Annexes to the annual report of the European Medicines Agency 2018

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 — Anne BUCHER[1], Carlo PETTINELLI (Alternates: Andrzej RYS, Stefano SORO)
- Belgium — Xavier DE CUYPER (Alternate: Greet MUSCH)
- Bulgaria — Assena STOIMENOVA (Alternate: Bogdan KIRILOV[2])
- Czech Republic — Irena STOROVÁ[3] (Alternate: Jiří BUREŠ)
- Denmark — Thomas SENDEROVITZ (Alternate: Mette AABOE HANSEN)
- Germany — Karl BROICH (Alternate: Thomas MULLER[4])
- Estonia — Kristin RAUDSEPP (Alternate: Alar IRS)
- Ireland — Lorraine NOLAN (Alternate: Rita PURCELL)
- Greece — Ekaterini ANTONIOU[5] (Alternate: Ioannis MALEMIS[6])
- Spain — María Jesús LAMAS DÍAZ[7] (Alternate: César HERNÁNDEZ)
- France — Dominique MARTIN (Alternate: Jean-Pierre ORAND)
- Croatia — Awaiting nomination (Alternate: Siniša TOMIĆ)
- Italy — Luca LI BASSI[8] (Alternate: Giuseppe AMATO[9])
- Cyprus — Loizos PANAYI (Alternate: Anna PAPHITOU[10])
- Latvia — Svens HENKUZENS (Alternate: Janis ZVEJNIEKS)
- Lithuania — Gintautas BARCYS (Alternate: Gediminas PRIDOTKAS)
- Luxembourg — Laurent MERTZ (Alternate: Jacqueline GENOUX-HAMES)
- Hungary — Awaiting nomination (Alternate: Beatrix HORVATH)
- Malta — John-Joseph BORG (Alternate: Gavril FLORES)

[1] Replaced Xavier PRATS-MONNÉ as of October 2018
[2] Replaced Svetlin SPIROV as of January 2018
[3] Replaced Zdenek BLAHUTA as of June 2018
[4] Replaced Birgit NAASE as of April 2018
[5] Replaced Despoina MAKRIDAKI as of October 2017
[6] Nominated as of June 2018
[7] Replaced Belén CRESPO SÁNCHEZ-EZNARRIAGA as of July 2018
[8] Replaced Mario MELAZZINI as of November 2018
[9] Replaced Nando MINNELLA as of November 2018
[10] Replaced Emilia MAVROKORDATOU as of June 2018

• Netherlands	Hugo HURTS (Alternate: Constant VAN BELKUM)
• Austria	Christa WIRTHUMER-HOCHE (Alternate: Thomas REICHHART[11])
• Poland	Grzegorz CESSAK (Alternate: Marcin KOLAKOWSKI)
• Portugal	Rui SANTOS IVO (Alternate: Awaiting nomination)
• Romania	Adriana COTEL[12] (Alternate: Ada GEORGESCU[13])
• Slovenia	Momir RADULOVIĆ[14] (Alternate: Stanislav PRIMOŽIČ)
• Slovakia	Zuzana BAŤOVÁ (Alternate: Judita HEDEROVA[15])
• Finland	Eija PELKONEN[16] (Alternate: Esa HEINONEN)
• Sweden	Catarina FORSMAN (Alternate: SARA ROSENMULLER)
• United Kingdom	Ian HUDSON (Alternate: Jonathan MOGFORD)
• Representatives of patients' organisations	Awaiting nomination 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: Martin STRICKER[17])
• Norway	Audun HÅGÅ (Alternate: Ivar VOLLSET)

[11] Replaced Sylvia FÜSZL as of January 2018
[12] Replaced Alexandru VELICU as of December 2018
[13] Replaced Alexandru VELICU as of March 2018
[14] Replaced Andreja CUFAR as of December 2018
[15] Nominated as of March 2018
[16] Replaced Sinikka RAJANIEMI as of October 2018
[17] Replaced Christina ZIMMER as of October 2018

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

Chair: Harald ENZMANN [1]
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)	Alternate: Loizos PANAYI [2]
• Ondrej SLANAR (Czech Republic)	Alternate: Tomas BORAN
• Sinan B. SARAC (Denmark)	Alternate: Mark AINSWORTH [3]
• Alar IRS (Estonia)	Alternate: *Awaiting nomination*
• Outi MAKI-IKOLA (Finland)	Alternate: Tuomo LAPVETELAINEN
• Alexandre MOREAU (France)	Alternate: Joseph EMMERICH
• Martina WEISE (Germany) [4]	Alternate: Janet Koenig [5]
• Constantinos MARKOPOULOS (Greece) [6]	Alternate: Eleftheria NIKOLAIDI [7]
• Agnes GYURASICS (Hungary)	Alternate: *Awaiting nomination* [8]
• Kolbeinn GUDMUNDSSON (Iceland)	Alternate: Hrefna GUDMUNDSDOTTIR
• Jayne CROWE (Ireland)	Alternate: Peter KIELY
• Daniela MELCHIORRI (Italy)	Alternate: Mario MELAZZINI [9]
• 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)	Alternate: Bjorg BOLSTAD
• Ewa BALKOWIEC-ISKRA (Poland)	Alternate: Marcin KOLAKOWSKI [10] [11]

[1] Elected as Chair as of September 2018, replacing Tomas SALMONSON
[2] Replaced Elena KAISI as of June 2018
[3] Replaced Hanne LOMHOLT LARSEN as of Febuary 2018
[4] Replaced Harald ENZMANN as of October 2018, with a swap of role from alternate to member
[5] Replaced Martina WEISE as of November 2018
[6] Replaced Eleftheria NIKOLAIDI as of October 2018
[7] Replaced Maria ORFANOU as of October 2018, with a swap of role from member to alternate
[8] Melinda SOBOR resigned as of June 2018
[9] Nominated as of June 2018

- Bruno SEPODES (Portugal) *(Vice-Chair)* [12] — Alternate: Fatima VENTURA
- Simona BADOI (Romania) — Alternate: Dana Gabriela MARIN
- Francisek DRAFI (Slovakia) — Alternate: Eva MALIKOVA
- Rajko KENDA (Slovenia) [13] — Alternate: Nevenka TRSINAR BRODT
- Concepcion PRIETO YERRO (Spain) — Alternate: Jorge CAMERERO JIMENEZ
- 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))
- Blanka HIRSCHLEROVA (Quality (non-biologicals) and Pharmacokinetics) [14] [15]
- Jan MUELLER-BERGHAUS (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))
- Koenraad NORGA (Pharmacology)
- Sol RUIZ (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))

[10] Nominated as of September 2018
[11] Aldona PALUCHOWSKA resigned as of May 2018
[12] Elected as Vice-Chair as of October 2018, replacing Harald ENZMANN as Vice-Chair
[13] Replaced Stanislav PRIMOZIC as of March 2018
[14] Nominated as of March 2018
[15] Jean-Louis ROBERT resigned as of January 2018

Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: Sabine STRAUS [1]
EMA contact: Anabela MARCAL

Members

• Jan NEUHAUSER (Austria)	Alternate: Daniela PHILADELPHY
• 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)	Alternate: Ioannis KKOLOS
• Eva JIRSOVA (Czech Republic)	Alternate: Jana LUKACISINOVA
• Doris STENVER (Denmark)	Alternate: Anette STARK [2]
• Maia UUSKULA (Estonia)	Alternate: Katrin KIISK
• Kirsti VILLIKKA (Finland)	Alternate: Kimmo JAAKKOLA
• Ghania CHAMOUNI (France)	Alternate: Adrien INOUBLI [3]
• Martin HUBER (Germany) *(Vice-Chair)* [4]	Alternate: Brigitte KELLER-STANISLAWSKI [5]
• Agni KAPOU (Greece)	Alternate: Sofia TRANTZA
• Julia PALLOS (Hungary)	Alternate: Melinda PALFI
• Gudrun STEFANSDOTTIR (Iceland) [6]	Alternate: Gudrun Kristin STEINGRIMSDOTTIR [7]
• Rhea FITZGERALD (Ireland) [8]	Alternate: Ronan GRIMES [9]
• Amelia CUPELLI (Italy) [10]	Alternate: *Awaiting nomination*
• Zane NEIKENA (Latvia)	Alternate: Zane STADE
• Jolanta GULBINOVIC (Lithuania)	Alternate: Ruta KERPAUSKIENE [11]
• Marcel BRUCH (Luxembourg)	Alternate: Anne-Cecile VUILEMIN [12]
• John Joseph BORG (Malta) [13]	Alternate: Benjamin MICALLEF [14]
• Menno VAN DER ELST (Netherlands) [15]	Alternate: Liana GROSS-MARTIROSYAN [16]

[1] Elected as Chair as of September 2018, replacing June Munro RAINE
[2] Nominated as of April 2018
[3] Replaced Caroline LABORDE as of July 2018
[4] Elected as Vice-Chair as of October 2018, replacing Almath SPOONER as Vice-Chair
[5] Replaced Valerie STRASSMANN as of July 2018
[6] Replaced Gudrun Kristin STEINGRIMSDOTTIR as of April 2018
[7] Replaced Hrefna GUDMUNSDOTTIR as of April 2018, with swap of role from member to alternate
[8] Replaced Almath SPOONER as of July 2018, with swap of role from alternate to member
[9] Nominated as of September 2018
[10] Replaced Carmela MACCHIARULO as of June 2018, with swap of role from alternate to member
[11] Replaced Simona KUDELIENE as of October 2018
[12] Replaced Nadine PETITPAIN as of March 2018
[13] Replaced Amy TANTI as of April 2018, with swap of role from alternate to member
[14] Replaced John Joseph BORG as of April 2018

- David BENEE OLSEN (Norway) — Alternate: Karen PERILLE HARG [17]
- Adam PRZYBYLKOWSKI (Poland) — Alternate: Katarzyna ZIOLKOWSKA
- Ana Sofia DINIZ MARTINS (Portugal) — Alternate: Marcia SILVA
- Roxana STROE (Romania) — Alternate: Andreia RULEA [18]
- Michal RADIK (Slovakia) [19] — Alternate: Tatiana MAGALOVA [20]
- Gabriela JAZBEC (Slovenia) [21] — Alternate: Jasmina KLOPCIC [22]
- Eva SEGOVIA (Spain) [23] — Alternate: Maria del PINAR RAYON [24]
- Ulla WANDEL LIMINGA (Sweden) — Alternate: Annika FOLIN [25]
- Julie WILLIAMS (United Kingdom) — Alternate: Patrick BATTY

Independent scientific experts nominated by the European Commission

- Birgitta GRUNDMARK [26]
- Daniel MORALES [27]
- Hedvig NORDENG [28]
- Antoine PARIENTE [29]
- Livia PULJAK [30]
- Stefan WEILER [31]

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

[15] Replaced Sabine STRAUS as of September 2018, with swap of role from alternate to member
[16] Replaced Menno VAN DER ELST as of September 2018
[17] Replaced Kristin Thorseng KVANDE as of May 2018
[18] Replaced Roxana DONDERA as of August 2018, who had replaced Nicolae Fotin as from January 2018
[19] Replaced Tatiana MAGALOVA as of May 2018
[20] Replaced Peter KOREN as of May 2018
[21] Replaced Milena RADOHA-BERGOC as of July 2018, with swap of role from alternate to member
[22] Replaced Gabriela JAZBEC as of July 2018
[23] Replaced Dolores MONTERO CORMINAS as of July 2018, with swap of role from alternate to member
[24] Replaced Eva SEGOVIA as of July 2018
[25] Replaced Qun-Ying YUE as of July 2018
[26] Replaced Thierry TRENQUE as of July 2018
[27] Replaced Marie Louise DE BRUIN as of July 2018
[28] Replaced Stephen J. W. Evans as of July 2018
[29] Replaced Brigitte KELLER-STANISLAWSKI as of July 2018
[30] Replaced Herve LE LOUET as of July 2018
[31] Replaced Lennart Antero WALDENLIND as of July 2018

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

Chair: David MURPHY (vice-chair: Helen JUKES)
EMA contact: Isaura DUARTE

Members and alternates

• Petra FALB (Austria)[1]	Alternate: Ines Lindner[2]
• Bruno URBAIN (Belgium)	Alternate: Frédéric KLEIN
• Emil KOZHUHAROV (Bulgaria)	Alternate: Svetoslav BRANCHEV
• Frane BOŽIĆ (Croatia)	Alternate: Svjetlana TERZIĆ
• Jiří BUREŠ (Czech Republic)	Alternate: Leona NEPEJCHALOVÁ
• Alia MICHAELIDOU-PATSIA (Cyprus)	Alternate: *awaiting nomination*
• Ellen-Margrethe VESTERGAARD (Denmark)	Alternate: Merete BLIXENKRONE-MØLLER
• Toomas TIIRATS (Estonia)	Alternate: *awaiting nomination*
• Tita-Maria MUHONEN (Finland)[3]	Alternate: Katariina. KIVILAHTI-MANTYLA[4]
• Jean-Claude ROUBY (France)	Alternate: Sylvie LOUET
• Gesine HAHN (Germany)	Alternate: Esther WERNER
• Ioannis MALEMIS (Greece)	Alternate: Angeliki TSIGOURI
• Gabor KULCSÁR (Hungary)	Alternate: Tibor SOÓS
• J. Gabriel BEECHINOR (Ireland)	Alternate: Mary O'GRADY
• Paolo PASQUALI (Italy)	Alternate: Antonio BATTISTI
• Zanda AUCE (Latvia)	Alternate: Renate MAKOVSKA
• Petras MAČIULSKIS (Lithuania)	Alternate: *awaiting nomination*
• Marc SCHMIT (Luxembourg)	Alternate: Marcel BRUCH
• Stephen SPITERI (Malta)	Alternate: *awaiting nomination*
• Peter HEKMAN (Netherlands)	Alternate: Jacqueline POOT
• Anna WACHNIK-ŚWIĘCICKA (Poland)	Alternate: Ewa AUGUSTYNOWICZ
• Maria AZEVEDO MENDES (Portugal)[5]	Alternate: *awaiting nomination*
• Lollita TABAN (Romania)	Alternate: Simona STURZU
• Judita HEDEROVÁ (Slovakia)	Alternate: Eva CHOBOTOVÁ
• Katarina ŠTRAUS (Slovenia)	Alternate: Maja TURK

[1] Replaced Brigitte HAUSER as of October 2018 meeting
[2] Replaced Petra FALB as of October 2018 meeting
[3] Replaced Martti NEVALAINEN as of February 2018 meeting
[4] Replaced Kristina LEHMANN as of February 2018 meeting
[5] Replaced João Pedro DUARTE DA SILVA as of December 2018 meeting

• Cristina MUÑOZ MADERO (Spain)	Alternate: Consuelo RUBIO MONTEJANO
• Frida HASSLUNG-WIKSTRÖM (Sweden)[6]	Alternate: Eva LANDER PERSSON
• Helen JUKES (United Kingdom)	Alternate: Rory Cooney[7]

EEA members

• Johann LENHARÐSSON (Iceland)	Alternate: *awaiting nomination*
• Hanne BERGENDAHL (Norway)	Alternate: Tonje HØY

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
• Ricardo CARAPETO GARCÍA[8]	Environmental risk assessment

[6] Swedish member and alternate swapped roles as of May 2018 meeting
[7] Replaced Noemi GARCIA DEL BLANCO as of December 2018 meeting
[8] Elected in December 2018, replaced Jason WEEKS

Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Violeta STOYANOVA-BENINSKA [1]
EMA contact: Anabela MARCAL

Members

- Brigitte BLOECHL-DAUM (Austria)
- Tim LEEST (Belgium)
- Lyubina Racheva TODOROVA (Bulgaria)
- Dinko VITEZIC (Croatia)
- Elena KAISIS (Cyprus) [2]
- Katerina KOPECKOVA (Czech Republic)
- Elisabeth PENNINGA (Denmark) [3]
- Vallo TILLMANN (Estonia)
- Karri PENTTILA (Finland)
- Annie LORENCE (France)
- Frauke NAUMANN-WINTER (Germany)
- Nikolaos SYPSAS (Greece)
- Zsofia GYULAI (Hungary) [4] [5]
- *Awaiting nomination* (Iceland) [6]
- Geraldine O'DEA (Ireland)
- Armando MAGRELLI (Italy) *(Vice-Chair)* [7]
- Irena ROGOVSKA (Latvia)
- Ausra MATULEVICIENE (Lithuania)
- Michel HOFFMAN (Luxembourg)
- Robert NISTICO (Malta)
- Elisabeth ROOK (Netherlands) [8]
- Ingrid WANG (Norway)
- Bozenna DEMBOWSKA-BAGINSKA (Poland)
- Dinah DUARTE (Portugal)

[1] Elected as Chair as of October 2018, replacing Bruno SEPODES
[2] Replaced Ioannis KKOLOS as of May 2018
[3] Replaced Jens ERSBOLL as of January 2018
[4] Nominated as of October 2018 Melinda SOBOR's mandate ended as of June 2018
[5] Melinda SOBOR resigned as of June 2018
[6] Sigurdur THORSTEINSSON's mandate ended as of May 2018
[7] Elected as Vice-Chair as of November 2018, replacing Lesley GREENE as Vice-Chair
[8] Replaced Violeta STOYANOVA-BENINSKA as from December 2018

- Olimpia NEAGU (Romania)
- Eva MALIKOVA (Slovakia)
- Martin MOZINA (Slovenia)
- Fernando MENDEZ HERMIDA (Spain)
- Darius MATUSEVICIUS (Sweden)
- Daniel O'CONNOR (United Kingdom)

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

- Ingeborg BARISIC
- Giuseppe CAPOVILLA
- Bruno SEPODES [9] [10]

Members representing patients' organisations nominated by the European Commission

- Marie Pauline EVERS
- Julian ISLA [11]
- Angelo Loris BRUNETTA [12]

[9] Nominated as of November 2018
[10] Kerstin WESTERMARK resigned as of June 2018 Bruno SEPODES mandate started as of November 2018
[11] Replaced Lesley GREENE as of June 2018
[12] Replaced Mario RICCIARDI as of June 2018

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: *Awaiting nomination* [1]
• Iliana IONKOVA (Bulgaria) [2] [3]	Alternate: *Awaiting nomination*
• Ivan KOSALEC (Croatia)	Alternate: Darko TRUMBETIC
• Maria STAVROU (Cyprus) [4]	Alternate: Elli LOIZIDOU [5]
• 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*
• *Awaiting nomination* (Ireland) [6]	Alternate: Una MOCKLER [7] [8]
• Alessandro ASSISI (Italy)	Alternate: Anna Maria SERRILLI
• Evita SKUKAUSKA (Latvia)	Alternate: Baiba JANSONE
• Rugile PILVINIENE (Lithuania)	Alternate: Audronis LUKOSIUS
• Marcel BRUCH (Luxembourg)	Alternate: Jacqueline GENOUX-HAMES
• Everaldo ATTARD (Malta)	Alternate: Andre MANGANI
• Emiel VAN GALEN (Netherlands) *(Vice-chair)*	Alternate: Burt H. KROES
• Steinar MADSEN (Norway)	Alternate: Gro FOSSUM
• Wojciech DYMOWSKI (Poland)	Alternate: Katarzyna TOMASZEWSKA

[1] Wim HUYGH resigned as of March 2018
[2] Iliana IONKOVA became member as of August 2018, with a swap of role from alternate to member
[3] Elena MUSTAKEROVA resigned as of April 2018
[4] Maria STAVROU's mandate ended as from April 2018. Eirini PERIKLEOUS replaced Maria STAVROU as from April 2018, with a swap of role from alternate to member. Maria STAVROU replaced Eirini PERIKLEOUS as of June 2018
[5] Replaced Eirini PERIKLEOUS as of April 2018
[6] Una MOCKLER became alternate as of October 2018, with a swap of role from member to alternate
[7] Replaced Rachel Cox as from October 2018, with a swap of role from member to alternate
[8] Rachel COX resigned as of August 2018

- Ana Paula MARTINS (Portugal) — Alternate: Eva MENDES
- Raluca IAVORSZKY (Romania) [9] [10] — Alternate: Ligia Elena DUTU [11] [12]
- Miroslava PETRIKOVA (Slovakia) — Alternate: Milan NAGY
- Samo KREFT (Slovenia) — Alternate: Barbara RAZINGER
- Adela NUNEZ VELAZQUEZ (Spain) — Alternate: Cristina MARTINEZ GARCIA
- Karin Erika SVEDLUND (Sweden) [13] — Alternate: Malin Kyllikki HOBRO SODERBERG
- Linda ANDERSON (United Kingdom) — Alternate: Elizabeth GRIFFITHS [14] [15]

Co-opted members

- Ewa BALKOWIEC ISKRA (Clinical pharmacology) [16]
- Heidi FOTH (Toxicology)
- Silvia GIROTTO (Paediatric medicine)
- Gert LAEKEMAN (Experimental/non-clinical pharmacology)
- Maria Helena PINTO FERREIRA (General and family medicine)

Observers

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

[9] Replaced Carmen PURDEL as of March 2018, with a swap of role from alternate to member
[10] Carmen PURDEL resigned as of February 2018
[11] Replaced Raluca IAVORSZKY as of June 2018
[12] Raluca IAVORSZKY became member as of March 2018, with a swap of role from alternate to member
[13] Replaced Per CLAESON as of January 2018
[14] Replaced Sue HARRIS as of September 2018
[15] Sue HARRIS resigned as of June 2018
[16] Nominated as of June 2018

Annex 7 – Members of the Committee for Advanced Therapies

Chair: Martina SCHUSSLER-LENZ
EMA contact: Patrick CELIS

Members

Members nominated from within the CHMP

- Jan MUELLER-BERGHAUS (Germany) [1] — Alternate: Egbert FLORY
- Romaldas MACIULAITIS (Lithuania) — Alternate: Vitalis BRIEDIS
- 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) *(Vice-Chair)* — Alternate: Corina SPREITZER
- Claire BEUNEU (Belgium) — Alternate: Belaid SEKKALI
- Rozalina KULAKSAZOVA (Bulgaria) — Alternate: Evelina SHUMKOVA
- Mirna GOLEMOVIC (Croatia) — Alternate: Nenad MEDIC [2]
- Marina IERIDI (Cyprus) — Alternate: Maria VASSILIOU
- Ivana HAUNEROVA (Czech Republic) — Alternate: Tomas BORAN
- Anne PASTOFT (Denmark) [3] — Alternate: Nanna Aaby KRUSE [4]
- Toivo MAIMETS (Estonia) — Alternate: Pille SAALIK [5]
- Heli SUILA (Finland) — Alternate: Olli TENHUNEN
- Violaine CLOSSON CARELLA (France) — Alternate: *Awaiting nomination*
- Asterios TSIFTSOGLOU (Greece) — Alternate: Angeliki ROBOTI
- Katalin LENGYEL (Hungary) [6] — Alternate: Balazs SARKADI
- Awaiting nomination (Iceland) — Alternate: *Awaiting nomination*
- Maura O'DONOVAN (Ireland) — Alternate: Niamh CURRAN
- Paolo GASPARINI (Italy) — Alternate: Giulio POMPILIO [7] [8]
- Una RIEKSTINA (Latvia) — Alternate: Liga SAULITE [9] [10]

[1] Replaced LUXEMBOURG as member nominated from within CHMP
[2] Replaced Ivica MALNAR as of May 2018
[3] Replaced Nanna Aaby KRUSE of October 2018, with a swap of role from alternate to member
[4] Replaced Anne PASTOFT as of October 2018, with a swap of role from member to alternate
[5] Nominated as of April 2018
[6] Replaced Krisztian FODOR as of February 2018
[7] Replaced LUCA SANGIORGI as of March 2018
[8] Luca SANGIORGI's mandate ended as of January 2018
[9] Replaced Aija LINE as of March 2018

