

Annexes to the annual report of the European Medicines Agency 2014

Table of contents

Annex 1 – Members of the Management Board	2
Annex 2 – Members of the Committee for Medicinal Products for Human Use	4
Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee.....	6
Annex 4 – Members of the Committee for Medicinal Products for Veterinary Use	8
Annex 5 – Members of the Committee on Orphan Medicinal Products	10
Annex 6 – Members of the Committee on Herbal Medicinal Products.....	12
Annex 07 – Committee for Advanced Therapies	14
Annex 8 – Members of the Paediatric Committee	16
Annex 9 – Working parties and working groups	18
Annex 10 – CHMP opinions in 2014 on medicinal products for human use	22
Annex 11 – CVMP opinions in 2014 on medicinal products for veterinary use.....	36
Annex 12 – COMP opinions in 2014 on designation of orphan medicinal products	41
Annex 13 – HMPC European Union herbal monographs in 2014.....	64
Annex 14 – PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2014.....	67
Annex 15 – Referral procedures overview 2014 – human medicines	99
Annex 16 – Arbitrations and referrals in 2014 – veterinary medicines.....	102
Annex 17 – Budget summaries 2013–2014	104
Annex 18 – European Medicines Agency Establishment Plan	105
Annex 19 – Annual report from the SME office.....	106
Annex 20 – Access to documents requests	107
Annex 21 – Media and public relations.....	109
Annex 22 – Publications by Agency staff members and experts in 2014	110

Annex 1 – Members of the Management Board

Chair: Kent WOODS

EMA contact: Nerimantas STEIKUNAS; Silvia FABIANI

Members

- European Parliament Guisepe NISTICÓ, Björn LEMMER
- European Commission Ladislav MIKO¹, Gwenole COZIGOU (Alternates: Andrzej RYS , Salvatore D'ACUNTO)
- Belgium Xavier DE CUYPER (Alternate: Greet MUSCH)
- Bulgaria Assena STOIMENOVA² (Alternate: Svetlin SPIROV³)
- Czech Republic Doubravka KOSTALOVA (Alternate: Jiří BUREŠ)
- Denmark Else SMITH (Alternate: Nina MOSS)
- Germany Walter SCHWERDTFEGER (Alternate: Klaus CICHUTEK)
- Estonia Kristin RAUDSEPP (Alternate: Alar IRS)
- Ireland Pat O'MAHONY (Alternate: Rita PURCELL)
- Greece Katerina FAMELI⁴ (Alternate: Giannis KARAFYLLIS⁵)
- Spain Belén CRESPO SÁNCHEZ-EZNARRIAGA (Alternate: Laura Franqueza GARCÍA)
- France Dominique MARTIN⁶ (Alternate: Jean-Pierre ORAND)
- Italy Luca PANI (Alternate: Gabriella CONTI⁷)
- Cyprus Loizos PANAYI⁸ (Alternate: Ioannis KKOLOS⁹)
- Latvia Inguna ADOVIČA (Alternate: Dace ŽIKUTE)
- Lithuania Gintautas BARCYS (Alternate: Gediminas PRIDOTKAS)
- Luxembourg Mike SCHWEBAG¹⁰ (Alternate: Jacqueline GENOUX-HAMES)
- Hungary Beatrix HORVÁTH (Alternate: Hilda KŐSZEGINÉ SZALAI)
- Malta John-Joseph BORG (Alternate: Gavril FLORES)
- Netherlands Hugo HURTS¹¹ (Alternate: Constant VAN BELKUM)

¹ Replaced Paola TESTORI COGGI as of November 2014

² Replaced Kiril NENOV as of September 2014

³ Replaced Zlatina GUEORGUIEVA as of September 2014

⁴ Replaced Ioannis TOUNTAS as of February 2014

⁵ Replaced Maria SKOUROLIAKOU as of February 2014

⁶ Replaced Dominique MARANINCHI as of September 2014

⁷ Replaced Paolo SIVIERO as of November 2014

⁸ Replaced Arthur ISSEYEGH as of January 2014

⁹ Replaced George ANTONIOU as of January 2014

¹⁰ Replaced Claude HEMMER as of December 2014

- Austria Christa WIRTHUMER-HOCHE (Alternate: Sylvia FÜSZL)
- Poland Grzegorz CESSAK (Alternate: Artur FALEK)
- Portugal Helder Mota Filipe (Alternate: Awaiting nomination)
- Romania Marius SAVU (Alternate: Marius TANASA)
- Slovenia Matej BREZNIK (Alternate: Stanislav PRIMOŽIČ)
- Slovakia Ján MAZÁG (Alternate: Barbora KUČEROVÁ)
- Finland Sinikka RAJANIEMI (Alternate: Pekka KURKI)
- Sweden Catarina FORSMAN¹² (Alternate: Bengt WITTGREN)
- United Kingdom Kent WOODS (Alternate: Ian HUDSON)
- Representatives of patients' organisations Nikos DEDES
W.H.J.M. Wim WIENTJENS
- Representative of doctors' organisations Wolf-Dieter LUDWIG
- Representative of veterinarians' organisations Christophe HUGNET

Observers

- Iceland Rannveig GUNNARSDÓTTIR (Alternate: Helga THORISDÓTTIR)
- Liechtenstein Brigitte BATLINER (Alternate: Christina ZIMMER)
- Norway Audun HÅGÅ (Alternate: Ivar VOLLSET)

¹¹ Replaced Aginus KALIS as of June 2014

¹² Replaced Christina ÅKERMAN as of October 2014

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

Chair: Tomas SALMONSON

EMA contact: Anthony HUMPHREYS

Members

- | | |
|--|---|
| • Andrea LASLOP (Austria) | Alternate: Milena STAIN |
| • Daniel BRASSEUR (Belgium) | Alternate: Bart VAN DER SCHUEREN |
| • Mila VLASKOVSKA (Bulgaria) | Alternate: Maria POPOVA-KIRADJIEVA ¹ |
| • Ivana MIKACIC (Croatia) | Alternate: Ana DUGONJIC |
| • Panayiotis TRIANTAFYLLIS (Cyprus) ² | Alternate: George SAVVA ³ |
| • Ondřej SLANAR (Czech Republic) | Alternate: Radka MONTONIOVA |
| • Jens HEISTERBERG (Denmark) | Alternate: Christian SCHNEIDER ⁴ |
| • Alar IRS (Estonia) | Alternate: Kersti OSELIN |
| • Outi MAKI-IKOLA (Finland) | Alternate: Janne KOMI |
| • Pierre DEMOLIS (France) (<i>Vice-Chair</i>) | Alternate: Joseph EMMERICH |
| • Harald ENZMANN (Germany) | Alternate: Martina WEISE |
| • Dimitrios KOUVELAS (Greece) ⁵ | Alternate: George AISLAITNER ⁶ |
| • Agnes GYURASICS (Hungary) | Alternate: Melinda SOBOR |
| • Kolbeinn GUDMUNDSSON (Iceland) | Alternate: Hrefna GUDMUNDSDOTTIR ⁷ |
| • David LYONS (Ireland) | Alternate: Patrick SALMON |
| • Daniela MELCHIORRI (Italy) ⁸ | Alternate: Luca PANI ⁹ |
| • Juris POKROTNIEKS (Latvia) | Alternate: Natalja KARPOVA |
| • Romaldas MACIULAITIS (Lithuania) | Alternate: Rugile PILVINIENE |
| • Jacqueline GENOUX-HAMES (Luxembourg) | Alternate: Carine DE BEAUFORT |
| • John Joseph BORG (Malta) | Alternate: Helen VELLA |
| • Pieter DE GRAEFF (Netherlands) | Alternate: Hans HILLEGE |
| • Karsten BRUINS SLOT (Norway) | Alternate: Ingunn HAGEN WESTGAARD |
| • Piotr FIEDOR (Poland) | Alternate: Aldona PALUCHOWSKA |
| • Bruno SEPODES (Portugal) | Alternate: Dinah DUARTE |

¹ Replaced Lyubina TODOROVA as of August 2014

² Replaced Emilia MAVROKORDATOU as of March 2014

³ Replaced Arthur ISSEYEGH as of March 2014

⁴ Replaced Jens ERSBOLL as of September 2014

⁵ Replaced Aikaterini MORAITI as of February 2014

⁶ Replaced Chrysoula NTAOUSANI as of the April 2014

⁷ Replaced Reynir ARNGRIMSSON as of July 2014

⁸ Switch of roles of member and alternate as of September 2014

⁹ Switch of roles of member and alternate as of September 2014

- Nela VILCEANU (Romania) Alternate: Dana MARIN
- Ján MAZAG (Slovakia) Alternate: Jana KLIMASOVA
- Stanislav PRIMOZIC (Slovenia) Alternate: Nevenka TRSINAR
- Concepcion PRIETO YERRO (Spain) Alternate: Arantxa SANCHO-LOPEZ
- Kristina DUNDER (Sweden) Alternate: Filip JOSEPHSON¹⁰
- Greg MARKEY (United Kingdom) Alternate: Rafe SUVARNA

Co-opted Members

- Robert James HEMMINGS (Medical statistics (clinical-trial methodology / epidemiology))¹¹
- Hubert G.M. LEUFKENS (Pharmacovigilance / Pharmacoepidemiology)
- Jan MUELLER-BERGHAUS (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))
- Jean-Louis ROBERT (Quality (non-biologicals))
- Sol RUIZ (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))

¹⁰ Replaced Bengt LJUNGBERG as of April 2014

¹¹ Re-elected during the February 2014 meeting

Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: June RAINE

EMA contact: Anthony HUMPHREYS

Members

- Harald HERKNER (Austria) Alternate: Jan NEUHAUSER¹
- Jean-Michel DOGNE (Belgium) Alternate: Veerle VERLINDEN
- Maria POPOVA-KIRADJIEVA (Bulgaria) Alternate: Yuliyana EFTIMOV
- Viola MACOLIĆ ŠARINIĆ (Croatia) Alternate: Marin BANOVAČ
- Nectaroula COOPER² (Cyprus) Alternate: *Awaiting nomination*³
- Jana MLADA (Czech Republic) Alternate: Eva JIRSOVA
- Doris STENVER (Denmark) Alternate: Torbjörn CALLREUS⁴
- Maia UUSKULA (Estonia) Alternate: Katrin KIISK
- Kirsti VILLIKKA (Finland) Alternate: Terhi LEHTINEN
- Arnaud BATZ⁵ (France) Alternate: Patrick MAISON⁶
- Martin HUBER (Germany) Alternate: Valerie STRASSMANN
- Leonidas KLIRONOMOS⁷ (Greece) Alternate: Agni KAPOU⁸
- Julia PALLOS (Hungary) Alternate: Melinda PALFI
- Guðrún Kristín STEINGRIMSDOTTIR (Iceland) Alternate: Hrefna GUDMUNSDOTTIR⁹
- Almath SPOONER (Ireland) (*Vice-Chair*) Alternate: Ruchika SHARMA
- Carmela MACCHIARULO (Italy) Alternate: AMELIA CUPELLI¹⁰
- Andis LACIS (Latvia) Alternate: Inguna ADOVICA
- Jolanta GULBINOVIC (Lithuania) Alternate: Rita DZETAVECKIENE
- Jacqueline GENOUX-HAMES (Luxembourg) Alternate: Nadine PETITPAIN
- Ami TANTI (Malta) Alternate: *Awaiting nomination*
- Sabine STRAUS (Netherlands) Alternate: Menno VAN DER ELST
- Ingebjorg BUAJORDET (Norway) Alternate: Pernille HARG
- Adam PRZYBYLKOWSKI (Poland) Alternate: Magdalena BUDNY¹¹

¹ Replaced Aleksandra MARTINOVIC as of July 2014

² Replaced Christos PETROU as of January 2014

³ Resigned Zena GUNTHER as of October 2014

⁴ Replaced Line MICHAN as of April 2014

⁵ Replaced Isabelle ROBINE as of July 2014

⁶ Nominated as of July 2014

⁷ Replaced George AISLAITNER as of May 2014

⁸ Replaced Leonidas KLIRONOMOS as of May 2014

⁹ Nominated as of February 2014

¹⁰ Replaced Jelena IVANOVIC as of December 2014

- Margarida GUIMARÃES (Portugal) Alternate: Magda PEDRO¹²
- Nicolae FOTIN (Romania) Alternate: Roxana STROE
- Tatiana MAGALOVA (Slovakia) Alternate: Anna MAREKOVA
- Milena RADOHA-BERGOČ (Slovenia) Alternate: Gabriela JAZBEC
- Dolores MONTERO COROMINAS (Spain) Alternate: Miguel MACIA
- Qun-Ying YUE (Sweden) Alternate: Ulla WÄNDEL LIMINGA
- Julie WILLIAMS (United Kingdom) Alternate: Rafe SUVARNA¹³

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

Members representing healthcare professionals nominated by the European Commission

- Filip BABYLON Alternate: Kirsten MYHR

Members representing patients' organisations nominated by the European Commission

- Albert VAN DER ZEIJDEN Alternate: Marco GRECO

¹¹ Replace Kamila CZAJKOWSKA as of November 2014

¹² Replaced Alexandra PÉGO as of November 2014

¹³ Replaced Julia DUNNE as of February 2014

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

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

European Medicines Agency contact: David MACKAY

Members and alternates

- Barbara ZEMANN (Austria) Alternate: Ines LINDNER
- Bruno URBAIN (Belgium) Alternate: Frederic KLEIN
- Emil KOZHUHAROV¹ (Bulgaria) Alternate: Bogdan AMINKOV
- Ljiljana MARKUS CIZELJ² (Croatia) Alternate: Frane BOZIC³
- Jiri BURES (Czech Republic) Alternate: Leona NEPEJCHALOVA
- Alia MICHAELIDOU-PATSIA (Cyprus) Alternate: *awaiting nomination*
- Ellen-Margrethe VESTERGAARD (Denmark) Alternate: Merete BLIXENKRONE-MOLLER
- Toomas TIIRATS (Estonia) Alternate: *awaiting nomination*
- Irmeli HAPPONEN (Finland) Alternate: Kristina LEHMANN
- Michael HOLZHAUSER-ALBERTI⁴ (France) Alternate: Jean-Claude ROUBY
- Cornelia IBRAHIM (Germany) Alternate: Esther WERNER
- Ioannis MALEMIS (Greece) Alternate: Angeliki TSIGOURI
- Gábor KULCSAR (Hungary) Alternate: Tibor SOOS
- David MURPHY (Ireland) Alternate: Gabriel J. BEECHINOR
- Maria TOLLIS (Italy) Alternate: Virgilio DONINI
- Zanda AUCE (Latvia) Alternate: Arvils JAKOVSKIS
- Petras MACIULSKIS (Lithuania) Alternate: *awaiting nomination*
- Marc SCHMIT (Luxembourg) Alternate: Marcel BRUCH
- Stephen SPITERI (Malta) Alternate: *awaiting nomination*
- G. Johan SCHEFFERLIE (Netherlands) Alternate: Peter HEKMAN
- Ewa AUGUSTYNOWICZ (Poland) Alternate: Anna WACHNIK-SWIECICKA
- João Pedro DUARTE DA SILVA (Portugal) Alternate: Maria AZEVEDO MENDES
- Lollita Sanda Camelia TABAN (Romania) Alternate: Simona STURZU
- Judita HEDEROVA (Slovakia) Alternate: Eva CHOBOTOVA
- Stane SRCIC (Slovenia) Alternate: Katarina STRAUS

¹ Replaced Damien ILIEV as of September 2014 meeting

² As of July 2014 meeting

³ AS of July 2014 meeting

⁴ French member and alternate swapped roles as of last day of December 2013 meeting

- Cristina MUNOZ MADERO (Spain)
- Eva LANDER PERSSON (Sweden)
- Helen JUKES (United Kingdom)

Alternate: Consuelo RUBIO MONTEJANO

Alternate: Frida HASSLUNG-WIKSTRÖM

Alternate: Anna-Maria BRADY

EEA observers

- Johann LENHARDSSON (Iceland)
- Hanne BERGENDAHL⁵ (Norway)

Alternate: *awaiting nomination*

Alternate: Tonje HOY⁶

Co-opted members

Co-opted member

- Keith BAPTISTE
- Rory BREATHNACH
- Christian FRIIS
- Boris KOLAR
- Wilhelm SCHLUMBOHM

Expertise

Antimicrobials

General clinical veterinary practice

MRLs/residues

Environmental risk assessment

Quality pharmaceuticals

⁵ Replaced Hans Kristian Ostensen as of May 2014 meeting

⁶ As of May 2014 meeting

Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Bruno SEPODES

EMA: Anthony HUMPHREYS

Members

- Brigitte BLOCHL-DAUM (Austria)
- Andre LHOIR (Belgium)
- Irena BRADINOVA (Bulgaria)
- Adriana ANDRIC (Croatia)
- Elena KAISI¹ (Cyprus)
- Katerina KUBACKOVA (Czech Republic)
- Jens ERSBOLL² (Denmark)
- Vallo TILLMANN (Estonia)
- Karri PENTTILA³ (Finland)
- Annie LORENCE (France)
- Frauke NAUMANN-WINTER (Germany)
- Nikolaos SYPSAS (Greece)
- Judit EGGENHOFER (Hungary)
- Sigurdur THORSTEINSSON (Iceland)
- Geraldine O'DEA (Ireland)
- Armando MAGRELLI (Italy)
- Dainis KRIEVINS (Latvia)
- Ausra MATULEVICIENE (Lithuania)
- Henri METZ (Luxembourg)
- Albert CILIA VINCENTI (Malta)
- Violeta STOYANOVA-BENINSKA (Netherlands)
- Lars GRAMSTAD (Norway)
- Bozenna DEMBOWSKA-BAGINSKA (Poland)
- Ana CORREA NUNES (Portugal)
- Flavia SALEH (Romania)
- Zuzana BATOVA⁴ (Slovakia)

¹ Replaced Ioannis KKOLOS as of February 2014

² Nominated as of August 2014

³ Nominated as of October 2014

- Martin MOZINA (Slovenia)
- Josep TORRENT-FARNELL (Spain)
- Kerstin WESTERMARK (Sweden)
- Daniel O'CONNOR (United Kingdom)

Members nominated by the European Commission on the EMA's recommendation

- Ingeborg BARISIC⁵
- Giuseppe CAPOVILLA⁶
- Aikaterini MORAITI

Members representing patients' organisations nominated by the European Commission

- Birthe Byskov HOLM
- Marie Pauline EVERS
- Lesley GREENE (*Vice-Chair*)

⁴ Nominated as of February 2014

⁵ Nominated as of June 2014

⁶ Nominated as of June 2014

Annex 6 – Members of the Committee on Herbal Medicinal Products

Chair: Werner KNOSS

EMA contact: Anthony HUMPHREYS

Members

- Reinhard LANGER (Austria) Alternate: Astrid OBMANN
- Heidi NEEF (Belgium) Alternate: Wim VERVAET
- Elena MUSTAKEROVA (Bulgaria) Alternate: Kapka KANEVA¹
- Ivan KOSALEC (Croatia) Alternate: Darko TRUMBETIC
- Maria STAVROU (Cyprus) Alternate: Irene PERICLEOUS
- Marie HEROUTOVA (Czech Republic) Alternate: Marketa PRIHODOVA
- Steffen BAGER (Denmark) Alternate: Nina DURR
- Evelin SAAR (Estonia) Alternate: Marje ZERNANT
- Eeva Sofia LEINONEN (Finland) Alternate: Sari KOSKI
- An LE (France) Alternate: Jacqueline VIGUET POUPELLOZ
- Jacqueline WIESNER (Germany) Alternate: Birgit MERZ
- Ioanna CHINO (Greece) Alternate: Zoe KARAMPOURMPOUNI²
- Zsuzsanna BIRO-SANDOR (Hungary) Alternate: Rita NEMETH
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- Anna CUNNEY³ (Ireland) Alternate: Una MOCKLER⁴
- Marisa DELBO (Italy) (*Vice-Chair*) Alternate: Anna Maria SERRILLI
- Dace KALKE (Latvia) Alternate: Baiba JANSONE
- Arturas KAZEMEKAITIS (Lithuania) Alternate: Audronis LUKOSIUS
- *Awaiting nomination*⁵ (Luxembourg) Alternate: Jacqueline GENOUX-HAMES
- Everaldo ATTARD (Malta) Alternate: Andre MANGANI
- Emiel VAN GALEN (Netherlands) Alternate: Burt H. KROES
- Steinar MADSEN (Norway) Alternate: Gro FOSSUM
- Wojciech DYMOWSKI (Poland) Alternate: Ewa BACKHAUS
- Ana Paula MARTINS (Portugal) Alternate: Eva MENDES
- Nadia GRIGORAS (Romania) Alternate: Carmen PURDEL

¹ Replaced Irina NIKOLOVA as of July 2014

² Replaced Eleni SKAL TSA as of September 2014

³ Replaced Niamh CURRAN as of September 2014

⁴ Replaced Anna CUNNEY as of September 2014

⁵ Mariette BACKES-LIES resigned as of November 2014

- Martina HUDECOVA (Slovakia) Alternate: Milan NAGY
- Barbara RAZINGER (Slovenia) Alternate: Samo KREFT
- Adela NUNEZ VELAZQUEZ (Spain) Alternate: *Awaiting nomination*
- Per CLAESON (Sweden) Alternate: Erika SVEDLUND⁶
- Linda ANDERSON (United Kingdom) Alternate: Sue HARRIS

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

- *Awaiting nomination* (Albania)
- *Awaiting nomination*⁷ (Bosnia and Herzegovina)
- *Awaiting nomination*⁸ (Bosnia and Herzegovina)
- Ulrich ROSE⁹ (Council of Europe, EDQM)
- Melanie BALD (Council of Europe, EDQM)
- *Awaiting nomination*¹⁰ (Kosovo under UNSC Resolution 1244/99)
- *Awaiting nomination*¹¹ (Macedonia, The Former Yugoslav Republic of)
- *Awaiting nomination*¹² (Macedonia, The Former Yugoslav Republic of)
- *Awaiting nomination*¹³ (Montenegro)
- *Awaiting nomination*¹⁴ (Serbia)
- *Awaiting nomination* (Turkey)

⁶ Replaced Barbro GERDEN as of February 2014

⁷ Biljana TUBIC until September 2014

⁸ Sasa PILIPOVIC until September 2014

⁹ Replaced Michael WIERER as of August 2014

¹⁰ Arianit JAKUPI until September 2014

¹¹ Merjem HADJIHAMZA until September 2014

¹² Dimche ZAFIROV until September 2014

¹³ Jasmina KRLIC until September 2014

¹⁴ Dragan DJUROVIC until September 2014

Annex 07 – Committee for Advanced Therapies

Chair: Paula SALMIKANGAS

EMA contact: Patrick CELIS

Members nominated from within the CHMP

- Romaldas MAČIULAITIS (Lithuania) Alternate: Jolanta GULBINOVIC
- Jean-Louis ROBERT (Luxembourg) Alternate: Guy BERCHEM
- John-Joseph BORG (Malta) Alternate: Anthony SAMUEL
- Bruno SEPODES (Portugal) Alternate: Margarida MENEZES-FERREIRA
- Sol RUIZ (Spain) Alternate: Marcos TIMÓN

Members

- Ilona G. REISCHL (Austria) Alternate: Martin BRUNNER
- Claire BEUNEU (Belgium) Alternate: Belaïd SEKKALI
- Rozalina KULAKSAZOVA¹ (Bulgaria) Alternate: Evelina SHUMKOVA²
- Sandra TOMLJENOVIC (Croatia) Alternate: Ivica MALNAR
- Anna PAPHITOU (Cyprus) Alternate: Ioannis KKOLOS³
- Tomáš BORÁŇ⁴ (Czech Republic) Alternate: Ivana HAUNEROVÁ⁵
- Sinan B. SARAC (Denmark) Alternate: Nanna Aaby KRUSE
- Toivo MAIMETS (Estonia) Alternate: Tarmo TIIDO
- Tiina PALOMÄKI⁶ (Finland) Alternate: Olli TENHUNEN⁷
- Nicolas FERRY (France) Alternate: Sophie LUCAS
- Martina SCHÜSSLER-LENZ⁸ (Germany) Alternate: Egbert FLORY⁹
(*Vice-Chair*)
- Asterios TSIFTSOGLU (Greece) Alternate: Angeliki ROBOTI
- Balázs SARKADI¹⁰ (Hungary) Alternate: Krisztian FODOR¹¹
- *Awaiting nomination*¹² (Iceland) Alternate: *Awaiting nomination*
- Maura O'DONOVAN (Ireland) Alternate: Maeve LALLY

¹ Replaced Lyubina R. TODOROVA as of January 2014

² Replaced Velislava TODOROVA as of January 2014

³ Replaced Maria VASILIOU as of October 2014

⁴ Switch of roles of member and alternate as of October 2014

⁵ Switch of roles of member and alternate as of October 2014

⁶ Replaced Paula SALMIKANGAS as of May 2014

⁷ Nominated as of April 2014

⁸ Switch of roles of member and alternate as of January 2014

⁹ Switch of roles of member and alternate as of January 2014

¹⁰ Nominated from his former position of Alternate as of August 2014

¹¹ Nominated as of August 2014

¹² Reynir ARNGRIMSSON resigned as of June 2014

- Paolo GASPARINI (Italy) Alternate: Luca SANGIORGI¹³
- Una RIEKSTINA¹⁴ (Latvia) Alternate: Aija LINĒ
- Johannes H. OVELGÖNNE (The Netherlands) Alternate: *Awaiting nomination*
- Marit HYSTAD (Norway) Alternate: Rune KJEKEN
- Dariusz ŚLADOWSKI (Poland) Alternate: Anna CIEŚLIK
- Simona BADOI (Romania) Alternate: Gianina-Nicoleta ANDREI
- Mikuláš HRUBIŠKO (Slovakia) Alternate: Ján KYSELOVIČ
- Metoda LIPNIK-STANGELJ (Slovenia) Alternate: Nevenka TRŠINAR
- Lennart ÅKERBLOM (Sweden) Alternate: Björn CARLSSON
- Elaine FRENCH¹⁵ (United Kingdom) Alternate: James MCBLANE

Members representing clinicians nominated by the European Commission

- Petrus DOEVENDANS Alternate: Esteve TRIAS-ADROHER
- Bernd GÄNSBACHER Alternate: Ramadan JASHARI

Members representing patients' organisations nominated by the European Commission

- Kieran BREEN Alternate: Mariëtte DRIESSENS
- Michele LIPUCCI DI PAOLA Alternate: *Awaiting nomination*¹⁶

Observers

- Karl-Heinz BUCHHEIT (EDQM)

¹³ Termination of mandate of Giulio COSSU as of January 2014, nominated as of December 2014

¹⁴ Replaced Jānis ANCANS as of April 2014

¹⁵ Nominated as of January 2014

¹⁶ Termination of mandate as of January 2014

Annex 8 – Members of the Paediatric Committee

Chair: Dirk MENTZER

EMA contact: Anthony HUMPHREYS

Members nominated from within the CHMP

- Agnes GYURASICS (Hungary) Alternate: Melinda SOBOR
- Romaldas MACIULAITIS (Lithuania) Alternate: Rugile PILVINIENE
- Carine DE BEAUFORT (Luxembourg) Alternate: Jacqueline GENOUX-HAMES
- Dana Gabriela MARIN (Roumania) Alternate: Nela VILCEANU

Members

- Karl-Heinz HUEMER (Austria) Alternate: Christoph MALE
- Koenraad NORGA (Belgium) (*Vice-chair*) Alternate: Jacqueline CARLEER
- Violeta IOTOVA (Bulgaria) Alternate: Vessela BOUDINOVA
- Marina DIMOV DI GIUSTI (Croatia) Alternate: Bernard KAIC
- Georgios SAVVA (Cyprus) Alternate: Andreas TELOUDES¹
- Jaroslav STERBA (Czech Republic)² Alternate: Peter SZITANYI³
- Marianne ORHOLM (Denmark) Alternate: Marta GRANSTROM
- Irja LUTSAR (Estonia) Alternate: Jana LASS
- Ann Marie KAUKONEN (Finland)⁴ Alternate: Maija PIHLAJAMAKI⁵
- Sylvie BENCHETRIT (France) Alternate: *Awaiting nomination*
- Birka LEHMANN (Germany) Alternate: Immanuel BARTH
- Grigorios MELAS (Greece)⁶ Alternate: Stefanos MANTAGOS⁷
- Gylfi OSKARSSON (Iceland) Alternate: *Awaiting nomination*⁸
- Brian AYLWARD (Ireland)⁹ Alternate: *Awaiting nomination*¹⁰
- Paolo ROSSI (Italy) Alternate: Francesca ROCCHI
- Dina APELE-FREIMANE (Latvia) Alternate: Kristine SUPE¹¹
- John Joseph BORG (Malta) Alternate: Herbert LENICKER
- Hendrik VAN DEN BERG (Netherlands) Alternate: Maaike VAN DARTEL

¹ Replaced Stefanos CHRISTODOULOU as of February 2014

² Replaced Peter SZITANYI as of October 2014 (also member until May 2014)

³ Replaced Martina FERTEK as of October 2014 (also alternate until May 2014)

⁴ Replaced Pirjo LAITINEN-PARKKONEN as of November 2014

⁵ Replaced Ann Marie KAUKONEN as of November 2014

⁶ Replaced Stefanos MANTAGOS as of April 2014

⁷ Nominated as of April 2014

⁸ Mandate of Kolbeinn GUDMUNDSSON expired as of December 2014

⁹ Replaced Kevin CONNOLLY as of October 2014

¹⁰ Brian AYLWARD became a member as of October 2014

¹¹ Nominated as of May 2014

- Siri WANG (Norway) Alternate: Ine BLANKENBERG SKOTTHEIM RUSTEN
- Marek MIGDAL (Poland) Alternate: Jolanta WITKOWSKA-OZOGOWSKA
- Helena FONSECA (Portugal) Alternate: Hugo TAVARES
- Michaela MECIAKOVA (Slovakia)¹² Alternate: Karol KRALINSKY¹³
- Stefan GROSEK (Slovenia) Alternate: *Awaiting nomination*¹⁴
- Fernando DE ANDRES TRELLES (Spain) Alternate: Maria Jesus FERNANDES CORTIZO
- Ninna GULLBERG (Sweden)¹⁵ Alternate: Anna-Karin HAMBERG¹⁶
- Angeliki SIAPKARA (United Kingdom)¹⁷ Alternate: Martina RIEGL¹⁸

Members representing healthcare professionals nominated by the European Commission

- Antje NEUBERT¹⁹ Alternate: Paolo PAOLUCCI
- Riccardo RICCARDI²⁰ Alternate: Maria Grazia VALSECCHI²¹
- Johannes TAMINIAU²² Alternate: Doina PLESCA²³

Members representing patients' organisations nominated by the European Commission

- Günter Karl-Heinz AUERSWALD²⁴ Alternate: Paola BAIARDI²⁵
- Michal ODERMARSKY Alternate: Milena STEVANOVIC
- Tsveta SCHYNS-LIHARSKA Alternate: Kerry LEESON-BEEVERS²⁶

¹² Nominated as of February 2014

¹³ Nominated as of February 2014

¹⁴ Tadej AVČIN resigned as of January 2014

¹⁵ Replaced Viveca Lena ODLIND as of December 2014

¹⁶ Replaced Ninna GULLBERG as of December 2014

¹⁷ Replaced Julia DUNNE as of February 2014

¹⁸ Replaced Angeliki SIAPKARA as of February 2014

¹⁹ Replaced Adriana CECI as of August 2014

²⁰ Replaced Jean-Pierre ABOULKER as of August 2014

²¹ Replaced Alexandra COMPAGNUCCI as of August 2014

²² Replaced Anthony NUNN as of August 2014

²³ Nominated as of August 2014

²⁴ Replaced Matthias KELLER as of August 2014

²⁵ Replaced Gerlind BODE as of August 2014

²⁶ Replaced Gerard NGUYEN as of August 2014

Annex 9 – Working parties and working groups

1. Committee for Medicinal Products for Human Use (CHMP)

CHMP standing working parties

- Healthcare Professionals' Working Party
- Biologics Working Party
- Patients' and Consumers' Working Party
- Quality Working Party
- Safety Working Party
- Scientific Advice Working Party

CHMP temporary working parties

- Biosimilar Medicinal Products Working Party
- Biostatistics Working Party
- Blood Products Working Party
- Cardiovascular Working Party
- Central Nervous System Working Party
- Infectious Diseases Working Party
- Oncology Working Party
- Pharmacogenomics Working Party
- Pharmacokinetics Working Party
- Rheumatology/Immunology Working Party
- Vaccines Working Party

Drafting groups

- Gastroenterology Drafting Group
- Radiopharmaceuticals Drafting Group

CHMP scientific advisory groups

- Scientific Advisory Group on Cardiovascular Issues
- Scientific Advisory Group on Anti-infectives
- Scientific Advisory Group on Diabetes/Endocrinology
- Scientific Advisory Group on HIV / Viral Diseases
- Scientific Advisory Group on Neurology

- Inter-Committee Scientific Advisory Group on Oncology
- Scientific Advisory Group on Psychiatry
- Scientific Advisory Group on Vaccines

Other CHMP-associated groups

- (Invented) Name Review Group
- Working Group on Quality Review of Documents
- Expert Group on the Application of the 3Rs in the Development of Medicinal Products
- Active Substance Master File Working Group
- Geriatric Expert Group
- Summary of Product Characteristics Advisory Group
- Modelling and Simulation Working Group
- Coordination Group
- Guidelines Consistency Group
- Good Manufacturing Practice Inspection Service Group
- Good Clinical Practice Inspection Service Group
- Good Laboratory Practice Inspection Service Group

2. Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP working parties

- Antimicrobials Working Party
- Efficacy Working Party
- Environmental Risk Assessment Working Party
- Immunologicals Working Party
- Quality Working Party
- Pharmacovigilance Working Party
- Safety Working Party
- Scientific Advice Working Party

CVMP scientific advisory group

- Inter-Committee Scientific Advisory Group on Oncology

Other CVMP-associated groups

- Ad Hoc Group on Veterinary Novel Therapies (ADVENT)
- Working Group on Quality Review of Documents

- Expert Group on the Application of the 3Rs in the Development of Medicinal Products
- Active Substance Master File Working Group
- Good Manufacturing Practice Inspection Services Group.

