

Annex 1 – Members of the Management Board

Chair: Kent WOODS

EMA contact: Nerimantas STEIKUNAS; Silvia FABIANI

Members

- European Parliament Guiseppa NISTICÓ, Björn LEMMER
- European Commission Paola TESTORI COGGI, Gwenole COZIGOU
(Alternates: Andzej RYS , Salvatore D'ACUNTO)
- Belgium Xavier DE CUYPER (Alternate: Greet MUSCH)
- Bulgaria Kiril NENOV¹ (Alternate: Zlatina GUEORGUIEVA²)
- Czech Republic Doubravka KOSTALOVA³ (Alternate: Jiří BUREŠ)
- Denmark Else SMITH (Alternate: Nina MOSS)
- Germany Walter SCHWERDTFEGER (Alternate: Klaus CICHUTEK)
- Estonia Kristin RAUDSEPP (Alternate: Alar IRS)
- Ireland Pat O'MAHONY (Alternate: Rita PURCELL)
- Greece Ioannis TOUNTAS (Alternate: Maria SKOURLIAKOU)
- Spain Belén CRESPO SÁNCHEZ-EZNARRIAGA (Alternate: Laura Franqueza GARCÍA)
- France Dominique MARANINCHI (Alternate: Jean-Pierre ORAND)
- Italy Luca PANI (Alternate: Paolo SIVIERO)
- Cyprus Arthur ISSEYEGH Alternate: George ANTONIOU)
- Latvia Inguna ADOVIČA (Alternate: Dace ĶIKUTE)
- Lithuania Gintautas BARCYS (Alternate: Gediminas PRIDOTKAS)
- Luxembourg Claude A HEMMER (Alternate: Jacqueline GENOUX-HAMES⁴)
- Hungary Beatrix HORVÁTH⁵ (Alternate: Hilda KŐSZEGINÉ SZALAI⁶)
- Malta John-Joseph BORG⁷ (Alternate: Gavril FLORES)

¹ Replaced Evelin YAKOV BLAGOEV as of December 2013

² Replaced Meri PEYCHEVA as of December 2013

³ Replaced Jiří DEML as of February 2013

⁴ Replaced Mariette BACKES LIES as of May 2013

⁵ Replaced Tamás L PAÁL as of October 2013

⁶ Replaced Beatrix HORVÁTH as of October 2013

⁷ Replaced Patricia VELLA BONNANO as of November 2013

- Netherlands Aginus A W KALIS (Alternate: Constant VAN BELKUM⁸)
- Austria Christa WIRTHUMER-HOCHE⁹ (Alternate: Sylvia FÜSZL)
- Poland Grzegorz CESSAK (Alternate: Artur FALLEK)
- Portugal Helder Mota Filipe (Alternate: Nuno VIEIRA E BRITO)
- Romania Marius SAVU (Alternate: Marius TANASA¹⁰)
- Slovenia Matej BREZNIK (Alternate: Stanislav PRIMOŽIČ)
- Slovakia Ján MAZÁG (Alternate: Barbora KUČEROVÁ¹¹)
- Finland Sinikka RAJANIEMI (Alternate: Pekka KURKI)
- Sweden Christina ÅKERMAN (Alternate: Bengt WITTGREN)
- United Kingdom Kent WOODS (Alternate: Ian HUDSON¹²)
- Representatives of patients' organisations Nikos DEDES
W.H.J.M. Wim WIENTJENS
- Representative of doctors' organisations Wolf-Dieter LUDWIG
- Representative of veterinarians' organisations Christophe HUGNET

Observers

- Iceland Rannveig GUNNARSDÓTTIR¹³ (Alternate: Helga THORISDÓTTIR¹⁴)
- Liechtenstein Brigitte BATLINER (Alternate: Christina ZIMMER¹⁵)
- Norway Audun HÅGÅ¹⁶ (Alternate: Ivar VOLLSET)

⁸ Replaced Rob DE HAAN as of May 2013

⁹ Replaced Marcus MÜLLNER as of October 2013

¹⁰ Replaced Simona BĂDOI as of November 2013

¹¹ Replaced Michaela GAJDOŠOVÁ as of May 2012

¹² Replaced Jonathan MOGFORD as of September 2013

¹³ Replaced Einar MAGNÚSSON as of May 2013

¹⁴ Replaced Rannveig GUNNARSDÓTTIR as of May 2013

¹⁵ Replaced Sabine ERNE as of January 2013

¹⁶ Replaced GRO RAMSTEN WESENBERG as of August 2013

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

Chair: Tomas SALMONSON

EMA contact: Anthony HUMPHREYS

Members

- John Joseph BORG (Malta) Alternate: Helen VELLA¹
- Daniel BRASSEUR² (Belgium) Alternate: Bart VAN DER SCHUEREN³
- Pieter de Graeff⁴ (Netherlands) Alternate: Hans HILLEGES
- Pierre Demolis (France)⁶ Alternate: Joseph EMMERICH⁷
- Kristina DUNDER (Sweden) Alternate: Bengt LJUNGBERG
- Harald ENZMANN (Germany) Alternate: Martina WEISE
- Piotr FIEDOR (Poland) Alternate: Aldona PALUCHOWSKA ⁸
- Jacqueline Genoux-Hames (Luxembourg) Alternate: Carine DE BEAUFORT
- Kolbeinn GUDMUNDSSON (Iceland) Alternate: Reynir ARNGRIMSSON
- Agnes Gyurasics (Hungary) Alternate: Melinda SOBOR⁹
- Jens HEISTERBERG (Denmark) Alternate: Jens Ersbøll
- Alar IRS (Estonia) Alternate: Kersti OSELIN¹⁰
- Andrea LASLOP (Austria) Alternate: Milena STAIN
- David LYONS (Ireland) Alternate: Patrick SALMON
- Romaldas Mačiulaitis (Lithuania) Alternate: Rugile PILVINIENE
- Outi MAKI-IKOLA (Finland) Alternate: Janne KOMI
- Greg MARKEY¹¹ (United Kingdom) Alternate: Rafe SuVARNA
- Emilia MAVROKORDATOU (Cyprus)¹² Alternate: Arthur Isseyegh¹³
- Ján MAZÁG (Slovakia) Alternate: Jana KLIMOSOVA ¹⁴
- Catherine MORAITI (Greece) Alternate: Chrysoula NTAOUSANI

¹ Replaced Patricia VELLA BONANNO as per December 2013 meeting

² Replaced Pieter NEELS as per September 2013 meeting

³ Replaced Walter JANSSENS as per September 2013 meeting

⁴ Replaced Barbara VAN ZWIETEN-BOOT as per September 2013 meeting

⁵ Replaced Pieter DE GRAEFF as per September 2013 meeting

⁶ Elected Vice-chair as per October 2013 meeting

⁷ Appointed alternate as per February 2013 meeting

⁸ Replaced Kinga BOROWICZ as per October 2013 meeting

⁹ Replaced János BORVENDEG as per June 2013 meeting

¹⁰ Replaced Irja LUTSAR as per March 2013 meeting

¹¹ Replaced Ian HUDSON as per September 2013 meeting

¹² Appointed as member as per April 2013 meeting (previously alternate)

¹³ Appointed as alternate as per April 2013 meeting (previously member)

¹⁴ Replaced Vlasta KÁKOSOVÁ as per June 2013 meeting

- Ivana MIKAČIĆ (Croatia)¹⁵ Alternate: Ana DUGONJIĆ
- Luca PANI (Italy)¹⁶ Alternate: Daniela MELCHIORRI¹⁷
- Juris PokrOtnieks (Latvia) Alternate: Natalja Karpova
- Concepcion PRIETO YERRO (Spain) Alternate: Arantxa SANCHO-LOPEZ
- Stanislav PRIMOZIC (Slovenia) Alternate: Nevenka TRSINAR
- Bruno SEPODES (Portugal) Alternate: Dinah DUARTE
- Ondřej SLANAR (Czech Republic) Alternate: Radka MONTONIOVA¹⁸
- Karsten BRUINS SLOT (Norway) Alternate: Ingunn HAGEN WESTGAARD
- Mila VLASKOVSKA (Bulgaria) Alternate: Lyubina TODOROVA
- Nela VILCEANU (Romania) Alternate: Dana MARIN

Co-opted members

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

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 (up to 08.13)/David HAERRY/Isabelle MOULON

EMA contact: Nathalie BERE

EMA/CHMP Working Group with Healthcare Professionals' Organisations

Chair: Gonzalo CALVO/Isabelle MOULON

EMA contact: Ivana SILVA

Joint CHMP/CVMP Quality Working Party

Chair: Jean-Louis ROBERT
LUIGETTI

EMA contact: Simona KECKESOVA/Riccardo

Safety Working Party

Chair: Jan Willem VAN DER LAAN

EMA contact: Frida RIVIERE/Jean-Marc VIDAL

Scientific Advice Working Party

Chair: Robert James HEMMINGS

EMA contact: Spiros VAMVAKAS/Jane MOSELEY

¹⁵ As of July 2013

¹⁶ Appointed as member as per April 2013 meeting (previously alternate)

¹⁷ Appointed as alternate as per April 2013 meeting (previously member)

¹⁸ Replaced Miloslav SALAVEC as per May 2013 meeting

Temporary working parties

Biosimilar Medicinal Products Working Party

Chair: Christian SCHNEIDER
GRAVANIS

EMA contact: Camille VLEMINCKX/Iordanis

Biostatistics Working Party

Chair: David Jonathan WRIGHT

EMA contact: Frank PETAVY

Blood Products Working Party

Chair: Anneliese HILGER

EMA contact: Glenda SILVESTER

Cardiovascular Working Party

Chair: Pieter DE GRAEFF

EMA contact: Anna BACZYNSKA

Central Nervous System Working Party

Chair: Karl BROICH

EMA contact: Malgorzata ZIENOWICZ

Infectious Diseases Working Party

Chair: Mair POWELL
GUZMAN

EMA contact: Radu BOTGROS/ Sabrina SPINOSA

Oncology Working Party

Chair: Bertil JONSSON

EMA contact: Irene PAPADOULI

Pharmacogenomics Working Party

Chair: Krishna PRASAD

EMA contact: Falk EHMANN/Marisa PAPALUCA

Pharmacokinetics Working Party

Chair: Jan WELINK

EMA contact: Margot MARTIN/Margaux PHILIPPE

Rheumatology/Immunology Working Party

Chair: - Jan MUELLER-BERGHHAUS

EMA contact: Radhouane CHERIF

Vaccine Working Party

Chair: Michael PFLEIDERER

EMA contact: Robin RUEPP/Manuela MURA

Temporary drafting groups

Gastroenterology Drafting Group

Chair: Elmer SCHABEL

EMA contact: Joachim MUSAUS

Respiratory Drafting Group

Chair: *Awaiting nomination*

EMA contact: Jaume GONZALEZ NOGUERAS

Urology Drafting Group

Chair: Kerstin CLAESSION

EMA contact: Joachim MUSAUS

Radiopharmaceuticals Drafting Group

Chair: Patrick SALMON

EMA contact: Silvy DA ROCHA DIAS

Scientific advisory groups

Scientific Advisory Group on Anti-infectives

Chair: Jaap T VAN DISSEL

EMA contact: Eric PELFRENE

(resigned in 06.2013/Acting: Barbara BANNISTER

Scientific Advisory Group on Cardiovascular Issues

Chair: *Awaiting nomination*

EMA contact: Radu POPESCU

Scientific Advisory Group on Diabetes/ Endocrinology

Chair: *Awaiting nomination*

EMA contact: Eberhard BLIND

Scientific Advisory Group on HIV/Viral Diseases

Chair: Daniel VITTECOQ

EMA contact: Margot MARTIN

Scientific Advisory Group on Neurology

Chair: Serge BAKCHINE

EMA contact: Pavel BALABANOV

Scientific Advisory Group on Oncology

Chair: JAN SCHELLENS

EMA contact: Francesco PIGNATTI

Scientific Advisory Group on Psychiatry

Chair: *Awaiting nomination*

EMA contact: Pavel BALABANOV

Scientific Advisory Group on Vaccines

Chair: Andrew POLLARD

EMA Contact: Sabrina SPINOSA GUZMAN

Other CHMP-associated groups**Invented Name Review Group**

Chair: Isabelle MOULON (up to 09.13)/Alexios SKARLATOS
TIJERA

EMA contact: Jose Angel FERRERO

Working Group on Quality Review of Documents

Chair: Alexios SKARLATOS

EMA contact: Monica BUCH GARCIA

Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: June RAINE

EMA contact: Anthony HUMPHREYS

Members

- George AISLAITNER (Greece) Alternate: Leonidas KLIRONOMOS
- Ingebjorg BUAJORDET (Norway) Alternate: Pernille HARG
- Jean-Michel DOGNE (Belgium) Alternate: Veerle VERLINDEN¹
- Nicolae FOTIN (Romania) Alternate: Roxana STROE²
- Jacqueline GENOUX-HAMES (Luxembourg) Alternate: Nadine PETITPAIN
- Jolanta GULBINOVIC (Lithuania) Alternate: Rita DZETAVECKIENE
- Harald HERKNER (Austria) Alternate: Aleksandra MARTINOVIC³
- Martin HUBER (Germany) Alternate: Valerie STRASSMANN⁴
- Andis LACIS (Latvia) Alternate: Inguna ADOVICA
- Carmela MACCHIARULO (Italy) Alternate: Jelena IVANOVIC⁵
- Viola MACOLIĆ ŠARINIĆ (Croatia)⁶ Alternate: Marin BANOVAČ⁷
- Tatiana MAGALOVA (Slovakia) Alternate: Anna MAREKOVA
- Jana MLADA (Czech Republic) Alternate: Eva JIRSOVA
- Dolores MONTERO (Spain) Alternate: Miguel MACIA
- Julia PALLOS (Hungary) Alternate: Melinda PALFI
- Margarida GUIMARÃES (Portugal)⁸ Alternate: Alexandra PÉGO⁹
- Christos PETROU (Cyprus) Alternate: Zena GUNTHER¹⁰
- Maria POPOVA-KIRADJIEVA (Bulgaria) Alternate: Yuliyán EFTIMOV
- Adam PRZYBYLKOWSKI (Poland) Alternate: Kamila CZAJKOWSKA¹¹
- Milena RADOHA-BERGOČ (Slovenia) Alternate: Gabriela JAZBEC
- Isabelle ROBINE (France) Alternate: *Awaiting nomination*
- Almath SPOONER (Ireland) Alternate: Ruchika SHRAMA¹²

¹ Replaced Virginie CHARTIER as of October 2013

² Replaced Daniela POMPONIU as of December 2013

³ Replaced Bettina SCHADE as of December 2013

⁴ Replaced Birgitta KÜTTING as of May 2013

⁵ Replaced Fernanda FERRAZIN as of November 2013

⁶ As of July 2013

⁷ As of July 2013

⁸ Replaced Alexandra PÉGO as of March 2013

⁹ Replaced Cristina FURTADO as of March 2013

¹⁰ Replaced Anastasia CHRISTODOULIDES as of October 2013

¹¹ Replaced Anna ARCAB as of April 2013

- Guðrún Kristín STEINGRIMSDOTTIR (Iceland) Alternate: Awaiting nomination
- Doris STENVER (Denmark) Alternate: Line MICHAN
- Sabine STRAUS (Netherlands) Alternate: Menno VAN DER ELST
- Ami TANTI (Malta) Alternate: Awaiting nomination
- Maia UUSKULA (Estonia) Alternate: Katrin KIISK
- Kirsti VILLIKKA (Finland) Alternate: Terhi LEHTINEN
- Julie WILLIAMS (United Kingdom) Alternate: Julia DUNNE
- Qun-Ying YUE (Sweden) Alternate: Ulla WÄNDEL LIMINGA

Independent scientific experts nominated by the European Commission

- Jane AHLQVIST RASTAD
- Marie Louise DE BRUIN
- Stephen J. W. EVANS
- Brigitte KELLER-STANISLAWSKI
- Herve LE LOUET
- Lennart WALDENLIND

Representative of healthcare professionals nominated by the European Commission

Members

- Filip BABYLON¹³ Alternate: Kirsten MYHR¹⁴

Representatives of patients organisations nominated by the European Commission

- Albert VAN DER ZEIJDEN¹⁵ Alternate: Marco GRECO¹⁶

¹² Replaced Dónal ÓG DONOVAN as of July 2013

¹³ As of May 2013

¹⁴ As of May 2013

¹⁵ As of May 2013

¹⁶ As of May 2013

Annex 4 – Members of the Committee for Medicinal Products for Veterinary Use

Chair: Anja HOLM (Vice-Chair: David MURPHY¹)

European Medicines Agency contact: David MACKAY

Members

- | | |
|---|---|
| • Zanda AUCE (Latvia) | Alternate: Arvils JAKOVSKIS |
| • Ewa AUGUSTYNOWICZ (Poland) | Alternate: Anna WACHNIK-ŚWIĘCICKA ² |
| • Jiří BUREŠ (Czech Republic) | Alternate: Leona NEPEJCHALOVÁ |
| • João Pedro DUARTE DA SILVA (Portugal) | Alternate: Maria AZEVEDO MENDES |
| • Irmeli HAPPONEN (Finland) | Alternate: Kristina LEHMANN |
| • Judita HEDEROVÁ (Slovakia) | Alternate: Eva CHOBOTOVÁ |
| • Cornelia IBRAHIM (Germany) | Alternate: Esther WERNER |
| • Damyan ILIEV (Bulgaria) | Alternate: Bogdan AMINKOV ³ |
| • Helen JUKES (United Kingdom) | Alternate: Anna-Maria BRADY |
| • Gábor KULCSÁR ⁴ (Hungary) | Alternate: Tibor SOÓS ⁵ |
| • Eva LANDER PERSSON ⁶ (Sweden) | Alternate: Frida HASSLUNG-WIKSTRÖM ⁷ |
| • Johann LENHARDSSON (Iceland) | Alternate: no nomination ⁸ |
| • Petras MAČIULSKIS (Lithuania) | Alternate: Ugne ZYMANTAITE |
| • Ioannis MALEMIS (Greece) | Alternate: Angeliki TSIGOURI |
| • Alia MICHAELIDOU-PATSIA ⁹ (Cyprus) | Alternate: no nomination |
| • Cristina MUÑOZ MADERO (Spain) | Alternate: Consuelo RUBIO MONTEJANO |
| • David MURPHY (Ireland) | Alternate: Gabriel BEECHINOR |
| • Hans Kristian ØSTENSEN (Norway) | Alternate: Hanne BERGENDAHL |
| • Jean-Claude ROUBY (France) | Alternate: Michael HOLZHAUSER-ALBERTI |
| • G. Johan SCHEFFERLIE (Netherlands) | Alternate: Peter HEKMAN |
| • Marc SCHMIT (Luxembourg) | Alternate: Marcel BRUCH ¹⁰ |
| • Stephen SPITERI (Malta) | Alternate: no nomination |
| • Stane SRČIČ (Slovenia) | Alternate: Katarina STRAUS |

¹ Replaced G. Johan SCHEFFERLIE as of July 2013 CVMP meeting

² Replaced Anna LUTYNSKA as of April 2013 CVMP meeting

³ Replaced Lubomir LASHEV as of July 2013 CVMP meeting

⁴ As of June 2013 CVMP meeting

⁵ As of June 2013 CVMP meeting

⁶ Replaced Karolina Törneke as of December 2013 CVMP meeting

⁷ Replaced Eva Lander-Persson as of December 2013 CVMP meeting

⁸ Halldór Runolfsson resigned as of February 2013 CVMP meeting

⁹ Replaced Ioanna Talioti as of December 2013 CVMP meeting

¹⁰ As of October 2013 meeting

- Lollita Sanda Camelia TABAN (Romania) Alternate: Simona STURZU
- Toomas TIIRATS¹¹ (Estonia) Alternate: no nomination
- Maria TOLLIS (Italy) Alternate: Virgilio DONINI
- Bruno URBAIN (Belgium) Alternate: Frédéric KLEIN
- Ellen-Margrethe VESTERGAARD (Denmark) Alternate: Merete BLIXENKRONE-MØLLER
- Barbara ZEMANN (Austria) Alternate: Ines LINDNER¹²

Co-opted members

- Keith BAPTISTE¹³ (Denmark)
- Rory BREATHNACH (Ireland)
- Christian FRIIS (Denmark)
- Boris KOLAR (Slovenia)
- Wilhelm SCHLUMBOHM (Germany)

Working parties, ad hoc groups and scientific advisory groups

Efficacy Working Party

Chair: Gesine HAHN

EMA contact: Fia WESTERHOLM¹⁴

Safety Working Party

Chair: Eva LANDER-PERSSON¹⁵

EMA contact: Isaura DUARTE

Immunologicals Working Party

Chair: Esther WERNER¹⁶

EMA contact: Fia WESTERHOLM

Scientific Advice Working Party

Chair: Rory BREATHNACH

EMA contact: Fia WESTERHOLM

Pharmacovigilance Working Party

Chair: Peter EKSTRÖM

EMA contact: Isaura DUARTE

Antimicrobial Working Party¹⁷

Chair: Helen JUKES¹⁸

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: Boris KOLAR

EMA contact: Isaura DUARTE

CMDv

Chair: Esther WERNER

EMA contact: Melanie LEIVERS

¹¹ As of April 2013 CVMP meeting

¹² Replaced Barbara ZEMANN as of February 2013 CVMP meeting

¹³ Replaced Claire Chauvin as of January 2013 CVMP meeting

¹⁴ Replaced Jill Kieffer as of January 2013

¹⁵ Replaced G. Johan Schefferlie as of December 2013

¹⁶ Replaced Jean-Claude Rouby as of December 2013

¹⁷ The Scientific Advisory Group on Antimicrobials became a working party as of January 2013 CVMP meeting

¹⁸ Replaced Karolina Törneke as of January 2013

Joint CHMP/CVMP JEG 3Rs

Chair: Sonja BEKEN

EMA contact: JEG-3Rs@ema.europa.eu

Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Bruno SEPODES

EMA contact: Jordi LLINARES GARCIA

Members

- Adriana ANDRIĆ¹ (Croatia)
- Brigitte BLÖCHL-DAUM (Austria)
- Irena BRADINOVA (Bulgaria)
- Birthe BYSKOV HOLM (patients' organisation representative)
- Albert CILIA VINCENTI (Malta)
- Ana CORRÊA NUNES (Portugal)
- Bożenna DEMBOWSKA-BAGIŃSKA (Poland)
- Judit EGGENHOFER (Hungary)
- Marie Pauline EVERS (patients' organisation representative)
- Lars GRAMSTAD (Norway)
- Lesley GREENE (patients' organisation representative) (*Vice-Chair*)
- Ioannis KKOLOS (Cyprus)
- Dainis KRIEVINS (Latvia)
- Kateřina KUBÁČKOVÁ (Czech Republic)
- André LHOIR (Belgium)
- Annie LORENCE (France)
- Armando MAGRELLI (Italy)
- Aušra MATULEVIČIENĖ (Lithuania)
- Henri METZ (Luxembourg)
- Aikaterini MORAITI (EMA representative)
- Martin MOŽINA (Slovenia)
- Frauke NAUMANN-WINTER² (Germany)
- Daniel O'CONNOR (United Kingdom)
- Geraldine O'DEA (Ireland)
- Veijo SAANO (Finland)
- Flavia SALEH (Romania)
- Violeta STOYANOVA-BENINSKA (Netherlands)

¹ Joined the Committee following the EU enlargement as of July 2013 meeting

² Replaced Rembert ELBERS as of June 2013 meeting

- Nikolaos SYPSAS (Greece)
- Sigurður THORSTEINSSON (Iceland)
- Vallo TILLMANN (Estonia)
- Josep TORRENT-FARNELL (Spain)
- Kerstin WESTERMARK (Sweden)
- *Awaiting nomination*³ (Denmark)
- *Awaiting nomination* (Slovak Republic)
- *Awaiting nomination*⁴ (EMA representative)
- *Awaiting nomination* (EMA representative)

Working parties, ad hoc groups and scientific advisory groups

Ad hoc group on efficiency improvement

Chair: Lesley GREENE

EMA contact: Jordi LLINARES GARCIA

Ad hoc group on biomarkers project

Chair: Marie Pauline EVERS

EMA contact: Stylianos TSIGKOS

³ Dorte MEYER resigned following the May 2013 meeting

⁴ János BORVENDÉG resigned following the May 2013 meeting

Annex 6 – Members of the Committee on Herbal Medicinal Products

Chair: Werner KNÖSS¹

EMA contact: Anthony HUMPHREYS

Members

- Linda ANDERSON (United Kingdom) Alternate: Sue HARRIS
- Everaldo ATTARD (Malta) Alternate: Andre MANGANI
- Mariette BACKES-LIES (Luxembourg) Alternate: Jacqueline GENOUX-HAMES
- Steffen BAGER (Denmark) Alternate: Nina DÜRR
- Zsuzsanna BIRÓ-SÁNDOR (Hungary) Alternate: Rita NÉMETH²
- Ioanna CHINOI (Greece) Alternate: Eleni SKAL TSA
- Per CLAESON (Sweden) Alternate: Barbro Gerden³
- Niamh CURRAN (Ireland) Alternate: Anna CUNNEY
- Marisa DELBÒ (Italy) (*Vice-Chair*)⁴ Alternate: Anna Maria SERRILLI⁵
- Wojciech DYMOWSKI (Poland) Alternate: Ewa BACKHAUS
- Nadia GRIGORAS (Romania) Alternate: Carmen PURDEL
- Marie HEROUTOVÁ (Czech Republic) Alternate: Markéta PŘÍHODOVÁ⁶
- Martina HUDECOVÁ (Slovakia)⁷ Alternate: Milan NAGY
- Dace KALKE (Latvia) Alternate: Baiba JANSONE
- Artūras KAŽEMEKAITIS (Lithuania) Alternate: Audronis LUKOŠIUS
- Ivan KOSALEC (Croatia)⁸ Alternate: Darko TRUMBETIĆ⁹
- Reinhard LÄNGER (Austria) Alternate: Astrid OBMANN¹⁰
- An Le (France)¹¹ Alternate: Jacqueline VIGUET POUPELLOZ
- Eeva Sofia LEINONEN (Finland) Alternate: Sari KOSKI
- Steinar MADSEN (Norway) Alternate: Gro FOSSUM
- Ana Paula MARTINS (Portugal) Alternate: Eva MENDES
- Elena MUSTAKEROVA (Bulgaria) Alternate: Irina NIKOLOVA

¹ Re-elected Chair as per November 2013 meeting

² Replaced Dezső CSUPOR as of April 2013

³ Replaced Barbro GERDEN as of February 2012

⁴ Elected Vice Chair as per November 2013 meeting

⁵ Alternate as of August 2013

⁶ Replaced Pavla MUZIKÁŘOVÁ as of September 2013

⁷ Replaced Ján SLÚKA as of October 2013

⁸ New EU Member State as per July 2013 meeting

⁹ New EU Member State as per July 2013 meeting

¹⁰ Replaced Martine SERNETZ as of July 2013

¹¹ Replaced Antoine SAWAYA as of September 2013

- Heidi NEEF (Belgium) Alternate: Wim VERVAET
- Adela NÚÑEZ VELÁZQUEZ (Spain) Alternate: *Awaiting nomination*
- Barbara RAZINGER (Slovenia)¹² Alternate: Samo KREFT¹³
- Evelin SAAR (Estonia) Alternate: Marje ZERNANT
- Panayiotis TRIANTAFYLLIS (Cyprus) Alternate: Maria STAVROU
- Emiel VAN GALEN (Netherlands) Alternate: Burt H. KROES
- Jacqueline WIESNER (Germany) Alternate: Birgit MERZ
- *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

- Izmir SHEHU (Albania)
- Saša PILIPOVIĆ (Bosnia and Herzegovina)
- Melanie BALD (Council of Europe, EDQM)
- Michael WIERER (Council of Europe, EDQM)
- Albana DIDA (Kosovo under UNSC Resolution 1244/99)
- Merjem HADJIHAMZA (Macedonia, The Former Yugoslav Republic of)¹⁴
- Milena ADZIC (Montenegro)¹⁵
- Dragan DJUROVIC (Serbia)

Working parties, ad hoc groups and scientific advisory groups

Working party on Community Monographs and Community List

Chair: Ioanna CHINOI

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

¹² Replaced Samo KREFT as of June 2013 (previously member)

¹³ Replaced Barbara RAZINGER as of June 2013 (previously alternate)

¹⁴ Replaced Dimche ZAFIROV replaced as of June 2013

¹⁵ Replaced Jasmina Krlić as of August 2013

Annex 7 – Members of the Paediatric Committee

Chair: Dirk MENTZER¹

EMA contact: Paolo TOMASI

Members

- Marina DIMOV DI GIUSTI (Croatia)² Alternate: Bernard Kaić
- 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
- Julia DUNNE (United Kingdom) Alternate: Angeliki SIAPKARA
- Helena FONSECA (Portugal) Alternate: Hugo TAVARES
- Viveca Lena ODLIND (Sweden)³ Alternate: Ninna GULLBERG⁴
- Agnes GYURASICS (CHMP, Hungary) Alternate: Melinda SOBOR⁵
- Stefan GROSEK (Slovenia)⁶ Alternate: Tadej AVCIN
- *Awaiting nomination* (Slovakia)⁷ Alternate: *Awaiting nomination*⁸
- Violeta IOTOVA (Bulgaria)⁹ Alternate: Vessela BOUDINOVA¹⁰
- Pirjo LAITINEN-PARKKONEN (Finland) Alternate: Ann Marie KAUKONEN
- Irja LUTSAR (Estonia) Alternate: Jana LASS¹¹
- Romaldas MAČIULAITIS (CHMP, Lithuania) Alternate: Rugile PILVINIENE
- Karl-Heinz HUEMER (Austria)¹² Alternate: Christoph MALE¹³
- Stefanos MANTAGOS (Greece) Alternate: *Awaiting nomination*
- Birka LEHMANN (Germany)¹⁴ Alternate: Immanuel BARTH¹⁵
- Marek MIGDAL (Poland) Alternate: Jolanta WITKOWSKA-OŻOGOWSKA
- Jaroslav STERBA (Czech Republic) Alternate: Peter SZITANYI