- Guy BERCHEM (Luxembourg) [11] [12] — Alternate: Anne-Cécile VUILEMIN [13]
- Johannes H. OVELGONNE (Netherlands) — Alternate: Carla HERBERTS
- Helga HAUGUM OLSEN (Norway) — Alternate: Rune KJEKEN
- Dariusz SLADOWSKI (Poland) — Alternate: Anna CIESLIK
- Simona BADOI (Romania) — Alternate: Gianina-Nicoleta ANDREI
- Lukas SLOVAK (Slovakia) [14] [15] — Alternate: *Awaiting nomination* [16]
- Metoda LIPNIK-STANGELJ (Slovenia) — Alternate: Nevenka TRSINAR BRODT
- Lisbeth BARKHOLT (Sweden) [17] — Alternate: Bjorn CARLSSON
- Christiane NIEDERLAENDER (Un. Kingdom) — Alternate: James MCBLANE

Members representing clinicians nominated by the European Commission

- Marc TURNER — Alternate: Francisco BLANCO
- Bernd GANSBACHER — Alternate: Willem FIBBE

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) — Alternate: Catherine Milne (EDQM) [18]

[10] Aija LINE's mandate ended as from January 2018
[11] Replaced Jean-Louis ROBERT as of March 2018, with a swap of role from alternate to member
[12] Jean-Louis ROBERT resigned as of January 2018
[13] Replaced Guy BERCHEM as of March 2018
[14] Replaced Jan KYSELOVIC of May 2018
[15] Jan KYSELOVIC replaced Mikulas HRUBISKO as of January 2018, with a swap of role from alternate to member
[16] JAN KYSELOVIC became member as of January 2018
[17] Replaced Lennart AKERBLOM as of January 2018
[18] Nominated as of October 2018

Annex 8 – Members of the Paediatric Committee

Chair: Dirk MENTZER
EMA contact: Anabela MARCAL

Members nominated from within the CHMP

• Agnes GYURASICS (Hungary)	Alternate: *Awaiting nomination* [1]
• Carola DE BEAUFORT (Luxembourg)	Alternate: Jacqueline GENOUX-HAMES
• Dana Gabriela MARIN (Romania)	Alternate: Simona BADOI

Members

• Karl-Heinz HUEMER (Austria)	Alternate: Johanna WERNSPERGER
• Koenraad NORGA (Belgium) *(Vice-chair)*	Alternate: Karen VAN MALDEREN
• 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)	Alternate: Mona Ring GATKE [2]
• Irja LUTSAR (Estonia)	Alternate: Jana LASS
• Ann Marie TOTTERMAN (Finland)	Alternate: Pia ANNUNEN [3]
• Sylvie BENCHETRIT (France)	Alternate: Dominique PLOIN
• Sabine SCHERER (Germany)	Alternate: Yuansheng SUN [4]
• 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)	Alternate: Goda VAITKEVICIENE
• John Joseph BORG (Malta)	Alternate: Herbert LENICKER
• Maaike VAN DARTEL (Netherlands)	Alternate: *Awaiting nomination*
• Siri WANG (Norway)	Alternate: Anette Solli KARLSEN [5]
• Marek MIGDAL (Poland)	Alternate: *Awaiting nomination* [6]

[1] Melinda SOBOR resigned as of June 2018
[2] Nominated as of February 2018
[3] Replaced Maija PIHLAJAMAKI as of April 2018
[4] Replaced Immanuel BARTH as of September 2018
[5] Replaced Ine SKOTTHEIM RUSTEN as of January 2018

- Helena FONSECA (Portugal) Alternate: Hugo TAVARES
- Peter SISOVSKY (Slovakia) Alternate: *Awaiting nomination*
- Stefan GROSEK (Slovenia) Alternate: Janez JAZBEC
- 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 Alternate: Catherine CORNU
- Fernando CABANAS Alternate: Jorrit GERRITSEN [7] [8]
- 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 Alternate: Viviana GIANNUZZI

[6] Irena MEISSNER WANTUCH resigned as of August 2018
[7] Replaced Riccardo RICCARDI as of November 2018
[8] Riccardo RICCARDI resigned as of September 2018

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	Keith PUGH	Simona GOVER / Piotr KRAUZE
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	Elena WOLFF-HOLZ	Silvy DA ROCHA DIAS
Biostatistics Working Party	Anja SCHIEL	Frank PETAVY
Blood Products Working Party	Jacqueline KERR	Caroline VOLTZ
Cardiovascular Working Party	Kristina DUNDER	Anna BACZYNSKA
Central Nervous System Working Party	Karl BROICH	Marta KOLLB-SIELECKA
Infectious Diseases Working Party	Maria Jesús FERNÁNDES CORTIZO	Radu BOTGROS
Modelling and Simulation Working Party	Kristin KARLSSON[1]	Efthymios MANOLIS
Oncology Working Party	Pierre DEMOLIS	Irene PAPADOULI
Pharmacogenomics Working Party	Krishna PRASAD	Falk EHMANN
Pharmacokinetics Working Party	Jan WELINK	Kevin BLAKE
Rheumatology/Immunology Working Party	Jan MUELLER-BERGHAUS	Margot MARTIN
Vaccines Working Party	Mair POWELL	Manuela MURA

[1] Elected in June 2018, replaced Ine Skottheim RUSTEN

Drafting groups

	Chair	EMA contact
Gastroenterology Drafting Group	Mark AINSWORTH	Joachim MUSAUS
Radiopharmaceuticals Drafting Group	Anabel CORTES BLANCO	Silvy DA ROCHA DIAS
Respiratory Drafting Group	Karolina TORNEKE	Catherine DRAI
Excipients Drafting Group	Dominique MASSET	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	Ana ZANOLETTY PEREZ
Working Group on Quality Review of Documents	Alexios SKARLATOS	Monica BUCH
Geriatric Expert Group	Katarina VUCIC	Francesca CERRETA
Summary of Product Characteristics Advisory Group	Laurent BRASSART	Laurent BRASSART
Guidelines Consistency Group	Aranzazu SANCHO-LOPEZ[2]	Andrea TAFT
Good Manufacturing and Distribution Practice Inspectors Working Group	Brendan CUDDY	Esther MARTINEZ
Good Clinical Practice Inspectors Working Group	Ana RODRIGUEZ	Ana RODRIGUEZ
Good Laboratory Practice Inspectors Working Group	Maria Antonietta ANTONELLI	Maria Antonietta ANTONELLI
Pharmacovigilance Inspectors Working Group	Anabela MARÇAL	Sophia MYLONA

[2] Elected in July 2018, replaced Barbara VAN ZWIETEN BOOT

	Chair	EMA contact
PAT Team	Keith PUGH	Monika MAYR

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
CVMP Efficacy Working Party (EWP-V)	Cristina MUNOZ MADERO	Isaura DUARTE / Nicholas JARRETT
CVMP Environmental Risk Assessment (ERAWP)	Jason WEEKS	Isaura DUARTE / Nicholas JARRETT
CVMP Immunologicals Working Party (IWP)	Esther WERNER	Ivo CLAASSEN[3]
CVMP Pharmacovigilance Working Party (PhVWP-V)	Els DEWAELE	Isaura DUARTE / Jordi TORREN EDO
CVMP Safety Working Party (SWP-V)	Stefan SCHEID[4]	Isaura DUARTE / Nicholas JARRETT[3]
Quality Working Party	Keith PUGH	Simona GOVER / Piotr KRAUZE
Scientific Advice Working Party (SAWP-V)	Rory BREATHNACH	Vladimir PUCOVSKY[5]

Other CVMP-associated groups

	Chair	EMA contact
CVMP Ad Hoc Group on Veterinary Novel Therapies (ADVENT)	Jean-Claude ROUBY	Minna LEPPANEN
Good Manufacturing and Distribution Practice Inspectors Working Group	Brendan CUDDY	Esther MARTINEZ
Pharmacovigilance Inspectors Working Group	Anabela MARÇAL	Sophia MYLONA
PAT Team	Keith PUGH	Monika MAYR

[3] From March 2018
[4] Elected April 2018, replaced Eva LANDER PERSSON
[5] From October 2018

Pharmacovigilance Risk Assessment Committee (PRAC)

	Chair	EMA contact
Signal Management Review Technical (SMART) Working Group work stream 1 (processes)	Menno van der ELST [6]/Georgy GENOV	Georgy GENOV / Aniello Santoro
Signal Management Review Technical (SMART) Working Group work stream 2 (methods)	Eugene van PUIJENBROEK, Jim SLATTERY	Jim SLATTERY / Gianmario CANDORE / Cosimo ZACCARIA
Granularity and Periodicity Advisory Group (GPAG)	Menno van der ELST	Margaux PHILIPPE[7]

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	Wieland PESCHEL

HMPC temporary drafting groups

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

Other HMPC-associated groups

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

[6] Replaced Sabine STRAUS in September 2018.
[7] Replaced Robin RUEPP in September 2018

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
Working Party on Pharmacovigilance Procedures Work Sharing	Maria Luisa CASINI	
Non-Prescription Medicinal Products Task Force	Martin HUBER	Silvy DA ROCHA DIAS

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	Janos KOVACS
Packaging and Labelling Working Group	Iveta OBROVSKA	Janos KOVACS
Notice to Applicants Working Group	Paula KAJASTE	Janos KOVACS
Autogenous Vaccines Working Group	Mariette SALERY	Janos KOVACS

	Chair	EMA contact
Borderline Products Working Group	Jose JONIS	Janos KOVACS
Legislation Working Group	Dries MINNE	Janos KOVACS
Working Group on Improvement of DCP/MRP	Mariette SALERY	Janos KOVACS
TOPRA Working Party	Paula KAJASTE	Janos KOVACS
Working Group on EU Network Training Centre	Laetitia LE LETTY	Janos KOVACS
CMDv Brexit Working Group	Laetitia LE LETTY	Janos KOVACS

Joint working parties, working groups and advisory groups

	Chair	EMA contact
Joint CHMP/CVMP Quality Working Party (QWP)	Keith PUGH	Brendan CUDDY / Simona GOVER / Piotr KRAUZE
Joint CMDh-CMDv-EMA-EDQM 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	Ellen-Margrethe VESTERGAARD	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/Vanessa FRADIN-DA ROS/Geraldine PORTIER
Joint CMDh-CMDv Variation Regulation Working Party	Susanne WINTERSCHEID	Silvy DA ROCHA DIAS
EMA/CMDh Working Party on Paediatric Regulation	Sarah BRANCH	Silvy DA ROCHA DIAS
GCP Inspectors WG/CMDh Working Party	Jayne CROWE	Maria Antonietta ANTONELLI
Extrapolation working group	Gerard PONS	
CTS Working Group	Dino SOUMPASIS	

Annex 10 – CHMP opinions on initial evaluations and extensions of therapeutic indication in 2018

This annex is available in an Excel spread sheet here.

Annex 11 – Guidelines and concept papers adopted by CHMP in 2018

Biologics Working Party

Reference number	Document	Status	Date
EMA/CHMP/BWP/303353/2010 Rev 3	CHMP position statement on Creutzfeldt-Jakob disease and plasma-derived and urine-derived medicinal products	Draft for public consultation	18 October 2018
EMA/CHMP/BWP/133540/2017	Guideline on quality aspects included in the product information for vaccines for human use	Final	18 October 2018
EMA/CHMP/BWP/192228/2017	Questions and Answers on Bovine Spongiform encephalopathies (BSE) and vaccines	Final	18 October 2018
EMA/CHMP/BWP/426390/2017	Question and Answer Document on the Haemagglutination Inhibition (HI) test for qualification of seasonal influenza vaccine (inactivated) seed preparations	Final	18 October 2018

Biosimilar Medicinal Product Working Party

Reference number	Document	Status	Date
EMEA/CHMP/BMWP/94528/2005 Rev. 1	Annex to Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues - Guideline on similar medicinal products containing somatropin	Final	28 June 2018
EMEA/CHMP/BMWP/301636/2008, Rev. 1	Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant erythropoietins	Final	28 June 2018
EMEA/CHMP/BMWP/31329/2005 Rev 1	Guideline on similar biological medicinal products containing recombinant granulocyte-colony stimulating factor	Draft for public consultation	26 July 2018

Biostatistics Working Party

Reference number	Document	Status	Date
EMA/492010/2018	Questions and Answers on Data Monitoring Committees issues	Final	26 July 2018
EMA/810713/2017	Questions and Answers on adequacy of the Mahalanobis Distance (MD) clarifying Appendix 1 to the guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1)	Draft for public consultation	26 July 2018
EMA/713584/2018	Questions and Answers on adjusting for cross over for estimating effects in oncology trials	Final	13 December 2018

Blood Products Working Party

Reference number	Document	Status	Date
EMA/CHMP/BPWP/94038/2007 Rev. 5	Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg)	Final	28 June 2018
EMA/CHMP/BPWP/94033/2007 rev. 3	Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)	Final	28 June 2018
EMA/CHMP/BPWP/144533/2009 rev. 2	Guideline on clinical investigation of recombinant and human plasma-derived factor VIII products	Final	26 July 2018
EMA/CHMP/BPWP/1619/1999 Rev. 3	Core summary of product characteristics for human plasma derived and recombinant coagulation factor VIII products	Final	26 July 2018
EMA/CHMP/BPWP/494462/2011 rev.3	Guideline on core SmPC for human albumin solution	Final	26 July 2018
EMA/CHMP/BPWP/144552/2009 rev.2 Corr.1	Guideline on clinical investigation of recombinant and human plasma derived factor IX products	Draft for public consultation	15 November 2018
EMA/CHMP/BPWP/1625/1999 rev.3	Guideline on core SmPC for human plasma derived and recombinant coagulation factor IX products	Draft for public consultation	15 November 2018

Cardiovascular Working Party

Reference number	Document	Status	Date
CPMP/EWP/1080/00 Rev. 2	Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus	Draft for public consultation	25 January 2018
EMA/CHMP/763438/2017	Paediatric Addendum on the guidelines on clinical 5 investigation of medicinal products for the treatment and 6 prophylaxis of venous thromboembolic disease	Draft for public consultation	18 October 2018
EMA/CHMP/78339/2018	Concept paper on the need for revision of the “Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Peripheral Arterial Occlusive Disease” (CHMP/EWP/714/98 rev 1)	Adopted for public consultation	18 October 2018

Committee for Advanced Therapies (CAT)

Reference number	Document	Status	Date
CHMP/CAT/GTWP/671639/ 2008 Rev.1	Quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells	Draft for public consultation	26 July 2018
EMEA/149995/2008 rev.1	Guideline on safety and efficacy and risk management for ATMPs	Draft for public consultation	1 February 2018

Central Nervous System Working Party

Reference number	Document	Status	Date
CPMP/EWP/553/95 Rev. 2	Guideline on medicinal products for the treatment of Alzheimer's disease and other dementias	Final	22 February 2018
CPMP/EWP/566/98 Rev. 3	Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders	Draft for public consultation	26 July 2018

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	March 2018
EMA/CHMP/187129/2016	Information for the package leaflet regarding dextrans used as excipients in medicinal products for human use	Draft for public consultation	19 November 2018
EMA/CHMP/186428/2016	Information for the package leaflet regarding lactose used as an excipient in medicinal products for human use	Draft for public consultation	19 November 2018
EMA/CHMP/190743/2016	Information for the package leaflet regarding polysorbates used as excipients in medicinal products for 6 human use	Draft for public consultation	19 November 2018
EMA/CHMP/332530/2015	Information for the package leaflet regarding proline used as an excipient in medicinal products for human use	Draft for public consultation	19 November 2018

Extrapolation Working Group

Reference number	Document	Status	Date
EMA/189724/2018	Reflection paper on the use of extrapolation in the development of medicines for paediatrics	Final	18 October 2018

Gastroenterology Drafting Group

Reference number	Document	Status	Date
CPMP/EWP/2284/99 Rev.2	Guideline on the development of new medicinal products for the treatment of Crohn's Disease	Final	28 June 2018
CHMP/EWP/18463/2006 Rev.1	Guideline on the development of new medicinal products for the treatment of Ulcerative Colitis	Final	28 June 2018
EMA/CHMP/299976/2018	Reflection paper on regulatory requirements for the 5 development of medicinal products for chronic non6 infectious liver diseases (PBC, PSC, NASH)	Draft for public consultation	15 November 2018

Geriatric Expert Group

Reference number	Document	Status	Date
EMA/CHMP/778709/2015	Reflection paper on physical frailty: instruments for baseline characterisation of older populations in clinical trials	Final	25 January 2018

ICH

Reference number	Document	Status	Date
EMA/CHMP/ICH/616110/2018	ICH guideline S11 on nonclinical safety testing in support of development of paediatric medicines	Draft for public consultation, step 2b	20 September 2018
EMA/CHMP/ICH/453684/2016	ICH S9 guideline on nonclinical evaluation for anticancer pharmaceuticals - questions and answers	Adopted, step 5	26 April 2018
EMA/CHMP/ICH/353369/2013	ICH Q3D Impurities: Guideline for Elemental Impurities.	Draft for public consultation, step 2b	26 April 2018
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	Adopted, step 5	22 February 2018
EMA/CHMP/ICH/493213/2018	ICH guideline M9 on biopharmaceutics classification system based biowaivers	Draft for public consultation, step 2b	26 July 2018

Infectious Diseases Working Party

Reference number	Document	Status	Date
CPMP/EWP/558/95 Rev. 3	Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections	Draft for public consultation	13 December 2018

Modelling and Simulation Working Party

Reference number	Document	Status	Date
None			

Oncology Working Party

Reference number	Document	Status	Date
EMA/CHMP/459559/2018	Guideline on the use of minimal residual disease as an endpoint in multiple myeloma studies	Draft for public consultation	26 July 2018

Reference number	Document	Status	Date
EMA/CHMP/755489/2018	Concept paper on the revision of the guideline on the evaluation of anticancer medicinal products in man (CHMP/205/95 Rev. 5)	Adopted for public consultation	13 December 2018

Pharmacogenomics Working Party

Reference number	Document	Status	Date
EMA/CHMP/268544/2016	Guideline on good pharmacogenomic practice	Final	22 February 2018

Pharmacokinetics Working Party

Reference number	Document	Status	Date
EMA/CHMP/PKWP/535116/2016	Reflection paper on investigation of pharmacokinetics and pharmacodynamics in the obese population	Draft for public consultation	25 January 2018
CPMP/EWP/239/95 Rev.1	Guideline on equivalence studies for the demonstration of therapeutic equivalence for locally applied, locally acting products in the gastrointestinal tract	Final	18 October 2018
EMA/CHMP/458101/2016	Guideline on the reporting of physiologically based pharmacokinetic (PBPK) modelling and simulation	Final	13 December 2018
EMA/CHMP/790333/2018	Cabozantinib tablet 20 mg, 40 mg and 60 mg, capsule 20 5 mg and 80 mg product-specific bioequivalence guidance	Draft for public consultation	13 December 2018
EMA/CHMP/802491/2018	Ezetimibe tablet 10 mg product-specific bioequivalence 5 guidance	Draft for public consultation	13 December2018
EMA/CHMP/291450/2018	Aliskiren film-coated tablets 150 mg and 300 mg product-specific bioequivalence guidance	Final	13 December 2018
EMA/CHMP/291499/2018	Apixaban film-coated tablets 2.5 and 5 mg product-specific bioequivalence guidance	Draft for public consultation	31 May 2018
EMA/CHMP/257026/2018	Gefitinib film-coated tablet 250 mg product-specific bioequivalence guidance	Draft for public consultation	31 May 2018
EMA/CHMP/291571/2018	Octreotide acetate depot powder and solvent for suspension for injection 10 mg, 20 mg or 30 mg product-specific bioequivalence guidance	Draft for public consultation	31 May 2018

Reference number	Document	Status	Date
EMA/CHMP/800775/2017	Pegylated liposomal doxorubicin hydrochloride concentrate for solution 2 mg/ml product-specific bioequivalence guidance	Final	13 December 2018
EMA/CHMP/800802/2017	Agomelatine oral tablet 25 mg product-specific bioequivalence guidance	Final	26 July 2018
EMA/CHMP/800794/2017	Vismodegib hard capsule 150 mg product-specific bioequivalence guidance	Final	26 July 2018
EMA/CHMP/800759/2017	Cholic acid capsules 50 mg and 250 mg product-specific bioequivalence guidance	Final	26 July 2018
EMA/CHMP/800789/2017	Ledipasvir/sofosbuvir film-coated tablet 90 mg/400 mg product-specific bioequivalence guidance	Final	26 July 2018
EMA/CHMP/800785/2017	Posaconazole gastro-resistant tablet 100 mg product-specific bioequivalence guidance	Final	26 July 2018
EMA/CHMP/246806/2018	Questions and Answer - Ferric citrate coordination complex 1g film-coated tablets - product specific equivalence guidance	Final	25 January 2018
EMA/CHMP/356878/2017	Rilpivirine film-coated tablets 25 mg product-specific bioequivalence guidance	Final	25 January 2018
EMA/CHMP/356877/2017	Paracetamol oral use immediate release formulations product-specific bioequivalence guidance	Final	25 January 2018
EMA/CHMP/356875/2017	Dronedarone film-coated tablets 400 mg product-specific bioequivalence guidance	Final	25 January 2018
EMA/CHMP/356874/2017	Dolutegravir film-coated tablets 10 mg, 25 mg and 50 mg product-specific bioequivalence guidance	Final	25 January 2018
EMA/CHMP/356876/2017	Ibuprofen oral use immediate release formulations 200 - 800 mg product-specific bioequivalence guidance	Final	31 May 2018
EMA/CHMP/421315/2017	Dimethyl fumarate gastro-resistant capsule 120 mg and 240 mg product-specific bioequivalence guidance	Final	31 May 2018
EMA/CHMP/805498/2016	Dabigatran etexilate hard capsule 75 mg, 110 mg and 150 mg product-specific bioequivalence guidance	Final	31 May 2018

Reference number	Document	Status	Date
EMA/CHMP/315234/2014/Rev.1	Tadalafil film-coated tablets 2.5 mg, 5 mg, 10 mg and 20 mg product-specific bioequivalence guidance	Final	25 January 2018
EMA/CHMP/158772/2016/Rev.1	Prasugrel hydrochloride film-coated tablets 5 mg and 10 mg product-specific bioequivalence guidance	Final	31 May 2018
EMA/CHMP/154812/2016/Rev.1	Paliperidone prolonged-release tablet 1.5 mg, 3 mg, 6 mg, 9 mg and 12 mg product-specific bioequivalence guidance	Final	31 May 2018

Quality Working Party

Reference number	Document	Status	Date
EMA/CHMP/CVMP/QWP/496873/2018	Guideline on the quality of water for pharmaceutical use	Adopted for consultation	28 June 2018
CHMP/QWP/227/02 Rev 4 EMEA/CVMP/134/02-Rev. 4	Guideline on Active Substance Master File Procedure	Adopted	18 October 2018
EMA/CHMP/CVMP/QWP/850374/2015	Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container	Adopted	15 November 2018
EMA/CHMP/QWP/708282/2018	Guideline on quality and equivalence of topical products	Adopted for consultation	15 November 2018
EMA/CVMP/QWP/798401/2015	Guideline on manufacture veterinary finished dosage form	Adopted for consultation	15 February 2018
EMA/CVMP/QWP/153641/2018	Draft reflection paper on risk management requirements for elemental impurities in veterinary medicinal products	Adopted for consultation	8 November 2018

