Annexes to the annual report of the European Medicines Agency 2016

Annex 1 – Members of the Management Board

Chair: Christa WIRTHUMER-HOCHE
EMA contact: Noël WATHION; Silvia FABIANI

Members

• European Parliament	Björn LEMMER, Tonio BORG[1]
• European Commission	Xavier PRATS-MONNÉ, Carlo PETTINELLI (Alternates: Andrzej RYS, Christian SIEBERT)
• Belgium	Xavier DE CUYPER (Alternate: Greet MUSCH)
• Bulgaria	Assena STOIMENOVA (Alternate: Svetlin SPIROV)
• Czech Republic	Zdenek BLAHUTA (Alternate: Jiří BUREŠ)
• Denmark	Thomas SENDEROVITZ[2] (Alternate: Mette AABOE HANSEN[3])
• Germany	Karl BROICH (Alternate: Klaus CICHUTEK)
• Estonia	Kristin RAUDSEPP (Alternate: Alar IRS)
• Ireland	Lorraine NOLAN[4] (Alternate: Rita PURCELL[5])
• Greece	Despoina MAKRIDAKI (Alternate: Giannis KARAFYLLIS)
• 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 (Alternate: Janis ZVEJNIEKS)
• Lithuania	Gintautas BARCYS (Alternate: Gediminas PRIDOTKAS)
• Luxembourg	Laurent MERTZ (Alternate: Jacqueline GENOUX-HAMES)
• Hungary	Csilla POZSGAY (Alternate: Beatrix Horvath[6])
• Malta	John-Joseph BORG (Alternate: Gavril FLORES)
• Netherlands	Hugo HURTS (Alternate: Constant VAN BELKUM)

[1] Replaced Guiseppe NISTICÓ as of May 2016
[2] Replaced Mette AABOE HANSEN as of June 2016
[3] Replaced Anna SKAT NIELSEN as of December 2016
[4] Replaced Rita PURCELL as of May 2016
[5] Replaced Lorraine NOLAN as of May 2016
[6] Replaced Hilda KŐSZEGINÉ SZALAI as of August 2016

• Austria	Christa WIRTHUMER-HOCHE (Alternate: Sylvia FÜSZL)
• Poland	Grzegorz CESSAK (Alternate: Awaiting nomination)
• Portugal	Helder MOTA FILIPE (Alternate: Awaiting nomination)
• Romania	NICOLAE FOTIN (Alternate: Marius TANASA)
• Slovenia	Andreja CUFAR (Alternate: Stanislav PRIMOŽIČ)
• Slovakia	Zuzana BAŤOVÁ[7] (Alternate: Valeria PERNISOVA)
• Finland	Sinikka RAJANIEMI (Alternate: Pekka KURKI)
• Sweden	Catarina FORSMAN (Alternate: SARA ROSENMULLER[8])
• United Kingdom	Ian HUDSON[9] (Alternate: Jonathan MOGFORD[10])
• Representatives of patients' organisations	Ilaria PASSARANI[11] Yann LE CAM[12]
• Representative of doctors' organisations	Wolf-Dieter LUDWIG
• Representative of veterinarians' organisations	Nancy DE BRIYNE[13]

Observers

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

[7] Replaced Ján MAZÁG as of October 2016
[8] Replaced Bengt WITTGREN as of October 2016
[9] Replaced Kent WOODS as of January 2016
[10] Replaced Ian HUDSON as of January 2016
[11] Replaced Nikos DEDES as of June 2016
[12] Replaced W.H.J.M. Wim WIENTJENS as of June 2016
[13] Replaced Christophe HUGNET as of June 2016

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

Chair: Tomas SALMONSON

EMA contact: Anabela MARCAL

Members

• Andrea LASLOP (Austria)	Alternate: Milena STAIN
• Bart VAN DER SCHUEREN (Belgium)[1],[2]	Alternate: Christophe FOCKE[3]
• Mila VLASKOVSKA (Bulgaria)	Alternate: Assena STOIMENOVA[4]
• Katarina VUCIC (Croatia)[5],[6]	Alternate: Selma ARAPOVIC DZAKULA[7]
• Panayiotis TRIANTAFYLLIS (Cyprus)	Alternate: George SAVVA
• Ondřej SLANAR (Czech Republic)	Alternate: Radka MONTONIOVA
• Sinan B. SARAC (Denmark)[8],[9]	Alternate: Hanne Lomholt LARSEN[10]
• Alar IRS (Estonia)	Alternate: *Awaiting nomination*[11]
• Outi MAKI-IKOLA (Finland)	Alternate: Tuomo LAPVETELAINEN
• Pierre DEMOLIS (France)	Alternate: Joseph EMMERICH
• Harald ENZMANN (Germany) *(Vice-Chair)*	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: Carola DE BEAUFORT
• John Joseph BORG (Malta)	Alternate: Helen VELLA
• Johann Lodewijk HILLEGE (Netherlands)[12],[13]	Alternate: Paula Boudewina VAN HENNIK[14]
• Karsten BRUINS SLOT (Norway)	Alternate: Bjorg BOLSTAD
• Piotr FIEDOR (Poland)	Alternate: Aldona PALUCHOWSKA
• Bruno SEPODES (Portugal)	Alternate: Fatima VENTURA[15]
• Nela VILCEANU (Romania)	Alternate: Dana Gabriela MARIN
• Nikola MORAVCOVA (Slovakia)[16],[17]	Alternate: Jana SCHWEIGERTOVA[18]
• Stanislav PRIMOZIC (Slovenia)	Alternate: Nevenka TRSINAR BRODT
• Concepcion PRIETO YERRO (Spain)	Alternate: Arantxa SANCHO-LOPEZ
• Kristina DUNDER (Sweden)	Alternate: Filip JOSEPHSON
• Greg MARKEY (United Kingdom)	Alternate: Nithyanandan NAGERCOIL

[1] Daniel BRASSEUR's membership ended as of July 2016
[2] Swap of roles from alternate to member as of July 2016
[3] Nominated as of December 2016
[4] Replaced Maria POPOVA-KIRADJIEVA as of October 2016
[5] Swap of roles from alternate to member as of October 2016
[6] Replaced Ines BAOTIC as of October 2016
[7] Nominated as of October 2016
[8] Jens HEISTERBERG resigned as of April 2016
[9] Switch of roles from alternate to member as of June 2016
[10] Nominated as of July 2016
[11] Kersti OSELIN's membership ended as of January 2016
[12] Pieter DE GRAEFF's membership ended as of August 2016
[13] Switch of roles from alternate to member as of August 2016
[14] Nominated as of August 2016
[15] Replaced Patricia SILVA as of March 2016
[16] Jan MAZAG's membership ended as of July 2016
[17] Nominated as of October 2016
[18] Replaced Ivana PANKUCHOVA as of March 2016

Co-opted members

- Robert James HEMMINGS (Medical statistics (clinical-trial methodology / epidemiology))
- Jan MUELLER-BERGHAUS (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))
- Koenraad NORGA (Pharmacology)[19]
- Jean-Louis ROBERT (Quality (non-biologicals))
- Sol RUIZ (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))

[19] Nominated as of January 2016

Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: June Munro RAINE
EMA contact: Anabela MARCAL

Members

• Jan NEUHAUSER (Austria)	Alternate: Marianne LUNZER
• Jean-Michel DOGNE (Belgium)	Alternate: Laurence DE FAYS[1]
• Maria POPOVA-KIRADJIEVA (Bulgaria)	Alternate: Yuliyan EFTIMOV
• Nikica MIROSEVIC SKVRCE (Croatia)[2]	Alternate: Zeljana MARGAN KOLETIC[3]
• 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
• Claire FERARD (France)[4],[5]	Alternate: Caroline LABORDE[6],[7]
• Martin HUBER (Germany)	Alternate: Valerie STRASSMANN
• Leonidas KLIRONOMOS (Greece)	Alternate: Agni KAPOU
• Julia PALLOS (Hungary)	Alternate: Melinda PALFI
• Gudrun Kristin STEINGRIMSDOTTIR (Iceland)	Alternate: Hrefna GUDMUNSDOTTIR
• Almath SPOONER (Ireland) *(Vice-Chair)*	Alternate: Ruchika SHARMA
• Carmela MACCHIARULO (Italy)	Alternate: Amelia CUPELLI
• Zane NEIKENA (Latvia)	Alternate: Zane STADE
• Jolanta GULBINOVIC (Lithuania)	Alternate: Simona KUDELIENE
• Marcel BRUCH (Luxembourg)	Alternate: Nadine PETITPAIN
• Ami TANTI (Malta)	Alternate: John Joseph BORG
• Sabine STRAUS (Netherlands)	Alternate: Menno VAN DER ELST
• Helga HAUGOM OLSEN (Norway)[8]	Alternate: Kristin Thorseng KVANDE
• Adam PRZYBYLKOWSKI (Poland)	Alternate: Magdalena BUDNY
• Ana Sofia DINIZ MARTINS (Portugal)[9]	Alternate: Marcia SILVA[10]

[1] Replaced Veerle VERLINDEN as of October 2016
[2] Replaced Marina Dimov DI GUISTI as of September 2016
[3] Replaced Viola MACOLIC SARINIC as of January 2016
[4] Isabelle ROBINE's membership ended as of May 2016
[5] Swap of roles from alternate to member as of October 2016
[6] Corinne FECHANT resigned as of February 2016
[7] Nominated as of October 2016
[8] Replaced Ingebjorg BUAJORDET as of August 2016
[9] Replaced Margarida GUIMARAES as of December 2016
[10] Replaced Leonor CHAMBEL as of December 2016

- Roxana STROE (Romania) Alternate: Nicolae FOTIN
- Tatiana MAGALOVA (Slovakia) Alternate: Miroslava MATIKOVA
- Milena RADOHA-BERGOC (Slovenia) Alternate: Gabriela JAZBEC
- Dolores MONTERO CORMINAS (Spain) Alternate: Eva SEGOVIA[11]
- Ulla WANDEL LIMINGA (Sweden) Alternate: Qun-Ying YUE
- Julie WILLIAMS (United Kingdom) Alternate: Rafe SUVARNA

Independent scientific experts nominated by the European Commission

- Thierry TRENQUE[12]
- Marie Louise DE BRUIN
- Stephen J. W. EVANS
- Brigitte KELLER-STANISLAWSKI
- Herve LE LOUET
- Lennart Antero WALDENLIND

Members representing healthcare professionals nominated by the European Commission

- Raymond ANDERSON[13] Alternate: Kirsten MYHR

Members representing patients organisations nominated by the European Commission

- Marco GRECO[14] Alternate: Albert VAN DER ZEIJDEN[14]

[11] Replaced Miguel MACIA as of May 2016
[12] Replaced Jane AHLQVIST RASTAD as of April 2016
[13] Replaced Filip BABYLON as of March 2016
[14] Swap of roles of member and alternate as of March 2016

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

Chair: David MURPHY[1] (Vice-Chair: Helen JUKES[2])
European Medicines Agency contact: David MACKAY

Members and alternates

• Barbara ZEMANN (Austria)	Alternate: Ulrike HEISSENBERGER[3]
• Bruno URBAIN (Belgium)	Alternate: Frederic KLEIN
• Emil KOZHUHAROV (Bulgaria)	Alternate: Svetoslav BRANCHEV
• 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 (Finland)	Alternate: Kristina LEHMANN
• Jean-Claude ROUBY (France)	Alternate: Sylvie LOUET
• Cornelia IBRAHIM (Germany)	Alternate: Esther WERNER
• Ioannis MALEMIS (Greece)	Alternate: Angeliki TSIGOURI
• Gabor KULCSAR (Hungary)	Alternate: Tibor SOOS
• J. Gabriel BEECHINOR (Ireland)[4]	Alternate: *awaiting nomination*
• Paolo PASQUALI (Italy)[5]	Alternate: Antonio BATTISTI[6]
• Zanda AUCE (Latvia)	Alternate: *awaiting nomination*
• Petras MACIULSKIS (Lithuania)	Alternate: Laimis JODKONIS[7]
• Marc SCHMIT (Luxembourg)	Alternate: Marcel BRUCH
• Stephen SPITERI (Malta)	Alternate: *awaiting nomination*[8]
• Peter HEKMAN (Netherlands)[9]	Alternate: *awaiting nomination*[10]
• Anna WACHNIK-SWIECICKA (Poland)[11]	Alternate: Ewa AUGUSTYNOWICZ
• Joao Pedro DUARTE DA SILVA (Portugal)	Alternate: Maria AZEVEDO MENDES

[1] Elected in June 2016, replaced Anja HOLM
[2] Elected in July 2016, replaced David MURPHY
[3] Replaced Ines LINDNER as of February 2016 meeting
[4] Replaced David MURPHY as of August 2016 meeting
[5] Replaced Maria TOLLIS as of June 2016 meeting
[6] Replaced Virgilio DONINI as of June 2016 meeting
[7] Replaced Sigitas SIRIUKAITIS as of December 2016 meeting
[8] Mandate of Arvils JAKOVSKIS terminated in September 2016
[9] Dutch member and alternate swapped roles as of September 2016 meeting
[10] G. Johan SCHEFFERLIE elected as co-opted member as of November 2016 meeting
[11] Polish member and alternate swapped roles as of March 2016 meeting

• Lollita TABAN (Romania)	Alternate: Simona STURZU
• Judita HEDEROVA (Slovakia)	Alternate: Eva CHOBOTOVA
• Stanko SRCIC (Slovenia)	Alternate: Katarina STRAUS
• Cristina MUNOZ MADERO (Spain)	Alternate: Consuelo RUBIO MONTEJANO
• Eva LANDER PERSSON (Sweden)	Alternate: Frida HASSLUNG-WIKSTROM
• Helen JUKES (United Kingdom)	Alternate: Noemi GARCIA DEL BLANCO[12]

EEA observers

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

Co-opted members

Co-opted member	**Expertise**
Keith BAPTISTE	Antimicrobials
Rory BREATHNACH	General clinical veterinary practice
G. Johan SCHEFFERLIE[13]	MRLs/residues
Wilhelm SCHLUMBOHM	Quality pharmaceuticals
Jason WEEKS[14]	Environmental risk assessment

[12] Replaced Anna-Maria BRADY as of May 2016 meeting
[13] Elected in October 2016, replaced Christian FRIIS as of November 2016 meeting
[14] Elected in October 2016, replaced Boris KOLAR as of January 2016 meeting

Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Bruno SEPODES
EMA contact: Anabela MARCAL

Members

- Brigitte BLOECHL-DAUM (Austria)
- Andre LHOIR (Belgium)
- Irena BRADINOVA (Bulgaria)
- Dinko VITEZIC (Croatia)[1]
- Andri ANDREOU (Cyprus)
- Katerina KOPECKOVA (Czech Republic)
- Jens ERSBOLL (Denmark)
- Vallo TILLMANN (Estonia)
- Karri PENTTILA (Finland)
- Annie LORENCE (France)
- Frauke NAUMANN-WINTER (Germany)
- Nikolaos SYPSAS (Greece)
- Melinda SOBOR (Hungary)[2]
- Sigurdur THORSTEINSSON (Iceland)
- Geraldine O'DEA (Ireland)
- Armando MAGRELLI (Italy)
- Irena ROGOVSKA (Latvia)[3]
- Ausra MATULEVICIENE (Lithuania)
- Michel HOFFMAN (Luxembourg)
- Robert NISTICO (Malta)[4]
- Violeta STOYANOVA-BENINSKA (Netherlands)
- Ingrid WANG (Norway)[5]
- Bozenna DEMBOWSKA-BAGINSKA (Poland)
- Dinah DUARTE (Portugal)
- Olimpia NEAGU (Romania)[6]

[1] Replaced Adriana ANDRIC as of January 2016
[2] Replaced Judit EGGENHOFER as of November 2016
[3] Replaced Dainis KRIEVINS as of April 2016
[4] Replaced Richard MUSCAT as of July 2016
[5] Nominated as of February 2016

- Eva MALIKOVA (Slovakia)[7]
- *Awaiting Nomination* (Slovenia)[8]
- Fernando MENDEZ HERMIDA (Spain)[9]
- Dan HENROHN (Sweden)[10]
- Daniel O'CONNOR (United Kingdom)

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

- Ingeborg BARISIC
- Giuseppe CAPOVILLA
- Kerstin WESTERMARK[11]

Members representing patients' organisations nominated by the European Commission

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

[6] Replaced Flavia SALEH as of February 2016
[7] Replaced Zuzana BATOVA as of February 2016
[8] Martin MOZINA's mandate expired as of October 2016
[9] Replaced Josep TORRENT-FARNELL as of November 2016
[10] Replaced Kerstin WESTERMARK as of January 2016
[11] Nominated as of October 2016

Annex 6 – Members of the Committee on Herbal Medicinal Products

Chair: Marisa DELBO[1]
EMA contact: Anabela MARCAL

Members

• Reinhard LANGER (Austria)	Alternate: Astrid OBMANN
• Heidi NEEF (Belgium)	Alternate: *Awaiting nomination*
• Elena MUSTAKEROVA (Bulgaria)	Alternate: *Awaiting nomination*[2]
• Ivan KOSALEC (Croatia)	Alternate: Darko TRUMBETIC
• Maria STAVROU (Cyprus)	Alternate: Eirini PERIKLEOUS
• Marie HEROUTOVA (Czech Republic)	Alternate: Marketa PRIHODOVA
• Steffen BAGER (Denmark)	Alternate: Nina DURR
• *Awaiting nomination* (Estonia)[3]	Alternate: *Awaiting nomination*[4]
• Eeva Sofia LEINONEN (Finland)	Alternate: Sari KOSKI
• An LE (France)	Alternate: *Awaiting nomination*[5]
• 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)	Alternate: Rachel COX[6],[7]
• *Awaiting nomination* (Italy)[8]	Alternate: Anna Maria SERRILLI
• Dace KALKE (Latvia)	Alternate: Baiba JANSONE
• Rugile PILVINIENE (Lithuania)	Alternate: Audronis LUKOSIUS
• Marcel BRUCH (Luxembourg)	Alternate: Jacqueline GENOUX-HAMES
• Everaldo ATTARD (Malta)	Alternate: Andre MANGANI
• Emiel VAN GALEN (Netherlands)	Alternate: Burt H. KROES
• Steinar MADSEN (Norway)	Alternate: Gro FOSSUM
• Wojciech DYMOWSKI (Poland)	Alternate: *Awaiting nomination*[9]

[1] Elected as Chair as of November 2016, replacing Werner KNOSS
[2] Kapka KANEVA's mandate ended as of June 2016
[3] Evelin SAAR's mandate expired as of September 2016
[4] Marje ZERNANT's mandate expired as of September 2016
[5] Jacqueline VIGUET POUPELLOZ's mandate expired as of September 2016
[6] Annamarie O'SULLIVAN resigned as of August 2016
[7] Nominated as of October 2016
[8] Marisa DELBO elected as Chair as of November 2016
[9] Ewa BACKHAUS' mandate expired as of May 2016

- Ana Paula MARTINS (Portugal) Alternate: Eva MENDES
- Nadia GRIGORAS (Romania) Alternate: Carmen PURDEL
- Miroslava PETRIKOVA (Slovakia)[10],[11] Alternate: Milan NAGY
- Samo KREFT (Slovenia)[12] Alternate: Barbara RAZINGER[13]
- Adela NUNEZ VELAZQUEZ (Spain) Alternate: Cristina MARTINEZ GARCIA
- 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)
- Heidi FOTH (Toxicology)[14],[15]
- Maria Helena PINTO FERREIRA (General and family medicine)

Observers

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

[10] Gabriela DUCHAJOVA resigned as of January 2016
[11] Miroslava PETRIKOVA nominated as of April 2016
[12] Swap of roles from alternate to member as of June 2016
[13] Swap of roles from member to alternate as of June 2016
[14] Olavi PELKONEN's mandate expired as of March 2016
[15] Nominated as of April 2016

Annex 7 – Committee for Advanced Therapies

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)	Alternate: Ivica MALNAR
• Anna PAPHITOU (Cyprus)	Alternate: Ioannis KKOLOS
• Tomas BORAN (Check Republic)	Alternate: Ivana HAUNEROVA
• Nanna Aaby KRUSE (Denmark)	Alternate: Anne PASTOFT[1]
• Toivo MAIMETS (Estonia)	Alternate: Tarmo TIIDO
• Tiina PALOMAKI (Finland)	Alternate: Olli TENHUNEN
• Violaine CLOSSON CARELLA (France)[2],[3]	Alternate: *Awaiting nomination*[3]
• Martina SCHUSSLER-LENZ (Germany)	Alternate: Egbert FLORY *(Vice-Chair)*
• Asterios TSIFTSOGLOU (Greece)	Alternate: Angeliki ROBOTI
• Krisztian FODOR (Hungary)	Alternate: Balazs SARKADI
• *Awaiting nomination* (Iceland)	Alternate: *Awaiting nomination*
• Maura O'DONOVAN (Ireland)	Alternate: Niamh CURRAN[4]
• Paolo GASPARINI (Italy)	Alternate: Luca SANGIORGI
• Una RIEKSTINA (Latvia)	Alternate: Aija LINE

[1] Nominated as of October 2016
[2] Nicolas FERRY's membership ended as of April 2016
[3] Switch of roles from alternate to member as of May 2016
[4] Replaced Maeve LALLY as of April 2016

- Johannes H. OVELGONNE (The 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 BRODT
- Lennart AKERBLOM (Sweden) Alternate: Bjorn CARLSSON
- Christiane NIEDERLAENDER (Un. Kingdom) Alternate: James MCBLANE

Members representing clinicians nominated by the European Commission

- Marc TURNER[5] Alternate: *Awaiting nomination*[6]
- Bernd GANSBACHER Alternate: *Awaiting nomination*[7]

Members representing patients' organisations nominated by the European Commission

- Mariette DRIESSENS[8] Alternate: Erik BRIERS[9]
- Kieran BREEN Alternate: Michele LIPUCCI DI PAOLA[10]

Observers

- Karl-Heinz BUCHHEIT (EDQM)

[5] Replaced Pieter DOEVENDANS as of July 2016
[6] Esteve TRIAS-ADROHER's mandate expired on June 2016
[7] Ramadan JASHARI's mandate expired on June 2016
[8] Switch of role from alternate to member as of July 2016
[9] Nominated as of July 2016
[10] Switch of role from member to alternate as of July 2016

Annex 8 – Members of the Paediatric Committee

Chair: Dirk MENTZER
EMA contact: Anabela MARCAL

Members nominated from within the CHMP

• Agnes GYURASICS (Hungary)	Alternate: Melinda SOBOR
• *Awaiting nomination* (Lithuania)[1]	Alternate: *Awaiting nomination*[2]
• Carola DE BEAUFORT (Luxembourg)	Alternate: Jacqueline GENOUX-HAMES
• Dana Gabriela MARIN (Romania)	Alternate: Nela VILCEANU

Members

• Karl-Heinz HUEMER (Austria)	Alternate: Johanna WERNSPERGER[3]
• Koenraad NORGA (Belgium) *(Vice-chair)*	Alternate: Jacqueline CARLEER
• Dimitar ROUSSINOV (Bulgaria)	Alternate: Vessela BOUDINOVA
• Adriana ANDRIC (Croatia)[4]	Alternate: Suzana MIMICA MATANOVIC[5],[6]
• Georgios SAVVA (Cyprus)	Alternate: Eirini PERIKLEOUS
• 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*
• Sabine SCHERER (Germany)[7,8]	Alternate: Immanuel BARTH[9],[10]
• Eleni KATSOMITI (Greece)[11]	Alternate: Anastasia MOUNTAKI[12]
• *Awaiting nomination* (Iceland)	Alternate: *Awaiting nomination*
• Brian AYLWARD (Ireland)	Alternate: *Awaiting nomination*
• Sara GALLUZZO (Italy)[13]	Alternate: Alessandro JENKNER[14],[15]

[1] Romaldas MACIULAITIS' mandate expired as of May 2016
[2] Rugile PILVINIENE's mandate expired as of May 2016
[3] Replaced Christoph MALE as of July 2016
[4] Replaced Suzana MIMICA MATANOVIC as of January 2016
[5] Replaced Marina DIMOV DI GIUSTI as of January 2016
[6] Swp of roles from member to alternate as of January 2016
[7] Replaced Immanuel BARTH as of January 2016
[8] Swap of roles from alternate to member as of September 2016
[9] Replaced Birka LEHMANN as of January 2016
[10] Swap of roles from member to alternate as of September 2016
[11] Replaced Grigorios MELAS as of July 2016
[12] Replaced Stefanos MANTAGOS as of July 2016
[13] Replaced Paolo ROSSI as of July 2016
[14] Francesca ROCCHI's mandate expired as of July 2016
[15] Nominated as of November 2016

• Dina APELE-FREIMANE (Latvia)	Alternate: Kristine SUPE
• John Joseph BORG (Malta)	Alternate: Herbert LENICKER
• Maaike VAN DARTEL (Netherlands)[16],[17]	Alternate: *Awaiting nomination*[17]
• Siri WANG (Norway)	Alternate: Ine SKOTTHEIM RUSTEN
• Marek MIGDAL (Poland)	Alternate: Jolanta WITKOWSKA-OZOGOWSKA[18],[19]
• Helena FONSECA (Portugal)	Alternate: Hugo TAVARES
• *Awaiting nomination* (Slovakia)	Alternate: *Awaiting nomination*
• Stefan GROSEK (Slovenia)	Alternate: *Awaiting nomination*
• Fernando DE ANDRES TRELLES (Spain)	Alternate: Maria Jesus FERNANDES CORTIZO
• Ninna GULLBERG (Sweden)	Alternate: Eva AGURELL[20]
• Angeliki SIAPKARA (United Kingdom)	Alternate: Martina RIEGL

Members representing healthcare professionals nominated by the European Commission

• Antje NEUBERT	Alternate: Paolo PAOLUCCI
• Riccardo RICCARDI	Alternate: Jorrit GERRITSEN[21],[22]
• 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: *Awaiting nomination*[23]

[16] Replaced Hendrik VAN DEN BERG as of July 2016
[17] Swap of roles from alternate to member as of July 2016
[18] Jolanta WITKOWSKA-OZOGOWSKA's mandate expired as of March 2016
[19] Nominated as of June 2016
[20] Replaced Anna-Karin HAMBERG as of March 2016
[21] Maria Grazia VALSECCHI resigned as of March 2016
[22] Nominated as of June 2016
[23] Kerry LEESON-BEEVERS' mandate ended as of December 2016

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	Elena WOLFF-HOLZ	Camille VLEMINCKX
Biostatistics Working Party	Anja SCHIEL	Frank PETAVY
Blood Products Working Party	Anneliese HILGER	Caroline VOLTZ
Cardiovascular Working Party	Pieter DE GRAEFF	Anna BACZYNSKA
Central Nervous System Working Party	Karl BROICH	Marta KOLLB-SIELECKA
Infectious Diseases Working Party	Anders LIGNELL	Radu BOTGROS
Oncology Working Party	Pierre DEMOLIS	Irene PAPADOULI
Pharmacogenomics Working Party	Krishna PRASAD	Falk EHMANN
Pharmacokinetics Working Party	Jan WELINK	Kevin BLAKE
Rheumatology/Immunology Working Party	Jan MUELLER-BERGHAUS	Daniela DA SILVA
Vaccines Working Party	Mair POWELL	Manuela MURA

Drafting groups

	Chair	EMA contact
Gastroenterology Drafting Group	Elmer SCHABEL	Joachim MUSAUS
Radiopharmaceuticals Drafting Group	Anabel CORTES BLANCO	Silvy DA ROCHA DIAS
Respiratory Drafting Group	Karolina TORNEKE	Margot MARTIN
Excipients Drafting Group	Dominique MASSET Laivi SAAREMAEL	Jean-Marc VIDAL Florence BORRELLY-KONYAKHIN

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
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
Working Group on Quality Review of Documents	Alexios SKARLATOS	Monica BUCH
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	Laura PIOPPO	Laura PIOPPO
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
Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMDv)	Gavin HALL	Melanie LEIVERS
CVMP Environmental Risk Assessment (ERAWP)	Jason WEEKS[1]	Isaura DUARTE
CVMP Immunologicals Working Party (IWP)	Esther WERNER	Fia WESTERHOLM
CVMP Pharmacovigilance Working Party (PhVWP-V)	Lisbet VESTERAGER BORGE[2]	Isaura DUARTE
CVMP Safety Working Party (SWP-V)	Eva LANDER-PERSSON	Isaura DUARTE
Scientific Advice Working Party (SAWP-V)	Rory BREATHNACH	Fia WESTERHOLM

Other CVMP-associated groups

	Chair	EMA contact
CVMP Ad Hoc Group on Veterinary Novel Therapies (ADVENT)[3]	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 for Orphan Medicinal Products (COMP)

COMP temporary working groups

	Chair	EMA contact
Protocol assistance working group	n/a	Matthias Hofer
Non-clinical Working Group	n/a	Maria Sheean

[1] Elected in April 2016, replaced Boris KOLAR
[2] Elected in December 2016, replaced Peter EKSTROM
[3] Established in December 2014, chair elected at January 2015 meeting

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

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

Ad-hoc drafting groups whenever needed to develop specific guidance

Paediatric Committee (PDCO)

PDCO working groups

	Chair	EMA contact
Formulation Working Group	Brian AYLWARD	Giovanni LESA
Non-clinical Working Group	Jaqueline CARLEER	Janina KARRES

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	Eugene van Puijenbroek and Jim Slattery	Jim Slattery, Gianmario Candore, Cosimo Zaccaria

Human Scientific Committees' Working Parties

	Chair	EMA contact
Patients' and Consumers' Working Party (PCWP)	Isabelle MOULON and Hans-Ulrich David HAERRY	Nathalie BERE
Healthcare Professionals' Working Party (HCPWP)	Isabelle MOULON and Gonzalo Calvo ROJAS	Ivana SILVA

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
CTS Working Group	Dino SOUMPASIS	
Working Party on Pharmacovigilance Procedures Work Sharing	Anne AMBROSE	

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
Active Substance Master File Working Group	Nienke RODENHUIS	Piotr KOZAREWICZ
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
Inter-Committee Scientific Advisory Group on Oncology	Jonas BERGH (Vice-Chair)	Francesco PIGNATTI
Working Group on Quality Review of Documents		
Joint PRAC/PDCO working group		Roberto DE LISA (D-DS), Lucia D'APOTE (PDCO secretariat)/Geraldine PORTIER (PRAC secretariat)
Joint CMDh-CMDv Variation Regulation Working Party	Susanne WINTERSCHEID, Roselien POPPE	Isabel CASTRO MARCHAN
EMA/CMDh Working Party on Paediatric Regulation	Sarah BRANCH	Isabel CASTRO MARCHAN

Annex 10 – CHMP opinions: initial evaluations and extensions of therapeutic indication

This annex is available in an Excel spread sheet here.

