Annex 1 – Members of the Management Board

Chair: Kent WOODS
EMA contact: Nerimantas STEIKUNAS; Silvia FABIANI

Members

• European Parliament	Guiseppe NISTICÓ, Björn LEMMER
• European Commission	Paola TESTORI COGGI, Gwenole Cozigou[1] (Alternates: Andzej RYS , Salvatore D'acunto[2])
• Belgium	Xavier DE CUYPER (Alternate: Greet MUSCH)
• Bulgaria	Evelin Yakov Blagoev[3] (Alternate: Meri Peycheva)
• Czech Republic	Jiří DEML (Alternate: Jiří BUREŠ)
• Denmark	Else Smith[4] (Alternate: Nina MOSS[5])
• Germany	Walter SCHWERDTFEGER (Alternate: Klaus CICHUTEK)
• Estonia	Kristin RAUDSEPP (Alternate: Alar IRS)
• Ireland	Pat O'MAHONY (Alternate: Rita PURCELL)
• Greece	Ioannis TOUNTAS (Alternate: Maria SKOUROLIAKOU)
• Spain	Belén CRESPO SÁNCHEZ-EZNARRIAGA (Alternate: Laura Franqueza GARCÍA)
• France	Dominique MARANINCHI (Alternate: Jean-Pierre Orand[6])
• Italy	Luca PANI (Alternate: Paolo SIVIERO)
• Cyprus	Arthur Isseyegh[7] (Alternate: George ANTONIOU)
• Latvia	Inguna ADOVICA (Alternate: Dace ĶIKUTE)
• Lithuania	Gintautas BARCYS (Alternate: Gediminas Pridotkas[8])
• Luxembourg	Claude A HEMMER (Alternate: Mariette BACKES-LIES)
• Hungary	Tamás L PAÁL (Alternate: Beatrix HORVÁTH)
• Malta	Patricia VELLA BONANNO (Alternate: Gavril FLORES)
• Netherlands	Aginus A W KALIS (Alternate: Rob DE HAAN)
• Austria	Marcus MÜLLNER (Alternate: Sylvia Füszl[9])

[1] Replaced Pedro ORTUN SILVAN as of December 2012
[2] Replaced Giulia del BRENNA as of January 2012
[3] Replaced Jasmina MIRCHEVA as of November 2012
[4] Replace Jytte LYNGVIG as of July 2012
[5] Replaced Dorthe EBERHRDT SØNDERGAARD as of July 2012
[6] Replaced Marc MORTUREUX as of March 2012
[7] Replaced Panayiota KOKKINOU as of December 2012
[8] Replaced Jonas MILIUS as of April 2012
[9] Replaced Christian KALCHER as of January 2012

• Poland	Grzegorz CESSAK (Alternate: Artur FALLEK)
• Portugal	Helder Mota Filipe[10] (Alternate: Nuno Vieira e Brito[11])
• Romania	Marious Savu[12] (Alternate: Simona BĂDOI)
• Slovenia	Matej Breznik[13] (Alternate: Stanislav Primožič[14])
• Slovakia	Ján MAZÁG (Alternate: Michaela GAJDOŠOVÁ)
• Finland	Sinikka RAJANIEMI (Alternate: Pekka KURKI)
• Sweden	Christina ÅKERMAN (Alternate: Bengt Wittgren[15])
• United Kingdom	Kent WOODS (Alternate: Jonathan MOGFORD)
• Representatives of patients' organisations	Awaiting nomination
• Representative of doctors' organisations	Awaiting nomination
• Representative of veterinarians' organisations	Awaiting nomination

Observers

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

[10] Replaced Jorge TORGAL as of September 2012
[11] Replaced Miguel OLIVEIRA CARDO as of September 2012
[12] Replaced Daniel BODA as of September 2012
[13] Replaced Martina CVELBAR as of July 2012
[14] Replaced Vesna KOBLAR as July 2012
[15] Replaced Johan LINDBERG as of May 2012

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

Chair: Tomas SALMONSON[1] [2]
EMA contact: Anthony HUMPHREYS

Members

• John Joseph BORG (Malta)	*Alternate:* Patricia VELLA BONANNO
• Pierre DEMOLIS (France)	*Alternate: awaiting nomination*[3]
• Kristina DUNDER (Sweden)[4]	*Alternate:* Bengt LJUNGBERG[5]
• Harald ENZMANN (Germany)	*Alternate:* Martina WEISE
• Piotr FIEDOR (Poland)	*Alternate:* Kinga BOROWICZ
• Jacqueline GENOUX-HAMES (Luxembourg)	*Alternate:* Carine DE BEAUFORT
• Kolbeinn GUDMUNDSSON (Iceland)	*Alternate:* Reynir ARNGRIMSSON
• Agnes GYURASICS (Hungary)	*Alternate:* János BORVENDÉG
• Jens HEISTERBERG (Denmark)	*Alternate:* Jens ERSBØLL
• Ian HUDSON (United Kingdom) *(vice-chair)*[6]	*Alternate:* Rafe SUVARNA
• Alar IRS (Estonia)	*Alternate:* Irja LUTSAR
• Arthur ISSEYEGH (Cyprus)	*Alternate:* Emilia MAVROKORDATOU
• Andrea LASLOP (Austria)	*Alternate:* Milena STAIN
• David LYONS (Ireland)	Alternate: Patrick SALMON
• Romaldas MAČIULAITIS (Lithuania)	Alternate: Rugile PILVINIENE
• Outi MAKI-IKOLA (Finland)[7]	*Alternate:* Janne KOMI
• Ján MAZÁG (Slovakia)	Alternate: Vlasta Kákošová
• Daniela MELCHIORRI (Italy)	*Alternate:* Luca PANI
• Aikaterini MORAITI (Greece) [8]	*Alternate:* Chrysoula NTAOUSANI[9]
• Pieter NEELS (Belgium)	Alternate: Walter JANSSENS[10]
• Juris POKROTNIEKS (Latvia)	*Alternate:* Natalja KARPOVA
• Concepcion PRIETO YERRO (Spain)	*Alternate:* Arantxa SANCHO-LOPEZ

[1] Replaced Eric ABADIE as per April 2012 meeting acting as chairman
[2] Elected Chairman as per September 2012 meeting
[3] Philippe Lechat resigned as per December 2012 meeting
[4] Replaced Tomas SALMONSON as per October 2012 meeting
[5] Replaced Kristina DUNDER as per November 2012 meeting
[6] Elected Vice Chairman as per October 2012 meeting
[7] Replaced Jaana KALLIO as per February 2012 meeting
[8] Replaced George AISLAITNER as per April 2012 meeting
[9] Replaced Catherine MORAITI as per April 2012 meeting
[10] Replaced Michel TOUNGOUZ NEVESSIGNSKY as per March 2012 meeting

- Stanislav PRIMOZIC (Slovenia)[11] Alternate: Nevenka TRSINAR
- Bruno SEPODES (Portugal)[12] *Alternate:* Dinah DUARTE[13]
- Ondřej SLANAR (Czech Republic)[14] *Alternate:* Miloslav SALAVEC[15]
- Karsten BRUINS SLOT (Norway) *Alternate:* Ingunn HAGEN WESTGAARD[16]
- Barbara VAN ZWIETEN-BOOT (Netherlands) *Alternate:* Pieter DE GRAEFF
- 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/Isabelle MOULON EMA contact: Nathalie BERE

Joint CHMP/CVMP Quality Working Party
Chair: Jean-Louis ROBERT EMA contact: Riccardo LUIGETTI/Simona Kečešová

Safety Working Party
Chair: Jan Willem VAN DER LAAN EMA contact: Maria NIETO GUTIERREZ

Scientific Advice Working Party
Chair: Robert James HEMMINGS EMA contact: Spiros VAMVAKAS

Temporary working parties

Biosimilar Medicinal Products Working Party
Chair: Christian SCHNEIDER EMA contact: Camille VLEMINCKX/Iordanis GRAVANIS

[11] Replaced Metoda LIPNIK-STANGELJ as per September 2012 meeting
[12] Replaced Beatriz SILVA LIMA as per August 2012 meeting
[13] Replaced Helder MOTA-FILIPE as per August 2012 meeting
[14] Replaced Miloslav SALAVEC as per October 2012 meeting
[15] Replaced Dalibor VALÍK as per September 2012 meeting
[16] Replaced Karsten BRUINS SLOT as per February 2012 meeting

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 Maria BACZYNSKA

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

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

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

Pharmacogenomics Working Party
Chair: Krishna PRASAD — EMA contact: Falk EHMANN

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

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

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

Temporary drafting groups

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

Respiratory Drafting Group
Chair: Steffen THIRSTRUP — EMA contact: Jaume GONZALEZ NOGUERAS

Urology Drafting Group
Chair: Kerstin CLAESSON — 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: Barbara BANNISTER — EMA contact: Eric PELFRENE

Scientific Advisory Group on Cardiovascular Issues
Chair: *Awaiting nomination* — EMA contact: Daniel GUSTAFSSON

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: Manuel HAAS

Scientific Advisory Group on Oncology

Chair: JAN SCHELLENS EMA contact: Francesco PIGNATTI

Scientific Advisory Group on Psychiatry

Chair: *Awaiting nomination* EMA contact: Florence BUTLEN-DUCUING

Scientific Advisory Group on Vaccines

Chair: Andrew POLLARD EMA Contact: Sabrina SPINOSA GUZMAN

Other CHMP-associated groups

EMA/CHMP Working Group with Healthcare Professionals' Organisations

Chair: Noël WATHION EMA contact: Ivana SILVA

Invented Name Review Group

Chair: Isabelle MOULON EMA contact: Jose Angel FERRERO TIJERA

Working Group on Quality Review of Documents

Chair: Alexios SKARLATOS EMA contact: Alexios SKARLATOS

Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: June RAINE
EMA contact: Anthony HUMPHREYS

Members

• Geroge AISLAITNER (Greece)	*Alternate*: Leonidas KLIRONOMOS
• Ingebjorg BUAJORDET (Norway)	*Alternate*: Pernille HARG
• Jean-Michel DOGNE (Belgium)	*Alternate*: Virginie CHARTIER
• Nicolae FOTIN (Romania)	*Alternate*: Daniela POMPONIU
• Jacqueline GENOUX-HAMES (Luxembourg)	*Alternate*: Nadine PETITPAIN
• Jolanta GULBINOVIC (Lithuania)	*Alternate*: Rita DZETAVECKIENE
• Harald HERKNER (Austria)	*Alternate*: Bettina SCHADE
• Martin HUBER (Germany)	*Alternate*: Birgitta KÜTTING
• Andis LACIS (Latvia)	*Alternate*: Inguna ADOVICA
• Carmela MACCHIARULO (Italy)	*Alternate*: Fernanda FERRAZIN
• 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
• Alexandra PEGO (Portugal)[1]	*Alternate*: Margarida GUIMARAES[2]
• Christos PETROU (Cyprus)	*Alternate*: *Awaiting nomination*[3]
• Maria POPOVA-KIRADJIEVA (Bulgaria)	*Alternate*: Yuliyan EFTIMOV
• Adam PRZYBYLKOWSKI (Poland)	*Alternate*: Awaiting nomination
• Milena RADOHA-BERGOC (Slovenia)	*Alternate*: Gabriela JAZBEC
• Isabelle ROBINE (France)	*Alternate*: Evelyne FALIP
• Almath SPOONER (Ireland)	*Alternate*: Dónal ÓG DONOVAN
• Guðrún Kristín STEINGRIMSDOTTIR (Iceland)	*Alternate*: *Awaiting nomination*
• Doris STENVER (Denmark)	*Alternate*: Line MICHAN[4]
• Sabine STRAUS (Netherlands)	Alternate: Menno VAN DER ELST

[1] Replaced Cristina FURTADO as of September 2012 meeting
[2] Replaced Alexandra PEGO as of September 2012 meeting
[3] Anna ARCAB stepped down as PRAC alternate in 2012
[4] Replaced Jens ERSBØLL as of December 2012 meeting

- Ami TANTI (Malta) — *Alternate*: *Awaiting nomination*[5]
- Maia UUSKULA (Estonia) — *Alternate*: Katrin KIISK
- Kirsti VILLIKKA (Finland) — *Alternate*: Terhi LEHTINEN
- Julie WILLIAMS (United Kingdom)[6] — *Alternate*: Julia DUNNE[7]
- 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

[5] Suzanne MAGRI DEMAJO stepped down as PRAC alternate in August 2012
[6] Replaced June RAINE as of September 2012
[7] Replaced Julie WILLIAMS (who replaced Sarah Morgan as of September 2012) as of October 2012

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

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

Members

- Ewa AUGUSTYNOWICZ (Poland) Alternate: Anna LUTYŃSKA
- Jean-Pierre BINDER (Austria) Alternate: Barbara ZEMANN
- Jiří BUREŠ (Czech Republic) Alternate: Alfred HERA
- João Pedro DUARTE DA SILVA (Portugal) Alternate: Maria Inês Flor DIAS
- Judita HEDEROVÁ (Slovakia) Alternate: Eva CHOBOTOVÁ
- Tonje HØY (Norway) Alternate: Hanne BERGENDAHL
- Damyan ILIEV (Bulgaria) Alternate: Lubomir LASHEV
- Helen JUKES[1] (United Kingdom) Alternate: Anna-Maria BRADY
- Petras MAČIULSKIS (Lithuania) Alternate: Awaiting nomination[2]
- Ioannis MALEMIS (Greece) Alternate: Angeliki TSIGOURI
- Cornelia IBRAHIM[3] (Germany) Alternate: Esther WERNER[4]
- Cristina MUÑOZ MADERO (Spain) Alternate: Consuelo RUBIO MONTEJANO
- David MURPHY (Ireland) Alternate: Gabriel BEECHINOR
- Jean-Claude ROUBY (France) Alternate: Michael HOLZHAUSER-ALBERTI
- Johann LENHARDSSON[5] (Iceland) Alternate: Halldór RUNÓLFSSON[6]
- G. Johan SCHEFFERLIE (Netherlands) (Vice-Chair) Alternate: Peter HEKMAN
- Valda SEJANE (Latvia) Alternate: Awaiting nomination
- Tibor SOÓS (Hungary) Alternate: Gábor KULCSÁR
- Stane SRČIČ (Slovenia) Alternate: Katarina STRAUS
- Lollita Sanda Camelia TABAN (Romania) Alternate: Simona STURZU
- Maria TOLLIS (Italy) Alternate: Virgilio DONINI
- Ave-Ly TOOMVAP (Estonia) Alternate: Helen MAHLA
- Ioanna TALIOTI[7] (Cyprus) Alternate: Alia MICHAELIDOU-PATSIA[8]

[1] Replaced Ruth KEARSLEY as of February 2011 meeting
[2] Resigned in September 2011, new nomination pending
[3] Replaced Manfred MOOS as of December 2011 meeting
[4] Replaced Cornelia IBRAHIM as of January 2012 meeting
[5] Replaced Halldór RUNÓLFSSON as of March 2011 meeting
[6] Replaced Johann LENHARDSSON as of March 2011 meeting

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• Karolina TÖRNEKE (Sweden)	Alternate: Henrik HOLST
• Bruno URBAIN (Belgium)	Alternate: Frédéric KLEIN[9]
• Ellen-Margrethe VESTERGAARD (Denmark)	Alternate: [10]Merete BLIXENKRONE-MØLLER
• Irmeli HAPPONEN[11] (Finland)	Alternate: Kristina LEHMANN
• Marc WIRTOR (Luxembourg)	Alternate: Jean BIEL[12]
• Awaiting nomination (Malta)	Alternate: Awaiting nomination

Co-opted

- Rory BREATHNACH (Ireland) (co-opted)
- Claire CHAUVIN[13] (France) (co-opted)
- Christian FRIIS (Denmark) (co-opted)
- Boris KOLAR (Slovenia) (co-opted)
- Wilhelm SCHLUMBOHM (Germany) (co-opted)

Working parties, ad hoc groups and scientific advisory groups

Efficacy Working Party

Chair: Michael HOLZHAUSER-ALBERTI — EMA contact: Jill KIEFFER

Safety Working Party

Chair: G. Johan SCHEFFERLIE — EMA contact: Isaura DUARTE

Immunologicals Working Party

Chair: Jean-Claude ROUBY — EMA contact: Jill KIEFFER

Scientific Advice Working Party

Chair: Rory BREATHNACH — EMA contact: Jill KIEFFER

Pharmacovigilance Working Party

Chair: Peter EKSTRÖM — EMA contact: Isaura DUARTE

Scientific Advisory Group on Antimicrobials

Chair: Karolina TÖRNEKE — EMA contact: Isaura DUARTE

Joint CHMP/CVMP Quality Working Party

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

Environmental Risk Assessment (temporary working party)

Chair: Joop DE KNECHT — EMA contact: Isaura DUARTE

CMD-v

Chair: Esther WERNER — EMA contact: Melanie LEIVERS

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[7] Replaced Pavlos TOUMAZOS as of September 2011 meeting
[8] Replaced Ioanna TALIOTI as of December 2011 meeting
[9] As of November 2011 meeting
[10] Replaced Lotte WINTHER as of January 2012 meeting
[11] Replaced Fia WESTERHOLM as of November 2011 meeting
[12] As of April 2011 meeting
[13] Replaced Peter EKSTRÕM as of February 2011 meeting

Annex 5 – Members of the Committee for Orphan Medicinal Products

Chair: Bruno SEPODES[1]
EMA contact: Jordi LLINARES GARCIA

Members

- Brigitte BLÖCHL-DAUM (Austria)
- János BORVENDÉG (EMA representative)
- Irena BRADINOVA[2] (Bulgaria)
- Birthe BYSKOV HOLM (patients' organisation representative)
- Albert CILIA VINCENTI (Malta)
- Ana CORRÊA NUNES (Portugal)
- Bożenna DEMBOWSKA-BAGIŃSKA (Poland)
- Judit EGGENHOFER (Hungary)
- Rembert ELBERS (Germany)
- Marie Pauline EVERS (patients' organisation representative)
- Lars GRAMSTAD (Norway)
- Lesley GREENE[3] (patients' organisation representative) *(Vice-Chair)*
- Ioannis KKOLOS (Cyprus)
- Dainis KRIEVINS (Latvia)
- Kateřina KUBÁČKOVÁ[4] (Czech Republic)
- André LHOIR (Belgium)
- Annie LORENCE[5] (France)
- Armando MAGRELLI[6] (Italy)
- Aušra MATULEVIČIENĖ (Lithuania)
- Henri METZ (Luxembourg)
- Dorthe MEYER[7] (Denmark)
- Aikaterini MORAITI [8] (EMA representative)

[1] Replaced Kerstin WESTERMARK as of September meeting.
[2] Replaced Mariana TODOROVA as of May meeting.
[3] Replaced Birthe BYSKOV-HOLM as of September meeting.
[4] Replaced Regina DEMLOVÁ as of September meeting.
[5] Replaced Emmanuel HÉRON as of July meeting.
[6] Replaced Maurizio CLEMENTI as of June meeting.
[7] Replaced Heidrun BOSCH-TRABERG as of December meeting.
[8] Replaced David LYONS as of July meeting.

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- Martin MOŽINA (Slovenia)
- Daniel O'CONNOR (United Kingdom)
- Geraldine O'DEA (Ireland)
- Veijo SAANO (Finland)
- Flavia SALEH (Romania)
- Violeta STOYANOVA-BENINSKA[9] (Netherlands)
- Nikolaos SYPSAS[10] (Greece)
- Sigurður THORSTEINSSON (Iceland)
- Vallo TILLMANN (Estonia)
- Josep TORRENT-FARNELL (Spain)
- Kerstin WESTERMARK [11] (Sweden)
- *Awaiting nomination*[12] (Slovak Republic)
- *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: Albertha VOORDOUW EMA contact: Stylianos TSIGKOS

[9] Replaced Albertha VOORDOUW as of June meeting.
[10] Replaced Aikaterini MORAITI as of September meeting.
[11] Replaced Björn BEERMANN as of September meeting.
[12] Milica MOLITORISOVÁ replaced Tatiana FOLTÁNOVÁ as of May meeting and subsequently resigned in November.

Annex 6 – Members of the Committee on Herbal Medicinal Products

Chair: Werner KNÖSS
EMA contact: Anthony HUMPHREYS

Members

• Linda ANDERSON (United Kingdom)	Alternate: Sue HARRIS
• Everaldo ATTARD (Malta)	Alternate: Andre MANGANI
• Mariette BACKES-LIES (Luxembourg)	Alternate: Jacqueline GENOUX-HAMES
• Steffen BAGER (Denmark)	Alternate: Nina DÜRR
• Zsuzsanna BIRÓ-SÁNDOR (Hungary)	Alternate: Dezső CSUPOR
• Ioanna CHINOU (Greece) *(Vice-Chair)*	Alternate: Eleni SKALTSA
• Per CLAESON (Sweden)	Alternate: Ubonwan CLAESON
• Niamh CURRAN (Ireland)[1]	Alternate: Anna CUNNEY[2]
• Marisa DELBÒ (Italy)	Alternate: *Awaiting nomination*
• Wojciech DYMOWSKI (Poland)	Alternate: Ewa BACKHAUS
• Nadia GRIGORAS (Romania)	Alternate: Carmen PURDEL
• Marie HEROUTOVÁ (Czech Republic)	Alternate: Pavla MUZIKÁŘOVÁ
• Dace KALKE (Latvia)	Alternate: Baiba JANSONE
• Artūras KAŽEMEKAITIS (Lithuania)	Alternate: Audronis LUKOŠIUS
• Samo KREFT (Slovenia)	Alternate: Barbara RAZINGER
• Reinhard LÄNGER (Austria)	Alternate: Martine SERNETZ
• 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
• Heidi NEEF (Belgium)	Alternate: Wim VERVAET[3]
• Adela NÚÑEZ VELÁZQUEZ (Spain)	Alternate: *Awaiting nomination*
• Evelin SAAR (Estonia)	Alternate: Marje ZERNANT
• Antoine SAWAYA (France)	Alternate: Jacqueline VIGUET POUPELLOZ

[1] Replaced Sinead HARRINGTON as of September 2012
[2] Replaced Niamh CURRAN as of September 2012
[3] Replaced Arnold J. VLIETINCK as of February 2012

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- Ján SLÚKA (Slovakia) Alternate: Milan NAGY
- 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

- Melanie BALD (Council of Europe, EDQM)
- Michael WIERER (Council of Europe, EDQM)
- Josipa CVEK (Croatia)
- Ivan KOSALEC (Croatia)
- Albana DIDA (Kosovo under UNSC Resolution 1244/99)
- Merjem HADJIHAMZA (Macedonia, The Former Yugoslav Republic of)
- Dimche ZAFIROV (Macedonia, The Former Yugoslav Republic of)
- Milena ADZIC (Montenegro)
- Dragan DJUROVIC (Serbia)

Working parties, ad hoc groups and scientific advisory groups

Working party on Community Monographs and Community List
Chair: Ioanna CHINOU EMA contact: Anthony HUMPHREYS

Organisational Matters Drafting Group
Chair: Emiel VAN GALEN EMA contact: Anthony HUMPHREYS

Quality Drafting Group
Chair: Burt H. KROES EMA contact: Anthony HUMPHREYS

Annex 7 – Members of the Paediatric Committee

Chair: Daniel BRASSEUR
EMA contact: Paolo TOMASI

Members

• Fernando de ANDRÉS TRELLES (Spain)	*Alternate:* Maria Jesús FERNÁNDES CORTIZO
• Dina APELE-FREIMANE (Latvia)	*Alternate: Awaiting nomination*
• Carine de BEAUFORT (CHMP Luxembourg)	*Alternate:* Jacqueline GENOUX-HAMES
• John Joseph BORG (Malta)	*Alternate:* Herbert LENICKER
• Kevin CONNOLLY (Ireland)	*Alternate:* Brian AYLWARD
• Julia DUNNE (United Kingdom)[1]	*Alternate:* Angeliki SIAPKARA [2]
• Helena FONSECA (Portugal)	*Alternate:* Hugo TAVARES
• Marta GRANSTRÖM (Sweden)	*Alternate:* Viveca Lena ODLIND
• Agnes GYURASICS (CHMP, Hungary)	*Alternate:* János BORVENDÉG
• Janez JAZBEC (Slovenia)	*Alternate:* Tadej AVCIN
• Vlasta KÁKOŠOVÁ (Slovakia)	*Alternate:* Jan MAZAG
• Dobrin KONSTANTINOV (Bulgaria)	*Alternate:* Margarita GUIZOVA
• Pirjo LAITINEN-PARKKONEN (Finland)	*Alternate:* Ann Marie KAUKONEN[3]
• Irja LUTSAR (Estonia)	*Alternate:* Alar IRS
• Romaldas MAČIULAITIS (CHMP, Lithuania)	*Alternate:* Rugile PILVINIENE
• Christoph MALE (Austria)	*Alternate:* Karl-Heinz HUEMER
• Stefanos MANTAGOS (Greece)	*Alternate: Awaiting nomination*
• Dirk MENTZER (Germany) *Vice Chair*	*Alternate:* Birka LEHMANN
• Marek MIGDAL (Poland)	*Alternate:* Jolanta WITKOWSKA-OŻOGOWSKA
• Hubert MOTTL (Czech Republic)	*Alternate:* Peter SZITANYI
• Koenraad NORGA (Belgium)	*Alternate:* Jacqueline CARLEER
• Marianne ORHOLM (Denmark)	*Alternate:* Dorthe MEYER
• Gylfi OSKARSSON (Iceland)	*Alternate:* Kolbeinn GUDMUNDSSON
• Gérard PONS (France)	*Alternate:* Sylvie BENCHETRIT
• Paolo ROSSI (Italy)	*Alternate:* Francesca ROCCHI
• Andreas TELOUDES (Cyprus)	*Alternate:* Stefanos CHRISTODOULOU

[1] Replaced Matthew THATCHER as of March 2012
[2] Replaced Timothy CHAMBERS as of November 2012
[3] Replaced Anne PAAVOLA as of March 2011

- Hendrik VAN DEN BERG (The Netherlands) *Alternate:* Johannes TAMINIAU
- Nela VILCEANU (CHMP, Romania) *Alternate:* Dana Gabriela MARIN
- 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*

Annex 8 – Members of the Committee for Advanced Therapies

Chair: Christian SCHNEIDER[1]
EMA contact: Patrick CELIS and Lucia D'APOTE

Members

Members nominated from within the CHMP

• John-Joseph BORG[2]	*Alternate:* Anthony SAMUEL[3]
• Romaldas MAČIULAITIS	*Alternate:* Jolanta GULBINOVIC
• Jean-Louis ROBERT	*Alternate:* Guy BERCHEM
• Sol RUIZ	*Alternate:* Marcos TIMÓN
• *Awaiting nomination*[4]	*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)[5]	*Alternate:* Balázs SARKADI[6]
• Egbert FLORY (Germany)	*Alternate:* Martina SCHÜSSLER LENZ
• Paolo GASPARINI (Italy)[7]	*Alternate:* Giulio COSSU[8]
• Ivana HAUNEROVÁ (Check Republic)	*Alternate:* Tomás BORÁŇ
• Mikulás HRUBIŠKO[9] (Slovakia)	*Alternate:* Ján KYSELOVIC[10]
• Marit HYSTAD (Norway)	*Alternate:* Rune KJEKEN
• Metoda LIPNIK[11] (Slovenia)	*Alternate:* Nevenka TRSINAR[12]
• Toivo MAIMETS (Estonia)	*Alternate:* Pille HARRISON[13]
• Golapan NARAYANAN (UK)	*Alternate:* Andrew CROSBIE
• Monica NEAGU (Romania)	*Alternate:* Simona BADOI[14]

