Annexes to the annual report of the European Medicines Agency 2017

Annex 1 – Members of the Management Board

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

Members

• European Parliament	Björn LEMMER, Tonio BORG
• European Commission	Xavier PRATS-MONNÉ, Carlo PETTINELLI (Alternates: Andrzej RYS, Stefano SORO[1])
• Belgium	Xavier DE CUYPER (Alternate: Greet MUSCH)
• Bulgaria	Assena STOIMENOVA (Alternate: Svetlin SPIROV)
• Czech Republic	Zděnek BLAHUTA (Alternate: Jiří BUREŠ)
• Denmark	Thomas SENDEROVITZ (Alternate: Mette AABOE HANSEN)
• Germany	Karl BROICH (Alternate: Birgit NAASE[2])
• Estonia	Kristin RAUDSEPP (Alternate: Alar IRS)
• Ireland	Lorraine NOLAN (Alternate: Rita PURCELL)
• Greece	Aikaterini ANTONIOU[3] (Alternate: Despoina MAKRIDAKI[4])
• Spain	Belén CRESPO SÁNCHEZ-EZNARRIAGA (Alternate: César HERNÁNDEZ[5])
• France	Dominique MARTIN (Alternate: Jean-Pierre ORAND)
• Croatia	Delfa RADIC KRISTO (Alternate: Siniša TOMIĆ)
• Italy	Mario MELAZZINI[6] (Alternate: Nando MINNELLA[7])
• Cyprus	Loizos PANAYI (Alternate: Emilia MAVROKORDATOU[8])
• 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)
• Malta	John-Joseph BORG (Alternate: Gavril FLORES)
• Netherlands	Hugo HURTS (Alternate: Constant VAN BELKUM)

[1] Replaced Christian SIEBERT as of January 2017
[2] Replaced Mette AABOE HANSEN as of June 2016
[3] Replaced Despoina MAKRIDAKI as of October 2017
[4] Replaced Giannis KARAFYLLIS as of October 2017
[5] Replaced Laura Franqueza GARCÍA as of June 2017
[6] Replaced Luca PANI as of March 2017
[7] Replaced Gabriella CONTI as of March 2017
[8] Replaced Ioannis KKOLOS as of July 2017

• Austria	Christa WIRTHUMER-HOCHE (Alternate: Sylvia FÜSZL)
• Poland	Grzegorz CESSAK (Alternate: Marcin KOLAKOWSKI[9])
• Portugal	Rui SANTOS IVO (Alternate: Awaiting nomination)
• Romania	NICOLAE FOTIN (Alternate: Alexandru VELICU[10])
• Slovenia	Andreja CUFAR (Alternate: Stanislav PRIMOŽIČ)
• Slovakia	Zuzana BAŤOVÁ (Alternate: Awaiting nomination)
• Finland	Sinikka RAJANIEMI (Alternate: Esa HEINONEN[11])
• Sweden	Catarina FORSMAN (Alternate: Sara ROSENMULLER)
• United Kingdom	Ian HUDSON (Alternate: Jonathan MOGFORD)
• Representatives of patients' organisations	Ilaria PASSARANI, Yann LE CAM
• Representative of doctors' organisations	Wolf-Dieter LUDWIG
• Representative of veterinarians' organisations	Nancy DE BRIYNE

Observers

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

[9] Nominated as of September 2017
[10] Replaced Marius TANASA as of November 2017
[11] Replaced Pekka KURKI as of January 2017

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)	Alternate: Christophe FOCKE
• Mila VLASKOVSKA (Bulgaria)	Alternate: Assena STOIMENOVA
• Katarina VUCIC (Croatia)	Alternate: Selma ARAPOVIC DZAKULA
• Emilia MAVROKORDATOU (Cyprus) [1]	Alternate: Elena KAISI [2] [3]
• Ondřej SLANAŘ (Czech Republic)	Alternate: Tomáš BORÁŇ[4]
• Sinan B. SARAC (Denmark)	Alternate: Hanne LOMHOLT LARSEN
• Alar IRS (Estonia)	Alternate: *Awaiting nomination*
• Outi MAKI-IKOLA (Finland)	Alternate: Tuomo LAPVETELAINEN
• Alexandre MOREAU (France) [5]	Alternate: Joseph EMMERICH
• Harald ENZMANN (Germany) *(Vice-Chair)*	Alternate: Martina WEISE
• Eleftheria NIKOLAIDI (Greece) [6]	Alternate: Maria ORFANOU [7]
• Agnes GYURASICS (Hungary)	Alternate: Melinda SOBOR
• Kolbeinn GUDMUNDSSON (Iceland)	Alternate: Hrefna GUDMUNDSDOTTIR
• Jayne CROWE (Ireland) [8]	Alternate: Peter KIELY [9]
• Daniela MELCHIORRI (Italy)	Alternate: *Awaiting nomination* [10]
• 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)	Alternate: Paula Boudewina VAN HENNIK
• Svein RUNE ANDERSEN (Norway) [11] [12]	Alternate: Bjorg BOLSTAD
• Ewa BALKOWIEC-ISKRA (Poland) [13]	Alternate: Aldona PALUCHOWSKA

[1] Replaced Panayiotis TRIANTAFYLLIS as of March 2017
[2] Replaced Panayiotis TRIANTAFYLLIS as of December 2017
[3] Panayiotis TRIANTAFYLLIS had replaced George SAVVA as of March 2017
[4] Replaced Radka MONTONIOVA as of June 2017
[5] Replaced Pierre DEMOLIS as of January 2017
[6] Replaced George AISLAITNER as of January 2017
[7] Replaced Maria Dimolkeia ZIOTOPOULOU as of November 2017
[8] Replaced David LYONS as of September 2017
[9] Replaced Patrick SALMON as of September 2017
[10] Luca PANI's mandate ended as of September 2017
[11] Karsten BRUINS SLOT resigned as of January 2017
[12] Nominated as of March 2017

- Bruno SEPODES (Portugal) — Alternate: Fatima VENTURA
- Simona BADOI (Romania) [14] — Alternate: Dana Gabriela MARIN
- František DRÁFI (Slovakia) [15] [16] — Alternate: Eva MALÍKOVÁ [17]
- Stanislav PRIMOZIC (Slovenia) — Alternate: Nevenka TRSINAR BRODT
- Concepcion PRIETO YERRO (Spain) — Alternate: Jorge CAMERERO JIMENEZ [18]
- Kristina DUNDER (Sweden) — Alternate: Filip JOSEPHSON
- Greg MARKEY (United Kingdom) — Alternate: Nithyanandan NAGERCOIL

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)
- Jean-Louis ROBERT (Quality (non-biologicals))
- Sol RUIZ (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))

[13] Replaced Piotr FIEDOR as of June 2017
[14] Replaced Nela VILCEANU as from July 2017
[15] Replaced Adriana ADAMEOVÁ as of September 2017
[16] Adriana ADAMEOVÁ had replaced Nikola MORAVCOVÁ as of May 2017
[17] Replaced Jana SCHWEIGERTOVÁ as from January 2017
[18] Replaced Arantxa SANCHO-LOPEZ as of May 2017

Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: June Munro RAINE
EMA contact: Anabela MARCAL

Members

• Jan NEUHAUSER (Austria)	Alternate: Daniela PHILADELPHY [1]
• Jean-Michel DOGNE (Belgium)	Alternate: Laurence DE FAYS
• Maria POPOVA-KIRADJIEVA (Bulgaria)	Alternate: Yuliyan EFTIMOV
• Nikica MIROSEVIC SKVRCE (Croatia)	Alternate: Zeljana MARGAN KOLETIC
• Andrei ANDREOU (Cyprus) [2]	Alternate: Ioannis KKOLOS [3]
• Eva JIRSOVÁ (Czech Republic) [4]	Alternate: Jana LUKAČIŠINOVÁ [5]
• Doris STENVER (Denmark)	Alternate: *Awaiting nomination* [6]
• Maia UUSKULA (Estonia)	Alternate: Katrin KIISK
• Kirsti VILLIKKA (Finland)	Alternate: Kimmo JAAKKOLA
• Ghania CHAMOUNI (France) [7]	Alternate: Caroline LABORDE
• Martin HUBER (Germany)	Alternate: Valerie STRASSMANN
• Agni KAPOU (Greece) [8]	Alternate: Sofia TRANTZA [9]
• Julia PALLOS (Hungary)	Alternate: Melinda PALFI
• Gudrun Kristin STEINGRIMSDOTTIR (Iceland)	Alternate: Hrefna GUDMUNSDOTTIR
• Almath SPOONER (Ireland) *(Vice-Chair)*	Alternate: Rhea FITZGERALD [10]
• Carmela MACCHIARULO (Italy)	Alternate: Amelia CUPELLI
• Zane NEIKENA (Latvia)	Alternate: Zane STADE
• Jolanta GULBINOVIC (Lithuania)	Alternate: Simona KUDELIENE
• Marcel BRUCH (Luxembourg)	Alternate: Nadine PETITPAIN
• Amy TANTI (Malta)	Alternate: John Joseph BORG
• Sabine STRAUS (Netherlands)	Alternate: Menno VAN DER ELST
• David BENEE OLSEN (Norway) [11]	Alternate: Kristin Thorseng KVANDE
• Adam PRZYBYLKOWSKI (Poland)	Alternate: Katarzyna ZIOLKOWSKA [12]

[1] Replaced Marianne LUNZER as of September 2017
[2] Replaced Nectaroula COOPER as of January 2017
[3] Nominated as from January 2017
[4] Replaced Jana MLADA as of June 2017
[5] Replaced Eva JIRSOVA as of June 2017
[6] Torbjorn CALLREUS resigned as of September 2017
[7] Replaced Claire FERARD as of June 2017
[8] Replaced Leonidas KLIRONOMOS as of May 2017
[9] Replaced Agni KAPOU as of May 2017
[10] Replaced Ruchika SHARMA as of May 2017
[11] Replaced Helga HAUGOM OLSEN as of May 2017
[12] Replaced Magdalena BUDNY as of November 2017

- Ana Sofia DINIZ MARTINS (Portugal) Alternate: Marcia SILVA
- Roxana STROE (Romania) Alternate: Nicolae FOTIN
- Tatiana MAGALOVÁ (Slovakia) Alternate: Peter KOREN [13] [14]
- Milena RADOHA-BERGOC (Slovenia) Alternate: Gabriela JAZBEC
- Dolores MONTERO CORMINAS (Spain) Alternate: Eva SEGOVIA
- Ulla WANDEL LIMINGA (Sweden) Alternate: Qun-Ying YUE
- Julie WILLIAMS (United Kingdom) Alternate: Patrick BATTY [15]

Independent scientific experts nominated by the European Commission

- Thierry TRENQUE
- 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 Alternate: Kirsten MYHR

Members representing patients organisations nominated by the European Commission

- Marco GRECO Alternate: Albert VAN DER ZEIJDEN

[13] Nominated as of May 2017
[14] Miroslova MATIKOVA resigned as from January 2017
[15] Replaced Rafe SUVARNA as of February 2017

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

Chair: David MURPHY (vice-chair: Helen JUKES)
EMA contact: Fia WESTERHOLM

Members and alternates

• Brigitte HAUSER (Austria)[1]	Alternate: Petra FALB[2]
• Bruno URBAIN (Belgium)	Alternate: Frederic KLEIN
• Emil KOZHUHAROV (Bulgaria)	Alternate: Svetoslav BRANCHEV
• Frane BOZIC (Croatia)[3]	Alternate: Svjetlana TERZIC[4]
• 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
• Gesine HAHN (Germany)[5]	Alternate: Esther WERNER
• Ioannis MALEMIS (Greece)	Alternate: Angeliki TSIGOURI
• Gabor KULCSAR (Hungary)	Alternate: Tibor SOOS
• J. Gabriel BEECHINOR (Ireland)	Alternate: Mary O'GRADY[6]
• Paolo PASQUALI (Italy)	Alternate: Antonio BATTISTI
• Zanda AUCE (Latvia)	Alternate: Renate MAKOVSKA[7]
• Petras MACIULSKIS (Lithuania)	Alternate: Laimis JODKONIS
• Marc SCHMIT (Luxembourg)	Alternate: Marcel BRUCH
• Stephen SPITERI (Malta)	Alternate: *awaiting nomination*
• Peter HEKMAN (Netherlands)	Alternate: Jacqueline POOT[8]
• Anna WACHNIK-SWIECICKA (Poland)	Alternate: Ewa AUGUSTYNOWICZ
• Joao Pedro DUARTE DA SILVA (Portugal)	Alternate: Maria AZEVEDO MENDES
• Lollita TABAN (Romania)	Alternate: Simona STURZU
• Judita HEDEROVA (Slovakia)	Alternate: Eva CHOBOTOVA

[1] Replaced Barbara ZEMANN as of March 2017 meeting
[2] Replaced Ulrike HEISSENBERGER as of March 2017 meeting
[3] Croatian member and alternate swapped roles as of January 2017 meeting
[4] Replaced Ljiljana MARKUS CIZELJ as of August 2017
[5] Replaced Cornelia IBRAHIM as of March 2017 meeting
[6] As of February 2017 meeting
[7] As of January 2017 meeting
[8] As of March 2017 meeting

- Katarina STRAUS (Slovenia)[9] — Alternate: Maja TURK[10]
- 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

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	MRLs/residues
• Wilhelm SCHLUMBOHM	Quality pharmaceuticals
• Jason WEEKS	Environmental risk assessment

[9] Replaced Stanko SRCIC as of March 2017 meeting
[10] Replaced Katarina STRAUS as of March 2017 meeting

Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Bruno SEPODES
EMA contact: Anabela MARCAL

Members

- Brigitte BLOECHL-DAUM (Austria)
- Tim LEEST (Belgium) [1]
- Lyubina Racheva TODOROVA (Bulgaria) [2]
- Dinko VITEZIC (Croatia)
- Ioannis KKOLOS (Cyprus) [3]
- 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)
- Sigurdur THORSTEINSSON (Iceland)
- Geraldine O'DEA (Ireland)
- Armando MAGRELLI (Italy)
- Irena ROGOVSKA (Latvia)
- Ausra MATULEVICIENE (Lithuania)
- Michel HOFFMAN (Luxembourg)
- Robert NISTICO (Malta)
- Violeta STOYANOVA-BENINSKA (Netherlands)
- Ingrid WANG (Norway)
- Bozenna DEMBOWSKA-BAGINSKA (Poland)
- Dinah DUARTE (Portugal)
- Olimpia NEAGU (Romania)
- Eva MALIKOVA (Slovakia)

[1] Replaced Andre LHOIR as of July 2017
[2] Replaced Irena BRADINOVA as of January 2017
[3] Replaced Andri ANDREOU as of January 2017

- Martin MOZINA (Slovenia) [4]
- Fernando MENDEZ HERMIDA (Spain)
- Darius MATUSEVICIUS (Sweden) [5] [6]
- Daniel O'CONNOR (United Kingdom)

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

- Ingeborg BARISIC
- Giuseppe CAPOVILLA
- Kerstin WESTERMARK

Members representing patients' organisations nominated by the European Commission

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

[4] Nominated as of January 2017
[5] Dan HENROHN's mandate ended as of October 2017
[6] Nominated as of December 2017

Annex 6 – Members of the Committee on Herbal Medicinal Products

Chair: Marisa DELBO
EMA contact: Anabela MARCAL

Members

• Reinhard LANGER (Austria)	Alternate: Astrid OBMANN
• Heidi NEEF (Belgium)	Alternate: Wim HUYGH [1]
• Elena MUSTAKEROVA (Bulgaria)	Alternate: Iliana IONKOVA [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)	Alternate: *Awaiting nomination*
• Eeva Sofia LEINONEN (Finland)	Alternate: Sari KOSKI
• An LE (France)	Alternate: *Awaiting nomination*
• 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
• Alessandro ASSISI (Italy) [3]	Alternate: Anna Maria SERRILLI
• Evita SKUKAUSKA (Latvia) [4]	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) *(Vice-chair)*	Alternate: Burt H. KROES
• Steinar MADSEN (Norway)	Alternate: Gro FOSSUM
• Wojciech DYMOWSKI (Poland)	Alternate: Katarzyna TOMASZEWSKA [5]
• Ana Paula MARTINS (Portugal)	Alternate: Eva MENDES
• Carmen PURDEL (Romania) [6]	Alternate: Raluca IAVORSZKY [7]

[1] Nominated as of February 2017
[2] Nominated as of February 2017
[3] Nominated as of March 2017
[4] Replaced Dace KALKE as of February 2017
[5] Nominated as of September 2017

- Miroslava PETRIKOVA (Slovakia) Alternate: Milan NAGY
- Samo KREFT (Slovenia) Alternate: Barbara RAZINGER
- Adela NUNEZ VELAZQUEZ (Spain) Alternate: Cristina MARTINEZ GARCIA
- Per CLAESON (Sweden) Alternate: Malin Kyllikki HOBRO SODERBERG [8] [9]
- Linda ANDERSON (United Kingdom) Alternate: Sue HARRIS

Co-opted members

- *Awaiting nomination* [10]
- Silvia GIROTTO (Paediatric medicine)
- Gert LAEKEMAN (Experimental/non-clinical pharmacology)
- Heidi FOTH (Toxicology)
- Maria Helena PINTO FERREIRA (General and family medicine)

Observers

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

[6] Replaced Nadia GRIGORAS as of February 2017
[7] Replaced Carmen PURDEL as of February 2017
[8] Erika SVEDLUN's mandate ended on 31 December 2016
[9] Malin Kyllikki HOBRO SODERBERG nominated as of May 2017
[10] Gioacchino CALAPAI's mandate ended as of November 2017

Annex 7 – Committee for Advanced Therapies

Chair: Martina SCHUSSLER-LENZ [1]
EMA contact: Patrick CELIS

Members

Members nominated from within the CHMP

• Romaldas MACIULAITIS (Lithuania)	Alternate: Vitalis BRIEDIS [2]
• 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: Corina SPREITZER [3]
• Claire BEUNEU (Belgium)	Alternate: Belaid SEKKALI
• Rozalina KULAKSAZOVA (Bulgaria)	Alternate: Evelina SHUMKOVA
• Mirna GOLEMOVIC (Croatia)	Alternate: Ivica MALNAR
• Marina IERIDI (Cyprus) [4]	Alternate: Maria VASSILIOU [5]
• Ivana HAUNEROVA (Czech Republic) [6]	Alternate: Tomas BORAN [7]
• Nanna Aaby KRUSE (Denmark)	Alternate: Anne PASTOFT
• Toivo MAIMETS (Estonia)	Alternate: *Awaiting nomination* [8]
• Heli SUILA (Finland) [9] [10] [11]	Alternate: Olli TENHUNEN
• Violaine CLOSSON CARELLA (France)	Alternate: *Awaiting nomination*
• Jan MUELLER-BERGHAUS (Germany) [12] [13]	Alternate: Egbert FLORY
• 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

[1] Elected as Chair as from February 2017
[2] Replaced Jolanta GULBINOVIC as of October 2017
[3] Replaced Martin BRUNNER as of April 2017
[4] Replaced Anna PAPHITOU as from March 2017
[5] Replaced Ioannis KKOLOS as from March 2017
[6] Swap of roles from alternate to member as of July 2017
[7] Swap of roles from member to alternate as of July 2017
[8] Tarmo TIIDO resigned as from June 2017
[9] Nominated as from October 2017
[10] Paula SALMIKANGAS resigned as of June 2017
[11] Paula SALMIKANGAS had replaced Tiina PALOMAKI as from January 2017
[12] Nominated as of March 2017
[13] Martina SCHUSSLER-LENZ was elected as Chair as from February 2017

- Paolo GASPARINI (Italy) Alternate: Luca SANGIORGI
- Una RIEKSTINA (Latvia) Alternate: Aija LINE
- Johannes H. OVELGONNE (Netherlands) Alternate: Carla HERBERTS [14]
- Helga HAUGUM OLSEN (Norway) [15] 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 Alternate: Francisco BLANCO [16]
- Bernd GANSBACHER Alternate: Willem FIBBE [17]

Members representing patients' organisations nominated by the European Commission

- Mariette DRIESSENS Alternate: Erik BRIERS
- Kieran BREEN Alternate: Michele LIPUCCI DI PAOLA

Observers

- Karl-Heinz BUCHHEIT (EDQM)

[14] Nominated as of May 2017
[15] Replaced Marik HYSTAD as from January 2017
[16] Nominated as of May 2017
[17] Nominated as of May 2017

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
- Carola DE BEAUFORT (Luxembourg) — Alternate: Jacqueline GENOUX-HAMES
- Dana Gabriela MARIN (Romania) — Alternate: Simona BADOI [1] [2]

Members

- Karl-Heinz HUEMER (Austria) — Alternate: Johanna WERNSPERGER
- Koenraad NORGA (Belgium) *(Vice-chair)* — Alternate: Karen VAN MALDEREN [3] [4]
- Dimitar ROUSSINOV (Bulgaria) — Alternate: Vessela BOUDINOVA
- Adriana ANDRIC (Croatia) — Alternate: Suzana MIMICA MATANOVIC
- Georgios SAVVA (Cyprus) — Alternate: Eirini PERIKLEOUS
- Jaroslav STERBA (Czech Republic) — Alternate: Peter SZITANYI
- Kirstine Moll HARBOE (Denmark) [5] — Alternate: *Awaiting nomination* [6]
- Irja LUTSAR (Estonia) — Alternate: Jana LASS
- Ann Marie KAUKONEN (Finland) — Alternate: Maija PIHLAJAMAKI
- Sylvie BENCHETRIT (France) — Alternate: Dominique PLOIN [7]
- Sabine SCHERER (Germany) — Alternate: Immanuel BARTH
- Eleni KATSOMITI (Greece) — Alternate: Anastasia MOUNTAKI
- *Awaiting nomination* (Iceland) — Alternate: *Awaiting nomination*
- Brian AYLWARD (Ireland) — Alternate: *Awaiting nomination*
- Sara GALLUZZO (Italy) — Alternate: Alessandro JENKNER
- Dina APELE-FREIMANE (Latvia) — Alternate: Kristine SUPE
- Sigita BUROKIENE (Lithuania) [8] — Alternate: Goda VAITKEVICIENE [9]
- John Joseph BORG (Malta) — Alternate: Herbert LENICKER
- Maaike VAN DARTEL (Netherlands) — Alternate: *Awaiting nomination*
- Siri WANG (Norway) — Alternate: Ine SKOTTHEIM RUSTEN