¹ Elected Chair as per September 2013 plenary

² New EU Member State as per July 2013 meeting

³ Replaced Marta GRANSTRÖM as of July 2013

⁴ Replaced Viveca Lena ODLIND as of July 2013

⁵ Replaced János BORVENDÉG as of June 2013

⁶ Replaced Janez JAZBEC of September 2013

⁷ Mandate of Vlasta KÁKOŠOVÁ expired as of May 2013

⁸ Mandate of Jan MAZAG expired as of May 2013

⁹ Replaced Dobrin KONSTANTINOV as of October 2013

¹⁰ Replaced Margarita GUIZOVA as of November 2013

¹¹ Replaced Alar IRS as of May 2013

¹² Replaced Christoph MALE as of July 2013

¹³ Replaced Karl-Heinz HUEMER as of July 2013

¹⁴ Replaced Dirk MENTZER as of September 2013

¹⁵ Replaced Birka LEHMANN as of September 2013

- Koenraad NORGA (Belgium) Vice-chair¹⁶ Alternate: Jacqueline CARLEER
- Marianne ORHOLM (Denmark) Alternate: Marta GRANSTRÖM¹⁷
- Gylfi OSKARSSON (Iceland) Alternate: Kolbeinn GUDMUNDSSON
- Sylvie BENCHETRIT (France)¹⁸ Alternate: *Awaiting nomination*
- Paolo ROSSI (Italy) Alternate: Francesca ROCCHI
- Georgios SAVVA (Cyprus)¹⁹ Alternate: Stefanos CHRISTODOULOU
- Hendrik van den BERG (The Netherlands) Alternate: Maaïke van DARTEL²⁰
- Dana Gabriela MARIN (CHMP, Romania)²¹ Alternate: Nela VILCEANU²²
- Siri WANG (Norway) Alternate: Ine BLANKENBERG SKOTTHEIM

Representatives of patients' and healthcare professionals' organisations

- Matthias KELLER (Patients organisation) Alternate: Gerlind BODE
- Michal ODERMARSKY (Patients organisation) Alternate: Milena STEVANOVIC
- Tsveta SCHYNS-LIHARSKA (Patients organisation) Alternate: Gerard NGUYEN
- Jean-Pierre ABOULKER (Health care professional) Alternate: Alexandra COMPAGNUCCI
- Adriana CECI (Health care professional) Alternate: Paolo PAOLUCCI
- Anthony NUNN (Health care professional) Alternate: *Awaiting nomination*

¹⁶ Elected Vice-chair as per September 2013 plenary

¹⁷ Replaced Dorthe MEYER as of June 2013

¹⁸ Replaced Gérard PONS as of July 2013

¹⁹ Replaced Andreas TELOUDES as of April 2013

²⁰ Replaced Johannes TAMINIAU as of July 2013

²¹ Replaced Nela VILCEANU as of November 2013

²² Replaced Dana Gabriela MARIN as of December 2013

Annex 8 – Committee for Advanced Therapies

Chair: Christian SCHNEIDER

EMA contact: Patrick CELIS

Members

Members nominated from within the CHMP

- John-Joseph BORG Alternate: Anthony SAMUEL
- Romaldas MAČIULAITIS Alternate: Jolanta GULBINOVIC
- Jean-Louis ROBERT Alternate: Guy BERCHEM
- Sol RUIZ Alternate: Marcos TIMÓN
- Bruno Sepodes¹ Alternate: Margarida MENEZES-FERREIRA

Members nominated by Member States

- Lennart ÅKERBLOM (Sweden) Alternate: Björn CARLSSON
- Jānis ANCĀNS (Latvia) Alternate: Ajine LINE
- Reynir ARNGRIMSSON (Iceland) Alternate: *Awaiting nomination*
- Claire BEUNEU (Belgium) Alternate: BELAÏD SEKKALI
- Zsuzsana BUZÁS (Hungary) Alternate: Balázs SARKADI
- Egbert FLORY (Germany) Alternate: Martina SCHÜSSLER LENZ
- Paolo GASPARINI (Italy) Alternate: Giulio COSSU
- Ivana HAUNEROVÁ (Check Republic) Alternate: Tomáš BORÁŇ
- Mikuláš HRUBIŠKO (Slovakia) Alternate: Ján KYSELOVIC
- Marit HYSTAD (Norway) Alternate: Rune KJEKEN
- Metoda LIPNIK (Slovenia) Alternate: Nevenka TRSINAR
- Toivo MAIMETS (Estonia) Alternate: Tarmo Tiido²
- Bridget HEELAN (UK)³ Alternate: James McBlane⁴
- Simona BADOI (Romania)⁵ Alternate: Gianina Andrei⁶
- Maura O'DONOVAN (Ireland) Alternate: Maeve Lally⁷
- Hans OVELGÖNNE (The Netherlands) Alternate: *Awaiting nomination*
- Anna PAPHITOU (Cyprus) Alternate: Maria VASILIOU

¹ CHMP/CAT member as of May 2013

² Replaced Pille Harrions in June 2013

³ Replaced Gopalan Narayanan in February and stood down in October 2013

⁴ Replaced Andrew Crosbie in February 2013

⁵ Replaced Monica Neagu in April 2013

⁶ Replaced Simona Badoi in April 2013

⁷ Replaced Niall MacAleenan in July 2013

- Ilona REISCHL (Austria) Alternate: Martin BRUNNER
- Paula SALMIKANGAS (Finland) Alternate: Olli TENHUNEN
- Dariusz SLADOWSKI (Poland) Alternate: Anna CIESLIK
- Lyubina TODOROVA (Bulgaria) Alternate: Vetslava TODOROVA
- Nicolas FERRY (France)⁸ Alternate: Sophie LUCAS SAMUEL
- Asterios TSIFTSOGLOU (Greece) Alternate: Angeliki ROPOTI
- Sinan Sarac (Denmark) Alternate: Nanna Aaby KRUSE
- Sandra Tomljenovic (Croatia)⁹ Alternate: Ivica Malnar

Observers

- Karl-Heinz Buchheit (EDQM)

Members representing patients' organisations¹⁰

- Michele Lipucci de Paola (EURORDIS) Alternate: Monica Ensini (EURORDIS)
- Kieran Breen (EPDA) Alternate: Mariette Driessens (EGAN)

Members representing clinicians¹¹

- Pieter Doevendans (ESCARDIO) Alternate: Esteve Trias-Adroher (EATB)
- Bernd Gänsbacher (IEO&T) Alternate: Ramadan Jashari (EATB)

⁸ Replaced J.-H. Trouvin in October 2012

⁹ New member state joined the EU in July 2013. Nominations of member and alternate

¹⁰ Commission decision from July 2013

¹¹ Commission decision from July 2013

Annex 9 – CHMP opinions in 2013 on medicinal products for human use

CHMP positive opinions 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 • Type of MA (*) | European Commission • Opinion received • Date of decision • Notification • Official Journal |
|--|---|--|---|--|
| • Abilify maintena • Aripiprazole | Otsuka Pharmaceutical Europe Ltd | • N05AX12 • treatment of schizophrenia | • 21/12/2012 • 19/09/2013 • 210 • 55 • STANDARD | • 23/09/2013 • 15/11/2013 • Not available • Not available |
| • Aubagio • Teriflunomide | Sanofi-Aventis Groupe | • L04AA • treatment of multiple sclerosis (MS) | • 21/02/2012 • 21/03/2013 • 201 • 190 • STANDARD | • 03/07/2013 • 26/08/2013 • 27/09/2013 • C282 |
| • Brintellix • Vortioxetine | H. Lundbeck A/S | • N06AX • treatment of major depressive episodes | • 18/09/2012 • 24/10/2013 • 210 • 188 • STANDARD | • 30/10/2013 • 18/12/2013 • Not available • Not available |
| • Cholib • Fenofibrate / simvastatin | Abbott Healthcare Products Ltd. | • C10 • is indicated as adjunctive therapy to reduce triglycerides and increase HDL-cholesterol levels | • 21/12/2011 • 27/06/2013 • 201 • 316 • STANDARD | • 04/07/2013 • 26/08/2013 • 27/09/2013 • C282 |
| • Erivedge • Vismodegib | Roche Registration Ltd | • L01 • the treatment of advanced basal cell carcinoma | • 21/12/2011 • 25/04/2013 • 208 • 281 • CONDITIONAL | • 07/05/2013 • 12/07/2013 • 28/06/2013 • C184 |
| • Evarrest • Human fibrinogen / human thrombin | Omrix Biopharmaceuticals N. V. | • B02BC30 • treatment of haemostasis and as an adjunct to haemostasis in bleeding. | • 21/03/2012 • 27/06/2013 • 201 • 260 • STANDARD | • Not available • 25/09/2013 • 25/10/2013 • C311 |
| • Fluenz tetra • Influenza vaccine (live attenuated, nasal) | MedImmune LLC | • J07BB03 • Prophylaxis of influenza in individuals 24 months to less than 18 years. | • 24/10/2012 • 19/09/2013 • 210 • 118 • STANDARD | • 23/09/2013 • 04/12/2013 • Not available • Not available |
| • Giotrif • Afatinib | Boehringer Ingelheim International GmbH | • L01XE13 • treatment of cell lung cancer (NSCLC) with Epidermal Growth Factor Receptor (EGFR) mutation(s). | • 19/09/2012 • 25/07/2013 • 210 • 97 • STANDARD | • 29/07/2013 • 25/09/2013 • 25/10/2013 • C311 |

| Product | Marketing authorisation holder | Therapeutic Area | EMA/CHMP | European Commission |
|--|---------------------------------------|---|--|--|
| <ul style="list-style-type: none"> • Brandname • INN | | <ul style="list-style-type: none"> • ATC Code • Summary of indication | <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal |
| <ul style="list-style-type: none"> • Hexacima • Diphtheria (d), tetanus (t), pertussis (acellular, component) (pa), hepatitis b (rdna) (hbv), poliomyelitis (inactivated) (ipv) and haemophilus influenzae type b (hib) conjugate vaccine (adsorbed) | Sanofi Pasteur | <ul style="list-style-type: none"> • J07CA09 • indicated of diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by Haemophilus influenzae type b. | <ul style="list-style-type: none"> • 19/09/2012 • 21/02/2013 • 117 (** Acc) • 39 • STANDARD | <ul style="list-style-type: none"> • 07/03/2013 • 17/04/2013 • 31/05/2013 • C154 |
| <ul style="list-style-type: none"> • Hexyon • Diphtheria (d), tetanus (t), pertussis (acellular, component) (pa), hepatitis b (rdna) (hbv), poliomyelitis (inactivated) (ipv) and haemophilus influenzae type b (hib) conjugate vaccine (adsorbed) | Sanofi Pasteur MSD, SNC | <ul style="list-style-type: none"> • J07CA09 • indicated of diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by Haemophilus influenzae type b. | <ul style="list-style-type: none"> • 19/09/2012 • 21/02/2013 • 116 (** Acc) • 39 • STANDARD | <ul style="list-style-type: none"> • 07/03/2013 • 17/04/2013 • 31/05/2013 • C154 |
| <ul style="list-style-type: none"> • Hyqvia • Human normal immunoglobulin | Baxter Innovations GmbH | <ul style="list-style-type: none"> • J06BA • Replacement therapy (primary immunodeficiency syndromes and secondary hypogammaglobulinemia). | <ul style="list-style-type: none"> • 18/10/2011 • 21/03/2013 • 201 • 316 • STANDARD | <ul style="list-style-type: none"> • 09/04/2013 • 16/05/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Imvanex • Modified vaccinia Ankara virus | Bavarian Nordic A/S | <ul style="list-style-type: none"> • J07BX • active immunisation against smallpox infection | <ul style="list-style-type: none"> • 21/03/2012 • 30/05/2013 • 209 • 224 • EXCEPTIONAL | <ul style="list-style-type: none"> • 12/06/2013 • 31/07/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Incresync • Alogliptin / pioglitazone | Takeda Pharma A/S | <ul style="list-style-type: none"> • A10BD09 • treatment of type 2 diabetes mellitus | <ul style="list-style-type: none"> • 19/06/2012 • 25/07/2013 • 210 • 160 • STANDARD | <ul style="list-style-type: none"> • 05/08/2013 • 19/09/2013 • 25/10/2013 • C311 |
| <ul style="list-style-type: none"> • Invokana • Canagliflozin | Janssen-Cilag International N.V. | <ul style="list-style-type: none"> • A10BX • treatment of type 2 diabetes mellitus | <ul style="list-style-type: none"> • 17/07/2012 • 19/09/2013 • 210 • 216 • STANDARD | <ul style="list-style-type: none"> • 26/09/2013 • 15/11/2013 • Not available • Not available |

| Product | Marketing authorisation holder | Therapeutic Area | EMA/CHMP | European Commission |
|---|---------------------------------------|--|--|--|
| <ul style="list-style-type: none"> • Brandname • INN | | <ul style="list-style-type: none"> • ATC Code • Summary of indication | <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal |
| <ul style="list-style-type: none"> • Izba • Travoprost | Alcon Laboratories (UK) Ltd | <ul style="list-style-type: none"> • S01EE04 • treatment of ocular hypertension or open-angle glaucoma | <ul style="list-style-type: none"> • 18/01/2013 • 18/12/2013 • 209 • 111 • STANDARD | <ul style="list-style-type: none"> • 15/01/2014 • 20/02/2014 • Not available • Not available |
| <ul style="list-style-type: none"> • Jetrea • Ocriplasmin | ThromboGenics NV | <ul style="list-style-type: none"> • S01 • treatment of symptomatic vitreomacular adhesion (VMA) | <ul style="list-style-type: none"> • 19/10/2011 • 17/01/2013 • 210 • 244 • STANDARD | <ul style="list-style-type: none"> • 24/01/2013 • 13/03/2013 • 26/04/2013 • C121 |
| <ul style="list-style-type: none"> • Kadcylla • Trastuzumab emtansine | Roche Registraton Ltd | <ul style="list-style-type: none"> • L01 • treatment of metastatic breast cancer | <ul style="list-style-type: none"> • 19/09/2012 • 19/09/2013 • 210 • 153 • STANDARD | <ul style="list-style-type: none"> • 24/09/2013 • 15/11/2013 • Not available • Not available |
| <ul style="list-style-type: none"> • Lemtrada • Alemtuzumab | Genzyme Therapeutics Ltd | <ul style="list-style-type: none"> • L04AA • treatment of multiple sclerosis (RRMS) | <ul style="list-style-type: none"> • 18/01/2013 • 27/06/2013 • 84 • 76 • STANDARD | <ul style="list-style-type: none"> • 12/07/2013 • 12/09/2013 • 25/10/2013 • C311 |
| <ul style="list-style-type: none"> • Lidocaine/prilocaine plethora • Lidocaine / prilocaïne | Plethora Solutions Ltd. | <ul style="list-style-type: none"> • N01BB20 • treatment of primary premature ejaculation in adult men. | <ul style="list-style-type: none"> • 20/06/2012 • 19/09/2013 • 210 • 244 • STANDARD | <ul style="list-style-type: none"> • 23/09/2013 • 15/11/2013 • Not available • Not available |
| <ul style="list-style-type: none"> • Lojuxta • Lomitapide | Aegerion Pharmaceuticals Limited | <ul style="list-style-type: none"> • C10AX • indicated as an adjunct to a low-fat diet | <ul style="list-style-type: none"> • 19/03/2012 • 30/05/2013 • 210 • 223 • EXCEPTIONAL | <ul style="list-style-type: none"> • 11/06/2013 • 31/07/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Lonquex • Lipegfilgrastim | Teva Pharma B.V. | <ul style="list-style-type: none"> • L03AA • Reduction in the duration of neutropenia and the incidence of febrile neutropenia | <ul style="list-style-type: none"> • 20/12/2011 • 30/05/2013 • 210 • 314 • STANDARD | <ul style="list-style-type: none"> • 07/06/2013 • 25/07/2013 • 30/08/2013 • C250 |
| <ul style="list-style-type: none"> • Mirvaso • Brimonidine | GALDERMA INTERNATIONAL | <ul style="list-style-type: none"> • D11 • treatment of facial erythema of rosacea | <ul style="list-style-type: none"> • 21/01/2013 • 19/12/2013 • 210 • 111 • STANDARD | <ul style="list-style-type: none"> • 14/01/2014 • 21/02/2014 • Not available • Not available |
| <ul style="list-style-type: none"> • Neuraceq • Florbetaben (18F) | Piramal Imaging GmbH | <ul style="list-style-type: none"> • V09AX • detection of β-amyloid in the brain | <ul style="list-style-type: none"> • 30/01/2013 • 19/12/2013 • 210 • 111 • STANDARD | <ul style="list-style-type: none"> • 08/01/2014 • 20/02/2014 • Not available • Not available |
| <ul style="list-style-type: none"> • Novoeight • Turoctocog alfa | Novo Nordisk A/S | <ul style="list-style-type: none"> • B02BD02 • Treatment of haemophilia A (congenital factor VIII deficiency). | <ul style="list-style-type: none"> • 21/11/2012 • 19/09/2013 • 210 • 90 • STANDARD | <ul style="list-style-type: none"> • 24/09/2013 • 13/11/2013 • Not available |

| Product | Marketing authorisation holder | Therapeutic Area | EMA/CHMP | European Commission |
|--|---|---|--|--|
| <ul style="list-style-type: none"> • Brandname • INN | | <ul style="list-style-type: none"> • ATC Code • Summary of indication | <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal |
| <ul style="list-style-type: none"> • Nuedexta • Dextromethorphan / quinidine | Jenson Pharmaceutical Services Ltd | <ul style="list-style-type: none"> • N07XX • treatment of pseudobulbar affect (PBA) | <ul style="list-style-type: none"> • 15/11/2011 • 25/04/2013 • 208 • 316 • STANDARD | <ul style="list-style-type: none"> • 02/05/2013 • 24/06/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Relvar ellipta • Fluticasone furoate / vilanterol | Glaxo Group Ltd | <ul style="list-style-type: none"> • R03AK • treatment of asthma and COPD | <ul style="list-style-type: none"> • 18/07/2012 • 19/09/2013 • 210 • 216 • STANDARD | <ul style="list-style-type: none"> • 30/09/2013 • 13/11/2013 • Not available • Not available |
| <ul style="list-style-type: none"> • Somatropin biopartners • Somatropin | BioPartners GmbH | <ul style="list-style-type: none"> • H01AC01 • indicated for the replacement therapy of endogenous growth hormone | <ul style="list-style-type: none"> • 22/02/2012 • 30/05/2013 • 209 • 252 • STANDARD | <ul style="list-style-type: none"> • 11/06/2013 • 05/08/2013 • 27/09/2013 • C282 |
| <ul style="list-style-type: none"> • Sovaldi • Sofosbuvir | Gilead Sciences International Ltd | <ul style="list-style-type: none"> • J05 • treatment of chronic hepatitis C (CHC) | <ul style="list-style-type: none"> • 21/05/2013 • 21/11/2013 • 152 (** Acc) • 32 • STANDARD | <ul style="list-style-type: none"> • 29/11/2013 • 16/01/2014 • Not available • Not available |
| <ul style="list-style-type: none"> • Spedra • Avanafil | Menarini International Operations Luxembourg S.A. | <ul style="list-style-type: none"> • G04BE • treatment of erectile dysfunction | <ul style="list-style-type: none"> • 20/03/2012 • 25/04/2013 • 210 • 188 • STANDARD | <ul style="list-style-type: none"> • 02/05/2013 • 21/06/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Stivarga • Regorafenib | Bayer Pharma AG | <ul style="list-style-type: none"> • L01XE21 • treatment of metastatic colorectal cancer (CRC) | <ul style="list-style-type: none"> • 23/05/2012 • 27/06/2013 • 210 • 188 • STANDARD | <ul style="list-style-type: none"> • 12/07/2013 • 26/08/2013 • 27/09/2013 • C282 |
| <ul style="list-style-type: none"> • Stribild • Elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil | Gilead Sciences International Ltd | <ul style="list-style-type: none"> • J05 • treatment of human immunodeficiency virus-1 (HIV-1) | <ul style="list-style-type: none"> • 20/12/2011 • 21/03/2013 • 201 • 253 • STANDARD | <ul style="list-style-type: none"> • 26/03/2013 • 24/05/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Tafinlar • Dabrafenib | GlaxoSmithKline Trading Services | <ul style="list-style-type: none"> • L01 • treatment of unresectable or metastatic melanoma with a BRAF V600 mutation | <ul style="list-style-type: none"> • 15/08/2012 • 27/06/2013 • 210 • 104 • STANDARD | <ul style="list-style-type: none"> • 08/07/2013 • 26/08/2013 • 27/09/2013 • C282 |
| <ul style="list-style-type: none"> • Tecfidera • Dimethyl fumarate | Biogen Idec Ltd | <ul style="list-style-type: none"> • N07XX • treatment of multiple sclerosis | <ul style="list-style-type: none"> • 21/03/2012 • 21/03/2013 • 201 • 162 • STANDARD | <ul style="list-style-type: none"> • 03/12/2013 • 30/01/2014 • Not available • Not available |
| <ul style="list-style-type: none"> • Tivicay • Dolutegravir | ViiV Healthcare | <ul style="list-style-type: none"> • J05 • treatment of Human Immunodeficiency Virus (HIV) | <ul style="list-style-type: none"> • 30/01/2013 • 21/11/2013 • 201 • 92 • STANDARD | <ul style="list-style-type: none"> • 28/11/2013 • 16/01/2014 • Not available • Not available |

| Product | Marketing authorisation holder | Therapeutic Area | EMA/CHMP | European Commission |
|---|---------------------------------------|--|--|--|
| <ul style="list-style-type: none"> • Brandname • INN | | <ul style="list-style-type: none"> • ATC Code • Summary of indication | <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal |
| <ul style="list-style-type: none"> • Tybost • Cobicistat | Gilead Sciences International Ltd | <ul style="list-style-type: none"> • J05 • indicated as a pharmacokinetic enhancer of the human immunodeficiency virus-1 (HIV-1) protease inhibitors atazanavir and darunavir in adults. | <ul style="list-style-type: none"> • 22/05/2012 • 25/07/2013 • 210 • 216 • STANDARD | <ul style="list-style-type: none"> • 26/07/2013 • 19/09/2013 • 25/10/2013 • C311 |
| <ul style="list-style-type: none"> • Ultibro breezhaler • Indacaterol / glycopyrronium bromide | Novartis Europharm Ltd | <ul style="list-style-type: none"> • R03 • treatment of chronic obstructive pulmonary disease (COPD) | <ul style="list-style-type: none"> • 24/10/2012 • 25/07/2013 • 201 • 71 • STANDARD | <ul style="list-style-type: none"> • 31/07/2013 • 19/09/2013 • 25/10/2013 • C311 |
| <ul style="list-style-type: none"> • Vipdomet • Alogliptin / metformin | Takeda Pharma A/S | <ul style="list-style-type: none"> • A10BD • treatment of diabetes mellitus | <ul style="list-style-type: none"> • 19/06/2012 • 25/07/2013 • 210 • 160 • STANDARD | <ul style="list-style-type: none"> • 05/08/2013 • 19/09/2013 • 25/10/2013 • C311 |
| <ul style="list-style-type: none"> • Vipidia • Alogliptin | Takeda Pharma A/S | <ul style="list-style-type: none"> • A10BH04 • indicated to improve glycaemic control in adult patients with type 2 diabetes mellitus | <ul style="list-style-type: none"> • 21/05/2012 • 25/07/2013 • 210 • 188 • STANDARD | <ul style="list-style-type: none"> • 05/08/2013 • 19/09/2013 • 25/10/2013 • C311 |
| <ul style="list-style-type: none"> • Vitakta • Elvitegravir | Gilead Sciences International Ltd | <ul style="list-style-type: none"> • J05AX11 • treatment of human immunodeficiency virus-1 (HIV-1) infection in antiretroviral treatment-experienced adults. | <ul style="list-style-type: none"> • 06/06/2012 • 19/09/2013 • 210 • 244 • STANDARD | <ul style="list-style-type: none"> • 24/09/2013 • 13/11/2013 • Not available • Not available |
| <ul style="list-style-type: none"> • Voncento • Human coagulation factor VIII / human von willebrand factor | CSL Behring GmbH | <ul style="list-style-type: none"> • B02BD06 • treatment and prevention of bleedings in von Willebrand disease (VWD) and Haemophilia A (congenital FVIII deficiency) | <ul style="list-style-type: none"> • 21/12/2011 • 30/05/2013 • 210 • 314 • STANDARD | <ul style="list-style-type: none"> • 21/06/2013 • 12/08/2013 • 27/09/2013 • C282 |
| <ul style="list-style-type: none"> • Xigduo • Dapagliflozin / metformin | Bristol-Myers Squibb/AstraZeneca EEIG | <ul style="list-style-type: none"> • A10B • treatment of type 2 diabetes mellitus | <ul style="list-style-type: none"> • 26/12/2012 • 21/11/2013 • 210 • 118 • STANDARD | <ul style="list-style-type: none"> • 27/11/2013 • 16/01/2014 • Not available |
| <ul style="list-style-type: none"> • Xofigo • Radium-223 | Bayer Pharma AG | <ul style="list-style-type: none"> • V10 • treatment of castration-resistant prostate cancer | <ul style="list-style-type: none"> • 28/01/2013 • 19/09/2013 • 183 (** Acc) • 50 • STANDARD | <ul style="list-style-type: none"> • 23/09/2013 • 13/11/2013 • Not available • Not available |

| Product | Marketing authorisation holder | Therapeutic Area | EMA/CHMP | European Commission |
|--|---------------------------------------|--|--|--|
| <ul style="list-style-type: none"> • Brandname • INN | | <ul style="list-style-type: none"> • ATC Code • Summary of indication | <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal |
| <ul style="list-style-type: none"> • Xoterna breezhaler • Indacaterol / glycopyrronium bromide | Novartis Europharm Ltd | <ul style="list-style-type: none"> • R03 • treatment of chronic obstructive pulmonary disease (COPD) | <ul style="list-style-type: none"> • 27/03/2013 • 25/07/2013 • 51 • 69 • STANDARD | <ul style="list-style-type: none"> • 30/07/2013 • 19/09/2013 • 25/10/2013 • C311 |
| <ul style="list-style-type: none"> • Xtandi • Enzalutamide | Astellas Pharma Europe B.V. | <ul style="list-style-type: none"> • L01 • treatment of prostate cancer | <ul style="list-style-type: none"> • 15/08/2012 • 25/04/2013 • 210 • 41 • STANDARD | <ul style="list-style-type: none"> • 16/05/2013 • 21/06/2013 • 28/06/2013 • C184 |

(*) This indicates whether the medicine was granted a positive opinion for a standard 5-year marketing authorisation, a conditional marketing authorisation or an authorisation under exceptional circumstances

(** Acc) means that the opinion was granted after an accelerated assessment

CHMP positive opinions on orphan medicinal products for human use

| Product <ul style="list-style-type: none"> • Brandname • INN | Marketing authorisation holder | Therapeutic Area <ul style="list-style-type: none"> • ATC Code • Summary of indication | EMA/CHMP <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal |
|--|----------------------------------|---|---|--|
| <ul style="list-style-type: none"> • Bosulif • Bosutinib | Pfizer Limited | <ul style="list-style-type: none"> • L01XE14 • treatment of myelogenous leukemia | <ul style="list-style-type: none"> • 17/08/2011 • 17/01/2013 • 210 • 307 • CONDITIONAL | <ul style="list-style-type: none"> • 24/01/2013 • 27/03/2013 • 26/04/2013 • C121 |
| <ul style="list-style-type: none"> • Cholic acid fgl • Cholic acid | FGK Representative Service GmbH | <ul style="list-style-type: none"> • A05AA03 • treatment of inborn errors of primary bile acid synthesis | <ul style="list-style-type: none"> • 20/03/2012 • 21/11/2013 • 182 • 370 • EXCEPTIONAL | <ul style="list-style-type: none"> • 27/11/2013 • Not available • Not available • Not available |
| <ul style="list-style-type: none"> • Cometriq • Cabozantinib | TMC Pharma Services Ltd | <ul style="list-style-type: none"> • L01XE • treatment of medullary thyroid carcinoma. | <ul style="list-style-type: none"> • 21/11/2012 • 19/12/2013 • 210 • 181 • CONDITIONAL | <ul style="list-style-type: none"> • 08/01/2014 • Not available • Not available • Not available |
| <ul style="list-style-type: none"> • Iclusig • Ponatinib | ARIAD Pharma Ltd | <ul style="list-style-type: none"> • L01XE • treatment of chronic myeloid leukaemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) | <ul style="list-style-type: none"> • 14/09/2012 • 21/03/2013 • 152 (** Acc) • 32 • STANDARD | <ul style="list-style-type: none"> • 27/03/2013 • 01/07/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Imnovid • Pomalidomide | Celgene Europe Limited | <ul style="list-style-type: none"> • L04 • in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma (MM) | <ul style="list-style-type: none"> • 19/06/2012 • 30/05/2013 • 210 • 132 • STANDARD | <ul style="list-style-type: none"> • 14/06/2013 • 05/08/2013 • 27/09/2013 • C282 |
| <ul style="list-style-type: none"> • Opsumit • Macitentan | Actelion Registration Ltd. | <ul style="list-style-type: none"> • C02 • treatment of pulmonary arterial hypertension (PAH) | <ul style="list-style-type: none"> • 20/11/2012 • 24/10/2013 • 208 • 127 • STANDARD | <ul style="list-style-type: none"> • 04/11/2013 • 20/12/2013 • Not available • Not available |
| <ul style="list-style-type: none"> • Para-aminosalicylic acid Lucane • Aminosalicilic acid | Lucane Pharma SAS | <ul style="list-style-type: none"> • J04AA01 • treatment of tuberculosis | <ul style="list-style-type: none"> • 21/03/2012 • 29/11/2013 • 218 • 398 • STANDARD | <ul style="list-style-type: none"> • 04/12/2013 • Not available • Not available |
| <ul style="list-style-type: none"> • Procsybi • Mercaptamine | Raptor Pharmaceuticals Europe BV | <ul style="list-style-type: none"> • A16AA04 • indicated for the management of cystinosis | <ul style="list-style-type: none"> • 21/03/2012 • 27/06/2013 • 201 • 260 • STANDARD | <ul style="list-style-type: none"> • 08/07/2013 • 06/09/2013 • 25/10/2013 • C311 |

| Product • Brandname • INN | Marketing authorisation holder | Therapeutic Area • ATC Code • Summary of indication | EMA/CHMP • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | European Commission • Opinion received • Date of decision • Notification • Official Journal |
|--|---------------------------------------|--|---|--|
| • Sirturo • Bedaquiline | Janssen-Cilag International N.V. | • J04A • treatment of pulmonary tuberculosis | • 17/09/2012 • 19/12/2013 • 210 • 244 • CONDITIONAL | • 13/01/2014 • 05/03/2014 • Not available • Not available |