Annex 10a – Guidelines and concept papers adopted by CHMP in 2016

Biologics Working Party

Reference number	Document	Status	Date
EMA/CHMP/BWP/187338/2014	Guideline on process validation for the manufacture of biotechnology-derived active substances and data to be provided in the regulatory submission	Finalisation	12/04/2016
EMA/CHMP/BWP/534898/2008	Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials	Draft adopted for public consultation	20.06.2016
EMA/CHMP/BWP/723009/2014	Reflection paper on viral safety of plasma-derived medicinal products with respect to Hepatitis E virus	Finalisation	20.06.2016
EMA/CHMP/BWP/532517/2008 Rev 1	Guideline on development, production, characterisation and specification for monoclonal antibodies and related products	Finalisation following updates in relation to 3Rs	07.07.2016
EMA/CHMP/BWP/271475/2006 Rev 1	Guideline on potency testing of cell based immunotherapy medicinal products for the treatment of cancer	Finalisation following updates in relation to 3Rs	07.07.2016
EMA/CHMP/BWP/3354/1999 Rev 1	Guideline on production and quality control of animal immunoglobulins and immunosera for human use	Finalisation following updates in relation to 3Rs	07.07.2016
EMA/CHMP/BWP/109166/2014	Guideline on production and quality control of cytokine products derived by biotechnological processes	Finalisation following updates in relation to 3Rs	07.07.2016
EMA/CHMP/BWP/434217/2016	Position statement on quality and safety assessment for the PMF certification with regards to donor deferral criteria for risk behaviour	Finalisation	28.09.2016

Biosimilar Medicinal Product Working Party

Reference number	Document	Status	Date
EMEA/CHMP/BMWP/118264/2007. Rev 1	Non-clinical and clinical development of similar biological medicinal products containing low-molecular-weight heparins	Final guideline	10 November 2016

Biostatistics Working Party

Reference number	Document	Status	Date
EMA/CHMP/720718/2016	Guideline on multiplicity issues in clinical trials	Draft adopted for public consultation	15 December 2016

Cardiovascular Working Party

Reference number	Document	Status	Date
EMA/CHMP/50549/2015	Reflection Paper on assessment of cardiovascular safety profile of medicinal products for the treatment of cardiovascular and metabolic diseases	Final	25/02/2016
EMA/CHMP/707532/2013	Paediatric addendum to the guideline on clinical investigation of medicinal products for the treatment of acute heart failure	Final	10/11/2016
EMA/CHMP/29947/2013/Rev. 4	Guideline on clinical investigation of medicinal products in the treatment of hypertension	Final	23/06/2016
EMA/CHMP/41230/2015 f	Guideline on clinical investigation of medicinal products for the treatment of venous thromboembolic disease	Final	25/02/2016
EMA/CPMP/EWP/6235/04 Rev. 1	Guideline on clinical investigation of medicinal products for the prophylaxis of venous thromboembolic risk in non-surgical patients	Final	10/11/2016
EMA/CHMP/392958/2015 f	Guideline on clinical investigation of medicinal products for the treatment of chronic cardiac failure	Draft – adopted by CHMP for 6 month public consultation	28/01/2016
EMA/CHMP/207892/2015	Guideline on the clinical investigation of new medicinal	Draft - adopted by CHMP for 6 month	1/04/2016

Reference number	Document	Status	Date
	products for the treatment of acute coronary syndrome	public consultation	
EMA/CHMP/748108/2013, Rev. 3	Guideline on clinical investigation of medicinal products in the treatment of lipid disorders	Final	23/06/2016
EMA/317855/2016	Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus	Concept paper – adopted for 3 month public consultation	23 June 2016

Central Nervous System Working Party

Reference number	Document	Status	Date
EMA/CHMP/598082/2013.pdf	Guideline on the clinical development of medicinal products for the treatment of autism-spectrum disorder	Draft - adopted for 6 month public consultation	25/02/2016
EMA/CHMP/350492/2016	Guideline on the investigation of suicidal ideation and behaviour	Concept paper not adopted yet	
EMA/CHMP/539931/2014	Guideline on medicinal products for the treatment of Alzheimer's disease and other dementias	Draft - adopted for 6 month public consultation	28/01/2016
EMA/CHMP/179671/2016	Guideline on clinical investigation of medicinal products for treatment of migraine	Concept paper – adopted for 3 month public consultation	13/10/2016
EMA/CHMP/183826/2016	Guideline on clinical investigation of medicinal products in the treatment of depression	Concept paper – adopted for 3 month public consultation	10/11/2016
EMA/CHMP/318360/2015	Guideline on clinical investigation of medicinal products for the treatment and prevention of bipolar disorder	Concept paper – adopted for 3 month public consultation	21/07/2016
EMA/CHMP/970057/2011	Guideline on the clinical development of medicinal products intended for the treatment of pain	Final adopted	15/12/2016
EMA/CHMP/179692/2016	Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders	Concept paper – adopted for 3 month public consultation	13/10/2016

ICH

Reference number	Document	Status	Date
EMA/CHMP/ICH/135/1995	Guideline for good clinical practice E6(R2)	Adopted, in implementation, Step 5	15 December 2016
EMA/CHMP/ICH/82260/2006	ICH guideline Q3C (R6) on impurities: guideline for residual solvents	Adopted, in implementation, Step 5	15 December 2016
EMA/CHMP/ICH/809509/2016	ICH guideline Q11 on development and manufacture of drug substances (chemical entities and biotechnological / biological entities) – questions and answers	Step 2b (adopted for release for consultation)	15 December 2016
EMA/CHMP/ICH/320985/2016	ICH Guideline S3A: Note for guidance on toxicokinetics: the assessment of systemic exposure in toxicity studies - 5 questions and answers	Step 2b (adopted for release for consultation)	26 May 2016
EMA/CHMP/ICH/453684/2016	ICH S9 guideline on nonclinical evaluation for anticancer pharmaceuticals - questions and answers	Step 2b (transmitted to CHMP)	21 July 2016
EMA/CPMP/ICH/2711/1999	ICH E11(R1) guideline on clinical investigation of medicinal products in the pediatric population	Step 2b (adopted for release for consultation)	14 September 2016
EMA/CHMP/ICH/453276/2016	ICH guideline E17 on general principles for planning and design of multi-regional clinical trials	Step 2b	21 July 2016
EMA/CHMP/ICH/11623/2016	ICH guideline E18 on genomic sampling and management of genomic data	Step 2b (adopted for release for consultation)	28 January 2016
EMA/CHMP/ICH/3943/2003	ICH guideline E2B (R3) - questions and answers	Step 5	June 2016

Infectious Diseases Working Party

Reference number	Document	Status	Date
EMA/CHMP/360458/2016	Concept paper on preparation of a guideline on the 4 evaluation of medicinal products indicated for the 5 treatment and prophylaxis of respiratory syncytial virus 6 (RSV) infection	Adopted for public consultation	13 October 2016

Pharmacogenomics Working Party

Reference number	Document	Status	Date
EMA/CHMP/268544/2016	Guideline on Good pharmacogenomic practice	Draft – adopted for 5 month public consultation	28/04/2016
EMA/CHMP/800914/2016	Guideline on companion diagnostics pending progress of the new IVD Regulation	Concept paper - not adopted yet	CP envisaged for publication for comments Q2 2017
EMA/CHMP/ICH/11623/2016	ICH E18 Guideline on genomic sampling and management of genomic data	Step 2b (adopted for release for consultation)	28 January 2016
CHMP/PGxWP/128435/06	Reflection paper on pharmacogenomics in oncology	CHMP (OWP/PGWP) decision not to update the RP as replaced by new section in Oncology guideline	3Q 2016

Pharmacokinetics Working Party

Reference number	Document	Status	Date
EMA/CHMP/211243/2014	Note for guidance on qualification and reporting of physiologically-based pharmacokinetics modelling and analyses	Draft – adopted for 6 month public consultation	21/07/2016
EMA/CHMP/535116/2016	Guidance on pharmacokinetics and dosing for obese patients	Draft – not adopted yet	
	Product-Specific guidance for demonstration of BioEquivalence (PSBEG): Batch 2 Batch 4 Batch 5 Batch 6	Batch 2 – Final adopted by CHMP Batch 4 – Final adopted by CHMP Batch 5 – Draft adopted for 3 month pub cons Batch 6 – Draft adopted for 3 month pub cons	01/04/2016 15/12/2016 21/07/2016 15/12/2016
CPMP/EWP/239/95	Addendum to the existing 'The Note for guidance on the clinical requirements for locally applied, locally acting products containing known constituents'	Draft guideline – not adopted yet	
EMEA/CHMP/EWP/147013/2004	Note for guidance on the Role of pharmacokinetics in the development of medicinal	Concept paper – submitted to GCG	03/10/2016

Reference number	Document	Status	Date
	products in the paediatric population		
CPMP/EWP/560/95/Rev.1 Corr.2**	Guideline on the investigation of drug interactions	Concept paper – not adopted yet	05/12/2016

Quality Working Party

Reference number	Document	Status	Date
EMA/1539/2017	Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container	Final	28 January 2016
EMA/1539/2017	Question and answer document on data requirements for sterilization processes or primary packaging materials subsequently used in an aseptic manufacturing process.	Final	28 January 2016
EMA/CHMP/CVMP/QWP/827156/2015	Question and answer document on API mixtures	Final	1 April 2016
EMA/CHMP/CVMP/QWP/37330/2016	Reflection paper on the Dissolution specification for generic oral immediate release products	Adopted for 3-months public consultation	1 April 2016
EMA/CHMP/CVMP/QWP/404276/2016	Question and answer document on product specific active substance information	Final	23 June 2016
EMA/404489/2016	Implementation Strategy of ICH Q3D Guideline	Adopted for 1-month public consultation	23 June 2016
EMA/454576/2016	Guideline on the chemistry of active substances	Final	21 July 2016
EMA/514583/2016	Question and answer document on deletion of a non-significant specification parameter	Final	15 September 2016
EMA/CHMP/QWP/651331/2016	Question and answer on quality requirements for orally inhaled products	Final	10 November 2016
EMA/CHMP/QWP/BWP/661488/2016	Concept paper on developing a guideline on Quality requirements of medicinal products containing a device component for delivery or use of the medicinal product	Adopted for 3-months public consultation	10 November 2016
EMA/CHMP/856101/2016	Question and answer document on "Improving the understanding of NORs, PARs, DSp and normal variability of	Final	10 November 2016

Reference number	Document	Status	Date
	process parameters"		
EMA/1539/2017	Implementation strategy of ICH Q3D guideline	Final	15 December 2016
EMA/CHMP/CVMP/QWP/102117/2017	Question and answer document on deletion of the heavy metals test in a specification.	Final	15 December 2016
EMA/CHMP/CVMP/QWP/BWP/428135/2016	Concept paper on the need for Revision of Note for guidance on quality of water for pharmaceutical use	Adopted for 3-months public consultation	15 December 2016

Respiratory Drafting Group

Reference number	Document	Status	Date
CHMP/EWP/9147/08	Guideline on the clinical development of medicinal products for the treatment of cystic fibrosis	Concept paper – adopted for 3 month public consultation	21/07/2016
CPMP/EWP/4151/00 Rev. 1	Requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of Asthma and Chronic Obstructive Pulmonary Disease (COPD) in adults and for use in the treatment of asthma in children and adolescents	Concept paper not adopted yet	

Rheumatology / Immunology Working Party

Reference number	Document	Status	Date
CPMP/EWP/4891/03 Rev.1	Guideline on the clinical investigation of medicinal products for the treatment of Axial Spondyloarthritis	Draft adopted for public consultation	23 June 2016

Safety Working Party

Reference number	Document	Status	Date
EMA/CHMP/SWP/65429/2016	Concept paper on the revision of the guideline on Environmental risk assessment	Published	28 April 2016

Reference number	Document	Status	Date
	of medicinal products for human use		
EMA/CHMP/SWP/44609/2010 Rev. 1	Questions and answers on the guideline on the environmental risk assessment of medicinal products for human use – Revision 1	Published for public consultation	26 March 2015
EMA/CHMP/446302/2016	Concept paper on the revision of the 'Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products	Published for public consultation	21 July 2016
EMEA/CHMP/SWP/28367/07 Rev. 1	Guideline on Strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products – revision 1	Published for public consultation	10 November 2016

Vaccines Working Party

Reference number	Document	Status	Date
EMA/CHMP/VWP/457259/2014	Guideline on Influenza Vaccines Non-clinical and Clinical Module	Final guideline	21 July 2016
EMA/CHMP/SWP/242917/2016	Questions and answers on the withdrawal of the CPMP Note for guidance on preclinical pharmacological and toxicological testing of vaccines (CPMP/SWP/465)	Final Questions and answers document	21 July 2016
EMA/CHMP/360458/2016	Concept paper on preparation of a guideline on the 4 evaluation of medicinal products indicated for the 5 treatment and prophylaxis of respiratory syncytial virus 6 (RSV) infection	Adopted for public consultation	13 October 2016

Annex 11 – CVMP opinions in 2016 on medicinal products for veterinary use

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
• Evalon • Coccidiosis vaccine (live) for chickens	LABORATORIOS HIPRA, S.A.	• Chicken • For active immunisation of chicks from 1 day of age to reduce clinical signs (diarrhoea), intestinal lesions and oocysts output associated with coccidiosis caused by Eimeria acervulina, Eimeria brunetti, Eimeria maxima, Eimeria necatrix and Eimeria tenella.	• 04/02/2015 • 18/02/2016 • 210 • 169	• 18/02/2016 • 16/03/2016 • 18/04/2016 • 20/04/2016 • C189 of 27/05/2016
• LETIFEND • Recombinant protein Q from Leishmania infantum MON-1	Laboratorios LETI, S.L. Unipersonal	• Dog • For active immunisation of non-infected dogs from 6 months of age to reduce the risk of developing an active infection and/or clinical disease after exposure to Leishmania infantum.	• 12/11/2014 • 18/02/2016 • 210 • 253	• 18/02/2016 • 16/03/2016 • 20/04/2016 • 22/04/2016 • C 189 of 27/05/2016
• CLYNAV • pUK-SPDV-poly2#1 DNA plasmid coding for salmon pancreas disease	Elanco Europe Ltd	• Atlantic salmon • For the active immunisation of Atlantic salmon to reduce impaired daily weight gain,	• 19/09/2013 • 21/04/2016 • 210 • 736	• 21/04/2016 • 18/05/2016 • Pending • Pending • Pending

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
virus proteins		and reduce mortality, and cardiac, pancreatic and skeletal muscle lesions caused by pancreas disease following infection with salmonid alphavirus subtype 3 (SAV3).		
• Sevohale • sevoflurane	Chanelle pharmaceuticals manufacturing Limited	• Dog • For the induction and maintenance of anaesthesia.	• 09/07/2015 • 21/04/2016 • 210 • 77	• 21/04/2016 • 18/05/2016 • 21/06/2016 • 24/06/2016 • C 277 of 29/07/2016
• Sedadex • dexmedetomidine	Le Vet Beheer B.V.	• Cat, Dog • Non-invasive, mildly to moderately painful, procedures and examinations which require restraint, sedation and analgesia in dogs and cats. Deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures. Premedication in dogs and cats before induction and maintenance of general anaesthesia.	• 23/09/2015 • 16/06/2016 • 210 • 57	• 16/06/2016 • 13/07/2016 • 12/08/2016 • 17/08/2016 • C 362 of 30/09/2016

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
• ERAVAC • rabbit haemorrhagic disease type 2 virus (RHDV2), inactivated	Laboratorios Hipra, S.A.	• Rabbit • For active immunisation of rabbits against rabbit haemorrhagic disease type 2 virus (RHDV2)	• 23/10/2015 • 14/07/2016 • 150 • 115	• 14/07/2016 • 10/08/2016 • 22/09/2016 • 26/09/2016 • C 399 of 28/10/2016
• VarroMed • oxalic acid dihydrate / formic acid	BeeVital GmbH	• Honey bee • Treatment of Varroa-mite infestation in bee colonies with and without brood	• 04/02/2015 • 06/10/2016 • 210 • 400	• 06/10/2016 • 04/11/2016 • 02/02/2017 • Pending • Pending
• HALAGON • halofuginone	Emdoka BVBA	• Newborn calf • to prevent or reduce diarrhoea in new born calves due to diagnosed Cryptosporidium parvum	• 21/10/2015 • 06/10/2016 • 210 • 141	• 06/10/2016 • 04/11/2016 • 13/12/2016 • 15/12/2016 • C 28 of 27/01/2017
• Cepedex • dexmedetomidine	CP-Pharma Handelsgesellschaft mbH	• Cat, Dog • Sedation and analgesia in dogs and cats.	• 16/03/2016 • 06/10/2016 • 180 • 24	• 06/10/2016 • 04/11/2016 • 13/12/2016 • 15/12/2016 • C 28 of 27/01/2017
• Coliprotec F4/F18 • live non-pathogenic Escherichia coli O8:K87 (F4ac) / live non-pathogenic Escherichia coli O141:K94 (F18ac)	Prevtec Microbia GmbH	• Pig • For active immunisation of pigs from 18 days of age against enterotoxigenic F4-positive and F18-positive Escherichia coli in order to reduce the incidence of moderate to severe post-weaning E. coli diarrhoea (PWD)	• 20/01/2016 • 10/11/2016 • 210 • 85	• 10/11/2016 • 07/12/2016 • 09/01/2017 • Pending • Pending

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
		in infected pigs and to reduce the faecal shedding of enterotoxigenic F4-positive and F18-positive E. coli from infected pigs.		
• Stronghold Plus • selamectin / sarolaner	Zoetis Belgium SA	• Cat • For cats with, or at risk from, mixed parasitic infestations by ticks and fleas, lice, mites, gastrointestinal nematodes or heartworm. The veterinary medicinal product is exclusively indicated when use against ticks and one or more of the other target parasites is indicated at the same time.	• 17/02/2016 • 08/12/2016 • 210 • 85	• 08/12/2016 • 09/01/2017 • Pending • Pending • Pending

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
• RESPIPORC FLUpan H1N1 • influenza A virus/Jena/VI5258/2009 (PanH1N1), inactivated	IDT Biologika GmbH	• Pig • Active immunisation of pigs against swine influenza caused by pandemic subtype H1N1v	• 21/10/2015 • 08/12/2016 • 210 • 204	• 08/12/2016 • Pending • Pending • Pending • Pending

CVMP opinions in 2016 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
• Hydrocortisone aceponate	• All ruminants and *Equidae*	• 13/03/2014 • 18/02/2016 • 210 • 185	• 19/02/2016 • 2016/1444 • L 235 of 31/08/2016
• Monepantel	• Bovine	• 04/02/2015 • 19/05/2016 • 210 • 260	• 20/05/2016 • 2016/1834 • L 280 of 18/10/2016
• Aluminium salicylate (after provisional MRLs)	• Bovine, caprine, *Equidae* and rabbits	• N/a • 14/07/2016 • 88 • N/a	• 15/07/2016 • 2016/2074 • L 320 of 26/11/2016
• Gamithromycin	• All ruminants except bovine	• 18/11/2015 • 14/07/2016 • 180 • 59	• 15/07/2016 • 2016/2045 • L 318 of 24/11/2016

Product • Substance	Target species	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Regulation • Official Journal
• Fluralaner	• Poultry	• 20/01/2016 • 06/10/2016 • 208 • 52	• 07/10/2016 • 2017/201 • L 32 of 02/07/2017

Negative opinions

None

Annex 11a – 2016 CVMP opinions on extensions of indication for medicinal products for veterinary use

Positive opinions

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CVMP opinion**	**European Commission decision date**
• DRAXXIN • tulathromycin	Zoetis Belgium SA	• QJ01FA94 • to add a new therapeutic indication for use in swine respiratory disease (SRD) associated with Bordetella bronchiseptica.	• 18/02/2016	• 27/04/2016
• DRAXXIN • tulathromycin	Zoetis Belgium SA	• QJ01FA94 • to add sheep as a target species for the 100 mg/ml strength.	• 08/09/2016	• 09/11/2016
• Poulvac E. coli • Avian colibacillosis vaccine (live)	Zoetis Belgium SA	• QI01AE04 • to add a new food producing target species (turkeys).	• 18/02/2016	• 12/04/2016
• Profender • praziquantel / emodepside	Bayer Animal Health GmbH	• QP52AA51 • to add the following therapeutic indications for Profender spot-on solution for cats: - Toxocara cati (L3 larvae) - treatment of queens during late pregnancy to prevent lactogenic transmission to the offspring - Dipylidium caninum (immature adult) - Aelurostrongylus abstrusus (adult)	• 17/03/2016	• 18/04/2016
• Trifexis • spinosad / milbemycin oxime	Eli Lilly and Company Limited	• QP54AB51 • to amend the indication for prevention of angiostrongylosis.	• 10/11/2016	• Pending

Annex 11b – Guidelines and concept papers adopted by CVMP in 2016

CVMP quality

Reference number	Document title	Status
EMA/CHMP/CVMP/QWP/850374/2015	Draft guideline on the sterilisation of the medicinal product, active substance, excipient and primary container.	Adopted for consultation February 2016 (End of consultation 13 October 2016)
	Questions and Answers (Q&A) on the data requirements for sterilisation processes of primary packaging material subsequently used in an aseptic manufacturing process	Adopted February 2016
	Questions and Answers (Q&A) relating to the SPC guideline for antimicrobials, in regard to suitable pack sizes for antimicrobials	Adopted February 2016
EMEA/CVMP/271/01-Rev.1	Revised note for guidance on limitations to the use of ethylene oxide in the manufacture of medicinal products	Noted March 2016
EMA/CHMP/CVMP/QWP/37330/2016	Draft reflection paper on the dissolution specification for generic oral immediate release products	Adopted for consultation April 2016 (End of consultation 13 August 2016)
	Monthly report on application procedures guidelines and related documents for veterinary medicines July 2016	Adopted June 2016
EMA/CVMP/QWP/3629/2016	Draft reflection paper on the chemical structure and properties criteria to be considered for the evaluation of new active substance (NAS) status of chemical substances in marketing authorisation applications for veterinary medicinal products	Adopted for consultation July 2016 (End of consultation 17 February 2017)
	Questions and Answers on the deletion of a non-significant specification parameter	Adopted October 2016
EMA/CVMP/QWP/637000/2016	Guideline on the chemistry of active substances	Adopted for consultation November 2016 (End of consultation 13 August 2017)

Reference number	Document title	Status
EMA/CHMP/CVMP/QWP/70278/2012-Rev.1, Corr.1	Guideline on process validation for finished products - information and data to be provided in regulatory submissions	Adopted November 2016
	Questions and Answers on removal of a general heavy metals test from a specification	Adopted December 2016
	Questions and Answers on improving the understanding of normal operating ranges, proven acceptable ranges, design spaces and normal variability of process parameters	Adopted December 2016
EMA/CVMP/QWP/128710/2004 – Rev.1	Guideline on quality data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market	Adopted December 2016

CVMP safety

Reference number	Document title	Status
EMA/CVMP/SWP/721059/2014	Draft guideline on user safety of topically administered veterinary medicinal products	Adopted for consultation June 2016 (End of consultation 31 December 2016)
EMA/CVMP/SWP/735325/2012	Draft guideline on approach towards harmonisation of withdrawal periods	Adopted for consultation July 2016 (End of consultation 31 January 2017)
EMA/CVMP/SWP/66781/2005 – Rev.1	Guideline on safety and residue data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market	Adopted December 2016

CVMP efficacy

Reference number	Document title	Status
EMA/CVMP/EWP/706701/2015	Draft concept paper for the revision on the guideline for the conduct of pharmacokinetic studies in target animal species (EMEA/CVMP/133/99-Final)	Adopted for consultation January 2016 (End of consultation 30 April 2016)

Reference number	Document title	Status
EMA/CVMP/344/1999-Rev.2	Revised draft guideline on the conduct of efficacy studies for intramammary products for use in cattle	Adopted for second consultation February 2016 (End of consultation 31 May 2016)
EMA/CVMP/EWP/573536/2013	Revised reflection paper on anthelmintic resistance	Adopted for second consultation April 2016 (End of consultation 31 July 2016)
EMA/CVMP/EWP/707453/2015	Concept paper for the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2/2007)	Adopted for consultation April 2016 (End of consultation 31 July 2016)
EMA/CVMP/EWP/706095/2015	Concept paper for the revision of the Guideline on anticoccidials for the therapy of coccidiosis in chickens, turkeys and geese (7AE15a Vol.7)	Adopted for consultation July 2016 (End of consultation 31 October 2016)
CVMP/EWP/005/2000-Rev.3	Revised guideline on the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats	Adopted July 2016
EMA/CVMP/EWP/707573/2015	Concept paper on the revision of the guideline for veterinary medicinal products for zootechnical purposes	Adopted for consultation December 2016 (End of consultation 31 March 2017)
EMA/CVMP/EWP/707299/2015	Concept paper for the revision of the guideline on veterinary medicinal products for fluid therapy in case of diarrhoea	Adopted for consultation December 2016 (End of consultation 31 March 2017)
EMA/CVMP/EWP/117899/2004–Rev.1	Guideline on efficacy and target animal safety data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market	Adopted December 2016

CVMP pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/357539/2015	Draft reflection paper on non-spontaneous adverse event reports	Adopted for consultation May 2016 (End of consultation 31 August 2016)
EMA/CVMP/90241/2009-Rev.8	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted June 2016
EMA/CVMP/PhVWP/288284/2007-Rev.9	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted June 2016
[Published on EMA website]	Questions and Answers on expressing the frequency of adverse reactions within the product information	Adopted July 2016

CVMP antimicrobials

Reference number	Document title	Status
EMA/CVMP/627/2001-Rev.1	Revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances	Adopted January 2016
EMA/CVMP/CHMP/231573/2016	Updated advice on the use of colistin in animals within the European Union	Adopted July 2016
EMA/CVMP/AWP/161553/2016	Concept paper for revision of the current guideline on the summary of product characteristics for antimicrobial products	Adopted for consultation July 2016 (End of consultation 31 October 2016)
EMA/CVMP/209189/2015	CVMP strategy on antimicrobials 2016-2020	Adopted October 2016

CVMP immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/123243/2006 – Rev.3	Draft revised guideline on data requirements for veterinary medicinal products intended for MUMS/limited market	Adopted for consultation January 2016 (End of consultation 31 July 2016)

Reference number	Document title	Status
EMA/CVMP/IWP/867401/2015	Concept paper on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use	Adopted for consultation April 2016 (End of consultation 31 July 2016)
EMA/CVMP/IWP/49593/2013	CVMP reflection paper on the risks that should be considered prior to the use of unauthorised vaccines in emergency situations	Adopted September 2016
EMA/CVMP/IWP/867388/2015	Concept paper for the revision of the guideline on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza (AI), Blue Tongue (BT) and Foot and Mouth Disease (FMD)	Adopted for consultation September 2016 (End of consultation 31 December 2016)
EMA/CVMP/IWP/867395/2015	Concept paper for the revision of the note for guidance on the use of adjuvanted veterinary vaccines	Adopted for consultation September 2016 (End of consultation 31 December 2016)
EMA/CVMP/IWP/206555/2010-Rev.1	Guideline on requirements for the production and control of immunological veterinary medicinal products	Adopted December 2016
EMA/CVMP/IWP/251741/2015	CVMP 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 December 2016

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/448211/2015	Reflection paper on the authorisation of veterinary medicinal products containing (potential) Persistent Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) substances	Adopted for consultation February 2016 (End of consultation 31 May 2016)
EMA/CVMP/ERA/349254/2014	Reflection paper on poorly extractable and/or non-radiolabelled substances	Adopted March 2016
EMA/CVMP/ERA/689041/2015	Draft guideline on the plant testing strategy for veterinary medicinal products	Adopted for consultation May 2016 (End of consultation 30 November 2016)