[1] Nela VILCEANU's mandate ended as of June 2017
[2] Simona BADOI nominated as of July 2017
[3] Jacqueline CARLEER's mandate expired as of April 2017
[4] Karen VAN MALDEREN nominated as of May 2017
[5] Replaced Marianne ORHOLM as of December 2017
[6] Kirstine Moll HARBOE replaced Marta GRANSTROM as of July 2017 and became member as of December 2017
[7] Nominated as of January 2017
[8] Nominated as of May 2017
[9] Nominated as of May 2017

- Marek MIGDAL (Poland) Alternate: Irena MEISSNER WANTUCH [10]
- Helena FONSECA (Portugal) Alternate: Hugo TAVARES
- Peter SISOVSKY (Slovakia) [11] Alternate: *Awaiting nomination*
- Stefan GROSEK (Slovenia) Alternate: Janez JAZBEC (Slovenia) [12]
- Fernando DE ANDRES TRELLES (Spain) Alternate: Maria Jesus FERNANDES CORTIZO
- Ninna GULLBERG (Sweden) Alternate: Eva AGURELL
- Angeliki SIAPKARA (United Kingdom) Alternate: Martina RIEGL

Members representing healthcare professionals nominated by the European Commission

- Francesca ROCCHI [13] Alternate: Catherine CORNU [14]
- Fernando CABANAS [15] Alternate: Riccardo RICCARDI [16]
- 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
- Dimitrios ATHANASIOU [17] Alternate: Viviana GIANNUZZI [18]

[10] Replaced Jolanta WITKOWSKA-OZOGOWSKA as of October 2017
[11] Nominated as of September 2017
[12] Nominated as of October 2017
[13] Replaced Antje NEUBERT as of August 2017
[14] Replaced Paolo PAOLUCCI as of August 2017
[15] Nominated as of August 2017
[16] Replaced Jorrit GERRITSEN as of August 2017
[17] Replaced Tsveta SCHYNS-LIHARSKA as of August 2017
[18] Nominated as of August 2017

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 Keith PUGH[1]	Simona GOVER
Safety Working Party	Jan-Willem VAN DER LAAN	Jean-Marc VIDAL Milton BONELLI
Scientific Advice Working Party	Robert James HEMMINGS	Spiros VAMVAKAS

CHMP temporary working parties

	Chair	EMA contact
Biosimilar Medicinal Products Working Party	Christian SCHNEIDER Elena WOLFF-HOLZ	Daniela DA SILVA Camille VLEMINCKX
Biostatistics Working Party	David Jonathan WRIGHT Anja SCHIEL	Frank PETAVY
Blood Products Working Party	Anneliese HILGER Jacqueline KERR	Caroline VOLTZ
Cardiovascular Working Party	Pieter DE GRAEFF	Anna BACZYNSKA
Central Nervous System Working Party	Karl BROICH	Marta KOLLB-SIELECKA
Infectious Diseases Working Party	Mair POWELL Anders LIGNELL	Radu BOTGROS
Oncology Working Party	Bertil JONSSON 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	Andreas KOUROUMALIS Daniela DA SILVA
Vaccines Working Party	Mair POWELL	Manuela MURA

[1] Elected July 2017, replaced Piet-Hein OVERHAUS

Drafting groups

	Chair	EMA contact
Gastroenterology Drafting Group	Elmer SCHABEL Mark AINSWORTH	Joachim MUSAUS
Radiopharmaceuticals Drafting Group	Patrick SALMON Anabel CORTES BLANCO	Silvy DA ROCHA DIAS
Respiratory Drafting Group	Karolina TORNEKE	Margot MARTIN Catherine DRAI
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

	Chair	EMA contact
Good Manufacturing and Distribution Practice Inspectors Working Group	Brendan CUDDY	Brendan CUDDY
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	Maria ALCARAZ

Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP working parties

	Chair	EMA contact
CVMP Antimicrobial Working Party (AWP)	Helen JUKES	Isaura DUARTE / Jordi TORREN EDO[2]
CVMP Efficacy Working Party (EWP-V)	Cristina MUNOZ MADERO[3]	Minna LEPPANEN / Nicholas JARRETT[4]
CVMP Environmental Risk Assessment (ERAWP)	Jason WEEKS[5]	Isaura DUARTE / Nicholas JARRETT[3]
CVMP Immunologicals Working Party (IWP)	Esther WERNER	Minna LEPPANEN
CVMP Pharmacovigilance Working Party (PhVWP-V)	Els DEWAELE[6]	Isaura DUARTE/ Jordi TORREN EDO[1]
CVMP Safety Working Party (SWP-V)	Eva LANDER-PERSSON	Isaura DUARTE / Nicholas JARRETT[3]
Quality Working Party	Jean-Louis ROBERT/ Keith PUGH[7]	Simona GOVER
Scientific Advice Working Party (SAWP-V)	Rory BREATHNACH	Minna LEPPANEN

Other CVMP-associated groups

	Chair	EMA contact
CVMP Ad Hoc Group on Veterinary Novel Therapies (ADVENT)[8]	Jean-Claude ROUBY	Minna LEPPANEN

[2] From September 2017
[3] Elected in January 2017, replaced Gesine HAHN
[4] From September 2017
[5] Elected in April 2016, replaced Boris KOLAR
[6] Elected in October 2017, replaced Lisbet VESTERAGER BORGE
[7] Elected in July 2017, replaced Piet-Hein OVERHAUS
[8] Established in December 2014, chair elected at January 2015 meeting

	Chair	EMA contact
Good Manufacturing and Distribution Practice Inspectors Working Group	Brendan CUDDY	Brendan CUDDY
Pharmacovigilance Inspectors Working Group	Anabela MARÇAL	Sophia MYLONA
PAT Team	Keith PUGH	Maria ALCARAZ

Pharmacovigilance Risk Assessment Committee (PRAC)

	Chair	EMA contact
SMART Working Group work stream 1 (processes)	Sabine STRAUS and Georgy GENOV	Georgy GENOV
SMART Working Group work stream 2 (methods)	Eugene van PUIJENBROEK and Jim SLATTERY	Jim SLATTERY, Gianmario CANDORE, Cosimo ZACCARIA

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

Committee on Herbal Medicinal Products (HMPC)

HMPC working parties

	Chair	EMA contact
Working Party on European Union Monographs and European Union List	Ioanna CHINOU	Erika SVEDLUND

HMPC temporary drafting groups

	Chair	EMA contact
Organisational Matters Drafting Group	Gert LAEKEMAN	Erika SVEDLUND
Quality Drafting Group	Linda ANDERSON	Wieland PESCHEL

Other HMPC-associated groups

	Chair	EMA contact
Good Manufacturing Practice Inspection Services Group	Brendan CUDDY	Brendan CUDDY

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

Human Scientific Committees' Working Parties

	Chair	EMA contact
Patients' and Consumers' Working Party (PCWP)	Juan GARCIA BURGOS and KAISA IMMONEN	Nathalie BERE
Healthcare Professionals' Working Party (HCPWP)	Juan GARCIA BURGOS 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	Malgorzata KURJANSKA
CTS Working Group	Dino SOUMPASIS	
Working Party on Pharmacovigilance Procedures Work Sharing	Maria Luisa CASINI	
Non-Prescription Medicinal Products Task Force	Martin HUBER	Isabel CASTRO MARCHAN

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	Emily DRURY[9]
Packaging Working Group	Iveta OBROVSKA	Emily DRURY
Notice to Applicants Working Group	Paula KAJASTE	Emily DRURY
Autogenous Vaccines Working Group	Mariette SALERY	Emily DRURY
Borderline Products Working Group	José JONIS	Emily DRURY
CMDv-Industry Variations Task Force	Gavin HALL	Emily DRURY

Joint working parties, working groups and advisory groups

	Chair	EMA contact
Joint CHMP/CVMP Quality Working Party (QWP)	Jean Louis ROBERT (Chair) Keith PUGH[10](Veterinary Vice-chair)	Brendan CUDDY
Active Substance Master File Working Group	Nienke RODENHUIS	Alberto GANAN JIMENEZ
Joint CHMP/CVMP Working Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products[11]	Ellen-Margrethe VESTERGAARD[12]	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), Simona GOVER (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
Extrapolation working group	Gerard PONS	CECILE OLLIVIER

[9] From June 2017
[10] Elected July 2017, replaced Piet Hein OVERHAUS
[11] The group changed name in 2017
[12] Elected in June 2017, replaced Sonja BEKEN

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

This annex is available in an Excel spread sheet here.

Annex 11 – Guidelines and concept papers adopted by CHMP

Biologics Working Party

Reference number	Document	Status	Date
EMA/CHMP/BWP/534898/2008 rev. 1	Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials	Final	14 September 2017
EMA/CHMP/BWP/310834/2012 Rev. 1	Influenza vaccines - quality module	Final	20 July 2017
EMA/CAT/424191/2017	Concept paper on the revision of the Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells	Adopted for a 3 month public consultation	20 July 2017

Biosimilar Medicinal Product Working Party

Reference number	Document	Status	Date
EMEA/CHMP/BMWP/14327/2006 Rev 1	Guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins	Final	18 May 2017

Biostatistics Working Party

Reference number	Document	Status	Date
EMA/CHMP/138502/2017	Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development	Draft adopted for public consultation	23 March 2017

Blood Products Working Party

Reference number	Document	Status	Date
EMA/CHMP/BPWP/144533/2009 Rev. 2	Guideline on clinical investigation of	Adopted for public consultation	12 October 2017

Reference number	Document	Status	Date
	recombinant and 4 human plasma-derived factor VIII products		
EMA/CHMP/BPWP/1619 /1999 Rev. 3	Core summary of product characteristics for human plasma-derived and recombinant coagulation factor VIII products	Adopted for public consultation	12 October 2017

Cardiovascular Working Party

Reference number	Document	Status	Date
CPMP/EWP/235/95, Rev.2	Guideline on clinical investigation of medicinal products for the treatment of chronic heart failure	Final	20 July 2017
EMA/CHMP/760125/2016	Guideline on clinical investigation of new medicinal products for the treatment of acute coronary syndrome	Final	20 July 2017
EMA/230866/2017	Concept paper on the need for a paediatric addendum of the guideline on clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic disease	Concept paper adopted for a 3 month public consultation	12 October 2017

Central Nervous System Working Party

Reference number	Document	Status	Date
EMA/CHMP/598082/2013	Guideline on the clinical development of medicinal products for the treatment of autism spectrum disorder (ASD)	Final	9 November 2017

Excipients Drafting Group

Reference number	Document	Status	Date
EMA/CHMP/302620/2017	Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668)	Final	20 July 2017

Gastroenterology Drafting Group

Reference number	Document	Status	Date
EMA/CHMP/197320/2017	Concept paper on the need for the development of a 5 reflection paper on regulatory requirements for the 6 development of medicinal products for chronic non7 infectious liver diseases (PBC, PSC, NASH)	Concept paper adopted for a 3 month public consultation	18 May 2017

Geriatric Expert Group

Reference number	Document	Status	Date
None			

ICH

Reference number	Document	Status	Date
EMA/CHMP/ICH/436221/2017	ICH E9 (R1) addendum on to the guideline on statistical principles for clinical trials estimands and sensitivity analysis in clinical trials	Draft adopted for public consultation, step 2b	20 July 2017
EMA/CPMP/ICH/2711/1999	ICH guideline E11(R1) on clinical investigation of medicinal products in the paediatric population	Adopted, in implementation, step 5	14 September 2017
EMA/CHMP/ICH/453276	ICH guideline E17 on	Adopted, in	14 December 2017

Reference number	Document	Status	Date
/2016 Rev.1	general principles for planning and design of multi-regional clinical trials	implementation, step 5	
EMA/CHMP/ICH/11623/2016	ICH guideline E18 on genomic sampling and management of genomic data	Adopted, in implementation, step 5	14 September 2017
EMA/CHMP/ICH/804273/2017	ICH guideline Q12 on technical and regulatory 4 considerations for pharmaceutical product lifecycle 5 management	Draft adopted for public consultation, step 2b	14 December 2017
EMA/CHMP/ICH/320985/2016	ICH Guideline S3A: Note for guidance on toxicokinetics: the assessment of systemic exposure in toxicity studies - questions and answers	Adopted, in implementation, step 5	14 December 2017
EMA/CHMP/ICH/544278/1998	Draft ICH S5 (R3) guideline on reproductive toxicology: detection of toxicity to reproduction for human pharmaceuticals	Draft adopted for public consultation, step 2b	20 July 2017
EMA/CHMP/ICH/809509/2016	ICH guideline Q11 on development and manufacture of drug substances (chemical entities and biotechnological / biological entities) – questions and answers	Final adoption by CHMP, step 5	14 September 2017
EMA/CHMP/ICH/83812/2013	ICH guideline M7(R1) on assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk	Adoption by CHMP for release for consultation, step 2b	20 July 2017
EMA/CHMP/ICH/3943/2003	ICH guideline E2B (R3) - questions and answers	Transmission to CHMP for adoption, step 5	20 July 2017
EMA/CHMP/ICH/287/1995	ICH guideline E2B (R3) on electronic transmission of	Transmission to CHMP for adoption, step 5	20 July 2017

Reference number	Document	Status	Date
	individual case safety reports (ICSRs) - data elements and message specification - implementation guide		

Infectious Diseases Working Party

Reference number	Document	Status	Date
CHMP/EWP/14377/2008 Rev. 1	Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address the clinical development of new agents to treat pulmonary disease due to Mycobacterium tuberculosis	Final	20 July 2017
EMA/CHMP/EWP/808940/2016	Concept paper on a guideline on the evaluation of medicinal products indicated for treatment of influenza	Adopted for a 3 month public consultation	21 April 2017

Oncology Working Party

Reference number	Document	Status	Date
CHMP/205/95 Rev. 5	Guideline on the evaluation of anticancer medicinal products in man	Final	22 September 2017
EMA/102314/2017	Concept paper on the need to revise Condition – Specific guidance, Appendix 4 to the guideline on the evaluation of anticancer medicinal products in man	Adopted for a 3 month public consultation	23 February 2017

Pharmacogenomics Working Party

Reference number	Document	Status	Date
EMA/CHMP/644998/2016	Concept paper on an addendum on terms and concepts of pharmacogenomic features related to metabolism to the Guideline on the use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products (EMA/CHMP/37646/2009)	Concept paper adopted for a 3 month public consultation	22 June 2017
EMA/CHMP/800914/2016	Concept paper on predictive biomarker-based assay development in the context of drug development and lifecycle	Concept paper adopted for a 3 month public consultation	20 July 2017

Pharmacokinetics Working Party

Reference number	Document	Status	Date
EMEA/CHMP/EWP/147013/2004	Concept paper on the revision of the Guideline on the Role of pharmacokinetics in the development of medicinal products in the paediatric population	Adopted for a 3-month public consultation	21 April 2017
CPMP/EWP/560/95/Rev.1 Corr.2**	Concept paper on the revision of the Guideline on the investigation of drug interactions	Adopted for a 3-month public consultation	23 March 2017
	Product-specific guidance for demonstration of Bioequivalence (PSBEG) - Batch 5	Final	23 February 2017
	Product-specific guidance for demonstration of	Final	22 June 2017

Reference number	Document	Status	Date
	Bioequivalence (PSBEG) - Batch 6		
	Product-specific guidance for demonstration of Bioequivalence (PSBEG) - Batch 7	Adopted for a 3-month public consultation	20 July 2017
	Product-specific guidance for demonstration of Bioequivalence (PSBEG) - Batch 8	Adopted for a 3 month public consultation	14 December 2017

Quality Working Party

Reference number	Document	Status	Date
EMA/CHMP/QWP/83432/2017	Concept paper on revision of the guideline on the pharmaceutical quality of inhalation and nasal products	Adopted for consultation	23 Feb 2017
EMA/CHMP/QWP/245074/2015	Guideline on manufacture of the finished dosage form	Adopted	20 July 2017
EMA/CHMP/QWP/545525/2017	Guideline on the requirements for the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials	Adopted	14 September 2017
EMA/CHMP/ICH/804373/2017	ICH guideline Q12 on technical and regulatory considerations for pharmaceutical product lifecycle management	Adopted for consultation	14 December 2017

Radiopharmaceutical Drafting Group

Reference number	Document	Status	Date
EMA/CHMP/337681/2016	Guideline on core SmPC and Package Leaflet for (68Ge/68Ga) generator	Final	20 July 2017
EMA/CHMP/745358/2016	Guideline on core SmPC and Package Leaflet for technetium (99mTc)	Draft adopted for a 3 month public consultation	12 October 2017

Reference number	Document	Status	Date
	macrosalb		
EMA/CHMP/337681/2016	Guideline on core SmPC and Package Leaflet for (68Ge-68Ga) generator	Final	20 July 2017
EMA/CHMP/630248/2017	Guideline on core SmPC and Package Leaflet for sodium iodide (131I) therapy capsule	Final	9 November 2017
EMA/CHMP/773757/2013	Guideline on core SmPC and Package Leaflet for (99Mo/99mTc) generator	Final	9 November 2017

Respiratory Drafting Group

Reference number	Document	Status	Date
EMA/CHMP/267194/2016	Concept paper on revision of the guideline on the 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 the treatment of asthma in children and adolescents.	Adopted for a 3 month public consultation	23 February 2017

Rheumatology/Immunology Working Party

Reference number	Document	Status	Date
CPMP/EWP/4891/03 Rev.1	Guideline on clinical investigation of medicinal product for the treatment of axial spondyloarthritis	Final	12 October 2017
CHMP/EWP/556/95 Rev.2	Guideline on clinical investigation of medicinal products for	Final	14 December 2017

Reference number	Document	Status	Date
	the treatment of rheumatoid arthritis		

Safety Working Party

Reference number	Document	Status	Date
EMA/780994/2017	Concept paper on the development of guidance on the non-clinical evaluation of radiopharmaceuticals	Final	20 July 2017

Vaccines Working Party

Reference number	Document	Status	Date
EMA/CHMP/VWP/124350/2017	Concept paper on revision of the Guideline on clinical development of vaccines	Adopted for a 3 month public consultation	18 May 2017
EMA/CHMP/257022/2017	Draft guideline on the clinical evaluation of medicinal products indicated for the prophylaxis or treatment of respiratory syncytial virus (RSV) disease	Adopted for a 6 month public consultation	12 October 2017

Annex 12 – CVMP opinions 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
• **Bovilis Blue-8** • Bluetongue virus vaccine (inactivated) serotype 8	• Intervet Internaitonal B.V.	• Cattle, sheep • For the active immunisation of cattle and sheep from 2.5 months of age to prevent viraemia* caused by bluetongue virus serotype 8	• 10/07/2017 • 07/09/2017 • 59 • 0	• 07/09/2017 • 04/10/2017 • 21/11/2017 • 23/11/2017 • C 447 of 29/09/2017
• **Credelio** • Lotilaner	• Elanco Europe Ltd	• Dogs, Cats • For the treatment of flea and tick infestations in dogs and cats	• 16/03/2016 • 16/02/2017 • 210 • 127	• 16/02/2017 • 15/03/2017 • 25/04/2017 • 27/04/2017 • C 171 of 30/05/2017
• **CYTOPOINT** • Lokivetmab	• Zoetis Belgium SA	• Dogs • Treatment of clinical manifestations of atopic dermatitis in dogs	• 17/02/2016 • 16/02/2017 • 210 • 155	• 16/02/2017 • 15/03/2017 • 25/04/2017 • 27/04/2017 • C 171 of 30/05/2017
• **Exzolt** • Fluralaner	• Intervet International B.V.	• Chickens • Treatment of poultry red mite (Dermanyssus gallinae) infestation in pullets, breeders and layer hens	• 10/08/2016 • 15/06/2017 • 210 • 99	• 15/06/2017 • 12/07/2017 • 18/08/2017 • 22/08/2017 • C 328 of 28/09/2017
• **GALLIPRANT** • Grapiprant	• Aratana Therapeutics NV	• Dogs • For the treatment of pain associated with mild to moderate osteoarthritis in dogs	• 1/02/2016 • 09/11/2017 • 210 • 421	• 09/11/2017 • 06/12/2017 • 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
• **Ingelvac PCV FLEX** • Porcine circovirus vaccine (inactivated)	• Boehringer Ingelheim Vetmedica GmbH	• Pig • For active immunisation of pigs with no PCV2 maternally derived antibodies from the age of 2 weeks against porcine circovirus type 2 (PCV2)	• 19/12/2016 • 16/03/2017 • 87 • 0	• 16/03/2017 • 12/04/2017 • 24/05/2017 • 30/05/2017 • C 208 of 30/06/2017
• **Innovax-ND-IBD** • Newcastle disease, infectious bursal disease and Marek's disease vaccine (live recombinant)	• Intervet International B.V.	• Chickens • For active immunisation of one-day-old chicks: - to reduce mortality and clinical signs caused by Newcastle disease (ND) virus, - to prevent mortality and to reduce clinical signs and lesions of Infectious bursal disease (IBD), - to reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus	• 21/09/2016 • 15/06/2017 • 210 • 57	• 15/06/2017 • 12/07/2017 • 22/08/2017 • 24/08/2017 • C 328 of 29/09/2017
• **MiPet Easecto** • Sarolaner	• Zoetis Belgium SA	• Dogs • Treatment of tick infestations, flea infestations, sarcoptic mange, ear mite infestations, and demodicosis	• 07/08/2017 • 05/10/2017 • 59 • 0	• 05/10/2017 • 16/11/2017 • 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
• **Nobivac Leufel** • Feline leukaemia vaccine (inactivated)	• Virbac S.A.	• Cats • Active immunisation of cats from eight weeks of age against feline leukaemia for the prevention of persistent viraemia and clinical signs of the related disease	• 10/07/2017 • 07/09/2017 • 59 • 0	• 07/09/2017 • 04/10/2017 • 06/11/2017 • 08/11/2017 • C 447 of 29/12/2017
• **Oxybee** • Oxalic acid dihydrate	• Dany Bienenwohl	• Honey bees • For the treatment of varroosis	• 19/10/2016 • 07/09/2017 • 210 • 113	• 07/09/2017 • 04/10/2017 • Pending • Pending • Pending
• **Prevomax** • Maropitant	• Le Vet Beheer B.V.	• Dogs, Cats • For the treatment and/or prevention of nausea and/or vomiting, in combination with other supportive measures	• 11/05/2016 • 12/04/2017 • 210 • 126	• 12/04/2017 • 11/05/2017 • 19/06/2017 • 21/03/2017 • C 245 of 28/07/2017
• **Rabitec** • Rabies vaccine (live, oral) for foxes and raccoon dogs	• IDT Biologika GmbH	• Foxes, raccoon dogs • For the active immunisation of foxes and raccoon dogs against rabies to prevent infection and mortality	• 16/11/2016 • 05/10/2017 • 208 • 115	• 05/10/2017 • 30/10/2017 • 01/12/2017 • 05/12/2017 • C 30 of 26/01/2018
• **RESPIPORC FLUpan H1N1** • Swine influenza vaccine (inactivated)	• IDT Biologika GmbH	• Pig • Active immunisation of pigs against swine influenza caused by pandemic	• 21/10/2015 • 16/03/2017 • 210 • 204	• 16/03/2017 • 12/04/2017 • 17/05/2017 • 19/05/2017 • C 208 of 30/06/2017