3. Committee for Orphan Medicinal Products (COMP)

COMP working party

- Patients' and Consumers' Working Party

COMP scientific advisory

- Inter-Committee Scientific Advisory Group on Oncology

4. Committee on Herbal Medicinal Products (HMPC)

HMPC working parties

- Working Party on European Union Monographs and European Union List
- Patients' and Consumers' Working Party

HMPC temporary drafting groups

- Organisational Matters Drafting Group
- Quality Drafting Group

HMPC scientific advisory

- Inter-Committee Scientific Advisory Group on Oncology

Other HMPC-associated groups

- Good Manufacturing Practice Inspection Services Group

5. Paediatric Committee (PDCO)

PDCO working groups

- Formulation Working Group
- Non-clinical Working Group
- Modelling and Simulation Working Group

PDCO scientific advisory group

- Inter-Committee Scientific Advisory Group on Oncology

6. Committee for Advanced Therapies (CAT)

CAT associated group

- European Medicines Agency / CAT and Medical Devices' Notified Body Collaboration Group

CAT scientific advisory group

- Inter-Committee Scientific Advisory Group on Oncology

Ad-hoc drafting groups whenever needed to develop specific guidance

7. Pharmacovigilance Risk Assessment Committee (PRAC)

8. Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)

9. Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMDv)

Annex 10 – CHMP opinions in 2014 on medicinal products for human use

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

Product <ul style="list-style-type: none"> • Brandname • INN 	Marketing authorisation holder	Therapeutic Area <ul style="list-style-type: none"> • ATC Code • Summary of indication 	EMA/CHMP <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • ANORO • UMECLIDINIUM BROMIDE / VILANTEROL 	Glaxo Group Ltd.	<ul style="list-style-type: none"> • R03A • treatment to of chronic obstructive pulmonary disease (COPD) 	<ul style="list-style-type: none"> • 28/01/2013 • 20/02/2014 • 205 • 182 • STANDARD 	<ul style="list-style-type: none"> • 18/03/2014 • 05/08/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Brimica Genuair • ACLIDINIUM BROMIDE / FORMOTEROL FUMARATE DIHYDRATE 	Almirall S.A	<ul style="list-style-type: none"> • R03AL • treatment of chronic obstructive pulmonary disease (COPD) 	<ul style="list-style-type: none"> • 24/02/2014 • 25/09/2014 • 116 • 97 • STANDARD 	<ul style="list-style-type: none"> • 01/10/2014 • 19/11/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Clopidogrel/Acetylsalicylic acid Teva • CLOPIDOGREL / ACETYLSALICYLIC ACID 	Teva Pharma B.V.	<ul style="list-style-type: none"> • B01AC30 • indicated for the prevention of atherothrombotic events 	<ul style="list-style-type: none"> • 05/08/2013 • 26/06/2014 • 212 • 98 • STANDARD 	<ul style="list-style-type: none"> • 27/06/2014 • 09/01/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Cosentyx • SECUKINUMAB 	Novartis Europharm Ltd	<ul style="list-style-type: none"> • L04AC10 • treatment of plaque psoriasis 	<ul style="list-style-type: none"> • 20/11/2013 • 20/11/2014 • 213 • 153 • STANDARD 	<ul style="list-style-type: none"> • 25/11/2014 • 15/01/2015
<ul style="list-style-type: none"> • Daklinza • DACLATASVIR 	Bristol-Myers Squibb Pharma EEIG	<ul style="list-style-type: none"> • J05AX • treatment of chronic hepatitis C virus • treatment of chronic hepatitis C virus (HCV) 	<ul style="list-style-type: none"> • 26/12/2013 • 26/06/2014 • 152 (** Acc) • 31 • STANDARD 	<ul style="list-style-type: none"> • 03/07/2014 • 22/08/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Duaklir Genuair • ACLIDINIUM BROMIDE / FORMOTEROL 	Almirall S.A	<ul style="list-style-type: none"> • R03AL • treatment of chronic obstructive pulmonary disease (COPD) 	<ul style="list-style-type: none"> • 20/11/2013 • 25/09/2014 • 213 • 97 • STANDARD 	<ul style="list-style-type: none"> • 01/10/2014 • 19/11/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Duavive • ESTROGENS CONJUGATED / BAZEDOXIFENE 	Pfizer Limited	<ul style="list-style-type: none"> • G03CX • treatment of oestrogen deficiency and osteoporosis 	<ul style="list-style-type: none"> • 16/07/2012 • 23/10/2014 • 201 • 624 • STANDARD 	<ul style="list-style-type: none"> • 29/10/2014 • 16/12/2014
<ul style="list-style-type: none"> • Egranli • BALUGRASTIM 	Teva Pharma B.V.	<ul style="list-style-type: none"> • L03AA • treatment of neutropenia 	<ul style="list-style-type: none"> • 21/05/2013 • 25/09/2014 • 213 • 279 • STANDARD 	<ul style="list-style-type: none"> • 02/10/2014 • .

Product	Marketing authorisation holder	Therapeutic Area	EMA/CHMP	European Commission
<ul style="list-style-type: none"> • Brandname • INN 		<ul style="list-style-type: none"> • ATC Code • Summary of indication 	<ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) 	<ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • Entyvio • VEDOLIZUMAB 	Takeda Pharma A/S	<ul style="list-style-type: none"> • L04AA • treatment of Ulcerative Colitis and Crohn's Disease 	<ul style="list-style-type: none"> • 27/03/2013 • 20/03/2014 • 210 • 149 • STANDARD 	<ul style="list-style-type: none"> • 25/03/2014 • 22/05/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Eperzan • ALBIGLUTIDE 	GlaxoSmithKline Trading Services	<ul style="list-style-type: none"> • A10BX • treatment of type 2 diabetes mellitus 	<ul style="list-style-type: none"> • 27/03/2013 • 23/01/2014 • 213 • 90 • STANDARD 	<ul style="list-style-type: none"> • 29/01/2014 • 21/03/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Exviera • DASABUVIR 	AbbVie Ltd.	<ul style="list-style-type: none"> • J05 • treatment of chronic hepatitis C 	<ul style="list-style-type: none"> • 26/05/2014 • 20/11/2014 • 152 (** Acc) • 25 • STANDARD 	<ul style="list-style-type: none"> • 27/11/2014 • 15/01/2015
<ul style="list-style-type: none"> • Harvoni • SOFOSBUVIR / LEDIPASVIR 	Gilead Sciences International Ltd	<ul style="list-style-type: none"> • J05 • treatment of chronic hepatitis C 	<ul style="list-style-type: none"> • 25/03/2014 • 25/09/2014 • 152 (** Acc) • 32 • STANDARD 	<ul style="list-style-type: none"> • 01/10/2014 • 17/11/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Hemangioli¹ • PROPRANOLOL 	PIERRE FABRE DERMATOLOGIE	<ul style="list-style-type: none"> • C07AA05 • treatment of proliferating infantile haemangioma 	<ul style="list-style-type: none"> • 26/03/2013 • 20/02/2014 • 213 • 118 • STANDARD 	<ul style="list-style-type: none"> • . • 23/04/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Incruse • UMECLIDINIUM BROMIDE 	Glaxo Group Ltd	<ul style="list-style-type: none"> • R03 • treatment of symptoms in adult patients with chronic obstructive pulmonary disease (COPD). 	<ul style="list-style-type: none"> • 22/05/2013 • 20/02/2014 • 204 • 71 • STANDARD 	<ul style="list-style-type: none"> • 28/02/2014 • 28/04/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Jardiance • EMPAGLIFLOZIN 	Boehringer Ingelheim International GmbH	<ul style="list-style-type: none"> • A10B • treatment of type II diabetes mellitus 	<ul style="list-style-type: none"> • 25/03/2013 • 20/03/2014 • 213 • 146 • STANDARD 	<ul style="list-style-type: none"> • 26/03/2014 • 22/05/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Latuda • LURASIDONE 	Takeda Pharma A/S	<ul style="list-style-type: none"> • N05AE05 • treatment of schizophrenia 	<ul style="list-style-type: none"> • 23/10/2012 • 23/01/2014 • 210 • 244 • STANDARD 	<ul style="list-style-type: none"> • 29/01/2014 • 21/03/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Laventair • UMECLIDINIUM BROMIDE / VILANTEROL 	Glaxo Group Ltd	<ul style="list-style-type: none"> • R03A • treatment to of chronic obstructive pulmonary disease (COPD) 	<ul style="list-style-type: none"> • 26/03/2013 • 20/02/2014 • 149 • 182 • STANDARD 	<ul style="list-style-type: none"> • 19/03/2014 • 05/08/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Lymphoseek • TILMANOCEPT 	Navidea Biopharmaceuticals Limited	<ul style="list-style-type: none"> • V09IA09 • used in the delineation and localisation of lymph nodes 	<ul style="list-style-type: none"> • 14/01/2013 • 25/09/2014 • 213 • 391 • STANDARD 	<ul style="list-style-type: none"> • 02/10/2014 • 19/11/2014 • 25/04/2014 • C123

Product	Marketing authorisation holder	Therapeutic Area	EMA/CHMP	European Commission
<ul style="list-style-type: none"> • Brandname • INN 		<ul style="list-style-type: none"> • ATC Code • Summary of indication 	<ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) 	<ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • Mekinist • TRAMETINIB 	Glaxo Group Ltd	<ul style="list-style-type: none"> • L01XE25 • treatment of unresectable or metastatic melanoma with a BRAF V600 mutation 	<ul style="list-style-type: none"> • 27/02/2013 • 25/04/2014 • 210 • 205 • STANDARD 	<ul style="list-style-type: none"> • . • 30/06/2014 • 31/05/2013 • C154
<ul style="list-style-type: none"> • Moventig • NALOXEGOL 	AstraZeneca AB	<ul style="list-style-type: none"> • A06AH03 • treatment of opioid-induced constipation (OIC) 	<ul style="list-style-type: none"> • 24/09/2013 • 25/09/2014 • 213 • 153 • STANDARD 	<ul style="list-style-type: none"> • 06/10/2014 • 12/08/2014
<ul style="list-style-type: none"> • Mysimba • NALTREXONE / BUPROPION 	Orexigen Therapeutics Ireland Limited	<ul style="list-style-type: none"> • A08AA • indicated for the management of obesity 	<ul style="list-style-type: none"> • 23/10/2013 • 18/12/2014 • 213 • 209 • STANDARD 	<ul style="list-style-type: none"> • 06/01/2015 • .
<ul style="list-style-type: none"> • Nuwiq • SIMOCTOCOG ALFA 	Octapharma AB	<ul style="list-style-type: none"> • B02BD02 • treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). (congenital factor VIII deficiency). 	<ul style="list-style-type: none"> • 21/06/2013 • 22/05/2014 • 213 • 118 • STANDARD 	<ul style="list-style-type: none"> • 04/06/2014 • 30/09/2014
<ul style="list-style-type: none"> • OLYSIO • SIMEPREVIR 	Janssen-Cilag International N.V.	<ul style="list-style-type: none"> • J05AE • treatment of chronic hepatitis C (CHC) genotype 1 or genotype 4 infection 	<ul style="list-style-type: none"> • 21/05/2013 • 20/03/2014 • 213 • 90 • STANDARD 	<ul style="list-style-type: none"> • 24/03/2014 • 14/05/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Otezla • APREMILAST 	Celgene Europe Limited	<ul style="list-style-type: none"> • L04AA32 • treatment of psoriatic arthritis, psoriasis 	<ul style="list-style-type: none"> • 13/12/2013 • 20/11/2014 • 213 • 117 • STANDARD 	<ul style="list-style-type: none"> • 26/11/2014 • 15/01/2015
<ul style="list-style-type: none"> • Plegridy • PEGINTERFERO N BETA-1A 	Biogen Idec Ltd	<ul style="list-style-type: none"> • L03AB • treatment of relapsing multiple sclerosis 	<ul style="list-style-type: none"> • 25/06/2013 • 22/05/2014 • 213 • 118 • STANDARD 	<ul style="list-style-type: none"> • 02/06/2014 • 18/07/2014 • 29/08/2014 • C290

Product	Marketing authorisation holder	Therapeutic Area	EMA/CHMP	European Commission
<ul style="list-style-type: none"> • Brandname • INN 		<ul style="list-style-type: none"> • ATC Code • Summary of indication 	<ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) 	<ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • Rezolsta • DARUNAVIR / COBICISTAT 	Janssen-Cilag International N.V.	<ul style="list-style-type: none"> • J05AR • treatment of HIV immunodeficiency virus (HIV-1) in <input type="checkbox"/> antiretroviral therapy (ART) naive adults. <input type="checkbox"/> ART-experienced adults with no darunavir resistance associated mutations (DRV-RAMs) and who have plasma HIV-1 RNA < 100,000 copies/ml and CD4+ cell count ≥ 1 	<ul style="list-style-type: none"> • 21/10/2013 • 25/09/2014 • 213 • 125 • STANDARD 	<ul style="list-style-type: none"> • 02/10/2014 • 19/11/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Rixubis • Nonacog gamma 	Baxter Innovations GmbH	<ul style="list-style-type: none"> • B02BD04 • treatment of haemophilia B 	<ul style="list-style-type: none"> • 13/11/2013 • 23/10/2014 • 204 • 134 • STANDARD 	<ul style="list-style-type: none"> • 30/10/2014 • 19/12/2014
<ul style="list-style-type: none"> • Senshio • OSPEMIFENE 	Shionogi Limited	<ul style="list-style-type: none"> • G03XC05 • treatment of vulvar and vaginal atrophy (VVA) 	<ul style="list-style-type: none"> • 25/03/2013 • 20/11/2014 • 213 • 391 • STANDARD 	<ul style="list-style-type: none"> • 26/11/2014 • 15/01/2015
<ul style="list-style-type: none"> • SIMBRINZA • BRINZOLAMIDE / BRIMONIDINE 	Alcon Laboratories (UK) Ltd	<ul style="list-style-type: none"> • S01 • Treatment of open-angle glaucoma or ocular hypertension. 	<ul style="list-style-type: none"> • 22/07/2013 • 22/05/2014 • 204 • 99 • STANDARD 	<ul style="list-style-type: none"> • 12/06/2014 • 18/07/2014 • 29/08/2014 • C290
<ul style="list-style-type: none"> • Triumeq • DOLUTEGRAVIR / ABACAVIR / LAMIVUDINE 	ViiV Healthcare Uk Limited	<ul style="list-style-type: none"> • J05AR • treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40 kg 	<ul style="list-style-type: none"> • 20/11/2013 • 26/06/2014 • 182 • 37 • STANDARD 	<ul style="list-style-type: none"> • 09/07/2014 • 09/01/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Trulicity • DULAGLUTIDE 	Eli Lilly Nederland B.V.	<ul style="list-style-type: none"> • A10 • treatment of type 2 diabetes mellitus 	<ul style="list-style-type: none"> • 23/10/2013 • 25/09/2014 • 213 • 125 • STANDARD 	<ul style="list-style-type: none"> • 09/10/2014 • 21/11/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Vargatef • NINTEDANIB 	Boehringer Ingelheim International GmbH	<ul style="list-style-type: none"> • L01XE • treatment of non-small cell lung cancer (NSCLC) 	<ul style="list-style-type: none"> • 22/10/2013 • 25/09/2014 • 213 • 125 • STANDARD 	<ul style="list-style-type: none"> • 06/10/2014 • 21/11/2014 • 25/04/2014 • C123

Product	Marketing authorisation holder	Therapeutic Area	EMA/CHMP	European Commission
<ul style="list-style-type: none"> • Brandname • INN 		<ul style="list-style-type: none"> • ATC Code • Summary of indication 	<ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) 	<ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • Velporo • MIXTURE OF POLYNUCLEAR IRON(III)-OXYHYDROXIDE, SUCROSE AND STARCHES 	Vifor Fresenius Medical Care Renal Pharma France	<ul style="list-style-type: none"> • V03AE05 • is indicated for the control of serum phosphorus levels in patients with end-stage renal disease (ESRD) 	<ul style="list-style-type: none"> • 30/01/2013 • 26/06/2014 • 211 • 302 • STANDARD 	<ul style="list-style-type: none"> • 04/07/2014 • 26/08/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Viekirax • OMBITASVIR / PARITAPREVIR / RITONAVIR 	AbbVie Ltd.	<ul style="list-style-type: none"> • J05 • treatment of chronic hepatitis C 	<ul style="list-style-type: none"> • 27/05/2014 • 20/11/2014 • 152 (** Acc) • 25 • STANDARD 	<ul style="list-style-type: none"> • 26/11/2014 • 15/01/2015
<ul style="list-style-type: none"> • VIZAMYL • FLUTEMETAMOL (18F) 	GE Healthcare Ltd	<ul style="list-style-type: none"> • V09AX04 • indicated for the visual detection of amyloid-beta neuritic plaques in the brains 	<ul style="list-style-type: none"> • 26/12/2012 • 26/06/2014 • 213 • 335 • STANDARD 	<ul style="list-style-type: none"> • . • 22/08/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Vokanamet • CANAGLIFLOZIN / METFORMIN 	Janssen-Cilag International N.V.	<ul style="list-style-type: none"> • A10BD • treatment of type 2 diabetes mellitus 	<ul style="list-style-type: none"> • 27/03/2013 • 20/02/2014 • 213 • 118 • STANDARD 	<ul style="list-style-type: none"> • 24/02/2014 • 23/04/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Xadago • SAFINAMIDE 	Zambon SpA	<ul style="list-style-type: none"> • N04B • treatment of Parkinson's disease (PD) 	<ul style="list-style-type: none"> • 20/12/2013 • 18/12/2014 • 204 • 154 • STANDARD 	<ul style="list-style-type: none"> • . • .
<ul style="list-style-type: none"> • Xultophy • INSULIN DEGLUDEC / LIRAGLUTIDE 	Novo Nordisk A/S	<ul style="list-style-type: none"> • A10 • treatment of type 2 diabetes mellitus 	<ul style="list-style-type: none"> • 19/06/2013 • 24/07/2014 • 204 • 190 • STANDARD 	<ul style="list-style-type: none"> • . • 18/09/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Xydalba • DALBAVANCIN 	Durata Therapeutics International B.V.	<ul style="list-style-type: none"> • J01XA04 • treatment of acute bacterial skin and skin structure infections (ABSSSI) 	<ul style="list-style-type: none"> • 26/12/2013 • 18/12/2014 • 213 • 145 • STANDARD 	<ul style="list-style-type: none"> • 05/01/2015 • 19/02/2015
<ul style="list-style-type: none"> • Zontivity • VORAPAXAR 	Merck Sharp & Dohme Limited	<ul style="list-style-type: none"> • B01 • indicated for the reduction of atherothrombotic events 	<ul style="list-style-type: none"> • 26/12/2013 • 20/11/2014 • 213 • 117 • STANDARD 	<ul style="list-style-type: none"> • 25/11/2014 • 19/01/2015
<ul style="list-style-type: none"> • Zydelig • IDELALISIB 	Gilead Sciences International Ltd	<ul style="list-style-type: none"> • L01XX • treatment of chronic lymphocytic leukaemia (CLL) and refractory indolent non-Hodgkin lymphoma (iNHL). 	<ul style="list-style-type: none"> • 19/11/2013 • 24/07/2014 • 204 • 43 • STANDARD 	<ul style="list-style-type: none"> • . • 18/09/2014 • 25/04/2014 • C123

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

¹ Hemangirol was granted a positive opinion for a paediatric-use marketing authorisation (PUMA)

CHMP positive opinions on orphan medicinal products for human use

Product <ul style="list-style-type: none"> • Brandname • INN 	Marketing authorisation holder	Therapeutic Area <ul style="list-style-type: none"> • ATC Code • Summary of indication 	EMA/CHMP <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • Adempas • RIOCIQUAT 	Bayer Pharma AG	<ul style="list-style-type: none"> • C02KX • treatment of Chronic thromboembolic pulmonary hypertension (CTEPH) and Pulmonary arterial hypertension (PAH) 	<ul style="list-style-type: none"> • 27/02/2013 • 23/01/2014 • 213 • 118 • STANDARD 	<ul style="list-style-type: none"> • 03/02/2014 • 27/03/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Cerdelga • ELIGLUSTAT 	Genzyme Europe BV	<ul style="list-style-type: none"> • A16AX10 • treatment of Gaucher disease type 1 	<ul style="list-style-type: none"> • 23/10/2013 • 20/11/2014 • 213 • 181 • STANDARD 	<ul style="list-style-type: none"> • 28/11/2014 • 19/01/2015
<ul style="list-style-type: none"> • CYRAMZA • RAMUCIRUMAB 	Eli Lilly Nederland B.V.	<ul style="list-style-type: none"> • L01XC • treatment of gastric cancer 	<ul style="list-style-type: none"> • 24/09/2013 • 25/09/2014 • 213 • 153 • STANDARD 	<ul style="list-style-type: none"> • 01/10/2014 • 19/12/2014
<ul style="list-style-type: none"> • Folcepri • Etarfolatide 	Endocyte Europe, B.V.	<ul style="list-style-type: none"> • V09 • indicated for single photon emission computed tomography (SPECT) imaging 	<ul style="list-style-type: none"> • 21/11/2012 • 20/03/2014 • 210 • 275 • CONDITIONAL 	<ul style="list-style-type: none"> • 22/03/2014 • .
<ul style="list-style-type: none"> • Gazyvaro • OBINUTUZUMAB 	Roche Registration Ltd	<ul style="list-style-type: none"> • L01XC15 • Treatment of chronic lymphocytic leukaemia 	<ul style="list-style-type: none"> • 20/05/2013 • 22/05/2014 • 204 • 162 • STANDARD 	<ul style="list-style-type: none"> • 28/05/2014 • 23/07/2014 • 29/08/2014 • C290
<ul style="list-style-type: none"> • Holoclar¹ • EX VIVO EXPANDED AUTOLOGOUS HUMAN CORNEAL EPITHELIAL CELLS CONTAINING STEM CELLS 	Chiesi Farmaceutici S.p.A.	<ul style="list-style-type: none"> • S01XA19 • treatment of limbal stem cell deficiency 	<ul style="list-style-type: none"> • 27/03/2013 • 18/12/2014 • 208 • 424 • CONDITIONAL 	<ul style="list-style-type: none"> • 23/12/2014 • 17/02/2015
<ul style="list-style-type: none"> • Imbruvica • IBRUTINIB 	Janssen-Cilag International NV	<ul style="list-style-type: none"> • L01XE • treatment of mantle cell lymphoma, chronic lymphocytic leukemia, small lymphocytic lymphoma 	<ul style="list-style-type: none"> • 18/11/2013 • 24/07/2014 • 204 • 43 • STANDARD 	<ul style="list-style-type: none"> • . • 21/10/2014 • 31/05/2013 • C154
<ul style="list-style-type: none"> • Ketoconazole HRA² • KETOCONAZOLE 	Laboratoire HRA Pharma	<ul style="list-style-type: none"> • J02AB02 • treatment of Cushing's syndrome 	<ul style="list-style-type: none"> • 26/02/2014 • 25/09/2014 • 152 (** Acc) • 60 • STANDARD 	<ul style="list-style-type: none"> • 02/10/2014 • 19/11/2014 • 25/04/2014 • C123

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Opinion • Active Time • Clock stop • Type of MA (*)	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Lynparza • OLAPARIB	AstraZeneca AB	• L01 • treatment of ovarian cancer	• 25/09/2013 • 23/10/2014 • 204 • 190 • STANDARD	• 29/10/2014 • 16/12/2014
• Neocepri • FOLIC ACID	Endocyte Europe, B.V.	• V04 • indicated for the enhancement of Folcepri single photon emission computed tomography (SPECT) image quality.	• 21/11/2012 • 20/03/2014 • 210 • 275 • CONDITIONAL	• 26/03/2014 • .
• OFEV • NINTEDANIB	Boehringer Ingelheim Pharma GmbH & Co. KG	• L01XE • treatment of Idiopathic Pulmonary Fibrosis (IPF)	• 28/05/2014 • 20/11/2014 • 152 (** Acc) • 25 • STANDARD	• 27/11/2014 • 15/01/2015
• Quinsair ³ • LEVOFLOXACIN	Aptalis Pharma SAS	• J01MA12 • indicated for chronic pulmonary infections	• 26/12/2013 • 18/12/2014 • 204 • 154 • STANDARD	• . • .
• SCENESSE • AFAMELANOTID E	Clinuvel (UK) Limited	• D02BB02 • treatment of phototoxicity	• 22/02/2012 • 23/10/2014 • 210 • 743 • EXCEPTIONAL	• 30/10/2014 • 22/12/2014
• SYLVANT • SILTUXIMAB	Janssen-Cilag International NV	• L04AC • treatment of multicentric Castleman's disease (MCD)	• 25/09/2013 • 20/03/2014 • 152 (** Acc) • 25 • STANDARD	• 31/03/2014 • 22/05/2014 • 25/04/2014 • C123
• Vimizim • ELOSULFASE ALFA	BioMarin Europe Ltd	• A16AB • Treatment of mucopolysaccharidos is	• 21/05/2013 • 20/02/2014 • 213 • 62 • STANDARD	• 28/02/2014 • 28/04/2014 • 25/04/2014 • C123
• Vynfinit • Vintafolide	Endocyte Europe, B.V.	• L01 • treatment of platinum resistant ovarian cancer (PROC)	• 21/11/2012 • 20/03/2014 • 210 • 275 • CONDITIONAL	• 26/03/2014 • .

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

¹ Holoclar is also an advanced therapy medicinal product.

² Ketoconazole HRA is a "well-established use" medicinal product.

