N/A	PM	Infectious diseases	Janssen-Cilag International NV	P/242/2011	30/09/2011
Lorcaserin	N/A	P	Endocrinology - gynaecology-fertility-metabolism	Arena Pharmaceutical Enterprises	P/243/2011	30/09/2011
L-Cysteinyl-L-prolyl-L-alanyl-L-valyl-L-lysyl-L-arginyl-L-aspartyl-L-valyl-L-aspartyl-L-leucyl-Lphenylalanyl- L-leucyl-L-threonine, acetate salt / L-Glutamyl-L-glutaminyl-L-valyl-L-alanyl-Lglutaminyl- L-tyrosyl-L-lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-Lasparaginyl- L-alanine, acetate salt / L-Lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-Lglutamyl- L-asparaginyl-L-alanyl-L-arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginyl-L-cysteinyl-Lvaline, acetate salt / L-Arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginyl-L-cysteinyl-L-valyl-L-aspartyl- L-alanyl-L-lysyl-L-methionyl-L-threonyl-L-glutamyl-L-glutamyl-L-aspartyl-L-lysyl-L-glutamic acid, acetate salt / L-Lysyl-L-glutamyl-L-asparaginyl-L-alanyl-L-leucyl-L-seryl-L-leucyl-L-leucyl-L-aspartyl-Llysyl- L-isoleucyl-L-tyrosyl-L-threonyl-L-seryl-L-prolyl-L-leucine, acetate salt / L-Threonyl-L-alanyl-Lmethionyl- L-lysyl-L-lysyl-L-isoleucyl-L-glutaminyl-L-aspartyl-L-cysteinyl-L-tyrosyl-L-valyl-L-glutamyl-Lasparaginyl- glycyl-L-leucyl-L-	N/A	P	Pneumology-allergology	Circassia Limited	P/244/2011	07/10/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
isoleucine, acetate salt / L-Seryl-L-arginyl-L-valyl-L-leucyl-L-aspartylglycyl- L-leucyl-L-valyl-L-methionyl-L-threonyl-L-threonyl-L-isoleucyl-L-seryl-L-seryl-L-seryl-L-lysine, acetate salt						
Furosemide	N/A	P	Uro-nephrology	KidzPharma Inc.	P/245/2011	21/10/2011
Selexipag	N/A	P	Cardiovascular disesases	Actelion Registration Ltd	P/246/2011	21/10/2011
(2S,3R,4R,5S,6R)-2-(4-Chloro-3-{3-[(S)-(tetrahydrofuran-3-yl)oxy]-benzyl}-phenyl)-6-hydroxymethyltetrahydro-pyran-3,4,5-triol / Linagliptin	N/A	W	Endocrinology – gynaecology – fertility - metabolism	Boehringer Ingelheim International GmbH	P/247/2011	21/10/2011
Perampanel	N/A	PM	Neurology	Eisai Ltd	P/248/2011	25/10/2011
Japanese encephalitis vaccine (inactivated, adsorbed)	Ixiaro	PM	Vaccines	Intercell AG	P/249/2011	25/10/2011
Influenza Virus Type A, H1N1 / Influenza Virus Type A, H3N2 / Influenza Virus Type B, Yamagata lineage / Influenza Virus Type B, Victoria lineage	N/A	PM	Vaccines	MedImmune Limited	P/250/2011	25/10/2011
Recombinant fusion protein linking human coagulation factor IX with human albumin	N/A	P	Haematology - hemostaseology	CSL Behring GmbH	P/251/2011	25/10/2011
Fluticasone propionate / formoterol fumarate	N/A	PM	Pneumology - allergology	Mundipharma Research Limited	P/252/2011	26/10/2011
(1R, 4S, 5S, 6S)-4-[[(2s)-2-Amino-4-(methylthio)-1-oxobutyl]amino]-2-thiabicyclo[3.1.0]hexane-4,6-dicarboxylic acid,2,2-dioxide, monohydrate (LY2140023)	N/A	P	Psychiatry	Eli Lilly and Company Limited	P/253/2011	26/10/2011
Pancreas powder	N/A	W	Gastroenterology - hepatology	Eurand Pharmaceuticals Limited	P/254/2011	26/10/2011
2'-O-methyl-uridylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5' O,O-	N/A	PM	Neurology	Glaxo Group Limited	P/255/2011	26/10/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-uridine sodium salt (exon 51 specific phosphorothioate oligonucleotide)						
Ceftaroline fosamil	N/A	PM	Infectious diseases	AstraZeneca AB	P/256/2011	26/10/2011
Lixivaptan	N/A	P	Endocrinology – gynaecology – fertility - metabolism	Cardiokine Biopharma, LLC	P/257/2011	26/10/2011
4-[[9-[(3S)-tetrahydro-3-furanyl]-8-[(2,4,6-trifluorophenyl)amino]-9H-purin-2-yl]amino]-transcyclohexanol (CC-930)	N/A	W	Pneumology - allergology	Celgene Europe Limited	P/258/2011	26/10/2011
Brinzolamide / brimonidine (tartrate)	N/A	W	Ophthalmology	Alcon Laboratories, Ltd. (UK)	P/259/2011	26/10/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Secretin	N/A	P	Diagnostic	Repligen Europe Limited	P/260/2011	28/10/2011
Doripenem (monohydrate)	Doribax	PM	Infectious diseases	Janssen-Cilag International NV	P/261/2011	28/10/2011
Temsirolimus	Torisel	W	Oncology	Pfizer Limited	P/262/2011	28/10/2011
Pitavastatin (calcium)	Livazo and associated names	PM	Endocrinology – gynaecology – fertility - metabolism	Kowa Pharmaceutical Europe Company Ltd	P/263/2011	28/10/2011
Ipilimumab	Yervoy	PM	Oncology	Bristol-Myers Squibb International Corporation	P/264/2011	28/10/2011
Ipilimumab	Yervoy	PM	Oncology	Bristol-Myers Squibb International Corporation	P/265/2011	28/10/2011
Pitavastatin (calcium)	Alipza and associated names	PM	Endocrinology – gynaecology – fertility - metabolism	Kowa Pharmaceutical Europe Company Ltd	P/266/2011	28/10/2011
Pitavastatin (calcium)	Vezepra and associated names	PM	Endocrinology – gynaecology – fertility - metabolism	Kowa Pharmaceutical Europe Company Ltd	P/267/2011	28/10/2011
Pitavastatin (calcium)	Pitavastatin and associated names	PM	Endocrinology – gynaecology – fertility - metabolism	Kowa Pharmaceutical Europe Company Ltd	P/268/2011	28/10/2011
Ombrabulin	N/A	PM	Oncology	Sanofi-aventis recherche & developpement	P/269/2011	28/10/2011
Clopidogrel (bisulphate) / acetylsalicylic acid	N/A	W	Cardiovascular diseases	TEVA Pharma B.V.	P/270/2011	28/10/2011
(2S,3R,4R,5S,6R)-2-(4-Chloro-3-{3-[(S)-(tetrahydrofuran-3-yl)oxy]-benzyl}-phenyl)-6-hydroxymethyltetrahydro-pyran-3,4,5-triol / metformin	N/A	W	Endocrinology – gynaecology – fertility - metabolism	Boehringer Ingelheim International GmbH	P/271/2011	28/10/2011
Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 4 conjugated to	Synflorix	PM	Vaccines	GlaxoSmithKline Biologicals S.A.	P/272/2011	28/10/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
protein D (derived from non-typeable haemophilus influenzae) carrier protein / 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 nontypeable 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						
Etravirine	Intelence	PM	Infectious diseases	Janssen-Cilag International N.V.	P/273/2011	28/10/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Peginterferon alfa-2a	Pegasys	PM	Infectious diseases	Roche Registration Ltd	P/274/2011	04/11/2011
Delamanid	N/A	P	Infectious diseases	Otsuka Frankfurt Research Institute GmbH	P/275/2011	11/11/2011
Human normal immunoglobulin	N/A	P	Immunology-rheumatology-transplantation	Octapharma Pharmazeutika Produktionsges.m.b.H	P/276/2011	25/11/2011