Radiopharmaceutical Drafting Group

Reference number	Document	Status	Date
None			

Respiratory Drafting Group

Reference number	Document	Status	Date
None			

Rheumatology / Immunology Working Party

Reference number	Document	Status	Date
EMA/CHMP/481820/2018 Corr.	Concept paper on the need to develop a reflection paper on development of medicinal products to prevent and treat acute kidney injury	Draft for public consultation	28 June 2018
EMA/CHMP/251023/2018	Concept paper on a Guideline for allergen products development in moderate to low-sized study population	Draft for public consultation	13 December 2018

Safety Working Party

Reference number	Document	Status	Date
EMA/CHMP/SWP/686140/2018	Guideline on the non-clinical requirements for radiopharmaceuticals	Draft for public consultation	15 November 2018
EMA/CHMP/SWP/545588/2017	Reflection paper on the qualification of non-genotoxic impurities	Draft for public consultation	15 November 2018
EMEA/CHMP/SWP/4447/00 Rev.1	Environmental risk assessment of medicinal products for human use	Draft for public consultation	15 November 2018

Vaccines Working Party

Reference number	Document	Status	Date
EMEA/CHMP/VWP/164653/05	Guideline on Clinical Development of new vaccines	Draft for public consultation	26 April 2018
EMA/CHMP/257022/2017	Guideline on the evaluation of medicinal products indicated for the prophylaxis or treatment of respiratory syncytial virus (RSV) disease	Final	18 October 2018

Annex 12 – CVMP opinions on medicinal products for veterinary use in 2018

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**
• Clevor • ropinirole	Orion Corporation	• Dogs • Induction of vomiting in dogs	• 19/10/2016 • 15/02/2018 • 210 • 274	• 15/02/2018 • 13/03/2018 • 13/04/2018 • 17/04/2018 • C 188 01/06/2018
• Bravecto Plus • fluralaner/moxidectin	Intervet International B.V.	• Cats • For the treatment of tick and flea infestations in cats. For the prevention of heartworm disease caused by Dirofilaria immitis in cats. For the treatment of infections with intestinal roundworm and hookworm in cats. The veterinary medicinal product is exclusively indicated when use against ticks or fleas and one or more of the other target parasites is indicated at the same time.	• 13/12/2016 • 15/03/2018 • 210 • 247	• 15/03/2018 • 11/04/2018 • 08/05/2018 • 16/05/2018 • C 229 29/06/2018
• Dany's BienenWohl • oxalic acid dihydrate	Dany's BienenWohl GmbH	• Honey bees • For the treatment of varroosis	• 19/02/2018 • 19/04/2018 • 59 • 0	• 19/04/2018 • 08/05/2018 • 14/06/2018 • 19/06/2018 • C 266 27/07/2018

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
• Ubac • *Streptococcus uberis* vaccine (inactivated)	Laboratorios Hipra, S.A.	• Cattle • For active immunisation of healthy cows and heifers to reduce the incidence of clinical intramammary infections caused by Streptococcus uberis, to reduce the somatic cell count in Streptococcus uberis positive quarter milk samples and to reduce milk production losses caused by Streptococcus uberis intramammary infections.	• 15/03/2017 • 25/05/2018 • 210 • 226	• 25/05/2018 • 21/06/2018 • 26/07/2018 • 30/07/2018 • C 309 31/08/2018
• Arti-Cell Forte[1] • chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cells	Global Stem cell Technology NV	• Horses • Reduction of mild to moderate recurrent lameness associated with non-septic joint inflammation in horses.	• 13/07/2017 • 21/06/2018 • 210 • 134	• 21/06/2018 • Pending • Pending • Pending • Pending
• Cortacare • hydrocortisone aceponate	Ecuphar NV	• Dogs • For symptomatic treatment of inflammatory and pruritic dermatoses in dogs	• 07/06/2017 • 21/06/2018 • 210 • 169	• 21/06/2018 • 25/07/2018 • 27/08/2018 • 29/08/2018 • C 349 28/09/2018
• Isemid • TORASEMIDE	CEVA Santé Animale	• Dogs • For treatment of clinical signs related to congestive heart failure in dogs,	• 12/07/2017 • 08/11/2018 • 210 • 274	• 08/11/2018 • 05/12/2018 • 09/01/2019 • 11/01/2019 • C 80

[1] Under re-consideration following request from EC

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
		including pulmonary oedema.		04/03/2019
• Syvazul BTV • Bluetongue virus vaccine (inactivated) (multistrain: 1-2 strains out of a set of 3)	LABORATORIOS SYVA, S.A.U	• Sheep, Cattle • For active immunisation of sheep and cattle against bluetongue virus serotypes 1, 4 and/or 8 (combination of maximum 2 serotypes)	• 10/05/2017 • 08/11/2018 • 210 • 337	• 08/11/2018 • 05/12/2018 • 09/01/2018 • 11/01/2019 • C 80 04/03/2019
• EVANT • Coccidiosis vaccine live for chickens	LABORATORIOS HIPRA, S.A.	• Chickens • For active immunisation of chicks from 1 day of age against coccidiosis.	• 20/12/2017 • 06/12/2018 • 210 • 141	• 06/12/2018 • 07/01/2019 • 05/02/2019 • Pending • Pending
• Kriptazen • HALOFUGINONE	Virbac S.A.	• Newborn calves • In new born calves prevention of diarrhoea due to diagnosed Cryptosporidium parvum, in farms with history of cryptosporidiosis and reduction of diarrhoea due to diagnosed Cryptosporidium parvum.	• 21/02/2018 • 06/12/2018 • 210 • 78	• 06/12/2018 • 10/01/2019 • 08/02/2019 • Pending • Pending

Negative opinions

Product • **Invented name** • **INN/Common name**	**Marketing authorisation holder**	**Therapeutic area** • **Target species** • **Summary of indication**	**EMA/CVMP** • **Validation** • **Opinion** • **Active time** • **Clock stop**	**European Commission** • **Opinion received** • **Transmission to EC** • **Decision** • **Notification** • **Official Journal**
• Horse Allo[2] • Allogeneic equine adipose-derived mesenchymal stem cells	Centauri Biotech SL	• Horses • For the treatment osteoarthritis in adult non-food producing horses. Demonstration of efficacy is based on a randomised controlled trial evaluating the efficacy of the treatment in horses with osteoarthritis.	• 12/01/2017 • 21/06/2018 • Pending • Pending	• 21.06.2018 • Pending • Pending • Pending • Pending
• HorStem[3] • Equine umbilical cord mesenchymal stem cells	EquiCord-Ymas S.L.	• Horses • Treatment of clinical symptomatology, lameness grade, synovial effusion and flexion pain, associated with mild to moderate degenerative joint disease (ostheoathrosis) in horses. Demonstration of efficacy is based on a randomised controlled clinical trial evaluation the efficacy of the product in equines with mild to moderate ostheoathrosis.	• 08/06/2016 • 11/10/2018 • Pending • Pending	• 11/10/2018 • Pending • Pending • Pending • Pending

[2] Under re-consideration following request from EC
[3] Under re-examination

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
• Longrange • eprinomectin	Merial	• Cattle • Treatment of the following parasites: Gastrointestinal Roundworms (Adult and L4): Ostertagia ostertagi/lyrata, Cooperia oncophora/surnabada, C. punctata, Haemonchus contortus, Trichostrongylus axei, T. colubriformis, Bunostomum phlebotomum, Nematodirus helvetianus, Oesophagostomum radiatum • Lungworm (Adults and L4): Dictyocaulus viviparus • Warbles (parasitic stages): Hypoderma bovis, H. lineatum • Mange mites: Sarcoptes scabiei var. bovis • Lice: Linognathus vituli, Haematopinus eurysternus, Solenoptes capillatus • Horn flies: Haematobia irritans • Prevention of reinfections with the following parasites: • Dictyocaulus	• 12/01/2017 • 21/06/2018 • 210 • 315	• 11/10/2018 • N/a • 12/12/2018 • 14/12/2018 • C 32 25/01/2019

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
		viviparus, Ostertagia ostertagi/lyrata, Trichostrongylus colubriformis, Haemonchus contortus, and Bunostomum phlebotomum; • Oesophagostomum radiatum, Cooperia oncophora/surnabada, C. punctata and Trichostrongylus axei.		

CVMP opinions in 2018 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
• Paromomycin	Poultry eggs	• 13/07/2016 • 15/02/2018	• 15/02/2018 • 2018/1967 • L 316
• Isoflurane	Porcine	• 10/05/2017 • 15/03/2018	• 15/03/2018 • 2018/1076 • L 194
• Diflubenzuron	Salmonidae	• 12/06/2014 • 15/03/2018	• 15/03/2018 • Pending • Pending
• Ovotransferrin	Chicken and poultry	• 07/06/2017 • 19/07/2018	• 19/07/2018 • 2019/83 • L 39

Negative opinions

There were not negative opinions on establishment of MRLs in 2018.

CVMP opinions on extensions of indication for medicinal products for veterinary use

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CVMP opinion**	**European Commission decision date**
• Advocate • imidacloprid / moxidectin	• Bayer Animal Health GmbH	• QP54AB52 • For dogs, cats and ferrets suffering from, or at risk from, mixed parasitic infections.	• 18/01/2018	• 20/02/2018
• AFTOVAXPURDOE • Foot-and-mouth disease vaccine (inactivated) (multistrain: 1-3 strains out of a set of 8)	• MERIAL	• QI02AA04 • Active immunisation of cattle, sheep and pigs from 2 weeks of age against foot-and-mouth disease to reduce clinical signs.	• 08/11/2018	• 12/12/2018
• ERAVAC • rabbit haemorrhagic disease type 2 virus (RHDV2), inactivated	• Laboratorios Hipra, S.A.	• QI08AA01 • For active immunisation of rabbits against rabbit haemorrhagic disease type 2 virus (RHDV2)	• 15/02/2018	• 22/03/2018

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CVMP opinion**	**European Commission decision date**
• Onsior • robenacoxib	• Elanco GmbH	• QM01AH91 • Relief of pain and inflammation associated with acute and chronic musculo-skeletal disorders in cats. For the reduction of moderate pain and inflammation associated with orthopaedic surgery in cats. • Treatment of pain and inflammation associated with chronic osteoarthritis in dogs. • Treatment of pain and inflammation associated with orthopaedic or soft tissue surgery in dogs and with soft tissue surgery in cats. For the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery in cats.	• 15/03/2018	• 26/04/2018
• Panacur AquaSol • fenbendazole	• Intervet International B.V.	• QP52AC13 • For the treatment and control of gastro-intestinal nematodes in pigs. For the treatment of gastro-intestinal nematodes in chickens.	• 18/01/2018	• 20/03/2018
• Pexion • imepitoin	• Boehringer Ingelheim Vetmedica GmbH	• QN03AX90 • For the reduction of the frequency of generalised seizures due to idiopathic epilepsy in dogs for use after careful evaluation of alternative treatment options. For the reduction of anxiety and fear associated with noise phobia in dogs.	• 25/05/2018	• 05/07/2018

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CVMP opinion**	**European Commission decision date**
• Porcilis PCV M Hyo • porcine circovirus type 2 orf2 subunit antigen / mycoplasma hyopneumoniae inactivated, strain atcc 25934	• Intervet International B.V.	• QI09AL • For the active immunisation of pigs to reduce viremia, virus load in lungs and lymphoid tissues, virus shedding caused by PCV2 infection, and severity of lung lesions caused by Mycoplasma hyopneumoniae infection	• 25/05/2018	• 27/06/2018
• Vectormune ND • cell-associated live recombinant turkey herpes virus (rHVT/ND) expressing the fusion protein of Newcastle diseases virus D-26 lentogenic strain	• Ceva-Phylaxia Co.Ltd	• QI01AD • For active immunisation of 18 day-old embryonated chicken eggs or one-day-old chicks to reduce mortality and clinical signs caused by Newcastle disease virus and to reduce mortality, clinical signs and lesions caused by Marek's disease virus with a phenotype 'virulent'.	• 18/01/2018	• 20/02/2018

Annex 13 – Guidelines and concept papers adopted by CVMP in 2018

CVMP quality

Reference number	Document title	Status
EMA/CVMP/QWP/798401/2015	Guideline on Manufacture of the veterinary finished dosage form	Adopted for consultation February 2018 (End of consultation 31 August 2019)
EMA/CHMP/CVMP/QWP/496873/2018	Guideline on the quality of water for pharmaceutical use	Adopted for consultation July 2018 (End of consultation 15 May 2019)
EMA/CVMP/QWP/153641/2018	Reflection paper on risk management requirements for elemental impurities in veterinary medicinal products	Adopted for consultation November 2018 (End of consultation 31 August 2019)
EMEA/CVMP/134/02 Rev 4	Guideline on Active Substance Master File Procedure	Adopted November 2018
EMA/CHMP/CVMP/QWP/850374/2015	Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container	Adopted December 2018

CVMP safety

Reference number	Document title	Status
EMA/CVMP/SWP/779037/2017	Concept paper for the revision of the guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market	Adopted for consultation January 2018 (End of consultation 28 February 2018)
EMA/CVMP/SWP/721059/2014	Guideline on user safety of topically administered veterinary medicinal products	Adopted April 2018
EMA/CHMP/CVMP/SWP/246844/2018	Questions and answers on implementation of risk-based prevention of cross-contamination in production and 'Guideline on setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities'	Adopted April 2018
EMA/CVMP/ERA/103555/2015	Guideline on assessing the environmental and human health risks of veterinary medicinal products in groundwater	Adopted April 2018

Reference number	Document title	Status
EMA/CVMP/SWP/735325/2012	Guideline on determination of withdrawal periods for edible tissues	Adopted September 2018
EMA/CVMP/SWP/66781/2005-Rev.2	Revised guideline on safety and residue data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market	Adopted for consultation December 2018 (End of consultation 31 August 2019)
EMA/CVMP/SWP/377245/2016	Guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products	Adopted December 2018

CVMP efficacy

Reference number	Document title	Status
EMA/CVMP/383441/2005-Rev.1	Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances	Adopted for consultation April 2018 (End of consultation 30 September 2018)
EMA/CVMP/EWP/278031/2015	Guideline on data requirements for veterinary medicinal products for the prevention of transmission of vector- borne diseases in dogs and cats	Adopted for consultation July 2018 (End of consultation 31 August 2019)
EMA/CVMP/EWP/310225/2014	Reflection paper on resistance in ectoparasites	Adopted for consultation September 2018 (End of consultation 31 August 2019)
EMA/CVMP/016/2000-Rev.3	Guideline on the conduct of bioequivalence studies for veterinary medicinal products	Adopted December 2018
EMA/CVMP/EWP/755916/2016	Guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances	Adopted for consultation December 2018 (End of consultation 31 August 2019)
EMA/CVMP/EWP/77872/2018	Questions and answers on the CVMP guideline on the “Guideline on veterinary medicinal products controlling Varroa destructor parasitosis in bees”	Adopted December 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 May 2018
EMA/CVMP/PhVWP/10418/2009-Rev10	Combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted June 2018
EMA/CVMP/PhVWP/288284/2007-Rev.11	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted June 2018
EMA/CVMP/PhVWP/145186/2013	Q&A on adverse event reporting	Adopted June 2018
EMA/CVMP/PhVWP/126661/2009	Q&A on preparation, management and assessment of periodic safety update reports (PSURs)	Adopted June 2018

CVMP antimicrobials

Reference number	Document title	Status
EMA/CVMP/383441/2005-Rev.1	Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances	Adopted for consultation April 2018 (End of consultation 30 September 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 June 2018
EMA/CVMP/AWP/706442/2013	Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals	Adopted for consultation July 2018 (End of consultation 31 October 2018)
EMA/CVMP/849775/2017	Reflection paper on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation	Adopted for consultation July 2018 (End of consultation 31 January 2019)

Reference number	Document title	Status
EMA/CVMP/AWP/842786/2015	Reflection paper on the use of aminopenicillins and their beta-lactamase inhibitor combinations in animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation September 2018 (End of consultation 21 December 2019)
EMA/CVMP/AWP/237294/2017	Reflection paper on off-label use of antimicrobials in veterinary medicine in the European Union	Adopted November 2018

CVMP immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/315887/2017	Guideline on the use of adjuvanted veterinary vaccines	Adopted for consultation June 2018 (End of consultation 15 January 2019)
EMA/CVMP/IWP/105506/2007-Rev.1	Revised guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD)	Adopted December 2018
EMA/CVMP/IWP/170689/2016	Guideline on requirements for the quality (production and control), safety and efficacy of allergen products for use in horses, dogs and cats	Adopted for consultation December 2018 (End of consultation 31 August 2019)

CVMP environmental risk assessment

Reference number	Document title	Status
EMEA/CVMP/ERA/172074/2008 Rev. 6	Questions and Answers on the implementation of the CVMP guideline on environmental impact assessment for veterinary medicinal products in support of the VICH GL6 (Phase I) and GL38 (Phase II)	Adopted January 2018
EMA/CVMP/ERA/103555/2015	Guideline on assessing the environmental and human health risks of veterinary medicinal products in groundwater	Adopted April 2018
EMA/CVMP/ERA/632109/2014	Reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products	Adopted for consultation November 2018 (End of consultation 31 August 2019)

CVMP novel therapies

No guidelines or working documents have yet been agreed in 2018.

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

Reference number	Document title	Status
EMA/CHMP/CVMP/3Rs/677407/2015	Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken	Adopted June 2018
EMA/CHMP/CVMP/3Rs/164002/2016	Reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs	Adopted June 2018

General

Reference number	Document title	Status
EMA/CVMP/VICH/517152/2013	VICH GL57: Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species	Adopted for consultation January 2018 (End of consultation 15 June 2018)
EMA/CVMP/VICH/335918/2016	VICH GL58 Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV	Adopted for consultation July 2018 (End of consultation 31 December 2018)
EMA/CVMP/VICH/176637/2014	VICH GL56 on Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods	Adopted July 2018