Reference number	Document title	Status
	Revised Questions and Answers document in support of the guidance on the implementation of CVMP Guideline on Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH Guidelines GL6 (Phase I) and GL38 (Phase II)	Adopted July 2016
EMA/CVMP/ERA/409350/2010	Draft guideline on the higher tier testing of veterinary medicinal products to dung fauna	Adopted for consultation July 2016 (End of consultation 31 January 2017)

CVMP novel therapies

Reference number	Document title	Status
EMA/CVMP/ADVENT/226871/2015	Problem statement on stem cell - based products for veterinary use	Adopted for consultation February 2016 (End of consultation 15 May 2016)
EMA/CVMP/ADVENT/276476/2015	Problem statement on monoclonal antibodies for veterinary use	Adopted for consultation February 2016 (End of consultation 15 May 2016)
EMA/CVMP/ADVENT/174610/2016	Problem statement on stem cells-based products: specific question on extraneous agents for veterinary use	Adopted for consultation June 2016 (End of consultation 30 September 2016)
EMA/CVMP/ADVENT/207268/2016	Problem statements on stem cell-based products for veterinary use: specific questions on tumorigenicity	Adopted for consultation June 2016 (End of consultation 30 September 2016)
EMA/CVMP/ADVENT/193811/2016	Problem statement on stem cell - based products for veterinary use: specific questions on target animal safety	Adopted for consultation June 2016 (End of consultation 30 September 2016)

Replacement, Reduction, Refinement of animal testing (3Rs)

Reference number	Document title	Status
EMA/CHMP/CVMP/JEG-3Rs/164002/2016	Reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs	Adopted for consultation April 2016 (End of consultation 31 October 2016)
EMA/CHMP/CVMP/JEG-3Rs/94436/2014	Draft guideline for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs	Adopted for consultation July 2016 (End of consultation 31 January 2017)
EMA/CHMP/CVMP/JEG-3Rs/677407/2015	Report on the review and update of European Medicines Agency (the Agency) guidelines to implement best practice with regard to 3Rs in regulatory testing of medicinal products	Adopted for consultation July 2016 (End of consultation 31 October 2016)
EMA/CHMP/CVMP/JEG-3Rs/450091/2012	Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches	Adopted December 2016

General

Reference number	Document title	Status
EMA/CVMP/VICH/582610/2009	VICH GL50: Revised guideline on Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use	Adopted for consultation following the sign-off by the VICH Steering Committee (End of consultation 1 August 2016)
EMA/CVMP/VICH/313610/2013	VICH GL55: Revised guideline on Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use	Adopted for consultation following the sign-off by the VICH Steering Committee (End of consultation 1 August 2016)
EMA/CVMP/VICH/699251/2010	VICH GL54: Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD)	Adopted December 2016

Annex 12 – COMP opinions in 2016 on designation of orphan medicinal products

Positive COMP designation opinions

Product INN	**Sponsor**	**Indication**	**EMA/COMP** • Submission • Start date • Opinion • Active time	**European Commission** • Opinion received • Date of decision
N-(4-Methoxyphenyl)-N,2,6-trimethylfuro[2,3-d]pyrimidin-4-amine	FLAG Therapeutics Ltd - United Kingdom	Treatment of glioma	• 28/10/2015 • 12/09/2016 • 21/01/2016 • (59 days/19 days)	• 29/01/2016 • 17/02/2016
Methyl 3-((2R)-2-hydroxy-4-(((((S)-1-methoxy-1-oxopropan-2-yl) amino)(phenoxy)phosphoryl)oxy)-3,3-dimethylbutanamido)propanoate	Retrophin Europe Limited - Ireland	Treatment of pantothenate-kinase-associated neurodegeneration	• 28/09/2015 • 26/10/2015 • 21/01/2016 • (87 days/19 days)	• 29/01/2016 • 17/02/2016
Venetoclax	Abbvie Ltd. - United Kingdom	Treatment of acute myeloid leukaemia	• 29/10/2015 • 23/11/2015 • 21/01/2016 • (59 days/19 days)	• 29/01/2016 • 17/02/2016
Tolfenamic acid	RV Developpement - France	Treatment of behavioural variant frontotemporal dementia	• 21/10/2015 • 23/11/2015 • 21/01/2016 • (59 days/19 days)	• 29/01/2016 • 17/02/2016
Tolfenamic acid	RV Developpement - France	Treatment of progressive supranuclear palsy	• 21/10/2015 • 23/11/2015 • 21/01/2016 • (59 days/19 days)	• 29/01/2016 • 17/02/2016
Humanised IgG4 monoclonal antibody against total complement component 1, subcomponent s	Assign Group Development UK Ltd - United Kingdom	Treatment of autoimmune haemolytic anaemia	• 25/09/2015 • 26/10/2015 • 21/01/2016 • (87 days/19 days)	• 29/01/2016 • 17/02/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
S3,S13-cyclo(D-tyrolsyl-L-isoleucyl-L-cysteinyl-L-valyl-1-methyl-L-tryptophyl-L-glutaminyl-L-aspartyl-L-tryptophyl-N-methyl-L-glycyl-L-alanyl-L-histidyl-L-arginyl-L-cysteinyl-N-methyl-L-isoleucinamide)	Amyndas Pharmaceuticals S.A. - Greece	Treatment of C3 glomerulopathy	• 25/06/2015 • 26/10/2015 • 21/01/2016 • (87 days/19 days)	• 29/01/2016 • 17/02/2016
Arsenic trioxide	Orsenix Holdings BV - The Netherlands	Treatment of acute myeloid leukaemia	• 22/09/2015 • 26/10/2015 • 21/01/2016 • (87 days/19 days)	• 29/01/2016 • 17/02/2016
DNA plasmid encoding a recombinant fusion protein consisting of the extracellular domain of human TNFα p55 receptor linked to the human IgG1 Fc domain	Eyevensys SA - France	Treatment of non-infectious uveitis	• 28/10/2015 • 23/11/2015 • 21/01/2016 • (59 days/19 days)	• 29/01/2016 • 17/02/2016
Diclofenamide	Prof Michael Hanna - United Kingdom	Treatment of periodic paralysis	• 27/10/2015 • 23/11/2015 • 21/01/2016 • (59 days/19 days)	• 29/01/2016 • 17/02/2016
Delta-9-tetrahydrocannabinol and cannabidiol from extracts of the Cannabis sativa L. plant	GW Research Ltd - United Kingdom	Treatment of glioma	• 24/11/2015 • 02/01/2016 • 21/01/2016 • (19 days/19 days)	• 29/01/2016 • 17/02/2016
2-ethylbutyl (2S)-2-{[(S)-{[(2R,3S,4R,5R)-5-(4-aminopyrrolo[2,1-f][1,2,4]triazin-7-yl)-5-cyano-3,4-dihydroxytetrahydrofuran-2-yl]methoxy}(phenoxy)phosphoryl]amino}propanoate	Gilead Sciences International Ltd - United Kingdom	Treatment of Ebola virus disease	• 26/10/2015 • 23/11/2015 • 21/01/2016 • (59 days/19 days)	• 29/01/2016 • 17/02/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Ex-vivo-expanded autologous fibroblasts transduced with lentiviral vector containing the *COL7A1* gene	Dr Waseem Qasim - United Kingdom	Treatment of epidermolysis bullosa	• 28/09/2015 • 26/10/2015 • 21/01/2016 • (87 days/19 days)	• 29/01/2016 • 17/02/2016
Allogeneic fetal human retinal progenitor cells expanded ex vivo	Voisin Consulting S.A.R.L. - France	Treatment of retinitis pigmentosa	• 29/10/2015 • 23/11/2015 • 21/01/2016 • (59 days/19 days)	• 29/01/2016 • 17/02/2016
Acalabrutinib	Acerta Pharma, BV - The Netherlands	Treatment of lymphoplasmacytic lymphoma	• 27/11/2015 • 02/01/2016 • 18/02/2016 • (47 days/21 days)	• 29/02/2016 • 21/03/2016
Acalabrutinib	Acerta Pharma, BV - The Netherlands	Treatment of mantle cell lymphoma	• 26/11/2015 • 02/01/2016 • 18/02/2016 • (47 days/21 days)	• 29/02/2016 • 21/03/2016
Synthetic double-stranded siRNA oligonucleotide directed against hydroxyacid oxidase 1 mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues	Alnylam UK Limited - United Kingdom	Treatment of primary hyperoxaluria type 1	• 25/10/2015 • 23/11/2015 • 18/02/2016 • (87 days/21 days)	• 29/02/2016 • 21/03/2016
Adeno-associated viral vector serotype 8 encoding human ornithine transcarbamylase	Pharma Gateway AB - Sweden	Treatment of ornithine transcarbamylase deficiency	• 25/11/2015 • 02/01/2016 • 18/02/2016 • (47 days/21 days)	• 29/02/2016 • 21/03/2016
Diaspirin cross-linked haemoglobin	New B Innovation (UK) Limited - United Kingdom	Treatment of oesophageal cancer	• 20/10/2015 • 02/01/2016 • 18/02/2016 • (47 days/21 days)	• 29/02/2016 • 21/03/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
N-acetyl-D-mannosamine monohydrate	Escala Therapeutics Ltd - United Kingdom	Treatment of GNE myopathy	• 25/11/2015 • 02/01/2016 • 18/02/2016 • (47 days/21 days)	• 29/02/2016 • 21/03/2016
Adeno-associated viral vector serotype 5 containing a B-domain deleted variant of human coagulation factor VIII gene	BioMarin Europe Ltd. - United Kingdom	Treatment of haemophilia A	• 26/11/2015 • 02/01/2016 • 18/02/2016 • (47 days/21 days)	• 29/02/2016 • 21/03/2016
Fenretinide	Clinipace GmbH - Germany	Treatment of cutaneous T-cell lymphoma	• 28/10/2015 • 23/11/2015 • 18/02/2016 • (87 days/21 days)	• 29/02/2016 • 21/03/2016
Allogeneic Epstein-Barr virus specific cytotoxic T lymphocytes	Atara Biotherapeutics Ireland Limited - Ireland	Treatment of post-transplant lymphoproliferative disorder	• 29/10/2015 • 23/11/2015 • 18/02/2016 • (87 days/21 days)	• 29/02/2016 • 21/03/2016
Exenatide	Alan Boyd Consultants Ltd - United Kingdom	Treatment of idiopathic intracranial hypertension	• 28/09/2015 • 02/01/2016 • 18/02/2016 • (47 days/21 days)	• 29/02/2016 • 21/03/2016
Florilglutamic acid (18F)	Piramal Imaging GmbH - Germany	Diagnosis of hepatocellular carcinoma	• 27/10/2015 • 23/11/2015 • 18/02/2016 • (87 days/21 days)	• 29/02/2016 • 21/03/2016
Acalabrutinib	Acerta Pharma, BV - The Netherlands	Treatment of chronic lymphocytic leukaemia / small lymphocytic lymphoma	• 26/10/2015 • 23/11/2015 • 18/02/2016 • (87 days/21 days)	• 29/02/2016 • 21/03/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Ubenimex	Eiger Biopharmaceuticals Europe Limited - United Kingdom	Treatment of pulmonary arterial hypertension	• 24/09/2015 • 23/11/2015 • 18/02/2016 • (87 days/21 days)	• 29/02/2016 • 21/03/2016
Fosbretabulin tromethamine	Diamond BioPharm Limited - United Kingdom	Treatment of gastro-entero-pancreatic neuroendocrine tumours	• 29/10/2015 • 23/11/2015 • 18/02/2016 • (87 days/21 days)	• 29/02/2016 • 21/03/2016
Sindbis virus envelope pseudotyped lentiviral vector encoding New York esophageal squamous cell carcinoma-1 protein	Immune Design Ltd - United Kingdom	Treatment of soft tissue sarcoma	• 02/12/2015 • 02/01/2016 • 18/02/2016 • (47 days/21 days)	• 29/02/2016 • 21/03/2016
Florilglutamic acid (18F)	Piramal Imaging GmbH - Germany	Diagnosis of glioma	• 27/10/2015 • 23/11/2015 • 18/02/2016 • (87 days/21 days)	• 29/02/2016 • 21/03/2016
Glucopyranosyl lipid A stable emulsion and recombinant New York esophageal squamous cell carcinoma-1 protein	Immune Design Ltd - United Kingdom	Treatment of soft tissue sarcoma	• 26/08/2015 • 23/11/2015 • 18/02/2016 • (87 days/21 days)	• 29/02/2016 • 21/03/2016
Human/murine chimeric monoclonal antibody against endoglin	Tracon Pharma Limited - United Kingdom	Treatment of soft tissue sarcoma	• 17/11/2015 • 02/01/2016 • 23/03/2016 • (81 days/23 days)	• 05/04/2016 • 28/04/2016
Fluocinolone acetonide	Campharm Ltd - United Kingdom	Treatment of non-infectious uveitis	• 23/11/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Recombinant adeno-associated viral vector serotype 9 carrying the gene for the human E6-AP ubiquitin protein ligase	Voisin Consulting S.A.R.L. - France	Treatment of Angelman syndrome	• 10/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
N-carboxymethyl-glycyl-L-threonyl-L-histidyl-L-3,3-diphenylalanyl-L-piperidincarboxy-3-yl-L-arginyl-L-S-methylthio-cystyl-L-arginyl-L-tryptophyl-aminohexanyl-N-carboxamidomethyl-glycine N-hexadecylamide	QRC Consultants Ltd - United Kingdom	Treatment of beta thalassaemia intermedia and major	• 09/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
Tyr-Met-Phe-Pro-Asn-Ala-Pro-Tyr-Leu, Ser-Gly-Gln-Ala-Tyr-Met-Phe-Pro-Asn-Ala-Pro-Tyr-Leu-Pro-Ser-Cys-Leu-Glu-Ser, Arg-Ser-Asp-Glu-Leu-Val-Arg-His-His-Asn-Met-His-Gln-Arg-Asn-Met-Thr-Lys-Leu and Pro-Gly-Cys-Asn-Lys-Arg-Tyr-Phe-Lys-Leu-Ser-His-Leu-Gln-Met-His-Ser-Arg-Lys-His-Thr-Gly	SELLAS Life Sciences Group UK, Limited - United Kingdom	Treatment of malignant mesothelioma	• 09/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
S-acetyl-(S)-4'-phosphopantetheine, calcium salt	Acies Bio d.o.o. - Slovenia	Treatment of pantothenate-kinase-associated neurodegeneration	• 10/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
Recombinant human cerebral dopamine neurotrophic factor	Herantis Pharma Plc - Finland	Treatment of amyotrophic lateral sclerosis	• 09/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
Brincidofovir	Chimerix UK Ltd - United Kingdom	Prevention of cytomegalovirus disease	• 26/11/2015 • 02/01/2016 • 23/03/2016 • (81 days/23 days)	• 05/04/2016 • 28/04/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Resiquimod	Galderma R&D - France	Treatment of cutaneous T-cell lymphoma	• 10/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
(1E,6E)-1,7-bis(3,4-dimethoxyphenyl)-4-cyclobutylmethyl-1,6-heptadiene-3,5-dione	Coté Orphan Consulting UK Limited - United Kingdom	Treatment of x-linked spinal and bulbar muscular atrophy (Kennedy's disease)	• 10/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
Tyr-Met-Phe-Pro-Asn-Ala-Pro-Tyr-Leu, Ser-Gly-Gln-Ala-Tyr-Met-Phe-Pro-Asn-Ala-Pro-Tyr-Leu-Pro-Ser-Cys-Leu-Glu-Ser, Arg-Ser-Asp-Glu-Leu-Val-Arg-His-His-Asn-Met-His-Gln-Arg-Asn-Met-Thr-Lys-Leu and Pro-Gly-Cys-Asn-Lys-Arg-Tyr-Phe-Lys-Leu-Ser-His-Leu-Gln-Met-His-Ser-Arg-Lys-His-Thr-Gly	SELLAS Life Sciences Group UK, Limited - United Kingdom	Treatment of acute myeloid leukaemia	• 26/11/2015 • 02/01/2016 • 23/03/2016 • (81 days/23 days)	• 05/04/2016 • 28/04/2016
2-methyl-1-[(4-[6-(trifluoromethyl)pyridin-2-yl]-6-{[2-(trifluoromethyl)pyridin-4-yl]amino}-1,3,5-triazin-2-yl)amino]propan-2-ol methanesulfonate	Celgene Europe Limited - United Kingdom	Treatment of acute myeloid leukaemia	• 10/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
Antisense oligonucleotide complementary to the exonic splicer enhancer sequence at intron 26 of the centrosomal protein 290 pre-mRNA	ProQR Therapeutics IV BV - The Netherlands	Treatment of Leber's congenital amaurosis	• 10/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
Autologous dermal fibroblasts genetically modified ex vivo with a lentiviral vector containing the human *COL7A1* gene	Intrexon Actobiotics N.V. - Belgium	Treatment of epidermolysis bullosa	• 19/11/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016

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Autologous stromal vascular cell fraction from adipose tissue	Cytori Ltd - United Kingdom	Treatment of systemic sclerosis	• 10/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
Cannabidiol	Richardson Associates Regulatory Affairs Ltd - United Kingdom	Prevention of graft versus host disease	• 10/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
Combination of 4-hydroxyandrostenedione Serenoa Serrulata fruit extract Alpha lipoic acid	Dr. Regenold GmbH Development·Regulatory·Market Access - Germany	Treatment of multiple symmetric lipomatosis	• 10/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
Humanised recombinant IgG4 anti-human tau antibody	Abbvie Ltd. - United Kingdom	Treatment of progressive supranuclear palsy	• 07/12/2015 • 25/01/2016 • 23/03/2016 • (58 days/23 days)	• 05/04/2016 • 28/04/2016
Polyethylene glycol-modified human recombinant truncated cystathionine beta-synthase	Alan Boyd Consultants Ltd - United Kingdom	Treatment of homocystinuria	• 29/01/2016 • 22/02/2016 • 21/04/2016 • (59 days/33 days)	• 27/04/2016 • 30/05/2016
Fc- and CDR-modified humanised monoclonal antibody against C5	Alexion Europe SAS - France	Treatment of paroxysmal nocturnal haemoglobinuria	• 09/12/2015 • 25/01/2016 • 21/04/2016 • (87 days/12 days)	• 27/04/2016 • 30/05/2016
Rimiducid	QRC Consultants Ltd - United Kingdom	Treatment of graft-versus-host disease	• 29/01/2016 • 22/02/2016 • 21/04/2016 • (59 days/33 days)	• 27/04/2016 • 30/05/2016

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Temsirolimus	Centro de Investigación Biomédica en Red (CIBER) - Spain	Treatment of adrenoleukodystrophy	• 29/01/2016 • 22/02/2016 • 21/04/2016 • (59 days/33 days)	• 27/04/2016 • 30/05/2016
Rovalpituzumab tesirine	Aceso Biologics Consulting Ltd - United Kingdom	Treatment of small cell lung cancer	• 29/01/2016 • 22/02/2016 • 21/04/2016 • (59 days/33 days)	• 27/04/2016 • 30/05/2016
Vemurafenib	Groupe d'étude des histiocytoses - France	Treatment of Langerhans cell histiocytosis	• 29/01/2016 • 22/02/2016 • 21/04/2016 • (59 days/33 days)	• 27/04/2016 • 30/05/2016
Arimoclomol citrate	Orphazyme ApS - Denmark	Treatment of inclusion body myositis	• 10/12/2015 • 25/01/2016 • 21/04/2016 • (87 days/33 days)	• 27/04/2016 • 30/05/2016
Pentosan polysulfate sodium	NextraResearch S.r.l. - Italy	Treatment of interstitial cystitis	• 19/01/2016 • 22/02/2016 • 21/04/2016 • (59 days/33 days)	• 27/04/2016 • 30/05/2016
H-Phe-Ser-Arg-Tyr-Ala-Arg-OH-acetate	QRC Consultants Ltd - United Kingdom	Treatment of amyotrophic lateral sclerosis	• 28/01/2016 • 22/02/2016 • 21/04/2016 • (59 days/13 days)	• 17/05/2016 • 30/05/2016
Autologous CD34+ cells transduced with lentiviral vector encoding the human beta globin gene	Fondazione Telethon - Italy	Treatment of beta thalassaemia intermedia and major	• 29/01/2016 • 22/02/2016 • 21/04/2016 • (59 days/33 days)	• 27/04/2016 • 30/05/2016

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4-[(2E)-1-oxo-3-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2-propen-1-yl]-1-piperazinecarboxamide	Shire Pharmaceuticals Ireland Limited - Ireland	Treatment of retinitis pigmentosa	• 29/10/2015 • 22/02/2016 • 21/04/2016 • (59 days/33 days)	• 27/04/2016 • 30/05/2016
(R)-6-(2-fluorophenyl)-N-(3-(2-((2-methoxyethyl)amino)ethyl)phenyl)-5,6-dihydrobenzo[h]quinazolin-2-amine dihydrochloride	QRC Consultants Ltd - United Kingdom	Treatment of biliary tract cancer	• 09/12/2015 • 22/02/2016 • 21/04/2016 • (59 days/33 days)	• 27/04/2016 • 30/05/2016
Recombinant adeno-associated viral vector containing the human *RPGR* gene	TMC Pharma Services Ltd - United Kingdom	Treatment of retinitis pigmentosa caused by mutations in the *RPGR* gene	• 18/01/2016 • 22/02/2016 • 21/04/2016 • (59 days/13 days)	• 17/05/2016 • 30/05/2016
Sodium nitrite and ethylenediaminetetraacetic acid	Arch Bio Ireland Ltd - Ireland	Treatment of cystic fibrosis	• 29/01/2016 • 22/02/2016 • 21/04/2016 • (59 days/33 days)	• 27/04/2016 • 30/05/2016
Recombinant protein derived from the saliva of the Ornithodoros moubata tick	Akari Therapeutics Plc - United Kingdom	Treatment of Guillain-Barré syndrome	• 19/02/2016 • 21/03/2016 • 19/05/2016 • (59 days/25 days)	• 02/06/2016 • 27/06/2016
Setmelanotide	TMC Pharma Services Ltd - United Kingdom	Treatment of Prader-Willi syndrome	• 22/02/2016 • 21/03/2016 • 19/05/2016 • (59 days/25 days)	• 02/06/2016 • 27/06/2016
Modified mRNA encoding the UGT1A1 protein	Alexion Europe SAS - France	Treatment of Crigler-Najjar syndrome	• 26/02/2016 • 21/03/2016 • 19/05/2016 • (59 days/25 days)	• 02/06/2016 • 27/06/2016

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Molgramostim	Savara ApS - Denmark	Treatment of acute respiratory distress syndrome	• 25/01/2016 • 22/02/2016 • 19/05/2016 • (87 days/25 days)	• 02/06/2016 • 27/06/2016
3-(5-amino-2-methyl-4-oxoquinazolin-3(4H)-yl)piperidine-2,6-dione hydrochloride	Celgene Europe Limited - United Kingdom	Treatment of diffuse large B-cell lymphoma	• 29/01/2016 • 22/02/2016 • 19/05/2016 • (87 days/25 days)	• 02/06/2016 • 27/06/2016
Donor T lymphocytes depleted ex vivo of host alloreactive T cells using photodynamic treatment	Kiadis Pharma Netherlands B.V. - The Netherlands	Treatment in haematopoietic stem cell transplantation	• 27/01/2016 • 22/02/2016 • 19/05/2016 • (87 days/25 days)	• 02/06/2016 • 27/06/2016
Recombinant humanised monoclonal IgG2 lambda antibody against human sclerostin	Mereo Biopharma Group Limited - United Kingdom	Treatment of osteogenesis imperfecta	• 10/03/2016 • 18/04/2016 • 19/05/2016 • (31 days/25 days)	• 02/06/2016 • 27/06/2016
Pyridoxine and L-pyroglutamic acid	FGK Representative Service Ltd. - United Kingdom	Treatment of fragile X syndrome	• 22/02/2016 • 21/03/2016 • 19/05/2016 • (59 days/25 days)	• 02/06/2016 • 27/06/2016
Diclofenamide	Sun Pharmaceutical Industries Europe B.V. - The Netherlands	Treatment of periodic paralysis	• 28/01/2016 • 21/03/2016 • 19/05/2016 • (59 days/25 days)	• 02/06/2016 • 27/06/2016
Eflornithine	Orbus Therapeutics Limited - United Kingdom	Treatment of glioma	• 28/01/2016 • 22/02/2016 • 19/05/2016 • (87 days/25 days)	• 02/06/2016 • 27/06/2016

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2'-O-(2-methoxyethyl) phosphorothioate antisense oligonucleotide targeting the growth hormone receptor	Coté Orphan Consulting UK Limited - United Kingdom	Treatment of acromegaly	• 29/01/2016 • 22/02/2016 • 19/05/2016 • (87 days/25 days)	• 02/06/2016 • 27/06/2016
Melatonin	Therapicon Srl - Italy	Treatment of neonatal sepsis	• 26/01/2016 • 22/02/2016 • 19/05/2016 • (87 days/25 days)	• 02/06/2016 • 27/06/2016
Humanised monoclonal antibody targeting interleukin-15	Dr Alain Vicari - France	Treatment of eosinophilic oesophagitis	• 21/01/2016 • 22/02/2016 • 19/05/2016 • (87 days/25 days)	• 02/06/2016 • 27/06/2016
Citric acid monohydrate	CATS Consultants GmbH - Germany	Treatment of acute liver failure	• 29/01/2016 • 22/02/2016 • 19/05/2016 • (87 days/25 days)	• 02/06/2016 • 27/06/2016
Humanised anti-IL-6 receptor monoclonal antibody	Chugai Pharma Europe Ltd - United Kingdom	Treatment of neuromyelitis optica spectrum disorders	• 29/01/2016 • 22/02/2016 • 19/05/2016 • (87 days/25 days)	• 02/06/2016 • 27/06/2016
Allogeneic donor-derived ex-vivo expanded T lymphocytes transduced with a retroviral vector containing inducible caspase 9 and truncated CD19	QRC Consultants Ltd - United Kingdom	Treatment in haematopoietic stem cell transplantation	• 29/01/2016 • 22/02/2016 • 19/05/2016 • (87 days/25 days)	• 02/06/2016 • 27/06/2016
Teriparatide	Alacrita LLP - United Kingdom	Treatment of hypoparathyroidism	• 22/02/2016 • 21/03/2016 • 19/05/2016 • (59 days/25 days)	• 02/06/2016 • 27/06/2016

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Cyclocreatine	Pharma Gateway AB - Sweden	Treatment of creatine deficiency syndromes	• 22/02/2016 • 21/03/2016 • 19/05/2016 • (59 days/25 days)	• 02/06/2016 • 27/06/2016
Triheptanoin	Vall d'Hebron Institute of Research - Spain	Treatment of McArdle's disease	• 18/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Mifamurtide	Delta Proteomics SAS - France	Treatment of hepatocellular carcinoma	• 18/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Recombinant human monoclonal antibody to insulin receptor	XOMA UK Limited - United Kingdom	Treatment of congenital hyperinsulinism	• 25/02/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Setmelanotide	TMC Pharma Services Ltd - United Kingdom	Treatment of pro-opiomelanocortin deficiency	• 16/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Sodium benzoate	Lucane Pharma SA - France	Treatment of carbamoyl-phosphate synthase-1 deficiency	• 11/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Sodium benzoate	Lucane Pharma SA - France	Treatment of citrullinaemia type 1	• 11/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016

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Sodium benzoate	Lucane Pharma SA - France	Treatment of hyperargininaemia	• 11/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Mifamurtide	Delta Proteomics SAS - France	Treatment of echinococcosis	• 18/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Sodium hypochlorite	Hypo-Stream Ltd - United Kingdom	Treatment of partial deep dermal and full thickness burns	• 17/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
16-base single-stranded peptide nucleic acid oligonucleotide linked to a 7 aminoacid peptide	Biogenera SpA - Italy	Treatment of soft tissue sarcoma	• 24/02/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Volanesorsen sodium	Ionis USA Ltd - United Kingdom	Treatment of familial partial lipodystrophy	• 18/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Sodium benzoate	Lucane Pharma SA - France	Treatment of ornithine transcarbamylase deficiency	• 11/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Brincidofovir	Chimerix UK Ltd - United Kingdom	Treatment of adenovirus infection in immunocompromised patients	• 18/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016