Tocilizumab	RoActemra	PM	Immunology-rheumatology-transplantation	Roche Registration Limited	P/277/2011	28/11/2011
N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid	N/A	PM	Vaccines	GlaxoSmithKline Biologicals s.a	P/278/2011	28/11/2011
Lanthanum carbonate hydrate	Fosrenol and associated names	PM	Uro-nephroogy	Shire Pharmaceutical Contracts Ltd	P/279/2011	28/11/2011
Tralokinumab	N/A	PM	Pneumology-allergology	MedImmune Ltd	P/280/2011	28/11/2011
Icosapent	N/A	W	Gastroenterology-hepatology	S.L.A. Pharma (UK) Limited	P/281/2011	28/11/2011
1-[2-(2,4-dimethylphenylsulfanyl) phenyl]piperazine (Lu AA21004)	N/A	PM	Psychiatry	H. Lundbeck A/S	P/282/2011	29/11/2011
Boceprevir	Victrelis	PM	Infectious diseases	Merck Sharp & Dohme Ltd	P/283/2011	29/11/2011
Iron (III)-oxyhydroxide	N/A	P	Uro-nephrology	Vifor France SA	P/284/2011	30/11/2011
Budesonide	Budiair and associated names	P	Neonatology-paediatric intensive care	Neurosis Consortium	P/285/2011	30/11/2011
Alemtuzumab	MabCampath	P	Neurology Oncology	Genzyme Europe B.V.	P/286/2011	30/11/2011
Purified antigen fractions of inactivated split virion Influenza	N/A	P	Vaccines	GlaxoSmithKline Biologicals S.A.	P/287/2011	01/12/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
virus type A, H1N1 / Influenza virus type A, H3N2 / Influenza virus type B, Victoria lineage / Influenza virus type B, Yamagata lineage						
Recombinant L-Asparaginase	N/A	PM	Oncology	medac Gesellschaft für klinische Spezialpräparate mbH	P/288/2011	02/12/2011
Zoledronic acid	Aclasta	PM	Endocrinology - gynaecology-fertility-metabolism	Novartis Europharm Limited	P/289/2011	02/12/2011
N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea (ABT-869)	N/A	PM	Oncology	Abbott Laboratories	P/290/2011	02/12/2011
Dopamine (hydrochloride)	N/A	P	Neonatology-paediatric intensive care	BrePco Biopharma Limited	P/291/2011	02/12/2011
Afamelanotide	N/A	P	Dermatology	Clinuvel (UK) Limited	P/292/2011	02/12/2011
Nonacog alfa (recombinant coagulation factor IX)	N/A	P	Haematology-haemostaseology	BAXTER Innovations GmbH	P/293/2011	08/12/2011
Bosentan monohydrate	Tracleer	PM	Cardiovascular diseases Immunology-rheumatology - transplantation Pneumology-allergology	Actelion Registration Ltd	P/294/2011	20/12/2011
Tiotropium bromide (monohydrate)	Spiriva Respimat and associated names Spiriva	PM	Pneumology-allergology	Boehringer Ingelheim International GmbH	P/295/2011	20/12/2011
Canakinumab	Ilaris	PM	Haematology-haemostaseology	Novartis Europharm Limited	P/296/2011	20/12/2011
Anidulafungin	Ecalta	PM	Infectious diseases	Pfizer Limited	P/297/2011	20/12/2011
Sitagliptin (phosphate monohydrate)	Januvia	PM	Endocrinology - gynaecology-fertility-metabolism	Merck Sharp and Dohme (Europe), Inc.	P/298/2011	20/12/2011
Alogliptin benzoate	N/A	PM	Endocrinology - gynaecology-fertility-metabolism	Takeda Global Research and Development Centre (Europe) Ltd.	P/299/2011	20/12/2011
Belimumab	Benlysta	PM	Immunology-rheumatology -	Glaxo Group Limited	P/300/2011	20/12/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
			transplantation			
Rupatadine fumarate	Rupafin and associated names	PM	Dermatology Pneumology-allergology	J. Uriach y Compañía, S.A.	P/301/2011	20/12/2011
Esketamine (hydrochloride)	N/A	W	Otorhinolaryngology	Auris Medical Limited	P/302/2011	20/12/2011
Macitentan	N/A	P	Cardiovascular diseases Immunology-rheumatology-transplantation Pneumology-allergology	Actelion Registration Ltd	P/303/2011	21/12/2011
Recombinant human granulocyte colony stimulating factor coupled with recombinant human albumin fusion protein	N/A	P	Haematology-haemostaseology Oncology	Teva GmbH	P/304/2011	20/12/2011
Human monoclonal antibody against IL-6 (CNTO 136)	N/A	P	Immunology-rheumatology-transplantation	Janssen-Cilag International NV	P/305/2011	20/12/2011
Lomitapide	N/A	P	Cardiovascular diseases	Aegerion Pharmaceuticals	P/306/2011	20/12/2011
Deferiprone	N/A	P	Haematology-haemostaseology	Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF),	P/307/2011	20/12/2011
Chimeric monoclonal anti-Shiga toxin (Stx) antibodies cαStx1 and cαStx2	N/A	P	Infectious diseases	LFB Biotechnologies	P/308/2011	20/12/2011
(1-(3-chloro-5-{[4-(4-chloro-2-thienyl)-5-(4-cyclohexylpiperazin-1-yl)-1,3-thiazol-2-yl]carbamoyl}-2- pyridyl)piperidine-4-carboxylic acid monomaleate) (E5501)	N/A	P	Haematology-haemostaseology	Eisai Limited	P/309/2011	20/12/2011
Insulin degludec Liraglutide	N/A	W	Endocrinology-gynaecology-fertility-metabolism	Novo Nordisk A/S	P/310/2011	20/12/2011
Maraviroc	Celsentri	PM	Infectious diseases	ViiV Healthcare UK Limited	P/311/2011	22/12/2011
Eltrombopag	Revolade	PM	Haematology-haemostaseology Gastroenterol	GlaxoSmithKline Trading Services Limited	P/312/2011	22/12/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
			ogy-hepatology Infectious diseases Oncology			
Anti-sclerostin human monoclonal antibody (AMG785)	N/A	W	Endocrinology - gynaecology-fertility-metabolism	Amgen Europe B.V	P/313/2011	22/12/2011
Solifenacin succinate	Vesicare and associated names	PM	Uro-nephrology	Astellas Pharma Europe B.V.	P/314/2011	22/12/2011
Atomoxetine (hydrochloride)	Strattera	P	Psychiatry	Eli Lilly & Company	P/315/2011	22/12/2011
Meningococcal group A oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenA-CRM) Meningococcal group C oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenC-CRM) Meningococcal group W-135 oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenW-CRM) Meningococcal group Y oligosaccharide Conjugated to Corynebacterium diphteriae CRM197 protein (MenY-CRM)	Menveo	C	Vaccines	Novartis Vaccines and Diagnostics S.r.L	N/A	20/05/2011
Azelastine (hydrochloride) / fluticasone (propionate)	N/A	C	Pneumology-allergology	MEDA Pharma GmbH & Co. KG	N/A	17/06/2011
Rotavirus type G1/rotavirus type G2/rotavirus type G3/rotavirus type G4/rotavirus type P1A[8]	RotaTeq	C	Vaccines	Sanofi Pasteur MSD SNC	N/A	15/07/2011
Infliximab	Remicade	C	Dermatology Gastroenterology-hepatology Immunology-rheumatology - transplantation	Janssen Biologics B.V.	N/A	09/09/2011
Rizatriptan (benzoate)	MAaxalt and associated names	C	Pain	Merck Sharp & Dohme (Europe) Inc.	N/A	09/09/2011