(*) This indicates whether the medicine was granted a positive opinion for a standard 5-year marketing authorisation, a conditional marketing authorisation or an authorisation under exceptional circumstances

(** Acc) means that the opinion was granted after an accelerated assessment

CHMP positive opinions on orphan medicinal products for human use - after re-examination procedure

| Product • Brandname • INN | Marketing authorisation holder | Therapeutic Area • ATC Code • Summary of indication | EMA/CHMP • Validation • Date of 1st opinion • Outcome of 1st opinion • Date of 2nd opinion • Outcome of 2nd opinion • Type of MA (*) | European Commission • Date of decision • Notification • Official Journal |
|--|---------------------------------------|---|---|--|
| • Defitelio • Defibrotide | Gentium S.p.A. | • B01AX01 • prevention and treatment of hepatic veno-occlusive disease | • 25/05/2011 • 21/03/2013 • NEGATIVE • 25/07/2013 • POSITIVE • EXCEPTIONAL | • 18/10/2013 • Not available • Not available |
| • Deltyba • Delamanid | Otsuka Novel Products GmbH | • J04A • treatment of multidrug-resistant tuberculosis (MDR-TB) | • 21/12/2011 • 25/07/2013 • NEGATIVE • 05/12/2013 • POSITIVE • CONDITIONAL | • Not available • Not available • Not available |

CHMP positive opinions on generic medicinal products for human use and hybrid, informed consent and well-established use applications

| Product | Marketing authorisation holder | Therapeutic Area | EMA/CHMP | European Commission |
|---|---|--|--|--|
| <ul style="list-style-type: none"> • Brandname • INN | | <ul style="list-style-type: none"> • ATC Code • Summary of indication | <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal |
| <ul style="list-style-type: none"> • Actelsar HCT • Telmisartan / Hydrochlorothiazide | Actavis Group hf | <ul style="list-style-type: none"> • C09DA07 • treatment of essential hypertension | <ul style="list-style-type: none"> • 23/05/2012 • 17/01/2013 • 210 • 27 • STANDARD | <ul style="list-style-type: none"> • 23/01/2013 • 13/03/2013 • 26/04/2013 • C121 |
| <ul style="list-style-type: none"> • Atosiban Sun • Atosiban | Sun Pharmaceutical Industries Europe B.V. | <ul style="list-style-type: none"> • G02CX01 • indicated to delay imminent pre-term birth in pregnant adult women | <ul style="list-style-type: none"> • 10/09/2012 • 30/05/2013 • 182 • 72 • STANDARD | <ul style="list-style-type: none"> • 30/05/2013 • 31/07/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Capecitabine Sun • Capecitabine | Sun Pharmaceutical Industries Europe B.V. | <ul style="list-style-type: none"> • L01BC06 • treatment of cancer | <ul style="list-style-type: none"> • 19/06/2012 • 25/04/2013 • 208 • 99 • STANDARD | <ul style="list-style-type: none"> • Not available • 21/06/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Imatinib Accord • Imatinib | Accord Healthcare Limited | <ul style="list-style-type: none"> • L01XE01 • treatment of leukaemia | <ul style="list-style-type: none"> • 20/06/2012 • 25/04/2013 • 182 • 128 • STANDARD | <ul style="list-style-type: none"> • 30/04/2013 • 01/07/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Imatinib Actavis • Imatinib | Actavis Group PTC ehf | <ul style="list-style-type: none"> • L01XE01 • the treatment of Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML) | <ul style="list-style-type: none"> • 21/12/2011 • 21/02/2013 • 210 • 216 • STANDARD | <ul style="list-style-type: none"> • 28/02/2013 • 17/04/2013 • 31/05/2013 • C154 |
| <ul style="list-style-type: none"> • Imatinib Medac • Imatinib | Medac | <ul style="list-style-type: none"> • L01XE01 • treatment of leukaemia | <ul style="list-style-type: none"> • 24/10/2012 • 25/07/2013 • 182 • 93 • STANDARD | <ul style="list-style-type: none"> • 05/08/2013 • 25/09/2013 • 25/10/2013 • C311 |
| <ul style="list-style-type: none"> • Levetiracetam Hospira • Levetiracetam | HOSPIRA UK LIMITED | <ul style="list-style-type: none"> • N03AX14 • the treatment of seizures | <ul style="list-style-type: none"> • 26/12/2012 • 24/10/2013 • 208 • 92 • STANDARD | <ul style="list-style-type: none"> • 27/11/2013 • 08/01/2014 • Not available |
| <ul style="list-style-type: none"> • Levodopa/Carbidopa/Entacapone Sandoz • Levodopa / Carbidopa / Entacapone | Orion Corporation | <ul style="list-style-type: none"> • N04BA03 • treatment of adult patients with treatment of Parkinson's disease | <ul style="list-style-type: none"> • 25/04/2013 • 19/09/2013 • 92 • 53 • STANDARD | <ul style="list-style-type: none"> • 23/09/2013 • 11/11/2013 • Not available • Not available |
| <ul style="list-style-type: none"> • Marixino • Memantine | Consilient Health Ltd. | <ul style="list-style-type: none"> • N06DX01 • treatment of Alzheimer's disease | <ul style="list-style-type: none"> • 19/06/2012 • 17/01/2013 • 182 • 30 • STANDARD | <ul style="list-style-type: none"> • 24/01/2013 • 29/04/2013 • 31/05/2013 • C154 |

| Product | Marketing authorisation holder | Therapeutic Area | EMA/CHMP | European Commission |
|--|---------------------------------------|--|--|--|
| <ul style="list-style-type: none"> • Brandname • INN | | <ul style="list-style-type: none"> • ATC Code • Summary of indication | <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal |
| <ul style="list-style-type: none"> • Memantine Accord • Memantine | Accord Healthcare Limited | <ul style="list-style-type: none"> • N06DX01 • Treatment of Alzheimer's disease. | <ul style="list-style-type: none"> • 18/09/2012 • 19/09/2013 • 210 • 153 • STANDARD | <ul style="list-style-type: none"> • 23/09/2013 • 04/12/2013 • Not available • Not available |
| <ul style="list-style-type: none"> • Memantine Lek • Memantine | Pharmathen S.A. | <ul style="list-style-type: none"> • N06DX01 • Treatment of Alzheimer's disease. | <ul style="list-style-type: none"> • 19/06/2012 • 21/02/2013 • 182 • 65 • STANDARD | <ul style="list-style-type: none"> • 28/02/2013 • 22/04/2013 • 31/05/2013 • C154 |
| <ul style="list-style-type: none"> • Memantine Mylan • Memantine | Generics (UK) Limited | <ul style="list-style-type: none"> • N06DX01 • treatment of Alzheimer's disease | <ul style="list-style-type: none"> • 18/07/2012 • 21/02/2013 • 182 • 37 • STANDARD | <ul style="list-style-type: none"> • 01/03/2013 • 22/04/2013 • Not available • Not available |
| <ul style="list-style-type: none"> • Memantine Ratiopharm • Memantine | ratiopharm GmbH | <ul style="list-style-type: none"> • N06DX01 • treatment of Alzheimer's disease | <ul style="list-style-type: none"> • 19/06/2012 • 21/03/2013 • 210 • 62 • STANDARD | <ul style="list-style-type: none"> • 26/03/2013 • 13/06/2013 • 30/08/2013 • C250 |
| <ul style="list-style-type: none"> • Nemdatine • Memantine | Actavis Group PTC ehf | <ul style="list-style-type: none"> • N06DX01 • treatment of Alzheimer's disease | <ul style="list-style-type: none"> • 19/06/2012 • 21/02/2013 • 208 • 36 • STANDARD | <ul style="list-style-type: none"> • 04/03/2013 • 22/04/2013 • 31/05/2013 • C154 |
| <ul style="list-style-type: none"> • Nexium Control • Esomeprazole | AstraZeneca AB | <ul style="list-style-type: none"> • A02BC05 • short-term treatment of reflux symptoms in adults. | <ul style="list-style-type: none"> • 17/07/2012 • 27/06/2013 • 210 • 132 • STANDARD | <ul style="list-style-type: none"> • 08/07/2013 • 26/08/2013 • 27/09/2013 • C282 |
| <ul style="list-style-type: none"> • Pheburane • Sodium Phenylbutyrate | Lucane Pharma | <ul style="list-style-type: none"> • A16AX03 • treatment of chronic management of urea cycle disorders | <ul style="list-style-type: none"> • 21/03/2012 • 21/02/2013 • 210 • 125 • STANDARD | <ul style="list-style-type: none"> • 01/03/2013 • 31/07/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Stayveer • Bosentan | Marklas Nederlands BV | <ul style="list-style-type: none"> • C02KX01 • Treatment of pulmonary arterial hypertension (PAH) | <ul style="list-style-type: none"> • 14/10/2012 • 21/03/2013 • 61 • 0 • STANDARD | <ul style="list-style-type: none"> • 09/04/2013 • 24/06/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Tolucombi • Telmisartan / Hydrochlorothiazide | Krka d.d. Novo mesto | <ul style="list-style-type: none"> • C09DA07 • treatment of essential hypertension | <ul style="list-style-type: none"> • 23/05/2012 • 17/01/2013 • 210 • 27 • STANDARD | <ul style="list-style-type: none"> • 28/01/2013 • 13/03/2013 • 26/04/2013 • C121 |

| Product • Brandname • INN | Marketing authorisation holder | Therapeutic Area • ATC Code • Summary of indication | EMA/CHMP • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | European Commission • Opinion received • Date of decision • Notification • Official Journal |
|---|---------------------------------------|--|--|--|
| <ul style="list-style-type: none"> • Voriconazole Accord • Voriconazole | Accord Healthcare Limited | <ul style="list-style-type: none"> • J02AC03 • Treatment of invasive aspergillosis, candidemia in non-neutropenic patients, fluconazole-resistant serious invasive Candida infections (including C. krusei), fungal infections caused by Scedosporium spp. and Fusarium spp. | <ul style="list-style-type: none"> • 20/06/2012 • 21/03/2013 • 182 • 93 • STANDARD | <ul style="list-style-type: none"> • 27/03/2013 • 16/05/2013 • 28/06/2013 • C184 |
| <ul style="list-style-type: none"> • Zoledronic Acid Accord • Zoledronic Acid | Accord Healthcare Limited | <ul style="list-style-type: none"> • M05BA08 • Prevention of skeletal related events and treatment of tumour-induced hypercalcaemia (TIH) | <ul style="list-style-type: none"> • 23/05/2012 • 21/11/2013 • 210 • 335 • STANDARD | <ul style="list-style-type: none"> • 27/11/2013 • 16/01/2014 • Not available • Not available |

(*) This indicates whether the medicine was granted a positive opinion for a standard 5-year marketing authorisation, a conditional marketing authorisation or an authorisation under exceptional circumstances

CHMP positive opinions on similar biological medicinal products for human use

| Product • Brandname • INN | Marketing authorisation holder | Therapeutic Area • ATC Code • Summary of indication | EMA/CHMP • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | European Commission • Opinion received • Date of decision • Notification • Official Journal |
|---|---------------------------------------|--|--|--|
| <ul style="list-style-type: none"> • Grastofil • Filgrastim | Apotex Europe BV | <ul style="list-style-type: none"> • L03AA02 • treatment of neutropenia | <ul style="list-style-type: none"> • 22/05/2012 • 25/07/2013 • 210 • 216 • STANDARD | <ul style="list-style-type: none"> • 05/08/2013 • 18/10/2013 • Not available • Not available |
| <ul style="list-style-type: none"> • Inflectra • Infliximab | HOSPIRA UK LIMITED | <ul style="list-style-type: none"> • L04AB02 • treatment of Rheumatoid arthritis, Adult and Paediatric Crohn's disease, Ulcerative colitis, Ankylosing spondylitis, Psoriatic arthritis, Psoriasis | <ul style="list-style-type: none"> • 13/07/2012 • 27/06/2013 • 89 • 260 • STANDARD | <ul style="list-style-type: none"> • 07/08/2013 • 10/09/2013 • 25/10/2013 • C311 |

| Product • Brandname • INN | Marketing authorisation holder | Therapeutic Area • ATC Code • Summary of indication | EMA/CHMP • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | European Commission • Opinion received • Date of decision • Notification • Official Journal |
|---|---------------------------------------|--|--|--|
| <ul style="list-style-type: none"> Ovaleap Follitropin alfa | Teva Pharma B.V. | <ul style="list-style-type: none"> G03GA05 treatment of anovulation (including polycystic ovarian syndrome) in women and stimulation of spermatogenesis in men. | <ul style="list-style-type: none"> 21/03/2012 25/07/2013 210 279 STANDARD | <ul style="list-style-type: none"> 14/08/2013 27/09/2013 25/10/2013 C311 |
| <ul style="list-style-type: none"> Remsima Infliximab | Celltrion Healthcare Hungary Kft. | <ul style="list-style-type: none"> L04AB02 treatment of Rheumatoid arthritis, Adult and Paediatric Crohn's disease, Ulcerative colitis, Ankylosing spondylitis, Psoriatic arthritis, Psoriasis | <ul style="list-style-type: none"> 21/03/2012 27/06/2013 201 260 STANDARD | <ul style="list-style-type: none"> 04/07/2013 10/09/2013 25/10/2013 C311 |

(*) This indicates whether the medicine was granted a positive opinion for a standard 5-year marketing authorisation, a conditional marketing authorisation or an authorisation under exceptional circumstances

CHMP positive opinions on advanced therapy medicinal products

| Product • Brandname • INN | Marketing authorisation holder | Therapeutic Area • ATC Code • Summary of indication | EMA/CHMP • Validation • Opinion • Active Time • Clock stop • Type of MA (*) | European Commission • Opinion received • Date of decision • Notification • Official Journal |
|--|---------------------------------------|---|--|--|
| <ul style="list-style-type: none"> MACI Matrix applied characterised autologous cultured chondrocytes | Genzyme Europe BV | <ul style="list-style-type: none"> M09AX02 repair of symptomatic cartilage defects of the knee | <ul style="list-style-type: none"> 20/09/2011 25/04/2013 205 375 STANDARD | <ul style="list-style-type: none"> 13/05/2013 27/06/2013 28/06/2013 C184 |
| <ul style="list-style-type: none"> Provenge Autologous peripheral blood mononuclear cells activated with pap-gm-csf (sipuleucel-t) | Dendreon UK LTD | <ul style="list-style-type: none"> L03AX17 treatment of metastatic castrate resistant prostate cancer | <ul style="list-style-type: none"> 25/01/2012 27/06/2013 201 284 STANDARD | <ul style="list-style-type: none"> 08/07/2013 06/09/2013 25/10/2013 C311 |

(*) This indicates whether the medicine was granted a positive opinion for a standard 5-year marketing authorisation, a conditional marketing authorisation or an authorisation under exceptional circumstances

CHMP positive opinions in the context of cooperation with the World Health Organization (WHO) for the evaluation of medicinal products intended exclusively for markets outside the European Union (EU)

| Product | Marketing authorisation holder | Therapeutic Area | EMA/CHMP |
|--|---------------------------------------|--|--|
| <ul style="list-style-type: none"> • Brandname • INN | | <ul style="list-style-type: none"> • ATC Code • Summary of indication | <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop |
| <ul style="list-style-type: none"> • Tritanrix HB • diphtheria (d), tetanus (t), pertussis (whole cell) (pw) and hepatitis b (rdna) (hbn) vaccine (adsorbed) | GlaxoSmithKline Biologicals S.A. | <ul style="list-style-type: none"> • J07CA05 • indicated for active immunisation against diphtheria, tetanus, pertussis and hepatitis B indicated for active immunisation against diphtheria, tetanus, pertussis and hepatitis B (HBV) | <ul style="list-style-type: none"> • 20/10/2013 • 19/12/2013 • 61 • 0 |

CHMP opinions in 2013 on medicinal products subject to a re-examination procedure

| Product | Marketing authorisation holder | Therapeutic Area | EMA/CHMP | European Commission |
|--|---------------------------------------|---|--|--|
| <ul style="list-style-type: none"> • Brandname • INN | | <ul style="list-style-type: none"> • ATC Code • Summary of indication | <ul style="list-style-type: none"> • Validation • Date of 1st opinion • Outcome of 1st opinion • Date of 2nd opinion • Outcome of 2nd opinion • Type of MA (*) | <ul style="list-style-type: none"> • Date of decision • Notification • Official Journal |
| <ul style="list-style-type: none"> • Aubagio • Teriflunomide | Sanofi-Aventis Groupe | <ul style="list-style-type: none"> • L04AA • treatment of multiple sclerosis (MS) | <ul style="list-style-type: none"> • 21/02/2012 • 21/03/2013 • POSITIVE • 27/06/2013 • POSITIVE • STANDARD | <ul style="list-style-type: none"> • 26/08/2013 • 27/09/2013 • C282 |
| <ul style="list-style-type: none"> • Defitelio • Defibrotide | Gentium S.p.A. | <ul style="list-style-type: none"> • B01AX01 • prevention and treatment of hepatic veno-occlusive disease | <ul style="list-style-type: none"> • 25/05/2011 • 21/03/2013 • NEGATIVE • 25/07/2013 • POSITIVE • EXCEPTIONAL | <ul style="list-style-type: none"> • 18/10/2013 • Not available • Not available |
| <ul style="list-style-type: none"> • Deltyba • Delamanid | Otsuka Novel Products GmbH | <ul style="list-style-type: none"> • J04A • treatment of multidrug-resistant tuberculosis (MDR-TB) | <ul style="list-style-type: none"> • 21/12/2011 • 25/07/2013 • NEGATIVE • 05/12/2013 • POSITIVE • CONDITIONAL | <ul style="list-style-type: none"> • Not available • Not available • Not available |

| Product • Brandname • INN | Marketing authorisation holder | Therapeutic Area • ATC Code • Summary of indication | EMA/CHMP • Validation • Date of 1st opinion • Outcome of 1st opinion • Date of 2nd opinion • Outcome of 2nd opinion • Type of MA (*) | European Commission • Date of decision • Notification • Official Journal |
|--|---------------------------------------|---|---|--|
| • Kynamro • Mipomersen | Genzyme Europe BV | • C10AX11 • treatment of cholesterol and hypercholesterolaemia | • 17/08/2011 • 13/12/2012 • NEGATIVE • 21/03/2013 • NEGATIVE | • 29/05/2013 • Not available • Not available |
| • Labazenit • Budesonide / salmeterol | Laboratoires SMB S.a. | • R03AK06 • treatment of asthma | • 19/10/2011 • 21/03/2013 • NEGATIVE • 27/06/2013 • NEGATIVE | • 06/09/2013 • Not available • Not available |
| • Qsiva • Phentermine / topiramate | VIVUS BV | • A08AA • treatment of obesity | • 19/01/2011 • 18/10/2012 • NEGATIVE • 21/02/2013 • NEGATIVE | • 14/05/2013 • Not available • Not available |
| • Tecfidera • Dimethyl fumarate | Biogen Idec Ltd | • N07XX • treatment of multiple sclerosis | • 21/03/2012 • 21/03/2013 • POSITIVE • 21/11/2013 • POSITIVE • STANDARD | • 30/01/2014 • Not available • Not available |
| • Xeljanz • Tofacitinib | Pfizer Limited | • L04AA • treatment of moderate to severe active rheumatoid arthritis (RA) | • 16/11/2011 • 25/04/2013 • NEGATIVE • 25/07/2013 • NEGATIVE | • 08/11/2013 • Not available • Not available |

(*) This indicates whether the medicine was granted a positive opinion for a standard 5-year marketing authorisation, a conditional marketing authorisation or an authorisation under exceptional circumstances

CHMP negative¹ opinions 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 |
|--|---------------------------------------|--|---|--|
| • Labazenit • Budesonide / salmeterol | Laboratoires SMB S.a. | • R03AK06 • treatment of asthma | • 19/10/2011 • 21/03/2013 • 201 • 316 | • 04/07/2013 • 06/09/2013 • Not available • Not available |

| 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 |
|--|---|---|---|--|
| • Masican • Masitinib | AB Science | • L01XE • treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) | • 18/07/2012 • 21/11/2013 • 201 • 288 | • 28/11/2013 • Not available • Not available • Not available |
| • Raxone • Idebenone | Santhera Pharmaceuticals (Deutschland) GmbH | • N06BX13 • treatment of Leber's Hereditary Optic Neuropathy | • 20/07/2011 • 17/01/2013 • 208 • 337 | • 24/01/2013 • Not available • Not available • Not available |
| • Winfuran • Nalfurafine | Toray International UK Ltd | • V03AX02 • treatment of uraemic pruritus (UP) | • 17/07/2012 • 19/12/2013 • 201 • 316 | • 13/01/2014 • Not available • Not available • Not available |
| • Xeljanz • Tofacitinib | Pfizer Limited | • L04AA • treatment of moderate to severe active rheumatoid arthritis (RA) | • 16/11/2011 • 25/04/2013 • 208 • 316 | • 12/08/2013 • 08/11/2013 • Not available • Not available |

(1) Please note that the products Defitelio and Delyba both received a negative first opinion in 2013, which after re-examination resulted in positive opinions. They are reported in a separate table under the other positive opinions for orphan medicinal products.

Centralised applications for medicinal products for human use – withdrawals in 2013 prior to opinion

| Product • Brandname • INN | Marketing authorisation holder | Therapeutic Area • ATC Code • Summary of indication | EMA/CHMP • Validation • Withdrawal • Active Time • Clock stop |
|---|--|---|--|
| • Belviq • Lorcaserin | Arena Pharmaceutical Enterprises Limited | • A08AA • as an adjunct to diet and exercise for weight control | • 21/03/2012 • 13/05/2013 • 182 • 121 |
| • Hyalograft C autograft • Cultured autologous chondrocytes on hyaluronan based scaffold | ANIKA THERAPEUTICS S.R.L. | • M09 • indicated for the surgical repair of symptomatic cartilage defects | • 21/03/2012 • 14/01/2013 • 121 • 0 |
| • IXinity • Trenonacog alfa / trenonacog alfa | Cangene Europe Limited | • B02BD • Treatment of hemophilia B | • 21/09/2011 • 19/06/2013 • 182 • 184 |
| • Lemtrada • Alemtuzumab | Genzyme Europe BV | • L04 • treatment of multiple sclerosis (RRMS) | • 19/06/2012 • 29/04/2013 • 182 • 93 |

| Product | Marketing authorisation holder | Therapeutic Area | EMA/CHMP |
|---|--|--|---|
| <ul style="list-style-type: none"> • Brandname • INN | | <ul style="list-style-type: none"> • ATC Code • Summary of indication | <ul style="list-style-type: none"> • Validation • Withdrawal • Active Time • Clock stop |
| <ul style="list-style-type: none"> • Omontys • Peginesatide | Takeda Global Research and Development Centre (Europe) | <ul style="list-style-type: none"> • B03XA • treatment of symptomatic anaemia associated with chronic kidney disease (CKD) | <ul style="list-style-type: none"> • 22/02/2012 • 20/06/2013 • 182 • 86 |
| <ul style="list-style-type: none"> • Oranera • Autologous oral mucosal epithelial cells | CellSeed Europe Ltd. | <ul style="list-style-type: none"> • S01X • treatment of limbal stem cell deficiency | <ul style="list-style-type: none"> • 22/06/2011 • 14/03/2013 • 121 • 0 |
| <ul style="list-style-type: none"> • Ruvise • Imatinib mesilate | Novartis Europharm Ltd | <ul style="list-style-type: none"> • L01XE01 • treatment of pulmonary arterial hypertension (PAH) | <ul style="list-style-type: none"> • 21/03/2012 • 17/01/2013 • 121 • 0 |

Centralised applications for medicinal products for human use – withdrawal in 2012 prior to opinion, but reported in 2013 due to cut-off date

| Product | Marketing authorisation holder | Therapeutic Area | EMA/CHMP |
|--|---------------------------------------|---|---|
| <ul style="list-style-type: none"> • Brandname • INN | | <ul style="list-style-type: none"> • ATC Code • Summary of indication | <ul style="list-style-type: none"> • Validation • Withdrawal • Active Time • Clock stop |
| <ul style="list-style-type: none"> • Memantine FGK • Memantine | FGK Representative Service GmbH | <ul style="list-style-type: none"> • N06DX01 • treatment of Alzheimer's disease | <ul style="list-style-type: none"> • 20/06/2012 • 18/12/2012 • 121 • 0 |