Annex 14 – COMP opinions on designation of orphan medicinal products in 2018

Positive COMP designation opinions

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Adeno-associated viral vector serotype 2/6 encoding zinc-finger nucleases and the human alpha L-iduronidase gene	Sangamo Therapeutics UK LTD - United Kingdom	Treatment of mucopolysaccharidosis type I	• 31/08/2017 • 18/09/2017 • 07/12/2017 • *(80 days/33 days)*	• 15/12/2017 • 17/01/2018
Recombinant adeno-associated viral vector serotype 2/1 encoding human beta-hexosaminidase alpha and beta subunits	University of Cambridge - United Kingdom	Treatment of GM2 gangliosidosis	• 27/09/2017 • 23/10/2017 • 07/12/2017 • *(45 days/33 days)*	• 15/12/2017 • 17/01/2018
Adeno-associated viral vector serotype 5 encoding a microRNA targeted to human huntingtin gene	uniQure biopharma B.V. - The Netherlands	Treatment of Huntington's disease	• 23/08/2017 • 18/09/2017 • 07/12/2017 • *(80 days/33 days)*	• 15/12/2017 • 17/01/2018
Vatiquinone	Edison Orphan Pharma BV - The Netherlands	Treatment of RARS2 syndrome	• 09/08/2017 • 23/10/2017 • 07/12/2017 • *(45 days/33 days)*	• 15/12/2017 • 17/01/2018
Humanised Fc-engineered monoclonal antibody against CD19	MWB Consulting S.A.R.L.. - France	Treatment of IgG4-related disease	• 31/08/2017 • 18/09/2017 • 07/12/2017 • *(80 days/33 days)*	• 15/12/2017 • 17/01/2018
N-[2,6-bis(1-methylethyl)phenyl]-N'-[[1-[4-(dimethylamino)phenyl]cyclopentyl]methyl]urea, hydrochloride salt	Millendo Therapeutics Ltd - United Kingdom	Treatment of congenital adrenal hyperplasia	• 27/09/2017 • 23/10/2017 • 07/12/2017 • *(45 days/33 days)*	• 15/12/2017 • 17/01/2018
Metformin and L-citrulline	Duchenne UK - United Kingdom	Treatment of Duchenne muscular dystrophy	• 29/08/2017 • 23/10/2017 • 07/12/2017 • *(45 days/33 days)*	• 15/12/2017 • 17/01/2018
Adeno-associated viral vector serotype 2/6 encoding zinc-finger nucleases and the human iduronate 2-sulfatase gene	Sangamo Therapeutics UK LTD - United Kingdom	Treatment of mucopolysaccharidosis type II (Hunter's syndrome)	• 31/08/2017 • 18/09/2017 • 07/12/2017 • *(80 days/33 days)*	• 15/12/2017 • 17/01/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
N-(bromoacetyl)-3,3-dinitroazetidine	Sirius Regulatory Consulting EU Limited - Ireland	Treatment of small cell lung cancer	• 31/08/2017 • 18/09/2017 • 07/12/2017 • *(80 days/33 days)*	• 15/12/2017 • 17/01/2018
Itacitinib	Incyte Biosciences Distribution B.V. - The Netherlands	Treatment of graft-versus-host disease	• 06/09/2017 • 23/10/2017 • 07/12/2017 • *(45 days/33 days)*	• 15/12/2017 • 17/01/2018
Pyrazolo[1,5-a]pyrimidine, 3-[4-chloro-2-(4-morpholinyl)-5-thiazolyl]-7-(1-ethylpropyl)-2,5-dimethyl-pyrazolo[1,3-a]pyrimidine	RegIntel Limited - Ireland	Treatment of congenital adrenal hyperplasia	• 31/08/2017 • 18/09/2017 • 07/12/2017 • *(80 days/33 days)*	• 15/12/2017 • 17/01/2018
Allogeneic umbilical cord blood CD34+ cells cultured ex vivo with Notch ligand Delta1	Voisin Consulting S.A.R.L. - France	Treatment in haematopoietic stem cell transplantation	• 28/09/2017 • 23/10/2017 • 07/12/2017 • *(45 days/33 days)*	• 15/12/2017 • 17/01/2018
Gilteritinib	Astellas Pharma Europe B.V. - The Netherlands	Treatment of acute myeloid leukaemia	• 22/09/2017 • 23/10/2017 • 07/12/2017 • *(45 days/33 days)*	• 15/12/2017 • 17/01/2018
Cannabidiol	GW Research Ltd - United Kingdom	Treatment of tuberous sclerosis	• 31/08/2017 • 23/10/2017 • 07/12/2017 • *(45 days/33 days)*	• 15/12/2017 • 17/01/2018
Ciclopirox	Atlas Molecular Pharma S.L. - Spain	Treatment of congenital erythropoietic porphyria	• 28/09/2017 • 23/10/2017 • 07/12/2017 • *(45 days/33 days)*	• 15/12/2017 • 17/01/2018
Hydroxychloroquine sulphate	Professor Pascale De Lonlay - France	Treatment of LIPIN1 disease	• 26/09/2017 • 23/10/2017 • 07/12/2017 • *(45 days/33 days)*	• 15/12/2017 • 17/01/2018
Sirolimus	Rare Partners srl Impresa Sociale - Italy	Treatment of sickle cell disease	• 28/09/2017 • 23/10/2017 • 07/12/2017 • *(45 days/34 days)*	• 15/12/2017 • 18/01/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
2'-O-(2-methoxyethyl)-modified antisense oligonucleotide targeting exon 13 in the USH2A gene	ProQR Therapeutics IV BV - The Netherlands	Treatment of retinitis pigmentosa	• 11/10/2017 • 20/11/2017 • 18/01/2018 • *(59 days/21 days)*	• 01/02/2018 • 22/02/2018
Rusalatide acetate	Raremoon Consulting Ltd - United Kingdom	Treatment of acute radiation syndrome	• 26/10/2017 • 20/11/2017 • 18/01/2018 • *(59 days/21 days)*	• 01/02/2018 • 22/02/2018
Levosimendan	Orion Corporation - Finland	Treatment of amyotrophic lateral sclerosis	• 22/09/2017 • 20/11/2017 • 18/01/2018 • *(59 days/21 days)*	• 01/02/2018 • 22/02/2018
Recombinant human monoclonal antibody against mannan-binding lectin-associated serine protease-2	Omeros London Limited - United Kingdom	Treatment of primary IgA nephropathy	• 26/10/2017 • 20/11/2017 • 18/01/2018 • *(59 days/21 days)*	• 01/02/2018 • 22/02/2018
Allogeneic CD4+ and CD25+ T lymphocytes ex vivo incubated with GP120	Universitätsmedizin der Johannes Gutenberg-Universität Mainz - Germany	Treatment in haematopoietic stem cell transplantation	• 22/08/2017 • 23/10/2017 • 18/01/2018 • *(87 days/21 days)*	• 01/02/2018 • 22/02/2018
Pyridoxal 5'-phosphate	Medicure Pharma Europe Limited - Ireland	Treatment of pyridoxamine 5'-phosphate oxidase deficiency	• 20/10/2017 • 20/11/2017 • 18/01/2018 • *(59 days/21 days)*	• 01/02/2018 • 22/02/2018
Seletalisib	UCB Biopharma S.P.R.L - Belgium	Treatment of activated phosphoinositide 3-kinase delta syndrome	• 24/10/2017 • 20/11/2017 • 18/01/2018 • *(59 days/21 days)*	• 01/02/2018 • 22/02/2018
6-{[(1R,2S)-2-aminocyclohexyl]amino}-7-fluoro-4-(1-methyl-1H-pyrazol-4-yl)-1,2-dihydro-3H-pyrrolo[3,4-c]pyridin-3-one monocitrate	Takeda Pharma A/S - Denmark	Treatment of acute myeloid leukaemia	• 28/09/2017 • 23/10/2017 • 18/01/2018 • *(87 days/21 days)*	• 01/02/2018 • 22/02/2018
Flucytosine	Richardson Associates Regulatory Affairs Ltd - Ireland	Treatment of glioma	• 28/09/2017 • 23/10/2017 • 18/01/2018 • *(87 days/21 days)*	• 01/02/2018 • 22/02/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
1-[[[4-(4-fluoro-2-methyl-1H-indol-5-yloxy)-6-methoxyquinolin-7-yl]oxy]methyl]cyclopropanamine-dihydrochloride	CATS Consultants GmbH - Germany	Treatment of soft tissue sarcoma	• 23/10/2017 • 20/11/2017 • 18/01/2018 • *(59 days/21 days)*	• 01/02/2018 • 22/02/2018
(R)-2-(5-cyano-2-(6-(methoxycarbonyl)-7-methyl-3-oxo-8-(3-(trifluoromethyl)phenyl)-2,3,5,8-tetrahydro-[1,2,4]triazolo[4,3-a]pyrimidine-5-yl)phenyl)-N,N,N-trimethylethanaminium methanesulfonate dehydrate	Chiesi Farmaceutici S.p.A. - Italy	Treatment of cystic fibrosis	• 23/10/2017 • 20/11/2017 • 18/01/2018 • *(59 days/21 days)*	• 01/02/2018 • 22/02/2018
Mertansine functionalised gold nanoconjugate	Midatech Pharma Plc - United Kingdom	Treatment of hepatocellular carcinoma	• 25/11/2016 • 23/10/2017 • 18/01/2018 • *(87 days/21 days)*	• 01/02/2018 • 22/02/2018
Vocimagene amiretrorepvec	Richardson Associates Regulatory Affairs Ltd - Ireland	Treatment of glioma	• 28/09/2017 • 23/10/2017 • 18/01/2018 • *(87 days/21 days)*	• 01/02/2018 • 22/02/2018
N-(tert-butylcarbamoyl)-5-cyano-2-((4'-(difluoromethoxy)-[1,1'-biphenyl]-3-yl)oxy)benzenesulfonamide	ATXA Therapeutics Limited - Ireland	Treatment of pulmonary arterial hypertension	• 20/10/2017 • 20/11/2017 • 18/01/2018 • *(59 days/21 days)*	• 01/02/2018 • 22/02/2018
Adenovirus-associated viral vector serotype 8 containing the human RPGR gene	Nightstar Therapeutics plc - United Kingdom	Treatment of retinitis pigmentosa	• 27/10/2017 • 20/11/2017 • 18/01/2018 • *(59 days/21 days)*	• 01/02/2018 • 22/02/2018
Cannabidivarin	GW Research Ltd - United Kingdom	Treatment of fragile X syndrome	• 26/10/2017 • 20/11/2017 • 18/01/2018 • *(59 days/21 days)*	• 01/02/2018 • 22/02/2018
Human monoclonal IgG2 antibody against tissue factor pathway inhibitor	Bayer AG - Germany	Treatment of haemophilia A	• 28/09/2017 • 23/10/2017 • 18/01/2018 • *(87 days/21 days)*	• 01/02/2018 • 22/02/2018
Gemfibrozil	IQVIA RDS Ireland Limited - Ireland	Treatment of neuronal ceroid lipofuscinosis	• 26/10/2017 • 18/12/2017 • 15/02/2018 • *(59 days/26 days)*	• 23/02/2018 • 21/03/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Dimethyl fumarate	PharmaBio Consulting - Germany	Treatment of Friedreich's ataxia	• 27/10/2017 • 20/11/2017 • 15/02/2018 • *(87 days/21 days)*	• 23/02/2018 • 21/03/2018
Docosahexaenoic acid ethyl ester	TurnKey PharmaConsulting Ireland Limited - Ireland	Treatment of sickle cell disease	• 23/11/2017 • 18/12/2017 • 15/02/2018 • *(59 days/26 days)*	• 23/02/2018 • 21/03/2018
Tazemetostat	IQVIA RDS Ireland Limited - Ireland	Treatment of malignant mesothelioma	• 22/11/2017 • 18/12/2017 • 15/02/2018 • *(59 days/26 days)*	• 23/02/2018 • 21/03/2018
Recombinant human acid alpha-glucosidase	Amicus Therapeutics UK Ltd - United Kingdom	Treatment of glycogen storage disease type II (Pompe's disease)	• 21/11/2017 • 18/12/2017 • 15/02/2018 • *(59 days/26 days)*	• 23/02/2018 • 21/03/2018
Miransertib	QRC Ireland - Ireland	Treatment of Proteus syndrome	• 16/11/2017 • 18/12/2017 • 15/02/2018 • *(59 days/26 days)*	• 23/02/2018 • 21/03/2018
(2S,4R)-1-(2-(3-acetyl-5-(2-methylpyrimidine-5-yl)-1H-indazol-1-yl)acetyl)-N-(6-bromopyridine-2-yl)-4-fluoropyrrolidine-2-carboxamide	FGK Representative Service GmbH - Germany	Treatment of C3 glomerulopathy	• 25/10/2017 • 20/11/2017 • 15/02/2018 • *(87 days/26 days)*	• 23/02/2018 • 21/03/2018
Efgartigimod alfa	argenx BVBA - Belgium	Treatment of myasthenia gravis	• 21/11/2017 • 18/12/2017 • 15/02/2018 • *(59 days/26 days)*	• 23/02/2018 • 21/03/2018
Recombinant modified ricin toxin A-chain subunit	Soligenix UK Ltd. - United Kingdom	Prevention of ricin poisoning	• 23/11/2017 • 18/12/2017 • 15/02/2018 • *(59 days/26 days)*	• 23/02/2018 • 21/03/2018
Ribavirin	Pharmadev Healthcare Ltd - Ireland	Treatment of Lassa fever	• 14/11/2017 • 18/12/2017 • 15/02/2018 • *(59 days/26 days)*	• 23/02/2018 • 21/03/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Ribavirin	Pharmadev Healthcare Ltd - Ireland	Treatment of Crimean-Congo haemorrhagic fever	• 14/11/2017 • 18/12/2017 • 15/02/2018 • *(59 days/26 days)*	• 23/02/2018 • 21/03/2018
Ivosidenib	Quality Regulatory Clinical Ireland Limited - Ireland	Treatment of biliary tract cancer	• 21/09/2017 • 20/11/2017 • 15/02/2018 • *(87 days/26 days)*	• 23/02/2018 • 21/03/2018
Tazemetostat	IQVIA RDS Ireland Limited - Ireland	Treatment of follicular lymphoma	• 26/10/2017 • 20/11/2017 • 15/02/2018 • *(87 days/26 days)*	• 23/02/2018 • 21/03/2018
Recombinant adeno-associated viral vector containing a codon-optimized Padua derivative of human coagulation factor IX cDNA	uniQure biopharma B.V. - The Netherlands	Treatment of haemophilia B	• 22/11/2017 • 18/12/2017 • 15/02/2018 • *(59 days/26 days)*	• 23/02/2018 • 21/03/2018
Patidegib	Blue-Reg Europe - France	Treatment of naevoid basal-cell carcinoma syndrome (Gorlin syndrome)	• 24/10/2017 • 20/11/2017 • 15/02/2018 • *(87 days/26 days)*	• 23/02/2018 • 21/03/2018
Larotrectinib	Bayer AG - Germany	Treatment of salivary gland cancer	• 25/10/2017 • 20/11/2017 • 15/02/2018 • *(87 days/26 days)*	• 23/02/2018 • 21/03/2018
Melatonin	Worphmed Srl - Italy	Treatment of neonatal encephalopathy	• 20/11/2017 • 18/12/2017 • 15/02/2018 • *(59 days/26 days)*	• 23/02/2018 • 21/03/2018
Tazemetostat	IQVIA RDS Ireland Limited - Ireland	Treatment of diffuse large B-cell lymphoma	• 26/10/2017 • 20/11/2017 • 15/02/2018 • *(87 days/26 days)*	• 23/02/2018 • 21/03/2018
Branaplam	Novartis Europharm Limited - Ireland	Treatment of 5q spinal muscular atrophy	• 05/12/2017 • 22/01/2018 • 15/03/2018 • *(52 days/25 days)*	• 22/03/2018 • 16/04/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Genetically modified replication-incompetent herpes simplex virus-1 expressing collagen VII	IDEA Innovative Drug European Associates Limited - United Kingdom	Treatment of epidermolysis bullosa	• 23/11/2017 • 18/12/2017 • 15/03/2018 • *(87 days/25 days)*	• 22/03/2018 • 16/04/2018
Autologous dendritic cells pulsed with killed ovarian cancer cells and matured by TLR3 ligand ex vivo	SOTIO a.s - Czech Republic	Treatment of ovarian cancer	• 23/11/2017 • 18/12/2017 • 15/03/2018 • *(87 days/25 days)*	• 22/03/2018 • 16/04/2018
Burosumab	Ultragenyx Germany GmbH - Germany	Treatment of phosphaturic mesenchymal tumour	• 24/02/2017 • 22/01/2018 • 15/03/2018 • *(52 days/25 days)*	• 22/03/2018 • 16/04/2018
Polatuzumab vedotin	Roche Registration GmbH - Germany	Treatment of diffuse large B-cell lymphoma	• 21/11/2017 • 18/12/2017 • 15/03/2018 • *(87 days/25 days)*	• 22/03/2018 • 16/04/2018
Adeno-associated viral vector serotype 9 encoding miRNA against human superoxide dismutase 1	Stolmár & Partner Patentanwälte PartG mbB - Germany	Treatment of amyotrophic lateral sclerosis	• 06/12/2017 • 22/01/2018 • 15/03/2018 • *(52 days/25 days)*	• 22/03/2018 • 16/04/2018
Adeno-associated viral vector serotype 8 containing the human acid alpha-glucosidase gene	Dr Philippe Moullier - France	Treatment of glycogen storage disease type II (Pompe's disease)	• 07/12/2017 • 22/01/2018 • 15/03/2018 • *(52 days/25 days)*	• 22/03/2018 • 16/04/2018
Bardoxolone methyl	Reata UK Limited - United Kingdom	Treatment of Alport syndrome	• 25/01/2018 • 26/02/2018 • 19/04/2018 • *(52 days/29 days)*	• 26/04/2018 • 25/05/2018
Equine immunoglobulin F(ab')2 fragments targeting Shiga toxin	Chemo Research S.L. - Spain	Prevention of haemolytic uraemic syndrome	• 04/12/2017 • 22/01/2018 • 19/04/2018 • *(87 days/29 days)*	• 26/04/2018 • 25/05/2018
Glucagon analogue linked to a human immunoglobulin Fc fragment	Hanmi Europe Limited - United Kingdom	Treatment of congenital hyperinsulinism	• 07/12/2017 • 26/02/2018 • 19/04/2018 • *(52 days/29 days)*	• 26/04/2018 • 25/05/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Itraconazole	Galephar M/F - Belgium	Prevention of invasive aspergillosis	• 06/12/2017 • 22/01/2018 • 19/04/2018 • *(87 days/29 days)*	• 26/04/2018 • 25/05/2018
Daratumumab	Janssen-Cilag International N.V. - Belgium	Treatment of AL amyloidosis	• 24/10/2017 • 26/02/2018 • 19/04/2018 • *(52 days/29 days)*	• 26/04/2018 • 25/05/2018
Synthetic double-stranded siRNA oligonucleotide targeted against transthyretin mRNA, with six phosphorothioate linkages in the backbone, and nine 2'-fluoro and thirty-five 2'-O-methyl nucleoside residues in the sequence, which is covalently linked via a phosphodiester group to a ligand containing three N-acetylgalactosamine residues	Alnylam UK Limited - United Kingdom	Treatment of transthyretin-mediated amyloidosis	• 24/01/2018 • 26/02/2018 • 19/04/2018 • *(52 days/29 days)*	• 26/04/2018 • 25/05/2018
H-Arg-Pro-Lys-Pro-Gln-Gln-Phe-2Thi-Gly-Leu-Met(O2)-NH2-DOTA-225-actinium	Dr. Regenold GmbH - Germany	Treatment of glioma	• 06/12/2017 • 22/01/2018 • 19/04/2018 • *(87 days/29 days)*	• 26/04/2018 • 25/05/2018
Adeno-associated viral vector serotype 9 containing the human CLN1 gene	Abeona Therapeutics Europe SL - Spain	Treatment of neuronal ceroid lipofuscinosis	• 25/01/2018 • 26/02/2018 • 19/04/2018 • *(52 days/29 days)*	• 26/04/2018 • 25/05/2018
Adeno-associated viral vector serotype 8 containing a functional copy of the codon-optimised F8 cDNA encoding the B-domain deleted human coagulation factor VIII	Baxalta Innovations GmbH - Austria	Treatment of haemophilia A	• 24/01/2018 • 26/02/2018 • 19/04/2018 • *(52 days/29 days)*	• 26/04/2018 • 25/05/2018
Ambroxol hydrochloride	Spedding Research Solutions SAS - France	Treatment of amyotrophic lateral sclerosis	• 23/11/2017 • 26/02/2018 • 19/04/2018 • *(52 days/29 days)*	• 26/04/2018 • 25/05/2018
1-(3-{4-[3,4-difluoro-2-(trifluoromethyl)phenyl]piperidine-1-carbonyl}-1H,4H,5H,6H,7H-pyrazolo[3,4- c]pyridin-6-yl)ethan-1-one	IQVIA RDS Ireland Limited - Ireland	Treatment of Stargardt's disease	• 25/01/2018 • 26/02/2018 • 19/04/2018 • *(52 days/29 days)*	• 26/04/2018 • 25/05/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Autologous CD4+ and CD8+ T cells expressing a CD19-specific chimeric antigen receptor	Celgene Europe Limited - United Kingdom	Treatment of follicular lymphoma	• 07/12/2017 • 22/01/2018 • 19/04/2018 • *(87 days/29 days)*	• 26/04/2018 • 25/05/2018
Modified mRNA encoding human methylmalonyl-coenzyme A mutase encapsulated into lipid nanoparticles	Pharma Gateway AB - Sweden	Treatment of methylmalonic acaidaemia	• 25/01/2018 • 26/02/2018 • 19/04/2018 • *(52 days/29 days)*	• 26/04/2018 • 25/05/2018
Three human monoclonal antibodies against the Ebola virus glycoprotein	Regeneron Ireland U.C. - Ireland	Treatment of Ebola virus disease	• 23/01/2018 • 26/02/2018 • 19/04/2018 • *(52 days/29 days)*	• 26/04/2018 • 25/05/2018
Deferiprone	Apotex Europe B.V. - The Netherlands	Treatment of neurodegeneration with brain iron accumulation	• 23/01/2018 • 26/02/2018 • 24/05/2018 • *(87 days/23 days)*	• 04/06/2018 • 27/06/2018
Recombinant human placental growth factor	IQVIA RDS Ireland Limited - Ireland	Treatment of pre-eclampsia	• 27/02/2018 • 26/03/2018 • 24/05/2018 • *(59 days/23 days)*	• 04/06/2018 • 27/06/2018
Recombinant adeno-associated vector serotype 9 containing human iduronidase gene	REGENXBIO EU Limited - Ireland	Treatment of mucopolysaccharidosis type I	• 26/02/2018 • 26/03/2018 • 24/05/2018 • *(59 days/23 days)*	• 04/06/2018 • 27/06/2018
Palovarotene	PPD Global Ltd - United Kingdom	Treatment of multiple osteochondromas	• 26/02/2018 • 26/03/2018 • 24/05/2018 • *(59 days/23 days)*	• 04/06/2018 • 27/06/2018
Omaveloxolone	Dr Stefan Blesse - Germany	Treatment of Friedreich's ataxia	• 27/02/2018 • 26/03/2018 • 24/05/2018 • *(59 days/23 days)*	• 04/06/2018 • 27/06/2018
Codon-optimised human ornithine transcarbamylase mRNA complexed with lipid-based nanoparticles	Real Regulatory Limited - Ireland	Treatment of ornithine transcarbamylase deficiency	• 23/02/2018 • 26/03/2018 • 24/05/2018 • *(59 days/23 days)*	• 04/06/2018 • 27/06/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
2-[(2S)-2-methyl-1,4-dioxa-8-azaspiro[4.5]dec-8-yl]-8-nitro-6-trifluoromethyl-4H-1,3-benzothiazin-4-one	Klinikum der Universität München - Germany	Treatment of tuberculosis	• 22/01/2018 • 26/03/2018 • 24/05/2018 • *(59 days/23 days)*	• 04/06/2018 • 27/06/2018
20-hydroxyecdysone	Biophytis - France	Treatment of Duchenne muscular dystrophy	• 25/01/2018 • 26/02/2018 • 24/05/2018 • *(87 days/23 days)*	• 04/06/2018 • 27/06/2018
Carmustine	ADIENNE S.r.l.S.U. - Italy	Treatment in haematopoietic stem cell transplantation	• 23/01/2018 • 26/02/2018 • 24/05/2018 • *(87 days/23 days)*	• 04/06/2018 • 27/06/2018
L-cystine bis(N'-methylpiperazide)	PharmaKrysto Ltd - United Kingdom	Treatment of cystinuria	• 24/01/2018 • 26/02/2018 • 24/05/2018 • *(87 days/23 days)*	• 04/06/2018 • 27/06/2018
Efpegsomatropin	Hanmi Europe Limited - United Kingdom	Treatment of growth hormone deficiency	• 24/01/2018 • 26/02/2018 • 24/05/2018 • *(87 days/23 days)*	• 04/06/2018 • 27/06/2018
(R)-1-(3-(aminomethyl) phenyl)-N-(5-((3-cyanophenyl)(cyclopropylmethylamino)methyl)-2-fluorophenyl)-3-(trifluoromethyl)-1H-pyrazole-5-carboxamide dihydrochloride	BioCryst UK Ltd - United Kingdom	Treatment of hereditary angioedema	• 18/01/2018 • 26/02/2018 • 24/05/2018 • *(87 days/23 days)*	• 04/06/2018 • 27/06/2018
Argon	Air Liquide Santé (International) - France	Treatment of perinatal asphyxia	• 27/02/2018 • 26/03/2018 • 24/05/2018 • *(59 days/23 days)*	• 04/06/2018 • 27/06/2018