Product INN	Invented	Type of	Therapeutic	Applicant	EMA	Signature
Insulin glargine	Optisulin	C	Endocrinology - gynaecology-fertility-metabolism	Sanofi-Aventis Deutschland GmbH	N/A	11/11/2011
Insulin glargine	Lantus	C	Endocrinology - gynaecology-fertility-metabolism	Sanofi-Aventis Deutschland GmbH	N/A	11/11/2011
Darunavir	Prezista	C	Infectious diseases	Janssen-Cilag International NV	N/A	09/12/2011
Etanercept	Enbrel	C	Dermatology Immunology-rheumatology - transplantation	Pfizer Limited	N/A	09/12/2011

Annex 16 – Guidelines and working documents in 2011

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 2011	Number of concept papers / guidelines / documents in progress during 2011	Number of guidelines / documents adopted during 2011
Biologics Working Party (BWP)	68	7	23	11
EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)	17	6	1	5
(Joint CHMP/CVMP) Quality Working Party (QWP)	85	5	8	5
Safety Working Party (SWP)	44	9	9	6
Biosimilar Medicinal Products Working Party (BMWP)	19	6	8	4
Biostatistics Working Party (BSWP)	4	4	3	0
Blood Products Working Party (BPWP)	26	2	7	3
Cardiovascular Working Party (CVWP)	4	6	12	4
Central Nervous System Working Party (CNSWP)	8	8	11	5
Infectious Diseases Working Party (IDWP)	4	4	4	4
Oncology Working Party (OWP)	4	4	5	2
Pharmacogenomics Working Party (PgWP)	10	4	4	0
Pharmacokinetics Working Party (PkWP)	3	1	4	3
Rheumatology/Immunology Working Party (RIWP)	0	4	4	0
Vaccine Working Party (VWP)	13	5	5	4
Gastroenterology Drafting Group (GEDG)	1	1	1	1
Respiratory Drafting Group (RDG)	0	0	2	0
Urology Drafting Group (UDG)	0	0	1	0
EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)	5	0	0	2
Name Review Group	1	2	2	1