[1] Re-elected as Chair in March 2012
[2] CHMP/CAT member as of February 2012
[3] Replaced Andrew Borg as of February 2012
[4] Beatriz Silva-Lima resigned as of July 2012
[5] Swap of roles of member and alternate as of January 2012
[6] Swap of roles of member and alternate as of January 2012
[7] Replaced Giovanni Migliaccio as of February 2012
[8] Replaced Maria-Cristina Galli as of February 2012
[9] Replaced Peter Turcani as of February 2012
[10] Replaced Mikulas Hrubisko (who changed from alternate to member) as of April 2012
[11] Replaced Robert Zorec as of August 2012
[12] Replaced Borut Štrukelj as of August 2012
[13] Resigned in October 2012

- Maura O'DONOVAN (Ireland) — *Alternate:* Niall MacALEENAN
- Hans OVELGÖNNE (The Netherlands) — *Alternate: awaiting nomination*
- Anna PAFITOU (Cyprus) — *Alternate: Maria VASILIOU*
- Ilona REISCHL (Austria) — *Alternate:* Martin BRUNNER
- Paula SALMIKANGAS (Finland) — *Alternate:* Olli TENHUNEN[15]
- Dariusz SLADOWSKI[16] (Poland) — *Alternate:* Anna CIESLIK[17]
- Lyubina TODOROVA (Bulgaria) — *Alternate:* Vetislava TODOROVA[18]
- Jean-Hugues TROUVIN (France) — *Alternate:* Sophie LUCAS SAMUEL
- Asterios TSIFTSOGLOU (Greece) — *Alternate:* Aggeliki ROPOTI[19]
- Tina ZINCK (Denmark) [20] — *Alternate:* Nanna Aaby KRUSE[21]

Observers

- Vanja NIKOLAC (Croatia) — *Alternate:* Biljana SIMPRAGA

Members representing patients' organisations

Awaiting nominations from the EC

Members representing clinicians

Awaiting nominations from the EC

[14] Replaced Gianina-Nicoleta Andrei as of January 2012
[15] Replaced Taina Methuen as of January 2012
[16] Replaced Andrzej FAL as of February 2012
[17] Replaced Mariusz Fraczek as of September 2012
[18] Replaced Rosen Georgiev as of January 2012
[19] Replaced Vasilios Kokkas as of January 2012
[20] Replaced Henrik Tang Vestergaard (whose membership ended in August 2012) as of October 2012
[21] Replaced Henrik Tang Vestergaard (who changed from alternate to member in April 2012) as of June 2012

Annex 9 – CHMP opinions in 2012 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	**European Commission** • Opinion received • Date of decision • Notification • Official Journal
• Adasuve • Loxapine	Alexza UK Ltd.	• N05AH01 • For rapid control of agitation	• 16/11/2011 • 13/12/2012 • 170 • 162	• 19/12/2012 • - - • - - • - -
• AMYViD • Florbetapir F18	Eli Lilly Nederland B.V.	• V09AX • Radiopharmaceutical for Positron Emission Tomography (PET)	• 24/01/2012 • 18/10/2012 • 202 • 65	• 06/11/2012 • 14/01/2013 • - - • - -
• Betmiga • Mirabegron	Astellas Pharma Europe B.V.	• G04B • Treatment of overactive bladder (OAB) syndrome	• 20/09/2011 • 18/10/2012 • 201 • 192	• 30/10/2012 • 20/12/2012 • - - • - -
• Bexsero • Meningococcal Group B Vaccine (Rdna, Component, Adsorbed)	Novartis Vaccines and Diagnostics S.r.l.	• J07AH09 • Active immunization against invasive disease caused by N. meningitidis serogroup B strains	• 19/01/2011 • 15/11/2012 • 201 • 465	• 19/11/2012 • 14/01/2013 • - - • - -
• BindRen • Colestilan	Mitsubishi Pharma Europe Ltd	• V03AE • Treatment of hyperphosphataemia	• 21/09/2011 • 20/09/2012 • 210 • 155	• 27/11/2012 • 21/01/2013 • - - • - -
• Bretaris Genuair • Aclidinium Bromide	Almirall S.A	• R03BB • Treatment of chronic obstructive pulmonary disease (COPD)	• 22/02/2012 • 24/05/2012 • 84 • 7	• 01/06/2012 • 20/07/2012 • 31/08/2012 • C264
• Constella • Linaclotide	Almirall S.A	• A03A • Treatment of irritable bowel syndrome (IBS)	• 19/10/2011 • 20/09/2012 • 210 • 127	• 21/09/2012 • 26/11/2012 • 28/12/2012 • C401
• Cuprymina • Copper (64Cu) Chloride	Sparkle Srl	• V • Radiopharmaceutical (radiolabelling of carrier molecules)	• 22/09/2010 • 21/06/2012 • 201 • 409	• 17/07/2012 • 23/08/2012 • 28/09/2012 • C293
• Eklira Genuair • Aclidinium Bromide	Almirall S.A	• R03BB • Maintenance treatment to relieve symptoms of chronic obstructive pulmonary disease (COPD)	• 17/08/2011 • 24/05/2012 • 208 • 73	• 20/06/2012 • 20/07/2012 • 31/08/2012 • C264

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
• Enurev Breezhaler • Glycopyrronium Bromide	Novartis Europharm Ltd	• R03BB • Relief of symptoms of chronic obstructive pulmonary disease (COPD)	• 20/12/2011 • 21/06/2012 • 183 • 0	• 21/08/2012 • 28/09/2012 • 28/12/2012 • C401
• Eylea • Aflibercept	Bayer Pharma AG	• S01LA05 • Treatment of neovascular (wet) age-related macular degeneration (AMD)	• 22/06/2011 • 20/09/2012 • 210 • 246	• 24/09/2012 • 22/11/2012 • 28/12/2012 • C401
• Forxiga • Dapagliflozin	Bristol-Myers Squibb/AstraZeneca EEIG	• A10B • Treatment of type 2 diabetes mellitus	• 10/01/2011 • 19/04/2012 • 208 • 248	• 08/10/2012 • 12/11/2012 • 28/12/2012 • C401
• Fycompa • Perampanel	Eisai Europe Ltd.	• N03AX22 • Treatment of partial-onset seizures	• 21/06/2011 • 24/05/2012 • 208 • 129	• 21/06/2012 • 23/07/2012 • 31/08/2012 • C264
• Inlyta • Axitinib	Pfizer Limited	• L01XE17 • Treatment of renal cell carcinoma (RCC)	• 25/05/2011 • 24/05/2012 • 210 • 155	• 01/06/2012 • 03/09/2012 • 28/12/2012 • C401
• Jentadueto • Linagliptin / Metformin Hydrochloride	Boehringer Ingelheim International GmbH	• A10BD11 • Treatment of type 2 diabetes mellitus	• 20/07/2011 • 24/05/2012 • 208 • 101	• 19/06/2012 • 20/07/2012 • 31/08/2012 • C264
• Krystexxa • Pegloticase	Savient Pharma Ireland Ltd.	• M04AX02 • Treatment of chronic gout	• 25/05/2011 • 18/10/2012 • 201 • 311	• 09/11/2012 • 08/01/2013 • - - • - -
• Lyxumia • Lixisenatide	Sanofi-Aventis	• A10BX • Treatment of type 2 diabetes mellitus	• 15/11/2011 • 28/11/2012 • 214 • 164	• 30/11/2012 • 01/02/2013 • - - • - -
• Nimenrix • Meningococcal Group A, C, W135 And Y Conjugate Vaccine	GlaxoSmithKline Biologicals	• J07AH08 • Immunization against invasive meningococcal diseases	• 23/03/2011 • 16/02/2012 • 210 • 120	• 05/03/2012 • 20/04/2012 • 25/05/2012 • C148
• Perjeta • Pertuzumab	Roche Registration Ltd	• L01 • Treatment of breast cancer	• 21/12/2011 • 13/12/2012 • 201 • 157	• 17/12/2012 • - - • - - • - -
• Picato • Ingenol Mebutate	Leo Pharma A/S	• D06BX • Treatment of actinic keratosis	• 16/08/2011 • 20/09/2012 • 210 • 190	• 24/09/2012 • 15/11/2012 • 28/12/2012 • C401
• Pixuvri • Pixantrone Dimaleate	CTI Life Sciences Limited	• L01DB11 • Treatment of non-Hodgkin lymphomas (NHL)	• 17/11/2010 • 16/02/2012 • 201 • 255	• 15/03/2012 • 10/05/2012 • 29/06/2012 • C190

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
• Rienso • Ferumoxytol	Takeda Global Research and Development Centre (Europe)	• B03 • Treatment of iron deficiency with chronic kidney disease (CKD)	• 23/06/2010 • 19/04/2012 • 208 • 458	• 20/04/2012 • 15/06/2012 • 20/06/2012 • C224
• Ryzodeg • Insulin Degludec And Insulin Aspart (Idegasp)	Novo Nordisk A/S	• A10 • Treatment of diabetes mellitus	• 19/10/2011 • 18/10/2012 • 201 • 164	• 30/10/2012 • 21/01/2013 • - - • - -
• Seebri Breezhaler • Glycopyrronium Bromide	Novartis Europharm Ltd	• R03BB • Relief of symptoms of chronic obstructive pulmonary disease (COPD)	• 21/09/2011 • 21/06/2012 • 201 • 73	• 01/08/2012 • 28/09/2012 • 28/12/2012 • C401
• Selincro • Nalmefene	H. Lundbeck A/S	• N07BB • Reduction of alcohol consumption	• 15/12/2011 • 13/12/2012 • 201 • 157	• 19/12/2012 • - - • - - • - -
• Tovanor Breezhaler • Glycopyrronium Bromide	Novartis Europharm Ltd	• R03BB • Relief of symptoms of chronic obstructive pulmonary disease (COPD)	• 20/12/2011 • 21/06/2012 • 183 • 0	• 01/08/2012 • 28/09/2012 • 28/12/2012 • C401
• Tresiba • Insulin Degludec	Novo Nordisk A/S	• A10 • Treatment of diabetes mellitus	• 19/10/2011 • 18/10/2012 • 201 • 164	• 30/10/2012 • 21/01/2013 • - - • - -
• XALKORI • Crizotinib	Pfizer Limited	• L01XE16 • Treatment of lung cancer	• 17/08/2011 • 19/07/2012 • 201 • 136	• 08/08/2012 • 23/10/2012 • 28/12/2012 • C401
• Zaltrap • Aflibercept	Sanofi-Aventis	• L01 • Treatment of metastatic colorectal cancer (MCRC)	• 20/12/2011 • 15/11/2012 • 210 • 120	• 22/11/2012 • - - • - - • - -
• Zinforo • Ceftaroline Fosamil	AstraZeneca AB	• J01DI02 • Treatment of skin and soft tissue infections (cSSTI) and community-acquired pneumonia (CAP)	• 19/01/2011 • 21/06/2012 • 201 • 318	• 29/06/2012 • 23/08/2012 • 28/09/2012 • C293

CHMP positive opinions on orphan medicinal products for human use

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CHMP** • Validation • Opinion • Active Time • Clock stop	**European Commission** • Opinion received • Date of decision • Notification • Official Journal
• Adcetris • Brentuximab Vedotin	Takeda Global Research and Development Centre (Europe)	• L01XC12 • Treatment Hodgkin lymphoma (HL) and systemic anaplastic large cell lymphoma (sALCL)	• 22/06/2011 • 19/07/2012 • 203 • 190	• 20/07/2012 • 25/10/2012 • 28/12/2012 • C401
• Dacogen • Decitabine	Janssen-Cilag International N.V.	• L01BC08 • Treatment of acute myeloid leukaemia (AML)	• 22/06/2011 • 19/07/2012 • 210 • 183	• 25/07/2012 • 20/09/2012 • 28/12/2012 • C401
• Jakavi • Ruxolitinib Phosphate	Novartis Europharm Ltd	• L01XE18 • Treatment of myelofibrosis	• 22/06/2011 • 19/04/2012 • 208 • 94	• 15/05/2012 • 23/08/2012 • 28/09/2012 • C293
• Kalydeco • Ivacaftor	Vertex Pharmaceuticals (U.K.) Ltd.	• R07AX • Treatment of cystic fibrosis (CF)	• 16/11/2011 • 24/05/2012 • 150 • 40	• 14/06/2012 • 23/07/2012 • 31/08/2012 • C264
• NexoBrid • Bromelain Enriched Proteolytic Enzyme Preparation From Ananas Comosus	Teva Pharma GmbH	• D03 • Removal of eschar	• 17/11/2010 • 20/09/2012 • 210 • 463	• 18/10/2012 • 18/12/2012 • - - • - -
• NovoThirteen • Catridecacog	Novo Nordisk A/S	• B02BD11 • Treatment of bleeding	• 13/05/2011 • 24/05/2012 • 208 • 157	• 20/06/2012 • 03/09/2012 • 28/12/2012 • C401
• Revestive • Teduglutide	Nycomed Danmark ApS	• A16AX08 • Treatment of Short Bowel Syndrome	• 23/03/2011 • 21/06/2012 • 201 • 255	• 18/07/2012 • 30/08/2012 • 28/09/2012 • C293
• Signifor • Pasireotide	Novartis Europharm Ltd	• H01CB05 • Treatment of Cushing's disease	• 20/10/2010 • 19/01/2012 • 214 • 242	• 26/01/2012 • 24/04/2012 • 25/05/2012 • C148

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

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CHMP** • Validation • Opinion • Active Time • Clock stop	**European Commission** • Opinion received • Date of decision • Notification • Official Journal
• Capecitabine Accord • Capecitabine	Accord Healthcare Ltd	• L01BC06 • Treatment of colon cancer, metastatic colorectal cancer and gastric cancer	• 23/03/2011 • 16/02/2012 • 210 • 120	• 19/03/2012 • 20/04/2012 • 25/05/2012 • C148
• Capecitabine medac • Capecitabine	Medac	• L01BC06 • Treatment of colon cancer	• 14/11/2011 • 20/09/2012 • 180 • 129	• 27/09/2012 • 19/11/2012 • 28/12/2012 • C401
• Capecitabine Teva • Capecitabine	Teva Pharma B.V.	• L01BC06 • Treatment of colon cancer, metastatic colorectal cancer, gastric cancer and breast cancer	• 23/03/2011 • 16/02/2012 • 210 • 120	• 14/03/2012 • 20/04/2012 • 25/05/2012 • C148
• Docetaxel Accord • Docetaxel	Accord Healthcare Limited	• L01CD02 • Treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, head and neck cancer	• 22/06/2011 • 15/03/2012 • 201 • 66	• 22/03/2012 • 22/05/2012 • 29/06/2012 • C190
• Docetaxel Kabi • Docetaxel	FRESENIUS KABI ONCOLOGY PLC	• L01CD02 • Treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer	• 22/06/2011 • 15/03/2012 • 201 • 66	• 17/04/2012 • 22/05/2012 • 29/06/2012 • C190
• Ecansya • Capecitabine	Krka d.d. Novo mesto	• L01BC06 • Treatment of cancer	• 05/10/2011 • 16/02/2012 • 89 • 31	• 20/03/2012 • 20/04/2012 • 25/05/2012 • C148
• Ibandronic acid Accord • Ibandronic Acid	Accord Healthcare Limited	• M05BA06 • Prevention of skeletal events	• 24/01/2012 • 20/09/2012 • 180 • 59	• 25/09/2012 • 19/11/2012 • 28/12/2012 • C401
• Imatinib Teva • Imatinib	Teva Pharma B.V.	• L01XE01 • Treatment of Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML)	• 21/12/2011 • 18/10/2012 • 201 • 101	• 30/10/2012 • 08/01/2013 • - - • - -

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
• Memantine Merz • Memantine Hydrochloride	Merz Pharmaceuticals GmbH	• N06DX01 • Treatment of Alzheimer's disease	• 26/06/2012 • 20/09/2012 • 60 • 0	• 25/09/2012 • 22/11/2012 • 28/12/2012 • C401
• Riluzole Zentiva • Riluzole	Aventis Pharma S.A.	• N07XX02 • Treatment of amyotrophic lateral sclerosis (ALS)	• 15/12/2011 • 16/02/2012 • 60 • 0	• 14/03/2012 • 07/05/2012 • 29/06/2012 • C190
• Sabervel • Irbesartan	Pharmathen S.A.	• C09CA04 • Treatment of essential hypertension	• 25/05/2011 • 16/02/2012 • 201 • 66	• 28/02/2012 • 13/04/2012 • 25/05/2012 • C148
• Sancuso • Granisetron	ProStrakan Limited	• A04AA02 • Prevention of nausea and vomiting	• 20/10/2010 • 16/02/2012 • 209 • 247	• 27/02/2012 • 20/04/2012 • 25/05/2012 • C148
• Zoledronic acid Actavis • Zoledronic Acid	Actavis Group hf	• M05BA08 • Prevention of skeletal related events and treatment of tumour-induced hypercalcaemia (TIH)	• 25/05/2011 • 16/02/2012 • 210 • 57	• 22/02/2012 • 20/04/2012 • 25/05/2012 • C148
• Zoledronic acid Hospira • Zoledronic Acid	HOSPIRA UK LIMITED	• M05BA08 • Prevention of skeletal related events and treatment of tumour-induced hypercalcaemia (TIH)	• 22/06/2011 • 20/09/2012 • 210 • 246	• 28/08/2012 • 19/11/2012 • 28/12/2012 • C401
• Zoledronic acid medac • Zoledronic Acid	Medac	• M05BA08 • Prevention of skeletal related events and tretment of tumour-induced hypercalcaemia (TIH)	• 25/05/2011 • 24/05/2012 • 208 • 157	• 04/06/2012 • 03/08/2012 • 28/09/2012 • C293
• Zoledronic acid Mylan • Zoledronic Acid	MYLAN S.A.S.	• M05BA08 • Prevention of skeletal related events and treatment of tumour-induced hypercalcaemia (TIH)	• 25/05/2011 • 21/06/2012 • 201 • 192	• 28/06/2012 • 23/08/2012 • 28/12/2012 • C401
• Zoledronic acid Teva • Zoledronic Acid	Teva Pharma B.V.	• M05BA08 • Prevention of skeletal related events and treatment of tumour-induced hypercalcaemia (TIH)	• 25/05/2011 • 15/03/2012 • 210 • 85	• 22/03/2012 • 16/08/2012 • 28/09/2012 • C293

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
• Zoledronic acid Teva Pharma • Zoledronic Acid	Teva Pharma B.V.	• M05BA08 • Treatment of osteoporosis	• 25/05/2011 • 15/03/2012 • 210 • 85	• 26/03/2012 • 16/08/2012 • 28/09/2012 • C293
• Zyclara • Imiquimod	Meda AB	• D06BB10 • Treatment of actinic keratoses (AK)	• 20/07/2011 • 21/06/2012 • 201 • 136	• 26/06/2012 • 23/08/2012 • 28/09/2012 • C293

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	**European Commission** • Opinion received • Date of decision • Notification • Official Journal
• None in 2012		•	•	•

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	**European Commission** • Opinion received • Date of decision • Notification • Official Journal
• None in 2012		•	•	•

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 • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CHMP** • Validation • Opinion • Active Time • Clock stop
• Hexaxim • 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	• J07CA09 • Vaccination against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive infections	• 20/07/2011 • 21/06/2012 • 204 • 0
• Pyramax • Pyronaridine / Artesunate	Shin Poong Pharmaceutical Co., Ltd.	• P01BF06 • Treatment of malaria	• 26/05/2010 • 16/02/2012 • 295 • 0

CHMP negative 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
• Acrescent • Memantine Hydrochloride / Donepezil Hydrochloride	H. Lundbeck A/S	• N06D • Treatment of Alzheimer's disease	• 21/06/2011 • 18/10/2012 • 201 • 283	• 09/11/2012 • - - • - - • - -
• Balaxur • Memantine Hydrochloride / Donepezil Hydrochloride	Merz Pharmaceuticals GmbH	• N06DA52 • Treatment of Alzheimer's disease	• 23/03/2012 • 18/10/2012 • 82 • 126	• 09/11/2012 • - - • - - • - -
• Elelyso • Taliglucerase Alfa	Pfizer Limited	• A16AB11 • Treatment of Gaucher disease	• 15/12/2010 • 03/07/2012 • 213 • 353	• 05/07/2012 • 25/10/2012 • 29/10/2012 • C371
• Fanaptum • Iloperidone	Vanda Pharmaceuticals Ltd.	• N05AX14 • Treatment of schizophrenia	• 20/07/2011 • 13/12/2012 • 201 • 311	• 11/01/2013 • - - • - - • - -

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
• Folotyn • Pralatrexate	Allos Therapeutics Ltd	• L01BA05 • Treatment of peripheral T-cell lymphoma	• 14/12/2010 • 19/01/2012 • 208 • 192	• 27/01/2012 • 21/06/2012 • 27/07/2012 • C224
• Istodax • Romidepsin	CELGENE EUROPE LIMITED	• L01XX39 • Treatment of peripheral T-cell lymphoma (PTCL)	• 23/03/2011 • 19/07/2012 • 201 • 283	• 01/08/2012 • 12/02/2013 • - - • - -
• Kynamro • Mipomersen	Genzyme Europe BV	• C10AX11 • Treatment of cholesterol and hypercholesterol-aemia	• 17/08/2011 • 13/12/2012 • 210 • 274	• 09/01/2013 • - - • - - • - -
• Qsiva • Phentermine / Topiramate	VIVUS BV	• A08AA • Treatment of obesity	• 19/01/2011 • 18/10/2012 • 201 • 437	• 25/10/2012 • - - • - - • - -

Centralised applications for medicinal products for human use – withdrawals in 2012 prior to opinion

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CHMP** • Validation • Withdrawal • Active Time • Clock stop
• Combimarv • Insulin Human	Marvel Lifesciences Ltd	• A10AD01 • Treatment of diabetes mellitus	• 25/01/2012 • 15/11/2012 • 121 • 0
• Egrifta • Tesamorelin	Ferrer Internacional, S.A.	• H01AC06 • Treatment of HIV infected patients with lipodystrophy	• 21/06/2011 • 21/06/2012 • 182 • 86
• Fluad Paediatric • Influenza Vaccine (Surface Antigen, Inactivated)	Novartis Vaccines and Diagnostics S.r.l.	• J07BB02 • Active immunization against influenza	• 15/12/2010 • 10/02/2012 • 182 • 184
• Isomarv medium • Insulin Human	Marvel Lifesciences Ltd	• A10AC01 • Treatment of diabetes mellitus	• 25/01/2012 • 15/11/2012 • 121 • 0
• JENZYL • Ridaforolimus	Merck Sharp & Dohme Limited	• L01XE • Treatment of metastatic soft tissue sarcoma or bone sarcoma	• 17/08/2011 • 27/11/2012 • 182 • 100

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CHMP** • Validation • Withdrawal • Active Time • Clock stop
• Loulla • Mercaptopurine	Only for children pharmaceuticals	• L01BB02 • Treatment of acute lymphatic leukemia	• 21/02/2012 • 19/12/2012 • 121 • 0
• Megestrol Acetate 125mg/ml Oral Suspension • Megestrol Acetate	Alkermes Pharma Ireland Ltd.	• L02AB01 • Treatment of anorexia, cachexia, or an unexplained significant weight loss	• 23/12/2009 • 06/03/2012 • 121 • 0
• Mulsevo • Semuloparin Sodium	Sanofi-Aventis	• B01 • Treatment of cancer	• 19/10/2011 • 09/07/2012 • 121 • 0
• Solumarv • Insulin Human	Marvel Lifesciences Ltd	• A10AB01 • Treatment of diabetes mellitus	• 25/01/2012 • 15/11/2012 • 121 • 0

Annex 10 – CVMP opinions in 2012 on medicinal products for veterinary use

Positive opinions

Product • **Invented name** • **INN**	• **Marketing authorisation holder**	**Therapeutic area** • **Target species** • **Summary of indication**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Opinion received** • **Date of decision** • **Notification** • **Official Journal**
• Zulvac 1+8 Bovis • Inactivated Bluetongue virus, serotype 1 and 8, strain BTV-1	• Pfizer Limited •	• Cattle • Vaccine for the active immunisation of cattle for the prevention of viraemia caused by Bluetongue Virus, serotype 1 and 8.	• 04/02/2011 • 12/01/2012 • 152 • 191	• 12/01/2012 • 08/03/2012 • 12/03/2012 • 27/04/2012
• Poulvac E. Coli	• Pfizer Limited •	• Chickens • Vaccine for the active immunisation to reduce mortality and lesions associated with E. Coli serotype 078	• 09/02/2011 • 11/04/2012 • 210 • 219	• 13/04/2012 • 15/06/2012 • 20/06/2012 • 27/07/2012
• Porcilis ColiClos	• Intervet International B.V.	• Piglets • Vaccine for the passive immunisation against E. Coli and C. perfringens	• 12/10/2010 • 11/04/2012 • 210 • 339	• 16/04/2012 • 14/06/2012 • 17/06/2012 • 27/07/2012
• Cardalis tablets • Benazepril and spironolactone	• Ceva Santé Animale	• Dogs • Indicated for the treatment of congestive heart failure caused by chronic degenerative valvular disease	• 13/07/2011 • 16/05/2012 • 208 • 99	• 16/05/2012 • 23/07/2012 • 25/07/2012 • 31/08/2012

Product • Invented name • INN	• Marketing authorisation holder	Therapeutic area • Target species • Summary of indication	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Nobivac L4	• Intervet International B.V.	• Dogs • Vaccine containing inactivated Leptospira strains and indicated for the active immunisation of dogs to reduce infection and/or urinary excretion caused by Leptospira strains.	• 04/01/2012 • 16/05/2012 • 201 • 256	• 16/05/2012 • 16/07/2012 • 18/07/2012 • 31/08/2012
• Contacera • Meloxicam	• Pfizer Limited	• Cattle, pigs and horses. • Anti-inflammatory and anti-rheumatic	• 12/10/2011 • 11/10/2012 • 210 • 156	• 11/10/2012 • 06/12/2012 • 07/12/2012
• Kexxtone • Monensin	• Eli Lilly and Company Limited	• Cattle • Reduction of the incidence of ketosis in the periparturient dairy cow/heifer	• 12/10/2011 • 08/11/2012 • 210 • 185	• 08/11/2012 • 28/01/2013 • 29/01/2013
• Semintra • Telmisartan	• Boehringer Ingelheim Vetmedica GmbH	• Cats • Chronic kidney disease	• 15/02/2012 • 13/12/2012 • 210 • 92	• 13/12/2012 • 13/02/2013 • 13/02/2013 •
• Pexion • Imepitoin	• Boehringer Ingelheim Vetmedica GmbH	• Dogs • Control of epilepsy	• 12/10/2011 • 13/12/2012 • 208 • 183	• 13/12/2012 • 25/02/2013 • 26/02/2013 •

