Annexes to the annual report of the European Medicines Agency 2015

** Correction: Excipients drafting group added in Annex 9, p.18.*

Annex 1 – Members of the Management Board

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

Members

• European Parliament	Guiseppe NISTICÓ, Björn LEMMER
• European Commission	Xavier PRATS-MONNÉ[1], Carlo PETTINELLI[2] (Alternates: Andrzej RYS ,Christian SIEBERT[3])
• Belgium	Xavier DE CUYPER (Alternate: Greet MUSCH)
• Bulgaria	Assena STOIMENOVA (Alternate: Svetlin SPIROV)
• Czech Republic	Zdenek BLAHUTA[4] (Alternate: Jiří BUREŠ)
• Denmark	Mette AABOE HANSEN[5] (Alternate: Anna SKAT NIELSEN[6])
• Germany	Karl BROICH[7] (Alternate: Klaus CICHUTEK)
• Estonia	Kristin RAUDSEPP (Alternate: Alar IRS)
• Ireland	Rita PURCELL[8] (Alternate: Lorraine NOLAN[9])
• Greece	Despoina MAKRIDAKI[10] (Alternate: Giannis KARAFYLLIS[11])
• Spain	Belén CRESPO SÁNCHEZ-EZNARRIAGA (Alternate: Laura Franqueza GARCÍA)
• France	Dominique MARTIN (Alternate: Jean-Pierre ORAND)
• Italy	Luca PANI (Alternate: Gabriella CONTI)
• Cyprus	Loizos PANAYI (Alternate: Ioannis KKOLOS)
• Latvia	Svens HENKUZENS[12] (Alternate: Janis ZVEJNIEKS[13])
• Lithuania	Gintautas BARCYS (Alternate: Gediminas PRIDOTKAS)
• Luxembourg	Laurent MERTZ[14] (Alternate: Jacqueline GENOUX-HAMES)

[1] Replaced Ladislav MIKO as of September 2015
[2] Replaced Gwenole COZIGOU as of June 2015
[3] Replaced Salvatore D'ACUNTO as of June 2015
[4] Replaced Doubravka KOSTALOVA as of April 2015
[5] Replaced Else SMITH as of June 2015
[6] Replaced Nina MOSS as of January 2015
[7] Replaced Walter SCHWERDTFEGER as of November 2015
[8] Replaced Pat O'MAHONY as of September 2015
[9] Replaced Rita PURCELL as of September 2015
[10] Replaced Katerina FAMELI as of May 2015
[11] Replaced Giannis KARAFYLLIS as of May 2015
[12] Replaced Inguna ADOVIČA as of December 2015
[13] Replaced Dace ĶIKUTE as of December 2015

• Hungary	Csilla POZSGAY[15] (Alternate: Hilda KŐSZEGINÉ SZALAI)
• Malta	John-Joseph BORG (Alternate: Gavril FLORES)
• Netherlands	Hugo HURTS (Alternate: Constant VAN BELKUM)
• Austria	Christa WIRTHUMER-HOCHE (Alternate: Sylvia FÜSZL)
• Poland	Grzegorz CESSAK (Alternate: Artur FALEK)
• Portugal	Helder MOTA FILIPE (Alternate: Awaiting nomination)
• Romania	NICOLAE FOTIN[16] (Alternate: Marius TANASA)
• Slovenia	Andreja CUFAR[17] (Alternate: Stanislav PRIMOŽIČ)
• Slovakia	Ján MAZÁG (Alternate: Valeria PERNISOVA[18])
• Finland	Sinikka RAJANIEMI (Alternate: Pekka KURKI)
• Sweden	Catarina FORSMAN (Alternate: Bengt WITTGREN)
• United Kingdom	Kent WOODS (Alternate: Ian HUDSON)
• Representatives of patients' organisations	Nikos DEDES W.H.J.M. Wim WIENTJENS
• Representative of	Wolf-Dieter LUDWIG doctors' organisations
• Representative of	Christophe HUGNET veterinarians' organisations

Observers

• Iceland	Runa HAUKSDOTTIR[19] (Alternate: Einar MAGNUSSON[20])
• Liechtenstein	Brigitte BATLINER (Alternate: Christina ZIMMER)
• Norway	Audun HÅGÅ (Alternate: Ivar VOLLSET)

[14] Replaced Mike Schwebag as of April 2015
[15] Replaced Beatrix HORVÁTH as of December 2015
[16] Replaced Marius SAVU as of November 2015
[17] Replaced Matej BREZNIK as of November 2015
[18] Replaced Barbora KUČEROVÁ as of July 2015
[19] Replaced Rannveig GUNNARSDÓTTIR as of November 2015
[20] Replaced Helga THORISDÓTTIR as of November 2015

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

Chairman: 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
• Viola MACOLIC SARINIC (Croatia)[1]	Alternate: Ana DUGONJIC
• Panayiotis TRIANTAFYLLIS (Cyprus)	Alternate: George SAVVA
• Ondřej SLANAR (Czech Republic)	Alternate: Radka MONTONIOVA
• Jens HEISTERBERG (Denmark)	Alternate: Sinan B. SARAC[2] [3]
• Alar IRS (Estonia)	Alternate: Kersti OSELIN
• Outi MAKI-IKOLA (Finland)	Alternate: Tuomo LAPVETELAINEN[4] [5]
• Pierre DEMOLIS (France) *(Vice-Chair)*	Alternate: Joseph EMMERICH
• Harald ENZMANN (Germany)	Alternate: Martina WEISE
• Dimitrios KOUVELAS (Greece)	Alternate: George AISLAITNER
• Agnes GYURASICS (Hungary)	Alternate: Melinda SOBOR
• Kolbeinn GUDMUNDSSON (Iceland)	Alternate: Hrefna GUDMUNDSDOTTIR
• David LYONS (Ireland)	Alternate: Patrick SALMON
• Daniela MELCHIORRI (Italy)	Alternate: Luca PANI
• 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: Bjorg BOLSTAD [6] [7]
• Piotr FIEDOR (Poland)	Alternate: Aldona PALUCHOWSKA

[1] Replaced Ivana MIKACIC as of May 2015
[2] Christian SCHNEIDER resigned as of August 2015
[3] Sinan B. SARAC nominated as of September 2015
[4] Janne KOMI resigned as of January 2015
[5] Tuomo LAPVETELAINEN nominated as of March 2015
[6] Ingunn HAGEN WESTGAARD resigned as of January 2015
[7] Bjorg BOLSTAD nominated as of October 2015

• Bruno SEPODES (Portugal)	Alternate: Patricia SILVA [8]
• Nela VILCEANU (Romania)	Alternate: Dana MARIN
• Jan MAZAG (Slovakia)	Alternate: Ivana PANKUCHOVA [9]
• Stanislav PRIMOZIC (Slovenia)	Alternate: Nevenka TRSINAR
• Concepcion PRIETO YERRO (Spain)	Alternate: Arantxa SANCHO-LOPEZ
• Kristina DUNDER (Sweden)	Alternate: Filip JOSEPHSON
• Greg MARKEY (United Kingdom)	Alternate: Nithyanandan NAGERCOIL [10] [11]

Co-opted Members

- Robert James HEMMINGS (Medical statistics (clinical-trial methodology / epidemiology))
- Jean-Louis ROBERT (Quality (non-biologicals))
- Sol RUIZ (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))
- *Awaiting nomination* [12]
- Jan MUELLER-BERGHAUS (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))

[8] Replaced Dinah DUARTE as of September 2015
[9] Replaced Jana KLIMASOVA as of February 2015
[10] Rafe SUVARNA resigned on November 2016
[11] Nithyanandan NAGERCOIL nominated as of December 2015
[12] Hubert G.M. LEUFKENS resigned as of July 2015

Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: June RAINE
EMA contact: Anthony HUMPHREYS

Members

• Jan NEUHAUSER (Austria)[1]	Alternate: Marianne LUNZER[2]
• Jean-Michel DOGNE (Belgium)	Alternate: Veerle VERLINDEN
• Maria POPOVA-KIRADJIEVA (Bulgaria)	Alternate: Yuliyan EFTIMOV
• Marina DIMOV DI GIUSTI (Croatia)[3]	Alternate: Viola MACOLIC SARINIC[4]
• Nectaroula COOPER (Cyprus)	Alternate: *Awaiting nomination*
• Jana MLADA (Czech Republic)	Alternate: Eva JIRSOVA
• Doris STENVER (Denmark)	Alternate: Torbjorn CALLREUS
• Maia UUSKULA (Estonia)	Alternate: Katrin KIISK
• Kirsti VILLIKKA (Finland)	Alternate: Kimmo JAAKKOLA[5]
• Isabelle ROBINE (France)[6]	Alternate: Corinne FECHANT[7]
• Martin HUBER (Germany)	Alternate: Valerie STRASSMANN
• Leonidas KLIRONOMOS (Greece)	Alternate: Agni KAPOU
• Julia PALLOS (Hungary)	Alternate: Melinda PALFI
• Guðrún Kristín STEINGRIMSDOTTIR (Iceland)	Alternate: Hrefna GUDMUNSDOTTIR
• Almath SPOONER (Ireland) *(Vice-Chair)*	Alternate: Ruchika SHARMA
• Carmela MACCHIARULO (Italy)	Alternate: AMELIA CUPELLI
• Zane NEIKENA (Latvia) [8] [9]	Alternate: Zane STADE [9] [10] [11]
• Jolanta GULBINOVIC (Lithuania)	Alternate: Simona KUDELIENE[12] [13] [14]
• Marcel BRUCH (Luxembourg)[15]	Alternate: Nadine PETITPAIN

[1] Replaced Harald HERKNER as of June 2015
[2] Replaced Jan NEUHAUSER as of June 2015
[3] Replaced Viola MACOLIC SARINIC as of June 2015
[4] Replaced Marin BANOVAC as of June 2015
[5] Replaced Terhi LEHTINEN as of July 2015
[6] Replaced Arnaud BATZ as of May 2015
[7] Replaced Patrick MAISON as of May 2015
[8] Andis LACIS resigned as of February 2015
[9] Switch of roles of member and alternate as of October 2015
[10] Zane NEIKENA replaced Inguna ADOVICA as of April 2015
[11] Zane STADE nominated as of December 2015
[12] Rita DZETAVECKIENE resigned as of January 2015
[13] Arturas KAZEMEKAITIS nominated as of January 2015 and resigned as of September 2015
[14] Simona KUDELIENE nominated as of November 2015
[15] Replaced Jacqueline GENOUX-HAMES as of March 2015

• Ami TANTI (Malta)	Alternate: John Joseph BORG[16]
• Sabine STRAUS (Netherlands)	Alternate: Menno VAN DER ELST
• Ingebjorg BUAJORDET (Norway)	Alternate: Kristin Thorseng KVANDE[17]
• Adam PRZYBYLKOWSKI (Poland)	Alternate: Magdalena BUDNY
• Margarida GUIMARAES (Portugal)	Alternate: Leonor CHAMBEL[18]
• Roxana STROE (Romania)[19]	Alternate: Nicolae FOTIN [19]
• Tatiana MAGALOVA (Slovakia)	Alternate: Miroslava MATIKOVA[20] [21] [22]
• Milena RADOHA-BERGOC (Slovenia)	Alternate: Gabriela JAZBEC
• Dolores MONTERO (Spain)	Alternate: Miguel MACIA
• Ulla WANDEL LIMINGA (Sweden) [23]	Alternate: Qun-Ying YUE [22]
• Julie WILLIAMS (United Kingdom)	Alternate: Rafe SUVARNA

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

[16] John Joseph BORG nominated as of March 2015
[17] Replaced Pernille HARG as of July 2015
[18] Replaced Magda PEDRO as of November 2015
[19] Switch of roles of member and alternate as of April 2015
[20] Anna MAREKOVA resigned as of January 2015
[21] Jana NOVAKOVA nominated as of January 2015 and resigned as of March 2015
[22] Miroslava MATIKOVA nominated as of March 2015
[23] Switch of roles of member and alternate as of June 2015

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 KOZHUHAROV (Bulgaria)	Alternate: Svetoslav BRANCHEV[1]
• Ljiljana MARKUS CIZELJ (Croatia)	Alternate: Frane BOZIC
• 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*
• Martti NEVALAINEN[2] (Finland)	Alternate: Kristina LEHMANN
• Jean-Claude ROUBY[3] (France)	Alternate: Sylvie LOUET[4]
• Cornelia IBRAHIM (Germany)	Alternate: Esther WERNER
• Ioannis MALEMIS (Greece)	Alternate: Angeliki TSIGOURI
• Gabor 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: Sigitas SIRIUKAITIS[5]
• 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 TABAN (Romania)	Alternate: Simona STURZU

[1] Replaced Bogdan AMINKOV as of September 2015 meeting
[2] Replaced Irmeli HAPPONEN as of February 2015 meeting
[3] Replaced Michael HOLZHAUSER-ALBERTI as of September 2015 meeting
[4] As of October 2015 meeting
[5] As of July 2015 meeting

- Judita HEDEROVA (Slovakia) — Alternate: Eva CHOBOTOVA
- Stane SRCIC (Slovenia) — Alternate: Katarina STRAUS
- Cristina MUNOZ MADERO (Spain) — Alternate: Consuelo RUBIO MONTEJANO
- Eva LANDER PERSSON (Sweden) — Alternate: Frida HASSLUNG-WIKSTRÖM
- Helen JUKES (United Kingdom) — Alternate: Anna-Maria BRADY

EEA observers

- Johann LENHARDSSON (Iceland) — Alternate: *awaiting nomination*
- Hanne BERGENDAHL (Norway) — Alternate: Tonje HOY

Co-opted members

Co-opted member	**Expertise**
• Keith BAPTISTE[6]	Antimicrobials
• Rory BREATHNACH	General clinical veterinary practice
• Christian FRIIS	MRLs/residues
• Boris KOLAR	Environmental risk assessment
• Wilhelm SCHLUMBOHM	Quality pharmaceuticals

[6] Re-elected during the December 2015 meeting

Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Bruno SEPODES
EMA contact: Anthony HUMPHREYS

Members

- Brigitte BLOCHL-DAUM (Austria)
- Andre LHOIR (Belgium)
- Irena BRADINOVA (Bulgaria)
- Adriana ANDRIC (Croatia)
- Andri ANDREOU (Cyprus)[1] [2]
- Katerina KUBACKOVA (Czech Republic)
- Jens ERSBOLL (Denmark)
- Vallo TILLMANN (Estonia)
- Karri PENTTILA (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)
- Michel HOFFMAN (Luxembourg)[3]
- Richard MUSCAT (Malta)[4] [5]
- Violeta STOYANOVA-BENINSKA (Netherlands)
- *Awaiting Nomination* (Norway)[6]
- Bozenna DEMBOWSKA-BAGINSKA (Poland)

[1] Elena KAISI resigned as of March 2015
[2] Andri ANDREOU nominated as of June 2015
[3] Replaced Henri METZ as of January 2015
[4] Albert CILIA VINCENTI resigned as of March 2015
[5] Richard MUSCAT nominated as of May 2015
[6] Lars GRAMSTAD resigned as of May 2015

- Dinah DUARTE (Portugal)[7] [8]
- Flavia SALEH (Romania)
- Zuzana BATOVA (Slovakia)
- 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 BARISIC
- Giuseppe CAPOVILLA
- *Awaiting Nomination*[9]

Members representing patients' organisations nominated by the European Commission

- Marie Pauline EVERS
- Lesley GREENE *(Vice-Chair)*
- Mario RICCIARDI[10]

[7] Ana CORREA NUNES resigned as of July 2015
[8] Dinah DUARTE nominated as of August 2015
[9] Aikaterini MORAITI's mandate expired as of June 2015
[10] Replaced Birthe Byskov HOLM as of July 2015

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: *Awaiting nomination*[1]
• Elena MUSTAKEROVA (Bulgaria)	Alternate: Kapka KANEVA
• 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 CHINOU (Greece)	Alternate: Zoe KARAMPOURMPOUNI
• Zsuzsanna BIRO-SANDOR (Hungary)	Alternate: Rita NEMETH
• *Awaiting nomination* (Iceland)	Alternate: *Awaiting nomination*
• Una MOCKLER (Ireland)[2]	Alternate: Annamarie O'SULLIVAN[3]
• Marisa DELBO (Italy) *(Vice-Chair)*	Alternate: Anna Maria SERRILLI
• Dace KALKE (Latvia)	Alternate: Baiba JANSONE
• Rugile PILVINIENE (Lithuania)[4] [5]	Alternate: Audronis LUKOSIUS
• Marcel BRUCH (Luxembourg)[6]	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

[1] Wim VERVAET resigned as of March 2015
[2] Replaced Anna CUNNEY as of September 2015
[3] Replaced Una MOCKLER as of September 2015
[4] Arturas KAZEMEKAITIS resigned as of September 2015
[5] Rugile PILVINIENE nominated as of October 2015
[6] Marcel BRUCH nominated as of March 2015

- Ana Paula MARTINS (Portugal) Alternate: Eva MENDES
- Nadia GRIGORAS (Romania) Alternate: Carmen PURDEL
- Gabriela DUCHAJOVA (Slovakia)[7] Alternate: Milan NAGY
- Barbara RAZINGER (Slovenia) Alternate: Samo KREFT
- Adela NUNEZ VELAZQUEZ (Spain) Alternate: Cristina MARTINEZ GARCIA[8]
- Per CLAESON (Sweden) Alternate: Erika SVEDLUND
- 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

- Ulrich ROSE (EDQM)
- Melanie BALD (EDQM)

[7] Replaced Martina HUDECOVA as of January 2015
[8] Cristina MARTINEZ GARCIA nominated as of October 2015

Annex 7 – Members of the Advanced Therapies Committee

Chair: Paula SALMIKANGAS
EMA contact: Patrick CELIS

Members

Members nominated from within the CHMP

• Romaldas MACIULAITIS (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 TIMON

Members nominated by Member States

• Ilona G. REISCHL (Austria)	Alternate: Martin BRUNNER
• Claire BEUNEU (Belgium)	Alternate: Belaid SEKKALI
• Rozalina KULAKSAZOVA (Bulgaria)	Alternate: Evelina SHUMKOVA
• Mirna GOLEMOVIC (Croatia) [1]	Alternate: Ivica MALNAR
• Anna PAPHITOU (Cyprus)	Alternate: Ioannis KKOLOS
• Tomas BORAN (Check Republic)	Alternate: Ivana HAUNEROVA
• Nanna Aaby KRUSE (Denmark) [2] [3]	Alternate: *Awaiting nomination* [2]
• Toivo MAIMETS (Estonia)	Alternate: Tarmo TIIDO
• Tiina PALOMAKI (Finland)	Alternate: Olli TENHUNEN
• Nicolas FERRY (France)	Alternate: Violaine CLOSSON [4] [5]
• Martina SCHUSSLER-LENZ (Germany) *(Vice-Chair)*	Alternate: Egbert FLORY
• Asterios TSIFTSOGLOU (Greece)	Alternate: Angeliki ROBOTI
• Krisztian FODOR (Hungary) [6]	Alternate: Balazs SARKADI [5]
• *Awaiting nomination* (Iceland)	Alternate: *Awaiting nomination*
• Maura O'DONOVAN (Ireland)	Alternate: Maeve LALLY

[1] Replaced Sandra TOMLJENOVIC as of December 2015
[2] Sinan B. SARAC resigned as of August 2015
[3] Switch of roles of member and alternate as of October 2015
[4] Sophie LUCAS resigned as of March 2015
[5] Violaine CLOSSON nominated as of June 2015
[6] Switch of roles of member and alternate as of February 2015

- Paolo GASPARINI (Italy) Alternate: Luca SANGIORGI [7]
- Una RIEKSTINA (Latvia) Alternate: Aija LINE
- Johannes H. OVELGONNE (Netherlands) Alternate: *Awaiting nomination*
- Marit HYSTAD (Norway) Alternate: Rune KJEKEN
- Dariusz SLADOWSKI (Poland) Alternate: Anna CIESLIK
- Simona BADOI (Romania) Alternate: Gianina-Nicoleta ANDREI
- Mikulas HRUBISKO (Slovakia) Alternate: Jan KYSELOVIC
- Metoda LIPNIK-STANGELJ (Slovenia) Alternate: Nevenka TRSINAR
- Lennart AKERBLOM (Sweden) Alternate: Bjorn CARLSSON
- Christiane NIEDERLAENDER (Un. Kingdom) [8] Alternate: James MCBLANE

Members representing clinicians nominated by the European Commission

- Pieter DOEVENDANS Alternate: Esteve TRIAS-ADROHER
- Bernd GANSBACHER Alternate: Ramadan JASHARI

Members representing patients' organisations nominated by the European Commission

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

Observers

- Karl-Heinz BUCHHEIT

[7] Luca Sangiorgi nominated as of January 2015
[8] Replaced Elaine FRENCH on July 2015

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 (Romania)	Alternate: Nela VILCEANU

Members

• Karl-Heinz HUEMER (Austria)	Alternate: Christoph MALE
• Koenraad NORGA (Belgium) *(Vice-chair)*	Alternate: Jacqueline CARLEER
• Dimitar ROUSSINOV (Bulgaria)[1]	Alternate: Vessela BOUDINOVA
• Suzana MIMICA MATANOVIC (Croatia)[2]	Alternate: Marina DIMOV DI GIUSTI[3]
• Georgios SAVVA (Cyprus)	Alternate: Irene PERICLEOUS[4]
• Jaroslav STERBA (Czech Republic)	Alternate: Peter SZITANYI
• Marianne ORHOLM (Denmark)	Alternate: Marta GRANSTROM
• Irja LUTSAR (Estonia)	Alternate: Jana LASS
• Ann Marie KAUKONEN (Finland)	Alternate: Maija PIHLAJAMAKI
• Sylvie BENCHETRIT (France)	Alternate: *Awaiting nomination*
• Birka LEHMANN (Germany)	Alternate: Immanuel BARTH
• Grigorios MELAS (Greece)	Alternate: Stefanos MANTAGOS
• *Awaiting nomination* (Iceland)[5]	Alternate: *Awaiting nomination*
• Brian AYLWARD (Ireland)	Alternate: *Awaiting nomination*
• Paolo ROSSI (Italy)	Alternate: Francesca ROCCHI
• Dina APELE-FREIMANE (Latvia)	Alternate: Kristine SUPE
• John Joseph BORG (Malta)	Alternate: Herbert LENICKER
• Hendrik VAN DEN BERG (Netherlands)	Alternate: Maaike VAN DARTEL

[1] Replaced Violeta IOTOVA as of November 2015
[2] Replaced Marina DIMOV DI GIUSTI as of July 2015
[3] Replaced Bernard KAIC as of July 2015
[4] Replaced Andreas TELOUDES as of March 2015
[5] Gylfi OSKARSSON resigned as of October 2015

- Siri WANG (Norway) Alternate: Ine BLANKENBERG SKOTTHEIM RUSTEN
- Marek MIGDAL (Poland) Alternate: Jolanta WITKOWSKA-OZOGOWSKA
- Helena FONSECA (Portugal) Alternate: Hugo TAVARES
- *Awaiting nomination* (Slovakia)[6] Alternate: *Awaiting nomination*[7]
- Stefan GROSEK (Slovenia) Alternate: *Awaiting nomination*
- Fernando DE ANDRES TRELLES (Spain) Alternate: Maria Jesus FERNANDES CORTIZO
- Ninna GULLBERG (Sweden) Alternate: Anna-Karin HAMBERG
- Angeliki SIAPKARA (United Kingdom) Alternate: Martina RIEGL

Members representing healthcare professionals nominated by the European Commission

- Antje NEUBERT Alternate: Paolo PAOLUCCI
- Riccardo RICCARDI Alternate: Maria Grazia VALSECCHI
- Johannes TAMINIAU Alternate: Doina PLESCA

Members representing patients' organisations nominated by the European Commission

- Günter Karl-Heinz AUERSWALD Alternate: Paola BAIARDI
- Michal ODERMARSKY Alternate: Milena STEVANOVIC
- Tsveta SCHYNS-LIHARSKA Alternate: Kerry LEESON-BEEVERS

[6] Michaela MECIAKOVA resigned as of July 2015
[7] Karol KRALINSKY resigned as of July 2015

Annex 9 – Working parties and working groups

Committee for Medicinal Products for Human Use (CHMP)

CHMP standing working parties

	Chair	EMA contact
Biologics Working Party	Sol RUIZ	Veronika JEKERLE
Quality Working Party	Jean-Louis ROBERT	Simona KECKESOVA
Safety Working Party	Jan-Willem VAN DER LAAN	Jean-Marc VIDAL
Scientific Advice Working Party	Robert James HEMMINGS	Spiros VAMVAKAS

CHMP temporary working parties

	Chair	EMA contact
Biosimilar Medicinal Products Working Party	Christian SCHNEIDER	Daniela DA SILVA
Biostatistics Working Party	David Jonathan WRIGHT	Frank PETAVY
Blood Products Working Party	Anneliese HILGER	Irene PAPADOULI
Cardiovascular Working Party	Pieter DE GRAEFF	Anna BACZYNSKA
Central Nervous System Working Party	Karl BROICH	Marta KOLLB-SIELECKA
Infectious Diseases Working Party	Mair POWELL	Radu BOTGROS
Oncology Working Party	Bertil JONSSON	Irene PAPADOULI
Pharmacogenomics Working Party	Krishna PRASAD	Falk EHMANN
Pharmacokinetics Working Party	Jan WELINK	Kevin BLAKE
Rheumatology/Immunology Working Party	Jan MUELLER-BERGHAUS	Andreas KOUROUMALIS
Vaccines Working Party	Vacant as of December 2015, Daniel BRASSEUR (acting chair)	Manuela MURA

Drafting groups

	Chair	EMA contact
Gastroenterology Drafting Group	Elmer SCHABEL	Joachim MUSAUS
Radiopharmaceuticals Drafting Group	Patrick SALMON	Silvy DA ROCHA DIAS
Excipients drafting group	Dominique MASSET	Jean-Marc VIDAL

CHMP scientific advisory groups

	Chair	**EMA contact**
Scientific Advisory Group on Cardiovascular Issues	N/A	Heidi JANSSEN
Scientific Advisory Group on Anti-infectives	N/A	Eric PELFRENE

	Chair	EMA contact
Scientific Advisory Group on Diabetes/Endocrinology	N/A	Eberhard BLIND
Scientific Advisory Group on HIV / Viral Diseases	Daniel VITTECOQ (Vice-Chair)	Sabrina SPINOSA
Scientific Advisory Group on Neurology	Serge BAKCHINE	Pavel BALABANOV
Scientific Advisory Group on Psychiatry	N/A	Florence BUTLEN
Scientific Advisory Group on Vaccines	Andrew POLLARD	Manuela MURA

Other CHMP-associated groups

	Chair	EMA contact
(Invented) Name Review Group	Alexios SKARLATOS	Jose Angel FERRERO TIJERA
Geriatric Expert Group	Niccolo' MARCHIONNI	Francesca CERRETA
Summary of Product Characteristics Advisory Group	Laurent BRASSART	Laurent BRASSART
Modelling and Simulation Working Group	Ine SKOTTHEIM RUSTEN	Efthymios MANOLIS
Guidelines Consistency Group	Barbara VAN ZWIETEN-BOOT	Andrea TAFT
Good Manufacturing and Distribution Practice Inspectors Working Group	David COCKBURN	David COCKBURN
Good Clinical Practice Inspectors Working Group	Ana RODRIGUEZ	Laura PIOPPO/ Thania-Aileen SPATHOPOULOU
Good Laboratory Practice Inspectors Working Group	Ana Rodriguez	Laura PIOPPO/Maria Antonietta ANTONELLI
Pharmacovigilance Inspectors Working Group	Anabela MARÇAL	Sophia MYLONA
PAT Team	Keith PUGH	Simona KECKESOVA

Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP working parties

	Chair	EMA contact
CVMP Antimicrobial Working Party (AWP)	Helen JUKES	Isaura DUARTE
CVMP Efficacy Working Party (EWP-V)	Gesine HAHN	Fia WESTERHOLM
CVMP Environmental Risk Assessment (ERAWP)	Boris KOLAR	Isaura DUARTE
CVMP Immunologicals Working Party (IWP)	Esther WERNER	Fia WESTERHOLM
CVMP Pharmacovigilance Working Party (PhVWP-V)	Peter EKSTROM	Isaura DUARTE
CVMP Safety Working Party (SWP-V)	Eva LANDER-PERSSON	Isaura DUARTE
Quality Working Party	Jean-Louis ROBERT	Simona KECKESOVA
Scientific Advice Working Party	Rory BREATHNACH	Fia WESTERHOLM

	Chair	EMA contact
(SAWP-V)		

Other CVMP-associated groups

	Chair	EMA contact
CVMP Ad Hoc Group on Veterinary Novel Therapies (ADVENT)[1]	Jean-Claude ROUBY	Fia WESTERHOLM
Good Manufacturing and Distribution Practice Inspectors Working Group	David COCKBURN	David COCKBURN
Pharmacovigilance Inspectors Working Group	Anabela MARÇAL	Sophia MYLONA
PAT Team	Keith PUGH	Simona KECKESOVA

Committee on Herbal Medicinal Products (HMPC)

HMPC working parties

	Chair	EMA contact
Working Party on European Union Monographs and European Union List	Ioanna CHINOU	Orsolya ROZA

HMPC temporary drafting groups

	Chair	EMA contact
Organisational Matters Drafting Group	Emiel van GALEN	Orsolya ROZA
Quality Drafting Group	Linda ANDERSON	Simona KECKESOVA/ Wieland PESCHEL

Other HMPC-associated groups

	Chair	EMA contact
Good Manufacturing Practice Inspection Services Group	David COCKBURN	David COCKBURN

Paediatric Committee (PDCO)

PDCO working groups

	Chair	EMA contact
Formulation Working Group	Brian AYLWARD	Giovanni LESA
Non-clinical Working Group	Jaqueline CARLEER	Janina KARRES
Modelling and Simulation Working Group	Gerard PONS	Cecile OLLIVIER

[1] Established in December 2014, chair elected at January 2015 meeting

Committee for Advanced Therapies (CAT)

CAT associated group

	Chair	EMA contact
European Medicines Agency / CAT and Medical Devices' Notified Body Collaboration Group	To be appointed	Patrick CELIS

Pharmacovigilance Risk Assessment Committee (PRAC)

	Chair	EMA contact
SMART Working Group work stream 1	Sabine STRAUS	Georgy GENOV
SMART Working Group work stream 2 and 3	N/A	Jim SLATTERY, Gianmario CANDORE

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

Other CMDh-associated groups

	Chair	EMA contact
GCP CMDh Working Party	Jayne CROWE	Mathilde MOREAU/ Maria Antonietta ANTONELLI

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

	Chair	EMA contact
Document Management Working Group	CMDv member from Member State giving EU Presidency	Melanie LEIVERS
Packaging Working Group	Iveta OBROVSKA	Melanie LEIVERS
Notice to Applicants Working Group	Abedi ALENOOSH	Melanie LEIVERS
Autogenous Vaccines Working Group	Mariette SALERY	Melanie LEIVERS
Borderline Products Working Group	Valérie VAN MERRIS	Melanie LEIVERS
CMDv-Industry Variations Task Force	Gavin HALL	Melanie LEIVERS

Joint working parties, working groups and advisory groups

	Chair	EMA contact
Joint CHMP/CVMP Quality Working Party (QWP)	Jean Louis ROBERT (Chair) Piet-Hein OVERHAUS (Veterinary Vice-chair)	David COCKBURN
Patients' and Consumers' Working Party (PCWP)	Isabelle MOULON and Hans-Ulrich David HAERRY	Nathalie BERE
Healthcare Professionals' Working	Isabelle MOULON and	Ivana SILVA

	Chair	EMA contact
Party (HCPWP)	Gonzalo Calvo ROJAS	
Joint CMDh-CMDv Variation Regulation Working Party	Susanne WINTERSCHEID, Roselien POPPE	Sennwitz MATTHIAS
Joint CHMP/CVMP Expert Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products (JEG 3Rs)	Sonja BEKEN	JEG-3Rs@ema.europa.eu
Joint PRAC/PDCO working group		Lucia d'Apote (PDCO secretariat)/Geraldine Portier (PRAC secretariat)
Working Group on Quality Review of Documents	Alexios SKARLATOS	Monica BUCH
Active Substance Master File Working Group		
Inter-Committee Scientific Advisory Group on Oncology	Jonas BERGH (Vice-Chair)	Francesco PIGNATTI

Annex 10 – CHMP opinions in 2015 on medicinal products for human use

The data are also available in an Excel document.