Working Party / Group	Subject of concept papers / guidelines / documents of significant scientific / therapeutic interest
Biologics Working Party	• Contribution to ICH Q11 guideline on development and manufacture of active substances intended to facilitate development of active substances using the quality by design paradigm • Review of approach taken to set specifications for biological medicinal products (leading to workshop in September 2011) • Review of guidelines for quality aspects of influenza vaccines (leading to workshop in December 2011 on improved potency assays for inactivated influenza vaccines)
EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)	• Fourth report on the progress of the interaction with patients' and consumers' organisations (2010) and results/analysis of the degree of satisfaction of patients and consumers involved in EMA activities during 2010 (EMA/MB/632696/2011) • The role of patients as members of the European Medicines Agency human scientific committees (EMA/351803/2010) • Outcome report on pilot phase for participation of patient representatives in Scientific Advisory Group (SAG) meetings (EMA/850028/2011) • Procedure for review of information on medicinal products by patients and consumers (EMA/174255/2010 Rev. 2) • Criteria to be fulfilled by patients' and consumers' organisations involved in the European Medicines Agency activities (EMA/MB/24913/2005 rev. 1) • Revision of the "Framework on the interaction between the EMEA and patients' and consumers' organisations (EMEA/354515/2005-Final)"
(Joint CHMP/CVMP) Quality Working Party (QWP)	• Revision of guideline on Real time Release Testing (formerly Parametric Release) • Revision of guideline on Process Validation • Guideline on Setting Specifications for Related Impurities in Antibiotics • Guideline on Pharmaceutical Development of Medicines for Paediatric Use • Revision of guideline on the Use of Near Infra Red Spectroscopy • Contribution to ICH Q11 guideline on development and manufacture of active substances
Safety Working Party	• Reflection paper on non-clinical studies for generic nanoparticle iron medicinal product applications • Questions and answers on the guideline on the environmental risk assessment of medicinal products for human use
Blood Products Working Party (BPWP)	• Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products • Guideline on the clinical investigation of recombinant and human plasma-derived factor IX products
Cardiovascular Working Party	• Guideline on clinical investigation of medicinal products in the treatment of diabetes mellitus • Revision of guidance on clinical investigation of medicinal products in the treatment of lipid disorders to address imaging surrogate endpoints • Guideline on clinical investigation of medicinal products for prevention of stroke and systemic embolic events in patients with atrial fibrillation • Guideline on clinical investigation of medicinal products for prophylaxis of high intra- and post-operative venous thromboembolic risk
Central Nervous System Working Party	• Guideline on clinical investigation of medicinal products in the treatment of depression addressing patient populations with treatment resistance or partial response, and paediatric and elderly populations • First guideline on clinical investigation of medicinal products for the treatment of neuromuscular diseases • Revision of guideline on medicinal products for the treatment of insomnia reflecting advances in scientific understanding of insomnia over the past two decades • Updating of guideline on clinical investigation of medicinal products in the treatment of schizophrenia addressing specific claims (cognitive deficit in schizophrenia, negative symptoms in schizophrenia, partial response, treatment resistant schizophrenia) and paediatric and elderly populations
Oncology Working Party	• Revision of anticancer guideline to include disease-specific sections

Pharmacokinetics Working Party (PkWP)	• First reflection paper on generation of quality, non-clinical and clinical data to support a marketing authorisation for intravenous liposomal medicinal products having formulation-specific distribution characteristics in-vivo and similar plasma concentrations that may not correlate to equivalent therapeutic performance. • New guidance document on validation of analytical methods to measure drug concentrations in biological matrices (such as serum, plasma, blood, urine, and saliva)
Vaccine Working Party	• Revision of guidelines for influenza vaccines
Respiratory Drafting Group	• Revision cystic fibrosis guideline
EMA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)	• Framework of interaction between the European Medicines Agency and healthcare professionals (EMA/688885/2010) • Criteria to be fulfilled by healthcare professionals' organisations involved in European Medicines Agency activities (EMA/161137/2011)
Name Review Group	• NRG position paper re-use of invented names of medicinal products

Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/016/00-Rev.3	Guideline on the conduct of bioequivalence studies for veterinary medicinal products	Adopted April 2011
EMA/CVMP/760764/2010	Concept paper on the revision of the CVMP Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances	Adopted for consultation, April 2011 (End of consultation 31 July 2011)
EMA/CVMP/EWP/459868/2008	Guideline on demonstration of target animal safety and efficacy of veterinary medicinal products intended for use in farmed finfish	Adopted May 2011
EMA/CVMP/EWP/325284/2011	Questions and Answers document in relation to the CVMP Guideline on pharmaceutical fixed combination products (EMEA/CVMP/83804/05)	Adopted October 2011
EMA/CVMP/EWP/82829/2009-Rev.1	Question and Answer document in relation to the CVMP guideline on testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats.	Adopted November 2011

CVMP Environmental Risk Assessment (ERA)

Reference number	Document title	Status
EMA/CVMP/ERA/147844/2011	Reflection paper on the testing strategy and risk assessment for plants	Adopted December 2011
EMA/CVMP/ERA/430327/2009	Guideline on determining the fate of veterinary medicinal products in manure	Adopted March 2011
EMA/CVMP/ERAWP/409328/2010	Reflection paper on risk mitigation measures related to the environmental risk assessment of veterinary medicinal products	Adopted for consultation, May 2011 (End of consultation 31 August 2011)

Reference number	Document title	Status
EMA/CVMP/ERA/172074/2008-Rev.3	Questions and answers document on implementation of ERA Guideline in support of VICH guidelines (GL 6 and GL 38)	Adopted July 2011