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

Product	Marketing authorisation holder	Therapeutic Area	EMA/CHMP	European Commission
<ul style="list-style-type: none"> • Brandname • INN 		<ul style="list-style-type: none"> • ATC Code • Summary of indication 	<ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) 	<ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • BiResp Spiromax • BUDESONIDE / FORMOTEROL 	Teva Pharma B.V.	<ul style="list-style-type: none"> • R03AK07 • treatment of asthma and COPD 	<ul style="list-style-type: none"> • 19/12/2013 • 20/02/2014 • 32 • 31 • STANDARD 	<ul style="list-style-type: none"> • 24/02/2014 • 28/04/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Budesonide/Formoterol Teva • BUDESONIDE / FORMOTEROL 	Teva Pharma B.V.	<ul style="list-style-type: none"> • R03AK07 • treatment of asthma and chronic obstructive pulmonary disease (COPD) 	<ul style="list-style-type: none"> • 26/03/2014 • 25/09/2014 • 154 • 30 • STANDARD 	<ul style="list-style-type: none"> • 03/10/2014 • 19/11/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Budesonide/Formoterol Teva Pharma B.V. • BUDESONIDE / FORMOTEROL 	Teva Pharma B.V.	<ul style="list-style-type: none"> • R03AK07 • treatment of asthma 	<ul style="list-style-type: none"> • 26/03/2014 • 25/09/2014 • 154 • 30 • STANDARD 	<ul style="list-style-type: none"> • 03/10/2014 • 19/11/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Busulfan Fresenius Kabi • BUSULFAN 	FRESENIUS KABI ONCOLOGY PLC	<ul style="list-style-type: none"> • L01AB01 • conditioning prior to conventional haematopoietic progenitor cell transplantation (HPCT) 	<ul style="list-style-type: none"> • 21/08/2013 • 24/07/2014 • 213 • 125 • STANDARD 	<ul style="list-style-type: none"> • 27/08/2014 • 22/09/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Clopidogrel ratiopharm • CLOPIDOGREL 	Teva Pharma B.V.	<ul style="list-style-type: none"> • B01AC04 • prevention of myocardial infarction and acute coronary syndrome Myocardial infarction, ischaemic stroke, peripheral arterial disease, acute coronary syndrome, prevention of atherothrombotic and thromboembolic events in atrial fibrillation Myocardial infar 	<ul style="list-style-type: none"> • 23/07/2014 • 18/12/2014 • 114 • 31 • STANDARD 	<ul style="list-style-type: none"> • 09/01/2015 • 19/02/2015
<ul style="list-style-type: none"> • Duloxetine Lilly • DULOXETINE 	Eli Lilly Nederland B.V.	<ul style="list-style-type: none"> • N06AX21 • treatment of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder 	<ul style="list-style-type: none"> • 23/05/2014 • 23/10/2014 • 122 • 30 • STANDARD 	<ul style="list-style-type: none"> • 28/10/2014 • 12/08/2014
<ul style="list-style-type: none"> • DuoResp Spiromax • BUDESONIDE / FORMOTEROL 	Teva Pharma B.V.	<ul style="list-style-type: none"> • R03AK07 • treatment of asthma and COPD 	<ul style="list-style-type: none"> • 25/02/2013 • 20/02/2014 • 213 • 118 • STANDARD 	<ul style="list-style-type: none"> • 24/02/2014 • 28/04/2014 • 25/04/2014 • C123

Product <ul style="list-style-type: none"> • Brandname • INN 	Marketing authorisation holder	Therapeutic Area <ul style="list-style-type: none"> • ATC Code • Summary of indication 	EMA/CHMP <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • Ebilfumin • OSELTAMIVIR 	Actavis Group PTC ehf	<ul style="list-style-type: none"> • J05AH02 • 1) Treatment of influenza in patients one year of age and older who present with symptoms typical of influenza, when influenza virus is circulating in the community. 2) Treatment of infants less than 1 year of age during a pandemic influenza outbreak. 3) 	<ul style="list-style-type: none"> • 21/05/2013 • 20/03/2014 • 204 • 99 • STANDARD 	<ul style="list-style-type: none"> • 01/04/2014 • 22/05/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Envarsus • TACROLIMUS 	Chiesi Farmaceutici S.p.A.	<ul style="list-style-type: none"> • L04AD02 • indicated for the prophylaxis of transplant rejection in adult kidney allograft recipients. 	<ul style="list-style-type: none"> • 22/05/2013 • 22/05/2014 • 213 • 153 • STANDARD 	<ul style="list-style-type: none"> • 28/05/2014 • 18/07/2014 • 29/08/2014 • C290
<ul style="list-style-type: none"> • Paliperidone Janssen • PALIPERIDONE 	Janssen-Cilag International NV	<ul style="list-style-type: none"> • N05AX13 • treatment of schizophrenia 	<ul style="list-style-type: none"> • 22/08/2014 • 23/10/2014 • 61 • 0 • STANDARD 	<ul style="list-style-type: none"> • 29/10/2014 • 12/05/2014
<ul style="list-style-type: none"> • Pregabalin Pfizer • PREGABALIN 	Pfizer Limited	<ul style="list-style-type: none"> • N03AX16 • treatment of neuropathic pain, epilepsy and Generalised Anxiety Disorder (GAD) 	<ul style="list-style-type: none"> • 20/12/2013 • 20/02/2014 • 61 • 0 • STANDARD 	<ul style="list-style-type: none"> • 26/02/2014 • 04/10/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Rasagiline ratiopharm • RASAGILINE 	Teva B.V.	<ul style="list-style-type: none"> • N04BD02 • treatment of Parkinson's disease 	<ul style="list-style-type: none"> • 19/09/2014 • 20/11/2014 • 61 • 0 • STANDARD 	<ul style="list-style-type: none"> • 26/11/2014 • 01/12/2015
<ul style="list-style-type: none"> • REVINTY ELLIPTA • FLUTICASONE FUROATE / VILANTEROL 	Glaxo Group Ltd	<ul style="list-style-type: none"> • R03AK • treatment of asthma 	<ul style="list-style-type: none"> • 19/01/2014 • 20/03/2014 • 61 • 0 • STANDARD 	<ul style="list-style-type: none"> • 26/03/2014 • 05/02/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Rivastigmine 3M Health Care Ltd. • RIVASTIGMINE 	3M Health Care Ltd	<ul style="list-style-type: none"> • N06DA03 • Treatment of Alzheimer's dementia. 	<ul style="list-style-type: none"> • 13/11/2013 • 23/01/2014 • 61 • 0 • STANDARD 	<ul style="list-style-type: none"> • 24/01/2014 • 04/03/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Sevelamer carbonate Zentiva • SEVELAMER 	Genzyme Europe BV	<ul style="list-style-type: none"> • V03AE02 • indicated for control of hyperphosphataemia 	<ul style="list-style-type: none"> • 27/07/2014 • 20/11/2014 • 94 • 23 • STANDARD 	<ul style="list-style-type: none"> • 26/11/2014 • 15/01/2015

Product <ul style="list-style-type: none"> • Brandname • INN 	Marketing authorisation holder	Therapeutic Area <ul style="list-style-type: none"> • ATC Code • Summary of indication 	EMA/CHMP <ul style="list-style-type: none"> • Validation • Opinion • Active Time • Clock stop • Type of MA (*) 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision • Notification • Official Journal
<ul style="list-style-type: none"> • Tadalafil Mylan • TADALAFIL 	GENERICS (UK) LIMITED	<ul style="list-style-type: none"> • G04BE08 • treatment of erectile dysfunction 	<ul style="list-style-type: none"> • 26/12/2013 • 25/09/2014 • 182 • 92 • STANDARD 	<ul style="list-style-type: none"> • 06/10/2014 • 21/11/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Tasermity • SEVELAMER 	Genzyme Europe BV	<ul style="list-style-type: none"> • V03AE02 • indicated for control of hyperphosphataemia 	<ul style="list-style-type: none"> • 27/07/2014 • 18/12/2014 • 122 • 23 • STANDARD 	<ul style="list-style-type: none"> • . • .
<ul style="list-style-type: none"> • Ulunar Breezhaler • INDACATEROL/ GLYCOPYRRONIUM BROMIDE 	Novartis Europharm Ltd	<ul style="list-style-type: none"> • R03A • bronchodilator treatment to relieve symptoms in adult treatment of chronic obstructive pulmonary disease (COPD) 	<ul style="list-style-type: none"> • 17/12/2013 • 20/02/2014 • 61 • 0 • STANDARD 	<ul style="list-style-type: none"> • 21/02/2014 • 23/04/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • VANTOBRA • TOBRAMYCIN 	PARI Pharma GmbH	<ul style="list-style-type: none"> • J01GB01 • treatment of chronic pulmonary infection 	<ul style="list-style-type: none"> • 24/10/2012 • 02/06/2014 • 210 • 372 • STANDARD 	<ul style="list-style-type: none"> • 28/01/2015 • .
<ul style="list-style-type: none"> • Vylaer Spiromax • BUDESONIDE / FORMOTEROL 	Teva Pharma B.V.	<ul style="list-style-type: none"> • R03AK07 • treatment of asthma and chronic obstructive pulmonary disease (COPD) 	<ul style="list-style-type: none"> • 26/03/2014 • 25/09/2014 • 154 • 30 • STANDARD 	<ul style="list-style-type: none"> • 02/10/2014 • 19/11/2014 • 25/04/2014 • C123
<ul style="list-style-type: none"> • Zoledronic acid Teva Generics • ZOLEDRONIC ACID 	Teva B.V.	<ul style="list-style-type: none"> • M05BA08 • treatment of osteoporosis and Paget's disease of the bone 	<ul style="list-style-type: none"> • 25/06/2013 • 23/01/2014 • 182 • 30 • STANDARD 	<ul style="list-style-type: none"> • 27/01/2014 • 27/03/2014 • 25/04/2014 • C123

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

(**) Ketoconazole HRA is a "well-established use" product but is included in the orphan medicinal product table.

CHMP positive opinions on similar biological medicinal products for human use

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Opinion • Active Time • Clock stop • Type of MA (*)	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Abasaglar • INSULIN GLARGINE	Eli Lilly Regional Operations GmbH	• A10AE04 • treatment of diabetes mellitus	• 26/06/2013 • 26/06/2014 • 199 • 167 • STANDARD	• 03/07/2014 • 09/09/2014 • 25/04/2014 • C123
• Accofil • FILGRASTIM	Accord Healthcare Ltd	• L03AA02 • indicated for neutropenia reduction in the duration of neutropenia and the incidence of febrile neutropenia	• 15/05/2014 • 24/07/2014 • 61 • 0 • STANDARD	• 11/08/2014 • 18/09/2014 • 25/04/2014 • C123
• Bemfola • FOLLITROPIN ALFA	Finnox Biotech AG	• G03GA05 • treatment of infertility	• 21/11/2012 • 23/01/2014 • 210 • 216 • STANDARD	• 05/02/2014 • 27/03/2014 • 25/04/2014 • C123

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

CHMP positive opinions on advanced therapy medicinal products

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Opinion • Active Time • Clock stop • Type of MA (*)	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Holoclar ¹ • EX VIVO EXPANDED AUTOLOGOUS HUMAN CORNEAL EPITHELIAL CELLS CONTAINING STEM CELLS	Chiesi Farmaceutici S.p.A.	• S01XA19 • treatment of limbal stem cell deficiency	• 27/03/2013 • 18/12/2014 • 208 • 424 • CONDITIONAL	• 23/12/2014 • 17/02/2015

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

¹ Holoclar is also included in the orphan medicinal product table.

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
• Hemoprostol • MISOPROSTOL	Linepharma International Limited	• G02AD • treatment and prevention of Post Partum Haemorrhage.	• 14/08/2012 • 23/01/2014 • 217 • 310

CHMP opinions in 2014 on medicinal products following a re-examination procedure

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Date of 1st opinion • Outcome of 1st opinion • Date of 2nd opinion • Outcome of 2nd opinion • Type of MA (*)	European Commission • Date of decision • Notification • Official Journal
• Translarna ¹ • Ataluren	PTC Therapeutics International Limited	• M09 • treatment of Duchenne muscular dystrophy	• 20/11/2012 • 23/01/2014 • NEGATIVE • 5/22/2014 • POSITIVE • CONDITIONAL	• 31/07/2014 • 8/29/2014 • C290 •
• Masican • MASITINIB	AB Science	• L01XE • treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST)	• 18/07/2012 • 21/11/2013 • NEGATIVE • 3/20/2014 • NEGATIVE	• 07/04/2014
• Masiviera • MASITINIB	AB Science	• L01XE • treatment of non resectable locally advanced or metastatic pancreatic cancer	• 19/09/2012 • 23/01/2014 • NEGATIVE • 5/22/2014 • NEGATIVE	•
• Nerventra • LAQUINIMOD	Teva Pharma GmbH	• N07 • treatment of multiple sclerosis	• 13/07/2012 • 23/01/2014 • NEGATIVE • 5/22/2014 • NEGATIVE	• 19/08/2014
• Reasanz • SERELAXIN	Novartis Europharm Ltd	• C01 • treatment of acute heart failure	• 30/01/2013 • 23/01/2014 • NEGATIVE • 5/22/2014 • NEGATIVE	• 08/05/2014

(*) This indicates whether the medicine was granted a positive opinion for a standard 5-year marketing authorisation, a conditional marketing authorisation or an authorisation under exceptional circumstances
¹ Translarna had an orphan designation at the time of CHMP opinion.

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
• Masiviera • MASITINIB	AB Science	• L01XE • treatment of non resectable locally advanced or metastatic pancreatic cancer	• 19/09/2012 • 23/01/2014 • 210 • 279	• . • .
• Nerventra • LAQUINIMOD	Teva Pharma GmbH	• N07 • treatment of multiple sclerosis	• 13/07/2012 • 23/01/2014 • 210 • 316	• . • 19/08/2014
• Reasanz • SERELAXIN	Novartis Europharm Ltd	• C01 • treatment of acute heart failure	• 30/01/2013 • 23/01/2014 • 210 • 141	• . • 08/05/2014

Translarna initially had a negative opinion, but following re-examination the CHMP issued a positive opinion.

Centralised applications for medicinal products for human use – withdrawals in 2014 prior to opinion

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Withdrawal • Active Time • Clock stop
• DITELOS • STRONTIUM RANELATE / COLECALCIFEROL	Les Laboratoires Servier	• M05BX • treatment of osteoporosis	• 23/05/2012 • 17/03/2014 • 121 • 0
• Faldaprevir Boehringer Ingelheim • FALDAPREVIR	Boehringer Ingelheim International GmbH	• J05AE • treatment of chronic genotype-1 hepatitis C virus (HCV) infection	• 20/11/2013 • 10/06/2014 • 0 (Acc) • 0
• HEPLISAV • HEPATITIS B SURFACE ANTIGEN	Dynavax International B.V.	• J07BC01 • indicated for active immunisation of adults against hepatitis B virus (HBV) infection	• 14/08/2012 • 10/02/2014 • 182 • 345
• Imagify • PERFLUBUTANE	Acusphere Ltd	• V08D • ultrasound imaging agent indicated for the detection of coronary artery disease (CAD)	• 23/10/2012 • 30/07/2014 • 182 • 212

Product <ul style="list-style-type: none"> • Brandname • INN 	Marketing authorisation holder	Therapeutic Area <ul style="list-style-type: none"> • ATC Code • Summary of indication 	EMA/CHMP <ul style="list-style-type: none"> • Validation • Withdrawal • Active Time • Clock stop
<ul style="list-style-type: none"> • ISSARLOS • STRONTIUM RANELATE / COLECALCIFEROL 	Les Laboratoires Servier	<ul style="list-style-type: none"> • M05BX • treatment of osteoporosis 	<ul style="list-style-type: none"> • 23/05/2012 • 17/03/2014 • 120 • 0
<ul style="list-style-type: none"> • Neofordex • DEXAMETHASONE 	LABORATOIRES CTRS - BOULOGNE BILLANCOURT	<ul style="list-style-type: none"> • H02AB02 • treatment of symptomatic multiple myeloma 	<ul style="list-style-type: none"> • 29/01/2013 • 11/07/2014 • 182 • 51

Annex 11 – CVMP opinions in 2014 on medicinal products for veterinary use

Positive opinions

Product <ul style="list-style-type: none"> • Invented name • INN/Common name 	Marketing authorisation holder	Therapeutic area <ul style="list-style-type: none"> • Target species • Summary of indication 	EMA/CVMP <ul style="list-style-type: none"> • Validation • Opinion • Active time • Clock stop 	European Commission <ul style="list-style-type: none"> • Opinion received • Transmission to EC • Decision • Notification • Official Journal
Fungitraxx Itraconazole	Avimedical B.V	Ornamental birds Treatment of aspergillosis and candidiasis.	07/11/2012 16/01/2014 210 225	16/01/2014 12/02/2014 12/03/2014 17/03/2014 C 123 of 25/04/2014
Equisolon Prednisolone	LE VET B.V.	Horse Alleviation of clinical recurrent airway obstruction (RAO) in combination with environmental control.	10/10/2012 16/01/2014 210 253	16/01/2014 12/02/2014 12/03/2014 14/03/2014 C 123 of 25/04/2014
Parvoduk Muscovy duck parvovirus	MERIAL	Muscovy duck Vaccine against duck parvovirus and Derzsy's disease.	07/11/2012 13/02/2014 203 260	13/02/2014 10/03/2014 11/04/2014 15/04/2014 C 165 of 29/05/2014
Versican Plus DHPPi/L4R Canine distemper virus, canine adenovirus, canine parvovirus, canine parainfluenza virus, leptospiras and rabies virus	Zoetis Belgium SA	Dog Vaccine against canine distemper, infectious hepatitis, infectious tracheobronchitis (kennel cough), parvovirus disease, leptospirosis and rabies.	20/03/2013 13/03/2014 203 155	13/03/2014 09/04/2014 07/05/2014 09/05/2014 C 199 of 27/06/2014
Versican Plus DHPPi/L4 Canine distemper virus, canine adenovirus, canine parvovirus, canine parainfluenza virus and leptospiras	Zoetis Belgium SA	Dog Vaccine against canine distemper, infectious hepatitis, infectious tracheobronchitis (kennel cough), parvovirus disease and leptospirosis.	15/05/2013 13/03/2014 210 92	13/03/2014 09/04/2014 07/05/2014 09/05/2014 C 199 of 27/06/2014
Vectra Felis Dinotefuran, pyriproxyfen	Ceva Santé Animale	Cats Treatment and prevention of flea infestations.	13/12/2012 10/04/2014 210 274	10/04/2014 06/05/2014 06/06/2014 11/06/2014 C 243 of 25/07/2014
Versican Plus Pi Canine parainfluenza virus	Zoetis Belgium SA	Dog Vaccine against canine parainfluenza virus.	12/06/2013 08/05/2014 210 120	08/05/2014 04/06/2014 04/07/2014 08/07/2014

Product <ul style="list-style-type: none"> Invented name INN/Common name 	Marketing authorisation holder	Therapeutic area <ul style="list-style-type: none"> Target species Summary of indication 	EMA/CVMP <ul style="list-style-type: none"> Validation Opinion Active time Clock stop 	European Commission <ul style="list-style-type: none"> Opinion received Transmission to EC Decision Notification Official Journal
				C 290 of 29/08/2014
Versican Plus DHPPi Canine distemper virus, canine adenovirus, canine parvovirus and canine parainfluenza virus	Zoetis Belgium SA	Dog Vaccine against canine distemper, infectious hepatitis, tracheobronchitis (kennel cough) and parvovirus disease.	12/06/2013 08/05/2014 210 120	08/05/2014 04/06/2014 04/07/2014 08/07/2014 C 290 of 29/08/2014
ERYSENG PARVO Porcine parvovirus, erysipelothrix	Laboratorios HIPRA, S.A.	Pig Vaccine against parvovirus disease and swine erysipelas.	13/02/2013 08/05/2014 210 239	08/05/2014 03/06/2014 08/07/2014 10/07/2014 C 290 of 29/08/2014
ERYSENG Erysipelothrix	Laboratorios HIPRA, S.A.	Pig Vaccine against swine erysipelas.	13/02/2013 08/05/2014 210 239	08/05/2014 03/06/2014 04/07/2014 08/07/2014 C 290 of 29/08/2014
OSURNIA Terbinafine, florfenicol and betamethasone acetate	Novartis Santé Animale S.A.S	Dog Treatment of bacterial and fungal external otitis.	11/07/2013 05/06/2014 210 120	05/06/2014 02/07/2014 31/07/2014 01/08/2014 C 290 of 29/08/2014
Versican Plus L4 Leptospiras	Zoetis Belgium SA	Dog Vaccine against leptospirosis.	10/07/2013 05/06/2014 210 120	05/06/2014 01/07/2014 31/07/2014 05/08/2014 C 290 of 29/08/2014
Versican Plus Pi/L4 Canine parainfluenza virus and leptospiras	Zoetis Belgium SA	Dog Vaccine against infectious tracheobronchitis (kennel cough) and leptospirosis.	10/07/2013 05/06/2014 210 120	05/06/2014 01/07/2014 31/07/2014 04/08/2014 C 290 of 29/08/2014
Versican Plus Pi/L4R Canine parainfluenza virus, leptospiras and rabies virus	Zoetis Belgium SA	Dog Vaccine against infectious tracheobronchitis (kennel cough), leptospirosis and rabies.	10/07/2013 05/06/2014 210 120	05/06/2014 01/07/2014 31/07/2014 04/08/2014 C 337 of 26/09/2014
Nobilis IB Primo QX Avian infectious bronchitis virus (IBV)	Intervet International B.V.	Chicken Vaccine against infectious bronchitis.	20/03/2013 10/07/2014 210 267	10/07/2014 06/08/2014 04/09/2014 08/09/2014 C 386 of 31/10/2014
Porcilis PCV M Hyo Porcine circovirus and Mycoplasma hyopneumoniae	Intervet International B.V.	Pig Vaccine against porcine circovirus disease and mycoplasmosis.	13/11/2013 11/09/2014 210 92	11/09/2014 08/10/2014 07/11/2014 11/11/2014 C 467 of

Product <ul style="list-style-type: none"> • Invented name • INN/Common name 	Marketing authorisation holder	Therapeutic area <ul style="list-style-type: none"> • Target species • Summary of indication 	EMA/CVMP <ul style="list-style-type: none"> • Validation • Opinion • Active time • Clock stop 	European Commission <ul style="list-style-type: none"> • Opinion received • Transmission to EC • Decision • Notification • Official Journal
				30/12/2014
Bovela Bovine viral diarrhoea virus	Boehringer Ingelheim Vetmedica GmbH	Cattle Vaccine against bovine viral diarrhoea (BVD).	10/07/2013 09/10/2014 210 246	09/10/2014 07/11/2014 22/12/2014 29/12/2014 C 32 of 30/01/2015
NEXGARD SPECTRA Afoxolaner and milbemycin oxime	MERIAL	Dog Treatment and/or prevention of parasite infestations.	05/02/2014 06/11/2014 208 66	06/11/2014 03/12/2014 15/01/2015 19/01/2015 C 71 of 27/02/2015
Suvaxyn CSF Marker Classical swine fever virus	Zoetis Belgium SA	Pig Vaccine against classical swine fever.	13/02/2013 11/12/2014 210 456	11/12/2014 09/01/2015 10/02/2015
Zulvac SBV Inactivated Schmallenberg virus	Zoetis Belgium SA	Sheep, cattle Vaccine against Schmallenberg virus disease.	11/12/2013 11/12/2014 210 155	11/12/2014 09/01/2015 06/02/2015

CVMP opinions in 2014 on establishment of MRLs

Positive opinions

Product <ul style="list-style-type: none"> Substance 	Target species	EMA/CVMP <ul style="list-style-type: none"> Validation Opinion Active time Clock stop 	European Commission <ul style="list-style-type: none"> Opinion received Regulation Official Journal
Barium selenate	All food producing species	N/a 10/04/2014 130 N/a	11/04/2014
Clodronic acid (in the form of disodium salt)	<i>Equidae</i>	11/12/2013 08/05/2014 148 0	14/05/2014
Eprinomectin	Ovine, caprine	N/a 05/06/2014 60 N/a	19/06/2014 1390/2014 L 369/65 of 24/12/2014
Tulathromycin	Ovine, caprine	15/05/2013 05/06/2014 210 176	19/06/2014 2015/152 L 26/16 of 31/01/2015
Doxycycline	All food producing species	18/09/2013 10/07/2014 210 86	23/07/2014 2015/151 L 26/13 of 31/01/2015
Gamithromycin	Porcine	14/08/2013 10/07/2014 210 120	23/07/2014 2015/150 L 26/10 of 31/01/2015
Hexaflumuron	Fin fish	12/06/2014 10/07/2014 210 183	23/07/2014
Methylprednisolone	<i>Equidae</i>	05/02/2014 10/07/2014 155 0	23/07/2014 2015/149 L 26/7 of 31/01/2015
Tulathromycin (modification of ADI and MRLs) after provisional MRLs	Bovine, porcine	N/a 10/07/2014 90 N/a	23/07/2014
Tylvalosin	Poultry eggs	14/11/2013 10/07/2014 180 59	23/07/2014

Product <ul style="list-style-type: none"> • Substance 	Target species	EMA/CVMP <ul style="list-style-type: none"> • Validation • Opinion • Active time • Clock stop 	European Commission <ul style="list-style-type: none"> • Opinion received • Regulation • Official Journal
Aluminium salicylate, basic	Bovine, caprine species, <i>Equidae</i> , rabbit	13/02/2014 09/10/2014 208 395	24/10/2014
Propyl 4-hydroxybenzoate and its sodium salt	All food producing species	11/06/2014 06/11/2014 148 0	21/11/2014
Virginiamycin	Poultry	16/10/2013 06/11/2014 208 178	21/11/2014
Potassium selenate, sodium selenate, sodium selenite	All food producing species	N/a 04/12/2014 207 0	09/12/2014