Annex 10 – CVMP opinions in 2013 on medicinal products for veterinary use

Positive opinions

| Product <ul style="list-style-type: none"> • Invented name • INN | <ul style="list-style-type: none"> • Marketing authorisation holder | Therapeutic area <ul style="list-style-type: none"> • Target species • Summary of indication | EMA/CVMP <ul style="list-style-type: none"> • Validation • Opinion • Active time • Clock stop | European Commission <ul style="list-style-type: none"> • Opinion received • Decision • Notification • Official Journal |
|--|---|---|--|---|
| <ul style="list-style-type: none"> • Meloxidolor • Meloxicam | <ul style="list-style-type: none"> • Le Vet Beheer B.V. | <ul style="list-style-type: none"> • Dogs, cats, cattle, pigs and horses • Anti-inflammatory and anti-rheumatic | <ul style="list-style-type: none"> • 15/12/2011 • 07/02/2013 • 210 • 212 | <ul style="list-style-type: none"> • 07/02/2013 • 22/04/2013 • 24/04/2013 • C 156 of 31/05/2013 |
| <ul style="list-style-type: none"> • ECOPORC Shiga • Genetically modified STx2e antigen | <ul style="list-style-type: none"> • IDT Biologika GmbH | <ul style="list-style-type: none"> • Piglets • Vaccine for the active immunisation to reduce the mortality and clinical signs of oedema disease | <ul style="list-style-type: none"> • 15/12/2011 • 07/02/2013 • 210 • 212 | <ul style="list-style-type: none"> • 08/02/2013 • 10/04/2013 • 12/04/2013 • C 156 of 31/05/2013 |
| <ul style="list-style-type: none"> • Oncept IL-2 • Feline interleukin-2 recombinant canarypox virus (vCP1338 virus) | <ul style="list-style-type: none"> • Merial | <ul style="list-style-type: none"> • Cats • Immunotherapy product to be used in addition to surgery and radiotherapy with fibrosarcoma without metastasis or lymph node involvement | <ul style="list-style-type: none"> • 09/11/2011 • 07/03/2013 • 205 • 280 | <ul style="list-style-type: none"> • 07/03/2013 • 03/05/2013 • 07/05/2013 • C 184 of 28/06/2013 |

| Product <ul style="list-style-type: none"> Invented name INN | <ul style="list-style-type: none"> Marketing authorisation holder | Therapeutic area <ul style="list-style-type: none"> Target species Summary of indication | EMA/CVMP <ul style="list-style-type: none"> Validation Opinion Active time Clock stop | European Commission <ul style="list-style-type: none"> Opinion received Decision Notification Official Journal |
|--|---|---|--|---|
| <ul style="list-style-type: none"> Equilis West Nile Inactivated chimeric Flavivirus strain YF-WN | <ul style="list-style-type: none"> Intervet International BV | <ul style="list-style-type: none"> Horses For the active immunisation of horses against West Nile virus (WNV) to prevent virus viraemia and to reduce clinical symptoms of disease and lesions in the brain | <ul style="list-style-type: none"> 17/01/2012 11/04/2013 208 240 | <ul style="list-style-type: none"> 11/04/2013 06/06/2013 16/07/2013 C 250 of 30/08/2013 |
| <ul style="list-style-type: none"> ProZinc Insulin (human) | <ul style="list-style-type: none"> Boehringer Ingelheim Vetmedica GmbH | <ul style="list-style-type: none"> Cats For the treatment of diabetes mellitus to achieve reduction of hyperglycaemia and improvement of associated clinical signs | <ul style="list-style-type: none"> 15/03/2012 16/05/2013 210 218 | <ul style="list-style-type: none"> 16/05/2013 12/07/2013 16/07/2013 C 250 of 30/08/2013 |
| <ul style="list-style-type: none"> AFTOVAXPUR DOE 1-3 inactivated, purified FMD virus(es) out of a set of 7 (multistrain) | <ul style="list-style-type: none"> MERIAL | <ul style="list-style-type: none"> Cattle, sheep, pigs Vaccine containing a maximum of three inactivated, purified foot-and-mouth-disease (FMD) virus strains out of seven authorised strains | <ul style="list-style-type: none"> 12/10/2012 16/05/2013 210 737 | <ul style="list-style-type: none"> 16/05/2013 15/07/2013 17/07/2013 C 250 of 30/08/2013 |

| Product <ul style="list-style-type: none"> Invented name INN | <ul style="list-style-type: none"> Marketing authorisation holder | Therapeutic area <ul style="list-style-type: none"> Target species Summary of indication | EMA/CVMP <ul style="list-style-type: none"> Validation Opinion Active time Clock stop | European Commission <ul style="list-style-type: none"> Opinion received Decision Notification Official Journal |
|--|---|--|--|---|
| <ul style="list-style-type: none"> APOQUEL Oclacitinib maleate | <ul style="list-style-type: none"> Zoetis Belgium SA | <ul style="list-style-type: none"> Dogs Treatment of clinical manifestations of pruritus associated with allergic dermatitis in dogs and treatment of clinical manifestations of atopic dermatitis in dogs. | <ul style="list-style-type: none"> 15/08/2012 18/07/2013 210 127 | <ul style="list-style-type: none"> 18/07/2013 12/09/2013 16/09/2013 C 311 of 25/10/2013 |
| <ul style="list-style-type: none"> Trifexis Spinosad/ milbemycin oxime | <ul style="list-style-type: none"> Eli Lilly & Co Ltd | <ul style="list-style-type: none"> Dogs Treatment and prevention of flea infestations in dogs when the concurrent prevention of heartworm disease and/or treatment of specified gastrointestinal nematode infections is indicated. | <ul style="list-style-type: none"> 15/02/2012 17/07/2013 210 308 | <ul style="list-style-type: none"> 18/07/2013 19/09/2013 23/09/2013 C 311 of 25/10/2013 |
| <ul style="list-style-type: none"> Broadline Fipronil/ eprinomectin/ praziquantel/ (S)-methoprene | <ul style="list-style-type: none"> MERIAL | <ul style="list-style-type: none"> Cats For cats with existing, or at risk from, mixed parasitic infections | <ul style="list-style-type: none"> 10/10/2012 10/10/2013 210 155 | <ul style="list-style-type: none"> 10/10/2013 04/12/2013 05/12/2013 C 29 of 31/01/2014 |

| Product <ul style="list-style-type: none"> Invented name INN | <ul style="list-style-type: none"> Marketing authorisation holder | Therapeutic area <ul style="list-style-type: none"> Target species Summary of indication | EMA/CVMP <ul style="list-style-type: none"> Validation Opinion Active time Clock stop | European Commission <ul style="list-style-type: none"> Opinion received Decision Notification Official Journal |
|---|--|---|--|---|
| <ul style="list-style-type: none"> Vectra 3D Dinotefuran/ pyriproxyfen/ permethrin | <ul style="list-style-type: none"> CEVA Santé Animale | <ul style="list-style-type: none"> Dogs Treatment and prevention of infestations by certain specified fleas and ticks. It is also intended for the prevention of bites from sand flies, mosquitoes and stable flies. | <ul style="list-style-type: none"> 12/10/2011 10/10/2013 203 526 | <ul style="list-style-type: none"> 10/10/2013 04/12/2013 05/12/2013 C 29 of 31/01/2014 |
| <ul style="list-style-type: none"> Bravecto Fluralaner | <ul style="list-style-type: none"> Intervet International B.V. | <ul style="list-style-type: none"> Dog For the treatment and prevention of tick (<i>Ixodes ricinus</i>, <i>Ixodes hexagonus</i>, <i>Ixodes scapularis</i>, <i>Dermacentor reticulatus</i>, <i>Dermacentor variabilis</i> and <i>Rhipicephalus sanguineus</i>) and flea (<i>Ctenocephalides felis</i>) infestations in dogs. | <ul style="list-style-type: none"> 12/12/2012 12/12/2013 210 155 | <ul style="list-style-type: none"> 12/12/2013 11/02/2014 |
| <ul style="list-style-type: none"> NexGard Afoxolaner | <ul style="list-style-type: none"> MERIAL | <ul style="list-style-type: none"> Dog Treatment and prevention of flea infestation in dogs | <ul style="list-style-type: none"> 08/11/2012 12/12/2013 210 190 | <ul style="list-style-type: none"> 12/12/2013 11/02/2014 |

Opinions on establishment of MRLs for new substances

| • Substance | • Target species | EMA/CVMP <ul style="list-style-type: none"> • Validation • Opinion • Active time • Clock stop | European Commission <ul style="list-style-type: none"> • Opinion received • Regulation • Official Journal |
|--|--|---|--|
| • Diclazuril | • Rabbits | <ul style="list-style-type: none"> • 12/09/2012 • 07/02/2013 • 148 • 0 | <ul style="list-style-type: none"> • 18/02/2013 • Regulation (EU) No 1235/2013 • L 322 of 03/12/2013 |
| • Butafosfan | • All mammalian food producing species | <ul style="list-style-type: none"> • 16/01/2013 • 13/06/2013 • 148 • 0 | <ul style="list-style-type: none"> • 26/06/2013 • Regulation (EU) No 20/2014 • L 8 of 11/01/2014 |
| • Chloroform | • All mammalian food producing species | <ul style="list-style-type: none"> • 11/10/2013 • 13/06/2013 • 175 • 71 | <ul style="list-style-type: none"> • 26/06/2013 • Regulation (EU) No 19/2014 • L 8 of 11/01/2014 |
| • Triptorelin acetate | • Porcine species | <ul style="list-style-type: none"> • 13/02/2013 • 18/07/2013 • 155 • 0 | <ul style="list-style-type: none"> • 18/07/2013 • Regulation (EU) No 200/2014 • L 62 of 04/03/2014 |
| • Tulathromycin (modification of ADI and MRLs) | • Bovine and porcine species | <ul style="list-style-type: none"> • 16/02/2012 • 10/10/2013 • 208 • 212 | <ul style="list-style-type: none"> • 24/10/2013 |
| • Triclabendazole (after provisional MRLs) | • All ruminants (milk) | <ul style="list-style-type: none"> • N/a • 07/11/2013 • 90 • 0 | <ul style="list-style-type: none"> • 15/11/2013 |
| • Cabergoline | • Bovine species | <ul style="list-style-type: none"> • 10/10/2012 • 12/12/2013 • 209 • 218 | <ul style="list-style-type: none"> • 18/12/2013 |
| • Lufenuron | • Fin fish | <ul style="list-style-type: none"> • 20/03/2013 • 12/12/2013 • 210 • 57 | <ul style="list-style-type: none"> • 18/12/2013 |
| • Clorsulon (after provisional MRLs) | • Bovine milk | <ul style="list-style-type: none"> • N/a • 12/12/2013 • 77 • 0 | <ul style="list-style-type: none"> • 18/12/2013 |
| • Closantel (after provisional MRLs) | • Bovine and ovine milk | <ul style="list-style-type: none"> • N/a • 12/12/2013 • 77 • 0 | <ul style="list-style-type: none"> • 18/12/2013 |

| | | | |
|--|---|---|--|
| <ul style="list-style-type: none">• Lasalocid | <ul style="list-style-type: none">• Poultry | <ul style="list-style-type: none">• 07/11/2012• 12/12/2013• 210• 155 | <ul style="list-style-type: none">• 18/12/2013 |
| <ul style="list-style-type: none">• Rafoxanide | <ul style="list-style-type: none">• Bovine and ovine milk | <ul style="list-style-type: none">• N/a• 12/12/2013• 173• 673 | <ul style="list-style-type: none">• 18/12/2013 |

Annex 11 – COMP opinions in 2013 on designation of orphan medicinal products

Positive COMP designation opinions

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|---|--|---|--|
| Humanised IgG1 kappa antibody against serum amyloid A and AL amyloid | Onclave Therapeutics Limited | Treatment of amyloid light-chain amyloidosis | 29/08/2012 09/11/2012 09/01/2013 <i>(61 days/22 days)</i> | 17/01/2013 08/02/2013 |
| Terguride | High Tech Participations GmbH | Treatment of systemic sclerosis | 17/10/2012 09/11/2012 09/01/2013 <i>(61 days/22 days)</i> | 17/01/2013 08/02/2013 |
| Cyclo-Cys-Gly-Gln-Arg-Glu-Thr-Pro-Glu-Gly-Ala-Glu-Ala-Lys-Pro-Trp-Tyr-Cys | Apeptico Forschung und Entwicklung GmbH | Treatment of high altitude pulmonary oedema | 26/09/2012 12/10/2012 09/01/2013 <i>(89 days/22 days)</i> | 17/01/2013 08/02/2013 |
| Recombinant adeno-associated viral vector containing the human CNGB3 gene | TMC Pharma Services Ltd | Treatment of achromatopsia caused by mutations in the CNGB3 gene | 17/07/2012 14/12/2012 09/01/2013 <i>(26 days/22 days)</i> | 17/01/2013 08/02/2013 |
| L-asparaginase encapsulated in erythrocytes | ERYtech Pharma S.A. | Treatment of acute myeloid leukaemia | 24/10/2012 09/11/2012 09/01/2013 <i>(61 days/22 days)</i> | 17/01/2013 08/02/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|--------------------------|--|---|--|
| Treprostinil sodium | SciPharm S.a.r.L | Treatment of chronic thromboembolic pulmonary hypertension | 27/09/2012 12/10/2012 09/01/2013 <i>(89 days/22 days)</i> | 17/01/2013 08/02/2013 |
| Progesterone | BHR Pharma Belgium | Treatment of moderate and severe traumatic brain injury | 25/09/2012 12/10/2012 09/01/2013 <i>(89 days/22 days)</i> | 17/01/2013 08/02/2013 |
| Humanised monoclonal antibody against myostatin | Pfizer Limited | Treatment of Duchenne muscular dystrophy | 22/10/2012 09/11/2012 09/01/2013 <i>(61 days/22 days)</i> | 17/01/2013 08/02/2013 |
| 4-[2-(6-methylpyridin-2-yl)-5,6-dihydro-4H-pyrrolo[1,2-b]pyrazol-3-yl]-quinoline-6-carboxamide monohydrate | Eli Lilly Nederland B.V. | Treatment of hepatocellular carcinoma | 22/10/2012 09/11/2012 06/02/2013 <i>(89 days/21 days)</i> | 19/02/2013 12/03/2013 |
| Recombinant human tripeptidyl-peptidase 1 | BioMarin Europe Ltd. | Treatment of neuronal ceroid lipofuscinosis type 2 | 23/11/2012 14/12/2012 06/02/2013 <i>(54 days/21 days)</i> | 19/02/2013 12/03/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|----------------------------------|--|---|--|
| Mepolizumab | Glaxo Group Limited | Treatment of Churg-Strauss syndrome | 21/11/2012 14/12/2012 06/02/2013 <i>(54 days/21 days)</i> | 19/02/2013 12/03/2013 |
| Recombinant adeno-associated viral vector containing the human retinoschisin gene | TMC Pharma Services Ltd | Treatment of X-linked juvenile retinoschisis | 17/07/2012 14/12/2012 06/02/2013 <i>(54 days/21 days)</i> | 19/02/2013 12/03/2013 |
| Ramiprilat | Iris Pharma | Treatment of Stargardt's disease | 23/11/2012 14/12/2012 06/02/2013 <i>(54 days/21 days)</i> | 19/02/2013 12/03/2013 |
| 1-[(3R)-3-[4-amino-3-(4-phenoxyphenyl)-1H-pyrazolo [3,4-d]pyrimidin-1-yl]-1-piperidinyl]-2-propen-1-one | Janssen-Cilag International N.V. | Treatment of mantle cell lymphoma | 21/11/2012 14/12/2012 06/02/2013 <i>(54 days/21 days)</i> | 19/02/2013 12/03/2013 |
| Recombinant human heat shock protein 70 | Orphazyme ApS | Treatment of Niemann-Pick disease, type C | 23/10/2012 09/11/2012 06/02/2013 <i>(89 days/19 days)</i> | 19/02/2013 12/03/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|--|---|--|---|
| Poloxamer 188 | Theradex (Europe) Ltd. | Treatment of sickle cell disease | 23/10/2012 09/11/2012 06/02/2013 (89 days/21 days) | 19/02/2013 12/03/2013 |
| Murine IgM monoclonal antibody binding to alpha beta T-Cell receptor | CTI Clinical Trial and Consulting Services | Prevention of graft rejection following solid organ transplantation | 24/10/2012 09/11/2012 06/02/2013 (89 days/21 days) | 19/02/2013 12/03/2013 |
| Gevokizumab | Les Laboratoires Servier | Treatment of chronic non-infectious uveitis | 23/10/2012 09/11/2012 06/02/2013 (89 days/21 days) | 19/02/2013 12/03/2013 |
| 2-[4-Methoxy-3-(2-m-tolyl-ethoxy)-benzoylamino]-indan-2-carboxylic acid | Sanofi-Aventis Groupe | Treatment of systemic sclerosis | 26/09/2012 14/12/2012 06/02/2013 (54 days/21 days) | 19/02/2013 12/03/2013 |
| Cyclo[L-alanyl-L-seryl-L-isoleucyl-L-prolyl-L-prolyl-L-glutamyl-L-lysyl-L-tyrosyl-D-prolyl-L-prolyl-(2S)-2-aminodecanoyl-L-alpha -glutamyl-L-threonyl] acetate salt | Polyphor UK Ltd | Treatment of congenital alpha-1antitrypsin deficiency | 24/10/2012 09/11/2012 06/02/2013 (89 days/28 days) | 20/02/2013 20/03/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|---|--|---|--|
| (S)-3-(1-(9H-purin-6-ylamino)ethyl)-8-chloro-2-phenylisoquinolin-1(2H)-one | Voisin Consulting S.A.R.L. | Treatment of chronic lymphocytic leukaemia | 11/12/2012 18/01/2013 20/03/2013 <i>(61 days/30 days)</i> | 27/03/2013 26/04/2013 |
| Nintedanib | Boehringer Ingelheim International GmbH | Treatment of idiopathic pulmonary fibrosis | 05/12/2012 18/01/2013 13/03/2013 <i>(54 days/30 days)</i> | 27/03/2013 26/04/2013 |
| 2-hydroxypropyl-beta-cyclodextrin | International Niemann-Pick Disease Alliance (INPDA) | Treatment of Niemann-Pick disease, type C | 10/12/2012 18/01/2013 13/03/2013 <i>(54 days/30 days)</i> | 27/03/2013 26/04/2013 |
| Lenvatinib | Eisai Europe Limited | Treatment of papillary thyroid cancer | 21/11/2012 14/12/2012 13/03/2013 <i>(89 days/30 days)</i> | 27/03/2013 26/04/2013 |
| 4-[2-(6-methylpyridin-2-yl)-5,6-dihydro-4H-pyrrolo[1,2-b]pyrazol-3-yl]-quinoline-6-carboxamide monohydrate | Eli Lilly Nederland B.V. | Treatment of Glioma | 21/11/2012 14/12/2012 13/03/2013 <i>(89 days/30 days)</i> | 27/03/2013 26/04/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|---|---|---|--|
| R,S-O-(3-piperidino-2-hydroxy-1-propyl)-nicotinic acid amidoxime dihydrochloride | N-GENE Kutatási és Fejlesztési Kft | Treatment of Duchenne muscular dystrophy | 29/11/2012 18/01/2013 13/03/2013 <i>(54 days/30 days)</i> | 27/03/2013 26/04/2013 |
| Lenvatinib | Eisai Europe Limited | Treatment of follicular thyroid cancer | 25/02/2013 14/12/2012 13/03/2013 <i>(89 days/30 days)</i> | 27/03/2013 26/04/2013 |
| Autologous CD34+ cells transduced with a lentiviral vector containing the human ADA gene | Prof. Bobby Gaspar | Treatment of adenosine deaminase-deficient severe combined immunodeficiency | 29/01/2013 15/02/2013 17/04/2013 <i>(61 days/25 days)</i> | 13/05/2013 07/06/2013 |
| Maribavir | ViroPharma SPRL | Treatment of cytomegalovirus disease in patients with impaired cell mediated immunity | 29/01/2013 15/02/2013 23/04/2013 <i>(67 days/25 days)</i> | 13/05/2013 07/06/2013 |
| Recombinant human transglutaminase 1 encapsulated into liposomes | Westfälische Wilhelms-Universität Münster | Treatment of transglutaminase-1-deficient autosomal recessive congenital ichthyosis | 21/01/2013 15/02/2013 17/04/2013 <i>(61 days/25 days)</i> | 13/05/2013 07/06/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|----------------------------------|---|---|--|
| Recombinant human CXCL8 mutant | ProtAffin Biotechnologie AG | Treatment of cystic fibrosis | 25/01/2013 15/02/2013 17/04/2013 <i>(61 days/25 days)</i> | 13/05/2013 07/06/2013 |
| Inotuzumab ozogamicin | Pfizer Limited | Treatment of B-cell acute lymphoblastic leukaemia | 10/12/2012 18/01/2013 17/04/2013 <i>(89 days/25 days)</i> | 13/05/2013 07/06/2013 |
| Recombinant human nerve growth factor | Dompé S.p.A. | Treatment of retinitis pigmentosa | 31/01/2013 15/02/2013 17/04/2013 <i>(61 days/25 days)</i> | 13/05/2013 07/06/2013 |
| Allogeneic bone marrow derived mesenchymal cells expanded ex vivo in synthetic media | Cell2B Advanced Therapeutics, SA | Treatment of graft-versus-host disease | 11/12/2012 18/01/2013 17/04/2013 <i>(89 days/25 days)</i> | 13/05/2013 07/06/2013 |
| N-[2,6-bis(1-methylethyl)phenyl]-N'-[[1-[4-(dimethylamino)phenyl]cyclopentyl]methyl]urea, hydrochloride salt | Atterocor Ltd | Treatment of adrenocortical carcinoma | 10/12/2012 18/01/2013 17/04/2013 <i>(89 days/25 days)</i> | 13/05/2013 07/06/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|---------------------------|---|---|--|
| Mexiletine hydrochloride | Prof Michael Hanna | Treatment of non-dystrophic myotonia | 23/11/2012 18/01/2013 17/04/2013 <i>(89 days/25 days)</i> | 13/05/2013 07/06/2013 |
| 5-[1-(2,6-dichlorobenzyl)piperidin-4-ylmethoxy]quinazolin-2,4-diamine dihydrochloride | Pfizer Limited | Treatment of 5q spinal muscular atrophy | 01/03/2013 15/03/2013 17/04/2013 <i>(33 days/25 days)</i> | 13/05/2013 07/06/2013 |
| N-methyl-4-({4-[(3-methyl(methylsulfonyl)aminopyrazin-2-yl)methyl]amino}-5-(trifluoromethyl)pyrimidin-2-yl)amino)benzamide hydrochloride | TMC Pharma Services Ltd | Treatment of malignant mesothelioma | 29/01/2013 15/02/2013 17/04/2013 <i>(61 days/25 days)</i> | 13/05/2013 07/06/2013 |
| Expanded human allogeneic neural retinal progenitor cells extracted from neural retina | ReNeuron Ltd | Treatment of retinitis pigmentosa | 27/02/2013 15/03/2013 15/05/2013 <i>(61 days/29 days)</i> | 21/05/2013 19/06/2013 |
| Unoprostone isopropyl | Sucampo Pharma Europe Ltd | Treatment of retinitis pigmentosa | 26/03/2013 12/04/2013 15/05/2013 <i>(33 days/29 days)</i> | 21/05/2013 19/06/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|--|--|---|--|
| Immortalised human C3A hepatoblastoma cells | Vital Therapies Limited | Treatment of acute liver failure | 28/02/2013 15/03/2013 21/05/2013 <i>(67 days/29 days)</i> | 21/05/2013 19/06/2013 |
| Adenovirus associated viral vector serotype 5 containing the human pde6 β gene | Centre Hospitalier Universitaire de Nantes | Treatment of retinitis pigmentosa | 28/02/2013 15/03/2013 15/05/2013 <i>(61 days/29 days)</i> | 21/05/2013 19/06/2013 |
| Synthetic double-stranded siRNA oligonucleotide directed against the keratin 6a N171K mutation | Alan Irvine | Treatment of pachyonychia congenita | 27/02/2013 15/03/2013 21/05/2013 <i>(67 days/29 days)</i> | 21/05/2013 19/06/2013 |
| Sodium chlorite | Shore Limited | Treatment of amyotrophic lateral sclerosis | 26/02/2013 15/03/2013 15/05/2013 <i>(61 days/29 days)</i> | 21/05/2013 19/06/2013 |
| Genetically modified serotype 5/3 adenovirus coding for granulocyte macrophage colony-stimulating factor | Oncos Therapeutics Oy | Treatment of soft tissue sarcoma | 25/03/2013 12/04/2013 15/05/2013 <i>(33 days/29 days)</i> | 21/05/2013 19/06/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|---|---|---|--|
| 4,6,4'-trymethylangelicin | Rare Partners srl Impresa Sociale | Treatment of cystic fibrosis | 22/02/2013 15/03/2013 15/05/2013 <i>(61 days/29 days)</i> | 21/05/2013 19/06/2013 |
| Recombinant human alpha-N-acetylglucosaminidase | Synageva BioPharma Ltd | Treatment of mucopolysaccharidosis type IIIB (Sanfilippo B syndrome) | 07/03/2013 12/04/2013 15/05/2013 <i>(33 days/29 days)</i> | 21/05/2013 19/06/2013 |
| Copper meso-5,15-bis[3-[(1,2-dicarba-closo-dodecaboranyl)methoxy]phenyl]-meso-10,20-dinitroporphyrin | MorEx Development Partners LLP | Treatment of squamous cell carcinoma of the head and neck in patients undergoing radiotherapy | 27/02/2013 15/03/2013 21/05/2013 <i>(67 days/37 days)</i> | 21/05/2013 27/06/2013 |
| Heterologous human adult liver-derived progenitor cells | Promethera Biosciences | Treatment of citrullinaemia type 2 | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Human hemin | Borders Technology Management Ltd | Prevention of ischaemia/reperfusion injury associated with solid organ transplantation | 21/02/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|--------------------------------|--|--|---|
| Recombinant human monoclonal antibody against hepatitis B virus | CRO-PharmaNet Services GmbH | Prevention of hepatitis B re-infection following liver transplantation | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Belinostat | TopoTarget A/S | Treatment of malignant thymoma | 22/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Fosbretabulin tromethamine | Diamond BioPharm Limited | Treatment of ovarian cancer | 22/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Ex-vivo expanded autologous human corneal epithelium containing stem cells | University Newcastle upon Tyne | Treatment of limbal stem cell deficiency | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Heterologous human adult liver-derived progenitor cells | Promethera Biosciences | Treatment of N-acetylglutamate synthetase (NAGS) deficiency | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|-------------------------------------|---|--|---|
| Heterologous human adult liver-derived progenitor cells | Promethera Biosciences | Treatment of citrullinaemia type 1 | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Heterologous human adult liver-derived progenitor cells | Promethera Biosciences | Treatment of argininosuccinic aciduria | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Heterologous human adult liver-derived progenitor cells | Promethera Biosciences | Treatment of ornithine translocase deficiency (hyperornithinaemia-hyperammonaemia homocitrullinuria (HHH) syndrome) | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Autologous bone marrow-derived mesenchymal stromal cells secreting neurotrophic factors | Brainstorm Cell Therapeutics UK Ltd | Treatment of amyotrophic lateral sclerosis | 29/01/2013 15/03/2013 13/06/2013 <i>(90 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Heterologous human adult liver-derived progenitor cells | Promethera Biosciences | Treatment of carbamoyl-phosphate synthase-1 deficiency | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|-----------------------------------|---|---|--|
| (S)-3-(1-(9H-purin-6-ylamino)ethyl)-8-chloro-2-phenylisoquinolin-1(2H)-one | Voisin Consulting S.A.R.L. | Treatment of follicular lymphoma | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Granulocyte macrophage colony stimulating factor | Serendex ApS | Treatment of pulmonary alveolar proteinosis | 13/07/2012 15/03/2013 13/06/2013 <i>(90 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Idelalisib | Gilead Sciences International Ltd | Treatment of follicular lymphoma | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Idelalisib | Gilead Sciences International Ltd | Treatment of lymphoplasmacytic lymphoma | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| (1-methyl-2-nitro-1H-imidazole-5-yl)methyl N,N'-bis(2-bromoethyl)diamidophosphate | Merck KGaA | Treatment of pancreatic cancer | 22/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|----------------------------------|---|---|--|
| Allogeneic motor neuron progenitor cells derived from human embryonic stem cells | California Stem Cell (UK) Ltd | Treatment of amyotrophic lateral sclerosis | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Daratumumab | Janssen-Cilag International N.V. | Treatment of plasma cell myeloma | 22/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Dexamethasone sodium phosphate for encapsulation in human autologous erythrocytes | Erydel S.p.A. | Treatment of ataxia telangiectasia | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Heterologous human adult liver-derived progenitor cells | Promethera Biosciences | Treatment of hyperargininaemia | 25/03/2013 12/04/2013 13/06/2013 <i>(62 days/28 days)</i> | 19/06/2013 17/07/2013 |
| Moxetumomab pasudotox | MedImmune Ltd | Treatment of B-lymphoblastic leukaemia/lymphoma | 27/02/2013 15/03/2013 13/06/2013 <i>(90 days/28 days)</i> | 19/06/2013 17/07/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|-------------|-----------------------------------|---|---|--|
| Idelalisib | Gilead Sciences International Ltd | Treatment of nodal marginal zone lymphoma | 25/03/2013 12/04/2013 11/07/2013 (90 days/24 days) | 12/07/2013 05/08/2013 |
| Cladribine | Lipomed GmbH | Treatment of mastocytosis | 21/05/2013 07/06/2013 11/07/2013 (34 days/24 days) | 12/07/2013 05/08/2013 |
| Sacrosidase | QOL Therapeutics UK Ltd | Treatment of congenital sucrase-isomaltase deficiency | 22/05/2013 07/06/2013 11/07/2013 (34 days/24 days) | 12/07/2013 05/08/2013 |
| Tolvaptan | Otsuka Pharmaceutical Europe Ltd | Treatment of autosomal dominant polycystic kidney disease | 25/03/2013 12/04/2013 11/07/2013 (90 days/24 days) | 12/07/2013 05/08/2013 |
| Idelalisib | Gilead Sciences International Ltd | Treatment of chronic lymphocytic leukaemia/small lymphocytic lymphoma | 25/03/2013 12/04/2013 11/07/2013 (90 days/24 days) | 12/07/2013 05/08/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|-----------------------------------|---|---|--|
| Idelalisib | Gilead Sciences International Ltd | Treatment of extranodal marginal zone lymphoma of mucosa-associated lymphoid tissue (MALT lymphoma) | 25/03/2013 12/04/2013 11/07/2013 <i>(90 days/24 days)</i> | 12/07/2013 05/08/2013 |
| Idelalisib | Gilead Sciences International Ltd | Treatment of splenic marginal zone lymphoma | 25/03/2013 12/04/2013 11/07/2013 <i>(90 days/24 days)</i> | 12/07/2013 05/08/2013 |
| Recombinant human growth hormone modified by fusion with two hydrophilic polypeptide chains | Larode Ltd | Treatment of growth hormone deficiency | 20/05/2013 07/06/2013 11/07/2013 <i>(34 days/24 days)</i> | 12/07/2013 05/08/2013 |
| Trans-N1-((1R,2S)-2-phenylcyclopropyl)cyclohexane-1,4-diamine bis-hydrochloride | Oryzon Genomics SA | Treatment of acute myeloid leukaemia | 25/03/2013 12/04/2013 11/07/2013 <i>(90 days/24 days)</i> | 12/07/2013 05/08/2013 |
| Eculizumab | Alexion Europe SAS | Treatment of neuromyelitis optica | 23/05/2013 07/06/2013 11/07/2013 <i>(34 days/24 days)</i> | 12/07/2013 05/08/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|----------------------------|---|---|--|
| Chimeric monoclonal antibody against claudin-18 splice variant 2 | GANYMED Pharmaceuticals AG | Treatment of pancreatic cancer | 14/05/2013 07/06/2013 11/07/2013 <i>(34 days/24 days)</i> | 12/07/2013 05/08/2013 |
| Pegylated recombinant anti Pseudomonas aeruginosa PcrV Fab' antibody | KaloBios Ltd | Treatment of Pseudomonas aeruginosa lung infection in cystic fibrosis | 20/05/2013 07/06/2013 11/07/2013 <i>(34 days/24 days)</i> | 12/07/2013 05/08/2013 |
| Human allogeneic bone marrow derived osteoblastic-like cells | Bone Therapeutics SA | Treatment of non-traumatic osteonecrosis | 29/04/2013 07/06/2013 11/07/2013 <i>(34 days/24 days)</i> | 12/07/2013 05/08/2013 |
| Octreotide acetate (oral use) | Larode Ltd | Treatment of acromegaly | 25/03/2013 12/04/2013 11/07/2013 <i>(90 days/24 days)</i> | 12/07/2013 05/08/2013 |
| Budesonide | Dr Falk Pharma GmbH | Treatment of eosinophilic oesophagitis | 17/05/2013 07/06/2013 11/07/2013 <i>(34 days/24 days)</i> | 12/07/2013 05/08/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|--|----------------------------------|---|--|
| Lipid-complexed cisplatin | Richardson Associates Regulatory Affairs Ltd | Treatment of osteosarcoma | 25/02/2013 12/04/2013 11/07/2013 <i>(90 days/24 days)</i> | 12/07/2013 05/08/2013 |
| (1R,3R,4R,5S)-3-O-[2-O-benzoyl-3-O-(sodium(2S)-3-cyclohexylpropanoate-2-yl)-β-D-galactopyranosyl]-4-O-(α-L-fucopyranosyl)-5-oroethylamido-cyclohexane-1-carboxylic acid (ethyl-2-amidyl-ethoxy-2-acetyl-(8-amino-1,3,6-naphthalene-tris sodium sulfonate) amide | Pfizer Limited | Treatment of sickle cell disease | 23/05/2013 07/06/2013 11/07/2013 <i>(34 days/24 days)</i> | 12/07/2013 05/08/2013 |
| Apremilast | Celgene Europe Limited | Treatment of Behçet's disease | 21/05/2013 07/06/2013 11/07/2013 <i>(34 days/24 days)</i> | 12/07/2013 05/08/2013 |
| Antisense oligonucleotide targeting the F508delta mutation of CFTR | ProQR Therapeutics BV | Treatment of cystic fibrosis | 26/06/2013 12/07/2013 04/09/2013 <i>(54 days/28 days)</i> | 09/09/2013 07/10/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|-----------------------------|---|---|--|
| Naproxcinod | NicOx | Treatment of Duchenne muscular dystrophy | 25/06/2013 12/07/2013 04/09/2013 <i>(54 days/28 days)</i> | 09/09/2013 07/10/2013 |
| L-Pyr-L-Glu-L-Gln-L-Leu-L-Glu-L-Arg-L-Ala-L-Leu-L-Asn-L-Ser-L-Ser | Araim Pharma Europe Ltd | Treatment of sarcoidosis | 22/05/2013 07/06/2013 04/09/2013 <i>(89 days/28 days)</i> | 09/09/2013 07/10/2013 |
| Autologous CD34+ cells transduced with a lentiviral vector containing the human Wiskott-Aldrich syndrome gene | Généthon | Treatment of Wiskott-Aldrich syndrome | 27/06/2013 12/07/2013 04/09/2013 <i>(54 days/28 days)</i> | 09/09/2013 07/10/2013 |
| Zoledronic acid | Axsome Therapeutics Limited | Treatment of complex regional pain syndrome | 21/06/2013 12/07/2013 04/09/2013 <i>(54 days/28 days)</i> | 09/09/2013 07/10/2013 |
| Recombinant human monoclonal IgM antibody targeting glucose-regulated protein 78 | Patrys GmbH | Treatment of plasma cell myeloma | 16/05/2013 07/06/2013 04/09/2013 <i>(89 days/28 days)</i> | 09/09/2013 07/10/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|---|---|--|---|
| Recombinant fusion protein linking coagulation factor VIIa with albumin | CSL Behring GmbH | Treatment of congenital factor VII deficiency | 25/03/2013 07/06/2013 04/09/2013 <i>(89 days/28 days)</i> | 09/09/2013 07/10/2013 |
| Autologous regulatory T cells with an immunophenotype of CD4+CD25hiFoxP3+ | iReg Medical AB | Prevention of graft rejection following solid organ transplantation | 25/03/2013 12/04/2013 11/07/2013 <i>(90 days/28 days)</i> | 09/09/2013 07/10/2013 |
| Mexiletine hydrochloride | Agenzia Industrie Difesa-Stabilimento Chimico Farmaceutico Militare | Treatment of myotonic disorders | 11/04/2013 07/06/2013 04/09/2013 <i>(89 days/28 days)</i> | 09/09/2013 07/10/2013 |
| 3,5-diiodothyropropionic acid | CATS Consultants GmbH | Treatment of the Allan-Herndon-Dudley Syndrome | 24/06/2013 12/07/2013 04/09/2013 <i>(54 days/28 days)</i> | 09/09/2013 07/10/2013 |
| Soraprazan | Katairo GmbH | Treatment of Stargardt's disease | 25/07/2013 09/08/2013 10/10/2013 <i>(62 days/22 days)</i> | 22/10/2013 13/11/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|----------------------------------|--|---|--|
| Synthetic 12 amino acids peptide designed after subcommissural organ-spondin | Neuronax SAS | Treatment of spinal cord injury | 25/07/2013 09/08/2013 10/10/2013 (62 days/22 days) | 22/10/2013 13/11/2013 |
| Sirolimus | S-Cubed Limited | Prevention of arteriovenous access dysfunction in patients undergoing surgical creation of an arteriovenous access for haemodialysis | 24/07/2013 09/08/2013 10/10/2013 (62 days/22 days) | 22/10/2013 13/11/2013 |
| Human monoclonal antibody against human interleukin 13 | Novartis Europharm Limited | Treatment of eosinophilic oesophagitis | 24/07/2013 09/08/2013 10/10/2013 (62 days/22 days) | 22/10/2013 13/11/2013 |
| Ibrutinib | Janssen-Cilag International N.V. | Treatment of diffuse large B-cell lymphoma | 24/07/2013 09/08/2013 10/10/2013 (62 days/22 days) | 22/10/2013 13/11/2013 |
| Sorafenib tosylate | Bayer HealthCare AG | Treatment of follicular thyroid cancer | 25/06/2013 12/07/2013 10/10/2013 (90 days/22 days) | 22/10/2013 13/11/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|----------------------------|--|---|--|
| Trebananib | Amgen Europe BV | Treatment of ovarian cancer | 25/07/2013 09/08/2013 10/10/2013 <i>(62 days/22 days)</i> | 22/10/2013 13/11/2013 |
| Recombinant human insulin receptor monoclonal antibody-fused iduronate 2-sulfatase | Voisin Consulting S.A.R.L. | Treatment of mucopolysaccharidosis type II (Hunter's syndrome) | 25/06/2013 12/07/2013 10/10/2013 <i>(90 days/22 days)</i> | 22/10/2013 13/11/2013 |
| Defibrotide | Gentium S.p.A. | Prevention of graft-versus-host disease | 27/06/2013 12/07/2013 10/10/2013 <i>(90 days/22 days)</i> | 22/10/2013 13/11/2013 |
| Autologous ex vivo expanded leukocytes treated with 5-aza-2'-deoxycytidine | CytoVac A/S | Treatment of glioma | 23/05/2013 12/07/2013 10/10/2013 <i>(90 days/22 days)</i> | 22/10/2013 13/11/2013 |
| Sorafenib tosylate | Bayer HealthCare AG | Treatment of papillary thyroid cancer | 25/06/2013 12/07/2013 10/10/2013 <i>(90 days/22 days)</i> | 22/10/2013 13/11/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|--------------------------------|--|--|---|
| Tivantinib | Daiichi Sankyo Development Ltd | Treatment of hepatocellular carcinoma | 24/07/2013 09/08/2013 10/10/2013 <i>(62 days/22 days)</i> | 22/10/2013 13/11/2013 |
| Allogeneic and autologous haptenised and irradiated cells and cell lysates derived from glioma | ERC Belgium | Treatment of glioma | 02/07/2013 09/08/2013 06/11/2013 <i>(89 days/23 days)</i> | 25/11/2013 18/12/2013 |
| Recombinant human type I pancreatic elastase | Proteon Therapeutics Limited | Prevention of arteriovenous access dysfunction in haemodialysis patients | 27/08/2013 13/09/2013 06/11/2013 <i>(54 days/23 days)</i> | 25/11/2013 18/12/2013 |
| Nitric oxide | Novoteris | Treatment of cystic fibrosis | 26/06/2013 13/09/2013 06/11/2013 <i>(54 days/23 days)</i> | 25/11/2013 18/12/2013 |
| Humanised monoclonal modified IgG4 antibody with bispecific structure targeting factors IX, IXa, X and Xa | Chugai Pharma Europe Ltd | Treatment of haemophilia A | 29/08/2013 13/09/2013 06/11/2013 <i>(54 days/23 days)</i> | 25/11/2013 18/12/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|--------------------------|--|---|--|
| (4R,5R)-1-[[4-[[4-[3,3-dibutyl-7-(dimethylamino)-2,3,4,5-tetrahydro-4-hydroxy-1,1-dioxido-1-benzothiepin-5-yl]phenoxy]methyl]phenyl]methyl]-4-aza-1-azoniabicyclo[2.2.2]octane Chloride | Lumena Pharma UK Limited | Treatment of progressive familial intrahepatic cholestasis | 25/07/2013 09/08/2013 06/11/2013 <i>(89 days/23 days)</i> | 25/11/2013 18/12/2013 |
| (4R,5R)-1-[[4-[[4-[3,3-dibutyl-7-(dimethylamino)-2,3,4,5-tetrahydro-4-hydroxy-1,1-dioxido-1-benzothiepin-5-yl]phenoxy]methyl]phenyl]methyl]-4-aza-1-azoniabicyclo[2.2.2]octane chloride | Lumena Pharma UK Limited | Treatment of primary sclerosing cholangitis | 25/07/2013 09/08/2013 06/11/2013 <i>(89 days/23 days)</i> | 25/11/2013 18/12/2013 |
| (4R,5R)-1-[[4-[[4-[3,3-dibutyl-7-(dimethylamino)-2,3,4,5-tetrahydro-4-hydroxy-1,1-dioxido-1-benzothiepin-5-yl]phenoxy]methyl]phenyl]methyl]-4-aza-1-azoniabicyclo[2.2.2]octane Chloride | Lumena Pharma UK Limited | Treatment of primary biliary cirrhosis | 25/07/2013 09/08/2013 06/11/2013 <i>(89 days/23 days)</i> | 25/11/2013 18/12/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|---|--|---|---|--|
| (4R,5R)-1-[[4-[[4-[3,3-dibutyl-7-(dimethylamino)-2,3,4,5-tetrahydro-4-hydroxy-1,1-dioxido-1-benzothiepin-5-yl]phenoxy]methyl]phenyl]methyl]-4-aza-1-azoniabicyclo[2.2.2]octane Chloride | Lumena Pharma UK Limited | Treatment of Alagille syndrome | 25/07/2013 09/08/2013 06/11/2013 <i>(89 days/23 days)</i> | 25/11/2013 18/12/2013 |
| Recombinant human parathyroid hormone | NPS Phama UK Ltd | Treatment of hypoparathyroidism | 27/06/2013 09/08/2013 06/11/2013 <i>(89 days/23 days)</i> | 25/11/2013 18/12/2013 |
| Lactobacillus acidophilus / Bifidobacterium bifidum | Laboratorio Farmaceutico S.I.T. s.r.l. | Prevention of necrotising enterocolitis | 23/07/2013 09/08/2013 06/11/2013 <i>(89 days/23 days)</i> | 25/11/2013 18/12/2013 |
| Ibrutinib | Janssen-Cilag International N.V. | Treatment of follicular lymphoma | 23/07/2013 09/08/2013 06/11/2013 <i>(89 days/23 days)</i> | 25/11/2013 18/12/2013 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|-----------------------------------|---|---|--|
| Poly[2-[(4-{[1-carboxy-2-(hexadecylcarbamoyl)ethyl]sulfanyl}-2,3-bis({2-[[[(2S)-2-(2-[(2R)-2-(name too long, check comment box) <td data-bbox="416 398 655 763">Coté Orphan Consulting UK Limited</td> <td data-bbox="660 398 981 763">Treatment of dengue</td> <td data-bbox="986 398 1209 763">29/08/2013 13/09/2013 06/11/2013 <i>(54 days/23 days)</i></td> <td data-bbox="1214 398 1469 763">25/11/2013 18/12/2013</td> | Coté Orphan Consulting UK Limited | Treatment of dengue | 29/08/2013 13/09/2013 06/11/2013 <i>(54 days/23 days)</i> | 25/11/2013 18/12/2013 |
| Fenfluramine hydrochloride | Brabant Pharma Limited | Treatment of Dravet syndrome | 28/08/2013 13/09/2013 06/11/2013 <i>(54 days/23 days)</i> | 25/11/2013 18/12/2013 |
| Obeticholic acid | Intercept Italia S.R.L. | Treatment of primary sclerosing cholangitis | 23/08/2013 13/09/2013 12/12/2013 <i>(90 days/28 days)</i> | 19/12/2013 16/01/2014 |
| N-(3-(5-fluoro-2-(4-(2-methoxyethoxy)phenylamino)pyrimidin-4-ylamino)phenyl)acrylamide benzenesulfonic acid salt | Celgene Europe Limited | Treatment of chronic lymphocytic leukaemia / small lymphocytic lymphoma | 24/09/2013 11/10/2013 12/12/2013 <i>(62 days/28 days)</i> | 19/12/2013 16/01/2014 |
| Amatuximab | Eisai Europe Limited | Treatment of malignant mesothelioma | 11/09/2013 11/10/2013 12/12/2013 <i>(62 days/28 days)</i> | 19/12/2013 16/01/2014 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|---|--|---|--|
| Lonafarnib | Eiger Biopharmaceuticals Europe Limited | The treatment of hepatitis delta virus (HDV) infection | 21/08/2013 13/09/2013 12/12/2013 <i>(90 days/28 days)</i> | 19/12/2013 16/01/2014 |
| Allantoin | ORS Oxford Ltd | Treatment of epidermolysis bullosa | 29/08/2013 13/09/2013 12/12/2013 <i>(90 days/28 days)</i> | 19/12/2013 16/01/2014 |
| Autologous dendritic cells pulsed with allogeneic tumour cell lysate | Amphera BV | Treatment of malignant mesothelioma | 27/08/2013 13/09/2013 12/12/2013 <i>(90 days/28 days)</i> | 19/12/2013 16/01/2014 |
| (2R,3R,4S,5R)-2-(6-amino-9H-purin-9-yl)-5-(((1r,3S)-3-(2-(5-(tert-butyl)-1Hbenzo[d]imidazol-2-yl)ethyl)cyclobutyl)(isopropyl)amino)methyl)tetrahydrofuran-3,4-diol | Voisin Consulting S.A.R.L. | Treatment of acute myeloid leukaemia | 29/08/2013 13/09/2013 12/12/2013 <i>(90 days/28 days)</i> | 19/12/2013 16/01/2014 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--|----------------------------|--|---|--|
| (2R,3R,4S,5R)-2-(6-amino-9H-purin-9-yl)-5-(((1r,3S)-3-(2-(5-(tert-butyl)-1Hbenzo[d]imidazol-2-yl)ethyl)cyclobutyl)(isopropyl)amino)methyl)tetrahydrofuran-3,4-diol | Voisin Consulting S.A.R.L. | Treatment of acute lymphoblastic leukaemia | 29/08/2013 13/09/2013 12/12/2013 <i>(90 days/28 days)</i> | 19/12/2013 16/01/2014 |
| Allogeneic bone-marrow derived ex-vivo expanded multipotent adult progenitor | ReGenesys BVBA | Prevention of graft-versus-host disease | 29/08/2013 13/09/2013 12/12/2013 <i>(90 days/28 days)</i> | 19/12/2013 16/01/2014 |
| Inecalcitol | Hybrigenics SA | Treatment of chronic lymphocytic leukaemia / small lymphocytic lymphoma | 16/07/2013 13/09/2013 12/12/2013 <i>(90 days/28 days)</i> | 19/12/2013 16/01/2014 |
| (6aS)-1,10-dimethoxy-6-methyl-5,6,6a,7-tetrahydro-4H-dibenzo[de,g]quinoline-2,9-diol | Valentia BioPharma S.L | Treatment of dystrophic myotonia | 21/08/2013 11/10/2013 17/12/2013 <i>(67 days/28 days)</i> | 19/12/2013 16/01/2014 |
| Adenovirus specific T-cells derived from allogeneic donor leukocytes, expanded ex vivo | Cell Medica Ltd. | Treatment of adenovirus infection in allogeneic haematopoietic stem cell transplant recipients | 23/08/2013 13/09/2013 12/12/2013 <i>(90 days/28 days)</i> | 19/12/2013 16/01/2014 |