CHMP positive opinions medicinal products for human use

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Akynzeo • Netupitant / palonosetron	Helsinn Birex Pharmaceuticals Ltd	New active substance	• A04AA55 • prevention of chemotherapy-induced nausea and vomiting (CINV)	• N • Yes	• 22/01/2014 • 26/03/2015 • 210 • 216 • STANDARD	• 27/05/2015 • 29/05/2015 • 26/06/2015
• Aripiprazole Accord • Aripiprazole	Accord Healthcare Ltd	Generic application	• N05AX12 • treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder	• N • No	• 20/08/2014 • 24/09/2015 • 210 • 188 • STANDARD	• 16/11/2015 • 19/11/2015 • 30/12/2015
• Aripiprazole Pharmathen • Aripiprazole	Pharmathen S.A.	Generic application	• N05AX12 • treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder	• N • No	• 21/07/2014 • 23/04/2015 • 210 • 62 • STANDARD	• 30/06/2015 • 02/07/2015 • 31/07/2015

Product • Brandname • INN	Marketing authorisation holder	Type of application (legal basis)	Therapeutic Area • ATC Code • Summary of indication	Other characteristics • Orphan designation at time of CHMP opinion • New active substance status	EMA/CHMP • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	European Commission • Date of decision • Notification • Official Journal
• Aripiprazole Sandoz • Aripiprazole	SANDOZ GmbH	Generic application/Hybrid application	• N05AX12 • treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder	• N • No	• 22/07/2014 • 25/06/2015 • 210 • 125 • STANDARD	• 20/08/2015 • 24/08/2015 • 25/09/2015
• Aripiprazole Zentiva • Aripiprazole	Zentiva, k.s.	Generic application	• N05AX12 • treatment of schizophrenia and prevention of manic episodes in bipolar I disorder	• N • No	• 21/07/2014 • 23/04/2015 • 210 • 62 • STANDARD	• 25/06/2015 • 29/06/2015 • 31/07/2015
• Benepali • Etanercept	Samsung Bioepis UK Limited (SBUK)	Similar biological application	• L04AB01 • treatment of arthritis	• N • No	• 19/12/2014 • 19/11/2015 • 210 • 118 • STANDARD	• 14/01/2016
• BLINCYTO • Blinatumomab	Amgen Europe B.V.	New active substance	• L01XC • treatment of Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia	• Y • Yes	• 24/10/2014 • 24/09/2015 • 210 • 118 • CONDITIONAL	• 23/11/2015 • 25/11/2015 • 30/12/2015
• Bortezomib Accord • Bortezomib	Accord Healthcare Ltd	Generic application	• L01XX32 • treatment of multiple myeloma	• N • No	• 25/06/2014 • 21/05/2015 • 210 • 118 • STANDARD	• 20/07/2015 • 23/07/2015 • 28/08/2015

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Briviact • Brivaracetam	UCB Pharma SA	New active substance	• N03AX23 • treatment of partial-onset seizures	• N • Yes	• 24/12/2014 • 19/11/2015 • 210 • 118 • STANDARD	• 14/01/2016
• Caspofungin Accord • Caspofungin	Accord Healthcare Ltd	Generic application	• J02AX04 • treatment of invasive candidiasis and invasive aspergillosis	• N • No	• 25/03/2015 • 17/12/2015 • 210 • 55 • STANDARD	•
• CIAMBRA • Pemetrexed	Menarini International Operations Luxembourg S.A.	Generic application	• L01BA04 • treament of malignant pleural mesothelioma and non-small cell lung cancer	• N • No	• 29/10/2014 • 24/09/2015 • 210 • 118 • STANDARD	• 02/12/2015
• Cinacalcet Mylan • Cinacalcet	MYLAN S.A.S.	Generic application	• H05BX01 • treatment of secondary hyperparathyroidism and hypercalcaemia	• N • No	• 21/01/2015 • 24/09/2015 • 180 • 66 • STANDARD	• 19/11/2015 • 23/11/2015 • 30/12/2015
• Cotellic • Cobimetinib	Roche Registration Limited	New active substance	• L01XE • treatment of metastatic melanoma	• N • Yes	• 17/09/2014 • 24/09/2015 • 210 • 153 • STANDARD	• 20/11/2015 • 24/11/2015 • 30/12/2015

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Cresemba • Isavuconazole	Basilea Medical Ltd	New active substance	• J02AC • treatment of aspergillosis and mucormycosis	• Y • Yes	• 19/08/2014 • 23/07/2015 • 210 • 125 • STANDARD	• 15/10/2015 • 19/10/2015 • 27/11/2015
• Duloxetine Mylan • Duloxetine	Generics UK Limited	Generic application	• N06AX21 • treatment of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder treatment of major depressive episodes, diabetic peripheral neuropathic pain and generalised anxiety disorder	• N • No	• 17/09/2014 • 23/04/2015 • 204 • 8 • STANDARD	• 19/06/2015 • 24/06/2015 • 31/07/2015
• Duloxetine Zentiva • Duloxetine	Zentiva k.s.	Generic application	• N06AX21 • treatment depressive disorder, diabetic neuropathic pain, anxiety disorder	• N • No	• 18/09/2014 • 25/06/2015 • 210 • 62 • STANDARD	• 20/08/2015 • 25/08/2015 • 25/09/2015
• DUTREBIS • Lamivudine / raltegravir potassium	Merck Sharp & Dohme Limited	Fixed combination application	• J05AR • treatment of human immunodeficiency virus (HIV-1)	• N • No	• 26/03/2014 • 22/01/2015 • 210 • 90 • STANDARD	• 26/03/2015 • 30/03/2015 • 05/05/2015

Product • Brandname • INN	Marketing authorisation holder	Type of application (legal basis)	Therapeutic Area • ATC Code • Summary of indication	Other characteristics • Orphan designation at time of CHMP opinion • New active substance status	EMA/CHMP • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	European Commission • Date of decision • Notification • Official Journal
• Ebymect • Dapagliflozin / metformin	AstraZeneca AB	Informed consent application	• A10BD15 • diabetes mellitus type 2	• N • No	• 27/07/2015 • 24/09/2015 • 60 • 0 • STANDARD	• 16/11/2015 • 18/11/2015 • 30/12/2015
• Edistride • Dapagliflozin	AstraZeneca AB	Informed consent application	• A10BX09 • treatment of diabetes mellitus	• N • No	• 27/07/2015 • 24/09/2015 • 60 • 0 • STANDARD	• 09/11/2015 • 12/11/2015 • 30/12/2015
• ELOCTA • Efmoroctocog alfa	Biogen Idec Ltd	New active substance	• B02 • treatment of Haemophilia A	• Y • Yes	• 28/10/2014 • 24/09/2015 • 210 • 118 • STANDARD	• 19/11/2015 • 23/11/2015 • 30/12/2015
• Entresto • Sacubitril / valsartan	Novartis Europharm Ltd	New active substance	• C09DX • treatment of heart failure (NYHA class II-IV)	• N • Yes	• 21/01/2015 • 24/09/2015 • 180 • 66 • STANDARD	• 19/11/2015 • 23/11/2015 • 30/12/2015
• Episalvan • Birch bark extract	Birken AG	New active substance	• D03 • treatment of partial thickness wounds	• N • Yes	• 29/10/2014 • 19/11/2015 • 210 • 174 • STANDARD	• 14/01/2016

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Eptifibatide Accord • Eptifibatide	Accord Healthcare Limited	Generic application	• B01AC16 • prevention of early myocardial infarction	• N • No	• 24/12/2014 • 19/11/2015 • 210 • 118 • STANDARD	• 11/01/2016
• EVOTAZ • Atazanavir / cobicistat	Bristol-Myers Squibb Pharma EEIG	Fixed combination application	• J05AR • treatment of HIV-1 infected combination with other antiretroviral medicinal products.	• N • No	• 22/07/2014 • 21/05/2015 • 210 • 90 • STANDARD	• 13/07/2015 • 15/07/2015 • 28/08/2015
• Farydak • Panobinostat	Novartis Europharm Ltd	New active substance	• L01XX42 • treatment of multiple myeloma	• Y • Yes	• 28/05/2014 • 25/06/2015 • 210 • 177 • STANDARD	• 28/08/2015 • 01/09/2015 • 25/09/2015
• Feraccru • Ferric maltol	Iron Therapeutics (UK) Ltd	New active substance	• B03AB • treatment of iron deficiency anaemia	• N • No	• 18/12/2014 • 17/12/2015 • 210 • 149 • STANDARD	•
• Fexeric • Ferric citrate coordination complex	Keryx Biopharma UK Ltd.	New active substance	• V03AE • treatment of hyperphosphataemia	• N • Yes	• 26/03/2014 • 23/07/2015 • 210 • 272 • STANDARD	• 23/09/2015 • 28/09/2015 • 30/10/2015

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Gardasil 9 • Human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed)	Sanofi Pasteur MSD	New active substance	• J07BM03 • prevention of human papillomavirus (HPV) related diseases	• N • Yes	• 26/03/2014 • 26/03/2015 • 210 • 153 • STANDARD	• 10/06/2015 • 12/06/2015 • 31/07/2015
• Genvoya • Elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide	Gilead Sciences International Ltd	New active substance	• J05AR • treatement of HIV-1	• N • Yes	• 24/12/2014 • 24/09/2015 • 210 • 62 • STANDARD	• 19/11/2015 • 23/11/2015 • 30/12/2015
• Hetlioz • Tasimelteon	Vanda Pharmaceuticals Ltd.	New active substance	• N05CH • treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)	• Y • Yes	• 28/05/2014 • 23/04/2015 • 210 • 118 • STANDARD	• 03/07/2015 • 07/07/2015 • 28/08/2015
• Iblias • Octocog alfa	Bayer Pharma AG	Known active substance	• B02BD02 • treatment and prophylaxis of haemophilia A Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)	• N • No	• 19/12/2014 • 17/12/2015 • 210 • 146 • STANDARD	•

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• IKERVIS • Ciclosporin	Santen Oy	Known active substance	• S01XA18 • treatment of keratitis	• N • No	• 26/12/2013 • 22/01/2015 • 212 • 181 • STANDARD	• 19/03/2015 • 23/03/2015 • 05/05/2015
• Imlygic • Talimogene laherparepvec	Amgen Europe B.V.	New active substance	• L01 • treatment of adults with melanoma that is regionally or distantly metastatic	• N • Yes	• 24/09/2014 • 22/10/2015 • 210 • 158 • STANDARD	• 16/12/2015
• Intuniv • Guanfacine	Shire Pharmaceuticals Ireland Ltd.	Known active substance	• C02AC02 • treatment of ADHD	• N • No	• 24/03/2014 • 23/07/2015 • 206 • 279 • STANDARD	• 17/09/2015 • 21/09/2015 • 30/10/2015
• IONSYS • Fentanyl	Incline Therapeutics Europe Ltd	Known active substance	• N02AB03 • treatment of acute moderate to severe post-operative pain	• N • No	• 22/09/2014 • 24/09/2015 • 210 • 153 • STANDARD	• 19/11/2015 • 23/11/2015 • 30/12/2015
• Ivabradine Anpharm • Ivabradine	"ANPHARM" Przedsiębiorstwo Farmaceutyczne S.A.	Informed consent application	• C01EB17 • treatment of angina pectoris	• N • No	• 24/05/2015 • 23/07/2015 • 60 • 0 • STANDARD	• 08/09/2015 • 10/09/2015 • 30/10/2015

Product • Brandname • INN	Marketing authorisation holder	Type of application (legal basis)	Therapeutic Area • ATC Code • Summary of indication	Other characteristics • Orphan designation at time of CHMP opinion • New active substance status	EMA/CHMP • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	European Commission • Date of decision • Notification • Official Journal
• Jinarc • Tolvaptan	Otsuka Pharmaceutical Europe Ltd	Known active substance	• G04 • treatment of kidney disease (ADPKD) kidney disease (ADPKD)	• Y • No	• 20/12/2013 • 26/02/2015 • 210 • 215 • STANDARD	• 27/05/2015 • 29/05/2015 • 26/06/2015
• Kanuma • Sebelipase alfa	Alexion Europe SAS	New active substance	• A16 • treatment of enzyme replacement therapy (ERT)	• Y • Yes	• 24/12/2014 • 25/06/2015 • 152 • 32 • STANDARD	• 28/08/2015 • 01/09/2015 • 25/09/2015
• Kengrexal • Cangrelor	The Medicines Company UK Ltd	New active substance	• B01AC25 • inhibitor indicated for the reduction of thrombotic cardiovascular events Hemaxiv is a P2Y12 platelet inhibitor indicated for the reduction of thrombotic cardiovascular events (including stent thrombosis) in adult patients with coronary artery disease und	• N • Yes	• 19/12/2013 • 22/01/2015 • 210 • 180 • STANDARD	• 23/03/2015 • 25/03/2015 • 05/05/2015
• Keytruda • Pembrolizumab	Merck Sharp & Dohme Limited	New active substance	• L01XC • treatment of melanoma	• N • Yes	• 25/06/2014 • 21/05/2015 • 204 • 127 • STANDARD	• 17/07/2015 • 21/07/2015 • 28/08/2015

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Kovaltry • Octocog alfa	Bayer Pharma AG	Known active substance	• B02BD02 • treatment and prophylaxis of haemophilia A Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)	• N • No	• 19/12/2014 • 17/12/2015 • 210 • 146 • STANDARD	•
• Kyprolis • Carfilzomib	Amgen Europe B.V.	New active substance	• L01XX45 • treatment of multiple myeloma	• Y • Yes	• 16/02/2015 • 24/09/2015 • 150 • 61 • STANDARD	• 19/11/2015 • 23/11/2015 • 30/12/2015
• Lenvima • Lenvatinib	Eisai Europe Ltd.	New active substance	• L01XE • treatment of papillary thyroid cancer Treatment of follicular thyroid cancer	• Y • Yes	• 17/09/2014 • 26/03/2015 • 152 • 32 • STANDARD	• 28/05/2015 • 01/06/2015 • 26/06/2015
• Lixiana • Edoxaban	Daiichi Sankyo Europe GmbH	New active substance	• B01 • prevention of stroke; embolism and treatment of venous thromboembolism	• N • Yes	• 26/02/2014 • 23/04/2015 • 210 • 209 • STANDARD	• 19/06/2015 • 23/06/2015 • 31/07/2015
• Lopinavir/Ritonavir Mylan • Lopinavir / ritonavir	MYLAN S.A.S.	Generic application	• J05AR10 • treatment of human immunodeficiency virus (HIV-1)	• N • No	• 22/01/2015 • 19/11/2015 • 203 • 99 • STANDARD	• 14/01/2016

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• LuMark • Lutetium, isotope of mass 177	I.D.B. Radiopharmacy B.V.	Well-established use application	• V09 • used only for the radiolabelling of carrier molecules	• N • No	• 26/02/2014 • 23/04/2015 • 210 • 209 • STANDARD	• 19/06/2015 • 23/06/2015 • 31/07/2015
• Neofordex • Dexamethason e	Laboratoires CTRS	Hybrid application	• H02AB02 • treatment of symptomatic multiple myeloma in combination with other medicinal products.	• Y • No	• 26/11/2014 • 17/12/2015 • 106 • 281 • STANDARD	•
• Nivolumab BMS • Nivolumab	Bristol-Myers Squibb Pharma EEIG	New active substance	• L01XC • treatment of cancer after prior chemotherapy	• N • Yes***	• 24/09/2014 • 21/05/2015 • 182 • 58 • STANDARD	• 20/07/2015 • 23/07/2015 • 28/08/2015
• Nucala • Mepolizumab	GlaxoSmithKline Trading Services	New active substance	• R03DX • treatment of asthma	• N • Yes	• 25/11/2014 • 24/09/2015 • 210 • 90 • STANDARD	• 02/12/2015
• Numient • Levodopa / carbidopa	Impax Laboratories Netherlands BV	Known active substance	• N04BA02 • symptomatic treatment of adult patients with Parkinson's disease	• N • No	• 26/11/2014 • 24/09/2015 • 210 • 90 • STANDARD	• 19/11/2015 • 23/11/2015 • 30/12/2015

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Obizur • Susoctocog alfa	Baxalta Innovations GmbH	New active substance	• B02 • treatment of acquired hemophilia	• Y • Yes	• 22/07/2014 • 23/07/2015 • 210 • 153 • EXCEPTIONAL	• 11/11/2015 • 13/11/2015 • 30/12/2015
• Odomzo • Sonidegib	Novartis Europharm Ltd	New active substance	• L01XX • treatment of basal cell carcinoma (BCC)	• N • Yes	• 23/05/2014 • 25/06/2015 • 210 • 181 • STANDARD	• 14/08/2015 • 18/08/2015 • 25/09/2015
• Omidria • Phenylephrine / ketorolac	Omeros London Limited	Known active substance	• S01 • maintenance of mydriasis, prevention of miosis and reduction of ocular pain replacement (ILR).	• N • No	• 24/09/2013 • 21/05/2015 • 210 • 394 • STANDARD	• 28/07/2015 • 30/07/2015 • 28/08/2015
• Oncaspar • Pegaspargase	Baxalta Innovations GmbH	Known active substance	• L01XX24 • indicated as combination therapy in acute lymphoblastic leukaemia (ALL)	• N • No	• 21/07/2014 • 19/11/2015 • 210 • 272 • STANDARD	• 14/01/2016
• OPDIVO • Nivolumab	Bristol-Myers Squibb Pharma EEIG	New active substance	• L01XC • treatment of advanced (unresectable or metastatic) melanoma in adults	• N • Yes***	• 24/09/2014 • 23/04/2015 • 175 • 37 • STANDARD	• 19/06/2015 • 24/06/2015 • 31/07/2015

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Orbactiv • Oritavancin	The Medicines Company UK Ltd	New active substance	• J01XA05 • treatment of complicated skin and soft tissue infections (cSSTI)	• N • Yes	• 26/02/2014 • 22/01/2015 • 210 • 118 • STANDARD	• 19/03/2015 • 23/03/2015 • 05/05/2015
• Orkambi • Lumacaftor / ivacaftor	Vertex Pharmaceuticals (Europe) Ltd.	New active substance	• R07AX • treatment of cystic fibrosis	• Y • Yes	• 26/11/2014 • 24/09/2015 • 210 • 90 • STANDARD	• 19/11/2015 • 24/11/2015 • 30/12/2015
• Pemetrexed Accord • Pemetrexed	Accord Healthcare Ltd	Generic application	• L01BA04 • unresectable malignant pleural mesothelioma metastatic non-small cell lung cancer	• N • No	• 26/11/2014 • 19/11/2015 • 210 • 146 • STANDARD	• 18/01/2016
• Pemetrexed Actavis • Pemetrexed	Actavis Group PTC ehf	Hybrid application	• L01BA04 • treatment of malignant pleural mesothelioma and non-small cell lung cancer	• N • No	• 26/02/2015 • 19/11/2015 • 0 • 64 • #N/A	• 18/01/2016
• Pemetrexed Hospira • Pemetrexed	Hospira UK Limited	Generic application	• L01BA04 • treatment of malignant pleural mesothelioma and non-small cell lung cancer (excluding predominantly squamous cell histology)	• N • No	• 29/10/2014 • 24/09/2015 • 210 • 118 • STANDARD	• 20/11/2015 • 24/11/2015 • 30/12/2015

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Pemetrexed Lilly • Pemetrexed	Eli Lilly Netherlands	Generic application	• L01BA04 • treatment of malignant pleural mesothelioma and non-small cell lung cancer	• N • No	• 18/12/2014 • 23/07/2015 • 182 • 30 • STANDARD	• 14/09/2015 • 16/09/2015 • 30/10/2015
• Pemetrexed medac • Pemetrexed	medac Gesellschaft fur klinische Spezialpraparate mbH	Generic application	• L01BA04 • treatment of malignant pleural mesothelioma and non-small cell lung cancer	• N • No	• 28/10/2014 • 24/09/2015 • 210 • 118 • STANDARD	• 27/11/2015 • 01/12/2015 • 30/12/2015
• Pemetrexed Sandoz • Pemetrexed	SANDOZ GmbH	Generic application	• L01BA04 • treatment of malignant pleural mesothelioma and non-samll cell lung cancer	• N • No	• 29/10/2014 • 23/07/2015 • 204 • 64 • STANDARD	• 18/09/2015 • 23/09/2015 • 30/10/2015
• Portrazza • Necitumumab	Eli Lilly Nederland B.V.	New active substance	• L01 • treatment of squamous non-small cell lung cancer	• N • Yes	• 17/12/2014 • 17/12/2015 • 204 • 155 • STANDARD	•
• Praluent • Alirocumab	sanofi-aventis groupe	New active substance	• C10 • reduction of low-density lipoprotein cholesterol (LDL-C) and increase high-density lipoprotein cholesterol (HDL-C).	• N • Yes	• 19/12/2014 • 23/07/2015 • 182 • 30 • STANDARD	• 23/09/2015 • 25/09/2015 • 30/10/2015

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Praxbind • Idarucizumab	Boehringer Ingelheim International GmbH	New active substance	• V03AB • prevention and treatment of dabigatran associated haemorrhage	• N • Yes	• 23/03/2015 • 24/09/2015 • 150 • 33 • STANDARD	• 20/11/2015 • 24/11/2015 • 30/12/2015
• Pregabalin Accord • Pregabalin	Accord Healthcare Limited	Generic application	• N03AX16 • treatment of epilepsy and generalised anxiety disorder (GAD)	• N • No	• 20/08/2014 • 25/06/2015 • 211 • 99 • STANDARD	• 28/08/2015 • 01/09/2015 • 25/09/2015
• Pregabalin Mylan • Pregabalin	Generics UK Limited	Generic application	• N03AX16 • treatment of epilepsy and generalised anxiety disorder (GAD)	• N • No	• 19/08/2014 • 23/04/2015 • 210 • 34 • STANDARD	• 25/06/2015 • 30/06/2015 • 31/07/2015
• Pregabalin Mylan Pharma • Pregabalin	Generics UK Limited	Generic application	• N03AX16 • treatment of neuropathic pain, epilepsy and generalised anxiety disorder (GAD)	• N • No	• 19/08/2014 • 23/04/2015 • 210 • 34 • STANDARD	• 25/06/2015 • 29/06/2015 • 31/07/2015
• Pregabalin Sandoz • Pregabalin	SANDOZ GmbH	Generic application	• N03AX16 • treatment of neuropathic pain, epilepsy and generalised anxiety disorder	• N • No	• 19/08/2014 • 23/04/2015 • 204 • 43 • STANDARD	• 19/06/2015 • 23/06/2015 • 31/07/2015

Product • Brandname • INN	Marketing authorisation holder	Type of application (legal basis)	Therapeutic Area • ATC Code • Summary of indication	Other characteristics • Orphan designation at time of CHMP opinion • New active substance status	EMA/CHMP • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	European Commission • Date of decision • Notification • Official Journal
• Pregabalin Sandoz GmbH • Pregabalin	SANDOZ GmbH	Generic application	• N03AX16 • treatment of epilepsy and generalised anxiety disorder (GAD)	• N • No	• 19/08/2014 • 23/04/2015 • 204 • 43 • STANDARD	• 19/06/2015 • 23/06/2015 • 31/07/2015
• Pregabalin Zentiva • Pregabalin	Zentiva, k.s.	Generic application	• N03AX16 • treatment of epilepsy and Generalised Anxiety Disorder (GAD)	• N • No	• 19/08/2014 • 21/05/2015 • 210 • 62 • STANDARD	• 17/07/2015 • 21/07/2015 • 28/08/2015
• Raplixa • Human fibrinogen / human thrombin	ProFibrix BV	Known active substance	• B02BC30 • treatment for improvement of haemostasis	• N • No	• 20/11/2013 • 22/01/2015 • 210 • 216 • STANDARD	• 19/03/2015 • 23/03/2015 • 05/05/2015
• RAVICTI • Glycerol phenylbutyrate	Horizon Therapeutics Limited	New active substance	• A16AX09 • treatment of patients with urea cycle disorders (UCD), ornithine transcarbamylase (OTC),argininosuccinate synthetase (ASS), arininosuccinate lyase (ASL), arginase I (ARG), CITRIN,ornithine translocase (HHH)	• Y • Yes	• 18/06/2014 • 24/09/2015 • 210 • 244 • STANDARD	• 27/11/2015 • 01/12/2015 • 30/12/2015

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Raxone • Idebenone	Santhera Pharmaceuticals (Deutschland) GmbH	Hybrid application	• N07 • treatment of Leber's Hereditary Optic Neuropathy (LHON)	• Y • No	• 28/05/2014 • 25/06/2015 • 211 • 183 • EXCEPTIONAL	• 08/09/2015 • 10/09/2015 • 30/10/2015
• Repatha • Evolocumab	Amgen Europe B.V.	New active substance	• C10AX13 • Hypercholesterolaemia and mixed dyslipidaemia and Homozygous familial hypercholesterolaemia	• N • Yes	• 23/09/2014 • 21/05/2015 • 204 • 36 • STANDARD	• 17/07/2015 • 21/07/2015 • 28/08/2015
• Respreeza • Human alpha1-proteinase inhibitor	CSL Behring GmbH	Known active substance	• B02AB02 • treatment of lung disease	• N • No	• 18/12/2013 • 25/06/2015 • 210 • 334 • STANDARD	• 20/08/2015 • 25/08/2015 • 25/09/2015
• Ristempa • Pegfilgrastim	Amgen Europe B.V.	Informed consent application	• L03AA13 • treatment of neutropenia	• N • No	• 19/09/2014 • 26/02/2015 • 92 • 67 • STANDARD	• 13/04/2015 • 15/04/2015 • 29/05/2015
• Saxenda • Liraglutide	Novo Nordisk A/S	Known active substance	• A10BX07 • treatement of obesity	• N • No	• 17/01/2014 • 22/01/2015 • 212 • 154 • STANDARD	• 23/03/2015 • 25/03/2015 • 05/05/2015

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Sivextro • Tedizolid phosphate	Merck Sharp & Dohme Limited	New active substance	• J01XX11 • treatment of acute bacterial skin and skin structure infections (ABSSSI); treatment of tissue infections (cSSTI)	• N • Yes	• 26/02/2014 • 22/01/2015 • 210 • 118 • STANDARD	• 23/03/2015 • 25/03/2015 • 05/05/2015
• Spectrila • Asparaginase	medac Gesellschaft fuer klinische Spezialpraeparate mbH	Known active substance	• L01XX02 • combination therapy for B/T cell lymphoblastic leukaemia (ALL) or B/T cell lymphoblastic lymphoma (LBL)	• Y • No	• 26/12/2013 • 19/11/2015 • 204 • 490 • STANDARD	• 14/01/2016
• Strensiq • Asfotase alfa	Alexion Europe SAS	New active substance	• A16AB • treatment of paediatric-onset hypophosphatasia	• Y • Yes	• 18/07/2014 • 25/06/2015 • 211 • 127 • EXCEPTIONAL	• 28/08/2015 • 01/09/2015 • 25/09/2015
• Synjardy • Empagliflozin / metformin	Boehringer Ingelheim GmbH	Fixed combination application	• A10BD • treatment of type II diabetes	• N • No	• 10/07/2014 • 26/03/2015 • 182 • 65 • STANDARD	• 27/05/2015 • 29/05/2015 • 26/06/2015
• TAGRISSO • Osimertinib	AstraZeneca AB	New active substance	• L01XE • non-small-cell lung cancer (NSCLC)	• N • Yes	• 24/06/2015 • 17/12/2015 • 150 • 26 • CONDITIONAL	• 02/02/2016