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/206555/2010	Guideline on requirements for the production and control of immunological veterinary medicinal products	Adopted for consultation, March 2011 (End of consultation 30 September 2011)
EMA/CVMP/IWP/314550/2010	Guideline on the design of studies to evaluate the safety and efficacy of fish vaccines	Adopted November 2011
EMA/CVMP/IWP/785621/2011	Concept paper on the need of revision of the position paper on indications for veterinary vaccines	Adopted for consultation, October 2011 (End of consultation 15 January 2012)
EMA/CVMP/IWP/314550/2010	Guideline on the design of studies to evaluate the safety and efficacy of fish vaccines	Adopted November 2011
EMA/CVMP/IWP/594618/2010	Guideline on the requirements for combined vaccines and associations of immunological veterinary medicinal products (IVMPs)	Adopted for consultation, November 2011 (End of consultation 30 April 2012)
EMA/CVMP/VICH/463/2002	VICH GL34 on Biologicals: Mycoplasma - Test for the detection of Mycoplasma contamination	Adopted for consultation, December 2011 (End of consultation 12 March 2012)
EMA/CVMP/VICH/582610/2009	VICH GL50 on Biologicals: Testing harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use	Adopted for consultation, December 2011 (End of consultation 12 June 2012)
EMA/675371/2011	EMA report on the implementation of the possibility for waiving the target animal batch safety test for immunological veterinary medicinal products in the European Union	Endorsed December 2011

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/471721/2006	Recommendation on the basic surveillance of EudraVigilance Veterinary (EVVet) data	Adopted February 2011
EMA/CVMP/PhVWP/44873/2011	Public bulletin - Veterinary pharmacovigilance for 2010	Adopted February 2011
EMA/CVMP/10418/2009-Rev.3	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted June 2011
EMA/CVMP/PhVWP/377827/2011	List of species and breeds for electronic reporting of suspected adverse reactions in veterinary pharmacovigilance	Adopted June 2011
EMA/CVMP/PhVWP/288284/2007-Rev.4	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted June 2011
SOP/V/4019	Standard operating procedure - Annual review of standard lists to be used in EudraVigilance Veterinary	Adopted June 2011

Reference number	Document title	Status
SOP/V/4032	Standard operating procedure - Safety monitoring of centrally authorised products	Adopted October 2011

Joint CHMP/CVMP Quality

Reference number	Document title	Status
EMEA/CHMP/CVMP/441071/2011	Stability testing for applications for variations to a Marketing Authorisation	Adopted for consultation, July 2011 (End of consultation 31 January 2012)
	Question and Answer document on active substance definition	Adopted July 2011
	Question and Answer document on reduced testing of starting materials	Adopted July 2011
	Question and Answer document on the appearance of tablets of different strengths	Adopted July 2011
EMA/CVMP/VICH/502/1999-Rev.1	VICH GL18(R) on residual solvents in new veterinary medicinal products, active substances and excipients	Adopted September 2011
EMA/CVMP/814/00-Rev.2	HMPC Guideline on quality of herbal medicinal products/traditional herbal medicinal products	Adopted September 2011
EMA/CVMP/815/00-Rev.2	HMPC Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products	Adopted September 2011
	Question and Answer document on the choice of primary packaging for sterile veterinary medicinal products	Adopted December 2011
	Question and Answer document on starting materials of herbal origin	Adopted December 2011
	Question and Answer document on how to handle some harmonised Ph. Eur. Chapters under the new variations system (Revised)	Adopted December 2011
	Question and Answer document on stability issues of pharmaceutical bulk products for use in the manufacture of drug products	Adopted December 2011
EMA/CVMP/VICH/858875/2011	VICH GL51 on Quality: Statistical evaluation of stability data	Adopted for consultation, December 2011 (End of consultation 12 June 2012)

CVMP Safety

Reference number	Document title	Status
EMEA/CVMP/VICH/463072/2009	VCHI GL46: Metabolism study to determine the quantity and identify the nature of residues	Adopted March 2011
EMEA/CVMP/VICH/463104/2009	VCHI GL47: Laboratory animals comparative metabolism studies	Adopted March 2011
EMEA/CVMP/VICH/463199/2009	VCHI GL48: Marker residue depletion studies to establish product withdrawal periods	Adopted March 2011

Reference number	Document title	Status
EMEA/CVMP/VICH/463202/2009	VCHI GL49: Validation of analytical methods used in residue depletion studies	Adopted March 2011
EMA/CVMP/VICH/467/2003	VCHI GL36: General approach to establish a microbiological ADI	Adopted for consultation, March 2011 (End of consultation 14 September 2011)
EMA/CVMP/90250/2010	Draft Guideline on risk characterisation an assessment of maximum residue limits (MRLs) for biocides.	Adopted for consultation, September 2011 (End of consultation 30 June 2012)

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMA/CVMP/SAGAM/736964/2009	Reflection paper on meticillin-resistant *Staphylococcus pseudintermedius* (MRSP)	Adopted January 2011
EMA/CVMP/287420/2010	CVMP Strategy on antimicrobials 2011-2015	Adopted July 2011
EMA/CVMP/SAGAM/435644/2011	Concept paper on Use of pleuromutilins in food-producing animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation, October 2011 (End of consultation 31 January 2012)
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, October 2011

General

Reference number	Document title	Status
EMA/347137/2010	Summary of procedures for consultation by CVMP of Scientific Advisory Groups (SAGs) and ad-hoc expert groups functioning as SAGs in relation to applications for authorisation for veterinary medicinal products	Adopted February 2011
EMA/CVMP/287420/2010	CVMP Strategy on antimicrobials 2011-2015	Adopted July 2011
EMA/CVMP/414812/2011	Question and answer document on the CVMP guideline on the SPC for antimicrobial products	Adopted July 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 2011	Number of concept papers/ guidelines/ documents in progress during 2011	Number of guidelines/ documents adopted in 2011
Committee for Orphan Medicinal Products	1	1	1	1

Scientific Committee	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest
Committee for Orphan Medicinal Products	• Reflection paper on biological markers and orphan designation