| Product INN | Sponsor | Indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--------------------|---------------------------|---|--|---|
| Sodium nitrite | Hope Pharmaceuticals, Ltd | Treatment of aneurysmal subarachnoid hemorrhage | 20/08/2013 13/09/2013 17/12/2013 <i>(95 days/28 days)</i> | 19/12/2013 16/01/2014 |

Negative COMP designation opinions

| Product INN | Sponsor | Summary of indication | EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time | European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision |
|--------------------|-----------------------------|---|--|---|
| Zoledronic acid | Axsome Therapeutics Limited | Treatment of complex regional pain syndrome | 28/08/2012 10/09/2012 06/02/2013 <i>(54 days/28 days)</i> | 15/03/2013 17/04/2013 |

Annex 12 – HMPC Community herbal monographs in 2013

Community herbal monographs

| Reference number | Document title | Status |
|------------------------|--|---|
| (EMA/HMPC/681468/2012) | Draft 'Public statement on <i>Adhatoda vasica</i> Nees, folium' | Released for public consultation January 2013 |
| (EMA/HMPC/681468/2012) | Public statement on <i>Adhatoda vasica</i> Nees, folium' | Adopted July 2013 |
| (EMA/HMPC/709282/2012) | Draft 'Public statement on <i>Andrographis paniculata</i> Nees, folium' | Released for public consultation January 2013 |
| (EMA/HMPC/709282/2012) | Public statement on <i>Andrographis paniculata</i> Nees, folium' | Adopted September 2013 |
| (EMA/HMPC/681574/2012) | Public statement on <i>Angelica sinensis</i> (Oliv.) Diels, radix | Adopted July 2013 |
| (EMA/HMPC/263273/2006) | Community herbal monograph on <i>Anisi aetheroleum</i> | Revision adopted November 2013 |
| (EMA/HMPC/137423/2006) | Community herbal monograph on <i>Anisi fructus</i> | Revision adopted November 2013 |
| (EMA/HMPC/198793/2012) | Draft 'Community herbal monograph on <i>Arnica montana</i> L., flos | Released for public consultation July 2013 |
| (EMA/HMPC/283630/2012) | Draft 'Community herbal monograph on <i>Camellia sinensis</i> (L.) Kuntze, non fermentatum folium' | Released for public consultation March 2013 |
| (EMA/HMPC/283630/2012) | Community herbal monograph on <i>Camelliae sinensis non fermentatum folium</i> , by a majority vote | Adopted November 2013 |
| (EMA/HMPC/604600/2012) | Draft 'Community herbal monograph on <i>Curcuma xanthorrhiza</i> Roxb., rhizoma | Adopted May 2013 |
| (EMA/HMPC/892618/2011) | Community herbal monograph on <i>Eucalyptus globulus</i> Labill., folium | Adoption January 2013 |
| (EMA/HMPC/121816/2010) | Community herbal monograph on <i>Cichorium intybus</i> L., radix | Adoption January 2013 |
| (EMA/HMPC/307781/2012) | Draft 'Community herbal monograph on <i>Eucalyptus globulus</i> Labill., <i>Eucalyptus polybractea</i> R.T. Baker and/or <i>Eucalyptus smithii</i> R.T. Baker, aetheroleum | Adopted May 2013 |
| (EMA/HMPC/313674/2012) | Draft 'Community herbal monograph on <i>Fucus vesiculosus</i> L., thallus | Adopted May 2013 |
| (EMA/HMPC/346737/2011) | Draft 'Community herbal monograph on <i>Juglans regia</i> L., folium' | Released for public consultation January 2013 |
| (EMA/HMPC/346737/2011) | Community herbal monograph on <i>Juglans regia</i> L., folium | Adopted July 2013 |
| (EMA/HMPC/604271/2012) | Draft 'Community herbal monograph on <i>Marrubium vulgare</i> L., herba' | Released for public consultation January 2013 |
| (EMA/HMPC/604271/2012) | Community herbal monograph on <i>Marrubium vulgare</i> L., herba | Adopted July 2013 |

| Reference number | Document title | Status |
|------------------------|---|---|
| (EMA/HMPC/320932/2012) | Draft 'Community herbal monograph on <i>Melaleuca alternifolia</i> (Maiden and Betche) Cheel and other species, aetheroleum | Released for public consultation July 2013 |
| (EMA/HMPC/281620/2013) | Draft 'Community list entry on <i>Melaleuca alternifolia</i> (Maiden and Betche) Cheel, aetheroleum | Released for public consultation July 2013 |
| (EMA/HMPC/196745/2012) | Community herbal monograph on <i>Melissa officinalis</i> L., folium | Revision adopted May 2013 |
| (EMA/HMPC/138317/2013) | Draft 'Community herbal monograph on <i>Ononis spinosa</i> L. and <i>Ononis arvensis</i> L., radix | Released for public consultation July 2013 |
| (EMA/HMPC/200429/2012) | Community herbal monograph on <i>Origanum dictamnus</i> L., herba | Adopted July 2013 |
| (EMA/HMPC/321233/2012) | Draft 'Community herbal monograph on <i>Panax ginseng</i> C. A. Meyer, radix' | Released for public consultation March 2013 |
| (EMA/HMPC/897344/2011) | Community herbal monograph on <i>Paullinia cupana</i> Kunth ex H.B.K. var. <i>sorbilis</i> (Mart.) Ducke, semen | Adoption January 2013 |
| (EMA/HMPC/317319/2012) | Draft 'Community herbal monograph on <i>Phaseolus vulgaris</i> L., fructus sine semine' | Released for public consultation March 2013 |
| (EMA/HMPC/317319/2012) | Community herbal monograph on <i>Phaseoli fructus sine semine</i> | Adopted November 2013 |
| (EMA/HMPC/599747/2012) | Community herbal monograph on <i>Plantago afra</i> L. et <i>Plantago indica</i> L., semen | Revision adopted May 2013 |
| (EMA/HMPC/304390/2012) | Community herbal monograph on <i>Plantago ovata</i> Forssk., semen | Revision adopted May 2013 |
| (EMA/HMPC/199774/2012) | Community herbal monograph on <i>Plantago ovata</i> Forssk., seminis tegumentum | Revision adopted May 2013 |
| (EMA/HMPC/137299/2013) | Draft 'Community herbal monograph on <i>Rosa gallica</i> L., <i>Rosa centifolia</i> L., <i>Rosa damascena</i> Mill., flos | Released for public consultation September 2013 |
| (EMA/HMPC/44211/2012) | Draft 'Community herbal monograph on <i>Rubus idaeus</i> L., folium' | Released for public consultation March 2013 |
| (EMA/HMPC/32465/2013) | Draft 'Public statement on <i>Sambucus nigra</i> L., fructus' | Released for public consultation March 2013 |
| (EMA/HMPC/734361/2011) | Community herbal monograph on <i>Solanum dulcamara</i> L., stipes | Adoption January 2013 |
| (EMA/HMPC/280193/2013) | Draft Community herbal monograph on <i>Sisymbrii officinalis</i> herba | Released for public consultation November 2013 |
| (EMA/HMPC/234113/2006) | Community herbal monograph on <i>Thymi herba</i> | Adopted November 2013 |
| (EMA/HMPC/681519/2012) | Public statement on <i>Withania somnifera</i> (L.) Dunal, radix | Adopted July 2013 |

| Reference number | Document title | Status |
|------------------------|--|---------------------|
| (EMA/HMPC/571119/2010) | in May 2012 for the 'Community herbal monograph on Glycyrrhiza glabra L. and/or Glycyrrhiza inflata Bat. and/or Glycyrrhiza uralensis Fisch., radix' (EMA/HMPC/571119/2010): a revised assessment report, revised list of references and revised overview of comments received during the consultation period; | Adoption March 2013 |
| (EMA/HMPC/130042/2010) | in September 2012 for the 'Community herbal monograph on Thymus vulgaris L. and Thymus zygis L., herba and Primula veris L. and Primula elatior (L.) Hill, radix' (EMA/HMPC/130042/2010): a revised monograph, revised assessment report, revised list of references and revised overview of comments received during the consultation period. | Adoption March 2013 |

Annex 13 – PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2013

| Product INN | Invented name – if available | Type of PDCO opinion ¹ | Therapeutic area | Applicant | EMA decision number | Signature date |
|---------------------------------------|--------------------------------|-----------------------------------|--|--|---------------------|----------------|
| Catridecacog | NovoThirteen | PM | Haematology-Hemostaseology | Novo Nordisk A/S | P/0001/2013 | 11/01/2013 |
| Tigecycline | Tygacil | PM | Other | Pfizer Limited | P/0002/2013 | 18/01/2013 |
| Liraglutide | EMEA/H/C/O 01026 | PM | Endocrinology - Gynaecology-Fertility-Metabolism | Novo Nordisk A/S | P/0003/2013 | 21/01/2013 |
| Propranolol hydrochloride | Not available at present | PM | Dermatology | PIERRE FABRE DERMATOLOGIE | P/0004/2013 | 21/01/2013 |
| Valganciclovir hydrochloride | Valcyte "and associated names" | PM | Infectious Diseases | Roche Registration Limited | P/0005/2013 | 21/01/2013 |
| Ceftaroline fosamil (established INN) | Zinforo | PM | Infectious Diseases | AstraZeneca AB | P/0006/2013 | 21/01/2013 |
| Morphine sulfate | Not available at present | W | Pain | QRxPharma Inc | P/0007/2013 | 21/01/2013 |
| Dapagliflozin | Forxiga | PM | Endocrinology - Gynaecology-Fertility-Metabolism | Bristol Myers Squibb /AstraZeneca EEIG | P/0008/2013 | 22/01/2013 |
| Atazanavir sulphate | REYATAZ | PM | Infectious Diseases | Bristol-Myers Squibb Pharma EEIG | P/0009/2013 | 22/01/2013 |
| amlodipine (besylate) | not available at | W | Cardiovascular Diseases Endocrinology - | Billev Pharma | P/0010/2013 | 22/01/2013 |

¹ P = PIP; PM = Modification of a PIP; W = Waiver; RP = Refusal of a PIP; RPM = Refusal of a Modification of a PIP; RW = Refusal of a Waiver

| | | | | | | |
|---|--|----|--|--|-----------------|------------|
| | present | | Gynaecology- Fertility- Metabolism | ApS | | |
| amlodipine besilate | not available at present | W | Cardiovascular Diseases | Billev Pharma Aps | P/0011/201 3 | 22/01/2013 |
| Everolimus | Votubia | P | Neurology Uro- nephrology | Novartis Europhar m Limited | P/0012/201 3 | 23/01/2013 |
| apixaban | Eliquis | P | Cardiovascular Diseases | Bristol- Myers Squibb / Pfizer EEIG | P/0013/201 3 | 23/01/2013 |
| Ferumoxytol | RIENSO | PM | Haematology- Hemostaseology | AMAG Pharmace uticals Inc. | P/0014/201 3 | 23/01/2013 |
| Laquinimod | Nerventra | PM | Neurology | Teva Pharma GmbH | P/0015/201 3 | 25/01/2013 |
| Dobutamine Hydrochloride | Not available at present | P | Cardiovascular Diseases Neonatology - Paediatric Intensive Care | Proveca Limited | P/0016/201 3 | 25/01/2013 |
| rituximab | MabThera | PM | Immunology- Rheumatology - Transplantatio n Oncology | Roche Products Ltd | P/0017/201 3 | 18/01/2013 |
| Tenofovir disoproxil (as fumarate) | Viread | PM | Infectious Diseases | Gilead Sciences Internatio nal Limited | P/0018/201 3 | 31/01/2013 |
| Solifenacin (succinate) | Vesicare and associated names | PM | Uro- nephrology | Astellas Pharma Europe B.V. | P/0019/201 3 | 01/02/2012 |
| Tiotropium bromide (monohydrate) | Spiriva Respimat Spiriva | P | Pneumology - Allergology | Boehringer Ingelheim Internatio nal GmbH | P/0020/201 3 | 15/02/2013 |
| Fluticasone furoate / triphenylacetic acid - 4- {(1R)-2-[(6-{2-[(2,6- dichlorobenzyl)oxy]ethoxy} hexyl) amino]-1- | N/A | PM | Pneumology - Allergology | Glaxo Group Limited | P/0021/201 3 | 15/02/2013 |

| | | | | | | |
|---|-----------------|----|--|-----------------------------------|-------------|------------|
| hydroxyethyl}-2-(hydroxymethyl)phenol | | | | | | |
| Strontium (succinate) | Protelos Osseor | W | Immunology-Rheumatology - Transplantation | Les Laboratoires Servier | P/0022/2013 | 25/02/2013 |
| Eribulin | Halaven | P | Oncology | Eisai Europe Ltd, | P/0023/2013 | 25/02/2013 |
| Conestat alfa | Ruconest | PM | Other | Pharming Group N.V. | P/0024/2013 | 26/02/2013 |
| C1 inhibitor | Cinryze | PM | Immunology-Rheumatology - Transplantation | ViroPharma SPRL | P/0025/2013 | 26/02/2013 |
| Aztreonam | Cayston | W | Infectious Diseases | Gilead Sciences International Ltd | P/0026/2013 | 26/02/2013 |
| Dimethyl fumarate | N/A | PM | Neurology | Biogen Idec Ltd. | P/0027/2013 | 26/02/2013 |
| 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-carboxyglycyl]amino]-alpha neuraminosyl]-2-deoxy-alpha-D-galactopyranosyl]-L-threonine]] (human) | N/A | PM | Oncology | Teva Pharma B.V. | P/0028/2013 | 26/02/2013 |
| Strontium succinate / Vitamin D3 | N/A | w | Immunology-Rheumatology - Transplantation | Les Laboratoires Servier | P/0029/2013 | 26/02/2013 |
| Proteinase, metallo-(synthetic nociceptin receptor-binding) 1290102-81-6 (AGN214868) | N/A | P | Pain Uro-nephrology | Allergan Pharmaceuticals Ireland | P/0030/2013 | 26/02/2013 |
| Hydrocortisone | N/A | W | Endocrinology - Gynaecology-Fertility-Metabolism | Diurnal Limited | P/0031/2013 | 26/02/2013 |
| Frovatriptan (succinate monohydrate) / dexketoprofen | N/A | W | Neurology | Menarini Ricerche | P/0032/2013 | 26/02/2013 |

| | | | | | | |
|---|---|----|--|-----------------------------------|-------------|------------|
| (trometamol) | | | | S.p.A. | | |
| 2,6-Bis-{(1-naphthalenyl-3,6-disulfonic acid)-oxyacetamido}-2,6-bis-2,6-bis-2,6-bis-(2,6-diamino-hexanoylamino)-2,6-diamino-hexanoic acid (diphenylmethyl)-amide, polysodium salt | N/A | P | Other | Starpharma Pty Ltd | P/0033/2013 | 26/02/2013 |
| Amlodipine (besylate) / atorvastatin (calcium) | N/A | W | Cardiovascular Diseases Endocrinology - Gynaecology-Fertility-Metabolism | HCS bvba | P/0034/2013 | 26/02/2013 |
| Lixisenatide | N/A | PM | Endocrinology - Gynaecology-Fertility-Metabolism | Sanofi-Aventis R&D | P/0035/2013 | 27/02/2013 |
| Darunavir / cobicistat | N/A | P | Infectious Diseases | Janssen-Cilag International NV | P/0036/2013 | 27/02/2013 |
| Azithromycin | N/A | P | Neonatology - Paediatric Intensive Care | Only for children pharmaceuticals | P/0037/2013 | 27/02/2013 |
| Perindopril / indapamide / amlodipine | N/A | W | Cardiovascular Diseases | Pharma-Regist Kft. | P/0038/2013 | 27/02/2013 |
| Valsartan / indapamide | N/A | W | Cardiovascular Diseases | Gedeon Richter Plc. | P/0039/2013 | 27/02/2013 |
| Amlodipine / losartan | N/A | W | Cardiovascular Diseases | Krka, d.d., Novo mesto | P/0040/2013 | 27/02/2013 |
| Beclometasone dipropionate / formoterol fumarate dihydrate | Foster and associated names Kantos and associated names Inuvair and associated names Kantos Master and associated | PM | Pneumology - Allergology | Chiesi Farmaceutici S.p.A. | P/0041/2013 | 25/02/2013 |