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
		subtype H1N1v		
• **Suvaxyn Circo** • Porcine circovirus vaccine (inactivated, recombinant) and mycoplasma hyopneumonia vaccine (inactivated)	• Zoetis Belgium SA	• Pigs for fattening • Active immunisation of pigs from 3 weeks against porcine circovirus type 2 (PCV2)	• 15/03/2017 • 07/12/2017 • 180 • 87	• 07/12/2017 • 08/01/2018 • Pending • Pending • Pending
• **Suvaxyn PRRS MLV** • Porcine respiratory and reproductive syndrome virus vaccine (live)	• Zoetis Belgium SA	• Pigs for fattening, Pigs for reproduction • For active immunisation of clinically healthy pigs from 1 day of age in a porcine respiratory and reproductive syndrome (PRRS) virus contaminated environment, to reduce viraemia and nasal shedding caused by infection with European strains of PRRS virus (genotype 1)	• 08/06/2016 • 15/06/2017 • 209 • 163	• 15/06/2017 • 12/07/2017 • 24/08/2017 • 28/08/2017 • C 328 of 29/09/2017
• **VEPURED** • *E. coli* verotoxoid vaccine (inactivated recombinant)	• Laboratorios Hipra, S.A.	• Pigs • Active immunisation of piglets from 2 days of age to prevent mortality and reduce clinical signs of oedema disease (caused by verotoxin 2e	• 08/06/2017 • 15/06/2017 • 209 • 163	• 15/06/2017 • 12/07/2017 • 17/08/2017 • 21/08/2017 • C 328 of 29/09/2017

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
		produced by E. coli) and to reduce the loss of daily weight gain during the finishing period		
• **Zeleris** • Florfenicol/meloxicam	• CEVA Santé Animale	• Cattle • For therapeutic treatment of bovine respiratory disease (BRD) associated with pyrexia due to Mannheimia haemolytica, Pasteurella multocida and Histophilus somni susceptible to florfenicol	• 22/12/2015 • 16/03/2017 • 210 • 239	• 16/03/2017 • 11/04/2017 • 15/05/2017 • 17/05/2017 • C 208 of 30/06/2017
• **Zulvac BTV Ovis** • Bluetongue vaccine (inactivated) (multistrain: 1-2 strains out of a set of 3)	• Zoetis Belgium SA	• Sheep • Active immunisation of sheep from 6 weeks of age for the prevention of viraemia caused by bluetongue virus, serotypes 1 and 8, and for the reduction of viraemia caused by bluetongue virus, serotype 4	• 21/10/2015 • 16/02/2017 • 210 • 274	• 16/02/2017 • 15/03/2017 • 25/04/2017 • 27/04/2017 • C 171 of 30/05/2017

Negative opinions

There were not negative CVMP opinions in 2017.

CVMP opinions on establishment of MRLs

Positive opinions

Product • Substance	**Target species**	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Regulation • Official Journal
• **Alarelin**	• All food producing species	• 16/11/2016 • 12/04/2017 • 147 • 0	• 12/04/2017 • 2017/1559 • L 237
• **Bromelain**	• Porcine	• 13/07/2016 • 12/05/2017 • 209 • 94	• 12/05/2017 • 2017/1558 • L 237
• **Eprinomectin**	• Fin fish	• 07/06/2017 • 09/11/2017 • 155 • 0	• 09/11/2017 • Pending • Pending
• **Fluazuron**	• Fin fish	• 10/05/2017 • 05/10/2017 • 148 • 0	• 05/10/207 • Pending • Pending
• **Porcine prolactin**	• Pigs	• 23/09/2015 • 09/11/2017 • 210 • 568	• 09/11/2017 • Pending • Pending
• **Solvent naphtha, light aromatic**	• All food producing species	• 21/10/2015 • 05/10/2017 • 210 • 505	• 05/10/2017 • Pending • Pending

Negative opinions

There were not negative opinions on establishment of MRLs in 2017.

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**
• Nexgard Spectra • afoxolaner / milbemycin oxime	MERIAL	• QP54AB51 • Treatment of flea and tick infestations when the concurrent prevention of heartworm disease (Dirofilaria immitis larvae), angiostrongylosis (reduction in level of immature adults (L5) and adults of Angiostrongylus vasorum) and/or treatment of gastrointestinal nematode infestations is indicated.	• 16/03/2017	• 15/05/2017
• Activyl Tick Plus • indoxacarb / permethrin	Intervet International B.V.	• QP53AC54 • Treatment of flea infestations (Ctenocephalides felis); the product has persistent insecticidal efficacy for up to 4 weeks against Ctenocephalides felis. The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).	• 12/04/2017	• 24/05/2017
• Broadline • fipronil / (s)-methoprene / eprinomectin / praziquantel	MERIAL	• QP54AA54 • For cats with, or at risk from mixed infestations by cestodes, nematodes and ectoparasites.	• 12/05/2017	• 13/06/2017
• Simparica • sarolaner	Zoetis Belgium SA	• QP53BE03 • For the treatment of tick infestations (Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinus and Rhipicephalus sanguineus). For the treatment of flea infestations (Ctenocephalides felis and Ctenocephalides canis). For the treatment of sarcoptic mange (Sarcoptes scabiei). For the treatment of ear mite infestations (Otodectes cynotis). For the treatment of demodicosis (Demodex canis).	• 07/09/2017	• 10/10/2017
• SevoFlo • Sevoflurane	Zoetis Belgium SA	• QN01AB08 • To add a new non-food producing target species (cats)	• 05/10/2017	• 14/11/2017

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CVMP opinion**	**European Commission decision date**
• Zactran • gamithromycin	MERIAL	• QJ01FA95 • Cattle: Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida and Histophilus somni. The presence of the disease in the herd should be established before metaphylactic use. Pigs: Treatment of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis and Bordetella bronchiseptica. Sheep: Treatment of infectious pododermatitis (foot rot) associated with virulent Dichelobacter nodosus and Fusobacterium necrophorum requiring systemic treatment.	• 07/12/2017	• 12/01/2018

Annex 13 – Guidelines and concept papers adopted by CVMP

CVMP quality

Reference number	Document title	Status
EMA/CHMP/CVMP/QWP/BWP/428135/2016	Draft Concept paper on the need for Revision of Note for guidance on quality of water for pharmaceutical use (H+V)	Adopted for consultation January 2017 (End of consultation 6 June 2017)
EMA/CHMP/CVMP/QWP/826771/2016	Corrigendum to Reflection paper on the Requirements for selection and justification of starting materials for the manufacture of chemical active substances	Adopted January 2017
EMA/CHMP/CVMP/QWP/336031/2017	Reflection paper on the dissolution specification for generic solid oral immediate release products with systemic action	Adopted July 2017
EMA/CVMP/QWP/3629/2016	Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of New Active Substance (NAS) status of chemical substances	Adopted July 2017
EMA/CVMP/QWP/631010/2017	Implementation of risk assessment requirements to control elemental impurities in veterinary medicinal products	Adopted for consultation October 2017 (End of consultation 16 November 2017)
EMA/CVMP/QWP/707366/2017	Guideline on the chemistry of active substances for veterinary medicinal products	Adopted December 2017
EMA/CVMP/QWP/631010/2017	Implementation of risk assessment requirements to control elemental impurities in veterinary medicinal products	Adopted December 2017

CVMP safety

Reference number	Document title	Status
EMA/CVMP/SWP/377245/2016	Guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products	Adopted for consultation February 2017 (End of consultation 31 August 2017)

CVMP efficacy

Reference number	Document title	Status
EMA/CVMP/344/1999-Rev.2	Guideline on the conduct of efficacy studies for intramammary products for use in cattle	Adopted January 2017
EMA/CVMP/EWP/573536/2013	Reflection paper on anthelmintic resistance	Adopted April 2017
EMA/CVMP/EWP/016/00-Rev.3	Revised guideline on the conduct of bioequivalence studies for veterinary medicinal products	Adopted for consultation April 2017 (End of consultation 31 October 2017)
EMA/CVMP/EWP/133/1999-Rev.1	Guideline on conduct of pharmacokinetic studies in target animal species	Adopted for consultation November 2017 (End of consultation 31 May 2018)
EMA/CVMP/EWP/158889/2017	Concept paper for the revision of the guideline on the summary of product characteristics for anthelmintics	Adopted for consultation December 2017 (End of consultation 31 March 2018)

CVMP pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/171122/2016	Revised recommendation for the basic surveillance of Eudravigilance Veterinary (EVVet) data for centrally authorised products (CAPs)	Adopted for consultation February 2017 (End of consultation 31 August 2017)
EMA/CVMP/PhVWP/303762/2012 - Rev. 1	Revised Questions and answers on serious non-fatal adverse events and reporting rules	Adopted April 2017
EMA/CVMP/PhVWP/357539/2015	Reflection paper on non-spontaneous adverse event reports (literature, internet and social media) for veterinary medicinal products	Adopted May 2017
EMA/CVMP/PhVWP/390033/2014 -Rev.1	Reflection paper on promotion of pharmacovigilance reporting	Adopted July 2017
EMA/CVMP/PhVWP/145186/2013 - Rev.2	Questions and answers on adverse event reporting	Adopted November 2017

CVMP antimicrobials

Reference number	Document title	Status
EMA/CVMP/AWP/237294/2017	Reflection paper on off-label use of antimicrobials in veterinary medicine in the European Union	Adopted for consultation July 2017 (End of consultation 19 January 2018)
EMA/CVMP/AWP/721118/2014	Reflection paper on use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation July 2017 (End of consultation 20 October 2017)

CVMP immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/592652/2014	CVMP Risk Management Strategy - Managing the risk of the potential presence of replication competent endogenous retrovirus RD114 in starting materials and final products of feline and canine vaccines	Adopted February 2017
EMA/CVMP/IWP/123243/2006-Rev.3	Guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species (MUMS)/limited market	Adopted April 2017
EMA/CVMP/IWP/105506/2007-Rev.1	Guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD)	Adopted for consultation September 2017 (End of consultation 31 March 2018)

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/ERA/103555/2015	Guideline on assessing the toxicological risk to human health and groundwater communities from veterinary pharmaceuticals in groundwater	Adopted for consultation February 2017 (End of consultation 31 August 2017)
EMA/CVMP/ERA/689041/2015	Guideline on the plant testing strategy for veterinary medicinal products	Adopted March 2017
EMA/CVMP/448211/2015	Authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and toxic	Adopted April 2017

Reference number	Document title	Status
	(PBT) or very persistent and very bioaccumulative (vPvB) substances	

CVMP novel therapies

Reference number	Document title	Status
EMA/CVMP/ADVENT/751229/2016	Questions and Answers on allogenic stem cell-based products for veterinary use: specific questions on sterility	Adopted June 2017
EMA/CVMP/ADVENT/803494/2016	Questions and Answers on allogenic stem cell-based products for veterinary use: Specific questions on extraneous agents	Adopted July 2017
EMA/CVMP/ADVENT/791465/2016	Questions and answers on allogenic mesenchymal stem cell-based products for veterinary use: specific questions on tumorigenicity	Adopted November 2017
EMA/CVMP/ADVENT/307606/2017	Questions and answers on monoclonal antibodies for veterinary use	Adopted December 2017

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

Reference number	Document title	Status
EMA/CHMP/CVMP/JEG-3Rs/94436/2014	Guidance for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs	Adopted November 2017
EMA/CHMP/CVMP/3Rs/614768/2017	Recommendation to marketing authorisation holders, highlighting recent measures in the veterinary field to promote replacement, reduction, and refinement (3Rs) measures described in the European Pharmacopoeia *Applicable to human vaccines from 01/01/2018*	Adopted December 2017

Reference number	Document title	Status
EMA/CVMP/3Rs/336802/2017	Recommendation to marketing authorisation holders, highlighting recent measures in the veterinary field to promote reduction, refinement and replacement (3Rs) measures described in the European Pharmacopoeia *Applicable to veterinary vaccines from 01/01/2017*	Adopted December 2017

General

Reference number	Document title	Status
EMA/CVMP/757903/2016	Question and answer on the information contained within section 5.1 of the SPC on pharmacodynamic properties for pharmaceutical products	Adopted February 2017
EMA/CVMP/370663/2009–Rev.3	Q&A - EMA guidance for companies requesting classification for products/indication as Minor Use Minor Species (MUMS)/limited market	Adopted October 2017
EMA/CVMP/388694/2014-Rev.1	Guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS) / limited market	Adopted October 2017
EMA/CVMP/321528/2017	Procedural advice to applicants/marketing authorisation holders on re-examination of CVMP opinions	Adopted November 2017
EMA/CVMP/SAWP/172329/2004	Guidance for applicants requesting scientific advice	Adopted December 2017
EMA/776723/2017	QRD guidance on the use of approved pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP) and decentralised procedures (DCP)	Adopted December 2017
EMA/364980/2017	Quick Response (QR) codes in the labelling and/or package leaflet of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised procedures (DCP) and national procedures	Adopted December 2017

Annex 14 – COMP opinions 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
Recombinant adeno-associated viral vector serotype 9 containing the human N-alpha-acetylglucosaminidase gene	Abeona Therapeutics Europe 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
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
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
(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
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
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
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
Pentosan polysulfate sodium	HV-Polysaccharides GmbH & Co. KG - Germany	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
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
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
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
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
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
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
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
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
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

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
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
Ex-vivo-expanded autologous keratinocytes transduced with retroviral vector containing the COL7A1 gene	Abeona Therapeutics Europe SL - Spain	Treatment of epidermolysis bullosa	• 28/10/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
Iodine (131I) murine IgG1 monoclonal antibody against CD276	Y-mAbs Therapeutics A/S - Denmark	Treatment of neuroblastoma	• 27/10/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
Tauroursodeoxycholic acid	Bruschettini s.r.l. - Italy	Treatment of amyotrophic lateral sclerosis	• 28/09/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
Vemurafenib	Groupe d'étude des histiocytoses - France	Treatment of Erdheim-Chester disease	• 28/10/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
Thalidomide	PlumeStars s.r.l. - Italy	Treatment of hereditary haemorrhagic telangiectasia	• 25/10/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
Propranolol hydrochloride	Consejo Superior de Investigaciones Cientificas (CSIC) - Spain	Treatment of von Hippel-Lindau disease	• 14/10/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
Humanised IgG4 monoclonal antibody to the human toll-like receptor type 2	Opsona Therapeutics Ltd - Ireland	Treatment of myelodysplastic syndromes	• 27/10/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
Humanised IgG4 monoclonal antibody to the human toll-like receptor type 2	Opsona Therapeutics Ltd - Ireland	Treatment of pancreatic cancer	• 27/10/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
26 base synthetic single-stranded fully phosphorothioated 2'-omethyl-RNA and DNA mixmer oligonucleotide-based compound	Eirgen Pharma Limited - Ireland	Treatment of Dravet syndrome	• 21/09/2016 • 24/10/2016 • 19/01/2017 • (87 days/31 days)	• 27/01/2017 • 27/02/2017

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
N-(4-(1-cyanocyclopentyl)phenyl)-2-(4-pyridinylmethyl)-amino-3-pyridinecarboxamide methanesulfonate	Sirius Regulatory Consulting Limited - United Kingdom	Treatment of gastric cancer	• 27/09/2016 • 24/10/2016 • 19/01/2017 • (87 days/31 days)	• 27/01/2017 • 27/02/2017
Autologous T-cells transduced with lentiviral vector encoding an anti-SLAMF7 CD28/CD3-zeta chimeric antigen receptor	Dr. Michael Hudecek - Germany	Treatment of plasma cell myeloma	• 27/10/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
5-(4,6-dimorpholino-1,3,5-triazin-2-yl)-4-(trifluoromethyl)pyridin-2-amine	Voisin Consulting S.A.R.L. - France	Treatment of diffuse large B-cell lymphoma	• 27/09/2016 • 24/10/2016 • 19/01/2017 • (87 days/31 days)	• 27/01/2017 • 27/02/2017
Soluble recombinant human fibroblast growth factor receptor	TherAchon SAS - France	Treatment of achondroplasia	• 27/10/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
Alpha-tocopherol and ascorbic acid	Advanced Medical Projects - Spain	Treatment of fragile X syndrome	• 21/05/2015 • 24/10/2016 • 19/01/2017 • (87 days/31 days)	• 27/01/2017 • 27/02/2017
Recombinant human club cell 10 KDa protein	EUDRAC Limited - United Kingdom	Treatment of bronchiolitis obliterans syndrome	• 28/09/2016 • 24/10/2016 • 19/01/2017 • (87 days/31 days)	• 27/01/2017 • 27/02/2017
Cyclo[L-alanyl-L-seryl-L-isoleucyl-L-prolyl-L-prolyl-L-glutaminyl-L-lysyl-L-tyrosyl-D-prolyl-L-prolyl-(2S)-2-aminodecanoyl-L-alpha-glutamyl-L-threonyl]-acetate salt	Polyphor UK Ltd - United Kingdom	Treatment of primary ciliary dyskineasia	• 28/09/2016 • 24/10/2016 • 19/01/2017 • (87 days/31 days)	• 27/01/2017 • 27/02/2017
1-(2,2-difluoro-2H-1,3-benzodioxol-5-yl)-N-{1-[(2R)-2,3-dihydroxypropyl]-6-fluoro-2-(1-hydroxy-2-methylpropan-2-yl)-1H-indol-5-yl}cyclopropane-1-carboxamide and ivacaftor	Vertex Pharmaceuticals (Europe) Limited - United Kingdom	Treatment of cystic fibrosis	• 24/06/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
505 amino acid protein, corresponding to amino acids 2-506 of the wild-type human histidyl-tRNA synthetase	Voisin Consulting S.A.R.L. - France	Treatment of limb-girdle muscular dystrophy	• 28/10/2016 • 21/11/2016 • 19/01/2017 • (59 days/31 days)	• 27/01/2017 • 27/02/2017
Fenfluramine hydrochloride	Zogenix International Limited - United Kingdom	Treatment of Lennox-Gastaut syndrome	• 28/09/2016 • 24/10/2016 • 19/01/2017 • (87 days/31 days)	• 27/01/2017 • 27/02/2017