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Taxespira • Docetaxel	Hospira UK Limited	Generic application	• L01CD02 • treatment of breast cancer, non small cell lung cancer, prostate cancer, metastatic gastric adenocarcinoma and head and neck cancer	• N • No	• 25/06/2014 • 25/06/2015 • 211 • 155 • STANDARD	• 28/08/2015 • 01/09/2015 • 25/09/2015
• Unituxin • Dinutuximab	United Therapeutics Europe Ltd	New active substance	• L01XC • treatment of neuroblastoma Treatment of high-risk neuroblastoma	• Y • Yes	• 18/12/2013 • 21/05/2015 • 210 • 299 • STANDARD	• 14/08/2015 • 18/08/2015 • 25/09/2015
• Vaxelis • Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inact.) and Haemophilus type b conjugate vaccine (adsorbed)	Sanofi Pasteur MSD SNC	New active substance	• J07CA09 • vaccination against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by Haemophilus influenzae typeb (Hib)	• N • No	• 21/01/2015 • 17/12/2015 • 210 • 118 • STANDARD	•

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Voriconazole Hospira • Voriconazole	HOSPIRA UK LIMITED	Generic application	• J02AC03 • treatment of fungal infections	• N • No	• 24/03/2014 • 26/03/2015 • 210 • 153 • STANDARD	• 27/05/2015 • 29/05/2015 • 26/06/2015
• Wakix • Pitolisant	BIOPROJET PHARMA	New active substance	• N06 • treatment of narcolepsy	• Y • Yes	• 18/05/2014 • 19/11/2015 • 204 • 337 • STANDARD	•
• Zalviso • Sufentanil	Grunenthal GmbH	Hybrid application	• N01AH03 • indicated for the management pain	• N • No	• 23/07/2014 • 23/07/2015 • 210 • 153 • STANDARD	• 18/09/2015 • 22/09/2015 • 30/10/2015
• Zerbaxa • Ceftolozane / tazobactam	Merck Sharp & Dohme Limited	New active substance	• J01 • treatment of intra-abdominal urinary tract infections	• N • Yes	• 20/08/2014 • 23/07/2015 • 210 • 125 • STANDARD	• 18/09/2015 • 22/09/2015 • 30/10/2015
• Zurampic • Lesinurad	AstraZeneca AB	New active substance	• M04AB • treatment of hyperuricaemia	• N • Yes	• 20/01/2015 • 17/12/2015 • 210 • 118 • STANDARD	•

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop • Type of MA (*)	**European Commission** • Date of decision • Notification • Official Journal
• Zykadia • Ceritinib	Novartis Europharm Ltd	New active substance	• L01XE28 • treatment of non-small cell lung cancer (NSCLC) treatment of anaplastic lymphomakinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC)	• N • Yes	• 25/03/2014 • 26/02/2015 • 210 • 125 • CONDITIONAL	• 06/05/2015 • 08/05/2015 • 26/06/2015

(*) 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

(**) This indicates that the medicinal product was evaluated under EMA accelerated assessment procedure

*(***)*Opdivo and Nivolumab BMS contain the same active substance, but are authorised for different indications.*

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
• Mosquirix™ • plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted)	GlaxoSmithKline Biologicals S.A.	• indicated for active immunisation against malaria	• 23/07/2014 • 23/07/2015 • 213 • 153

CHMP negative opinions on medicinal products for human use

Product • Brandname • INN	**Marketing authorisation holder**	**Type of application (legal basis)**	**Therapeutic Area** • ATC Code • Summary of indication	**Other characteristics** • Orphan designation at time of CHMP opinion • New active substance status	**EMA/CHMP** • Validation • Opinion • Active Time (Acc**) • Clock stop	**European Commission** • Opinion received • Date of decision • Notification • Official Journal
• Dropcys • Mercaptamine	Lucane Pharma	Well-established use application	• S01XA21 • treatment of corneal cystine deposits	• Y • No	• 26/11/2014 • 17/12/2015 • 210 • 177	•
• Heparesc • Human heterologous liver cells	Cytonet GmbH&Co KG	New active substance	• A16 • treatment of urea cycle disorders (UCD)	• Y • Yes	• 26/12/2013 • 22/10/2015 • 208 • 339	• 21/12/2015

Product • Brandname • INN	Marketing authorisation holder	Type of application (legal basis)	Therapeutic Area • ATC Code • Summary of indication	Other characteristics • Orphan designation at time of CHMP opinion • New active substance status	EMA/CHMP • Validation • Opinion • Active Time (Acc**) • Clock stop	European Commission • Opinion received • Date of decision • Notification • Official Journal
• Lympreva • Dasiprotimut-T	Biovest Europe Ltd	New active substance	• L03AX • treatment of non-Hodgkin's lymphoma (FL)	• Y • Yes	• 26/12/2013 • 23/04/2015 • 204 • 280	• 03/07/2015 • 07/07/2015 • 28/08/2015
• Solumarv • Insulin human	Marvel Lifesciences Ltd	Similar biological application	• A10AB01 • treatment of diabetes	• N • No	• 25/06/2014 • 19/11/2015 • 210 • 303	•

Centralised applications for medicinal products for human use – withdrawals in 2015 prior to opinion

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Withdrawal • Active Time • Clock stop
• Aripiprazole Mylan • Aripiprazole	Generics UK Limited	• N05AX12 • treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder	• 23/07/2014 • 05/07/2015 • 121 • 0
• Corluxin • Mifepristone	FGK Representative Service GmbH	• treatment of Cushing's syndrome	• 20/11/2013 • 23/03/2015 • 182 • 184

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CHMP** • Validation • Withdrawal • Active Time • Clock stop
• Duloxetine Sandoz • Duloxetine	SANDOZ GmbH	• N06AX21 • Treatment in adults of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder.	• 16/09/2014 • 04/10/2015 • 121 • 0
• KETOCONAZOLE AID-SCFM • Ketoconazole	AGENZIA INDUSTRIE DIFESA-STABILIMENTO CHIMICO FARMACEUTICO MILITARE	• V03 • treatment of Cushing's syndrome	• 18/12/2013 • 05/06/2015 • 121 • 0
• Veraseal • Human fibrinogen / human thrombin	Instituto Grifols, S.A.	• B02BC • supportive treatment for improvement of haemostasis and as a suture support in vascular surgery	• 28/10/2014 • 29/09/2015 • 182 • 149

Annex 10a – Opinions adopted by the Committee for Medicinal Products for Human Use – extensions of indication

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CHMP opinion**	**European Commission decision date**
• Abraxane • Paclitaxel	Celgene Europe Limited	• L01CD01 • 1st line NSCLC	• 22/01/2015	• 26/02/2015
• Adenuric • Febuxostat	Menarini International Operations Luxembourg S.A.	• M04AA03 • Hyperuricaemia	• 26/02/2015	• 08/04/2015
• Aloxi • Palonosetron	Helsinn Birex Pharmaceuticals Ltd.	• A04AA05 • Paediatric CINV	• 22/01/2015	• 24/02/2015
• Avastin • Bevacizumab	Roche Registration Limited	• L01XC07 • Metastatic carcinoma of the cervix	• 26/02/2015	• 30/03/2015
• Brilique • Ticagrelor	AstraZeneca AB	• B01AC24 • History of Myocardial Infarction	• 17/12/2015	• 18/02/2016
• Cimzia • Certolizumab pegol	UCB Pharma SA	• L04AB05 • Treatment of active rheumatoid arthritis	• 19/11/2015	• 16/12/2015
• Cosentyx • Secukinumab	Novartis Europharm Ltd	• L04AC10 • Active psoriatic arthritis	• 22/10/2015	• 19/11/2015
• Cosentyx • Secukinumab	Novartis Europharm Ltd	• L04AC10 • Active ankylosing spondylitis	• 22/10/2015	• 19/11/2015
• Cubicin • Daptomycin	Novartis Europharm Ltd	• J01XX09 • Complicated skin and soft-tissue infections" (cSSTI),	• 22/10/2015	• 19/11/2015
• Cyramza • Ramucirumab	Eli Lilly Nederland B.V.	• L01XC • Locally advanced or metastatic non-small cell lung cancer with progression after platinum-based chemo	• 17/12/2015	• 25/01/2016
• Cyramza • Ramucirumab	Eli Lilly Nederland B.V.	• L01XC • Metastatic colorectal cancer (mCRC) with disease progression	• 17/12/2015	• 25/01/2016
• Edurant • Rilpivirine	Janssen-Cilag International N.V.	• J05AG05 • ARV treatment-naïve paediatric patients aged 12 to <18 years of age	• 22/10/2015	• 20/11/2015

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CHMP opinion**	**European Commission decision date**
• EMEND • Aprepitant	Merck Sharp & Dohme Limited	• A04AD12 • Prevention of nausea and vomiting in cancer chemotherapy	• 22/10/2015	• 16/12/2015
• Esmya • Ulipristal	Gedeon Richter Plc.	• G03AD02 • Intermittent treatment of moderate to severe symptoms of uterine fibroids	• 23/04/2015	• 27/05/2015
• Eylea • Aflibercept	Bayer Pharma AG	• S01LA05 • Macular oedema	• 22/01/2015	• 24/02/2015
• Eylea • Aflibercept	Bayer Pharma AG	• S01LA05 • Visual impairment due to myopic choroidal neovascularisation	• 24/09/2015	• 28/10/2015
• Fycompa • Perampanel	Eisai Europe Ltd.	• N03AX22 • Adjunctive treatment of primary generalised tonic-clonic seizures	• 21/05/2015	• 22/06/2015
• Gilenya • Fingolimod	Novartis Europharm Ltd	• L04AA27 • Highly active disease despite a full and adequate course of treatment	• 24/09/2015	• 28/10/2015
• Humira • Adalimumab	AbbVie Ltd.	• L04AB04 • Chronic plaque psoriasis in children and adolescents	• 26/02/2015	• 26/03/2015
• Humira • Adalimumab	AbbVie Ltd.	• L04AB04 • Severe hidradenitis suppurativa	• 25/06/2015	• 28/07/2015
• Imbruvica • Ibrutinib	Janssen-Cilag International NV	• L01XE27 • Waldenström's macroglobulinaemia	• 21/05/2015	• 03/07/2015
• Invega • Paliperidone	Janssen-Cilag International N.V.	• N05AX13 • Depressive symptom domain of schizoaffective disorder	• 23/04/2015	• 28/05/2015
• Jakavi • Ruxolitinib	Novartis Europharm Ltd	• L01XE18 • Polycythaemia vera	• 22/01/2015	• 11/03/2015
• Kalydeco • Ivacaftor	Vertex Pharmaceuticals (Europe) Ltd.	• R07AX02 • Treatment of cystic fibrosis in patients aged 18 years and older who have a R117H mutation in the CFT	• 24/09/2015	• 16/11/2015

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP opinion	European Commission decision date
• Kuvan • Sapropterin	BioMarin International Limited	• A16AX07 • 'treatment of hyperphenylalaninaemia	• 21/05/2015	• 22/06/2015
• Levemir • Insulin detemir	Novo Nordisk A/S	• A10AE05 • Type 2 diabetes mellitus	• 23/04/2015	• 27/05/2015
• Levemir • Insulin detemir	Novo Nordisk A/S	• A10AE05 • Levemir in children	• 25/06/2015	• 28/07/2015
• Mekinist • Trametinib	Novartis Europharm Ltd	• L01XE25 • Unresectable or metastatic melanoma	• 23/07/2015	• 25/08/2015
• Nplate • Romiplostim	Amgen Europe B.V.	• B02BX04 • Second line treatment of all non-splenectomised patients	• 17/12/2015	• 22/01/2016
• OPDIVO • Nivolumab	Bristol-Myers Squibb Pharma EEIG	• L01XC • NSCLC (as per Nivolumab BMS MAA)	• 24/09/2015	• 28/10/2015
• Perjeta • Pertuzumab	Roche Registration Limited	• L01XC13 • HER2-positive, locally advanced, inflammatory, or early stage breast cancer	• 25/06/2015	• 28/07/2015
• Prevenar 13 • Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)	Pfizer Limited	• J07AL02 • Pneumonia	• 22/01/2015	• 26/02/2015
• Pyramax • Pyronaridine / artesunate	Shin Poong Pharmaceutical Co., Ltd.	• P01BF06 • Treatment of malaria	• 19/11/2015	•
• Qutenza • Capsaicin	Astellas Pharma Europe B.V.	• N01BX04 • Treatment of diabetic patients with peripheral neuropathic pain	• 23/07/2015	• 20/08/2015
• Rebetol • Ribavirin	Merck Sharp & Dohme Limited	• J05AB04 • Treatment of hepatitis C	• 24/09/2015	• 28/10/2015
• Relistor • Methylnaltrexone bromide	PharmaSwiss Ceska Republika s.r.o	• A06AH01 • Opioid induced constipation	• 23/04/2015	• 27/05/2015
• Resolor • Prucalopride	Shire Pharmaceuticals Ireland Ltd.	• A06AX05 • Indication into the male population	• 23/04/2015	• 27/05/2015

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP opinion	European Commission decision date
• Revolade • Eltrombopag / eltrombopag olamine	Novartis Europharm Ltd	• B02BX05 • Severe aplastic anaemia (SAA)	• 23/07/2015	• 25/08/2015
• Revolade • Eltrombopag / eltrombopag olamine	Novartis Europharm Ltd	• B02BX05 • Use of Revolade to non-splenectomized patients	• 17/12/2015	• 28/01/2016
• Simponi • Golimumab	Janssen Biologics B.V.	• L04AB06 • Non radiographic axial spondyloarthritis	• 21/05/2015	• 22/06/2015
• Soliris • Eculizumab	Alexion Europe SAS	• L04AA25 • Paroxysmal nocturnal haemoglobinuria (PNH)	• 26/02/2015	• 30/03/2015
• Stelara • Ustekinumab	Janssen-Cilag International N.V.	• L04AC05 • Moderate to severe plaque psoriasis	• 21/05/2015	• 22/06/2015
• Sustiva • Efavirenz	Bristol-Myers Squibb Pharma EEIG	• J05AG03 • HIV-1 paediatric	• 26/02/2015	• 08/04/2015
• Tafinlar • Dabrafenib	Novartis Europharm Ltd	• L01XE23 • Unresectable or metastatic melanoma	• 23/07/2015	• 25/08/2015
• Tamiflu • Oseltamivir	Roche Registration Limited	• J05AH02 • Influenza in infants	• 26/03/2015	• 05/05/2015
• Tarceva • Erlotinib	Roche Registration Limited	• L01XE03 • Limit maintenance treatment to NSCLC patients with an EGFR-activating mutation	• 17/12/2015	• 25/01/2016
• Tygacil • Tigecycline	Pfizer Limited	• J01AA12 • Indication in children	• 23/04/2015	• 28/05/2015
• Vectibix • Panitumumab	Amgen Europe B.V.	• L01XC08 • Wild-type RAS metastatic colorectal cancer	• 26/02/2015	• 31/03/2015
• Vidaza • Azacitidine	Celgene Europe Limited	• L01BC07 • AML	• 24/09/2015	• 28/10/2015
• Volibris • Ambrisentan	Glaxo Group Ltd	• C02KX02 • Treatment of pulmonary arterial hypertension (PAH), in adult patients of WHO Functional Class (FC) II	• 22/10/2015	• 20/11/2015

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP opinion	European Commission decision date
• Voncento • Human coagulation factor VIII / human von willebrand factor	CSL Behring GmbH	• B02BD06 • Prophylactic treatment of patients with Von Willebrand Disease (VWD)	• 25/06/2015	• 31/07/2015
• XALKORI • Crizotinib	Pfizer Limited	• L01XE16 • Anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)	• 22/10/2015	• 23/11/2015
• Xultophy • Insulin degludec / liraglutide	Novo Nordisk A/S	• A10AE • Transfer of patients	• 21/05/2015	• 25/06/2015
• Zutectra • Human hepatitis B immunoglobuli n	Biotest Pharma GmbH	• J06BB04 • Prevention of hepatitis B virus re-infection after liver transplantation	• 19/11/2015	• 16/12/2015

Centralised applications for medicinal products for human use – withdrawals in 2015 prior to opinion

Product • Brandname • INN	Marketing authorisation holder	Therapeutic Area • ATC Code • Summary of indication	EMA/CHMP • Validation • Withdrawal • Active Time • Clock stop
• Aripiprazole Mylan • Aripiprazole	Generics UK Limited	• N05AX12 • treatment of schizophrenia and treatment and prevention of manic episodes in bipolar I disorder	• 23/07/2014 • 05/07/2015 • 121 • 0
• Corluxin • Mifepristone	FGK Representative Service GmbH	• treatment of Cushing's syndrome	• 20/11/2013 • 23/03/2015 • 182 • 184
• Duloxetine Sandoz • Duloxetine	SANDOZ GmbH	• N06AX21 • Treatment in adults of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder.	• 16/09/2014 • 04/10/2015 • 121 • 0

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CHMP** • Validation • Withdrawal • Active Time • Clock stop
• KETOCONAZOLE AID-SCFM • Ketoconazole	AGENZIA INDUSTRIE DIFESA-STABILIMENTO CHIMICO FARMACEUTICO MILITARE	• V03 • treatment of Cushing's syndrome	• 18/12/2013 • 05/06/2015 • 121 • 0
• Veraseal • Human fibrinogen / human thrombin	Instituto Grifols, S.A.	• B02BC • supportive treatment for improvement of haemostasis and as a suture support in vascular surgery	• 28/10/2014 • 29/09/2015 • 182 • 149
• VitroGro ECM • Insulin-like growth factor 1 segment	BSI Group	• hard-to-heal wounds,primarily venous leg ulcers	• 25/09/2013 • #N/A • 182 • 184

Annex 10b – Guidelines adopted by Committee for Medicinal Products for Human Use

Biologics Working Party

Reference number	Document	Status	Date
EMA/CHMP/BWP/126802/2012	Guideline on the adventitious agent safety of urine-derived medicinal products	Adopted	May
EMA/CHMP/BWP/548524/2008	Guideline on epidemiological data on blood transmissible infections	Adopted for 3-months public consultation	May
EMA/CHMP/BWP/723009/2014	Reflection paper on viral safety of plasma-derived medicinal products with respect to hepatitis E virus	Adopted for 3-months public consultation	June

Biosimilar Medicinal Product Working Party

Reference number	Document	Status	Date
EMEA/CHMP/BMWP/32775/2005 Rev. 1	Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues	Adopted	February
EMA/CHMP/BMWP/214262/2015	Concept paper on the revision of the guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant granulocyte-colony stimulating factor	Adopted for 3-months public consultation	July
EMEA/CHMP/BMWP/14327/2006 Rev1	Guideline on Immunogenicity assessment of biotechnology-derived therapeutic proteins	Adopted for 4-months public consultation	September
EMA/CHMP/BMWP/693108/2015	Concept paper on the revision of the Reflection Paper on non-clinical and clinical development of similar biological medicinal products containing recombinant interferon alpha or pegylated recombinant interferon alpha	Adopted for 3-months public consultation	December

Biostatistics Working Party

Reference number	Document	Status	Date
EMA/CHMP/295050/2013	Guideline on adjustment for baseline covariates in clinical trials	Adopted	February

Blood Products Working Party

Reference number	Document	Status	Date
EMA/CHMP/BPWP/143744/2011 rev. 1	Guideline on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration	Adopted	February
EMA/CHMP/BPWP/144552/2009 rev 1	Guideline on clinical investigation of recombinant and human plasma-derived factor IX products	Adopted	May
EMA/CHMP/BPWP/144533/2009 rev 1	Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products	Adopted for 1 month public consultation	May
EMA/CHMP/BPWP/1619/1999 rev. 2	Guideline on core SmPC for human plasma derived and recombinant coagulation factor VIII products	Adopted for 1 month public consultation	May
EMA/CHMP/BPWP/598816/2010 rev. 1-1	Guideline on core SmPC for plasma-derived fibrin sealant/ haemostatic products	Adopted	June
EMA/CHMP/BPWP/410415/2011 rev 1	Guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg)	Adopted	July
EMA/CHMP/BPWP/585257/2009	Guideline on the clinical investigation of hepatitis B immunoglobulins	Adopted	July
EMA/CHMP/BPWP/691754/2013 Rev 1	Guideline on core SmPC for Human Fibrinogen Products	Adopted	July

Cardiovascular Working Party

Reference number	Document	Status	Date
EMA/CHMP/41230/2015 Rev.1	Draft Guideline on clinical investigation of medicinal products for the treatment of	Adopted	February

Reference number	Document	Status	Date
	venous thromboembolic disease		
EMA/CHMP/206815/2013	Paediatric Addendum to the Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Hypertension	Adopted	February
EMA/CHMP/707532/2013	Paediatric Addendum on the CHMP Guideline on clinical investigation of medicinal products for the treatment of acute heart failure	Adopted for 6-months public consultation	May
EMA/CHMP/50549/2015	Reflection paper on assessment of cardiovascular risk of medicinal products for the treatment of cardiovascular and metabolic diseases	Adopted	May
CPMP/EWP/2986/03 Rev. 1	Guideline on clinical investigation of medicinal products for the treatment of acute heart failure	Adopted	May
EMA/CHMP/311805/2014	Guideline on clinical evaluation of medicinal products used in weight management	Adopted	September
EMA/CHMP/41252/2015	Guideline on clinical investigation of medicinal products for prevention of venous thromboembolism (VTE) in non-surgical patients	Adopted for 6-months public consultation	October

Central Nervous System Working Party

Reference number	Document	Status	Date
EMA/CHMP/771815/2011 Rev. 2	Guideline on clinical investigation of medicinal products for the treatment of Multiple Sclerosis	Adopted	March
EMA/531686/2015	Guideline on clinical investigation of medicinal products for the treatment of amyotrophic lateral sclerosis (ALS)	Adopted	November
EMA/CHMP/CNSWP/236981/2011	Guideline on the clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular	Adopted	December

Reference number	Document	Status	Date
	dystrophy		
EMA/CHMP/970057/2011	Guideline on the clinical development of medicinal products intended for the treatment of pain	Adopted for 3-months public consultation	December

Excipients Drafting Group

Reference number	Document	Status	Date
EMA/CHMP/495737/2013	Questions and answers on benzalkonium chloride in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'	Adopted	February
EMA/CHMP/495737/2013	Questions and answers on benzalkonium chloride in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'	Adopted	February
EMA/CHMP/338679/2014	Questions and answers on Sodium as excipient in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev.1)	Adopted for 3-months public consultation	May
EMA/CHMP/704219/2013	Questions and Answers on Wheat starch (containing gluten) in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev. 1)	Adopted	May
EMA/CHMP/619104/2013	Questions and answers on boron (boric acid and borates) in the context of the revision of the guideline on 'Excipients in the label and package leaflet of	Adopted for 3-months public consultation	July

Reference number	Document	Status	Date
	medicinal products for human use'		
EMA/CHMP/606830/2014	Questions and answers on Sodium laurilsulfate in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'	Adopted for 3-months public consultation	July

Gastroenterology Drafting Group

Reference number	Document	Status	Date
EMA/CHMP/336243/2013	Guideline on the evaluation of medicinal products for the treatment of chronic constipation (including opioid induced constipation) and for bowel cleansing	Adopted	June

Geriatric Expert Group

Reference number	Document	Status	Date
EMA/CHMP/778709/2015	Points to Consider on Frailty: Evaluation Instruments for Baseline Characterisation of Clinical trial populations	Adopted for 5-months public consultation	December

ICH

Reference number	Document	Status	Date
EMA/CHMP/ICH/135/1995	Guideline for good clinical practice E6(R2)	Adopted for 6-months public consultation	July
EMA/CHMP/ICH/458894/2015	Application of the principles of the ICH M7 guideline to calculation of compound-specific acceptable intakes	Adopted for 6-months public consultation	July
EMA/CHMP/ICH/820/2003	ICH guideline M8 on eCTD – questions and answers	Adopted	July
EMA/CHMP/ICH/468930/2015	ICH guideline Q7 on good manufacturing practice for active pharmaceutical ingredients – questions and	Adopted	July

Reference number	Document	Status	Date
	answers		
EMA/CHMP/ICH/82260/2006	Q3C (R6): Impurities: guideline for residual solvents	Adopted for 3-months public consultation	July
EMA/CPMP/ICH/2887/1999	ICH guideline M4E(R2) - Common Technical Document for the Registration of Pharmaceuticals for Human Use – Efficacy	Adopted for 6-months public consultation	September

Infectious Diseases Working Party

Reference number	Document	Status	Date
EMA/CHMP/594085/2015	Guideline on the use of pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products	Adopted for 6-months public consultation	September

Oncology Working Party

Reference number	Document	Status	Date
EMA/130525/2015	Concept paper on the need to revise the “Guideline on the evaluation of anticancer medicinal products in man” in order to provide guidance on the reporting of safety data from clinical trials	Adopted for 3-months public consultation	February
EMA/CHMP/151853/2014	Guideline on the role of pathological complete response as an endpoint in neoadjuvant breast cancer studies	Adopted	July
EMA/629967/2014	Guideline on the use of minimal residual disease as an endpoint in chronic lymphocytic leukaemia studies	Adopted	December

Pharmacogenomics Working Party

Reference number	Document	Status	Date
EMA/CHMP/281371/2013	Guideline on key aspects for the use of pharmacogenomics in the pharmacovigilance of medicinal products	Adopted	September

Pharmacokinetics Working Party

Reference number	Document	Status	Date
EMA/CHMP/736403/2014 Rev.2	Compilation of individual product-specific guidance on demonstration of bioequivalence	Adopted	March
EMEA/CHMP/EWP/192217/2009 Rev. 1 Corr. 2	Guideline on bioanalytical method validation	Adopted	May
CPMP/EWP/560/95/Rev. 1 Corr. 2	Guideline on the Investigation of Drug Interactions	Adopted	May
EMA/618604/2008 Rev. 12	Questions & Answers: positions on specific questions addressed to the Pharmacokinetics Working Party (PKWP)	Adopted	June
EMA/CHMP/PKWP/36761/2015	Prasugrel film-coated tablets 5 and 10 mg Product-Specific Bioequivalence Guidance	Adopted for 6-months public consultation	June
EMA/CHMP/PKWP/269533/2015	Asenapine sublingual tablets 5 and 10 mg Product-Specific Bioequivalence Guidance	Adopted for 6-months public consultation	June
EMA/CHMP/PKWP/36869/2015	Sitagliptin film-coated tablets 25, 50 and 100 mg Product-Specific Bioequivalence Guidance	Adopted for 6-months public consultation	June
EMA/CHMP/PKWP/253507/2015	Zonisamide hard capsules 25, 50 and 100 mg, orodispersible tablets 25, 50, 100 and 300 mg Product-Specific Bioequivalence Guidance	Adopted for 6-months public consultation	June
EMA/CHMP/PKWP/151748/2015	Entecavir film-coated tablets 0.5 and 1 mg, oral solution 0.05mg/ml product-specific bioequivalence guidance	Adopted for 3-months public consultation	September
EMA/CHMP/PKWP/152216/2015	Lenalidomide hard gelatine capsules 2.5, 5, 7.5, 10, 15 and 25mg product-specific bioequivalence guidance	Adopted for 3-months public consultation	September
EMA/CHMP/PKWP/151340/2015	Rivaroxaban film-coated tablets 2.5, 10, 15 and 20mg product-specific bioequivalence guidance	Adopted for 3-months public consultation	September
EMA/CHMP/PKWP/36648/2015	Tacrolimus granules for oral suspension 0.2 and 1 mg product-specific bioequivalence guidance	Adopted for 3-months public consultation	September
EMA/CHMP/PKWP/151478/	Ticagrelor film-coated tablets	Adopted for 3-months	September

Reference number	Document	Status	Date
2015	90mg product-specific bioequivalence guidance	public consultation	
EMA/618604/2008 Rev. 13	Revision of Questions & Answers: positions on specific questions addressed to the Pharmacokinetics Working Party (PKWP)	Adopted	November
EMA/CHMP/83874/2014	Guideline on the evaluation of the pharmacokinetics of medicinal products in patients with decreased renal function	Adopted	December

Quality Working Party

Reference number	Document	Status	Date
EMA/CHMP/QWP/96664/2015	Draft Guideline on the Chemistry of Active Substances	Adopted for 6-months public consultation	February
EMA/CHMP/CVMP/QWP/776887/2014	Question-and-answer document on plastic containers for eye drops	Adopted	February
EMA/CHMP/QWP/104928/2015	Question-and-answer document on the calculation of thresholds to set limits for impurities in the finished product specification	Adopted	February
EMA/CHMP/QWP/558185/2014	Concept paper on the development of a guideline on quality and equivalence of topical products	Adopted for 3-months public consultation	February
EMA/CHMP/QWP/109127/2015	Elemental impurities in Marketed Products - Recommendations for implementation	Adopted	February
EMA/CHMP/QWP/126334/2015	Concept paper on the need for Revision of the Guideline on the Requirements to the Chemical and Pharmaceutical Quality Documentation concerning Investigational Medicinal Products in Clinical Trials	Adopted for 3-months public consultation	February
EMA/CHMP/QWP/104223/2015	Reflection paper on the chemical structure and properties criteria to be considered for the evaluation	Adopted for 3-months public consultation	February

Reference number	Document	Status	Date
	of New Active Substance (NAS) status of chemical substances		
EMA/CHMP/QWP/245074/2015	Guideline on Manufacture of the Finished Dosage Form	Adopted for 6-months public consultation	April
EMA/CHMP/CVMP/QWP/284008/2015	Reflection paper on the use of cocrystals of active substances in medicinal products	Adopted	June
EMA/CHMP/CVMP/QWP/390257/2015	Questions and Answers What is understood by "manufactured by complex manufacturing processes" in change code B.II.b.4 (change in batch size of the finished product) or in change code B.II.b.1 (replacement or addition of a manufacturing site)? H+V	Adopted	June
EMA/834816/2015	Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials	Adopted for 6-months public consultation	December
EMA/CHMP/QWP/104223/2015	Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of New Active Substance (NAS) status of chemical substances	Adopted	December

Radiopharmaceutical Drafting Group

Reference number	Document	Status	Date
EMA/212874/2015	Guideline on core SmPC and Package Leaflet for sodium fluoride (18F)	Adopted	June

Respiratory Drafting Group

Reference number	Document	Status	Date
CHMP/EWP/2922/01 Rev.1	Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Asthma	Adopted	October