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|---|--|----|-----------------------------------|---|-------------|------------|
| | names | | | | | |
| Cilengitide | N/A | PM | Oncology | Merck KGaA, | P/0042/2013 | 01/03/2013 |
| Boceprevir | Victrelis | PM | Infectious diseases | Merck Sharp & Dohme Ltd | P/0043/2013 | 01/03/2013 |
| Volasertib | N/A | P | Oncology | Boehringer Ingelheim International GmbH | P/0044/2013 | 01/03/2013 |
| Enzastaurin (hydrochloride) | N/A | P | Oncology | Eli Lilly & Company Limited | P/0045/2013 | 01/03/2013 |
| Obinutuzumab | N/A | P | Oncology | Roche Registration Limited | P/0046/2013 | 01/03/2013 |
| Talimogene laherparepvec | N/A | P | Oncology | Amgen Europe B.V. | P/0047/2013 | 01/03/2013 |
| N-{4-Chloro-2-[(1-oxido-4-pyridinyl)carbonyl]phenyl}-4-(1,1-dimethylethyl)benzenesulfonamide, sodium salt | N/A | P | Gastroenterology-Hepatology Other | Glaxo Group Limited | P/0048/2013 | 01/03/2013 |
| Tapentadol (hydrochloride) | Palexia and associated names Yantil and associated names Tapentadol and associated names | PM | Pain | Grünenthal GmbH | P/0049/2013 | 01/03/2013 |
| Tapentadol (hydrochloride) | Palexia and associated names Yantil and associated names Tapentadol and associated names | PM | Pain | Grünenthal GmbH | P/0050/2013 | 01/03/2013 |

| | | | | | | |
|----------------------------|--|-----|---|---|-------------|------------|
| Tapentadol (hydrochloride) | Palexia and associated names Yantil and associated names Tapentadol and associated names | PM | Pain | Grünenthal GmbH | P/0051/2013 | 01/03/2013 |
| Asfotase alfa | N/A | P | Endocrinology - Gynaecology- Fertility- Metabolism | Alexion Europe SAS | P/0052/2013 | 01/03/2013 |
| Vedolizumab | N/A | PM | Gastroenterology- Hepatology | Takeda Global Research & Development Centre (Europe) Ltd, | P/0053/2013 | 20/03/2013 |
| Mepolizumab | N/A | PM | Pneumology - Allergology | Glaxo Group Limited | P/0054/2013 | 25/03/2013 |
| Etoxybamide | N/A | P | Anaesthesiology Neurology | Dr. Franz Köhler Chemie GmbH | P/0055/2013 | 25/03/2013 |
| Oritavancin (diphosphate) | N/A | P | Dermatology Infectious Diseases | The Medicines Company | P/0056/2013 | 25/03/2013 |
| Dalbavancin | N/A | PM | Infectious diseases | Durata Therapeutics, Inc. | P/0057/2013 | 26/03/2013 |
| Everolimus | Votubia | RPM | Neurology Uro- nephrology | Novartis Europharm Ltd | P/0058/2013 | 26/03/2013 |
| Everolimus | Afinitor Certican and associated names | PM | Immunology- Rheumatology - Transplantation | Novartis Europharm Ltd | P/0059/2013 | 26/03/2013 |
| Aprepitant | Emend | PM | Oncology | Merck Sharp & Dohme Ltd | P/0060/2013 | 26/03/2013 |

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|----------------------------|--------------------|----|--|--|-----------------|------------|
| Saxagliptin | Onglyza | PM | Endocrinology - Gynaecology- Fertility- Metabolism | Bristol Myers Squibb / AstraZene ca EEIG | P/0061/201 3 | 26/03/2013 |
| Ambrisentan | Volibris | PM | Cardiovascula r diseases | Glaxo Group Limited | P/0062/201 3 | 26/03/2013 |
| Belimumab | Benlysta | PM | Immunology- Rheumatology - Transplantatio n | Glaxo Group Limited | P/0063/201 3 | 26/03/2013 |
| Guanfacine (hydrochloride) | N/A | PM | Psychiatry | Shire Pharmace uticals Contracts Ltd. | P/0064/201 3 | 26/03/2013 |
| Bimatoprost | Lumigan Latisse | PM | Dermatology Ophthalmolog y | Allergan Pharmace uticals Ireland | P/0065/201 3 | 26/03/2013 |
| Elvitegravir | N/A | PM | Infectious diseases | Gilead Sciences Internatio nal Limited | P/0066/201 3 | 26/03/2013 |
| Sarilumab | N/A | P | Immunology- Rheumatology - Transplantatio n | Sanofi- Aventis recherche & développe ment, | P/0067/201 3 | 26/03/2013 |
| Anacetrapib | N/A | P | Cardiovascula r diseases | Merck Sharp & Dohme (Europe), Inc. | P/0068/201 3 | 26/03/2013 |
| Baricitinib | N/A | P | Immunology- Rheumatology - Transplantatio n | Eli Lilly & Company Limited | P/0069/201 3 | 26/03/2013 |
| Hexaminolevulinate | Hexvix | W | Diagnostic Endocrinology - Gynaecology- Fertility- Metabolism Oncology | Photocure ASA | P/0070/201 3 | 26/03/2013 |

| | | | | | | |
|---|---------|----|---|--|-------------|------------|
| Autologous CD34+ Cells Transduced ex-vivo with Retroviral Vector (GIADAI) Containing Human Adenosine Deaminase Gene from cDNA | N/A | P | Immunology-Rheumatology - Transplantation | Glaxo Group Ltd | P/0071/2013 | 26/03/2013 |
| Pegylated human recombinant factor VIII (BAX 855) | N/A | P | Haematology-Hemostaseology | Baxter Innovations GmbH | P/0072/2013 | 26/03/2013 |
| Gabapentin | N/A | P | Pain | PHARM SRL | P/0073/2013 | 26/03/2013 |
| Clonidine (Hydrochloride) | N/A | P | Anaesthesiology | Therakind Limited | P/0074/2013 | 26/03/2013 |
| Alendronic acid / colecalciferol | N/A | W | Immunology-Rheumatology - Transplantation | TEVA Pharma B.V. | P/0075/2013 | 26/03/2013 |
| Lutetium [177 Lu] | N/A | W | Other | I.D.B. Radiopharmacy B.V. | P/0076/2013 | 26/03/2013 |
| Bisoprolol / amlodipine | N/A | W | Cardiovascular diseases | Krka, d.d., Novo mesto | P/0077/2013 | 26/03/2013 |
| Brivaracetam | N/A | PM | Neurology | UCB Pharma SA | P/0078/2013 | 27/03/2013 |
| Vancomycin | N/A | P | Infectious diseases Neonatology - Paediatric Intensive Care | Fondazione PENTA Onlus | P/0079/2013 | 27/03/2013 |
| Sialic acid | N/A | W | Other | Ultragenyx Pharmaceutical Inc. | P/0080/2013 | 27/03/2013 |
| Retigabine | Trobalt | PM | Neurology | Glaxo Group Limited | P/0081/2013 | 27/03/2013 |
| 1-(2R,5R)-5-ethynyl-5-(hydroxymethyl)-2,5-dihydro-2-furanyl)-5-methyl-2,4(1H,3H)-pyrimidinedione (BMS-986001) | N/A | P | Infectious diseases | Bristol-Myers Squibb International Corporation | P/0082/2013 | 27/03/2013 |
| Ceftazidime / Avibactam | N/A | P | Infectious diseases | AstraZene | P/0083/2013 | 26/04/2013 |

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| | | | | ca AB | 3 | |
| Recombinant L-asparaginase | N/A | PM | Oncology | Medac Gesellschaft für klinische Spezialpräparate mbH | P/0084/2013 | 29/04/2013 |
| Voclosporin | N/A | PM | Ophthalmology | Lux Biosciences GmbH | P/0085/2013 | 29/04/2013 |
| Denosumab | EMA/H/C/O 01120 EMA/H/C/O 02173 | P | Endocrinology - Gynaecology-Fertility-Metabolism | Amgen Europe B.V. | P/0086/2013 | 29/04/2013 |
| Ceftobiprole medocaril (sodium) | N/A | PM | Infectious diseases | Basilea Pharmaceutica International Ltd | P/0087/2013 | 29/04/2013 |
| Nilotinib | Tasigna | PM | Oncology | Novartis Europharm Ltd | P/0088/2013 | 29/04/2013 |
| Peginterferon alfa-2a | Pegasys | PM | Infectious diseases | Roche Registration Limited | P/0089/2013 | 29/04/2013 |
| Bosentan | Tracleer | PM | Cardiovascular Diseases Immunology-Rheumatology - Transplantation Pneumology - Allergology | Actelion Registration Ltd | P/0090/2013 | 29/04/2013 |
| Turoctocog alfa | N/A | PM | Haematology-Hemostaseology | Novo Nordisk A/S | P/0091/2013 | 29/04/2013 |
| Bucelipase alfa | N/A | PM | Gastroenterology-hepatology | Swedish Orphan Biovitrum AB | P/0092/2013 | 29/04/2013 |
| Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; Escherichia coli) / Neisseria | N/A | P | Vaccines | Pfizer | P/0093/2013 | 29/04/2013 |

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|---|------------------|----|---|---|-------------|------------|
| meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; Escherichia coli) (rLP2086) | | | | | | |
| rdESAT-6 / rCFP-10 | N/A | PM | Diagnostic | Statens Serum Institut | P/0094/2013 | 29/04/2013 |
| Atomoxetine (hydrochloride) | Strattera | PM | Psychiatry | Eli Lilly & Company | P/0095/2013 | 29/04/2013 |
| Surotomycin | N/A | P | Infectious diseases | Cubist Pharmaceuticals, Inc. | P/0096/2013 | 29/04/2013 |
| Zanamivir | Relenza | P | Infectious diseases | GlaxoSmithKline Research and Development Limited, | P/0097/2013 | 29/04/2013 |
| Chlormethine | N/A | W | Dermatology Oncology | Ceptaris Therapeutics Inc. | P/0098/2013 | 29/04/2013 |
| Raltegravir | EMEA/H/C/O 00860 | PM | Oncology | Merck Sharp & Dohme (Europe), Inc. | P/0099/2013 | 30/04/2013 |
| Decitabine | Dacogen | PM | Oncology | Janssen-Cilag International NV | P/0100/2013 | 30/04/2013 |
| Ivabradine (hydrochloride) | Corlentor | PM | Cardiovascular Diseases | Les Laboratoires Servier | P/0101/2013 | 30/04/2013 |
| Ivabradine (hydrochloride) | Procoralan | PM | Cardiovascular Diseases | Les Laboratoires Servier | P/0102/2013 | 30/04/2013 |
| Pixantrone (dimaleate) | Pixuvri | PM | Oncology | CTI Life Sciences | P/0103/2013 | 30/04/2013 |
| Treosulfan | N/A | PM | Immunology-Rheumatology - Transplantation | medac Gesellschaft für klinische | P/0104/2013 | 30/04/2013 |

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| | | | Oncology | Spezialpräparate mbH | | |
| Bedaquiline (fumarate) | N/A | PM | Infectious diseases | Janssen Infectious Diseases BVBA | P/0105/2013 | 30/04/2013 |
| Linaclotide | Constella | PM | Gastroenterology-Hepatology | Almirall S.A. | P/0106/2013 | 30/04/2013 |
| (3aR,4S,7aR)-Octahydro-4-hydroxy-4-[(3-methylphenyl)ethynyl]-1H-indole-1-carboxylic acid methyl ester | N/A | PM | Neurology | Novartis Europharm Ltd | P/0107/2013 | 30/04/2013 |
| Canagliflozin | N/A | PM | Endocrinology - Gynaecology-Fertility-Metabolism | Janssen-Cilag International N.V | P/0108/2013 | 30/04/2013 |
| Epratuzumab | N/A | P | Immunology-Rheumatology - Transplantation | UCB Pharma S.A. | P/0109/2013 | 30/04/2013 |
| Bumetanide | N/A | P | Neurology | Neurochlor | P/0110/2013 | 30/04/2013 |
| Palivizumab | Synagis | P | Neonatology - Paediatric Intensive Care | AbbVie Ltd | P/0111/2013 | 30/04/2013 |
| Recombinant human lysosomal acid lipase | N/A | P | Endocrinology - Gynaecology-Fertility-Metabolism Gastroenterology-Hepatology | Synageva BioPharma Ltd | P/0112/2013 | 30/04/2013 |
| Amlodipine (besilate) / losartan (potassium) | N/A | W | Cardiovascular diseases | GlaxoSmithKline Trading Services Limited | P/0113/2013 | 30/04/2013 |
| Solifenacin (succinate) | Vesicare and associated names | PM | Uro-nephrology | Astellas Pharma Europe B.V. | P/0114/2013 | 26/04/2013 |
| Solifenacin (succinate) | Vesicare and associated names | P | Uro-nephrology | Astellas Pharma Europe B.V. | P/0115/2013 | 26/04/2013 |

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|--|----------|----|---|---------------------------------------|-------------|------------|
| Paclitaxel | Abraxane | P | Oncology | Celgene Europe Limited | P/0116/2013 | 26/04/2013 |
| Fingolimod (hydrochloride) | Gilenya | PM | Neurology | Novartis Europharm Limited | P/0117/2013 | 26/04/2013 |
| Dasatinib | Sprycel | PM | Oncology | Bristol-Myers Squibb Pharma EEIG | P/0118/2013 | 02/05/2013 |
| Autologous haematopoietic stem cells transduced with lentiviral vector Lenti-D encoding the human ATP-binding cassette, sub-family D (ALD), member 1 (ABCD1) from cDNA | N/A | P | Dermatology Gastroenterology- Hepatology Immunology- Rheumatology - Transplantation | Bluebird bio France | P/0119/2013 | 03/05/2013 |
| Clostridium botulinum toxin type A, purified neurotoxin | N/A | W | Dermatology | Janssen Biologics B.V. | P/0120/2013 | 03/05/2013 |
| Adalimumab | Humira | P | Dermatology | AbbVie Ltd. | P/0121/2013 | 03/05/2013 |
| Concentrate of proteolytic enzymes in bromelain | NexoBrid | PM | Other | Teva Pharma GmbH | P/0122/2013 | 28/05/2013 |
| Sitagliptin | Januvia | PM | Endocrinology - Gynaecology- Fertility- Metabolism | Merck Sharp and Dohme (Europe), Inc. | P/0123/2013 | 28/05/2013 |
| Aztreonam | Cayston | PM | Infectious diseases | Gilead Sciences International Limited | P/0124/2013 | 28/05/2013 |
| Lenvatinib | N/A | P | Oncology | Eisai Europe Limited | P/0125/2013 | 28/05/2013 |
| Benralizumab | N/A | P | Pneumology - Allergology | MedImmune Ltd | P/0126/2013 | 28/05/2013 |
| Anti proprotein convertase subtilisin/kexin type 9 human monoclonal | N/A | P | Cardiovascular diseases | Amgen Europe | P/0127/2013 | 28/05/2013 |

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|---|---------|----|---|-----------------------------|-------------|------------|
| antibody (AMG 145) | | | | B.V | | |
| Menotrophin | N/A | W | Endocrinology - Gynaecology-Fertility-Metabolism | Laboratoires Genevrier | P/0128/2013 | 28/05/2013 |
| Ivabradine (hydrochloride) / metoprolol (tartrate) | N/A | W | Cardiovascular diseases | Les Laboratoires Servier | P/0129/2013 | 28/05/2013 |
| Valsartan / hydrochlorothiazide + rosuvastatin | N/A | W | Cardiovascular diseases | Krka, d.d., Novo mesto | P/0130/2013 | 28/05/2013 |
| Rosuvastatin / ezetimibe | N/A | W | Cardiovascular diseases | EGIS Pharmaceuticals PLC | P/0131/2013 | 28/05/2013 |
| acosamide | Vimpat | P | Neurology | UCB Pharma S.A. | P/0132/2013 | 31/05/2013 |
| Oseltamivir (phosphate) | Tamiflu | PM | Infectious diseases | Roche Registration Ltd | P/0133/2013 | 07/06/2013 |
| Isavuconazonium (sulfate) | N/A | P | Infectious diseases | Astellas Pharma Europe B.V. | P/0134/2013 | 14/06/2013 |
| Isavuconazonium (sulfate) | N/A | P | Infectious diseases | Astellas Pharma Europe B.V. | P/0135/2013 | 14/06/2013 |
| Phenylephrine hydrochloride / ketorolac trometamol (OMS302) | N/A | P | Ophthalmology | Omeros Corporation | P/0136/2013 | 14/06/2013 |
| Adalimumab | Humira | PM | Gastroenterology-Hepatology-Immunology-Rheumatology - Transplantation | AbbVie Limited | P/0137/2013 | 21/06/2013 |
| ataluren (3-[5-(2-fluorophenyl)-[1,2,4]oxadiazole-3-yl]-benzoic acid) | N/A | PM | Pneumology - Allergology | PTC Therapeutics, Limited | P/0138/2013 | 21/06/2013 |
| Apremilast | N/A | PM | Dermatology-Immunology-Rheumatology - Transplantation | Celgene Europe Limited | P/0139/2013 | 24/06/2013 |

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|---|---------------------|----|--|---|-------------|------------|
| Zoledronic acid | Aclasta | PM | Other | Novartis Europharm Limited | P/0140/2013 | 03/07/2013 |
| Canakinumab | Ilaris | PM | Immunology- Rheumatology - Transplantation | Novartis Europharm Limited | P/0141/2013 | 03/07/2013 |
| Icatibant acetate | Firazyr | PM | Other | Shire Orphan Therapies GmbH | P/0142/2013 | 03/07/2013 |
| Clostridium Botulinum neurotoxin type A (150 kD), free of complexing proteins | Xeomin Bocouture | P | Neurology | Merz Pharmaceuticals GmbH | P/0143/2013 | 03/07/2013 |
| Terbinafine hydrochloride | N/A | P | Dermatology | Polichem SA | P/0144/2013 | 03/07/2013 |
| Cebranopadol | N/A | P | Pain | Grünenthal GmbH | P/0145/2013 | 03/07/2013 |
| Estetrol / Drospirenone | N/A | P | Endocrinology - Gynaecology- Fertility- Metabolism | Estetra S.A. | P/0146/2013 | 03/07/2013 |
| Metformin (hydrochloride) | N/A | P | Endocrinology - Gynaecology- Fertility- Metabolism | EffRx Pharmaceuticals SA | P/0147/2013 | 03/07/2013 |
| Ketoprofen / Omeprazole | N/A | W | Pain | Conventia Healthcare LLP | P/0148/2013 | 03/07/2013 |
| Ibrutinib | N/A | W | Oncology | Janssen- Cilag International N.V. | P/0149/2013 | 03/07/2013 |
| Zolpidem (tartrate) | N/A | W | Psychiatry | Transcept Pharmaceuticals, Inc | P/0150/2013 | 03/07/2013 |
| Voriconazole | Vfend | P | Infectious diseases | Pfizer Limited | P/0151/2013 | 05/07/2013 |
| Human coagulation Factor VIII / von Willebrand Factor | N/A | PM | Haematology- Hemostaseology | CSL Behring | P/0152/2013 | 05/07/2013 |
| Cysteamine hydrochloride | N/A | PM | Ophthalmology | Orphan Europe SARL | P/0153/2013 | 05/07/2013 |

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|--------------------------------------|-----------|----|---|--|-----------------|------------|
| Selexipag | N/A | PM | Other | Actelion Registratio n Ltd | P/0154/201 3 | 05/07/2013 |
| Evacetrapib | N/A | P | Cardiovascula r Diseases Endocrinology - Gynaecology- Fertility- Metabolism | Eli Lilly and Company | P/0155/201 3 | 05/07/2013 |
| Dry extract from Betulae cortex | N/A | P | Dermatology | Birken AG | P/0156/201 3 | 05/07/2013 |
| Human fibrinogen / human thrombin | N/A | P | Haematology- Hemostaseolo gy Other | ProFibrix BV | P/0157/201 3 | 05/07/2013 |
| Glycopyrronium (bromide) | N/A | P | Neurology | Proveca Limited | P/0158/201 3 | 05/07/2013 |
| Ixazomib (citrate) | N/A | W | Haematology- Hemostaseolo gy | Takeda Global Research & Developm ent Centre (Europe) Ltd | P/0159/201 3 | 05/07/2013 |
| Mifepristone | N/A | P | Endocrinology - Gynaecology- Fertility- Metabolism | Corcept Therapeuti cs Incorporat ed | P/0160/201 3 | 08/07/2013 |
| Perampanel | Fycompa | PM | Neurology | Eisai Europe Limited | P/0161/201 3 | 29/07/2013 |
| Etravirine | Intelence | PM | Infectious Diseases | Janssen- Cilag Internatio nal N.V. | P/0162/201 3 | 29/07/2013 |
| Rivaroxaban | Xarelto | PM | Cardiovascula r Diseases | Bayer Pharma AG | P/0163/201 3 | 29/07/2013 |
| C1 inhibitor | Cinryze | PM | Immunology- Rheumatology - Transplantatio n | ViroPharm a SPRL | P/0164/201 3 | 29/07/2013 |
| Sildenafil | Revatio | PM | Other | Pfizer Limited | P/0165/201 3 | 29/07/2013 |
| 2'-O-methyl-uridylyl-(3'→5') | N/A | PM | Neurology | Glaxo | P/0166/201 | 30/07/2013 |

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|--|-----|----|---------------------|---------------------------------------|-------------|------------|
| <p>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,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-cytidylyl-(3'→5' O,O-phosphorothioyl)-2'-O-methyl-uridine sodium salt (exon 51 specific phosphorothioate oligonucleotide)</p> | | | | Group Limited | 3 | |
| Cobicistat | N/A | PM | Infectious Diseases | Gilead Sciences International Limited | P/0167/2013 | 30/07/2013 |
| Recombinant Varicella Zoster Virus (VZV) | N/A | P | Vaccines | GlaxoSmit hKline | P/0168/2013 | 30/07/2013 |

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|--|---------------------------------------|----|--|----------------------------------|-------------|------------|
| glycoprotein E antigen | | | | Biologicals SA | | |
| Tofacitinib | N/A | PM | Immunology-Rheumatology - Transplantation | Pfizer Limited | P/0169/2013 | 30/07/2013 |
| Tofacitinib | N/A | PM | Dermatology | Pfizer Limited | P/0170/2013 | 30/07/2013 |
| Purified antigen fractions of inactivated split virion Influenza virus type A, H1N1 / Influenza virus type A, H3N2 / Influenza virus type B, Victoria lineage / Influenza virus type B, Yamagata lineage | Influsplit Tetra and associated names | PM | Vaccines | GlaxoSmithKline Biologicals S.A. | P/0171/2013 | 30/07/2013 |
| Human normal immunoglobulin | Gammaplex | PM | Haematology-Hemostaseology Immunology-Rheumatology - Transplantation | Bio Products Laboratory Limited | P/0172/2013 | 30/07/2013 |
| 3-[[4-[(1S)-1-[4-(4-tert-butylphenyl)-3,5-dimethylphenoxy]-4,4,4-trifluorobutyl]benzoyl]amino]propanoic acid | N/A | P | Endocrinology - Gynaecology-Fertility-Metabolism | Eli Lilly and Company | P/0173/2013 | 30/07/2013 |
| Alpha tocotrienol quinone | N/A | P | Neurology | Edison Orphan Pharma BV | P/0174/2013 | 30/07/2013 |
| Lopinavir / lamivudine / ritonavir / zidovudine | N/A | W | Infectious Diseases | AbbVie Limited | P/0175/2013 | 30/07/2013 |
| Glucarpidase | N/A | P | Oncology | BTG International Ltd | P/0176/2013 | 30/07/2013 |
| Esketamine | N/A | RW | Psychiatry | Janssen-Cilag International N.V. | P/0177/2013 | 30/07/2013 |
| Pegylated proline-interferon alpha-2b | N/A | W | Haematology-Hemostaseology | AOP Orphan Pharmaceuticals AG | P/0178/2013 | 30/07/2013 |
| Clopidogrel (hydrogen sulphate) / acetylsalicylic | N/A | W | Cardiovascular Diseases | BILLEV PHARMA | P/0179/2013 | 30/07/2013 |

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| acid | | | | ApS | 3 | |
| Amlodipine / ramipril | N/A | W | Cardiovascular Diseases | Adamed Sp. z o.o. | P/0180/2013 | 30/07/2013 |
| Colistimethate sodium | Colobreathe | PM | Infectious Diseases | Forest Laboratories UK Limited | P/0181/2013 | 30/07/2013 |
| Laquinimod (sodium) | N/A | PM | Neurology | Teva Pharma GmbH | P/0182/2013 | 31/07/2013 |
| Ferric citrate | N/A | P | Uro-nephrology | KERYX BIOPHARMACEUTICALS | P/0183/2013 | 31/07/2013 |
| Capsici acris extractum spissum normatum | N/A | P | Pain | Momaja s.r.o. | P/0184/2013 | 31/07/2013 |
| Tocilizumab | RoActemra | PM | Immunology-Rheumatology - Transplantation | Roche Registration Limited | P/0185/2013 | 30/07/2013 |
| Elvitegravir | N/A | PM | Infectious Diseases | Gilead Sciences International Limited | P/0186/2013 | 02/08/2013 |
| Levofloxacin (hemihydrate) | N/A | PM | Pneumology - Allergology | Aptalis Pharma SAS | P/0187/2013 | 08/08/2013 |
| Naltrexone (hydrochloride) / bupropion (hydrochloride) | N/A | P | Other | Orexigen Therapeutics, Inc. | P/0188/2013 | 08/08/2013 |
| Solifenacin (succinate) | Vesicare and associated names | PM | Uro-nephrology | Astellas Pharma Europe B.V. | P/0189/2013 | 09/08/2013 |
| Solifenacin (succinate) | Vesicare and associated names | PM | Uro-nephrology | Astellas Pharma Europe B.V. | P/0190/2013 | 09/08/2013 |
| Mirabegron | Betmiga | PM | Uro-nephrology | Astellas Pharma Europe B.V. | P/0191/2013 | 09/08/2013 |