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Autologous Epstein-Barr virus specific T-cells derived from peripheral blood mononuclear cells, expanded ex vivo	Cell Medica Ltd. - United Kingdom	Treatment of post-transplant lymphoproliferative disorders	• 18/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Autologous Epstein-Barr virus specific T-cells derived from peripheral blood mononuclear cells, expanded ex vivo	Cell Medica Ltd. - United Kingdom	Treatment of extranodal NK/T cell lymphoma, nasal type	• 18/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/19 days)	• 25/06/2016 • 14/07/2016
2-[4-(1-methyl-4-pyridin-4-yl-1H-pyrazol-3-yl)-phenoxymethyl]-quinoline succinic acid	Pfizer Limited - United Kingdom	Treatment of Huntington's disease	• 16/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Dimethyl fumarate	Immungenetics AG - Germany	Treatment of bullous pemphigoid	• 17/02/2016 • 21/03/2016 • 16/06/2016 • (87 days/17 days)	• 27/06/2016 • 14/07/2016
Sirolimus	Best Regulatory Consulting Ltd - United Kingdom	Treatment of sporadic lymphangioleiomyomatosis	• 25/02/2016 • 21/03/2016 • 16/06/2016 • (87 days/17 days)	• 27/06/2016 • 14/07/2016
Adeno-associated viral vector serotype 2.7m8 containing the *ChrimsonR-tdTomato* gene	GenSight Biologics - France	Treatment of retinitis pigmentosa	• 15/02/2016 • 16/06/2016 • (87 days/17 days)	• 27/06/2016 • 14/07/2016
3-[4-(1H-imidazol-1-ylmethyl)phenyl]-5-(2-methylpropyl)thiophene-2-[(N-butyloxylcarbamate)-sulphonamide] sodium salt	Vicore Pharma AB - Sweden	Treatment of idiopathic pulmonary fibrosis	• 26/02/2016 • 21/03/2016 • 16/06/2016 • (87 days/17 days)	• 27/06/2016 • 14/07/2016
Poly (oxy-1,2-ethanediyl), alpha-(carboxymethyl)-omega-methoxy-,amide with arginase 1 [cobalt cofactor] (synthetic human) (1:10), trimer	ERA Consulting GmbH - Germany	Treatment of hyperargininaemia	• 25/02/2016 • 21/03/2016 • 16/06/2016 • (87 days/17 days)	• 27/06/2016 • 14/07/2016

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Autologous CD4+ and CD8+ T cells transduced with lentiviral vector containing an affinity-enhanced T-cell receptor targeting the New York esophageal antigen-1	Adaptimmune Limited - United Kingdom	Treatment of soft tissue sarcoma	• 16/03/2016 • 18/04/2016 • 16/06/2016 • (59 days/17 days)	• 27/06/2016 • 14/07/2016
Melatonin	Therapicon Srl - Italy	Treatment of necrotising enterocolitis	• 11/01/2016 • 22/02/2016 • 19/05/2016 • (87 days/63 days)	• 30/05/2016 • 01/08/2016
Sodium benzoate	Lucane Pharma SA - France	Treatment of lysinuric protein intolerance	• 11/03/2016 • 18/04/2016 • 13/07/2016 • (86 days/31 days)	• 29/07/2016 • 29/08/2016
Recombinant human interleukin-12	Coté Orphan Consulting UK Limited - United Kingdom	Treatment of acute radiation syndrome	• 23/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Valproic Acid	Vall d'Hebron Institute of Research - Spain	Treatment of McArdle's disease	• 18/03/2016 • 18/04/2016 • 13/07/2016 • (86 days/31 days)	• 29/07/2016 • 29/08/2016
Temozolomide	Double Bond Pharmaceutical AB - Sweden	Treatment of glioma	• 16/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
6'-(R)-methyl-5-O-(5-amino-5,6-dideoxy-α-L-talofuranosyl)-paromamine sulfate	Coté Orphan Consulting UK Limited - United Kingdom	Treatment of mucopolysaccharidosis type I	• 23/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016

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Nintedanib	Boehringer Ingelheim International GmbH - Germany	Treatment of systemic sclerosis	• 19/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Autologous mesenchymal stromal cells on a decellularised tracheal scaffold from a cadaveric donor	Videregen Ltd - United Kingdom	Treatment of tracheal stenosis	• 17/03/2016 • 18/04/2016 • 13/07/2016 • (86 days/31 days)	• 29/07/2016 • 29/08/2016
Cisplatin	PlumeStars s.r.l. - Italy	Treatment of malignant mesothelioma	• 23/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Masitinib mesilate	AB Science - France	Treatment of amyotrophic lateral sclerosis	• 18/03/2016 • 18/04/2016 • 13/07/2016 • (86 days/31 days)	• 29/07/2016 • 29/08/2016
L-Pyr-L-Glu-L-Gln-L-Leu-L-Glu-L-Arg-L-Ala-L-Leu-L-Asn-L-Ser-L-Ser	Araim Pharma Europe Ltd - UK	Prevention of graft loss in pancreatic islet transplantation	• 19/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Cannabidiol	Richardson Associates Regulatory Affairs Ltd - United Kingdom	Treatment of graft-versus-host disease	• 23/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Recombinant humanised monoclonal antibody against human complement component C5a	Alexion Europe SAS - France	Treatment of graft-versus-host disease	• 23/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016

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Zoledronic acid	Laboratorio Italiano Biochimico Farmaceutico Lisapharma S.p.A. - Italy	Treatment of glioma	• 17/03/2016 • 18/04/2016 • 13/07/2016 • (86 days/31 days)	• 29/07/2016 • 29/08/2016
Recombinant human acid alpha-glucosidase conjugated with mannose-6-phosphate analogues	NanoMedSyn - France	Treatment of glycogen storage disease type II (Pompe's disease)	• 20/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Fimaporfin	PCI Biotech AS - Norway	Treatment of cholangiocarcinoma	• 23/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Sodium benzoate	Lucane Pharma SA - France	Treatment of ornithine translocase deficiency	• 11/03/2016 • 18/04/2016 • 13/07/2016 • (86 days/31 days)	• 29/07/2016 • 29/08/2016
Recombinant protein derived from the saliva of the Ornithodoros moubata tick	Akari Therapeutics Plc - United Kingdom	Treatment of paroxysmal nocturnal haemoglobinuria	• 18/03/2016 • 18/04/2016 • 13/07/2016 • (86 days/31 days)	• 29/07/2016 • 29/08/2016
2-((2-ethyl-6-(4-(2-(3-hydroxyazetidin-1-yl)-2-oxoethyl)-piperazin-1-yl)-8-methylimidazo[1,2-alpha]pyridin-3-yl)-(methyl)amino)-4-(4-fluorophenyl)-thiazole-5-carbonitrile	Galapagos NV - Belgium	Treatment of idiopathic pulmonary fibrosis	• 17/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016

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2-(1,5-dimethyl-3-phenyl-1H-pyrrol-2-yl)-N-{4-[4-(5-fluoro-pyrimidin-2-yl)piperazin-1-yl]-phenyl}-2-oxo-acetamide	F2G Ltd - United Kingdom	Treatment of scedosporiosis	• 23/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Adeno-associated viral vector serotype 9 containing the human mini-dystrophin gene	Advanced Biotherapeutics Consulting SARL - France	Treatment of Duchenne muscular dystrophy	• 20/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Adenovirus associated viral vector serotype 5 containing the human *RPGR* gene	MeiraGTx UK II Limited - United Kingdom	Treatment of retinitis pigmentosa	• 23/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Methotrexate	aimAKU (Associazione Italiana Malati di Alcaptonuria) - Italy	Treatment of alkaptonuria	• 16/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Synthetic double-stranded siRNA oligonucleotide directed against delta-aminolevulinic acid synthase 1 mRNA, covalently linked to a ligand containing three N-acetylgalactosamine residues	Alnylam UK Limited - United Kingdom	Treatment of acute hepatic porphyria	• 23/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Synthetic ribonucleic acid oligonucleotide directed against superoxide dismutase 1 messenger ribonucleic acid	Biogen Idec Limited - United Kingdom	Treatment of amyotrophic lateral sclerosis	• 23/05/2016 • 13/06/2016 • 13/07/2016 • (30 days/31 days)	• 29/07/2016 • 29/08/2016
Xenon	Neuroprotexeon Ltd - United Kingdom	Treatment of ischemia reperfusion injury associated with cardiac arrest	• 23/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016

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Crenolanib besylate	Arog Pharmaceuticals Europe Ltd - Ireland	Treatment of acute myeloid leukemia	• 23/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
Autologous mononuclear cells derived from human cord blood	BrainRepair UG (haftungsbeschränkt) - Germany	Treatment of periventricular leukomalacia	• 22/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
Adeno-associated viral vector serotype 2/2 containing a gene encoding the channelrhodopsin-2 protein	Alacrita LLP - United Kingdom	Treatment of retinitis pigmentosa	• 24/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
Exendin (9-39)	Eiger Biopharmaceuticals Europe Limited - United Kingdom	Treatment of noninsulinoma pancreatogenous hypoglycaemia syndrome	• 16/03/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
Venetoclax	Abbvie Ltd. - United Kingdom	Treatment of multiple myeloma	• 23/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
Adeno-associated viral vector serotype 5 containing the human *RLBP1* gene	HORAMA SA - France	Treatment of retinitis pigmentosa	• 23/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
(E)-(6-((N-methyl-((3-methylbenzofuran-2-yl) methyl)amino)-3-oxoprop-1-en-1-yl)-2-oxo-3,4-dihydro- 1,8-naphthyridin-1(2H)-yl)methyl phosphate, bis ethanolamine salt	Voisin Consulting S.A.R.L. - France	Treatment of osteomyelitis	• 23/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Autologous mononuclear cells derived from human cord blood	BrainRepair UG (haftungsbeschränkt) - Germany	Treatment of neonatal encephalopathy	• 21/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD19	Novartis Europharm Limited - United Kingdom	Treatment of diffuse large B-cell lymphoma	• 17/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
Human monoclonal IgG1 antibody against tissue factor pathway inhibitor	Pfizer Limited - United Kingdom	Treatment of haemophilia A	• 18/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
Fenretinide	Clinipace GmbH - Germany	Treatment of peripheral T-cell lymphoma	• 21/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
P-ethoxy growth factor receptor-bound protein 2 (Grb2) antisense oligonucleotide	Clinical Network Services (UK) Ltd - United Kingdom	Treatment of acute myeloid leukaemia	• 24/06/2016 • 18/07/2016 • 13/09/2016 • (57 days/24 days)	• 20/09/2016 • 14/10/2016
Ubiquinol	Centro de Investigación Biomédica en Red (CIBER) - Spain	Treatment of coenzyme Q10 deficiency syndrome	• 24/06/2016 • 18/07/2016 • 13/09/2016 • (57 days/24 days)	• 20/09/2016 • 14/10/2016
(6aR, 10aR)-3-(1',1'-dimethylheptyl)- delta-8-tetrahydro-cannabinol-9-carboxylic acid	TMC Pharma Services Ltd - United Kingdom	Treatment of cystic fibrosis	• 22/05/2016 • 08/09/2016 • 13/06/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Hematopoietic stem cells modified with a lentiviral vector containing the *CD18* gene	Centro de Investigación Biomédica en Red (CIBER) - Spain	Treatment of leukocyte adhesion deficiency type I	• 24/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
Carbamazepine	University of Newcastle upon Tyne - United Kingdom	Treatment of metaphyseal chondrodysplasia, Schmid-type	• 24/06/2016 • 18/07/2016 • 13/09/2016 • (57 days/24 days)	• 20/09/2016 • 14/10/2016
Mogamulizumab	Kyowa Kirin Limited - United Kingdom	Treatment of cutaneous T-cell lymphoma	• 18/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
Radio-iodinated (131I) anti-CD45 murine monoclonal antibody	PharmaLex UK Services Limited - United Kingdom	Treatment in haematopoietic stem cell transplantation	• 18/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
Self-complementary adeno-associated viral vector serotype 9 vector containing the *SGSH* gene	Ser-mes Planificación SL - Spain	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome)	• 23/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
N-[(2S)-5-{[(1R, 2S)-2-(4-fluorophenyl)cyclopropyl] amino}-1-(4-methylpiperazin-1-yl)-1-oxopentan-2-yl]-4-(1H-1,2,3-triazol-1-yl)benzamide, bis-tosylate salt	Imago BioSciences Ltd. - United Kingdom	Treatment of myelofibrosis	• 23/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
Crenolanib besylate	Arog Pharmaceuticals Europe Ltd - Ireland	Treatment of soft tissue sarcoma	• 14/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
A non-covalent trimer of tumor necrosis factor fused to an antibody specific to the extra-domain B of fibronectin in single-chain variable fragment format	Philogen S.p.A. - Italy	Treatment of soft tissue sarcoma	• 23/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
2-(1,5-dimethyl-3-phenyl-1H-pyrrol-2-yl)- N-{4-[4-(5-fluoro-pyrimidin-2-yl) piperazin- 1-yl]-phenyl}-2-oxo-acetamide	F2G Ltd - United Kingdom	Treatment of invasive aspergillosis	• 23/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
Venetoclax	Abbvie Ltd. - United Kingdom	Treatment of diffuse large B-cell lymphoma	• 23/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
Acebutolol hydrochloride	Therapicon Srl - Italy	Treatment of Smith-Magenis syndrome	• 13/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
Synthetic-15-amino acid macrocyclic peptide acylated with a polyethyleneglycol palmitoylated linker	Ra Europe Limited - United Kingdom	Treatment of paroxysmal nocturnal haemoglobinuria	• 23/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
Melatonin	Therapicon Srl - Italy	Treatment of Smith-Magenis syndrome	• 13/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
Recombinant adeno-associated viral vector encoding a human micro-dystrophin gene under the control of a muscle specific promoter	Pharma Gateway AB - Sweden	Treatment of Duchenne muscular dystrophy	• 24/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Tadekinig alfa	Coté Orphan Consulting UK Limited - United Kingdom	Treatment of haemophagocytic lymphohistiocytosis	• 24/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
Tetrofosmin	ProActina - Greece	Diagnosis of glioma	• 22/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
Chemically modified human recombinant sulfamidase	Swedish Orphan Biovitrum AB (publ) - Sweden	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome)	• 22/06/2016 • 18/07/2016 • 08/09/2016 • (52 days/24 days)	• 20/09/2016 • 14/10/2016
Lutetium-177(3+), S2,S7-cyclo[N-{4,7,10-Tricarboxymethyl-1,4,7,10-tetraaza-cyclododecan-1-yl-acetyl}-4-chloro-L-phenylalanyl-D-cysteinyl-4-[(4S)-2,6-dioxo-1,3-diazinane-4-carboxamido]-L-phenylalanyl-4-(carbamoylamino)-D-phenylalanyl-L-lysyl-L-threonyl-L-cysteinyl-D-tyrosinamide]	Ipsen Pharma - France	Treatment of gastroenteropancreatic neuroendocrine tumours	• 17/05/2016 • 13/06/2016 • 08/09/2016 • (87 days/24 days)	• 20/09/2016 • 14/10/2016
Ibrutinib	Janssen-Cilag International N.V. - Belgium	Treatment of graft-versus-host disease	• 19/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016
L-selenomethionine	Université de Montpellier - France	Treatment of facioscapulohumeral muscular dystrophy	• 19/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Particles comprised of methacrylic acid based co-polymer, cross-linked with a bi-functional cross-linker, purified to bind L-phenylalanine and L-phenylalanine containing peptides	MipSalus ApS - Denmark	Treatment of hyperphenylalaninemia	• 13/03/2016 • 12/09/2016 • 06/10/2016 • (24 days/29 days)	• 20/10/2016 • 18/11/2016
Recombinant adeno-associated viral vector serotype 2 carrying the gene for the human aromatic L-amino acid decarboxylase protein	Voisin Consulting S.A.R.L. - France	Treatment of aromatic L-amino acid decarboxylase deficiency	• 20/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016
Sodium benzoate	Lucane Pharma SA - France	Treatment of N-acetylglutamate synthase deficiency	• 20/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016
Tyr-Gly-Arg-Lys-Lys-Arg-Arg-Gln-Arg-Arg-Gly-Gly-Asp-Leu-Leu-Pro-Arg-Gly-Ser	Dr Ulrich Granzers - Germany	Treatment of Huntington's disease	• 18/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016
Zinc gluconate	Université de Montpellier - France	Treatment of facioscapulohumeral muscular dystrophy	• 19/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016
Budesonide	Pharmalink AB - Sweden	Treatment of primary IgA nephropathy	• 21/06/2016 • 18/07/2016 • 06/10/2016 • (80 days/29 days)	• 20/10/2016 • 18/11/2016
Synthetic human hepcidin	EMAS Pharma Limited - United Kingdom	Treatment of sickle cell disease	• 22/06/2016 • 18/07/2016 • 06/10/2016 • (80 days/29 days)	• 20/10/2016 • 18/11/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Sodium benzoate	Lucane Pharma SA - France	Treatment of argininosuccinic aciduria	• 20/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016
Human monoclonal antibody against activin A	Regeneron Ireland - Ireland	Treatment of fibrodysplasia ossificans progressiva	• 20/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016
Live-attenuated non-replicative Pseudomonas aeruginosa strain expressing large T antigen of Merkel cell polyomavirus	APCure SAS - France	Treatment of Merkel cell carcinoma	• 24/06/2016 • 18/07/2016 • 06/10/2016 • (80 days/29 days)	• 20/10/2016 • 18/11/2016
N-(5-(6-chloro-2,2-difluorobenzo[d][1,3]dioxol-5-yl)pyrazin-2-yl)-2-fluoro-6-methylbenzamide	EMAS Pharma Limited - United Kingdom	Treatment of acute pancreatitis	• 20/06/2016 • 18/07/2016 • 06/10/2016 • (80 days/29 days)	• 20/10/2016 • 18/11/2016
5-[4-[2-(5-(1-hydroxyethyl)-2-pyridinyl)ethoxy]benzyl]-2,4-thiazolidinedione hydrochloride	Minoryx Therapeutics S.L. - Spain	Treatment of adrenoleukodystrophy	• 20/06/2016 • 18/07/2016 • 06/10/2016 • (80 days/29 days)	• 20/10/2016 • 18/11/2016
Brincidofovir	Chimerix UK Ltd - United Kingdom	Treatment of smallpox	• 19/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016
Vaccine consisting of 5 survivin peptides with different human leukocyte antigen restrictions	Dr Ulrich Granzers - Germany	Treatment of ovarian cancer	• 24/06/2016 • 18/07/2016 • 06/10/2016 • (80 days/29 days)	• 20/10/2016 • 18/11/2016
R-azasetron besylate	Sensorion - France	Treatment of sudden sensorineural hearing loss	• 23/05/2016 • 18/07/2016 • 06/10/2016 • (80 days/29 days)	• 20/10/2016 • 18/11/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Adeno-associated viral vector serotype 8 containing the human *UGT1A1* gene	Audentes Therapeutics UK Limited - United Kingdom	Treatment of Crigler Najjar syndrome	• 17/06/2016 • 18/07/2016 • 06/10/2016 • (80 days/29 days)	• 20/10/2016 • 18/11/2016
Allogeneic cytomegalovirus-specific cytotoxic T lymphocytes	Atara Biotherapeutics Ireland Limited - Ireland	Treatment of cytomegalovirus infection in patients with impaired cell-mediated immunity	• 24/06/2016 • 18/07/2016 • 06/10/2016 • (80 days/29 days)	• 20/10/2016 • 18/11/2016
Valproic acid	Valcuria AB - Sweden	Treatment of diffuse large B-Cell lymphoma	• 23/06/2016 • 18/07/2016 • 06/10/2016 • (80 days/29 days)	• 20/10/2016 • 18/11/2016
2-hydroxy-6-((2-(1-isopropyl-1H-pyrazol-5-yl)pyridin-3-yl) methoxy)benzaldehyde	SynteractHCR Deutschland GmbH - Germany	Treatment of sickle cell disease	• 20/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016
Adeno-associated viral vector serotype 8 containing the human glucose-6-phosphatase gene	Pharma Gateway AB - Sweden	Treatment of glycogen storage disease type Ia	• 13/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016
Alpha-tocopherol	Université de Montpellier - France	Treatment of facioscapulohumeral muscular dystrophy	• 19/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016
Ascorbic acid	Université de Montpellier - France	Treatment of facioscapulohumeral muscular dystrophy	• 19/07/2016 • 15/08/2016 • 06/10/2016 • (52 days/29 days)	• 20/10/2016 • 18/11/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Allogeneic peripheral blood mononuclear cells incubated ex vivo with 16, 16-dimethyl prostaglandin E2 and dexamethasone	Fate Therapeutics Ltd - United Kingdom	Treatment in haematopoietic stem cell transplantation	• 24/06/2016 • 18/07/2016 • 06/10/2016 • (80 days/29 days)	• 20/10/2016 • 18/11/2016
Ibudilast	MediciNova (Europe) Limited - United Kingdom	Treatment of amyotrophic lateral sclerosis	• 20/07/2016 • 12/09/2016 • 04/11/2016 • (53 days/28 days)	• 14/11/2016 • 12/12/2016
Arsenic trioxide	Medsenic - France	Treatment of graft-versus-host disease	• 29/08/2016 • 12/09/2016 • 04/11/2016 • (53 days/28 days)	• 14/11/2016 • 12/12/2016
Udenafil	Mapi Ireland Limited - Ireland	Treatment of functional single ventricle congenital heart disease	• 30/08/2016 • 12/09/2016 • 04/11/2016 • (53 days/28 days)	• 14/11/2016 • 12/12/2016
Recombinant self-complementary adeno-associated viral vector serotype 9 encoding the human *CLN3* gene	Ser-mes Planificación SL - Spain	Treatment of neuronal ceroid lipofuscinosis	• 24/08/2016 • 12/09/2016 • 04/11/2016 • (53 days/28 days)	• 14/11/2016 • 12/12/2016
Metformin	Centro de Investigación Biomédica en Red (CIBER) - Spain	Treatment of progressive myoclonic epilepsy type 2 (Lafora disease)	• 19/07/2016 • 12/09/2016 • 04/11/2016 • (53 days/28 days)	• 14/11/2016 • 12/12/2016
Dantrolene sodium	Alan Boyd Consultants Ltd - United Kingdom	Treatment of Wolfram syndrome	• 27/08/2016 • 12/09/2016 • 04/11/2016 • (53 days/28 days)	• 14/11/2016 • 12/12/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
68Ga-DOTA-pABzA-DIG-dPhe-Gln-Trp-Ala-Val-Gly-His-NHCH[(CH2-CH(CH3)2]2	Advanced Accelerator Applications - France	Diagnosis of gastrointestinal stromal tumours	• 30/08/2016 • 12/09/2016 • 04/11/2016 • (53 days/28 days)	• 14/11/2016 • 12/12/2016
Ivosidenib	QRC Consultants Ltd - United Kingdom	Treatment of acute myeloid leukaemia	• 24/08/2016 • 12/09/2016 • 04/11/2016 • (53 days/28 days)	• 14/11/2016 • 12/12/2016
Cabiralizumab	Albany Regulatory Consulting Ltd - United Kingdom	Treatment of tenosynovial giant cell tumour, localised and diffuse type	• 14/07/2016 • 15/08/2016 • 04/11/2016 • (81 days/28 days)	• 14/11/2016 • 12/12/2016
Propranolol	The Anticancer Fund - Belgium	Treatment of soft tissue sarcoma	• 05/07/2016 • 15/08/2016 • 04/11/2016 • (81 days/28 days)	• 14/11/2016 • 12/12/2016
Adeno-associated viral vector serotype 8 encoding engineered rhodopsin DNA-binding repressor and human rhodopsin expression cassettes	Fondazione Telethon - Italy	Treatment of retinitis pigmentosa	• 08/07/2016 • 15/08/2016 • 04/11/2016 • (81 days/28 days)	• 14/11/2016 • 12/12/2016
Avelumab	Merck Serono Europe Limited - United Kingdom	Treatment of gastric cancer	• 14/07/2016 • 15/08/2016 • 04/11/2016 • (81 days/28 days)	• 14/11/2016 • 12/12/2016
Pegylated recombinant human interleukin-10	Larode Ltd - United Kingdom	Treatment of pancreatic cancer	• 22/08/2016 • 12/09/2016 • 04/11/2016 • (53 days/28 days)	• 14/11/2016 • 12/12/2016

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Adeno-associated viral vector serotype 8 containing the human *CNGA3* gene under the control of a cone arrestin promoter	Universitätsklinikum Tübingen (UKT) - Germany	Treatment of achromatopsia caused by mutations in the *CNGA3* gene	• 11/08/2016 • 12/09/2016 • 04/11/2016 • (53 days/28 days)	• 14/11/2016 • 12/12/2016
Pr-D-Cys-Met-Pip-Arg-Leu-Arg-Sar-Cys-Lys-Arg-Pro-Tyr-Tle-Leu-OH	VECT-HORUS - France	Treatment of perinatal asphyxia	• 13/09/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
Humanised IgG1 monoclonal antibody against the receptor-binding site of human placental growth factor	Oncurious NV - Belgium	Treatment of medulloblastoma	• 28/09/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
Recombinant adeno-associated viral vector serotype 9 containing the human N-alpha-acetylglucosaminidase gene	Ser-mes Planificación SL - Spain	Treatment of mucopolysaccharidosis type IIIB (Sanfilippo B syndrome)	• 26/09/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
Antroquinonol	Biological Consulting Europe Ltd - United Kingdom	Treatment of pancreatic cancer	• 28/09/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
Leuprorelin acetate	Stichting Centre for Human Drug Research (CHDR) - The Netherlands	Treatment of congenital hypogonadotropic hypogonadism	• 20/05/2016 • 12/09/2016 • 08/12/2016 • (87 days/28 days)	• 15/12/2016 • 12/01/2017
Pentosan polysulfate sodium	Kyoto Tech Limited - United Kingdom	Treatment of interstitial cystitis	• 15/06/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
(6aR, 10aR)-3-(1',1'-dimethylheptyl)-delta-8-tetrahydro-cannabinol-9-carboxylic acid	TMC Pharma Services Ltd - United Kingdom	Treatment of systemic sclerosis	• 28/09/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
Fluticasone propionate	Adare Pharmaceuticals srl - Italy	Treatment of eosinophilic oesophagitis	• 27/09/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
Hydroxychloroquine	Centre Hospitalier Universitaire d' Angers	Treatment of antiphospholipid syndrome	• 30/08/2016 • 12/09/2016 • 08/12/2016 • (87 days/28 days)	• 15/12/2016 • 12/01/2017
Pioglitazone hydrochloride	Regiomedica GmbH - Germany	Treatment of sudden sensorineural hearing loss	• 11/08/2016 • 12/09/2016 • 08/12/2016 • (87 days/28 days)	• 15/12/2016 • 12/01/2017
Human donor haematopoietic stem and progenitor cells that have been treated ex vivo with the protein transduction domain of the HIV-1 transactivation protein fused to MYC transcription factor	Coté Orphan Consulting UK Limited - United Kingdom	Treatment in haematopoietic stem cell transplantation	• 18/08/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
Trans-resveratrol	Luis Pereira de Almeida - Portugal	Treatment of spinocerebellar ataxia	• 30/08/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
Genetically modified adeno-associated viral vector serotype 9 expressing shRNA as well as a codon-optimised shRNA-insensitive wildtype PABPN1	Clinipace GmbH - Germany	Treatment of oculopharyngeal muscular dystrophy	• 23/08/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Doxorubicin hydrochloride in a lipid-based pegylated nanoparticle modified with a 31-aminoacid peptide targeting nucleolin	TREAT U, S.A. - Portugal	Treatment of malignant mesothelioma	• 28/09/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
Autologous dendritic cells incubated ex vivo with zebularine and factor VIII	Idogen AB - Sweden	Treatment of haemophilia A	• 28/09/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
[5,10,15,20-Tetrakis(4-carboxyphenyl)-21H,23H-porphine] manganese(III) chloride	Institut Pasteur - France	Treatment of Cockayne syndrome	• 30/08/2016 • 12/09/2016 • 08/12/2016 • (87 days/28 days)	• 15/12/2016 • 12/01/2017
5-aminolevulinic acid	Centre Hospitalier Universitaire de Lille - France	Treatment of glioma	• 30/08/2016 • 12/09/2016 • 08/12/2016 • (87 days/28 days)	• 15/12/2016 • 12/01/2017
Recombinant IgG degrading enzyme of Streptococcus pyogenes	Hansa Medical AB - Sweden	Prevention of graft rejection following solid organ transplantation	• 28/09/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
Human hepatoma cell line HepaRG in bioartificial liver	Hep-Art Medical Devices BV - The Netherlands	Treatment of acute liver failure	• 23/09/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017
3-pentylbenzeneacetic acid sodium salt	ProMetic Pharma SMT Limited - United Kingdom	Treatment of Alström syndrome	• 27/09/2016 • 24/10/2016 • 08/12/2016 • (45 days/28 days)	• 15/12/2016 • 12/01/2017

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
Naltrexone	Able AB - Sweden	Treatment of fibromyalgia	• 22/02/2016 • 21/03/2016 • 06/10/2016 • 199 days /43 days	• 20/10/2016 • 02/12/2016
3-(3-Methanesulfonyl-phenyl)-1-propyl-piperidine Hydrochloride	A. Carlsson Research AB - Sweden	Treatment of narcolepsy	• 18/03/2016 • 18/04/2016 • 13/07/2016 • (86 days/25 days)	• 07/11/2016 • 02/12/2016

Annex 13 – HMPC European Union herbal monographs in 2016

Abbreviations: TU – traditional use

WEU – well established use

LE – list entry

MO – monograph

European Union herbal monographs - Final

Reference number	Document title	Adoption / Outcome*
First Assessment		
EMA/HMPC/159075/2014	Crataegi folium cum flore	05/04/2016 / MO-TU
EMA/HMPC/41108/2015	Helichrysi flos	05/04/2016 / MO-TU
EMA/HMPC/166517/2015	Origani majoranae herba	20/09/2016 / MO-TU
EMA/HMPC/46758/2015	Pistacia lentiscus, resinum (mastix)	02/02/2016 / MO-TU
EMA/HMPC/143658/2015	Polygoni avicularis herba	05/04/2016 / MO-TU
EMA/HMPC/680626/2013	Pruni africanae cortex	12/07/2016 / MO-TU
EMA/HMPC/572974/2014	Ricini oleum	02/02/2016 / MO-WEU
EMA/HMPC/39453/2015	Sideritis herba	12/07/2016 / MO-TU, LE
Revision		
EMA/HMPC/625788/2015	Aloe	22/11/2016 / MO-WEU
EMA/HMPC/436679/2015	Althaeae radix	12/07/2016 / MO-TU
EMA/HMPC/453725/2016	Boldi folium	22/11/2016 / MO-TU
EMA/HMPC/278091/2015	Equiseti herba	02/02/2016 / MO-TU
EMA/HMPC/627057/2015	Harpagophyti radix	12/07/2016 / MO-TU
EMA/HMPC/277152/2015	Salviae officinalis folium	20/09/2016 / MO-TU
EMA/HMPC/84990/2015	Thymi herba/ Primulae radix	05/04/2016 / MO-TU-WEU
EMA/HMPC/278053/2015	Valerianae aetheroleum	02/02/2016 / MO-TU
EMA/HMPC/150848/2015	Valerianae radix	02/02/2016 / MO-TU-WEU, LE

European Union List entries – adopted for transfer to Eur. Com.