Opinions on establishment of MRLs for new substances

• **Substance** • **INN**	• **Target species**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Opinion received** • **Date of regulation** • **Official Journal**
Sodium salicylate (After provisional MRLs)	• Turkeys	• n/a • 09/02/2012 • 90 • 0	• 15/02/2012 • 12/10/2012 • 13/10/2012
Prednisolone	• Horses	• 12/10/2011 • 08/03/2012; *14/06/2012 (Re-examination)* • 148 *+56* • 0	• 20/06/2012
Monensin	• Bovine species	• 15/06/2011 • 08/03/2012 • 205 • 63	• 21/03/2012 • 23/01/2013 • 24/01/2013
Phoxim	• All food producing except fin fish	• 04/01/2011 • 08/03/2012 • 210 • 220	• 21/03/2012 • 11/12/2012 • 12/12/2012
Diclazuril	• Poultry	• 09/11/2011 • 13/04/2012 • 156 • 0	• 23/04/2012 • 08/02/2013 • 09/02/2013
Double stranded ribonucleic acid homologous to viral ribonucleic acid coding for part of the coat protein and part of the intergenic region of Israel Acute Paralysis Virus	• Bees	• 09/10/2010 • 13/04/2012 • 210 • 312	• 23/04/2012;
Eprinomectin	• Ovine and caprine	• 18/05/2010 • 13/04/2012 • 183 • 423	• 23/04/2012 • 08/02/2013 • 09/02/2013
Monepantel	• Ovine and caprine milk	• 13/09/2011 • 16/05/2012 • 210 • 36	• 25/05/2012

Manganese carbonate	• All food producing species	• 15/02/2012 • 12/07/2012 • 148 • 0	• 25/07/2012
Neomycin	• All food producing species	• 16/09/2010 • 10/11/2011; *08/03/2012 (Re-examination)* • 210 + 59 213	• 21/03/2012

Annex 11 – COMP opinions in 2012 on designation of orphan medicinal products

Positive COMP designation opinions

Product INN	**Sponsor**	**Indication**	**EMA/COMP** • **Submission** • **Start date** • **Opinion** • **Active time**	**European Commission** • **Opinion received** • **Date of decision**
Glucagon	Biodel UK Limited - UK	Treatment of congenital hyperinsulinism	• 26/10/2011 • 11/11/2011 • 11/01/2012 • (61 days/28 days)	• 06/02/2012 • 05/03/2012
Sialic acid	NDA Regulatory Science Ltd - UK	Treatment of hereditary inclusion body myopathy	• 20/10/2011 • 11/11/2011 • 11/01/2012 • (61 days/20 days)	• 14/02/2012 • 05/03/2012
(1-methyl-2-nitro-1H-imidazole-5-yl)methyl N,N'-bis(2-bromoethyl) diamido-phosphate	Ockham Europe Limited - United Kingdom	Treatment of soft tissue sarcoma	• 27/09/2011 • 14/10/2011 • 11/01/2012 • (89 days/28 days)	• • 06/02/2012 • 05/03/2012
Human monoclonal antibody targeting Staphylococcus aureus alpha-toxin	Envestia Limited - United Kingdom	Treatment of pneumonia caused by Staphylococcus aureus	• 21/10/2011 • 11/11/2011 • 11/01/2012 • (61 days/28 days)	• 06/02/2012 • 05/03/2012
Heterologous human adult liver-derived stem cells	Fresenius Medical Care Deutschland GmbH - Germany	Treatment of carbamoyl phosphate synthase 1 deficiency	• 20/10/2011 • 11/11/2011 • 11/01/2012 • (61 days/20 days)	• • 14/02/2012 • 05/03/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Sodium nitrite	FGK Representative Service GmbH - Germany	Treatment of pulmonary arterial hypertension	• 28/09/2011 • 14/10/2011 • 11/01/2012 • (89 days/28 days)	• 06/02/2012 • 05/03/2012
Doxycycline hyclate	Giampaolo Merlini - Italy	Treatment of systemic amyloidosis caused by beta-2 microglobulin	• 30/09/2011 • 14/10/2011 • 11/01/2012 • (89 days/28 days)	• 06/02/2012 • 05/03/2012
6-ethynyl-1-(pentan-3-yl)-1H-imidazo[4,5-b]pyrazin-2(3H)-one	ICON Clinical Research (UK) Limited (Buckinghamshire) - UK	Treatment of amyotrophic lateral sclerosis	• 24/10/2011 • 11/11/2011 • 11/01/2012 • (61 days/20 days)	• 14/02/2012 • 05/03/2012
Recombinant human beta-glucuronidase	NDA Regulatory Science Ltd - UK	Treatment of mucopolysaccharidosis type VII (Sly syndrome)	• 20/10/2011 • 11/11/2011 • 11/01/2012 • (61 days/29 days)	• 21/02/2012 • 21/03/2012
Adeno-associated viral vector of serotype 5 containing the human alanine-glyoxylate aminotransferase gene	uniQure biopharma B.V. - The Netherlands	Treatment of primary hyperoxaluria type 1	• 17/10/2011 • 11/11/2011 • 11/01/2012 • (61 days/29 days)	• 21/02/2012 • 21/03/2012
Carbetocin	Ferring Pharmaceuticals A/S - Denmark	Treatment of Prader-Willi syndrome	• 03/10/2011 • 14/10/2011 • 03/02/2012 • (112 days/29 days)	• 21/02/2012 • 21/03/2012
Genistein sodium salt dihydrate	Axcentua Pharmaceuticals AB - Sweden	Treatment of mucopolysaccharidosis type III (Sanfilippo syndrome)	• 24/10/2011 • 11/11/2011 • 08/02/2012 • (89 days/28 days)	• 05/03/2012 • 02/04/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Melatonin	Dr Nicola J Robertson - UK	Treatment of perinatal asphyxia	• 25/10/2011 • 11/11/2011 • 08/02/2012 • (89 days/28 days)	• 05/03/2012 • 02/04/2012
Sodium thiosulfate	Aptiv Solutions (UK) Limited - United Kingdom	Treatment of calciphylaxis	• 28/11/2011 • 12/12/2011 • 08/02/2012 • (58 days/28 days)	• 05/03/2012 • 02/04/2012
Linsitinib	Astellas Pharma Europe B.V. - The Netherlands	Treatment of adrenal cortical carcinoma	• 25/11/2011 • 12/12/2011 • 08/02/2012 • (58 days/28 days)	• 05/03/2012 • 02/04/2012
Dipalmitoyl-phosphatidyl-choline, 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphoglycerol, sodium salt, synthetic Surfactant Protein C analogue and synthetic Surfactant Protein B analogue	Chiesi Farmaceutici S.P.A. - Italy	Treatment of respiratory distress syndrome in premature neonates of less than 37 weeks of gestational age	• 28/11/2011 • 12/12/2011 • 08/02/2012 • (58 days/28 days)	• 05/03/2012 • 02/04/2012
Adenovirus associated viral vector serotype 2 containing the human RPE65 gene	Alan Boyd Consultants Ltd - UK	Treatment of Leber's congenital amaurosis	• 28/11/2011 • 12/12/2011 • 08/02/2012 • (58 days/28 days)	• 05/03/2012 • 02/04/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Antisense oligonucleotide targeted to the SMN2 gene	Isis USA Ltd - UK	Treatment of 5q spinal muscular atrophy	• 11/11/2011 • 12/12/2011 • 08/02/2012 • (58 days/28 days)	• 05/03/2012 • 02/04/2012
Oleylphospho-choline	Dafra Pharma International nv - Belgium	Treatment of leishmaniasis	• 25/10/2011 • 11/11/2011 • 05/03/2012 • (115 days/38 days)	• 16/03/2012 • 23/04/2012
Ketoconazole	Laboratoire HRA Pharma - France	Treatment of Cushing's syndrome	• 20/10/2011 • 11/11/2011 • 05/03/2012 • (115 days/38 days)	• 16/03/2012 • 23/04/2012
Heterologous human adult liver-derived stem cells	Fresenius Medical Care Deutschland GmbH - Germany	Treatment of acute liver failure	• 12/12/2011 • 12/10/2011 • 08/03/2012 • (52 days/30 days)	• 27/03/2012 • 26/04/2012
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. - Belgium	Treatment of chronic lymphocytic leukaemia	• 08/12/2011 • 16/01/2012 • 08/03/2012 • (52 days/30 days)	• 27/03/2012 • 26/04/2012
Recombinant human methionine proinsulin	ProRetina Therapeutics S.L. - Spain	Treatment of retinitis pigmentosa	• 26/01/2012 • 13/02/2012 • 08/03/2012 • (24 days/30 days)	• 27/03/2012 • 26/04/2012
(E)-2,4,6-trimethoxystyryl-3-carboxymethyl-amino-4-methoxybenzyl-sulfone sodium salt	JJGConsultancy Ltd - United Kingdom	Treatment of myelodysplastic syndromes	• 12/12/2011 • 16/01/2012 • 08/03/2012 • (52 days/30 days)	• 27/03/2012 • 26/04/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Vosaroxin	Sunesis Europe Ltd - UK	Treatment of acute myeloid leukaemia	• 09/12/2011 • 16/01/2012 • 08/03/2012 • (52 days/30 days)	• 27/03/2012 • 26/04/2012
N-hydroxy-4-(3-methyl-2-(S)-phenyl-butyrylamino) benzamide	Sirius Regulatory Consulting Limited - UK	Treatment of neurofibromatosis type 2	• 12/12/2011 • 16/01/2012 • 08/03/2012 • (52 days/30 days)	• 27/03/2012 • 26/04/2012
Halofuginone hydrobromide	Biological Consulting Europe Ltd - UK	Treatment of Duchenne muscular dystrophy	• 12/12/2011 • 16/01/2012 • 08/03/2012 • (52 days/30 days)	• 27/03/2012 • 26/04/2012
Pegylated recombinant factor VIII	Novo Nordisk A/S - Denmark	Treatment of haemophilia A	• 25/11/2011 • 12/12/2011 • 08/03/2012 • (87 days/27 days)	• 30/03/2012 • 26/04/2012
Exon 53 specific phosphorothioate oligonucleotide	Prosensa Therapeutics B.V. - The Netherlands	Treatment of Duchenne muscular dystrophy	• 23/11/2011 • 12/12/2011 • 08/03/2012 • (87 days/30 days)	• 27/03/2012 • 26/04/2012
Exon 45 specific phosphorothioate oligonucleotide	Prosensa Therapeutics B.V. - The Netherlands	Treatment of Duchenne muscular dystrophy	• 23/11/2011 • 12/12/2011 • 08/03/2012 • (87 days/30 days)	• 27/03/2012 • 26/04/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
2-Allyl-1-[6-(1-hydroxy-1-methylethyl) pyridin-2-yl]-6-{[4-(4-methylpiperazin-1-yl)phenyl]amino}-1,2-dihydro-3H-pyrazolo[3,4-d] pyrimidin-3-one	Merck Sharp & Dohme Limited - UK	Treatment of ovarian cancer	• 05/12/2011 • 16/01/2012 • 08/03/2012 • (52 days/30 days)	• 27/03/2012 • 26/04/2012
Pomalidomide	Celgene Europe Limited - United Kingdom	Treatment of systemic sclerosis	• 12/12/2011 • 16/01/2012 • 08/03/2012 • (52 days/30 days)	• 27/03/2012 • 26/04/2012
Chimeric monoclonal antibody against kappa myeloma antigen	Gregory Fryer Associates Ltd - UK	Treatment of multiple myeloma	• 24/10/2011 • 11/11/2011 • 11/01/2012 • (61 days/109 days)	• 03/02/2012 • 22/05/2012
Allogeneic human dendritic cells derived from a CD34+ progenitor cell line	DCPrime BV - The Netherlands	Treatment of acute myeloid leukaemia	• 22/08/2011 • 14/10/2011 • 11/01/2012 • (89 days/109 days)	• 03/02/2012 • 22/05/2012
Chlormethine	TMC Pharma Services Ltd - UK	Treatment of cutaneous T-cell lymphoma	• 28/09/2011 • 14/10/2011 • 11/01/2012 • (89 days/109 days)	• 03/02/2012 • 22/05/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Yttrium (90Y)-DTPA-radiolabelled chimeric monoclonal antibody against frizzled homologue 10	Laboratoires OncoTherapy Science France, S.A.R.L - France	Treatment of soft tissue sarcoma	• 09/12/2011 • 16/01/2012 • 08/03/2012 • (52 days/25 days)	• 30/04/2012 • 25/05/2012
N-hydroxy-4-(3-methyl-2-(S)-phenyl-butyrylamino) benzamide	Sirius Regulatory Consulting Limited - UK	Treatment of meningioma	• 12/12/2011 • 16/01/2012 • 12/04/2012 • (87 days/23 days)	• 14/05/2012 • 06/06/2012
Letermovir	AiCuris GmbH & Co. KG - Germany	Treatment of cytomegalovirus disease in patients with impaired cell mediated immunity	• 27/01/2012 • 13/02/2012 • 12/04/2012 • (59 days/23 days)	• 14/05/2012 • 06/06/2012
Polyinosine-polycytidylic acid coupled with the polycationic polyethylene-imine	Bioncotech Therapeutics S.L. - Spain	Treatment of pancreatic cancer	• 03/02/2012 • 13/02/2012 • 12/04/2012 • (59 days/23 days)	• 14/05/2012 • 06/06/2012
Autologous haematopoietic stem cells transduced with lentiviral vector Lenti-D encoding the human ABCD1 cDNA	bluebird bio France - France	Treatment of adrenoleukodystrophy	• 30/01/2012 • 13/02/2012 • 12/04/2012 • (59 days/23 days)	• 14/05/2012 • 06/06/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
1-(4-{4-amino-7-[1-(2-hydroxyethyl)-1H- pyrazol-4-yl] thieno [3,2-c]pyridin-3-yl}phenyl)-3-(3-fluorophenyl)urea	AbbVie Ltd - UK	Treatment of ovarian cancer	• 20/01/2012 • 13/02/2012 • 12/04/2012 • (59 days/23 days)	• 14/05/2012 • 06/06/2012
N-hydroxy-4-(3-methyl-2-(S)-phenyl-butyrylamino) benzamide	Sirius Regulatory Consulting Limited - UK	Treatment of schwannoma	• 12/12/2011 • 16/01/2012 • 12/04/2012 • (87 days/23 days)	• 14/05/2012 • 06/06/2012
Adenovirus-associated vector containing human Fas-c gene	Gregory Fryer Associates Ltd - UK	Treatment of glioma	• 09/12/2011 • 16/01/2012 • 12/04/2012 • (87 days/23 days)	• 14/05/2012 • 06/06/2012
Autologous CD34+ cells transfected with lentiviral vector containing the Wiskott-Aldrich syndrome protein gene	Fondazione Telethon - Italy	Treatment of Wiskott-Aldrich syndrome	• 27/01/2012 • 13/02/2012 • 12/04/2012 • (59 days/23 days)	• 14/05/2012 • 06/06/2012
Talarozole	Stiefel Laboratories (Maidenhead) Limited - United Kingdom	Treatment of recessive X-linked ichthyosis	• 24/01/2012 • 13/02/2012 • 11/05/2012 • (88 days/29 days)	• 05/06/2012 • 04/07/2012
Levoglutamide	Emmaus Medical Europe Limited - UK	Treatment of sickle cell disease	• 30/01/2012 • 13/02/2012 • 11/05/2012 • (88 days/29 days)	• 05/06/2012 • 04/07/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
16 base single stranded peptide nucleic acid oligonucleotide - 7 aminoacids peptide	Biogenera srl - Italy	Treatment of neuroblastoma	• 24/02/2012 • 16/03/2012 • 11/05/2012 • (56 days/29 days)	• 05/06/2012 • 04/07/2012
Ataluren	PTC Therapeutics, Limited - UK	Treatment of Becker muscular dystrophy	• 01/03/2012 • 16/03/2012 • 11/05/2012 • (56 days/29 days)	• 05/06/2012 • 04/07/2012
Recombinant human interleukin-7	CYTHERIS SA - France	Treatment of progressive multifocal leukoencephalopathy	• 30/01/2012 • 13/02/2012 • 11/05/2012 • (88 days/29 days)	• 05/06/2012 • 04/07/2012
Givinostat	Italfarmaco S.p.A. - Italy	Treatment of Duchenne muscular dystrophy	• 29/02/2012 • 16/03/2012 • 11/05/2012 • (56 days/29 days)	• 05/06/2012 • 04/07/2012
Eculizumab	Alexion Europe SAS - France	Treatment of infection-associated haemolytic uraemic syndrome	• 27/01/2012 • 13/02/2012 • 11/05/2012 • (88 days/29 days)	• 05/06/2012 • 04/07/2012
2S, 4R ketoconazole	Cortendo AB - Sweden	Treatment of Cushing's syndrome	• 05/03/2012 • 16/03/2012 • 11/05/2012 • (56 days/29 days)	• 05/06/2012 • 04/07/2012
Talarozole	Stiefel Laboratories (Maidenhead) Limited - United Kingdom	Treatment of keratinopathic ichthyosis	• 24/01/2012 • 13/02/2012 • 11/05/2012 • (88 days/29 days)	• 05/06/2012 • 04/07/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Human Erythrocytes encapsulating Inositol Hexaphosphate	ERYtech Pharma S.A. - France	Treatment of sickle cell disease	• 02/03/2012 • 16/03/2012 • 11/05/2012 • (56 days/29 days)	• 05/06/2012 • 04/07/2012
Ramucirumab	Eli Lilly Nederland B.V. - The Netherlands	Treatment of gastric cancer	• 01/03/2012 • 16/03/2012 • 11/05/2012 • (56 days/29 days)	• 05/06/2012 • 04/07/2012
Ramucirumab	Eli Lilly Nederland B.V. - The Netherlands	Treatment of hepatocellular carcinoma	• 01/03/2012 • 16/03/2012 • 11/05/2012 • (56 days/23 days)	• 11/06/2012 • 04/07/2012
Talarozole	Stiefel Laboratories (Maidenhead) Limited - United Kingdom	Treatment of autosomal recessive congenital ichthyosis	• 24/01/2012 • 13/02/2012 • 11/05/2012 • (88 days/29 days)	• 05/06/2012 • 04/07/2012
Recombinant adeno-associated viral vector containing human acid alfa-glucosidase-gene	TMC Pharma Services Ltd - UK	Treatment of glycogen storage disease type II (Pompe's disease)	• 15/02/2012 • 16/03/2012 • 21/05/2012 • (66 days/29 days)	• 05/06/2012 • 04/07/2012
Metreleptin	Aptiv Solutions (UK) Limited - United Kingdom	Treatment of Lawrence syndrome	• 29/02/2012 • 16/03/2012 • 13/06/2012 • (89 days/29 days)	• 18/06/2012 • 17/07/2012
Recombinant human pentraxin-2	Appletree Europe S.à.r.l. - Luxembourg	Treatment of idiopathic pulmonary fibrosis	• 26/03/2012 • 13/04/2012 • 13/06/2012 • (61 days/29 days)	• 18/06/2012 • 17/07/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Hexasodium phytate	Sanifit Laboratoris, S.L. - Spain	Treatment of calciphylaxis	• 22/03/2012 • 13/04/2012 • 13/06/2012 • (61 days/29 days)	• 18/06/2012 • 17/07/2012
Human Apotransferrin	Sanquin Blood Supply Foundation - The Netherlands	Treatment of congenital hypotransferrinaemia	• 26/03/2012 • 13/04/2012 • 13/06/2012 • (61 days/29 days)	• 18/06/2012 • 17/07/2012
(2S)-2-{[(2R)-2-[({[3,3-dibutyl-7-(methylthio)-1,1-dioxido-5-phenyl-2,3,4,5-tetrahydro-1,2,5-benzothiadiazepin-8-yl]oxy}acetyl) amino]-2-(4-hydroxyphenyl) acetyl]amino} butanoic acid	Albireo AB - Sweden	Treatment of progressive familial intrahepatic cholestasis	• 23/02/2012 • 13/04/2012 • 13/06/2012 • (61 days/29 days)	• 18/06/2012 • 17/07/2012
Metreleptin	Aptiv Solutions (UK) Limited - United Kingdom	Treatment of Barraquer-Simons syndrome	• 29/02/2012 • 16/03/2012 • 13/06/2012 • (89 days/29 days)	• 18/06/2012 • 17/07/2012
Metreleptin	Aptiv Solutions (UK) Limited - United Kingdom	Treatment of Berardinelli-Seip syndrome	• 29/02/2012 • 16/03/2012 • 13/06/2012 • (89 days/29 days)	• 18/06/2012 • 17/07/2012
1-[(2-Chloro-4-methoxyphenoxy)methyl]-4-[(2,6-dichlorophenoxy) methyl]benzene	ViroDefense Ltd - United Kingdom	Prevention of poliomyelitis in patients with immunodeficiencies deemed at risk	• 24/02/2012 • 16/03/2012 • 13/06/2012 • (89 days/29 days)	• 18/06/2012 • 17/07/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Metreleptin	Aptiv Solutions (UK) Limited - United Kingdom	Treatment of familial partial lipodystrophy	• 29/02/2012 • 16/03/2012 • 13/06/2012 • (89 days/29 days)	• 18/06/2012 • 17/07/2012
N-Butyldeoxy-galactono-jirimycin	Actelion Registration Limited - United Kingdom	Treatment of Fabry disease	• 22/03/2012 • 13/04/2012 • 11/07/2012 • (89 days/22 days)	• 18/07/2012 • 09/08/2012
Humanised monoclonal antibody targeting P-selectin	Quintiles Ireland Ltd - Ireland	Treatment of sickle cell disease	• 24/02/2012 • 13/04/2012 • 11/07/2012 • (89 days/22 days)	• 18/07/2012 • 09/08/2012
Vatreptacog alfa (activated)	Novo Nordisk A/S - Denmark	Treatment of haemophilia A	• 22/05/2012 • 08/06/2012 • 11/07/2012 • (33 days/22 days)	• 18/07/2012 • 09/08/2012
Recombinant anti-CD3-bi-single-chain-Fv-diphtheria toxin fusion protein	AOP Orphan Pharmaceuticals AG - Austria	Treatment of cutaneous T-cell lymphoma	• 23/05/2012 • 08/06/2012 • 11/07/2012 • (33 days/22 days)	• 18/07/2012 • 09/08/2012
Ketoconazole	Agenzia Industrie Difesa-Stabilimento Chimico Farmaceutico Militare - Italy	Treatment of Cushing's syndrome	• 22/05/2012 • 08/06/2012 • 11/07/2012 • (33 days/22 days)	• 18/07/2012 • 09/08/2012
Elotuzumab	Bristol-Myers Squibb Pharma EEIG - UK	Treatment of multiple myeloma	• 17/05/2012 • 08/06/2012 • 11/07/2012 • (33 days/22 days)	• 18/07/2012 • 09/08/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Vatreptacog alfa (activated)	Novo Nordisk A/S - Denmark	Treatment of haemophilia B	• 22/05/2012 • 08/06/2012 • 11/07/2012 • (33 days/22 days)	• 18/07/2012 • 09/08/2012
Recombinant human monoclonal antibody against activin receptor type IIB	Novartis Europharm Limited - UK	Treatment of inclusion body myositis	• 26/03/2012 • 13/04/2012 • 11/07/2012 • (89 days/22 days)	• 18/07/2012 • 09/08/2012
Humanised monoclonal antibody against epidermal growth factor receptor	AbbVie Ltd - UK	Treatment of glioma	• 26/03/2012 • 13/04/2012 • 11/07/2012 • (89 days/22 days)	• 18/07/2012 • 09/08/2012
(2S)-2-{[(2R)-2-[({[3,3-dibutyl-7-(methylthio)-1,1-dioxido-5-phenyl-2,3,4,5-tetrahydro-1,2,5-benzothiadiazepin-8-yl]oxy}acetyl) amino]-2-(4-hydroxyphenyl) acetyl]amino} butanoic acid	Albireo AB - Sweden	Treatment of primary biliary cirrhosis	• 23/02/2012 • 13/04/2012 • 11/07/2012 • (89 days/22 days)	• 18/07/2012 • 09/08/2012
Recombinant anti-CD3-bi-single-chain-Fv-diphtheria toxin fusion protein	AOP Orphan Pharmaceuticals AG - Austria	Treatment of peripheral T-cell lymphoma (nodal, other extranodal and leukaemic/ disseminated)	• 26/03/2012 • 13/04/2012 • 11/07/2012 • (89 days/22 days)	• 18/07/2012 • 09/08/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Covalently closed DNA plasmids coding for cytomegalovirus phosphoprotein 65 and glycoprotein B genes	Astellas Pharma Europe B.V. - The Netherlands	Prevention of cytomegalovirus disease in patients with impaired cell mediated immunity deemed at risk	• 26/01/2012 • 13/04/2012 • 11/07/2012 • (89 days/22 days)	• 18/07/2012 • 09/08/2012
(2S)-2-{[(2R)-2-[({[3,3-dibutyl-7-(methylthio)-1,1-dioxido-5-phenyl-2,3,4,5-tetrahydro-1,2,5-benzothiadiazepin-8-yl]oxy}acetyl) amino]-2-(4-hydroxyphenyl) acetyl]amino} butanoic acid	Albireo AB - Sweden	Treatment of Alagille syndrome	• 23/02/2012 • 13/04/2012 • 11/07/2012 • (89 days/22 days)	• 18/07/2012 • 09/08/2012
N-[4-[[(2-amino-3,4-dihydro-4-oxo-6-pteridinyl)methyl] amino]benzoyl]-D-gamma-glutamyl-(2S)-2-amino-beta-alanyl-L-alpha-aspartyl-L-cysteine to be used with folic acid	Endocyte Europe B.V. - The Netherlands	Diagnosis of positive folate receptor status in ovarian cancer	• 11/05/2012 • 08/06/2012 • 23/07/2012 • (45 days/48 days)	• 24/07/2012 • 10/09/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Folic acid to be used with N-[4-[[(2-amino-3,4-dihydro-4-oxo-6-pteridinyl)methyl]amino]benzoyl]-D-gamma-glutamyl-(2S)-2-amino-beta-alanyl-L-alpha-aspartyl-L-cysteine	Endocyte Europe B.V. - The Netherlands	Diagnosis of positive folate receptor status in ovarian cancer	• 11/05/2012 • 08/06/2012 • 23/07/2012 • (45 days/48 days)	• 24/07/2012 • 10/09/2012
Trans-4-[4-[5-[[6-(trifluoromethyl)-3-pyridinyl]amino]-2-pyridinyl]phenyl] cyclohexane acetic acid, sodium salt	Novartis Europharm Limited - UK	Treatment of familial chylomicronaemia syndrome (type I hyperliporpoteinaemia)	• 22/05/2012 • 08/06/2012 • 11/07/2012 • (33 days/58 days)	• 18/09/2012 • 14/09/2012
Mavoglurant	Novartis Europharm Limited - UK	Treatment of fragile X syndrome	• 16/05/2012 • 08/06/2012 • 05/09/2012 • (89 days/26 days)	• 14/09/2012 • 10/10/2012
Obinutuzumab	Roche Registration Limited - UK	Treatment of chronic lymphocytic leukemia	• 22/06/2012 • 09/07/2012 • 05/09/2012 • (58 days/26 days)	• 14/09/2012 • 10/10/2012
Recombinant human lecithin cholesterol acyltransferase	Alphacore Pharma Limited - United Kingdom	Treatment of lecithin cholesterol acyltransferase deficiency	• 04/06/2012 • 09/07/2012 • 05/09/2012 • (58 days/26 days)	• 14/09/2012 • 10/10/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Lurbinectedin	Pharma Mar SA Sociedad Unipersonal - Spain	Treatment of ovarian cancer	• 22/06/2012 • 09/07/2012 • 05/09/2012 • (58 days/26 days)	• 14/09/2012 • 10/10/2012
Humanised monoclonal IgG4 antibody against tissue factor pathway inhibitor	Novo Nordisk A/S - Denmark	Treatment of haemophilia A	• 20/06/2012 • 09/07/2012 • 05/09/2012 • (58 days/26 days)	• 14/09/2012 • 10/10/2012
Belinostat	TopoTarget A/S - Denmark	Treatment of peripheral T-cell lymphoma (nodal, other extranodal and leukemic/disseminated)	• 25/06/2012 • 09/07/2012 • 05/09/2012 • (58 days/26 days)	• 14/09/2012 • 10/10/2012
Liposomal daunorubicin	Galen Limited - UK	Treatment of acute myeloid leukaemia	• 12/07/2012 • 10/08/2012 • 05/09/2012 • (26 days/23 days)	• 17/09/2012 • 10/10/2012
[2-Cyano-3-cyclopropyl-3-hydroxy-N-(3-methyl-4-trifluoromethyl-phenyl)prop-2-enamide]	Algiax Pharmaceuticals GmbH - Germany	Treatment of traumatic spinal cord injury	• 24/05/2012 • 08/06/2012 • 05/09/2012 • (89 days/26 days)	• 14/09/2012 • 10/10/2012
Rucaparib	Clovis Oncology UK Limited - United Kingdom	treatment of ovarian cancer	• 23/05/2012 • 08/06/2012 • 05/09/2012 • (89 days/23 days)	• 17/09/2012 • 10/10/2012
Asp-Arg-Val-Tyr-Ile-His-Pro	Tarix Pharmaceuticals Limited - Cyprus	Treatment of acute lung injury	• 17/05/2012 • 08/06/2012 • 05/09/2012 • (89 days/26 days)	• 14/09/2012 • 10/10/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Alpha-1 proteinase inhibitor (for inhalation use)	Grifols Deutschland GmbH - Germany	Treatment of cystic fibrosis	• 16/05/2012 • 09/07/2012 • 05/09/2012 • (58 days/26 days)	• 14/09/2012 • 10/10/2012
Mixture of two allogeneic human pancreatic cancer cell lines stably transduced with a retroviral vector encoding the murine alpha-(1,3)-galactosyl-transferase gene	European Medical Advisory Services Limited - United Kingdom	Treatment of pancreatic cancer	• 18/05/2012 • 09/07/2012 • 05/09/2012 • (58 days/26 days)	• 14/09/2012 • 10/10/2012
Panobinostat	Novartis Europharm Limited - UK	Treatment of multiple myeloma	• 19/07/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012
Milciclib maleate	Nerviano Medical Science Srl - Italy	Treatment of malignant thymoma	• 19/06/2012 • 09/07/2012 • 05/10/2012 • (88 days/27 days)	• 12/10/2012 • 08/11/2012
Tafamidis	Pfizer Limited - UK	Treatment of senile systemic amyloidosis	• 19/07/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012
Tralokinumab	MedImmune Ltd - UK	Treatment of idiopathic pulmonary fibrosis	• 17/07/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012
Recombinant human dyskerin	Advanced Medical Projects - Spain	Treatment of dyskeratosis congenita	• 24/10/2011 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Naloxone hydrochloride dihydrate	Winston Laboratories Ltd - United Kingdom	Treatment of cutaneous T-cell lymphoma	• 20/04/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012
Melarsoprol	Pr. Peter Kennedy - UK	Treatment of African trypanosomiasis	• 19/07/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012
Ixazomib	Takeda Global Research and Development Centre (Europe) Ltd - United Kingdom	Treatment of systemic light chain amyloidosis	• 17/07/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012
Chimeric monoclonal antibody against GD2	APEIRON Biologics AG - Austria	Treatment of neuroblastoma	• 18/07/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012
Canakinumab	Novartis Europharm Limited - UK	Treatment of tumour necrosis factor receptor-associated periodic syndrome	• 17/05/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012
Alisertib	Takeda Global Research and Development Centre (Europe) Ltd - United Kingdom	Treatment of ovarian cancer	• 17/07/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Adeno-associated viral vector encoding an inducible short hairpin RNA targeting claudin-5 (prior to administration of 17-dimethylamino-ethylamino-17-demethocy-geldanamycin)	Avena Therapeutics Ltd - Ireland	Treatment of retinitis pigmentosa	• 06/08/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012
IL-12-secreting dendritic cells, loaded with autologous tumour lysate	Activartis Biotech GmbH - Austria	Treatment of glioma	• 12/06/2012 • 09/07/2012 • 05/10/2012 • (88 days/27 days)	• 12/10/2012 • 08/11/2012
Encapsulated human retinal pigment epithelial cell line transfected with plasmid vector expressing human ciliary neurotropic factor	Enpharma Ltd - UK	Treatment of macular telangiectasia type 2	• 12/12/2011 • 09/07/2012 • 05/10/2012 • (88 days/27 days)	• 12/10/2012 • 08/11/2012
Synthetic double-stranded siRNA oligonucleotide directed against Claudin-5 complexed with polyethylene-imine (prior to administration of doxorubicin)	Avena Therapeutics Ltd - Ireland	Treatment of glioma	• 06/08/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Erdosteine	Rafifarm SRL - Romania	Treatment of mercury toxicity	• 20/07/2012 • 10/08/2012 • 05/10/2012 • (56 days/27 days)	• 12/10/2012 • 08/11/2012
17-(Dimethylamino-ethylamino)-17-demethoxy-geldanamycin (after administration of adeno-associated viral vector encoding an inducible short hairpin RNA targeting claudin-5)	Avena Therapeutics Ltd - Ireland	Treatment of retinitis pigmentosa	• 27/02/2012 • 16/03/2012 • 11/05/2012 • (56 days/176 days)	• 05/06/2012 • 28/11/2012
Doxorubicin (administered after synthetic double-stranded siRNA oligonucleotide directed against claudin-5 complexed with polyethylene-imine)	Avena Therapeutics Ltd - Ireland	Treatment of glioma	• 17/02/2012 • 16/03/2012 • 11/05/2012 • (56 days/176 days)	• 05/06/2012 • 28/11/2012
Erdosteine	Rafifarm SRL - Romania	Treatment of lead toxicity	• 29/08/2012 • 10/09/2012 • 07/11/2012 • (58 days/23 days)	• 13/11/2012 • 06/12/2012
Allopurinol sodium	Pharmathen S.A. - Greece	Treatment of perinatal asphyxia	• 30/08/2012 • 10/09/2012 • 07/11/2012 • (58 days/23 days)	• 13/11/2012 • 06/12/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Cyclo(-gamma-aminobutyryl-L-phenylalanyl-L-tryptophanyl-D-tryptophanyl-L-lysyl-L-threonyl-L phenylalanyl-N-3-carboxypropyl)-glycine amide, acetate salt	Dr Ulrich Granzer - Germany	Treatment of acromegaly	• 16/07/2012 • 10/08/2012 • 07/11/2012 • (89 days/23 days	• 13/11/2012 • 06/12/2012
Exon 55 specific phosphorothioate oligonucleotide	Prosensa Therapeutics B.V. - The Netherlands	Treatment of Duchenne muscular dystrophy	• 22/08/2012 • 10/09/2012 • 07/11/2012 • (58 days/23 days)	• 13/11/2012 • 06/12/2012
Exon 52 specific phosphorothioate oligonucleotide	Prosensa Therapeutics B.V. - The Netherlands	Treatment of Duchenne muscular dystrophy	• 22/08/2012 • 10/09/2012 • 07/11/2012 • (58 days/23 days)	• 13/11/2012 • 06/12/2012
Triheptanoin	B. Braun Melsungen AG - Germany	Treatment of long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency	• 23/08/2012 • 10/09/2012 • 07/11/2012 • (58 days/23 days)	• 13/11/2012 • 06/12/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
4-(4-{[2-(4-chlorophenyl)-4,4-dimethylcyclohex-1-en-1-yl]methyl}piperazin-1-yl)-N-({3-nitro-4-[(tetrahydro-2H-pyran-4-ylmethyl)amino]phenyl}sulfonyl)-2-(1H-pyrrolo[2,3-b]pyridin-5-yloxy)benzamide	AbbVie Ltd - UK	Treatment of chronic lymphocytic leukaemia	• 24/08/2012 • 10/09/2012 • 07/11/2012 • (58 days/23 days)	• 13/11/2012 • 06/12/2012
Humanised single chain monoclonal antibody against CD37	Emergent Product Development UK Limited - United Kingdom	Treatment chronic lymphocytic leukaemia	• 29/08/2012 • 10/09/2012 • 07/11/2012 • (58 days/23 days)	• 13/11/2012 • 06/12/2012
Maytansinoid-conjugated human monoclonal antibody against mesothelin	Bayer Pharma AG - Germany	Treatment of malignant mesothelioma	• 17/05/2012 • 10/09/2012 • 07/11/2012 • (58 days/23 days)	• 13/11/2012 • 06/12/2012
Artesunate	Dafra Pharma International nv - Belgium	Treatment of malaria	• 22/08/2012 • 10/09/2012 • 07/11/2012 • (58 days/23 days)	• 13/11/2012 • 06/12/2012
Voclosporin	Granzer Regulatory Consulting & Services - Germany	Treatment of non-infectious uveitis	• 19/07/2012 • 10/08/2012 • 07/11/2012 • (89 days/23 days)	• 13/11/2012 • 06/12/2012