Committee on Herbal Medicinal Products (HMPC)

Reference number	Document title	Status
EMA/HMPC/732886/2010	Public statement on the use of herbal medicinal products containing thujone	Adopted for release for public consultation January 2011
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	Adopted September 2011
EMA/HMPC/473587/2011	Public statement on the interpretation of therapeutic indications appropriate to traditional herbal medicinal products	Adopted September 2011

HMPC Quality Drafting Group

Reference number	Document title	Status
EMA/HMPC/41500/2010 Rev.1	Revised Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products	Adopted November 2011
EMA/HMPC/111298/2011	Concept paper on the revision of the guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products (EMA/HMPC/71049/2007)	Adopted for release for public consultation March 2011 Adopted November 2011

HMPC Organisational Matters Drafting Group

Reference number	Document title	Status
EMA/HMPC/127670/2011	Guidance for companies seeking scientific support and advice on traditional herbal medicinal products	Adopted for release for public consultation July 2011
EMA/HMPC/119889/2005 Rev.1	Template for request for scientific support and advice on traditional herbal medicinal products	Adopted for release for public consultation July 2011
EMA/HMPC/124695/2011	Procedure for the systematic review of adopted Community herbal monographs and supporting documents	Adopted for release for public consultation July 2011

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 July 2011
EMA/HMPC/75972/2010	Template for a public statement when no Community herbal monograph is established	Adopted July 2011
EMA/HMPC/463090/2011	Template for submission of questions raised by HMPC members or NCA for discussion by the HMPC	Adopted July 2011
EMA/HMPC/107436/2005 Rev. 6	Revised Template for a Community herbal monograph	Adopted July 2011
EMA/HMPC/1004/2006 Rev. 4	Revised Procedure for call for scientific data for use in HMPC assessment works	Adopted July 2011

Committee for Advanced Therapies (CAT)

Scientific Committee / Working Party	Total number of adopted guidelines/ documents for which committee is responsible	Number of concept papers/ guidelines/ documents initiated in 2011	Number of concept papers/ guidelines/ documents in progress during 2011	Number of guidelines/ documents adopted in 2011
Committee for Advanced Therapies	4	0	0	1
Cell-based Products Working Party (CPWP)	6	2	4	1
Gene Therapy Working Party (GTWP)	16	1	2	2

Scientific Committee	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest
Committee for Advanced Therapies	• Draft Guideline on the risk-based approach according to Annex I, part IV of Directive 2001/83/EC for ATMPs.
Committee for Advanced Therapies	• Revision of the Gene therapy parental guideline

GCP Inspectors Working group

Reference number	Document title	Status
EMA/INS/GCP/600788/2011	Reflection paper on the use of interactive response technologies (interactive voice/web response systems) in clinical trials	draft: consultation open till 15/2/2012
EMA/INS/GCP/394194/2011	Reflection paper on risk-based quality management in clinical trials	draft: consultation open till 15/2/2012
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000016.jsp&mid=WC0b01ac05800296c5	Question and answer: Expectations of European Union (EU) competent authorities on the use of electronic trial master files	

Annex 17 – Arbitration and Community referrals overview 2011

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	14/04/2011	celecoxib
Article 5(3) procedure of Regulation (EC) No 726/2004	19/05/2011	diphtheria and tetanus toxoid (DT) and diphtheria/tetanus toxoid/pertussis (DTwP) antigen for vaccines
Article 5(3) procedure of Regulation (EC) No 726/2004	23/06/2011	isoniazide/rifampicine/pyrazinamide/ ethambutol/rifabutin
Article 5(3) procedure of Regulation (EC) No 726/2004	21/07/2011	human normal immunoglobulin
Article 5(3) procedure of Regulation (EC) No 726/2004	22/09/2011	teicoplanin
Article 5(3) procedure of Regulation (EC) No 726/2004	22/09/2011	propylene glycol
Article 5(3) procedure of Regulation (EC) No 726/2004	20/10/2011	non-selective non-steroidal anti-inflammatory drugs
Article 20 procedure of Regulation (EC) No 726/2004	20/01/2011	dronedarone
Article 20 procedure of Regulation (EC) No 726/2004	17/03/2011	lenalidomide
Article 20 procedure of Regulation (EC) No 726/2004	17/03/2011	pioglitazone
Article 20 procedure of Regulation (EC) No 726/2004	17/03/2011	pioglitazone
Article 20 procedure of Regulation (EC) No 726/2004	17/03/2011	pioglitazone/metformin hydrochloride
Article 20 procedure of Regulation (EC) No 726/2004	17/03/2011	pioglitazone/metformin hydrochloride
Article 20 procedure of Regulation (EC) No 726/2004	17/03/2011	pioglitazone/glimepiride
Article 20 procedure of Regulation (EC) No 726/2004	23/06/2011	Japanese encephalitis vaccine
Article 20 procedure of Regulation (EC) No 726/2004	21/07/2011	lacosamide
Article 20 procedure of Regulation (EC) No 726/2004	22/09/2011	orlistat
Article 20 procedure of Regulation (EC) No 726/2004	22/09/2011	orlistat
Article 20 procedure of Regulation (EC) No 726/2004	20/10/2011	strontium ranelate
Article 20 procedure of Regulation (EC) No 726/2004	20/10/2011	strontium ranelate
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	bivalirudin

Type of referral	Date of CHMP start of procedure	International non-proprietary name (INN)
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	busulfan
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	doxorubicin hydrochlorid
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	aztreonam
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	histamine dihydrochloride
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	anidulafungin
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	perflutren
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	mifamurtide
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	eculizumab
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	temsirolimus
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	bortezomib
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	telavancin
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	azacitidine
Article 20 procedure of Regulation (EC) No 726/2004	17/11/2011	cidofovir
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	orlistat
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	methoxy polyethylene glycol-epoetin beta
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	peginterferon alfa-2a
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	oseltamivir phosphate
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	capecitabine
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	orlistat
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	rituximab
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	aliskiren
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	aliskiren
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	aliskiren/amlodipine
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	aliskiren
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	aliskiren hemifumarate/hydrochlorothiazide