Reference number	Document title	Adoption *
First Assessment		
EMA/HMPC/150543/2015	Sideritis herba	12/07/2016
EMA/HMPC/150849/2015	Valerianae radix	02/02/2016
Revision		
	none	

European Union herbal monographs - Draft

Reference number	Document title	Adoption / Outcome*
First Assessment		
EMA/HMPC/7685/2013	Allii sativi bulbus	12/07/2016
EMA/HMPC/220599/2016	Lecithinum ex soya	12/07/2016
EMA/HMPC/166517/2015	Origani majoranae herba	02/02/2016
EMA/HMPC/294187/2013	Silybi marianae fructus (2nd draft)	20/09/2016
EMA/HMPC/338914/2016	Soiae oleum raffinatum	12/07/2016
EMA/HMPC/224755/2016	Species diureticae	20/09/2016
Revision		
EMA/HMPC/424583/2016	Echinaceae purpureae radix	22/11/2016
EMA/HMPC/627057/2015	Harpagophyti radix	02/02/2016
EMA/HMPC/277152/2015	Salviae officinalis folium	02/02/2016
EMA/HMPC/464684/2016	Vitis viniferae folium	22/11/2016

European Union List entries - Draft

Reference number	Document title	Adoption *
First Assessment		
EMA/HMPC/685372/2014	Crataegi folium cum flore	05/04/2016
Revision		
	none	

Public statements

Reference number	Document title	Adoption
Drafts		
EMA/HMPC/762952/2015	Paeoniae radix rubra	02/02/2016
EMA/HMPC/150787/2015	Paeoniae radix alba	02/02/2016
EMA/HMPC/450588/2016	Piperis methystici rhizoma	22/11/2016
Final		
EMA/HMPC/712649/2014	Balsamum peruvianum	31/05/2016
EMA/HMPC/599993/2014	Salviae fruticosae folium	31/05/2016

Annex 14 – PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2016

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 Date	Decision Number
PEGylated recombinant factor VIII		PIP Modification	Modification agreed	Haematology-Hemostaseology	Baxalta Innovations GmbH	11/12/2015	08/01/2016	P/0001/2016
Ataluren	Translarna	PIP Modification	Modification agreed	Neurology	PTC Therapeutics International Limited	11/12/2015	14/01/2016	P/0002/2016
Ustekinumab	Stelara	PIP Modification	Modification agreed	Dermatology Immunology-Rheumatology-Transplantation	Janssen-Cilag International NV	11/12/2015	15/01/2016	P/0003/2016
Conestat alfa	Ruconest	PIP Modification	Modification agreed	Other	Pharming Group N.V.	11/12/2015	22/01/2016	P/0004/2016
Clostridium Botulinum neurotoxin type A (150 kD), free of complexing proteins	Xeomin Bocouture	PIP Modification	Modification agreed	Neurology	Merz Pharmaceuticals GmbH	11/12/2015	25/01/2016	P/0005/2016
Human heterologous liver cells		PIP Modification	Modification agreed	Gastroenterology -Hepatology	Cytonet GmbH & Co. KG	11/12/2015	29/01/2016	P/0006/2016
Mepolizumab		PIP Modification	Modification agreed	Haematology-Hemostaseology	GSK Trading Services Limited	11/12/2015	29/01/2016	P/0007/2016
Cinacalcet hydrochloride	Mimpara	PIP Modification	Modification agreed	Uro-nephrology	Amgen Europe B.V.	11/12/2015	29/01/2016	P/0008/2016
Retigabine	Trobalt	PIP Modification	Modification agreed	Neurology	Glaxo Group Limited	11/12/2015	29/01/2016	P/0009/2016
Peginterferon alfa-2a	Pegasys	PIP Modification	Modification agreed	Infectious Diseases	Roche Registration Ltd	11/12/2015	29/01/2016	P/0010/2016
Osilodrostat		PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novartis Europharm Limited	11/12/2015	29/01/2016	P/0011/2016
Rilpivirine (hydrochloride)	EDURANT	PIP Modification	Modification agreed	Infectious Diseases	Janssen-Cilag International NV	11/12/2015	29/01/2016	P/0012/2016
Selepressin		PIP Modification	Modification agreed	Cardiovascular Diseases	Ferring Pharmaceuticals A/S	11/12/2015	29/01/2016	P/0013/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Blinatumomab		PIP Modification	Modification agreed	Oncology	Amgen Europe B.V.	11/12/2015	29/01/2016	P/0014/2016
Vedolizumab	Entyvio	PIP Modification	Modification agreed	Gastroenterology -Hepatology	Takeda Pharma A/S	11/12/2015	29/01/2016	P/0015/2016
Bosutinib		PIP Modification	Modification agreed	Oncology	Pfizer Limited	11/12/2015	29/01/2016	P/0016/2016
Dulaglutide	Trulicity	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Eli Lilly & Company	11/12/2015	29/01/2016	P/0017/2016
Sonidegib	Odomzo	PIP Modification	Modification agreed	Oncology	Novartis Europharm Ltd.	11/12/2015	29/01/2016	P/0018/2016
Canagliflozin	Invokana	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Janssen-Cilag International NV	11/12/2015	29/01/2016	P/0019/2016
Sirukumab		PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Janssen-Cilag International N.V.	11/12/2015	29/01/2016	P/0020/2016
Nonacog gamma	Rixubis	PIP Modification	Modification agreed	Haematology-Hemostaseology	Baxalta Innovations GmbH	11/12/2015	29/01/2016	P/0021/2016
Dabrafenib	Tafinlar	PIP Modification	Modification agreed	Oncology	Novartis Europharm Limited	11/12/2015	29/01/2016	P/0022/2016
Albiglutide	Eperzan	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	GlaxoSmithKline Trading Services Limited	11/12/2015	29/01/2016	P/0023/2016
Trametinib	Mekinist	PIP Modification	Modification agreed	Oncology	Novartis Europharm Limited	11/12/2015	29/01/2016	P/0024/2016
Damoctocog alfa pegol		PIP Modification	Modification agreed	Haematology-Hemostaseology	Bayer Pharma AG	11/12/2015	29/01/2016	P/0025/2016
Vancomycin		PIP Modification	Modification agreed	Infectious Diseases	Fondazione PENTA Onlus	11/12/2015	29/01/2016	P/0026/2016
Abrilumab		PIP	PIP agreed	Gastroenterology -Hepatology	MedImmune Ltd	11/12/2015	29/01/2016	P/0027/2016
17 beta-estradiol / etonogestrel		PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme (Europe), Inc.	11/12/2015	29/01/2016	P/0028/2016
Eteplirsen		PIP	PIP agreed	Neurology	Sarepta International C.V.	11/12/2015	29/01/2016	P/0029/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Rilpivirine / Dolutegravir		PIP	PIP agreed	Infectious Diseases	ViiV Healthcare Limited	11/12/2015	29/01/2016	P/0030/2016
Revusiran		Full Waiver	Full waiver granted	Cardiovascular Diseases Neurology	Alnylam Pharmaceuticals, Inc.	11/12/2015	29/01/2016	P/0031/2016
Pexiganan (acetate)		Full Waiver	Full waiver granted	Infectious Diseases	Dipexium Pharmaceuticals, Inc.	11/12/2015	29/01/2016	P/0032/2016
Tiprelestat		Full Waiver	Full waiver granted	Gastroenterology -Hepatology Oncology	Proteo Biotech AG	11/12/2015	29/01/2016	P/0033/2016
(3Z,5S)-5-(hydroxymethyl)-1-[(2'-methyl[1,1'-biphenyl]-4-yl)-carbonyl]-3-pyrrolidinone-O-methyloxime		Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	ObsEva Ireland Limited	11/12/2015	29/01/2016	P/0034/2016
13C-Methacetin		PIP	PIP agreed	Diagnostic Gastroenterology -Hepatology	Humedics GmbH	11/12/2015	01/02/2016	P/0035/2016
Processed Nerve Allograft (human)		Full Waiver	Full waiver granted	Other	AxoGen Corporation	11/12/2015	05/02/2016	P/0036/2016
Recombinant human antibody against the respiratory syncytial virus fusion protein (REGN2222)		PIP	PIP agreed	Infectious Diseases	Regeneron Ireland	11/12/2015	12/02/2016	P/0037/2016
Rufinamide	Inovelon	PIP Modification	Modification agreed	Neurology	Eisai Limited	29/01/2016	19/02/2016	P/0038/2016
Midostaurin		PIP Modification	Modification agreed	Oncology	Novartis Europharm Ltd	29/01/2016	19/02/2016	P/0039/2016
Nivolumab	Opdivo	PIP	PIP agreed	Oncology	Bristol-Myers Squibb Pharma EEIG	29/01/2016	19/02/2016	P/0040/2016
Humanised IgG4 monoclonal antibody against extracellular tau (BMS-986168)		Full Waiver	Full waiver granted	Neurology	Bristol-Myers Squibb International Corporation	29/01/2016	19/02/2016	P/0041/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Tapentadol (hydrochloride)	Palexia and associated names Yantil and associated names Tapentadol and associated names	PIP Modification	Modification agreed	Pain	Grünenthal GmbH	29/01/2016	26/02/2016	P/0042/2016
Tapentadol (hydrochloride)	Palexia and associated names Yantil and associated names Tapentadol and associated names	PIP Modification	Modification agreed	Pain	Grünenthal GmbH	29/01/2016	26/02/2016	P/0043/2016
Tapentadol (hydrochloride)	Palexia and associated names Yantil and associated names Tapentadol and associated names	PIP Modification	Modification agreed	Pain	Grünenthal GmbH	29/01/2016	26/02/2016	P/0044/2016
Tolvaptan	Samsca and associated names	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Otsuka Pharmaceutical Europe Ltd.	29/01/2016	26/02/2016	P/0045/2016
Eculizumab	Soliris	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Alexion Europe SAS	29/01/2016	26/02/2016	P/0046/2016
Rolapitant		PIP	PIP agreed	Gastroenterology-Hepatology	TESARO UK Ltd	29/01/2016	03/03/2016	P/0047/2016
Ramipril / amlodipine		Full Waiver	Full waiver granted	Cardiovascular Diseases	Krka, d.d., Novo mesto	29/01/2016	04/02/2016	P/0048/2016
Macitentan	Opsumit	PIP Modification	Modification agreed	Cardiovascular Diseases	Actelion Registration Ltd.	29/01/2016	18/03/2016	P/0049/2016
Loxapine		PIP Modification	Modification agreed	Psychiatry	Ferrer Internacional, S.A.	29/01/2016	18/03/2016	P/0050/2016
Binimetinib		PIP	PIP agreed	Oncology	Pierre Fabre Médicament.	29/01/2016	18/03/2016	P/0051/2016
Basmisanil		PIP Modification	Modification agreed	Psychiatry	Roche Registration Ltd	29/01/2016	18/03/2016	P/0052/2016
Tasimelteon	Hetlioz	PIP Modification	Modification agreed	Neurology	Vanda Pharmaceuticals Ltd.	29/01/2016	18/03/2016	P/0053/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Encorafenib		PIP	PIP agreed	Oncology	Pierre Fabre Médicament	29/01/2016	18/03/2016	P/0054/2016
Fluoroestradiol (18F)		Full Waiver	Full waiver granted	Diagnostic	Florentin Artner	29/01/2016	18/03/2016	P/0055/2016
Dalbavancin	Xydalba	PIP Modification	Modification agreed	Infectious Diseases	Durata Therapeutics International B.V	29/01/2016	18/03/2016	P/0056/2016
Dabigatran etexilate	Pradaxa	PIP Modification	Modification agreed	Cardiovascular Diseases Haematology-Hemostaseology	Boehringer Ingelheim International GmbH	29/01/2016	18/03/2016	P/0057/2016
Denosumab	Prolia XGEVA	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Amgen Europe B.V.	29/01/2016	18/03/2016	P/0058/2016
Saxagliptin	Onglyza	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	29/01/2016	18/03/2016	P/0059/2016
Rituximab	MabThera	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Roche Registration Limited	29/01/2016	18/03/2016	P/0060/2016
Pazopanib	Votrient	PIP Modification	Modification agreed	Oncology Uro-nephrology	Novartis Europharm Limited	29/01/2016	18/03/2016	P/0061/2016
Trenonacog alfa		PIP Modification	Modification agreed	Haematology-Hemostaseology	Cangene Europe Limited	29/01/2016	18/03/2016	P/0062/2016
Dapagliflozin	Forxiga	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	29/01/2016	18/03/2016	P/0063/2016
Aztreonam	Cayston	PIP Modification	Modification agreed	Infectious Diseases	Gilead Sciences International Limited	29/01/2016	18/03/2016	P/0064/2016
Meropenem		PIP Modification	Modification agreed	Infectious Diseases Neonatology - Paediatric Intensive Care	NeoMero Consortium	29/01/2016	18/03/2016	P/0065/2016
Romosozumab		PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Amgen Europe B.V.	29/01/2016	18/03/2016	P/0066/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Human fibrinogen / human thrombin	Evicel Evarrest	PIP Modification	Modification agreed	Other	Omrix Biopharmaceuticals N.V.	29/01/2016	18/03/2016	P/0067/2016
Recombinant dimer of 6 kD early secretory antigenic target / recombinant 10 kD culture filtrate protein		PIP Modification	Modification agreed	Diagnostic	Statens Serum Institut	29/01/2016	18/03/2016	P/0068/2016
Ferric maltol		PIP Modification	Modification agreed	Haematology-Hemostaseology	Iron Therapeutics (UK) Ltd.	29/01/2016	18/03/2016	P/0069/2016
Evolocumab	Repatha	PIP Modification	Modification agreed	Cardiovascular Diseases	Amgen Europe B.V.	29/01/2016	18/03/2016	P/0070/2016
Naltrexone (hydrochloride) / bupropion (hydrochloride)	Mysimba	PIP Modification	Modification agreed	Other	Orexigen Therapeutics Ireland Limited	29/01/2016	18/03/2016	P/0071/2016
Dupilumab		PIP Modification	Modification agreed	Dermatology	Regeneron Pharmaceuticals, Inc	29/01/2016	18/03/2016	P/0072/2016
Guselkumab		PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Janssen Cilag International NV	29/01/2016	18/03/2016	P/0073/2016
Etelcalcetide		PIP Modification	Modification agreed	Uro-nephrology	Amgen Europe B.V.	29/01/2016	18/03/2016	P/0074/2016
Naloxone (hydrochloride)		PIP Modification	Modification agreed	Gastroenterology -Hepatology Pain	Develco Pharma GmbH	29/01/2016	18/03/2016	P/0075/2016
Cariprazine (hydrochloride)		PIP Modification	Modification agreed	Psychiatry	Gedeon Richter Plc.	29/01/2016	18/03/2016	P/0076/2016
Biotin		Full Waiver	Full waiver granted	Neurology	MEDDAY SAS	29/01/2016	18/03/2016	P/0077/2016
Gemtuzumab linked to ozogamicin		PIP	PIP agreed	Haematology-Hemostaseology Oncology	Pfizer Limited	29/01/2016	18/03/2016	P/0078/2016
Arimoclomol (citrate)		PIP	PIP agreed	Neurology	Orphazyme ApS	29/01/2016	18/03/2016	P/0079/2016
Exenatide		PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Les Laboratoires Servier	29/01/2016	18/03/2016	P/0080/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
(2R,3R,4R,5R)-5-(4-amino-2-oxopyrimidin-1(2H)-yl)-2-(chloromethyl)-4-fluoro-2-((isobutyryloxy)methyl)tetrahydrofuran-3-yl isobutyrate (ALS-008176)		PIP	PIP agreed	Infectious Diseases	Alios Biopharma, Inc	29/01/2016	18/03/2016	P/0081/2016
Tetracaine (hydrochloride) / oxymetazoline (hydrochloride)		PIP	PIP agreed	Anaesthesiology	St. Renatus, LLC	29/01/2016	18/03/2016	P/0082/2016
Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human Wiskott Aldrich Syndrome (WAS) cDNA sequence		PIP	PIP agreed	Immunology-Rheumatology-Transplantation	GlaxoSmithKline Trading Services Limited	29/01/2016	18/03/2016	P/0083/2016
Human normal immunoglobulin		PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Octapharma Pharmazeutika Produktionsges.m.b.H	29/01/2016	18/03/2016	P/0084/2016
Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	Foclivia and associated names	PIP	PIP agreed	Vaccines	Novartis Vaccines Influenza S.r.l.	29/01/2016	18/03/2016	P/0085/2016
Recombinant human monoclonal antibody against growth differentiation factor 8 (REGN1033)		Full Waiver	Full waiver granted	Neurology	Regeneron Pharmaceuticals, Inc	29/01/2016	18/03/2016	P/0086/2016
Testosterone		Full Waiver	Full waiver granted	Ophthalmology	Allergan Pharmaceuticals Ireland	29/01/2016	18/03/2016	P/0087/2016
Levamisole (hydrochloride)		PIP	PIP agreed	Uro-nephrology	ACE Pharmaceuticals BV	29/01/2016	18/03/2016	P/0088/2016
Azithromycin / Miconazole / Sulfamethoxazole		Full Waiver	Full waiver granted	Dermatology	Lukács és Társa Gyógyszerkereskedelmi Bt.	29/01/2016	22/03/2016	P/0089/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Tapentadol (hydrochloride)	Palexia and associated names Yantil and associated names Tapentadol and associated names	PIP Modification	Modification agreed	Pain	Grünenthal GmbH	26/02/2016	18/03/2016	P/0090/2016
Tapentadol (hydrochloride)	Palexia and associated names Yantil and associated names Tapentadol and associated names	PIP Modification	Modification agreed	Pain	Grünenthal GmbH	26/02/2016	18/03/2016	P/0091/2016
Tapentadol (hydrochloride)	Palexia and associated names Yantil and associated names Tapentadol and associated names	PIP Modification	Modification agreed	Pain	Grünenthal GmbH	26/02/2016	18/03/2016	P/0092/2016
Octenidine (dihydrochloride)		PIP	PIP agreed	Oto-rhino-laryngology	Cassella-med GmbH & Co. KG	26/02/2016	22/03/2016	P/0093/2016
Adalimumab	Humira	PIP Modification	Modification agreed	Dermatology Gastroenterology -Hepatology Immunology- Rheumatology- Transplantation Ophthalmology	AbbVie Limited	26/02/2016	18/03/2016	P/0094/2016
Pitavastatin (calcium)	Livazo and associated names	PIP Modification	Modification agreed	Endocrinology- Gynaecology- Fertility- Metabolism	Kowa Pharmaceutical Europe Company Ltd	26/02/2016	15/04/2016	P/0095/2016
Pitavastatin (calcium)	Alipza and associated names	PIP Modification	Modification agreed	Endocrinology- Gynaecology- Fertility- Metabolism	Kowa Pharmaceutical Europe Company Ltd	26/02/2016	15/04/2016	P/0096/2016
Boceprevir	Victrelis	PIP Modification	Modification agreed	Infectious Diseases	Merck Sharp & Dohme Ltd	26/02/2016	15/04/2016	P/0097/2016
Fidaxomicin	Dificlir	PIP Modification	Modification agreed	Infectious Diseases	Astellas Pharma Europe B.V	26/02/2016	15/04/2016	P/0098/2016
Tralokinumab		PIP Modification	Modification agreed	Pneumology - Allergology	MedImmune Ltd	26/02/2016	15/04/2016	P/0099/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Ixekizumab		PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Eli Lilly & Company Limited	26/02/2016	15/04/2016	P/0100/2016
Certolizumab pegol	Cimzia	PIP	PIP agreed	Dermatology	UCB Pharma S.A.	26/02/2016	15/04/2016	P/0101/2016
Alirocumab		PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Sanofi-aventis Recherche & développement	26/02/2016	15/04/2016	P/0102/2016
Coagulation Factor VIIa (Recombinant)		PIP Modification	Modification agreed	Haematology-Hemostaseology Oncology	LFB SA	29/04/2016	04/05/2016	P/0103/2016
Indacaterol (acetate) / mometasone (furoate)		PIP Modification	Modification agreed	Pneumology - Allergology	Novartis Europharm Limited	26/02/2016	15/04/2016	P/0104/2016
Talimogene laherparepvec	Imlygic	PIP Modification	Modification agreed	Oncology	Amgen Europe B.V.	26/02/2016	15/04/2016	P/0105/2016
Potassium citrate monohydrated / Potassium hydrogen carbonate		PIP Modification	Modification agreed	Uro-nephrology	Advicenne Pharma	26/02/2016	15/04/2016	P/0106/2016
Olesoxime		PIP Modification	Modification agreed	Neurology	Roche Registration Limited	26/02/2016	15/04/2016	P/0107/2016
Humanised monoclonal antibody against myostatin		PIP	PIP agreed	Neurology	Pfizer Limited	26/02/2016	15/04/2016	P/0108/2016
Recombinant human alpha-galactosidase A (PRX 102)		PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Protalix Ltd	26/02/2016	15/04/2016	P/0109/2016
Gallium [68Ga]		Full Waiver	Full waiver granted	Other	IRE-Elit SA	26/02/2016	15/04/2016	P/0110/2016
Human normal immunoglobulin		PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Grifols Therapeutics Inc.	26/02/2016	15/04/2016	P/0111/2016
Atorvastatin / Perindopril (arginine)		Full Waiver	Full waiver granted	Cardiovascular Diseases	Les Laboratoires Servier	26/02/2016	15/04/2016	P/0112/2016
Finasteride		Full Waiver	Full waiver granted	Dermatology	Polichem S.A.	26/02/2016	15/04/2016	P/0113/2016
Montelukast (sodium) / levocetirizine (dihydrochloride)		Full Waiver	Full waiver granted	Pneumology - Allergology	Invest Bielany Sp. z o.o.	26/02/2016	15/04/2016	P/0114/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Heterologous Human Adult Liver-derived Progenitor Cells (HHALPC)		PIP Modification	Modification agreed	Gastroenterology -Hepatology	Promethera Biosciences	26/02/2016	15/04/2016	P/0115/2016
Rufinamide	Inovelon	PIP Modification	Modification agreed	Neurology	Eisai Limited	01/04/2016	15/04/2016	P/0116/2016
Levodopa		Full Waiver	Full waiver granted	Neurology	Acorda Therapeutics, Inc.	01/04/2016	22/04/2016	P/0117/2016
Perampanel	Fycompa	PIP Modification	Modification agreed	Neurology	Eisai Europe Limited	01/04/2016	22/04/2016	P/0118/2016
Solithromycin		PIP Modification	Modification agreed	Infectious Diseases	Triskel EU Services	01/04/2016	28/04/2016	P/0119/2016
Solithromycin		PIP	PIP agreed	Infectious Diseases	Triskel EU Services	01/04/2016	28/04/2016	P/0120/2016
sofosbuvir / velpatasvir / a derivative of (2S,3S,4R)-3-ethyl-4-hydroxypyrrolidine-2-carboxylic acid		PIP	PIP agreed	Infectious Diseases	Gilead Sciences International Ltd	01/04/2016	29/04/2016	P/0121/2016
ataluren	Translarna	PIP Modification	Modification agreed	Neurology	PTC Therapeutics International Limited	01/04/2016	29/04/2016	P/0122/2016
Darunavir / cobicistat / emtricitabine / tenofovir alafenamide		PIP	PIP agreed	Infectious Diseases	Janssen-Cilag International NV	01/04/2016	12/05/2016	P/0123/2016
Everolimus	Votubia	PIP Modification	Modification agreed	Neurology	Novartis Europharm Limited	26/02/2016	15/04/2016	P/0124/2016
Denosumab	XGEVA	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism Immunology-Rheumatology-Transplantation Oncology	Amgen Europe B.V.	01/04/2016	20/05/2016	P/0125/2016
Rivaroxaban	Xarelto	PIP Modification	Modification agreed	Cardiovascular Diseases	Bayer Pharma AG	01/04/2016	20/05/2016	P/0126/2016
Tadalafil	Adcirca, Cialis	PIP Modification	Modification agreed	Cardiovascular Diseases	Eli Lilly and Company Ltd	01/04/2016	20/05/2016	P/0127/2016
Sitagliptin (phosphate monohydrate)	Xelevia	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp and Dohme (Europe), Inc.	01/04/2016	20/05/2016	P/0128/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Sitagliptin (phosphate monohydrate)	Tesavel	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp and Dohme (Europe), Inc.	01/04/2016	20/05/2016	P/0129/2016
Exenatide	Byetta, Bydureon	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	01/04/2016	20/05/2016	P/0130/2016
Vorapaxar		PIP Modification	Modification agreed	Cardiovascular Diseases	Merck Sharp & Dohme (Europe), Inc.	01/04/2016	20/05/2016	P/0131/2016
Dimethyl fumarate	Tecfidera	PIP Modification	Modification agreed	Neurology	Biogen Idec Ltd	01/04/2016	20/05/2016	P/0132/2016
Lixisenatide	Lyxumia	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	sanofi-aventis R&D	01/04/2016	20/05/2016	P/0133/2016
Cabozantinib	Cometriq	PIP Modification	Modification agreed	Oncology	Exelixis Inc	01/04/2016	20/05/2016	P/0134/2016
Pitolisant	Wakix	PIP Modification	Modification agreed	Neurology	BIOPROJET PHARMA	01/04/2016	20/05/2016	P/0135/2016
Drospirenone		PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	LABORATIORIOS LEÓN FARMA, S.A.	01/04/2016	20/05/2016	P/0136/2016
Selumetinib		PIP Modification	Modification agreed	Oncology	AstraZeneca AB	01/04/2016	20/05/2016	P/0137/2016
Allantoin		PIP Modification	Modification agreed	Dermatology	Scioderm, Inc.	01/04/2016	20/05/2016	P/0138/2016
Doravirine		PIP	PIP agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	01/04/2016	20/05/2016	P/0139/2016
Doravirine		PIP	PIP agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	01/04/2016	20/05/2016	P/0140/2016
Anti-respiratory syncytial virus human IgG1κ monoclonal antibody (MEDI8897)		PIP	PIP agreed	Infectious Diseases	MedImmune Limited	01/04/2016	20/05/2016	P/0141/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Diclofenac (sodium) / capsaicin		Full Waiver	Full waiver granted	Pain	Boehringer Ingelheim International GmbH	01/04/2016	20/05/2016	P/0142/2016
Hydrogen Peroxide		Full Waiver	Full waiver granted	Dermatology	Aclaris Therapeutics, Inc.	01/04/2016	20/05/2016	P/0143/2016
Human recombinant IgG1 monoclonal antibody targeting fibroblast growth factor 23 (KRN23)		PIP	PIP agreed	Other	Ultragenyx Pharmaceutical Inc.	01/04/2016	23/05/2016	P/0144/2016
KEOC liquid extract ethanolic 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus lemon (L.) Burm. (fresh fruit) / Paullinia cupana Kunth / Theobroma cacao L.		PIP	PIP agreed	Dermatology	Legacy Healthcare	01/04/2016	23/05/2016	P/0145/2016
Recombinant humanized anti-MMP9 monoclonal antibody IgG4 (GS-5745)		PIP	PIP agreed	Gastroenterology -Hepatology	Gilead Sciences International Ltd	29/04/2016	27/05/2016	P/0146/2016
Darbepoetin alfa	Aranesp	PIP Modification	Modification agreed	Oncology	Amgen Europe B.V.	29/04/2016	14/06/2016	P/0147/2016
Melatonin	Circadin	PIP Modification	Modification agreed	Neurology	RAD Neurim Pharmaceuticals EEC Ltd	29/04/2016	14/06/2016	P/0148/2016
Efmorocotocog alfa	Elocta	PIP Modification	Modification agreed	Haematology-Hemostaseology	Biogen Idec Ltd	29/04/2016	14/06/2016	P/0149/2016
Ibrutinib	Imbruvica	PIP Modification	Modification agreed	Oncology	Janssen-Cilag International N.V.	29/04/2016	14/06/2016	P/0150/2016
Peanut flour		PIP	PIP agreed	Pneumology - Allergology	Cambridge Allergy Ltd	29/04/2016	14/06/2016	P/0151/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
(3aR,7S,10S,12R,21E,24aR)-7-tert-butyl-N-[(1R,2R)-2-(difluoromethyl)-1-{[(1-methylcyclopropyl)sulfonyl] carbamoyl}cyclopropyl]-20,20-difluoro-5,8-dioxo-2,3,3a,5,6,7,8,11,12,20,23,24a-dodecahydro-1H,10H-9,12-methanocyclopenta[18,19][1,10,17,3,6] trioxadiazacyclononadecino[11,12-b]quinoxaline-10-carboxamide (AbbVie internal name: ABT-493)		PIP	PIP agreed	Infectious Diseases	AbbVie Ltd	29/04/2016	14/06/2016	P/0152/2016
Ibuprofen / Tramadol		Full Waiver	Full waiver granted	Pain	FARMALIDER, S.A.	29/04/2016	14/06/2016	P/0153/2016
Liraglutide	Saxenda	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	29/04/2016	15/06/2016	P/0154/2016
Raltegravir	Isentress	PIP Modification	Modification agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	29/04/2016	15/06/2016	P/0155/2016
Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins	Xeomin Bocouture	PIP Modification	Modification agreed	Neurology	Merz Pharmaceuticals GmbH	29/04/2016	15/06/2016	P/0156/2016
Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins	Xeomin Bocouture	PIP Modification	Modification agreed	Dermatology Neurology Ophthalmology	Merz Pharmaceuticals GmbH	29/04/2016	15/06/2016	P/0157/2016
Naloxegol		PIP Modification	Modification agreed	Gastroenterology -Hepatology	AstraZeneca AB	29/04/2016	15/06/2016	P/0158/2016
Tafluprost	Taflotan and associated names	PIP Modification	Negative	Ophthalmology	Santen Oy	29/04/2016	15/06/2016	P/0159/2016
Ferric citrate (coordination complex)	Fexeric	PIP Modification	Modification agreed	Uro-nephrology	Keryx Biopharma UK Ltd.	29/04/2016	15/06/2016	P/0160/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Tolvaptan	Samsca and associated names	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Otsuka Pharmaceutical Europe Ltd.	29/04/2016	15/06/2016	P/0161/2016
Retosiban		PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	GlaxoSmithKline Trading Services Limited	29/04/2016	15/06/2016	P/0162/2016
Imipenem (monohydrate) / cilastatin (sodium) / relebactam (MK-7655A)		PIP	PIP agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	29/04/2016	15/06/2016	P/0163/2016
Bexagliflozin		PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Theracos Sub, LLC	29/04/2016	15/06/2016	P/0164/2016
Imetelstat		Full Waiver	Full waiver granted	Oncology	Janssen-Cilag International N.V	29/04/2016	15/06/2016	P/0165/2016
Olmesartan (medoxomil)/Rosuvastatin (calcium)		Full Waiver	Full waiver granted	Cardiovascular Diseases	Daewoong Pharmaceutical Co., Ltd.	29/04/2016	15/06/2016	P/0166/2016
Eltrombopag	Revolade	PIP Modification	Modification agreed	Haematology-Hemostaseology	Novartis Europharm Limited	29/04/2016	15/06/2016	P/0167/2016
Secukinumab	Cosentyx	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	29/04/2016	17/06/2016	P/0168/2016
Sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate (BLI800)	Izinova (and associated names)	PIP Modification	Modification agreed	Gastroenterology-Hepatology	IPSEN Pharma	29/04/2016	17/06/2016	P/0169/2016
Alemtuzumab	Lemtrada	PIP Modification	Modification agreed	Neurology	Genzyme Europe B.V.	29/04/2016	17/06/2016	P/0170/2016
Atrasentan (hydrochloride)		PIP Modification	Modification agreed	Uro-nephrology	AbbVie, Ltd	29/04/2016	17/06/2016	P/0171/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)		PIP	PIP agreed	Vaccines	Seqirus S.r.l.	29/04/2016	17/06/2016	P/0172/2016
Ciclosporin		Full Waiver	Full waiver granted	Ophthalmology	Laboratoires Théa	29/04/2016	17/06/2016	P/0173/2016
Sofosbuvir / ledipasvir	Harvoni	PIP Modification	Modification agreed	Infectious Diseases	Gilead Sciences International Ltd	27/05/2016	30/06/2016	P/0174/2016
Deferasirox	Exjade	PIP Modification	Modification agreed	Haematology-Hemostaseology	Novartis Europharm Limited	27/05/2016	30/06/2016	P/0175/2016
Liraglutide	Victoza	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	27/05/2016	01/07/2016	P/0176/2016
Eleclazine		PIP	PIP agreed	Cardiovascular Diseases	Gilead Sciences International Ltd	27/05/2016	08/07/2016	P/0177/2016
Eleclazine		PIP	PIP agreed	Cardiovascular Diseases	Gilead Sciences International Ltd	27/05/2016	08/07/2016	P/0178/2016
Levamisole (hydrochloride)		PIP Modification	Modification agreed	Uro-nephrology	ACE Pharmaceuticals BV	24/06/2016	08/07/2016	P/0179/2016
Solithromycin		PIP Modification	Modification agreed	Infectious Diseases	Triskel EU Services, Ltd	24/06/2016	15/07/2016	P/0180/2016
Eltrombopag	Revolade	PIP Modification	Modification agreed	Haematology-Hemostaseology	Novartis Europharm Limited	27/05/2016	15/07/2016	P/0181/2016
Brivaracetam	Briviact	PIP Modification	Modification agreed	Neurology	UCB Pharma SA	27/05/2016	15/07/2016	P/0182/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Belimumab	Benlysta	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Glaxo Group Limited	27/05/2016	15/07/2016	P/0183/2016
Decitabine	Dacogen	PIP Modification	Negative	Oncology	Janssen-Cilag International NV	27/05/2016	15/07/2016	P/0184/2016
Eculizumab	Soliris	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Alexion Europe SAS	27/05/2016	15/07/2016	P/0185/2016
Cadazolid		PIP	PIP agreed	Infectious Diseases	Actelion Registration Ltd.	27/05/2016	15/07/2016	P/0186/2016
Landiolol (hydrochloride)		PIP Modification	Modification agreed	Cardiovascular Diseases	AOP Orphan Pharmaceuticals AG	27/05/2016	15/07/2016	P/0187/2016
Recombinant dimer of 6 kD early secretory antigenic target / recombinant 10 kD culture filtrate protein		PIP Modification	Modification agreed	Diagnostic	Statens Serum Institut	27/05/2016	15/07/2016	P/0188/2016
Caplacizumab		PIP Modification	Modification agreed	Haematology-Hemostaseology	Ablynx NV	27/05/2016	15/07/2016	P/0189/2016
Regorafenib	Stivarga	PIP Modification	Modification agreed	Oncology	Bayer Pharma	27/05/2016	15/07/2016	P/0190/2016
Agomelatine	Valdoxan Thymanax	PIP Modification	Modification agreed	Psychiatry	Les Laboratoires Servier	27/05/2016	15/07/2016	P/0191/2016
Baricitinib		PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Eli Lilly & Company Limited	27/05/2016	15/07/2016	P/0192/2016
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 (VX-661) / ivacaftor methylpropan-2-yl)-1H-indol-5-yl}cyclopropanecarboxamide (VX-661) / ivacaftor		PIP Modification	Modification agreed	Pneumology - Allergology	Vertex Pharamceuticals (Europe) Ltd	27/05/2016	15/07/2016	P/0193/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Metreleptin		PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Aegerion Pharmaceuticals Ltd	27/05/2016	15/07/2016	P/0194/2016
Indacaterol (acetate) / Glycopyrronium (bromide) / Mometasone (furoate) (QVM149)		PIP	PIP agreed	Pneumology - Allergology	Novartis Europharm Ltd.	27/05/2016	15/07/2016	P/0195/2016
Emicizumab		PIP	PIP agreed	Haematology-Hemostaseology	Roche Registration Limited	27/05/2016	15/07/2016	P/0196/2016
Corifollitropin alfa		PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme Limited	27/05/2016	18/07/2016	P/0197/2016
(3-((4-Benzoyl-1-piperazinyl)(oxo)acetyl)-4-methoxy-7-(3-methyl-1H-1,2,4-triazol-1-yl)-1Hpyrrolo[2,3-c]pyridin-1-yl)methyl dihydrogen phosphate, 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1) (BMS-663068)		PIP Modification	Modification agreed	Infectious Diseases	Bristol-Myers Squibb International Corporation	24/06/2016	15/07/2016	P/0198/2016
Andexanet alfa		PIP	PIP agreed	Other	Portola Pharma UK Limited	24/06/2016	18/07/2016	P/0199/2016
Adalimumab	Humira	PIP Modification	Modification agreed	Dermatology Gastroenterology -Hepatology Immunology-Rheumatology-Transplantation Ophthalmology	AbbVie Limited	24/06/2016	22/07/2016	P/0200/2016
Eculizumab	Soliris	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Alexion Europe SAS	24/06/2016	28/07/2016	P/0201/2016
Recombinant human beta-glucuronidase (rhGUS, UX003)		PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Ultragenyx Germany GmbH	24/06/2016	28/07/2016	P/0202/2016
Quizartinib		PIP	PIP agreed	Oncology	Daiichi Sankyo Europe GmbH	24/06/2016	22/07/2016	P/0203/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Pembrolizumab	Keytruda	PIP	PIP agreed	Oncology	Merck Sharp & Dohme (Europe), Inc.	24/06/2016	01/08/2016	P/0204/2016
Risankizumab		PIP	PIP agreed	Dermatology Gastroenterology -Hepatology Immunology-Rheumatology-Transplantation Pneumology - Allergology	Boehringer Ingelheim International GmbH	24/06/2016	04/08/2016	P/0205/2016
Rilpivirine (as hydrochloride)	Edurant	PIP Modification	Modification agreed	Infectious Diseases	Janssen-Cilag International NV	24/06/2016	12/08/2016	P/0206/2016
Turoctocog alfa	NovoEight	PIP Modification	Modification agreed	Haematology-Hemostaseology	Novo Nordisk A/S	24/06/2016	12/08/2016	P/0207/2016
Anidulafungin	Ecalta	PIP Modification	Modification agreed	Infectious Diseases	Pfizer Limited	24/06/2016	12/08/2016	P/0208/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Pneumococcal polysaccharide serotype 6B conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 18C conjugated to tetanus toxoid / Pneumococcal polysaccharide serotype 5 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 19F conjugated to diphtheria 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 4 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal	Synflorix	PIP Modification	Modification agreed	Vaccines	GlaxoSmithKline Biologicals S.A.	24/06/2016	12/08/2016	P/0209/2016
polysaccharide serotype 23F conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype								