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Triheptanoin	B. Braun Melsungen AG - Germany	Treatment of very long-chain acyl-CoA dehydrogenase deficiency	• 23/08/2012 • 10/09/2012 • 07/11/2012 • (58 days/23 days)	• 13/11/2012 • 06/12/2012
Alisertib	Takeda Global Research and Development Centre (Europe) Ltd - United Kingdom	Treatment of peripheral T-cell lymphoma (nodal, other extranodal and leukaemic/ disseminated)	• 09/07/2012 • 10/08/2012 • 07/11/2012 • (89 days/23 days)	• 13/11/2012 • 06/12/2012
Terguride	Serodapharm GmbH - Germany	Treatment of systemic sclerosis	• 28/09/2012 • 28/09/2012 • 06/12/2012 • (55 days/41 days)	• 14/12/2012 • 24/01/2013
Recombinant modified human growth hormone	Richardson Associates Regulatory Affairs Ltd - United Kingdom	Treatment of growth hormone deficiency	• 29/08/2012 • 29/08/2012 • 06/12/2012 • (87 days/41 days)	• 14/12/2012 • 24/01/2013
1,2:5,6-Dianhydrogalactitol	IDIS Ltd - UK	Treatment of glioma	• 27/09/2012 • 27/09/2012 • 06/12/2012 • (55 days/41 days)	• 14/12/2012 • 24/01/2013
Adeno-associated viral vector serotype 9 containing the human N-acetylglucosaminidase alpha gene	Laboratorios del Dr. Esteve, S.A. - Spain	Treatment of mucopolysaccharidosis type IIIB (Sanfilippo B syndrome)	• 27/09/2012 • 27/09/2012 • 06/12/2012 • (55 days/41 days)	• 14/12/2012 • 24/01/2013

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Allogeneic motor neuron progenitor cells derived from human embryonic stem cells	California Stem Cell (UK) Ltd - UK	Treatment of 5q spinal muscular atrophy	• 25/09/2012 • 25/09/2012 • 06/12/2012 • (55 days/41 days)	• 14/12/2012 • 24/01/2013
Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human βA-T87Q-globin gene	bluebird bio France - France	Treatment of beta-thalassemia intermedia and major	• 27/09/2012 • 27/09/2012 • 06/12/2012 • (55 days/41 days)	• 14/12/2012 • 24/01/2013
Chimeric monoclonal antibody against claudin 6	GANYMED Pharmaceuticals AG - Germany	Treatment of ovarian cancer	• 26/09/2012 • 26/09/2012 • 06/12/2012 • (55 days/41 days)	• 14/12/2012 • 24/01/2013
Choline tetrathiomolybdate	Medical Need Europe AB - Sweden	Treatment of Wilson's disease	• 26/09/2012 • 26/09/2012 • 06/12/2012 • (55 days/41 days)	• 14/12/2012 • 24/01/2013
Encapsulated human retinal pigment epithelial cell line transfected with plasmid vector expressing human ciliary neurotrophic factor	Enpharma Ltd - UK	Treatment of retinitis pigmentosa	• 12/12/2011 • 12/12/2011 • 06/12/2012 • (55 days/41 days)	• 14/12/2012 • 24/01/2013

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Eflornithine in combination with sulindac	Cancer Prevention Pharma Limited - UK	Treatment of familial adenomatous polyposis	• 28/08/2012 • 28/08/2012 • 06/12/2012 • (87 days/41 days)	• 14/12/2012 • 24/01/2013
Recombinant human monoclonal antibody of the IgG1 kappa class against prostate stem cell antigen	Astellas Pharma Europe B.V. - The Netherlands	Treatment of pancreatic cancer	• 27/09/2012 • 27/09/2012 • 06/12/2012 • (55 days/41 days)	• 14/12/2012 • 24/01/2013
Lenalidomide	Celgene Europe Limited - United Kingdom	Treatment of follicular lymphoma	• 18/10/2012 • 18/10/2012 • 06/12/2012 • (27 days/41 days)	• 14/12/2012 • 24/01/2013
Modified recombinant human C-type natriuretic peptide	BioMarin Europe Ltd. - United Kingdom	Treatment of achondroplasia	• 27/09/2012 • 27/09/2012 • 06/12/2012 • (55 days/41 days)	• 14/12/2012 • 24/01/2013

Negative COMP designation opinions

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Tariquidar	Avaant Holdings Ltd - UK	Treatment of P-gp positive breast cancer	• 25/11/2011 • 12/12/2011 • 08/03/2012 • (87days/21 days)	• 06/07/2012 • 27/07/2012

Annex 12 – HMPC Community herbal monographs in 2012

Community herbal monographs

Reference number	Document title	Status
EMA/HMPC/347189/2011	Public statement on Allii cepae bulbus	Adopted March 2012
EMA/HMPC/681574/2012	Public statement on Angelicae sinensis radix	Released for public consultation November 2012
EMA/HMPC/121816/2010	Community herbal monograph on Cichorii intybi radix	Released for public consultation May 2012
EMA/HMPC/528177/2011	Public statement on Citri bergami aetheroleum	Adopted May 2012
EMA/HMPC/136024/2010	Community herbal monograph on Cucurbitae semen	Adopted November 2012
EMA/HMPC/688216/2008	Community herbal monograph on Echinaceae angustifoliae radix	Adopted March 2012
EMA/HMPC/892618/2011	Community herbal monograph on Eucalypti folium	Released for public consultation March 2012
EMA/HMPC/239271/2011	Community herbal monograph on Fraxini folium	Adopted March 2012
EMA/HMPC/748220/2011	Community herbal monograph on Grindeliae herba	Released for public consultation March 2012 Adopted November 2012
EMA/HMPC/354156/2011	Community herbal monograph on Hippocastani cortex	Adopted May 2012
EMA/HMPC/143181/2010	Community herbal monograph on Lavendulae aetheroleum	Adopted March 2012
EMA/HMPC/734125/2010	Community herbal monograph on Lavendulae flos	Adopted March 2012
EMA/HMPC/524621/2011	Community herbal monograph on Levistici radix	Released for public consultation March 2012 Adopted November 2012
EMA/HMPC/571119/2010	Community herbal monograph on Liquiritiae radix	Adopted May 2012
EMA/HMPC/200429/2012	Community herbal monograph on Origani dictamni herba	Released for public consultation November 2012
EMA/HMPC/897344/2011	Community herbal monograph on Paulliniae semen	Released for public consultation May 2012
EMA/HMPC/560961/2010	Community herbal monograph on Pelargonii radix	Adopted November 2012
EMA/HMPC/136582/2012	Community herbal monograph on Primulae flos	Revision adopted September 2012
EMA/HMPC/104095/2012	Community herbal monograph on Primulae radix	Revision adopted September 2012
EMA/HMPC/232091/2011	Community herbal monograph on Rhodiolae roseae rhizoma et radix	Adopted March 2012
EMA/HMPC/734361/2011	Community herbal monograph on Solani dulcamarae stipites	Released for public consultation March 2012
EMA/HMPC/130042/2010	Community herbal monograph on Thymi herba/Primulae radix	Adopted September 2012 (published in 2013 after revision)

Reference number	Document title	Status
EMA/HMPC/337066/2011	Community herbal monograph on Tiliae flos	Adopted May 2012
EMA/HMPC/510064/2011	Public statement on Tiliae tomentosae flos	Adopted May 2012
EMA/HMPC/461160/2008	Community herbal monograph on Urticae radix	Adopted September 2012
EMA/HMPC/57109/2011	Public statement on Visci albi herba	Adopted November 2012
EMA/HMPC/749154/2010	Community herbal monograph on Zingiberis rhizoma	Adopted March 2012
EMA/HMPC/681519/2012	Public statement on Withaniae somniferae radix	Released for public consultation November 2012

Annex 13 – PDCO opinions and Agency decisions on paediatric investigation plans and waivers in 2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
Morphine (hydrochloride)	N/A	P	Neonatology-paediatric intensive care Pain	EPMC Pharma SPRL	P/0001/2012	20/01/2012
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract from the pollen of Betula alba	N/A	PM	Pneumology-allergology	LETI Pharma GmbH	P/0002/2012	23/01/2012
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch, alder and hazel pollen	N/A	PM	Pneumology-allergology	LETI Pharma GmbH	P/0003/2012	23/01/2012
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch pollen	N/A	PM	Pneumology-allergology	LETI Pharma GmbH	P/0004/2012	23/01/2012
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch, alder and hazel pollen	N/A	PM	Pneumology-allergology	LETI Pharma GmbH	P/0005/2012	23/01/2012
Everolimus	Certican and associated names Afinitor	PM	Immunology-rheumatology-transplantation	Novartis Europharm Limited	P/0006/2012	24/01/2012
Denosumab	Xgeva Prolia	PM	Endocrinology-gynaecology-fertility-metabolism Immunology-	Amgen Europe B.V.	P/0007/2012	24/01/2012