Annex 12 – COMP opinions in 2014 on designation of orphan medicinal products

Positive COMP designation opinions

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
3-Chloro-4-fluorophenyl-[4-fluoro-4-{{(5-methylpyrimidin-2-ylmethyl)amino}methyl}piperidin-1-yl]methanone	Neurolix UK Ltd. - United Kingdom	Treatment of Rett syndrome	<ul style="list-style-type: none"> • 18/10/2013 • 08/11/2013 • 09/01/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
Eculizumab	Alexion Europe SAS - France	Prevention of delayed graft function after solid organ transplantation	<ul style="list-style-type: none"> • 25/09/2013 • 11/10/2013 • 09/01/2014 • (90 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
Cysteamine	Istituto Europeo per la Ricerca sulla Fibrosi Cistica - ONLUS - Italy	Treatment of cystic fibrosis	<ul style="list-style-type: none"> • 26/09/2013 • 11/10/2013 • 09/01/2014 • (90 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
Diacerein	Prof. Johann W. Bauer - Austria	Treatment of epidermolysis bullosa	<ul style="list-style-type: none"> • 23/09/2013 • 11/10/2013 • 09/01/2014 • (90 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
Phosphorothioate oligonucleotide targeted to apolipoprotein C-III	Isis USA Ltd - UK	Treatment of familial chylomicronemia syndrome	<ul style="list-style-type: none"> • 23/10/2013 • 08/11/2013 • 09/01/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
11-(4-Dimethylamino-3-hydroxy-6-methyl-tetrahydro-pyran-2-yloxy)-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-1-oxa-6-aza-cyclopentadecane-13,15-dione	Synovo GmbH - Germany	Treatment of cystic fibrosis	<ul style="list-style-type: none"> • 26/09/2013 • 11/10/2013 • 09/01/2014 • (90 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
Ruxolitinib	Novartis Europharm Limited - United Kingdom	Treatment of polycythaemia vera	<ul style="list-style-type: none"> • 21/10/2013 • 08/11/2013 • 15/01/2014 • (68 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
⁶⁸ Ga-2,2'-(7-(4-((S)-1-((4S,7S,10S,13R,16S,19R)-4-((R)-1-amino-3-(4-hydroxyphenyl)-1-oxopropan-2-ylcarbamoyl)-10-(4-aminobutyl)-16-(4-((S)-2,6-dioxohexahydropyrimidine-4-carboxamido)benzyl)-7-((R)-1-hydroxyethyl)-6,9,12,15,18-pentaaxo-13-(4-ureidobenzyl)-1,2-dithia-5,8,11,14,17-pentaazacycloicosan-19-ylamino)-3-(4-chlorophenyl)-1-oxopropan-2-ylamino)-1-carboxy-4-oxobutyl)-1,4,7-triazonane-1,4-diy)diacetic acid	OctreoPharm Sciences GmbH - Germany	Diagnosis of gastro-entero-pancreatic neuroendocrine tumours	<ul style="list-style-type: none"> • 23/10/2013 • 08/11/2013 • 09/01/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
N-({Carbamoylmethyl-[3-(2-oxo-pyrrolidin-1-yl)-propyl]-carbamoyl}-methyl)-2-[2-(2-fluorophenyl)-ethylamino]-N-isobutyl-acetamide	Bionure Farma SL - Spain	Treatment of optic neuritis	<ul style="list-style-type: none"> • 23/10/2013 • 08/11/2013 • 15/01/2014 • (68 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
Gallium [Ga-68]-N-[(4,7,10-Tricarboxymethyl-1,4,7,10-tetraazacyclododec-1-yl)acetyl]-D-phenylalanyl-L-cysteinyl-L-tyrosyl-D-tryptophanyl-L-lysyl-L-threoninyl-L-cysteinyl-L-threonine-cyclic(2-7)disulfide	Advanced Accelerator Applications SA - France	Diagnosis of gastro-entero-pancreatic neuroendocrine tumours	<ul style="list-style-type: none"> • 25/09/2013 • 11/10/2013 • 09/01/2014 • (90 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
Recombinant human acid ceramidase	QOL Therapeutics UK Ltd - United Kingdom	Treatment of Farber disease	<ul style="list-style-type: none"> • 18/10/2013 • 08/11/2013 • 09/01/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
Autologous dendritic cells pulsed with tumour antigen-derived synthetic peptides (MAGE-1, HER-2, AIM-2, TRP-2, gp-100, and interleukin-13 receptor alpha)	Diamond BioPharm Limited - United Kingdom	Treatment of glioma	<ul style="list-style-type: none"> • 23/10/2013 • 08/11/2013 • 09/01/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Pioglitazone	Minoryx Therapeutics S.L. - Spain	Treatment of adrenoleukodystrophy	<ul style="list-style-type: none"> • 22/10/2013 • 08/11/2013 • 09/01/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
Mixture of recombinant human IgG1 monoclonal antibodies against human cytomegalovirus envelope glycoproteins	Roche Registration Limited - United Kingdom	Prevention of congenital cytomegalovirus infection following primary cytomegalovirus infection	<ul style="list-style-type: none"> • 22/08/2013 • 11/10/2013 • 09/01/2014 • (90 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
Asp-Arg-Val-Tyr-Ile-His-Pro	Gregory Fryer Associates Ltd - United Kingdom	Treatment of Duchenne muscular dystrophy	<ul style="list-style-type: none"> • 15/10/2013 • 08/11/2013 • 09/01/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 30/01/2014 • 19/02/2014
Volasertib	Boehringer Ingelheim International GmbH - Germany	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> • 11/11/2013 • 13/12/2013 • 06/02/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 27/02/2014 • 26/03/2014
Cysteamine bitartrate	Raptor Pharmaceuticals Europe BV - The Netherlands	Treatment of pancreatic cancer	<ul style="list-style-type: none"> • 17/10/2013 • 08/11/2013 • 06/02/2014 • (90 days/27 days) 	<ul style="list-style-type: none"> • 27/02/2014 • 26/03/2014
Ex vivo cultured human mesenchymal stromal cells	iCell Science AB - Sweden	Prevention of graft rejection following solid organ transplantation	<ul style="list-style-type: none"> • 20/10/2013 • 08/11/2013 • 06/02/2014 • (90 days/27 days) 	<ul style="list-style-type: none"> • 27/02/2014 • 26/03/2014
Adeno-associated viral vector serotype 8 containing the human GUCY2D gene	Fondazione Telethon - Italy	Treatment of Leber's congenital amaurosis	<ul style="list-style-type: none"> • 18/11/2013 • 08/11/2013 • 06/02/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 27/02/2014 • 26/03/2014
Doxorubicin(6-maleimidocaproyl)hydrazide	Eudax Srl - Italy	Treatment of soft tissue sarcoma	<ul style="list-style-type: none"> • 27/11/2013 • 13/12/2013 • 06/02/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 27/02/2014 • 26/03/2014
Recombinant human alpha-glucosidase conjugated with multiple copies of synthetic bismannose-6-phosphate-tetramannose glycan	Genzyme Europe BV - The Netherlands	Treatment of glycogen storage disease type II (Pompe's disease)	<ul style="list-style-type: none"> • 17/09/2013 • 08/11/2013 • 06/02/2014 • (90 days/27 days) 	<ul style="list-style-type: none"> • 27/02/2014 • 26/03/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Autologous CD34+ cells transduced with a lentiviral vector containing the human RAG1 gene	Prof. F.J.T.Staal - The Netherlands	Treatment of recombination-activating gene 1 deficient severe combined immunodeficiency	<ul style="list-style-type: none"> • 27/11/2013 • 13/12/2013 • 06/02/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 27/02/2014 • 26/03/2014
Eculizumab	Alexion Europe SAS - France	Prevention of graft rejection following solid organ transplantation	<ul style="list-style-type: none"> • 23/10/2013 • 08/11/2013 • 06/02/2014 • (90 days/27 days) 	<ul style="list-style-type: none"> • 27/02/2014 • 26/03/2014
Fixed dose combination of (R-S) baclofen, naltrexone hydrochloride and D-sorbitol	Pharnext SAS - France	Treatment of Charcot-Marie-Tooth disease type 1A	<ul style="list-style-type: none"> • 28/11/2013 • 13/12/2013 • 06/02/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 27/02/2014 • 26/03/2014
Phosphorothioate oligonucleotide targeted to transthyretin	Isis USA Ltd - UK	Treatment of ATTR amyloidosis	<ul style="list-style-type: none"> • 27/06/2013 • 08/11/2013 • 06/02/2014 • (90 days/27 days) 	<ul style="list-style-type: none"> • 27/02/2014 • 26/03/2014
Amikacin sulfate	Insmmed Limited - United Kingdom	Treatment of nontuberculous mycobacterial lung disease	<ul style="list-style-type: none"> • 28/11/2013 • 13/12/2013 • 06/02/2014 • (55 days/40 days) 	<ul style="list-style-type: none"> • 27/02/2014 • 08/04/2014
Recombinant human surfactant protein D	Dr Ulrich Granzer - Germany	Prevention of bronchopulmonary dysplasia	<ul style="list-style-type: none"> • 22/10/2013 • 08/11/2013 • 06/02/2014 • (90 days/16 days) 	<ul style="list-style-type: none"> • 26/03/2014 • 11/04/2014
Caffeine citrate	Viridian Pharma Ltd - United Kingdom	Prevention of bronchopulmonary dysplasia	<ul style="list-style-type: none"> • 08/10/2013 • 08/11/2013 • 06/02/2014 • (90 days/16 days) 	<ul style="list-style-type: none"> • 26/03/2014 • 11/04/2014
Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human beta A-T87Q-globin gene	bluebird bio France - France	Treatment of sickle cell disease	<ul style="list-style-type: none"> • 25/11/2013 • 13/12/2013 • 12/03/2014 • (89 days/29 days) 	<ul style="list-style-type: none"> • 31/03/2014 • 29/04/2014
Synthetic double-stranded siRNA oligonucleotide directed against transthyretin mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues	Alnylam UK Limited - United Kingdom	Treatment of ATTR amyloidosis	<ul style="list-style-type: none"> • 28/11/2013 • 13/12/2013 • 12/03/2014 • (89 days/29 days) 	<ul style="list-style-type: none"> • 31/03/2014 • 29/04/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD19	Novartis Europharm Limited - United Kingdom	Treatment of B-lymphoblastic leukaemia/lymphoma	<ul style="list-style-type: none"> • 26/11/2013 • 13/12/2013 • 12/03/2014 • (89 days/29 days) 	<ul style="list-style-type: none"> • 31/03/2014 • 29/04/2014
Genetically modified serotype 5/3 adenovirus coding for granulocyte macrophage colony-stimulating factor	Oncos Therapeutics Oy - Finland	Treatment of ovarian cancer	<ul style="list-style-type: none"> • 22/11/2013 • 13/12/2013 • 12/03/2014 • (89 days/29 days) 	<ul style="list-style-type: none"> • 31/03/2014 • 29/04/2014
Humanized monoclonal antibody against CD38	Sanofi-Aventis Groupe - France	Treatment of plasma cell myeloma	<ul style="list-style-type: none"> • 06/12/2013 • 16/01/2014 • 12/03/2014 • (55 days/29 days) 	<ul style="list-style-type: none"> • 31/03/2014 • 29/04/2014
Ibrutinib	Janssen-Cilag International N.V. - Belgium	Treatment of lymphoplasmacytic lymphoma	<ul style="list-style-type: none"> • 25/11/2013 • 16/01/2014 • 12/03/2014 • (55 days/29 days) 	<ul style="list-style-type: none"> • 31/03/2014 • 29/04/2014
(5R,5aR,8aR,9S)-9-[[4,6-O-[(R)-Ethylidene]-β-D-glucopyranosyl]-oxy]-5-(4-({[(2,2-dimethyl-1,3-dioxolan-4-yl)methoxy]carbonyl}oxy)-3,5-dimethoxyphenyl)-5,8,8a,9-tetrahydroisobenzofuro[5,6-f][1,3]benzodioxol-6(5aH)-one	CellAct Pharma GmbH - Germany	Treatment of biliary tract cancers	<ul style="list-style-type: none"> • 08/12/2013 • 16/01/2014 • 09/04/2014 • (83 days/29 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 04/06/2014
Autologous dendritic cells pulsed with RNA from glioma stem cells	Epitarget AS - Norway	Treatment of glioma	<ul style="list-style-type: none"> • 13/01/2014 • 14/02/2014 • 09/04/2014 • (54 days/29 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 04/06/2014
Adeno-associated viral vector serotype 2 containing the human CHM gene encoding human Rab escort protein 1	Alan Boyd Consultants Ltd - United Kingdom	Treatment of choroideraemia	<ul style="list-style-type: none"> • 30/01/2014 • 14/02/2014 • 09/04/2014 • (54 days/29 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 04/06/2014
Recombinant human alpha 1 chain homotrimer of type VII collagen	Shire Pharmaceuticals (Ireland) Limited - Ireland	Treatment of epidermolysis bullosa	<ul style="list-style-type: none"> • 10/12/2013 • 16/01/2014 • 09/04/2014 • (83 days/29 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 04/06/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
177Lu-tetraxetan-tetulumab	Nordic Nanovector AS - Norway	Treatment of follicular lymphoma	<ul style="list-style-type: none"> • 09/12/2013 • 16/01/2014 • 09/04/2014 • (83 days/29 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 04/06/2014
Paclitaxel-succinate-Arg-Arg-Leu-Ser-Tyr-Ser-Arg-Arg-Arg-Phe	CLL Pharma - France	Treatment of glioma	<ul style="list-style-type: none"> • 27/01/2014 • 14/02/2014 • 09/04/2014 • (54 days/29 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 04/06/2014
Plasmid DNA encoding the human cystic fibrosis transmembrane conductance regulator gene complexed with a non-viral, cationic lipid based gene transfer agent	Imperial Innovations Limited - United Kingdom	Treatment of cystic fibrosis	<ul style="list-style-type: none"> • 30/01/2014 • 14/02/2014 • 09/04/2014 • (54 days/29 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 04/06/2014
Isavuconazonium sulfate	Basilea Medical Ltd - United Kingdom	Treatment of mucormycosis	<ul style="list-style-type: none"> • 29/01/2014 • 14/02/2014 • 09/04/2014 • (54 days/29 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 04/06/2014
Lutetium (177Lu) edotreotide	ITG Isotope Technologies Garching GmbH - Germany	Treatment of gastro-entero-pancreatic neuroendocrine tumours	<ul style="list-style-type: none"> • 03/12/2013 • 16/01/2014 • 09/04/2014 • (83 days/29 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 04/06/2014
4-(4-Methoxy-phenylamino)-6-methylcarbamyloquinoline-3-carboxylic acid	Clanotech AB - Sweden	Prevention of scarring in post-glaucoma filtration surgery	<ul style="list-style-type: none"> • 30/01/2014 • 14/02/2014 • 09/04/2014 • (54 days/29 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 04/06/2014
Aganirsen	Gene Signal SAS - France	Treatment of central retinal vein occlusion	<ul style="list-style-type: none"> • 29/01/2014 • 14/02/2014 • 09/04/2014 • (54 days/35 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 10/06/2014
Autologous CD34+ cells transduced with a lentiviral vector containing the human SGSH gene	Cochamo Systems Ltd - United Kingdom	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome)	<ul style="list-style-type: none"> • 29/01/2014 • 14/02/2014 • 09/04/2014 • (54 days/35 days) 	<ul style="list-style-type: none"> • 06/05/2014 • 10/06/2014
Afamelanotide	Clinuvel UK Limited - United Kingdom	Treatment of familial benign chronic pemphigus (Hailey-Hailey disease)	<ul style="list-style-type: none"> • 24/02/2014 • 14/03/2014 • 14/05/2014 • (61 days/28 days) 	<ul style="list-style-type: none"> • 06/06/2014 • 04/07/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> Submission Start date Opinion Active time 	European Commission <ul style="list-style-type: none"> Opinion received Date of decision
1-(2,2-difluoro-1,3-benzodioxol-5-yl)-N-{1-[(2R)-2,3-dihydroxypropyl]-6-fluoro-2-(1-hydroxy-2-methylpropan-2-yl)-1Hindol-5-yl} cyclopropanecarb oxamide	Vertex Pharmaceuticals (U.K.) Limited - United Kingdom	Treatment of cystic fibrosis	<ul style="list-style-type: none"> 23/01/2014 14/02/2014 14/05/2014 (89 days/28 days) 	<ul style="list-style-type: none"> 06/06/2014 04/07/2014
Norursodeoxycholic acid	Dr Falk Pharma GmbH - Germany	Treatment of primary sclerosing cholangitis	<ul style="list-style-type: none"> 26/02/2014 14/03/2014 14/05/2014 (61 days/28 days) 	<ul style="list-style-type: none"> 06/06/2014 04/07/2014
Beloranib	Dr Ulrich Granzer - Germany	Treatment of Prader-Willi syndrome	<ul style="list-style-type: none"> 26/02/2014 14/03/2014 14/05/2014 (61 days/28 days) 	<ul style="list-style-type: none"> 06/06/2014 04/07/2014
Mixture of two adeno-associated viral vectors of serotype 8 containing the 5'-half sequence of human ABCA4 gene and the 3'-half sequence of human ABCA4 gene	Fondazione Telethon - Italy	Treatment of Stargardt's disease	<ul style="list-style-type: none"> 28/01/2014 14/02/2014 14/05/2014 (89 days/28 days) 	<ul style="list-style-type: none"> 06/06/2014 04/07/2014
Mixture of two adeno-associated viral vectors of serotype 8 containing the 5'-half sequence of human MYO7A gene and the 3'-half sequence of human MYO7A gene	Fondazione Telethon - Italy	Treatment of Usher syndrome	<ul style="list-style-type: none"> 28/01/2014 14/02/2014 14/05/2014 (89 days/28 days) 	<ul style="list-style-type: none"> 06/06/2014 04/07/2014
Adeno-associated viral vector serotype 2 containing the human REP1 gene	NightstaRx Ltd. - United Kingdom	Treatment of choroideremia	<ul style="list-style-type: none"> 27/02/2014 14/03/2014 14/05/2014 (61 days/28 days) 	<ul style="list-style-type: none"> 06/06/2014 04/07/2014
Humanised Fc engineered monoclonal antibody against CD19	MorphoSys AG - Germany	Treatment of chronic lymphocytic leukaemia/small lymphocytic lymphoma	<ul style="list-style-type: none"> 25/02/2014 14/03/2014 14/05/2014 (61 days/28 days) 	<ul style="list-style-type: none"> 06/06/2014 04/07/2014
Isavuconazonium sulfate	Basilea Medical Ltd - United Kingdom	Treatment of invasive aspergillosis	<ul style="list-style-type: none"> 29/01/2014 14/02/2014 14/05/2014 (89 days/28 days) 	<ul style="list-style-type: none"> 06/06/2014 04/07/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Recombinant human alpha-1 microglobulin	A1M Pharma AB - Sweden	Treatment of pre-eclampsia	<ul style="list-style-type: none"> • 27/02/2014 • 14/03/2014 • 14/05/2014 • (61 days/28 days) 	<ul style="list-style-type: none"> • 06/06/2014 • 04/07/2014
Riociguat	Bayer Pharma AG - Germany	Treatment of systemic sclerosis	<ul style="list-style-type: none"> • 24/03/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 29/07/2014
Cediranib	AstraZeneca AB - Sweden	Treatment of ovarian cancer	<ul style="list-style-type: none"> • 27/03/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Humanised recombinant monoclonal antibody against epidermal growth factor receptor conjugated to maleimidocaproyl monomethylauristatin F	AbbVie Ltd - United Kingdom	Treatment of glioma	<ul style="list-style-type: none"> • 27/03/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Recombinant fusion protein consisting of a modified form of the extracellular domain of human activin receptor IIB linked to the human IgG1 Fc domain	IDEA Innovative Drug European Associates Limited - United Kingdom	Treatment of beta-thalassaemia intermedia and major	<ul style="list-style-type: none"> • 24/03/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Humanised anti-alpha v beta 6 monoclonal antibody	Biogen Idec Limited - UK	Treatment of idiopathic pulmonary fibrosis	<ul style="list-style-type: none"> • 26/03/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Adeno-associated viral vector serotype 9 containing the human cardiac calsequestrin gene	Fondazione Salvatore Maugeri Clinica del Lavoro e della Riabilitazione - Italy	Treatment of catecholaminergic polymorphic ventricular tachycardia	<ul style="list-style-type: none"> • 20/03/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Oxytocin	Maithé Tauber - France	Treatment of Prader-Willi syndrome	<ul style="list-style-type: none"> • 26/03/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Sodium acetate salt of the synthetic peptide H-D-Ala-Ser-Pro-Met-Leu-Val-Ala-Tyr-Asp-D-Ala-OH	Dr Ulrich Granzer - Germany	Treatment for necrotising soft tissue infections	<ul style="list-style-type: none"> • 28/02/2014 • 14/03/2014 • 12/06/2014 • (90 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Carboxy pyrrolidine hexanoyl pyrrolidine carboxylate	GlaxoSmithKline Trading Services Limited - Ireland	Treatment of AL amyloidosis	<ul style="list-style-type: none"> • 25/02/2014 • 14/03/2014 • 12/06/2014 • (90 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Recombinant monoclonal antibody to human serum amyloid P component	GlaxoSmithKline Trading Services Limited - Ireland	Treatment of AL amyloidosis	<ul style="list-style-type: none"> • 25/02/2014 • 14/03/2014 • 12/06/2014 • (90 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Cysteamine bitartrate	Raptor Pharmaceuticals Europe BV - The Netherlands	Treatment of Huntington's disease	<ul style="list-style-type: none"> • 27/03/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Marizomib	Richardson Associates Regulatory Affairs Ltd - United Kingdom	Treatment of plasma cell myeloma	<ul style="list-style-type: none"> • 28/02/2014 • 14/03/2014 • 12/06/2014 • (90 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Rilotumumab	Amgen Europe BV - The Netherlands	Treatment of gastric cancer	<ul style="list-style-type: none"> • 30/01/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Eculizumab	Alexion Europe SAS - France	Treatment of myasthenia gravis	<ul style="list-style-type: none"> • 27/03/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Synthetic double-stranded siRNA oligonucleotide directed against antithrombin mRNA that is covalently linked to a ligand containing three N-acetylgalactosamine residues	Alnylam UK Limited - United Kingdom	Treatment of haemophilia A	<ul style="list-style-type: none"> • 20/03/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Synthetic double-stranded siRNA oligonucleotide directed against antithrombin mRNA that is covalently linked to a ligand containing three N-acetylgalactosamine residues	Alnylam UK Limited - United Kingdom	Treatment of haemophilia B	<ul style="list-style-type: none"> • 21/03/2014 • 11/04/2014 • 12/06/2014 • (62 days/26 days) 	<ul style="list-style-type: none"> • 03/07/2014 • 29/07/2014
Ulinastatin	BSV BioScience GmbH - Germany	Treatment of acute pancreatitis	<ul style="list-style-type: none"> • 27/03/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Gevokizumab	Les Laboratoires Servier - France	Treatment of Schnitzler syndrome	<ul style="list-style-type: none"> • 26/03/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Vector based on an adeno-associated virus serotype 2 backbone, pseudo-serotyped with a type 8 capsid, which carries the coding sequence of the human TYMP gene under the control of the human thyroxine binding globulin promoter	Vall d'Hebron Institute of Research - Spain	Treatment of mitochondrial neurogastrointestinal encephalomyopathy	<ul style="list-style-type: none"> • 20/05/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
17 α ,21-dihydroxy-16 α -methyl-pregna-1,4,9(11)-triene-3,20-dione	NDA Group AB - Sweden	Treatment of Duchenne muscular dystrophy	<ul style="list-style-type: none"> • 24/03/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
(3S)-1-azabicyclo[2.2.2]oct-3-yl {2-[2-(4-fluorophenyl)-1,3-thiazol-4-yl]propan-2-yl}carbamate	Genzyme Europe BV - The Netherlands	Treatment of Fabry disease	<ul style="list-style-type: none"> • 25/03/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
4-[(2R,3S,4R,5S)-4-(4-Chloro-2-fluorophenyl)-3-(3-chloro-2-fluorophenyl)-4-cyano-5-(2,2-dimethyl-propyl)-pyrrolidine-2-carbonyl]-amino}-3-methoxy-benzoic acid	Roche Registration Limited - United Kingdom	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> • 21/05/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Retinol	Dr Philipp Heinrich Novak - Austria	Prevention of bronchopulmonary dysplasia	<ul style="list-style-type: none"> • 30/01/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Recombinant human diamine oxidase	Medical University of Vienna - Austria	Treatment of mastocytosis	<ul style="list-style-type: none"> • 07/05/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
2-(2-methyl-5-nitro-1H-imidazol-1-yl)ethylsulfamide	DualTpharma B.V. - The Netherlands	Treatment of small cell lung cancer	<ul style="list-style-type: none"> • 19/05/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Recombinant factor VIIa modified with three terminal repeats derived from the β chain of human chorionic gonadotropin	Richardson Associates Regulatory Affairs Ltd - United Kingdom	Treatment of haemophilia B	<ul style="list-style-type: none"> • 28/03/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Recombinant factor VIIa modified with three terminal repeats derived from the β chain of human chorionic gonadotropin	Richardson Associates Regulatory Affairs Ltd - United Kingdom	Treatment of congenital factor VII deficiency	<ul style="list-style-type: none"> • 26/03/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Lumacaftor/ivacaftor	Vertex Pharmaceuticals (U.K.) Limited - United Kingdom	Treatment of cystic fibrosis	<ul style="list-style-type: none"> • 27/02/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Recombinant factor VIIa modified with three terminal repeats derived from the β chain of human chorionic gonadotropin	Richardson Associates Regulatory Affairs Ltd - United Kingdom	Treatment of haemophilia A	<ul style="list-style-type: none"> • 28/03/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Lentiviral vector containing the human liver and erythroid pyruvate kinase (PKLR) gene	Centro de Investigación Biomédica en Red (CIBER) - Spain	Treatment of pyruvate kinase deficiency	<ul style="list-style-type: none"> • 21/05/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Humanised IgG1 monoclonal antibody against human KIR3DL2	Innate Pharma S.A. - France	Treatment of cutaneous T-cell lymphoma	<ul style="list-style-type: none"> • 15/05/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Sodium ascorbate and menadione sodium bisulfite	JGConsultancy Ltd - United Kingdom	Treatment of autosomal dominant polycystic liver disease	<ul style="list-style-type: none"> • 24/03/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
[5-Amino-1-(4-fluoro-phenyl)-1H-pyrazol-4-yl]-[3-(2,3-dihydroxy-propoxy)-phenyl]-methanone	Synovo GmbH - Germany	Treatment of pancreatic cancer	<ul style="list-style-type: none"> • 19/05/2014 • 10/06/2014 • 21/07/2014 • (41 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Adeno-associated viral vector serotype 8 containing the human UGT1A1 gene	Fondazione Telethon - Italy	Treatment of Crigler-Najjar syndrome	<ul style="list-style-type: none"> • 16/05/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Recombinant human apolipoprotein A-I in a complex with phospholipids	Cerenis Therapeutics Holding SA - France	Treatment of ATP-binding cassette transporter A1 deficiency	<ul style="list-style-type: none"> • 27/03/2014 • 11/04/2014 • 21/07/2014 • (101 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Recombinant fusion protein consisting of a modified form of the extracellular domain of human Activin Receptor IIB linked to the human IgG1 Fc domain	IDEA Innovative Drug European Associates Limited - United Kingdom	Treatment of myelodysplastic syndromes	<ul style="list-style-type: none"> • 24/03/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Recombinant human apolipoprotein A-I in a complex with phospholipids	Cerenis Therapeutics Holding SA - France	Treatment of apolipoprotein A-I deficiency	<ul style="list-style-type: none"> • 27/03/2014 • 11/04/2014 • 10/07/2014 • (90 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Obinutuzumab	Roche Registration Limited - United Kingdom	Treatment of diffuse large B-cell lymphoma	<ul style="list-style-type: none"> • 20/05/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
(Z)-3-(3-(3,5-bis(trifluoromethyl)phenyl)-1H-1,2,4-triazol-1-yl)-N'-(pyrazin-2-yl)acrylohydrazide	Clinipace GmbH - Germany	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> • 27/03/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Variant of recombinant human fibroblast growth factor 19	Diamond BioPharm Limited - United Kingdom	Treatment of primary biliary cirrhosis	<ul style="list-style-type: none"> • 21/05/2014 • 10/06/2014 • 21/07/2014 • (41 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
(Z)-3-(3-(3,5-bis(trifluoromethyl)phenyl)-1H-1,2,4-triazol-1-yl)-N'-(pyrazin-2-yl)acrylohydrazide	Clinipace GmbH - Germany	Treatment of diffuse large B cell lymphoma	<ul style="list-style-type: none"> • 27/03/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
S3,S13-cyclo(D-tyrosyl-L-isoleucyl-L-cysteinyl-L-valyl-1-methyl-L-tryptophyl-L-glutamyl-L-aspartyl-L-tryptophyl-N-methyl-L-glycyl-L-alanyl-L-histidyl-L-arginyl-L-cysteinyl-N-methyl-L-isoleucinamide)	Amyndas Pharmaceuticals S.A. - Greece	Treatment of paroxysmal nocturnal haemoglobinuria	<ul style="list-style-type: none"> • 21/05/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Macromolecular conjugate of heparin sodium on a polymer backbone	Corline Systems AB - Sweden	Prevention of ischaemia-reperfusion injury associated with solid organ transplantation	<ul style="list-style-type: none"> • 20/05/2014 • 10/06/2014 • 10/07/2014 • (30 days/31 days) 	<ul style="list-style-type: none"> • 22/07/2014 • 22/08/2014
Recombinant human monoclonal IgG1 antibody for fibroblast growth factor 23	NDA Group AB - Sweden	Treatment of X-linked hypophosphataemia	<ul style="list-style-type: none"> • 26/06/2014 • 11/07/2014 • 04/09/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 15/10/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Glucagon	S-cubed Limited - United Kingdom	Treatment of congenital hyperinsulinism	<ul style="list-style-type: none"> • 26/06/2014 • 11/07/2014 • 04/09/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Acamprosate calcium	Real Regulatory Limited - Ireland	Treatment of fragile X syndrome	<ul style="list-style-type: none"> • 26/06/2014 • 11/07/2014 • 04/09/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Osilodrostat	Novartis Europharm Limited - United Kingdom	Treatment of Cushing's syndrome	<ul style="list-style-type: none"> • 21/05/2014 • 10/06/2014 • 04/09/2014 • (86 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Nitric oxide	PD Dr.med. Joachim Riethmüller - Germany	Treatment of cystic fibrosis	<ul style="list-style-type: none"> • 11/03/2014 • 11/07/2014 • 04/09/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Cultured allogeneic corneal limbal stem cells	NHS National Services Scotland Trading as Scottish National Blood Transfusion Service - United Kingdom	Treatment of limbal stem cell deficiency	<ul style="list-style-type: none"> • 23/05/2014 • 10/06/2014 • 04/09/2014 • (86 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Pyridoxal 5'-phosphate	Great Ormond Street Hospital for Children, NHS Foundation Trust - United Kingdom	Treatment of pyridoxamine 5'-phosphate oxidase deficiency	<ul style="list-style-type: none"> • 21/05/2014 • 11/07/2014 • 04/09/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
(S)-2-(1-((6-amino-5-cyanopyrimidin-4-yl)amino)ethyl)-4-oxo-3-phenyl-3,4-dihydropyrrolo[2,1-f][1,2,4]triazine-5-carbonitrile	Almirall S.A. - Spain	Treatment of Pemphigus	<ul style="list-style-type: none"> • 20/05/2014 • 10/06/2014 • 04/09/2014 • (86 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Recombinant human insulin receptor monoclonal antibody-fused- α -L-iduronidase	Voisin Consulting S.A.R.L. - France	Treatment of mucopolysaccharidosis type I	<ul style="list-style-type: none"> • 26/06/2014 • 11/07/2014 • 04/09/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Cannabidiol	GW Pharma Ltd - United Kingdom	Treatment of Dravet syndrome	<ul style="list-style-type: none"> • 15/05/2014 • 10/06/2014 • 04/09/2014 • (86 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Adeno-associated viral vector serotype 8 containing the human UGT1A1 gene	Généthon - France	Treatment of Crigler-Najjar syndrome	<ul style="list-style-type: none"> • 25/06/2014 • 11/07/2014 • 04/09/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Raxibacumab	GlaxoSmithKline Trading Services Limited - Ireland	Treatment of inhalation anthrax disease	<ul style="list-style-type: none"> • 26/06/2014 • 11/07/2014 • 04/09/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Recombinant human bone morphogenetic protein 4	STEMGEN S.p.A - Italy	Treatment of glioma	<ul style="list-style-type: none"> • 18/06/2014 • 11/07/2014 • 04/09/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Recombinant human monoclonal antibody of the IgG1 kappa class against human macrophage colony-stimulating factor	Novartis Europharm Limited - United Kingdom	Treatment of tenosynovial giant cell tumour, localised and diffused type	<ul style="list-style-type: none"> • 21/05/2014 • 10/06/2014 • 04/09/2014 • (86 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
(S)-6-hydroxy-2,5,7,8-tetramethyl-N-((R)-piperidin-3-yl)chroman-2-carboxamide hydrochloride	Khondrion BV - The Netherlands	Treatment of Leigh syndrome	<ul style="list-style-type: none"> • 27/03/2014 • 10/06/2014 • 04/09/2014 • (86 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Immunoglobulin G1, anti-(human tumour-associated calcium signal transducer 2)(human-Mus musculus monoclonal hRS7 heavy chain), disulfide with human-Mus musculus monoclonal hRS7 κ-chain, dimer, hexakis(thioether) with (4S)-4-[[[[4-[[[(2S)-2-(4-aminobutyl)-2-[[2-[2-[[26-[4-[[[4-[(3-mercapto-2,5-dioxo-1-pyrrolidinyl)methyl]cyclohexyl]carbonyl]amino]methyl]-1H-1,2,3-triazol-1-yl]-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl]amino]-2-oxoethoxy]acetyl]amino]-1-oxoethyl]amino]phenyl]methoxy]carbonyl]oxy]-4,11-diethyl-9-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione	Immunomedics GmbH - Germany	Treatment of pancreatic cancer	<ul style="list-style-type: none"> • 14/05/2014 • 10/06/2014 • 04/09/2014 • (86 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Oxalobacter formigenes strain HC-1	OxThera AB - Sweden	Treatment of short bowel syndrome	<ul style="list-style-type: none"> • 14/05/2014 • 10/06/2014 • 04/09/2014 • (86 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Cysteamine hydrochloride	Lucane Pharma SA - France	Treatment of cystinosis	<ul style="list-style-type: none"> • 21/05/2014 • 10/06/2014 • 04/09/2014 • (86 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
(3S)-(+)-(5-chloro-2-methoxyphenyl)-1,3-dihydro-3-fluoro-6-(trifluoromethyl)-2H-indol-2-one	Centre National de la Recherche Scientifique (CNRS) - France	Treatment of fragile X syndrome	<ul style="list-style-type: none"> • 21/05/2014 • 11/07/2014 • 04/09/2014 • (55 days/27 days) 	<ul style="list-style-type: none"> • 18/09/2014 • 15/10/2014
Selinexor	Clinipace GmbH - Germany	Treatment of chronic lymphocytic leukaemia/small lymphocytic lymphoma	<ul style="list-style-type: none"> • 13/05/2014 • 11/07/2014 • 09/10/2014 • (90 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
(2R,3S)-2-(4-Cyclopentylaminophenyl)-1-(2-fluoro-6-methylbenzoyl)piperidine-3-carboxylic acid(4-methyl-3-trifluoromethylphenyl)amide	ChemoCentryx Limited - United Kingdom	Treatment of microscopic polyangiitis	<ul style="list-style-type: none"> • 18/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Diaspirin cross-linked haemoglobin	New B Innovation (UK) Limited - United Kingdom	Treatment of hepatocellular carcinoma	<ul style="list-style-type: none"> • 22/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Donor T lymphocytes depleted ex vivo of host alloreactive T cells using photodynamic treatment	Kiadis Pharma Netherlands B.V - The Netherlands	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> • 21/05/2014 • 11/07/2014 • 09/10/2014 • (90 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
A combination of H-Lys-Lys-Gly-Pro-Arg-Cys(SH)-Leu-Thr-Arg-Tyr-Tyr-Ser-Ser-Phe-Val-Asn-Met-Glu-Gly-Lys-Lys-OH and H-Lys-Lys-Gly-Asp-Asn-Ile-Met-Val-Thr-Phe-Arg-Asn-Gln-Ala-Ser-Arg-Pro-Tyr-Gly-Lys-Lys-OH	Apitope International NV - Belgium	Treatment of haemophilia A	<ul style="list-style-type: none"> • 25/06/2014 • 11/07/2014 • 09/10/2014 • (90 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Adeno-associated viral vector serotype 8 containing the human MD1 gene	Généthon - France	Treatment of Duchenne muscular dystrophy	<ul style="list-style-type: none"> • 23/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
1-(6-benzothiazolylsulfonyl)-5-chloro-1H-indole-2-butanoic acid	Inventiva - France	Treatment of systemic sclerosis	<ul style="list-style-type: none"> • 26/06/2014 • 11/07/2014 • 09/10/2014 • (90 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Bazedoxifene acetate	Consejo Superior de Investigaciones Cientificas (CSIC) - Spain	Treatment of hereditary haemorrhagic telangiectasia	<ul style="list-style-type: none"> • 16/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
4-[[[(1S,4S)-5-[[4-[4-(Oxazol-2-yl)phenoxy]phenyl]methyl]-2,5-diazabicyclo[2.2.1]hept-2-yl]methyl]benzoic acid	Coté Orphan Consulting UK Limited - United Kingdom	Treatment of cystic fibrosis	<ul style="list-style-type: none"> • 26/06/2014 • 11/07/2014 • 09/10/2014 • (90 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Olaptesed pegol	Noxxon Pharma AG - Germany	Treatment of glioma	<ul style="list-style-type: none"> • 26/06/2014 • 18/08/2014 • 09/10/2014 • (52 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Humanized IgG1 monoclonal antibody against human eotaxin-2	CBR Biotech Strategies GmbH - Germany	Treatment of systemic sclerosis	<ul style="list-style-type: none"> • 18/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Pro-Pro-Thr-Val-Pro-Thr-Arg	Prof Alain Taieb - France	Treatment of xeroderma pigmentosum	<ul style="list-style-type: none"> • 22/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Mexiletine hydrochloride	Temmler Pharma GmbH & Co. KG - Germany	Treatment of myotonic disorders	<ul style="list-style-type: none"> • 30/04/2014 • 11/07/2014 • 09/10/2014 • (90 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Palovarotene	Medpace Germany GmbH - Germany	Treatment of fibrodysplasia ossificans progressiva	<ul style="list-style-type: none"> • 17/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Siponimod	Novartis Europharm Limited - United Kingdom	Treatment of polymyositis	<ul style="list-style-type: none"> • 17/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Chloroquine	DualTpharma B.V. - The Netherlands	Treatment of glioma	<ul style="list-style-type: none"> • 22/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Arimoclomol citrate	Orphazyme ApS - Denmark	Treatment of Niemann-Pick disease, type C	<ul style="list-style-type: none"> • 22/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/29 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
(2R,3S)-2-(4-Cyclopentylaminophenyl)-1-(2-fluoro-6-methylbenzoyl)piperidine-3-carboxylic acid(4-methyl-3-trifluoromethylphenyl)amide	ChemoCentryx Limited - United Kingdom	Treatment of granulomatosis with polyangiitis	<ul style="list-style-type: none"> • 18/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/20 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
(3S)-1-azabicyclo[2.2.2]oct-3-yl {2-[2-(4-fluorophenyl)-1,3-thiazol-4-yl]propan-2-yl}carbamate	Genzyme Europe BV - The Netherlands	Treatment of Gaucher disease	<ul style="list-style-type: none"> • 21/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/30 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Selinexor	Clinipace GmbH - Germany	Treatment of plasma cell myeloma	<ul style="list-style-type: none"> • 19/05/2014 • 11/07/2014 • 09/10/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Recombinant human Pentraxin-2	FGK Representative Service GmbH - Germany	Treatment of primary myelofibrosis	<ul style="list-style-type: none"> • 25/06/2014 • 11/07/2014 • 09/10/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Recombinant human Pentraxin-2	FGK Representative Service GmbH - Germany	Treatment of post-polycythaemia vera myelofibrosis	<ul style="list-style-type: none"> • 25/06/2014 • 11/07/2014 • 09/10/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Pentosan polysulfate sodium	Plexcera Therapeutics EU Limited - Ireland	Treatment of mucopolysaccharidosis type I	<ul style="list-style-type: none"> • 25/06/2014 • 18/08/2014 • 09/10/2014 • (52 days/30 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Siponimod (INN)	Novartis Europharm Limited - United Kingdom	Treatment of dermatomyositis	<ul style="list-style-type: none"> • 17/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/30 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Recombinant human Pentraxin-2	FGK Representative Service GmbH - Germany	Treatment of post-essential thrombocythaemia myelofibrosis	<ul style="list-style-type: none"> • 25/06/2014 • 11/07/2014 • 09/10/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Ataluren	PTC Therapeutics, Limited - United Kingdom	Treatment of mucopolysaccharidosis type I	<ul style="list-style-type: none"> • 22/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/30 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
1-(6-benzothiazolylsulfonyl)-5-chloro-1H-indole-2-butanoic acid	Inventiva - France	Treatment of idiopathic pulmonary fibrosis	<ul style="list-style-type: none"> • 26/06/2014 • 11/07/2014 • 09/10/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Imatinib	Numedicus Limited - United Kingdom	Treatment of acute respiratory distress syndrome	<ul style="list-style-type: none"> • 06/06/2014 • 11/07/2014 • 09/10/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Dantrolene sodium	Eagle Laboratories Ltd - United Kingdom	Treatment of malignant hyperthermia	<ul style="list-style-type: none"> • 22/07/2014 • 18/08/2014 • 09/10/2014 • (52 days/30 days) 	<ul style="list-style-type: none"> • 20/10/2014 • 19/11/2014
Single-chain urokinase plasminogen activator	Coté Orphan Consulting UK Limited - United Kingdom	Treatment of pleural empyema	<ul style="list-style-type: none"> • 25/06/2014 • 18/08/2014 • 13/11/2014 • (87 days/20 days) 	<ul style="list-style-type: none"> • 16/12/2014
Genetically modified serotype 5/3 adenovirus coding for granulocyte macrophage colony-stimulating factor	Oncos Therapeutics Oy - Finland	Treatment of malignant mesothelioma	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Allogeneic adipose-derived adult mesenchymal stem cells contained in a fibrin-based bioengineered dermis	Biodan Yelah S.L. - Spain	Treatment of epidermolysis bullosa	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Plerixafor	Groupe d'étude des neutropénies - France	Treatment of WHIM syndrome	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3 zeta chimeric antigen receptor	Kite Pharma UK, Ltd - United Kingdom	Treatment of diffuse large B cell lymphoma	<ul style="list-style-type: none"> • 20/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Amikacin sulfate	PlumeStars s.r.l. - Italy	Treatment of Pseudomonas aeruginosa lung infection in cystic fibrosis	<ul style="list-style-type: none"> • 27/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Edaravone	Treeway B.V. - The Netherlands	Treatment of amyotrophic lateral sclerosis	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
5,5'-(4-(trifluoromethyl)benzylazanediy)bis(methylene)diquinolin-8-ol	Prof. Olivier Blin	Treatment of glioma	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Heat-killed Mycobacterium obuense (whole cell)	Immodulon Therapeutics Ltd - United Kingdom	Treatment of pancreatic cancer	<ul style="list-style-type: none"> • 15/07/2014 • 18/08/2014 • 13/11/2014 • (87 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Allogeneic CD34+ cells expanded ex-vivo with an aryl hydrocarbon receptor antagonist	Novartis Europharm Limited - United Kingdom	Treatment of acute lymphoblastic leukaemia	<ul style="list-style-type: none"> • 25/06/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Pegylated recombinant human hyaluronidase PH20	Pharm. Research Associates (UK) Limited - United Kingdom	Treatment of pancreatic cancer	<ul style="list-style-type: none"> • 26/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Adenovirus serotype 5 containing partial E1A deletion and an integrin-binding domain	Alan Boyd Consultants Ltd - United Kingdom	Treatment of glioma	<ul style="list-style-type: none"> • 27/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
((E)-1-(4'-chlorophenyl)-3-(4-hydroxy-3-methoxyphenyl)prop-2-en-1-one)	Centre National de la Recherche Scientifique (CNRS) - France	Treatment of WHIM syndrome	<ul style="list-style-type: none"> • 07/07/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Allogeneic bone marrow derived mesenchymal cells expanded ex vivo in synthetic media	Cell2B Advanced Therapeutics, SA - Portugal	Prevention of graft-versus-host disease	<ul style="list-style-type: none"> • 22/07/2014 • 18/08/2014 • 13/11/2014 • (87 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Adeno-associated viral vector serotype rh.10 carrying the human N-sulfoglucosamine sulfohydrolase cDNA	LYSOGENE - France	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome)	<ul style="list-style-type: none"> • 22/07/2014 • 18/08/2014 • 13/11/2014 • (87 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
(1S,4R,5R,7S)-3,4-dibenzyl-2-oxo-6,8-dioxo-3-azabicyclo[3.2.1]octane-7-carboxylic acid-L-lysine	MIMETECH S.r.l. - Italy	Treatment of neurotrophic keratitis	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
5-bromo-N-(prop-2-yn-1-yl)-2-(1H-1,2,4-triazol-1-yl)pyrimidine-4,6-diamine	Palobiofarma S.L. - Spain	Treatment of Huntington's disease	<ul style="list-style-type: none"> • 22/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Chenodeoxycholic acid	Sigma-Tau Pharma Ltd - United Kingdom	Treatment of inborn errors of primary bile acid synthesis	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Benserazide hydrochloride	Isabelle Ramirez - Germany	Treatment of beta-thalassemia intermedia and major	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Exisulind	Firc Institute of Molecular Oncology (IFOM) - Italy	Treatment of familial cerebral cavernous malformations	<ul style="list-style-type: none"> • 22/07/2014 • 18/08/2014 • 13/11/2014 • (87 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Bevacizumab	Dr Sophie Dupuis-Girod - France	Treatment of hereditary haemorrhagic telangiectasia	<ul style="list-style-type: none"> • 12/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
1-(2-isopropoxyethyl)-2-thioxo-1,2,3,5-tetrahydropyrrolo[3,2-d]pyrimidin-4-one	AstraZeneca AB - Sweden	Treatment of multiple system atrophy	<ul style="list-style-type: none"> • 22/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Allogeneic ex vivo-generated natural killer cells from CD34+ umbilical cord blood progenitor cells	IPD-Therapeutics BV - The Netherlands	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> • 25/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Autologous collagen type II-specific regulatory T cells (Common)	TxCell - France	Treatment of non-infectious uveitis	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
5-[8-methyl-9-(1-methylethyl)-2-(4-morpholinyl)-9H-purin-6-yl]-2-pyrimidinamine	TMC Pharma Services Ltd - United Kingdom	Treatment of malignant mesothelioma	<ul style="list-style-type: none"> • 21/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
2-hydroxymethyl-2-methoxymethyl-1-azabicyclo[2,2,2]octan-3-one	Aprea AB - Sweden	Treatment of ovarian cancer	<ul style="list-style-type: none"> • 22/07/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014
Riluzole	Dr Laurent Vinay - France	Treatment of traumatic spinal cord injury	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 13/11/2014 • (62 days/20 days) 	<ul style="list-style-type: none"> • 26/11/2014 • 16/12/2014