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Autologous adipose tissue-derived mesenchymal stem cells	SPC GmbH - Germany	Treatment of thromboangiitis obliterans (Buerger's disease)	• 29/08/2016 • 27/02/2017 • 16/02/2017 • (59 days/21 days)	• 27/02/2017 • 20/03/2017
Ketoconazole	Grupo Español de Tumores Huérfanos e Infrecuentes (GETHI) - Spain	Treatment of granulosa cell tumours	• 28/09/2016 • 24/10/2016 • 16/02/2017 • (115 days/21 days)	• 27/02/2017 • 20/03/2017
Phosphoinositide 3-kinase gamma peptide	Kither Biotech s.r.l. - Italy	Treatment of cystic fibrosis	• 24/11/2016 • 19/12/2016 • 16/02/2017 • (59 days/21 days)	• 27/02/2017 • 20/03/2017
Allogeneic, ex vivo expanded, umbilical cord blood-derived, hematopoietic CD34+ progenitor cells and allogeneic, non-expanded, umbilical cord blood-derived, hematopoietic mature myeloid and lymphoid cells	Regulatory Resources Group Ltd - United Kingdom	Treatment in haematopoietic stem cell transplantation	• 13/10/2016 • 19/12/2016 • 16/02/2017 • (59 days/21 days)	• 27/02/2017 • 20/03/2017
(3'R,4'S,5'R)-N-[(3R,6S)-6-carbamoyltetrahydro-2H-pyran-3-yl]-6''-chloro-4'-(2-chloro-3-fluoropyridin-4-yl)-4,4-dimethyl-2''-oxo-1'',2''-dihydrodispiro[cyclohexane-1,2'-pyrrolidine-3',3''-indole]-5'-carboxamide mono(4-methylbenzenesulfonate) monohydrate	Daiichi Sankyo Europe GmbH - Germany	Treatment of soft tissue sarcoma	• 26/08/2016 • 19/12/2016 • 16/02/2017 • (59 days/21 days)	• 27/02/2017 • 20/03/2017
Megestrol acetate	Grupo Español de Tumores Huérfanos e Infrecuentes (GETHI) - Spain	Treatment of granulosa cell tumours	• 28/09/2016 • 24/10/2016 • 16/02/2017 • (115 days/21 days)	• 27/02/2017 • 20/03/2017
Adeno-associated viral vector serotype 8 containing the human alpha-galactosidase A gene	Freeline Therapeutics Ltd - United Kingdom	Treatment of Fabry disease	• 27/10/2016 • 19/12/2016 • 16/02/2017 • (59 days/21 days)	• 27/02/2017 • 20/03/2017
Adeno-associated virus serotype rh.10 expressing beta-galactosidase	LYSOGENE - France	Treatment of GM1 gangliosidosis	• 26/10/2016 • 19/12/2016 • 16/02/2017 • (59 days/21 days)	• 27/02/2017 • 20/03/2017
Adeno-associated viral vector serotype LK03 encoding human ornithine transcarbamylase	Dr Julien Baruteau - United Kingdom	Treatment of ornithine transcarbamylase deficiency	• 25/11/2016 • 19/12/2016 • 16/02/2017 • (59 days/21 days)	• 27/02/2017 • 20/03/2017

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Inebilizumab	AstraZeneca AB - Sweden	Treatment of neuromyelitis optica spectrum disorders	• 25/10/2016 • 21/11/2016 • 16/02/2017 • (87 days/21 days)	• 27/02/2017 • 20/03/2017
Cannabidiol	GW Research Ltd - United Kingdom	Treatment of Lennox-Gastaut syndrome	• 27/10/2016 • 21/11/2016 • 16/02/2017 • (87 days/21 days)	• 27/02/2017 • 20/03/2017
Acetylleucine	IntraBio Ltd - United Kingdom	Treatment of Niemann-Pick disease	• 27/10/2016 • 21/11/2016 • 16/02/2017 • (87 days/21 days)	• 27/02/2017 • 20/03/2017
Poly-cyclodextrin-bis-cysteine-PEG3400-camptothecin-conjugate	Viadoc Business Solutions Limited - United Kingdom	Treatment of ovarian cancer	• 24/11/2016 • 19/12/2016 • 16/02/2017 • (59 days/21 days)	• 27/02/2017 • 20/03/2017
Antisense oligonucleotide targeting the USH2A gene	ProQR Therapeutics IV BV - The Netherlands	Treatment of retinitis pigmentosa	• 28/10/2016 • 21/11/2016 • 16/02/2017 • (87 days/21 days)	• 27/02/2017 • 20/03/2017
Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human B cell maturation antigen with 4-1BB and CD3-zeta intracellular signalling domains	Celgene Europe Limited - United Kingdom	Treatment of multiple myeloma	• 26/10/2016 • 19/12/2016 • 15/03/2017 • (86 days/28 days)	• 23/03/2017 • 20/04/2017
Thymidine and deoxycytidine	Vall d'Hebron Institute of Research - Spain	Treatment of mitochondrial DNA depletion syndrome, myopathic form	• 02/12/2016 • 13/01/2017 • 15/03/2017 • (61 days/28 days)	• 23/03/2017 • 20/04/2017
Modified messenger ribonucleic acid encoding human ornithine transcarbamylase enzyme encapsulated into lipid nanoparticles	PhaseRx Ireland, Ltd - Ireland	Treatment of ornithine transcarbamylase deficiency	• 09/12/2016 • 13/01/2017 • 15/03/2017 • (61 days/28 days)	• 23/03/2017 • 20/04/2017
Emeramide	NBMI Science Limited - Ireland	Prevention of mercury toxicity	• 13/12/2016 • 13/01/2017 • 15/03/2017 • (61 days/28 days)	• 23/03/2017 • 20/04/2017
Human normal immunoglobulin	Hôpital Foch - France	Treatment in solid organ transplantation	• 28/10/2016 • 19/12/2016 • 15/03/2017 • (86 days/28 days)	• 23/03/2017 • 20/04/2017

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Rituximab	Hôpital Foch - France	Treatment in solid organ transplantation	• 28/10/2016 • 19/12/2016 • 15/03/2017 • (86 days/28 days)	• 23/03/2017 • 20/04/2017
(S)-8-{2-amino-6-[1-(5-chloro-biphenyl-2-yl)-(R)-2,2,2-trifluoro-ethoxy]-pyrimidin-4-yl}-2,8-diaza-spiro[4.5]decane-3-carboxylic acid ethyl ester)	Biological Consulting Europe Ltd - United Kingdom	Treatment of pulmonary arterial hypertension	• 23/11/2016 • 19/12/2016 • 15/03/2017 • (86 days/28 days)	• 23/03/2017 • 20/04/2017
N-[(1R)-1-phenylethyl]-6-{1H-pyrazolo[3,4-d]pyrimidin-4-yl}quinazolin-2-amine	Sentinel Oncology Limited - United Kingdom	Treatment of fragile X syndrome	• 11/11/2016 • 19/12/2016 • 15/03/2017 • (86 days/28 days)	• 23/03/2017 • 20/04/2017
Autologous adult bone marrow-derived non-expanded CD133+ haematopoietic stem cells	Igenomix, S.L. - Spain	Treatment of Asherman's syndrome	• 25/11/2016 • 19/12/2016 • 15/03/2017 • (86 days/28 days)	• 23/03/2017 • 20/04/2017
Estetrol	Mithra Pharmaceuticals S.A. - Belgium	Treatment of neonatal encephalopathy	• 25/11/2016 • 19/12/2016 • 15/03/2017 • (86 days/36 days)	• 23/03/2017 • 28/04/2017
Ursodeoxycholic acid	IntraBio Ltd - United Kingdom	Treatment of Niemann-Pick disease	• 01/12/2016 • 13/01/2017 • 11/04/2017 • (88 days/25 days)	• 27/04/2017 • 22/05/2017
Tamoxifen citrate	GB Pharma Srl - Italy	Treatment of cystic fibrosis	• 24/01/2017 • 13/02/2017 • 11/04/2017 • (57 days/25 days)	• 27/04/2017 • 22/05/2017
Sodium (1R, 3R, 4R, 5S)-3-({2-N-acetylamino-2-deoxy-3-O-[(1S)-1-carboxylato-2-cyclohexylethyl]-β-D-galactopyranosyl}oxy)-4-({6-deoxy-α-L-galactopyranosyl}oxy)-5-ethyl-cyclohexan-1-yl-(38-oxo-2,5,8,11,14,17,20,23,26,29,32,35-dodecaoxa-39-azahentetracontan-41-yl) carboxamide	TMC Pharma Services Ltd - United Kingdom	Treatment of acute myeloid leukaemia	• 26/01/2017 • 13/02/2017 • 11/04/2017 • (57 days/25 days)	• 27/04/2017 • 22/05/2017
Recombinant human interleukin-7 fused to a hybrid crystallisable fragment region of a human antibody	NeoImmuneTech, INC., Spółka Akcyjna, Oddział w Polsce - Poland	Treatment of idiopathic CD4 lymphocytopenia	• 08/12/2016 • 13/02/2017 • 11/04/2017 • (57 days/25 days)	• 27/04/2017 • 22/05/2017

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Recombinant adeno-associated viral vector serotype 6 encoding the B-domain-deleted human factor VIII	Coté Orphan Consulting UK Limited - United Kingdom	Treatment of haemophilia A	• 27/01/2017 • 13/02/2017 • 11/04/2017 • (57 days/25 days)	• 27/04/2017 • 22/05/2017
Chimeric locked nucleic acid deoxynucleoside phosphorothioate-linked oligonucleotide inhibitor directed against microRNA-155-5p	Miragen Therapeutics Europe Ltd - United Kingdom	Treatment of cutaneous T-cell lymphoma	• 26/01/2017 • 13/02/2017 • 11/04/2017 • (57 days/25 days)	• 27/04/2017 • 22/05/2017
225Ac-lintuzumab	Voisin Consulting S.A.R.L. - France	Treatment of acute myeloid leukaemia	• 07/12/2016 • 13/01/2017 • 11/04/2017 • (88 days/25 days)	• 27/04/2017 • 22/05/2017
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-,15,15'-diester with N-acetyl-L-isoleucyl-L-cysteinyl-L-valyl-1-methyl-L-tryptophyl-L-glutaminyl-L-.alpha.-aspartyl-L-tryptophylglycyl-L-alanyl-L-histidyl-L-arginyl-L-cysteinyl-L-threonyl-2-[2-(2-aminoethoxy)ethoxy]acetyl-N6-carboxy-L-lysinamide cyclic (2.fwdarw.12)-(disulfide); where two identical synthetic peptide domains are covalently linked at the ends of the polyethylene glycol chain	Best Regulatory Consulting Ltd - United Kingdom	Treatment of paroxysmal nocturnal haemoglobinuria	• 16/01/2017 • 13/02/2017 • 11/04/2017 • (57 days/25 days)	• 27/04/2017 • 22/05/2017
Synthetic glucagon analogue modified to contain 7 amino acid substitutions	Zealand Pharma A/S - Denmark	Treatment of congenital hyperinsulinism	• 02/01/2017 • 13/02/2017 • 12/05/2017 • (88 days/32 days)	• 19/05/2017 • 20/06/2017
Recombinant human factor IX protein modified with three point mutations	Voisin Consulting S.A.R.L. - France	Treatment of haemophilia B	• 27/01/2017 • 13/02/2017 • 12/05/2017 • (88 days/32 days)	• 19/05/2017 • 20/06/2017
Asp-Arg-Val-Tyr-Ile-His-Pro	Envigo Pharma Consulting Limited - United Kingdom	Treatment of epidermolysis bullosa	• 28/02/2017 • 20/03/2017 • 12/05/2017 • (53 days/32 days)	• 19/05/2017 • 20/06/2017
Sildenafil	Avivia Beheer BV - The Netherlands	Treatment of congenital diaphragmatic hernia	• 24/11/2016 • 13/02/2017 • 12/05/2017 • (88 days/32 days)	• 19/05/2017 • 20/06/2017
Tripotassium citrate monohydrate and potassium hydrogen carbonate	Advicenne Pharma SA - France	Treatment of distal renal tubular acidosis	• 27/01/2017 • 13/02/2017 • 12/05/2017 • (88 days/32 days)	• 19/05/2017 • 20/06/2017

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Sirolimus	Vale Pharmaceuticals Limited - Ireland	Treatment of tuberous sclerosis	• 25/01/2017 • 13/02/2017 • 12/05/2017 • (88 days/32 days)	• 19/05/2017 • 20/06/2017
Decitabine and tetrahydrouridine	Ulrich Muehlner - Germany	Treatment of sickle cell disease	• 26/01/2017 • 13/02/2017 • 12/05/2017 • (88 days/32 days)	• 19/05/2017 • 20/06/2017
Ibutamoren mesilate	Richardson Associates Regulatory Affairs Ltd - United Kingdom	Treatment of growth hormone deficiency	• 27/01/2017 • 13/02/2017 • 12/05/2017 • (88 days/32 days)	• 19/05/2017 • 20/06/2017
Pentamer formyl thiophene acetic acid	NeuroScios GmbH - Austria	Treatment of Creutzfeldt-Jakob disease	• 28/02/2017 • 20/03/2017 • 12/05/2017 • (53 days/32 days)	• 19/05/2017 • 20/06/2017
Avacopan	ChemoCentryx Limited - United Kingdom	Treatment of C3 glomerulopathy	• 28/02/2017 • 20/03/2017 • 12/05/2017 • (53 days/32 days)	• 19/05/2017 • 20/06/2017
(S)-1-(4-fluorophenyl)-1-(2-(4-(6-(1-methyl-1H-pyrazol-4-yl)pyrrolo[2,1-f][1,2,4]triazin-4-yl)piperazin-yl)pyrimidin-5-yl)ethan-1-amine	PhaRA bvba - Belgium	Treatment of gastrointestinal stromal tumours	• 16/03/2017 • 18/04/2017 • 15/06/2017 • (58 days/26 days)	• 21/06/2017 • 17/07/2017
Tirapazamine	PhaRA bvba - Belgium	Treatment of hepatocellular carcinoma	• 16/03/2017 • 21/06/2017 • 15/06/2017 • (58 days/26 days)	• 21/06/2017 • 17/07/2017
Retinol	orphanix GmbH - Austria	Prevention of retinopathy of prematurity	• 23/03/2017 • 21/06/2017 • 15/06/2017 • (58 days/26 days)	• 21/06/2017 • 17/07/2017
Polyphenyl(disodium 3-O-sulfo-beta-D-glucopyranuronate)-(1→3)-beta-D-galactopyranoside	SFL Regulatory Affairs Consulting Ltd - United Kingdom	Treatment of anti-MAG neuropathy	• 22/03/2017 • 21/06/2017 • 15/06/2017 • (58 days/26 days)	• 21/06/2017 • 17/07/2017
Autologous CD4+ and CD8+ T cells expressing a CD19-specific chimeric antigen receptor	Celgene Europe Limited - United Kingdom	Treatment of diffuse large B-cell lymphoma	• 22/03/2017 • 21/06/2017 • 15/06/2017 • (58 days/26 days)	• 21/06/2017 • 17/07/2017

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Sirolimus	Raremoon Consulting Ltd - United Kingdom	Treatment of pachyonychia congenita	• 24/02/2017 • 20/03/2017 • 15/06/2017 • (87 days/26 days)	• 21/06/2017 • 17/07/2017
Recombinant human antibody directed against misfolded human superoxide dismutase 1	The Medical & Regulatory Partnership Limited - United Kingdom	Treatment of amyotrophic lateral sclerosis	• 28/02/2017 • 20/03/2017 • 15/06/2017 • (87 days/26 days)	• 21/06/2017 • 17/07/2017
Oxymetazoline hydrochloride	RDD Pharma Limited - United Kingdom	Treatment of spinal cord injury	• 09/12/2016 • 20/03/2017 • 15/06/2017 • (87 days/26 days)	• 21/06/2017 • 17/07/2017
Bacillus subtilis oxalate decarboxylase	Allena Pharmaceuticals Ireland Limited - Ireland	Treatment of primary hyperoxaluria	• 24/03/2017 • 18/04/2017 • 15/06/2017 • (58 days/26 days)	• 21/06/2017 • 17/07/2017
Adeno-associated viral vector serotype Anc80 containing the truncated human ATP7B gene under the control of the human alpha-1 antitrypsin promoter	Vivet Therapeutics SAS - France	Treatment of Wilson's disease	• 19/05/2017 • 12/06/2017 • 13/07/2017 • (31 days/30 days)	• 24/07/2017 • 23/08/2017
Tacrolimus	Vivus B.V. - The Netherlands	Treatment of pulmonary arterial hypertension	• 22/05/2017 • 12/06/2017 • 13/07/2017 • (31 days/30 days)	• 24/07/2017 • 23/08/2017
Purified pasteurised and freeze-dried cell-wall fragments from Mycobacterium tuberculosis strain RUTI	Archivel Farma S.L. - Spain	Treatment of tuberculosis	• 22/05/2017 • 12/06/2017 • 13/07/2017 • (31 days/30 days)	• 24/07/2017 • 23/08/2017
Picropodophyllin	Axelar AB - Sweden	Treatment of glioma	• 18/05/2017 • 12/06/2017 • 13/07/2017 • (31 days/30 days)	• 24/07/2017 • 23/08/2017
Recombinant fragment of human surfactant protein-D	Trimunocor Ltd - United Kingdom	Prevention of bronchopulmonary dysplasia	• 23/03/2017 • 18/04/2017 • 13/07/2017 • (86 days/21 days)	• 02/08/2017 • 23/08/2017
Teicoplanin	Neupharma S.r.l. - Italy	Treatment of cystic fibrosis	• 19/05/2017 • 12/06/2017 • 13/07/2017 • (31 days/30 days)	• 24/07/2017 • 23/08/2017

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Recombinant truncated N-terminal fragment of human lens epithelium derived growth factor	Dorian Regulatory Affairs BV - The Netherlands	Treatment of retinitis pigmentosa	• 20/05/2017 • 12/06/2017 • 13/07/2017 • (31 days/30 days)	• 24/07/2017 • 23/08/2017
Antisense oligonucleotide targeting exon 13 in the USH2A gene	ProQR Therapeutics IV BV - The Netherlands	Treatment of retinitis pigmentosa	• 22/05/2017 • 12/06/2017 • 13/07/2017 • (31 days/30 days)	• 24/07/2017 • 23/08/2017
Odiparcil	Inventiva - France	Treatment of mucopolysaccharidosis type VI (Maroteaux-Lamy syndrome)	• 21/03/2017 • 18/04/2017 • 13/07/2017 • (86 days/30 days)	• 24/07/2017 • 23/08/2017
Asunercept	Apogenix AG - Germany	Treatment of myelodysplastic syndromes	• 23/03/2017 • 18/04/2017 • 13/07/2017 • (86 days/21 days)	• 02/08/2017 • 23/08/2017
Sodium 2-hydroxylinoleate	Ability Pharmaceuticals SL - Spain	Treatment of pancreatic cancer	• 18/05/2017 • 12/06/2017 • 13/07/2017 • (31 days/30 days)	• 24/07/2017 • 23/08/2017
Sirolimus	Best Regulatory Consulting Ltd - United Kingdom	Treatment of tuberous sclerosis	• 22/03/2017 • 12/06/2017 • 13/07/2017 • (31 days/30 days)	• 24/07/2017 • 23/08/2017
Recombinant adeno-associated viral vector serotype 5 carrying the gene for the human frataxin protein	Voisin Consulting S.A.R.L. - France	Treatment of Friedreich's ataxia	• 22/05/2017 • 12/06/2017 • 13/07/2017 • (31 days/30 days)	• 24/07/2017 • 23/08/2017
N-{2-[(6-{[(2,6-dichloro-3,5-dimethoxyphenyl)carbamoyl](methyl)amino}pyrimidin-4-yl)amino]-5-(4-ethylpiperazin-1-yl)phenyl}prop-2-enamide	Eisai Europe Limited - United Kingdom	Treatment of hepatocellular carcinoma	• 23/03/2017 • 18/04/2017 • 13/07/2017 • (86 days/30 days)	• 24/07/2017 • 23/08/2017
Itraconazole	Mayne Pharma UK Limited - United Kingdom	Treatment of naevoid basal-cell carcinoma syndrome (Gorlin syndrome)	• 23/03/2017 • 18/04/2017 • 13/07/2017 • (86 days/30 days)	• 24/07/2017 • 23/08/2017
Salmonella typhi Ty21a strain transfected with a plasmid vector encoding the human vascular endothelial growth factor receptor 2	Vaximm GmbH - Germany	Treatment of glioma	• 17/05/2017 • 12/06/2017 • 13/07/2017 • (31 days/30 days)	• 24/07/2017 • 23/08/2017

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Glucopyranosyl lipid A	Immune Design Ltd - United Kingdom	Treatment of follicular lymphoma	• 06/06/2017 • 14/07/2017 • 07/09/2017 • (55 days/24 days)	• 19/09/2017 • 13/10/2017
Recombinant monoclonal antibody to sialic acid-binding Ig-like lectin 8	Envestia Limited - United Kingdom	Treatment of mastocytosis	• 20/05/2017 • 12/06/2017 • 07/09/2017 • (87 days/27 days)	• 19/09/2017 • 16/10/2017
Pracinostat	Helsinn Birex Pharmaceuticals Ltd - Ireland	Treatment of acute myeloid leukaemia	• 02/06/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
Seladelpar	Larode Ltd - United Kingdom	Treatment of primary biliary cholangitis	• 23/06/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
Siplizumab	ITB-MED AB - Sweden	Treatment in solid organ transplantation	• 11/06/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
Autologous ex-vivo-expanded peripheral polyclonal lymphocytes enriched in activated natural killer cells	CellProtect Nordic Pharmaceuticals AB - Sweden	Treatment of multiple myeloma	• 26/06/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
Synthetic cyclic 8 amino acid analogue of human unacylated ghrelin	Alizé Pharma - France	Treatment of Prader-Willi syndrome	• 17/05/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
Humanised monoclonal antibody targeting B-cell maturation antigen conjugated with maleimidocaproyl monomethyl auristatin F	GlaxoSmithKline Trading Services Limited - Ireland	Treatment of multiple myeloma	• 18/05/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
Recombinant adeno-associated viral vector serotype 5 encoding Staphylococcus aureus Cas9 endonuclease and two guide RNAs complementary to two regions of intron 26 of the CEP290 gene	Pharma Gateway AB - Sweden	Treatment of Leber's congenital amaurosis	• 19/05/2017 • 12/06/2017 • 07/09/2017 • (87 days/27 days)	• 19/09/2017 • 16/10/2017
Entospletinib	Gilead Sciences International Ltd - United Kingdom	Treatment of acute myeloid leukaemia	• 17/03/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017