Rheumatology / Immunology Working Party

Reference number	Document	Status	Date
EMA/CHMP/80184/2015	Concept paper on clinical investigation of medicinal products for the treatment of Axial Spondyloarthritis	Adopted for 3-months public consultation	February
EMA/CHMP/51230/2013	Guideline on clinical investigation of medicinal products for the treatment of systemic lupus erythematosus and lupus nephritis	Adopted	February
CPMP/EWP/556/95 Rev. 2	Guideline on clinical investigation of medicinal products other than NSAIDs for treatment of rheumatoid arthritis	Adopted for 5-months public consultation	March
EMA/CHMP/239770/2014 Rev. 2	Guideline on clinical investigation of medicinal products for the treatment of juvenile idiopathic arthritis	Adopted	November

Safety Working Party

Reference number	Document	Status	Date
EMA/CHMP/SWP/620008/2012	Reflection paper on the data requirements for intravenous iron-based nano-colloidal products developed with reference to an innovator medicinal product	Adopted	March
EMA/CHMP/SWP/44609/2010 Rev. 1	Questions and answers on 'Guideline on the environmental risk assessment of medicinal products for human use'	Adopted for 3-months public consultation	March

Reference number	Document	Status	Date
EMA/CHMP/CVMP/JEG-3Rs/243112/2015	Recommendation to marketing authorisation holders, highlighting recent updates for 3Rs methods described in the European Pharmacopoeia	Adopted	June
EMA/CHMP/SWP/272921/2012	Reflection paper on the use of methyl- and propylparaben as excipients in human medicinal products for oral use	Adopted	October
EMA/CHMP/SWP/2145/2000 Rev. 1	Guideline on Non-Clinical Local Tolerance Testing of Medicinal Products	Adopted	October
EMA/CHMP/SWP/211900/2015	Concept paper on a Proposal to limit the applicability of the CPMP/CVMP Note for Guidance on Limitations to the Use of Ethylene Oxide in the Manufacture of Medicinal Products (CPMP/QWP/159/01) to veterinary medicinal products	Adopted	October

Scientific Advice Working Party

Reference number	Document	Status	Date
EMA/CHMP/689925/2014	Revision of the Guideline on clinical development of fixed combination medicinal products	Adopted for 6-months public consultation	April

Vaccines Working Party

Reference number	Document	Status	Date
EMA/56793/2014	Guideline on influenza vaccines – submission and procedural requirements	Adopted	May

Annex 11 – Opinions adopted by the Committee for Medicinal Products for Veterinary Use – initial evaluation

Positive opinions

Product • Invented name • INN/Common name	**Marketing authorisation holder**	**Therapeutic area** • Target species • Summary of indication	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Transmission to EC • Decision • Notification • Official Journal
• **Coliprotec F4** • Porcine post-weaning diarrhoea vaccine (live)	Prevtec Microbia GmbH	• Pig • Vaccine against post-weaning diarrhoea	• 12/03/2014 • 15/01/2015 • 210 • 99	• 15/01/2015 • 11/02/2015 • 16/03/2015 • 18/03/2015 • C 148 of 05/05/2015
• **Sileo** • Dexmedetomidine hydrochloride	Orion Corporation	• Dog • Alleviation of acute anxiety and fear associated with noise	• 16/10/2013 • 10/04/2015 • 210 • 331	• 10/04/2015 • 07/05/2015 • 10/06/2015 • 12/06/2015 • C 252 of 31/07/2015
• **Innovax-ILT** • Chicken infectious laryngotracheitis and Marek's disease vaccine (live)	Intervet International B.V.	• Chicken • Vaccine against infectious laryngotracheitis and Marek's disease	• 12/03/2014 • 07/05/2015 • 210 • 211	• 07/05/2015 • 03/06/2015 • 03/07/2015 • 07/07/2015 • C 285 of 28/08/2015
• **Canigen L4** • Canine leptospira vaccine (live)	Intervet International B.V.	• Dog • Vaccine for the active immunisation of dogs against Leishmania	• 12/01/2015 • 07/05/2015 • 89 • 26	• 07/05/2015 • 02/06/2015 • 03/07/2015 • 07/07/2015 • C 285 of 28/08/2015
• **UpCard** • Torasemide	Vétoquinol SA	• Dog • Congestive heart failure	• 12/03/2014 • 04/06/2015 • 210 • 239	• 04/06/2015 • 01/07/2015 • 31/07/2015 • 04/08/2015 • C 285 of 28/08/2015
• **FORTEKOR PLUS** • Pimobendan/Benazepril hydrochloride	Elanco Europe Ltd	• Dog • Congestive heart failure	• 11/12/2013 • 09/07/2015 • 210 • 365	• 09/07/2015 • 05/08/2015 • 08/09/2015 • 10/09/2015 C 361 of

Product • Invented name • INN/Common name	**Marketing authorisation holder**	**Therapeutic area** • Target species • Summary of indication	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Transmission to EC • Decision • Notification • Official Journal
				30/10/2015
• **PORCILIS PCV ID** • Porcine circovirus vaccine (inactivated)	Intervet International B.V.	• Pig • Vaccine against porcine circovirus type 2 infection	• 13/08/2014 • 09/07/2015 • 210 • 120	• 09/07/2015 • 31/07/2015 • 28/08/2015 • 01/09/2015 • C 318 of 25/09/2015
• **Vectormune ND** • Newcastle disease and Marek's disease vaccine (live)	CEVA-Phylaxia Veterinary Biologicals Co. Ltd.	• Chicken • Vaccine against Newcastle disease and Marek's disease	• 14/05/2014 • 09/07/2015 • 210 • 211	• 09/07/2015 • 04/08/2015 • 08/09/2015 • 10/09/2015 • C 361 of 30/10/2015
• **Novaquin** • Meloxicam	Le Vet Beheer B.V.	• Horse • Alleviation of inflammation and relief of pain in acute and chronic musculo-skeletal disorders	• 13/03/2014 • 09/07/2015 • 210 • 274	• 09/07/2015 • 05/08/2015 • 08/09/2015 • 10/09/2015 • C 361 of 30/10/2015
• **Zycortal** • Desoxycortone Pivalate	Dechra Limited	• Dog • Replacement therapy for mineralocorticoid deficiency with primary hypoadrenocorticism (Addison's disease)	• 14/05/2014 • 10/09/2015 • 210 • 274	• 10/09/2015 • 07/10/2015 • 06/11/2015 • 10/11/2015 • C 439 of 30/12/2015
• **Simparica** • Sarolaner	Zoetis Belgium SA	• Dog • Treatment of fleas, ticks and sarcoptic mange	• 11/12/2014 • 10/09/2015 • 210 • 63	• 10/09/2015 • 07/10/2015 • 06/11/2015 • 10/11/2015 • C 439 of 30/12/2015
• **Suvaxyn Circo+MH RTU** • Mycoplasma hyopneumoniae (inactivated) and	Zoetis Belgium SA	• Pig • Vaccine against porcine circovirus type 2 and Mycoplasma	• 15/10/2014 • 10/09/2015 • 210 • 120	• 10/09/2015 • 07/10/2015 • 06/11/2015 • 10/11/2015 • C 439 of

Product • Invented name • INN/Common name	Marketing authorisation holder	Therapeutic area • Target species • Summary of indication	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Transmission to EC • Decision • Notification • Official Journal
Porcine Circovirus vaccine (inactivated)		hyopneumoniae infection		30/12/2015
• **Velactis** • Cabergoline	CEVA Santé Animale	• Dairy cow • Prevention of intra-mammary infections; reduction in milk leakage; reduction in discomfort due to a reduction in udder engorgement and udder pressure, in relation to the dry period	• 18/09/2013 • 08/10/2015 • 210 • 540	• 08/10/2015 • 04/11/2015 • 09/12/2015 • 11/12/2015 • C 35 of 29/01/2016
• **Imrestor** • Pegbovigrastim	Eli Lilly and Company Limited	• Dairy cattle, Heifer • Reduction in the risk of clinical mastitis	• 17/09/2014 • 08/10/2015 • 210 • 176	• 08/10/2015 • 04/11/2015 • 09/12/2015 • 11/12/2015 • C 35 of 29/01/2016

Negative opinions

Product • Invented name • INN/Common name	Marketing authorisation holder	Therapeutic area • Target species • Summary of indication	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Transmission to EC • Decision • Notification • Official Journal
• **Lodipressine** • Amlodipine	• Le Vet Veheer B.V.	• Cat • treatment of systemic arterial hypertension	• 16/10/2013 • 07/05/2015 • 210 • 246	• 07/05/2015 • 10/06/2015 • 08/07/2015 • 10/07/2015 • C285 of 28/08/2015

Annex 11a – Opinions adopted by the Committee for Medicinal Products for Veterinary Use – extensions of indication

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CVMP opinion**	**European Commission decision date**
• Broadline • Fipronil, (S)-methoprene, epinomectin, praziquantel	MERIAL	• QP54AA	• 12/03/2015	• 13/04/2015
• Zuprevo • tildipirosin	Intervet International B.V	• QJ01FA96	• 12/02/2015	• 16/03/2015
• Advocate • Imidacloprid, moxidectin	Bayer Animal Health GmbH	• QP54AB52	• 09/07/2015	• 06/08/2015

CVMP opinions on establishment of MRLs

Positive opinions

Product • Substance	**Target species**	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Regulation • Official Journal
• Sisapronil	• Bovine, caprine	• 12/12/2013 • 15/01/2015 • 210 • 190 • 07/05/2015	• 11/05/2015 • 2015/2062 • L 301 of 18/11/2015
• Diethylene glycol monoethyl ether	• All food producing species	• 17/09/2014 • 12/02/2015 • 148 • 0	• 16/02/2015 • 2015/1820 • L265 of 10/10/2015
• Diflubenzuron	• *Salmonidae*	• N/a • 07/05/2015 • 202 • 168	• 07/05/2015
• Purified semi-solid extract from *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts)	• Bees	• 05/02/2014 • 07/05/2015 • 210 • 246	• 11/05/2015

Product • Substance	**Target species**	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Regulation • Official Journal
• Gentamicin	• All mammalian food producing species and fin fish	• N/a • 08/10/2015 • 102 • 0	• 08/10/2015
• Rafoxanide	• Bovine and ovine milk	• N/a • 06/11/2015 • N/a • 0	• 06/11/2015 • 681/2014 • L 182 of 10/07/2015
• Copper carbonate	• All food producing species	• 09/07/2015 • 10/12/2015 • 158 • 0	• 11/12/2015
• Eprinomectin (after provisional MRLs)	• All ruminants	• N/a • 10/12/2015 • 90 • 0	• 11/12/2015

Annex 11b – Guidelines adopted by Committee for Medicinal Products for Veterinary Use

CVMP quality

Reference number	Document title	Status
[Published on EMA website after adoption at CHMP]	Question and Answer document on plastic containers for eye drops.	Adopted February 2015
EMA/214328/2015	Q&A How should the trem “veterinary use only” or “drug substance not used in human medicine” be interpreted with regard to the limit for unspecified impurities for active substances	Adopted March 2015
EMA/CHMP/CVMP/QWP/284008/2015	Reflection paper on the use of cocrystals of active substances in medicinal products	Adopted June 2015
EMA/CHMP/CVMP/QWP/390257/2015	Questions and Answers What is understood by “manufactured by complex manufacturing processes” in change code B.II.b.4 (change in batch size of the finished product) or in change code B.II.b.1 (replacement or addition of a manufacturing site)? H+V	Adopted June 2015
EMA/CVMP/QWP/360463/2015	Concept paper on the need for revision of the veterinary note of guidance on manufacture of the finished dosage form	Adopted for consultation July 2015 (End of consultation 31 October 2015)
EMA/CVMP/QWP/107359/2015	Concept paper on the need for a single veterinary note for guidance on the chemistry of active substances	Adopted for consultation July 2015 (End of consultation 31 October 2015)

CVMP safety

Reference number	Document title	Status
EMA/CVMP/90250/2010	Guideline on risk characterisation and assessment of MRLs for biocides used in animal husbandry.	Adopted January 2015
EMA/CVMP/VICH/463199/2009	VICH GL48(R): Revised guideline on Studies to Evaluate the Metabolism and Residues Kinetics of Veterinary	Adopted February 2015

Reference number	Document title	Status
	Drugs in Human Food-producing Animals: Marker Residue Depletion Studies to establish Product Withdrawal Periods.	
EMA/CVMP/VICH/463202/2009	VICH GL49(R): Revised guideline on Studies to Evaluate the Metabolism and Residues Kinetics of Veterinary Drugs in Human Food-producing Animals: Validation of Analytical Methods used in Residue Depletion Studies.	Adopted February 2015
EMA/CVMP/VICH/699251/2010	VICH GL54: Guideline on studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD), for release for public consultation in the EU at step 4 of the VICH process	Adopted March 2015

CVMP efficacy

Reference number	Document title	Status
EMEA/CVMP/EWP/005/2000-Rev.3	Revised guideline for the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in dogs and cats.	Adopted for consultation March 2015 (End of consultation, 30 September 2015)

CVMP pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/390033/2014	Reflection paper on promotion of pharmacovigilance reporting.	Adopted March 2015
EMA/CVMP/PhVWP/901279/2011	Recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products	Adopted by CVMP in April and by HMA in May 2015
EMA/CVMP/90241/2009	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted June 2015
EMA/CVMP/PhVWP/288284/2007	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in	Adopted June 2015

Reference number	Document title	Status
	animals and humans	
EMA/CVMP/PhVWP/590073/2015	Concept paper on revision of the recommendation for the basic surveillance of data contained in EudraVigilance Veterinary	Adopted for consultation November 2015 (End of consultation, 29 February 2016)
EMA/CVMP/PhVWP/145186/2013-Rev1	Revised Questions and Answers on adverse event reporting	Adopted December 2015

CVMP antimicrobials

Reference number	Document title	Status
EMA/CVMP/AWP/401740/2013	Reflection paper on the risk of antimicrobial resistance transfer from companion animals.	Adopted January 2015
EMA/CVMP/EWP/261180/2012	Revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances.	Adopted for consultation February 2015 (End of consultation, 31 May 2015)
EMA/CVMP/AWP/706442/2013	Draft new guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals.	Adopted for consultation February 2015 (End of consultation, 31 August 2015)
EMA/CVMP/AWP/37203/2015	Concept paper for the development of a reflection paper on the use of extended-spectrum penicillins in animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation July 2015 (End of consultation, 31 October 2015)
EMA/CVMP/209189/2015	CVMP Strategy on Antimicrobials 2016-2020	Adopted for consultation November 2015 (End of consultation, 29 February 2016)

CVMP immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/205351/2006-Rev.1	Draft revised guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be	Adopted for consultation January 2015 (End of consultation, 30 April

Reference number	Document title	Status
	contaminated with bovine viral diarrhoea virus (BVDV).	2015)
EMA/CVMP/IWP/206555/2010-Rev.1	Draft revised guideline on requirements for the production and control of immunological veterinary medicinal products	Adopted for consultation July 2015 (End of consultation, 31 January 2016)
EMA/CVMP/IWP/251741/2015	Draft reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products	Adopted for consultation July 2015 (End of consultation, 31 January 2016)
EMA/CVMP/IWP/351882/2015	Concept paper on requirements for the production and control of allergen products for use in animals	Adopted for consultation September 2015 (End of consultation, 31 December 2015)
EMA/CVMP/IWP/205351/2006-Rev.1	Revised guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea virus (BVDV)	Adopted September 2015
EMA/CVMP/IWP/37924/2014	Reflection paper on the use of heat treatment to inactivate endogenous retroviruses in live immunological veterinary medicinal products	Adopted September 2015
EMA/CVMP/IWP/37620/2014	Reflection paper on the replacement of cell lines used for the production of immunological veterinary medicinal products	Adopted September 2015
EMA/CVMP/IWP/309514/2015	Concept paper on guidance on statistical principles for clinical trials for veterinary immunological medicinal products	Adopted for consultation December 2015 (End of consultation 31 March 2016)

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/ERA/349254/2014	Draft reflection paper on poorly extractable and/or non-radiolabelled substances.	Adopted for consultation March 2015 (End of consultation, 31 August 2015)
EMA/CVMP/ERA/698394/2014	Concept paper on the testing strategy and risk assessment for plants in Phase II of the environmental risk assessment for veterinary medicinal products	Adopted for consultation June 2015 (End of consultation, 30 September 2015)
EMA/CVMP/ERA/52740/2012	Guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products.	Adopted September 2015

General

Reference number	Document title	Status
EMA/CVMP/VICH/758781/2013	VICH GL53: Guideline on electronic exchange of documents: electronic file formats, for implementation.	Adopted March 2015
EMA/CVMP/VICH/751935/2013	VICH GL52: Bioequivalence: blood level bioequivalence study	Adopted September 2015
EMA/CVMP/450781/2015	Guideline on the principles for preparing assessment reports for veterinary medicinal products	Adopted December 2015
EMA/CVMP/550607/2015	Question and Answer document on solvents in the centralised procedure.	Adopted for consultation December 2015 (End of consultation 31 March 2016)

Annex 12 – Opinions adopted by the Committee on Orphan Medicinal Products

Positive COMP designation opinions

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Lactobacillus reuteri	Infant Bacterial Therapeutics AB - Sweden	Prevention of necrotising enterocolitis	02/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
3-[2-(4-carbamimidoyl-phenylcarbamoyl)-5-methoxy-4-vinyl-phenyl]-6-(cyclopropylmethyl-carbamoyl)-pyridine-2-carboxylic acid	BioCryst UK Ltd. - United Kingdom	Treatment of hereditary angioedema	20/08/2014 13/10/2014 09/01/2015 *(88 days/24 days)*	19/01/2015 12/02/2015
N-(3-(4-(3-(diisobutylamino)propyl)piperazin-1-yl)propyl)-1H-benzo[d]imidazol-2-amine disulphate salt	AlzProtect sas - France	Treatment of progressive supranuclear palsy	29/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
Myriocin	Nanovector s.r.l. - Italy	Treatment of retinitis pigmentosa	30/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
Olaratumab	Eli Lilly Nederland B.V. - The Netherlands	Treatment of soft tissue sarcoma	30/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
Ulocuplumab	Bristol-Myers Squibb Pharma EEIG - United Kingdom	Treatment of acute myeloid leukaemia	29/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
Recombinant human glutamate oxaloacetate transaminase 1	Dr. Regenold GmbH Development·Regulatory·Market Access - Germany	Treatment of glioma	28/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
Mazindol	HAC Pharma - France	Treatment of narcolepsy	28/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
Sevufparin sodium	Dilaforette AB -	Treatment of	23/09/2014	19/01/2015

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
	Sweden	sickle cell disease	13/10/2014 09/01/2015 *(88 days/24 days)*	12/02/2015
Chimeric group B adenovirus (11p/3) with deletions in the E3 and E4 regions	PsiOxus Therapeutics Ltd - United Kingdom	Treatment of ovarian cancer	24/09/2014 13/10/2014 09/01/2015 *(88 days/24 days)*	19/01/2015 12/02/2015
Allogeneic CD4+ and CD8+ T lymphocytes ex vivo incubated with synthetic peptides of the viral antigens of cytomegalovirus, adenovirus and Epstein-Barr virus	Miltenyi Biotec GmbH - Germany	Treatment of cytomegalovirus infection following haematopoietic stem cell transplantation	27/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
505 amino acid protein, corresponding to amino acids 2-506 of the wild type human histidyl-tRNA synthetase	Voisin Consulting S.A.R.L. - France	Treatment of facioscapulohumeral muscular dystrophy	30/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
Nitroglycerin	Covis Pharma S.à.r.l. - Luxembourg	Treatment of systemic sclerosis	26/09/2014 13/10/2014 09/01/2015 *(88 days/24 days)*	19/01/2015 12/02/2015
Fibrinogen-coated albumin spheres	Fibreu Limited - United Kingdom	Treatment of Ebola virus disease	29/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
Alvocidib	Theorem Clinical Research GmbH - Germany	Treatment of acute myeloid leukaemia	14/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
2'-O-methyl phosphorothioate RNA oligonucleotide, 5' m5CUGm5CUGm5CUGm5CUGm5CUGm5CUGm5CUG-3'	BioMarin International Limited - Ireland	Treatment of Huntington's disease	18/08/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
5-hydroxymethyl-2-furfural	Baxalta Innovations GmbH - Austria	Treatment of sickle cell disease	27/10/2014 17/11/2014 09/01/2015 *(53 days/24 days)*	19/01/2015 12/02/2015
Allogeneic CD4+ and CD8+ T lymphocytes ex vivo incubated with synthetic peptides of the viral antigens of	Miltenyi Biotec GmbH - Germany	Treatment of adenovirus infection following	27/10/2014/ 17/11/2014 09/01/2015/ *(53 days/23 days)*	24/02/2015 19/03/2015

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
cytomegalovirus, adenovirus and Epstein-Barr virus		haematopoietic stem cell transplantation		
Allogeneic CD4+ and CD8+ T lymphocytes ex vivo incubated with synthetic peptides of the viral antigens of cytomegalovirus, adenovirus and Epstein-Barr virus	Miltenyi Biotec GmbH - Germany	treatment of Epstein-Barr virus infection following haematopoietic stem cell transplantation	27/10/2014/ 17/11/2014 09/01/2015/ *(53 days/23 days)*	24/02/2015 19/03/2015
Lenvatinib	Eisai Europe Limited - United Kingdom	Treatment of hepatocellular carcinoma	26/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Ex-vivo-expanded autologous human keratinocytes containing epidermal stem cells transduced with a COL7A1-encoding retroviral vector	Chiesi Farmaceutici S.p.A. - Italy	Treatment of epidermolysis bullosa	27/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Ex-vivo-expanded autologous human keratinocytes containing epidermal stem cells transduced with a LAMB3-encoding retroviral vector	Chiesi Farmaceutici S.p.A. - Italy	Treatment of epidermolysis bullosa	27/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Recombinant human monoclonal antibody binding to vascular adhesion protein-1	Biotie Therapies Corp - Finland	Treatment of primary sclerosing cholangitis	25/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Tideglusib	QRC Consultants Ltd. - United Kingdom	Treatment of fragile X syndrome	28/10/2014 17/11/2014 12/02/2015 *(87 days/23 days)*	24/02/2015 19/03/2015
Autologous adipose tissue-derived stromal vascular fraction cells	Assistance Publique Hôpitaux de Marseille - France	Treatment of systemic sclerosis	27/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Sodium 3-[(4aR,6R,7R,7aS)-7-hydroxy-2-oxido-2-sulfanylidene-4a,6,7,7a-tetrahydro-4H-furo[3,2-d][1,3,2]dioxaphosphinin-6-	Universitätskliniku m Tübingen (UKT) - Germany	Treatment of retinitis pigmentosa	26/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
yl]-2-bromo-6-phenyl-5H-imidazo[1,2-a]purin-9-one				
Enoxacin	Dr. Regenold GmbH Development·Regulatory·Market Access - Germany	Treatment of amyotrophic lateral sclerosis	25/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Human reovirus type 3 Dearing strain	Oncolytics Biotech (UK) Limited - United Kingdom	Treatment of ovarian cancer	27/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Ex-vivo-expanded autologous human keratinocytes containing epidermal stem cells transduced with a COL17A1-encoding retroviral vector	Chiesi Farmaceutici S.p.A. - Italy	Treatment of epidermolysis bullosa	27/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Melphalan flufenamide	Oncopeptides AB - Sweden	Treatment of plasma cell myeloma	27/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Chimeric 2'-O-(2-methoxyethyl) modified oligonucleotide targeted to huntingtin RNA	Isis USA Ltd - United Kingdom	Treatment of Huntington's disease	29/10/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
5,10,15,20-tetrakis(2,6-difluoro-3-N-methylsulfamoylphenyl)bacteriochlorin	Luzitin S.A. - Portugal	Treatment of biliary tract cancer	27/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Trientine tetrahydrochloride	GMP-Orphan SA - France	Treatment of Wilson's disease	04/01/2015 19/01/2015 12/02/2015 *(24 days/23 days)*	24/02/2015 19/03/2015
Recombinant human club cell 10 KDa protein	RLM Consulting - Belgium	Prevention of bronchopulmonary dysplasia	30/10/2014 17/11/2014 12/02/2015 *(87 days/23 days)*	24/02/2015 19/03/2015
[5-(5-chloro-1H-pyrrolo[2,3-b]pyridin-3-ylmethyl)-pyridin-2-yl]-(6-trifluoromethyl-	Daiichi Sankyo Development Ltd - United Kingdom	Treatment of tenosynovial giant cell tumour,	21/11/2014 20/12/2014 12/02/2015	24/02/2015 19/03/2015

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
pyridin-3-ylmethyl)-amine hydrochloride		localised and diffuse type	*(54 days/23 days)*	
Adeno-associated viral vector serotype 9 containing the human glucocerebrosidase gene	Gauchers Association - United Kingdom	Treatment of Gaucher disease	27/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Human plasma-derived alpha-1 proteinase inhibitor	Richardson Associates Regulatory Affairs Ltd - United Kingdom	Treatment of graft-versus-host disease	30/10/2014 17/11/2014 12/02/2015 *(87 days/23 days)*	24/02/2015 19/03/2015
5'-ASCSASTSCSASGSTSCSTSGSASUSASASGSCSTSA-3'	CTI Clinical Trial and Consulting Services Europe GmbH - Germany	Treatment of Alport syndrome	10/10/2014 17/11/2014 12/02/2015 *(87 days/23 days)*	24/02/2015 19/03/2015
Gallium (68Ga)-edotreotide	Advanced Accelerator Applications SA - France	Diagnosis of gastro-entero-pancreatic neuroendocrine tumours	26/09/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
Humanised anti-folate receptor 1 monoclonal antibody conjugated to maytansinoid DM4	ImmunoGen Europe Limited - United Kingdom	Treatment of ovarian cancer	25/11/2014 20/12/2014 12/02/2015 *(54 days/23 days)*	24/02/2015 19/03/2015
6-ethoxy-7-methoxy-2-(2-methylsulfanylphenyl)-3,1-benzoxazin-4-one	Sixera Pharma AB - Sweden	Treatment of Netherton syndrome	30/10/2014 17/11/2014 12/02/2015 *(87 days/23 days)*	24/02/2015 19/03/2015
Recombinant human mesencephalic astrocyte-derived neurotrophic factor	Clinipace GmbH - Germany	Treatment of retinitis pigmentosa	10/12/2014 19/01/2015 19/03/2015 *(59 days/25 days)*	30/03/2015 24/04/2015
Fluciclovine (18F)	Blue Earth Diagnostics Ltd - United Kingdom	Diagnosis of glioma	24/11/2014 20/12/2014 25/03/2015 *(95 days/25 days)*	30/03/2015 24/04/2015
Xenon	Neuroprotexeon Ltd - United Kingdom	Treatment of perinatal asphyxia	09/12/2014 19/01/2015 19/03/2015 *(59 days/25 days)*	30/03/2015 24/04/2015
Sodium 2-hydroxylinoleate	Ability	Treatment of	10/12/2014	30/03/2015

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
	Pharmaceuticals SL - Spain	neuroblastoma	19/01/2015 25/03/2015 *(65 days/25 days)*	24/04/2015
Nitric oxide	Biological Consulting Europe Ltd - United Kingdom	Treatment of cystic fibrosis	10/12/2014 19/01/2015 19/03/2015 *(59 days/25 days)*	30/03/2015 24/04/2015
1-(4-(N-glycylamido) phenyl)-3-trifluoromethyl-5-(phenanthren-2-yl)-pyrazole-hydrochloride	Arno Therapeutics UK, Limited - United Kingdom	Treatment of tularaemia	27/11/2014 20/12/2014 19/03/2015 *(89 days/25 days)*	30/03/2015 24/04/2015
1-(4-(N-glycylamido) phenyl)-3-trifluoromethyl-5-(phenanthren-2-yl)-pyrazole-hydrochloride	Arno Therapeutics UK, Limited - United Kingdom	Treatment of cryptococcosis	27/11/2014 20/12/2014 19/03/2015 *(89 days/25 days)*	30/03/2015 24/04/2015
Ecothiopate iodide	JJGConsultancy Ltd - United Kingdom	Treatment of Stargardt's disease	27/11/2014 20/12/2014 19/03/2015 *(89 days/25 days)*	30/03/2015 24/04/2015
Rimeporide	EUDRAC Limited - United Kingdom	Treatment of Duchenne muscular dystrophy	27/11/2014 20/12/2014 19/03/2015 *(89 days/25 days)*	30/03/2015 24/04/2015
Recombinant monoclonal IgG1 antibody against T-cell immune response cDNA 7	Nekonal S.a.r.l.	Prevention of graft rejection following solid organ transplantation	27/11/2014 20/12/2014 19/03/2015 *(89 days/25 days)*	30/03/2015 24/04/2015
Rintatolimod	NV Hemispherx BioPharma Europe - Belgium	Treatment of Ebola virus disease	25/11/2014 20/12/2014 19/03/2015 *(89 days/25 days)*	30/03/2015 24/04/2015
Human reovirus type 3 Dearing strain	Oncolytics Biotech (UK) Limited - United Kingdom	Treatment of pancreatic cancer	27/11/2014 20/12/2014 19/03/2015 *(89 days/25 days)*	30/03/2015 24/04/2015
Adeno-associated viral vector serotype 5 containing the human CHM gene	HORAMA SAS - France	Treatment of choroideremia	08/12/2014 19/01/2015 19/03/2015 *(59 days/25 days)*	30/03/2015 24/04/2015
Lenalidomide	Celgene Europe Limited - United	Treatment of marginal zone	25/11/2014 20/12/2014	30/03/2015 24/04/2015