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Ponatinib hydrochloride	ARIAD Pharma Ltd - United Kingdom	Treatment of malignant gastro-intestinal stromal tumours	<ul style="list-style-type: none"> • 23/09/2014 • 13/10/2014 • 11/12/2014 • (59 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Sodium valproate	Alan Boyd Consultants Ltd - United Kingdom	Treatment of Wolfram syndrome	<ul style="list-style-type: none"> • 26/09/2014 • 13/10/2014 • 11/12/2014 • (59 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Recombinant human alkaline phosphatase	AM-Pharma BV - The Netherlands	Treatment of hypophosphatasia	<ul style="list-style-type: none"> • 26/09/2014 • 13/10/2014 • 11/12/2014 • (59 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Synthetic signal peptide of human Mucin-1 (amino acids 1-21)	Richardson Associates Regulatory Affairs Ltd - United Kingdom	Treatment of plasma cell myeloma	<ul style="list-style-type: none"> • 25/09/2014 • 13/10/2014 • 11/12/2014 • (59 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Allogeneic peripheral blood mononuclear cells induced to an early apoptotic state	Richardson Associates Regulatory Affairs Ltd - United Kingdom	Prevention of graft-versus- host disease	<ul style="list-style-type: none"> • 25/09/2014 • 13/10/2014 • 11/12/2014 • (59 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
N-methyl-4-({4-[(3-methyl(methylsulfonyl)amino)pyrazin-2-yl)methyl]amino}-5-(trifluoromethyl)pyrimidin-2-yl)amino)benzamide hydrochloride	TMC Pharma Services Ltd - United Kingdom	Treatment of ovarian cancer	<ul style="list-style-type: none"> • 26/09/2014 • 13/10/2014 • 11/12/2014 • (59 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
A lentiviral vector pseudotyped by the Indiana serotype of the vesicular stomatitis virus G protein encoding an antigen derived from the Tax, HBZ, p12I and p30II HTLV-1 proteins	THERAVECTYS - France	Treatment of the adult T-cell leukaemia/lymphoma	<ul style="list-style-type: none"> • 25/08/2014 • 12/09/2014 • 11/12/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
A lentiviral vector pseudotyped by the New-Jersey serotype of the vesicular stomatitis virus G protein encoding an antigen derived from the Tax, HBZ, p12I and p30II HTLV-1 proteins	THERAVECTYS - France	Treatment of the adult T-cell leukaemia/lymphoma	<ul style="list-style-type: none"> • 25/08/2014 • 12/09/2014 • 11/12/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Tenofovir disoproxil fumarate	Dr Yanick Crow - France	Treatment of Aicardi-Goutières syndrome	<ul style="list-style-type: none"> • 24/08/2014 • 12/09/2014 • 11/12/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Sodium thiosulfate	Hope Pharmaceuticals, Ltd - United Kingdom	Treatment for calciphylaxis	<ul style="list-style-type: none"> • 07/08/2014 • 12/09/2014 • 11/12/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Humanised Fc engineered monoclonal antibody against CD19	MorphoSys AG - Germany	Treatment of diffuse large B-cell lymphoma	<ul style="list-style-type: none"> • 25/09/2014 • 13/10/2014 • 11/12/2014 • (59 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Chimeric fusion protein of recombinant human alpha-N-acetylglucosaminidase and human insulin-like growth factor 2	BioMarin Europe Ltd. - United Kingdom	Treatment of mucopolysaccharidosis type III B (Sanfilippo B syndrome)	<ul style="list-style-type: none"> • 24/09/2014 • 13/10/2014 • 11/12/2014 • (59 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Allogeneic, umbilical cord blood-derived, ex vivo-expanded, haematopoietic CD133+ cells / allogeneic, umbilical cord blood-derived, non-expanded, haematopoietic CD133- cells	Regulatory Resources Group Ltd - United Kingdom	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 11/12/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Chimeric monoclonal antibody specific to O-acetyl-GD2 antigen	Atlab Pharma SAS - France	Treatment of neuroblastoma	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 11/12/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Adeno-associated viral vector serotype 8 containing the human factor-VII gene	Professor Edward G. Tuddenham - United Kingdom	Treatment of congenital factor VII deficiency	<ul style="list-style-type: none"> • 26/09/2014 • 13/10/2014 • 11/12/2014 • (59 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Emtricitabine	Dr Yanick Crow - France	Treatment of Aicardi-Goutières syndrome	<ul style="list-style-type: none"> • 24/08/2014 • 12/09/2014 • 11/12/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Recombinant human aspartylglucosaminidase	ACE Biosciences A/S - Denmark	Treatment of aspartylglucosaminuria	<ul style="list-style-type: none"> • 26/08/2014 • 12/09/2014 • 11/12/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015

Product INN	Sponsor	Indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Herpes simplex type 1 virus containing cellular B-myb gene as tumour-specific promoter	Karcinolys S.A.S - France	Treatment of pancreatic cancer	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 11/12/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Pentosan polysulfate sodium	Dr Ulrich Granzer - Germany	Treatment of interstitial cystitis	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 11/12/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Adenoviral vector serotype 5 containing the vascular endothelial growth factor D isoform (preprocessed short form) from a CMV promoter	Magnus Invention Management Ltd - United Kingdom	Treatment of placental insufficiency	<ul style="list-style-type: none"> • 28/08/2014 • 12/09/2014 • 11/12/2014 • (90 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015
Pegylated recombinant arginine deiminase	Designerx Europe Limited - United Kingdom	Treatment of malignant mesothelioma	<ul style="list-style-type: none"> • 07/05/2014 • 13/10/2014 • 11/12/2014 • (59 days/30 days) 	<ul style="list-style-type: none"> • 16/12/2014 • 15/01/2015

Negative COMP designation opinions

Product INN	Sponsor	Summary of indication	EMA/COMP <ul style="list-style-type: none"> • Submission • Start date • Opinion • Active time 	European Commission <ul style="list-style-type: none"> • Opinion received • Date of decision
Sodium ascorbate and menadione sodium bisulfite	JJGConsultancy Ltd - United Kingdom	Treatment of autosomal dominant polycystic kidney disease	<ul style="list-style-type: none"> • 24/03/2014 • 11/04/2014 • 21/07/2014 • 101 days/3 days 	<ul style="list-style-type: none"> • 08/12/2014 • 11/12/2014
5-Chloro-N2-[2-isopropoxy-5-methyl-4-(4-piperidinyl)phenyl]-N4-[2-(isopropylsulfonyl)phenyl]-2,4-pyrimidinediamine	Novartis Europharm Limited - United Kingdom	Treatment of non-small cell lung carcinoma (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive	<ul style="list-style-type: none"> • 23/07/2013 • 09/08/2013 • 17/02/2014 • 192 days/29 days 	<ul style="list-style-type: none"> • 27/02/2014 • 28/03/2014

Annex 13 – HMPC European Union herbal monographs in 2014

European Union herbal monographs - Final

Reference number	Document title	Adoption / Outcome*
First Assessment		
EMA/HMPC/198793/2012	<i>Arnica montana</i> L., flos (Arnicae flos)	May 2014/ TU
EMA/HMPC/604600/2012	<i>Curcuma xanthorrhiza</i> Roxb. (<i>C. xanthorrhiza</i> D. Dietrich), rhizoma (Curcumae xanthorrhizae rhizoma)	Jan 2014/ TU
EMA/HMPC/307781/2012	<i>Eucalyptus globulus</i> Labill., <i>Eucalyptus polybractea</i> R.T. Baker and/or <i>Eucalyptus smithii</i> R.T. Baker, aetheroleum (Eucalypti aetheroleum)	Mar 2014/ TU
EMA/HMPC/313674/2012	<i>Fucus vesiculosus</i> , L., thallus (Fucus vesiculosus)	May 2014/ TU
EMA/HMPC/321233/2012	<i>Panax ginseng</i> , C. A. Meyer, radix (Ginseng radix)	Mar 2014/ TU
EMA/HMPC/678891/2013	<i>Cetraria islandica</i> L. Acharius s.l., thallus (Lichen islandicus)	Nov 2014/ TU
EMA/HMPC/320930/2012	<i>Melaleuca alternifolia</i> (Maiden and Betch) Cheel, <i>M. linariifolia</i> Smith, <i>M. dissitiflora</i> F. Mueller and/or other species of <i>Melaleuca</i> , aetheroleum (Melaleucae alternifoliae aetheroleum)	Nov 2014/ TU
EMA/HMPC/138317/2013	<i>Ononis spinosa</i> L., radix (Ononidis radix)	Mar 2014/ TU
EMA/HMPC/137299/2013	<i>Rosa gallica</i> L., <i>Rosa centifolia</i> L., <i>Rosa damascena</i> Mill., flos (Rosae flos)	Jul 2014/ TU
EMA/HMPC/44211/2012	<i>Rubus idaeus</i> L., folium (Rubi idaei folium)	Jan 2014/ TU
EMA/HMPC/280193/2013	<i>Sisymbrium officinale</i> L. Scop, herba (Sisymbrii officinalis herba)	Sep 2014/ TU
Revision		
EMA/HMPC/573241/2014	<i>Betula pendula</i> Roth., <i>Betula pubescens</i> Ehrh., as well as hybrids of both species, folium (Betulae folium)	Nov 2014/ TU
EMA/HMPC/48704/2014	<i>Echinacea purpurea</i> L. Moench, herba recens (Echinaceae purpureae herba)	Nov 2014/ TU+WEU
EMA/253144/2015	<i>Eleutherococcus senticosus</i> (Rupr. et Maxim.) Maxim.), radix (Eleutherococci radix)	Mar 2014/ TU
EMA/HMPC/682384/2013	<i>Humulus lupulus</i> L., flos (Lupuli flos)	May 2014/ TU
EMA/HMPC/669740/2013	<i>Passiflora incarnate</i> L., herba (Passiflorae herba)	Mar 2014/TU

*TU= Traditional Use, WEU= Well Established Use

European Union herbal monographs - Draft

Reference number	Document title	Adoption / Outcome*
First Assessment		
EMA/HMPC/321097/2012	<i>Ginkgo biloba</i> L., folium (Ginkgo folium)	Jan 2014/ TU+WEU
EMA/HMPC/680597/2013	<i>Agrimonia eupatoria</i> L., herba (Agrimoniae herba)	May 2014/ TU
EMA/HMPC/678891/2013	<i>Cetraria islandica</i> (L.)Acharius s.l., thallus (Lichen islandicus)	May 2014/TU
EMA/HMPC/278814/2010	<i>Matricaria recutita</i> L., aetheroleum (Matricariae aetheroleum)	Jul 2014/TU
EMA/HMPC/55843/2011	<i>Matricaria recutita</i> L., flos, (Matricariae flos)	Jul 2014/TU
EMA/HMPC/680374/2013	<i>Hieracium pilosella</i> L., herba (Pilosellae herba)	Jul 2014/TU
EMA/HMPC/680372/2013	<i>Eschscholzia californica</i> Cham., herba (Eschscholziae herba)	Jul 2014/TU
EMA/HMPC/674139/2013	<i>Capsicum annuum</i> L. var. <i>minimum</i> (Miller) Heiser and small fruited varieties of <i>Capsicum frutescens</i> L., fructus (Capsici fructus)	Jul 2014/WEU
EMA/HMPC/159075/2014	<i>Crataegus</i> spp., folium cum flore (Crataegi folium cum flore)	Sep 2014/TU
EMA/HMPC/280079/2013	<i>Serenoa repens</i> (W. Bartram) Small, fructus (Sabalise serrulatae fructus)	Nov 2014/ TU+WEU
EMA/HMPC/715094/2013	<i>Carum carvi</i> L., aetheroleum (Carvi aetheroleum)	Nov 2014/ TU
EMA/HMPC/715092/2013	<i>Carum carvi</i> L., fructus (Carvi fructus)	Nov 2014/ TU

*TU= Traditional Use, WEU= Well Established Use

European Union List entries

Reference number	Document title	Adoption *
First Assessment		
EMA/HMPC/281620/2013	<i>Melaleuca alternifolia</i> (Maiden and Betch) Cheel, <i>M. linariifolia</i> Smith, <i>M. dissitiflora</i> F. Mueller and/or other species of <i>Melaleuca</i> , aetheroleum (Melaleucaae alternifoliae aetheroleum)	Nov 2014
Revision		
EMA/HMPC/680616/2013	<i>Eleutherococcus senticosus</i> (Rupr. et Maxim.) Maxim.), radix (Eleutherococci radix)	Mar 2014

* adopted for transfer to the European Commission

Public statements

Reference number	Document title	Adoption
Drafts		
EMA/HMPC/161476/2014	<i>Picrorhiza kurroa</i> Royle ex Benth, radix (Picrorhizae kurroae rhizoma et radix)	Jul 2014
Final		
EMA/HMPC/32465/2013	<i>Sambucus nigra</i> L., fructus (Sambuci fructus)	Jan 2014

Annex 14 – PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2014

First PIP applications (with or without partial waivers), product-specific waivers, modifications of agreed PIP

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
(1aR,12bS)-8-Cyclohexyl-N-(dimethylsulfamoyl)-11-methoxy-1a-(((1R,5S)-3-methyl-3,8-diazabicyclo[3.2.1]oct-8-yl)carbonyl)-1,1a,2,12b-tetrahydrocyclopropa[d]indolo[2,1-a][2]benzazepine-5-carboxamide hydrochloride (company code BMS-791325) / asunaprevir / daclatasvir dihydrochloride	not available at present	PIP modification	PIP agreed	Infectious Diseases	Bristol-Myers Squibb International Corporation	12/12/2014	P/0002/2015	15/01/2015
Amlodipine / Perindopril erbumine	Perindopril Erbumine/Amlodipine Actavis	Full Waiver	Full waiver granted	Cardiovascular Diseases	Actavis Group PTC ehf	12/12/2014	P/0028/2015	30/01/2015
Amlodipine besilate / Candesartan cilexetil	not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Krka, d.d., Novo mesto	12/12/2014	P/0026/2015	30/01/2015
Benralizumab	Not available at present	PIP modification	PIP agreed	Pneumology - Allergology	MedImmune Ltd	12/12/2014	P/0018/2015	30/01/2015
Denosumab	XGEVA	PIP modification	PIP agreed	Immunology- Rheumatology- Transplantation / Endocrinology- Gynaecology- Fertility-Metabolism / Oncology	Amgen Europe B.V.	12/12/2014	P/0006/2015	30/01/2015
Eluxadoline	Xenryma	PIP	PIP agreed	Gastroenterology- Hepatology	Furiex Pharmaceuticals, Inc	12/12/2014	P/0021/2015	30/01/2015
Empagliflozin	Jardiance	PIP modification	PIP agreed	Endocrinology- Gynaecology- Fertility-Metabolism	Boehringer Ingelheim International GmbH	12/12/2014	P/0016/2015	30/01/2015
Eslicarbazepine acetate	Zebinix	PIP modification	PIP agreed	Neurology	BIAL - Portela & Ca, SA	12/12/2014	P/0015/2015	30/01/2015

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
Everolimus	Afinitor and associated names	Full Waiver	Full waiver granted	Oncology	Novartis Europharm Ltd	12/12/2014	P/0004/2015	30/01/2015
Finerenone	Not available at present	PIP	PIP agreed	Uro-nephrology	Bayer Pharma AG	12/12/2014	P/0025/2015	30/01/2015
Human Papillomavirus type 18 L1 protein / Human Papillomavirus type 16 L1 protein	Cervarix	Full Waiver	Full waiver granted	Vaccines	GlaxoSmithKline Biologicals SA	12/12/2014	P/0008/2015	30/01/2015
Lutetium [177 Lu] (chloride)	Not available at present	Full Waiver	Full waiver granted	Other / Oncology	ITG Isotope Technologies Garching GmbH	12/12/2014	P/0029/2015	30/01/2015
Melatonin	Circadin	PIP modification	PIP agreed	Neurology	RAD Neurim Pharmaceuticals EEC Ltd	12/12/2014	P/0012/2015	30/01/2015
Reslizumab	REZLEO (pending FDA review)	PIP	PIP agreed	Pneumology - Allergology	Teva Pharma GmbH	12/12/2014	P/0017/2015	30/01/2015
Surotomycin	not available at present	PIP modification	PIP agreed	Infectious Diseases	Cubist (UK) Ltd.	12/12/2014	P/0019/2015	30/01/2015
Tiotropium bromide (monohydrate) [quantities relate to tiotropium]	Spiriva Respimat 2.5 microgram, solution for inhalation, Spiriva 18 microgram, inhalation powder, hard capsule	PIP modification	PIP agreed	Pneumology - Allergology	Boehringer Ingelheim International GmbH	12/12/2014	P/0005/2015	30/01/2015
conestat alfa	Ruconest	PIP modification	PIP agreed	Other	Pharming Group N.V.	12/12/2014	P/0010/2015	30/01/2015
elbasvir	Not available at present	PIP	PIP agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	12/12/2014	P/0023/2015	30/01/2015
elbasvir / grazoprevir	Not available at present	PIP	PIP agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	12/12/2014	P/0024/2015	30/01/2015
eltrombopag (eltrombopag olamine)	Revolade	PIP modification	PIP agreed	Infectious Diseases / Oncology / Gastroenterology-Hepatology / Haematology-Hemostaseology	GlaxoSmithKline Trading Services Limited	12/12/2014	P/0007/2015	30/01/2015
grazoprevir	Not available at present	PIP	PIP agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	12/12/2014	P/0022/2015	30/01/2015