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Glasdegib maleate	Pfizer Limited - United Kingdom	Treatment of acute myeloid leukaemia	• 15/06/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
Cannabidivarin	GW Research Ltd - United Kingdom	Treatment of Rett syndrome	• 30/05/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
Bitopertin	Roche Registration Limited - United Kingdom	Treatment of beta-thalassaemia intermedia and major	• 22/06/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
5-amino-1-(2-methyl-1H-benzo[d]imidazol-5-yl)-1H-pyrazol-4-yl 1H-indol-2-yl ketone mono[(S)-2-hydroxysuccinate]	Voisin Consulting S.A.R.L. - France	Treatment of biliary tract cancer	• 26/06/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
(S)-3-((S)-2-(2-((2,6-difluorophenyl)amino)-2-oxoacetamido)propanamido)-4-oxo-5-(2,3,5,6-tetrafluorophenoxy)pentanoic acid	Pharma Gateway AB - Sweden	Treatment of primary sclerosing cholangitis	• 18/05/2017 • 12/06/2017 • 07/09/2017 • (87 days/27 days)	• 19/09/2017 • 16/10/2017
Cannabidiol	GW Research Ltd - United Kingdom	Treatment of West syndrome	• 18/05/2017 • 12/06/2017 • 07/09/2017 • (87 days/27 days)	• 19/09/2017 • 16/10/2017
Ofranergene obadenovec	Envigo Pharma Consulting Limited - United Kingdom	Treatment of ovarian cancer	• 14/03/2017 • 12/06/2017 • 07/09/2017 • (87 days/27 days)	• 19/09/2017 • 16/10/2017
Adenoviral vector of serotype 5 modified to contain a chimeric sequence consisting of a minimal urokinase-type plasminogen activator receptor promoter preceded by three Notch-responsive elements, and coated with oligopeptide end-modified poly (beta-amino) esters	Sagetis Biotech, S.L. - Spain	Treatment of pancreatic cancer	• 22/06/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
2-[N-(2-hydroxyethyl)]-N-(4-methoxybenzenesulfonyl)]amino-N-(4-chlorocinnamyl)-N-methylbenzylamine	Repositioning SAS - France	Treatment of Charcot-Marie-Tooth disease	• 23/03/2017 • 14/07/2017 • 07/09/2017 • (55 days/27 days)	• 19/09/2017 • 16/10/2017
Diazoxide choline	Soleno Therapeutics UK Ltd - United Kingdom	Treatment of Prader-Willi syndrome	• 23/06/2017 • 14/07/2017 • 05/10/2017 • (83 days/27 days)	• 12/10/2017 • 08/11/2017

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Tiratricol	Medical Need Europe AB - Sweden	Treatment of Allan-Herndon-Dudley syndrome	• 03/07/2017 • 03/08/2017 • 05/10/2017 • (63 days/27 days)	• 12/10/2017 • 08/11/2017
Tamoxifen citrate	Duchenne UK - United Kingdom	Treatment of Duchenne muscular dystrophy	• 14/07/2017 • 03/08/2017 • 05/10/2017 • (63 days/27 days)	• 12/10/2017 • 08/11/2017
Recombinant adeno-associated viral vector serotype 9 containing human iduronate-2-sulfatase gene	REGENXBIO EU Limited - Ireland	Treatment of mucopolysaccharidosis type II (Hunter's syndrome)	• 14/07/2017 • 03/08/2017 • 05/10/2017 • (63 days/27 days)	• 12/10/2017 • 08/11/2017
(1'R,6'R)-3-(benzylamine)-6-hydroxy-3'-methyl-4-pentyl-6'-(prop-1-en-2-yl)-[1,1'-bi(cyclohexane)]-2',3,6-triene-2,5-dione	Quintiles Ireland Limited - Ireland	Treatment of systemic sclerosis	• 17/07/2017 • 03/08/2017 • 05/10/2017 • (63 days/27 days)	• 12/10/2017 • 08/11/2017
(R)-troloxamide quinone	Edison Orphan Pharma BV - The Netherlands	Treatment of amyotrophic lateral sclerosis	• 15/07/2017 • 03/08/2017 • 05/10/2017 • (63 days/27 days)	• 12/10/2017 • 08/11/2017
N-(2-aminophenyl)-4-(1-[(1,3-dimethyl-1H-pyrazol-4-yl) methyl]piperidin)benzamide	Celleron Therapeutics Limited - United Kingdom	Treatment of peripheral T-cell lymphoma	• 26/06/2017 • 14/07/2017 • 05/10/2017 • (83 days/27 days)	• 12/10/2017 • 08/11/2017
C1-esterase-inhibitor human	CSL Behring GmbH - Germany	Treatment in solid organ transplantation	• 12/06/2017 • 14/07/2017 • 05/10/2017 • (83 days/27 days)	• 12/10/2017 • 08/11/2017
1,4-diamino-2,3-dicyano-1,4-bis[2-aminophenylthio] butadiene	Edvince AB - Sweden	Treatment of non-traumatic subarachnoid haemorrhage	• 26/06/2017 • 14/07/2017 • 05/10/2017 • (83 days/27 days)	• 12/10/2017 • 08/11/2017
1-[4-bromo-5-[1-ethyl-7-(methylamino)-2-oxo-1,2-dihydro-1,6-naphthyridin-3-yl]-2-fluorophenyl]-3-phenylurea	Worldwide Clinical Trials Limited - United Kingdom	Treatment of gastrointestinal stromal tumours	• 26/06/2017 • 14/07/2017 • 05/10/2017 • (83 days/27 days)	• 12/10/2017 • 08/11/2017
Concizumab	Novo Nordisk A/S - Denmark	Treatment of haemophilia B	• 26/06/2017 • 14/07/2017 • 05/10/2017 • (83 days/27 days)	• 12/10/2017 • 08/11/2017

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4-amino-1-[(1S,4R,5S)-2-fluoro-4,5-dihydroxy-3-(hydroxymethyl)cyclopent-2-en-1-yl]pyrimidin-2-one	Quintiles Ireland Limited - Ireland	Treatment of pancreatic cancer	• 26/06/2017 • 03/08/2017 • 05/10/2017 • (63 days/27 days)	• 12/10/2017 • 08/11/2017
Antisense oligonucleotide targeting exon 73 in the COL7A1 gene	ProQR Therapeutics VII BV - The Netherlands	Treatment of epidermolysis bullosa	• 17/07/2017 • 03/08/2017 • 05/10/2017 • (63 days/27 days)	• 12/10/2017 • 08/11/2017
2-isopropyl-3H-naphtho[1,2-d]imidazole-4,5-dione	NeuroVive Pharmaceutical AB - Sweden	Treatment of mitochondrial encephalomyopathy, lactic acidosis and stroke-like episodes	• 14/07/2017 • 03/08/2017 • 31/10/2017 • (89 days/25 days)	• 17/11/2017 • 12/12/2017
Modified messenger ribonucleic acid encoding human argininosuccinate lyase enzyme encapsulated into lipid nanoparticles	PhaseRx Ireland, Ltd - Ireland	Treatment of argininosuccinic aciduria	• 28/08/2017 • 18/09/2017 • 31/10/2017 • (43 days/25 days)	• 17/11/2017 • 12/12/2017
Agammaglobulinaemia tyrosine kinase	Clinical Network Services (UK) Ltd - United Kingdom	Treatment of pemphigus	• 30/08/2017 • 18/09/2017 • 31/10/2017 • (43 days/25 days)	• 17/11/2017 • 12/12/2017
Adenovirus associated viral vector serotype 8 containing the human AIPL1 gene	MeiraGTx UK II Limited - United Kingdom	Treatment of Leber's congenital amaurosis	• 31/08/2017 • 18/09/2017 • 31/10/2017 • (43 days/25 days)	• 17/11/2017 • 12/12/2017
Acetylleucine	IntraBio Ltd - United Kingdom	Treatment of GM2 gangliosidosis	• 30/08/2017 • 18/09/2017 • 31/10/2017 • (43 days/25 days)	• 17/11/2017 • 12/12/2017
(2S,4R)-1-(2-(3-acetyl-5-(2-methylpyrimidin-5-yl)-1H-indazol-1-yl)acetyl)-N-(6-bromopyridin-2-yl)-4-fluoropyrrolidine-2-carboxamide	FGK Representative Service GmbH - Germany	Treatment of paroxysmal nocturnal haemoglobinuria	• 29/08/2017 • 18/09/2017 • 31/10/2017 • (43 days/25 days)	• 17/11/2017 • 12/12/2017
4-hydroxy-2,2,6,6-tetramethylpiperidine-N-oxyl	Premier Research Group Limited - United Kingdom	Treatment of familial cerebral cavernous malformation	• 14/07/2017 • 03/08/2017 • 31/10/2017 • (89 days/25 days)	• 17/11/2017 • 12/12/2017
Venetoclax	Abbvie Ltd. - United Kingdom	Treatment of mantle cell lymphoma	• 13/07/2017 • 18/09/2017 • 31/10/2017 • (43 days/25 days)	• 17/11/2017 • 12/12/2017

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Pegunigalsidase alfa	Protalix B.V. - The Netherlands	Treatment of Fabry disease	• 17/07/2017 • 03/08/2017 • 31/10/2017 • (89 days/25 days)	• 17/11/2017 • 12/12/2017

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
20% I.V. fat emulsion consisting of 20% soybean oil, 1.2% egg yolk phospholipids, 2.25% glycerin, and water for injection	Alan Boyd Consultants Ltd - United Kingdom	Treatment of poisoning by local anesthetics	• 15/03/2016 • 15/08/2016 • 03/04/2017 • (231/16days	• 04/04/2017 • 20/04/2017

Annex 15 – HMPC European Union herbal monographs

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/220599/2016	Lecithinum ex soya	31/01/2017 / TU
EMA/HMPC/338914/2016	Soiae oleum raffinatum	31/01/2017 / TU
EMA/HMPC/224755/2016	Species diureticae	28/03/2017 / TU
EMA/HMPC/7685/2013	Allii sativi bulbus	18/06/2017 / TU
Revision		
EMA/HMPC/80630/2016	Salicis cortex	31/01/2017 / WEU+TU
EMA/HMPC/359238/2016	Oleae folium	31/01/2017 / TU
EMA/HMPC/751490/2016	Absinthii herba	30/05/2017 / TU
EMA/HMPC/424583/2016	Echinaceae purpureae radix	30/05/2017 / TU
EMA/HMPC/464684/2016	Vitis viniferae folium	30/05/2017 / WEU+TU
EMA/HMPC/745353/2016	Ribis nigri folium	19/05/2017 / TU
EMA/HMPC/325716/2017	Hederae helicis folium	21/11/2017 / WEU
EMA/HMPC/44166/2016	Meliloti herba	21/11/2017 / TU

European Union List entries – adopted for transfer to European Commission

None

European Union herbal monographs - Draft

Reference number	Document title	Adoption / Outcome*
First Assessment		
	none	
Revision		
EMA/HMPC/572705/2014	Menthae piperitae folium	31/01/2017
EMA/HMPC/745353/2016	Ribis nigri folium	31/01/2017
EMA/HMPC/44166/2016	Meliloti herba	28/03/2017
EMA/HMPC/750269/2016	Uvae ursi folium	28/03/2017
EMA/HMPC/48745/2017	Cimicifugae rhizoma	18/07/2017
EMA/HMPC/625849/2015	Sennae folium	18/07/2017
EMA/HMPC/228761/2016	Sennae fructus	18/07/2017
EMA/HMPC/329755/2017	Curcumae longae rhizoma	21/11/2017
EMA/HMPC/327107/2017	Valerianae radix/Lupuli flos	21/11/2017

European Union List entries - Draft

None

Public statements

Reference number	Document title	Adoption
Drafts		
EMA/HMPC/461814/2016	Glycini semen	31/01/2017
Final		
EMA/HMPC/150787/2015	Paeonia radix alba	31/01/2017 /PS
EMA/HMPC/762952/2015	Paeonia radix rubra	31/01/2017 /PS
EMA/HMPC/450588/2016	Piperis methystici rhizoma	21/11/2017 /PS

Annex 16 – PDCO opinions and EMEA decisions on paediatric investigation plans and waivers