[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

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
			rheumatology - transplantation Oncology			
Telaprevir	Incivo	PM	Infectious diseases	Tibotec BVBA	P/0008/2012	24/01/2012
Darbepoetin alfa	Aranesp	PM	Cardiovascular diseases Oncology Uro-nephrology	Amgen Europe B.V	P/0009/2012	24/01/2012
Elvitegravir	N/A	P	Infectious diseases	Gilead Sciences International Limited	P/0010/2012	24/01/2012
Lebrikizumab	N/A	P	Pneumology-allergology	Roche Products Limited	P/0011/2012	24/01/2012
Recombinant dimer of 6 kD early secretory antigenic target / recombinant 10 kD culture filtrate protein	N/A	P	Diagnostics	Statens Serum Institut	P/0012/2012	24/01/2012
Treprostinil (diethanolamine)	N/A	P	Cardiovascular diseases	United Therapeutics Europe Ltd	P/0013/2012	24/01/2012
Netupitant / palonosetron	N/A	W	Oncology Other	Helsinn Birex Pharmaceuticals Limited	P/0014/2012	24/01/2012
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	N/A	P	Vaccines	Sanofi pasteur	P/0015/2012	24/01/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
to tetanus protein / Purified Filamentous Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Purified Diphtheria Toxoid (DTaP-IPV-HepB-PRP-T)						
Brivaracetam	N/A	PM	Nerology	UCB Pharma SA	P/0016/2012	25/01/2012
Methyl aminolevulinate (hydrochloride)	N/A	P	Dermatology	Photocure ASA	P/0017/2012	25/01/2012
Ezetimibe / atorvastatin (calcium)	N/A	W	Cardiovascular diseases	Merck Sharp & Dohme (Europe), Inc.	P/0018/2012	25/01/2012
Bevacizumab	Avastin	PM	Oncology	Roche Registration Ltd	P/0019/2012	27/01/2012
Ticagrelor	Brilique Possia	PM	Cardiovascular diseases	AstraZeneca AB	P/0020/2012	27/01/2012
Cyclophosphamide	N/A	P	Oncology	Keocyt SAS	P/0021/2012	27/01/2012
Culture expanded autologous chondrocytes	N/A	P	Other	Fidia Advanced Biopolymers S.r.l.	P/0022/2012	27/01/2012
(S)-3'-(OH)-desazadesferrithiocin-polyether, magnesium salt (FBS0701)	N/A	PM	Haematology-haemostaseology	FerroKin BioSciences Ltd	P/0023/2012	27/01/2012
N-{3-[5-(2-Amino-4-pyrimidinyl)-2-(1,1-dimethylethyl)-1,3-thiazol-4-yl]-2-fluorophenyl}-2,6-difluorobenzene sulfonamide, methanesulfonate salt (GSK2118436)	N/A	P	Oncology	GlaxoSmithKline Trading Service Limited	P/0024/2012	27/01/2012
Human fibrinogen / human thrombin	Evicel	P	Other	Omrix Biopharmaceuticals	P/0025/2012	27/01/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
				SA		
Diltiazem (hydrochloride)	N/A	W	Gastroenterology-hepatology	S.L.A. Pharma (UK) Limited	P/0026/2012	27/01/2012
Laquinimod (sodium)	N/A	PM	Neurology	Teva Pharma GmbH	P/0027/2012	27/01/2012
Imatinib mesilate	Glivec	PM	Oncology	Novartis Europharm Limited	P/0028/2012	27/01/2012
Semuloparin sodium	N/A	PM	Haematology-haemostaseology	Sanofi-aventis Recherche & Développement	P/0029/2012	30/01/2012
Rilpivirine (hydrochloride)	N/A	PM	Infectious diseases	Janssen-Cilag International NV	P/0030/2012	02/02/2012
Ivabradine (hydrochloride)	Corlentor	PM	Cardiovascular disease	Les Laboratoires Servier	P/0031/2012	02/02/2012
Ivabradine (hydrochloride)	Procoralan	PM	Cardiovascular disease	Les Laboratoires Servier	P/0032/2012	02/02/2012
Dabigatran etexilate	Pradaxa	PM	Haematology-haemostaseology Cardiovascular diseases	Boehringer Ingelheim International GmbH	P/0033/2012	03/02/2012
Inactivated Type 1 Poliovirus (Mahoney) / Purified Fimbriae Types 2 and 3 (FIM) / Purified Tetanus Toxoid / Polyribosylribitol phosphate (PRP) from Haemophilus influenzae type b as PRP-OMPC / Purified Pertussis Toxoid (PT) / Purified Filamentous	N/A	PM	Vaccines	Sanofi Pasteur MSD SNC	P/0034/2012	03/02/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Inactivated Type 3 Poliovirus (Saukett) / Inactivated Type 2 Poliovirus (MEF-1) / Purified Pertactin (PRN) / Purified Diphteria Toxoid (V419)						
2-Iminobiotin	N/A	P	Neonatology-paediatric intensive care	Neurophyxia B.V.	P/0035/2012	03/02/2012
Pixantrone	N/A	PM	Oncology	CTI Life Sciences, Ltd	P/0036/2012	13/02/2012
Romiplostim	Nplate	PM	Haematology-haemostaseology	Amgen Europe B.V.	P/0037/2012	20/02/2012
Modified Vaccinia Ankara - Bavarian Nordic virus (smallpox)	N/A	P	Vaccines	Bavarian Nordic A/S	P/0038/2012	24/02/2012
Ivacaftor	N/A	PM	Other	Vertex Pharmaceuticals Incorporated	P/0039/2012	24/02/2012
Recombinant Porcine Factor VIII, B-Domain Deleted	N/A	W	Haematology-haemostaseology	Inspiration Biopharmaceuticals EU, Ltd.	P/0040/2012	24/02/2012
Eliglustat (tartrate)	N/A	P	Endocrinology-gynaecology-fertility-metabolism	Genzyme Europe B.V.	P/0041/2012	28/02/2012
Clostridium Botulinum neurotoxin type A (150 kD), free of complexing proteins	Xeomin Bocouture	P	Neurology Ophthalmology Dermatology	Merz Pharmaceuticals GmbH	P/0042/2012	28/02/2012
Elacytarabine	N/A	P	Oncology	Clavis Pharma ASA	P/0043/2012	28/02/2012
N-[3-[3-cyclopropyl-5-[(2-	N/A	P	Oncology	GlaxoSmit	P/0044/201	28/02/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
fluoro-4-iodophenyl)amino]- 6,8-dimethyl-2,4,7-trioxo-3,4,6,7-tetrahydropyrido[4,3-D]pyrimidin-1(2H)-yl]phenyl]acetamide, dimethylsulfoxide solvate (GSK1120212)				hKline Trading Service Limited	2	
Sunitinib	Sutent	PM	Oncology	Pfizer Limited	P/0045/2012	29/02/2012
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/0046/2012	29/02/2012
Fibrinogen concentrate / thrombin preparation / aprotinin / calcium chloride	N/A	P	Other	Kedrion S.p.A.	P/0047/2012	29/02/2012
Recombinant human A Disintegrin and Metalloprotease with Thrombospind Type-1 Motifs 13	N/A	P	Haematology-haemostaseology	Baxter Innovations GmbH	P/0048/2012	29/02/2012
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/0049/2012	01/03/2012
Guanfacine (hydrochloride)	N/A	PM	Psychiatry	Shire Pharmaceuticals Contracts Ltd.	P/0050/2012	02/03/2012
Hepatitis B (rDNA) surface	N/A	P	Vaccines	Dynavax	P/0051/201	02/03/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
antigen adjuvanted				International BV	2	
Rubidium (82Rb) chloride	N/A	P	Diagnostic	Advanced Accelerator Applications	P/0052/2012	23/03/2012
Lisdexamfetamine (dimesylate)	N/A	PM	Psychiatry	Shire Pharmaceutical Contracts Ltd	P/0053/2012	23/03/2012
Deoxycholic acid	N/A	W	Dermatology	Intendis GmbH	P/0054/2012	23/03/2012
Rabeprazole (sodium)	Pariet and associated names	PM	Gastroenterology-Hepatology	Eisai Limited	P/0055/2012	26/03/2012
Prucalopride succinate	Resolor	PM	Gastroenterology-Hepatology	Shire-Movetis NV	P/0056/2012	26/03/2012
Lanthanum carbonate hydrate	Fosrenol and associated names	PM	Uro-nephrology	Shire Pharmaceutical Contracts Ltd	P/0057/2012	26/03/2012
Eslicarbazepine (acetate)	Zebinix Exalief	PM	Neurology	BIAL - Portela & Ca, SA	P/0058/2012	26/03/2012
Rubidium (82Rb) chloride	N/A	P	Diagnostic	Jubilant DraxImage Inc.	P/0059/2012	26/03/2012
Anti-von Willebrand Factor Nanobody (ALX-0081)	N/A	P	Haematology-Hemostaseology	Ablynx NV	P/0060/2012	26/03/2012
Ezetimibe	Ezetrol and associated names	PM	Cardiovascular Diseases	MSD-SP Limited	P/0061/2012	28/03/2012
Ustekinumab	Stelara	P	Immunology-Rheumatology-Transplantation	Janssen-Cilag International NV	P/0062/2012	28/03/2012
Decitabine	N/A	PM	Oncology	Janssen-Cilag	P/0063/2012	28/03/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
				International NV		
(3R,4R)-4-methyl-3-(methyl-7H-pyrrolo[2,3-d]pyrimidin-4-ylamino)-β-oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (CP-690,550-10)	N/A	PM	Immunology-Rheumatology-Transplantation	Pfizer Limited	P/0064/2012	28/03/2012
Nitisinone	Orfadin	P	Endocrinology-Gynaecology-Fertility-Metabolism	Swedish Orphan Biovitrum International AB	P/0065/2012	28/03/2012
Anakinra	Kineret	P	Immunology-Rheumatology-Transplantation	Swedish Orphan Biovitrum AB (publ)	P/0066/2012	28/03/2012
Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 4 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 5 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 6B conjugated to protein D (derived from nontypeable haemophilus influenzae) carrier protein / pneumococcal	Synflorix	PM	Vaccines	GlaxoSmithKline Biologicals S.A.	P/0067/2012	30/03/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
polysaccharide serotype 7F conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 9V conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 14 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 18C conjugated to tetanus toxoid / pneumococcal polysaccharide serotype 19F conjugated to diphtheria toxoid / pneumococcal polysaccharide serotype 23F conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein						
Rituximab	MabThera	P	Immunology-Rheumatology - Transplantation Oncology	Roche Registration Limited	P/0068/2012	04/04/2012
Ataluren	N/A	PM	Neurology	Voisin Consulting SARL	P/0069/2012	04/04/2012
Sildenafil citrate	Revatio	PM	Cardiovascular diseases	Pfizer Limited	P/0070/2012	04/04/2012
Doripenem (monohydrate)	Doribax	PM	Infectious diseases	Janssen-Cilag Internatio	P/0071/2012	04/04/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
				nal NV		
Ceftaroline fosamil	N/A	PM	Infectious diseases	AstraZeneca AB	P/0072/2012	04/04/2012
Coagulation Factor IX (recombinant)	N/A	PM	Haematology-hemostaseology	Inspiration Biopharmaceuticals EU, Ltd.	P/0073/2012	04/04/2012
Treprostinil	Remodulin and associated names	PM	Cardovascular diseases	United Therapeutics Europe Ltd	P/0074/2012	25/04/2012
Artemether Lumefantrine	Riamet	PM	Infectious diseases	Novartis Europharm Limited	P/0075/2012	25/04/2012
Lixisenatide	N/A	PM	Endocrinology-gynaecology-fertility-metabolism	Sanofi-Aventis R&D	P/0076/2012	25/04/2012
Clopidogrel (hydrogen sulfate) Acetyl salicylic acid	N/A	W	Cardiovascular diseases	Sandoz BV	P/0077/2012	25/04/2012
Apixaban	Eliquis	PM	Cardiovascular diseases	Bristol-Myers Squibb/Pfizer EEIG	P/0078/2012	27/04/2012
Human normal immunoglobulin	Gammagen	PM	Dermatology	Orfagen	P/0079/2012	27/04/2012
Boceprevir	Victrelis	PM	Infectious Diseases	Merck Sharp & Dohme Ltd	P/0080/2012	27/04/2012
Human coagulation Factor VIII von Willebrand Factor	N/A	PM	Haematology-Hemostaseology	CSL Behring	P/0081/2012	30/04/2012
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	N/A	PM	Vaccines	Sanofi Pasteur	P/0082/2012	03/05/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
to tetanus protein / Purified Filamentous Haemagglutinin (FHA) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Purified Diphtheria Toxoid (DTaP-IPVHepB-PRP-T)						
Belatacept	Nulojix	PM	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb Pharma EEIG	P/0083/2012	16/05/2012
Liraglutide	Victoza	P	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	P/0084/2012	21/05/2012
L-Cysteinyl-L-prolyl-L-alanyl-L-valyl-L-lysyl-L-arginyl-L-aspartyl-L-valyl-L-aspartyl-L-leucyl-Lphenylalanyl-L-leucyl-L-threonine, hydrochloride salt / L-Glutamyl-L-glutaminyl-L-valyl-L-alanyl-Lglutaminyl-L-tyrosyl-L-lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-Lasparaginyl-L-alanine, acetate salt / L-Lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-Lglutamyl-L-asparaginyl-L-alanyl-L-arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginyl-L-cysteinyl-Lvaline, acetate salt / L-Arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginyl-L-cysteinyl-L-valyl-L-aspartyl-L-alanyl-L-lysyl-L-methionyl-L-threonyl-L-	N/A	PM	Oto-rhino-laryngology Pneumology - Allergology	Circassia Limited	P/0085/2012	21/05/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
glutamyl-L-glutamyl-L-aspartyl-L-lysyl-L-glutamic acid, acetate salt / L-Lysyl-L-glutamyl-L-asparaginyl-L-alanyl-L-leucyl-L-seryl-L-leucyl-L-leucyl-L-aspartyl-Llysyl-L-isoleucyl-L-tyrosyl-L-threonyl-L-seryl-L-prolyl-L-leucine, acetate salt / L-Threonyl-L-alanyl-Lmethionyl-L-lysyl-L-lysyl-L-isoleucyl-L-glutaminyl-L-aspartyl-L-cysteinyl-L-tyrosyl-L-valyl-L-glutamyl-Lasparaginyl-glycyl-L-leucyl-L-isoleucine, acetate salt / L-Seryl-L-arginyl-L-valyl-L-leucyl-L-aspartylglycyl-L-leucyl-L-valyl-L-methionyl-L-threonyl-L-threonyl-L-isoleucyl-L-seryl-L-seryl-L-seryl-L-lysine, acetate salt						
Ferumoxytol	N/A	PM	Haematology-Hemostaseology	AMAG Pharmaceuticals, Inc.	P/0086/2012	25/05/2012
Macitentan	N/A	PM	Cardiovascular Diseases Immunology-Rheumatology - Transplantation Pneumology - Allergology	Actelion Registration Ltd	P/0087/2012	25/05/2012
Dolutegravir	N/A	PM	Infectious diseases	ViiV Healthcare UK Ltd.	P/0088/2012	29/05/2012
Bimatoprost	Lumigan	P	Dermatology	Allergan Pharmaceuticals Ireland	P/0089/2012	29/05/2012
ixekizumab	N/A	P	Immunology-rheumatology	Eli Lilly & Company	P/0090/2012	29/05/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
			- transplantation	Limited		
Vonicog alfa	N/A	P	Haematology-haemostaseology	Baxter Innovations GmbH	P/0091/2012	29/05/2012
Nifedipine / candesartan (cilexetil)	N/A	W	Cardiovascular Diseases	Bayer Pharma AG	P/0092/2012	29/05/2012
Voclosporin	N/A	PM	Ophthalmology	Lux Biosciences GmbH	P/0093/2012	30/05/2012
Nalfurafine (hydrochloride)	N/A	PM	Other	Toray International U.K. Limited	P/0094/2012	30/05/2012
Clevidipine butyrate	Cleviprex and associated names	PM	Cardiovascular diseases	The Medicines Company UK Ltd.	P/0095/2012	30/05/2012
Trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl)propionate-(S)-3'-methyl-2'-(pentanoyl{2''-(tetrazol-5-ylate)biphenyl-4'-ylmethyl}amino)butyrate] hemipentahydrate (LCZ696)	N/A	P	Cardiovascular diseases	Novartis Europharm Ltd.	P/0096/2012	30/05/2012
Bosentan	Tracleer	PM	Cardiovascular diseases	Actelion Registration Ltd	P/0097/2012	30/05/2012
Ivabradine (hydrochloride)	Corlentor	PM	Cardiovascular diseases	Les Laboratoires Servier	P/0098/2012	30/05/2012
Ivabradine (hydrochloride)	Procoralan	PM	Cardiovascular diseases	Les Laboratoires Servier	P/0099/2012	30/05/2012
Anti-BAFF monoclonal antibody (LY2127399)	N/A	P	Immunology-Rheumatology-Transplantation	Eli Lilly & Company Limited	P/0100/2012	30/05/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
poly (oxy-1,2-ethanediyl), α-hydro-ω-methoxy-, 28B-ester with 28B-(N6-carboxy-L-Lysine)-29B-L-prolineinsulin (human) (LY 2605541)	N/A	P	Endocrinology - Gynaecology-Fertility-Metabolism	Eli Lilly & Company Limited	P/0101/2012	30/05/2012
Agomelatine	Valdoxan Thymanax	P	Psychiatry	Les Laboratoires Servier	P/0102/2012	30/05/2012
Glimepiride Atorvastatin (calcium)	N/A	W	Cardiovascular Diseases Endocrinology - Gynaecology-Fertility-Metabolism	GlaxoSmithKline Trading Services Limited	P/0103/2012	30/05/2012
Masitinib (mesylate)	N/A	W	Oncology	AB Science	P/0104/2012	01/06/2012
Tiotropium bromide (monohydrate)	Spiriva Respimat and associated names Spiriva	PM	Pneumology - Allergology	Boehringer Ingelheim International GmbH	P/0105/2012	04/06/2012
Golimumab	Simponi	P	Gastroenterology-Hepatology/ Immunology-Rheumatology - Transplantation	Janssen Biologics B.V.	P/0106/2012	08/06/2012
Modified grass pollen extract	N/A	PM	Pneumology - Allergology	Allergy Therapeutics (UK) Ltd.	P/0107/2012	08/06/2012
Canakinumab	Ilaris	PM	Immunology-Rheumatology - Transplantation	Novartis Europharm Limited	P/0108/2012	08/06/2012
Tenofovir (disoproxil fumarate)	Viread	PM	Infectious Diseases	Gilead Sciences Internatio	P/0109/2012	08/06/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
				nal Limited		
Bivalirudin	Angiox	RP	Cardiovascular Diseases	The Medicines Company UK Limited	P/0110/2012	18/06/2012
Asenapine (maleate)	Sycrest	PM	Psychiatry	N.V. Organon	P/0111/2012	29/06/2012
Voriconazole	Vfend	PM	Infectious Diseases	Pfizer Limited	P/0112/2012	22/06/2012
Ozenoxacin	N/A	PM	Infectious Diseases	Ferrer Internacional, S.A.	P/0113/2012	29/06/2012
Amlodipine (besilate) / valsartan	N/A	W	Cardiovascular Diseases	Synthon B.V.	P/0114/2012	29/06/2012
Ipilimumab	Yervoy	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	P/0115/2012	02/07/2012
Ipilimumab	Yervoy	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	P/0116/2012	02/07/2012
Melatonin	Circadin	P	Neurology	RAD Neurim Pharmaceuticals EEC Ltd	P/0117/2012	02/07/2012
Tadalafil	Adcirca Cialis	PM	Cardiovascular Diseases	Eli Lilly and Company Limited	P/0118/2012	02/07/2012
Azithromycin (monohydrate)	N/A	P	Dermatology/ Infectious Diseases	Ixodes AG, Zürih	P/0119/2012	02/07/2012
Cinacalcet hydrochloride	Mimpara	PM	Uro-nephrology	Amgen Europe B.V.	P/0120/2012	03/07/2012
Lumacaftor	N/A	P	Pneumology - Allergology	Voisin Consulting SARL	P/0121/2012	03/07/2012
Liraglutide	Victoza	PM	Endocrinology	Novo	P/0122/201	04/07/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
			- Gynaecology- Fertility- Metabolism	Nordisk A/S	2	
Perampanel	N/A	PM	Neurology	Eisai Ltd	P/0123/2012	04/07/2012
Alisporivir	N/A	W	Infectious Diseases	Novartis Europharm Ltd	P/0124/2012	04/07/2012
Bimatoprost	Lumigan 0.1 mg/ml eye drops, solution Lumigan 0.3 mg/ml eye drops, solution	PM	Dermatology/ Ophthalmology	Allergan Pharmaceuticals Ireland	P/0125/2012	04/07/2012
(3aR,4S,7aR)-Octahydro-4-hydroxy-4-[(3-methylphenyl)ethynyl]-1H-indole-1-carboxylic acid methyl ester (AFQ056)	N/A	PM	Neurology	Novartis Europharm Ltd	P/0126/2012	04/07/2012
Odanacatib	N/A	P	Immunology- Rheumatology - Transplantation	Merck Sharp & Dohme (Europe), Inc.	P/0127/2012	04/07/2012
Cabozantinib	N/A	P	Oncology	Exelixis, Inc.	P/0128/2012	04/07/2012
Ulimorelin	N/A	P	Gastroenterology- Hepatology	Norgine Ltd	P/0129/2012	04/07/2012
Albiglutide	N/A	P	Endocrinology - Gynaecology- Fertility- Metabolism	GlaxoSmithKline LLC	P/0130/2012	04/07/2012
Ponatinib	N/A	P	Oncology	ARIAD Pharma, Ltd.	P/0131/2012	04/07/2012
Tafluprost	Taflotan and associated names	P	Ophthalmology	Merck Sharp & Dohme	P/0132/2012	04/07/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
				(Europe), Inc.		
Abatacept	Orencia	PM	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb Pharma EEIG	P/0133/2012	02/07/2012
Rivaroxaban	Xarelto	PM	Cardiovascular Diseases	Bayer Pharma AG	P/0134/2012	06/07/2012
Ezetimibe	Ezetrol and associated names	W	Cardiovascular Diseases	MSD-SP Limited	P/0135/2012	20/07/2012
Aripiprazole	Abilify	PM	Psychiatry	Otsuka Pharmaceutical Europe Ltd.	P/0136/2012	20/07/2012
Bilastine	Bilaxten and associated names	PM	Dermatology Oto-rhino-laryngology Pneumology - Allergology	Faes Farma S.A.	P/0137/2012	20/07/2012
Human normal immunoglobulin	N/A	PM	Haematology-Hemostaseology Immunology-Rheumatology-Transplantation	Octapharma Pharmazeutika Produktionsges.m.b.H	P/0138/2012	20/07/2012
Serelaxin	N/A	P	Cardiovascular Diseases	Novartis Europharm Ltd.	P/0139/2012	20/07/2012
Potassium (chloride) / magnesium (sulphate heptahydrate) / procaine (hydrochloride) / xylitol	N/A	P	Other	Swiss Cardio Technologies AG	P/0140/2012	20/07/2012
Ezetimibe / simvastatin	Inegy and associated names	W	Cardiovascular Diseases	MSD-SP Limited	P/0141/2012	23/07/2012
Ethanol	N/A	P	Dermatology	Orphagen	P/0142/2012	23/07/2012
Propranolol hydrochloride	N/A	PM	Dermatology	Pierre	P/0143/201	23/07/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
				Fabre Dermatologie	2	
Lopinavir / ritonavir	Kaletra	PM	Infectious diseases	Abbott Laboratories Limited	P/0144/2012	23/07/2012
Lurasidone (hydrochloride)	N/A	P	Psychiatry	Takeda Global Research & Development Centre (Europe) Ltd.	P/0145/2012	23/07/2012
Tobramycin	Tobi Podhaler	PM	Infectious Diseases Pneumology - Allergology	Novartis Europharm Limited	P/0146/2012	24/07/2012
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract from the pollen of Betula alba	N/A	PM	Pneumology-allergology	LETI Pharma GmbH	P/0147/2012	24/07/2012
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch, alder and hazel pollen	N/A	PM	Pneumology-allergology	LETI Pharma GmbH	P/0148/2012	24/07/2012
Tivantinib	N/A	RW	Oncology	Daiichi Sankyo Development Limited	P/0149/2012	24/07/2012
Turoctocog alpha	N/A	PM	Haematology-Hemostaseology	Novo Nordisk A/S	P/0150/2012	16/07/2012
Aprepitant	Emend	PM	Oncology	Merck Sharp & Dohme Ltd.	P/0151/2012	25/07/2012
Purified antigen fractions of inactivated split virion	Prepandrix Pandemic	PM	Vaccines	GlaxoSmithKline	P/0152/2012	25/07/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
Influenza H5N1	influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmith Kline Biologicals			Biologicals S.A.		
Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05/ (H5N1)	Pumarix	PM	Vaccines	GlaxoSmithKline Biologicals S.A.	P/0153/2012	25/07/2012
Human coagulation Factor VIII / von Willebrand Factor	N/A	PM	Haematology-haemostaseology	CSL Behring	P/0154/2012	25/07/2012
Ivacaftor	N/A	PM	Other	Vertex Pharmaceuticals Incorporated	P/0155/2012	24/07/2012
Fosaprepitant	Ivemend	PM	Oncology	Merck Sharp & Dohme Ltd	P/0156/2012	25/07/2012
Velaglucerase alfa	N/A	PM	Endocrinology-gynaecology-fertility-metabolism	Shire Pharmaceuticals Ireland Limited	P/0157/2012	25/07/2012
Sildenafil	Revatio	PM	Other	Pfizer Limited	P/0158/2012	25/07/2012
Nonacog alfa	N/A	PM	Haematology-Hemostaseology	Baxter Innovations GmbH	P/0159/2012	25/07/2012
7-[4-(4-Benzo[b]thiophen-4-ylpiperazin-1-yl)butoxy]quinolin-2(1H)-one (OPC-34712)	N/A	P	Psychiatry	Otsuka Frankfurt Research Institute GmbH	P/0160/2012	25/07/2012
Pneumococcal Polysaccharide Serotype 1 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 3	Prevenar 13	PM	Vaccines	Pfizer Ltd	P/0161/2012	20/07/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
– Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 4 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 5 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 6B – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 9V – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 14 – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 18C – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate, Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate						
Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 4 conjugated to protein D (derived from	Synflorix	PM	Vaccines	GlaxoSmithKline Biologicals S.A.	P/0162/2012	23/07/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 5 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 6B conjugated to protein D (derived from nontypeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 7F conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 9V conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 14 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 18C conjugated to tetanus toxoid / pneumococcal polysaccharide serotype 19F conjugated to diphtheria toxoid / pneumococcal polysaccharide serotype 23F conjugated to protein D (derived from non-typeable haemophilus influenzae)						