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
ledipasvir / sofosbuvir	Harvoni	PIP modification	PIP agreed	Infectious Diseases	Gilead Sciences International Ltd	12/12/2014	P/0003/2015	16/01/2015
linagliptin	Trajenta	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	12/12/2014	P/0001/2015	07/01/2015
mirabegron	Betmiga	PIP modification	PIP agreed	Uro-nephrology	Astellas Pharma Europe B.V.	12/12/2014	P/0014/2015	30/01/2015
raltegravir	ISENTRESS	PIP modification	PIP agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	12/12/2014	P/0009/2015	30/01/2015
recombinant human heparan N-sulfatase (rhHNS)	not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism / Neurology	Shire Human Genetic Therapies AB	12/12/2014	P/0027/2015	30/01/2015
rilpivirine (as hydrochloride)	EDURANT	PIP modification	PIP agreed	Infectious Diseases	Janssen-Cilag International NV	12/12/2014	P/0344/2014	22/12/2014
roxadustat	Please see recommended INN above	PIP	PIP agreed	Haematology-Hemostaseology	Astellas Pharma Europe B.V.	12/12/2014	P/0020/2015	30/01/2015
secukinumab	Cosentyx	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	Novartis Europharm Ltd	12/12/2014	P/0011/2015	30/01/2015
tofacitinib	Xeljanz	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	Pfizer Limited	12/12/2014	P/0013/2015	30/01/2015
Calcium (carbonate) / cholecalciferol (in combination with ibandronic acid) / Calcium (carbonate) / cholecalciferol (in combination with ibandronic acid)	Ossica CalciplusD	Full Waiver	Full waiver granted	Other	Gedeon Richter Plc.	14/11/2014	P/0341/2014	22/12/2014
Calcium (carbonate) / cholecalciferol (in combination with zoledronic acid (monohydrate)) / Calcium (carbonate) / cholecalciferol (in combination with zoledronic acid (monohydrate))	Zoledronic acid Richter CalciplusD	Full Waiver	Full waiver granted	Oncology	Gedeon Richter Plc.	14/11/2014	P/0325/2014	19/12/2014
Clostridium difficile Toxin B human monoclonal antibody	not available at present	PIP	PIP agreed	Infectious Diseases	Merck Sharp & Dohme (Europe),	14/11/2014	P/0340/2014	22/12/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
					Inc.			
Covalently closed DNA plasmids coding for cytomegalovirus phosphoprotein 65 and glycoprotein B genes	not available at present	PIP	PIP agreed	Infectious Diseases	Astellas Pharma Europe B.V.	14/11/2014	P/0338/2014	22/12/2014
Dapagliflozin / Saxagliptin	Not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	14/11/2014	P/0322/2014	19/12/2014
Drisapersen	Not available at present	PIP modification	PIP agreed	Neurology	Prosensa Therapeutics B.V.	14/11/2014	P/0342/2014	12/12/2014
Human Fibrinogen	not available at present	PIP modification	PIP agreed	Haematology-Hemostaseology	Octapharma Pharmazeutika Produktionsges.m.b.H	14/11/2014	P/0334/2014	22/12/2014
Human normal immunoglobulin for subcutaneous use	Not available at present	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology	Kedrion S.p.A.	14/11/2014	P/0319/2014	19/12/2014
Ibandronic acid (in combination with calcium (carbonate) / cholecalciferol)	Ossica CalciplusD	Full Waiver	Full waiver granted	Other	Gedeon Richter Plc.	14/11/2014	P/0339/2014	22/12/2014
Liraglutide	Victoza	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	14/11/2014	P/0318/2014	19/12/2014
MEDI9929 - human immunoglobulin G2λ monoclonal antibody directed against thymic stromal lymphopoietin (TSLP)	Not Available at present	PIP	PIP agreed	Pneumology - Allergology	AstraZeneca Global Regulatory Affairs	14/11/2014	P/0316/2014	05/12/2014
Mepolizumab	Not available at present	PIP	PIP agreed	Pneumology - Allergology	GSK Trading Services Limited	14/11/2014	P/0326/2014	22/12/2014
Nonacog beta pegol	not available at present	PIP modification	PIP agreed	Haematology-Hemostaseology	Novo Nordisk A/S	14/11/2014	P/0329/2014	11/12/2014
Pollen from Dactylis glomerata, Lolium perenne, Phleum pratense, Festuca pratensis, Secale cereale	Avanz 4 grass mix and rye	PIP modification	PIP agreed	Other	ALK-Abelló A/S	14/11/2014	P/0330/2014	22/12/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
Pollen from Phleum pratense	Avanz Phleum pratense	PIP modification	PIP agreed	Other	ALK-Abelló A/S	14/11/2014	P/0320/2014	19/12/2014
Ramipril / Amlodipine	Amlodipine + Ramipril Saleta	Full Waiver	Full waiver granted	Cardiovascular Diseases	HELM PORTUGAL, LDA.	14/11/2014	P/0323/2014	19/12/2014
Recombinant Coagulation Factor VIII SingleChain (rVIII-SingleChain)	Lonoctocog alfa	PIP modification	PIP agreed	Haematology-Hemostaseology	CSL Behring GmbH	14/11/2014	P/0335/2014	22/12/2014
Tolvaptan	Samsca, Jinarc	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Otsuka Pharmaceutical Europe Ltd.	14/11/2014	P/0336/2014	22/12/2014
Urofollitropin	Stimogen 75 IU/150 IU/225 IU/300 IU Powder and solvent for solution for injection	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	Regiomedica GmbH	14/11/2014	P/0321/2014	19/12/2014
Zoledronic acid (monohydrate) (in combination with calcium (carbonate) / cholecalciferol)	Zoledronic acid Richter CalciplusD	Full Waiver	Full waiver granted	Oncology	Gedeon Richter Plc.	14/11/2014	P/0324/2014	19/12/2014
bilastine	Bilaxten and associated names	PIP modification	PIP agreed	Dermatology / Pneumology - Allergology / Oto-rhino-laryngology	Faes Farma S.A.	14/11/2014	P/0327/2014	11/12/2014
dabrafenib	Tafinlar	PIP modification	PIP agreed	Oncology	GlaxoSmithKline Trading Service Limited	14/11/2014	P/0332/2014	22/12/2014
deferiprone	not available at present	PIP modification	PIP agreed	Haematology-Hemostaseology	Consorzio per Valutazioni Biologiche e Farmacologiche	14/11/2014	P/0331/2014	22/12/2014
ivacaftor / lumacaftor	not available at present	PIP modification	PIP agreed	Pneumology - Allergology	Vertex Pharmaceuticals (Europe) Ltd.	14/11/2014	P/0337/2014	22/12/2014
posaconazole	Noxafil	PIP modification	PIP agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	14/11/2014	P/0328/2014	22/12/2014
serelaxin	REASANZ	PIP modification	PIP agreed	Cardiovascular Diseases	Novartis Europharm Ltd.	14/11/2014	P/0333/2014	22/12/2014
vedolizumab	Entyvio	PIP modification	PIP agreed	Gastroenterology-Hepatology	Takeda Pharma A/S	14/11/2014	P/0317/2014	12/12/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n. n.	Decision signature date
(R)-7-Chloro-benzo[b]thiophene-2-carboxylic acid (1-azabicyclo[2.2.2]oct-3-yl)-amide hydrochloride hydrate	Not available at present	PIP	PIP agreed	Psychiatry / Neurology	FORUM Pharmaceuticals, Inc.	04/11/2014	P/0288/2014	12/12/2014
Dapagliflozin	Forxiga	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Bristol Myers Squibb /AstraZeneca EEIG	10/10/2014	P/0310/2014	25/11/2014
Eculizumab	SOLIRIS	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	ALEXION EUROPE SAS	10/10/2014	P/0290/2014	24/07/2014
Fluticasone furoate / vilanterol	Fluticasone Furoate (INN), Vilanterol Trifenatate (INN)	PIP modification	PIP agreed	Pneumology - Allergology	Glaxo Group Limited	10/10/2014	P/0291/2014	24/10/2014
Fluticasone propionate / Formoterol fumarate	Flutiform	PIP modification	PIP agreed	Pneumology - Allergology	Mundipharma Research Limited	10/10/2014	P/0297/2014	24/11/2014
Glycopyrronium bromide	not available at present	PIP	Negative	Oto-rhino-laryngology / Neurology	Desitin Arzneimittel GmbH	10/10/2014	P/0343/2014	22/12/2014
Heterologous Human Adult Liver-derived Progenitor Cells (HHAPLC)	HepaStem Promethera	PIP modification	PIP agreed	Gastroenterology-Hepatology	Promethera Biosciences	10/10/2014	P/0314/2014	24/11/2014
Human Thrombin (Component 2) / Human Fibrinogen (Component 1)	Not available yet	PIP	PIP agreed	Other	Instituto Grifols, S.A.	10/10/2014	P/0289/2014	24/10/2014
Inotuzumab Ozogamicin	Not available	PIP	PIP agreed	Oncology / Haematology-Hemostaseology	Pfizer Ltd.	10/10/2014	P/0304/2014	24/11/2014
L-asparaginase encapsulated in erythrocytes	GRASPA	PIP modification	PIP agreed	Oncology	ERYTECH pharma S.A.	10/10/2014	P/0300/2014	24/11/2014
Lomitapide (as lomitapide mesylate)	Lojuxta	PIP modification	PIP agreed	Other	Aegerion Pharmaceuticals Limited	10/10/2014	P/0312/2014	26/11/2014
Naloxone (hydrochloride)	not available at present	PIP	PIP agreed	Pain / Gastroenterology-Hepatology	Develco Pharma GmbH	10/10/2014	P/0305/2014	24/11/2014
Pandemic live attenuated influenza virus (H5N1)	Not available at present	PIP	PIP agreed	Vaccines	MedImmune Limited	10/10/2014	P/0313/2014	26/11/2014
Perampanel	Fycompa	PIP modification	PIP agreed	Neurology	Eisai Europe Limited	10/10/2014	P/0301/2014	24/11/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
Polyethylene glycol (PEG) 3350	Not available at present	Full Waiver	Full waiver granted	Gastroenterology- Hepatology	MAYOLY SPINDLER	10/10/2014	P/0308/2014	24/11/2014
Recombinant fusion protein consisting of Human Coagulation Factor IX attached to the Fc domain of Human IgG1 (rFIXFc)	Not available at present	PIP modification	PIP agreed	Haematology- Hemostaseology	Biogen Idec Ltd	10/10/2014	P/0303/2014	24/11/2014
Ticagrelor	BRILIQUE	PIP modification	PIP agreed	Cardiovascular Diseases	AstraZeneca AB	10/10/2014	P/0295/2014	30/10/2014
Tigecycline	Tygalil	PIP modification	PIP agreed	Other	Pfizer Limited	10/10/2014	P/0292/2014	24/10/2014
Varicella-zoster virus (live, attenuated)	ZOSTAVAX	Full Waiver	Full waiver granted	Vaccines	Sanofi Pasteur MSD SNC	10/10/2014	P/0309/2014	24/11/2014
abaloparatide	not available at present	Full Waiver	Full waiver granted	Endocrinology- Gynaecology- Fertility-Metabolism	Triskel EU Services, Ltd (Jean-Yves le Cotonnec)	10/10/2014	P/0307/2014	24/11/2014
asenapine (maleate)	Sycrest	PIP modification	PIP agreed	Psychiatry	N.V. Organon	10/10/2014	P/0299/2014	24/11/2014
belimumab	BENLYSTA™	PIP modification	PIP agreed	Immunology- Rheumatology- Transplantation	Glaxo Group Limited	10/10/2014	P/0302/2014	24/11/2014
delta-9-tetrahydrocannabinol / cannabidiol	Sativex	PIP	PIP agreed	Neurology	GW Pharma Ltd	10/10/2014	P/0298/2014	24/11/2014
midostaurin	not available at present	PIP modification	PIP agreed	Oncology	Novartis Europharm Ltd	10/10/2014	P/0296/2014	07/11/2014
purified adenylate cyclase recombinant protein carrying sub-fragments of the early protein E7 antigen from human papillomavirus strain 18 (recombinant CyaA-HPV18E7) / Purified adenylate cyclase recombinant protein carrying sub-fragments of the early protein E7 antigen from human papillomavirus strain 16 (recombinant CyaA-HPV16E7)	ProCervix	Full Waiver	Full waiver granted	Vaccines	Gentical S.A.	10/10/2014	P/0306/2014	24/11/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
thiocolchicoside / diclofenac sodium	Diclotio	Full Waiver	Full waiver granted	Pain	Epifarma Srl	10/10/2014	P/0311/2014	25/11/2014
valsartan / amlodipine besylate	Exforge	Full Waiver	Full waiver granted	Cardiovascular Diseases	Novartis Europharm Ltd.	10/10/2014	P/0315/2014	05/12/2014
4-((2R,3S,4R,5S)-3-(3-chloro-2-fluorophenyl)-4-(4-chloro-2-fluorophenyl)-4-cyano-5-neopentylpyrrolidine-2-carboxamido)-3-methoxybenzoic acid	Not available at present	PIP	PIP agreed	Oncology	Roche Registration Ltd	12/09/2014	P/0285/2014	28/10/2014
Allantoin	Not available at present	PIP	PIP agreed	Dermatology	Scioderm, Inc.	12/09/2014	P/0266/2014	13/10/2014
Belimumab	BENLYSTA™	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Glaxo Group Limited	12/09/2014	P/0276/2014	28/10/2014
Bimatoprost	Lumigan and invented names	PIP modification	Full waiver granted	Ophthalmology / Dermatology	Allergan Pharmaceuticals Ireland	12/09/2014	P/0293/2014	30/10/2014
Cabotegravir (proposed INN)	Not available at present	PIP	PIP agreed	Infectious Diseases	ViiV Healthcare UK Limited	12/09/2014	P/0272/2014	27/10/2014
Calcium chloride / Aprotinin / Thrombin / Fibrinogen	Silketal	PIP modification	PIP agreed	Other	Kedrion S.p.A.	12/09/2014	P/0280/2014	30/10/2014
Cholera Vaccine, Live Attenuated, Oral (strain CVD 103-HgR)	Not available at present	PIP	PIP agreed	Vaccines	PaxVax Inc.	12/09/2014	P/0286/2014	28/10/2014
Delamanid	Delyba 50 mg film-coated tablets, (not available yet for the dispersible tablet)	PIP modification	PIP agreed	Infectious Diseases	Otsuka Frankfurt Research Institute GmbH	12/09/2014	P/0281/2014	28/10/2014
Fidaxomicin	Difclir	PIP modification	PIP agreed	Infectious Diseases	Astellas Pharma Europe B.V.	12/09/2014	P/0264/2014	03/10/2014
Glycopyrronium bromide	Sialanar	PIP modification	PIP agreed	Neurology	Proveca Limited	12/09/2014	P/0240/2014	26/09/2014
Human normal immunoglobulin	HyQvia 100 mg/ml solution for infusion for subcutaneous use	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	Baxter Innovations GmbH	12/09/2014	P/0278/2014	30/10/2014
Landiolol (hydrochloride)	Rapibloc	PIP	PIP agreed	Cardiovascular Diseases	AOP Orphan Pharmaceuticals AG	12/09/2014	P/0283/2014	30/10/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n. n.	Decision signature date
MAGE-A3 recombinant protein	zastumotide	PIP modification	Full waiver granted	Oncology	GlaxoSmithKline Biologicals s.a	12/09/2014	P/0294/2014	30/10/2014
Molidustat (sodium)	Not available at present	PIP	PIP agreed	Haematology-Hemostaseology	Bayer Pharma AG	12/09/2014	P/0273/2014	27/10/2014
Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; Escherichia coli) / Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; Escherichia coli)	Not available yet	PIP modification	PIP agreed	Vaccines	Pfizer Ltd	12/09/2014	P/0279/2014	28/10/2014
Piperaquine phosphate anhydride / dihydroartemisinin	Eurartesim	PIP modification	Negative	Infectious Diseases	Sigma-Tau SpA	12/09/2014	P/0265/2014	10/10/2014
Recombinant fusion protein linking coagulation factor IX with albumin	Albutrepenonacog alfa	PIP modification	PIP agreed	Haematology-Hemostaseology	CSL Behring GmbH	12/09/2014	P/0269/2014	27/10/2014
Regorafenib	Stivarga	PIP modification	PIP agreed	Oncology	Bayer Pharma AG	12/09/2014	P/0270/2014	27/10/2014
Rufinamide	Inovelon 40 mg/mL Oral Suspension	PIP modification	PIP agreed	Neurology	Eisai Limited	12/09/2014	P/0277/2014	28/10/2014
Solifenacin (succinate)	Vesicare	PIP modification	PIP agreed	Uro-nephrology	Astellas Pharma Europe B.V.	12/09/2014	P/0260/2014	29/09/2014
						12/09/2014	P/0261/2014	29/09/2014
Tabalumab	Not available at present	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	Eli Lilly and Company Limited	12/09/2014	P/0268/2014	27/10/2014
ambrisentan	Volibris	PIP modification	PIP agreed	Cardiovascular Diseases	Glaxo group Limited	12/09/2014	P/0267/2014	16/10/2014
ibrutinib	Imbruvica	Full Waiver	Full waiver granted	Oncology	Janssen-Cilag International N.V.	12/09/2014	P/0271/2014	27/10/2014
lacosamide	VIMPAT	PIP modification	PIP agreed	Neurology	UCB Pharma S.A.	12/09/2014	P/0275/2014	28/10/2014
lenvatinib	Lenvima	PIP modification	PIP agreed	Oncology	Eisai Europe Limited	12/09/2014	P/0282/2014	28/10/2014
sotagliflozin	not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-	Lexicon Celtic Limited	12/09/2014	P/0287/2014	28/10/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
				Fertility-Metabolism				
turoctocog alfa pegol	Not available at present	PIP modification	PIP agreed	Haematology-Hemostaseology	Novo Nordisk A/S	12/09/2014	P/0284/2014	28/10/2014
von Willebrand Factor / Human coagulation Factor VIII	Voncento	PIP modification	PIP agreed	Haematology-Hemostaseology	CSL Behring	12/09/2014	P/0274/2014	28/10/2014
Alogliptin	Vipidia	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Takeda Development Centre Europe Ltd	15/08/2014	P/0242/2014	29/09/2014
Amikacin sulfate	Liposomal Amikacin for Inhalation (LAI) (formerly Arikace™)	PIP modification	PIP agreed	Infectious Diseases / Pneumology - Allergology	Insmed Limited	15/08/2014	P/0248/2014	30/09/2014
Brentuximab vedotin	Adcetris	PIP modification	PIP agreed	Oncology	Takeda Pharma A/S	15/08/2014	P/0263/2014	03/10/2014
Brexpiprazole	Not available at present	PIP modification	PIP agreed	Psychiatry	Otsuka Europe Development and Commercialisation Ltd, Zweigniederlassung Frankfurt am Main	15/08/2014	P/0243/2014	29/09/2014
Brodalumab	Not available at present	PIP	PIP agreed	Dermatology	Amgen Europe B.V.	15/08/2014	P/0235/2014	08/09/2014
D-Argininamide, N-acetyl-D-cysteiny-D-alanyl-D-arginyl-D-arginyl-D-arginyl-D-alanyl-, disulfide with L-cysteine (AMG 416)	Not available at present	PIP	PIP agreed	Uro-nephrology	Amgen Europe B.V.	15/08/2014	P/0259/2014	01/10/2014
Edoxaban tosylate	Edoxaban	PIP modification	PIP agreed	Cardiovascular Diseases	Daiichi Sankyo Development Limited	15/08/2014	P/0250/2014	30/09/2014
Eltrombopag (olamine)	Revolade	PIP	PIP agreed	Infectious Diseases / Oncology / Gastroenterology-Hepatology / Haematology-Hemostaseology	GlaxoSmithKline Trading Services Limited	15/08/2014	P/0262/2014	03/10/2014
Expanded human allogeneic mesenchymal adult stem cells extracted from adipose tissue (eASCs)	Not yet available	PIP	PIP agreed	Gastroenterology-Hepatology	TiGenix, S.A.U.	15/08/2014	P/0253/2014	29/09/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
Ibuprofen (sodium dihydrate)	not available at present	PIP	PIP agreed	Other / Pain	Proveca Limited	15/08/2014	P/0255/2014	30/09/2014
Mepolizumab	Not available at present	PIP modification	PIP agreed	Pneumology - Allergology	GSK Trading Services Limited	15/08/2014	P/0234/2014	29/08/2014
Metformin hydrochloride	EX404 Metformin HCl 650 mg Effervescent granules	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	EffRx Pharmaceuticals SA	15/08/2014	P/0244/2014	29/09/2014
Migalastat (hydrochloride)	not available at present	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Amicus Therapeutics UK Ltd	15/08/2014	P/0256/2014	01/10/2014
Nanobody directed towards the fusion protein of human respiratory syncytial virus (ALX-0171)	Not available at present	PIP	PIP agreed	Neonatology - Paediatric Intensive Care	Ablynx NV	15/08/2014	P/0246/2014	29/09/2014
Potassium citrate monohydrated / Potassium hydrogen carbonate	not available at present	PIP	PIP agreed	Uro-nephrology	Advicenne Pharma	15/08/2014	P/0252/2014	30/09/2014
Potassium hydrogen carbonate / Potassium citrate monohydrated	not available at present	PIP	PIP agreed	Uro-nephrology	Advicenne Pharma	15/08/2014	P/0257/2014	01/10/2014
Recombinant soluble fusion protein with a modified form of the extracellular domain of human activin receptor 11B linked to the human IgG1 Fc domain	Not available at present	PIP	PIP agreed	Haematology-Hemostaseology	Acceleron Pharma, Inc.	15/08/2014	P/0245/2014	29/09/2014
Secukinumab	Not available at present	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	15/08/2014	P/0247/2014	30/09/2014
Sirukumab	Not available at present	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	Janssen-Cilag International N.V.	15/08/2014	P/0251/2014	30/09/2014
Sunitinib	Sutent	PIP modification	Negative	Oncology	Pfizer Limited	15/08/2014		00/00/0
Tedizolid (phosphate)	Sivextro	PIP modification	PIP agreed	Infectious Diseases	Cubist Pharmaceuticals (UK) Limited	15/08/2014	P/0258/2014	01/10/2014
Tenofovir disoproxil (as fumarate)	Viread	PIP modification	PIP agreed	Infectious Diseases	Gilead Sciences International Limited	15/08/2014	P/0249/2014	30/09/2014
dabigatran etexilate mesilate	Pradaxa	PIP modification	PIP agreed	Cardiovascular Diseases / Haematology-	Boehringer Ingelheim International GmbH	15/08/2014	P/0241/2014	29/09/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
				Hemostaseology				
solithromycin	not available at present	PIP	PIP agreed	Infectious Diseases	Triskel EU Services, Ltd	15/08/2014	P/0254/2014	30/09/2014
(R)-2-[3-({Benzoxazol-2-yl}[3-(4-methoxyphenoxy)propyl]amino)methyl]phenoxy]butanoic acid	not available at present	Full Waiver	Negative	Cardiovascular Diseases	Kowa Research Europe Ltd	18/07/2014	P/0222/2014	03/09/2014
4-{[(1R,2s,3S,5s,7s)-5-Hydroxy-2-adamantyl]amino}-1H-pyrrolo[2,3-b]pyridine-5-carboxamide monohydrobromide	Not available at present	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Janssen Cilag International NV	18/07/2014	P/0221/2014	03/09/2014
Aliskiren	Rasilez	PIP modification	PIP agreed	Cardiovascular Diseases	Novartis Europharm Limited	18/07/2014	P/0227/2014	05/09/2014
CODA001 - natural, unmodified antisense oligonucleotide (30-mer) with nucleotide sequence 5'-GTAATTGCGGCAAGAAGAAT TGTTTCTGTC-3'	Nexagon	Full Waiver	Full waiver granted	Dermatology	CoDa Therapeutics Inc	18/07/2014	P/0233/2014	05/09/2014
Cobicistat	Tybost	PIP modification	PIP agreed	Infectious Diseases	Gilead Sciences International Limited	18/07/2014	P/0212/2014	01/09/2014
Enalapril maleate	Not available at present	PIP modification	PIP agreed	Cardiovascular Diseases	Proveca Limited	18/07/2014	P/0219/2014	03/09/2014
Ertugliflozin	Not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp and Dohme (Europe), Inc.	18/07/2014	P/0214/2014	01/09/2014
Ferric citrate (pharmaceutical grade)	Fexeric (previously: "Zerenex")	PIP modification	PIP agreed	Uro-nephrology	Keryx Biopharmaceuticals, Inc.	18/07/2014	P/0218/2014	03/09/2014
Foclivia: Influenza virus surface antigens of pandemic strain tbd / Focetria: Influenza virus surface antigens of strain - A/California/07/2009 (H1N1v) / PIV: Influenza virus surface antigens of	Focetria and associated names, Aflunov and associated names, Prepandemic Influenza Vaccine and associated names, Foclivia and associated names	PIP modification	Negative	Vaccines	Novartis Vaccines and Diagnostics S.r.l.	18/07/2014	P/0230/2014	05/09/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
strain - A/Vietnam /1194 (H5N1v) / Aflunov: Influenza virus surface antigens of strain - A/turkey/Turkey/1/05 (H5N1v)								
Idelalisib	Not available at present	PIP modification	PIP agreed	Oncology	Gilead Sciences International Ltd	18/07/2014	P/0220/2014	03/09/2014
Maraviroc	Celsentri	PIP modification	PIP agreed	Infectious Diseases	ViiV Healthcare UK Limited	18/07/2014	P/0224/2014	05/09/2014
N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid	Nimenrix	PIP modification	PIP agreed	Vaccines	GlaxoSmithKline Biologicals s.a	18/07/2014	P/0228/2014	05/09/2014
Propan-2-yl N-[(S)-({[(2R)-1-(6-amino-9H-purin-9-yl)propan-2-yl]-oxy}methyl)(phenoxy)phosphoryl]-l-alaninate, (2E)-but-2-enedioate (2:1)	Not available at present	PIP	PIP agreed	Infectious Diseases	Gilead Sciences International Ltd.	18/07/2014	P/0209/2014	11/08/2014
Tadalafil	Cialis, Adcirca	PIP modification	PIP agreed	Cardiovascular Diseases	Eli Lilly and Company Ltd	18/07/2014	P/0229/2014	05/09/2014
Tapentadol	Palexia	PIP modification	PIP agreed	Pain	Grünenthal GmbH	18/07/2014	P/0236/2014	19/09/2014
						18/07/2014	P/0237/2014	19/09/2014
						18/07/2014	P/0238/2014	19/09/2014
Trifarotene	Not available at present	PIP	PIP agreed	Dermatology	Galderma International	18/07/2014	P/0231/2014	05/09/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
apremilast	Not available at present	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Celgene Europe Limited	18/07/2014	P/0217/2014	03/09/2014
bisoprolol / perindopril	Not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Les Laboratoires Servier	18/07/2014	P/0213/2014	01/09/2014
bromfenac (sodium sesquihydrate)	BromSite	Full Waiver	Full waiver granted	Ophthalmology	InSite Vision Incorporated	18/07/2014	P/0232/2014	05/09/2014
dalbavancin	Xydalba	PIP modification	PIP agreed	Infectious Diseases	Durata Therapeutics International B.V.	18/07/2014	P/0223/2014	05/09/2014
golimumab	Simponi	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	Janssen Biologics BV	18/07/2014	P/0226/2014	05/09/2014
insulin aspart / insulin degludec	Ryzodeg	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	18/07/2014	P/0215/2014	03/09/2014
telaprevir	Incivo	PIP modification	Negative	Infectious Diseases	Janssen Infectious Diseases BVBA	18/07/2014	P/0225/2014	05/09/2014
tofacitinib	XELJANZ	PIP modification	PIP agreed	Dermatology	Pfizer Limited	18/07/2014	P/0216/2014	03/09/2014
valsartan / rosuvastatin	not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases	Krka, d.d., Novo mesto	18/07/2014	P/0211/2014	22/08/2014
(1aR,12bS)-8-Cyclohexyl-N-(dimethylsulfamoyl)-11-methoxy-1a-(((1R,5S)-3-methyl-3,8-diazabicyclo[3.2.1]oct-8-yl)carbonyl)-1,1a,2,12b-tetrahydrocyclopropa[d]indolo[2,1-a][2]benzazepine-5-carboxamide hydrochloride (company code BMS-791325) / asunaprevir / daclatasvir dihydrochloride	not available at present	PIP	PIP agreed	Infectious Diseases	Bristol-Myers Squibb International Corporation	20/06/2014	P/0182/2014	17/07/2014
(S)-Pyrrolidine-2-carboxylic acid compound with (2S,3R,4R,5S,6R)-2-(3-((2,3-dihydrobenzo[b][1,4]dioxin-6-yl)methyl)-4-	not available at present-Product code: LK066	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novartis Europharm Ltd.	20/06/2014	P/0183/2014	24/07/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
ethylphenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol (2:1).								
Asfotase alfa	Strensiq	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Alexion Europe SAS	20/06/2014	P/0176/2014	02/07/2014
Autologous CD34+ cells transduced ex vivo with retroviral vector (GIADAI) containing human adenosine deaminase gene from cDNA	Strimvelis	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	GlaxoSmithKline Trading Services Limited	20/06/2014	P/0190/2014	06/08/2014
Cangrelor (tetrasodium)	not available at present	PIP modification	PIP agreed	Cardiovascular Diseases	The Medicines Company UK Ltd.	20/06/2014	P/0203/2014	08/08/2014
Captopril	Not available at present	PIP	PIP agreed	Cardiovascular Diseases	Proveca Limited	20/06/2014	P/0206/2014	08/08/2014
Deferasirox	Exjade	PIP modification	PIP agreed	Haematology-Hemostaseology	Novartis Europharm Limited	20/06/2014	P/0199/2014	08/08/2014
Human coagulation factor X	FACTOR X	PIP modification	PIP agreed	Haematology-Hemostaseology	Bio Products Laboratory Ltd	20/06/2014	P/0188/2014	06/08/2014
Mifepristone	Corluxin	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Corcept Therapeutics Incorporated	20/06/2014	P/0202/2014	08/08/2014
N-[(1,3-dicyclohexyl-6-hydroxy-2,4-dioxo-1,2,3,4-tetrahydro-5-pyrimidinyl)carbonyl]glycine (GSK1278863)	Not available at present (GSK1278863 is used as a reference to)	PIP	PIP agreed	Uro-nephrology / Haematology-Hemostaseology	GlaxoSmithKline Trading Services Limited	20/06/2014	P/0191/2014	06/08/2014
Ranibizumab	Lucentis	Full Waiver	Full waiver granted	Ophthalmology	Novartis Europharm Limited	20/06/2014	P/0185/2014	06/08/2014
		PIP	PIP agreed	Ophthalmology	Novartis Europharm Limited	20/06/2014	P/0186/2014	06/08/2014
Recombinant Coagulation Factor VIII SingleChain (rVIII-SC)	Lonococog alfa	PIP modification	PIP agreed	Haematology-Hemostaseology	CSL Behring GmbH	20/06/2014	P/0189/2014	06/08/2014
Recombinant human lysosomal acid lipase	Not available at present	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism / Gastroenterology-Hepatology	Synageva BioPharma Ltd.	20/06/2014	P/0179/2014	11/07/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
Riociguat	ADEMPAS	PIP modification	PIP agreed	Cardiovascular Diseases	Bayer Pharma AG	20/06/2014	P/0187/2014	06/08/2014
Silicic acid, sodium zirconium (4+) salt (3:2:1) hydrate	Not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	ZS Pharma, Inc.	20/06/2014	P/0210/2014	12/08/2014
Sofosbuvir	Sovaldi	PIP modification	PIP agreed	Infectious Diseases	Gilead Sciences International Ltd.	20/06/2014	P/0178/2014	07/07/2014
Sofosbuvir / ledipasvir	Not available at present	PIP modification	PIP agreed	Infectious Diseases	Gilead Sciences International Ltd	20/06/2014	P/0181/2014	17/07/2014
Tobramycin	TOBI	PIP	PIP agreed	Infectious Diseases / Pneumology - Allergology	Novartis Europharm Ltd.	20/06/2014	P/0184/2014	06/08/2014
	TOBI Podhaler	PIP modification	PIP agreed	Infectious Diseases / Pneumology - Allergology	Novartis Europharm Ltd.	20/06/2014	P/0177/2014	07/07/2014
Tofacitinib	Xeljanz	PIP	PIP agreed	Gastroenterology-Hepatology	Pfizer Limited	20/06/2014	P/0195/2014	08/08/2014
Valaciclovir Hydrochloride	Valaciclovir Pharmathen	PIP	PIP agreed	Infectious Diseases	Pharmathen S.A.	20/06/2014	P/0207/2014	08/08/2014
Vosaroxin	Not available at present	PIP	PIP agreed	Oncology	Sunesis Europe Ltd	20/06/2014	P/0204/2014	08/08/2014
acetylsalicylic acid / rosuvastatin	not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	EGIS Pharmaceuticals PLC	20/06/2014	P/0201/2014	08/08/2014
daclatasvir	Daklinza	PIP modification	PIP agreed		Bristol-Myers Squibb International Corporation	20/06/2014	P/0180/2014	17/07/2014
dupilumab	not available at present	PIP	PIP agreed	Pneumology - Allergology	sanofi-aventis recherche & développement	20/06/2014	P/0192/2014	06/08/2014
exenatide	Bydureon, Byetta	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Bristol-Myers Squibb/AstraZeneca EEIG	20/06/2014	P/0197/2014	08/08/2014
human recombinant follicle-stimulating hormone (FE 999049)	Not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	Ferring Pharmaceuticals A/S	20/06/2014	P/0200/2014	08/08/2014
pacritinib	not available at present	Full Waiver	Full waiver granted	Oncology	CTI Life Sciences, Ltd	20/06/2014	P/0193/2014	06/08/2014
recombinant parathyroid hormone [rhPTH(1-84)]	Natpar	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	NPS Pharma Holdings Limited	20/06/2014	P/0205/2014	08/08/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
rilpivirine (as hydrochloride)	EDURANT	PIP modification	PIP agreed	Infectious Diseases	Janssen-Cilag International NV	20/06/2014	P/0194/2014	08/08/2014
sildenafil	Revatio	PIP modification	PIP agreed	Other	Pfizer Limited	20/06/2014	P/0196/2014	08/08/2014
tirasemtiv	not available at present	Full Waiver	Full waiver granted	Neurology	Cytokinetics Inc.	20/06/2014	P/0208/2014	08/08/2014
tralokinumab	Not available at present	PIP modification	PIP agreed	Pneumology - Allergology	MedImmune Ltd	20/06/2014	P/0198/2014	08/08/2014
vortioxetine	Brintellix	PIP modification	PIP agreed	Psychiatry	H. Lundbeck A/S	20/06/2014	P/0239/2014	22/09/2014
Adalimumab	Humira	PIP modification	PIP agreed	Immunology- Rheumatology- Transplantation / Gastroenterology- Hepatology	AbbVie Limited	23/05/2014	P/0162/2014	13/06/2014
Aflibercept	Eylea	Full Waiver	Full waiver granted	Ophthalmology	Bayer Pharma AG	23/05/2014	P/0165/2014	27/06/2014
Apremilast	Otezla	PIP modification	PIP agreed	Immunology- Rheumatology- Transplantation	Celgene Europe Limited	23/05/2014	P/0166/2014	08/07/2014
Insulin detemir	Levemir	PIP modification	PIP agreed	Endocrinology- Gynaecology- Fertility- Metabolism	Novo Nordisk A/S	23/05/2014	P/0172/2014	11/07/2014
Insulin peglispro	Not available at present	PIP modification	PIP agreed	Endocrinology- Gynaecology- Fertility- Metabolism	Eli Lilly and Company	23/05/2014	P/0168/2014	08/07/2014
Mepolizumab	Not available at present	PIP modification	PIP agreed	Pneumology - Allergology	GSK Trading Services Limited	23/05/2014	P/0161/2014	12/06/2014
Obeticholic Acid (6 alpha-ethylchenodeoxycholic acid)	Not available at present	PIP	PIP agreed	Gastroenterology- Hepatology	Intercept Italia s.r.l.	23/05/2014	P/0175/2014	11/07/2014
Ozenoxacin	Not available at present	PIP modification	PIP agreed	Infectious Diseases	Ferrer Internacional S.A.	23/05/2014	P/0167/2014	08/07/2014
Perampanel	Fycompa	PIP modification	PIP agreed	Neurology	Eisai Europe Limited	23/05/2014	P/0160/2014	11/06/2014
Vigabatrin	Not available at present	PIP	PIP agreed	Neurology	TARGEON SAS	23/05/2014	P/0173/2014	11/07/2014
dupilumab	not available at present	PIP	PIP agreed	Dermatology	Regeneron Pharmaceuticals, Inc	23/05/2014	P/0169/2014	08/07/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
linagliptin (as base)	Trajenta	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	23/05/2014	P/0163/2014	16/06/2014
recombinant 10 kD culture filtrate protein / Recombinant dimer of 6 kD early secretory antigenic target	Not available at present	PIP modification	PIP agreed	Diagnostic	Statens Serum Institut	23/05/2014	P/0171/2014	09/07/2014
sitagliptin phosphate	Januvia (and related products)	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp and Dohme (Europe), Inc.	23/05/2014	P/0170/2014	09/07/2014
tafluprost	TAFLOTAN and associated names	PIP modification	PIP agreed	Ophthalmology	Santen Oy	23/05/2014	P/0174/2014	11/07/2014
tasimelteon	Hetlioz	PIP	PIP agreed	Neurology	Vanda Pharmaceuticals Ltd.	23/05/2014	P/0141/2014	28/05/2014
insulin degludec	Tresiba	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	15/05/2014	P/0129/2014	20/05/2014
(11beta,17beta)-17-hydroxy-11-[4-(methylsulfonyl)phenyl]-17-(pentafluoroethyl)estra-4,9-dien-3-one	not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	Bayer Pharma AG	25/04/2014	P/0152/2014	13/06/2014
5-(4,6-dimethyl-1H-benzimidazol-2-yl)-4-methyl-N-[3-(1-methyl-4-piperidinyl)propyl]-2-pyrimidinamine 2,3-dihydroxybutanedioate hydrate (1:0.5:4)	Not available at present	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Janssen Cilag International NV	25/04/2014	P/0150/2014	13/06/2014
AGOMELATINE	VALDOXAN, THYMANAX	PIP modification	PIP agreed	Psychiatry	Les Laboratoires Servier	25/04/2014	P/0146/2014	13/06/2014
Abatacept	ORENCIA	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb Pharma EEIG	25/04/2014	P/0128/2014	22/05/2014
Adeno-associated viral vector serotype 9 containing human sulfamidase gene	Not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Laboratorios Dr.Esteve S.A	25/04/2014	P/0149/2014	13/06/2014
Anamorelin Hydrochloride	Adlumiz	PIP	Full waiver granted	Other	Helsinn Therapeutics (U.S.), Inc.	25/04/2014	P/0134/2014	10/06/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
Autologous CD34+ cells transduced with lentiviral vector containing the human Wiskott Aldrich Syndrom Protein gene.	not available at present	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology	GENETHON	25/04/2014	P/0137/2014	11/06/2014
Avibactam / Ceftazidime	not available at present	PIP modification	PIP agreed	Infectious Diseases	AstraZeneca AB	25/04/2014	P/0133/2014	10/06/2014
Brivaracetam	Not available at present	PIP modification	PIP agreed	Neurology	UCB Pharma SA	25/04/2014	P/0127/2014	22/05/2014
Expanded autologous bone marrow-derived osteoblastic cells	PREOB®	PIP	PIP agreed	Other	Bone Therapeutics S.A.	25/04/2014	P/0164/2014	25/06/2014
Fibrinogen (human plasma-derived)	Not available at present	PIP modification	PIP agreed	Haematology-Hemostaseology	LFB Biotechnologies	25/04/2014	P/0136/2014	11/06/2014
Freeze dried culture of Lactobacillus casei subspecies rhamnosus Döderleini (Lcr35)	GYNOPHILUS	PIP	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism / Infectious Diseases	PROBIONOV	25/04/2014	P/0155/2014	16/06/2014
Gevokizumab	Not available at present	PIP	PIP agreed	Ophthalmology	Les Laboratoires SERVIER	25/04/2014	P/0148/2014	13/06/2014
Lubiprostone	Amitiza	PIP modification	PIP agreed	Gastroenterology-Hepatology	Sucampo Pharma Europe Ltd.	25/04/2014	P/0142/2014	13/06/2014
Ocrelizumab	Not available yet	PIP modification	PIP agreed	Neurology	Roche Registration Ltd.	25/04/2014	P/0143/2014	13/06/2014
PEGylated recombinant factor VIII	Not available at present	PIP modification	PIP agreed	Haematology-Hemostaseology	Baxter Innovations GmbH	25/04/2014	P/0139/2014	11/06/2014
Peginterferon alfa-2a	Pegasys	PIP modification	PIP agreed	Infectious Diseases	Roche Registration Ltd	25/04/2014	P/0130/2014	10/06/2014
Ramipril / Amlodipine besilate	not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Pharmaceutical Works Polpharma SA	25/04/2014	P/0154/2014	13/06/2014
Recombinant fusion protein linking coagulation factor IX with albumin	not available at present	PIP modification	PIP agreed	Haematology-Hemostaseology	CSL Behring GmbH	25/04/2014	P/0138/2014	11/06/2014
Recombinant human beta-glucuronidase (rhGUS, UX003)	Not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Ultragenyx Pharmaceutical Inc.	25/04/2014	P/0151/2014	13/06/2014
Tazobactam / Ceftolozane	Not available at present	PIP modification	PIP agreed	Infectious Diseases	Cubist Pharmaceuticals (UK) Limited	25/04/2014	P/0126/2014	16/05/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n. n.	Decision signature date
amoxicillin	QUADRIPYL	Full Waiver	Full waiver granted	Infectious Diseases / Gastroenterology-Hepatology	MAYOLY-SPINDLER	25/04/2014	P/0156/2014	18/06/2014
clarithromycin	QUADRIPYL	Full Waiver	Full waiver granted	Infectious Diseases / Gastroenterology-Hepatology	MAYOLY-SPINDLER	25/04/2014	P/0157/2014	18/06/2014
cobimetinib	not available at present	PIP modification	PIP agreed	Oncology	Roche Registration Limited	25/04/2014	P/0124/2014	16/05/2014
conestat alfa	Ruconest	PIP modification	PIP agreed	Other	Pharming Group N.V.	25/04/2014	P/0131/2014	10/06/2014
daclizumab	Not available at present	PIP modification	PIP agreed	Neurology	Biogen Idec Ltd	25/04/2014	P/0147/2014	13/06/2014
entecaventricavir (monohydrate)ir (monohydrate)	Baraclude	PIP modification	PIP agreed	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	25/04/2014	P/0125/2014	16/05/2014
lesinurad	not available at present	Full Waiver	Full waiver granted	Immunology-Rheumatology-Transplantation	AstraZeneca AB - Astrazeneca European Regulatory Affairs	25/04/2014	P/0153/2014	13/06/2014
metronidazole	QUADRIPYL	Full Waiver	Full waiver granted	Infectious Diseases / Gastroenterology-Hepatology	MAYOLY-SPINDLER	25/04/2014	P/0158/2014	18/06/2014
pantoprazole	QUADRIPYL	Full Waiver	Full waiver granted	Infectious Diseases / Gastroenterology-Hepatology	MAYOLY-SPINDLER	25/04/2014	P/0159/2014	18/06/2014
pazopanib (5-[[4-[(2,3-Dimethyl-2H-indazol-6-yl)methylamino]-2-pyrimidimyl]amino]-2-methylbenzenesulfonamide monohydrochloride	VOTRIENT	PIP modification	PIP agreed	Oncology	Glaxo Group Limited	25/04/2014	P/0132/2014	10/06/2014
pyridoxine (hydrochloride) / doxylamine (succinate)	Diclectin	PIP	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	Duchesnay Inc.	25/04/2014	P/0140/2014	11/06/2014
raltegravir	ISENTRESS	PIP modification	PIP agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	25/04/2014	P/0135/2014	11/06/2014
secukinumab	Cosentyx	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation / Dermatology	Novartis Europharm Ltd	25/04/2014	P/0144/2014	13/06/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
Canagliflozin (1s)-1,5-anhydro-1-[3-[[5-(4-fluorophenyl)-2-thienyl]methyl]-4-methylphenyl]-D-glucitol hemihydrate	Canagliflozin	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Janssen-Cilag International N.V.	21/03/2014	P/0119/2014	07/05/2014
Chimeric anti-disialoganglioside (GD2) monoclonal antibody (ch14.18/CHO)	not available at present	PIP	PIP agreed	Oncology	APEIRON Biologics AG	21/03/2014	P/0094/2014	07/04/2014
Cobicistat / Atazanavir	Not available at the present	PIP	PIP agreed	Infectious Diseases	Bristol-Myers Squibb International Corporation	21/03/2014	P/0090/2014	04/04/2014
Drospirenone	SLINDA	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	LABORATORIOS LEÓN FARMA, S.A.	21/03/2014	P/0110/2014	05/05/2014
Enalapril (maleate)	Enalapril Pharmathen	PIP	PIP agreed	Cardiovascular Diseases	Pharmathen S.A.	21/03/2014	P/0112/2014	05/05/2014
Eribulin	Halaven	PIP modification	PIP agreed	Oncology	Eisai Europe Ltd	21/03/2014	P/0109/2014	05/05/2014
Febuxostat	Adenuric	PIP	PIP agreed	Oncology	Menarini International Operations Luxembourg S.A.	21/03/2014	P/0117/2014	06/05/2014
Human Normal Immunoglobulin	Not available at present	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	LFB Biotechnologies	21/03/2014	P/0091/2014	04/04/2014
Initial chemical name: 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 Updated chemical name: Octadecasodium hexakis(4-{{(1S,3R)-1-([1,1'-biphenyl]-4-ylmethyl)-4-ethoxy-3-methyl-4-oxobutyl}amino}-4-	not available at present	PIP modification	PIP agreed	Cardiovascular Diseases	Novartis Europharm Limited	21/03/2014	P/0106/2014	05/05/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
oxobutanoate) hexakis(N-pentanoyl-N-{ [2'-(1H-tetrazol-1-id-5-yl)[1,1'-biphenyl]-4-yl]methyl}-L-valinate)—water (1/15)								
Ipilimumab	Yervoy	PIP modification	PIP agreed	Oncology	Bristol-Myers Squibb Pharma EEIG	21/03/2014	P/0092/2014	07/04/2014
						21/03/2014	P/0093/2014	07/04/2014
Levonorgestrel / Anastrozole	not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	Bayer Pharma AG	21/03/2014	P/0104/2014	02/05/2014
Live, attenuated, chimeric dengue virus, serotype 4 / Live, attenuated, chimeric dengue virus, serotype 3 / Live, attenuated, chimeric dengue virus, serotype 2 / Live, attenuated, chimeric dengue virus, serotype 1	Not available at present	PIP	PIP agreed	Vaccines	Sanofi Pasteur SA	21/03/2014	P/0113/2014	05/05/2014
Methyl aminolevulinate hydrochloride	Visonac	PIP modification	PIP agreed	Dermatology	Photocure AS	21/03/2014	P/0115/2014	06/05/2014
N-{2-(2,3-Difluorobenzylthio)-6-[(2R,3S)-3,4-dihydroxybut-2-yloxy]pyrimidin-4-yl}azetidine-1-sulfonamide	not available at present	PIP	PIP agreed	Pneumology - Allergology	AstraZeneca AB	21/03/2014	P/0103/2014	02/05/2014
Naloxegol	To be decided	PIP modification	PIP agreed	Gastroenterology-Hepatology	AstraZeneca AB	21/03/2014	P/0108/2014	05/05/2014
Octocog alfa	not available at present	PIP modification	PIP agreed	Haematology-Hemostaseology	Bayer Pharma AG	21/03/2014	P/0107/2014	05/05/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-methoxy-133 ester with granulocyte colony-stimulating factor [methionyl,133-[O-[2-(acetylamino)-6-O-[N-[N-carboxyglycyl)amino]-alpha neuraminosyl]-2-deoxy-alpha-D-galactopyranosyl]-L-threonine]] (human)	Lonquex	PIP modification	PIP agreed	Oncology	Teva Pharma B.V	21/03/2014	P/0116/2014	06/05/2014
Pradigastat	(not available at present)	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novartis Europharm Limited	21/03/2014	P/0120/2014	07/05/2014
Recombinant human alpha-mannosidase	Not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Zymenex	21/03/2014	P/0122/2014	07/05/2014
Romiplostim	Nplate	PIP modification	PIP agreed	Haematology-Hemostaseology	Amgen Europe BV	21/03/2014	P/0114/2014	06/05/2014
Tapentadol (hydrochloride)	Palexia	PIP modification	PIP agreed	Pain	Grünenthal GmbH	21/03/2014	P/0095/2014	07/04/2014
						21/03/2014	P/0096/2014	07/04/2014
						21/03/2014	P/0097/2014	07/04/2014
Tiotropium bromide (monohydrate) [quantities relate to tiotropium]	Spiriva Respimat 2.5 microgram, solution for inhalation, Spiriva 18 microgram, inhalation powder, hard capsule	PIP modification	PIP agreed	Pneumology - Allergology	Boehringer Ingelheim International GmbH	21/03/2014	P/0101/2014	11/04/2014
alirocumab (SAR236553/REGN727)	Not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	sanofi-aventis recherche & développement	21/03/2014	P/0100/2014	11/04/2014
amlodipine / rosuvastatin	not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases	Krka, d.d., Novo mesto	21/03/2014	P/0121/2014	07/05/2014
atazanavir sulphate	REYATAZ	PIP modification	PIP agreed	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	21/03/2014	P/0098/2014	10/04/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
corifollitropin alfa	Elonva	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme Limited	21/03/2014	P/0102/2014	02/05/2014
everolimus	Certican and associated names	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	21/03/2014	P/0105/2014	05/05/2014
fentanyl (hydrochloride)	IONSYS	PIP	PIP agreed	Pain	Incline Therapeutics Europe Ltd.	21/03/2014	P/0111/2014	05/05/2014
ivacaftor / lumacaftor	not available at present	PIP	PIP agreed	Pneumology - Allergology	Vertex Pharmaceuticals (Europe) Ltd.	21/03/2014	P/0118/2014	06/05/2014
teriflunomide	AUBAGIO	PIP modification	PIP agreed	Neurology	sanofi-aventis R&D	21/03/2014	P/0099/2014	11/04/2014
von Willebrand Factor / Human coagulation Factor VIII	Voncento	PIP modification	PIP agreed	Haematology-Hemostaseology	Doerthe Vingerhoet, Senior Manager Regulatory Affairs	21/03/2014	P/0123/2014	08/05/2014
(E)-4-[(5-Phenyl-1,3,4-thiadiazol-2-yl)oxy]-1-azoniatricyclo[3.3.1.1 ^{3,7}]decane 3,4-dicarboxy-3-hydroxybutanoate hydrate	Not available at present	PIP	PIP agreed	Psychiatry / Neurology	AbbVie Ltd.	14/02/2014	P/0081/2014	02/04/2014
Adalimumab	Humira	PIP	PIP agreed	Immunology-Rheumatology-Transplantation / Ophthalmology / Dermatology / Gastroenterology-Hepatology	AbbVie Ltd.	14/02/2014	P/0070/2014	18/03/2014
Allergoid preparation of Phleum pratense pollen extract	Allergovit® Phleum	PIP	PIP agreed	Pneumology - Allergology	Allergopharma GmbH & Co. KG	14/02/2014	P/0067/2014	14/03/2014
Anti proprotein convertase subtilisin kexin type 9 humanized monoclonal antibody	Not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases	Pfizer Limited	14/02/2014	P/0080/2014	02/04/2014
Anti-PD1 humanized monoclonal antibody / Anti-PD1 humanized monoclonal antibody / Anti-PD1 humanized monoclonal antibody	Not yet available at present	PIP	PIP agreed	Oncology	Merck Sharp & Dohme (Europe), Inc	14/02/2014	P/0059/2014	07/03/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
Anti-human interleukin 23 p19 humanised IgG1/Ig kappa mAb	Not available at present	PIP	PIP agreed	Dermatology	Merck Sharp & Dohme (Europe), Inc.	14/02/2014	P/0058/2014	06/03/2014
Bimatoprost	Lumigan and invented names	PIP modification	PIP agreed	Ophthalmology / Dermatology	Allergan Pharmaceuticals Ireland	14/02/2014	P/0076/2014	02/04/2014
Ceftaroline fosamil (established INN)	Zinforo	PIP modification	PIP agreed	Infectious Diseases	AstraZeneca AB	14/02/2014	P/0074/2014	02/04/2014
Ceftobiprole medocaril sodium	Zevtera	PIP modification	PIP agreed	Infectious Diseases	Basilea Pharmaceutica International Ltd.	14/02/2014	P/0083/2014	04/04/2014
Concentrate of proteolytic enzymes enriched in bromelain	NexoBrid	PIP modification	PIP agreed	Other / Dermatology	MediWound Germany GmbH	14/02/2014	P/0072/2014	01/04/2014
Cyclic Pyranopterin Monophosphate Monohydrobromide Dihydrate	Not available at present	PIP	PIP agreed	Other	Alexion Europe SAS	14/02/2014	P/0071/2014	21/03/2014
Fidaxomicin (Dificlir)	Dificlir	PIP modification	PIP agreed	Infectious Diseases	Astellas Pharma Europe B.V.	14/02/2014	P/0063/2014	07/03/2014
Herpes simplex 1 virus thymidine kinase and truncated low affinity nerve growth factor receptor transfected donor lymphocytes	Not available at present	PIP	PIP agreed	Oncology	MolMed S.p.A.	14/02/2014	P/0057/2014	06/03/2014
Human normal immunoglobulin	Not available at present	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology	Kedrion S.p.A.	14/02/2014	P/0085/2014	04/04/2014
Human normal immunoglobulin for intravenous use	Not available at present	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology	Kedrion S.p.A.	14/02/2014	P/0075/2014	02/04/2014
Laquinimod	Nerventra	PIP modification	PIP agreed	Neurology	Teva Pharma GmbH	14/02/2014	P/0086/2014	04/04/2014
Loxapine	ADASUVE	PIP modification	PIP agreed	Psychiatry	Alexza UK, Limited	14/02/2014	P/0088/2014	04/04/2014
Oseltamivir Phosphate	Tamiflu	PIP modification	PIP agreed	Infectious Diseases	Roche Registration Ltd	14/02/2014	P/0062/2014	07/03/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
RNA, [2'-O-(2-methoxyethyl)](P-thio)(m5U- m5C-A- m5C-m5U-m5U-m5U- m5C-A-m5U-A-A-m5U-G- m5C-m5U-G-G)	not available at present	PIP	PIP agreed	Neurology	Isis Pharmaceuticals	14/02/2014	P/0082/2014	31/03/2014
Recombinant fusion protein consisting of Human Coagulation Factor VIII attached to the Fc domain of Human IgG1 (rFVIII Fc)	Not available at present	PIP modification	PIP agreed	Haematology-Hemostaseology	Biogen Idec Ltd	14/02/2014	P/0077/2014	02/04/2014
Sirolimus	Opsiria	PIP	PIP agreed	Ophthalmology	Santen Incorporated	14/02/2014	P/0079/2014	02/04/2014
Sucroferric oxyhydroxide (mixture of iron(III)-oxyhydroxide, sucrose, starch) (PA21)	Velphoro	PIP modification	PIP agreed	Uro-nephrology	Vifor Fresenius Medical Care Renal Pharma	14/02/2014	P/0087/2014	04/04/2014
Trametinib	MEKINIST	PIP modification	PIP agreed	Oncology	Glaxo Group Limited	14/02/2014	P/0078/2014	02/04/2014
dimethanesulfonate / avizafone hydrochloride / atropine sulphate	INEUROPE New Gen	Full Waiver	Full waiver granted	Other / Neurology	service de santé des armées	14/02/2014	P/0089/2014	04/04/2014
entecavir (monohydrate)	Baraclude	PIP modification	PIP agreed	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	14/02/2014	P/0061/2014	07/03/2014
glycerol phenylbutyrate (GPB)	not available at present	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Hyperion Therapeutics, Ltd.	14/02/2014	P/0068/2014	14/03/2014
golimumab	Simponi	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	Janssen Biologics B.V.	14/02/2014	P/0073/2014	02/04/2014
ivacaftor	Kalydeco	PIP modification	PIP agreed	Other	Vertex Pharmaceuticals Incorporated	14/02/2014	P/0060/2014	07/03/2014
nivolumab	Not available at present.	PIP	PIP agreed	Oncology	Bristol-Myers Squibb International Corporation	14/02/2014	P/0064/2014	07/03/2014
rivaroxaban	Xarelto	PIP modification	PIP agreed	Cardiovascular Diseases	Bayer Pharma AG	14/02/2014	P/0084/2014	04/04/2014
rupatadine fumarate	rupafin and associated names	PIP modification	PIP agreed	Dermatology / Pneumology - Allergology / Oto-rhino-laryngology	J. Uriach y Compañía, S.A.	14/02/2014	P/0043/2014	26/02/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
Idarucizumab	not available at present	PIP	PIP agreed	Other	Boehringer Ingelheim International GmbH	30/01/2014	P/0069/2014	17/03/2014
Cinacalcet (as hydrochloride)	Mimpara	PIP modification	PIP agreed	Uro-nephrology	Amgen Europe B.V.	17/01/2014	P/0044/2014	07/03/2014
Clazakizumab	not available at present	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb International Corporation	17/01/2014	P/0029/2014	13/02/2014
Darbepoetin alfa	Aranesp	PIP modification	PIP agreed	Cardiovascular Diseases / Oncology / Uro-nephrology	Amgen Europe B.V.	17/01/2014	P/0042/2014	05/03/2014
Dulaglutide	Not available at present	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Eli Lilly & Company	17/01/2014	P/0039/2014	05/03/2014
Edoxaban tosylate	Edoxaban	PIP modification	PIP agreed	Cardiovascular Diseases	Daiichi Sankyo Development Limited	17/01/2014	P/0028/2014	27/01/2014
Elobixibat	Not available at present	PIP	PIP agreed	Gastroenterology-Hepatology	Ferring Pharmaceuticals A/S	17/01/2014	P/0053/2014	07/03/2014
Enalapril Maleate	not available at present	PIP	PIP agreed	Cardiovascular Diseases	Proveca Limited	17/01/2014	P/0050/2014	07/03/2014
FLUOCINOLONE ACETONIDE	OTOKEN	PIP	Full waiver granted	Oto-rhinolaryngology	Laboratorios SALVAT	17/01/2014	P/0041/2014	05/03/2014
Glycopyrronium Bromide	not available at present	PIP modification	PIP agreed	Neurology	Proveca Limited	17/01/2014	P/0052/2014	07/03/2014
Human normal immunoglobulin	not available at present	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Baxter Innovations GmbH	17/01/2014	P/0047/2014	11/03/2014
Lanthanum carbonate hydrate	"Fosrenol" in the RMS (Sweden) and associated name "Foznol"	PIP modification	PIP agreed	Uro-nephrology	Shire Pharmaceutical Contracts Ltd	17/01/2014	P/0037/2014	05/03/2014
Lenvatinib	Not available at present	PIP modification	PIP agreed	Oncology	Eisai Europe Ltd	17/01/2014	P/0040/2014	05/03/2014
Metformin / Ertugliflozin	Not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme (Europe), Inc.	17/01/2014	P/0054/2014	07/03/2014
Ocriplasmin	JETREA	Full Waiver	Full waiver granted	Ophthalmology	ThromboGenics NV	17/01/2014	P/0049/2014	07/03/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
Pneumococcal polysaccharide serotype 23F conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 19F conjugated to diphtheria toxoid / Pneumococcal polysaccharide serotype 18C conjugated to tetanus toxoid / Pneumococcal polysaccharide serotype 14 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 7F 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 5 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 4	Synflorix	PIP modification	PIP agreed	Vaccines	GlaxoSmithKline Biologicals S.A.	17/01/2014	P/0030/2014	21/02/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n.	Decision signature date
conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein								
Potassium chloride / Sodium chloride / Simeticone / Citric acid, anhydrous / Sodium citrate / Sodium sulphate, anhydrous / Macrogol 4000	EASYGOL® powder for oral solution	PIP	PIP agreed	Gastroenterology-Hepatology	ALFA WASSERMANN S.p.A.	17/01/2014	P/0051/2014	07/03/2014
Ramipril / Amlodipine besilate	BR/AM	Full Waiver	Full waiver granted	Cardiovascular Diseases	Brunifarma Research s.r.l.	17/01/2014	P/0066/2014	10/03/2014
Recombinant human growth hormone modified by fusion with two hydrophilic polypeptide chains (VRS-317)	not available at present	PIP	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	Versartis, Inc.	17/01/2014	P/0065/2014	10/03/2014
Rubidium Rb-82 Chloride	Ruby-Fill (Rubidium Rb-82 Generator)	PIP modification	PIP agreed	Diagnostic	Jubilant DraxImage Inc.	17/01/2014	P/0048/2014	07/03/2014
Sitagliptin / Ertugliflozin	Not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme (Europe), Inc.	17/01/2014	P/0032/2014	03/03/2014
Telmisartan / Amlodipine besylate	not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Zentiva k.s.	17/01/2014	P/0055/2014	07/03/2014
Trenonacog alfa	IXinity	PIP modification	PIP agreed	Haematology-Hemostaseology	Cangene Europe Ltd	17/01/2014	P/0038/2014	05/03/2014
Treosulfan	Treograft	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation / Oncology	medac Gesellschaft für klinische Spezialpräparate mbH	17/01/2014	P/0033/2014	04/03/2014
linagliptin (as base)	Trajenta	PIP modification	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	17/01/2014	P/0046/2014	07/03/2014
telaprevir	Incivo	PIP modification	PIP agreed	Infectious Diseases	Janssen-Cilag International NV	17/01/2014	P/0034/2014	05/03/2014