Givinostat	Italfarmaco S.p.A. - Italy	Treatment of Becker muscular dystrophy	• 23/03/2018 • 23/04/2018 • 21/06/2018 • *(59 days/26 days)*	• 05/07/2018 • 31/07/2018
Allogeneic bone marrow derived mesenchymal stromal cells, ex-vivo expanded	medac Gesellschaft für klinische Spezialpräparate mbH (WEDEL) - Germany	Treatment of graft-versus-host disease	• 23/02/2018 • 23/04/2018 • 21/06/2018 • *(59 days/26 days)*	• 05/07/2018 • 31/07/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Tetracosactide	Mallinckrodt Specialty Pharmaceuticals Ireland Limited - Ireland	Treatment of Duchenne muscular dystrophy	• 21/03/2018 • 23/04/2018 • 21/06/2018 • *(59 days/26 days)*	• 05/07/2018 • 31/07/2018
Synthetic double-stranded siRNA oligonucleotide directed against lactate dehydrogenase A mRNA and containing four modified nucleosides which form a ligand cluster of four N-acetylgalactosamine residues	Dicerna EU Limited - United Kingdom	Treatment of primary hyperoxaluria	• 22/03/2018 • 23/04/2018 • 21/06/2018 • *(59 days/26 days)*	• 05/07/2018 • 31/07/2018
Selumetinib	AstraZeneca AB - Sweden	Treatment of neurofibromatosis type 1	• 22/03/2018 • 23/04/2018 • 21/06/2018 • *(59 days/26 days)*	• 05/07/2018 • 31/07/2018
Recombinant human ectonucleotide pyrophosphatase/phosphodiesterase 1 fused to the Fc fragment of IgG1	Inozyme Pharma Ireland Ltd - Ireland	Treatment of ectonucleotide pyrophosphatase/ phosphodiesterase 1 deficiency	• 23/03/2018 • 23/04/2018 • 21/06/2018 • *(59 days/26 days)*	• 05/07/2018 • 31/07/2018
N-acetylgalactosamine-conjugated synthetic double-stranded oligomer specific to serpin family A member 1 gene	Pharma Gateway AB - Sweden	Treatment of congenital alpha-1 antitrypsin deficiency	• 23/03/2018 • 23/04/2018 • 21/06/2018 • *(59 days/26 days)*	• 05/07/2018 • 31/07/2018
Ex-vivo fused autologous human bone marrow-derived mesenchymal stem cell with allogenic human myoblast	Dystrogen Therapeutics S.A. - Poland	Treatment of Duchenne muscular dystrophy	• 26/02/2018 • 26/03/2018 • 21/06/2018 • *(87 days/26 days)*	• 05/07/2018 • 31/07/2018
Adenovirus associated viral vector serotype 2/8 containing the human CNGA3 gene	MeiraGTx UK II Limited - United Kingdom	Treatment of achromatopsia	• 22/03/2018 • 23/04/2018 • 21/06/2018 • *(59 days/26 days)*	• 05/07/2018 • 31/07/2018
2'-O-(2-methoxyethyl) antisense oligonucleotide targeting microtubule-associated protein tau pre-mRNA	Ionis USA Ltd - United Kingdom	Treatment of behavioural variant frontotemporal dementia	• 23/03/2018 • 23/04/2018 • 21/06/2018 • *(59 days/26 days)*	• 05/07/2018 • 31/07/2018
Synthetic antisense oligonucleotide directed against human dystrophin pre-mRNA	Wave life Sciences Ireland Limited - Ireland	Treatment of Duchenne muscular dystrophy	• 27/02/2018 • 26/03/2018 • 21/06/2018 • *(87 days/26 days)*	• 05/07/2018 • 31/07/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Tamibarotene	Lakeside Regulatory Consulting Services Ltd - United Kingdom	Treatment of acute myeloid leukaemia	• 26/02/2018 • 26/03/2018 • 21/06/2018 • *(87 days/26 days)*	• 05/07/2018 • 31/07/2018
Combination of carboplatin and sodium valproate	Dr Ulrich Granzer - Germany	Treatment of glioma	• 27/02/2018 • 26/03/2018 • 21/06/2018 • *(87 days/26 days)*	• 05/07/2018 • 31/07/2018
Liposomal mannose-1-phosphate	Glycomine SARL - France	Treatment of phosphomannomutase-2 congenital disorder of glycosylation	• 23/03/2018 • 23/04/2018 • 21/06/2018 • *(59 days/26 days)*	• 05/07/2018 • 31/07/2018
Tilorone	Professor Marjukka Myllärniemi - Finland	Treatment of idiopathic pulmonary fibrosis	• 15/03/2018 • 23/04/2018 • 19/07/2018 • *(87 days/28 days)*	• 27/07/2018 • 24/08/2018
Autologous glioma tumour cells treated with antisense molecule directed against the insulin-like growth factor type 1 receptor	Pharma Gateway AB - Sweden	Treatment of glioma	• 22/03/2018 • 18/06/2018 • 25/07/2018 • *(37 days/28 days)*	• 27/07/2018 • 24/08/2018
Acetylleucine	IntraBio Limited - United Kingdom	Treatment of spinocerebellar ataxia	• 24/05/2018 • 18/06/2018 • 25/07/2018 • *(37 days/28 days)*	• 27/07/2018 • 24/08/2018
1-(3-methylbutanoyl)-L-aspartyl-L-threonyl-L-histidyl-L-phenylalanyl-L-prolyl-(L-cystinyl-L-isoleucyl-[(N6-(S)-4-carboxy-4-palmitamidobutanoyl)-L-lysinyl]-L-phenylalanyl-L-glutamyl-L-prolyl-L-arginyl-L-serinyl-L-lysinyl-L-glycinyl-L-cystinyl)-L-lysinamide, disulfide, acetate	IQVIA RDS Ireland Limited - Ireland	Treatment of beta-thalassaemia intermedia and major	• 24/05/2018 • 18/06/2018 • 19/07/2018 • *(31 days/28 days)*	• 27/07/2018 • 24/08/2018
Pemigatinib	Incyte Biosciences Distribution B.V. - The Netherlands	Treatment of biliary tract cancer	• 02/03/2018 • 18/06/2018 • 19/07/2018 • *(31 days/28*	• 27/07/2018 • 24/08/2018
Obiltoxaximab	SFL Regulatory Services GmbH - Austria	Treatment of anthrax	• 18/05/2018 • 18/06/2018 • 19/07/2018 • *(31 days/28 days)*	• 27/07/2018 • 24/08/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
(3R,3aS,9R,9aS,9bS)-3-((dimethylamino)methyl)-9-hydroxy-6,9-dimethyl-3,3a,4,5,7,8,9,9a-octahydroazuleno[4,5-b]furan-2(9bH)-one fumarate	IQVIA RDS Ireland Limited - Ireland	Treatment of glioma	• 23/03/2018 • 23/04/2018 • 19/07/2018 • *(87 days/28 days)*	• 27/07/2018 • 24/08/2018
(S)-(−)-3-(4-aminophenyl)-2-methoxypropanoic acid	Nogra Pharma Limited - Ireland	Treatment of idiopathic pulmonary fibrosis	• 24/04/2018 • 18/06/2018 • 19/07/2018 • *(31 days/28 days)*	• 27/07/2018 • 24/08/2018
Adeno-associated viral vector serotype hu68 containing the human SMN1 gene	Biogen Idec Limited - United Kingdom	Treatment of spinal muscular atrophy	• 23/03/2018 • 23/04/2018 • 19/07/2018 • *(87 days/28 days)*	• 27/07/2018 • 24/08/2018
Somapacitan	Novo Nordisk A/S - Denmark	Treatment of growth hormone deficiency	• 21/03/2018 • 23/04/2018 • 19/07/2018 • *(87 days/28 days)*	• 27/07/2018 • 24/08/2018
Bertilimumab	IQVIA RDS Ireland Limited - Ireland	Treatment of bullous pemphigoid	• 24/05/2018 • 18/06/2018 • 19/07/2018 • *(31 days/28 days)*	• 27/07/2018 • 24/08/2018
CD34+ haematopoietic stem and progenitor cells with CD3+ T-cells	IQVIA RDS Ireland Limited - Ireland	Treatment in solid organ transplantation	• 24/05/2018 • 18/06/2018 • 19/07/2018 • *(31 days/28 days)*	• 27/07/2018 • 24/08/2018
Copanlisib	Bayer AG - Germany	Treatment of marginal zone lymphoma	• 23/03/2018 • 23/04/2018 • 19/07/2018 • *(87 days/28 days)*	• 27/07/2018 • 24/08/2018
1-(2-hydroxyethyl)-8-{[5-(4-methylpiperazin-1-yl)-2-(trifluoromethoxy) phenyl]amino}-4,5-dihydro-1H-pyrazolo[4,3-h]quinazoline-3-carboxamide fumarate salt	Pharm Research Associates (UK) Limited - United Kingdom	Treatment of acute myeloid leukaemia	• 22/02/2018/ • 25/07/2018/ • *(93 days/28 days)*	• 27/07/2018 • 24/08/2018
Recombinant human monoclonal antibody against mannan-binding lectin-associated serine protease-2	Omeros London Limited - United Kingdom	Treatment in haematopoietic stem cell transplantation	• 22/03/2018 • 23/04/2018 • 19/07/2018 • *(87 days/28 days)*	• 27/07/2018 • 24/08/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Peptides YMFPNAPYL, SGQAYMFPNAPYLPSCLES, RSDELVRHHNMHQRNMTKL and PGCNKRYFKLSHLQMHSRKHTG	Sellas Life Sciences Limited - Ireland	Treatment of multiple myeloma	• 24/05/2018 • 18/06/2018 • 13/09/2018 • *(87 days/29 days)*	• 27/09/2018 • 26/10/2018
Recombinant adeno-associated viral vector containing a bioengineered capsid and a codon-optimised expression cassette to drive the expression of the SQ form of a B-domain deleted human coagulation factor VIII	Spark Therapeutics Ireland Limited - Ireland	Treatment of haemophilia A	• 26/06/2018 • 16/07/2018 • 13/09/2018 • *(59 days/29 days)*	• 27/09/2018 • 26/10/2018
Glycine, L-alanine, L-arginine, L-aspartic acid, L-cysteine, L-cystine, L-glutamic acid, L-histidine, L-lysine monohydrate, L-methionine, L-phenylalanine, L-proline, L-serine, L-threonine, L-tryptophan, L-tyrosine, taurine	Orphan Europe SARL - France	Treatment of maple syrup urine disease	• 29/05/2018 • 16/07/2018 • 13/09/2018 • *(59 days/29 days)*	• 27/09/2018 • 26/10/2018
6'-(R)-methyl-5-O-(5-amino-5,6-dideoxy-alpha-L-talofuranosyl)-paromamine sulfate	FGK Representative Service GmbH - Germany	Treatment of cystic fibrosis	• 18/06/2018 • 16/07/2018 • 13/09/2018 • *(59 days/29 days)*	• 27/09/2018 • 26/10/2018
Autologous CD34+ haematopoietic stem and progenitor cells genetically modified with the lentiviral vector IDUA LV, encoding for the alpha-L-iduronidase cDNA	Fondazione Telethon - Italy	Treatment of mucopolysaccharidosis type I	• 28/06/2018 • 16/07/2018 • 13/09/2018 • *(59 days/29 days)*	• 27/09/2018 • 26/10/2018
Recombinant adeno-associated viral vector serotype S3 containing codon-optimised expression cassette encoding human coagulation factor IX variant	Freeline Therapeutics Ltd - United Kingdom	Treatment of haemophilia B	• 29/06/2018 • 16/07/2018 • 13/09/2018 • *(59 days/29 days)*	• 27/09/2018 • 26/10/2018
Avapritinib	PhaRA bvba - Belgium	Treatment of mastocytosis	• 18/05/2018 • 18/06/2018 • 13/09/2018 • *(87 days/29 days)*	• 27/09/2018 • 26/10/2018
Melatonin	Worphmed Srl - Italy	Treatment of acute radiation syndrome	• 11/05/2018 • 18/06/2018 • 13/09/2018 • *(87 days/29 days)*	• 27/09/2018 • 26/10/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Gefitinib	Consorcio Centro de Investigación Biomédica en Red, M.P. - Spain	Treatment of Fanconi anaemia	• 24/05/2018 • 18/06/2018 • 13/09/2018 • *(87 days/29 days)*	• 27/09/2018 • 26/10/2018
(6aR,10aR)-3-(1,1-dimethylheptyl)-delta8-tetrahydro-cannabinol-9-carboxylic acid	Accelsiors CRO and Consultancy Services Ltd - Hungary	Treatment of dermatomyositis	• 28/06/2018 • 16/07/2018 • 13/09/2018 • *(59 days/29 days)*	• 27/09/2018 • 26/10/2018
6-(2-hydroxy-2-methylpropoxy)-4-(6-(6-((6-methoxypyridin-3-yl)methyl)-3,6-diazabicyclo[3.1.1]heptan-3-yl)pyridin-3-yl)pyrazolo[1,5-a]pyridine-3-carbonitrile	Loxo Oncology Limited - United Kingdom	Treatment of medullary thyroid carcinoma	• 29/06/2018 • 16/07/2018 • 13/09/2018 • *(59 days/29 days)*	• 27/09/2018 • 26/10/2018
Fidanacogene elaparvovec	Pfizer Europe MA EEIG - Belgium	Treatment of haemophilia B	• 28/06/2018 • 13/08/2018 • 18/10/2018 • *(66 days/28 days)*	• 22/10/2018 • 19/11/2018
Setmelanotide	TMC Pharma Services Ltd - United Kingdom	Treatment of leptin receptor deficiency	• 16/07/2018 • 13/08/2018 • 18/10/2018 • *(66 days/28 days)*	• 22/10/2018 • 19/11/2018
Ile-Ser-Ile-Thr-Glu-Ile-Lys-Gly-Val-Ile-Val-His-Arg-Ile-Glu-Thr-Ile-Leu-Phe-Lys-Lys-Lys-Lys-Glu-Met-Pro-Ser-Glu-Glu-Gly-Tyr-Gln-Asp	United Neuroscience Limited - Ireland	Treatment of multiple system atrophy	• 17/07/2018 • 13/08/2018 • 18/10/2018 • *(66 days/28 days)*	• 22/10/2018 • 19/11/2018
Human apotransferrin	Sanquin Plasma Products B.V. - The Netherlands	Treatment of beta-thalassaemia intermedia and major	• 27/06/2018 • 13/08/2018 • 18/10/2018 • *(66 days/28 days)*	• 22/10/2018 • 19/11/2018
H-Arg-Pro-Lys-Pro-Gln-Gln-Phe-2Thi-Gly-Leu-Met(O2)-NH2-DOTA-213-bismuth	Dr. Regenold GmbH - Germany	Treatment of glioma	• 17/07/2018 • 13/08/2018 • 18/10/2018 • *(66 days/28 days)*	• 22/10/2018 • 19/11/2018
ex vivo fused normal allogeneic human myoblast with autologous human myoblast derived from Duchenne muscular dystrophy affected donor	Dystrogen Therapeutics S.A. - Poland	Treatment of Duchenne muscular dystrophy	• 12/07/2018 • 13/08/2018 • 18/10/2018 • *(66 days/28 days)*	• 22/10/2018 • 19/11/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
ex vivo fused normal allogeneic human myoblast with another normal allogeneic human myoblast	Dystrogen Therapeutics S.A. - Poland	Treatment of Duchenne muscular dystrophy	• 12/07/2018 • 13/08/2018 • 18/10/2018 • *(66 days/28 days)*	• 22/10/2018 • 19/11/2018
Etamsylate	Consejo Superior de Investigaciones Cientificas (CSIC) - Spain	Treatment of hereditary haemorrhagic telangiectasia	• 13/07/2018 • 13/08/2018 • 18/10/2018 • *(66 days/28 days)*	• 22/10/2018 • 19/11/2018
Allogeneic faecal microbiota, pooled	MaaT PHARMA - France	Treatment of graft-versus-host disease	• 29/06/2018 • 13/08/2018 • 11/10/2018 • *(59 days/28 days)*	• 22/10/2018 • 19/11/2018
5-{(1R,2R)-2-[(cyclopropylmethyl)amino]cyclopropyl}-N-(tetrahydro-2H-pyran-4-yl)thiophene-3-carboxamide monohydrochloride	Takeda Pharma A/S - Denmark	Treatment of Kabuki syndrome	• 20/03/2018 • 16/07/2018 • 11/10/2018 • *(87 days/28 days)*	• 22/10/2018 • 19/11/2018
Apraglutide	IQVIA RDS Ireland Limited - Ireland	Treatment of short bowel syndrome	• 28/06/2018 • 16/07/2018 • 18/10/2018 • *(94 days/28 days)*	• 22/10/2018 • 19/11/2018
Anti-GD2 monoclonal antibody 3F8 humanised	Y-mAbs Therapeutics A/S - Denmark	Treatment of neuroblastoma	• 29/06/2018 • 16/07/2018 • 18/10/2018 • *(94 days/28 days)*	• 22/10/2018 • 19/11/2018
Larotrectinib	Bayer AG - Germany	Treatment of papillary thyroid cancer	• 28/06/2018 • 16/07/2018 • 18/10/2018 • *(94 days/28 days)*	• 22/10/2018 • 19/11/2018
Larotrectinib	Bayer AG - Germany	Treatment of glioma	• 28/06/2018 • 16/07/2018 • 18/10/2018 • *(94 days/28 days)*	• 22/10/2018 • 19/11/2018
3-(3-(3,5-dimethyl-1H-pyrazol-4-yl)propoxy)-4- fluorobenzoic acid	Pharma Gateway AB - Sweden	Treatment of ATTR amyloidosis	• 24/05/2018 • 16/07/2018 • 11/10/2018 • *(87 days/28 days)*	• 22/10/2018 • 19/11/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Glucagon	Pharma Gateway AB - Sweden	Treatment of noninsulinoma pancreatogenous hypoglycaemia syndrome	• 27/06/2018 • 16/07/2018 • 11/10/2018 • *(87 days/28 days)*	• 22/10/2018 • 19/11/2018
Imlifidase	Hansa Biopharma AB - Sweden	Treatment of anti-glomerular basement membrane disease	• 24/05/2018 • 16/07/2018 • 18/10/2018 • *(94 days/28 days)*	• 22/10/2018 • 19/11/2018
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	Santhera Pharmaceuticals (Deutschland) GmbH - Germany	Treatment of cystic fibrosis	• 26/06/2018 • 16/07/2018 • 11/10/2018 • *(87 days/28 days)*	• 22/10/2018 • 19/11/2018
Autologous human adipose perivascular stromal cells genetically modified to secrete soluble tumor necrosis factor-related apoptosis-inducing ligand	Rigenerand S.r.l. - Italy	Treatment of pancreatic cancer	• 28/06/2018 • 16/07/2018 • 11/10/2018 • *(87 days/28 days)*	• 22/10/2018 • 19/11/2018
Anetumab ravtansine	Bayer AG - Germany	Treatment of ovarian cancer	• 07/12/2017 • 16/07/2018 • 11/10/2018 • *(87 days/28 days)*	• 22/10/2018 • 19/11/2018
Lisocabtagene maraleucel	Celgene Europe B.V. - The Netherlands	Treatment of primary mediastinal large-B-cell lymphoma	• 29/06/2018 • 16/07/2018 • 18/10/2018 • *(94 days/28 days)*	• 22/10/2018 • 19/11/2018
Propagermanium	Quality Regulatory Clinical Ireland Limited - Ireland	Treatment of focal segmental glomerulosclerosis	• 21/06/2018 • 16/07/2018 • 11/10/2018 • *(87 days/28 days)*	• 22/10/2018 • 19/11/2018
6,8-bis(benzylthio)octanoic acid	IQVIA RDS Ireland Limited - Ireland	Treatment of acute myeloid leukaemia	• 30/08/2018 • 12/09/2018 • 08/11/2018 • *(57 days/24 days)*	• 20/11/2018 • 14/12/2018
6-fluoro-9-methyl-9H-pyrido[3,4-b]-indole	AudioCure Pharma GmbH - Germany	Treatment of sudden sensorineural hearing loss	• 30/08/2018 • 12/09/2018 • 08/11/2018 • *(57 days/28 days)*	• 16/11/2018 • 14/12/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Adeno-associated virus serotype HSC15 expressing human phenylalanine hydroxylase	Yes Pharmaceutical Development Services GmbH - Germany	Treatment of phenylanaline hydroxylase deficiency	• 20/08/2018 • 12/09/2018 • 08/11/2018 • *(57 days/24 days)*	• 20/11/2018 • 14/12/2018
Allogeneic ABCB5-positive limbal stem cells	Rheacell GmbH & Co. KG - Germany	Treatment of limbal stem cell deficiency	• 23/08/2018 • 12/09/2018 • 08/11/2018 • *(57 days/24 days)*	• 20/11/2018 • 14/12/2018
Bifunctional fusion protein composed of two extracellular domains of transforming growth factor beta receptor II fused with a human immunoglobulin G1 monoclonal antibody against programmed death ligand 1	Merck Europe B.V. - The Netherlands	Treatment of biliary tract cancer	• 22/08/2018 • 12/09/2018 • 08/11/2018 • *(57 days/24 days)*	• 20/11/2018 • 14/12/2018
C1 esterase inhibitor (human)	Shire Pharmaceuticals Ireland Limited - Ireland	Treatment in solid organ transplantation	• 30/08/2018 • 12/09/2018 • 08/11/2018 • *(57 days/28 days)*	• 26/11/2018 • 14/12/2018
Lonafarnib	Eiger Biopharmaceuticals Europe Limited - United Kingdom	Treatment of Hutchinson-Gilford progeria syndrome	• 28/08/2018 • 12/09/2018 • 08/11/2018 • *(57 days/24 days)*	• 20/11/2018 • 14/12/2018
6,8-bis(benzylthio)octanoic acid	IQVIA RDS Ireland Limited - Ireland	Treatment of pancreatic cancer	• 30/08/2018 • 12/09/2018 • 08/11/2018 • *(57 days/24 days)*	• 20/11/2018 • 14/12/2018
Pevonedistat	Takeda Pharma A/S - Denmark	Treatment of myelodysplastic syndromes	• 30/08/2018 • 12/09/2018 • 08/11/2018/ • *(57 days/28 days)*	• 16/11/2018 • 14/12/2018
Afatinib	Consorcio Centro de Investigación Biomédica en Red, M.P. - Spain	Treatment of Fanconi anaemia	• 15/07/2018 • 13/08/2018 • 08/11/2018 • *(87 days/24 days)*	• 20/11/2018 • 14/12/2018
Marizomib	Celgene Europe B.V. - The Netherlands	Treatment of glioma	• 29/08/2018 • 12/09/2018 • 08/11/2018 • *(57 days/24 days)*	• 20/11/2018 • 14/12/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
(4-{(2S,4S)-4-ethoxy-1-[(5-methoxy-7-methyl-1H-indol-4-yl)methyl]piperidin-2-yl}benzoic acid-hydrogen chloride(1/1))	Novartis Europharm Limited - Ireland	Treatment of C3 glomerulopathy	• 27/08/2018 • 12/09/2018 • 08/11/2018/ • *(57 days/28 days)*	• 16/11/2018 • 14/12/2018
(2S)-2-{[(2R)-2-[({[3,3-dibutyl-7-(methylthio)-1,1-dioxido-5-phenyl-2,3,4,5-tetrahydro-1,2,5-benzothiadiazepin-8-yl]oxy}acetyl)amino]-2-(4-hydroxyphenyl)acetyl]amino}butanoic acid	Albireo AB - Sweden	Treatment of biliary atresia	• 30/08/2018 • 12/09/2018 • 08/11/2018 • *(57 days/24 days)*	• 20/11/2018 • 14/12/2018
Sodium 2-hydroxylinoleate	Ability Pharmaceuticals SL - Spain	Treatment of biliary tract cancer	• 16/07/2018 • 13/08/2018 • 08/11/2018 • *(87 days/24 days)*	• 20/11/2018 • 14/12/2018
Ivacaftor, N-(1,3-dimethyl-1H-pyrazole-4-sulfonyl)-6-[3-(3,3,3-trifluoro-2,2-dimethylpropoxy)-1H-pyrazol-1-yl]-2-[(4S)-2,2,4-trimethylpyrrolidin-1-yl]pyridine-3-carboxamide, tezacaftor	Vertex Pharmaceuticals (Europe) Limited - United Kingdom	Treatment of cystic fibrosis	• 13/07/2018 • 13/08/2018 • 08/11/2018 • *(87 days/28 days)*	• 16/11/2018 • 14/12/2018
Acetylcysteine	MUCPharm Pty Ltd - United Kingdom	Treatment of pseudomyxoma peritonei	• 17/07/2018 • 13/08/2018 • 08/11/2018 • *(87 days/24 days)*	• 20/11/2018 • 14/12/2018
Venglustat	Genzyme Europe BV - The Netherlands	Treatment of autosomal dominant polycystic kidney disease	• 17/07/2018 • 13/08/2018 • 08/11/2018 • *(87 days/24 days)*	• 20/11/2018 • 14/12/2018
Human anti-promyostatin monoclonal antibody	Yes Pharmaceutical Development Services GmbH - Germany	Treatment of spinal muscular atrophy	• 13/07/2018 • 13/08/2018 • 08/11/2018 • *(87 days/24 days)*	• 20/11/2018 • 14/12/2018
Adeno-associated viral vector expressing human 21-hydroxylase	Pharma Gateway AB - Sweden	Treatment of congenital adrenal hyperplasia	• 13/07/2018 • 13/08/2018 • 08/11/2018 • *(87 days/24 days)*	• 20/11/2018 • 14/12/2018
Ivacaftor, potassium(benzenesulfonyl)({[6-(3-{2-[1-(trifluoromethyl) cyclopropyl]ethoxy}-1H-pyrazol-1-yl)-2-[(4S)-2,2,4-trimethylpyrrolidin-1-yl]pyridin-3-yl]carbonyl})azanide,tezacaftor	Vertex Pharmaceuticals (Europe) Limited - United Kingdom	Treatment of cystic fibrosis	• 13/07/2018 • 13/08/2018 • 08/11/2018 • *(87 days/28 days)*	• 16/11/2018 • 14/12/2018