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
carrier protein						
Misoprostol	N/A	P	Endocrinology - Gynaecology- Fertility- Metabolism Other	Ferring pharmaceuticals A/S	P/0163/2012	23/07/2012
Eculizumab	Soliris	P	Immunology- Rheumatology - Transplantation	Voisin Consulting	P/0164/2012	23/07/2012
Asunaprevir	N/A	P	Infectious diseases	Bristol-Myers Squibb International Corporation	P/0165/2012	26/07/2012
Daclatasvir	N/A	P	Infectious diseases	Bristol-Myers Squibb International Corporation	P/0166/2012	26/07/2012
Peginterferon lambda-1a	N/A	P	Infectious diseases	Bristol-Myers Squibb International Corporation	P/0167/2012	26/07/2012
MAGE-A3 recombinant protein	N/A	P	Oncology	GlaxoSmithKline Biologicals	P/0168/2012	26/07/2012
Zoledronic acid	Aclasta	RPM	Endocrinology - Gynaecology- Fertility- Metabolism	Novartis Europharm Limited	P/0169/2012	27/07/2012
Romiplostim	Nplate	PM	Haematology- Hemostaseology	Amgen Europe B.V.,	P/0170/2012	27/07/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
Apremilast	N/A	PM	Immunology-Rheumatology-Transplantation	Celgene Europe Limited	P/0171/2012	27/07/2012
Human normal immunoglobulin	N/A	PM	Immunology-Rheumatology-Transplantation	Baxter Innovations GmbH	P/0172/2012	27/07/2012
Trivalent, seasonal, recombinant influenza hemagglutinin vaccine	N/A	P	Infectious Diseases Vaccines	Protein Sciences Europa	P/0173/2012	27/07/2012
Migalastat (hydrochloride)	N/A	P	Endocrinology-Gynaecology-Fertility-Metabolism	Glaxo Group Limited	P/0174/2012	27/07/2012
Tafluprost / timolol	N/A	W	Ophthalmology	Santen Oy	P/0175/2012	27/07/2012
Emtricitabine / rilpivirine (hydrochloride) / tenofovir (disoproxil fumarate) [FTC/RPV/TDF]	Eviplera	PM	Infectious Diseases	Gilead Sciences International Limited	P/0176/2012	03/08/2012
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/0177/2012	17/08/2012
Catridecacog	N/A	PM	Haematology-Hemostaseology	Novo Nordisk A/S	P/0178/2012	20/08/2012
Tocilizumab	RoActemra	PM	Immunology-Rheumatology-	Roche Registration Limited	P/0179/2012	20/08/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
			Transplantation			
Autologous tumour-derived immunoglobulin idiotype coupled to keyhole limpet haemocyanin	N/A	W	Oncology	Biovest Europe Ltd.	P/0180/2012	20/08/2012
Rosuvastatin ezetimibe	N/A	W	Cardiovascular Diseases	EGIS Pharmaceuticals PLC	P/0181/2012	20/08/2012
Pegylated human interferon beta-1a	N/A	P	Neurology	Biogen Idec Ltd.	P/0182/2012	21/08/2012
Naloxegol	N/A	P	Gastroenterology-Hepatology	AstraZeneca AB	P/0183/2012	21/08/2012
Indacaterol (acetate) / mometasone (furoate)	N/A	P	Pneumology - Allergology	Novartis Europharm Limited	P/0184/2012	21/08/2012
Amikacin (sulfate)	N/A	PM	Infectious Diseases/Pneumology - Allergology	Insmed Incorporated	P/0185/2012	21/08/2012
Sitagliptin / atorvastatin	N/A	W	Endocrinology - Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme (Europe), Inc.	P/0186/2012	21/08/2012
[N-((2S,3R,3aS,3´R,4a´R,6S,6a´R,6b´S,7aR,12a´S,12b´S,Z)-3,6,11´,12b´-tetramethyl-2´,3a,3´,4,4´,4a´,5,5´,6,6´,6a´,6b´,7,7a,7´,8´,10´,12´,12a´,12b´-icosahydro-1´H,3Hspiro[furo[3,2-b]pyridine-2,9´-naphtho[2,1-a]azulene]-3´-yl)methanesulfonamide hydrochloride]	N/A	W	Oncology	Voisin Consulting	P/0187/2012	21/08/2012
Amlodipine (besilate) / lisinopril (dihydrate) / rosuvastatin (calcium)	N/A	W	Cardiovascular Diseases	Gedeon Richter Plc.	P/0188/2012	21/08/2012
Olokizumab	N/A	P	Immunology-Rheumatology	UCB Pharma	P/0189/2012	22/08/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
			- Transplantation	S.A.		
Lubiprostone	N/A	PM	Gastroenterology- Hepatology/ Other	Sucampo Pharma Europe Ltd	P/0190/2012	24/08/2012
Pazopanib	Votrient	PM	Oncology	Glaxo Group Limited	P/0191/2012	24/08/2012
N-[6-(cis-2,6-Dimethylmorpholin-4-yl)pyridine-3-yl]-2-methyl-4'-(trifluoromethoxy) [1,1'-biphenyl]-3-carboxamide diphosphate (LDE225)	N/A	P	Oncology	Novartis Europharm Limited	P/0192/2012	24/08/2012
Human fibrinogen / human thrombin	Evicel	PM	Other	Omrix Biopharmaceuticals NV	P/0193/2012	24/08/2012
Pitolisant	N/A	P	Neurology	Bioprojet Pharma	P/0194/2012	24/08/2012
Co-crystal of tramadol (hydrochloride) / celecoxib	N/A	W	Pain	Laboratorios del Dr. Esteve S.A.	P/0195/2012	24/08/2012
Fibrinogen (human plasma-derived)	N/A	PM	Haematology-Hemostaseology	LFB Biotechnologies	P/0196/2012	24/08/2012
Human Normal Immunoglobulin	N/A	PM	Immunology-Rheumatology - Transplantation	LFB Biotechnologies	P/0197/2012	24/08/2012
Apremilast	N/A	P	Dermatology	Celgene Europe Limited	P/0198/2012	24/08/2012
Ex-vivo expanded human autologous epithelium containing stem cells	N/A	P	Ophthalmology	Chiesi Farmaceutici S.p.A.	P/0199/2012	24/08/2012
Human Fibrinogen	N/A	P	Haematology-Hemostaseology	Octapharma GmbH	P/0200/2012	24/08/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
Recombinant human antibody against activin type IIB receptors	N/A	W	Neurology	Novartis Europharm Limited	P/0201/2012	24/08/2012
Ataluren	N/A	PM	Neurology	PTC Therapeutics Limited	P/0202/2012	30/08/2012
Split influenza virus, inactivated containing antigens equivalent to the B-like strain (B/Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (B/Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain	N/A	P	Vaccines	Sanofi Pasteur SA Sanofi Pasteur MSD	P/0203/2012	31/08/2012
Dasatinib	Sprycel	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	P/0204/2012	03/09/2012
Etravirine	Intelence	PM	Infectious Diseases	Janssen-Cilag International N.V.	P/0205/2012	07/09/2012
Oseltamivir (phosphate)	Tamiflu	PM	Infectious Diseases	Roche Registration Ltd	P/0206/2012	17/09/2012
Dapagliflozin	N/A	PM	Endocrinology - Gynaecology-Fertility-Metabolism	Bristol Myers Squibb /AstraZeneca EEIG	P/0207/2012	21/09/2012
Certolizumab pegol	Cimzia	P	Immunology-Rheumatology - Transplantatio	UCB Pharma SA	P/0208/2012	27/09/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
			n			
Ceftobiprole medocaril (sodium)	N/A	P	Infectious Diseases	Basilea Pharmaceutica International Ltd.	P/0209/2012	27/09/2012
Influenza virus surface antigens (haemagglutinin (HA) and neuraminidase) A/California/7/2009 (H1N1) – like strain used A/Brisbane/10/2010, A/Perth/16/2009 (H3N2) - like strain used NYMC X-187 derived from A/Victoria/210/2009, B/Brisbane/60/2008	Optaflu	PM	Vaccines	Novartis Vaccines and Diagnostics BV	P/0210/2012	28/09/2012
Denosumab	Xgeva (previously Amgiva) Prolia	PM	Endocrinology - Gynaecology-Fertility-Metabolism Immunology-Rheumatology - Transplantation Oncology	Amgen Europe B.V.	P/0211/2012	28/09/2012
Ceftobiprole medocaril sodium	N/A	PM	Infectious Diseases	Basilea Pharmaceutica International Ltd.	P/0212/2012	28/09/2012
Lapatinib (ditosylate monohydrate)	Tyverb	W	Oncology	Glaxo Group Ltd	P/0213/2012	28/09/2012
Human Cell Line recombinant human Factor VIII (human-cl rhFVIII) / Human Coagulation Factor VIII (rDNA)	N/A	PM	Haematology-Hemostaseology	Octapharma Pharmazeutika Produktionsges.m.b.H	P/0214/2012	28/09/2012
Recombinant single chain coagulation factor VIII	N/A	P	Haematology-Hemostaseology	CSL Behring GmbH	P/0215/2012	28/09/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
Pegylated B-domain-deleted sequence-modified recombinant human factor VIII	N/A	P	Haematology-Hemostaseology	Bayer Pharma AG	P/0216/2012	28/09/2012
Icosapent ethyl	N/A	W	Cardiovascular Diseases	Amarin Pharmaceuticals Ireland Limited	P/0217/2012	28/09/2012
Tapentadol (hydrochloride)	Palexia Yantil	PM	Pain	Grünenthal GmbH	P/0218/2012	28/09/2012
Tapentadol (hydrochloride)	Palexia Yantil	PM	Pain	Grünenthal GmbH	P/0219/2012	28/09/2012
Tapentadol (hydrochloride)	Palexia Yantil	PM	Pain	Grünenthal GmbH	P/0220/2012	28/09/2012
Chloroprocaine (hydrochloride)	N/A	PM	Anaesthesiology	Sintetica Italia S.r.l.	P/0221/2012	01/10/2012
Ioforminol	N/A	P	Diagnostic	GE Healthcare	P/0222/2012	01/10/2012
Rosuvastatin / acetylsalicylic acid	N/A	W	Cardiovascular Diseases	EGIS Pharmaceuticals PLC	P/0223/2012	01/10/2012
Azilsartan medoxomil / chlortalidone	N/A	W	Cardiovascular Diseases	Takeda Global Research and Development Centre (Europe) Limited	P/0224/2012	01/10/2012
Retigabine	Trobalt	PM	Neurology	Glaxo Group Limited	P/0225/2012	03/10/2012
Ustekinumab	Stelara	PM	Dermatology Immunology-Rheumatology - Transplantation	Janssen-Cilag International NV	P/0226/2012	03/10/2012
Glycopegylated recombinant coagulation factor VIII	N/A	P	Haematology-Hemostaseology	Novo Nordisk A/S	P/0227/2012	03/10/2012
Dabigatran etexilate	Pradaxa	PM	Cardiovascular Diseases	Boehringer Ingelheim	P/0228/2012	01/10/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
			Haematology-Hemostaseology	International GmbH		
Bitopertin	N/A	P	Psychiatry	Roche Registration Limited	P/0229/2012	04/10/2012
Pitavastatin (calcium)	Livazo and associated names	PM	Endocrinology - Gynaecology-Fertility-Metabolism	Kowa Pharmaceutical Europe Company Ltd	P/0230/2012	05/10/2012
Pitavastatin (calcium)	Alipza and associated names	PM	Endocrinology - Gynaecology-Fertility-Metabolism	Kowa Pharmaceutical Europe Company Ltd	P/0231/2012	05/10/2012
Pitavastatin (calcium)	Vezepra and associated names	PM	Endocrinology - Gynaecology-Fertility-Metabolism	Kowa Pharmaceutical Europe Company Ltd	P/0232/2012	05/10/2012
Pitavastatin (calcium)	Pitavastatin and associated names	PM	Endocrinology - Gynaecology-Fertility-Metabolism	Kowa Pharmaceutical Europe Company Ltd	P/0233/2012	05/10/2012
Influenza Virus Type A, H1N1 / Influenza Virus Type A, H3N2 / Influenza Virus Type B, Yamagata lineage / Influenza Virus Type B, Victoria lineage	N/A	PM	Vaccines	MedImmune Limited	P/0234/2012	12/10/2012
Bevacizumab	Avastin	PM	Oncology	Roche Registration Ltd.	P/0235/2012	22/10/2012
Telbivudine	Sebivo	PM	Gastroenterology-Hepatology	Novartis Europharma Limited	P/0236/2012	22/10/2012
Human heterologous liver	N/A	P	Gastroenterol	Cytonet	P/0237/201	22/10/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
cells			ogy-Hepatology	GmbH&Co. KG	2	
Ciclosporin	N/A	PM	Ophthalmology	Novagali Pharma S.A.S	P/0238/2012	22/10/2012
Cobicistat	N/A	PM	Infectious Diseases	Gilead Sciences International Limited	P/0239/2012	22/10/2012
Recombinant human N-acetylgalactosamine-6-sulfatase	N/A	PM	Endocrinology - Gynaecology-Fertility-Metabolism	BioMarin Europe Limited	P/0240/2012	22/10/2012
Delamanid	N/A	PM	Infectious Diseases	Otsuka Frankfurt Research Institute GmbH	P/0241/2012	22/10/2012
Fostamatinib	N/A	W	Immunology-Rheumatology - Transplantation	Astrazeneca AB	P/0242/2012	22/10/2012
Dermatophagoides pteronyssinus I dermatophagoides farinae	N/A	P	Oto-rhino-laryngology Pneumology - Allergology	ALK-Abell6 A/S	P/0243/2012	22/10/2012
Dexketoprofen (trometamol) / tramadol (hydrochloride)	N/A	W	Pain	Menarini Ricerche SpA	P/0244/2012	22/10/2012
Amlodipine (besylate) / candesartan (cilexetil)	N/A	W	Cardiovascular Diseases	Zentiva k.s.	P/0245/2012	22/10/2012
Perindopril (tosilate) / amlodipine (besilate)	N/A	W	Cardiovascular Diseases	Teva Pharma B.V.	P/0246/2012	22/10/2012
Atorvastatin / ramipril / acetyl salicylic acid	N/A	W	Cardiovascular Diseases	Ferrer Internacional, S.A.	P/0247/2012	22/10/2012
Folic acid	N/A	W	Diagnostic Oncology	Endocyte Europe B.V.	P/0248/2012	23/10/2012
Etarfolatide	N/A	W	Diagnostic	Endocyte	P/0249/201	23/10/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
			Oncology	Europe B.V.	2	
Tazarotene	N/A	PM	Dermatology	Orfagen	P/0250/2012	24/10/2012
Peginesatide	N/A	PM	Haematology-Hemostaseology	Takeda Global Research & Development Centre (Europe) Ltd	P/0251/2012	24/10/2012
Natalizumab	Tysabri	P	Neurology	Elan Pharma International Limited	P/0252/2012	19/10/2012
Spheroids of human autologous matrix-associated chondrocytes	N/A	P	Other	co.don AG	P/0253/2012	30/11/2012
Riociguat	N/A	PM	Cardiovascular Diseases	Bayer Schering Pharma AG	P/0254/2012	22/10/2012
Ticagrelor	Brilique Possia	PM	Cardiovascular Diseases	Astrazeneca AB	P/0255/2012	26/10/2012
Aripiprazole	Abilify	PM	Psychiatry	Otsuka Pharmaceutical Europe Ltd.	P/0256/2012	26/10/2012
Tofacitinib (citrate)	N/A	P	Dermatology Immunology-Rheumatology - Transplantation	Pfizer Limited	P/0257/2012	26/10/2012
Regorafenib	N/A	P	Oncology	Bayer Pharma AG	P/0258/2012	31/10/2012
Adalimumab	Humira	PM	Dermatology/ Gastroenterology-Hepatology/	Abbott Laboratories Ltd	P/0259/2012	19/11/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
			Immunology-Rheumatology-Transplantation			
Alpha1-proteinase inhibitor	N/A	W	Other/ Pneumology - Allergology	CSL Behring GmbH	P/0260/2012	19/11/2012
N-tert-butyl-3-[(5-methyl-2-{[4-(2-pyrrolidin-1-ylethoxy)phenyl]amino}pyrimidin-4-yl)amino]benzenesulfonamide dihydrochloride monohydrate (SAR302503A)	N/A	W	Oncology	sanofi-aventis R&D	P/0261/2012	19/11/2012
Nicotinic acid / laropiprant	Tredaptive	PM	Cardiovascular Diseases	Merck Sharp & Dohme Ltd.	P/0262/2012	20/11/2012
Methoxy polyethylene glycol - epoetin beta	Mircera	PM	Haematology-Hemostaseology	Roche Registration Limited	P/0263/2012	20/11/2012
Methoxyflurane	N/A	PM	Pain	Orion Clinical Services	P/0264/2012	20/11/2012
Levofloxacin (hemihydrate)	N/A	P	Pneumology - Allergology	Mpex London Limited	P/0265/2012	20/11/2012
(2R,3S,5R)-2-(2,5-Difluorophenyl)-5-[2,6-dihydro-2-(methylsulfonyl)pyrrolo[3,4-c]pyrazol-5(4H)-yl]tetrahydro-2H-pyran-3-amine (MK-3102)	N/A	P	Endocrinology - Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme (Europe), Inc.	P/0266/2012	20/11/2012
Travoprost	Travatan	P	Ophthalmology	Alcon Laboratories (UK) Ltd.	P/0267/2012	20/11/2012
Lopinavir / ritonavir / lamivudine	N/A	W	Infectious Diseases	Abbott Laboratories Limited	P/0268/2012	20/11/2012
Perindopril / indapamide /	N/A	W	Cardiovascula	Krka, d.d.,	P/0269/201	20/11/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
amlodipine			r Diseases	Novo mesto	2	
Amlodipine (besylate) / valsartan	N/A	W	Cardiovascular Diseases	Zentiva, k.s.	P/0270/2012	20/11/2012
Ezetimibe / rosuvastatin	N/A	W	Cardiovascular Diseases/ Endocrinology - Gynaecology- Fertility- Metabolism	Zentiva, k.s.	P/0271/2012	20/11/2012
Fingolimod (hydrochloride)	Gilenya	PM	Neurology	Novartis Europharm Limited	P/0272/2012	21/11/2012
Azilsartan medoxomil	Edarbi Ipreziv	PM	Cardiovascular Diseases	Takeda Global Research and Development Centre (Europe) Ltd	P/0273/2012	21/11/2012
Nilotinib	Tasigna	PM	Oncology	Novartis Europharm Ltd	P/0274/2012	21/11/2012
Human normal immunoglobulin	N/A	PM	Haematology- Hemostaseology/ Immunology- Rheumatology - Transplantation	Kedrion S.p.A.	P/0275/2012	21/11/2012
Simeprevir	N/A	PM	Infectious Diseases	Janssen Infectious Diseases BVBA	P/0276/2012	21/11/2012
Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal	Synflorix	PM	Vaccines	GlaxoSmithKline Biologicals S.A.	P/0277/2012	21/11/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
polysaccharide serotype 4 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 5 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 6B conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 7F conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 9V conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 14 conjugated to protein D (derived from non-typeable haemophilus influenzae) carrier protein / pneumococcal polysaccharide serotype 18C conjugated to tetanus toxoid / pneumococcal polysaccharide serotype 19F conjugated to diphtheria toxoid / pneumococcal polysaccharide serotype 23F conjugated to protein						

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
D (derived from non-typeable haemophilus influenzae) carrier protein						
Brentuximab vedotin	N/A	PM	Oncology	Takeda Global Research and Development Centre (Europe) Ltd	P/0278/2012	21/11/2012
Lebrikizumab	N/A	PM	Pneumology - Allergology	Roche Products Limited	P/0279/2012	21/11/2012
Tazobactam / ceftolozane	N/A	P	Infectious Diseases	Cubist Pharmaceuticals, Inc.	P/0280/2012	21/11/2012
Brimonidine tartrate	N/A	W	Dermatology	Galderma International	P/0281/2012	21/11/2012
Icatibant	Firazyr	W	Other	Shire Orphan Therapies GmbH	P/0282/2012	23/11/2012
Bosentan	Tracleer	PM	Cardiovascular Diseases/ Immunology-Rheumatology - Transplantation/ Pneumology - Allergology	Actelion Registration Ltd	P/0283/2012	23/11/2012
Eslicarbazepine (acetate)	Zebinix	PM	Neurology	BIAL - Portela & Ca, SA	P/0284/2012	23/11/2012
Artemether / lumefantrine	Riamet	PM	Infectious Diseases	Novartis Europharm Limited	P/0285/2012	23/11/2012
Ponesimod	N/A	P	Neurology	Actelion Registration Limited	P/0286/2012	23/11/2012
Dolutegravir / abacavir /	N/A	P	Infectious	ViiV	P/0287/201	23/11/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
lamivudine			Diseases	Healthcare UK Limited.	2	
Serelaxin	N/A	PM	Cardiovascular Diseases	Novartis Europharm Ltd.	P/0288/2012	26/11/2012
posaconazole	Noxafil	P	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	P/0289/2012	07/12/2012
cannabidiol / delta-9-tetrahydrocannabinol	Sativex	PM	Neurology	GW Pharma Ltd	P/0290/2012	18/12/2012
Treprostinil	Remodulin and associated names	PM	Cardiovascular Diseases	United Therapeutics Europe, Ltd.	P/0291/2012	18/12/2012
Ustekinumab	Stelara	PM	Immunology-Rheumatology-Transplantation	Janssen-Cilag International NV	P/0292/2012	18/12/2012
Prucalopride	Resolor	PM	Gastroenterology-Hepatology	Shire-Movetis NV	P/0293/2012	18/12/2012
(S)-Isopropyl 2-((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl)methoxy)(phenoxy)phosphorylamino)-Propanoate (GS-7977)	N/A	P	Infectious Diseases	Gilead Sciences International Ltd.	P/0294/2012	18/12/2012
Chimeric anti-disialoganglioside (GD2) monoclonal antibody (NSC764038)	N/A	P	Oncology	United Therapeutics Europe Limited	P/0295/2012	18/12/2012
Elagolix	N/A	W	Endocrinology-Gynaecology-Fertility-Metabolism	AbbVie Ltd	P/0296/2012	18/12/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
Elagolix	N/A	W	Endocrinology - Gynaecology- Fertility- Metabolism	AbbVie Ltd	P/0297/2012	18/12/2012
Ivermectin	N/A	W	Dermatology	GALDERMA R&D	P/0298/2012	18/12/2012
Skeletal muscle derived cells	N/A	W	Uro-nephrology	Innovacell Biotechnologie AG	P/0299/2012	18/12/2012
Ivacaftor	Kalydeco	PM	Other	Vertex Pharmaceuticals Incorporated	P/0300/2012	20/12/2012
Faldaprevir	N/A	P	Infectious Diseases	Boehringer Ingelheim International GmbH	P/0301/2012	20/12/2012
N-[6-(cis-2,6-Dimethylmorpholin-4-yl)pyridine-3-yl]-2-methyl-4'-(trifluoromethoxy) [1,1'-biphenyl]-3-carboxamide diphosphate (LDE225)	N/A	PM	Oncology	Novartis Europharm Limited	P/0302/2012	20/12/2012
Dextran, 3-[(2-aminoethyl)thio]propyl 17-carboxy-10,13,16-tris(carboxymethyl)-8-oxo-4-thia-7,10,13,16-tetraazaheptadec-1-yl 3-[[2-[[1-imino-2-(Dmannopyranosylthio) ethyl]amino]ethyl]thio]propyl ether	N/A	P	Diagnostic Oncology Other	Navidea Biopharmaceuticals Limited	P/0303/2012	20/12/2012
Outer Membrane Vesicles (OMV) from N. meningitidis Strain NZ 98/254 / recombinant Neisseria meningitis group B Protein 936-741 / meningococcal group W-135 oligosaccharides	N/A	P	Vaccines	Novartis Vaccines and Diagnostics S.r.l.	P/0304/2012	20/12/2012

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
conjugated to Corynebacterium diphtheriae CRM197 protein / meningococcal group A oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / recombinant Neisseria meningitis group B Protein 287-953 / recombinant Neisseria meningitis group B Protein 961c / meningococcal group Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein (MenABCWY)						
Human normal immunoglobulin (LFB-IgSC)	N/A	P	Immunology-Rheumatology-Transplantation	LFB Biotechnologies	P/0305/2012	20/12/2012
Eculizumab	Soliris	PM	Immunology-Rheumatology-Transplantation	Alexion Europe SAS	P/0306/2012	21/12/2013
Eltrombopag	Revolade	PM	Haematology-Hemostaseology	GlaxoSmithKline Trading Services Limited	P/0307/2012	21/12/2013
Linagliptin	Trajenta	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	P/0308/2012	21/12/2013
Empagliflozin	N/A	PM	Endocrinology	Boehringer	P/0309/201	21/12/2013

Product INN	Invented name – if available	Type of PDCO opinion [1]	Therapeutic area	Applicant	EMA decision number	Signature date
			- Gynaecology-Fertility-Metabolism	Ingelheim International GmbH	2	
Human dermal fibroblasts cultured on bioresorbable polyglactin mesh (ABH001)	N/A	P	Dermatology	TMC Pharma	P/0310/2012	21/12/2013
Expanded autologous bone marrow-derived osteoblastic cells	N/A	W	Other	Bone Therapeutics S.A.	P/0311/2012	21/12/2013
Sitagliptin	Januvia	PM	Endocrinology - Gynaecology-Fertility-Metabolism	Merck Sharp and Dohme (Europe), Inc.	P/0312/2012	21/12/2013
Fidaxomicin	Dificlir	PM	Infectious Diseases	Astellas Pharma Europe B.V.	P/0313/2012	21/12/2013

Annex 14 – Arbitration and Community referrals overview 2012 – human medicines

Referrals made to the CHMP

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
meprobamate	22/09/2011	19/01/2012	Article 107(2) of Directive 2001/83/EC
beclomethasone dipropionate/formoterol fumarate	13/12/2012	ongoing	Article 13 of Commission Regulation (EC) No 1234/2008
venoforton	15/03/2012	24/05/2012	Article 16c(1)(c) of Directive 2001/83/EC
aliskiren	15/12/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
aliskiren	15/12/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
aliskiren	15/12/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
aliskiren/amlodipine	15/12/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
aliskiren/amlodipine/ hydrochlorothiazide	15/12/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
aliskiren/hydrochlorothiazide	15/12/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
aliskiren/hydrochlorothiazide	15/12/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
aliskiren/hydrochlorothiazide	15/12/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
anidulafungin	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
azacitidine	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
aztreonam	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
bazedoxifene	19/07/2012	19/07/2012	Article 20 procedure of Regulation (EC) No 726/2004
bivalirudin	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
bortezomib	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
busulfan	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
capecitabine	15/12/2011	19/07/2012	Article 20 procedure of Regulation (EC) No 726/2004

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
cidofovir	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
doripenem	19/01/2012	21/06/2012	Article 20 procedure of Regulation (EC) No 726/2004
doxorubicin hydrochloride	17/11/2011	15/03/2012	Article 20 procedure of Regulation (EC) No 726/2004
eculizumab	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
fentanyl	19/07/2012	19/07/2012	Article 20 procedure of Regulation (EC) No 726/2004
fingolimod	19/01/2012	19/04/2012	Article 20 procedure of Regulation (EC) No 726/2004
histamine dihydrochloride	17/11/2011	15/03/2012	Article 20 procedure of Regulation (EC) No 726/2004
human fibrinogen/human thrombin	24/05/2012	15/11/2012	Article 20 procedure of Regulation (EC) No 726/2004
Japanese encephalitis vaccine (inactivated, adsorbed)	23/06/2011	15/03/2012	Article 20 procedure of Regulation (EC) No 726/2004
measles, mumps and rubella vaccine (live)	15/03/2012	13/12/2012	Article 20 procedure of Regulation (EC) No 726/2004
measles, mumps, rubella and varicella vaccine (live)	15/03/2012	13/12/2012	Article 20 procedure of Regulation (EC) No 726/2004
methoxy polyethylene glycol-epoetin beta	15/12/2011	19/07/2012	Article 20 procedure of Regulation (EC) No 726/2004
mifamurtide	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
orlistat	22/09/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
orlistat	22/09/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
orlistat	15/12/2011	19/07/2012	Article 20 procedure of Regulation (EC) No 726/2004
orlistat	15/12/2011	19/07/2012	Article 20 procedure of Regulation (EC) No 726/2004
oseltamivir	15/12/2011	19/07/2012	Article 20 procedure of Regulation (EC) No 726/2004
peginterferon alfa-2a	15/12/2011	19/07/2012	Article 20 procedure of Regulation (EC) No 726/2004
perflutren	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
ribavirin	19/07/2012	20/09/2012	Article 20 procedure of Regulation (EC) No 726/2004
ribavirin	19/07/2012	20/09/2012	Article 20 procedure of Regulation (EC) No 726/2004
rituximab	15/12/2011	24/05/2012	Article 20 procedure of Regulation (EC) No 726/2004

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
strontium ranelate	20/10/2011	15/03/2012	Article 20 procedure of Regulation (EC) No 726/2004
strontium ranelate	20/10/2011	15/03/2012	Article 20 procedure of Regulation (EC) No 726/2004
telavancin	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
temozolomide	19/07/2012	20/09/2012	Article 20 procedure of Regulation (EC) No 726/2004
temsirolimus	17/11/2011	16/02/2012	Article 20 procedure of Regulation (EC) No 726/2004
temsirolimus	19/07/2012	19/07/2012	Article 20 procedure of Regulation (EC) No 726/2004
tigecycline	19/07/2012	20/09/2012	Article 20 procedure of Regulation (EC) No 726/2004
zoster vaccine (live)	15/03/2012	13/12/2012	Article 20 procedure of Regulation (EC) No 726/2004
ethinylestradiol/drospirenone	15/03/2012	19/04/2012	Article 29(4) of Directive 2001/83/EC
fluticasone propionate/formoterol fumarate	19/01/2012	19/04/2012	Article 29(4) of Directive 2001/83/EC
fluticasone propionate/formoterol fumarate	19/01/2012	19/04/2012	Article 29(4) of Directive 2001/83/EC
furosemide	24/05/2012	18/10/2012	Article 29(4) of Directive 2001/83/EC
glimepiride	21/06/2012	19/07/2012	Article 29(4) of Directive 2001/83/EC
levothyroxine sodium	16/02/2012	18/10/2012	Article 29(4) of Directive 2001/83/EC
loratadine	19/01/2012	21/06/2012	Article 29(4) of Directive 2001/83/EC
mifepristone	15/03/2012	21/06/2012	Article 29(4) of Directive 2001/83/EC
mometasone furoate	15/03/2012	19/07/2012	Article 29(4) of Directive 2001/83/EC
ceftriaxone	16/02/2012	ongoing	Article 30 of Directive 2001/83/EC
cefuroxime axetil	22/04/2010	24/05/2012	Article 30 of Directive 2001/83/EC
cefuroxime sodium	22/04/2010	24/05/2012	Article 30 of Directive 2001/83/EC
epoprostenol	23/06/2011	24/05/2012	Article 30 of Directive 2001/83/EC
letrozole	23/09/2010	15/03/2012	Article 30 of Directive 2001/83/EC
levofloxacin	21/10/2010	24/05/2012	Article 30 of Directive 2001/83/EC

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
measles, mumps and rubella vaccine (live)	23/06/2011	15/03/2012	Article 30 of Directive 2001/83/EC
aprotinin/aminocaproic acid/tranexamic acid	18/03/2010	16/02/2012	Article 31 of Directive 2001/83/EC
calcitonin	29/01/2011	19/07/2012	Article 31 of Directive 2001/83/EC
cilazapril, leflunomide, fenofibrato	01/08/2012	20/09/2012 (4 opinions)	Article 31 of Directive 2001/83/EC
ergot derivatives	19/01/2012	ongoing	Article 31 of Directive 2001/83/EC
estradiol	21/06/2012	ongoing	Article 31 of Directive 2001/83/EC
human fibrinogen/human thrombin	24/05/2012	15/11/2012 13/12/2012	Article 31 of Directive 2001/83/EC
methysergide	24/05/2012	ongoing	Article 31 of Directive 2001/83/EC
orlistat	22/09/2011	16/02/2012	Article 31 of Directive 2001/83/EC
monovalent and multivalent measles, mumps, rubella and varicella vaccines (live)	15/03/2012	13/12/2012	Article 31 of Directive 2001/83/EC
tolperisone	21/07/2011	21/06/2012	Article 31 of Directive 2001/83/EC
trimetazidine	19/05/2011	21/06/2012	Article 31 of Directive 2001/83/EC
nicarpidine	19/07/2012	ongoing	Article 31 of Directive 2001/83/EC - non-PhVig
human normal immunoglobulin	17/03/2011	16/02/2012	Article 36 of Directive 2001/83/EC
influenza vaccine, purified antigen	15/12/2011	19/07/2012	Article 36 of Directive 2001/83/EC
human normal immunoglobulin	21/07/2011	15/03/2012	Article 5(3) procedure of Regulation (EC) No 726/2004
immunological differences of pandemic vaccines	18/10/2012	18/10/2012	Article 5(3) procedure of Regulation (EC) No 726/2004
isoniazid, rifampicin, pyrazinamide, ethambutol, rifabutin	23/06/2011	16/02/2012	Article 5(3) procedure of Regulation (EC) No 726/2004
non-selective non-steroidal anti-inflammatory drugs	20/10/2011	18/10/2012	Article 5(3) procedure of Regulation (EC) No 726/2004
protamine	20/09/2012	15/11/2012	Article 5(3) procedure of Regulation (EC) No 726/2004
ethinylestradiol/drospirenone	21/07/2011	19/04/2012	Article 6(12) of Commission Regulation (EC) No 1084/2003
ethinylestradiol/drospirenone	21/07/2011	19/04/2012	Article 6(12) of Commission Regulation (EC) No 1084/2003

Where not end date is given the procedure is still on-going.

Referrals made to the PRAC

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
codeine	03/10/2012	ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83 - PhVig
diclofenac	31/10/2012	ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83 - PhVig
terbutaline, salbutamol, hexoprenaline, ritodrine, fenoterol, isoxsuprine	29/11/2012	ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83 - PhVig
hydroxyethyl starch	29/11/2012	ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83 - PhVig
almitrine	29/11/2012	ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83 - PhVig
diacerein	29/11/2012	ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83 - PhVig

Where no end date is given the procedure is still on-going.