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
vemurafenib	Zelboraf	PIP Modification	Modification agreed	Oncology	Roche Registration Limited	24/06/2016	12/08/2016	P/0210/2016
Brentuximab vedotin	Adcetris	PIP Modification	Modification agreed	Oncology	Takeda Pharma A/S	24/06/2016	12/08/2016	P/0211/2016
Budesonide		PIP Modification	Modification agreed	Pneumology - Allergology	Vectura Limited	24/06/2016	12/08/2016	P/0212/2016
Benralizumab		PIP Modification	Modification agreed	Pneumology - Allergology	AstraZeneca AB	24/06/2016	12/08/2016	P/0213/2016
Lurasidone hydrochloride	Latuda	PIP Modification	Modification agreed	Psychiatry	Sunovion Pharmaceuticals Ltd.	24/06/2016	12/08/2016	P/0214/2016
Dinutuximab	Unituxin	PIP Modification	Modification agreed	Oncology	United Therapeutics Europe Limited	24/06/2016	12/08/2016	P/0215/2016
Cabotegravir		PIP	PIP agreed	Infectious Diseases Gastroenterology -Hepatology	ViiV Healthcare UK Limited	24/06/2016	12/08/2016	P/0216/2016
Semaglutide		PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk	24/06/2016	12/08/2016	P/0217/2016
Elobixibat		PIP Modification	Modification agreed	Gastroenterology -Hepatology	Elobix AB	24/06/2016	15/08/2016	P/0218/2016
Dupilumab		PIP Modification	Modification agreed	Dermatology	Regeneron Pharmaceuticals, Inc	24/06/2016	12/08/2016	P/0219/2016
Lumacaftor / ivacaftor	Orkambi	PIP Modification	Modification agreed	Other	Vertex Pharmaceuticals (Europe) Limited	24/06/2016	26/08/2016	P/0220/2016
Tenofovir alafenamide (as fumarate)		PIP Modification	Modification agreed	Infectious Diseases	Gilead Sciences International Ltd.	24/06/2016	12/08/2016	P/0221/2016
Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human ARSA cDNA sequence (GSK2696274)		PIP	PIP agreed	Other	GlaxoSmithKline Trading Services Limited	24/06/2016	12/08/2016	P/0222/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
3-[[5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl]methyl]-1-(2,2,2-trifluoroethyl)-1,3-dihydro-3-[[5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl]methyl]-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-c]pyridine-2-one (JNJ-53718678)		PIP	PIP agreed	Infectious Diseases	Janssen-Cilag International NV	24/06/2016	12/08/2016	P/0223/2016
Lusutrombopag		Full Waiver	Full waiver granted	Haematology-Hemostaseology	Shionogi Limited	24/06/2016	12/08/2016	P/0224/2016
Amlodipine / Rosuvastatin		Full Waiver	Full waiver granted	Cardiovascular Diseases	Adamed Sp. z o.o.	24/06/2016	12/08/2016	P/0225/2016
Ramipril / amlodipine / hydrochlorothiazide		Full Waiver	Full waiver granted	Cardiovascular Diseases	Adamed Sp. z o.o.	24/06/2016	12/08/2016	P/0226/2016
Dulaglutide	Trulicity	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Eli Lilly & Company	27/05/2016	26/08/2016	P/0227/2016
Cathine (hydrochloride)		PIP	PIP agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Schuck GmbH	22/07/2016	12/08/2016	P/0228/2016
Eculizumab	Soliris	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Alexion Europe SAS	22/07/2016	01/09/2016	P/0229/2016
Fingolimod (hydrochloride)	Gilenya	PIP Modification	Modification agreed	Neurology	Novartis Europharm Limited	22/07/2016	09/09/2016	P/0230/2016
Dihydroartemisinin / piperaquine phosphate anhydride	Eurartesim	PIP Modification	Modification agreed	Infectious Diseases	Sigma-Tau SpA	22/07/2016	09/09/2016	P/0231/2016
Lanthanum carbonate hydrate	Fosrenol and associated names)	PIP Modification	Modification agreed	Uro-nephrology	Shire Pharmaceutical Contracts Ltd	22/07/2016	09/09/2016	P/0232/2016
Ixekizumab	Taltz	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Eli Lilly & Company Limited	22/07/2016	09/09/2016	P/0233/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Brexpiprazole		PIP Modification	Modification agreed	Psychiatry	Otsuka Europe Development and Commercialisation Ltd, Zweigniederlassung Frankfurt am Main	22/07/2016	09/09/2016	P/0234/2016
Evolocumab	Repatha	PIP Modification	Modification agreed	Cardiovascular Diseases	Amgen Europe B.V.	22/07/2016	09/09/2016	P/0235/2016
Derivative of 4H-pyrazolo[3,4-d]pyrimidin-4-one		PIP	PIP agreed	Psychiatry	Boehringer Ingelheim International GmbH	22/07/2016	09/09/2016	P/0236/2016
Elafibranor		PIP	PIP agreed	Gastroenterology-Hepatology	Genfit SA	22/07/2016	09/09/2016	P/0237/2016
Rosuvastatin (calcium) / Ezetimibe		Full Waiver	Full waiver granted	Cardiovascular Diseases	Adamed sp z o.o.	22/07/2016	09/09/2016	P/0238/2016
Lesinurad / allopurinol		Full Waiver	Full waiver granted	Immunology-Rheumatology-Transplantation	AstraZeneca AB	22/07/2016	09/09/2016	P/0239/2016
(S)-lactic acid		Full Waiver	Full waiver granted	Endocrinology-Gynaecology-Fertility-Metabolism	YES Pharmaceutical Development Services GmbH	22/07/2016	09/09/2016	P/0240/2016
Lubiprostone	Amitiza	PIP Modification	Modification agreed	Gastroenterology-Hepatology	Sucampo AG	22/07/2016	09/09/2016	P/0241/2016
Autologous cartilage derived cultured chondrocytes		PIP	PIP agreed	Other	TETEC AG	22/07/2016	09/09/2016	P/0242/2016
Macitentan / tadalafil		Full Waiver	Full waiver granted	Cardiovascular Diseases	Actelion Registration Ltd.	22/07/2016	09/09/2016	P/0243/2016
Humanized IgG1, kappa anti-serum amyloid A and anti-AL amyloid antibody		Full Waiver	Full waiver granted	Cardiovascular Diseases Haematology-Hemostaseology	Prothena Therapeutics Limited	22/07/2016	09/09/2016	P/0244/2016
Amlodipine (besylate) / perindopril (erbumine) / indapamide		Full Waiver	Full waiver granted	Cardiovascular Diseases	Zentiva, k.s.	22/07/2016	09/09/2016	P/0245/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Allogeneic human neural stem cells genetically modified to express c-MycERTAM, a c-Myc and modified oestrogen receptor fusion protein (CTX0E03)		Full Waiver	Full waiver granted	Neurology	ReNeuron Ltd	22/07/2016	12/09/2016	P/0246/2016
Vedolizumab	Entyvio	PIP Modification	Modification agreed	Gastroenterology -Hepatology	Takeda Pharma A/S	22/07/2016	13/09/2016	P/0247/2016
Cerliponase alfa		PIP Modification	Modification agreed	Neurology	BioMarin International Limited	19/08/2016	05/09/2016	P/0248/2016
Sapropterin dihydrochloride	Kuvan	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	BioMarin International Limited	19/08/2016	09/09/2016	P/0249/2016
Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein (BMS-986089)		PIP	PIP agreed	Neurology	Bristol-Myers Squibb International Corporation	19/08/2016	09/09/2016	P/0250/2016
Nusinersen		PIP Modification	Modification agreed	Neurology	Biogen Idec Ltd	19/08/2016	23/09/2016	P/0251/2016
Linaclotide	Constella	PIP Modification	Modification agreed	Gastroenterology -Hepatology	Allergan Pharmaceuticals International Limited	16/09/2016	26/09/2016	P/0252/2016
Angiotensin II (LJPC-501)		PIP	Negative	Other	La Jolla Pharmaceutical Company, Inc.	16/09/2016	26/09/2016	P/0253/2016
Apixaban	Eliquis	PIP Modification	Modification agreed	Cardiovascular Diseases	Bristol-Myers Squibb / Pfizer EEIG	19/08/2016	05/10/2016	P/0254/2016
Alogliptin	Vipidia	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Takeda Development Centre Europe Ltd	19/08/2016	05/10/2016	P/0255/2016
Reslizumab		PIP Modification	Modification agreed	Pneumology - Allergology	Teva Pharmaceuticals Europe	19/08/2016	05/10/2016	P/0256/2016
Zuretinol (acetate)		PIP Modification	Modification agreed	Ophthalmology	QLT Ophthalmics (UK), Ltd.	19/08/2016	05/10/2016	P/0257/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Recombinant respiratory syncytial virus vaccine		Full Waiver	Full waiver granted	Infectious Diseases	MedImmune Limited	19/08/2016	05/10/2016	P/0258/2016
Selepressin	N/A	PIP Modification	Modification agreed	Cardiovascular Diseases	Ferring Pharmaceuticals A/S	19/08/2016	05/10/2016	P/0259/2016
Autologous CD34+ cells transduced with lentiviral vector containing the human Wiskott Aldrich Syndrom Protein gene	N/A	PIP Modification	Modification agreed	Immunology-Rheumatology-Transplantation	Genethon	19/08/2016	05/10/2016	P/0260/2016
Eftrenonacog alfa	ALPROLIX	PIP Modification	Modification agreed	Haematology-Hemostaseology	Biogen Idec Ltd	19/08/2016	05/10/2016	P/0261/2016
Copanlisib		PIP	PIP agreed	Oncology	Bayer Pharma AG	19/08/2016	05/10/2016	P/0262/2016
Lifitegrast		Full Waiver	Full waiver granted	Ophthalmology	Shire Pharmaceuticals Ireland Limited	19/08/2016	05/10/2016	P/0263/2016
Tedizolid (phosphate)	Sivextro	PIP Modification	Modification agreed	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	19/08/2016	05/10/2016	P/0264/2016
Human recombinant IgG1 monoclonal antibody targeting fibroblast growth factor 23 (KRN23)		PIP Modification	Modification agreed	Other	Ultragenyx Pharmaceutical Inc.	19/08/2016	05/10/2016	P/0265/2016
Ragweed pollen extract *(Ambrosia artemisiifolia)*		PIP	PIP agreed	Pneumology - Allergology	ALK Abelló A/S	19/08/2016	05/10/2016	P/0266/2016
Ibuprofen / paracetamol		Full Waiver	Full waiver granted	Pain	FARMALIDER, S.A	19/08/2016	05/10/2016	P/0267/2016
Guadecitabine		PIP	PIP agreed	Oncology	Otsuka Europe Development and Commercialisation Ltd.,	19/08/2016	07/10/2016	P/0268/2016
Delamanid	Deltyba	PIP Modification	Modification agreed	Infectious Diseases	Otsuka Europe Development and Commercialisation Ltd.	19/08/2016	07/10/2016	P/0269/2016
Human Fibrinogen / Human Thrombin		PIP Modification	Negative	Other	Instituto Grifols, S.A.	19/08/2016	07/10/2016	P/0270/2016
Gentamicin (sulphate)		Full Waiver	Full waiver granted	Dermatology	Innocoll	19/08/2016	07/10/2016	P/0271/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Albiglutide	Eperzan	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Glaxo Group Limited	19/08/2016	07/10/2016	P/0272/2016
Recombinant, CHO cell expressed, fully human IgG1, kappa light chain, monoclonal antibody		PIP	PIP agreed	Other	Dyax Corp.	19/08/2016	05/10/2016	P/0273/2016
Elvitegravir	Vitekta	PIP Modification	Modification agreed	Infectious Diseases	Gilead Sciences International Ltd	19/08/2016	07/10/2016	P/0274/2016
Peanut flour		PIP Modification	Modification agreed	Pneumology - Allergology	Aimmune Therapeutics	19/08/2016	07/10/2016	P/0275/2016
Fluticasone furoate / vilanterol	Relvar Ellipta and associated names	PIP Modification	Modification agreed	Pneumology - Allergology	Glaxo Group Limited	19/08/2016	10/10/2016	P/0276/2016
18F fluoromisonidazole		Full Waiver	Negative	Diagnostic Oncology	RadioMedic s.r.o.	19/08/2016	05/10/2016	P/0277/2016
Macrogol 3350 / sodium sulfate / sodium chloride / potassium chloride / sodium ascorbate / ascorbic acid (NER1006)		PIP	PIP agreed	Gastroenterology -Hepatology	Norgine Ltd.	16/09/2016	07/10/2016	P/0278/2016
Eteplirsen		PIP Modification	Modification agreed	Neurology	AVI Biopharma International Ltd	16/09/2016	07/10/2016	P/0279/2016
Recombinant human nerve growth factor		PIP Modification	Modification agreed	Ophthalmology	Dompé farmaceutici S.p.A.	16/09/2016	12/10/2016	P/0280/2016
Mepolizumab	Nucala	PIP Modification	Modification agreed	Pneumology - Allergology	GSK Trading Services Limited	16/09/2016	04/11/2016	P/0281/2016
Dabigatran etexilate	Pradaxa	PIP Modification	Modification agreed	Cardiovascular Diseases Haematology-Hemostaseology	Boehringer Ingelheim International GmbH	16/09/2016	04/11/2016	P/0282/2016
Ataluren	Translarna	PIP Modification	Modification agreed	Neurology	PTC Therapeutics International, Limited	16/09/2016	04/11/2016	P/0283/2016
Ataluren	Translarna	PIP Modification	Modification agreed	Pneumology - Allergology	PTC Therapeutics International, Limited	16/09/2016	04/11/2016	P/0284/2016
Alipogene tiparvovec	Glybera	PIP Modification	Modification agreed	Cardiovascular Diseases	uniQure biopharma B.V.	16/09/2016	04/11/2016	P/0285/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Human normal immunoglobulin	NAXIGLO and associated names	PIP Modification	Modification agreed	Haematology-Hemostaseology Immunology-Rheumatology-Transplantation	Kedrion S.p.A.	16/09/2016	04/11/2016	P/0286/2016
Mirabegron	Betmiga	PIP Modification	Modification agreed	Uro-nephrology	Astellas Pharma Europe B.V.	16/09/2016	04/11/2016	P/0287/2016
Mirabegron	Betmiga	PIP Modification	Modification agreed	Uro-nephrology	Astellas Pharma Europe B.V.	16/09/2016	04/11/2016	P/0288/2016
Riociguat	Adempas	PIP Modification	Modification agreed	Cardiovascular Diseases	Bayer Pharma AG	16/09/2016	04/11/2016	P/0289/2016
Allogeneic Mesenchymal Precursor Cells (rexlemestrocel-L)		Full Waiver	Full waiver granted	Other	Mesoblast UK Limited	16/09/2016	04/11/2016	P/0290/2016
Sirukumab		Full Waiver	Full waiver granted	Immunology-Rheumatology-Transplantation	Janssen-Cilag International N.V.	16/09/2016	04/11/2016	P/0291/2016
Serelaxin		PIP Modification	Modification agreed	Cardiovascular Diseases	Novartis Europharm Limited	16/09/2016	04/11/2016	P/0292/2016
Potassium (chloride) / magnesium (sulphate heptahydrate) / procaine (hydrochloride) / xylitol		PIP Modification	Modification agreed	Other	MIT Gesundheit GmbH	16/09/2016	04/11/2016	P/0293/2016
Tolvaptan	Samsca and associated names	PIP Modification	Negative	Endocrinology-Gynaecology-Fertility-Metabolism	Otsuka Pharmaceutical Europe Ltd.	16/09/2016	04/11/2016	P/0294/2016
Human fibrinogen / human thrombin	Raplixa	PIP Modification	Modification agreed	Haematology-Hemostaseology Other	Mallinckrodt Pharmaceuticals	16/09/2016	04/11/2016	P/0295/2016
Sodium zirconium cyclosilicate		PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	ZS Pharma, Inc	16/09/2016	04/11/2016	P/0296/2016
Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human βA-T87Q-globin gene		PIP Modification	Modification agreed	Haematology-Hemostaseology	bluebird bio France	16/09/2016	04/11/2016	P/0297/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Humanised chimeric antibody with a humanised H chain and a chimeric (mouse V-domain, human C-domain) L chain against epidermal growth factor receptor conjugated to maleimidocaproyl monomethylauristatin F (ABT-414) L chain against epidermal growth factor receptor conjugated to maleimidocaproyl monomethylauristatin F (ABT-414)		PIP	PIP agreed	Oncology	AbbVie Ltd	16/09/2016	04/11/2016	P/0298/2016
Olaratumab		PIP Modification	Modification agreed	Oncology	Eli Lilly and Company Limited	16/09/2016	04/11/2016	P/0299/2016
Monoclonal IgG1 anti-influenza A antibody		PIP	PIP agreed	Infectious Diseases	Roche Products Limited	16/09/2016	04/11/2016	P/0300/2016
Immunoglobulin G2, anti-(human α-calcitonin gene-related peptide/β-calcitonin gene-related peptide) (human-Mus musculus monoclonal TEV-48125 heavy chain), disulphide with human-Mus musculus monoclonal TEV-48125 light chain, dimer (TEV-48125)		PIP	PIP agreed	Neurology	Teva Pharma GmbH	16/09/2016	04/11/2016	P/0301/2016
Birch pollen extract (Betula verrucosa)		PIP	PIP agreed	Pneumology - Allergology	ALK Abelló A/S	16/09/2016	04/11/2016	P/0302/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)/ Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2)/ Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage)/ Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage)		PIP	PIP agreed	Vaccines	NDA Regulatory Service GmbH	16/09/2016	04/11/2016	P/0303/2016
Perindopril / amlodipine		Full Waiver	Full waiver granted	Cardiovascular Diseases	ERREKAPPA EUROTERAPICI S.p.A.	16/09/2016	04/11/2016	P/0304/2016
Ciclosporin		Full Waiver	Full waiver granted	Ophthalmology	Drug Delivery Solutions ApS	16/09/2016	04/11/2016	P/0305/2016
Amlodipine / atorvastatin		Full Waiver	Full waiver granted	Cardiovascular Diseases	ELPEN Pharmaceutical Co. Inc	16/09/2016	04/11/2016	P/0306/2016
Amlodipine / Valsartan / Hydrochlorothiazide		Full Waiver	Full waiver granted	Cardiovascular Diseases	ELPEN Pharmaceutical Co. Inc	16/09/2016	04/11/2016	P/0307/2016
Candesartan / amlodipine		Full Waiver	Full waiver granted	Cardiovascular Diseases	CIPROS S.r.l.	16/09/2016	04/11/2016	P/0308/2016
Elvitegravir / emtricitabine / tenofovir disoproxil (as fumarate) / cobicistat	Stribild	PIP Modification	Modification agreed	Infectious Diseases	Gilead Sciences International Ltd	14/10/2016	04/11/2016	P/0309/2016
Pixantrone (dimaleate)	Pixuvri	PIP Modification	Modification agreed	Oncology	CTI Life Sciences Limited	14/10/2016	04/11/2016	P/0310/2016
Daclatasvir	Daklinza	PIP Modification	Modification agreed	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	14/10/2016	07/11/2016	P/0311/2016
Naldemedine (tosylate)		PIP	PIP agreed	Gastroenterology -Hepatology	Shionogi Limited	14/10/2016	11/11/2016	P/0312/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Complex of povidone and iodine / dexamethasone (SHP640)		PIP	PIP agreed	Ophthalmology	Shire Pharmaceuticals Ireland Ltd	11/11/2016	21/12/2016	P/0313/2016
Metreleptin		PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Aegerion Pharmaceuticals Ltd	11/11/2016	25/11/2016	P/0314/2016
Tapentadol (hydrochloride)	Palexia and associated names Yantil and associated names Tapentadol and associated names	PIP Modification	Modification agreed	Pain	Grünenthal GmbH	14/10/2016	02/12/2016	P/0315/2016
Cannabidiol / delta-9-tetrahydrocannabinol	Sativex	PIP Modification	Modification agreed	Neurology	GW Pharma Ltd	14/10/2016	02/12/2016	P/0316/2016
Ceftobiprole medocaril (sodium)	Zevtera and associated names	PIP Modification	Modification agreed	Infectious Diseases	Basilea Pharmaceutica International Ltd.	14/10/2016	05/12/2016	P/0317/2016
Telavancin (hydrochloride)	Vibativ	PIP Modification	Modification agreed	Infectious Diseases	Clinigen Healthcare Ltd	14/10/2016	02/12/2016	P/0318/2016
Tapentadol (hydrochloride)	Palexia and associated names Yantil and associated names Tapentadol and associated names	PIP Modification	Modification agreed	Pain	Grünenthal GmbH	14/10/2016	02/12/2016	P/0319/2016
Methoxyflurane	Penthrox	PIP Modification	Modification agreed	Pain	Medical Developments UK Ltd	16/12/2016	21/12/2016	P/0320/2016
Sunitinib	Sutent	PIP Modification	Modification agreed	Oncology	Pfizer Limited	14/10/2016	02/12/2016	P/0321/2016
Ambrisentan	Volibris	PIP Modification	Modification agreed	Cardiovascular Diseases	Glaxo Group Limited	14/10/2016	02/12/2016	P/0322/2016
Perampanel	Fycompa	PIP Modification	Modification agreed	Neurology	Eisai Europe Limited	14/10/2016	02/12/2016	P/0323/2016
Linagliptin	Trajenta	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	14/10/2016	02/12/2016	P/0324/2016
Bosutinib	Bosulif	PIP Modification	Modification agreed	Oncology	Pfizer Limited	14/10/2016	02/12/2016	P/0325/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Empagliflozin	Jardiance	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	14/10/2016	02/12/2016	P/0326/2016
Loxapine	Adasuve	PIP Modification	Modification agreed	Psychiatry	Ferrer Internacional, S.A.	14/10/2016	02/12/2016	P/0327/2016
Migalastat (hydrochloride)	Galafold	PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Amicus Therapeutics UK Ltd	14/10/2016	02/12/2016	P/0328/2016
Autologous haematopoietic stem cells transduced with lentiviral vector Lenti-D encoding the human ATP-binding cassette, sub-family D (ALD), member 1 (ABCD1) from cDNA		PIP Modification	Modification agreed	Neurology	bluebird bio France	14/10/2016	02/12/2016	P/0329/2016
Eribulin	Halaven	PIP Modification	Modification agreed	Oncology	Eisai Europe Ltd	14/10/2016	02/12/2016	P/0330/2016
Dobutamine (hydrochloride)		PIP Modification	Modification agreed	Cardiovascular Diseases	Proveca Limited	14/10/2016	02/12/2016	P/0331/2016
Naltrexone (hydrochloride) / bupropion (hydrochloride)	Mysimba	PIP Modification	Modification agreed	Other	Orexigen Therapeutics Ireland Limited	14/10/2016	02/12/2016	P/0332/2016
Inotuzumab ozogamicin		PIP Modification	Modification agreed	Haematology-Hemostaseology	Pfizer Limited	14/10/2016	02/12/2016	P/0333/2016
Semaglutide		PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	14/10/2016	02/12/2016	P/0334/2016
Fentanyl (hydrochloride)	Ionsys	PIP Modification	Modification agreed	Pain	Incline Therapeutics Europe Ltd.	14/10/2016	02/12/2016	P/0335/2016
Eravacycline		PIP Modification	Modification agreed	Infectious Diseases	Tetraphase Pharmaceuticals, Inc.	14/10/2016	02/12/2016	P/0336/2016
Autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD19 (CTL019)		PIP Modification	Modification agreed	Oncology	Novartis Europharm Limited	14/10/2016	02/12/2016	P/0337/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Derivative of 4H-pyrazolo[3,4-d]pyrimidin-4-one		PIP	Negative	Psychiatry	Boehringer Ingelheim International GmbH	14/10/2016	02/12/2016	P/0338/2016
Bictegravir / emtricitabine / tenofovir alafenamide		PIP Modification	Modification agreed	Infectious Diseases	Gilead Sciences International Ltd.	14/10/2016	02/12/2016	P/0339/2016
Peramivir		PIP	PIP agreed	Infectious Diseases	BioCryst UK Ltd. (c/o Morgan Lewis & Bockius)	11/11/2016	25/11/2016	P/0340/2016
Galcanezumab		PIP	PIP agreed	Neurology	Eli Lilly and Company Limited	14/10/2016	05/12/2016	P/0341/2016
Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin (rVIIa-FP; CSL689)		PIP	PIP agreed	Haematology-Hemostaseology	CSL Behring GmbH	14/10/2016	02/12/2016	P/0342/2016
Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin (rVIIa-FP; CSL689)		PIP	PIP agreed	Haematology-Hemostaseology	CSL Behring GmbH	14/10/2016	02/12/2016	P/0343/2016
Inebilizumab		PIP	PIP agreed	Neurology	MedImmune, LLC (a wholly owned subsidiary of AstraZeneca PLC)	14/10/2016	02/12/2016	P/0344/2016
Teprotumumab		Full Waiver	Full waiver granted	Ophthalmology	River Vision Development Corporation	14/10/2016	02/12/2016	P/0345/2016
N-[5-(4-Bromophenyl)-6-[2-[(5-bromo-2-pyrimidinyl)oxy]ethoxy]-4-pyrimidinyl]-sulfamide		Full Waiver	Full waiver granted	Cardiovascular Diseases	Actelion Registration Ltd.	14/10/2016	02/12/2016	P/0346/2016
Synthetic double-stranded siRNA oligonucleotide directed against p53 mRNA (QPI-1002)		Full Waiver	Full waiver granted	Immunology-Rheumatology-Transplantation	Quark Pharmaceuticals Inc.	14/10/2016	05/12/2016	P/0347/2016
Chlorhexidine gluconate / isopropyl alcohol		PIP	Full waiver granted	Dermatology	GAMA Healthcare Ltd	14/10/2016	02/12/2016	P/0348/2016
Terguride (hydrogenmaleate)		Full Waiver	Negative	Immunology-Rheumatology-Transplantation	medac Gesellschaft für klinische Spezialpräparate mbH	14/10/2016	02/12/2016	P/0349/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Antithrombin alfa	Recombinant human antithrombin	PIP	Negative	Haematology-Hemostaseology	GTC Biotherapeutics UK Limited	19/10/2016	02/12/2016	P/0350/2016
Pimavanserin		PIP	PIP agreed	Psychiatry	ACADIA Pharmaceuticals Inc.	11/11/2016	02/12/2016	P/0351/2016
Betrixaban		PIP	PIP agreed	Cardiovascular Diseases	Portola Pharma UK Limited	11/11/2016	02/12/2016	P/0352/2016
Talimogene laherparepvec	Imlygic	PIP Modification	Modification agreed	Oncology	Amgen Europe B.V.	11/11/2016	09/12/2016	P/0353/2016
Sacubitril / valsartan	Entresto	PIP Modification	Modification agreed	Cardiovascular Diseases	Novartis Europharm Ltd.	11/11/2016	21/12/2016	P/0354/2016
Ceftaroline fosamil	Zinforo	PIP Modification	Modification agreed	Infectious Diseases	AstraZeneca AB	11/11/2016	21/12/2016	P/0355/2016
Eculizumab	Soliris	PIP	PIP agreed	Immunology-Rheumatology-Transplantation	Alexion Europe SAS	11/11/2016	21/12/2016	P/0356/2016
Deferiprone		PIP Modification	Modification agreed	Haematology-Hemostaseology	Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF) - Coordinator for DEEP Project (HEALTH-F4-2010-261483)	11/11/2016	21/12/2016	P/0357/2016
Fosnetupitant / palonosetron	Akynzeo	Full Waiver	Negative	Other	Helsinn Birex Pharmaceuticals Limited	11/11/2016	21/12/2016	P/0358/2016
Estetrol / drospirenone		PIP Modification	Modification agreed	Endocrinology-Gynaecology-Fertility-Metabolism	Estetra SPRL	11/11/2016	21/12/2016	P/0359/2016
Octenidine (dihydrochloride)		PIP	PIP agreed	Neonatology - Paediatric Intensive Care	Schülke & Mayr GmbH	11/11/2016	21/12/2016	P/0360/2016
Allantoin		PIP Modification	Modification agreed	Dermatology	Scioderm, Inc.	11/11/2016	20/12/2016	P/0361/2016
Finerenone		PIP Modification	Modification agreed	Uro-nephrology	Bayer Pharma AG	11/11/2016	21/12/2016	P/0362/2016