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
	Kingdom	lymphoma	19/03/2015 *(89 days/25 days)*	
Phenol, 4-[2-(aminomethyl)-4-thiazolyl]-2,6-bis(1,1-dimethylethyl) monohydrochloride	Ipsen Pharma - France	Treatment of Huntington's disease	08/12/2014 19/01/2015 19/03/2015 *(59 days/25 days)*	30/03/2015 24/04/2015
Reduced oxidised N-acetyl heparin	Sigma-Tau Rare Disease Limited - United Kingdom	Treatment of plasma cell myeloma	18/11/2014 19/01/2015 16/04/2015 *(87 days/28 days)*	23/04/2015 21/05/2015
Trehalose	Dr Ulrich Granzer - Germany	Treatment of oculopharyngeal muscular dystrophy	28/01/2015 16/02/2015 16/04/2015 *(59 days/28 days)*	23/04/2015 21/05/2015
Triheptanoin	Ultragenyx UK Limited - United Kingdom	Treatment of glucose transporter type-1 deficiency syndrome	28/01/2015 16/02/2015 16/04/2015 *(59 days/28 days)*	23/04/2015 21/05/2015
Humanised anti-CD37 monoclonal antibody conjugated to maytansinoid DM1	ImmunoGen Europe Limited - United Kingdom	Treatment of diffuse large B-cell lymphoma	27/01/2015 16/02/2015 16/04/2015 *(59 days/28 days)*	23/04/2015 21/05/2015
Allopurinol sodium	ACE Pharmaceuticals BV - The Netherlands	Treatment of perinatal asphyxia	26/01/2015 16/02/2015 16/04/2015 *(59 days/28 days)*	23/04/2015 21/05/2015
Adult human bone-marrow-derived, ex-vivo-expanded, pooled allogeneic mesenchymal stromal cells	Regulatory Resources Group Ltd - United Kingdom	Treatment of thromboangiitis obliterans (Buerger's disease)	30/01/2015 16/02/2015 16/04/2015 *(59 days/28 days)*	23/04/2015 21/05/2015
5,7-dichloro-2-dimethylaminomethyl-8-hydroxyquinoline hydrochloride	Prana Biotechnology UK Limited - United Kingdom	Treatment of Huntington's disease	30/01/2015 16/02/2015 16/04/2015 *(59 days/28 days)*	23/04/2015 21/05/2015
2-(7-ethoxy-4-(3-fluorophenyl)-1-oxophthalazin-2(1H)-yl)-N-methyl-N-(2-methylbenzo[d]oxazol-6-yl)acetamide	Clinical Network Services (UK) Ltd - United Kingdom	Treatment of cystic fibrosis	30/01/2015 16/02/2015 16/04/2015 *(59 days/28 days)*	23/04/2015 21/05/2015

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Adeno-associated viral vector serotype 9 containing the human HGSNAT gene	Cochamo Systems Ltd - United Kingdom	Treatment of mucopolysaccharidosis IIIC (Sanfilippo C syndrome)	10/12/2014 19/01/2015 16/04/2015 *(87 days/58 days)*	23/04/2015 21/05/2015
Triamcinolone acetonide	S-cubed Limited - United Kingdom	Treatment of non-infectious uveitis	10/12/2014 19/01/2015 16/04/2015 *(87 days/28 days)*	23/04/2015 21/05/2015
AASSGVSTPGSAGHDIITEQPRS	Centre National de la Recherche Scientifique (CNRS) - France	Treatment of Huntington's disease	10/12/2014 19/01/2015 16/04/2015 *(87 days/28 days)*	23/04/2015 21/05/2015
Fusion proteins composed by a genetically modified Cholera Toxin Subunit A1, peptides from the acetylcholine receptor alpha chain and a dimer of the D fragment from Staphylococcus aureus protein A	Toleranzia AB - Sweden	Treatment of myasthenia gravis	10/12/2014 19/01/2015 16/04/2015 *(87 days/28 days)*	23/04/2015 21/05/2015
{2-amino-8-[4-(pyrrolidinylcarbonyl)phenyl]-(3H-benzo[f]azepin-4-yl)}-N,N-dipropylcarboxamide	Right Track Regulatory Limited - United Kingdom	Treatment of ovarian cancer	09/12/2014 19/01/2015 16/04/2015 *(87 days/28 days)*	23/04/2015 21/05/2015
Adeno-associated viral vector serotype 9 containing the human SMN gene	AveXis EU, Ltd - Ireland	Treatment of spinal muscular atrophy	24/02/2015 23/03/2015 13/05/2015 *(51 days/29 days)*	21/05/2015 19/06/2015
Adeno-associated viral vector containing the human factor IX gene	Baxalta Innovations GmbH - Austria	Treatment of haemophilia B	21/01/2015 23/03/2015 13/05/2015 *(51 days/29 days)*	21/05/2015 19/06/2015
Allogeneic ex-vivo-expanded human umbilical cord blood-derived mesenchymal stem cells	PSR Group B.V. - The Netherlands	Prevention of bronchopulmonary dysplasia	29/01/2015 16/02/2015 13/05/2015 *(86 days/29 days)*	21/05/2015 19/06/2015
Antisense oligonucleotide directed against TGF-β2 mRNA	Isarna Therapeutics GmbH - Germany	Prevention of scarring post glaucoma filtration surgery	30/01/2015 16/02/2015 13/05/2015 *(86 days/29 days)*	21/05/2015 19/06/2015
Synthetic 47-amino acid N-	MYR GmbH -	Treatment of	22/12/2014	21/05/2015

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
myristoylated lipopeptide, derived from the preS region of hepatits B virus	Germany	hepatitis delta virus infection	16/02/2015 13/05/2015 *(86 days/29 days)*	19/06/2015
Obinutuzumab	Roche Registration Limited - United Kingdom	Treatment of follicular lymphoma	30/01/2015 16/02/2015 13/05/2015 *(86 days/29 days)*	21/05/2015 19/06/2015
3-{[2,3,5,6-tetrafluoro-3'-(trifluoromethoxy)biphenyl-4-yl]carbamoyl}thiophene-2-carboxylic acid	Panoptes Pharma Ges.m.b.H - Austria	Treatment of non-infectious uveitis	30/01/2015 16/02/2015 13/05/2015 *(86 days/29 days)*	21/05/2015 19/06/2015
Edaravone	Mitsubishi Tanabe Pharma Europe Ltd - United Kingdom	Treatment of amyotrophic lateral sclerosis	27/02/2015 23/03/2015 13/05/2015 *(51 days/29 days)*	21/05/2015 19/06/2015
Trehalose	Dr Ulrich Granzer - Germany	Treatment of spinocerebellar ataxia	28/01/2015 23/03/2015 13/05/2015 *(51 days/29 days)*	21/05/2015 19/06/2015
Triheptanoin	Ultragenyx UK Limited - United Kingdom	Treatment of very long-chain acyl-CoA dehydrogenase deficiency	20/02/2015 23/03/2015 13/05/2015 *(51 days/29 days)*	21/05/2015 19/06/2015
Obinutuzumab	Roche Registration Limited - United Kingdom	Treatment of marginal zone lymphoma	30/01/2015 16/02/2015 13/05/2015 *(86 days/29 days)*	21/05/2015 19/06/2015
Triheptanoin	Ultragenyx UK Limited - United Kingdom	Treatment of mitochondrial trifunctional protein deficiency	24/03/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Synthetic double-stranded RNA oligonucleotide specific to hydroxyacid oxidase 1 gene	Dicerna EU Limited - United Kingdom	Treatment of primary hyperoxaluria type 1	25/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Triheptanoin	Ultragenyx UK Limited - United Kingdom	Treatment of carnitine palmitoyl transferase II deficiency	24/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Triheptanoin	Ultragenyx UK	Treatment of	24/03/2015	06/07/2015

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	Limited - United Kingdom	long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency	20/04/2015 18/06/2015 *(59 days/22 days)*	28/07/2015
Modified adenovirus serotype 5/35 containing a CMV promoter-driven transgene cassette with the human transgenes for a membrane-bound CD40 ligand (TMZ-CD40L) and full length 4-1BBL	Lokon Pharma AB - Sweden	Treatment of pancreatic cancer	13/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Inecalcitol	Hybrigenics SA - France	Treatment of acute myeloid leukaemia	25/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Hydrocinnamate-[Orn-Pro-dCha-Trp-Arg]acetate	PBS Regulatory Consulting Group Limited - United Kingdom	Treatment of amyotrophic lateral sclerosis	25/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Humanised IgG4 monoclonal antibody against extracellular tau	Bristol-Myers Squibb Pharma EEIG - United Kingdom	Treatment of progressive supranuclear palsy	24/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Glycyl-L-2-methylprolyl-L-glutamic acid	QRC Consultants Ltd. - United Kingdom	Treatment of Fragile X syndrome	25/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Cannabidiol	GW Pharma Ltd - United Kingdom	Treatment of perinatal asphyxia	24/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Anti-H5N1 equine immunoglobulin F(ab')2 fragments	Fab'entech - France	Treatment of avian influenza	29/01/2015 23/03/2015 18/06/2015 *(87 days/22 days)*	06/07/2015 28/07/2015
Beloranib	Dr Ulrich Granzer - Germany	Treatment of craniopharyngioma	25/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Sarizotan hydrochloride	Newron Pharmaceuticals SpA - Italy	Treatment of Rett syndrome	26/03/2015 20/04/2015 18/06/2015	06/07/2015 28/07/2015

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			(59 days/22 days)	
Doxorubicin	Double Bond Pharmaceutical AB - Sweden	Treatment of hepatoblastoma	30/01/2015 23/03/2015 18/06/2015 *(87 days/22 days)*	06/07/2015 28/07/2015
Synthetic hypericin	Kinesys Consulting Ltd - United Kingdom	Treatment of cutaneous T-cell lymphoma	27/02/2015 23/03/2015 18/06/2015 *(87 days/22 days)*	06/07/2015 28/07/2015
Human plasminogen	ProMetic BioTherapeutics Ltd - United Kingdom	Treatment of plasminogen deficiency	08/12/2014 23/03/2015 18/06/2015 *(87 days/22 days)*	06/07/2015 28/07/2015
2-((3-((4-((3-aminopropyl)amino)butyl)amino)propyl)amino)-N-((5S,5aS,8aR,9R)-9-(4-hydroxy-3,5-dimethoxyphenyl)-8-oxo-5,5a,6,8,8a,9-hexahydrofuro[3',4':6,7]naphtho[2,3-d][1,3]dioxol-5-yl)acetamide, tetrahydrochloride	Pierre Fabre Médicament - France	Treatment of acute myeloid leukaemia	20/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Adenovirus-associated viral vector serotype 2 containing the human RPE65 gene	Alan Boyd Consultants Ltd - United Kingdom	Treatment of retinitis pigmentosa	23/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Allogeneic human adult stem cells, isolated from skeletal muscle and expanded ex vivo	Karl Rouger - France	Treatment of Duchenne muscular dystrophy	24/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Artesunate	Dr Ulrich Granzer - Germany	Treatment of malaria	24/03/2015 20/04/2015 18/06/2015 *(59 days/22 days)*	06/07/2015 28/07/2015
Lanreotide acetate	Prof. Dr R.T.Gansevoort - The Netherlands	Treatment of autosomal dominant polycystic kidney disease	20/02/2015 23/03/2015 18/06/2015 *(87 days/19 days)*	22/07/2015 10/08/2015
Recombinant human acid	Plexcera	Treatment of	28/04/2015	22/07/2015

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ceramidase	Therapeutics EU Limited - Ireland	cystic fibrosis	08/06/2015 16/07/2015 *(38 days/14 days)*	10/08/2015
2-(2-phenylvinyl)-4-[4-methylpiperazin-1-yl)]-6-(5-methyl-2H-pyrazol-3-yl-amino)-pyrimidine L(+) tartrate salt	Dr Ulrich Granzer - Germany	Treatment of hepatocellular carcinoma	21/05/2015 08/06/2015 16/07/2015 *(38 days/14 days)*	22/07/2015 10/08/2015
Fibrinogen-coated albumin spheres	Fibreu Limited - United Kingdom	Treatment of acute radiation syndrome	16/04/2015 08/06/2015 16/07/2015 *(38 days/14 days)*	22/07/2015 10/08/2015
CD33-directed antibody-drug conjugate consisting of an antibody conjugated to a DNA cross-linking pyrrolobenzodiazepine dimer drug	Seattle Genetics UK, Limited - United Kingdom	Treatment of acute myeloid leukaemia	21/05/2015 08/06/2015 16/07/2015 *(38 days/14 days)*	22/07/2015 10/08/2015
Fixed-dose combination of fosfomycin disodium and tobramycin	CURx Pharma (UK) Limited - United Kingdom	Treatment of cystic fibrosis	12/05/2015 08/06/2015 16/07/2015 *(38 days/14 days)*	22/07/2015 10/08/2015
Verucerfont	Neurocrine Therapeutics Ltd - Ireland	Treatment of congenital adrenal hyperplasia	05/05/2015 08/06/2015 16/07/2015 *(38 days/14 days)*	22/07/2015 10/08/2015
Allogeneic umbilical cord blood cells treated ex vivo with 16,16-dimethyl prostaglandin E2	Fate Therapeutics, LTD - United Kingdom	Treatment of acute lymphoblastic leukaemia	22/05/2015 08/06/2015 16/07/2015 *(38 days/14 days)*	22/07/2015 10/08/2015
Adeno-associated viral vector serotype 9 containing the human iduronate-2-sulfatase gene	Laboratorios del Dr. Esteve, S.A. - Spain	Treatment of mucopolysaccharidosis type II (Hunter's syndrome)	18/05/2015 08/06/2015 16/07/2015 *(38 days/14 days)*	22/07/2015 10/08/2015
Ibrutinib	Janssen-Cilag International N.V. - Belgium	Treatment of marginal zone lymphoma	20/05/2015 08/06/2015 16/07/2015 *(38 days/14 days)*	22/07/2015 10/08/2015
(S)-6-hydroxy-2,5,7,8-tetramethyl-N-((R)-piperidin-	Khondrion BV - The Netherlands	Treatment of mitochondrial	21/05/2015 08/06/2015	22/07/2015 10/08/2015

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3-yl)chroman-2-carboxamide hydrochloride		encephalomyopathy, lactic acidosis, and stroke-like episodes	16/07/2015 *(38 days/14 days)*	
Human allogeneic bone-marrow-derived osteoblastic cells	Bone Therapeutics SA - Belgium	Treatment of osteogenesis imperfecta	23/03/2015 20/04/2015 16/07/2015 *(87 days/14 days)*	22/07/2015 10/08/2015
Glycyl-L-2-methylprolyl-L-glutamic acid	QRC Consultants Ltd. - United Kingdom	Treatment of Rett syndrome	25/03/2015 20/04/2015 16/07/2015 *(87 days/14 days)*	22/07/2015 10/08/2015
Insulin human (rDNA)	Sirius Regulatory Consulting Limited - UK	Treatment of short bowel syndrome	25/03/2015 20/04/2015 16/07/2015 *(87 days/14 days)*	22/07/2015 10/08/2015
2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxythymidylyl-(3',5'-phosphoryl)- 2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl -(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidilyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxythymidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-	PhaRA bvba - Belgium	Treatment of diffuse large B-cell lymphoma	21/05/2015 08/06/2015 16/07/2015 *(87 days/14 days)*	22/07/2015 10/08/2015

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deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidine, sodium salt				
Adeno-associated viral vector serotype 8 containing the human MTM1 gene	Audentes Therapeutics UK Limited - United Kingdom	Treatment of X-linked myotubular myopathy	18/05/2015 08/06/2015 16/07/2015 *(87 days/14 days)*	22/07/2015 10/08/2015
Sirolimus	Desitin Arzneimittel GmbH - Germany	Treatment of tuberous sclerosis	23/06/2015 13/07/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015
N-(2-((4Z,7Z,10Z,13Z,16Z,19Z)-docosa-4,7,10,13,16,19-hexaenamido)ethyl)-2-hydroxybenzamide	FGK Representative Service GmbH - Germany	Treatment of Duchenne muscular dystrophy	26/06/2015 13/07/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015
Recombinant adeno-associated viral vector containing the human CNGA3 gene	TMC Pharma Services Ltd - United Kingdom	Treatment of achromatopsia caused by mutations in the CNGA3 gene	19/06/2015 13/07/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015
Synthetic peptide L-Cysteine, L-cysteinylglycyl-L-glutaminyl-L-arginyl-L-.alpha.-glutamyl-L-threonyl-L-prolyl-L-.alpha.-glutamylglycyl-L-alanyl-L-.alpha.-glutamyl-L-alanyl-L-lysyl-L-prolyl-L-tryptophyl-L-tyrosyl-, cyclic (1.fwdarw.17)-disulfide	Apeptico Forschung und Entwicklung GmbH - Austria	Treatment of primary graft dysfunction following lung transplantation	17/05/2015 08/06/2015 03/09/2015 *(87 days/22 days)*	17/09/2015 09/10/2015
Three chimeric human/murine monoclonal antibodies against the Ebola (Zaire) surface glycoprotein	Dr Stefan Blesse - Germany	Treatment for Ebola virus disease	24/06/2015 08/06/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015

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Recombinant human interleukin-3 truncated diphtheria toxin fusion protein	Spector Consulting SAS - France	Treatment of acute myeloid leukaemia	26/06/2015 13/07/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015
A highly purified formulation of Staphylococcus aureus protein A	Coté Orphan Consulting UK Limited - United Kingdom	Treatment of immune thrombocytopenia	26/06/2015 13/07/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015
Ataluren	PTC Therapeutics International Limited - Ireland	Treatment of aniridia	26/06/2015 13/07/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015
Recombinant human IgG1 kappa light chain monoclonal antibody targeting plasma kallikrein	Dyax Ltd - United Kingdom	Treatment of hereditary angioedema	18/05/2015 08/06/2015 03/09/2015 *(87 days/22 days)*	17/09/2015 09/10/2015
Synthetic hepcidin	Emas Pharma Ltd - United Kingdom	Treatment of beta thalassaemia intermedia and major	13/05/2015 08/06/2015 03/09/2015 *(87 days/22 days)*	17/09/2015 09/10/2015
Autologous human peripheral blood Vdelta1+ T lymphocytes activated in vitro by cytokine and monoclonal antibody treatment	Lymphact - Lymphocyte Activation Technologies S.A. - Portugal	Treatment of chronic lymphocytic leukaemia/ small lymphocytic lymphoma	27/01/2015 16/02/2015 03/09/2015 *(199 days- appeal/ 22 days)*	17/09/2015 09/10/2015
Dronabinol and cannabidiol	GW Research Ltd - United Kingdom	Treatment of glioma	26/06/2015 13/07/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015
2-(2-chlorophenyl)-4-[3-(dimethylamino)phenyl]-5-methyl-1H-pyrazolo[4,3-C]pyridine-3,6(2H,5H)-dione	GenKyoTex Innovation S.A.S. - France	Treatment of systemic sclerosis	25/06/2015 13/07/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015
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 mantle cell lymphoma	19/05/2015 08/06/2015 03/09/2015 *(87 days/22 days)*	17/09/2015 09/10/2015
Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta	Kite Pharma UK, Ltd - United Kingdom	Treatment of primary mediastinal large	19/05/2015 08/06/2015 03/09/2015	17/09/2015 09/10/2015

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chimeric antigen receptor		B-cell lymphoma	*(87 days/22 days)*	
2-chloro-N6-(3-iodobenzyl)adenosine-5'-N-methyluronamide	PBS Regulatory Consulting Group Limited - United Kingdom	Treatment of hepatocellular carcinoma	27/06/2015 13/07/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015
Nimodipine	Dr Stefan Blesse - Germany	Treatment of aneurysmal subarachnoid haemorrhage	21/05/2015 13/07/2015 03/09/2015 *(87 days/22 days)*	17/09/2015 09/10/2015
3-pentylbenzeneacetic acid sodium salt	ProMetic BioTherapeutics Ltd - United Kingdom	Treatment of idiopathic pulmonary fibrosis	19/05/2015 13/07/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015
Ovine-specific immunoglobulin (Fab) fragments raised against Vipera berus venom	MicroPharm Limited - United Kingdom	Treatment of snakebite envenomation	11/05/2015 08/06/2015 03/09/2015 *(87 days/22 days)*	17/09/2015 09/10/2015
Mazindol	NeuroLifeSciences - France	Treatment of narcolepsy	09/01/2015 13/07/2015 03/09/2015 *(52 days/22 days)*	17/09/2015 09/10/2015
Sodium phenylbutyrate	Fondazione Telethon - Italy	Treatment of pyruvate dehydrogenase complex deficiency	20/07/2015 17/08/2015 08/10/2015 *(52 days/26 days)*	16/10/2015 11/11/2015
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 acute lymphoblastic leukaemia	26/06/2015 13/07/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015
Adeno-associated viral vector serotype 8 encoding the human ATP7B gene under the control of the human alpha-1 antitrypsin promoter	Aligen Therapeutics S.L. - Spain	Treatment of Wilson's disease	26/06/2015 17/08/2015 08/10/2015 *(52 days/26 days)*	16/10/2015 11/11/2015
N-[5-(3,5-difluorobenzyl)-1H-indazol-3-yl]-4-(4 methylpiperazin-1-yl)-2-(tetrahydro-2H-pyran-4-ylamino)benzamide	Pharma Gateway AB - Sweden	Treatment of neuroblastoma	20/07/2015 17/08/2015 08/10/2015 *(52 days/26 days)*	16/10/2015 11/11/2015
Autologous T cells transduced with retroviral vector encoding	Kite Pharma UK, Ltd - United	Treatment of follicular	20/07/2015 17/08/2015	16/10/2015 11/11/2015

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an anti-CD19 CD28/CD3-zeta chimeric antigen receptor	Kingdom	lymphoma	08/10/2015 *(52 days/26 days)*	
Pentetrazol	Balance Therapeutics, Limited - United Kingdom	Treatment of idiopathic hypersomnia	21/06/2015 13/07/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015
Azacitidine	Celgene Europe Limited - United Kingdom	Treatment of nasopharyngeal carcinoma	23/06/2015 13/07/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015
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 chronic lymphocytic leukaemia/small lymphocytic lymphoma	26/06/2015 13/07/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015
Recombinant human interleukin-3 truncated diphtheria toxin fusion protein	Spector Consulting SAS - France	Treatment of blastic plasmacytoid dendritic cell neoplasm	07/05/2015 13/07/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015
Humanised fusion protein consisting of extracellular domain of CD24 linked to IgG1 Fc domain	Enpharma Ltd - United Kingdom	Prevention of graft-versus-host disease	29/06/2015 13/07/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015
Interferon alfa-n3	NV Hemispherx BioPharma Europe - Belgium	Treatment of Middle East respiratory syndrome	17/06/2015 13/07/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015
(5S,8S,10aR)-N-benzhydryl-5-((S)-2-(methylamino)propanamido)-3-(3-methylbutanoyl)-6-oxodecahydropyrrolo[1,2-a][1,5]diazocine-8-carboxamide	ASPHALION, SL - Spain	Treatment of ovarian cancer	15/07/2015 17/08/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015
Adenovirus associated viral vector serotype 8 containing the human CNGB3 gene	Athena Vision Ltd - United Kingdom	Treatment of achromatopsia caused by mutations in the CNGB3 gene	16/07/2015 17/08/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015

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Humanised monoclonal antibody of the IgG4 kappa isotype targeting CD47	The Chancellor, Masters and Scholars of the University of Oxford - United Kingdom	Treatment of acute myeloid leukaemia	20/07/2015 17/08/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015
Adenovirus associated viral vector serotype 5 containing the human RPE65 gene	Athena Vision Ltd - United Kingdom	Treatment of Leber's congenital amaurosis	16/07/2015 17/08/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015
4'-[(2-Butyl-4-oxo-1,3-diazaspiro[4.4]non-1-en-3-yl)methyl]-N-(4,5-dimethyl-3-isoxazolyl)-2'-(ethoxymethyl)-[1,1'-biphenyl]-2-sulfonamide	Retrophin Europe Limited - Ireland	Treatment of focal segmental glomerulosclerosis	26/06/2015 13/07/2015 08/10/2015 *(87 days/26 days)*	16/10/2015 11/11/2015
Bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts	Voisin Consulting S.A.R.L. - France	Treatment of partial deep dermal and full thickness burns	27/08/2015 14/09/2015 12/11/2015 *(59 days/24 days)*	20/11/2015 14/12/2015
Adeno-associated virus viral vector serotype rh10 encoding containing the human factor IX gene	Pharma Gateway AB - Sweden	Treatment of haemophilia B	27/08/2015 14/09/2015 12/11/2015 *(59 days/24 days)*	20/11/2015 14/12/2015
Sirolimus	Rare Partners srl Impresa Sociale - Italy	Treatment of beta-thalassaemia intermedia and major	20/07/2015 17/08/2015 12/11/2015 *(87 days/24 days)*	20/11/2015 14/12/2015
Synthetic peptide L-Cysteine, L-cysteinylglycyl-L-glutaminyl-L-arginyl-L-.alpha.-glutamyl-L-threonyl-L-prolyl-L-.alpha.-glutamylglycyl-L-alanyl-L-.alpha.-glutamyl-L-alanyl-L-lysyl-L-prolyl-L-tryptophyl-L-tyrosyl-, cyclic (1.fwdarw.17)-disulfide	Apeptico Forschung und Entwicklung GmbH - Austria	Treatment of pseudohypoaldosteronism type 1B	20/08/2015 14/09/2015 12/11/2015 *(59 days/24 days)*	20/11/2015 14/12/2015
Sodium (2R,3S,5R)-5-(4-amino-2-oxo-1,3,5-triazin-1(2H)-yl)-2-(hydroxymethyl)tetrahydrofuran-3-yl ((2R,3S,5R)-5-(2-	Otsuka Pharmaceutical Europe Ltd - United Kingdom	Treatment of acute myeloid leukaemia	26/08/2015 14/09/2015 12/11/2015 *(59 days/24 days)*	20/11/2015 14/12/2015

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amino-6-oxo-1H-purin-9(6H)-yl)-3-hydroxytetrahydrofuran-2-yl)methyl phosphate				
Recombinant human monoclonal IgG1 antibody against programmed death ligand-1	Merck KGaA - Germany	Treatment of Merkel cell carcinoma	12/08/2015 14/09/2015 12/11/2015 *(59 days/24 days)*	20/11/2015 14/12/2015
Live attenuated Listeria monocytogenes delta actA/delta inlB strain expressing human mesothelin	Medpace Germany GmbH - Germany	Treatment of malignant mesothelioma	26/08/2015 14/09/2015 12/11/2015 *(59 days/24 days)*	20/11/2015 14/12/2015
Live attenuated Listeria monocytogenes bioengineered with a chimeric human epidermal growth factor receptor 2 fused to a truncated form of the Lm protein listeriolysin O	Coté Orphan Consulting UK Limited - United Kingdom	Treatment of osteosarcoma	27/08/2015 14/09/2015 12/11/2015 *(59 days/24 days)*	20/11/2015 14/12/2015
Recombinant human nerve growth factor	Dompé farmaceutici S.p.A. - Italy	Treatment of neurotrophic keratitis	20/07/2015 17/08/2015 12/11/2015 *(87 days/24 days)*	20/11/2015 14/12/2015
(R)-1-[1-(4-acetoxy-3,3-dimethyl-2-oxo-butyl)-2-oxo-5-(pyridin-2-yl)-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl]-3-(3-methylamino-phenyl)-urea	Trio Medicines Ltd - United Kingdom	Treatment of gastro-entero-pancreatic neuroendocrine tumours	20/07/2015 17/08/2015 12/11/2015 *(87 days/24 days)*	20/11/2015 14/12/2015
2-(2-chlorobenzylidene)hydrazinecarboximidamide acetate	Inflectis Bioscience - France	Treatment of Charcot-Marie-Tooth disease	27/08/2015 14/09/2015 12/11/2015 *(59 days/24 days)*	20/11/2015 14/12/2015
[4-aminobutanoic acid-glycyl-L-glutaminyl-L-arginyl-L-.alpha.-glutamyl-L-threonyl-L-prolyl-L-.alpha.-glutamylglycyl-L-alanyl-L-.alpha.-glutamyl-L-alanyl-L-lysyl-L-prolyl-L-tryptophyl-L-tyrosyl-L-aspartyl](cyclo 1-Dgamma17)	Apeptico Forschung und Entwicklung GmbH - Austria	Treatment of pseudohypoaldosteronism type 1B	24/08/2015 14/09/2015 12/11/2015 *(59 days/24 days)*	20/11/2015 14/12/2015
Combretastatin A1-	Diamond BioPharm	Treatment of	20/07/2015	20/11/2015

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diphosphate	Limited - United Kingdom	acute myeloid leukaemia	17/08/2015 12/11/2015 *(87 days/24 days)*	14/12/2015
2-amino-2-[2-[2-chloro-4-[[3-(phenylmethoxy)phenyl]thio]phenyl]ethyl]-1,3-propanediol hydrochloride	Novartis Europharm Limited - United Kingdom	Prevention of graft-versus-host disease	16/07/2015 17/08/2015 12/11/2015 *(87 days/24 days)*	20/11/2015 14/12/2015
Variant of recombinant human fibroblast growth factor 19	Diamond BioPharm Limited - United Kingdom	Treatment of primary sclerosing cholangitis	20/07/2015 17/08/2015 12/11/2015 *(87 days/24 days)*	20/11/2015 14/12/2015
Imetelstat sodium	Janssen-Cilag International N.V. - Belgium	Treatment of myelofibrosis	24/08/2015 14/09/2015 12/11/2015 *(59 days/24 days)*	20/11/2015 14/12/2015
Live attenuated Listeria monocytogenes transfected with plasmids encoding the HPV-16E7 protein fused to a truncated fragment of the Lm protein listeriolysin O	Dr Ulrich Granzer - Germany	Treatment of anal cancer	27/08/2015 26/10/2015 10/12/2015 *(45 days/26 days)*	16/12/2015 11/01/2016
Synthetic double-stranded oligomer specific to the SERPINA1 gene and containing a cholesterol-conjugated, acyclic nucleobase analogue	Pharma Gateway AB - Sweden	Treatment of congenital alpha-1 antitrypsin deficiency	24/09/2015 26/10/2015 10/12/2015 *(45 days/26 days)*	16/12/2015 11/01/2016
Sodium benzoate	Syri Limited - United Kingdom	Treatment of argininosuccinic aciduria	14/07/2015 14/09/2015 10/12/2015 *(87 days/26 days)*	16/12/2015 11/01/2016
Sodium benzoate	Syri Limited - United Kingdom	Treatment of hyperargininaemia	14/07/2015 14/09/2015 10/12/2015 *(87 days/26 days)*	16/12/2015 11/01/2016
Two allogenic irradiated pancreatic tumour cell lines	Medpace Germany GmbH - Germany	Treatment of pancreatic cancer	27/08/2015 14/09/2015 10/12/2015 *(87 days/26 days)*	16/12/2015 11/01/2016
Live attenuated Listeria monocytogenes delta actA/delta inlB strain expressing human mesothelin	Medpace Germany GmbH - Germany	Treatment of pancreatic cancer	27/08/2015 14/09/2015 10/12/2015 *(87 days/26 days)*	16/12/2015 11/01/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Entolimod	TMC Pharma Services Ltd - United Kingdom	Treatment of acute radiation syndrome	28/09/2015 26/10/2015 10/12/2015 *(45 days/26 days)*	16/12/2015 11/01/2016
(S)-N-(5-((R)-2-(2,5-difluorophenyl)pyrrolidin-1-yl)pyrazolo[1,5-a]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate	TMC Pharma Services Ltd - United Kingdom	Treatment of soft tissue sarcoma	28/09/2015 26/10/2015 10/12/2015 *(45 days/26 days)*	16/12/2015 11/01/2016
Glibenclamide	AMMTeK - France	Treatment of neonatal diabetes	10/08/2015 14/09/2015 12/11/2015 *(59 days/25 days)*	21/12/2015 15/01/2016