Annex 15 – Arbitration and Community referrals overview 2012 – veterinary medicines

Type of referral	• **Date of clock start** • **CVMP opinion**	• **Product name** • **INN**
Referral under Art. 34 of Directive 2001/82/EC	• 09/11/2010 • 13/06/2012	• Baytril 10% oral solution and associated names • Enrofloxacin
Referral under Art. 35 of Directive 2001/82/EC	• 09/03/2011 • 08/03/2012 • 13/06/2012 (re-examination)	• Veterinary medicinal products containing active substances belonging to the class of flukicides for which no MRL has been established in milk and which are intended for use in ruminants producing milk for human consumption
Referral under Art. 33(4) of Directive 2001/82/EC	• 04/05/2011 • 08/02/2012	• Prontax 5 mg/ml pour-on solution for cattle • Doramectin
Referral under Art. 33(4) of Directive 2001/82/EC	• 04/05/2011 • 08/02/2012	• Prontax 10 mg/ml solution for injection for sheep, cattle and pigs • Doramectin
Referral under Art. 35 of Directive 2001/82/EC	• 04/05/2011 • 08/03/2012	• All pre-mixes for medicated feedingstuffs containing 40, 100 or 200 g tilmicosin per kg pre-mix • Tilmicosin
Referral under Art. 34 of Directive 2001/82/EC	• 14/09/2011 • 08/03/2012	• Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus and Prazitel Plus and associated names • Praziquantel, pyrantel and febantel
Referral under Art. 35 of Directive 2001/82/EC	• 15/09/2011	• All long acting formulations for injection containing barium selenate for all food producing species • Barium selenate
Procedure under Art. 30(3) of Regulation (EC) No 726/2004	• 15/09/2011 • 11/07/2012	• N/a • Dapsone

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
Referral under Article 33(4) of Directive 2001/82/EC	• 12/10/2011 • 13/06/2012	• Nuflor 300 mg/ml solution for injection for cattle and sheep • Florfenicol
Referral under Article 35 of Directive 2001/82/EC	• 12/10/2011 • 13/04/2012	• Hipralona Enro-S and its generics • Enrofloxacin
Referral under Article 33(4) of Directive 2001/82/EC	• 10/01/2012 • 13/06/2012	• Nuflor Swine Once 450 mg/ml solution for injection • Florfenicol
Referral under Article 35 of Directive 2001/82/EC	• 12/04/2012	• All injectable and pour-on veterinary medicinal products containing doramectin that are intended for use in mammalian foodproducing species • Doramectin
Referral under Art. 34 of Directive 2001/82/EC	• 15/05/2012	• Micotil 300 Injectie and associated names • Tilmicosin
Referral under Article 33(4) of Directive 2001/82/EC	• 15/05/2012	• Florgane 300 mg/ml suspension for injection for cattle and pigs • Florfenicol
Referral under Article 33(4) of Directive 2001/82/EC	• 11/07/2012 • 08/11/2012	• Melosolute 40 mg/ml solution for injection for cattle, pigs and horses • Meloxicam
Referral under Article 33(4) of Directive 2001/82/EC	• 11/07/2012	• 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	• 12/09/2012	• 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	• 12/09/2012	• Dexadreson 2 mg/ml and associated names, and generic products thereof, including pending applications • Dexamethasone

Type of referral	• Date of clock start • CVMP opinion	• Product name • INN
Referral under Article 34 of Directive 2001/82/EC	• 10/10/2012	• Linco-Spectin 100 and its associated names • Lincomycin, spectinomycin
Referral under Article 34 of Directive 2001/82/EC	• 07/11/2012	• 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	• 07/11/2012	• 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	• 07/11/2012	• Soludox 500 mg/g powder for use in drinking water for pigs and chickens • Doxycycline hyclate

Annex 16 – Budget summaries 2011–2012

The summarised comparative budget statements for 2011 and 2012 are as follows:

		2011 (final)[3]		2012 (budget)[2]		2012 (final)[3]	
		€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
	Revenue						
1+5	Fees and charges	159,634	*80.1%*	181,905	*81.8%*	182,912	*81.8%*
200	General EU contribution	28,042	*14.1%*	21,466	*9.6%*	21,466	*9.6%*
200	Surplus of previous year	5,477	*2.7%*	9,875	*4.4%*	9,875	*4.4%*
201	Special EU contribution for orphan medicinal products	4,720	*2.4%*	7,500	*3.4%*	7,491	*3.4%*
300	Contribution from EEA	784	*0.4%*	753	*0.3%*	753	*0.3%*
600	Community programmes	389	*0.2%*	640	*0.3%*	128	*0.1%*
5+9	Other	301	*0.2%*	350	*0.2%*	902	*0.4%*
	TOTAL REVENUE	**199,346**	*100.0%*	**222,489**	*100.0%*	**223,527**	*100.0%*
	Expenditure						
	Staff						
11	Staff in active employment	66,845	*33.1%*	71,009	*31.9%*	69,457	*31.7%*
13	Mission expenses	502	*0.2%*	745	*0.3%*	575	*0.3%*
14	Socio-medical infrastructure	572	*0.3%*	597	*0.3%*	557	*0.3%*
15	Exchange of civil servants and experts	2,274	*1.1%*	2,405	*1.1%*	2,293	*1.0%*
16	Social welfare	205	*0.1%*	255	*0.1%*	236	*0.1%*
17	Representation expenses	22	*0.0%*	30	*0.0%*	15	*0.0%*
18	Staff insurances	2,120	*1.0%*	2,253	*1.0%*	2,118	*1.0%*
	Total Title 1	**72,539**	*35.9%*	**77,294**	*34.7%*	**75,251**	*34.4%*
	Building / equipment						
20	Investment in immovable property, renting of building and associated costs	20,069	*9.9%*	21,491	*9.7%*	21,066	*9.6%*
21	Expenditure on corporate data processing	8,659	*4.3%*	7,536	*3.4%*	7,108	*3.2%*
22	Movable property [..]	1,474	*0.7%*	1,480	*0.7%*	1,351	*0.6%*
23	Other administrative expenditure	826	*0.4%*	858	*0.4%*	785	*0.4%*
24	Postage and communications	499	*0.2%*	478	*0.2%*	401	*0.2%*
25	Expenditure on other meetings	87	*0.0%*	122	*0.1%*	105	*0.0%*
	Total Title 2	**31,613**	*15.6%*	**31,965**	*14.4%*	**30,817**	*14.1%*
	Operational expenditure						
300	Meetings	7,431	*3.7%*	6,766	*3.0%*	6,759	*3.1%*
301	Evaluation of medicines	69,461	*34.4%*	82,181	*36.9%*	82,146	*37.5%*
302	Translations	3,912	*1.9%*	4,067	*1.8%*	3,958	*1.8%*
303	Studies and consultants	76	*0.0%*	2,064	*0.9%*	2,044	*0.9%*
304	Publications	99	*0.0%*	101	*0.0%*	76	*0.0%*
305	Community programmes	444	*0.2%*	308	*0.1%*	298	*0.1%*
31	Expenditure on business related ICT projects	16,491	*8.2%*	17,743	*8.0%*	17,662	*8.1%*
	Total Title 3	**97,912**	*48.5%*	**113,230**	*50.9%*	**112,945**	*51.6%*
	TOTAL EXPENDITURE	**202,063**	*100.0%*	**222,489**	*100.0%*	**219,013**	*100.0%*

[1] Financial Year 2011: as per final accounts

[2] Financial Year 2012: as per final budget

[3] Financial Year 2012: as per provisional accounts

Annex 17 – Establishment plan

Category and grade	TEMPORARY POSTS					
	POSTS 2012				POSTS 2013	
	Authorised		Actual as per 31.12.2012		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	1	-	1	-	0
AD 15	-	4	-	4	-	4
AD 14	-	6	-	6	-	6
AD 13	-	7	-	7	-	8
AD 12	-	38	-	38	-	38
AD 11	-	38	-	36	-	38
AD 10	-	34	-	33	-	36
AD 9	-	39	-	37	-	40
AD 8	-	47	-	44	-	47
AD 7	-	45	-	44	-	45
AD 6	-	37	-	37	-	42
AD 5	-	33	-	33	-	42
Total AD	**0**	**329**	**0**	**320**	**0**	**346**
AST 11	-	2	-	2	-	2
AST 10	-	5	-	4	-	5
AST 9	-	7	-	7	-	7
AST 8	-	13	-	13	-	13
AST 7	-	20	-	20	-	20
AST 6	-	33	-	33	-	33
AST 5	-	35	-	35	-	35
AST 4	-	51	-	50	-	51
AST 3	-	37	-	35	-	39
AST 2	-	40	-	38	-	40
AST 1	-	18	-	18	-	20
Total AST	**0**	**261**	**0**	**255**	**0**	**265**
Grand Total	**0**	**590**	**0**	**575**	**0**	**611**

Other staff	Planned (FTE[1]) 2012	Actual (FTE) 2012	Actual as per 31.12.2012	Planned (FTE) 2013
CONTRACT AGENTS	**132**	**116**	**106**	**125**
NATIONAL EXPERTS	**15**	**15**	**16**	**15**

[1] FTE=Full Time Equivalent

Annex 18 – Annual report from the SME Office

The 2012 report from the SME Office can be found via the following link:

http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2013/02/WC500138925.pdf

Annex 19 – Requests for access to documents

Requests received and pages released

Year	Number of requests received	Number of pages released
2010	114	7,090
2011	191	1,019,187
2012	281	685,489

Decisions on access in 2012

Access given	2012
Yes	49
Partial	137
No	82
Pending	3
Void	10
Total	281

Appeals in 2012

Appeals	2012
Total	6
Final refusal	5
Release	1

Affiliation (per new request in 2012)

Affiliation	Number of requests received	In %	Number of pages released	In %
Not-for-profit organisation	1	0.36	11,097	1.62
EU Institution (EC etc)	2	0.71	0	0.00
Regulator outside EU	5	1.78	196	0.03
EU NCA	5	1.78	704	0.10
Patients organisation	4	1.42	5,095	0.74
Healthcare professional	11	3.91	5,551	0.81
Consultant	27	9.61	37,514	5.47
General public	23	8.19	58,884	8.59
Academia/Research institute	24	8.54	101,604	14.82
Legal	40	14.23	160,640	23.43
Media	47	16.73	100,171	14.61
Pharmaceutical industry	91	32.38	204,031	29.76
Other	1	0.36	2	0.00
Total	281	100	685,489	100

Annex 20 – Publications by Agency staff members and experts in 2012

Bahri P, Harrison-Woolrych M.
Focussing on risk communication about medicines - Why now?
Drug Saf. 2012 Nov 1; 35(11):971-5

Bahri P, Harrison-Woolrych M.
How to Improve Communication for the Safe Use of Medicines? Discussions on Social Marketing and Patient-Tailored Approaches at the Annual Meetings of the WHO Programme for International Drug Monitoring
Drug Saf. 2012 Dec 1; 35(12):1073-9

Blake KV, Devries CS, Arlett P, Kurz X, Fitt H; for the European Network of Centres for Pharmacoepidemiology Pharmacovigilance.
Increasing scientific standards, independence and transparency in post-authorisation studies: the role of the European Network of Centres for Pharmacovigilance and Pharmacoepidemiology.
Pharmacoepidemiol Drug Saf. 2012 Jul; 21(7):690-696

Blake KV, Moore N, Kurz X, ENCePP
Making available observational study protocols and results: the role of ENCePP Circulation: Cardiovascular Quality and Outcomes.
Reply to: 2012; 5:4 418-419, CIRCOUTCOMES

Butlen-Ducuing F, Haas M, Pani L, Zwieten-Boot B, Broich K.
DSM-5 and Clinical Trials in Psychopharmacology: Progress or Step Backwards?
Nat Rev Drug Discov. 2012 Aug; 11(8):583-4

Calderon MA, Gerth van Wijk R, Eichler I, Matricardi PM, Varga EM, Kopp MV, Eng P, Niggemann B, Nieto A, Valovirta E, Eigenmann PA, Pajno G, Bufe A, Halken S, Beyer K, Wahn U.
Perspectives on allergen-specific immunotherapy in childhood: an EAACI position statement.
Pediatr Allergy Immunol. 2012 Jun;23(4):300-6

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Drug policy for an aging population--the European Medicines Agency's geriatric medicines strategy
N Engl J Med. 2012 Nov 22; 367(21):1972-4

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Biomarkers of sarcopenia in clinical trials-recommendations from the International Working Group on Sarcopenia.
Cachexia Sarcopenia Muscle. 2012 Sep; 3(3):181-90

Eichler HG, Abadie E, Baker M, Rasi G.
Fifty years after thalidomide; what role for drug regulators?
Br J Clin Pharmacol. 2012 Nov; 74(5):731-3

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Open Clinical Trial Data for all? A view from regulators
PLoS Med. 2012 Apr; 9(4)

Eichler HG, Oye K, Baird LG, Abadie E, Brown J, L Drum C, Ferguson J, Garner S, Honig P, Hukkelhoven M, Lim JC, Lim R, Lumpkin MM, Neil G, O'Rourke B, Pezalla E, Shoda D, Seyfert-Margolis V, Sigal EV, Sobotka J, Tan D, Unger TF, Hirsch G.
Adaptive Licensing: Taking the Next Step in the Evolution of Drug Approval
Clin Pharmacol Ther. 2012 Mar;91(3):426-37

Galli MC.
Long-term follow-up of cancer patients treated with gene therapy medicinal products.
J Gene Med. 2012 Jun; 14(6):440-2

Gaydos B, Koch A, Miller F, Posch M, Vandemeulebroecke M, Wang SJ.
Perspective on Adaptive Designs: 4 years European Medicines Agency Reflection Paper, 1 year draft US FDA Guidance – where are we now?
Clin. Invest. (2012) 2(3), 235–240

Gispen-de Wied C, Stoyanova V, Yu Y, Isaac M, Pani L, de Andres-Trelles F.
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Vaccine. 2012 Nov 19; 30(49):7123-9

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The European Medicines Agency review of cabazitaxel (Jevtana) for the treatment of hormone refractory metastatic prostate cancer: Summary of the scientific assessment of the Committee for Medicinal Products for Human Use (CHMP)
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Clin Cancer Res. 2012 Sep 1; 18(17):4491-7

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Regulatory Rapporteur – Vol 9, No 6: 5-8, June 2012

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BMC Bioinformatics. 2012 May 6; 13:81

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Drug Saf 2012; 35 (4): 1-16

Annex 21 – Performance of the centralised procedure (human medicines)

Performance of the Agency's scientific procedures in 2012: medicinal products for human use

Executive summary

This annual report on the performance of the Agency's scientific procedures conveys descriptive statistics on initial marketing authorisation applications (MAAs) and extension of indication applications (hereafter referred to as extension applications) for authorised medicinal products with a Committee for Medicinal Products for Human Use (CHMP) outcome in 2012.

The main findings are the following:

- The total number of initial MAAs with an outcome in 2012 (77) decreased by 26% compared to 2011 (104). This is due to a decrease in multiple (8 vs 16 in 2011) and generic applications (14 vs 26 in 2011). On the contrary, the number of extension applications increased (61 vs 50 in 2011).
- In terms of eligibility for the centralised procedure for initial applications, there was a re-surge of applications for biotechnological products following a steady decrease since 2009.
- The number of stand-alone initial MAAs remained constant (49 vs 50 in 2011). On the other hand, stand-alone extension applications (i.e. excluding generic, hybrid and similar biological applications) increased (48 vs 43 in 2011). The success rate (percentage of positive CHMP opinions) among such initial applications remained high (76% vs 80% in 2011) as did the success rate of stand-alone extension applications (83% vs 84% in 2011). The success rate was slightly lower for orphan medicinal products (OMPs) (69% vs 67% in 2011) and even lower for applications from small and medium-sized enterprises (SMEs) (37% vs 50% in 2011).
- The proportion of stand-alone initial MAAs for which scientific advice was provided decreased to 69% (34 out of 49) compared to 76% in 2011 but remained above the rather stable 55-60% in 2008-2010. The success rate for applications for which scientific advice was given (79%) was higher compared to those without it (67%). Use of scientific advice for stand-alone extension applications (22% in 2012 vs 16% in 2011) was low in comparison with initial applications.
- The consultation of scientific advisory groups (SAG) or ad hoc expert groups for initial MAAs was 27% (13 out of 49 applications; vs 20-21% in 2010-2011). This remained low for extension applications (6% (3 applications) in 2012 vs 7% (3 applications) in 2011).
- New active substance (NAS) applications (stand-alone applications for substances never previously authorised in the EU) continued to increase with 39 applications in 2012 compared to 30 in 2011 and 22 in 2010. For these applications, the failure rate in 2012 (18%) was slightly lower than that reported in 2011 and 2010 (23% in both years).

Initial marketing authorisation applications

Introduction

This annual report covers initial MAAs with a CHMP outcome during 2012 (from 01/01/2012 until 31/12/2012). This is defined as a positive or negative CHMP opinion or withdrawal of a MAA in 2012, irrespective of the timing of the European Commission (EC) decision, if any, on the opinion. Only

outcomes normally foreseen in the evaluation procedure (i.e. initial opinion and re-examination opinion, if any) were counted. CHMP opinions, whether initial or after re-examination, that were subject to later revisions have not been considered. There were no applications with a CHMP outcome in 2012 which already had a CHMP outcome in previous years (e.g. due to re-examination in 2012 of the initial CHMP opinion reached at the end of 2011). The report does not cover applications for ancillary substances used in medical devices or plasma master file applications.

Two analyses have been conducted for initial MAAs. The first focuses on eligibility to the centralised procedure. For the purposes of this analysis, multiple applications (i.e. applications which rely on the same dossier of a 'parent' application) have been excluded and only the 'parent' application has been included in the analysis. Similarly, the so-called 'informed consent' applications have been excluded as they are considered multiple for the purposes of this report, in that they are entirely based on the dossier of a reference product. Multiple applications can only be submitted while the application of the parent is still ongoing whereas, after the granting of the MA of the parent/reference product, an informed consent application is the only possible legal route for 'multiple' applications. The data set for this analysis is referred to as the 'Eligibility Set'.

The second analysis focuses on the general success rate and that of specific subsets based on applications (i.e. OMPs, applications from SMEs and products for which scientific advice was given) and on procedural aspects (consultation of SAGs or ad hoc expert groups). This analysis has been conducted on the 'stand-alone' analysis set which excludes generic, hybrid and similar biological (biosimilar) applications. Stand-alone applications rely on their own data for the purposes of establishing the efficacy and safety of the medicinal product and do not rely on the dossier of other medicinal products towards this end. The second analysis is repeated on a further subset of applications which additionally excludes applications for active pharmaceutical substances which had already been authorised in at least one EU/EEA country, independently of the indication for which they were authorised and whether authorised through centralised, mutual recognition, decentralised or purely national procedures. This subset is referred to as the 'NAS Set' in this report[1].

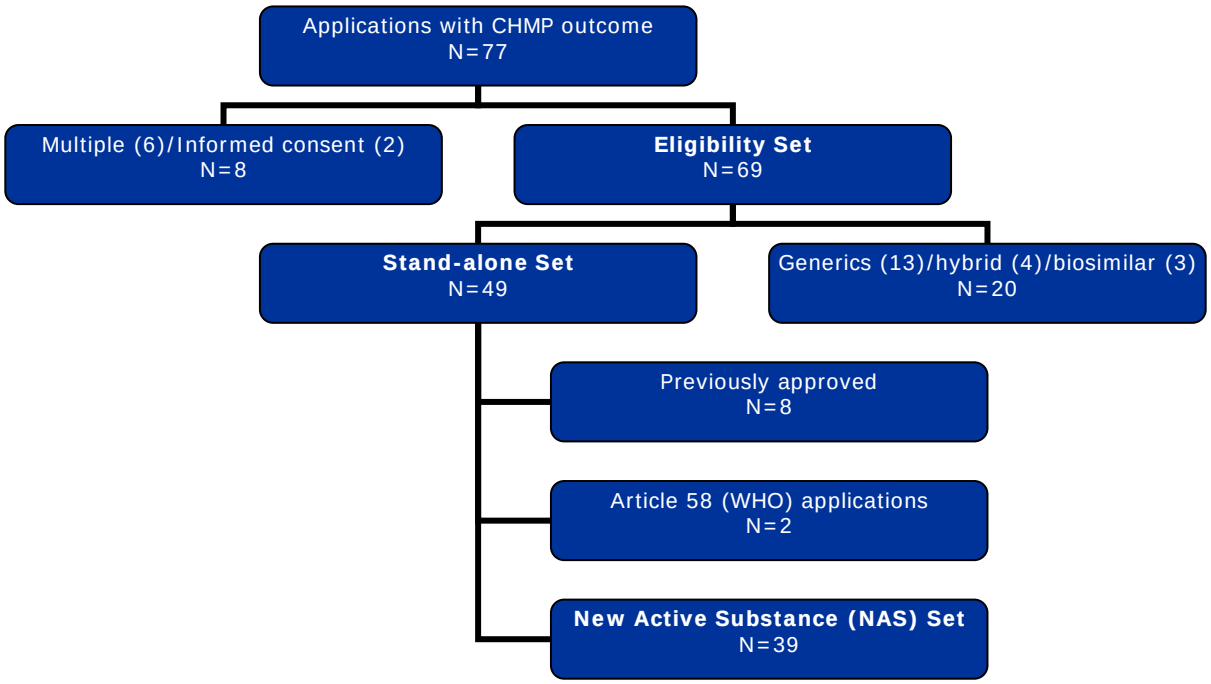
Analysis sets

In 2012, there was a total of 77 initial MAAs that reached an outcome in the CHMP scientific evaluation (see Figure 1) compared to 104 reported in 2011. By excluding 6 multiple and 2 informed consent applications, 69 applications were considered for the purposes of the analysis on the eligibility basis for the centralised procedure. By excluding 13 applications with a generic legal basis, 4 applications with a hybrid legal basis and 3 applications with a similar biological (biosimilar) legal basis, 49 stand-alone applications were considered for the other two analyses, i.e. the analysis of all (49) stand-alone applications and the analysis of applications including a NAS (39 out of 49 applications).

[1] The term "new active substance" is defined in EU pharmaceutical legislation to include novel molecules that are either chemically-synthesised or from a biological source, as follows:
- a chemical, biological or radiopharmaceutical substance not previously authorised as a medicinal product in the European Union;
- an isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously authorised as a medicinal product in the European Union but differing in properties with regard to safety and efficacy from that chemical substance previously authorised;
- a biological substance previously authorised as a medicinal product in the European Union, but differing in molecular structure, nature of the source material or manufacturing process;
- a radiopharmaceutical substance which is a radionuclide, or a ligand not previously authorised as a medicinal product in the European Union, or the coupling mechanism to link the molecule and the radionuclide has not been authorised previously in the European Union.
The definition of New Active Substance (NAS) used in this report further excludes biosimilar applications, as these were deemed not to be truly 'new' developments but rather similar to generic and hybrid applications. This modified definition of NAS is similar but not identical to the US FDA definitions of New Molecular Entity (NME) and New Biologic Entity (NBE). For more details, see Eichler H-G, *et al*. New drug approval success rate in Europe in 2009. Nat Rev Drug Discov. May;9(5):355-6 (2010).

The decrease in the overall number of application outcomes compared to 2011 (77 vs 104) was primarily due to the decrease in multiple and informed consent applications (10 multiple and 6 informed consent applications in 2011 compared with 8 multiple and 2 informed consent applications in 2012), as well as the decrease in generic applications (see discussion under Eligibility Set below).

Figure 1: Schematic representation of initial marketing authorisations with an outcome in 2012 and definition of analysis subsets (in bold)



Fourteen applications for orphan medicinal products reached an outcome in 2012. One of these (Loulla) was a hybrid application and 13 were stand-alone applications. The majority of these (12 out of 13) included a NAS (Adcetris, Dacogen, Folotyn, Inlyta, Istodax, Jakavi, Jenzyl, Kalydeco, Nexobrid, Novo Thirteen, Revestive and Signifir) and only one (Elelyso) included a previously authorised substance.

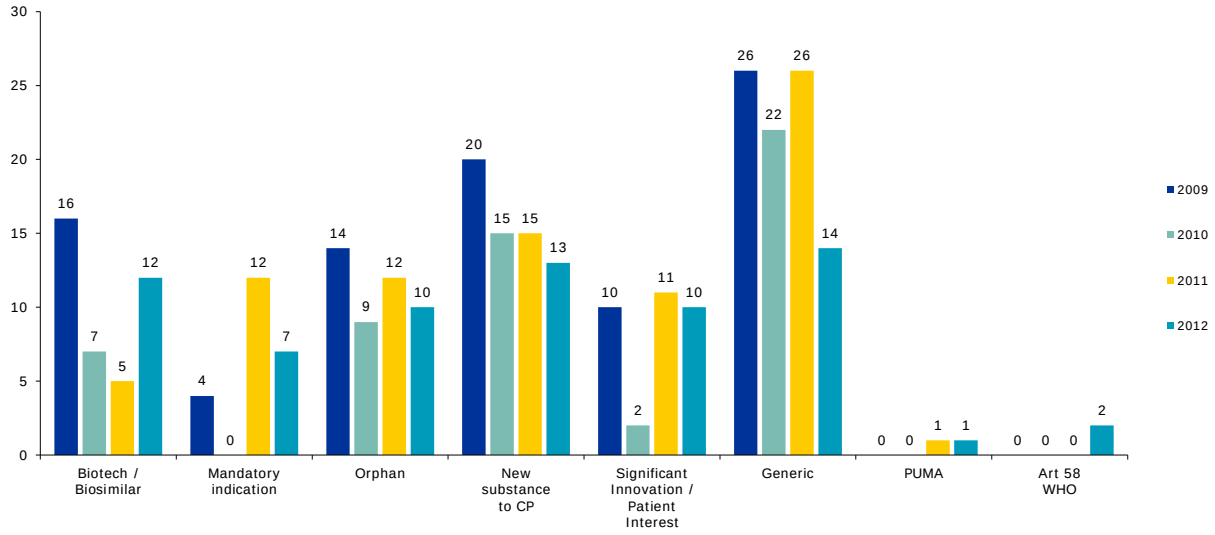
Twelve applications submitted by SMEs had an outcome in 2012. Three of these were biosimilar applications (Solumarv, Isomarv and Combimarv) and 1 was a hybrid application (Loulla). There were 8 stand-alone applications, 3 of which included previously authorised active substances (Adasuve, Qsiva and SecreFlo) and 5 included a NAS (Cuprymina, Egrifta, Fanaptum, Folotyn and Krystexxa).

There were no advanced therapy applications with an outcome in 2012 ("outcome" as defined in the introduction).

Eligibility to the centralised procedure: Eligibility Set (N=69)

Eligibility criteria for 69 applications with an outcome in 2012 are shown in Figure 2 alongside the data reported in 2011, 2010 and 2009. These include 49 stand-alone applications (compared to 50 in 2011) which correspond to 71% (49 out of 69) of applications in the eligibility set (compared to 61%, 50 out of 82, in 2011). Generic applications (13) and hybrid applications (4) decreased compared with 2011 (26 generics and 3 hybrids), while the number of biosimilar applications increased slightly (3 in 2012 vs 1 in 2011).