Active Substance(s)	Invented Name	Applicant's request	PDCO Opinion	Therapeutic Areas	Applicant	Opinion Date	Decision Date	Decision Number
Dipalmitoylphosphatidylcholine / 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphoglycerol sodium salt / synthetic surfactant protein C analogue / synthetic surfactant protein B analogue (CHF 5633)		PIP	PIP agreed	Neonatology - Paediatric Intensive Care	Chiesi Farmaceutici SpA	11/11/2016	21/12/2016	P/0363/2016
KEOC liquid extract ethanolic 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus lemon (L.) Burm. (fresh fruit) / Paullinia cupana Kunth / Theobroma cacao L.		PIP Modification	Modification agreed	Dermatology	Legacy Healthcare	11/11/2016	20/12/2016	P/0364/2016
Galcanezumab		PIP	PIP agreed	Neurology	Eli Lilly and Company Limited	11/11/2016	21/12/2016	P/0365/2016
Ibuprofen		Full Waiver	Full waiver granted	Other Pain	Strides Shasun Limited (Formulation Division)	11/11/2016	20/12/2016	P/0366/2016
DNA plasmid encoding HPV type 16 consensus E6 and E7 proteins (pGX3001) / DNA plasmid encoding HPV type 18 consensus E6 and E7 proteins (pGX3002)		Full Waiver	Full waiver granted	Infectious Diseases Vaccines	Inovio Pharmaceuticals Inc.	11/11/2016	21/12/2016	P/0367/2016
Netarsudil		Full Waiver	Full waiver granted	Ophthalmology	Aerie Pharmaceuticals Ireland, Ltd.	11/11/2016	21/12/2016	P/0368/2016
Botulinum toxin, Type A		Full Waiver	Full waiver granted	Dermatology	Evolus Inc.	11/11/2016	21/12/2016	P/0369/2016

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

Active Substance(s)	Therapeutic area(s)	Applicant	PDCO Opinion date

Everolimus	Neurology	Novartis Europharm Limited	29/01/2016
velaglucerase alfa	Endocrinology-Gynaecology-Fertility-Metabolism	Shire Pharmaceuticals Ireland Limited	29/01/2016
Human normal immunoglobulin	Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology	Bio Products Laboratory Limited	29/01/2016
Ozenoxacin	Infectious Diseases	Ferrer Internacional, S.A.	29/01/2016
Bevacizumab	Oncology	F.Hoffmann-La Roche Ltd	26/02/2016
Canakinumab	Immunology-Rheumatology-Transplantation	Novartis Europharm Ltd.	26/02/2016
Canakinumab	Immunology-Rheumatology-Transplantation	Novartis Europharm Ltd.	26/02/2016
C1inhibitor (human)	Immunology-Rheumatology-Transplantation	NPS Pharma Holdings Limited (now part of Shire)	26/02/2016
Adalimumab	Immunology-Rheumatology-Transplantation / Dermatology	AbbVie Ltd	01/04/2016
maraviroc	Infectious Diseases	ViiV Healthcare UK Limited	29/04/2016
Tobramycin	Infectious Diseases	Novartis Europharm Limited	29/04/2016
Ciclosporin	Ophthalmology	SANTEN OY	29/04/2016
Recombinant Human TriPeptidyl Peptidase 1 (rhTPP1) NEGATIVE	Neurology	BioMarin International Limited	27/05/2016
Tiotropium bromide (monohydrate)	Pneumology - Allergology	Boehringer Ingelheim International GmbH	27/05/2016
cinacalcet	Uro-nephrology	Amgen Europe B.V.	27/05/2016
Diphtheria toxoid-2IU / Tetanus toxoid-20IU / Bordetella pertussis antigen : Pertussis toxoid-8µg Filamentous Haemagglutinin-8µg Pertactin-2.5µg / Inactivated poliovirus: type 1 (Mahoney strain)-40D Inactivated poliovirus: type 2 (MEF-1 strain)-8D Inactivated poliovirus: type 3 (Saukett strain)-32D	Vaccines	GlaxoSmithKline Biologicals S.A	27/05/2016
Aripiprazole	Psychiatry	Otsuka Pharmaceutical Europe Ltd.	24/06/2016
Levamisole (hydrochloride)	Uro-nephrology	ACE Pharmaceuticals BV	22/07/2016
Pitavastatin calcium	Endocrinology-Gynaecology-Fertility-Metabolism	Kowa Pharmaceutical Europe Co. Ltd.	19/08/2016
Pitavastatin calcium	Endocrinology-Gynaecology-Fertility-Metabolism	Kowa Pharmaceutical Europe Co. Ltd.	19/08/2016
icatibant	Other	Shire Orphan Therapies GmbH	19/08/2016

rufinamide	Neurology	Eisai Limited	16/09/2016
Adalimumab	Immunology-Rheumatology-Transplantation / Ophthalmology / Dermatology / Gastroenterology-Hepatology	AbbVie Ltd	14/10/2016
deferasirox	Haematology-Hemostaseology	Novartis Europharm Limited	14/10/2016
Hydrocortisone	Endocrinology-Gynaecology-Fertility-Metabolism	DIURNAL LIMITED	14/10/2016
Nilotinib	Oncology	Novartis Europharm Ltd.	11/11/2016
Catridecacog	Haematology-Hemostaseology	Novo Nordisk A/S	16/12/2016
Fibrinogen (human plasma-derived)	Haematology-Hemostaseology	LFB Biotechnologies	16/12/2016
Solifenacin (succinate)	Uro-nephrology	Astellas Pharma Europe B.V.	16/12/2016
Cobicistat / elvitegravir / tenofovir disoproxil / emtricitabine	Infectious Diseases	Gilead Sciences International Ltd.	16/12/2016
tenofovir disoproxil fumarate / emtricitabine	Infectious Diseases	Gilead Sciences International Ltd.	16/12/2016
natalizumab	Neurology	Biogen Idec Ltd	16/12/2016
Dinutuximab	Oncology	United Therapeutics Europe Limited	16/12/2016

Annex 15 – Referral procedures overview 2016 – human medicines

Referrals made to the CHMP

Procedure name (International non-proprietary name (INN) or common name)	Start of procedure	End of procedure	Type of referral
Cymevene i.v. and associated names (ganciclovir)	25/09/2014	25/02/2016	Article 30 of Directive 2001/83/EC
Medicinal products under development for the treatment of Ebola (various)	25/09/2014	28/01/2016	Article 5(3) of Regulation (EC) No 726/2004
Novantrone and associated names (mitoxantrone)	23/10/2014	28/04/2016	Article 30 of Directive 2001/83/EC
Clenil and associated names (beclometasone dipropionate)	25/06/2015	15/09/2016	Article 30 of Directive 2001/83/EC
Durogesic and associated names (fentanyl)	24/09/2015	21/07/2016	Article 30 of Directive 2001/83/EC
Linxyd and associated names (linezolid)	24/09/2015	MA withdrawn[1]	Article 29(4) of Directive 2001/83/EC
Linezolid Accord and associated names (linezolid)	24/09/2015	MA withdrawn[2]	Article 29(4) of Directive 2001/83/EC
Otipax and associated names (lidocaine hydrochloride)	22/10/2015	MA withdrawn[3]	Article 29(4) of Directive 2001/83/EC
Levonelle 1500mcg tablets and associated names (levonorgestrel)	22/10/2015	26/05/2016	Article 13 of Regulation (EC) No 1234/2008
Tobramycin VVB and associated names (tobramycin)	22/10/2015	28/01/2016	Article 29(4) of Directive 2001/83/EC
Lovenox and associated names (enoxaparin)	19/11/2015	15/12/2016	Article 30 of Directive 2001/83/EC
Metformin containing medicinal products (metformin)	28/01/2016	13/10/2016	Article 31 of Directive 2001/83/EC
Diclofenac 50 mg tablets (diclofenac epolamine)	25/02/2016	21/07/2016	Article 29(4) of Directive 2001/83/EC
Dienogest/Ethinylestradiol containing medicinal products (dienogest/ethinylestradiol)	25/02/2016	ongoing	Article 31 of Directive 2001/83/EC
Alkem (cefuroxime, riluzole, ibuprofen)	01/04/2016	23/06/2016	Article 31 of Directive 2001/83/EC
Vancomycin containing medicinal products (vancomycin)	01/04/2016	ongoing	Article 31 of Directive 2001/83/EC

[1] MA withdrawn in January 2016
[2] MA withdrawn in January 2016
[3] MA withdrawn in April 2016

Procedure name (International non-proprietary name (INN) or common name)	Start of procedure	End of procedure	Type of referral
Symbioflor 2 and associated names (Escherichia coli bacteria (cells and autolysate))	01/04/2016	ongoing	Article 31 of Directive 2001/83/EC
Semler (abacavir/ lamivudine, amoxicillin, atovaquone/ proguanil, celecoxib, duloxetine, ebastine, eletriptan, eprosartan, erlotinib, etoricoxib, irbesartan/ hydrochlorothiazide, pregabalin, rasagiline, rosuvastatin, saquinavir, tramadol/ paracetamol)	28/04/2016	21/07/2016	Article 31 of Directive 2001/83/EC
Pharmaceutics International Inc. (Ammonaps (sodium phenylbutyrate), Lutinus and associated names (progesterone), Dutasteride Actavis and associated names (dutasteride), SoliCol D3 (colecalciferol))	23/06/2016	13/10/2016[4]	Article 31 of Directive 2001/83/EC
Paracetamol/ibuprofen 500 mg/150 mg (paracetamol/ ibuprofen)	10/11/2016	ongoing	Article 29(4) of Directive 2001/83/EC
Micro Therapeutic Research (various)	15/12/2016	ongoing	Article 31 of Directive 2001/83/EC

Referrals made to the PRAC

Procedure name (international non-proprietary name (INN))	Start of procedure	End of procedure	Type of referral
Inhaled corticosteroids containing medicinal products indicated in the treatment of chronic obstructive pulmonary disease (beclomethasone, budesonide, flunisolide, fluticasone propionate, fluticasone furoate)	07/05/2015	28/04/2016	Article 31 of Directive 2001/83/EC
Tysabri (natalizumab)	07/05/2015	25/02/2016	Article 20 of Regulation (EC) No 726/2004
SGLT2 inhibitors-containing medicinal products (canagliflozin, dapagliflozin, empagliflozin)	11/06/2015	25/02/2016	Article 20 of Regulation (EC) No 726/2004

[4] CHMP opinion date after revision

Procedure name (international non-proprietary name (INN))	Start of procedure	End of procedure	Type of referral
Fusafungine-containing medicinal products for oromucosal and nasal use (fusafungine)	10/09/2015	31/03/2016	Article 31 of Directive 2001/83/EC
Gadolinium containing medicinal products (gadolinium)	17/03/2016	ongoing	Article 31 of Directive 2001/83/EC
Direct-acting antivirals (DAAs) indicated for the treatment of hepatitis C (interferon free) (daclatasvir, dasabuvir, simeprevir, sofosbuvir, sofosbuvir/ledipasvir, ombitasvir/paritaprevir/ritonavir)	17/03/2016	15/12/2016	Article 20 of Regulation (EC) No 726/2004
Zydelig (idelalisib)	17/03/2016	21/07/2016	Article 20 of Regulation (EC) No 726/2004
SGLT2 inhibitors and lower limb amputation (canagliflozin, dapagliflozin, empagliflozin)	14/04/2016	ongoing	Article 20 of Regulation (EC) No 726/2004
Retinoids containing medicinal products (acitretin, adapalene, alitretinoin, bexarotene, isotretinoin, tretinoin, tazarotene)	07/07/2016	ongoing	Article 31 of Directive 2001/83/EC
Paracetamol modified or prolonged release tablets (paracetamol)	07/07/2016	ongoing	Article 31 of Directive 2001/83/EC
Human and recombinant coagulation factor VIII containing medicinal products (human coagulation factor VIII; efmoroctocog alfa; moroctocog alfa; octocog alfa; simoctocog alfa; susoctocog alfa; turoctocog alfa)	07/07/2016	ongoing	Article 31 of Directive 2001/83/EC
Lactose of bovine origin for IV/IM use in acute allergic reactions containing medicinal products (methylprednisolone)	01/12/2016	ongoing	Article 31 of Directive 2001/83/EC

Annex 16 – Arbitrations and referrals in 2016 – veterinary medicines

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• Referral under Article 35 of Directive 2001/82/EC	• 10/04/2013 • 19/05/2016	• Veterinary medicinal products containing altrenogest to be administered orally to pigs and horses • Altrenogest
• Referral under Article 35 of Directive 2001/82/EC	• 05/05/2015 • 19/05/2016	• 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	• 04/05/2015 • 21/04/2016	• 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 34 of Directive 2001/82/EC	• 24/08/2015	• Denagard 45% and associated names • Tiamulin fumarate
• Procedure under Article 33(4) of Directive 2001/82/EC	• 29/09/2015 • 17/03/2016	• CattleMarker IBR Inactivated emulsion for injection for cattle • Infectious bovine rhinotracheitis vaccine
• Referral under Article 35 of Directive 2001/82/EC	• 08/01/2016 • 10/11/2016	• Veterinary medicinal products containing gentamicin as solution for injection for cattle and pigs • Gentamicin
• Referral under Article 35 of Directive 2001/82/EC	• 01/02/2016	• Veterinary medicinal products containing zinc oxide to be administered orally to food-producing species • Zinc oxide
• Referral under Article 35 of Directive 2001/82/EC	• 02/05/2016	• Veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for intramuscular use in cattle • Methylprednisolone hydrogen succinate
• Procedure under Article 45 of	• 16/06/2016 • 14/07/2016	• Velactis • Cabergoline

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
Regulation 726/2004		
• Referral under Article 35 of Directive 2001/82/EC	• 22/06/2016	• Veterinary medicinal products containing tylosin to be administered parenterally and intended for the treatment of bovine mastitis caused by Mycoplasma spp • Tylosin
• Referral under Article 34 of Directive 2001/82/EC	• 24/06/2016	• Girolan and its associated name Apralan • Apramycin sulfate
• Referral under Article 34 of Directive 2001/82/EC	• 05/06/2016	• Lincocin and associated names • Lincomycin
• Referral under Article 35 of Directive 2001/82/EC	• 01/09/2016	• Zanil and associated names, and generic products thereof • Oxyclozanide

Annex 17 – Budget summaries 2015–2016

The summarised comparative budget statements for 2015 and 2016 are as follows:

		2015 (final)[1]		2016 (budget)[2]		2016 (prov.)[3]	
		€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
	Revenue						
1+5	Fees and charges	251,490	*82.7%*	270,590	*87.7%*	272,588	*89.3%*
200	General EU contribution	18,669	*6.1%*	2,038	*0.7%*	2,038	*0.7%*
201	Special EU contribution for orphan medicinal products	13,212	*4.3%*	12,785	*4.1%*	12,769	*4.2%*
300	Contribution from EEA	554	*0.2%*	410	*0.1%*	56	*0.0%*
600	External assigned revenue	17,559	*5.8%*	19,559	*6.3%*	15,276	*5.0%*
700	Balance from previous year	1,499	*0.5%*	1,950	*0.6%*	1,950	*0.6%*
5+9	Other	1,135	*0.4%*	1,090	*0.4%*	421	*0.1%*
	TOTAL REVENUE	**304,119**	*100.0%*	**308,422**	*100.0%*	**305,099**	*100.0%*
	Expenditure						
	Staff						
11	Staff in active employment	94,091	*31.9%*	93,019	*30.2%*	91,821	*30.9%*
13	Duty travel	623	*0.2%*	710	*0.2%*	683	*0.2%*
14	Socio-medical infrastructure	783	*0.3%*	881	*0.3%*	865	*0.3%*
15	Exchange of civil servants and experts	5,105	*1.7%*	6,152	*2.0%*	5,647	*1.9%*
16	Social welfare	528	*0.2%*	503	*0.2%*	472	*0.2%*
17	Representation expenses	137	*0.0%*	100	*0.0%*	56	*0.0%*
18	Staff insurances	2,382	*0.8%*	11,252	*3.6%*	11,186	*3.8%*
	Total Title 1	**103,651**	*35.1%*	**112,617**	*36.5%*	**110,729**	*37.3%*
	Building / equipment						
20	Investment in immovable property, renting of building and associated costs	30,263	*10.3%*	27,377	*8.9%*	22,529	*7.6%*
21	Expenditure on corporate data processing	16,522	*5.6%*	16,224	*5.3%*	15,502	*5.2%*
22	Movable property [..]	1,337	*0.5%*	1,809	*0.6%*	1,284	*0.4%*
23	Other administrative expenditure	1,145	*0.4%*	1,128	*0.4%*	847	*0.3%*
24	Postage	108	*0.0%*	183	*0.1%*	93	*0.0%*
25	Expenditure on other meetings	46	*0.0%*	171	*0.1%*	152	*0.1%*
	Total Title 2	**49,422**	*16.7%*	**46,892**	*15.2%*	**40,407**	*13.6%*
	Operational expenditure						
300	Meetings	7,993	*2.7%*	7,937	*2.6%*	7,924	*2.7%*
301	Evaluation of medicines	107,952	*36.6%*	117,502	*38.1%*	114,509	*38.6%*
302	Translations	3,742	*1.3%*	3,770	*1.2%*	3,759	*1.3%*
303	Studies and consultants	8,151	*2.8%*	6,588	*2.1%*	6,570	*2.2%*
304	Publications	138	*0.0%*	154	*0.0%*	152	*0.1%*
305	Community programmes	0	*0.0%*	0	*0.0%*	0	*0.0%*
31	Expenditure on business related IT projects	14,106	*4.8%*	12,962	*4.2%*	12,962	*4.4%*
	Total Title 3	**142,082**	*48.1%*	**148,913**	*48.3%*	**145,877**	*49.1%*
	TOTAL EXPENDITURE	**295,154**	*100.0%*	**308,422**	*100.0%*	**297,013**	*100.0%*

[1] Financial Year 2015: as per final accounts; rounded to nearest thousand Euro

[2] Financial Year 2016: as per final budget

[3] Financial Year 2016: as per provisional accounts; rounded to nearest thousand Euro

Annex 18 – European Medicines Agency Establishment Plan

Category and grade	TEMPORARY POSTS					
	POSTS 2016				POSTS 2017	
	Authorised		Actual as per 31.12.2016		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	0	-	0	-	0
AD 15	-	4	-	2	-	4
AD 14	-	6	-	6	-	6
AD 13	-	9	-	9	-	11
AD 12	-	42	-	39	-	40
AD 11	-	38	-	37	-	40
AD 10	-	44	-	44	-	43
AD 9	-	37	-	37	-	42
AD 8	-	54	-	54	-	53
AD 7	-	54	-	54	-	61
AD 6	-	37	-	37	-	37
AD 5	-	18	-	18	-	3
Total AD	**0**	**343**	**0**	**337**	**0**	**340**
AST 11	-	2	-	2	-	2
AST 10	-	5	-	5	-	6
AST 9	-	7	-	7	-	7
AST 8	-	16	-	16	-	16
AST 7	-	19	-	17	-	19
AST 6	-	39	-	39	-	43
AST 5	-	43	-	42	-	43
AST 4	-	49	-	49	-	52
AST 3	-	47	-	46	-	45
AST 2	-	32	-	27	-	23
AST 1	-	0	-	0	-	0
Total AST	**0**	**259**	**0**	**250**	**0**	**256**
Grand Total	**0**	**602**	**0**	**587**	**0**	**596**