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Bromelain	MUCPharm Pty Ltd - United Kingdom	Treatment of pseudomyxoma peritonei	• 17/07/2018 • 13/08/2018 • 08/11/2018 • *(87 days/24 days)*	• 20/11/2018 • 14/12/2018

Negative COMP designation opinions

Product INN	Sponsor	Indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Melatonin	Therapicon Srl - Italy	Treatment of non-traumatic subarachnoid haemorrhage	• 27/06/2017 • 14/07/2017 • 15/03/2018 • (244 days/27 days)	• 20/03/2018 • 16/04/2018
Melatonin	Therapicon Srl - Italy	Treatment of partial deep dermal and full thickness burns	• 17/03/2017 • 12/06/2017 • 12/02/2018 • (246 days/29 days)	• 12/02/2018 • 13/03/2018
Diacerein	Therapicon S.r.l.	Treatment of epidermolysis bullosa	• 18/07/2018 • 12/09/2018 • 08/11/2018 • (57 days/XX days)	• 21/02/2018 • awaited

Annex 15 – HMPC European Union herbal monographs in 2018

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/294187/2013	Silybi mariani fructus	04/06/2018 / TU
EMA/HMPC/432278/2015	Fragariae folium	20/11/2018 / TU
EMA/HMPC/749510/2016	Malvae folium	20/11/2018 / TU
EMA/HMPC/749511/2016	Malvae sylvestris flos	20/11/2018 / TU
Revision		
EMA/HMPC/750269/2016	Uvae ursi folium	30/01/2018 / TU
EMA/HMPC/48745/2017	Cimicifugae rhizoma	27/03/2018 / WEU
EMA/HMPC/606742/2017	Agni casti fructus	27/03/2018 / TU + WEU
EMA/HMPC/437450/2017	Calendulae flos	27/03/2018 / TU
EMA/HMPC/194014/2017	Cynarae folium	27/03/2018 / TU
EMA/HMPC/611512/2016	Sambuci flos	27/03/2018 / TU
EMA/HMPC/611537/2016	Verbasci flos	27/03/2018 / TU
EMA/HMPC/444244/2015	Pelargonii radix	05/06/2018 / TU
EMA/HMPC/737380/2018	Echinaceae pallidae radix	05/06/2018 / TU
EMA/HMPC/753041/2017	Oenotherae biennis oleum	05/06/2018 / TU
EMA/HMPC/329755/2017	Curcumae longae rhizoma	25/09/2018 / TU
EMA/HMPC/625849/2015	Sennae folium	25/09/2018 / WEU
EMA/HMPC/228761/2016	Sennae fructus	25/09/2018 / WEU
EMA/HMPC/607861/2017	Gentianae radix	20/11/2018 / TU
EMA/HMPC/188804/2017	Rusci aculeati rhizoma	20/11/2018 / TU

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

Reference number	Document title	Adoption *
First Assessment		
	none	
Revision		
	none	

European Union herbal monographs - Draft

Reference number	Document title	Adoption / Outcome*
First Assessment		
EMA/HMPC/432278/2015	Fragariae folium	27/03/2018 / TU
EMA/HMPC/749510/2016	Malvae folium	05/06/2018 / TU

Reference number	Document title	Adoption / Outcome*
EMA/HMPC/749511/2016	Malvae sylvestris flos	05/06/2018 / TU
	Revision	
EMA/HMPC/188804/2017	Rusci aculeati rhizoma	30/01/2018 / TU
EMA/HMPC/45508/2017	Hyperici herba (TU)	30/01/2018 / TU
EMA/HMPC/607861/2017	Gentianae radix	27/03/2018 / TU

European Union List entries - Draft

Reference number	Document title	Adoption *
	First Assessment	
	none	
	Revision	
	none	

Monograph / list entry reviews

Reference number	Document title	Adoption / Outcome
	Final decision	
EMA/HMPC/732731/2017	Avenae fructus	27/03/2018 / no revision
EMA/HMPC/732731/2017	Avenae herba	27/03/2018 / no revision
EMA/HMPC/627591/2017	Polypodii rhizoma	05/06/2018 / no revision
EMA/HMPC/178578/2018	Hippocastani semen	05/06/2018 / revision required
EMA/HMPC/364552/2018	Myrrha	24/03/2018 / no revision
EMA/HMPC/179592/2018	Trigonellae foenugraeci semen	24/03/2018 / revision required
EMA/HMPC/637898/2018	Echinaceae angustifoliae radix	20/11/2018 / no revision

Public statements

Reference number	Document title	Adoption
	Drafts	
	none	
	Final	
EMA/HMPC/461814/2016	Glycini semen	05/06/2018 / PS

Annex 16 – PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2018

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
Lacosamide	Vimpat	PM	Neurology	UCB Pharma S.A.	08/01/2018	P/0001/2018
Artenimol / piperaquine phosphate anhydride	Eurartesim	PM	Infectious Diseases	Alfasigma SpA	04/01/2018	P/0002/2018
Glutamine (Levoglutamide)		P	Haematology-Hemostaseology	Emmaus Medical Europe Ltd.	04/01/2018	P/0003/2018
L-asparaginase encapsulated in erythrocytes		PM	Oncology	ERYTECH pharma S.A.	04/01/2018	P/0004/2018
Lumacaftor / ivacaftor	Orkambi	PM	Other	Vertex Pharmaceuticals (Europe) Limited	15/01/2018	P/0005/2018
Gilteritinib (as fumarate)		P	Haematology-Hemostaseology, Oncology	Astellas Pharma Europe B.V.	19/01/2018	P/0006/2018
Burosumab		PM	Other	Ultragenyx Pharmaceutical Inc.	30/01/2018	P/0007/2018
Pembrolizumab	Keytruda	PM	Oncology	Merck Sharp & Dohme (Europe), Inc.	30/01/2018	P/0008/2018
Atazanavir (sulphate) / cobicistat	Evotaz	PM	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	30/01/2018	P/0009/2018
Reslizumab	Cinqaero	PM	Pneumology - Allergology	Teva Pharmaceuticals Europe	30/01/2018	P/0010/2018
Ixekizumab	Taltz	PM	Immunology-Rheumatology-	Eli Lilly & Company Limited	30/01/2018	P/0011/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
			Transplantation			
Matrix applied characterised autologous cultured chondrocytes	MACI	PM	Other	Vericel Denmark ApS	30/01/2018	P/0012/2018
Ceftaroline fosamil	Zinforo	PM	Infectious Diseases	Pfizer Limited	26/01/2018	P/0013/2018
Chloroprocaine (hydrochloride)	Ampres	P	Anaesthesiology	Sintetica GmbH	30/01/2018	P/0014/2018
Regadenoson	Rapiscan	PM	Cardiovascular Diseases	Rapidscan Pharma EU Solutions (RPS) EU Limited	30/01/2018	P/0015/2018
Conestat alfa	Ruconest	PM	Other	Pharming Group N.V.	30/01/2018	P/0016/2018
Dienogest / ethinyl estradiol		P	Endocrinology-Gynaecology-Fertility-Metabolism	Exeltis France S.A.	30/01/2018	P/0017/2018
Obiltoxaximab		P	Infectious Diseases	SFL Regulatory Affairs Consulting Ltd.	30/01/2018	P/0018/2018
Recombinant Clostridium difficile toxoid A / recombinant Clostridium difficile toxoid B		PM	Vaccines	Pfizer Limited	30/01/2018	P/0019/2018
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)		RPM	Diagnostic	GUERBET	30/01/2018	P/0020/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Human normal immunoglobulin		PM	Immunology-Rheumatology-Transplantation	Octapharma Pharmazeutika Produktionsges.m.b.H	30/01/2018	P/0021/2018
Upadacitinib (ABT-494)		P	Immunology-Rheumatology-Transplantation	AbbVie Ltd	30/01/2018	P/0022/2018
1,4-dihydro-1-[(2R)-2-(2-methoxyphenyl)-2-[(tetrahydro-2H-pyran-4-yl)oxy]ethyl]-α,α,5-trimethyl-6-(2-oxazolyl)-2,4-dioxo-thieno[2,3-d]pyrimidine-3(2H)-acetic acid (GS-0976)		P	Gastroenterology-Hepatology	Gilead Sciences International Ltd.	30/01/2018	P/0023/2018
Maralixibat chloride		P	Gastroenterology-Hepatology	Shire Pharmaceuticals Limited Ireland	30/01/2018	P/0024/2018
N-[(1,3-dicyclohexyl-6-hydroxy-2,4-dioxo-1,2,3,4-tetrahydro-5-pyrimidinyl)carbonyl]glycine (GSK1278863)		PM	Haematology-Hemostaseology, Uro-nephrology	GlaxoSmithKline R & D	30/01/2018	P/0025/2018
Baricitinib	Olumiant	PM	Immunology-Rheumatology-Transplantation	Eli Lilly and Company Limited	30/01/2018	P/0026/2018
Midostaurin	Rydapt	PM	Oncology	Novartis Europharm Ltd	05/03/2018	P/0027/2018
Empagliflozin	Jardiance	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	30/01/2018	P/0028/2018
Fluorocholine (18F)		W	Diagnostic	UJV Rez, a. s.	30/01/2018	P/0029/2018
Birch pollen extract (Betula verrucosa)		PM	Pneumology -	ALK Abelló A/S	30/01/2018	P/0030/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
			Allergology			
Tedizolid (phosphate)	Sivextro	PM	Infectious Diseases	Merck Sharp & Dohme (Europe) Inc.	30/01/2018	P/0031/2018
Linagliptin	Trajenta	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	30/01/2018	P/0032/2018
Sitagliptin	Januvia	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp and Dohme (Europe), Inc.	30/01/2018	P/0033/2018
Lucerastat		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Idorsia Pharmaceuticals Deutschland GmbH	30/01/2018	P/0034/2018
Tofacitinib	Xeljanz	PM	Immunology-Rheumatology-Transplantation	Pfizer Limited	30/01/2018	P/0035/2018
Tucatinib		W	Oncology	Cascadian Therapeutics Luxembourg S.A.R.L.	30/01/2018	P/0036/2018
Tenofovir alafenamide	Vemlidy	W	Infectious Diseases	Gilead Sciences International Ltd.	30/01/2018	P/0037/2018
Recombinant human epidermal growth factor		W	Endocrinology-Gynaecology-Fertility-Metabolism, Other	Praxis Pharmaceuticals S.A	30/01/2018	P/0038/2018
Rosuvastatin (calcium)/ acetylsalicylic acid		W	Cardiovascular Diseases	Adamed Sp. z o.o.	16/02/2018	P/0039/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Recombinant Neisseria meningitidis group B NHBA fusion protein / recombinant Neisseria meningitidis group B NadA protein / recombinant Neisseria meningitidis group B fHbp fusion protein / Outer Membrane Vesicles (OMV) from Neisseria meningitidis group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4	Bexsero	PM	Vaccines	GSK Vaccines S.r.l.	16/02/2018	P/0040/2018
Posaconazole	Noxafil	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	16/02/2018	P/0041/2018
Dasatinib	Sprycel	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	16/02/2018	P/0042/2018
Pembrolizumab	KEYTRUDA	PM	Oncology	Merck Sharp & Dohme (Europe), Inc.	16/02/2018	P/0043/2018
Influenza virus surface antigens (haemagglutinin and neuraminidase) of the following strains: A/(H1N1), A/(H3N2), B/Yamagata lineage, B/Victoria lineage	Influvac Tetra	PM	Vaccines	Abbott Biologicals B.V.	16/02/2018	P/0044/2018
Ivacaftor	Kalydeco	PM	Other	Vertex Pharmaceuticals (Europe) Limited	16/02/2018	P/0045/2018
Upadacitinib (ABT-494)		P	Immunology-Rheumatology-Transplantation	AbbVie Ltd	16/02/2018	P/0046/2018
Alirocumab	Praluent	PM	Endocrinology-Gynaecology-Fertility-	Sanofi-aventis Recherche &	19/02/2018	P/0047/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
			Metabolism	Developpement		
Lacosamide	Vimpat	PM	Neurology	UCB Pharma S.A.	22/02/2018	P/0048/2018
Nivolumab	Opdivo	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	22/02/2018	P/0049/2018
Nivolumab	Opdivo	PM	Oncology	Bristol-Myers Squibb Pharma EEIG		P/0050/2018
Brivaracetam	Briviact	PM	Neurology	UCB Pharma S.A.	22/02/2018	P/0051/2018
Brivaracetam	Briviact	PM	Neurology	UCB Pharma S.A.	22/02/2018	P/0052/2018
Sodium zirconium cyclosilicate		PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	01/03/2018	P/0053/2018
Pevonedistat		P	Oncology	Takeda Pharma A/S	02/03/2018	P/0054/2018
Lanadelumab (DX-2930)		PM	Other	Shire Pharmaceuticals Ireland Limited	09/03/2018	P/0055/2018
Dermatophagoides pteronyssinus / dermatophagoides farinae allergen extract	ACARIZAX and associated names	PM	Pneumology - Allergology	ALK-Abelló A/S	16/03/2018	P/0056/2018
Indacaterol (acetate) / mometasone (furoate)		PM	Pneumology - Allergology	Novartis Europharm Limited	16/03/2018	P/0057/2018
Lonoctocog alfa	Afstyla	PM	Haematology-Hemostaseology	CSL Behring GmbH	16/03/2018	P/0058/2018
dapagliflozin / metformin (hydrochloride)		W	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	16/03/2018	P/0059/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Octocog alfa	Iblias Kovaltry	PM	Haematology-Hemostaseology	Bayer AG	16/03/2018	P/0060/2018
Ruxolitinib(phosphate)	Jakavi	W	Oncology	Novartis Europharm Limited	16/03/2018	P/0061/2018
Fidaxomicin	Dificlir	PM	Infectious Diseases	Astellas Pharma Europe B.V.	16/03/2018	P/0062/2018
Veliparib		W	Oncology	AbbVie Ltd	16/03/2018	P/0063/2018
Osilodrostat		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Novartis Europharm Limited	16/03/2018	P/0064/2018
Golimumab	Simponi	PM	Immunology-Rheumatology-Transplantation	Janssen Biologics B.V.	16/03/2018	P/0065/2018
Venglustat		W	Endocrinology-Gynaecology-Fertility-Metabolism	Genzyme Europe B.V.	16/03/2018	P/0066/2018
Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human betaA-T87Q-globin gene		PM	Haematology-Hemostaseology	bluebird bio France	16/03/2018	P/0067/2018
Erenumab		PM	Neurology	Novartis Europharm Limited	16/03/2018	P/0068/2018
1-(2,2-difluoro-1,3-benzodioxol-5-yl)-N-{1-[(2R)-2,3-dihydroxypropyl]-6-fluoro-2-(1-hydroxy-2-methylpropan-2-yl)-1Hindol-5-yl}cyclopropanecarboxamide (VX-661) / ivacaftor		PM	Pneumology - Allergology	Vertex Pharmaceuticals (Europe) Ltd.	16/03/2018	P/0069/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Tanezumab		P	Pain	Pfizer Limited	16/03/2018	P/0070/2018
Encorafenib		PM	Oncology	Pierre Fabre Médicament	16/03/2018	P/0071/2018
Selumetinib		PM	Oncology	AstraZeneca AB	16/03/2018	P/0072/2018
Pemafibrate		W	Cardiovascular Diseases Endocrinology-Gynaecology-Fertility-Metabolism	Kowa Research Europe Ltd	16/03/2018	P/0073/2018
Binimetinib		PM	Oncology	Pierre Fabre Médicament	16/03/2018	P/0074/2018
Anifrolumab		P	Immunology-Rheumatology-Transplantation	AstraZeneca AB	16/03/2018	P/0075/2018
Fluticasone furoate / umeclidinium bromide / vilanterol trifenatate		P	Pneumology - Allergology	GlaxoSmithKline Trading Services Limited	16/03/2018	P/0076/2018
Crizanlizumab		P	Haematology-Hemostaseology	Novartis Europharm Limited	16/03/2018	P/0077/2018
Adeno-associated viral vector serotype rh.10 carrying the human Nsulfoglucosamine Nsulfoglucosaminesulfohydrolase cDNA (LYS-SAF302)		P	Neurology	LYSOGENE	16/03/2018	P/0078/2018
Insulin human (NTRA-2112)		P	Gastroenterology-Hepatology Neonatology - Paediatric Intensive Care	Nutrinia, Ltd.	16/03/2018	P/0079/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Pyridopyrimidione SMN2 Splicing Modifier		PM	Neurology	Roche Registration Limited	16/03/2018	P/0080/2018
Tremelimumab		P	Oncology	AstraZeneca AB	16/03/2018	P/0081/2018
Durvalumab		P	Oncology	AstraZeneca AB	16/03/2018	P/0082/2018
Tralokinumab		P	Dermatology	LEO Pharma A/S	16/03/2018	P/0083/2018
Vamorolone		P	Other	ReveraGen BioPharma Ltd	16/03/2018	P/0084/2018
Rolapitant	Varuby	PM	Haematology-Hemostaseology	Tesaro UK Ltd	16/03/2018	P/0085/2018
Ibuprofen		W	Other Pain	Farmalíder, S.A.	16/03/2018	P/0086/2018
Entinostat Polymorph B		W	Oncology	Syndax Pharmaceuticals, Inc.	16/03/2018	P/0087/2018
Niraparib		W	Oncology	Janssen Research & Development	16/03/2018	P/0088/2018
Trazodone (hydrochloride) / gabapentin		W	Pain	Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F. - S.p.A.	16/03/2018	P/0089/2018
Rosuvastatin / ezetimibe		W	Cardiovascular Diseases	ELPEN Pharmaceutical Co. Inc	16/03/2018	P/0090/2018
T-cell bispecific antibody targeting carcinoembryonic antigen expressed on tumor cells and CD3 epsilon chain present on T-cells		W	Oncology	Roche Registration Limited	16/03/2018	P/0091/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Dapagliflozin / saxagliptin / metformin (hydrochloride)		W	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	16/03/2018	P/0092/2018
Candesartan (cilexetil) / amlodipine (besylate)		W	Cardiovascular Diseases	Midas Pharma GmbH	16/03/2018	P/0093/2018
Treprostinil (sodium)		W	Cardiovascular Diseases	SciPharm Sàrl	16/03/2018	P/0094/2018
Non-pathogenic bacterial lysate of Escherichia coli and Enterococcus faecalis		W	Gastroenterology-Hepatology	SymbioPharm GmbH	16/03/2018	P/0095/2018
Levothyroxine (sodium)		W	Endocrinology-Gynaecology-Fertility-Metabolism	IBSA Farmaceutici Italia Srl	16/03/2018	P/0096/2018
(RS)-Bacoflen / Naltrexone HCl / D-Sorbitol (PXT3003)		P	Neurology	Pharnext SA	16/03/2018	P/0097/2018
Denosumab	Xgeva Prolia	PM	Endocrinology-Gynaecology-Fertility-Metabolism Immunology-Rheumatology-Transplantation Oncology	Amgen Europe B.V.	16/03/2018	P/0098/2018
Abatacept	Orencia	PM	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb Pharma EEIG	15/03/2018	P/0099/2018
Humanized recombinant IgG4 anti-human tau antibody		W	Neurology	AbbVie Ltd	15/03/2018	P/0100/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Crisaborole		PM	Dermatology	Pfizer Ltd	15/03/2018	P/0101/2018
Quizartinib		PM	Oncology	Daiichi Sankyo Europe GmbH	16/03/2018	P/0102/2018
Plazomicin (sulfate)		P	Infectious Diseases	Achaogen, Inc.	19/03/2018	P/0103/2018
Obeticholic acid	Ocaliva	P	Gastroenterology-Hepatology	Intercept Pharma Ltd.	11/04/2018	P/0104/2018
Evolocumab	Repatha	PM	Cardiovascular Diseases	Amgen Europe B.V.	11/04/2018	P/0105/2018
Tilmanocept	Lymphoseek	PM	Diagnostic, Oncology	Norgine BV	11/04/2018	P/0106/2018
Benralizumab	Fasenra	PM	Pneumology - Allergology	AstraZeneca AB	11/04/2018	P/0107/2018
Dopamine		PM	Cardiovascular Diseases	BrePco Biopharma Limited	11/04/2018	P/0108/2018
Vedolizumab	Entyvio	PM	Gastroenterology-Hepatology	Takeda Pharma A/S	11/04/2018	P/0109/2018
Methoxyflurane	Penthrox	PM	Pain	Medical Developments UK Ltd	11/04/2018	P/0110/2018
Tapentadol (hydrochloride)	Palexia and associated names Yantil and associated names Tapentadol and associated names	PM	Pain	Grünenthal GmbH	11/04/2018	P/0111/2018
Concentrate of proteolytic enzymes in bromelain	NexoBrid	RPM	Other	MediWound Germany GmbH	11/04/2018	P/0112/2018
Dalbavancin	Xydalba	PM	Infectious Diseases	Allergan Pharmaceuticals	11/04/2018	P/0113/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
				International Limited		
Enfortumab vedotin		W	Oncology	Astellas Pharma Europe B.V.	11/04/2018	P/0114/2018
Calcium, N,N'-1,2-ethanediylbis[N-[[3-(hydroxy-2-methyl-5-[(phosphonooxy)methyl]-4-pyridinyl]methyl]glycine] manganese complexes		W	Oncology Other	PledPharma AB	11/04/2018	P/0115/2018
Rovalpituzumab tesirineRovalpituzumab tesirine		W	Oncology	AbbVie Ltd	11/04/2018	P/0116/2018
Polatuzumab vedotin		W	Oncology	Roche Registration Limited	11/04/2018	P/0117/2018
Influenza virus H1 haemagglutinin / influenza virus H3 haemagglutinin /influenza virus haemagglutinin from strain B Victoria lineage / influenza virus haemagglutinin from strain B Yamagata lineage (expressed as virus-like particle [VLP])		P	Vaccines	Medicago Inc.	11/04/2018	P/0118/2018
Autologous CD4+ and CD8+ T cells expressing a CD19-specific chimeric antigen receptor (JCAR017)		PM	Oncology	Celgene Europe Limited	11/04/2018	P/0119/2018
Andexanet alfa		PM	Other	Portola Pharma UK Limited	11/04/2018	P/0120/2018
Palovarotene		PM	Other	Clementia Pharmaceuticals Inc.	11/04/2018	P/0121/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Luspatercept		PM	Haematology-Hemostaseology	Celgene Europe Ltd	11/04/2018	P/0122/2018
Nusinersen	Spinraza	PM	Neurology	Biogen Idec Ltd	11/04/2018	P/0123/2018
Fevipiprant		P	Pneumology - Allergology	Novartis EuroPharm Ltd.	11/04/2018	P/0124/2018
Ixazomib	Ninlaro	P	Oncology	Takeda Pharm A/S	11/04/2018	P/0125/2018
Ezetimibe / rosuvastatin	Zenon Suvezen	W	Cardiovascular Diseases	Zentiva, k.s.	11/04/2018	P/0126/2018
Peginterferon beta-1a	Plegridy	PM	Neurology	Biogen Idec Ltd	11/04/2018	P/0127/2018
Ponesimod		PM	Neurology	Actelion Registration Ltd	11/04/2018	P/0128/2018
Guselkumab	Tremfya	PM	Immunology-Rheumatology-Transplantation	Janssen Cilag International NV	06/04/2018	P/0129/2018
Angiotensin II (LJPC-501)		PM	Cardiovascular Diseases	La Jolla Pharmaceutical II B.V.	06/04/2018	P/0130/2018
Clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins	Xeomin Bocouture	W	Neurology Ophthalmology	Merz Pharmaceuticals GmbH	13/04/2018	P/0131/2018
Testosterone		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Acerus Biopharma Inc.	16/04/2018	P/0132/2018
Eszopiclone		W	Psychiatry	Alfred E. Tiefenbacher (GmbH & Co. KG)	07/05/2018	P/0133/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
(2R)-2-Amino-1-[3-({2-[p-(4-{3-[(3,S-diamino-6-chloro-2-pyrazinyl)ca rbonyl]guanidino }butyl)phenoxy]ethyl}{ 3-[(2R)-2-am ino-6-guanidinohexanoyla mino] propyl }amino)propylamino]-6-guanidino-1-hexanone hexahydrochloride		W	Ophthalmology	Shire Pharmaceuticals Ireland Limited	07/05/2018	P/0134/2018
Ibuprofen / paracetamol		W	Other Pain	Farmalíder, S.A.	07/05/2018	P/0135/2018
Inebilizumab		PM	Neurology	MedImmune, LLC (affiliate of AstraZeneca)	07/05/2018	P/0136/2018
Galcanezumab		PM	Neurology	Eli Lilly and Company Limited	07/05/2018	P/0137/2018
Liquid ethanolic extract 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus limon (L.) Burm. f. (fresh fruit), Paullinia cupana Kunth, Theobroma cacao L.		PM	Dermatology	LEGACY HEALTHCARE	07/05/2018	P/0138/2018
Emtricitabine / tenofovir alafenamide	Descovy	P	Infectious Diseases	Gilead Sciences International Ltd.	07/05/2018	P/0139/2018
Fosnetupitant / palonosetron	Akynzeo	P	Other	Helsinn Birex Pharmaceuticals Limited	07/05/2018	P/0140/2018
Edoxaban (tosylate)	Lixiana	PM	Cardiovascular Diseases Haematology-Hemostaseology	Daiichi Sankyo Europe GmbH	07/05/2018	P/0141/2018
Ranibizumab	Lucentis	W	Ophthalmology	Novartis Europharm Limited	07/05/2018	P/0142/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Peginterferon alfa-2a	Pegasys	PM	Infectious Diseases	Roche Registration GmbH	07/05/2018	P/0143/2018
Treprostinil	Remodulin and associated names	PM	Cardiovascular Diseases	Ferrer Internacional, S.A.	07/05/2018	P/0144/2018
Amlodipine / irbesartan		W	Cardiovascular Diseases	WIN MEDICA S.A.	07/05/2018	P/0145/2018
Naloxone (hydrochloride)		PM	Gastroenterology-Hepatology Other Pain	Develco Pharma GmbH	07/05/2018	P/0146/2018
Sunitinib	Sutent	PM	Oncology	Pfizer Limited	07/05/2018	P/0147/2018
Delafloxacin		W	Infectious Diseases	A.Menarini - IndustrieFarmaceutiche Riunite - s.r.l.	18/05/2018	P/0148/2018
Ceftazidime / avibactam	Zavicefta	PM	Infectious Diseases	Pfizer Limited	17/05/2018	P/0149/2018
Sofosbuvir / velpatasvir	Epclusa	PM	Infectious Diseases	Gilead Sciences International Ltd.	18/05/2018	P/0150/2018
Lamivudine / dolutegravir		PM	Infectious Diseases	ViiV Healthcare UK Limited	18/05/2018	P/0151/2018
Emapalumab		PM	Immunology-Rheumatology-Transplantation	Novimmune B.V	18/05/2018	P/0152/2018
Apixaban	Eliquis	PM	Cardiovascular Diseases	Bristol-Myers Squibb / Pfizer EEIG	25/05/2018	P/0153/2018
Apixaban	Eliquis	PM	Cardiovascular Diseases	Bristol-Myers Squibb / Pfizer EEIG	25/05/2018	P/0154/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
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 / split influenza virus, inactivated containing antigens equivalent to the B-like strain		W	Vaccines	Sanofi Pasteur	25/05/2018	P/0155/2018
Isatuximab		P	Oncology	Sanofi-Aventis Recherche & Développement	15/06/2018	P/0156/2018
Baricitinib	Olumiant	PM	Immunology-Rheumatology-Transplantation	Eli Lilly and Company Limited	15/06/2018	P/0157/2018
Dupilumab	Dupixent	PM	Dermatology	Regeneron Pharmaceuticals, Inc	15/06/2018	P/0158/2018
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.	15/06/2018	P/0159/2018
Lurasidone (hydrochloride)	Latuda	PM	Psychiatry	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.p.A.	15/06/2018	P/0160/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Spheroids of human autologous matrix-associated chondrocytes	Spherox	PM	Other	CO.DON AG	15/06/2018	P/0161/2018
Verapamil / trandolapril		W	Cardiovascular Diseases	Abbott Laboratories	15/06/2018	P/0162/2018
Apremilast	Otezla	PM	Dermatology	Celgene Europe Limited	15/06/2018	P/0163/2018
Setmelanotide		P	Nutrition	Rhythm Pharmaceuticals, Inc	15/06/2018	P/0164/2018
Empagliflozin	Jardiance	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	15/06/2018	P/0165/2018
Glecaprevir / pibrentasvir	Maviret	PM	Infectious Diseases	AbbVie Ltd	15/06/2018	P/0166/2018
Lasmiditan		P	Neurology	Eli Lilly and Company Limited	15/06/2018	P/0167/2018
Betrixaban		PM	Cardiovascular Diseases	Portola Pharma UK Limited	18/06/2018	P/0168/2018
Andecaliximab		W	Oncology	Gilead Sciences International Ltd	15/06/2018	P/0169/2018
Peanut flour		PM	Pneumology - Allergology	Aimmune Therapeutics Inc	15/06/2018	P/0170/2018
Emtricitabine / tenofovir alafenamide	Descovy	PM	Infectious Diseases	Gilead Sciences International Ltd.	15/06/2018	P/0171/2018
Sofosbuvir	Sovaldi	PM	Infectious Diseases	Gilead Sciences International Ltd.	15/06/2018	P/0172/2018
Etelcalcetide	Parsabiv	PM	Uro-nephrology	Amgen Europe B.V.	15/06/2018	P/0173/2018
Dasabuvir (sodium monohydrate)	Exviera	PM	Infectious Diseases	Abbvie Ltd	15/06/2018	P/0174/2018
Lubiprostone	Amitiza	PM	Gastroenterology-Hepatology	Sucampo AG	15/06/2018	P/0175/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Ceftaroline fosamil	Zinforo	PM	Infectious Diseases	Pfizer Limited	15/06/2018	P/0176/2018
Fenfluramine (hydrochloride)		PM	Neurology	Zogenix International Ltd	15/06/2018	P/0177/2018
Somapacitan		W	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	15/06/2018	P/0178/2018
Ombitasvir / paritaprevir / ritonavir	Viekirax	PM	Infectious Diseases	Abbvie Ltd	15/06/2018	P/0179/2018
Daratumumab	Darzalex	P	Oncology	Janssen-Cilag international N.V.	15/06/2018	P/0180/2018
Tocilizumab	RoActemra	PM	Immunology-Rheumatology-Transplantation	Roche Registration GmbH	12/06/2018	P/0181/2018
Larotrectinib		PM	Oncology	Bayer AG	15/06/2018	P/0182/2018
Abatacept	Orencia	W	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb Pharma EEIG	22/06/2018	P/0183/2018
Liposomal ciclosporin A (L-CsA)		RW	Immunology-Rheumatology-Transplantation	Breath Therapeutics GmbH	17/07/2018	P/0184/2018
Bempedoic acid		PM	Cardiovascular Diseases	Esperion Therapeutics, Inc.	17/07/2018	P/0185/2018
Rimiducid		PM	Immunology-Rheumatology-Transplantation	Bellicum Pharma Ltd.	17/07/2018	P/0186/2018
Upadacitinib		W	Immunology-Rheumatology-Transplantation	AbbVie Ltd	17/07/2018	P/0187/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Pitolisant	Wakix	PM	Neurology	BIOPROJET PHARMA	17/07/2018	P/0188/2018
Brodalumab		PM	Dermatology	LEO Pharma A/S	17/07/2018	P/0189/2018
Ustekinumab	Stelara	P	Gastroenterology-Hepatology	Janssen-Cilag International NV	17/07/2018	P/0190/2018
Glycerol phenylbutyrate	Ravicti	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Horizon Pharma Ireland Limited	17/07/2018	P/0191/2018
Trandolapril		RW	Cardiovascular Diseases	Abbott Laboratories	17/07/2018	P/0192/2018
Bimekizumab		P	Dermatology	UCB Biopharma SPRL	17/07/2018	P/0193/2018
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)		PM	Immunology-Rheumatology-Transplantation	Bellicum Pharma Ltd	17/07/2018	P/0194/2018
Fostamatinib		W	Other	Rigel Pharmaceuticals Ltd	17/07/2018	P/0195/2018
Sucroferric oxyhydroxide (mixture of iron (III)-oxyhydroxide, sucrose, starch) (PA21)	Velphoro	PM	Uro-nephrology	Vifor Fresenius Medical Care Renal Pharma France	17/07/2018	P/0196/2018
Sirolimus		PM	Ophthalmology	Santen Incorporated	19/07/2018	P/0197/2018
Gabapentin		PM	Pain	PHARM Srl	19/07/2018	P/0198/2018
Fibrinogen / thrombin / aprotinin / calcium chloride		PM	Other	Kedrion S.p.A.	19/07/2018	P/0199/2018
Eculizumab	Soliris	PM	Immunology-Rheumatology-Transplantation	Alexion Europe SAS	19/07/2018	P/0200/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Empagliflozin	Jardiance	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	19/07/2018	P/0201/2018
Dapagliflozin	Forxiga	W	Cardiovascular Diseases	AstraZeneca AB	19/07/2018	P/0202/2018
Tofacitinib	Xeljanz	PM	Immunology-Rheumatology-Transplantation	Pfizer Limited	17/07/2018	P/0203/2018
Linagliptin	Trajenta	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	19/07/2018	P/0204/2018
Ticagrelor	Brilique	PM	Cardiovascular Diseases Haematology-Hemostaseology	AstraZeneca AB	19/07/2018	P/0205/2018
Bilastine	Bilaxten and associated names	W	Dermatology Oto-rhino-laryngology Pneumology - Allergology	FAES FARMA S.A.	19/07/2018	P/0206/2018
(R)-2-amino-3-phenylpropylcarbamate hydrochloride (solriamfetol)		P	Neurology	Jazz Pharmaceuticals UK Ltd	17/07/2018	P/0207/2018
Itacitinib		P	Immunology-Rheumatology-Transplantation	Incyte Biosciences UK Ltd.	17/07/2018	P/0208/2018
Palbociclib	Ibrance	P	Oncology	Pfizer Limited	17/07/2018	P/0209/2018
Mexiletine (hydrochloride)		PM	Other	Lupin (Europe) Ltd.	17/07/2018	P/0210/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Influenza virus surface antigens (haemagglutinin and neuraminidase) of the following strains: A/(H1N1), A/(H3N2), B/Yamagata lineage, B/Victoria lineage	Influvac Tetra	PM	Vaccines	Abbott Biologicals B.V.	17/07/2018	P/0211/2018
Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human ARSA cDNA sequence (GSK2696274)		PM	Other	Orchard Therapeutics Ltd.	17/07/2018	P/0212/2018
Arimoclomol (citrate)		PM	Neurology	Orphazyme A/S	17/07/2018	P/0213/2018
Potassium citrate monohydrated / potassium hydrogen carbonate (ADV7103)		PM	Uro-nephrology	Advicenne	17/07/2018	P/0214/2018
Tasimelteon	Hetlioz	PM	Neurology	Vanda Pharmaceuticals	17/07/2018	P/0215/2018
Cobimetinib	Cotellic	PM	Oncology	Roche Registration GmbH	17/07/2018	P/0216/2018
Nitrous oxide		W	Anaesthesiology Pain	Società Italiana Carburo Ossigeno Spa SICO	19/07/2018	P/0217/2018
Patidegib		W	Dermatology	Pellepharm, Inc	17/07/2018	P/0218/2018
Purified inactivated rabies virus (WISTAR PM/WI 38-1503-3M strain)		P	Vaccines	Sanofi Pasteur S.A.	17/07/2018	P/0219/2018
Dasiglucagon		P	Endocrinology-Gynaecology-Fertility-Metabolism	Zealand Pharma A/S	19/07/2018	P/0220/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Ligelizumab		PM	Dermatology	Novartis Europharm Ltd.	17/07/2018	P/0221/2018
Recombinant varicella zoster virus (VZV) glycoprotein E	Shingrix	PM	Vaccines	GlaxoSmithKline Biologicals SA	17/07/2018	P/0222/2018
Citric acid (as citric acid anhydrous) / sodium chloride / simeticone / macrogol 4000 / sodium citrate /sodium sulfate (as sodium sulfate anhydrous) / potassium chloride (PMF104)	Clensia	PM	Gastroenterology-Hepatology	Alfasigma S.p.A.	17/07/2018	P/0223/2018
2-hydroxypropyl-ß-cyclodextrin (HP-ß-CD)		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Mallinckrodt Pharmaceuticals Ireland Ltd	17/07/2018	P/0224/2018
Vonicog alfa		PM	Haematology-Hemostaseology	Baxalta Innovations GmbH	17/07/2018	P/0225/2018
Febuxostat	Adenuric	W	Oncology	Menarini International Operations Luxembourg S.A.	20/07/2018	P/0226/2018
Pixantrone (as dimaleate)	Pixuvri	W	Oncology	CTI Life Sciences Limited	20/07/2018	P/0227/2018
Moxonidine		RW	Cardiovascular Diseases	Abbott Laboratories	29/07/2018	P/0228/2018
Recombinant IgG degrading enzyme of Streptococcus pyogenes		P	Immunology-Rheumatology-Transplantation	Hansa Medical AB	30/07/2018	P/0229/2018
Risankizumab		PM	Gastroenterology-Hepatology	AbbVie Ltd	03/08/2018	P/0230/2018
Risankizumab		PM	Gastroenterology-Hepatology	AbbVie Ltd	03/08/2018	P/0231/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3- zeta chimeric antigen receptor		W	Oncology	Kite Pharma EU B.V.	15/08/2018	P/0232/2018
Roxadustat		RPM	Haematology-Hemostaseology	Astellas Pharma Europe B.V.	15/08/2018	P/0233/2018
Vortioxetine	Brintellix	PM	Psychiatry	H. Lundbeck A/S	15/08/2018	P/0234/2018
His-Ser-Gln-Gly-Thr-Phe-Thr-Ser-Asp-Lys(γ-Glu-palmitoyl)-Ser-Glu-Tyr-Leu-Asp-Ser-Glu-Arg-Ala-Arg-Asp-Phe-Val-Ala-Trp-Leu-Glu-Ala-Gly-Gly-OH (MEDI0382)		P	Endocrinology-Gynaecology-Fertility-Metabolism	MedImmune Limited	15/08/2018	P/0235/2018
Trimeric, recombinant HIV-1 envelope glycoprotein 140 of Clade C, adjuvanted with aluminium phosphate [Clade C gp140]		P	Infectious Diseases Vaccines	Janssen-Cilag International NV	15/08/2018	P/0236/2018
Trimeric, recombinant HIV-1 envelope glycoprotein 140 of Clade C / trimeric, recombinant HIV-1 envelope glycoprotein 140 containing motifs of multiple HIV-1 variants, adjuvanted with aluminium phosphate [Clade C gp140/ Mosaic gp140]		P	Infectious Diseases Vaccines	Janssen-Cilag International NV	15/08/2018	P/0237/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Serotype 26 adenovirus encoding mosaic 1 HIV-1 group-specific antigen and polymerase proteins (Ad26.Mos1.Gag-Pol) / serotype 26 adenovirus encoding mosaic 2 HIV-1 group-specific antigen and polymerase proteins (Ad26.Mos2.Gag-Pol) / serotype 26 adenovirus encoding mosaic 1 HIV-1 envelope protein (Ad26.Mos1.Env) / serotype 26 adenovirus encoding mosaic 2S HIV-1 envelope protein (Ad26.Mos2S.Env) [Ad26.Mos4.HIV]		P	Infectious Diseases Vaccines	Janssen-Cilag International NV	15/08/2018	P/0238/2018
Glasdegib		W	Oncology	Pfizer Limited	15/08/2018	P/0239/2018
Octenidine (dihydrochloride)		W	Infectious Diseases Other	Schülke & Mayr GmbH	15/08/2018	P/0240/2018
Setrusumab		P	Other	Mereo Biopharma 3 Ltd	15/08/2018	P/0241/2018
Avelumab	Bavencio	PM	Oncology	Merck KGaA	15/08/2018	P/0242/2018
Andexanet alfa		PM	Other	Portola Pharma UK Limited	15/08/2018	P/0243/2018
Benralizumab	Fasenra	PM	Pneumology - Allergology	AstraZeneca AB	15/08/2018	P/0244/2018
Irbesartan / amlodipine		W	Cardiovascular Diseases	Sanofi- Aventis Research & Development	15/08/2018	P/0245/2018