Active substance(s)	Invented name	Applicant's request	Type of PDCO Opinion	Therapeutic area(s)	Applicant	Opinion Actual Date	EMA decision n. n.	Decision signature date
thiocolchicoside / diclofenac sodium	Muscoplus	Full Waiver	Full waiver granted	Pain	Epifarma Srl	17/01/2014	P/0056/2014	07/03/2014
tofacitinib	XELJANZ	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation / Dermatology	Pfizer Limited	17/01/2014	P/0036/2014	05/03/2014
	Xeljanz	PIP modification	PIP agreed	Immunology-Rheumatology-Transplantation	Pfizer Limited	17/01/2014	P/0035/2014	05/03/2014
ustekinumab	STELARA	PIP	PIP agreed	Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology	Janssen-Cilag International NV	17/01/2014	P/0045/2014	07/03/2014

Opinions on final/full compliance check (does not include interim/partial compliance check procedures)

Active substance(s)	Therapeutic Area(s)	Applicant	PDCO opinion date
Anakinra	Immunology-Rheumatology-Transplantation	Swedish Orphan Biovitrum AB (publ)	12/12/2014
Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted), containing antigen equivalent to Influenza A/California/7/2009 (Produced at Quebec manufacturing site)	Vaccines	GlaxoSmithKline Biologicals S.A.	12/12/2014
Purified antigen fractions of inactivated split virion Influenza virus type A, H1N1 A/California/7/2009	Vaccines	GlaxoSmithKline Biologicals S.A.	12/12/2014
Tigecycline	Other	Pfizer Limited	12/12/2014
Autologous CD34+ cells transduced ex vivo with retroviral vector (GIADAI) containing human adenosine deaminase gene from cDNA	Immunology-Rheumatology-Transplantation	GlaxoSmithKline Trading Services Limited	14/11/2014
Eltrombopag	Infectious Diseases / Oncology / Gastroenterology-Hepatology /	GlaxoSmithKline Trading Services Limited	14/11/2014

Active substance(s)	Therapeutic Area(s)	Applicant	PDCO opinion date
	Haematology-Hemostaseology		
Glycopyrronium bromide	Neurology	Proveca Limited	14/11/2014
Insulin detemir	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	14/11/2014
Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), inactivated poliovirus and Haemophilus type b (meningococcal protein conjugate) vaccine (adsorbed)	Vaccines	Sanofi Pasteur MSD	10/10/2014
Ivabradine hydrochloride	Cardiovascular Diseases	LES LABORATOIRES SERVIER	10/10/2014
Pneumococcal Polysaccharide Serotype 5 - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 7F - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 23F - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 1 - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 3 - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 6B - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 18C - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 9V - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 14 - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 19A - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 6A - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 4 - Diphtheria-CRM197 conjugate / Pneumococcal Polysaccharide Serotype 19F - Diphtheria-CRM197 conjugate	Vaccines	Pfizer Limited	10/10/2014
Sapropterin dihydrochloride	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Serono Europe Ltd	10/10/2014
aprepitant	Oncology	Merck Sharp & Dohme (Europe) Inc.	10/10/2014

Active substance(s)	Therapeutic Area(s)	Applicant	PDCO opinion date
fosaprepitant dimeglumine	Oncology	Merck Sharp & Dohme (Europe) Inc.	10/10/2014
golimumab	Immunology-Rheumatology-Transplantation	Janssen Biologics BV	10/10/2014
Benzylpenicilloyl octa-L-lysine / Sodium benzylpenilloate	Diagnostic	DIATER, Laboratorio de Diagnóstico y Aplicaciones Terapéuticas, S.A	12/09/2014
Tobramycin	Infectious Diseases	Novartis Europharm Ltd.	12/09/2014
Adalimumab	Immunology-Rheumatology-Transplantation / Dermatology	AbbVie Limited	20/06/2014
Vandetanib	Oncology	AstraZeneca AB	20/06/2014
entecavir	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	20/06/2014
gadobutrol	Diagnostic	Bayer Pharma AG	20/06/2014
Human normal immunoglobulin	Immunology-Rheumatology-Transplantation	LFB Biotechnologies	23/05/2014
Insulin degludec	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	23/05/2014
travoprost	Ophthalmology	Alcon Laboratories (UK) Ltd	23/05/2014
Rupadatine fumarate	Dermatology / Pneumology - Allergology / Oto-rhino-laryngology	J. Uriach y Compañía, S.A.	21/03/2014
bosentan as monohydrate	Cardiovascular Diseases	Actelion Registration Ltd	21/03/2014
lamivudine / raltegravir	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	21/03/2014
Anagrelide hydrochloride	Haematology-Hemostaseology	Shire Pharmaceutical Contracts Limited	14/02/2014
Human Papillomavirus 9-valent Vaccine recombinant (Types 6, 11, 16, 18, 31, 33, 45, 52, 58)	Vaccines	Sanofi Pasteur MSD S.N.C.	17/01/2014
Nitisinone	Endocrinology-Gynaecology-Fertility-Metabolism	Swedish Orphan Biovitrum International AB	17/01/2014

Annex 15 – Referral procedures overview 2014 – human medicines

Referrals made to the CHMP

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
propylene glycol in medicinal products for children	22/09/2011	20/03/2014	Article 5(3) procedure of Regulation (EC) No 726/2004
ceftriaxone	16/02/2012	23/01/2014	Article 30 of Directive 2001/83/EC
methysergide	24/05/2012	20/02/2014	Article 31 of Directive 2001/83/EC
octreotide acetate	30/05/2013	26/06/2014	Article 30 of Directive 2001/83/EC
octreotide acetate	30/05/2013	26/06/2014	Article 30 of Directive 2001/83/EC
dexamfetamine	27/06/2013	22/05/2014	Article 29(4) of Directive 2001/83/EC
quetiapine	27/06/2013	22/05/2014	Article 30 of Directive 2001/83/EC
colistin, colistimethate sodium	19/09/2013	23/10/2014	Article 31 of Directive 2001/83/EC
mometasone furoate	19/09/2013	20/11/2014	Article 30 of Directive 2001/83/EC
ephedrine hydrochloride, arsenous, anhydride, lidocaine	24/10/2013	25/04/2014	Article 31 of Directive 2001/83/EC
lidocaine/prilocaine	24/10/2013	25/09/2014	Article 30 of Directive 2001/83/EC
felodipine	21/11/2013	23/10/2014	Article 30 of Directive 2001/83/EC
rosuvastatin	24/12/2013	25/04/2014	Article 29 of Regulation (EC) No 1901/2006
levonorgestrel, ulipristal	23/01/2014	24/07/2014	Article 31 of Directive 2001/83/EC
levonorgestrel / ethinylestradiol	20/02/2014	26/06/2014	Article 29(4) of Directive 2001/83/EC
epinephrine (adrenaline)	29/04/2014	ongoing	Article 31 of Directive 2001/83/EC
oxycodone hydrochloride / naloxone hydrochloride	22/05/2014	23/10/2014	Article 13 of Commission Regulation (EC) No 1234/2008
haloperidol	26/06/2014	ongoing	Article 30 of Directive 2001/83/EC
haloperidol	26/06/2014	ongoing	Article 30 of Directive 2001/83/EC
medicinal products under development for the treatment of Ebola	25/09/2014	ongoing	Article 5(3) procedure of Regulation (EC) No 726/2004
ganciclovir	25/09/2014	ongoing	Article 30 of Directive 2001/83/EC
GVK Bio	25/09/2014	ongoing	Article 31 of Directive 2001/83/EC
mitoxantrone	23/10/2014	ongoing	Article 30 of Directive 2001/83/EC