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

Active Substance(s)	**Invented Name**	**PDCO Opinion**	**Therapeutic areas**	**Applicant**	**Decision date**	**Decision Number**
Anti-(human calcitonin gene-related peptide receptor) human monoclonal antibody (AMG 334)		P	Neurology	Novartis Europharm Limited	04/01/2017	P/0370/2016
Beclometasone (dipropionate) / formoterol (fumarate dihydrate)	Foster and associated names, Kantos and associated names, Kantos Master and associated names, Inuvair and associated names	PM	Pneumology - Allergology	Chiesi Farmaceutici S.p.A.	05/01/2017	P/0001/2017
Belatacept	Nulojix	PM	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb Pharma EEIG	12/01/2017	P/0002/2017
Ipilimumab	Yervoy	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	12/01/2017	P/0003/2017
Nivolumab	Opidovo	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	13/01/2017	P/0004/2017
Abatacept	Orencia	P	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb Pharma EEIG	16/01/2017	P/0005/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Concentrate of proteolytic enzymes in bromelain	NexoBrid	PM	Dermatology Other	MediWound Germany GmbH	31/01/2017	P/0006/2017
Eltrombopag	Revolade	PM	Haematology-Hemostaseology	Novartis Europharm Limited	31/01/2017	P/0007/2017
Idursulfase		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Shire Human Genetic Therapies AB	31/01/2017	P/0008/2017
Ocrelizumab		PM	Neurology	Roche Registration Ltd	31/01/2017	P/0009/2017
Ranibizumab	Lucentis	PM	Ophthalmology	Novartis Europharm Limited	31/01/2017	P/0010/2017
Midostaurin		PM	Oncology	Novartis Europharm Ltd	31/01/2017	P/0011/2017
Edoxaban (tosylate)	Lixiana	PM	Cardiovascular Diseases	Daiichi Sankyo Europe GmbH	31/01/2017	P/0012/2017
Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; Escherichia coli) / Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B;		PM	Vaccines	Pfizer Ltd	31/01/2017	P/0013/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Escherichia coli)						
Budesonide		PM	Pneumology - Allergology	Vectura Limited	31/01/2017	P/0014/2017
Terbinafine (hydrochloride)		PM	Dermatology	Polichem SA	31/01/2017	P/0015/2017
Bumetanide		RPM	Neurology	Neurochlore	31/01/2017	P/0016/2017
Paclitaxel	Abraxane	PM	Oncology	Celgene Europe Limited	31/01/2017	P/0017/2017
Idelalisib	Zydelig	PM	Oncology	Gilead Sciences International Ltd	30/01/2017	P/0018/2017
Citric acid (as citric acid anhydrous) / sodium chloride / simeticone / macrogol 4000 / sodium citrate /sodium sulfate (as sodium sulfate anhydrous) / potassium chloride (PMF104)		PM	Gastroenterology-Hepatology	Alfa Wassermann S.p.A.	31/01/2017	P/0019/2017
Esketamine (hydrochloride)		P	Psychiatry	Janssen-Cilag International NV	31/01/2017	P/0020/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Dupilumab		PM	Pneumology - Allergology	Sanofi-Aventis Recherche & Développement	03/02/2017	P/0021/2017
Nanobody directed towards the fusion protein of human respiratory syncytial virus (ALX-0171)		PM	Neonatology - Paediatric Intensive Care	Ablynx NV	30/01/2017	P/0022/2017
Ciprofloxacin (hydrochloride)		P	Infectious Diseases	Aradigm Limited	13/02/2017	P/0023/2017
Emtricitabine / tenofovir alafenamide	Descovy	PM	Infectious Diseases	Gilead Sciences International Ltd.	31/01/2017	P/0024/2017
Grazoprevir / elbasvir	Zepatier	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	31/01/2017	P/0025/2017
Humanised anti-IL-6 receptor (IL-6R) monoclonal antibody		PM	Neurology	CHUGAI PHARMA EUROPE LTD.	27/01/2017	P/0026/2017
Patiromer calcium		PM	Other	Vifor Fresenius Medical Care Renal Pharma France	31/01/2017	P/0027/2017
Rilpivirine / Dolutegravir		PM	Infectious Diseases	ViiV Healthcare UK Limited	10/02/2017	P/0028/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
4-amino-1-[5-chloro-2,5-dideoxy-2-fluoro-3-O-(2-methylpropanoyl)-4-[[(2-methylpropanoyl)oxy]methyl]-α-L-lyxofuranosyl]-2(1H)-pyrimidinone (JNJ-64041575)		PM	Infectious Diseases	Janssen-Cilag International NV	27/01/2017	P/0029/2017
2-hydroxypropyl-ß-cyclodextrin		P	Endocrinology-Gynaecology-Fertility-Metabolism	Vtesse Europe Ltd	31/01/2017	P/0030/2017
Volanesorsen		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Ionis Pharmaceuticals	30/01/2017	P/0031/2017
mirvetuximab soravtansine	Not Available	W	Oncology	ImmunoGen Europe Limited	31/01/2017	P/0032/2017
Autologous CD34+ cells transduced with lentiviral vector encoding the human beta-globin gene	not available at present	P	Haematology-Hemostaseology	Fondazione Telethon	31/01/2017	P/0033/2017
Fc- and CDR-modified humanized monoclonal antibody against C5	not available at present	P	Haematology-Hemostaseology	Alexion Europe SAS	30/01/2017	P/0034/2017
vadadustat	not available at present	P	Haematology-Hemostaseology	Akebia Therapeutics, Inc.	31/01/2017	P/0035/2017
pegvaliase	not available at present	P	Endocrinology-Gynaecology-Fertility-Metabolism	BioMarin International Limited	31/01/2017	P/0036/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Amlodipine besylate	Not available at present	W	Cardiovascular Diseases	Midas Pharma GmbH	31/01/2017	P/0037/2017
ambrisentan	not available at present	P	Cardiovascular Diseases	Glaxo Group Limited	30/01/2017	P/0038/2017
(2-Hydroxyethyl)trimethylammonium 3-[2-fluoro-5-(2,3-difluoro-6-methoxybenzyloxy)-4- methoxyphenyl]-2,4-dioxo-1,2,3,4-tetrahydrothieno[3,4-d]pyrimidine-5-carboxylate	not available at present	W	Endocrinology-Gynaecology-Fertility-Metabolism	ObsEva Ireland Limited	31/01/2017	P/0039/2017
Apolipoprotein A-1 (ApoA-1)	not available at present	W	Cardiovascular Diseases	CSL Behring GmbH	31/01/2017	P/0040/2017
Doxorubicin (hydrochloride)	Not available at present (Doxorubicin Transdrug is used in the interim)	W	Oncology	ONXEO	31/01/2017	P/0041/2017
(1S, 3S, 4R)-4-[(3aS, 4R, 5S,7aS)-4-(aminomethyl)-7a-methyl-1-methylidene-octahydro-1H-inden-5-yl]-3-(hydroxymethyl)-4-methylcyclohexan-1-ol; acetic acid salt	Not available at present	W	Uro-nephrology	Aquinox Pharmaceuticals (Canada) Inc.	30/01/2017	P/0042/2017
Varicella-zoster virus (inactivated)	not available at present	P	Vaccines	Merck Sharp & Dohme (Europe), Inc	31/01/2017	P/0043/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Naldemedine (tosylate)		PM	Gastroenterology-Hepatology	Shionogi Limited	17/02/2017	P/0044/2017
Testosterone		P	Endocrinology-Gynaecology-Fertility-Metabolism	Acerus Pharmaceuticals SRL	17/02/2017	P/0045/2017
Lacosamide	Vimpat	PM	Neurology	UCB Pharma S.A.	17/02/2017	P/0046/2017
Mepolizumab	Nucala	PM	Pneumology - Allergology	GSK Trading Services Limited	17/03/2017	P/0047/2017
Brivaracetam	Briviact	PM	Neurology	UCB Pharma S.A.	23/02/2017	P/0048/2017
Methoxy polyethylene glycol - epoetin beta	Mircera	RPM	Haematology-Hemostaseology	Roche Registration Limited	06/03/2017	P/0049/2017
Fingolimod (hydrochloride)	Gilenya	PM	Neurology	Novartis Europharm Limited	03/04/2017	P/0050/2017
Saxagliptin	Onglyza	PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	17/03/2017	P/0051/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Conestat alfa	Ruconest	PM	Other	Pharming Group N.V.	17/03/2017	P/0052/2017
Anidulafungin	Ecalta	PM	Infectious Diseases	Pfizer Limited	17/03/2017	P/0053/2017
Tofacitinib		PM	Immunology-Rheumatology-Transplantation	Pfizer Limited	17/03/2017	P/0054/2017
Tofacitinib		PM	Dermatology	Pfizer Limited	17/03/2017	P/0055/2017
Mirabegron	Betmiga	PM	Uro-nephrology	Astellas Pharma Europe B.V.	16/03/2017	P/0056/2017
Influenza virus surface antigens - A/turkey/Turkey/1/05 (H5N1)	Aflunov and associated trade names	PM	Vaccines	Seqirus S.r.l.	17/03/2017	P/0057/2017
Fidaxomicin	Dificlir	PM	Infectious Diseases	Astellas Pharma Europe B.V.	17/03/2017	P/0058/2017
Treosulfan		PM	Immunology-Rheumatology-Transplantation Oncology	medac Gesellschaft für klinische Spezialpräparate mbH	17/03/2017	P/0059/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Cobicistat	Tybost	PM	Infectious Diseases	Gilead Sciences International Ltd.	17/03/2017	P/0060/2017
Tafluprost	Taflotan and associated names	PM	Ophthalmology	Santen Oy	17/03/2017	P/0061/2017
Ceftazidime / avibactam	Zavicefta	PM	Infectious Diseases	AstraZeneca AB	17/03/2017	P/0062/2017
Sofosbuvir / ledipasvir	Harvoni	PM	Infectious Diseases	Gilead Sciences International Ltd.	16/03/2017	P/0063/2017
Sirolimus		PM	Ophthalmology	Santen Incorporated	17/03/2017	P/0064/2017
Cobimetinib	Cotellic	PM	Oncology	Roche Registration Limited	17/03/2017	P/0065/2017
Dasabuvir (sodium monohydrate)	Exviera	PM	Infectious Diseases	Abbvie Ltd	17/03/2017	P/0066/2017
Ombitasvir / paritaprevir / ritonavir	Viekirax	PM	Infectious Diseases	Abbvie Ltd	17/03/2017	P/0067/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Somapacitan		W	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	17/03/2017	P/0068/2017
Dupilumab		PM	Dermatology	Regeneron Pharmaceuticals, Inc	03/04/2017	P/0069/2017
Vericiguat		PM	Cardiovascular Diseases	Bayer Pharma AG	17/03/2017	P/0070/2017
Avelumab		P	Oncology	Merck KGaA	17/03/2017	P/0071/2017
5-(4-cyclopropyl-1H-imidazol-1-yl)-2-fluoro-N-(6-(4-isopropyl-4H-1,2,4-triazol-3-yl)pyridi-2-yl)-4-methylbenzamide		W	Gastroenterology-Hepatology	Gilead Sciences International Ltd.	17/03/2017	P/0072/2017
8-chloro-5-methyl-1-[trans-4-(pyridin-2-yloxy)cyclohexyl]-5,6-dihydro-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (RO5285119)		P	Neurology	Roche Registration Ltd	17/03/2017	P/0073/2017
Lamivudine / dolutegravir		P	Infectious Diseases	ViiV Healthcare UK Limited	17/03/2017	P/0074/2017
Recombinant human alpha-glucosidase conjugated with synthetic bismannose-6-phosphate-tetra-mannose glycan (neoGAA)		P	Endocrinology-Gynaecology-Fertility-Metabolism	Genzyme Europe B.V.	17/03/2017	P/0075/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Gadolinium, [α3,α6,α9-tris[3-[(2,3-dihydroxypropyl)amino]-3-oxopropyl]-3,6,9,15-tetraazabicyclo[9.3.1]pentadeca-1(15),11,13-triene-3,6,9-triacetato(3-)-κN3,κN6,κN9,κN15,κO3,κO6,κO9]-(P03277)		P	Diagnostic	GUERBET	17/03/2017	P/0076/2017
Autologous CD34+ hematopoietic stem cells transduced ex vivo with EFS lentiviral vector encoding for the human adenosine deaminase gene		P	Immunology-Rheumatology-Transplantation	Pr Bobby Gaspar	17/03/2017	P/0077/2017
T-lymphocytes enriched leukocyte preparation depleted ex vivo of host host-alloreactive T cells using photodynamic treatment (ATIR101)		P	Immunology-Rheumatology-Transplantation Oncology	Kiadis Pharma Netherlands B.V.	17/03/2017	P/0078/2017
Alpelisib		W	Oncology	Novartis Europharm Ltd	17/03/2017	P/0079/2017
Methylphenidate (hydrochloride)		W	Neurology	Mundipharma Research Limited	16/03/2017	P/0080/2017
Atorvastatin (calcium) / ezetimibe		W	Cardiovascular Diseases	Midas Pharma GmbH	17/03/2017	P/0081/2017
Avacopan		P	Immunology-Rheumatology-Transplantation	ChemoCentryx, Ltd.	22/05/2017	P/0082/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Vigabatrin		PM	Neurology	ORPHELIA Pharma SA	16/03/2017	P/0083/2017
Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein (BMS-986089)		PM	Neurology	Bristol-Myers Squibb International Corporation	16/03/2017	P/0084/2017
Baclofen		W	Psychiatry	Ethypharm	17/03/2017	P/0085/2017
Lumacaftor / ivacaftor	Orkambi	PM	Other	Vertex Pharmaceuticals (Europe) Limited	16/03/2017	P/0086/2017
Talimogene laherparepvec	Imlygic	PM	Oncology	Amgen Europe B.V.	24/03/2017	P/0087/2017
Ceftolozane / tazobactam	Zerbaxa	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	29/03/2017	P/0088/2017
Melatonin	Circadin	PM	Neurology	RAD Neurim Pharmaceuticals EEC Ltd	06/04/2017	P/0089/2017
Letermovir		PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	11/04/2017	P/0090/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Regorafenib	Stivarga	PM	Oncology	Bayer Pharma AG	11/04/2017	P/0091/2017
Posaconazole	Noxafil	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	11/04/2017	P/0092/2017
Telaprevir		PM	Infectious Diseases	Janssen-Cilag International NV	11/04/2017	P/0093/2017
Bempedoic acid (ETC-1002)		P	Cardiovascular Diseases Other	Esperion Therapeutics, Inc.	11/04/2017	P/0094/2017
rVSVΔG-ZEBOV-GP		P	Vaccines	Merck Sharp & Dohme (Europe) Inc.	11/04/2017	P/0095/2017
Oritavancin (diphosphate)	Orbactiv	PM	Dermatology Infectious Diseases	The Medicines Company	11/04/2017	P/0096/2017
Recombinant human N-acetylglucosaminidase (rhNAGLU)		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Alexion Europe SAS	11/04/2017	P/0097/2017
Siponimod (hemifumarate)		PM	Neurology	Novartis Europharm Limited	11/04/2017	P/0098/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Trifarotene		PM	Dermatology	Galderma R&D	11/04/2017	P/0099/2017
Ibrutinib	Imbruvica	PM	Oncology	Janssen-Cilag International N.V.	11/04/2017	P/0100/2017
Evolocumab	Repatha	PM	Cardiovascular Diseases	Amgen Europe B.V.	11/04/2017	P/0101/2017
Ferric maltol	Feraccru	PM	Haematology-Hemostaseology	Shield TX (UK) Limited	11/04/2017	P/0102/2017
Candesartan / amlodipine		W	Cardiovascular Diseases	ERREKAPPA EUROTERAPICI S.p.A.	11/04/2017	P/0103/2017
Entolimod		P	Other	Cleveland BioLabs Inc	11/04/2017	P/0104/2017
Macimorelin		P	Diagnostic Endocrinology-Gynaecology-Fertility-Metabolism	Aeterna Zentaris GmbH	11/04/2017	P/0105/2017
Human fibrinogen concentrate (BT524)		P	Haematology-Hemostaseology	Biotest AG	11/04/2017	P/0106/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Lenvatinib	LENVIMA Kisplyx	PM	Oncology	Eisai Europe Ltd	11/04/2017	P/0107/2017
Oseltamivir (phosphate)	Tamiflu	PM	Infectious Diseases	Roche Registration Limited	11/04/2017	P/0108/2017
Ustekinumab	Stelara	PM	Immunology-Rheumatology-Transplantation	Janssen-Cilag International NV	11/04/2017	P/0109/2017
Amlodipine / perindopril		W	Cardiovascular Diseases	CIPROS S.r.l.	11/04/2017	P/0110/2017
Prasugrel (hydrochloride) / acetylsalicylic acid		W	Cardiovascular Diseases	Daiichi Sankyo Europe GmbH	11/04/2017	P/0111/2017
Olodaterol (hydrochloride)	Striverdi Respimat	P	Pneumology - Allergology	Boehringer Ingelheim International GmbH	11/04/2017	P/0112/2017
Rituximab	MabThera	PM	Immunology-Rheumatology-Transplantation Oncology	Roche Registration Limited	11/04/2017	P/0113/2017
Tobramycin	TOBI Podhaler	W	Infectious Diseases	Novartis Europharm Limited	11/04/2017	P/0114/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Doravirine		PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	21/04/2017	P/0115/2017
Doravirine / lamivudine / tenofovir disoproxil (fumarate)		PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	28/04/2017	P/0116/2017
3,6-diamino-2,5-bis{N-[(1R)-1-carboxy-2-hydroxyethyl]carbamoyl}pyrazine (MB-102)		P	Diagnostic Uro-nephrology	MediBeacon Inc.	05/05/2017	P/0117/2017
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)		PM	Infectious Diseases	Janssen-Cilag International NV	05/05/2017	P/0118/2017
Mepolizumab	Nucala	W	Pneumology - Allergology	GSK Trading Services Limited	05/05/2017	P/0119/2017
Tapentadol (hydrochloride)	Palexia and associated names Yantil and associated names Tapentadol and associated names	PM	Pain	Grünenthal GmbH	05/05/2017	P/0120/2017
Recombinant modified human growth hormone		RP	Endocrinology-Gynaecology-Fertility-Metabolism	Richardson Associates Regulatory Affairs Ltd	05/05/2017	P/0121/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Small interfering RNA targeting human TRPV1 mRNA		W	Ophthalmology	Sylentis SAU	05/05/2017	P/0122/2017
Dopamine		P	Cardiovascular Diseases	BrePco Biopharma Limited	05/05/2017	P/0123/2017
Nintedanib	Vargatef Ofev	W	Oncology	Boehringer Ingelheim International GmbH	05/05/2017	P/0124/2017
Ramipril / indapamide		W	Cardiovascular Diseases	Pharmaceutical Works Polpharma SA	05/05/2017	P/0125/2017
Erdafitinib		W	Oncology	Janssen-Cilag International N.V	05/05/2017	P/0126/2017
Ponatinib	Iclusig	PM	Oncology	Incyte Biosciences UK Ltd.	05/05/2017	P/0127/2017
Cinacalcet (hydrochloride)	Mimpara	PM	Uro-nephrology	Amgen Europe B.V.	12/05/2017	P/0128/2017
Split influenza virus, inactivated containing antigens equivalent to the B-like strain (B/Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (B/Victoria	Vaxigrip Tetra	PM	Vaccines	Sanofi Pasteur	08/05/2017	P/0129/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
lineage) / Split influenza virus, inactivated (B/Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain						
Rosuvastatin (calcium) / Ezetimibe		W	Cardiovascular Diseases	Neopharmed Gentili S.r.l	07/06/2017	P/0130/2017
Buprenorphine (hydrochloride)		W	Psychiatry	Titan Pharmaceuticals Inc.	07/06/2017	P/0131/2017
Nimodipine		W	Neurology	Edge Therapeutics, Inc.	07/06/2017	P/0132/2017
Soybean oil / Medium-chain triglycerides / Olive oil / Fish oil / Acetyl-cysteine / Alanine / Arginine / Glycine / Histidine / Isoleucin / Leucine / Lysine acetate / Methionine / Phenylalanine / Proline / Serine / Threonine / Tryptophan / Tyrosine / Valine / Glucose / Calcium chloride / Sodium glycerophosphate / Magnesium sulphate / Potassium chloride / Sodium acetate / Zinc sulphate / Malic acid		W	Nutrition	Fresenius Kabi Deutschland GmbH	07/06/2017	P/0133/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Polihexanide (PHMB)		W	Ophthalmology	Società Industria Farmaceutica Italiana (S.I.F.I.) SpA	07/06/2017	P/0134/2017
Pimodivir		P	Infectious Diseases	Janssen-Cilag International NV	07/06/2017	P/0135/2017
Cannabidiol		P	Neurology	GW Research Ltd	07/06/2017	P/0136/2017
Rimiducid		P	Immunology-Rheumatology-Transplantation	Bellicum Pharma Ltd.	07/06/2017	P/0137/2017
Expanded donor-derived allogenic T cells transduced with the retroviral vector expressing the transgenes for inducible caspase9 and the truncated CD19 selectable marker (BPX-501)		P	Immunology-Rheumatology-Transplantation	Bellicum Pharma Ltd.	07/06/2017	P/0138/2017
Olaratumab	Lartruvo	PM	Oncology	Eli Lilly and Company Limited	07/06/2017	P/0139/2017
Enalapril (maleate)		PM	Cardiovascular Diseases	Ethicare GmbH	07/06/2017	P/0140/2017
Indacaterol (acetate) / mometasone (furoate)		PM	Pneumology - Allergology	Novartis Europharm Limited	07/06/2017	P/0141/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Turoctocog alfa pegol		PM	Haematology-Hemostaseology	Novo Nordisk A/S	07/06/2017	P/0142/2017
Laquinimod (sodium)		W	Neurology	Teva GmbH	07/06/2017	P/0143/2017
Rubidium (82Rb) chloride	Ruby-Fill (82Sr/82Rb Generator)	PM	Diagnostic	Jubilant DraxImage Inc.	07/06/2017	P/0144/2017
Apremilast	Otezla	PM	Dermatology	Celgene Europe Limited	07/06/2017	P/0145/2017
Vedolizumab	Entyvio	PM	Gastroenterology-Hepatology	Takeda Pharma A/S	07/06/2017	P/0146/2017
Ivacaftor	Kalydeco	PM	Other	Vertex Pharmaceuticals (Europe) Limited	07/06/2017	P/0147/2017
Tapentadol (hydrochloride)	Palexia, Yantil, Tapentadol and associated names	PM	Pain	Grünenthal GmbH	07/06/2017	P/0148/2017
Human recombinant IgG1 monoclonal antibody targeting fibroblast growth factor 23 (KRN23)		PM	Other	Ultragenyx Pharmaceutical Inc.	07/06/2017	P/0149/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Sirukumab		PM	Immunology-Rheumatology-Transplantation	Janssen-Cilag International NV	09/06/2017	P/0150/2017
Isavuconazonium (sulfate)	Cresemba	PM	Infectious Diseases	Basilea Pharmaceutica International Ltd.	07/06/2017	P/0151/2017
Telbivudine	Sebivo	PM	Gastroenterology-Hepatology	Novartis Europharm Limited	07/06/2017	P/0152/2017
Lacosamide	Vimpat	P	Neurology	UCB Pharma S.A.	02/06/2017	P/0153/2017
Lacosamide	Vimpat	PM	Neurology	UCB Pharma S.A.	02/06/2017	P/0154/2017
Mexiletine (hydrochloride)		P	Other	Lupin (Europe) Ltd.	02/06/2017	P/0155/2017
Fluocinolone acetonide		P	Ophthalmology	CAMPHARM Limited	08/06/2017	P/0156/2017
Fluticasone (furoate) / vilanterol	Relvar Ellipta and associated names	PM	Pneumology - Allergology	Glaxo Group Limited	09/06/2017	P/0157/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Apremilast	Otezla	PM	Immunology-Rheumatology-Transplantation	Celgene Europe Limited	29/06/2017	P/0158/2017
Ibuprofen / pseudoephedrine		W	Infectious Diseases	Farmalider, S.A.	30/06/2017	P/0159/2017
Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human ARSA cDNA sequence (GSK2696274)		PM	Other	GlaxoSmithKline Trading Services Limited	30/06/2017	P/0160/2017
Ozanimod		PM	Neurology	Celgene Europe Limited	30/06/2017	P/0161/2017
Empagliflozin	Jardiance	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	30/06/2017	P/0162/2017
Pazopanib	Votrient	PM	Oncology	Novartis Europharm Limited	30/06/2017	P/0163/2017
Ferric maltol	Feraccru	PM	Haematology-Hemostaseology	Shield TX (UK) Limited	03/07/2017	P/0164/2017
Teriflunomide	Aubagio	PM	Neurology	Genzyme Europe B.V. / Sanofi-Aventis groupe	03/07/2017	P/0165/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Aciclovir	Sitavig and associated names	PM	Infectious Diseases	ONXEO	03/07/2017	P/0166/2017
Dimethyl fumarate	Tecfidera	PM	Neurology	Biogen Idec Ltd	30/06/2017	P/0167/2017
Omadacycline		PM	Infectious Diseases	Paratek UK Limited	03/07/2017	P/0168/2017
Omadacycline		PM	Infectious Diseases	Paratek UK Limited	03/07/2017	P/0169/2017
Ticagrelor	Brilique	PM	Cardiovascular Diseases	AstraZeneca AB	03/07/2017	P/0170/2017
Methoxyflurane	Penthrox	PM	Pain	Medical Developments UK Ltd	03/07/2017	P/0171/2017
Cysteamine (hydrochloride)	Cystadrops	PM	Ophthalmology	Orphan Europe SARL	31/07/2017	P/0172/2017
Colistimethate sodium	Colobreathe	PM	Infectious Diseases	TEVA B.V.	03/07/2017	P/0173/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Miridesap		W	Haematology-Hemostaseology	GlaxoSmithKline Trading Services Limited	03/07/2017	P/0174/2017
Dezamizumab		W	Cardiovascular Diseases	GlaxoSmithKline Trading Services Limited	03/07/2017	P/0175/2017
Dezamizumab		W	Haematology-Hemostaseology	GlaxoSmithKline Trading Services Limited	03/07/2017	P/0176/2017
Olmesartan medoxomil / amlodipine (besilate) / hydrochlorothiazide		W	Cardiovascular Diseases	Accord Healthcare, S.L.U.	03/07/2017	P/0177/2017
Radium Ra223 dichloride	Xofigo	W	Oncology	Bayer AG	03/07/2017	P/0178/2017
Larotrectinib		P	Oncology	Loxo Oncology, Inc.	03/07/2017	P/0179/2017
Live, attenuated, chimeric dengue virus, serotype 1 / live, attenuated dengue virus, serotype 2 / live, attenuated, chimeric dengue virus, serotype 3 / live attenuated, chimeric dengue virus, serotype 4		P	Vaccines	Takeda Vaccines, Inc.	03/07/2017	P/0180/2017
Atazanavir / cobicistat	Evotaz	PM	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	30/06/2017	P/0181/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Dobutamine		PM	Cardiovascular Diseases	Proveca Limited	03/07/2017	P/0182/2017
Lonoctocog alfa	Afstyla	PM	Haematology-Hemostaseology	CSL Behring GmbH	03/07/2017	P/0183/2017
Econazole (nitrate) / benzydamine (hydrochloride)		W	Endocrinology-Gynaecology-Fertility-Metabolism	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	30/06/2017	P/0184/2017
Rosuvastatin (calcium) / ezetimibe		W	Cardiovascular Diseases	BENEDETTI & Co. S.r.l.	30/06/2017	P/0185/2017
Rosuvastatin (calcium) / ezetimibe		W	Cardiovascular Diseases	Errekappa Euroterapici S.p.A.	30/06/2017	P/0186/2017
Miridesap		W	Cardiovascular Diseases	GlaxoSmithKline Trading Services Limited	03/07/2017	P/0187/2017
Rosuvastatin / amlodipine		W	Cardiovascular Diseases	ERREKAPPA EUROTERAPICI S.p.A.	03/07/2017	P/0188/2017
Rosuvastatin / amlodipine		W	Cardiovascular Diseases	CIPROS S.R.L.	03/07/2017	P/0189/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Sofosbuvir / velpatasvir	Epclusa	PM	Infectious Diseases	Gilead Sciences International Ltd.	03/07/2017	P/0190/2017
Abacavir / lamivudine / efavirenz		W	Infectious Diseases	Lek Pharmaceuticals d.d.	30/06/2017	P/0191/2017
Certolizumab pegol	Cimzia	W	Immunology-Rheumatology-Transplantation	UCB Pharma S.A.	03/07/2017	P/0192/2017
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		PM	Pneumology - Allergology	Vertex Pharamceuticals (Europe) lTd	03/07/2017	P/0193/2017
Rivaroxaban	Xarelto	PM	Cardiovascular Diseases	Bayer Pharma AG	03/07/2017	P/0194/2017
Damoctocog alfa pegol		PM	Haematology-Hemostaseology	Bayer AG	10/07/2017	P/0195/2017
Apixaban	Eliquis	PM	Cardiovascular Diseases	Bristol-Myers Squibb / Pfizer EEIG	14/07/2017	P/0196/2017
Treosulfan		PM	Immunology-Rheumatology-Transplantation	medac Gesellschaft für klinische Spezialpräparate	14/07/2017	P/0197/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
				mbH		
Lumacaftor / ivacaftor	Orkambi	PM	Other	Vertex Pharmaceuticals (Europe) Limited	14/07/2017	P/0198/2017
Fc- and CDR-modified humanised monoclonal antibody against C5		P	Haematology-Hemostaseology	Alexion Europe SAS	14/07/2017	P/0199/2017
Liposomal combination of cytarabine and daunorubicin		P	Oncology	Jazz Pharmaceuticals Ireland Limited	21/07/2017	P/0200/2017
Pexastimogene devacirepvec		W	Oncology	Transgene S.A.	14/07/2017	P/0201/2017
Methacholine chloride	Provocholine	W	Diagnostic	MWK Healthcare Ltd	09/08/2017	P/0202/2017
Diclofenac (sodium)	Pennsaid	W	Pain	Dimethaid (UK) Limited	09/08/2017	P/0203/2017
Asfotase alfa		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Alexion Europe SAS	09/08/2017	P/0204/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Canagliflozin	Invokana	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Janssen-Cilag International NV	09/08/2017	P/0205/2017
Semaglutide		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk	09/08/2017	P/0206/2017
Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin (rVIIa-FP; CSL689)		PM	Haematology-Hemostaseology	CSL Behring GmbH	09/08/2017	P/0207/2017
H-Tyr-Gly-Arg-Lys-Lys-Arg-Arg-Gln-Arg-Arg-Arg-Lys-Leu-Ser-Ser-Ile-Glu-Ser-Asp-Val-OH (YGRKKRRQRRRKLSSIESDV)		W	Neurology	NoNO Inc.	09/08/2017	P/0208/2017
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 (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) [QIVc]		P	Vaccines	Seqirus UK Limited	09/08/2017	P/0209/2017
Sotagliflozin		PM	Endocrinology-Gynaecology-Fertility-Metabolism	sanofi-aventis R&D	09/08/2017	P/0210/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide	Genvoya	PM	Infectious Diseases	Gilead Sciences International Ltd.	09/08/2017	P/0211/2017
Zanamivir	Relenza	PM	Infectious Diseases	GlaxoSmithKline Trading Services Limited	09/08/2017	P/0212/2017
Obeticholic acid (6 alpha-ethylchenodeoxycholic acid)	Ocaliva	PM	Gastroenterology-Hepatology	Intercept Pharma Ltd.	09/08/2017	P/0213/2017
Coagulation Factor VIIa (Recombinant)		PM	Haematology-Hemostaseology	LFB SA	09/08/2017	P/0214/2017
Macitentan	Opsumit	W	Cardiovascular Diseases	Actelion Registration Ltd.	09/08/2017	P/0215/2017
Empagliflozin	Jardiance	W	Cardiovascular Diseases Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	09/08/2017	P/0216/2017
Tocilizumab	RoActemra	P	Immunology-Rheumatology-Transplantation	Roche Registration Limited	09/08/2017	P/0217/2017
Liraglutide	Victoza	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	09/08/2017	P/0218/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Luspatercept		PM	Haematology-Hemostaseology	Celgene Europe Ltd	09/08/2017	P/0219/2017
DaxibotulinumtoxinA		W	Other	Revance Therapeutics Inc	09/08/2017	P/0220/2017
5, 7-dihydroxy-2-[3-hydroxy-4-methoxy-2-(2-methyl-2-propenyl) phenyl]-6, 8-bis (2-methyl-2-propenyl)-4H-chromen-4-one		W	Cardiovascular Diseases	Ilkos Therapeutic Inc	11/08/2017	P/0221/2017
Osimertinib (as mesylate)	Tagrisso	W	Oncology	AstraZeneca AB	09/08/2017	P/0222/2017
Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin (rVIIa-FP; CSL689)		PM	Haematology-Hemostaseology	CSL Behring GmbH	11/08/2017	P/0223/2017
Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein (BMS-986089)		PM	Neurology	Roche Registration Ltd	11/08/2017	P/0224/2017
Allantoin		PM	Dermatology	Scioderm, Inc.	11/08/2017	P/0225/2017
Sodium zirconium cyclosilicate	Lokelma	PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	11/08/2017	P/0226/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Sotagliflozin		PM	Endocrinology-Gynaecology-Fertility-Metabolism	sanofi-aventis R&D	09/08/2017	P/0227/2017
Recombinant varicella zoster virus (VZV) glycoprotein E		PM	Vaccines	GlaxoSmithKline Biologicals SA	09/08/2017	P/0228/2017
Dolutegravir / abacavir / lamivudine	Triumeq	PM	Infectious Diseases	ViiV Healthcare UK Limited	09/08/2017	P/0229/2017
Recombinant fusion protein linking human coagulation factor IX with human albumin	Albutrepenonacog alfa	PM	Haematology-Hemostaseology	CSL Behring GmbH	09/08/2017	P/0230/2017
Chlorhexidine gluconate / isopropyl alcohol		RPM	Other	3M Health Care Limited	11/08/2017	P/0231/2017
Brentuximab vedotin	Adcetris	PM	Oncology	Takeda Pharma A/S	11/08/2017	P/0232/2017
Romiplostim	Nplate	PM	Haematology-Hemostaseology	Amgen Europe B.V.	11/08/2017	P/0233/2017
Decitabine	Dacogen	PM	Oncology	Janssen-Cilag International NV	09/08/2017	P/0234/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Venetoclax	Venclyxto	P	Haematology-Hemostaseology Oncology	AbbVie Ltd	09/08/2017	P/0235/2017
Recombinant humanized anti-alpha-synuclein IgG1 monoclonal antibody		W	Neurology	Roche Registration Limited	09/08/2017	P/0236/2017
Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor		P	Oncology	Kite Pharma EU B.V.	09/08/2017	P/0237/2017
Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor		P	Oncology	Kite Pharma EU B.V.	09/08/2017	P/0238/2017
Mepolizumab	Nucala	PM	Pneumology - Allergology	GlaxoSmithKline Trading Services	11/08/2017	P/0239/2017
Brivaracetam	Briviact	PM	Neurology	UCB Pharma S.A.	11/08/2017	P/0240/2017
Lefamulin		P	Infectious Diseases	Nabriva Therapeutics AG	04/09/2017	P/0241/2017
Tilmanocept	Lymphoseek	PM	Diagnostic Oncology	Norgine BV	04/09/2017	P/0242/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Fidaxomicin	Dificlir	PM	Infectious Diseases	Astellas Pharma Europe B.V.	04/09/2017	P/0243/2017
Exenatide	Bydureon, Byetta	PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	04/09/2017	P/0244/2017
Salmeterol (xinafoate) / fluticasone (propionate)		W	Pneumology - Allergology	Teva Pharmaceuticals Europe B.V.	04/09/2017	P/0245/2017
Human normal immunoglobulin		W	Immunology-Rheumatology-Transplantation Haematology-Hemostaseology	Kedrion S.p.A.	04/09/2017	P/0246/2017
Litoxetine (benzoate)		W	Uro-nephrology	Ixaltis SA	04/09/2017	P/0247/2017
Human normal immunoglobulin		W	Immunology-Rheumatology-Transplantation	Biotest AG	04/09/2017	P/0248/2017
Atacicept		P	Immunology-Rheumatology-Transplantation	Merck KGaA	05/09/2017	P/0249/2017
Human normal immunoglobulin		W	Immunology-Rheumatology-Transplantation	ProMetic BioTherapeutics Ltd	08/09/2017	P/0250/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Fenfluramine (hydrochloride)		P	Neurology	Zogenix International Ltd	08/09/2017	P/0251/2017
Selonsertib		P	Gastroenterology-Hepatology	Gilead Sciences International Ltd.	04/09/2017	P/0252/2017
Darunavir / cobicistat / emtricitabine / tenofovir alafenamide		PM	Infectious Diseases	Janssen-Cilag International NV	04/09/2017	P/0253/2017
Burosumab		W	Other	Ultragenyx Pharmaceutical Inc.	08/09/2017	P/0254/2017
Grazoprevir / elbasvir	Zepatier	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	04/09/2017	P/0255/2017
Darunavir / cobicistat	Rezolsta	PM	Infectious Diseases	Janssen-Cilag International NV	04/09/2017	P/0256/2017
Lurasidone (hydrochloride)	Latuda	RP	Psychiatry	Sunovion Pharmaceuticals Ltd.	04/09/2017	P/0257/2017
Human fibrinogen		PM	Haematology-Hemostaseology	Octapharma Pharmazeutika Produktionsges. m. b. H	04/09/2017	P/0258/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Trametinib (dimethyl sulfoxide)	Mekinist	PM	Oncology	Novartis Europharm Limited	04/09/2017	P/0259/2017
Dabrafenib (mesilate)	Tafinlar	PM	Oncology	Novartis Europharm Limited	04/09/2017	P/0260/2017
Lipegfilgrastim	Lonquex	PM	Oncology	UAB ”Sicor Biotech“	04/09/2017	P/0261/2017
Tenofovir (disoproxil fumarate)	Viread	PM	Infectious Diseases	Gilead Sciences International Ltd	04/09/2017	P/0262/2017
Sunitinib	Sutent	PM	Oncology	Pfizer Limited	04/09/2017	P/0263/2017
Daratumumab	Darzalex	W	Oncology	Janssen-Cilag International N.V.	04/09/2017	P/0264/2017
Fluticasone (propionate)		W	Pneumology - Allergology	Teva Pharmaceuticals Europe B.V.	04/09/2017	P/0265/2017
Autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD19 (CTL019)		P	Oncology	Novartis Europharm Limited	04/09/2017	P/0266/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
L-asparaginase encapsulated in erythrocytes		PM	Oncology	ERYTECH pharma S.A.	04/09/2017	P/0267/2017
Avacopan		PM	Immunology-Rheumatology-Transplantation	ChemoCentryx, Ltd.	07/09/2017	P/0268/2017
Alirocumab	Praluent	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Sanofi-aventis Recherche & Developpement	04/09/2017	P/0269/2017
Autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD19 (CTL019)		PM	Oncology	Novartis Europharm Limited	22/09/2017	P/0270/2017
Angiotensin II (LJPC-501)		P	Other	La Jolla Pharmaceutical II B.V.	04/10/2017	P/0271/2017
Recombinant human monoclonal antibody to GM-CSF (GSK3196165)		P	Immunology-Rheumatology-Transplantation	GlaxoSmithKline Trading Services Limited	04/10/2017	P/0272/2017
Filgotinib		P	Immunology-Rheumatology-Transplantation	Gilead Sciences International Ltd.	04/10/2017	P/0273/2017
Tenofovir alafenamide (as fumarate)	Vemlidy	PM	Infectious Diseases	Gilead Sciences International Ltd.	04/10/2017	P/0274/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Roxadustat		PM	Haematology-Hemostaseology	Astellas Pharma Europe B.V.	04/10/2017	P/0275/2017
Human fibrinogen / human thrombin	Raplixa	PM	Haematology-Hemostaseology	Mallinckrodt Pharmaceuticals Ireland Ltd	04/10/2017	P/0276/2017
Ceftolozane / tazobactam	Zerbaxa	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	04/10/2017	P/0277/2017
Japanese encephalitis vaccine (inactivated, adsorbed)	Ixiaro	PM	Vaccines	Valneva Austria GmbH	04/10/2017	P/0278/2017
Lenalidomide	Revlimid	W	Oncology	Celgene Europe Limited	04/10/2017	P/0279/2017
Eltrombopag	Revolade	PM	Haematology-Hemostaseology	Novartis Europharm Limited	04/10/2017	P/0280/2017
Netarsudil / Latanoprost		W	Ophthalmology	Aerie Pharmaceuticals Ireland Ltd	04/10/2017	P/0281/2017
Ramucirumab	Cyramza	W	Oncology	Eli Lilly and Company Limited	04/10/2017	P/0282/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
(Z)-N-(3-bromo-4-fluorophenyl)-N'-hydroxy-4-(2-(sulfamoylamino)ethylamino)-1,2,5-oxadiazole-3-carboximidamide		P	Oncology	Incyte Corporation	04/10/2017	P/0283/2017
Pyridopyrimidione SMN2 splicing modifier		P	Neurology	Roche Registration Limited	04/10/2017	P/0284/2017
Entospletinib		P	Oncology	Gilead Sciences International Ltd	04/10/2017	P/0285/2017
5-(4-Fluoro-1-benzothiophen-2-yl)-8-methyl-1,9-dihydro-2H-[1,3]oxazolo[4,5-H][2,3]benzodiazepin-2-one (S44819)		P	Neurology	Les Laboratoires Servier	04/10/2017	P/0286/2017
Autologous CD4+ and CD8+ T cells expressing a CD19-specific chimeric antigen receptor (JCAR017)		P	Oncology	Celgene Europe Limited	04/10/2017	P/0287/2017
Benralizumab		W	Oto-rhino-laryngology	AstraZeneca AB	04/10/2017	P/0288/2017
Phenyl- and piperidin-containing derivative of amiloride (BI 443651)		P	Pneumology - Allergology	Boehringer Ingelheim International GmbH	04/10/2017	P/0289/2017
Bisoprolol (fumarate) / perindopril arginine / amlodipine		W	Cardiovascular Diseases	Les Laboratoires Servier	04/10/2017	P/0290/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Amlodipine (besylate) / candesartan (cilexetil) / hydrochlorothiazide		W	Cardiovascular Diseases	Zentiva, k.s.	04/10/2017	P/0291/2017
Naloxegol	Moventig	PM	Gastroenterology-Hepatology	Kyowa Kirin Pharmaceutical Development Limited	04/10/2017	P/0292/2017
Enasidenib		P	Oncology	Celgene Europe Ltd	04/10/2017	P/0293/2017
Influenza virus surface antigens (haemagglutinin) of strain A (H1N1) / influenza virus surface antigens (haemagglutinin) of strain A (H3N2) / influenza virus surface antigens (haemagglutinin) of strain B (Victoria lineage) / influenza virus surface antigens (haemagglutinin) of strain B (Yamagata lineage)		P	Infectious Diseases	Adimmune Corporation	04/10/2017	P/0294/2017
Entolimod		PM	Other	Cleveland Biolabs, Inc	29/09/2017	P/0295/2017
Tofacitinib	Xeljanz	PM	Immunology-Rheumatology-Transplantation	Pfizer Limited	04/10/2017	P/0296/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Ibrutinib	IMBRUVICA	W	Oncology	Janssen-Cilag International N.V.	04/10/2017	P/0297/2017
Ibrutinib	IMBRUVICA	W	Oncology	Janssen-Cilag International N.V.	04/10/2017	P/0298/2017
Liposomal combination of cytarabine and daunorubicin		PM	Oncology	Jazz Pharmaceuticals Ireland Limited	04/10/2017	P/0299/2017
Guselkumab		PM	Immunology-Rheumatology-Transplantation	Janssen Cilag International NV	04/10/2017	P/0300/2017
Dabigatran etexilate mesilate	Pradaxa	PM	Cardiovascular Diseases Haematology-Hemostaseology	Boehringer Ingelheim International GmbH	06/10/2017	P/0301/2017
Dapagliflozin	Forxiga	PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	12/10/2017	P/0302/2017
1H-Isoindol-1-one,2-[[1-[2-(4-fluorophenyl)-2-oxoethyl]-4-piperidinyl]methyl]-2,3-dihydro-,hydrochloride, hydrate (1:1:2) (MIN-101)		PR	Psychiatry	Minerva Neurosciences, Inc.	08/11/2017	P/0303/2017
Meldonium dihydrate		W	Cardiovascular Diseases	ELC GROUP s.r.o., Karolinská	31/10/2017	P/0304/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Capmatinib		W	Oncology	Novartis Europharm Ltd	30/10/2017	P/0305/2017
(2S)-2-{[(2R)-2-[({[3,3-dibutyl-7-(methylthio)-1,1-dioxido-5-phenyl-2,3,4,5-tetrahydro-1,2,5-benzothiadiazepin-8-l]oxy}acetyl)amino]-2-(4-hydroxyphenyl)acetyl]amino}butanoic acid (A4250)		P	Gastroenterology-Hepatology	Albireo AB	31/10/2017	P/0306/2017
Andexanet alfa		PM	Other	Portola Pharma UK Limited	30/10/2017	P/0307/2017
Fremanezumab		PM	Neurology	Teva GmbH	31/10/2017	P/0308/2017
Acalabrutinib		PM	Oncology	ACERTA PHARMA, BV	30/10/2017	P/0309/2017
Erenumab		PM	Neurology	Novartis Europharm Limited	31/10/2017	P/0310/2017
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		PM	Pneumology - Allergology	Vertex Pharmaceuticals (Europe) Ltd.	31/10/2017	P/0311/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Cabotegravir		PM	Infectious Diseases	ViiV Healthcare UK Limited	30/10/2017	P/0312/2017
Febuxostat	Adenuric	PM	Oncology	Menarini International Operations Luxembourg S.A.	30/10/2017	P/0313/2017
Ceftazidime / avibactam	Zavicefta	PM	Infectious Diseases	Pfizer Limited	31/10/2017	P/0314/2017
Maribavir		PM	Infectious Diseases	Shire Pharmaceuticals Ireland Limited	31/10/2017	P/0315/2017
Everolimus	Votubia	PM	Neurology, Uro-nephrology	Novartis Europharm Limited	31/10/2017	P/0316/2017
Methoxy polyethylene glycol - epoetin beta	Mircera	PM	Haematology-Hemostaseology	Roche Registration Limited	31/10/2017	P/0317/2017
Tapentadol	Palexia and associated names Yantil and associated names Tapentadol and associated names	PM	Pain	Grünenthal GmbH	31/10/2017	P/0318/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Veliparib		W	Oncology	AbbVie Ltd	31/10/2017	P/0319/2017
Beclometasone (dipropionate) / formoterol (fumarate dihydrate)	Foster and associated names Kantos and associated names Inuvair and associated names Kantos Master and associated names	PM	Pneumology - Allergology	Chiesi Farmaceutici S.p.A.	31/10/2017	P/0320/2017
Tralokinumab		PM	Pneumology - Allergology	MedImmune Ltd	31/10/2017	P/0321/2017
Edoxaban (tosylate)	Lixiana	PM	Cardiovascular Diseases Haematology-Hemostaseology	Daiichi Sankyo Europe GmbH	31/10/2017	P/0322/2017
Eculizumab	Soliris	PM	Immunology-Rheumatology-Transplantation	Alexion Europe SAS	31/10/2017	P/0323/2017
Recombinant Human A Disintegrin and Metalloprotease with Thrombospondin Type-1 Motifs 13		PM	Haematology-Hemostaseology	Baxalta Innovations GmbH	31/10/2017	P/0324/2017
Active substance(s): Recombinant parathyroid hormone	Natpar	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Shire Pharmaceuticals Ireland Limited	31/10/2017	P/0325/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Gemtuzumab ozogamicin		PM	Oncology	Pfizer Limited	31/10/2017	P/0326/2017
Domagrozumab		PM	Neurology	Pfizer Limited	31/10/2017	P/0327/2017
Influenza virus surface antigens (haemagglutinin and neuraminidase) of the following strains: A/(H1N1), A/(H3N2), B/Yamagata lineage, B/Victoria lineage		PM	Vaccines	Abbott Biologicals B.V.	31/10/2017	P/0328/2017
Ligelizumab		P	Dermatology	Novartis Europharm Ltd.	30/10/2017	P/0329/2017
Lactobacillus reuteri (IBP-9414)		P	Gastroenterology-Hepatology Neonatology - Paediatric Intensive Care Other	Infant Bacterial Therapeutics AB	31/10/2017	P/0330/2017
Autologous CD34+ hematopoietic stem cells transduced ex vivo with EFS lentiviral vector encoding for the human adenosine deaminase gene		PM	Immunology-Rheumatology-Transplantation	Pr Bobby Gaspar	31/10/2017	P/0331/2017
Amlodipine / irbesartan / hydrochlorothiazide		W	Cardiovascular Diseases	Win Medica S.A.,	31/10/2017	P/0332/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Pilocarpine (hydrochloride) / Oxymetazoline (hydrochloride)		W	Ophthalmology	Allergan Pharmaceuticals International Limited	31/10/2017	P/0333/2017
Bempedoic acid / ezetimibe		W	Cardiovascular Diseases	Esperion Therapeutics, Inc.	31/10/2017	P/0334/2017
Rosuvastatin / ezetimibe		W	Cardiovascular Diseases Endocrinology-Gynaecology-Fertility-Metabolism	Krka, d.d., Novo mesto	31/10/2017	P/0335/2017
Lacosamide	Vimpat	PM	Neurology	UCB Pharma S.A.	30/10/2017	P/0336/2017
Sotagliflozin		PM	Endocrinology-Gynaecology-Fertility-Metabolism	sanofi-aventis R&D	30/10/2017	P/0337/2017
Crisaborole		P	Dermatology	Pfizer Ltd	10/11/2017	P/0338/2017
pneumococcal polysaccharide serotype 1 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 3 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 4 – diphtheria CRM197 conjugate / pneumococcal		P	Vaccines	Merck Sharp & Dohme (Europe), Inc.	10/11/2017	P/0339/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
polysaccharide serotype 5 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 6A – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 6B – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 7F – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 9V – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 14 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 18C – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 19A – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 19F – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 22F – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 23F – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 33F – diphtheria CRM197 conjugate (15-valent pneumococcal polysaccharide conjugate vaccine [V114])						