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|---|------------------------------------|----|---|---|-----------------|------------|
| Rilpivirine (hydrochloride) | EMA/H/C/O 02264 | PM | Infectious Diseases | Janssen- Cilag Internatio nal NV | P/0192/201 3 | 15/08/2013 |
| Rupadatine fumarate | Rupafin and associated names | PM | Dermatology Oto-rhino- laryngology Pneumology - Allergology | J. Uriach y Compañía, S.A. | P/0193/201 3 | 13/08/2013 |
| Idursulfase | N/A | P | Endocrinology - Gynaecology- Fertility- Metabolism | Shire Human Genetic Therapies AB | P/0194/201 3 | 29/08/2013 |
| Ipilimumab | Yervoy | PM | Oncology | Bristol- Myers Squibb Pharma EEIG | P/0195/201 3 | 02/09/2013 |
| Human Papillomavirus Type 6 L1 protein / Human Papillomavirus Type 11 L1 protein / Human Papillomavirus Type 16 L1 protein / Human Papillomavirus Type 18 L1 protein / Human Papillomavirus Type 31 L1 protein / Human Papillomavirus Type 33 L1 protein / Human Papillomavirus Type 45 L1 protein / Human Papillomavirus Type 52 L1 protein / Human Papillomavirus Type 58 L1 protein | N/A | PM | Vaccines | Sanofi Pasteur MSD SNC | P/0196/201 3 | 02/09/2013 |
| Eslicarbazepine (acetate) | Zebinix | PM | Neurology | BIAL - Portela & Ca, SA | P/0197/201 3 | 02/09/2013 |
| Recombinant fusion protein consisting of human coagulation factor IX attached to the Fc domain of human IgG1 (rFIXFc) | N/A | PM | Haematology- Hemostaseolo gy | Biogen Idec Ltd | P/0198/201 3 | 02/09/2013 |
| L-CysteinyI-L-prolyI-L- alanyl-L-valyl-L-lysyl-L- arginyl-L-aspartyl-L-valyl- | N/A | PM | Oto-rhino- laryngology Pneumology - Allergology | Circassia Limited | P/0199/201 3 | 02/09/2013 |

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|--|-----|----|-----------|------------------|-------------|------------|
| <p>L-aspartyl-L-leucyl-L-phenylalanyl-L-leucyl-L-threonine, hydrochloride salt / L-Glutamyl-L-glutaminy-L-valyl-L-alanyl-L-glutaminy-L-tyrosyl-L-lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginy-L-alanine, acetate salt / L-Lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginy-L-alanyl-L-arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginy-L-cysteinyl-L-valine, acetate salt / L-Arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginy-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-asparaginy-L-alanyl-L-leucyl-L-seryl-L-leucyl-L-leucyl-L-aspartyl-L-lysyl-L-isoleucyl-L-tyrosyl-L-threonyl-L-seryl-L-prolyl-L-leucine, acetate salt / L-Threonyl-L-alanyl-L-methionyl-L-lysyl-L-lysyl-L-isoleucyl-L-glutaminy-L-aspartyl-L-cysteinyl-L-tyrosyl-L-valyl-L-glutamyl-L-asparaginy-L-glycyl-L-leucyl-L-isoleucine, acetate salt / L-Seryl-L-arginyl-L-valyl-L-leucyl-L-aspartyl-glycyl-L-leucyl-L-valyl-L-methionyl-L-threonyl-L-threonyl-L-isoleucyl-L-seryl-L-seryl-L-seryl-L-lysine, acetate salt</p> | | | | | | |
| Pitolisant (hydrochloride) | N/A | PM | Neurology | Bioprojet Pharma | P/0200/2013 | 02/09/2013 |

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|--|---------|----|--|------------------------------------|-------------|------------|
| Retosiban | N/A | P | Endocrinology - Gynaecology-Fertility-Metabolism | Glaxo Group Limited | P/0201/2013 | 02/09/2013 |
| Mifepristone | N/A | W | Endocrinology - Gynaecology-Fertility-Metabolism | Laboratorios Litaphar, S.A. | P/0202/2013 | 02/09/2013 |
| Pomalidomide | N/A | W | Haematology-Hemostaseology | Celgene Europe Ltd | P/0203/2013 | 02/09/2013 |
| Modified grass pollen extract | N/A | PM | Pneumology - Allergology | Allergy Therapeutics (UK) Limited | P/0204/2013 | 03/09/2013 |
| Alipogene tiparvovec | Glybera | PM | Cardiovascular Diseases | uniQure biopharma B.V. | P/0205/2013 | 04/09/2013 |
| Fibrinogen concentrate / thrombin preparation / aprotinin / calcium chloride | N/A | PM | Other | Kedrion S.p.A. | P/0206/2013 | 05/09/2013 |
| Recombinant fusion protein consisting of Human Coagulation Factor VIII attached to the Fc domain of Human IgG1 (rFVIII-Fc) | N/A | PM | Haematology-Hemostaseology | Biogen Idec Ltd | P/0207/2013 | 05/09/2013 |
| Chimeric anti-disialoganglioside (GD2) monoclonal antibody (NSC764038) | N/A | PM | Oncology | United Therapeutics Europe Limited | P/0208/2013 | 05/09/2013 |
| Glibenclamide | N/A | P | Endocrinology - Gynaecology-Fertility-Metabolism Other | AMMTeK | P/0209/2013 | 05/09/2013 |
| Cangrelor (tetrasodium) | N/A | P | Cardiovascular Diseases | The Medicines Company UK Ltd. | P/0210/2013 | 05/09/2013 |
| Thrombomodulin alfa | N/A | P | Infectious Diseases | Asahi Kasei Pharma Corporation | P/0211/2013 | 05/09/2013 |
| Risedronate sodium / | N/A | W | Other | Pharma | P/0212/2013 | 05/09/2013 |

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|--|------------------------------------|----|---|--|-----------------|------------|
| colecalfiferol | | | | Patent Kft. | 3 | |
| Acotiamide | N/A | RW | Gastroenterology- Hepatology | Zeria Pharmaceutical Co Ltd | P/0213/201 3 | 05/09/2013 |
| Glycerol phenylbutyrate (GPB) | N/A | P | Endocrinology - Gynaecology- Fertility- Metabolism | Hyperion Therapeutics, Ltd. | P/0214/201 3 | 04/09/2013 |
| Daclizumab | N/A | P | Neurology | Biogen Idec Ltd | P/0215/201 3 | 04/09/2013 |
| Fluticasone furoate / triphenylacetic acid - 4- {(1R)-2-[(6-{2-[(2,6- dichlorobenzyl)oxy]ethoxy} hexyl) amino]-1- hydroxyethyl}-2- (hydroxymethyl)phenol | N/A | PM | Pneumology - Allergology | Glaxo Group Limited | P/0216/201 3 | 30/08/2013 |
| Exenatide | Byetta Bydureon | PM | Endocrinology - Gynaecology- Fertility- Metabolism | Bristol- Myers Squibb/AstraZeneca EEIG | P/0217/201 3 | 06/09/2013 |
| Budesonide | N/A | P | Pneumology - Allergology | Activaero GmbH | P/0218/201 3 | 06/09/2013 |
| Loxapine | N/A | PM | Psychiatry | Alexza UK, Limited | P/0219/201 3 | 06/09/2013 |
| Valganciclovir | Valcyte and associated names | PM | Infectious Diseases | Roche Registration Limited | P/0220/201 3 | 06/09/2013 |
| Tolvaptan | Samsca | P | Endocrinology - Gynaecology- Fertility- Metabolism Uro- nephrology | Otsuka Pharmaceutical Europe Ltd. | P/0221/201 3 | 09/09/2013 |
| Vorapaxar | N/A | P | Cardiovascular Diseases | Merck Sharp & Dohme (Europe), Inc | P/0222/201 3 | 16/09/2013 |
| Azilsartan medoxomil | Edarbi Ipreziv | PM | Cardiovascular Diseases | Takeda Global Research and Development | P/0223/201 3 | 23/09/2013 |

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|--|--|----|---|--|-----------------|------------|
| | | | | ent Centre (Europe) Ltd | | |
| Belimumab | Benlysta | PM | Immunology- Rheumatology - Transplantation | Glaxo Group Limited | P/0224/201 3 | 23/09/2013 |
| Decitabine | Dacogen | PM | Oncology | Janssen- Cilag Internatio nal NV | P/0225/201 3 | 23/09/2013 |
| Nonacog beta pegol | N/A | PM | Haematology- Hemostaseology | Novo Nordisk A/S | P/0226/201 3 | 23/09/2013 |
| Odanacatib | N/A | PM | Immunology- Rheumatology - Transplantation | Merck Sharp & Dohme (Europe), Inc. | P/0227/201 3 | 23/09/2013 |
| Iron as iron maltol (iron(III)-maltol complex) | N/A | P | Haematology- Hemostaseology | Iron Therapeuti cs (UK) Ltd. | P/0228/201 3 | 23/09/2013 |
| Purified Tetanus Toxoid / Inactivated Type 1 Poliovirus (Mahoney) / Inactivated Type 2 Poliovirus (MEF-1) / Inactivated Type 3 Poliovirus (Saukett) / Purified Pertussis Toxoid (PT) / Haemophilus influenzae type b polysaccharide conjugated to tetanus protein / Purified Filamentous Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Purified Diphtheria Toxoid (DTaP- IPV-HepB-PRP-T) | Hexacima and associated names | PM | Vaccines | Sanofi Pasteur SA | P/0229/201 3 | 23/09/2013 |
| Perindopril (erbumine) / Amlodipin (besylate) | N/A | W | Cardiovascula r Diseases | Zentiva k.s. | P/0230/201 3 | 23/09/2013 |
| Valsartan / atorvastatin | N/A | W | Cardiovascula r Diseases | GlaxoSmit hKline | P/0231/201 3 | 23/09/2013 |

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|------------------------------------|-----------|----|--|---|-------------|------------|
| | | | | Trading Services Limited | | |
| Sapropterin Dihydrochloride | Kuvan | P | Endocrinology - Gynaecology-Fertility-Metabolism | Merck KGaA | P/0232/2013 | 23/09/2013 |
| Metformin / rosuvastatin | N/A | W | Cardiovascular Diseases Endocrinology - Gynaecology-Fertility-Metabolism | Fontane Pharma GmbH | P/0233/2013 | 23/09/2013 |
| Mepolizumab | N/A | PM | Pneumology - Allergology | Glaxo Group Limited | P/0234/2013 | 24/09/2013 |
| Apixaban | Eliquis | PM | Cardiovascular Diseases | Bristol-Myers Squibb / Pfizer EEIG | P/0235/2013 | 24/09/2013 |
| Teduglutide | Revestive | PM | Gastroenterology-Hepatology | Nycomed Danmark ApS | P/0236/2013 | 24/09/2013 |
| Sonidegib | N/A | PM | Oncology | Novartis Europharm Limited | P/0237/2013 | 24/09/2013 |
| Insulin peglispro | N/A | PM | Endocrinology - Gynaecology-Fertility-Metabolism | Eli Lilly and Company | P/0238/2013 | 24/09/2013 |
| Dabrafenib (mesilate) | N/A | PM | Oncology | GlaxoSmit hKline Trading Service Limited | P/0239/2013 | 24/09/2013 |
| Deleobuvir | N/A | P | Infectious Diseases | Boehringer Ingelheim International GmbH | P/0240/2013 | 24/09/2013 |
| Ramipril / amlodipine (besilate) | N/A | W | Cardiovascular Diseases | GlaxoSmit hKline Trading Services Limited | P/0241/2013 | 24/09/2013 |
| Calcium (citrate) / colecalciferol | N/A | W | Other | Pharma Patent Kft. | P/0242/2013 | 24/09/2013 |

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|---|--|----|---|------------------------------------|-------------|------------|
| Clostridium difficile toxin A human monoclonal antibody / Clostridium difficile toxin B human monoclonal antibody | N/A | P | Infectious Diseases | Merck Sharp & Dohme (Europe), Inc | P/0243/2013 | 21/09/2013 |
| Edoxaban (tosylate) | N/A | PM | Cardiovascular Diseases | Daiichi Sankyo Development Limited | P/0244/2013 | 04/10/2013 |
| Dalbavancin | N/A | PM | Infectious Diseases | NDA Regulatory Science Ltd | P/0245/2013 | 04/10/2013 |
| Exon 45 specific phosphorothioate oligonucleotide | N/A | P | Other | Prosensa Therapeutics B.V. | P/0246/2013 | 04/10/2013 |
| Exon 53 specific phosphorothioate oligonucleotide | N/A | P | Other | Prosensa Therapeutics B.V. | P/0247/2013 | 04/10/2013 |
| Sofosbuvir / ledipasvir | N/A | P | Infectious Diseases | Gilead Sciences International Ltd. | P/0248/2013 | 10/10/2013 |
| Tedizolid (phosphate) | N/A | P | Infectious Diseases | Trius Therapeutics Inc. | P/0249/2013 | 18/10/2013 |
| Human heterologous liver cells | N/A | PM | Gastroenterology-Hepatology | Cytonet GmbH&Co. KG | P/0250/2013 | 21/10/2013 |
| Everolimus | Afinitor Certican and associated names | PM | Immunology-Rheumatology - Transplantation | Novartis Europharm Limited | P/0251/2013 | 29/10/2013 |
| Denosumab | Xgeva (previously Amgiva) Prolia | PM | Endocrinology - Gynaecology-Fertility-Metabolism Immunology-Rheumatology - Transplantation Oncology | Amgen Europe B.V. | P/0252/2013 | 29/10/2013 |
| Plerixafor | Mozobil | PM | Immunology-Rheumatology - Transplantation | Genzyme Europe | P/0253/2013 | 29/10/2013 |

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|---|------------|----|---|---|-------------|------------|
| | | | n Oncology | B.V. | | |
| Purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005(H5N1) like strain used (PR8-IBCDC-RG2) | Pumarix | PM | Vaccines | GlaxoSmit hKline Biologicals S.A. | P/0254/2013 | 30/10/2013 |
| Pegloticase | Krystexxa | W | Immunology- Rheumatology - Transplantatio n | Savient Pharmace uticals, Inc. | P/0255/2013 | 29/10/2013 |
| Regadenoson | Rapiscan | PM | Cardiovascula r Diseases | Rapidcan Pharma Solutions EU Limited | P/0256/2013 | 29/10/2013 |
| Melatonin | Circadin | PM | Neurology | RAD Neurim Pharmace uticals EEC Ltd | P/0257/2013 | 29/10/2013 |
| Lebrikizumab | N/A | PM | Pneumology - Allergology | Roche Products Limited | P/0258/2013 | 29/10/2013 |
| Octocog alfa | N/A | PM | Haematology- Hemostaseolo gy | Bayer Pharma AG | P/0259/2013 | 29/10/2013 |
| Recombinant human tripeptidyl peptidase-1 | N/A | P | Neurology | BioMarin Europe Limited | P/0260/2013 | 29/10/2013 |
| Amlodipine / atorvastatin | N/A | W | Cardiovascula r Diseases Endocrinology - Gynaecology- Fertility- Metabolism | Pharmace utical Works Polpharma SA | P/0261/2013 | 29/10/2013 |
| Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals: Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004(H5N1) like strain used (NIBRG-14) | Adjupanrix | PM | Vaccines | GlaxoSmit hKline Biologicals S.A. | P/0262/2013 | 30/10/2013 |

| | | | | | | |
|--|-------------------------------------|----|-----------------------------|--------------------------------------|-------------|------------|
| Ivacaftor | Kalydeco | PM | Other | Vertex Pharmaceuticals (Europe) Ltd. | P/0263/2013 | 30/10/2013 |
| Diphtheria toxoid / Tetanus toxoid / Bordetella pertussis antigen: Pertussis toxoid / Bordetella pertussis antigen: Filamentous Haemagglutinin / Bordetella pertussis antigen: Pertactin / Inactivated poliovirus: type 1 (Mahoney strain) / Inactivated poliovirus: type 2 (MEF-1 strain) / Inactivated poliovirus: type 3 (Saukett strain) | Boostrix Polio and associated names | PM | Vaccines | GlaxoSmithKline Biologicals S.A. | P/0264/2013 | 30/10/2013 |
| Guanfacine (hydrochloride) | N/A | PM | Psychiatry | Shire Pharmaceuticals Contracts Ltd. | P/0265/2013 | 30/10/2013 |
| Autologous CD34+ cells transduced with lentiviral vector containing the human Wiskott Aldrich Syndrome Protein gene | N/A | P | Haematology-Hemostaseology | GENETHON (Non profit association) | P/0266/2013 | 30/10/2013 |
| Ozenoxacin | N/A | PM | Infectious Diseases | Ferrer International S.A | P/0267/2013 | 30/10/2013 |
| Lurasidone (hydrochloride) | N/A | PM | Psychiatry | Takeda Pharma A/S | P/0269/2013 | 30/10/2013 |
| Eptacog alfa (activated) | N/A | P | Haematology-Hemostaseology | Baxter Innovations GmbH | P/0270/2013 | 30/10/2013 |
| Quilizumab | N/A | P | Pneumology - Allergology | Roche Registration Limited | P/0271/2013 | 30/10/2013 |
| (4R,5R)-1-[[4-[[4-[3,3-dibutyl-7-(dimethylamino)-2,3,4,5-tetrahydro-4-hydroxy-1,1-dioxido-1-benzothiepin-5- | N/A | W | Gastroenterology-Hepatology | Lumena Pharmaceuticals Inc | P/0272/2013 | 30/10/2013 |

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|--|--|----|--|---|-------------|------------|
| yl]phenoxy]methyl]phenyl]methyl]-4-aza-1-azoniabicyclo[2.2.2]octane chloride | | | | | | |
| Ezetimibe / atorvastatin | N/A | W | Cardiovascular Diseases | Fontane Pharma GmbH | P/0273/2013 | 30/10/2013 |
| Ezetimibe / rosuvastatin | N/A | W | Cardiovascular Diseases | Fontane Pharma GmbH | P/0274/2013 | 30/10/2013 |
| Rufinamide | Inovelon | PM | Neurology | Eisai Limited | P/0275/2013 | 30/10/2013 |
| Nitisinone | Orfadin | PM | Endocrinology - Gynaecology-Fertility-Metabolism | Swedish Orphan Biovitrum International AB | P/0276/2013 | 30/10/2013 |
| Insulin degludec | Tresiba | PM | Endocrinology - Gynaecology-Fertility-Metabolism | Novo Nordisk A/S | P/0277/2013 | 24/10/2013 |
| Idelalisib | N/A | P | Oncology | Gilead Sciences International Limited | P/0278/2013 | 31/10/2013 |
| Tapentadol (hydrochloride) | Palexia and associated names Yantil and associated names Tapentadol and associated names | PM | Pain | Grünenthal GmbH | P/0279/2013 | 08/11/2013 |
| Tapentadol (hydrochloride) | Palexia and associated names Yantil and associated names Tapentadol and associated names | PM | Pain | Grünenthal GmbH | P/0280/2013 | 08/11/2013 |

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|----------------------------|--|----|---------------|---------------------|-------------|------------|
| Tapentadol (hydrochloride) | Palexia and associated names Yantil and associated names Tapentadol and associated names | PM | Pain | Grünentha I GmbH | P/0281/2013 | 08/11/2013 |
| Tapentadol (hydrochloride) | Palexia and associated names Yantil and associated names Tapentadol and associated names | PM | Pain | Grünentha I GmbH | P/0282/2013 | 08/11/2013 |
| Tapentadol (hydrochloride) | Palexia and associated names Yantil and associated names Tapentadol and associated names | PM | Pain | Grünentha I GmbH | P/0283/2013 | 08/11/2013 |
| Tapentadol (hydrochloride) | Palexia and associated names Yantil and associated names Tapentadol and associated names | PM | Pain | Grünentha I GmbH | P/0284/2013 | 08/11/2013 |
| Vandetanib | Caprelsa | PM | Oncology | AstraZeneca AB | P/0285/2013 | 29/11/2013 |
| Retigabine | Trobalt | PM | Neurology | Glaxo Group Limited | P/0286/2013 | 29/11/2013 |
| Cysteamine hydrochloride | N/A | PM | Ophthalmology | ORPHAN | P/0287/2013 | 29/11/2013 |

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|---|--|-----|---|--|-------------|------------|
| | | | | EUROPE SARL | 3 | |
| Bilastine | Bilaxten and associated names | PM | Dermatology, Oto-rhinolaryngology, Pneumology - Allergology | Faes Farma S.A. | P/0288/2013 | 29/11/2013 |
| 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 | Nimenrix | PM | Vaccines | GlaxoSmit hKline Biologicals s.a | P/0289/2013 | 29/11/2013 |
| Human normal immunoglobulin | N/A | PM | Haematology-Hemostaseology, Immunology-Rheumatology - Transplantation | Kedrion S.p.A. | P/0290/2013 | 29/11/2013 |
| 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/0291/2013 | 29/11/2013 |
| Dapagliflozin | Forxiga | PM | Endocrinology - Gynaecology-Fertility-Metabolism | Bristol Myers Squibb /AstraZeneca EEIG | P/0292/2013 | 29/11/2013 |
| Riociguat | N/A | RPM | Cardiovascular Diseases | Bayer Pharma AG | P/0293/2013 | 29/11/2013 |
| Autologous cartilage derived cultured | N/A | PM | Other | Genzyme Europe BV | P/0294/2013 | 29/11/2013 |

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|---|----------|----|--|--|-----------------|------------|
| chondrocytes | | | | | | |
| Certolizumab pegol | Cimzia | PM | Immunology- Rheumatology - Transplantation | UCB Pharma S.A. | P/0295/201 3 | 29/11/2013 |
| Delamanid | N/A | PM | Infectious Diseases | Otsuka Frankfurt Research Institute GmbH | P/0296/201 3 | 29/11/2013 |
| Alirocumab | N/A | P | Endocrinology - Gynaecology- Fertility- Metabolism | sanofi- aventis recherche & développe ment | P/0297/201 3 | 29/11/2013 |
| Travoprost | Travatan | PM | Ophthalmolog y | Alcon Laboratori es (UK) Ltd. | P/0298/201 3 | 29/11/2013 |
| Sodium benzylpenilloate / benzylpenicilloyl octa- L- lysine | N/A | P | Diagnostic | Diater Laboratori o de Diagnóstico o y Aplicacion es Terapéutic as, S.A. | P/0299/201 3 | 29/11/2013 |
| Amlodipine (besylate) / perindopril (arginine) / atorvastatin (calcium trihydrate) | N/A | W | Cardiovascula r Diseases, Endocrinology - Gynaecology- Fertility- Metabolism | Les Laboratoi es Servier | P/0300/201 3 | 29/11/2013 |
| Odanacatib / colecalciferol | N/A | W | Immunology- Rheumatology - Transplantation | Merck Sharp & Dohme (Europe), Inc. | P/0301/201 3 | 29/11/2013 |
| Metformin hydrochloride / rosuvastatin calcium | N/A | W | Cardiovascula r Diseases, Endocrinology - Gynaecology- Fertility- Metabolism | GlaxoSmit hKline Trading Services Limited | P/0303/201 3 | 29/11/2013 |
| Synthetic double-stranded siRNA oligonucleotide | N/A | W | Neurology | Alnylam Pharmace | P/0304/201 3 | 29/11/2013 |

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|-------------------------------------|---------|----|---|----------------------------------|-------------|------------|
| directed against transthyretin mRNA | | | | uticals, Inc. | | |
| Brivaracetam | N/A | PM | Neurology | UCB Pharma SA | P/0305/2013 | 28/11/2013 |
| Lanreotide (acetate) | N/A | W | Endocrinology - Gynaecology- Fertility- Metabolism Gastroenterology- Hepatology Oncology | Ipsen Pharma | P/0302/2013 | 29/11/2013 |
| Asfotase alfa | N/A | P | Treatment of hypophosphatasia | Alexion Europe SAS | P/0306/2013 | 05/12/2013 |
| Perampanel | Fycompa | P | Treatment of treatment - resistant epilepsies (localisation-related or generalised epilepsies and age-related epilepsy syndromes) | Eisai Europe Limited | P/0307/2013 | 13/12/2013 |
| Treprostinil | N/A | PM | Cardiovascular Diseases | United Therapeutics Europe, Ltd. | P/0308/2013 | 19/12/2013 |
| Golimumab | Simponi | PM | Immunology- Rheumatology - Transplantation | Janssen Biologics B.V. | P/0309/2013 | 19/12/2013 |
| Rilpivirine (hydrochloride) | Edurant | PM | Infectious Diseases | Janssen-Cilag International NV | P/0323/2013 | 19/12/2013 |
| Cysteamine hydrochloride | N/A | PM | Ophthalmology | ORPHAN EUROPE SARL | P/0322/2013 | 19/12/2013 |
| Adalimumab | Humira | PM | Dermatology Gastroenterology- Hepatology Immunology- Rheumatology - Transplantation | AbbVie Limited | P/0324/2013 | 19/12/2013 |
| Lisdexamfetamine (dimesylate) | N/A | PM | Psychiatry | Shire Pharmaceutical | P/0321/2013 | 19/12/2013 |

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|--|--------|----|-----------------------------|---------------------------------------|-------------|------------|
| | | | | Contracts Ltd | | |
| Anagrelide | Xagrid | PM | 44 1256 894708 | Shire Pharmaceutical Contracts Ltd | P/0325/2013 | 19/12/2013 |
| Elvitegravir | N/A | PM | Infectious Diseases | Gilead Sciences International Limited | P/0310/2013 | 19/12/2013 |
| Gadobutrol | N/A | PM | Diagnostic | Bayer Pharma AG | P/0311/2013 | 19/12/2013 |
| Sitavig and associated names | N/A | PM | Infectious Diseases | BioAlliance PHARMA | P/0312/2013 | 19/12/2013 |
| Heterologous Human Adult Liver-derived Progenitor Cells (HHALPC) | N/A | P | Gastroenterology-Hepatology | Promethera Biosciences | P/0313/2013 | 19/12/2013 |
| Lumacaftor | N/A | PM | Pneumology - Allergology | Vertex Pharmaceuticals (Europe) Ltd. | P/0268/2013 | 19/12/2013 |
| Sodium N-{6-[3-tert-Butyl-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-2-methoxyphenyl]naphthalen-2-yl} methanesulfonamide hydrate (ABT-333) | N/A | P | Infectious Diseases | AbbVie Ltd | P/0314/2013 | 19/12/2013 |
| 2R,6S,12Z,13aS,14aR,16aS)-N-(cyclopropylsulfonyl)-6-[[[(5-methylpyrazin-2-yl)carbonyl]amino]-5,16-dioxo-2-(phenanthridin-6-yloxy)-1,2,3,6,7,8,9,10,11,13a,14,15,16,16a-tetradecahydrocyclopropa[e]pyrrolo[1,2-a][1,4]diazacyclopentadecine-14a(5H)-carboxamide | N/A | P | Infectious Diseases | AbbVie Ltd | P/0315/2013 | 19/12/2013 |

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|--|-----|---|--|-----------------------------|-------------|------------|
| hydrate (ABT-450) / Dimethyl ((2S,5S)-1-(4-tert-butylphenyl)pyrrolidine-2,5-diyl)bis(benzene-4,1-diylcarbamoyl(2S)pyrrolidine-2,1-diyl[(2S)-3-methyl-1-oxobutane-1,2-diyl])biscarbamate hydrate) (ABT-267) / ritonavir | | | | | | |
| Acetylsalicylic acid / omeprazole | N/A | W | Cardiovascular Diseases | Pozen UK Limited | P/0316/2013 | 19/12/2013 |
| Estetrol / Levonorgestrel | N/A | P | Endocrinology - Gynaecology-Fertility-Metabolism | Estetra S.A. | P/0317/2013 | 19/12/2013 |
| Alpha-1 antitrypsin | N/A | W | Pneumology - Allergology | Triskel EU Services, Ltd. | P/0318/2013 | 19/12/2013 |
| Solifenacin (succinate) / mirabegron | N/A | W | Uro-nephrology | Astellas Pharma Europe B.V. | P/0319/2013 | 19/12/2013 |
| Amlodipine (besilate) / olmesartan (medoxomil) | N/A | W | Cardiovascular Diseases | Zentiva k.s. | P/0320/2013 | 19/12/2013 |