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		PM	Oncology	Incyte Corporation	15/08/2018	P/0246/2018
Romosozumab		PM	Endocrinology-Gynaecology-Fertility-Metabolism	UCB Pharma S.A.	15/08/2018	P/0247/2018
Venglustat		W	Endocrinology-Gynaecology-Fertility-Metabolism Uro-nephrology	Genzyme Europe B.V.	15/08/2018	P/0248/2018
Influenza virus surface antigens - A/turkey/Turkey/1/05 (H5N1)	Aflunov and associated names	PM	Vaccines	Seqirus S.r.l.	15/08/2018	P/0249/2018
Tralokinumab		PM	Dermatology	LEO Pharma A/S	15/08/2018	P/0250/2018
Oseltamivir (phosphate)	Tamiflu	PM	Infectious Diseases	Roche Registration GmbH	14/08/2018	P/0251/2018
Osilodrostat		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Novartis Europharm Limited	15/08/2018	P/0252/2018
Ciprofloxacin (hydrochloride)		PM	Infectious Diseases	Aradigm Limited	15/08/2018	P/0253/2018
Luspatercept		W	Haematology-Hemostaseology	Celgene Europe Ltd	15/08/2018	P/0254/2018
Navitoclax		W	Oncology	AbbVie Ltd	14/08/2018	P/0255/2018
Veliparib		W	Oncology	AbbVie Ltd	14/08/2018	P/0256/2018
Paclitaxel	Abraxane	PM	Oncology	Celgene Europe Limited	14/08/2018	P/0257/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Olipudase alfa		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Genzyme Europe B.V.	15/08/2018	P/0258/2018
Balovaptan		PM	Neurology	Roche Registration GmbH	15/08/2018	P/0259/2018
Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	Foclivia and associated names	PM	Vaccines	Seqirus S.r.l.	15/08/2018	P/0260/2018
Fc- and CDR-modified humanized monoclonal antibody against C5 (ALXN1210)		PM	Haematology-Hemostaseology Uro-nephrology	Alexion Europe SAS	15/08/2018	P/0261/2018
Olaparib	Lynparza	P	Oncology	AstraZeneca AB	15/08/2018	P/0262/2018
Ferric pyrophosphate citrate		P	Haematology-Hemostaseology Uro-nephrology	Rockwell Medical, Inc.	15/08/2018	P/0263/2018
Eribulin	Halaven	PM	Oncology	Eisai Europe Ltd	15/08/2018	P/0264/2018
Alicaforsen		P	Gastroenterology-Hepatology	Atlantic Pharmaceuticals (Holdings) Ltd	01/10/2018	P/0265/2018
Cefiderocol		P	Infectious Diseases	Shionogi Limited	14/08/2018	P/0266/2018
Elotuzumab	Empliciti	W	Oncology	Bristol-Myers Squibb Pharma EEIG	13/08/2018	P/0267/2018
Quizartinib		PM	Oncology	Daiichi Sankyo Europe GmbH	16/08/2018	P/0268/2018
Omadacycline		PM	Infectious Diseases	Paratek UK Limited	16/08/2018	P/0269/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Entrectinib		P	Oncology	Roche Registration GmBH	16/08/2018	P/0270/2018
Ibalizumab		PM	Infectious Diseases	Theratechnologies International Limited	17/08/2018	P/0271/2018
Onasemnogenum abeparvovecum		P	Neurology	AveXis Netherlands B.V.	14/08/2018	P/0272/2018
Landiolol (hydrochloride)	Rapibloc, Landiobloc, Raploc, Runrapiq	PM	Cardiovascular Diseases	AOP Orphan Pharmaceuticals AG	14/08/2018	P/0273/2018
Emtricitabine / rilpivirine (hydrochloride) / tenofovir (disoproxil fumarate)	Eviplera	W	Infectious Diseases	Gilead Sciences International Ltd.	23/08/2018	P/0274/2018
Tofacitinib	Xeljanz	PM	Gastroenterology-Hepatology	Pfizer Limited	31/08/2018	P/0275/2018
Nadofaragene firadenovec		W	Oncology	Trizell Ltd.	12/09/2018	P/0276/2018
Levofloxacin / Dexamethasone		W	Ophthalmology	NTC srl	12/09/2018	P/0277/2018
Anti-alpha synuclein monoclonal antibody (BIIB054)		W	Neurology	Biogen Idec Limited	12/09/2018	P/0278/2018
Tepotinib		W	Oncology	Merck KGaA	12/09/2018	P/0279/2018
Ivosidenib		P	Oncology	Agios Pharmaceuticals, Inc.	12/09/2018	P/0280/2018
Anti-mucosal addressin cell adhesion molecule antibody (SHP647)		P	Gastroenterology-Hepatology	Shire Pharmaceuticals Ireland Limited	12/09/2018	P/0281/2018
Autologous cartilage derived cultured chondrocytes		P	Other	TETEC AG	12/09/2018	P/0282/2018
Mirikizumab		P	Dermatology	Eli Lilly and Company	12/09/2018	P/0283/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Human donor haematopoietic stem and progenitor cells (HSPC) that have been treated ex vivo with the protein transduction domain of the HIV-1 transactivation protein fused to MYC transcription factor (TBX-1400)		P	Immunology-Rheumatology-Transplantation	Taiga Biotechnologies, Inc	12/09/2018	P/0284/2018
Human fibrinogen concentrate (BT524)		PM	Haematology-Hemostaseology	Biotest AG	12/09/2018	P/0285/2018
Recombinant human alpha-galactosidase A (PRX 102)		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Protalix Ltd	12/09/2018	P/0286/2018
Sarizotan (hydrochloride)		P	Neurology	Newron Pharmaceuticals SpA	12/09/2018	P/0287/2018
Vamorolone		PM	Other	ReveraGen BioPharma Ltd	12/09/2018	P/0288/2018
Palovarotene		PM	Other	Clementia Pharmaceuticals Inc.	12/09/2018	P/0289/2018
Autologous haematopoietic stem cells transduced with lentiviral vector Lenti-D encoding the human ATP-binding cassette, subfamily D, member 1 (ABCD1) cDNA		PM	Neurology	bluebird bio France	12/09/2018	P/0290/2018
Baricitinib	Olumiant	P	Dermatology	Eli Lilly and Company Limited	12/09/2018	P/0291/2018
Indacaterol (acetate) / mometasone (furoate)		PM	Pneumology - Allergology	Novartis Europharm Limited	12/09/2018	P/0292/2018
Ponatinib	Iclusig	PM	Oncology	Incyte Biosciences Distribution B.V	12/09/2018	P/0293/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Caplacizumab		PM	Haematology-Hemostaseology	Ablynx NV	12/09/2018	P/0294/2018
Loxapine	Adasuve	PM	Psychiatry	Ferrer Internacional, S.A.	12/09/2018	P/0295/2018
Eftrenonacog alfa	Alprolix	PM	Haematology-Hemostaseology	Swedish Orphan Biovitrum AB (publ)	12/09/2018	P/0296/2018
Exenatide	Byetta Bydureon	PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	12/09/2018	P/0297/2018
Eliglustat	Cerdelga	PM	Other	Genzyme Europe B.V.	12/09/2018	P/0298/2018
Retigabine	Trobalt	W	Neurology	Glaxo Group Limited	12/09/2018	P/0299/2018
Mepolizumab	Nucala	PM	Pneumology - Allergology	GSK Trading Services Limited	12/09/2018	P/0300/2018
Cariprazine (hydrochloride)	Reagila	PM	Psychiatry	Gedeon Richter Plc.	12/09/2018	P/0301/2018
Fasinumab		W	Pain	Regeneron Ireland U.C.	12/09/2018	P/0302/2018
Lanthanum carbonate hydrate	Fosrenol and associated names	PM	Uro-nephrology	Shire Pharmaceutical Contracts Ltd	12/09/2018	P/0303/2018
Dupilumab		PM	Pneumology - Allergology	sanofi-aventis recherche & développement	12/09/2018	P/0304/2018
Interferon beta-1a		P	Pneumology - Allergology	Faron Pharmaceuticals Ltd	12/09/2018	P/0305/2018
Emapalumab		PM	Immunology-Rheumatology-Transplantation	Novimmune B.V	12/09/2018	P/0306/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Dapagliflozin	Forxiga	PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	12/09/2018	P/0307/2018
Perampanel	Fycompa	PM	Neurology	Eisai Europe Limited	12/09/2018	P/0308/2018
Omega-3-acid ethyl esters 90 / rosuvastatin (calcium)		W	Cardiovascular Diseases	Kuhnil Pharm. CO.,Ltd.	12/09/2018	P/0309/2018
Darunavir / cobicistat / emtricitabine / tenofovir alafenamide	Symtuza	PM	Infectious Diseases	Janssen-Cilag International NV	01/10/2018	P/0310/2018
Acetylsalicylic acid / rosuvastatin (calcium) / perindopril (tert-butylamine) / indapamide (hemihydrate)		W	Cardiovascular Diseases	SmartGenRx Pty Ltd	12/09/2018	P/0311/2018
Sodium thiosulfate (STS)		P	Oncology	Fennec Pharmaceuticals, Inc.	12/09/2018	P/0312/2018
Belimumab	Benlysta	PM	Immunology-Rheumatology-Transplantation	Glaxo Group Limited	12/09/2018	P/0313/2018
Isavuconazonium (sulfate)	Cresemba	PM	Infectious Diseases	Basilea Pharmaceutica International Ltd.	12/09/2018	P/0314/2018
Macrogol 3350 / sodium ascorbate / sodium sulfate / ascorbic acid / sodium chloride / potassium chloride (NER1006)		PM	Gastroenterology-Hepatology	Norgine Limited	12/09/2018	P/0315/2018
Brexpiprazole		PM	Psychiatry	Otsuka Europe Development and Commercialisation Limited, Zweigniederlassung,	12/09/2018	P/0316/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
				Frankfurt am Main		
Arimoclomol citrate		W	Neurology	Orphazyme A/S	12/09/2018	P/0317/2018
Monovalent, recombinant, replication-incompetent human adenovirus serotype 26-vectored vaccine encoding the pre-fusion conformation-stabilised F protein derived from the RSV A2 strain		P	Infectious Diseases Vaccines	Janssen-Cilag International NV	12/09/2018	P/0318/2018
Recombinant human acid ceramidase (RVT-801)		P	Other	Enzyvant Farber Ireland Ltd	12/09/2018	P/0319/2018
Afatinib	Giotrif	P	Oncology	Boehringer Ingelheim International GmbH	12/09/2018	P/0320/2018
Inclisiran sodium		P	Endocrinology-Gynaecology-Fertility-Metabolism	The Medicines Company UK Ltd.	12/09/2018	P/0321/2018
Rilpivirine (hydrochloride)	EDURANT	PM	Infectious Diseases	Janssen-Cilag International NV	12/09/2018	P/0322/2018
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)		RPM	Diagnostic	GUERBET	12/09/2018	P/0323/2018
Ertugliflozin	Steglatro	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme (Europe), Inc.	12/09/2018	P/0324/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Simeprevir	Olysio	W	Infectious Diseases	Janssen-Cilag International NV	12/09/2018	P/0325/2018
diphtheria toxin interleukin-3 Fusion Protein		W	Oncology	Stemline Therapeutics, Inc.	14/09/2018	P/0326/2018
Brentuximab vedotin	Adcetris	W	Oncology	Takeda Pharma A/S	08/10/2018	P/0327/2018
Cell-free solution of lysed Escherichia coli culture, strain Laves	Colibiogen oral Synerga Colibiogen mild	W	Gastroenterology-Hepatology	Laves-Arzneimittel GmbH	08/10/2018	P/0328/2018
Pamiparib		W	Oncology	BeiGene, Ltd.	08/10/2018	P/0329/2018
3-(3-(3,5-Dimethyl-1H-pyrazol-4-yl)propoxy)-4-fluorobenzoic acid		W	Cardiovascular Diseases Neurology	Eidos Therapeutics, Inc.	08/10/2018	P/0330/2018
Telisotuzumab vedotin		W	Oncology	AbbVie Ltd.	08/10/2018	P/0331/2018
Ianalumab		W	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	09/10/2018	P/0332/2018
Atorvastatin (calcium trihydrate) / perindopril (arginine) / indapamide		W	Cardiovascular Diseases	Les Laboratoires Servier	08/10/2018	P/0333/2018
Autologous dendritic cells pulsed with allogeneic tumour cell lysate		W	Oncology	Amphera BV	08/10/2018	P/0334/2018
Sarilumab	Kevzara	W	Immunology-Rheumatology-Transplantation	Sanofi-aventis recherche et développement	08/10/2018	P/0335/2018
Eflapegrastim		RW	Haematology-Hemostaseology Oncology	Spectrum Pharmaceuticals, Inc.	08/10/2018	P/0336/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Synthetic ribonucleic acid oligonucleotide directed against superoxide dismutase 1 (SOD1) messenger ribonucleic acid		W	Neurology	Biogen Idec Ltd	08/10/2018	P/0337/2018
Clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins	Xeomin Bocouture	W rev	Neurology Ophthalmology	Merz Pharmaceuticals GmbH	12/10/2018	P/0338/2018
Calcifediol		P	Uro-nephrology	Vifor Fresenius Medical Care Renal Pharma France	08/11/2018	P/0339/2018
Ceftazidime / avibactam	Zavicefta	PM	Infectious Diseases	Pfizer Limited	08/11/2018	P/0340/2018
Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)		PM	Vaccines	Seqirus Netherlands B.V.	08/11/2018	P/0341/2018
Peanut allergen extract		PM	Pneumology - Allergology	DBV Technologies S.A	09/11/2018	P/0342/2018
Conestat alfa	Ruconest	PM	Other	Pharming Group N.V.	08/11/2018	P/0343/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Fosnetupitant / palonosetron	Akynzeo	PM	Other	Helsinn Birex Pharmaceuticals Limited	08/11/2018	P/0344/2018
Idelalisib	Zydelig	W	Oncology	Gilead Sciences International Ltd	09/11/2018	P/0345/2018
Amikacin (sulfate)		PM	Infectious Diseases Pneumology - Allergology	Insmed Limited	08/11/2018	P/0346/2018
Pneumococcal polysaccharide serotype 1 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 3 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 4 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 5 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 6A – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 6B – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 7F – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 9V – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 14 – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype 18C – diphtheria CRM197 conjugate / pneumococcal polysaccharide serotype		PM	Vaccines	Merck Sharp & Dohme (Europe), Inc.	16/11/2018	P/0347/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
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])						
Brincidofovir		P	Infectious Diseases	Chimerix UK Limited	16/11/2018	P/0348/2018
Brincidofovir		P	Infectious Diseases	Chimerix UK Limited	16/11/2018	P/0349/2018
Brigatinib		P	Oncology	Takeda Pharm A/S	15/11/2018	P/0350/2018
Ixekizumab	Taltz	PM	Immunology-Rheumatology-Transplantation	Eli Lilly & Company Limited	20/11/2018	P/0351/2018
Ixekizumab	Taltz	P	Immunology-Rheumatology-Transplantation	Eli Lilly & Company Limited	20/11/2018	P/0352/2018
Ivacaftor	Kalydeco	PM	Other	Vertex Pharmaceuticals (Europe) Limited	22/11/2018	P/0353/2018
Fenfluramine (hydrochloride)		PM	Neurology	Zogenix International Ltd	30/11/2018	P/0354/2018
Potassium citrate monohydrated / potassium hydrogen carbonate		PM	Uro-nephrology	Advicenne Pharma	07/12/2018	P/0355/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Sarilumab	Kevzara	W	Immunology-Rheumatology-Transplantation	Sanofi-aventis recherche et développement	07/12/2018	P/0356/2018
Enalapril (maleate)		PM	Cardiovascular Diseases	Ethicare GmbH	07/12/2018	P/0357/2018
Lasmiditan		PM	Neurology	Eli Lilly and Company Limited	07/12/2018	P/0358/2018
Alectinib	Alecensa	W	Oncology	Roche Registration GmbH	07/12/2018	P/0359/2018
Risdiplam (RO7034067)		PM	Neurology	Roche Registration GmbH	07/12/2018	P/0360/2018
Crizotinib	Xalkori	W	Oncology	Pfizer Limited	07/12/2018	P/0361/2018
Phenylephrine hydrochloride / ketorolac trometamol (OMS302)		W	Ophthalmology	Omeros Corporation	07/12/2018	P/0362/2018
(RS)-baclofen / Naltrexone HCl / D-Sorbitol (PXT3003)		PM	Neurology	Pharnext SA	07/12/2018	P/0363/2018
Eculizumab	Soliris	PM	Neurology	Alexion Europe SAS	06/12/2018	P/0364/2018
Tezepelumab		PM	Pneumology - Allergology	AstraZeneca AB	07/12/2018	P/0365/2018
4-((2R,3S,4R,5S)-3-(3-chloro-2-fluorophenyl)-4-(4-chloro-2-fluorophenyl)-4-cyano-5-neopentylpyrrolidine-2-carboxamido)-3-methoxybenzoic acid (idasanutlin)		PM	Oncology	Roche Registration GmbH	07/12/2018	P/0366/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Nanobody directed towards the fusion protein of human respiratory syncytial virus (ALX-0171)		PM	Neonatology - Paediatric Intensive Care	Ablynx NV	07/12/2018	P/0367/2018
Edoxaban (tosylate)	Lixiana	PM	Cardiovascular Diseases Haematology-Hemostaseology	Daiichi Sankyo Europe GmbH	07/12/2018	P/0368/2018
Complex of povidone and iodine / dexamethasone (SHP640)		PM	Ophthalmology	Shire Pharmaceuticals Ireland Ltd	07/12/2018	P/0369/2018
Ex-vivo expanded human autologous epithelium containing stem cells	Holoclar	PM	Ophthalmology	Chiesi Farmaceutici S.p.A.	07/12/2018	P/0370/2018
Filgotinib		PM	Immunology-Rheumatology-Transplantation	Gilead Sciences International Ltd.	06/12/2018	P/0371/2018
Secukinumab	Cosentyx	PM	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	07/12/2018	P/0372/2018
Dapagliflozin	Forxiga	W	Uro-nephrology	AstraZeneca AB	07/12/2018	P/0373/2018
Atorvastatin / ezetimibe		W	Cardiovascular Diseases	QualipharmaCon Kft.	07/12/2018	P/0374/2018
Molibresib		W	Oncology	GlaxoSmithKline Trading Services Limited	07/12/2018	P/0375/2018
Ixazomib	Ninlaro	PM	Oncology	Takeda Pharm A/S	07/12/2018	P/0376/2018
Peanut flour		PM	Pneumology - Allergology	Aimmune Therapeutics Inc	07/12/2018	P/0377/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Tolvaptan	Samsca and associated names	PM	Endocrinology-Gynaecology-Fertility-Metabolism Uro-nephrology	Otsuka Pharmaceutical Europe Ltd.	07/12/2018	P/0378/2018
Avadomide		W	Oncology	Celgene Europe Limited	07/12/2018	P/0379/2018
Lixisenatide	Lyxumia	PM	Endocrinology-Gynaecology-Fertility-Metabolism	sanofi-aventis R&D	07/12/2018	P/0380/2018
Cholera vaccine, live attenuated, oral (strain CVD 103-HgR)		PM	Vaccines	PaxVax Netherlands B.V.	07/12/2018	P/0381/2018
Ibuprofen		W	Pain	Medherant Ltd.	07/12/2018	P/0382/2018
Ipatasertib		W	Oncology	Roche Registration GmbH	07/12/2018	P/0383/2018
Selinexor		W	Oncology	Karyopharm Europe GmbH	06/12/2018	P/0384/2018
Letermovir	Prevymis	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	07/12/2018	P/0385/2018
Pemigatinib		W	Oncology	Incyte Biosciences Distribution B.V.	06/12/2018	P/0386/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) [QIVc]		PM	Vaccines	Seqirus UK Limited	06/12/2018	P/0387/2018
Liposomal combination of cytarabine and daunorubicin	Vyxeos	PM	Oncology	Jazz Pharmaceuticals Ireland Limited	07/12/2018	P/0388/2018
Lenvatinib	LENVIMA Kisplyx	PM	Oncology	Eisai Europe Ltd	07/12/2018	P/0389/2018
SER-109 (Eubacterial Spores, Purified Suspension, Encapsulated)		P	Infectious Diseases	Seres Therapeutics UK Ltd.	07/12/2018	P/0390/2018
Janus Kinase-1 inhibitor (PF-04965842)		P	Dermatology	Pfizer Ltd	07/12/2018	P/0391/2018
Cenicriviroc		P	Gastroenterology-Hepatology	Allergan Pharmaceuticals International Limited	07/12/2018	P/0392/2018
Evobrutinib		P	Neurology	Merck KGaA	06/12/2018	P/0393/2018
Upadacitinib		P	Dermatology Immunology-Rheumatology-Transplantation	AbbVie Ltd	07/12/2018	P/0394/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Tadalafil	Adcirca Cialis	PM	Cardiovascular Diseases	Eli Lilly and Company Ltd	07/11/2018	P/0395/2018
Flurpiridaz F18		W	Cardiovascular Diseases	GE Healthcare, Inc.	07/12/2018	P/0396/2018
Certolizumab pegol	Cimzia	W	Dermatology	UCB Pharma SA	07/12/2018	P/0397/2018
Apremilast	Otezla	PM	Immunology-Rheumatology-Transplantation	Celgene Europe Limited	06/12/2018	P/0398/2018
Dabigatran etexilate mesilate	Pradaxa	PM	Cardiovascular Diseases Haematology-Hemostaseology	Boehringer Ingelheim International GmbH	07/12/2018	P/0399/2018
Autologous CD34+ hematopoietic stem cells transduced ex vivo with EFS lentiviral vector encoding for the human adenosine deaminase gene		PM	Immunology-Rheumatology-Transplantation	Orchard Therapeutics Limited	26/11/2018	P/0400/2018
Rabeprazole (sodium)	Pariet and associated names	PM	Gastroenterology-Hepatology	Eisai Limited	03/12/2018	P/0401/2018
Bupivacaine		P	Pain	Pacira Ltd	07/12/2018	P/0402/2018
Bedaquiline (fumarate)	SIRTURO	PM	Infectious Diseases	Janssen-Cilag International NV	19/12/2018	P/0403/2018
Evinacumab		P	Endocrinology-Gynaecology-Fertility-Metabolism	Regeneron Ireland U.C.	20/12/2018	P/0404/2018
Pazopanib	Votrient	PM	Oncology	Novartis Europharm Limited	20/12/2018	P/0405/2018
Ceftobiprole medocaril (sodium)	Zevtera and associated names	PM	Infectious Diseases	Basilea Pharmaceutica International Ltd.	20/12/2018	P/0406/2018