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Bumetanide		PM	Neurology	Les Laboratoires Servier	10/11/2017	P/0340/2017
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 (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) [QIVc]		PM	Vaccines	Seqirus UK Limited	16/11/2017	P/0341/2017
Adalimumab	Humira	PM	Dermatology Gastroenterology-Hepatology Immunology-Rheumatology-Transplantation Ophthalmology	AbbVie Limited	10/11/2017	P/0342/2017
Risankizumab			Immunology-Rheumatology-Transplantation	AbbVie Ltd	23/11/2017	P/0343/2017
Avacopan		PM	Immunology-Rheumatology-Transplantation	ChemoCentryx, Ltd.	23/11/2017	P/0344/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Ozanimod		PM	Neurology	Celgene Europe Limited	23/11/2017	P/0345/2017
Thrombomodulin alfa		PM	Infectious Diseases	Asahi Kasei Pharma America Corporation	01/12/2017	P/0346/2017
Tolvaptan	Samsca and associated names	RPM	Endocrinology-Gynaecology-Fertility-Metabolism	Otsuka Pharmaceutical Europe Ltd.	01/12/2017	P/0347/2017
sarilumab	Kevzara	PM	Immunology-Rheumatology-Transplantation	sanofi-aventis recherche et développement	01/12/2017	P/0348/2017
Ruxolitinib (phosphate)	Jakavi	W	Oncology	Novartis Europharm Limited	01/12/2017	P/0349/2017
Mirabegron	Betmiga	RPM	Uro-nephrology	Astellas Pharma Europe B.V.	01/12/2017	P/0350/2017
Teduglutide	Revestive	PM	Gastroenterology-Hepatology	Shire Pharmaceuticals Ireland Limited	01/12/2017	P/0351/2017
Secukinumab	Cosentyx	PM	Immunology-Rheumatology-Transplantation	Novartis Europharm Ltd	01/12/2017	P/0352/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Lubiprostone	Amitiza	PM	Gastroenterology-Hepatology	Sucampo AG	01/12/2017	P/0353/2017
Telavancin (hydrochloride)	Vibativ	PM	Infectious Diseases	Theravance Biopharma Ireland Ltd.	01/12/2017	P/0354/2017
Tapentadol (hydrochloride)	Palexia and associated names Yantil and associated names Tapentadol and associated names	PM	Pain	Grünenthal GmbH	01/12/2017	P/0355/2017
Fc- and CDR-modified humanised monoclonal antibody against C5		PM	Haematology-Hemostaseology	Alexion Europe SAS	01/12/2017	P/0356/2017
Allopregnanolone		P	Psychiatry	Sage Therapeutics Inc	01/12/2017	P/0357/2017
Emapalumab		P	Immunology-Rheumatology-Transplantation	Novimmune B.V	01/12/2017	P/0358/2017
Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus		P	Vaccines	Sanofi Pasteur Inc.	01/12/2017	P/0359/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid (MenACYW)						
Avelumab	Bavencio	PM	Oncology	Merck KGaA	01/12/2017	P/0361/2017
Lumicitabine		PM	Infectious Diseases	Janssen-Cilag International NV	01/12/2017	P/0362/2017
Upadacitinib		PM	Immunology-Rheumatology-Transplantation	AbbVie Ltd	01/12/2017	P/0363/2017
Palovarotene		PM	Other	Clementia Pharmaceuticals Inc.	01/12/2017	P/0364/2017
Naltrexone (hydrochloride) / bupropion (hydrochloride)	Mysimba	PM	Other	Orexigen Therapeutics Ireland Limited	01/12/2017	P/0365/2017
Soluble human T cell receptor (TCR) directed against the glycoprotein 100 (gp100) melanoma antigen, linked to the single-chain variable fragment (ScFv) domain of the anti-cluster of differentiation 3 (CD3) antibody		W	Oncology	Immunocore Ltd	01/12/2017	P/0366/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Human Neutrophil Elastase Inhibitor (CHF6333)		RW	Pneumology - Allergology	Chiesi Farmaceutici S.p.A	01/12/2017	P/0367/2017
Vonapanitase		W	Cardiovascular Diseases	Proteon Therapeutics Limited	01/12/2017	P/0368/2017
Opicinumab		W	Neurology	Biogen Idec Limited	01/12/2017	P/0369/2017
Tolonium chloride		W	Other	Cumdente GmbH	01/12/2017	P/0370/2017
Bedaquiline (fumarate)	SIRTURO	PM	Infectious Diseases	Janssen-Cilag International NV	04/01/2017	P/0371/2016
Recombinant humanised IgG4 monoclonal antibody against MSRV-Envelope protein (GNbAC1)		P	Neurology	GeNeuro SA	01/12/2017	P/0371/2017
Iron hydroxyethyl amylopectin heptonate		P	Haematology-Hemostaseology	iron4u	01/12/2017	P/0372/2017
Synthetic double-stranded siRNA oligonucleotide directed against hydroxyacid oxidase 1 mRNA that is covalently linked to a ligand containing three N-acetylgalactosamine residues		P	Gastroenterology-Hepatology	Alnylam UK Limited	01/12/2017	P/0373/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
(ALN-GO1)						
Atorvastatin / ezetimibe		W	Cardiovascular Diseases	EGIS Pharmaceuticals PLC	01/12/2017	P/0374/2017
Eculizumab	Soliris	PM	Neurology	Alexion Europe SAS	01/12/2017	P/0375/2017
Resminostat		W	Oncology	4SC AG	01/12/2017	P/0376/2017
Omega-3-carboxylic acids		PM	Cardiovascular Diseases	AstraZeneca AB	01/12/2017	P/0377/2017
Lanadelumab (DX-2930)		PM	Other	Shire Pharmaceuticals Ireland Limited	01/12/2017	P/0378/2017
Vosoritide (BMN 111)		P	Other	BioMarin International Limited	19/12/2017	P/0379/2017
Human normal immunoglobulin		PM	Immunology-Rheumatology-Transplantation	Grifols Therapeutics Inc	19/12/2017	P/0380/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Susoctocog alfa	Obizur	P	Haematology-Hemostaseology	Baxalta Innovations GmbH	19/12/2017	P/0381/2017
Sildenafil	Revatio	PM	Other	Pfizer Limited	19/12/2017	P/0382/2017
Carotuximab		P	Oncology	TRACON Pharma Limited	19/12/2017	P/0383/2017
Budesonide		P	Pneumology - Allergology	Pearl Therapeutics, Inc.	19/12/2017	P/0384/2017
Cemilimab		P	Oncology	Regeneron Ireland U.C.	19/12/2017	P/0385/2017
Fremanezumab		P	Neurology	Teva GmbH	19/12/2017	P/0386/2017
Bezlotoxumab	Zinplava	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	19/12/2017	P/0387/2017
Eluxadoline	Truberzi	PM	Gastroenterology-Hepatology	Allergan Limited	19/12/2017	P/0388/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Human coagulation factor X	Coagadex	PM	Haematology-Hemostaseology	Bio Products Laboratory Limited	19/12/2017	P/0389/2017
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of Phleum pratense pollen		PM	Pneumology - Allergology	LETI Pharma GmbH	19/12/2017	P/0390/2017
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis pollen (Grasses-Mix) (1/5) each		PM	Pneumology - Allergology	LETI Pharma GmbH	19/12/2017	P/0391/2017
Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of equal amounts of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis pollen (Grasses-Mix) and Secale cereale (Cultivated Rye) pollen (50/50)		PM	Pneumology - Allergology	LETI Pharma GmbH	19/12/2017	P/0392/2017
Ataluren	Translarna	PM	Neurology	PTC Therapeutics International, Limited	19/12/2017	P/0393/2017
Synthetic double-stranded small interfering RNA (siRNA) oligonucleotide specific to the mRNA of the caspase 2 gene		W	Ophthalmology	Quark Pharmaceuticals, Inc.	19/12/2017	P/0394/2017