Type of referral	Date of CHMP start of procedure	International non-proprietary name (INN)
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	aliskiren hemifumarate/hydrochlorothiazide
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	aliskiren/hydrochlorothiazide
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	aliskiren/amlodipine/hydrochlorothiazide
Article 29(4) of Directive 2001/83/EC	17/03/2011	dapoxetine hydrochloride
Article 29(4) of Directive 2001/83/EC	23/06/2011	dexamethasone
Article 30 of Directive 2001/83/EC	17/02/2011	amlodipine besilate
Article 30 of Directive 2001/83/EC	23/06/2011	epoprostenol
Article 30 of Directive 2001/83/EC	23/06/2011	measles vaccines, combinations with mumps and rubella (live attenuated)
Article 30 of Directive 2001/83/EC	17/11/2011	teicoplanin
Article 30 of Directive 2001/83/EC	15/12/2011	ciclosporin
Article 30 of Directive 2001/83/EC	15/12/2011	ciclosporin
Article 31 of Directive 2001/83/EC	20/01/2011	calcitonin
Article 31 of Directive 2001/83/EC	20/01/2011	Baxter peritoneal dialysis solutions
Article 31 of Directive 2001/83/EC	17/02/2011	pholcodine
Article 31 of Directive 2001/83/EC	19/05/2011	trimetazidine
Article 31 of Directive 2001/83/EC	19/05/2011	cilostazol
Article 31 of Directive 2001/83/EC	21/07/2011	ketoconazole
Article 31 of Directive 2001/83/EC	21/07/2011	tolperisone
Article 31 of Directive 2001/83/EC	22/09/2011	orlistat
Article 31 of Directive 2001/83/EC	15/12/2011	iron containing medicinal products (solution for injection, intravenous use)
Article 31 of Directive 2001/83/EC	15/12/2011	metoclopramide
Article 36 of Directive 2001/83/EC	17/03/2011	human normal immunoglobulin
Article 36 of Directive 2001/83/EC	17/03/2011	goserelin
Article 36 of Directive 2001/83/EC	17/03/2011	goserelin
Article 36 of Directive 2001/83/EC	17/03/2011	goserelin
Article 36 of Directive 2001/83/EC	15/12/2011	influenza vaccine (purified split virus)
Article 107(2) of Directive 2001/83/EC	17/02/2011	buflomedil
Article 107(2) of Directive 2001/83/EC	22/09/2011	meprobamate
Article 13 of Commission Regulation (EC) No 1234/2008	19/05/2011	somatropin
Article 6(12) of Commission Regulation (EC) No 1084/2003	21/07/2011	ethinylestradiol/drospirenone
Article 6(12) of Commission Regulation (EC) No 1084/2003	21/07/2011	ethinylestradiol/drospirenone

Procedures finalised

Type of referral	Date of CHMP start of procedure	International non-proprietary name (INN)
Article 5(3) procedure of Regulation (EC) No 726/2004	19/05/2011	celecoxib
Article 5(3) procedure of Regulation (EC) No 726/2004	23/06/2011	diphtheria and tetanus toxoid (DT) and diphtheria/tetanus toxoid/pertussis (DTwP) antigen for vaccines
Article 5(3) procedure of Regulation (EC) No 726/2004	20/10/2011	receptor antagonists
Article 20 procedure of Regulation (EC) No 726/2004	14/04/2011	zoledronic acid
Article 20 procedure of Regulation (EC) No 726/2004	14/04/2011	alendronic acid/colecalciferol
Article 20 procedure of Regulation (EC) No 726/2004	14/04/2011	ibandronic acid
Article 20 procedure of Regulation (EC) No 726/2004	14/04/2011	ibandronic acid
Article 20 procedure of Regulation (EC) No 726/2004	14/04/2011	ibandronic acid
Article 20 procedure of Regulation (EC) No 726/2004	14/04/2011	alendronic acid/colecalciferol
Article 20 procedure of Regulation (EC) No 726/2004	14/04/2011	ibandronic acid
Article 20 procedure of Regulation (EC) No 726/2004	14/04/2011	alendronic acid/colecalciferol
Article 20 procedure of Regulation (EC) No 726/2004	14/04/2011	zoledronic acid
Article 20 procedure of Regulation (EC) No 726/2004	21/07/2011	pioglitazone
Article 20 procedure of Regulation (EC) No 726/2004	21/07/2011	pioglitazone/metformin hydrochloride
Article 20 procedure of Regulation (EC) No 726/2004	21/07/2011	pioglitazone/metformin hydrochloride
Article 20 procedure of Regulation (EC) No 726/2004	21/07/2011	pioglitazone
Article 20 procedure of Regulation (EC) No 726/2004	21/07/2011	pioglitazone/glimepiride
Article 20 procedure of Regulation (EC) No 726/2004	21/07/2011	influenza vaccine (H1N1)
Article 20 procedure of Regulation (EC) No 726/2004	22/09/2011	dronedarone
Article 20 procedure of Regulation (EC) No 726/2004	22/09/2011	lenalidomide
Article 20 procedure of Regulation (EC) No 726/2004	22/09/2011	lacosamide
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	somatropin
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	somatropin
Article 20 procedure of Regulation (EC) No 726/2004	15/12/2011	somatropin