Negative COMP designation opinions

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Nalbuphine hydrochloride	Trevi Therapeutics Limited - United Kingdom	Treatment of uremic pruritus	30/10/2014 17/11/2014 27/02/2015 *(102 days/30 days)*	03/06/2015 03/07/2015

Annex 13 – European Union herbal monographs in 2015

European Union herbal monographs – Final

Abbreviations: TU – traditional use; WEU – well established use; LE – list entry

Reference number	Document title	Adoption / Outcome*
First Assessment		
EMA/HMPC/680597/2013	Agrimoniae herba	28/01/2015 Monograph (TU)
EMA/HMPC/674139/2013	Capsici fructus	05/05/2015 Monograph (WEU)
EMA/HMPC/715094/2013	Carvi aetheroleum	07/07/2015 Monograph (TU)
EMA/HMPC/715092/2013	Carvi fructus	07/07/2015 Monograph (TU)
EMA/HMPC/712511/2014	Epilobii herba	24/11/2015 Monograph (TU)
EMA/HMPC/680372/2013	Eschscholziae herba	28/01/2015 Monograph (TU)
EMA/HMPC/321097/2012	Ginkgo folium	28/01/2015 Monograph (TU+WEU)
EMA/HMPC/278814/2010	Matricariae aetheroleum	07/07/2015 Monograph (TU)
EMA/HMPC/55843/2011	Matricariae flos	07/07/2015 Monograph (TU)
EMA/HMPC/678995/2013	Myrtilli fructus siccus	29/09/2015 Monograph (TU)
EMA/HMPC/375808/2014	Myrtilli fructus recens	29/09/2015 Monograph (TU)
EMA/HMPC/680374/2013	Pilosellae herba cum radice	05/05/2015 Monograph (TU)
EMA/HMPC/280079/2013	Sabalis serrulatae fructus	24/11/2015 Monograph (TU+WEU)
EMA/HMPC/572846/2009	Symphyti radix	05/05/2015 Monograph (TU)
Revision		
EMA/HMPC/277493/2015	Centaurii herba	24/11/2015 Monograph (TU)
EMA/HMPC/586888/2014	Hederae helicis folium	24/11/2015 Monograph (WEU)
EMA/HMPC/377675/2014	Lini semen	10/03/2015 Monograph (TU+WEU)

European Union herbal monographs - Draft

Reference number	Document title	Adoption / Outcome*
First Assessment		
EMA/HMPC/41108/2015	Helichrysi flos	29/09/2015 Monograph (TU)
EMA/HMPC/46758/2015	Pistacia lentiscus, resinum (mastix)	07/07/2015 Monograph (TU)
EMA/HMPC/680624/2013	Pruni africanae cortex	24/11/2015 Monograph (TU)
EMA/HMPC/572974/2014	Ricini oleum	07/07/2015 Monograph (WEU)
EMA/HMPC/39453/2015	Sideritis herba	07/07/2015 Monograph (TU+LE)
EMA/HMPC/294187/2013	Silybi mariani fructus	07/07/2015 Monograph (TU+WEU)
Revision		
EMA/HMPC/436679/2015	Althaeae radix	24/11/2015 Monograph (TU)
EMA/HMPC/278091/2015	Equiseti herba	07/07/2015 Monograph (TU)
EMA/HMPC/444244/2015	Pelargonii radix	29/09/2015 Monograph (TU)
EMA/HMPC/84990/2015	Thymi herba/Primulae radix	28/01/2015 Monograph (TU+WEU)
EMA/HMPC/278053/2015	Valerianae aetheroleum	07/07/2015 Monograph (TU)
EMA/HMPC/150848/2015	Valerianae radix	07/07/2015 Monograph (TU+WEU+LE)

European Union List entries - Draft

Reference number	Document title	Adoption *
First Assessment		
EMA/HMPC/150543/2015	Sideritis herba	07/07/2015
EMA/HMPC/150849/2015	Valerianae radix	07/07/2015
Revision		

Public statements

Reference number	Document title	Adoption
Drafts		
EMA/HMPC/712649/2014	Balsamum peruvianum	24/11/2015
EMA/HMPC/599993/2014	Salviae fruticosae folium	24/11/2015
Final		

Reference number	Document title	Adoption
EMA/HMPC/161476/2014	Picrorhizae kurroae rhizoma	28/01/2015
EMA/HMPC/588732/2014	Uncariae tomentosae cortex	24/11/2015

Annex 14 – Paediatric Committee opinions and EMEA decisions on paediatric investigation plans and waivers in 2015

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

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
(1-methyl-2-nitro-1H-imidazole-5-yl)methyl N,N'-bis(2-bromoethyl) diamidophosphate	not available at present	PIP	PIP agreed	Oncology	Merck KGaA	16/01/2015	P/0045/2015	06/03/2015
Allantoin	ZORBLISA	PIP Modification	Modification agreed	Dermatology	Scioderm, Inc.	16/01/2015	P/0031/2015	12/02/2015
Amikacin	ARIKAYCE(TM) [formerly Liposomal Amikacin for Inhalation (LAI)]	PIP Modification	Modification agreed	Infectious Diseases / Pneumology - Allergology	Insmed Limited	16/01/2015	P/0030/2015	30/01/2015
Amlodipine / Candesartan	Not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Adamed Sp. z o.o.	16/01/2015	P/0051/2015	06/03/2015
Amlodipine / Perindopril	Not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Adamed Sp. z o.o.	16/01/2015	P/0050/2015	06/03/2015
Coagulation Factor VIIa (Recombinant)	not available at present	PIP	PIP agreed	Haematology-Hemostaseology	LFB SA	16/01/2015	P/0042/2015	06/03/2015
Deferasirox	Exjade	PIP Modification	Modification agreed	Haematology-Hemostaseology	Novartis Europharm Limited	16/01/2015	P/0039/2015	06/03/2015
Efinaconazole	Not available at present	PIP	PIP agreed	Infectious Diseases / Dermatology	PharmaSwiss Česká republika s.r.o.	16/01/2015	P/0047/2015	06/03/2015
Human thrombin / Human fibrinogen	Raplixa	PIP Modification	Modification agreed	Other / Haematology-Hemostaseology	ProFibrix BV	16/01/2015	P/0043/2015	06/03/2015
Hydromorphone	not available at	Full Waiver	Full waiver	Other / Pain /	Develco	16/01/2015	P/0048/2015	06/03/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
hydrochloride / Naloxone hydrochloride	present		granted	Gastroenterology-Hepatology	Pharma GmbH			
Inactivated poliovirus: type 3 (Saukett strain) / Inactivated poliovirus: type 2 (MEF-1 strain) / Inactivated poliovirus: type 1 (Mahoney strain) / Bordetella pertussis antigen : Pertactin / Bordetella pertussis antigen : Filamentous Haemagglutinin / Bordetella pertussis antigen : Pertussis toxoid / Tetanus toxoid / Diphtheria toxoid	Boostrix Polio and associated names	PIP Modification	Modification agreed	Vaccines	GlaxoSmithKline Biologocals S.A.	16/01/2015	P/0035/2015	06/03/2015
Lixisenatide	Lyxumia	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	sanofi-aventis R&D	16/01/2015	P/0037/2015	06/03/2015
Oxycodone hydrochloride / Naloxone hydrochloride	not available at present	Full Waiver	Full waiver granted	Other / Pain / Gastroenterology-Hepatology	Develco Pharma GmbH	16/01/2015	P/0049/2015	06/03/2015
Peginterferon beta-1a	Plegridy	PIP Modification	Modification agreed	Neurology	Biogen Idec Ltd	16/01/2015	P/0040/2015	06/03/2015
Sieved freeze-dried allergen extract of Dermatophagoides farinae / Sieved freeze-dried allergen extract of Dermatophagoides pteronyssinus	Not available at present	PIP Modification	Modification agreed	Pneumology - Allergology	STALLERGENES	16/01/2015	P/0033/2015	06/03/2015
Tenofovir Alafenamide / Emtricitabine	Not available at present	PIP	PIP agreed	Infectious Diseases	Gilead Sciences International Ltd.	16/01/2015	P/0032/2015	16/02/2015
albiglutide	Eperzan	PIP	Modification	Endocrinology-	GlaxoSmithKli	16/01/2015	P/0041/2015	06/03/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
		Modification	agreed	Gynaecology-Fertility-Metabolism	ne Trading Services Limited			
eravacycline	not available at present	PIP	PIP agreed	Infectious Diseases	Tetraphase Pharmaceuticals, Inc.	16/01/2015	P/0046/2015	06/03/2015
insulin aspart / insulin degludec	Ryzodeg	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	16/01/2015	P/0034/2015	06/03/2015
olesoxime	not available at present	PIP	PIP agreed	Neurology	Roche Registration Limited	16/01/2015	P/0044/2015	06/03/2015
riociguat	Adempas	PIP Modification	Modification agreed	Cardiovascular Diseases	Bayer Pharma AG	16/01/2015	P/0036/2015	06/03/2015
A derivative of 2-methyl-6-(5-methyl-3-phenyl-isoxazol-4-ylmethoxy)-pyridine (RG1662)	Not available at present	PIP	PIP agreed	Psychiatry	Roche Registration Ltd	13/02/2015	P/0075/2015	01/04/2015
AGOMELATINE	VALDOXAN, THYMANAX	PIP Modification	Modification agreed	Psychiatry	Les Laboratoires Servier	13/02/2015	P/0068/2015	01/04/2015
Anti programmed death-ligand 1 (PD-L1) monoclonal antibody (MPDL3280A)	Not available at present	PIP	PIP agreed	Oncology	Roche Registration Ltd	13/02/2015	P/0076/2015	01/04/2015
Anti proprotein convertase subtilisin/kexin type 9 human monoclonal antibody (AMG 145)	Not available at present	PIP Modification	Modification agreed	Cardiovascular Diseases	Amgen Europe B.V	13/02/2015	P/0071/2015	01/04/2015
Avibactam / Ceftazidime	not available at present	PIP Modification	Modification agreed	Infectious Diseases	AstraZeneca AB	13/02/2015	P/0052/2015	06/03/2015
C3BS-CQR-1	Not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Cardio3 BioSciences SA	13/02/2015	P/0077/2015	01/04/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
Canagliflozin	INVOKANA	PIP Modification	Negative	Endocrinology-Gynaecology-Fertility-Metabolism	Janssen-Cilag International N.V.	13/02/2015	P/0066/2015	01/04/2015
Canakinumab	Ilaris	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Novartis Europharm Ltd	13/02/2015	P/0057/2015	01/04/2015
Canakinumab	NA	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Novartis Europharm Ltd	13/02/2015	P/0058/2015	01/04/2015
Clostridium Botulinum neurotoxin type A (150 kD), free of complexing proteins	Xeomin, Bocouture	PIP Modification	Modification agreed	Ophthalmology / Dermatology / Neurology	Merz Pharmaceuticals GmbH	13/02/2015	P/0067/2015	01/04/2015
Damoctocog alfa pegol	not available at present	PIP Modification	Modification agreed	Haematology-Hemostaseology	Bayer Pharma AG	13/02/2015	P/0070/2015	01/04/2015
Dapagliflozin	FORXIGA	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	13/02/2015	P/0064/2015	01/04/2015
Dolutegravir (DTG)	TIVICAY	PIP Modification	Modification agreed	Infectious Diseases	ViiV Healthcare UK Ltd.	13/02/2015	P/0061/2015	01/04/2015
Glibenclamide	GLIBENTEK	PIP Modification	Modification agreed	Other / Endocrinology-Gynaecology-Fertility-Metabolism	AMMTeK	13/02/2015	P/0072/2015	01/04/2015
Ibuprofen/Codeine	Ibucode	Full Waiver	Full waiver granted	Pain	Laboratórios Vitória, S.A.	13/02/2015	P/0078/2015	01/04/2015
Lamivudine (3TC) / Abacavir (ABC) / Dolutegravir (DTG)	TRIUMEQ	PIP Modification	Modification agreed	Infectious Diseases	ViiV Healthcare UK Limited	13/02/2015	P/0069/2015	01/04/2015
Obeticholic Acid (6 alpha-ethylchenodeoxycholic acid)	Not available at present	PIP Modification	Modification agreed	Gastroenterology-Hepatology	Intercept Italia s.r.l.	13/02/2015	P/0038/2015	20/03/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
Sulbactam (in the form of sodium salt) / Ceftriaxone (in the form of sodium salt)	Elores 1000 mg/500 mg Powder for solution for injection or infusion	PIP	PIP agreed	Infectious Diseases	Venus Pharma GmbH	13/02/2015	P/0054/2015	09/03/2015
Tapentadol	Yantil, Tapentadol Grünenthal, Palexia	PIP Modification	Modification agreed	Pain	Grünenthal GmbH	13/02/2015	P/0056/2015	01/04/2015
Tetrabenazine	Not available at present	PIP	PIP agreed	Neurology	Advicenne Pharma	13/02/2015	P/0074/2015	01/04/2015
Treprostinil	Remodulin	PIP Modification	Negative	Cardiovascular Diseases	United Therapeutics Europe Limited	13/02/2015	P/0059/2015	01/04/2015
bedaquiline (fumarate)	SIRTURO	PIP Modification	Modification agreed	Infectious Diseases	Janssen Infectious Diseases BVBA	13/02/2015	P/0065/2015	01/04/2015
belimumab	BENLYSTA™	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Glaxo Group Limited	13/02/2015	P/0063/2015	01/04/2015
ferumoxytol	Rienso	PIP Modification	Modification agreed	Haematology-Hemostaseology	AMAG Pharmaceuticals, Inc.	13/02/2015	P/0060/2015	01/04/2015
olipudase alfa	not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Genzyme Europe B.V.	13/02/2015	P/0053/2015	06/03/2015
retosiban	Not available at present	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	GlaxoSmithKline Trading Services Limited	13/02/2015	P/0073/2015	01/04/2015
sitagliptin phosphate	Januvia (and related products)	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp and Dohme (Europe), Inc.	13/02/2015	P/0062/2015	01/04/2015
A derivative of (S)-methyl (2-(2-(1H-imidazol-2-	Not available at present	PIP	PIP agreed	Infectious Diseases	Gilead Sciences	20/03/2015	P/0099/2015	08/05/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
yl)pyrrolidin-1-yl)-2-oxoethyl)carbamate / Sofosbuvir					International Ltd.			
Autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD19	not available at present	PIP	PIP agreed	Oncology	Novartis Europharm Limited	20/03/2015	P/0103/2015	11/05/2015
Bilastine	Bilaxten and associated names	PIP Modification	Modification agreed	Dermatology / Pneumology - Allergology / Oto-rhino-laryngology	Faes Farma, S.A.	20/03/2015	P/0102/2015	11/05/2015
Cinacalcet (as hydrochloride)	Mimpara	PIP Modification	Modification agreed	Uro-nephrology	Amgen Europe B.V.	20/03/2015	P/0084/2015	08/05/2015
Human normal immunoglobulin	HyQvia	Full Waiver	Full waiver granted	Neurology	Baxter Innovations GmbH	20/03/2015		00/00/0
Ibodutant	not available at present	PIP	PIP agreed	Gastroenterology-Hepatology	Menarini Ricerche S.p.A.	20/03/2015	P/0104/2015	11/05/2015
Ipilimumab	Yervoy	PIP Modification	Modification agreed	Oncology	Bristol-Myers Squibb Pharma EEIG	20/03/2015	P/0085/2015	08/05/2015
L-Pyr-L-Glu-L-Gln-L-Leu-L-Glu-L-Arg-L-Ala-L-Leu-L-Asn-L-Ser-L-Ser	not available at present	Full Waiver	Full waiver granted	Neurology	ARAIM PHARMA EUROPE LTD.	20/03/2015	P/0101/2015	08/05/2015
Liraglutide	Saxenda	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	20/03/2015	P/0086/2015	08/05/2015
Mepolizumab	Not available at present	PIP Modification	Modification agreed	Haematology-Hemostaseology	GSK Trading Services Limited	20/03/2015	P/0083/2015	08/05/2015
N. meningitidis serogroup Y polysaccharide conjugated	Nimenrix	PIP Modification	Modification agreed	Vaccines	GlaxoSmithKline Biologicals	20/03/2015	P/0089/2015	08/05/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
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					s.a			
Pandemic Influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals: Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004(H5N1) like strain used (NIBRG-14)	Adjupanrix	PIP Modification	Modification agreed	Vaccines	GlaxoSmithKline Biologicals S.A.	20/03/2015	P/0087/2015	08/05/2015
Purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005(H5N1) like strain used (PR8-IBCDC-RG2)	Pumarix	PIP Modification	Modification agreed	Vaccines	GlaxoSmithKline Biologicals S.A.	20/03/2015	P/0088/2015	08/05/2015
Reparixin	Not available at present	Full Waiver	Full waiver granted	Immunology-Rheumatology-Transplantation	Dompé farmaceutici SpA	20/03/2015	P/0100/2015	08/05/2015
SBC-103, recombinant human N-acetylglucosaminidase (rhNAGLU)	Not Available	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Alexion Europe SAS	20/03/2015	P/0082/2015	10/04/2015
Semaglutide	Semaglutide	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	20/03/2015	P/0095/2015	08/05/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
Simtuzumab	Not available at present	PIP	PIP agreed	Gastroenterology-Hepatology	Gilead Sciences International Ltd	20/03/2015	P/0096/2015	08/05/2015
Tanezumab	Not available at present	Full Waiver	Negative	Pain	Pfizer Limited	20/03/2015		00/00/0
anidulafungin	Ecalta	PIP Modification	Modification agreed	Infectious Diseases	Pfizer Limited	20/03/2015	P/0091/2015	08/05/2015
atorvastatin (calcium trihydrate) / Ezetimibe	Atozet and associated names, Orvatez and associated names, Tioblis and associated names, Kexrolt and associated names	Full Waiver	Full waiver granted	Cardiovascular Diseases	Merck Sharp & Dohme Ltd	20/03/2015	P/0079/2015	10/04/2015
belatacept	NULOJIX	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb Pharma EEIG	20/03/2015	P/0080/2015	10/04/2015
human recombinant interleukin-2	Not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Iltoo Pharma	20/03/2015	P/0097/2015	08/05/2015
ivacaftor / 1-(2,2-difluoro-1,3-benzodioxol-5-yl)-N-{1-[(2R)-2,3-dihydroxypropyl]-6-fluoro-2-(1-hydroxy-2-methylpropan-2-yl)-1H-indol-5-yl}cyclopropanecarboxamide	Not available at present	PIP	PIP agreed	Pneumology - Allergology	Vertex Pharmaceuticals (Ltd)	20/03/2015	P/0098/2015	08/05/2015
masitinib (mesylate)	not available at present	PIP	Full waiver granted	Other	AB Science SA	20/03/2015	P/0093/2015	08/05/2015
pixantrone (as dimaleate)	Pixuvri	PIP Modification	Modification agreed	Oncology	CTI Life Sciences Limited	20/03/2015	P/0081/2015	10/04/2015
recombinant human N-acetylgalactosamine-6-	Vimizim (elosulfase alfa)	PIP Modification	Modification agreed	Endocrinology-Gynaecology-	BioMarin Europe	20/03/2015	P/0055/2015	30/03/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
sulfatase				Fertility-Metabolism	Limited			
rivaroxaban	Xarelto	PIP Modification	Modification agreed	Cardiovascular Diseases	Bayer Pharma AG	20/03/2015	P/0090/2015	08/05/2015
sildenafil	Revatio	PIP Modification	Modification agreed	Other	Pfizer Limited	20/03/2015	P/0092/2015	08/05/2015
zanamivir	Relenza	PIP Modification	Modification agreed	Infectious Diseases	GlaxoSmithKline Trading Services Limited	20/03/2015	P/0094/2015	08/05/2015
Alogliptin benzoate (as alogliptin)	Vipidia	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Takeda Development Centre Europe Ltd	17/04/2015	P/0114/2015	05/06/2015
Dronedarone / Ranolazine	not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Gilead Sciences International Ltd	17/04/2015	P/0129/2015	05/06/2015
Dulaglutide	Trulicity	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Eli Lilly & Company	17/04/2015	P/0105/2015	29/04/2015
Human Fibrinogen	not available at present	PIP Modification	Modification agreed	Haematology-Hemostaseology	Octapharma Pharmazeutika Produktionsges.m.b.H	17/04/2015	P/0119/2015	05/06/2015
Human normal immunoglobulin for subcutaneous use	not available at the moment	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology	Kedrion S.p.A.	17/04/2015	P/0113/2015	05/06/2015
Humanised monoclonal antibody IgG2 recognising the interleukin-31 receptor A (IL-31RA)	not available at present	PIP	PIP agreed	Dermatology	Chugai Pharma Europe Ltd	17/04/2015	P/0106/2015	13/05/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
Norovirus GII.4 Virus-Like Particle antigen / Norovirus GI.1 Virus-Like Particle antigen	Not available at present	PIP	PIP agreed	Vaccines	Takeda Vaccines, Inc.	17/04/2015	P/0125/2015	05/06/2015
Palovarotene	Not available at present	PIP	PIP agreed	Other	Clementia Pharmaceuticals Inc.	17/04/2015	P/0127/2015	05/06/2015
Peanut allergen extract	Not available at present	PIP	PIP agreed	Pneumology - Allergology	DBV Technologies S.A.	17/04/2015	P/0121/2015	05/06/2015
Solifenacin succinate	Vesicare	PIP Modification	Modification agreed	Uro-nephrology	Astellas Pharma Europe B.V.	17/04/2015	P/0115/2015	05/06/2015
Telavancin hydrochloride	Vibativ	PIP Modification	Modification agreed	Infectious Diseases	Clinigen Healthcare Ltd	17/04/2015	P/0111/2015	05/06/2015
Tenofovir Alafenamide / Rilpivirine / Emtricitabine	Not available at present	PIP	PIP agreed	Infectious Diseases	Gilead Sciences International Ltd	17/04/2015	P/0107/2015	13/05/2015
apixaban	Eliquis	PIP Modification	Modification agreed	Cardiovascular Diseases	Bristol-Myers Squibb / Pfizer EEIG	17/04/2015	P/0110/2015	05/06/2015
artemether (20 mg) and lumefantrine (120 mg)	Riamet	PIP Modification	Modification agreed	Infectious Diseases	Novartis Europharm Limited	17/04/2015	P/0118/2015	05/06/2015
dupilumab	not available at present	PIP Modification	Modification agreed	Dermatology	Regeneron Pharmaceuticals, Inc	17/04/2015	P/0122/2015	05/06/2015
epratuzumab	Not available at present	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	UCB Pharma S.A.	17/04/2015	P/0120/2015	05/06/2015
ivacaftor	Kalydeco	PIP Modification	Modification agreed	Other	Vertex Pharmaceuticals (Europe)	17/04/2015	P/0112/2015	05/06/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
					Ltd			
levomilnacipran	not available at present	Full Waiver	Negative	Neurology	Pierre Fabre Medicament	17/04/2015	P/0128/2015	05/06/2015
mirabegron	Betmiga	PIP	PIP agreed	Uro-nephrology	Astellas Pharma Europe B.V.	17/04/2015	P/0117/2015	05/06/2015
mirabegron	Betmiga, UPI EMA/179728	PIP Modification	Modification agreed	Uro-nephrology	Astellas Pharma Europe B.V.	17/04/2015	P/0116/2015	05/06/2015
misoprostol	Angusta dispersible tablet	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Azanta Danmark A/S	17/04/2015	P/0124/2015	05/06/2015
tasimelteon	Hetlioz	PIP Modification	Modification agreed	Neurology	Vanda Pharmaceuticals Ltd.	17/04/2015	P/0123/2015	05/06/2015
vericiguat	not available at present	PIP	PIP agreed	Cardiovascular Diseases	Bayer Pharma AG	17/04/2015	P/0126/2015	05/06/2015
(4R,5R)-1-[[4-[[4-[3,3-dibutyl-7-(dimethylamino)-2,3,4,5-tetrahydro-4-hydroxy-1,1-dioxido-1-benzothiepin-5-yl]phenoxy]methyl]phenyl]methyl]-4-aza-1-azoniabicyclo[2.2.2]octane chloride (SHP625)	Not available at present	PIP	PIP agreed	Gastroenterology-Hepatology	Lumena Pharmaceuticals Inc	22/05/2015	P/0149/2015	10/07/2015
Acetylsalicylic acid / Perindopril arginine / Atorvastatin calcium trihydrate	Not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases	Les Laboratoires Servier	22/05/2015	P/0151/2015	10/07/2015
Adalimumab	Humira	PIP Modification	Modification agreed	Immunology-Rheumatology-	AbbVie Limited	22/05/2015	P/0131/2015	12/06/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
				Transplantation / Gastroenterology-Hepatology				
Benralizumab	Not available at present	PIP Modification	Modification agreed	Pneumology - Allergology	MedImmune Ltd	22/05/2015	P/0146/2015	10/07/2015
Calcipotriol	Not available at present	PIP	PIP agreed	Dermatology	Polichem SA	22/05/2015	P/0153/2015	10/07/2015
Cariprazine hydrochloride	Reagila	PIP	PIP agreed	Psychiatry	Gedeon Richter Plc.	22/05/2015	P/0156/2015	10/07/2015
Clonidine	not available at present	Full Waiver	Full waiver granted	Pain	BioDelivery Sciences International, Inc.	22/05/2015	P/0158/2015	10/07/2015
Dimethyl fumarate	Tecfidera	PIP Modification	Modification agreed	Neurology	Biogen Idec Ltd.	22/05/2015	P/0144/2015	10/07/2015
Drisapersen	Not available at present	PIP Modification	Modification agreed	Neurology	BioMarin International Limited	22/05/2015	P/0130/2015	10/06/2015
Eribulin	Halaven	PIP Modification	Modification agreed	Oncology	Eisai Europe Ltd	22/05/2015	P/0136/2015	15/06/2015
Etrolizumab	Not available at present	PIP Modification	Modification agreed	Gastroenterology-Hepatology	Roche Products Limited	22/05/2015	P/0148/2015	10/07/2015
Human normal immunoglobulin for intravenous use	Not available at present	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology	Kedrion S.p.A.	22/05/2015	P/0143/2015	10/07/2015
Humanized anti-IL-6 receptor (IL-6R) monoclonal antibody	Not available at present	PIP	PIP agreed	Neurology	CHUGAI PHARMA EUROPE LTD	22/05/2015	P/0154/2015	10/07/2015
Loxapine	ADASUVE	PIP Modification	Modification agreed	Psychiatry	Ferrer Internacional, S.A.	22/05/2015	P/0145/2015	10/07/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
Mepolizumab	Nucala	PIP Modification	Modification agreed	Pneumology - Allergology	GSK Trading Services Limited	22/05/2015	P/0139/2015	10/07/2015
Meropenem	Not available	PIP Modification	Modification agreed	Neonatology - Paediatric Intensive Care / Infectious Diseases	NeoMero Consortium	22/05/2015	P/0159/2015	13/07/2015
Momelotinib	Not available at present	PIP	PIP agreed	Oncology	Gilead Sciences International Ltd	22/05/2015	P/0157/2015	10/07/2015
Recombinant Coagulation Factor VIII SingleChain (rVIII-SingleChain)	Lonoctocog alfa	PIP Modification	Modification agreed	Haematology-Hemostaseology	CSL Behring GmbH	22/05/2015	P/0109/2015	01/06/2015
Selumetinib	not available at present	PIP	PIP agreed	Oncology	AstraZeneca AB	22/05/2015	P/0152/2015	10/07/2015
Sunitinib malate	Sutent	PIP Modification	Modification agreed	Oncology	Pfizer Limited	22/05/2015	P/0108/2015	01/06/2015
Teduglutide ([gly2] recombinant human glucagon-like peptide)	Revestive (R)	PIP Modification	Modification agreed	Gastroenterology-Hepatology	NPS Pharma Holdings Limited	22/05/2015	P/0137/2015	26/06/2015
Tocilizumab	RoActemra	Full Waiver	Full waiver granted	Immunology-Rheumatology-Transplantation	Roche Registration Limited	22/05/2015	P/0135/2015	15/06/2015
Tocilizumab	RoActemra	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Roche Registration Limited	22/05/2015	P/0134/2015	15/06/2015
ataluren	Translarna	PIP Modification	Modification agreed	Neurology	PTC Therapeutics International, Limited	22/05/2015	P/0132/2015	12/06/2015
ataluren	Translarna	PIP Modification	Modification agreed	Pneumology - Allergology	PTC Therapeutics	22/05/2015	P/0133/2015	12/06/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
					International, Limited			
ciclosporin	VEKACIA®	PIP Modification	Modification agreed	Ophthalmology	SANTEN SAS	22/05/2015	P/0142/2015	10/07/2015
dalbavancin	Xydalba	PIP Modification	Modification agreed	Infectious Diseases	Durata Therapeutics International B.V.	22/05/2015	P/0138/2015	10/07/2015
dupilumab	Not available	PIP Modification	Modification agreed	Pneumology - Allergology	sanofi-aventis Recherche & Développement	22/05/2015	P/0160/2015	13/07/2015
gabapentin	Not available at present	PIP Modification	Modification agreed	Pain	PHARM SRL	22/05/2015	P/0147/2015	10/07/2015
letermovir	not available at present	PIP	PIP agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	22/05/2015	P/0155/2015	10/07/2015
posaconazole	Noxafil	PIP Modification	Modification agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	22/05/2015	P/0141/2015	10/07/2015
secukinumab	Cosentyx	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Novartis Europharm Ltd	22/05/2015	P/0140/2015	10/07/2015
sotagliflozin	not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Lexicon Celtic Limited	22/05/2015	P/0150/2015	10/07/2015
(S)-1-{5-Phenyl-4-[(pyridin-2-ylmethyl)-amino]-thieno[2,3-d]pyrimidin-2-yl}-piperidine-3-carboxylic acid (2-hydroxy-ethyl)-amide	Not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Xention Limited	19/06/2015	P/0179/2015	07/08/2015
Apremilast	Otezla	PIP Modification	Modification agreed	Immunology-Rheumatology-	Celgene Europe	19/06/2015	P/0166/2015	07/08/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
				Transplantation	Limited			
Apremilast	Otezla	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation		19/06/2015	P/0167/2015	07/08/2015
Atrasentan hydrochloride	Not available at present	PIP	PIP agreed	Uro-nephrology	AbbVie, Ltd	19/06/2015	P/0175/2015	07/08/2015
Brentuximab vedotin	Adcetris	Full Waiver	Full waiver granted	Oncology	Takeda Pharma A/S	19/06/2015	P/0168/2015	07/08/2015
Clonidine (hydrochloride)	Not available at present	PIP Modification	Modification agreed	Anaesthesiology	Therakind Limited	19/06/2015	P/0172/2015	07/08/2015
DNA, d(P-thio)([2'-0-(2-methoxyethyl)]m5rU-[2'-0-(2-methoxyethyl)]m5rC-[2'-0-(2-methoxyethyl)]m5rU-[2'-0-(2-methoxyethyl)]m5rU-[2'-0-(2-methoxyethyl)]rG-G-T-T-A-m5C-A-T-G-A-A-[2'-0-(2-methoxyethyl)]rA-[2'-0-(2-methoxyethyl)]m5rU-[2'-0-(2-methoxyethyl)]m5rC-[2'-0-(2-methoxyethy l)]m5rC-[2'-0-(2-methoxyethyl)]m5rC), sodium salt	Not available at present	Full Waiver	Full waiver granted	Neurology	Isis Pharmaceuticals, Inc.	19/06/2015	P/0181/2015	07/08/2015
Dapagliflozin	Forxiga	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	19/06/2015	P/0161/2015	09/07/2015
Enalapril (maleate)	Not applicable	PIP	PIP agreed	Cardiovascular Diseases	Ethicare GmbH	19/06/2015	P/0176/2015	07/08/2015
Human Thrombin / Human Fibrinogen	EVARREST, EVICEL	PIP Modification	Modification agreed	Other	Omrix Biopharmaceuticals N.V.	19/06/2015	P/0171/2015	07/08/2015
Influenza virus surface	Influvac® Quadrivalent	PIP	PIP agreed	Vaccines	Abbott	19/06/2015	P/0182/2015	07/08/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
antigens (haemagglutinin and neuraminidase) of the following strains: A/(H1N1), A/(H3N2), B/Yamagata lineage, B/Victoria lineage	(to be confirmed)				Biologicals B.V.			
Ivabradine (hydrochloride) / Carvedilol	Not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Les Laboratoires Servier	19/06/2015	P/0178/2015	07/08/2015
L-Seryl-L-arginyl-L-valyl-L-leucyl-L-aspartyl-glycyl-L-leucyl-L-valyl-L-methionyl-L-threonyl-L-threonyl-L-isoleucyl-L-seryl-L-seryl-L-seryl-L-lysine, acetate salt / L-Threonyl-L-alanyl-L-methionyl-L-lysyl-L-lysyl-L-isoleucyl-L-glutaminyl-L-aspartyl-L-cysteinyl-L-tyrosyl-L-valyl-L-glutamyl-L-asparaginyl-glycyl-L-leucyl-L-isoleucine, acetate salt / L-Lysyl-L-glutamyl-L-asparaginyl-L-alanyl-L-leucyl-L-seryl-L-leucyl-L-leucyl-L-aspartyl-L-lysyl-L-isoleucyl-L-tyrosyl-L-threonyl-L-seryl-L-prolyl-L-leucine, acetate salt / L-Arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginyl-L-cysteinyl-L-valyl-L-aspartyl-L-alanyl-L-lysyl-L-methionyl-L-threonyl-L-glutamyl-L-glutamyl-L-aspartyl-L-lysyl-L-glutamic acid, acetate salt / L-Lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginyl-L-alanyl-L-arginyl-L-isoleucyl-L-leucyl-	Not available at present	PIP Modification	Modification agreed	Pneumology - Allergology / Oto-rhino-laryngology	Circassia Limited	19/06/2015	P/0170/2015	07/08/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
L-lysyl-L-asparaginyl-L-cysteinyl-L-valine, acetate salt / L-Glutamyl-L-glutaminyl-L-valyl-L-alanyl-L-glutaminyl-L-tyrosyl-L-lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginyl-L-alanine, acetate salt / L-Cysteinyl-L-prolyl-L-alanyl-L-valyl-L-lysyl-L-arginyl-L-aspartyl-L-valyl-L-aspartyl-L-leucyl-L-phenylalanyl-L-leucyl-L-threonine, hydrochloride salt								
Live, attenuated, chimeric dengue virus, serotype 3 / Live, attenuated, chimeric dengue virus, serotype 2 / Live, attenuated, chimeric dengue virus, serotype 1 / Live, attenuated, chimeric dengue virus, serotype 4	Dengvaxia/DengueVax	PIP Modification	Modification agreed	Vaccines	Sanofi pasteur	19/06/2015	P/0174/2015	07/08/2015
Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; Escherichia coli) / Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; Escherichia coli)	Trumenba, Abrytna and Mabnara	PIP Modification	Modification agreed	Vaccines	Pfizer Ltd	19/06/2015	P/0169/2015	07/08/2015
Recombinant human nerve growth factor	Not available at present	PIP	PIP agreed	Ophthalmology	Dompé farmaceutici SpA	19/06/2015	P/0177/2015	07/08/2015
Rifamycin	Not available at present	Full Waiver	Full waiver granted	Infectious Diseases	Dr. Falk Pharma GmbH	19/06/2015	P/0180/2015	07/08/2015
Sebelipase alfa	Kanuma	PIP	Modification	Endocrinology-	Alexion	19/06/2015	P/0173/2015	07/08/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
		Modification	agreed	Gynaecology-Fertility-Metabolism / Gastroenterology-Hepatology	Europe SAS			
Tadalafil	Cialis, Adcirca	PIP Modification	Modification agreed	Cardiovascular Diseases	Eli Lilly and Company Ltd	19/06/2015	P/0165/2015	07/08/2015
etravirine	Intelence	PIP Modification	Modification agreed	Infectious Diseases	Janssen-Cilag International NV	19/06/2015	P/0163/2015	07/08/2015
ipilimumab	Yervoy	PIP Modification	Modification agreed	Oncology	Bristol-Myers Squibb Pharma EEIG	19/06/2015	P/0162/2015	10/07/2015
ivacaftor / lumacaftor	Orkambi	PIP Modification	Modification agreed	Pneumology - Allergology	Vertex Pharmaceuticals (Europe) Ltd.	19/06/2015	P/0185/2015	24/08/2015
vilanterol / fluticasone furoate	Relvar Ellipta	PIP Modification	Modification agreed	Pneumology - Allergology	Glaxo Group Limited	19/06/2015	P/0164/2015	07/08/2015
glucagon	not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Lilly UK	09/07/2015	P/0184/2015	21/08/2015
Azithromycin	AzaSite	PIP	Full waiver granted	Ophthalmology	Laboratoires Doliage (Groupe Nicox)	17/07/2015	P/0203/2015	04/09/2015
Bilastine	Bilaxten and associated names	PIP Modification	Modification agreed	Dermatology / Pneumology - Allergology / Oto-rhino-laryngology	Faes Farma, S.A.	17/07/2015	P/0189/2015	04/09/2015
Eliglustat	Cerdelga	PIP Modification	Modification agreed	Other	Genzyme Europe B.V.	17/07/2015	P/0191/2015	04/09/2015
Human normal immunoglobulin	HyQvia	PIP Modification	Modification agreed	Immunology-Rheumatology-	Baxalta Innovations	17/07/2015	P/0186/2015	27/08/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
				Transplantation	GmbH			
Hydrochlorothiazide / Nebivolol hydrochloride	Nebivolol/Hydrochlorothiazide Actavis	Full Waiver	Full waiver granted	Cardiovascular Diseases	Actavis Group PTC ehf	17/07/2015	P/0200/2015	04/09/2015
L-asparaginase encapsulated in erythrocytes	GRASPA	PIP Modification	Modification agreed	Oncology	ERYTECH pharma S.A.	17/07/2015	P/0188/2015	04/09/2015
Omecamtiv mecarbil	not available at present	PIP	PIP agreed	Cardiovascular Diseases	Amgen Europe B.V.	17/07/2015	P/0197/2015	04/09/2015
Ozanimod	Not available at present	PIP	PIP agreed	Neurology	Receptos UK Limited	17/07/2015	P/0198/2015	04/09/2015
Raxibacumab	Not available at present	PIP	PIP agreed	Infectious Diseases	GlaxoSmithKline Trading Services Limited	17/07/2015	P/0196/2015	04/09/2015
Tenofovir (disoproxil fumarate)	Viread	PIP Modification	Modification agreed	Infectious Diseases	Gilead Sciences International Ltd	17/07/2015	P/0192/2015	04/09/2015
Tenofovir Alafenamide / Emtricitabine / Cobicistat / Elvitegravir	Not available at present	PIP Modification	Modification agreed	Infectious Diseases	Gilead Sciences International Ltd.	17/07/2015	P/0195/2015	04/09/2015
amlodipine / perindopril (tert-butylamine) / rosuvastatin	not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases	Krka, d.d., Novo mesto	17/07/2015	P/0202/2015	04/09/2015
enclomifene (citrate)	Not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	Renable Pharma Limited	17/07/2015	P/0204/2015	04/09/2015
indapamide / perindopril (tert-butylamine) / rosuvastatin	not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism /	Krka, d.d., Novo mesto	17/07/2015	P/0201/2015	04/09/2014