Annex 14 – Referral procedures overview 2013 – human medicines

Referrals made to the CHMP

| International non-proprietary name (INN) | Start of procedure | End of procedure | Type of referral |
|---|--------------------|------------------|---|
| cilostazol | 19/05/2011 | 21/03/2013 | Article 31 of Directive 2001/83/EC |
| ketoconazole | 21/07/2011 | 25/07/2013 | Article 31 of Directive 2001/83/EC |
| teicoplanin | 22/09/2011 | 21/03/2013 | Article 5(3) procedure of Regulation (EC) No 726/2004 |
| teicoplanin | 17/11/2011 | 30/05/2013 | Article 30 of Directive 2001/83/EC |
| ciclosporin | 15/12/2011 | 27/06/2013 | Article 30 of Directive 2001/83/EC |
| ciclosporin | 15/12/2011 | 27/06/2013 | Article 30 of Directive 2001/83/EC |
| iron sucrose complex; iron(III)-hydroxide dextran complex; ferric carboxymaltose; sodium ferric gluconate complex; iron(III) isomaltoside complex | 15/12/2011 | 27/06/2013 | Article 31 of Directive 2001/83/EC |
| metoclopramide | 15/12/2011 | 24/10/2013 | Article 31 of Directive 2001/83/EC |
| dihydroergocryptine | 19/01/2012 | 27/06/2013 | Article 31 of Directive 2001/83/EC |
| dihydroergocristine | 19/01/2012 | 27/06/2013 | Article 31 of Directive 2001/83/EC |
| nicergoline | 19/01/2012 | 27/06/2013 | Article 31 of Directive 2001/83/EC |
| dihydroergotamine | 19/01/2012 | 27/06/2013 | Article 31 of Directive 2001/83/EC |
| dihydroergotoxine | 19/01/2012 | 24/10/2013 | Article 31 of Directive 2001/83/EC |
| furosemide | 24/05/2012 | 21/02/2013 | Article 29(4) of Directive 2001/83/EC |
| estradiol* | 21/06/2012 | ongoing | Article 31 of Directive 2001/83/EC |
| nicardipine | 19/07/2012 | 24/10/2013 | Article 31 of Directive 2001/83/EC |
| beclometasone dipropionate, formoterol fumarate | 13/12/2012 | 17/01/2013 | Article 13 of Commission Regulation (EC) No 1234/2008 |
| simvastatin | 21/02/2013 | 21/03/2013 | Article 29(4) of Directive |

| International non-proprietary name (INN) | Start of procedure | End of procedure | Type of referral |
|---|--------------------|------------------|---|
| | | | 2001/83/EC |
| methylphenidate | 21/02/2013 | 25/07/2013 | Article 29(4) of Directive 2001/83/EC |
| methylphenidate | 21/02/2013 | 25/07/2013 | Article 29(4) of Directive 2001/83/EC |
| thiocolchicoside | 21/02/2013 | 21/11/2013 | Article 31 of Directive 2001/83/EC |
| prednisolone sodium phosphate | 21/03/2013 | 27/06/2013 | Article 29(4) of Directive 2001/83/EC |
| didanosine | 21/03/2013 | 19/09/2013 | Article 29(4) of Directive 2001/83/EC |
| alendronic acid and alfacacidol | 21/03/2013 | 19/12/2013 | Article 29(4) of Directive 2001/83/EC |
| exenatide, liraglutide, lixisenatide, sitagliptin, vildagliptin, saxagliptin, linagliptin | 25/04/2013 | 25/07/2013 | Article 5(3) procedure of Regulation (EC) No 726/2004 |
| octreotide acetate | 30/05/2013 | ongoing | Article 30 of Directive 2001/83/EC |
| octreotide acetate | 30/05/2013 | ongoing | Article 30 of Directive 2001/83/EC |
| dexamfetamine sulphate | 27/06/2013 | ongoing | Article 29(4) of Directive 2001/83/EC |
| quetiapine | 27/06/2013 | ongoing | Article 30 of Directive 2001/83/EC |
| amoxicilin | 25/07/2013 | ongoing | Article 30 of Directive 2001/83/EC |
| colistimethate sodium, colistin | 19/09/2013 | ongoing | Article 5(3) procedure of Regulation (EC) No 726/2004 |
| colistimethate sodium, colistin | 19/09/2013 | ongoing | Article 31 of Directive 2001/83/EC |
| mometasone furoate | 19/09/2013 | ongoing | Article 30 of Directive 2001/83/EC |
| human albumin, denatured | 24/10/2013 | 19/12/2013 | Article 29(4) of Directive 2001/83/EC |
| lidocaine/prilocaine | 24/10/2013 | ongoing | Article 30 of Directive 2001/83/EC |
| lidocaine, ephedrine hydrochloride, arsenic trioxide | 24/10/2013 | ongoing | Article 31 of Directive 2001/83/EC |
| tibolone | 21/11/2013 | 19/12/2013 | Article 29(4) of Directive 2001/83/EC |
| tibolone | 21/11/2013 | 19/12/2013 | Article 29(4) of Directive 2001/83/EC |
| felodipine | 21/11/2013 | ongoing | Article 30 of Directive 2001/83/EC |

| International non-proprietary name (INN) | Start of procedure | End of procedure | Type of referral |
|--|--------------------|------------------|--|
| nicorandil | 19/12/2013 | ongoing | Article 30 of Directive 2001/83/EC |
| rosuvastatin calcium | 19/12/2013 | ongoing | Article 29 of Regulation (EC) No 1901/2006 |

* *A re-examination is ongoing for this procedure.*

Referrals made to the PRAC

| International non-proprietary name (INN) | Start of procedure | End of procedure | Type of referral |
|--|--------------------|------------------|--|
| almitrine | 29/11/2012 | 29/05/2013 | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| codeine | 03/10/2012 | 26/06/2013 | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| diclofenac | 31/10/2012 | 26/06/2013 | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| hydroxyethyl starch | 29/11/2012 | 23/10/2013 | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| terbutaline, salbutamol, hexoprenaline, ritrodine, fenoterol | 29/11/2012 | 23/10/2013 | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| nicotinic acid/laropiprant | 20/12/2012* | 10/01/2013 | Article 20 of Regulation (EC) No 726/2004 following Article 107i procedure of Directive 2001/83/EC |
| nicotinic acid/laropiprant | 20/12/2012* | 10/01/2013 | Article 20 of Regulation (EC) No 726/2004 following Article 107i procedure of Directive 2001/83/EC |
| nicotinic acid/laropiprant | 20/12/2012* | 10/01/2013 | Article 20 of Regulation (EC) No 726/2004 following Article 107i procedure of Directive 2001/83/EC |
| tetrazepam | 10/01/2013 | 24/04/2013 | Article 107i of Directive 2001/83/EC |
| cyproterone/ethinylestradiol | 07/02/2013 | 29/05/2013 | Article 107i of Directive 2001/83/EC |
| desogestrel, gestodene, norgestimate, etonogestrel, drospirenone, dienogest, chlormadinone, norgestimate, nomegestrol acetate/estradiol, norelgestromin/ethinylestradiol | 07/02/2013 | 21/11/2013 | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| flupirtine | 07/03/2013 | 26/06/2013 | Article 107i of Directive 2001/83/EC |

| International non-proprietary name (INN) | Start of procedure | End of procedure | Type of referral |
|---|--------------------|------------------|---|
| domperidone | 07/03/2013 | ongoing | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| acipimox | 07/03/2013 | 18/12/2013 | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| Recombinant coagulation factor VIII (octocog alfa) | 07/03/2013 | 19/12/2013 | Article 20 of Regulation (EC) No 726/2004 following Article 31 procedure of Directive 2001/83/EC |
| captopril, imidapril, zofenopril, candesartan, delapril, telmisartan, aliskiren, moexipril, enalapril, valsartan, fosinopril, irbesartan, perindopril, quinapril, ramipril, eprosartan, olmesartan, trandolapril, losartan, azilsartan, lisinopril, spirapril, benazepril, cilazapril | 16/05/2013 | ongoing | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| strontium ranelate | 16/05/2013 | ongoing | Article 20 of Regulation (EC) No 726/2004 following Article 31 procedure of Directive 2001/83/EC |
| Parenteral nutrition emulsion for infusion | 13/06/2013 | 18/09/2013 | Article 107i of Directive 2001/83/EC |
| zolpidem | 11/07/2013 | ongoing | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| hydroxyethyl starch | 11/07/2013 | 23/10/2013 | Article 107i of Directive 2001/83/EC |
| bromocriptine | 05/09/2013 | ongoing | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| sodium valproate, valproic acid, valproate semisodium, valpromide | 10/10/2013 | ongoing | Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC |
| ponatinib hydrochloride | 05/12/2013 | ongoing | Article 20 of Regulation (EC) No 726/2004 following Article 107(j)(2) procedure of Directive 2001/83/EC |

* This procedure started end of December 2012 via written procedure and for reporting purposes is reflected in 2013.

Referrals made to the HMPC

| International non-proprietary name (INN) | Start of procedure | End of procedure | Type of referral |
|--|--------------------|------------------|---|
| Passiflora incarnata L., herba | 15/01/2013 | 12/03/2013 | Article 16c(1)(c) of Directive 2001/83/EC |

Annex 15 – Arbitrations and referrals 2013 – veterinary medicines

| Type of referral | <ul style="list-style-type: none"> Date of clock start CVMP opinion | <ul style="list-style-type: none"> Product name INN |
|--|---|--|
| Referral under Article 35 of Directive 2001/82/EC | <ul style="list-style-type: none"> 15/09/2011 11/04/2013 18/07/2013 (re-examination) | <ul style="list-style-type: none"> All long acting formulations for injection containing barium selenate for all food producing species Barium selenate |
| Referral under Article 33(4) of Directive 2001/82/EC | <ul style="list-style-type: none"> 12/10/2011 13/06/2012 07/02/2013 (re-examination) | <ul style="list-style-type: none"> Nuflor Swine Once 450 mg/ml Florfenicol |
| Referral under Article 35 of Directive 2001/82/EC | <ul style="list-style-type: none"> 12/04/2012 12/06/2013 | <ul style="list-style-type: none"> All injectable and pour-on veterinary medicinal products containing doramectin that are intended for use in mammalian food-producing species Doramectin |
| Referral under Art. 34 of Directive 2001/82/EC | <ul style="list-style-type: none"> 15/05/2012 18/07/2013 | <ul style="list-style-type: none"> Micotil 300 Injectie and associated names Tilmicosin |
| Referral under Article 33(4) of Directive 2001/82/EC | <ul style="list-style-type: none"> 15/05/2012 07/03/2013 | <ul style="list-style-type: none"> Florgane 300 mg/ml suspension for injection for cattle and pigs Florfenicol |
| Referral under Article 33(4) of Directive 2001/82/EC | <ul style="list-style-type: none"> 11/07/2012 10/04/2013 | <ul style="list-style-type: none"> Strenzen 500/125 mg/g powder for use in drinking water for pigs Amoxicillin/clavulanic acid |
| Referral under Article 35 of Directive 2001/82/EC | <ul style="list-style-type: none"> 12/09/2012 | <ul style="list-style-type: none"> Suanovil 20 and associated names, Captalin and associated names and generic products thereof, including pending applications Spiramycin |
| Referral under Article 35 of Directive 2001/82/EC | <ul style="list-style-type: none"> 12/09/2012 18/07/2013 | <ul style="list-style-type: none"> Dexadreson 2 mg/ml and associated names, and generic products thereof, including pending applications Dexamethasone |
| Referral under Article 34 of Directive 2001/82/EC | <ul style="list-style-type: none"> 10/10/2012 | <ul style="list-style-type: none"> Linco-Spectin 100 and its associated names Lincomycin, spectinomycin |

| Type of referral | <ul style="list-style-type: none"> • Date of clock start • CVMP opinion | <ul style="list-style-type: none"> • Product name • INN |
|--|---|--|
| Referral under Article 34 of Directive 2001/82/EC | <ul style="list-style-type: none"> • 07/11/2012 | <ul style="list-style-type: none"> • Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names • Enrofloxacin |
| Referral under Article 35 of Directive 2001/82/EC | <ul style="list-style-type: none"> • 07/11/2012 • 07/11/2013 | <ul style="list-style-type: none"> • All veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys • Enrofloxacin |
| Referral under Article 13 of Regulation (EC) No. 1234/2008 | <ul style="list-style-type: none"> • 07/11/2012 • 07/03/2013 • 12/06/2013 (re-examination) | <ul style="list-style-type: none"> • Soludox 500 mg/g powder for use in drinking water for pigs and chickens • Doxycycline hyclate |
| Referral under Article 30(3) of Regulation 726/2004 | <ul style="list-style-type: none"> • 10/01/2013 | <ul style="list-style-type: none"> • Lidocaine • Lidocaine |
| Referral under Article 33(4) of Directive 2001/82/EC | <ul style="list-style-type: none"> • 07/03/2013 • 17/07/2013 | <ul style="list-style-type: none"> • Deltanil 10 mg/ml Pour-on Solution for cattle and sheep and Deltanil 100 mg Spot-on Solution for cattle • Deltamethrin |
| Referral under Article 33(4) of Directive 2001/82/EC | <ul style="list-style-type: none"> • 07/03/2013 • 18/07/2013 | <ul style="list-style-type: none"> • Suifertil 4 mg/ml Oral Solution for Pigs • Altrenogest |
| Referral under Article 35 of Directive 2001/82/EC | <ul style="list-style-type: none"> • 10/04/2013 | <ul style="list-style-type: none"> • All veterinary medicinal products containing altrenogest to be administered orally to pigs and horses • Altrenogest |
| Referral under Article 13 of Regulation (EC) No. 1234/2008 | <ul style="list-style-type: none"> • 10/04/2013 • 16/07/2013 | <ul style="list-style-type: none"> • Cydectin TriclaMox pour-on solution for use in cattle • Triclabendazole and moxidectin |
| Referral under Article 33(4) of Directive 2001/82/EC | <ul style="list-style-type: none"> • 16/05/2013 | <ul style="list-style-type: none"> • Norbonex 5-mg/ml pour-on solution for beef and dairy cattle • Eprinomectin |

| Type of referral | <ul style="list-style-type: none"> • Date of clock start • CVMP opinion | <ul style="list-style-type: none"> • Product name • INN |
|---|---|---|
| Referral under Article 33(4) of Directive 2001/82/EC | <ul style="list-style-type: none"> • 16/05/2013 • 11/12/2013 | <ul style="list-style-type: none"> • Fiprex CAT 52.5 mg spot-on solution for cats, Fiprex S 75 mg spot-on solution for dogs, Fiprex M 150 mg spot-on solution for dogs, Fiprex L 300 mg spot-on solution for dogs and Fiprex XL 412.5 mg spot-on solution for dogs • Fipronil |
| Referral under Article 35 of Directive 2001/82/EC | <ul style="list-style-type: none"> • 16/05/2013 | <ul style="list-style-type: none"> • Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC • Enrofloxacin |
| Referral under Article 45 of Regulation (EC) No. 726/2004 | <ul style="list-style-type: none"> • 16/05/2013 • 10/10/2013 | <ul style="list-style-type: none"> • Suvaxyn PCV (inactivated vaccine) |
| Referral under Article 35 of Directive 2001/82/EC | <ul style="list-style-type: none"> • 06/11/2013 | <ul style="list-style-type: none"> • All veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs • Tylosin |

Annex 16 – Budget summaries 2012–2013

The summarised comparative budget statements for 2012 and 2013 are as follows:

| | | 2012 (final) ¹ | | 2013 (budget) ² | | 2013 (final) ³ | |
|---|--|---------------------------|---------------|----------------------------|---------------|---------------------------|---------------|
| | | € '000 | % of total | € '000 | % of total | € '000 | % of total |
| Revenue | | | | | | | |
| 1+5 | Fees and charges | 182,912 | 81.8% | 210,587 | 83.7% | 198,865 | 82.7% |
| 200 | General EU contribution | 21,466 | 9.6% | 32,630 | 13.0% | 32,630 | 13.6% |
| 200 | Surplus of previous year | 9,875 | 4.4% | 0 | 0.0% | 0 | 0.0% |
| 201 | Special EU contribution for orphan medicinal products | 7,491 | 3.4% | 6,600 | 2.6% | 6,509 | 2.7% |
| 300 | Contribution from EEA | 753 | 0.3% | 1,098 | 0.4% | 1,098 | 0.5% |
| 600 | External assigned revenue | 128 | 0.1% | 520 | 0.2% | 700 | 0.3% |
| 5+9 | Other | 902 | 0.4% | 125 | 0.0% | 585 | 0.2% |
| | TOTAL REVENUE | 223,527 | 100.0% | 251,560 | 100.0% | 240,387 | 100.0% |
| Expenditure | | | | | | | |
| Staff | | | | | | | |
| 11 | Staff in active employment | 69,457 | 31.7% | 75,002 | 29.8% | 71,497 | 29.4% |
| 13 | Mission expenses | 575 | 0.3% | 465 | 0.2% | 409 | 0.2% |
| 14 | Socio-medical infrastructure | 557 | 0.3% | 541 | 0.2% | 521 | 0.2% |
| 15 | Exchange of civil servants and experts | 2,293 | 1.0% | 2,791 | 1.1% | 2,672 | 1.1% |
| 16 | Social welfare | 236 | 0.1% | 312 | 0.1% | 277 | 0.1% |
| 17 | Representation expenses | 15 | 0.0% | 36 | 0.0% | 28 | 0.0% |
| 18 | Staff insurances | 2,118 | 1.0% | 2,255 | 0.9% | 2,149 | 0.9% |
| | <i>Total Title 1</i> | 75,251 | 34.4% | 81,402 | 32.4% | 77,552 | 31.9% |
| Building/equipment | | | | | | | |
| 20 | Investment in immovable property, renting of building and associated costs | 21,066 | 9.6% | 48,924 | 19.4% | 45,889 | 18.9% |
| 21 | Expenditure on corporate data processing | 7,108 | 3.2% | 13,919 | 5.5% | 13,821 | 5.7% |
| 22 | Movable property [...] | 1,351 | 0.6% | 1,180 | 0.5% | 1,009 | 0.4% |
| 23 | Other administrative expenditure | 785 | 0.4% | 864 | 0.3% | 795 | 0.3% |
| 24 | Postage | 401 | 0.2% | 451 | 0.2% | 444 | 0.2% |
| 25 | Expenditure on other meetings | 105 | 0.0% | 125 | 0.0% | 98 | 0.0% |
| | <i>Total Title 2</i> | 30,817 | 14.1% | 65,463 | 26.0% | 62,056 | 25.5% |
| Operational expenditure | | | | | | | |
| 300 | Meetings | 6,759 | 3.1% | 6,587 | 2.6% | 6,305 | 2.6% |
| 301 | Evaluation of medicines | 81,992 | 37.5% | 80,474 | 32.0% | 80,018 | 32.9% |
| 302 | Translations | 3,958 | 1.8% | 5,212 | 2.1% | 5,182 | 2.1% |
| 303 | Studies and consultants | 2,044 | 0.9% | 2,040 | 0.8% | 2,031 | 0.8% |
| 304 | Publications | 76 | 0.0% | 106 | 0.0% | 71 | 0.0% |
| 305 | Community programmes | 298 | 0.1% | 400 | 0.2% | 340 | 0.1% |
| 31 | Expenditure on business related ICT projects | 17,662 | 8.1% | 9,876 | 3.9% | 9,863 | 4.1% |
| | <i>Total Title 3</i> | 112,790 | 51.5% | 104,695 | 41.6% | 103,811 | 42.6% |
| | TOTAL EXPENDITURE | 218,858 | 100.0% | 251,560 | 100.0% | 243,419 | 100.0% |
| ¹ Financial Year 2012: as per final accounts; rounded to nearest thousand Euro ² Financial Year 2013: as per final budget ³ Financial Year 2013: as per provisional accounts; rounded to nearest thousand Euro | | | | | | | |

Annex 17 – European Medicines Agency establishment plan

| Category and grade | TEMPORARY POSTS | | | | | |
|--------------------|-----------------|-----------------|--------------------------|-----------------|-----------------|-----------------|
| | POSTS 2013 | | | | POSTS 2014 | |
| | Authorised | | Actual as per 31.12.2013 | | Authorised | |
| | Permanent posts | Temporary posts | Permanent posts | Temporary posts | Permanent posts | Temporary posts |
| AD 16 | - | 0 | - | 0 | - | 0 |
| AD 15 | - | 4 | - | 4 | - | 4 |
| AD 14 | - | 6 | - | 6 | - | 6 |
| AD 13 | - | 8 | - | 7 | - | 8 |
| AD 12 | - | 38 | - | 36 | - | 42 |
| AD 11 | - | 38 | - | 36 | - | 38 |
| AD 10 | - | 36 | - | 33 | - | 36 |
| AD 9 | - | 40 | - | 36 | - | 37 |
| AD 8 | - | 47 | - | 46 | - | 49 |
| AD 7 | - | 45 | - | 44 | - | 51 |
| AD 6 | - | 42 | - | 41 | - | 39 |
| AD 5 | - | 42 | - | 33 | - | 30 |
| Total AD | 0 | 346 | 0 | 322 | 0 | 340 |
| AST 11 | - | 2 | - | 2 | - | 2 |
| AST 10 | - | 5 | - | 5 | - | 5 |
| AST 9 | - | 7 | - | 7 | - | 7 |
| AST 8 | - | 13 | - | 13 | - | 15 |
| AST 7 | - | 20 | - | 20 | - | 19 |
| AST 6 | - | 33 | - | 31 | - | 36 |
| AST 5 | - | 35 | - | 34 | - | 37 |
| AST 4 | - | 51 | - | 50 | - | 55 |
| AST 3 | - | 39 | - | 39 | - | 39 |
| AST 2 | - | 40 | - | 40 | - | 34 |
| AST 1 | - | 20 | - | 20 | - | 10 |
| Total AST | 0 | 265 | 0 | 266 | 0 | 259 |
| Grand Total | 0 | 611 | 0 | 583 | 0 | 599 |

| Other staff | Planned (FTE) ¹ 2013 | Actual (FTE) 2013 | Actual as per 31.12.2013 | Planned (FTE) 2014 |
|-------------------------|---------------------------------|-------------------|--------------------------|--------------------|
| CONTRACT AGENTS | 125 | 99 | 92 | 130 |
| NATIONAL EXPERTS | 15 | 16.5 | 15.5 | 25 |

¹ FTE=Full Time Equivalent

Annex 18 – Annual report from the SME office

The 2013 report from the SME office can be found at the following link:

http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2014/01/WC500160238.pdf

Annex 19 – Access to documents requests

Requests received and pages released

| Year | Number of requests received | Number of pages released |
|-------------|-----------------------------|--------------------------|
| 2013 | 290 | 316,760 |

Decisions on access in 2013

| | |
|--------------|------------|
| Access given | |
| Yes | 73 |
| Partial | 69 |
| No | 125 |
| Pending | 23 |
| Total | 290 |

Appeals in 2013

| | |
|---------------|-----------|
| Appeals | |
| Final refusal | 13 |
| Release | 4 |
| Partial | 7 |
| Pending | 1 |
| Total | 25 |

Affiliation (per new request in 2013)

| Affiliation | Number of requests received | In % | Number of pages released | In % |
|-----------------------------|-----------------------------|-------|--------------------------|--------|
| Not-for-profit organisation | 1 | 0.34 | 9 | 0.002 |
| EU Institution (EC etc) | 3 | 1.03 | 1 | 0.0003 |
| Regulator outside EU | 3 | 1.03 | 20 | 0.006 |
| EU NCA | 7 | 2.40 | 41 | 0.013 |
| Patients organisation | 2 | 0.69 | 543 | 0.17 |
| Healthcare professional | 10 | 3.44 | 948 | 0.30 |
| Consultant | 12 | 4.12 | 10,300 | 3.25 |
| General public | 7 | 2.40 | 170 | 0.05 |
| Academia/Research institute | 34 | 11.68 | 260,361 | 82.20 |
| Legal | 67 | 23.02 | 3,604 | 1.14 |
| Media | 37 | 12.71 | 26,648 | 8.41 |
| Pharmaceutical industry | 103 | 35.39 | 10,317 | 3.25 |
| Other | 4 | 1.38 | 798 | 0.26 |
| Total | 290 | | 316,760 | |

Annex 20 – Publications by Agency staff members and experts in 2013

Abbing-Karahagopian V, Kurz X, de Vries F, van Staa TP, Alvarez Y, Hesse U, Hasford J, van Dijk L, de Abajo FJ, Weil JG, Grimaldi-Bensouda L, Egberts AC, Reynolds RF, Klungel OH

Bridging differences in outcomes of pharmacoepidemiological studies: Design and first results of the PROTECT project

Curr Clin Pharmacol. 2013 Nov 11. (Epub ahead of print 2013)

Baird LG, Trusheim MR, Eichler HG, Berndt ER, Hirsch G.

Comparison of Stakeholder Metrics for Traditional and Adaptive Development and Licensing Approaches to Drug Development

Therapeutic Innovation & Regulatory Science. Drug Information Journal July 2013 vol. 47 no. 4 474-483

Barkholt L, Flory E, Jekerle V, Lucas-Samuel S, Ahnert P, Bisset L, Büscher D, Fibbe W, Foussat A, Kwa M, Lantz O, Mačiulaitis R, Palomäki T, Schneider CK, Sensebé L, Tachdjian G, Tarte K, Tosca L, Salmikangas P.

Risk of tumorigenicity in mesenchymal stromal cell-based therapies-Bridging scientific observations and regulatory viewpoints

Cytotherapy. 2013 Jul;15(7):753-9

Berntgen M, Enzmann H, Schabel E, Prieto Yerro C, Gómez-Outes A, Salmonson T, Musaus J.

Linaclotide for treatment of irritable bowel syndrome – The view of European regulators

Dig Liver Dis. 2013 Sep;45(9):724-6

Beyer AR, Fasolo B, Phillips LD, de Graeff PA, Hillege HL.

Risk Perception of Prescription Drugs: Results of a Survey Among Experts in the European Regulatory Network

Med Decis Making. 2013 May;33(4):579-92

Brassart L, Skarlatos A, Camanas Saez L, Cerreta F.

Product information and older people: how to assist informed prescription and safe therapeutic use?

Regulatory Rapporteur – Vol 10, No 7/8, July/August 2013

Breckenridge A, Eichler HG.

Towards a Prevention Model of Healthcare

Nat Rev Drug Discov. 2013 Aug;12(8):563-4

Callréus T, Schneider CK.

The Emergence of Regulatory Science in Pharmaceutical Medicine

Pharm. Med (2013) 27: 345-351

Da Rocha Dias S, Salmonson T, van Zwieten-Boot B, Jonsson B, Marchetti S, Schellens JH, Giuliani R, Pignatti F.

The European Medicines Agency review of vemurafenib (Zelboraf) for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma: Summary of the scientific assessment of the Committee for Medicinal Products for Human Use (CHMP)

Eur J Cancer 49, no 7 (2013): 1654-61

Egger GF, Herold R, Rodriguez A, Manent N, Sweeney F, Saint Raymond A.

European Union Clinical Trials Register: on the way to more transparency of clinical trial data.

Expert Rev Clin Pharmacol. 2013 Sep;6(5):457-9

Ehmann F, Papaluca Amati M, Salmonson T, Posch M, Vamvakas S, Hemmings R, Eichler HG and Schneider CK.

Gatekeepers and Enablers – how drug regulators respond to a challenging and changing environment by moving toward a proactive attitude

Clin Pharmacol Ther. 2013 May;93(5):425-32

Ehmann F, Sakai-Kato K, Duncan R, Hernán Pérez de la Ossa D, Pita R, Vidal JM, Kohli A, Tothfalusi L, Sanh A, Tinton S, Robert JL, Silva Lima B, Amati MP.

Next-generation nanomedicines and nanosimilars: EU regulators' initiatives relating to the development and evaluation of nanomedicines
Nanomedicine (Lond). 2013 May;8(5):849-56

Eichler HG, Bloechl-Daum B, Brasseur D, Breckenridge A, Leufkens H, Raine J, Salmonson T, Schneider CK, Rasi G.

The risks of risk aversion in drug regulation
Nat Rev Drug Discov. 2013 Dec;12(12):907-16

Eichler HG, Pétavy F, Pignatti F, Rasi G.

Access to patient-level trial data - A boon to regulators?
N Engl J Med. 2013 Oct 24;369(17):1577-9

Elmgren L, Li X, Wilson C, Ball R, Wang J, Cichutek K, Pflleiderer M, Kato A, Cavaleri M, Southern J, Jivapaisarnpong T, Minor P, Griffiths E, Sohn Y, Wood D.

A global regulatory science agenda for vaccines
Vaccine. 2013 Apr 18;31 Suppl 2:B163-75

Franco P.

Orphan Drugs: The Regulatory Environment

Drug Discovery Today Volume 18, Numbers 3/4 February 2013, page 163-172

Gravanis I, Lopez AS, Hemmings RJ, Jiménez JC, Garcia-Carbonero R, Gallego IG, Giménez EV, O'Connor D, Giuliani R, Salmonson T, Pignatti F.

The European Medicines Agency review of abiraterone (Zytiga) for the treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen and in asymptomatic or mildly symptomatic chemotherapy-naive adult men not yet eligible for chemotherapy: Summary of the scientific assessment of the Committee for Medicinal Products for Human Use (CHMP)
Oncologist. 2013;18(9):1032-42.

Gravanis I.

Geriatric Oncology: European Union Regulatory Perspectives and Initiatives
J Geriatr Oncol. 2013 Apr;4(2):202-4

Henshall C, Sansom L, Eichler HG, Lemgruber A, Longson C, O'Rourke B, Tunis S

Understanding the role and evidence expectations of health technology assessment and coverage/payer bodies: what are they looking for, and how and why does this differ from what regulators require?
Therapeutic Innovation & Regulatory Science November 28, 2013

Hilger A, Arras-Reiter C, Keller-Stanislawski B, Ljungberg B, Male C, Mentzer D, Seitz R, Silvester G.

Comment on: Mannucci, P. M. Evolution of the European guidelines for the clinical development of factor VIII products
Haemophilia. 2013 May;19(3):349-50

Janssens E.

Pharmaceuticals: EU Initiative to Tackle Medication Errors – Proposals and Challenges
European Journal of Risk Regulation 3/2013: pp. 388-391

Karres J, Tomasi P.

New medicines for type II diabetes in adolescents: many products, few patients
Expert Rev. Clin. Pharmacol. 6(3), 227-229 (2013)

Köhne CH, Bedenne L, Carrato A, Bouché O, Popov I, Gaspà L, Valladares M, Rougier P, Gog C, Reichardt P, Wils J, Pignatti F, Biertz F.

A Randomised Phase III Intergroup Trial Comparing High-Dose Infusional 5-Fluorouracil with or without Folinic Acid with Standard Bolus 5-Fluorouracil/Folinic Acid in the Adjuvant Treatment of Stage III Colon Cancer: The Pan-European Trial in Adjuvant Colon Cancer 2 Study
Eur J Cancer 49, no. 8 (2013): 1868-75

Liberti L, McAuslane N, Patel P, Breckenridge A, Eichler HG, Peterson R.

Regulatory review: How do agencies ensure the quality of decision making?
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