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Sirolimus		W	Other	Vascular Therapies, Inc.	19/12/2017	P/0395/2017
Trazodone (hydrochloride)	Trittico and associated names	P	Neurology	Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F - S.p.A	19/12/2017	P/0396/2017
Brazikumab		P	Gastroenterology-Hepatology	Allergan Limited	19/12/2017	P/0397/2017
Ibrutinib	Imbruvica	PM	Oncology	Janssen-Cilag International N.V.	19/12/2017	P/0398/2017
Human fibrinogen / human thrombin	Evicel Evarrest	PM	Other	Omrix Biopharmaceuticals N.V.	19/12/2017	P/0399/2017
Recombinant human glutamic acid decarboxylase (rhGAD65)		RPM	Endocrinology-Gynaecology-Fertility-Metabolism	Diamyd Medical AB	19/12/2017	P/0400/2017
Blinatumomab	Blincyto	PM	Oncology	Amgen Europe B.V.	19/12/2017	P/0401/2017
Inotuzumab ozogamicin	Besponsa	PM	Haematology-Hemostaseology Oncology	Pfizer Ltd	19/12/2017	P/0402/2017

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

Active substance(s)	**Therapeutic area(s)**	**Applicant**	**PDCO opinion date**
Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins	Neurology	Merz Pharmaceuticals GmbH	15/12/2017
Dasatinib	Oncology	Bristol-Myers Squibb Pharma EEIG	15/12/2017
Fingolimod (hydrochloride)	Neurology	Novartis Europharm Limited	10/11/2017
Japanese encephalitis vaccine (inactivated, adsorbed)	Vaccines	Valneva Austria GmbH	10/11/2017
Recombinant human nerve growth factor	Ophthalmology	Dompé farmaceutici SpA	10/11/2017
Mepolizumab	Pneumology - Allergology	GSK TRADING SERVICES LIMITED	10/11/2017
Damoctocog alfa pegol	Haematology-Hemostaseology	Bayer AG	18/08/2017
Asenapine (maleate)	Psychiatry	N.V. Organon	18/08/2017
Vigabatrin	Neurology	ORPHELIA Pharma SA	21/07/2017
Split influenza virus, inactivated containing antigen equivalent to A/H3N2-like strain / Split influenza virus, inactivated containing antigen equivalent to B-like strain (B/Yamagata lineage) / Split influenza virus, inactivated containing antigen equivalent to A/H1N1-like strain / Split influenza virus, inactivated containing antigen equivalent to B-like strain (B/Victoria lineage)	Vaccines	Sanofi Pasteur SA	23/06/2017
Raltegravir	Infectious Diseases	Merck Sharp & Dohme (Europe) Inc.	19/06/2017
Cinacalcet	Uro-nephrology	Amgen Europe B.V	19/05/2017
Adenovirus associated viral vector serotype 2 containing the human RPE65 gene	Ophthalmology	Spark Therapeutics Inc.	21/04/2017
Melatonin	Neurology	RAD Neurim Pharmaceuticals EEC Ltd	21/04/2017
Purified antigen fractions of inactivated split virion Influenza virus type A, H1N1 / Influenza virus type A, H3N2 / Influenza virus type B, Victoria lineage / Influenza virus type B,	Vaccines	GlaxoSmithKline Biologicals S.A.	21/04/2017

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Yamagata lineage			
Tetracaine (hydrochloride) / oxymetazoline (hydrochloride)	Anaesthesiology	St. Renatus, LLC	21/04/2017
Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human Wiskott Aldrich Syndrome (WAS) cDNA sequence	Immunology-Rheumatology-Transplantation	GlaxoSmithKline Trading Services Ltd	24/03/2017
Darbepoetin alfa	Oncology / Uro-nephrology	Amgen Ltd.	24/03/2017
Ipilimumab	Oncology	Bristol-Myers Squibb Pharma EEIG	24/02/2017
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	Vaccines	GlaxoSmithKline Biologicals S.A.	27/01/2017

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 23F conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 7F conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein			
Purified Pertussis Toxoid (PT) / Purified Tetanus Toxoid / Purified Diphtheria Toxoid / Inactivated Type 2 Poliovirus (MEF-1) / Purified Filamentous Haemagglutinin (FHA) / Inactivated Type 1 Poliovirus (Mahoney) / Hepatitis B Surface Antigen, recombinant	Vaccines	Sanofi Pasteur	27/01/2017

Annex 17 – Referral procedures overview – 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**
Haloperidol decanoate	26/06/2014	23/02/2017	Article 30 of Directive 2001/83/EC
haloperidol	26/06/2014	23/02/2017	Article 30 of Directive 2001/83/EC
etoposide phosphate	22/10/2015	21/04/2017	Article 30 of Directive 2001/83/EC
etoposide	22/10/2015	21/04/2017	Article 30 of Directive 2001/83/EC
amitriptyline	17/12/2015	23/02/2017	Article 30 of Directive 2001/83/EC
desloratadine	17/12/2015	22/06/2017	Article 5(3) of Regulation (EC) No 726/2004
dienogest/ethinylestradiol	25/02/2016	26/01/2017	Article 31 of Directive 2001/83/EC
vancomycin	01/04/2016	18/05/2017	Article 31 of Directive 2001/83/EC
escherichia coli bacteria (cells and autolysate)	01/04/2016	22/06/2017	Article 31 of Directive 2001/83/EC
paracetamol/ibuprofen 500mg/150mg	10/11/2016	18/05/2017	Article 29(4) of Directive 2001/83/EC
Micro Therapeutic Research (various)	15/12/2016	23/05/2017	Article 31 of Directive 2001/83/EC
sodium oxybate	26/01/2017	12/10/2017[1]	Article 29(4) of Directive 2001/83/EC
dexrazoxane	23/02/2017	18/05/2017	Article 13 of Regulation (EC) No 1234/2008
mepivacaine	14/09/2017	ongoing	Article 30 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**
gadobenic acid, gadobutrol, gadodiamide, gadopentetic acid, gadoteric acid, gadoteridol, gadoversetamide, gadoxetic acid	17/03/2016	20/07/2017[2]	Article 31 of Directive 2001/83/EC

[1] CHMP opinion date after re-examination procedure
[2] CHMP opinion date after re-examination procedure

Procedure name (international non-proprietary name (INN))	Start of procedure	End of procedure	Type of referral
canagliflozin, dapagliflozin, empagliflozin	14/04/2016	23/02/2017	Article 20 of Regulation (EC) No 726/2004
paracetamol, modified and prolonged release	07/07/2016	13/12/2017[3]	Article 31 of Directive 2001/83/EC
human coagulation factor VIII; efmoroctocog alfa; moroctocog alfa; octocog alfa; simoctocog alfa; susoctocog alfa; turoctocog alfa	07/07/2016	14/09/2017[4]	Article 31 of Directive 2001/83/EC
methylprednisolone	01/12/2016	31/07/2017	Article 31 of Directive 2001/83/EC
nalidixic acid, pipemidic acid, cinoxacin, enoxacin, pefloxacin, lomefloxacin, ciprofloxacin, levofloxacin, ofloxacin, moxifloxacin, norfloxacin, prulifloxacin, rufloxacin, flumequin	09/02/2017	ongoing	Article 31 of Directive 2001/83/EC
sodium valproate, valproic acid, valproate semisodium, valpromide, valproate magnesium	09/03/2017	ongoing	Article 31 of Directive 2001/83/EC
daclizumab	09/06/2017	09/11/2017	Article 20 of Regulation (EC) No 726/2004
flupirtine	26/10/2017	ongoing	Article 31 of Directive 2001/83/EC
hydroxyethyl starch	26/10/2017	ongoing	Article 107i of Directive 2001/83/EC
radium Ra223 dichloride	30/11/2017	ongoing	Article 20 of Regulation (EC) No 726/2004
ulipristal acetate	30/11/2017	ongoing	Article 20 of Regulation (EC) No 726/2004

[3] CMDh position date after re-examination procedure
[4] CHMP opinion date after re-examination procedure

Annex 18 – Arbitrations and referrals – veterinary medicines

Type of procedure	**Date** • **Clock start** • **CVMP opinion**	**Product** • **Product name** • **INN**
Referral under Article 34 of Directive 2001/82/EC	• 09/09/2015 • 12/04/2017	• Denagard 45% and associated names • Tiamulin hydrogen fumarate
Referral under Article 35 of Directive 2001/82/EC	• 05/11/2015 • 11/05/2017	• All veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses • Moxidectin
Referral under Article 35 of Directive 2001/82/EC (re-examination)	• 17/02/2016 • 08/12/2016 • 16/03/2017 (re-examination)	• All 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	• 18/05/2016 • 16/03/2017	• Veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for intramuscular use in cattle • Methylprednisolone hydrogen succinate
Referral under Article 35 of Directive 2001/82/EC	• 13/07/2016 • 16/03/2017	• 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	• 13/07/2016 • 05/10/2017	• Girolan and its associated name Apralan • Apramycin sulfate
Referral under Article 34 of Directive 2001/82/EC	• 13/07/2016 • 13/07/2017	• Lincocin and associated names • Lincomycin
Referral under Article 35 of Directive 2001/82/EC	• 07/09/2016 • 13/07/2017	• Zanil and associated names, and generic products thereof • Oxyclozanide
Referral under Article 13 of Regulation (EC) No. 1234/2008	• 06/09/2017	• Seresto and its associated name Foresto • Imidacloprid and flumethrin

Annex 19 – Budget summaries 2016–2017

The summarised comparative budget statements for 2016 and 2017 are as follows:

		2016 (final)[1]		2017 (budget)[2]		2017 (prov.)[3]	
		€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
	Revenue						
100	Fees and charges	272,588	*89.3%*	285,140	*86.1%*	278,813	*87.9%*
200	General EU contribution	2,038	*0.7%*	2,438	*0.7%*	2,438	*0.8%*
201	Special EU contribution for orphan medicinal products	12,769	*4.2%*	13,687	*4.1%*	13,268	*4.2%*
300	Contribution from EEA	56	*0.0%*	398	*0.1%*	60	*0.0%*
600	External assigned revenue	15,276	*5.0%*	15,774	*4.8%*	9,666	*3.0%*
700	Balance from previous year	1,950	*0.6%*	12,767	*3.9%*	12,767	*4.0%*
5+9	Other	421	*0.1%*	1,062	*0.3%*	348	*0.1%*
	TOTAL REVENUE	**305,099**	*100.0%*	**331,266**	*100.0%*	**317,360**	*100.0%*
	Expenditure						
	Staff						
11	Staff in active employment	91,821	*30.9%*	111,494	*33.7%*	99,892	*32.5%*
12	Staff recruitment			230	*0.1%*	120	*0.0%*
13	Duty travel	683	*0.2%*	1,026	*0.3%*	861	*0.3%*
14	Socio-medical infrastructure	865	*0.3%*	699	*0.2%*	717	*0.2%*
15	Training	5,647	*1.9%*	1,061	*0.3%*	741	*0.2%*
16	Social welfare	472	*0.2%*	4,525	*1.4%*	4,365	*1.4%*
17	Representation expenses	56	*0.0%*	105	*0.0%*	97	*0.0%*
18	Staff insurances	11,186	*3.8%*				
	Total Title 1	**110,729**	*37.3%*	**119,140**	*36.0%*	**106,793**	*34.7%*
	Building/equipment						
20	Investment in immovable property, renting of building and associated costs	22,529	*7.6%*	24,567	*7.4%*	22,736	*7.4%*
21	Expenditure on corporate data processing	15,502	*5.2%*	20,692	*6.2%*	21,201	*6.9%*
22	Movable property [..]	1,284	*0.4%*	974	*0.3%*	747	*0.2%*
23	Other administrative expenditure	847	*0.3%*	1,203	*0.4%*	594	*0.2%*
24	Postage	93	*0.0%*	97	*0.0%*	65	*0.0%*
25	Expenditure on other meetings	152	*0.1%*	373	*0.1%*	340	*0.1%*
26	Restaurant & catering			795	*0.2%*	753	*0.2%*
27	Information & publishing			1,401	*0.4%*	882	*0.3%*
28	Business consultancy & audit svcs.			4,203	*1.3%*	2,046	*0.7%*
	Total Title 2	**40,407**	*13.6%*	**54,305**	*16.4%*	**49,364**	*16.0%*
	Operational expenditure						
300	Meetings	7,924	*2.7%*	9,349	*2.8%*	8,655	*2.8%*
301	Evaluation of medicines	114,509	*38.6%*	118,692	*35.8%*	114,725	*37.3%*
302	Translations	3,759	*1.3%*	4,833	*1.5%*	4,752	*1.5%*
303	Scientific studies & svcs.	6,570	*2.2%*	3,950	*1.2%*	3,471	*1.1%*
304	Publications	152	*0.1%*				
31	Expenditure on business related IT projects	12,962	*4.4%*	20,997	*6.3%*	20,064	*6.5%*
	Total Title 3	**145,877**	*49.1%*	**157,821**	*47.6%*	**151,667**	*49.3%*
	TOTAL EXPENDITURE	**297,013**	*100.0%*	**331,266**	*100.0%*	**307,824**	*100.0%*

[1] Financial Year 2016: as per final accounts; rounded to nearest thousand Euro

[2] Financial Year 2017: as per final budget

[3] Financial Year 2017: as per provisional accounts; rounded to nearest thousand Euro

Annex 20 – European Medicines Agency Establishment Plan

Category and grade	TEMPORARY POSTS					
	POSTS 2017				POSTS 2018	
	Authorised		Actual as per 31.12.2017		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	0	-	0	-	0
AD 15	-	4	-	3	-	3
AD 14	-	6	-	6	-	7
AD 13	-	11	-	11	-	11
AD 12	-	40	-	35	-	43
AD 11	-	40	-	40	-	43
AD 10	-	43	-	43	-	41
AD 9	-	42	-	42	-	45
AD 8	-	53	-	53	-	59
AD 7	-	61	-	61	-	65
AD 6	-	37	-	37	-	23
AD 5	-	3	-	3	-	0
Total AD	**0**	**340**	**0**	**334**	**0**	**340**
AST 11	-	2	-	2	-	2
AST 10	-	6	-	6	-	7
AST 9	-	7	-	7	-	6
AST 8	-	16	-	16	-	16
AST 7	-	19	-	18	-	22
AST 6	-	43	-	43	-	42
AST 5	-	43	-	39	-	46
AST 4	-	52	-	52	-	57
AST 3	-	45	-	44	-	46
AST 2	-	23	-	22	-	7
AST 1	-	0	-	0	-	0
Total AST	**0**	**256**	**0**	**249**	**0**	**251**
Grand Total	**0**	**596**	**0**	**583**	**0**	**591**

Other staff	**Planned (FTE[1]) 2017**	**Actual (FTE[1]) 2017**	**Actual headcount 31.12.2017**	**Planned (FTE[1]) 2018**
CONTRACT AGENTS	**158**	**145**	**147**	**200**
NATIONAL EXPERTS	**45**	**36**	**36**	**39**

[1] FTE=Full Time Equivalent

Annex 21 – Access to documents requests

Requests received and pages released

Year	Number of requests received	Number of pages released
2017	865	487,092

Initial decisions on access in 2017[2]

Access given	
Yes	582
Partial	14
No	43
Not Applicable[3]	78
Total closed	**715**
Pending	355

Refusal

Legal basis	Full	Partial
4.1(a) – Protection of public interest	0	0
4.1(b) – Protection of privacy	4	1
4.2 1st ind – Protection of commercial interest	40	12
4.2 2nd ind – Protection of court proceedings	1	0
4.2 3rd ind – Protection of inspections	1	0
4.3 1st par – Protection of decision making process	14	1
4.3 2nd par – Protection of the Agency's decision making process	0	1
4.5 – Protection of Member States	0	0
Total	**60**	**15**

Decision on confirmatory applications in 2017[4]

Appeals	
Final refusal	5
Release	0
Partial	3
Not Applicable[5]	5
Total closed	**13**
Pending	3

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

Refusal

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

Affiliation (per initial requests and appeals in 2017)

Affiliation	Number of requests received	In %	Number of pages released[6]	In %
Not-for-profit organisation	17	2	11,177	2
EU Institution (EC etc)	0	0	0	0
Regulator outside EU	1	0	0	0
EU NCA	1	0	46	0
Patients or Consumer	147	17	56,679	12
Healthcare professional	54	6	52,545	11
Academia/Research institute	68	8	170,865	35
Legal	73	8	20,900	4
Media	30	3	2,111	0
Pharmaceutical industry	379	44	143,921	30
Consultant	95	11	28,848	6
Total	**865**	**100**	**487,092**	**100**

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

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