Referrals made to the PRAC

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
domperidone	07/03/2013	24/04/2014	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
diacerein	07/03/2013	23/07/2014 ¹	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
strontium ranelate	16/05/2013	20/02/2014	Article 20 of Regulation (EC) No 726/2004 following Article 107i procedure of Directive 2001/83/EC
aliskiren, azilsartan, benazepril, candersartan, captopril, cilazapril, delapril, enalapril, eprosartan, fosinopril, imidapril, irbesartan, lisinopril, losartan, moexipril, olmesartan, perindopril, quinapril, ramipril, spirapril, telmisartan, trandolapril, valsartan, zofenopril	16/05/2013	22/05/2014	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
zolpidem	11/07/2013	24/04/2014	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
bromocriptine	05/09/2013	20/08/2014	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
sodium valproate, valproic acid, valproate semisodium, valpromide	10/10/2013	19/11/2014	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
ponatinib	05/12/2013	23/10/2014	Article 20 of Regulation (EC) No 726/2004 following Article 107i procedure of Directive 2001/83/EC
testosterone	10/04/2014	19/11/2014	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
codeine	10/04/2014	ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
ambroxol, bromhexine	10/04/2014	ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
methadone	10/04/2014	23/07/2014	Article 107i of Directive 2001/83/EC

¹ CMDh position date after re-examination procedure

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
hydroxyzine	08/05/2014	ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
ivabradine	08/05/2014	20/11/2014	Article 20 of Regulation (EC) No 726/2004 following Article 107i procedure of Directive 2001/83/EC
ibuprofen, dexibuprofen	13/06/2014	ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC

Referrals made to CAT

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
matrix applied characterised autologous cultured chondrocytes	19/09/2014	25/09/2014	Article 20 of Regulation (EC) No 726/2004

Annex 16 – Arbitrations and referrals in 2014 – veterinary medicines

Type of procedure	Date <ul style="list-style-type: none"> • Clock start • CVMP opinion 	Product <ul style="list-style-type: none"> • Product name • INN
Referral under Article 35 of Directive 2001/82/EC	12/09/2012 09/09/2014	Suanovil 20 and associated names, Captalin and associated names and generic products thereof Spiramycin
Referral under Article 34 of Directive 2001/82/EC	10/10/2012 10/04/2014	Linco-Spectin 100 and its associated names Lincomycin, spectinomycin
Referral under Article 34 of Directive 2001/82/EC	07/11/2012 09/04/2014	Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names Enrofloxacin
Procedure under Article 30(3) of Regulation (EC) No 726/2004	10/01/2013	Potential risk for the consumer resulting from the use of lidocaine in food producing species Lidocaine
Referral under Article 35 of Directive 2001/82/EC	10/04/2013	All veterinary medicinal products containing altrenogest to be administered orally to pigs and horses Altrenogest
Referral under Article 35 of Directive 2001/82/EC	16/05/2013 09/04/2014	Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names and related veterinary medicinal products Enrofloxacin
Referral under Article 33(4) of Directive 2001/82/EC	16/05/2013 15/01/2014	Norbonex 5-mg/ml pour-on solution for beef and dairy cattle Eprinomectin
Referral under Article 35 of Directive 2001/82/EC	06/11/2013 08/05/2014	All veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs Tylosin
Referral under Article 33(4) Directive 2001/82/EC	16/05/2013 11/12/2013 09/04/2014 (re-examination)	Fiprex CAT 52.5 mg spot-on solution for cats, Fiprex S 75 mg spot-on solution for dogs, Fiprex M 150 mg spot-on solution for dogs, Fiprex L 300 mg spot-on solution for dogs and Fiprex XL 412.5 mg spot-on solution for dogs Fipronil
Referral under Article 13 of Regulation (EC) No 1234/2008	12/02/2014 07/10/2014	Resflor solution injectable associated names Florfenicol, flunixin
Referral under Article 13 of Regulation (EC) No 1234/2008	12/02/2014 24/06/2014 (variation application withdrawn by marketing authorisation holder)	Ubrolexin intramammary suspension for lactating dairy cows Cephalexin, kanamycin
Referral under Article 35 of Directive 2001/82/EC	12/03/2014 06/11/2014	All veterinary medicinal products containing gentamicin presented as solutions for injection to be administered in horses

Type of procedure	Date <ul style="list-style-type: none"> • Clock start • CVMP opinion 	Product <ul style="list-style-type: none"> • Product name • INN
		Gentamicin
Referral under Article 35 of Directive 2001/82/EC	04/06/2014 11/12/2014	All veterinary medicinal products containing colistin to be administered orally Colistin
Procedure under Article 30(3) of Regulation (EC) No 726/2004	10/09/2014 11/12/2014	Risks to vultures and other necrophagous bird populations in the European Union in connection with the use of veterinary medicinal products containing the substance diclofenac Diclofenac
Referral under Article 33(4) Directive 2001/82/EC	08/10/2014	Gutal 1000 g/kg premix for medicated feeding stuff for pigs Zinc oxide
Referral under Article 33(4) of Directive 2001/82/EC	05/11/2014	Coglapix vakcina A.U.V. suspension for injection for pigs <i>Actinobacillus pleuropneumoniae</i> strains serotype 1 and 2

Annex 17 – Budget summaries 2013–2014

The summarised comparative budget statements for 2013 and 2014 are as follows:

		2013 (final) ¹		2014 (budget) ²		2014 (provisional) ³	
		€ '000	% of total	€ '000	% of total	€ '000	% of total
Revenue							
1+5	Fees and charges	198,865	82.7%	228,156	80.8%	217,670	80.1%
200	General EU contribution	32,630	13.6%	23,730	8.4%	23,957	8.8%
201	Special EU contribution for orphan medicinal products	6,509	2.7%	9,500	3.4%	9,432	3.5%
300	Contribution from EEA	1,098	0.5%	902	0.3%	675	0.2%
600	External assigned revenue	700	0.3%	19,283	6.8%	18,904	7.0%
5+9	Other	585	0.2%	903	0.3%	1,147	0.4%
	TOTAL REVENUE	240,387	100.0%	282,474	100.0%	271,786	100.0%
Expenditure							
Staff							
11	Staff in active employment	71,497	29.4%	89,862	31.8%	84,352	31.7%
13	Duty travel	409	0.2%	605	0.2%	540	0.2%
14	Socio-medical infrastructure	521	0.2%	806	0.3%	805	0.3%
15	Exchange of civil servants and experts	2,672	1.1%	3,674	1.3%	3,016	1.1%
16	Social welfare	277	0.1%	335	0.1%	323	0.1%
17	Representation expenses	28	0.0%	54	0.0%	53	0.0%
18	Staff insurances	2,149	0.9%	2,395	0.8%	2,255	0.8%
	<i>Total Title 1</i>	77,552	31.9%	97,731	34.6%	91,344	34.3%
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	45,889	18.9%	40,916	14.5%	39,175	14.7%
21	Expenditure on corporate data processing	13,821	5.7%	15,748	5.6%	12,499	4.7%
22	Movable property [...]	1,009	0.4%	2,245	0.8%	1,927	0.7%
23	Other administrative expenditure	795	0.3%	2,171	0.8%	1,417	0.5%
24	Postage	444	0.2%	184	0.1%	130	0.0%
25	Expenditure on other meetings	98	0.0%	136	0.0%	102	0.0%
	<i>Total Title 2</i>	62,056	25.5%	61,400	21.7%	55,251	20.7%
Operational expenditure							
300	Meetings	6,305	2.6%	7,623	2.7%	7,126	2.7%
301	Evaluation of medicines	80,018	32.9%	97,251	34.4%	96,145	36.1%
302	Translations	5,182	2.1%	5,032	1.8%	4,325	1.6%
303	Studies and consultants	2,031	0.8%	5,229	1.9%	4,730	1.8%
304	Publications	71	0.0%	166	0.1%	163	0.1%
305	Community programmes	340	0.1%	0	0.0%	0	0.0%
31	Expenditure on business related ICT projects	9,863	4.1%	8,042	2.8%	7,336	2.8%
	<i>Total Title 3</i>	103,811	42.6%	123,343	43.7%	119,825	45.0%
	TOTAL EXPENDITURE	243,419	100.0%	282,474	100.0%	266,420	100.0%

¹ Financial Year 2013: as per final accounts; rounded to nearest thousand Euro

² Financial Year 2014: as per final budget

³ Financial Year 2014: as per provisional accounts; rounded to nearest thousand Euro

Annex 18 – European Medicines Agency Establishment Plan

Category and grade	TEMPORARY POSTS					
	POSTS 2014				POSTS 2015	
	Authorised		Actual as per 31.12.2014		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	0	-	0	-	0
AD 15	-	4	-	4	-	4
AD 14	-	6	-	6	-	6
AD 13	-	8	-	7	-	9
AD 12	-	42	-	39	-	42
AD 11	-	38	-	36	-	37
AD 10	-	36	-	35	-	40
AD 9	-	37	-	34	-	36
AD 8	-	49	-	47	-	52
AD 7	-	51	-	51	-	52
AD 6	-	39	-	39	-	36
AD 5	-	30	-	29	-	26
Total AD	0	340	0	327	0	340
AST 11	-	2	-	2	-	2
AST 10	-	5	-	5	-	5
AST 9	-	7	-	7	-	7
AST 8	-	15	-	14	-	16
AST 7	-	19	-	19	-	19
AST 6	-	36	-	34	-	39
AST 5	-	37	-	36	-	42
AST 4	-	55	-	55	-	49
AST 3	-	39	-	38	-	43
AST 2	-	34	-	33	-	37
AST 1	-	10	-	10	-	0
Total AST	0	259	0	253	0	259
Grand Total	0	599	0	580	0	599

Other staff	Planned (FTE ¹) 2014	Actual (FTE) 2014	Actual as per 31.12.2014	Planned (FTE) 2015
CONTRACT AGENTS	130	116	144	130
NATIONAL EXPERTS	25	18	28	50

¹ FTE=Full Time Equivalent

Annex 19 – Annual report from the SME office

The 2014 report from the SME office can be found at the following link:

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2015/02/WC500181837.pdf

Annex 20 – Access to documents requests

Requests received and pages released

Year	Number of requests received	Number of pages released
2014	416	167,309

Decisions on access in 2014¹

Access given	
Yes	229
Partial	15
No	70
Not Applicable ²	66
Total closed	380
Pending	60

Decision on appeals in 2014³

Appeals	
Final refusal	14
Release	25
Partial	2
Not Applicable ⁴	1
Total closed	42
Pending	3

¹ Including initial requests received in previous years but closed in 2014

² Request became RFI / Document is not held by the Agency / Clarification is not received / Withdrawn

³ Including appeals received in previous years but closed in 2014

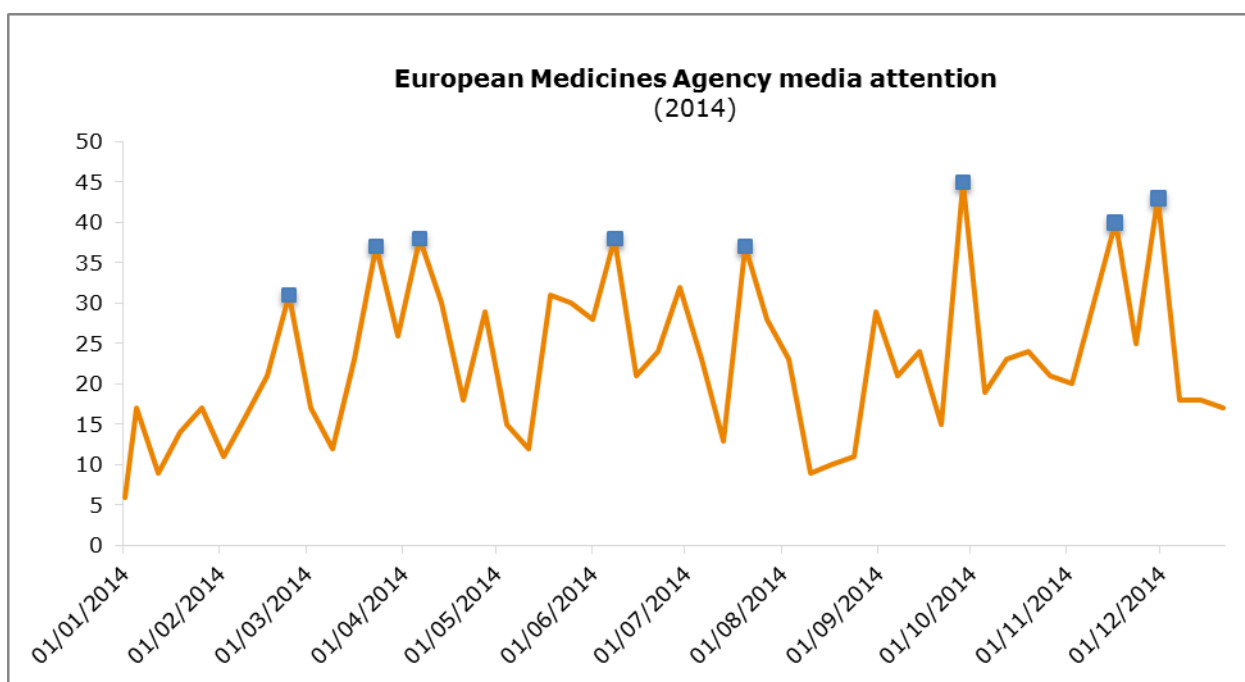
⁴ Withdrawn

Affiliation (per initial requests and appeals in 2014)

Affiliation	Number of requests received	In %	Number of pages released ⁵	In %
Not-for-profit organisation	3	0.7	1,361	0.8
EU Institution (EC etc)	5	1.2	22	0.1
Regulator outside EU	1	0.2	17	0.0
EU NCA	5	1.2	285	0.2
Patients or Consumer	14	3.4	980	0.6
Healthcare professional	8	1.9	742	0.4
Academia/Research institute	35	8.4	23,836	14.2
Legal	66	15.9	59,637	35.6
Media	56	13.5	33,652	20.1
Pharmaceutical industry	196	47.1	43,849	26.2
Other	27	6.5	2,928	1.8
	416	100	167,309	100

⁵ Including initial requests and appeals received in previous years but closed in 2014

Annex 21 – Media and public relations



The stories that made the news:

- *February 2014:* Safety reviews of Protelos and domperidone
- *March 2014:* –Launch of the adaptive pathways pilot
- *April 2014:* Withdrawal of its court case against EMA's decision to give access to documents by Abbvie
- *June 2014:* EMA Management Board agrees to policy on publication of clinical trial data with more user-friendly amendments
- *July 2014:* Submission of an application to assess a malaria vaccine under Art. 58 for use outside the European Union; review of the application to switch conditions of use of the emergency contraceptive EllaOne from prescription to non-prescription.
- *October 2014:* Adoption of the policy on publication of clinical trial by EMA's Management Board; review of possible Ebola treatments by CHMP; involvement of patients in the risk-benefit discussions of the CHMP
- *November 2014:* Ruling by the EU civil servant tribunal to annul the 2013 selection procedure for the EMA Executive Director on formal grounds; updates to EMA's handling of declarations of interests policy
- *December 2014:* CHMP starts reviewing medicines for which authorisation is based on studies conducted at GVK Biosciences in Hyder; PRAC review of Fluad provides assurance about the safety of influenza vaccine; EMA Management Board discusses next steps after judgment of EU Civil Service Tribunal

Annex 22 – Publications by Agency staff members and experts in 2014

Abed I.

The approval process of medicines in Europe.
Medical Writing 2014; 23(2), 117-121

Abou-El-Enein M, Bauer G, Reinke P, Renner M, Schneider CK.

A roadmap toward clinical translation of genetically-modified stem cells for treatment of HIV
Trends Mol Med. 2014 Nov; 20(11):632-42.

Aartsma-Rus A, Ferlini A, Goemans N, Pasmooij AM, Wells DJ, Bushby K, Vroom E, Balabanov P.

Translational and regulatory challenges for exon skipping therapies
Hum Gene Ther. 2014 Oct; 25(10):885-92

Abbing-Karahagopian V, Huerta C, Souverein PC, de Abajo F, Leufkens HG, Slattery J, Alvarez Y, Miret M, Gil M, Oliva B, Hesse U, Requena G, de Vries F, Rottenkolber M, Schmiedl S, Reynolds R, Schlienger RG, de Groot MC, Klungel OH, van Staa TP, van Dijk L, Egberts AC, Gardarsdottir H, De Bruin ML.

Antidepressant prescribing in five European countries: application of common definitions to assess the prevalence, clinical observations, and methodological implications
Eur J Clin Pharmacol. 2014 Jul; 70(7):849-57

Arlett P, Portier G, de Lisa R, Blake K, Wathion N, Dogne JM, Spooner A, Raine J, Rasi G.

Proactively managing the risk of marketed drugs: experience with the EMA Pharmacovigilance Risk Assessment Committee
Nature Reviews Drug Discovery 2014; 13:395-397

Arlett P, Postigo R, Janssen H, Spooner A.

Periodic Benefit-Risk Evaluation Report: A European Union Regulatory Perspective
Pharmaceutical Medicine. December 2014, Volume 28, Issue 6, pp 309-315 Date: 31 Oct 2014

Arlett P, Sarac SB, Thomson A, Davies C, Teixeira T, Blake KV, Stenver D.

The European Medicines Agency's use of prioritised independent research for best evidence in regulatory action on diclofenac
Pharmacoepidemiology and Drug Safety 2014; 23(4): 431-434.

Baird LG, Banken R, Eichler HG, Kristensen FB, Lee DK, Lim JC, Lim R, Longson C, Pezalla E, Salmonson T, Samaha D, Tunis S, Woodcock J, Hirsch G.

Accelerated Access to Innovative Medicines for Patients in Need
Clin Pharmacol Ther. 2014 Nov; 96(5):559-71

Balabanov P, Haas M, Elferink A, Bakchine S, Broich K.

Addressing the regulatory and scientific challenges in multiple sclerosis - a statement from the EU regulators
Mult Scler. 2014 Sep; 20(10):1282-1287

Beckmann J, Hagemann U, Bahri P, Bate A, Boyd IW, Dal Pan GJ, Edwards BD, Edwards IR, Hartigan-Go K, Lindquist M, McEwen J, Moride Y, Olsson S, Pal SN, Soulaymani-Bencheikh R, Tuccori M, Vaca CP, Wong IC.

Teaching Pharmacovigilance: The WHO/UMC-ISoP Core Elements of a Comprehensive Modular Curriculum
Drug Saf. 2014; 37: 743-759

Berntgen M, Gourvil A, Pavlovic M, Goettsch W, Eichler HG, Kristensen FB.

Improving the contribution of regulatory assessment reports to health technology assessments – a collaboration between the European Medicines Agency and the European Network for Health Technology Assessment
Value Health. 2014 Jul; 17(5):634-41

Blake KV, Zaccaria C, Domergue F, La Mache E, Saint-Raymond A, Hidalgo-Simon A.

Comparison Between Paediatric and Adult Suspected Adverse Drug Reactions Reported to the European Medicines Agency: Implications for Pharmacovigilance
Paediatric Drugs 2014; 16(4): 309-319

Bonini S, Eichler HG, Wathion N, Rasi G.

Transparency of clinical trials – The European Medicines Agency driving a learning process
N Engl J Med. 2014 Dec 25; 371(26):2452-5

Borg JJ, Laslop A, Pani L, Maciulaitis R, Melchiorri D.

Reflections on Decisions Made on the Well-Established Use of Medicinal Products by EU Regulators and the ECJ
Sci Pharm. 2014; 82: 655–663

Borg JJ, Tomasi P, Pani L, Aislaitner G, Pirozynski M, Leufkens H, Melchiorri D.

Licensing of Generic Medicines: Are There Any Challenges Left? A Pharmaceutical Regulatory Perspective
Sci Pharm. 2014; 82: 847–856

Caneva L, Bonelli M, Papaluca-Amati M, Vidal JM.

Critical review on the Environmental Risk Assessment of Medicinal products for Human Use in the centralised procedure
Regulatory Toxicology and Pharmacology 68 (2014) 312-316

Cerreta F, Temple R, Asahina Y, Connaire C.

Regulatory activities to address the needs of older patients
J Nutr Health Aging. 2015 Feb; 19(2):232-3

Cortes-Blanco A, Prieto-Yerro C, Martinez-Lazaro R, Zamora J, Jiménez-Huete A, Haberkamp M, Pohly J, Enzmann H, Zinserling J, Strassmann V, Broich K.

Florbetapir (18F) for brain amyloid positron emission tomography: Highlights on the European marketing approval
Alzheimers Dement. 2014 Oct; 10(5 Suppl):S395-9

de Groot MC, Schuerch M, de Vries F, Hesse U, Oliva B, Gil M, Huerta C, Requena G, de Abajo F, Afonso AS, Souverein PC, Alvarez Y, Slattery J, Rottenkolber M, Schmiedl S, Van Dijk L, Schlienger RG, Reynolds R, Klungel OH.

Antiepileptic drug use in seven electronic health record databases in Europe: A methodologic comparison
Epilepsia. 2014 May; 55(5):666-73

Egan AG, Blind E, Dunder K, Graeff de PA, Hummer BT, Bourcier T, Rosebraugh C.

Pancreatic Safety of Incretin-Based Drugs — FDA and EMA Assessment
N Engl J Med 370; 2014; 794-797

Egger GF, Manent N.

Re: Non-publication and delayed publication of randomized trials on vaccines: survey
BMJ 2014; 348:g3058

Franco P, Porta N, Holliday JD, Willett P.

The use of 2D fingerprint methods to support the assessment of similarity in orphan drug legislation
J Cheminform. 2014 Feb 1; 6(1):5

Giezen TJ, Schneider CK.

Safety assessment of biosimilars in Europe: a regulatory perspective
GaBI Journal 2014; 4:180-3.

Gravanis I, Vleminckx C, Jonsson B, Pignatti F

The changing world of oncology drug development: the regulatory bodies' perspective
Chin Clin Oncol 2014; 3(2):22

Grave K, Mackay D, Muller A, Torren-Edo J.

European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) - establishment of the project and key outputs
Regulatory Rapporteur – Vol 11, No 9, September 2014: 4-9

Grave K, Torren-Edo J, Muller A, Greko C, Moulin G and Mackay D.

Variations in the sales and sales patterns of veterinary antimicrobial agents in 25 European countries
J Antimicrob Chemother 2014; 69: 2284-91

Hampson LV, Herold R, Posch M, Saperia J, Whitehead A.

Bridging the gap: A review of dose-investigations in paediatric investigation plans
Br J Clin Pharmacol. 2014 Oct;78(4):898-907

Hanaizi Z, Unkrig C, Enzmann H, Camarero J, Sancho-Lopez A, Salmonson T, Gisselbrecht C, Laane E, Pignatti F.

The European Medicines Agency review of bosutinib for the treatment of adult patients with chronic myelogenous leukaemia: Summary of the scientific assessment of the Committee for Medicinal Products for Human Use
Oncologist. 2014 Apr;19(4):421-5

Herold R, Saint-Raymond A, Norga K.

Too few medicines for children with Cancer
JAMA Pediatr. 2014 Jun;168(6):583

Hill DL, Schwarz AJ, Isaac M, Pani L, Vamvakas S, Hemmings R, Carrillo MC, Yu P, Sun J, Beckett L, Boccardi M, Brewer J, Brumfield M, Cantillon M, Cole PE, Fox N, Frisoni GB, Jack C, Kelleher T, Luo F, Novak G, Maguire P, Meibach R, Patterson P, Bain L, Sampaio C, Raunig D, Soares H, Suh J, Wang H, Wolz R, Stephenson D.

Coalition Against Major Diseases/European Medicines Agency biomarker qualification of hippocampal volume for enrichment of clinical trials in predementia stages of Alzheimer's disease
Alzheimers Dement. 2014 Jul;10(4):421-429

Lincker H, Ziogas C, Carr M, Portia N, Eichler HG.

Regulatory watch: Where do new medicines originate from in the EU?
Nat Rev Drug Disc 2014 (13), 92-93

Mackay D, Grave K, Muller A, Torren-Edo J.

Key success factors for surveys of antimicrobial sales and use in the European Union
Responsible and Prudent use of Antimicrobial Agents for animals. International Solidarity to fight against Antimicrobial Resistance. OIE Global Conference, Paris, France, 13- 15 March 20 13. p 28-31

Mariz S, Tsigkos S, Fregonese L, Aarum S, Dehlink R, Llinares J, Sepodes B.

The orphan framework as a new opportunity: an expert opinion
Expert Opinion Orphan Drugs. November 2014, Vol. 2, No. 11 , Pages 1181-1186

Mentzer D, Desfontaine E, Tomasi PA.

The importance and challenge of pediatric trials of hemophilia drugs
Nat Med. 2014 May;20(5):465

Narayanan G, Cossu G, Galli MC, Flory E, Ovelgonne H, Salmikangas P, Schneider CK, Trouvin JH.

Clinical development of gene therapy needs a tailored approach: a regulatory perspective from the European Union.
Hum Gene Ther Clin Dev. 2014 Mar;25(1):1-6.

Nofziger C, Papaluca M, Terzic A, Waldman S, Paulmichl M.

Policies to aid the adoption of personalized medicine
Nat Rev Drug Discov. 2014 Mar;13(3):159-60

Pacurariu AC, Coloma PM, van Haren A, Genov G, Sturkenboom MC, Straus SM.

A description of signals during the first 18 months of the EMA Pharmacovigilance Risk Assessment Committee
Drug Saf. 2014 Dec;37(12):1059-66

Peschel W.

The use of community herbal monographs to facilitate registrations and authorisations of herbal medicinal products in the European Union 2004-2012
J Ethnopharmacol. 2014 Dec 2;158 Pt B: 471-86

Pfleiderer M, Trouvin JH, Brasseur D, Gränstrom M, Shivji R, Mura M, Cavaleri M.

Brief Report for Vaccine - Summary of knowledge gaps related to quality and efficacy of current influenza vaccines

Vaccine. 2014 Jul 31;32(35):4586-91

Pignatti F, Ehmann F, Hemmings R, Jonsson B, Nuebling M, Papaluca-Amati M, Posch M, Rasi G.
Cancer drug development and the evolving regulatory framework for companion diagnostics in the European union

Clin Cancer Res. 2014 Mar 15;20(6):1458-68.

Pignatti F, Jonsson B, Blumenthal G, Justice R.

Assessment of benefits and risks in development of targeted therapies for cancer - The view of regulatory authorities

Mol Oncol. 2014 Oct 16. pii: S1574-7891(14)00242-7. [Epub ahead of print]

Quijano Ruiz B, Desfontaine E, Arenas-López S, Wang S.

Pediatric formulation issues identified in Paediatric Investigation Plans

Expert Rev Clin Pharmacol. 2014 Jan;7(1):25-30

Requena G, Abbing-Karahagopian V, Huerta C, De Bruin ML, Alvarez Y, Miret M, Hesse U, Gardarsdottir H, Souverein PC, Slattery J, Schneider C, Rottenkolber M, Schmiedl S, Gil M, De Groot MC, Bate A, Ruigómez A, García Rodríguez LA, Johansson S, de Vries F, Montero D, Schlienger R, Reynolds R, Klungel OH, de Abajo FJ.

Trends in incidence rates of hip and femur fractures in five European countries, 2003-2009: a comparison using electronic health care records databases

Calcif Tissue Int. 2014;94(6):580-9.

Shankar G, Arkin S, Cocea L, Devanarayan V, Kirshner S, Kromminga A, Quarmby V, Richards S, Schneider CK, Subramanyam M, Swanson S, Verthelyi D, Yim S; American Association of Pharmaceutical Scientists.

A Harmonized Strategy for the Assessment and Reporting of the Clinical Immunogenicity of Therapeutic Proteins and Peptides.

AAPS J. 2014 Jul;16(4):658-73

Smith M, Bahri P, Dal Pan G, Banerjee S, Mol P, Dey D.

Benefit-Risk Assessment, Communication and Evaluation (BRACE) throughout the Life Cycle of Therapeutic Products: Overall Perspective and Role of the Pharmacoepidemiologist

Pharmacoepidemiol Drug Saf. 2014; 23(S1): 364-365

Sun H, Vesely R, Taminiau J, Sztanyi P, Papadopoulos EJ, Isaac M, Klein A, Uzu S, Griebel D, Mulberg AE; International Inflammatory Bowel Disease Working Group

Steps toward harmonization for clinical development of medicines in pediatric ulcerative colitis-a global scientific discussion, part 1: efficacy endpoints and disease outcome assessments

J Pediatr Gastroenterol Nutr. 2014 Jun;58(6):679-83

Sun H, Vesely R, Nelson RM, Taminiau J, Sztanyi P, Isaac M, Klein A, Uzu S, Griebel D, Mulberg AE; International Inflammatory Bowel Disease Working Group.

Steps toward harmonization for clinical development of medicines in pediatric ulcerative colitis-a global scientific discussion, part 2: data extrapolation, trial design, and pharmacokinetics.

J Pediatr Gastroenterol Nutr. 2014 Jun;58(6):684-8

Tsiftoglou AS, Trouvin JH, Calvo G, Ruiz S.

Demonstration of Biosimilarity, Extrapolation of Indications and Other Challenges Related to Biosimilars in Europe

BioDrugs. 2014 Dec;28(6):479-86

Tsigkos S, Llinares J, Mariz S, Aarum S, Fregonese L, Dembowska-Baginska B, Elbers R, Evers P, Foltanova T, Lhoir A, Corrêa-Nunes A, O'Connor D, Voordouw A, Westermark K, Sepodes B.

Use of biomarkers in the context of Orphan Medicines Designation in the European Union

Orphanet Journal of Rare Diseases 2014, 9:13

Tsigkos S, Mariz S, Llinares J, Fregonese L, Aarum S, , Naumann-Winter F, Westermark K, Sepodes B.

Establishing medical plausibility in the context of orphan medicines designation in the European Union
Orphanet Journal of Rare Diseases 2014, 9:175

van Aerts LA, De Smet K, Reichmann G, van der Laan JW, Schneider CK.

Biosimilars entering the clinic without animal studies
mAbs, 6:5, 1155-1162

van Riet-Nales DA, Römken EG, Saint-Raymond A, Kozarewicz P, Schobben AF, Egberts TC, Rademaker CM.

Oral medicines for children in the European paediatric investigation plans
PLoS One. 2014 Jun 4;9(6)

Weise M, Kurki P, Wolff-Holz E, Bielsky MC, Schneider CK.

Biosimilars: the science of extrapolation.
Blood. 2014 Nov 20;124(22):3191-6. doi: 10.1182/blood-2014-06-583617