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
				Cardiovascular Diseases				
lacosamide	VIMPAT	PIP Modification	Modification agreed	Neurology	UCB Pharma S.A.	17/07/2015	P/0183/2015	17/08/2015
mometasone furoate / indacaterol acetate	not available at present	PIP Modification	Modification agreed	Pneumology - Allergology	Novartis Europharm Limited	17/07/2015	P/0193/2015	04/09/2015
raltegravir	ISENTRESS	PIP Modification	Modification agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	17/07/2015	P/0187/2015	04/09/2015
recombinant human tripeptidyl peptidase 1 (rhTPP1	Not available at present	PIP Modification	Modification agreed	Neurology	BioMarin International Limited	17/07/2015	P/0209/2015	18/09/2015
retosiban	Not available at present	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	GlaxoSmithKline Trading Services Limited	17/07/2015	P/0194/2015	04/09/2015
torasemide / lisinopril	not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Accupharma spółka z ograniczoną odpowiedzialnością	17/07/2015	P/0199/2015	04/09/2015
vortioxetine	Brintellix	PIP Modification	Modification agreed	Psychiatry	H. Lundbeck A/S	17/07/2015	P/0190/2015	04/09/2015
Adenovirus associated viral vector serotype 2 containing the human RPE65 gene	Not available at present	PIP	PIP agreed	Ophthalmology	Spark Therapeutics Inc	14/08/2015	P/0221/2015	02/10/2015
Alpha Connexin C-terminal 1 peptide (ACT1)	Granexin gel	Full Waiver	Full waiver granted	Dermatology	FirstString Research Inc	14/08/2015	P/0225/2015	02/10/2015
Anti programmed death-ligand 1 (PD-L1) monoclonal antibody (MPDL3280A)	Not available at present	PIP Modification	Modification agreed	Oncology	Roche Registration Ltd	14/08/2015	P/0220/2015	02/10/2015
Azilsartan medoxomil	Edarbi	PIP Modification	Modification agreed	Cardiovascular Diseases	Takeda Development	14/08/2015	P/0210/2015	02/10/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
					Centre Europe Limited			
Botulinum Neurotoxin Type A	Not available at present	Full Waiver	Full waiver granted	Dermatology	CROMA PHARMA GmbH	14/08/2015	P/0224/2015	02/10/2015
Brexpiprazole	Not available at present	PIP Modification	Modification agreed	Psychiatry	Otsuka Europe Development and Commercialisation Ltd, Zweigniederlassung Frankfurt am Main	14/08/2015	P/0215/2015	02/10/2015
Canagliflozin (1s)-1,5-anhydro-1-[3-[[5-(4-fluorophenyl)-2-thienyl]methyl]-4-methylphenyl]-D-glucitol hemihydrate	Invokana	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Janssen-Cilag International NV	14/08/2015	P/0212/2015	02/10/2015
Dopamine hydrochloride	Not available at present	PIP Modification	Modification agreed	Cardiovascular Diseases	BrePco Biopharma Limited	14/08/2015	P/0213/2015	02/10/2015
Empagliflozin	Jardiance	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	14/08/2015	P/0211/2015	02/10/2015
Naloxone (hydrochloride)	not available at present	PIP Modification	Modification agreed	Pain / Gastroenterology-Hepatology	Develco Pharma GmbH	14/08/2015	P/0219/2015	02/10/2015
Naloxone hydrochloride / Hydromorphone hydrochloride	Not available at present	Full Waiver	Full waiver granted	Pain	Mundipharma Research GmbH & Co. KG	14/08/2015	P/0223/2015	02/10/2015
Odanacatib	not available at present	PIP Modification	Modification agreed	Immunology-Rheumatology-	Merck Sharp & Dohme	14/08/2015	P/0206/2015	07/09/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
				Transplantation	(Europe), Inc.			
Pegylated recombinant factor VIII	Not available at present	PIP Modification	Modification agreed	Haematology-Hemostaseology	Baxalta Innovations GmbH	14/08/2015	P/0208/2015	11/09/2015
Sucroferric oxyhydroxide (mixture of iron(III)-oxyhydroxide, sucrose, starch) (PA21)	Velphoro	PIP Modification	Modification agreed	Uro-nephrology	Vifor Fresenius Medical Care Renal Pharma France	14/08/2015	P/0205/2015	04/09/2015
Vonicog alfa (recombinant human von Willebrand Factor)	Not available at present	PIP Modification	Modification agreed	Haematology-Hemostaseology	Baxalta Innovations GmbH	14/08/2015	P/0214/2015	02/10/2015
acotiamide	not available at present	PIP	PIP agreed	Gastroenterology-Hepatology	Zeria Pharmaceutical Co Ltd	14/08/2015	P/0218/2015	02/10/2015
azacitidine	Vidaza (azacitidine)	PIP Modification	Modification agreed	Oncology / Haematology-Hemostaseology	Celgene Europe Ltd	14/08/2015	P/0217/2015	02/10/2015
linagliptin	Trajenta	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	14/08/2015	P/0207/2015	10/09/2015
peanut flour	Not available at present - currently known as CPNA	PIP	PIP agreed	Pneumology - Allergology	Aimmune Therapeutics	14/08/2015	P/0222/2015	02/10/2015
tafluprost	TAFLOTAN and associated names	PIP Modification	Modification agreed	Ophthalmology	Santen Oy	14/08/2015	P/0216/2015	02/10/2015
(3-((4-Benzoyl-1-piperazinyl)(oxo)acetyl)-4-methoxy-7-(3-methyl-1H-1,2,4-triazol-1-yl)-1H-pyrrolo[2,3-c]pyridin-1-yl)methyl dihydrogen phosphate, 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1) (BMS-	Not available at present	PIP	PIP agreed	Infectious Diseases	Bristol-Myers Squibb International Corporation	11/09/2015	P/0258/2015	30/10/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
663068)								
18F-fluoroestradiol	EstroTep	Full Waiver	Full waiver granted	Diagnostic / Oncology	LABORATOIRES CYCLOPHARMA	11/09/2015	P/0262/2015	30/10/2015
Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human βA-T87Q-globin gene	not available at present	PIP	PIP agreed	Haematology-Hemostaseology	bluebird bio France	11/09/2015	P/0257/2015	30/10/2015
Brivaracetam	Not available at present	PIP Modification	Modification agreed	Neurology	UCB Pharma SA	11/09/2015	P/0242/2015	30/10/2015
Calcium, hydrolyzed divinylbenzene-Me 2-fluoro-2-propenoate-1,7-octadiene polymer sorbitol complexes	Not available at present	PIP	PIP agreed	Other	Vifor Fresenius Medical Care Renal Pharma France	11/09/2015	P/0235/2015	27/10/2015
Canakinumab	Ilaris	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Novartis Europharm Ltd	11/09/2015	P/0238/2015	30/10/2015
Ceftazidime / Avibactam	Zavicefta	PIP Modification	Modification agreed	Infectious Diseases	AstraZeneca AB	11/09/2015	P/0251/2015	30/10/2015
Chloroprocaine Hydrochloride	Ampres/Clorotekal/Decelex	PIP Modification	Full waiver granted	Anaesthesiology	Sintetica Italia Srl	11/09/2015	P/0231/2015	27/10/2015
Ciclosporin	Restasis	Full Waiver	Full waiver granted	Ophthalmology	Allergan Pharmaceuticals Ireland	11/09/2015	P/0234/2015	27/10/2015
Dapagliflozin	Forxiga	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca ab	11/09/2015	P/0247/2015	30/10/2015
Everolimus	Votubia	PIP Modification	Modification agreed	Uro-nephrology / Neurology	Novartis Europharm Limited	11/09/2015	P/0236/2015	30/10/2015
Ex vivo expanded	Holoclar	PIP	Modification	Ophthalmology	Chiesi	11/09/2015	P/0248/2015	30/10/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
autologous human corneal epithelial cells containing stem cells		Modification	agreed		Farmaceutici S.p.A.			
Gevokizumab	Not available at present	Full Waiver	Full waiver granted	Immunology-Rheumatology-Transplantation	Les laboratoires Servier	11/09/2015	P/0253/2015	30/10/2015
L-Cysteine, L-leucyl-L-α-glutamyl-L-α-glutamyl-L-lysyl-L-lysylglycyl-L-asparaginyl-L-tyrosyl-L-valyl-L-valyl-L-threonyl-L-α-aspartyl-L-histidyl-S-[1-[(4-carboxycyclohexyl)methyl]-2,5-dioxo-3-pyrrolidinyl]-,complex with hemocyanin (Megathura crenulata)	Not available at present	Full Waiver	Full waiver granted	Oncology	Celldex Therapeutics, Inc.	11/09/2015	P/0259/2015	30/10/2015
Lonoctocog alfa	SOLCHAYN	PIP Modification	Modification agreed	Haematology-Hemostaseology	CSL Behring GmbH	11/09/2015	P/0227/2015	02/10/2015
Maraviroc	Celsentri	PIP Modification	Modification agreed	Infectious Diseases	ViiV Healthcare UK Ltd	11/09/2015	P/0237/2015	30/10/2015
Melatonin	Circadin	PIP Modification	Modification agreed	Neurology	RAD Neurim Pharmaceuticals EEC Ltd	11/09/2015	P/0244/2015	30/10/2015
Meropenem trihydrate (in combination with vaborbactam)	not available at present	PIP	PIP agreed	Infectious Diseases	Rempex Pharmaceuticals, a wholly-owned subsidiary of The Medicines Company	11/09/2015	P/0229/2015	22/10/2015
Mogamulizumab	not available at present	Full Waiver	Full waiver granted	Oncology	ProStrakan Ltd	11/09/2015	P/0260/2015	30/10/2015
Mogamulizumab	not available at present	Full Waiver	Full waiver granted	Oncology		11/09/2015	P/0261/2015	30/10/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
Nintedanib	Ofev	Full Waiver	Full waiver granted	Immunology-Rheumatology-Transplantation / Pneumology - Allergology	Boehringer Ingelheim International GmbH	11/09/2015	P/0233/2015	27/10/2015
Recommended INN for LCZ696: sacubitril/valsartan / Octadecasodium hexakis(4-{[(1S,3R)-1-([1,1´-biphenyl]-4-ylmethyl)-4-ethoxy-3-methyl-4-oxobutyl]amino}-4-oxobutanoate) hexakis(N-pentanoyl-N-{[2´-(1H-tetrazol-1-id-5-yl)[1,1´-biphenyl]-4-yl]methyl}-L-valinate)—water (1/15)	Not available at present	PIP Modification	Modification agreed	Cardiovascular Diseases	Novartis Europharm Ltd	11/09/2015	P/0240/2015	30/10/2015
Ritonavir / Paritaprevir / Ombitasvir / Dasabuvir	Not available at present	PIP	Full waiver granted	Infectious Diseases	AbbVie Ltd	11/09/2015	P/0228/2015	02/10/2015
Simtuzumab	Not available at present	PIP	PIP agreed	Pneumology - Allergology	Gilead Sciences International Ltd	11/09/2015	P/0254/2015	30/10/2015
Split influenza virus, inactivated containing antigens equivalent to the B-like strain Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (B/Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-	Not available at present (INN: Influenza vaccine (split virion, inactivated))	PIP Modification	Modification agreed	Vaccines	Sanofi Pasteur (SP),	11/09/2015	P/0249/2015	30/10/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
like strain								
Teduglutide ([gly2] recombinant human glucagon-like peptide)	Revestive (R)	PIP Modification	Modification agreed	Gastroenterology-Hepatology	Shire Pharmaceuticals Ireland Limited	11/09/2015	P/0245/2015	30/10/2015
begelomab	BEGEDINA (proposed)	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	ADIENNE S.r.l. S.U.	11/09/2015	P/0226/2015	02/10/2015
canakinumab	Ilaris	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	11/09/2015	P/0239/2015	30/10/2015
darbepoetin alfa	Aranesp	PIP Modification	Modification agreed	Oncology / Uro-nephrology	Amgen Europe B.V.	11/09/2015	P/0241/2015	30/10/2015
fluciclovine (18F)	Not available at present	PIP	PIP agreed	Diagnostic / Oncology	Blue Earth Diagnostics Ltd	11/09/2015	P/0256/2015	30/10/2015
gabapentin	not available	PIP Modification	Modification agreed	Pain	PHARM SRL	11/09/2015	P/0250/2015	30/10/2015
ibrutinib	Imbruvica	PIP	PIP agreed	Oncology	Janssen-Cilag International N.V.	11/09/2015	P/0252/2015	30/10/2015
icatibant acetate	Firazyr	PIP Modification	Modification agreed	Other	Shire Orphan Therapies GmbH	11/09/2015	P/0243/2015	30/10/2015
recombinant parathyroid hormone [rhPTH(1-84)]	Natpar	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	NPS Pharma Holdings Limited	11/09/2015	P/0255/2015	30/10/2015
tenofovir disoproxil / rilpivirine / emtricitabine	Eviplera	PIP Modification	Modification agreed	Infectious Diseases	Gilead Sciences International Ltd	11/09/2015	P/0232/2015	27/10/2015
vaborbactam (in combination with	not available at present	PIP	PIP agreed	Infectious Diseases	Rempex Pharmaceutica	11/09/2015	P/0230/2015	22/10/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
meropenem)					ls, a wholly-owned subsidiary of The Medicines Company			
volasertib	not available at present	PIP Modification	Modification agreed	Oncology	Boehringer Ingelheim International GmbH	11/09/2015	P/0246/2015	30/10/2015
(3S,4R)-3-ethyl-4-(3H-imidazo[1,2-a]pyrrolo[2,3-e]pyrazin-8-yl)-N-(2,2,2-trifluoroethyl)pyrrolidine-1-carboxamide (2R,3R)-2,3-dihydroxybutanedioate (ABT 494)	Not available at present	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	AbbVie Ltd	09/10/2015	P/0288/2015	27/11/2015
4-Amino-2-butoxy-8-[3-(pyrrolidin-1-ylmethyl)benzyl]-7,8-dihydropteridin-6(5H)-one (GS-9620)	not available at present	PIP	PIP agreed	Infectious Diseases	Gilead Sciences International Ltd.	09/10/2015	P/0289/2015	27/11/2015
ASP1707	Not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	Astellas Pharma Europe B.V.	09/10/2015	P/0292/2015	27/11/2015
Allergen extracts of Dermatophagoides farinae and Dermatophagoides pteronyssinus (each 50%)	SLIToneULTRA Der. far. + Der. pte (former Allerbio Sublingual Forte)	PIP Modification	Modification agreed	Other	ALK-Abelló A/S	09/10/2015	P/0280/2015	27/11/2015
Allergenes from Dermatophagoides pteronyssinus and Dermatophagoides farinae	Avanz Mite mix	PIP Modification	Modification agreed	Other	ALK-Abelló A/S	09/10/2015	P/0274/2015	27/11/2015
Benralizumab	Not available at present	PIP Modification	Modification agreed	Pneumology - Allergology	MedImmune Ltd	09/10/2015	P/0283/2015	27/11/2015
Dermatophagoides	SQ HDM SLIT-tablet	PIP	Modification	Pneumology -	ALK-Abelló	09/10/2015	P/0284/2015	27/11/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
pteronyssinus/Dermatophagoides farinae (50%/50%)	(previously ALK HDM AIT)	Modification	agreed	Allergology	A/S			
Dimethyl fumarate (DMF)	not available at present	PIP	Full waiver granted	Dermatology	Almirall S.A., 151, Barcelona – Spain	09/10/2015	P/0287/2015	26/11/2015
Elvitegravir	Vitekta	PIP Modification	Modification agreed	Infectious Diseases	Gilead Sciences International Ltd	09/10/2015	P/0265/2015	06/11/2015
Febuxostat	Adenuric	PIP Modification	Modification agreed	Oncology	Menarini International Operations Luxembourg S.A.	09/10/2015	P/0285/2015	27/11/2015
Lebrikizumab	not available at present	PIP Modification	Modification agreed	Pneumology - Allergology	Roche Product Limited	09/10/2015	P/0281/2015	27/11/2015
Lomitapide (as lomitapide mesylate)	Lojuxta	PIP Modification	Modification agreed	Other	Aegerion Pharmaceuticals Limited	09/10/2015	P/0282/2015	27/11/2015
Olaratumab	Not available at present	PIP	PIP agreed	Oncology	Eli Lilly and Company Limited	09/10/2015	P/0290/2015	27/11/2015
Oseltamivir Phosphate	Tamiflu	PIP Modification	Modification agreed	Infectious Diseases	Roche Registration Limited	09/10/2015	P/0267/2015	27/11/2015
Peanut allergen extract	Not available at present	PIP Modification	Modification agreed	Pneumology - Allergology	DBV Technologies S.A.	09/10/2015	P/0286/2015	27/11/2015
Pollen from Alnus glutinosa, Betula verrucosa and Corylus avellana	Avanz Tree mix	PIP Modification	Modification agreed	Other	ALK-Abelló A/S	09/10/2015	P/0276/2015	27/11/2015
Pollen from Betula pendula	SLIToneULTRA Birch (former Allerbio Sublingual Forte)	PIP Modification	Modification agreed	Other	ALK-Abelló A/S	09/10/2015	P/0278/2015	27/11/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
Pollen from Betula pendula, Corylus avellana and Alnus glutinosa (33 % each)	SLITone ULTRA Birch+Hazel+Alder (former Allerbio Sublingual Forte)	PIP Modification	Modification agreed	Other	ALK-Abelló A/S	09/10/2015	P/0277/2015	27/11/2015
Pollen from Betula verrucosa	Avanz Birch	PIP Modification	Modification agreed	Other	ALK-Abelló A/S	09/10/2015	P/0273/2015	27/11/2015
Pollen from Dactylis glomarata (16%), Lolium perenne (16%), Phleum pratense (16%), Poa pratensis (16%), Anthoxanthum odoratum (16 %) and Secale cereale (20%)	SLIToneULTRA 5-grass mix + rye (former Allerbio Sublingual Forte)	PIP Modification	Modification agreed	Other	ALK-Abelló A/S	09/10/2015	P/0279/2015	27/11/2015
Pollen from Dactylis glomerata, Lolium perenne, Phleum pratense, Festuca pratensis, Secale cereale	Avanz 4 grass mix and rye	PIP Modification	Modification agreed	Other	ALK-Abelló A/S	09/10/2015	P/0272/2015	27/11/2015
Pollen from Phleum pratense	Avanz Phleum pratense	PIP Modification	Modification agreed	Other	ALK-Abelló A/S	09/10/2015	P/0275/2015	27/11/2015
Rufinamide	Inovelon 40 mg/mL Oral Suspension	PIP Modification	Negative	Neurology	Eisai Limited	09/10/2015	P/0263/2015	30/10/2015
Tocilizumab	RoActemra	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Roche Registration Limited	09/10/2015	P/0266/2015	27/11/2015
Vigabatrin	Not available at present	PIP Modification	Modification agreed	Neurology	ORPHELIA Pharma SA	09/10/2015	P/0271/2015	27/11/2015
Yersinia pestis recombinant F1V antigen (rF1V: F1 capsular protein fused to V antigen) vaccine	Not available at present	Full Waiver	Negative	Vaccines	DynPort Vaccine Company LLC	09/10/2015		00/00/0
amlodipine (besilate) / Olmesartan medoxomil	not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases	Krka, d.d., Novo mesto	09/10/2015	P/0293/2015	27/11/2015
amlodipine (besilate) /	not available at	Full Waiver	Full waiver	Cardiovascular	Krka, d.d.,	09/10/2015	P/0264/2015	30/10/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
Telmisartan	present		granted	Diseases	Novo mesto			
mirabegron	Betmiga	PIP Modification	Modification agreed	Uro-nephrology	Astellas Pharma Europe B.V.	09/10/2015	P/0269/2015	27/11/2015
recombinant human growth hormone fused to hybrid Fc composed of the hinge region and N-terminal of CH2 domain of IgD and C-terminal of CH2 and full CH3 domain of IgG4 (hGH-hyFc)	GX-H9	PIP	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	Genexine, Inc.	09/10/2015	P/0291/2015	27/11/2015
rivaroxaban	Xarelto	PIP Modification	Modification agreed	Cardiovascular Diseases	Bayer Pharma AG	09/10/2015	P/0268/2015	27/11/2015
Apremilast	Otezla	PIP Modification	Modification agreed	Dermatology	Celgene Europe Limited	13/11/2015	P/0300/2015	21/12/2015
C1 inhibitor (human)	Cinryze	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	NPS Pharma Holdings Limited	13/11/2015	P/0299/2015	21/12/2015
Ceftaroline fosamil (established INN)	Zinforo	PIP Modification	Modification agreed	Infectious Diseases	AstraZeneca AB	13/11/2015	P/0301/2015	21/12/2015
Delamanid	Deltyba 50 mg film-coated tablets	PIP Modification	Modification agreed	Infectious Diseases	Otsuka Europe Development and Commercialisation Ltd.	13/11/2015	P/0306/2015	21/12/2015
Ethosuximide	Not available at present	PIP	PIP agreed	Neurology	Advicenne Pharma	13/11/2015	P/0315/2015	21/12/2015
Human normal immunoglobulin	Gammaplex	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Bio Products Laboratory Limited	13/11/2015	P/0295/2015	03/12/2015
Inactivated poliovirus type 3 (Saukett) / Inactivated poliovirus type 2 (MEF-1) / Inactivated poliovirus type 1	Not available at present	Full Waiver	Full waiver granted	Vaccines	Statens Serum Institut	13/11/2015	P/0320/2015	21/12/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
(Brunhilde)								
Ketoprofen	Gesicpad K	Full Waiver	Full waiver granted	Pain	Promo International S.r.l.	13/11/2015	P/0317/2015	21/12/2015
Lamivudine (3TC) / Abacavir (ABC) / Dolutegravir (DTG)	TRIUMEQ	PIP Modification	Modification agreed	Infectious Diseases	ViiV Healthcare UK Limited	13/11/2015	P/0308/2015	21/12/2015
Lipegfilgrastim	Lonquex	PIP Modification	Modification agreed	Oncology	UAB "Sicor Biotech"	13/11/2015	P/0303/2015	21/12/2015
Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; Escherichia coli) / Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; Escherichia coli)	Trumenba, Abrytna and Mabnara	PIP Modification	Modification agreed	Vaccines	Pfizer	13/11/2015	P/0304/2015	21/12/2015
Nilotinib	Tasigna	PIP Modification	Modification agreed	Oncology	Novartis Europharm Ltd.	13/11/2015	P/0297/2015	21/12/2015
Obeticholic Acid (6 alpha-ethylchenodeoxycholic acid)	Not available at present	PIP Modification	Modification agreed	Gastroenterology-Hepatology	Intercept Italia s.r.l.	13/11/2015	P/0310/2015	21/12/2015
Odanacatib	not available at present	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Merck Sharp & Dohme (Europe), Inc.	13/11/2015	P/0307/2015	21/12/2015
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	Synflorix	PIP Modification	Modification agreed	Vaccines	GlaxoSmithKline Biologicals S.A.	13/11/2015	P/0270/2015	03/12/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
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 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable								