Figure 2: Eligibility criteria for initial marketing authorisation applications (Eligibility Set)



The products considered eligible for the centralised procedure in 2012 are listed by category below:

- Biotechnological (12): Bexsero, Combimarv (biosimilar), Elelyso, Eylea, Isomarv (biosimilar), Krystexxa, Nono Thirteen, Perjeta, Ryzodeg, Solumarv (biosimilar), Tresiba, and Zaltrap;
- Mandatory indication (7): Forxiga, Inlyta, Jentadueto, Jenzyl, Lyxumia, Pixuvri, and Xalkori;
- OMPs (10): Adcetris, Dacogen, Folotyn, Istodax, Jakavi, Kalydeco, Loulla, Nexobrid, Revestive, and Signifor;
- New substance to centralised procedure[2] (13): BindRen, Constella, Cuprymina, Egrifta, Eklira Genuair, Fanaptum, Fycompa, Kynamro, Mulsevo, Nimenrix, Picato, SecreFlo, and Zinforo;
- Significant innovation / patient interest (10): Acrescent, Adasuve, AMYVid, Betmiga, Megestrol Acetate, Qsiva, Rienso, Sancuso, Seebri Breezhaler, and Selincro;
- Generic (14): Capecitabine Accord, Capecitabine medac, Capecitabine Teva, Docetaxel Accord, Docetaxel Kabi, Ibandronic acid Accord, Imatinib Teva, Zoledronic acid Actavis, Zoledronic acid Hospira, Zoledronic acid medac, Zoledronic acid Mylan, Zoledronic acid Teva, Zoledronic acid Teva Pharma, and Zyclara;
- Paediatric use marketing authorisation (PUMA) (1): Fluad;
- Article 58 (opinion in collaboration with WHO for products to be used in non-EU countries) (2): Hexaxim and Pyramax.

It should be noted that the generic subset (14 applications) above includes 13 applications granted eligibility to the centralised procedure as generics of centrally authorised products and 1 application (Zyclara) for a generic of a centrally authorised product submitted on a hybrid legal basis. The subset of 4 hybrid applications additionally includes 3 hybrid applications (Loulla, Megestrol Acetate, and Sancuso) of previously non-centrally authorised medicinal products.

[2] This eligibility basis is generally referred to as New Active Substance meaning that the substance is new to the centralised procedure although it may have been previously authorised via national procedures in the EU/EEA. In order to avoid confusion with the "New Active Substance Set" used in this analysis, this eligibility basis has been renamed 'New substance to CP' for the purposes of this report.

Outcome of marketing authorisation applications: Stand-alone Set (N=49)

Of the 49 stand-alone applications, 37 (76%) reached a positive CHMP outcome whereas 12 (24%) were unsuccessful (negative opinion or withdrawn). Four (Elelyso, Folotyn, Istodax and Jenzyl) of the 13 orphan medicinal products had an unfavourable outcome as did 5 (Egrifta, Fanaptum, Folotyn, Qsiva and SecreFlo) of the 8 applications that were submitted by SMEs. On the other hand, only 1 (Elelyso) of the 9 applications for biotechnology products had an unfavourable outcome.

Three applications were approved conditionally (Adcetris, Pixuvri and Xalkori) and there were no applications approved under exceptional circumstances. Kalydeco was subject to accelerated assessment.

Scientific advice was given for 34 out of 49 applications (69%, compared with 76% in 2011 and 55-60% in 2008-2010), 27 (79%) of which had a positive CHMP outcome. Of the 7 (21%) applications with an unfavourable outcome despite having received scientific advice, the majority (5, 71%) were submitted by SMEs (Egrifta, Fanaptum, Folotyn, Qsiva and SecreFlo), one of which was an OMP (Folotyn).

During the assessment of 13 (27%) applications (Adasuve, Adcetris, Egrifta, Folotyn, Forxiga, Inlyta, Istodax, Kynamro, Nexobrid, Pyramax, Qsiva, Selincro and Tresiba) the CHMP consulted SAGs or ad hoc expert groups prior to its final recommendation. This is slightly higher than the 20% reported in 2011 and 21% reported in 2010.

Table 1: Outcomes of initial marketing authorisation applications (Stand-alone Set, N=49)

	Positive[3]	Negative/Withdrawn[3]	Total[4]
Stand-alone Set	37 (76%)	12 (24%)	49 (100%)
OMP	9 (69%)	4 (31%)	13 (27%)
Non-OMP	28 (78%)	8 (22%)	36 (73%)
SME applicant	3 (37%)	5 (63%)	8 (16%)
Non-SME applicant	34 (83%)	7 (17%)	41 (84%)
Scientific advice given	27 (79%)	7 (21%)	34 (69%)
Scientific advice not given	10 (67%)	5 (33%)	15 (31%)

Outcome of Marketing Authorisation Applications: NAS Set (N=39)

Thirty-nine (80%) out of 49 stand-alone applications in 2012 (compared with 30 (out of 50, 60%) applications in 2011 and 22 (out of 33, 66%) applications in 2010) were considered as containing a NAS (Table 2). Eight stand-alone applications did not contain a NAS and two applications (Hexaxim and Pyramax) were for medicines intended for use outside the EU (Article 58 applications) for which the NAS categorisation was not applicable. The success rate of applications containing a NAS was 82% (32 out of 39) in 2012 compared with 77% in 2011 and 2010 and 60% in 2009.

[3] Numbers in parentheses denote percentages of applications in the row category
[4] Numbers in parentheses denote percentages of total applications

Table 2: Outcomes of initial marketing authorisation applications (NAS Set, N=39)

	Positive[3]	Negative / Withdrawn[3]	Total[4]
NAS Set	32 (82%)	7 (18%)	39 (100%)
OMP	9 (75%)	3 (25%)	12 (31%)
Non-OMP	23 (85%)	4 (15%)	27 (69%)
SME applicant	2 (40%)	3 (60%)	5 (13%)
Non-SME applicant	30 (88%)	4 (12%)	34 (87%)
Scientific advice given	26 (84%)	5 (16%)	31 (79%)
Scientific advice not given	6 (75%)	2 (25%)	8 (21%)

In the national decentralised procedure 2 new active substances reached an outcome in 2012 compared with 1 in 2011 and 4 in 2010.

Applications for extension of indication

Introduction

The analysis conducted related to applications for extension of indication for centrally authorised products that reached a CHMP outcome (positive or negative opinion or withdrawal of application) in 2012. Multiple and informed consent applications were excluded. Applications for extension of indication for generics, hybrids and biosimilars as a follow-up to respective changes in the indication of reference products were also excluded.

With regard to outcome, a differentiation is made between applications that received a positive CHMP opinion with changes to section 4.1 (therapeutic indications) of the summary of product characteristics (SmPC) and applications with a positive CHMP opinion but with SmPC changes excluding a change in the therapeutic indication (most commonly changes in section 5.1 of the SmPC).

Analysis

In 2012, the CHMP completed the assessment of 61 applications for extensions of indications for centrally authorised products. Thirteen of these were multiple applications. The remaining 48 applications were thus taken into account in the subsequent analyses (Analysis Set, see Figure 3). Forty-two out of the 48 applications (88%) reached a positive opinion (compared with 93% in 2011). For 2 procedures the positive opinion related to updates of the product information other than section 4.1 of the SmPC (therapeutic indications). Five procedures were withdrawn before CHMP opinion and for one procedure a negative opinion was adopted (see Table 3).

Scientific advice was given in relation to the new indication for 8 of the 48 applications (22%, compared with 16% in 2011) and SAGs or ad hoc expert groups were consulted during the review of 3 extension of indication applications (6%, see Table 3).

Figure 3: Schematic representation of extension of indication applications concluded in 2012

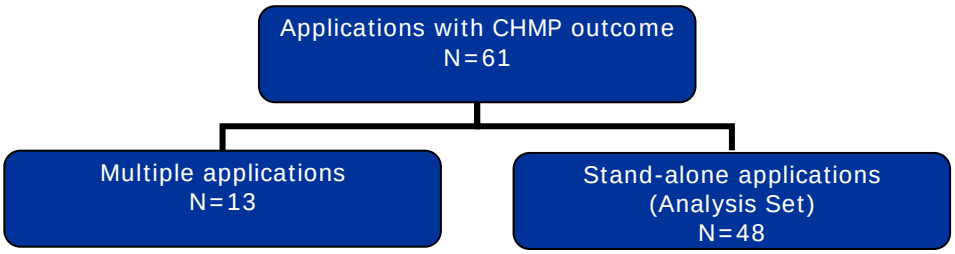


Table 3: Outcomes of extension of indication applications (Analysis Set, N=48)

	Positive with indication change[5]	Positive without indication change[6]	Negative / Withdrawn[6]	Total[6]
All applications	40 (83%)	2 (4%)	6 (13%)	48 (100%)
Scientific advice given	9 (90%)	0 (0%)	1 (10%)	10 (20%)
Scientific advice not given	31 (82%)	2 (5%)	5 (13%)	38 (80%)

[5] Numbers in parentheses denote percentages of applications in the row category
[6] Numbers in parentheses denote percentages of total applications

ANNEX

Table 4: Stand-alone initial marketing authorisation applications for products considered to contain a NAS with CHMP outcome in 2012 (N=39)

Name	INN*	Eligibility	Therapeutic Area	CHMP Outcome
Positive Outcomes (n=32)				
Adcetris	brentuximab vedotin	Orphan Medicinal Product	Hodgkin's lymphoma, Anaplastic Large Cell Lymphoma (ALCL)	Positive by consensus
AMYViD	florbetapir [18F]	Significant Innovation/ Patient Interest	Alzheimer's Disease	Positive by consensus
Betmiga	mirabegron	Significant Innovation/ Patient Interest	Overactive bladder (OAB) syndrome	Positive by consensus
Bexsero	meningococcal group B vaccine (rDNA, component, adsorbed)	Biotech Medicinal Product	Meningococcal group B vaccine	Positive by consensus
BindRen	colestilan	New Substance to CP**	Hyperphosphataemia in Chronic Kidney Disease (CKD)	Positive by consensus
Constella	linaclotide	New Substance to CP**	Irritable Bowel Syndrome with Constipation (IBS-C)	Positive by consensus
Cuprymina	copper (64Cu) chloride	New Substance to CP**	Radiopharmaceutical precursor	Positive by consensus
Dacogen	decitabine	Orphan Medicinal Product	Acute myeloid leukaemia	Positive by consensus
Eklira Genuair	aclidinium bromide	New Substance to CP**	Chronic obstructive pulmonary disease (COPD)	Positive by consensus
Eylea	aflibercept	Biotech Medicinal Product	Age-related macular degeneration (AMD)	Positive by consensus
Forxiga	dapagliflozin	Mandatory Therapeutic Indication	Type II diabetes mellitus	Positive by consensus
Fycompa	perampanel	New Substance to CP**	Partial-onset seizures, epilepsy	Positive by consensus
Inlyta	axitinib	Mandatory Therapeutic Indication	Renal cell carcinoma	Positive by majority
Jakavi	ruxolitinib	Orphan Medicinal Product	Chronic idiopathic myelofibrosis and myelofibrosis secondary to polycythaemia vera or essential thrombocythaemia	Positive by consensus

Name	INN*	Eligibility	Therapeutic Area	CHMP Outcome
Kalydeco	ivacaftor	Orphan Medicinal Product	Cystic fibrosis	Positive by consensus
Krystexxa	pegloticase	Biotech Medicinal Product	Gout	Positive by consensus
Lyxumia	lixisenatide	New Substance to CP**	Diabetes mellitus	Positive by consensus
NexoBrid	concentrate of proteolytic enzymes enriched in bromelain	Orphan Medicinal Product	Removal of eschar in deep partial- and full-thickness thermal burns	Positive by majority
Nimenrix	meningococcal group A, C, W-135 and Y conjugate vaccine	New Substance to CP**	Meningococcal vaccine	Positive by consensus
NovoThirteen	catridecacog	Biotech Medicinal Product	Bleeding prophylaxis in congenital factor XIII A-subunit deficiency	Positive by consensus
Perjeta	pertuzumab	Biotech Medicinal Product	Breast cancer	Positive by consensus
Picato	ingenol mebutate	New Substance to CP**	Actinic keratosis	Positive by consensus
Pixuvri	pixantrone	Mandatory Therapeutic Indication	Non-Hodgkin's lymphomas	Positive by majority
Revestive	teduglutide	Orphan Medicinal Product	Short bowel syndrome	Positive by consensus
Rienso	ferumoxytol	Significant Innovation/ Patient Interest	Iron deficiency with chronic kidney disease (CKD)	Positive by majority
Ryzodeg	insulin degludec/insulin aspart	Biotech Medicinal Product	Diabetes mellitus	Positive by consensus
Selincro	nalmefene	Significant Innovation/ Patient Interest	Alcohol dependence	Positive by majority
Signifor	pasireotide	Orphan Medicinal Product	Cushing's disease	Positive by consensus
Tresiba	insulin degludec	Biotech Medicinal Product	Diabetes mellitus	Positive by consensus
Xalkori	crizotinib	Mandatory Therapeutic Indication	Non-Small Cell Lung Cancer (NSCLC)	Positive by consensus
Zaltrap	aflibercept	Biotech Medicinal Product	Colorectal cancer	Positive by majority
Zinforo	ceftaroline fosamil	New Substance to CP**	Complicated skin and soft tissue infections (cSSTI) and Community-acquired pneumonia (CAP)	Positive by consensus
Negative Outcomes (n=7)				
Egrifta	tesamorelin	New Substance to CP**	lipodystrophy in HIV-infected patients	Withdrawn prior to opinion

Name	INN*	Eligibility	Therapeutic Area	CHMP Outcome
Fanaptum	iloperidone	New Substance to CP**	schizophrenia	Negative by majority
Folotyn	pralatrexate	Orphan Medicinal Product	peripheral T-cell lymphoma	Negative after appeal by majority
Istodax	romidepsin	Orphan Medicinal Product	peripheral T-cell lymphoma (PTCL)	Negative after appeal by majority
Jenzyl	ridaforolimus	Mandatory Therapeutic Indication	soft tissue sarcoma, bone sarcoma	Withdrawn prior to opinion
Kynamro	mipomersen	New Substance to CP**	familial hypercholesterol-aemia	Negative by consensus
Mulsevo	semuloparin sodium	New Substance to CP**	prophylaxis (prevention) of venous thromboembolism (VTE) in cancer patients	Withdrawn prior to opinion

* INN: International non-proprietary name
** CP: centralised procedure – this eligibility basis is referred to as 'New Active Substance', but it has been renamed for the purposes of this report to avoid confusion

Table 5: Stand-alone initial marketing authorisation applications for products not considered to contain a NAS with CHMP outcome in 2012 (N=10)

Name	INN*	Eligibility	Therapeutic Area	CHMP Outcome
Acrescent	memantine/ donepezil	Significant Innovation/ Patient Interest	Alzheimer's disease	Negative by consensus
Adasuve	loxapine	Significant Innovation/ Patient Interest	schizophrenia, bipolar disorder	Positive by consensus
Elelyso	taliglucerase alfa	Biotech Medicinal Product	type I Gaucher's disease	Negative by consensus
Fluad	influenza vaccine (surface antigen, inactivated, adjuvanted)	Paediatric use marketing authorisation	prophylaxis of influenza, influenza vaccine	Withdrawn prior to opinion
Jentadueto	linagliptin/ metformin	Mandatory Therapeutic Indication	type II diabetes mellitus	Positive by consensus
Qsiva	phentermine/ topiramate	Significant Innovation/ Patient Interest	Weight loss, obesity	Negative by majority
Seebri Breezhaler	glycopyrronium bromide	Significant Innovation/ Patient Interest	chronic obstructive pulmonary disease (COPD)	Withdrawn prior to opinion
SecreFlo	secretin	New Substance to CP**	diagnostic agent used in magnetic resonance holangiopancreato-graphy (MRCP) to improve pancreatic duct visualisation	Positive by consensus
Hexaxim	diphtheria, tetanus, pertussis (acellular,	Article 58 WHO	prophylaxis against diphtheria, tetanus,	Positive by consensus

Name	INN*	Eligibility	Therapeutic Area	CHMP Outcome
	component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus influenzae type b conjugate vaccine (adsorbed)		pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type b infections	
Pyramax	pyronaridine tetraphosphate/ artesunate	Article 58 WHO	malaria	Positive by consensus

* INN: International non-proprietary name
** CP: centralised procedure – this eligibility basis is referred to as 'New Active Substance', but it has been renamed for the purposes of this report to avoid confusion

Table 6: Multiple, informed consent, generic, hybrid and biosimilar initial marketing authorisation applications with CHMP outcome in 2012 (N=28)

Name	INN*	Reference medicinal product
Generics (n=13)		
Capecitabine Accord	capecitabine	Generic of Xeloda
Capecitabine medac	capecitabine	Generic of Xeloda
Capecitabine Teva	capecitabine	Generic of Xeloda
Docetaxel Accord	docetaxel	Generic of Taxotere
Docetaxel Kabi	docetaxel	Generic of Taxotere
Ibandronic acid Accord	ibandronic acid	Generic of Bondronat
Imatinib Teva	imatinib	Generic of Glivec
Zoledronic acid Actavis	zoledronic Acid	Generic of Zometa
Zoledronic acid Hospira	zoledronic acid	Generic of Zometa
Zoledronic acid medac	zoledronic acid	Generic of Aclasta and Zometa
Zoledronic acid Mylan	zoledronic acid	Generic of Zometa
Zoledronic acid Teva	zoledronic acid	Generic of Zometa
Zoledronic acid Teva Pharma	zoledronic acid	Generic of Aclasta
Hybrids (n=4)		
Megestrol Acetate	megestrol	Hybrid of Megace
Loulla	mercaptopurine	Hybrid of Purinethol
Sancuso	granisetron	Hybrid of Kytril
Zyclara	imiquimod	Hybrid of Aldara
Similar biologicals (biosimilars, n=3)		
Combimarv	Human insulin	Biosimilar of Humulin M3
Isomarv	Human insulin	Biosimilar of Humulin I
Solumarv	Human insulin	Biosimilar of Humulin S
Multiple applications (n=7)		
Balaxur	memantine/donepezil	Multiple of Acrescent
Bretaris Genuair	aclidinium bromide	Multiple of Eklira Genuair
Capecitabine Krka	capecitabine	Multiple of Capecitabine Accord
Enurev Breezhaler	glycopyrronium bromide	Multiple of Seebri Breezhaler
Riluzole Zentiva	riluzole	Multiple of Rilutek

Name	INN*	Reference medicinal product	
Sabervel		irbesartan	Multiple of Aprovel
Tovanor Breezhaler		glycopyrronium bromide	Multiple of Seebri Breezhaler
Informed consent (n=1)			
Memantine Merz		memantine	Original medicinal product: Axura

* INN: International non-proprietary name

Table 7: Stand-alone extension of indication applications with CHMP outcome in 2012 (N=48)

Name	INN*	Procedure number	Scope of indication extension**
Positive CHMP outcome (n=40)			
Abilify	aripiprazole	EMEA/H/C/000471/II/0082	Paediatric bipolar I disorder
Avastin	bevacizumab	EMEA/H/C/000582/II/0046	Second line treatment of ovarian cancer
BYETTA	exenatide	EMEA/H/C/000698/II/0029	Type II diabetes mellitus as adjunct to insulin and metformin and/or pioglitazone
Cayston	aztreonam lysine	EMEA/H/C/000996/II/0018	Paediatric cystic fibrosis
Cialis	tadalafil	EMEA/H/C/000436/II/0060	Treatment of benign prostatic hyperplasia
Eliquis	apixaban	EMEA/H/C/002148/X/0004	Prevention of stroke and systemic embolism in atrial fibrillation
Enbrel	etanercept	EMEA/H/C/000262/II/0145	Juvenile idiopathic oligoarthritis, paediatric psoriatic arthritis, paediatric enthesitis-related arthritis
Eucreas	vildagliptin/ metformin hydrochloride	EMEA/H/C/000807/WS/0257	Type II diabetes mellitus as adjunct to insulin
Eucreas	vildagliptin/ metformin hydrochloride	EMEA/H/C/000807/WS/0272	Type II diabetes mellitus in combination with a sulphonylurea
Exjade	deferasirox	EMEA/H/C/000670/II/0026	Non transfusion-dependent thalassaemia syndromes
Galvus	vildagliptin	EMEA/H/C/000771/WS/0257	Type II diabetes mellitus as adjunct to insulin and metformin
Galvus	vildagliptin	EMEA/H/C/000771/WS/0272	Type II diabetes mellitus in combination with metformin and a sulphonylurea
Humira	adalimumab	EMEA/H/C/000481/II/0082	Ulcerative colitis
Humira	adalimumab	EMEA/H/C/000481/II/0085	Axial spondyloarthritis
Humira	adalimumab	EMEA/H/C/000481/II/0088	Paediatric Crohn's disease
Humira	adalimumab	EMEA/H/C/000481/II/0094	Moderately active Crohn's disease
Ilaris	canakinumab	EMEA/H/C/001109/II/0021	Cryopyrin-Associated Periodic Syndromes (CAPS) in children 2-4 years of age (and body weight of 7.5-15

Name	INN*	Procedure number	Scope of indication extension**
			Kg)
Intelence	etravirine	EMEA/H/C/000900/X/0018	Paediatric second line treatment of HIV 1 infection
Isentress	raltegravir	EMEA/H/C/000860/X/0024	Paediatric HIV1 infection
Ixiaro	Japanese Encephalitis Vaccine (inactivated, adsorbed)	EMEA/H/C/000963/II/0039	Paediatric Japanese encephalitis virus infection
Komboglyze	saxagliptin/ metformin	EMEA/H/C/002059/II/0004	Type II diabetes mellitus as adjunct to insulin
Lantus	insulin glargine	EMEA/H/C/000284/II/0075	Paediatric diabetes mellitus in children aged 2 years and above
Menveo	MenACWY	EMEA/H/C/001095/II/0017	Immunisation against meningococcus infection in children aged 2 years and above
PegIntron	peginterferon alfa-2b	EMEA/H/C/000280/WS/0216	Hepatitis C infection in combination with ribavirin and boceprevir
Prevenar 13	pneumococcal saccharide conjugated vaccine, adsorbed	EMEA/H/C/001104/II/0055	Immunisation against pneumococcal infection in children 5 to 17 years of age
Prezista	darunavir	EMEA/H/C/000707/X/0041	Paediatric HIV1 infection in children 3-6 years of age (and body weight of 15-20 Kg)
ProQuad	combined measles, mumps, rubella and varicella virus vaccine	EMEA/H/C/000622/II/0055	Vaccination against measles, mumps, rubella and varicella in children 9-12 months of age
Protelos	strontium ranelate	EMEA/H/C/000560/II/0031	Male osteoporosis
Rebetol	ribavirin	EMEA/H/C/000246/WS/0216	Hepatitis C infection in combination with ribavirin and boceprevir
Remicade	infliximab	EMEA/H/C/000240/II/0150	Paediatric ulcerative colitis
RotaTeq	rotavirus vaccine	EMEA/H/C/000669/II/0031	Prevention of rotavirus gastroenteritis in infants 26-32 weeks of age
Thyrogen	thyrotropin alfa	EMEA/H/C/000220/II/0059	Pre-therapeutic stimulation of thyroid in combination with a range of 30-100 mCi (1.1-3.7 GBq) radioiodine for thyroid ablation
Trajenta	linagliptin	EMEA/H/C/002110/II/0004	Type II diabetes mellitus as adjunct to insulin
Viread	tenofovir disoproxil fumarate	EMEA/H/C/00419/II/115	Paediatric chronic Hepatitis B
Viread	tenofovir disoproxil fumarate	EMEA/H/C/00419/II/119	Paediatric HIV1 infection
Votrient	pazopanib	EMEA/H/C/001141/II/007	Soft tissue sarcoma

Name	INN*	Procedure number	Scope of indication extension**
Votubia	everolimus	EMEA/H/C/002311/II/0004	Tuberous sclerosis complex (TSC) with renal angiomyolipoma
Xarelto	rivaroxaban	EMEA/H/C/000944/II/0018	Pulmonary embolism and prevention of any recurrent deep vein thrombosis (DVT)
Zonegran	zonisamide	EMEA/H/C/000577/II/0059	Partial seizures as monotherapy
Zytiga	abiraterone	EMEA/H/C/002321/II/0004	Chemotherapy naïve prostate cancer
Positive CHMP outcome without indication change (n=2)			
Exelon	rivastigmine	EMEA/H/C/000169/WS/0132	Dementia in Parkinson's disease
Kogenate Bayer	octocog alfa	EMEA/H/C/000275/WS/0193	Haemophilia A with Factor VIII inhibitors
Negative CHMP outcome/Withdrawn (n=6)			
Afinitor	everolimus	EMEA/H/C/0001038/II/0020	Breast cancer
Erbitux	cetuximab	EMEA/H/C/000558/II/0043	Non-small cell lung cancer
Qutenza	capsaicin	EMEA/H/C/00909/II/20	Peripheral neuropathic pain excluding pain from diabetic neuropathy
Revlimid	Lenalidomide	EMEA/H/C/717/X/0046	First line treatment and maintenance treatment of multiple myeloma
Tyverb	lapatinib	EMEA/H/C/000795/II/0017	Breast cancer in combination with paclitaxel
Velcade	bortezomib	EMEA/H/C/000539/II/0055	Follicular non-Hodgkin's lymphoma

* INN: International non-proprietary name
** This is not the detailed indication, but the general disease/condition newly included in the authorised indication(s). In case of extension of an existing indication, further details (age, line of treatment, etc.) are included to distinguish from the prior existing indication.

Table 7: Multiple extension of indication applications with CHMP outcome in 2012 (N=13)

Name	INN*	Procedure number	Reference medicinal product
Helixate NexGen	octocog alfa	EMEA/H/C/000276/WS/0193	Kogenate Bayer
Icandra	vildagliptin plus metformin hydrochloride	EMEA/H/C/001050/WS/0257	Eucreas
Icandra	vildagliptin plus metformin hydrochloride	EMEA/H/C/001050/WS/0272	Eucreas
Jalra	vildagliptin	EMEA/H/C/001048/WS/0257	Galvus
Jalra	vildagliptin	EMEA/H/C/001048/WS/0272	Galvus
Optisulin	insulin glargine	EMEA/H/C/000309/II/0064	Lantus
Osseor	strontium ranelate	EMEA/H/C/000561/II/0027	Protelos
Prometax	rivastigmine	EMEA/H/C/000255/II/0132	Exelon
Viraferonpeg	peginterferon alfa-2b	EMEA/H/C/000329/WS/0216	PegIntron

Name	INN*	Procedure number	Reference medicinal product
Xiliarx	vildagliptin	EMEA/H/C/001051/WS/0257	Galvus
Xiliarx	vildagliptin	EMEA/H/C/001051/WS/0272	Galvus
Zomarist	vildagliptin plus metformin hydrochloride	EMEA/H/C/001049/WS/0257	Eucreas
Zomarist	vildagliptin plus metformin hydrochloride	EMEA/H/C/001049/WS/0272	Eucreas

* INN: International non-proprietary name