Other staff	Planned (FTE[1]) 2016	Actual (FTE[1]) 2016	Actual headcount 31.12.2016	Planned (FTE[1]) 2017
CONTRACT AGENTS	**145**	**143**	**143**	**158**
NATIONAL EXPERTS	**40**	**36**	**38**	**45**

[1] FTE=Full Time Equivalent

Annex 19 – Access to documents requests

Requests received and pages released

Year	Number of requests received	Number of pages released
2016	**823**	380,911

Initial decisions on access in 2016[2]

Access given	
Yes	542
Partial	17
No	44
Not Applicable[3]	75
Total closed	**678**
Pending	247

Refusal

Legal basis	**Full**	**Partial**
4.1(a) – Protection of public interest	1	0
4.1(b) – Protection of privacy	1	0
4.2 1st ind – Protection of commercial interest	21	16
4.2 2nd ind – Protection of court proceedings	0	0
4.2 3rd ind – Protection of inspections	5	0
4.3 1st par – Protection of decision making process	13	0
4.3 2nd par – Protection of the Agency's decision making process	0	0
4.5 – Protection of Member States	3	1
Total	**44**	**17**

[2] Including initial requests received in previous years but closed in 2015
[3] Request became RFI / Document is not held by the Agency / Clarification is not received / Withdrawn

Decision on confirmatory applications in 2016[4]

Appeals	
Final refusal	4
Release	1
Partial	4
Not Applicable[5]	1
Total closed	**10**
Pending	0

Refusal

Legal basis	**Full**	**Partial**
4.1(a) – Protection of public interest	0	0
4.1(b) – Protection of privacy	1	1
4.2 1st ind – Protection of commercial interest	2	0
4.2 2nd ind – Protection of court proceedings	0	0
4.2 3rd ind – Protection of inspections	1	0
4.3 1st par – Protection of decision making process	0	0
4.3 2nd par – Protection of the Agency's decision making process	0	0
4.5 – Protection of Member States	0	0
Total	**4**	**1**

[4] Including appeals received in previous years but closed in 2015
[5] Withdrawn

Affiliation (per initial requests and appeals in 2016)

Affiliation	Number of requests received	In %	Number of pages released[6]	In %
Not-for-profit organisation	7	0.17	642	0.17
EU Institution (EC etc)	1	0.12	139	0.04
Regulator outside EU	2	0.24	0	0.00
EU NCA	4	0.49	103	0.03
Patients or Consumer	55	6.68	36388	9.55
Healthcare professional	24	2.92	16294	4.28
Academia/Research institute	66	8.02	120323	31.59
Legal	91	11.06	38463	10.10
Media	38	4.62	5960	1.56
Pharmaceutical industry	449	54.56	148013	38.86
Consultant	86	10.45	13044	3.42
Other	n/a	0.00	1542	0.40
Total	**823**	**100**	**380,911**	**100**

[6] Including initial requests and appeals received in previous years but closed in 2015

Annex 20 – Publications by Agency staff members and experts in 2016

Blake KV, Saint-Raymond A, Zaccaria C, Domergue F, Pelle B, Slattery J.
Enhanced Paediatric Pharmacovigilance at the European Medicines Agency: A Novel Query Applied to Adverse Drug Reaction Reports
Paediatr Drugs. 2016 Feb;18(1):55-63

Bonini S, Rasi G.
First-in-Human Clinical Trials - What We Can Learn from Tragic Failures.
N Engl J Med. 2016 Nov 3;375(18):1788-1789

Brauer R, Ruigómez A, Downey G, Bate A, Garcia Rodriguez LA, Huerta C, Gil M,de Abajo F, Requena G, Alvarez Y, Slattery J, de Groot M, Souverein P, Hesse U,Rottenkolber M, Schmiedl S, de Vries F, Tepie MF, Schlienger R, Smeeth L, Douglas I, Reynolds R, Klungel O.
Prevalence of antibiotic use: a comparison across various European health care data sources.
Pharmacoepidemiol Drug Saf. 2016 Mar;25 Suppl 1:11-20

Breckenridge A, Eichler HG, Jarow JP.
Precision medicine and the changing role of regulatory agencies.
Nat Rev Drug Discov. 2016 Dec;15(12):805-806

Butlen-Ducuing, Pétavy F, Guizzaro L, Zienowicz M, Salmonson T, Haas M, Corruble E, Alteri A.
Regulatory watch: Challenges in drug development for central nervous system disorders: a European Medicines Agency perspective.
Nat Rev Drug Discov. 2016 Nov 29;15(12):813-814

Cavaleri M, Thomson A, Salmonson T, Hemmings RJ.
A viewpoint on European Medicines Agency experience with investigational medicinal products for Ebola.
Clin Trials. 2016 Feb;13(1):101-4

Cerreta F, Ankri J, Bowen D, Cherubini A, Cruz Jentoft AJ, Guðmundsson A, Haberkamp M, Jansen P, Marchionni N, Morgan S, Rönnemaa E, Petrovic M, Pilotto A, Rosa M, Wildiers H.
Baseline frailty evaluation in drug development
J Frailty Aging 2016;5(3):139-140

Ciani O, Buyse M, Drummond M, Rasi G, Saad ED, Taylor RS.
Use of surrogate end points in healthcare policy: a proposal for adoption of a validation framework.
Nat Rev Drug Discov. 2016 Jul;15(7):516

Cook G, France G, Holte Ø, Lorenti G, Tainsh D.
Summary of the EMA Joint Regulators/Industry QbD workshop (London, UK; 28-29 January 2014).
PDA J Pharm Sci Technol. 2016 Mar-Apr;70(2):163-76

Cox E, Cavaleri M, Eichler HG, Woodcock J, Borio L.
Facilitating Antibacterial Drug Development in a Time of Great Need
Clin Infect Dis. (2016) 63 (suppl 2): S27-S28.

de Groot MC, Candore G, Uddin MJ, Souverein PC, Ali MS, Belitser SV, Huerta C, Groenwold RH, Alvarez Y, Slattery J, Korevaar J, Hoes AW, Roes KC, de Boer A, Douglas IJ, Schlienger RG, Reynolds R, Klungel OH, Gardarsdottir H.
Case-only designs for studying the association of antidepressants and hip or femur fracture.
Pharmacoepidemiol Drug Saf. 2016 Mar;25 Suppl 1:103-13

Donnelly H, Alemayehu D, Botgros R, Comic-Savic S, Eisenstein B, Lorenz B, Merchant K, Pelfrene E, Reith C, Santiago J, Tiernan R, Wunderink R, Tenaerts P, Knirsch C.
Streamlining Safety Data Collection in Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia Trials: Recommendations of the Clinical Trials Transformation Initiative Antibacterial Drug Development Project Team.

Clin Infect Dis. 2016 Aug 15;63 Suppl 2:S39-45.

Egger GF, Wharton GT, Malli S, Temeck J, Murphy MD, Tomasi P.
A Comparative Review of Waivers Granted in Pediatric Drug Development by FDA and EMA from 2007-2013
Therapeutic Innovation & Regulatory Science, 2016, 1-9

Ehmann F, Pita R.
The EU is ready for non-biological complex medicinal products
Generics and Biosimilars Initiative Journal (GaBI Journal). 2016;5(1):30-5

Eichler HG, Bloechl-Daum B, Bauer P, Bretz F, Brown J, Hampson LV, Honig P, Krams M, Leufkens H, Lim R, Lumpkin MM, Murphy MJ, Pignatti F, Posch M, Schneeweiss S, Trusheim M, Koenig F.
"Threshold-crossing": A Useful Way to Establish the Counterfactual in Clinical Trials?
Clin Pharmacol Ther. 2016 Dec;100(6):699-712.

Eichler HG, Hurts H, Broich K, Rasi G
Drug Regulation and Pricing - Can Regulators Influence Affordability?
N Engl J Med. 2016 May 12;374(19):1807-1809

Gadroen K, Straus SM, Pacurariu A, Weibel D, Kurz X, Sturkenboom MC.
Patterns of spontaneous reports on narcolepsy following administration of pandemic influenza vaccine; a case series of individual case safety reports in Eudravigilance.
Vaccine. 2016 Sep 22;34(41):4892-7

Garcia-Larsen V, Del Giacco SR, Moreira A, Bonini M, Haahtela T, Bonini S, Carlsen KH, Agache I, Fonseca J, Papadopoulos NG, Delgado L.
Dietary intake and risk of asthma in children and adults: protocol for a systematic review and meta-analysis.
Clin Transl Allergy. 2016 Apr 28;6:17.

Goedecke T, Ord K, Newbould V, Brosch S, Arlett P.
Medication Errors: New EU Good Practice Guide on Risk Minimisation and Error Prevention.
Drug Safety 2016, 39(6): 491-500

Gravanis I, Tzogani K, van Hennik P, de Graeff P, Schmitt P, Mueller-Berghaus J, Salmonson T, Gisselbrecht C, Laane E, Bergmann L, Pignatti F.
The European Medicines Agency review of brentuximab vedotin (Adcetris) for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma or systemic anaplastic large cell lymphoma
Oncologist. 2016 Jan;21(1):102-9

Grimaldi-Bensouda L, Klungel O, Kurz X, de Groot MC, Maciel Afonso AS, de Bruin ML, Reynolds R, Rossignol M.
Calcium channel blockers and cancer risk: an analysis using the UK Clinical Practice Research Datalink (CPRD)
BMJ Open. 2016 Jan 8;6(1):e009147.

Gupta A, Mathad JS, Abdel-Rahman SM, Albano JD, Botgros R, Brown V, Browning RS, Dawson L, Dooley KE, Gnanashanmugam D, Grinsztejn B, Hernandez-Diaz S, Jean-Philippe P, Kim P, Lyerly AD, Mirochnick M, Mofenson LM, Montepiedra G, Piper J, Sahin L, Savic R, Smith B, Spiegel H, Swaminathan S, Watts DH, White A.
Toward Earlier Inclusion of Pregnant and Postpartum Women in Tuberculosis Drug Trials: Consensus Statements From an International Expert Panel.
Clin Infect Dis. 2016 Mar 15;62(6):761-9.

Hallgreen CE, Mt-Isa S, Lieftucht A, Phillips LD, Hughes D, Talbot S, Asiimwe A, Downey G, Genov G, Hermann R, Noel R, Peters R, Micaleff A, Tzoulaki I, Ashby D; PROTECT Benefit-Risk group..
Literature review of visual representation of the results of benefit-risk assessments of medicinal products Pharmacoepidemiol Drug Saf. 2016 Mar;25(3):238-50

Healy MJ, Tong W, Ostroff S, Eichler HG, Patak A, Neuspiel M, Deluyker H, Slikker W Jr.
Regulatory bioinformatics for food and drug safety.
Regul Toxicol Pharmacol. 2016 Oct;80:342-7.

Huerta C, Abbing-Karahagopian V, Requena G, Oliva B, Alvarez Y, Gardarsdottir H, Miret M, Schneider C, Gil M, Souverein PC, De Bruin ML, Slattery J, De Groot MC, Hesse U, Rottenkolber M, Schmiedl S, Montero D, Bate A, Ruigomez A, García-Rodríguez LA, Johansson S, de Vries F, Schlienger RG, Reynolds RF, Klungel OH, de Abajo FJ.
Exposure to benzodiazepines (anxiolytics, hypnotics and related drugs) in seven European electronic healthcare databases: a cross-national descriptive study from the PROTECT-EU Project.
Pharmacoepidemiol Drug Saf. 2016 Mar;25 Suppl 1:56-65.

Jutel M, Agache I, Bonini S, Burks AW, Calderon M, Canonica W, Cox L, Demoly P, Frew AJ, O'Hehir R, Kleine-Tebbe J, Muraro A, Lack G, Larenas D, Levin M, Martin BL, Nelson H, Pawankar R, Pfaar O, van Ree R, Sampson H, Sublett JL, Sugita K, Du Toit G, Werfel T, Gerth van Wijk R, Zhang L, Akdis M, Akdis CA.
International Consensus on Allergen Immunotherapy II: Mechanisms, standardization, and pharmacoeconomics.
J Allergy Clin Immunol. 2016 Feb;137(2):358-68.

Kelly LE, Davies EH, Saint-Raymond A, Tomasi P, Offringa M.
Important issues in the justification of a control treatment in paediatric drug trials.
Arch Dis Child. 2016 Oct;101(10):962-7.

Klungel OH, Kurz X, de Groot MC, Schlienger RG, Tcherny-Lessenot S, Grimaldi L, Ibáñez L, Groenwold RH, Reynolds RF.
Multi-centre, multi-database studies with common protocols: lessons learnt from the IMI PROTECT project.
Pharmacoepidemiol Drug Saf. 2016 Mar;25 Suppl 1:156-65.

Knirsch C, Alemayehu D, Botgros R, Comic-Savic S, Friedland D, Holland TL, Merchant K, Noel GJ, Pelfrene E, Reith C, Santiago J, Tiernan R, Tenearts P, Goldsack JC, Fowler VG Jr.
Improving Conduct and Feasibility of Clinical Trials to Evaluate Antibacterial Drugs to Treat Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Recommendations of the Clinical Trials Transformation Initiative Antibacterial Drug Development Project Team
Clin Infect Dis. 2016 Aug 15;63 Suppl 2:S29-36.

Krischke M, Hempel G, Völler S, André N, D'Incalci M, Bisogno G, Köpcke W, Borowski M, Herold R, Boddy AV, Boos J.
Pharmacokinetic and pharmacodynamic study of doxorubicin in children with cancer: results of a "European Pediatric Oncology Off-patents Medicines Consortium" trial.
Cancer Chemother Pharmacol. 2016 Dec;78(6):1175-1184.

Loth E, Spooren W, Ham LM, Isaac MB, Auriche-Benichou C, Banaschewski T, Baron-Cohen S, Broich K, Bölte S, Bourgeron T, Charman T, Collier D, de Andres-Trelles F, Durston S, Ecker C, Elferink A, Haberkamp M, Hemmings R, Johnson MH, Jones EJ, Khwaja OS, Lenton S, Mason L, Mantua V, Meyer-Lindenberg A, Lombardo MV, O'Dwyer L, Okamoto K, Pandina GJ, Pani L, Persico AM, Simonoff E, Tauscher-Wisniewski S, Llinares-Garcia J, Vamvakas S, Williams S, Buitelaar JK, Murphy DG.
Identification and Validation of Biomarkers for Autism Spectrum Disorders
Nat Rev Drug Discov. 2016 Jan;15(1):70-3.

Luzon E, Blake K, Cole S, Nordmark A, Versantvoort C, Berglund EG.
Physiologically based pharmacokinetic modeling in regulatory decision-making at the European Medicines Agency
Clin Pharmacol Ther. 2016 Oct 22

Maciá-Martínez MA, de Abajo FJ, Roberts G, Slattery J, Thakrar B, Wisniewski AF.
An Empirical Approach to Explore the Relationship Between Measures of Disproportionate Reporting and Relative Risks from Analytical Studies.
Drug Saf. 2016 Jan;39(1):29-43

Mariz S, Reese JH, Westermark K, Greene L, Goto T, Hoshino T, Llinares-Garcia J, Sepodes B.
Worldwide collaboration for orphan drug designation.
Nat Rev Drug Discov. 2016 Jun 1;15(6):440-1.

Martinalbo J, Bowen D, Camarero J, Chapelin M, Démolis P, Foggi P, Jonsson B, Llinares J, Moreau A, O'Connor D, Oliveira J, Vamvakas S, Pignatti F.
Early market access of cancer drugs in the EU
Ann Oncol. 2016 Jan;27(1):

Meeker-O'Connell A, Glessner C, Behm M, Mulinde J, Roach N, Sweeney F, Tenaerts P, Landray MJ.
Enhancing clinical evidence by proactively building quality into clinical trials
Clin Trials. 2016 Aug;13(4):439-44

Molinuevo JL, Cami J, Carné X, Carrillo MC, Georges J, Isaac MB, Khachaturian Z, Kim SY, Morris JC, Pasquier F, Ritchie C, Sperling R, Karlawish J.
Ethical challenges in preclinical Alzheimer's disease observational studies and trials: Results of the Barcelona summit.
Alzheimers Dement. 2016 May;12(5):614-22.

Morel T, Lhoir A, Picavet E, Mariz S, Sepodes B, Llinares J, Cassiman D.
Regulatory watch: The orphan drug pipeline in Europe.
Nat Rev Drug Discov. 2016 Jun 1;15(6):376

Nair H, Ramilo O, Eichler I, Pelfrene E, Mejias A, Polack FP, Pouwels KB, Langley JM, Nunes M, Van der Maas N, Kragten–Tabatabaie L, Baraldi E, Heikkinen T, Fauroux B, Sharland M, Park C, Manzoni P, Papadopoulos NG, Martinón–Torres F, Stein R, Bont L, in collaboration with Respiratory Syncytial Virus Network (ReSViNET)
Meeting Report: Harmonization of RSV therapeutics – from design to performance
J. of Global Health (2016); 6, 010205

Nieto M, Demolis P, Béhanzin E, Moreau A, Hudson I, Flores B, Stemplewski H, Salmonson T, Gisselbrecht C, Bowen D, Pignatti F.
The European Medicines Agency review of decitabine (Dacogen) for the treatment of adult patients with acute myeloid leukaemia (AML): Summary of the scientific assessment of the Committee for Medicinal Products for Human Use (CHMP)
Oncologist. 2016 Jun;21(6):692-700.

Oye KA, Eichler HG, Hoos A, Mori Y, Mullin TM, Pearson M.
Pharmaceuticals licensing and reimbursement in the European Union, United States and Japan
Clin Pharmacol Ther. 2016 Dec;100(6):626-632

Papathanasiou P, Brassart L, Blake P, Hart A, Whitbread L, Pembrey R, Kieffer J.
Transparency in drug regulation: public assessment reports in Europe and Australia.
Drug Discov Today Vol 21, Issue 11, Nov 2016: 1806-1813

Pearson AD, Herold R, Rousseau R, Copland C, Bradley-Garelik B, Binner D, Capdeville R, Caron H, Carleer J, Chesler L, Geoerger B, Kearns P, Marshall LV, Pfister SM, Schleiermacher G, Skolnik J, Spadoni C, Sterba J, van den Berg H, Uttenreuther-Fischer M, Witt O, Norga K, Vassal G; Members of Working Group 1 of the Paediatric Platform of ACCELERATE
Implementation of mechanism of action biology-driven early drug development for children with cancer.
Eur J Cancer. 2016 Jul;62:124-31

Pelfrene E, Willebrand E, Cavaleiro Sanches A, Sebris Z, Cavaleri M.
Bacteriophage therapy: a regulatory perspective
J Antimicrob Chemother. 2016 Aug;71(8):2071-4

Perrone F, Jommi C, Di Maio M, Gimigliano A, Gridelli C, Pignata S, Ciardiello F, Nuzzo F, de Matteis A, Del Mastro L, Bryce J, Daniele G, Morabito A, Piccirillo MC, Rocco G, Guizzaro, Gallo C.
The association of financial difficulties with clinical outcomes in cancer patients: secondary analysis of 16 academic prospective clinical trials conducted in Italy.
Ann Oncol. 2016 Dec;27(12):2224-2229.

Pignatti F, Martinalbo J, Jonsson B, Foggi P.
Reply to the letter to the editor 'Number-Needed-To-Treat for pricing costly anti-cancer drugs. The example of Regorafenib in metastatic colorectal cancer' by Graziano et al.
Ann Oncol. 2016 May;27(5):958.

Pinheiro L, Blake K, Januskiene J, Yue QY, Arlett P.
Geographical variation in reporting Interstitial Lung Disease as an adverse drug reaction: findings from a European Medicines Agency analysis of reports in EudraVigilance
Pharmacoepidemiol Drug Saf. 2016 Jun;25(6):705-12

Pita R, Ehmann F, Papaluca M.
Nanomedicines in the EU - Regulatory overview
AAPS J. 2016 Nov;18(6):1576-1582

Postmus D, Mavris M, Hillege HL, Salmonson T, Ryll B, Plate A, Moulon I, Eichler HG, Bere N, Pignatti F.
Incorporating Patient Preferences Into Drug Development and Regulatory Decision Making: Results From a Quantitative Pilot Study With Cancer Patients, Carers, and Regulators
Clin Pharmacol Ther. 2016 May;99(5):548-54.

Reynolds RF, Kurz X, de Groot MC, Schlienger RG, Grimaldi-Bensouda L, Tcherny-Lessenot S, Klungel OH.
The IMI PROTECT project: purpose, organizational structure, and procedures.
Pharmacoepidemiol Drug Saf. 2016 Mar;25 Suppl 1:5-10.

Saint-Raymond A, de Vries CS.
Medicine safety in pregnancy and ambitions for the EU medicine regulatory framework
Clin Pharmacol Ther. 2016 Jul;100(1):21-3

Saint-Raymond A, Pelle B, Zaccaria C, Sennwitz M, Branch S.
Usage of unpublished paediatric data
Arch Dis Child. 2016 Jan;101(1):81-4

Salmonson T, Janssen H, Sudhop T, Stahl E.
Regulatory Reply to the ATMOSPHERE Data Monitoring Committee.
N Engl J Med. 2016 Apr 21;374(16):1585-6.

Schneeweiss S, Eichler HG, Garcia-Altes A, Chinn C, Eggimann AV, Garner S, Goettsch W, Lim R, Löbker W, Martin D, Müller T, Park BJ, Platt R, Priddy S, Ruhl M, Spooner A, Vannieuwenhuyse B, Willke RJ.
Real World Data in Adaptive Biomedical Innovation: A Framework for Generating Evidence Fit for Decision-Making.
Clin Pharmacol Ther. 2016 Dec;100(6):633-646.

Schuerch M, Gasse C, Robinson NJ, Alvarez Y, Walls R, Mors O, Christensen J, Hesse U, de Groot M, Schlienger R, Reynolds R, Klungel O, de Vries F.
Impact of varying outcomes and definitions of suicidality on the associations of antiepileptic drugs and suicidality: comparisons from UK Clinical Practice Research Datalink (CPRD) and Danish national registries (DNR).
Pharmacoepidemiol Drug Saf. 2016 Mar;25 Suppl 1:142-55

Schüssler-Lenz M, Beuneu C, Menezes-Ferreira M, Jekerle V, Bartunek J, Chamuleau S, Celis P, Doevendans P, O'Donovan M, Hill J, Hystad M, Jovinge S, Kyselovič J, Lipnik-Stangelj M, Maciulaitis R, Prasad K, Samuel A, Tenhunen O, Tonn T, Rosano G, Zeiher A, Salmikangas P.
Cell-based therapies for cardiac repair: a meeting report on scientific observations and European regulatory viewpoints.
Eur J Heart Fail. 2016 Feb;18(2):133-41.

Seabroke S, Candore G, Juhlin K, Quarcoo N, Wisniewski A, Arani R, Painter J, Tregunno P, Noren N, Slattery J.
Performance of Stratified and Subgrouped Disproportionality. Analyses in Spontaneous Databases
Drug Saf. 2016 39:355–364

Sepodes B.
Regulation Of Orphan Medicinal Products In Europe: History Trends And Challenges.
Clin Ther. 2016 Oct 6;38(10S):e7-e8

Slattery J.
Measuring signal detection performance. Can we trust negative controls and do we need them?
Drug Saf. 2016 May;39(5):371-3

Souverein PC, Abbing-Karahagopian V, Martin E, Huerta C, de Abajo F, Leufkens HG, Candore G, Alvarez Y, Slattery J, Miret M, Requena G, Gil MJ, Groenwold RH, Reynolds R, Schlienger RG, Logie JW, de Groot MC, Klungel OH, van Staa TP, Egberts TC, De Bruin ML, Gardarsdottir H.
Understanding inconsistency in the results from observational pharmacoepidemiological studies: the case of antidepressant use and risk of hip/femur fractures.
Pharmacoepidemiol Drug Saf. 2016 Mar;25 Suppl 1:88-102.

Spindler P, Bach KF, Schmiegelow M, Bedlington N, Eichler HG.
Innovation of medical products: the evolution of regulatory science, research and education
Therapeutic Innovation & Regulatory Science, 2016, Vol. 50(1) 44-48

Straub V, Balabanov P, Bushby K, Ensini M, Goemans N, De Luca A, Pereda A, Hemmings R, Campion G, Kaye E, Arechavala-Gomeza V, Goyenvalle A, Niks E, Velldhuizen O, Furlong P, Stoyanova-Beninska V, Wood MJ, Johnson A, Mercuri E, Muntoni F, Sepodes B, Haas M, Vroom E, Aartsma-Rus A.
Stakeholder cooperation to overcome challenges in orphan medicine development: the example of Duchenne muscular dystrophy
The Lancet Neurology , Volume 15 , Issue 8 , 882 – 890

Sun H, Vesely R, Lee KJ, Klein A, Ikima M, Mulberg AE; International Inflammatory Bowel Disease (i-IBD) Working Group
Pediatric Crohn's Disease Clinical Outcome Assessments and Biomarkers: Current State and Path Forward for Global Collaboration.
J Pediatr Gastroenterol Nutr. 2016 Jun 2.

Tafuri G, Pagnini M, Moseley J, Massari M, Petavy F, Behring A, Catalan A, Gajraj E, Hedberg N, Obach M, Osipenko L, Russo P, Van De Casteele M, Zebedin EM, Rasi G, Vamvakas S.
How aligned are the perspectives of EU regulators and HTA bodies? A comparative analysis of regulatory-HTA parallel scientific advice.
Br J Clin Pharmacol. 2016 Oct;82(4):965-73

Tamborlane WV, Haymond MW, Dunger D, Shankar R, Gubitosi-Klug R, Bethin K, Karres J, Tomasi P, Libman I, Hale PH, Portman R, Klingensmith G, Reed M, Blumer J, Giacoia G, for the NICHD Diabetes Working Group
Expanding Treatment Options for Youth with Type 2 Diabetes: Current Problems and Proposed Solutions
Diabetes Care 2016;39:323–329

Turner MA, Davis JM, McCune S, Bax R, Portman RJ, Hudson LD.
The International Neonatal Consortium: Collaborating to Advance Regulatory Science for Neonates
Pediatr Res. 2016 Oct;80(4):462-4

Uddin MJ, Groenwold RH, de Boer A, Gardarsdottir H, Martin E, Candore G, Belitser SV, Hoes AW, Roes KC, Klungel OH.
Instrumental variables analysis using multiple databases: an example of antidepressant use and risk of hip fracture.
Pharmacoepidemiol Drug Saf. 2016 Mar;25 Suppl 1:122-31.

Udo R, Tcherny-Lessenot S, Brauer R, Dolin P, Irvine D, Wang Y, Auclert L, Juhaeri J, Kurz X, Abenhaim L, Grimaldi L, De Bruin ML.
The risk of acute liver injury associated with the use of antibiotics--evaluating robustness of results in the pharmacoepidemiological research on outcomes of therapeutics by a European consortium (PROTECT) project.
Pharmacoepidemiol Drug Saf. 2016 Mar;25 Suppl 1:47-55.

Van Riet-Nales DA, Hussain N, Sundberg KA, Eggenschwyler D, Ferris C, Robert JL, Cerreta F.
Regulatory incentives to ensure better medicines for older people: from ICH E7 to the EMA reflection paper on quality aspects.
Int J Pharm. 2016 May 2. pii: S0378-5173(16)30367-2

Vicini P, Fields O, Lai E, Litwack ED, Martin AM, Morgan TM, Pacanowski MA, Papaluca M, Perez OD, Ringel MS, Robson M, Sakul H, Vockley J, Zaks T, Dolsten M, Søgaard M.
Precision Medicine in the Age of Big Data: The Present and Future Role of Large Scale Unbiased Sequencing in Drug Discovery and Development
Clin Pharmacol Ther. 2016 Feb;99(2):198-207

Willkommen H, Blümel J, Brorson K, Chen D, Chen Q, Gröner A, Kreil TR, Ruffing M, Ruiz S, Scott D, Silvester G.
Meeting Report: 2015 PDA Virus & TSE Safety Forum.
PDA J Pharm Sci Technol. 2016 Mar-Apr;70(2):177-88.

Wisniewski AFZ, Bate A, Bousquet C, Brueckner A, Candore G, Juhlin K, Marcia-Martinez MA, Manlik K, Quarcoo N, Seabroke S, Slattery J, Southworth H, Thakrar B, Tregunno P, Van Holle L, Kayser M, Noren GN.
Good Signal Detection Practices: Evidence from IMI PROTECT
Drug Saf. 2016 Mar 7

Zannad F, Stough WG, Lipicky RJ, Tamargo J, Bakris GL, Borer JS, Alonso García Mde L, Hadjadj S, Koenig W, Kupfer S, McCullough PA, Mosenzon O, Pocock S, Scheen AJ, Sourij H, Van der Schueren B, Stahre C, White WB, Calvo G.
Assessment of cardiovascular risk of new drugs for the treatment of diabetes mellitus: risk assessment vs. risk aversion.
Eur Heart J Cardiovasc Pharmacother. 2016 Jul;2(3):200-5

Ziogas C.
A regulator's insights for SMEs in the biologics and advanced therapies sectors
Regulatory Rapporteur – Vol 13, No 2, February 2016