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
Haemophilus influenzae) carrier protein								
Recombinant human monoclonal IgG1 antibody directed against Programmed Death Ligand-1 (anti-PD-L1) (MSB0010718C)	Not available at present	Full Waiver	Full waiver granted	Oncology	Merck KGaA	13/11/2015	P/0319/2015	21/12/2015
Tenofovir alafenamide / to be provided by applicant (GS-9883) / Emtricitabine	Not available at present	PIP	PIP agreed	Infectious Diseases	Gilead Sciences International Ltd	13/11/2015	P/0316/2015	21/12/2015
Tenofovir disoproxil fumarate / Emtricitabine	Truvada	PIP	PIP agreed	Infectious Diseases	Gilead Sciences International Ltd.	13/11/2015	P/0294/2015	03/12/2015
Vosaroxin	QINPREZO	PIP Modification	Modification agreed	Oncology	Sunesis Europe Ltd	13/11/2015	P/0296/2015	04/12/2015
dupilumab	not available at present	Full Waiver	Full waiver granted	Oto-rhino-laryngology	sanofi-aventis recherche & développement	13/11/2015	P/0311/2015	21/12/2015
edoxaban tosilate	Lixiana	PIP Modification	Modification agreed	Cardiovascular Diseases	Daiichi Sankyo Development Ltd	13/11/2015	P/0302/2015	21/12/2015
elbasvir	Not available at present	PIP Modification	Modification agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	13/11/2015	P/0313/2015	21/12/2015
elbasvir / grazoprevir	Not available at present	PIP Modification	Modification agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	13/11/2015	P/0314/2015	21/12/2015
grazoprevir	Not available at present	PIP Modification	Modification agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	13/11/2015	P/0312/2015	21/12/2015
lorcaserin (the drug	not available at	PIP	Modification	Endocrinology-	Eisai Limited	13/11/2015	P/0305/2015	21/12/2015

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
substance is the hemihydrate form of the hydrochloride salt of lorcaserin	present	Modification	agreed	Gynaecology-Fertility-Metabolism	UK			
telotristat etiprate	Not available at present	Full Waiver	Full waiver granted	Gastroenterology-Hepatology	IPSEN PHARMA	13/11/2015	P/0318/2015	21/12/2015
ticagrelor	Brilique	PIP Modification	Modification agreed	Cardiovascular Diseases	AstraZeneca AB	13/11/2015	P/0298/2015	21/12/2015
tilmanocept	Lymphoseek	PIP Modification	Modification agreed	Diagnostic / Oncology	Navidea Biopharmaceuticals Limited	13/11/2015	P/0309/2015	21/12/2015
(3Z,5S)-5-(hydroxymethyl)-1-[(2'-methyl[1,1'-biphenyl]-4-yl) carbonyl]-3-pyrrolidinone-O-methyloxime	not available at present	Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	ObsEva Ireland Limited	11/12/2015	P/0034/2016	29/01/2016
13C-Methacetin	Not available at present	PIP	PIP agreed	Diagnostic / Gastroenterology-Hepatology	Humedics GmbH	11/12/2015	P/0035/2016	01/02/2016
17ß-estradiol (E2) / etonogestrel (ENG)	not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme (Europe), Inc.	11/12/2015	P/0028/2016	29/01/2016
Blinatumomab	BLINCYTO	PIP Modification	Modification agreed	Oncology	Amgen Europe B.V.	11/12/2015	P/0014/2016	29/01/2016
Bosutinib	Bosulif	PIP Modification	Modification agreed	Oncology	Pfizer Limited	11/12/2015	P/0016/2016	29/01/2016
Canagliflozin (1s)-1,5-anhydro-1-[3-[[5-(4-fluorophenyl)-2-thienyl]methyl]-4-methylphenyl]-D-glucitol hemihydrate	Invokana	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Janssen-Cilag International NV	11/12/2015	P/0019/2016	29/01/2016
Cinacalcet (as hydrochloride)	Mimpara	PIP Modification	Modification agreed	Uro-nephrology		11/12/2015	P/0008/2016	29/01/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins	Xeomin, Bocouture (not foreseen for the treatment of sialorrhea)	PIP Modification	Modification agreed	Neurology	Merz Pharmaceuticals GmbH	11/12/2015	P/0005/2016	25/01/2016
Damoctocog alfa pegol	not available at present	PIP Modification	Modification agreed	Haematology-Hemostaseology	Bayer Pharma AG	11/12/2015	P/0025/2016	29/01/2016
Human heterologous liver cells	Heparesc	PIP Modification	Modification agreed		Cytonet GmbH & Co. KG	11/12/2015	P/0006/2016	29/01/2016
Mepolizumab	Not available at present	PIP Modification	Modification agreed	Haematology-Hemostaseology	GSK Trading Services Limited	11/12/2015	P/0007/2016	29/01/2016
Nonacog gamma	RIXUBIS	PIP Modification	Modification agreed	Haematology-Hemostaseology	Baxalta Innovations GmbH	11/12/2015	P/0021/2016	29/01/2016
Peginterferon alfa-2a	Pegasys	PIP Modification	Modification agreed	Infectious Diseases	Roche Registration Ltd	11/12/2015	P/0010/2016	29/01/2016
Pegylated recombinant factor VIII	Not available at present	PIP Modification	Modification agreed	Haematology-Hemostaseology	Baxalta Innovations GmbH	11/12/2015	P/0001/2016	08/01/2016
Pexiganan acetate	Locilex®	Full Waiver	Full waiver granted	Infectious Diseases	Dipexium Pharmaceuticals, Inc.	11/12/2015	P/0032/2016	29/01/2016
Processed Nerve Allograft (Human)	Avance® Nerve Graft	Full Waiver	Full waiver granted	Other	AxoGen Corporation	11/12/2015	P/0036/2016	05/02/2016
Recombinant human antibody against the respiratory syncytial virus fusion protein	Not available at present	PIP	PIP agreed	Infectious Diseases	Regeneron Ireland	11/12/2015	P/0037/2016	00/00/0
Retigabine	Trobalt	PIP Modification	Modification agreed	Neurology	Glaxo Group Limited	11/12/2015	P/0009/2016	29/01/2016
Rilpivirine (RPV) / Dolutegravir (DTG)	not available at present	PIP	PIP agreed	Infectious Diseases	ViiV Healthcare	11/12/2015	P/0030/2016	29/01/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
					Limited			
Selepressin	Not available at present	PIP Modification	Modification agreed	Cardiovascular Diseases	Ferring Pharmaceuticals A/S	11/12/2015	P/0013/2016	29/01/2016
Sirukumab	not available at present	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Janssen-Cilag International N.V.	11/12/2015	P/0020/2016	29/01/2016
Tiprelestat	not available at present	Full Waiver	Full waiver granted	Oncology / Gastroenterology-Hepatology	Proteo Biotech AG	11/12/2015	P/0033/2016	29/01/2016
Trametinib	MEKINIST	PIP Modification	Modification agreed	Oncology	Novartis Europharm Limited	11/12/2015	P/0024/2016	29/01/2016
abrilumab	not available at present	PIP	PIP agreed	Gastroenterology-Hepatology	MedImmune Ltd (Affiliate of AstraZeneca AB)	11/12/2015	P/0027/2016	29/01/2016
albiglutide	Eperzan	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	GlaxoSmithKline Trading Services Limited	11/12/2015	P/0023/2016	29/01/2016
ataluren	Translarna	PIP Modification	Modification agreed	Neurology	PTC Therapeutics International Limited	11/12/2015	P/0002/2016	14/01/2016
conestat alfa	Ruconest	PIP Modification	Modification agreed	Other	Pharming Group N.V.	11/12/2015	P/0004/2016	22/01/2016
dabrafenib	Tafinlar	PIP Modification	Modification agreed	Oncology	Novartis Europharm Limited	11/12/2015	P/0022/2016	29/01/2016
dulaglutide	Trulicity	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Eli Lilly & Company	11/12/2015	P/0017/2016	29/01/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision N.	Decision Date
eteplirsen	Not available at present	PIP	PIP agreed	Neurology	Sarepta International C.V.	11/12/2015	P/0029/2016	29/01/2016
osilodrostat	not available at present	PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novartis Europharm Limited	11/12/2015	P/0011/2016	29/01/2016
revusiran	not available at present	Full Waiver	Full waiver granted	Cardiovascular Diseases / Neurology	Alnylam Pharmaceuticals, Inc.	11/12/2015	P/0031/2016	29/01/2016
rilpivirine (as hydrochloride)	EDURANT	PIP Modification	Modification agreed	Infectious Diseases	Janssen-Cilag International NV	11/12/2015	P/0012/2016	29/01/2016
sonidegib	Odomzo	PIP Modification	Modification agreed	Oncology	Novartis Europharm Ltd.	11/12/2015	P/0018/2016	29/01/2016
ustekinumab	STELARA	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation / Dermatology	Janssen-Cilag International NV	11/12/2015	P/0003/2016	15/01/2016
vancomycin	not available at present	PIP Modification	Modification agreed	Neonatology - Paediatric Intensive Care / Infectious Diseases	Fondazione PENTA Onlus	11/12/2015	P/0026/2016	29/01/2016
vedolizumab	Entyvio	PIP Modification	Modification agreed	Gastroenterology-Hepatology	Takeda Pharma A/S	11/12/2015	P/0015/2016	29/01/2016

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

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Artemether / Lumefantrine	Other	Novartis Europharm Limited	09/10/2015
Bevacizumab	Oncology	F.Hoffmann-La Roche Ltd	13/11/2015

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Bilastine	Dermatology / Pneumology - Allergology / Oto-rhino-laryngology	FAES FARMA, S.A.	13/11/2015
Canakinumab	Immunology-Rheumatology-Transplantation	Novartis Europharm LTD	09/10/2015
Canakinumab	Immunology-Rheumatology-Transplantation	Novartis Europharm Ltd	19/06/2015
Everolimus	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	22/05/2015
Fluticasone Propinate / Formoterol fumarate dihydrate	Pneumology - Allergology	Mundipharma Research Limited	13/02/2015
Human normal immunoglobulin	Immunology-Rheumatology-Transplantation	Baxalta Innovations GmbH	30/10/2015
Human normal immunoglobulin	Immunology-Rheumatology-Transplantation	Baxter Innovations GmbH	16/01/2015
Insulin aspart / Insulin degludec	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	11/09/2015
Sieved freeze-dried allergen extract of Dermatophagoides pteronyssinus / Sieved freeze-dried allergen extract of Dermatophagoides farinae	Pneumology - Allergology	Stallergenes S.A.	19/06/2015
Solifenacin (succinate)	Uro-nephrology	Astellas Pharma Europe B.V.	22/05/2015
atazanavir (as sulphate)	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	13/02/2015
eculizumab	Immunology-Rheumatology-Transplantation	ALEXION EUROPE SAS	22/05/2015
ipilimumab	Oncology	Bristol-Myers Squibb Pharma EEIG	11/12/2015
lopinavir/ritonavir	Infectious Diseases	AbbVie Ltd.	17/07/2015
von Willebrand Factor / Human coagulation Factor VIII	Haematology-Hemostaseology	CSL Behring GmbH	22/05/2015

Annex 15 – Referral procedures overview 2015 – human medicines

Referrals made to the CHMP

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
amoxicillin	25/07/2013	25/06/2015	Article 30 of Directive 2001/83/EC
polymyxin-based products	19/09/2013	26/02/2015	Article 5(3) procedure of Regulation (EC) No 726/2004
nicorandil	19/12/2013	26/03/2015	Article 30 of Directive 2001/83/EC
adrenaline (epinephrine)	25/04/2014	25/06/2015	Article 31 of Directive 2001/83/EC
GVK Bio	25/09/2014	21/05/2015[1]	Article 31 of Directive 2001/83/EC
tolperisone	22/01/2015	23/04/2015	Article 29(4) of Directive 2001/83/EC
tolperisone	22/01/2015	23/04/2015	Article 29(4) of Directive 2001/83/EC
diclofenac epolamine	26/03/2015	MA withdrawn[2]	Article 29(4) of Directive 2001/83/EC
beclometasone dipropionate	25/06/2015	Ongoing	Article 30 of Directive 2001/83/EC
dibotermin alfa	23/07/2015	22/10/2015	Article 20 of Regulation (EC) 726/2004
linezolid	24/09/2015	Ongoing	Article 29(4) of Directive 2001/83/EC
linezolid	24/09/2015	Ongoing	Article 29(4) of Directive 2001/83/EC
fentanyl	24/09/2015	Ongoing	Article 30 of Directive 2001/83/EC
etoposide	22/10/2015	Ongoing	Article 30 of Directive 2001/83/EC
etoposide phosphate	22/10/2015	Ongoing	Article 30 of Directive 2001/83/EC
lidocaine hydrochloride	22/10/2015	Ongoing	Article 29(4) of Directive 2001/83/EC
levonorgestrel	22/10/2015	Ongoing	Article 13 of Commission Regulation (EC) No 1234/2008

[1] CHMP opinion date after re-examination procedure
[2] MA withdrawn in September 2015

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
tobramycin	22/10/2015	Ongoing	Article 29(4) of Directive 2001/83/EC
enoxaparin	19/11/2015	Ongoing	Article 30 of Directive 2001/83/EC
amitriptyline	17/12/2015	Ongoing	Article 30 of Directive 2001/83/EC
desloratadine	17/12/2015	Ongoing	Article 5(3) procedure of Regulation (EC) No 726/2004

Referrals made to the PRAC

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
ambroxol and bromhexine	10/04/2014	18/11/2015[3]	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
codeine	10/04/2014	22/04/2015	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
hydroxyzine	08/05/2014	25/03/2015	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
Ibuprofen, dexibuprofen	13/06/2014	20/05/2015	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
beclomethasone, budesonide, flunisolide, fluticasone propionate, fluticasone furoate	07/05/2015	Ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC
natalizumab	07/05/2015	Ongoing	Article 20 of Regulation (EC) No 726/2004 following Article 107i procedure of Directive 2001/83/EC
canagliflozin, dapagliflozin, empagliflozin	11/06/2015	Ongoing	Article 20 of Regulation (EC) No 726/2004 following Article 107i procedure of Directive 2001/83/EC
human papillomavirus vaccine [types 16, 18] (recombinant,	09/07/2015	19/11/2015	Article 20 of Regulation (EC) No 726/2004 following Article

[3] CMDh position date after revision

International non-proprietary name (INN)	Start of procedure	End of procedure	Type of referral
adjuvanted, adsorbed), human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed), human papillomavirus 9-valent vaccine (recombinant, adsorbed)			107i procedure of Directive 2001/83/EC
fusafungine	10/09/2015	Ongoing	Article 31 of Directive 2001/83/EC following Article 107(j)(2) procedure of Directive 2001/83/EC

Annex 16 – Arbitrations and referrals in 2015 – veterinary medicines

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
Procedure under Article 30(3) of Regulation 726/2004	• 10/01/2013 • 10/04/2015	• Not applicable • 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 33(4) Directive 2001/82/EC	• 08/10/2014 • 06/05/2015	• Gutal 1000 g/kg premix for medicated feeding stuff for pigs • Zinc oxide
Procedure under Article 33(4) of Directive 2001/82/EC	• 05/11/2014 • 03/06/2015	• Coglapix vakcina A.U.V. suspension for injection for pigs • *Actinobacillus pleuropneumoniae* strains serotype 1 and 2
Referral under Article 35 of Directive 2001/82/EC	• 06/05/2015	• All veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry • Lincomycin and spectinomycin
Referral under Article 35 of Directive 2001/82/EC	• 06/05/2015	• All veterinary medicinal products containing colistin in combination with other antimicrobial substances to be administered orally • Colistin in combination with other antimicrobial substances
Referral under Article 33(4) Directive 2001/82/EC	• 03/06/2015 • 04/11/2015	• Solamocta 697 mg/g powder for use in drinking water for chickens, ducks and turkeys • Amoxicillin
Procedure under Article 78 of Directive 2001/82/EC	• 08/07/2015 • 08/10/2015	• Closamectin pour-on solution and associated names • Closantel and ivermectin
Referral under Article 34 of Directive 2001/82/EC	• 09/09/2015	• Denagard 45% and associated names • Tiamulin hydrogen fumarate
Referral under Article 33(4) Directive 2001/82/EC	• 07/10/2015	• CattleMarker IBR Inactivated emulsion for injection for cattle • Infectious bovine rhinotracheitis (IBR) vaccine
Referral under Article 35 of Directive 2001/82/EC	• 05/11/2015	• All veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses

Annex 17 – Budget summaries

The summarised comparative budget statements for 2014 and 2015 are as follows:

		2014 (final)[1]		2015 (budget)[2]		2015 (final)[3]	
		€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
	Revenue						
1+5	Fees and charges	217,670	*80.1%*	255,251	*82.8%*	251,490	*82.7%*
200	General EU contribution	20,504	*7.5%*	18,604	*6.0%*	18,669	*6.1%*
201	Special EU contribution for orphan medicinal products	9,432	*3.5%*	12,911	*4.2%*	13,212	*4.3%*
300	Contribution from EEA	675	*0.2%*	936	*0.3%*	554	*0.2%*
600	External assigned revenue	18,904	*7.0%*	17,767	*5.8%*	17,559	*5.8%*
700	Balance from previous year	3,453	*1.3%*	1,500	*0.5%*	1,499	*0.5%*
5+9	Other	1,147	*0.4%*	1,128	*0.4%*	1,135	*0.4%*
	TOTAL REVENUE	**271,786**	*100.0%*	**308,097**	*100.0%*	**304,119**	*100.0%*
	Expenditure						
	Staff						
11	Staff in active employment	84,352	*31.7%*	94,888	*30.8%*	94,034	*31.9%*
13	Duty travel	540	*0.2%*	666	*0.2%*	622	*0.2%*
14	Socio-medical infrastructure	805	*0.3%*	845	*0.3%*	783	*0.3%*
15	Exchange of civil servants and experts	3,016	*1.1%*	5,498	*1.8%*	5,105	*1.7%*
16	Social welfare	323	*0.1%*	545	*0.2%*	528	*0.2%*
17	Representation expenses	53	*0.0%*	149	*0.0%*	137	*0.0%*
18	Staff insurances	2,255	*0.8%*	2,386	*0.8%*	2,382	*0.8%*
	Total Title 1	**91,344**	*34.3%*	**104,977**	*34.1%*	**103,592**	*35.1%*
	Building / equipment						
20	Investment in immovable property, renting of building and associated costs	39,175	*14.7%*	34,156	*11.1%*	30,263	*10.3%*
21	Expenditure on corporate data processing	12,499	*4.7%*	19,534	*6.3%*	16,522	*5.6%*
22	Movable property [..]	1,927	*0.7%*	2,178	*0.7%*	1,337	*0.5%*
23	Other administrative expenditure	1,417	*0.5%*	1,619	*0.5%*	1,145	*0.4%*
24	Postage	130	*0.0%*	153	*0.0%*	108	*0.0%*
25	Expenditure on other meetings	102	*0.0%*	107	*0.0%*	46	*0.0%*
	Total Title 2	**55,251**	*20.7%*	**57,747**	*18.7%*	**49,422**	*16.7%*
	Operational expenditure						
300	Meetings	7,126	*2.7%*	8,904	*2.9%*	7,993	*2.7%*
301	Evaluation of medicines	96,145	*36.1%*	108,614	*35.3%*	107,952	*36.6%*
302	Translations	4,325	*1.6%*	4,321	*1.4%*	3,742	*1.3%*
303	Studies and consultants	4,730	*1.8%*	9,138	*3.0%*	8,151	*2.8%*
304	Publications	163	*0.1%*	173	*0.1%*	138	*0.0%*
305	Community programmes	0	*0.0%*	0	*0.0%*	0	*0.0%*
31	Expenditure on business related IT projects	7,336	*2.8%*	14,223	*4.6%*	14,106	*4.8%*
	Total Title 3	**119,825**	*45.0%*	**145,373**	*47.2%*	**142,082**	*48.1%*
	TOTAL EXPENDITURE	**266,420**	*100.0%*	**308,097**	*100.0%*	**295,096**	*100.0%*

[1] Financial Year 2014: as per final accounts; rounded to nearest thousand Euro

[2] Financial Year 2015: as per final budget

[3] Financial Year 2015: as per provisional accounts; rounded to nearest thousand Euro

Annex 18 – European Medicines Agency Establishment Plan

Category and grade	TEMPORARY POSTS					
	POSTS 2015				POSTS 2016	
	Authorised		Actual as per 31.12.2015		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	0	-	0	-	0
AD 15	-	4	-	3	-	4
AD 14	-	6	-	5	-	6
AD 13	-	9	-	9	-	9
AD 12	-	42	-	41	-	42
AD 11	-	37	-	36	-	38
AD 10	-	40	-	39	-	44
AD 9	-	36	-	36	-	37
AD 8	-	52	-	51	-	54
AD 7	-	52	-	51	-	54
AD 6	-	36	-	36	-	37
AD 5	-	26	-	26	-	18
Total AD	**0**	**340**	**0**	**333**	**0**	**343**
AST 11	-	2	-	2	-	2
AST 10	-	5	-	5	-	5
AST 9	-	7	-	6	-	7
AST 8	-	16	-	16	-	16
AST 7	-	19	-	18	-	19
AST 6	-	39	-	38	-	39
AST 5	-	42	-	42	-	43
AST 4	-	49	-	49	-	49
AST 3	-	43	-	41	-	47
AST 2	-	37	-	37	-	32
AST 1	-	0	-	0	-	0
Total AST	**0**	**259**	**0**	**254**	**0**	**259**
Grand Total	**0**	**599**	**0**	**587**	**0**	**602**

Other staff	Planned (FTE[1]) 2015	Actual (FTE) 2015	Actual headcount 31.12.2015	Planned (FTE) 2016
CONTRACT AGENTS	**146**	**156**	**153**	**145**
NATIONAL EXPERTS	**34**	**33**	**35**	**40**

[1] FTE=Full Time Equivalent

Annex 19 – Requests for access to documents

Requests received and pages released

Year	Number of requests received	Number of pages released
2015	701	333,999

Decisions on access in 2015[1]

Access given	
Yes	445
Partial	8
No	48
Not Applicable[2]	96
Total closed	597
Pending	126

Decision on appeals in 2015[3]

Appeals	
Final refusal	10
Release	6
Partial	1
Not Applicable[4]	0
Total closed	17
Pending	3

Affiliation (per initial requests and appeals in 2015)

Affiliation	Number of requests received	In %	Number of pages released[5]	In %
Not-for-profit organisation	3	0.43	4	0.00
EU Institution (EC etc)	2	0.29	327	0.10
Regulator outside EU	1	0.14	0	0.00
EU NCA	1	0.14	1,246	0.37
Patients or Consumer	22	3.14	8,890	2.66
Healthcare professional	22	3.14	479	0.14
Academia/Research institute	58	8.27	77,382	23.17
Legal	77	10.98	33,534	10.04

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

Affiliation	Number of requests received	In %	Number of pages released[5]	In %
Media	47	6.70	17,395	5.21
Pharmaceutical industry	420	59.91	169,567	50.77
Consultant	17	2.43	871	0.26
Other	31	4.42	24,304	7.28

Annex 20 – Publications by Agency staff members and experts in 2015

Bahri P, Dodoo AN, Edwards BD, Edwards IR, Fermont I, Hagemann U, Hartigan-Go K, Hugman B, Mol PG.
The ISoP CommSIG for improving medicinal product risk communication – a new special interest group of the International Society of Pharmacovigilance
Drug Saf. 2015; 38: 621-627

Bartlett JA, Brewster M, Brown P, Cabral-Lilly D, Cruz CN, David R, Eickhoff WM, Haubenreisser S, Jacobs A, Malinoski F, Morefield E, Nalubola R, Prud'homme RK, Sadrieh N, Sayes CM, Shahbazian H, Subbarao N, Tamarkin L, Tyner K, Uppoor R, Whittaker-Caulk M, Zamboni W.
Summary report of PQRI Workshop on Nanomaterial Drug Products: Current Experience and Management of Potential Risks
AAPS J. 2015 Jan;17(1):44-64

Blind E, de Graeff PA, Meurs I, Holtkamp F, Baczynska A, Janssen H.
The European Medicines Agency's approval of proprotein convertase subtilisin/kexin type 9 inhibitors
Eur Heart J. 2015 Dec 27

Bonelli M, Di Giuseppe F, Beken S.
Impact analysis of ICH S9 on non-clinical development of anticancer drugs
Regul Toxicol Pharmacol. 2015 Oct;73(1):361-6

Both L, Botgros R, Cavaleri M.
Analysis of licensed over-the-counter (OTC) antibiotics in the European Union and Norway, 2012
Euro Surveill. 2015 Aug 27;20(34)

Butlen-Ducuing F, Zienowicz M, Pétavy F, Haas M, Salmonson T, Eichler HG, Rasi G.
European regulatory experience with drugs for central nervous system disorders
Nat Rev Drug Discov. 2015 Feb;14(2):89-90

Candore G, Juhlin K, Manlik K, Thakrar B, Quarcoo N, Seabroke S, Wisniewski A, Slattery J.
Comparison of statistical signal detection methods within and across spontaneous reporting databases
Drug Saf. 2015 Jun;38(6):577-87

Catry B, Cavaleri M, Baptiste K, Grave K, Grein K, Holm A, Jukes H, Liebana E, Lopez Navas A, Mackay D, Magiorakos AP, Moreno Romo MA, Moulin G, Muñoz Madero C, Matias Ferreira Pomba MC, Powell M, Pyörälä S, Rantala M, Ružauskas M, Sanders P, Teale C, Threlfall EJ, Törneke K, van Duijkeren E, Torren Edo J.
Use of colistin-containing products in animals within the European Union and European Economic Area (EU/EEA): development of resistance and possible impact on human and animal health
Int J Antimicrob Agents. 2015 Sep;46(3):297-306

Cavaleri M, Manolis E.
Hollow Fibre System Model for Tuberculosis: The European Medicines Agency Experience
Clin Infect Dis. 2015 Aug 15;61 Suppl 1:S1-4

Cohen J, Vincent JL, Adhikari NK, Machado FR, Angus DC, Calandra T, Jaton K, Giulieri S, Delaloye J, Opal S, Tracey K, van der Poll T, Pelfrene E.
Sepsis - A Roadmap for Future Research
Lancet Infect Dis. 2015 May;15(5):581-614

Dal Pan GJ, Arlett PR.
The US Food and Drug Administration-European Medicines Agency Collaboration in Pharmacovigilance: Common Objectives and Common Challenges
Drug Saf. 2015 Jan;38(1):13-5

Dodt J, Hubbard AR, Wicks SJ, Gray E, Neugebauer B, Charton E, Silvester G.
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