Type of referral	Date of CHMP start of procedure	International non-proprietary name (INN)
Article 29(4) of Directive 2001/83/EC	17/02/2011	docetaxel anhydrous
Article 29(4) of Directive 2001/83/EC	17/03/2011	clotrimazole
Article 29(4) of Directive 2001/83/EC	21/07/2011	dexamethasone
Article 29(4) of Directive 2001/83/EC	20/10/2011	dapoxetine hydrochloride
Article 30 of Directive 2001/83/EC	17/03/2011	anastrozole
Article 30 of Directive 2001/83/EC	19/05/2011	granisetron
Article 30 of Directive 2001/83/EC	23/06/2011	fluconazole
Article 30 of Directive 2001/83/EC	21/07/2011	amlodipine besilate
Article 31 of Directive 2001/83/EC	14/04/2011	zoledronic acid/alendronic acid/colecalciferol/ibandronic acid
Article 31 of Directive 2001/83/EC	14/04/2011	human normal immunoglobulin
Article 31 of Directive 2001/83/EC	23/06/2011	dexrazoxane
Article 31 of Directive 2001/83/EC	23/06/2011	nimesulide
Article 31 of Directive 2001/83/EC	22/09/2011	Baxter peritoneal dialysis solutions
Article 31 of Directive 2001/83/EC	22/09/2011	terpenic derivatives containing suppositories
Article 31 of Directive 2001/83/EC	17/11/2011	pholcodine
Article 36 of Directive 2001/83/EC	23/06/2011	goserelin
Article 36 of Directive 2001/83/EC	23/06/2011	goserelin
Article 36 of Directive 2001/83/EC	23/06/2011	goserelin
Article 107(2) of Directive 2001/83/EC	17/11/2011	buflomedil
Article 107(2) of Directive 2001/83/EC	15/12/2011	somatropin
Article 13 of Commission Regulation (EC) No 1234/2008	15/12/2011	somatropin

Referrals made to the CVMP

Type of referral	• Clock start • CVMP opinion	• Product name • INN
Referral under Art. 34 of Directive 2001/82/EC	• 11/11/2009 • 10/11/2011	• Fortekor vet and associated names • Benazepril hydrochloride
Referral under Art. 34 of Directive 2001/82/EC	• 14/04/2010 • 07/06/2011	• Synulox Lactating Cow and associated names • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010 • 07/04/2011	• Combimox Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010 • 07/04/2011	• Nisamox Lactating Cow • Amoxicillin, clavulanic acid, prednisolone
Referral under Art. 33(4) of Directive 2001/82/EC	• 14/07/2010 • 07/04/2011	• Combisyn Lactating Cow • Amoxicillin, clavulanic acid, prednisolone

Type of referral	• Clock start • CVMP opinion	• Product name • INN
Referral under Art. 34 of Directive 2001/82/EC	• 14/07/2010 • 04/05/2011	• Doxycycline 50% WSP and associated names • Doxycycline hyclate
Referral under Art. 34 of Directive 2001/82/EC	• 14/07/2010 • 04/05/2011	• Doxyfar 50% WSP and associated names • Doxycycline hyclate
Referral under Art. 34 of Directive 2001/82/EC	• 09/11/2010	• Baytril 10% oral solution and associated names • Enrofloxacin
Referral under Art. 33(4) of Directive 2001/82/EC	• 09/02/2011 • 08/06/2011	• Clavudale 50 mg tablet for cats and dogs • Amoxicillin and clavulanic acid
Referral under Art. 35 of Directive 2001/82/EC	• 09/03/2011	• Veterinary medicinal products containing active substances belonging to the class of flukicides for which no MRL has been established in milk
Referral under Art. 35 of Directive 2001/82/EC	• 06/04/2011 • 13/10/2011	• All veterinary medicinal products containing systemically administered (parenteral and oral) 3rd and 4th generation cephalosporins and intended for use in food producing species • Cefquinome and ceftiofur
Referral under Art. 33(4) of Directive 2001/82/EC	• 04/05/2011	• Prontax 5 mg/ml pour-on solution for cattle • Doramectin
Referral under Art. 33(4) of Directive 2001/82/EC	• 04/05/2011	• Prontax 10 mg/ml solution for injection for sheep, cattle and pigs • Doramectin
Referral under Art. 35 of Directive 2001/82/EC	• 04/05/2011	• All pre-mixes for medicated feedingstuffs containing 40, 100 or 200 g tilmicosin per kg pre-mix • Tilmicosin
Referral under Art. 78 of Directive 2001/82/EC	• 04/05/2011 • 14/07/2011	• HIPRABOVIS PNEUMOS Emulsion for injection for cattle and associated names • Inactivated *Mannheimia haemolytica* and *Histophilus somni*
Referral under Art. 34 of Directive 2001/82/EC	• 14/09/2011	• Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus and Prazitel Plus and associated names • Praziquantel, pyrantel and febantel
Referral under Art. 35 of Directive 2001/82/EC	• 15/09/2011	• All long acting formulations for injection containing barium selenate for all food producing species • barium selenate
Procedure under Art. 30(3) of Regulation (EC) No 726/2004	• 15/09/2011	• N/A • Dapsone
Procedure under Article 33(4) of Directive 2001/82/EC	• 12/10/2011	• Nuflor 300 mg/ml solution for injection for cattle and sheep • Florfenicol
Procedure under Article 35 of Directive 2001/82/EC	• 12/10/2011	• Hipralona Enro-S and its generics • Enrofloxacin

Annex 18 – Publications by Agency staff members and experts in 2011

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Annex 19 – 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

E-mail: vet-phv@ema.europa.eu
Direct telephone: +44 (0)20 7418 8624 (for use only as stated in the relevant instructions)
Fax: +44 (0)20 7418 8447

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

For instructions and contact points

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

SME Office

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

SME office contact point:

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

Certificates of a medicinal product

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

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

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

PMF/VAMF EMA certificates

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

For enquiries concerning PMF certificates

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

For enquiries concerning VAMF certificates

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

ATMP certification

The Agency issues a certificate of quality and where available non clinical data submitted by SMEs developing Advanced Therapy Medicinal Products (ATMPs) in conformity with the arrangements laid down by Community legislation. The Agency ATMP certification process is an assessment of the certification application dossier.

For enquiries concerning ATMPs certificates

Caroline VOLTZ
Direct telephone: +44 (0)20 7523 7660
Fax: +44 (0)20 7418 8545
E-mail: caroline.voltz@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:

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:

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