Active Substance(s)	Invented Name	PDCO Opinion	Therapeutic areas	Applicant	Decision date	Decision Number
Lumacaftor / ivacaftor	Orkambi	PM	Other	Vertex Pharmaceuticals (Europe) Limited	19/12/2018	P/0407/2018

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

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Liraglutide	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk	14/12/2018
belimumab	Immunology-Rheumatology-Transplantation	Glaxo Group Limited	16/11/2018
fidaxomicin	Infectious Diseases	Astellas Pharma Europe B.V.	16/11/2018
Ceftaroline fosamil	Infectious Diseases	Pfizer Limited	19/10/2018
Ranibizumab	Ophthalmology	Novartis Europharm Limited	19/10/2018
Glycerol Phenylbutyrate	Endocrinology-Gynaecology-Fertility-Metabolism	Horizon Pharma Ireland Limited	21/09/2018
Human normal immunoglobulin	Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology	Octapharma Pharmazeutika Produktionsges.m.b.H	21/09/2018
Paclitaxel	Oncology	Celgene Europe Ltd	21/09/2018
Lacosamide	Neurology	UCB Pharma S.A.	27/07/2018
Nonacog gamma	Haematology-Hemostaseology	Baxalta Innovations GmbH	29/06/2018
Trifarotene	Dermatology	GALDERMA R&D	29/06/2018
nusinersen	Neurology	Biogen Idec Ltd	29/06/2018
sunitinib malate	Oncology	Pfizer Limited	29/06/2018
Everolimus	Neurology	Novartis Europharm Limited	01/06/2018
Drospirenone	Endocrinology-Gynaecology-Fertility-Metabolism	LABORATIORIOS LEÓN FARMA, S.A.	23/03/2018
abatacept	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb Pharma EEIG	23/03/2018
Tocilizumab	Immunology-Rheumatology-Transplantation	Roche Registration Limited	23/02/2018

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
dasatinib (as monohydrate)	Oncology	Bristol-Myers Squibb Pharma EEIG	23/02/2018
Human coagulation factor X	Haematology-Hemostaseology	Bio Products Laboratory Ltd	26/01/2018
Plerixafor	Oncology	Genzyme Europe B.V.	26/01/2018
piperaquine tetraphosphate / artenimol	Infectious Diseases	Alfasigma S.p.A.	26/01/2018

Annex 17 – Referral procedures overview 2018 – 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
Scandonest and associated names (mepivacaine)	14/09/2017	31/05/2018	Article 30 of Directive 2001/83/EC
Omega-3 acid ethyl esters – containing medicinal products for oral use in secondary prevention after myocardial infarction (various)	22/03/2018	18/10/2018[1]	Article 31 of Directive 2001/83/EC
Diclofenac Sodium Spray Gel 4 % Cutaneous Spray, Solution and associated names (diclofenac sodium)	26/04/2018	15/11/2018	Article 29(4) of Directive 2001/83/EC
Paclitaxel Hetero and associated names (paclitaxel)	26/04/2018	18/10/2018	Article 29(4) of Directive 2001/83/EC
Gentamicin (solution for infusion/solution for injection) (gentamicin)	30/04/2018	15/11/2018	Article 5(3) of Regulation (EC) No 726/2004
Metamizole-containing medicinal products (metamizole sodium)	31/05/2018	13/12/2018	Article 31 of Directive 2001/83/EC
Norethisterone and ethinylestradiol containing medicinal products (norethisterone and ethinylestradiol)	31/05/2018	18/10/2018	Article 5(3) of Regulation (EC) No 726/2004
Bacterial lysates-containing medicinal products for respiratory conditions (various)	28/06/2018	ongoing	Article 31 of Directive 2001/83/EC
Angiotensin-II-receptor antagonists (sartans) containing a tetrazole group (various)	16/07/2018	ongoing	Article 31 of Directive 2001/83/EC
Septanest and associated names (articaine (hydrochloride)/ adrenaline (tartrate))	26/07/2018	ongoing	Article 30 of Directive 2001/83/EC
Syner-Kinase and associated names (urokinase)	26/07/2018	ongoing	Article 29(4) of Directive 2001/83/EC
Perlinring and associated names (etonogestrel/ethinylestradiol)	23/08/2018	18/10/2018	Article 29(4) of Directive 2001/83/EC
Diotop 75 mg / 20 mg modified-release capsules, hard and associated names (diclofenac/omeprazole)	18/10/2018	15/11/2018	Article 29(4) of Directive 2001/83/EC
Basiron AC and associated names (benzoyl peroxide)	13/12/2018	ongoing	Article 13 of Regulation (EC) No 1234/2008

[1] Re-examination is ongoing

Procedure name (international non-proprietary name (INN) or common name)	Start of procedure	End of procedure	Type of referral
Fosfomycin-containing medicinal products (fosfomycin calcium, fosfomycin disodium, fosfomycin sodium, fosfomycin trometamol)	13/12/2018	ongoing	Article 31 of Directive 2001/83/EC
Norethisterone/ethinylestradiol containing medicinal products (norethisterone and ethinylestradiol)	13/12/2018	ongoing	Article 5(3) of Regulation (EC) No 726/2004

Referrals made to the PRAC

Procedure name (international non-proprietary name (INN) or common name)	Start of procedure	End of procedure	Type of referral
Retinoids containing medicinal products (acitretin, adapalene, alitretinoin, bexarotene, isotretinoin, tretinoin, tazarotene)	07/07/2016	22/03/2018	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Quinolone and fluoroquinolone medicinal products for systemic and inhalation use (nalidixic acid, pipemidic acid, cinoxacin, enoxacin, pefloxacin, lomefloxacin, ciprofloxacin, levofloxacin, ofloxacin, moxifloxacin, norfloxacin, prulifloxacin, rufloxacin, flumequine)	09/02/2017	15/11/2018	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Medicinal products containing substances related to valproate	09/03/2017	21/03/2018	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Flupirtine-containing medicinal products (Flupirtine)	26/10/2017	21/03/2018	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Hydroxyethyl starch (HES) containing medicinal products (hydroxyethyl starch)	26/10/2017	27/06/2018[2]	Article 107i of Directive 2001/83/EC
Xofigo (radium Ra223 dichloride)	30/11/2017	26/07/2018	Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data
Esmya (ulipristal acetate)	30/11/2017	31/05/2018	Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data
Zinbryta (daclizumab beta)	08/03/2018	31/05/2018	Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data

[2] Date for revised CMDh position, initial position was adopted on 24/01/2018

Procedure name (international non-proprietary name (INN) or common name)	Start of procedure	End of procedure	Type of referral
Methotrexate containing medicinal products (methotrexate)	12/04/2018	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Annex 18 – Arbitrations and referrals in 2018 – veterinary medicines

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
Referral under Article 34 of Directive 2001/82/EC (re-examination)	• 13/07/2016 • 05/10/2017 • 15/02/2018	• Girolan and its associated name Apralan • Apramycin sulfate
Referral under Article 13 of Regulation (EC) No. 1234/2008	• 06/09/2017 • 15/02/2018	• Seresto and its associated name Foresto • Imidacloprid and flumethrin
Referral under Article 35 of Directive 2001/82/EC	• 14/02/2018	• Veterinary medicinal products containing 50 mg closantel per ml presented as solutions for injection for subcutaneous use in sheep • Closantel
Procedure under Article 30(3) of Regulation (EC) No. 726/2004	• 14/03/2018 • 19/07/2018	• Veterinary medicinal products for food producing species containing diethanolamine as an excipient • Diethanolamine (excipient)
Procedure under Article 30(3) of Regulation (EC) No. 726/2004	• 18/04/2018 • 08/11/2018	• Veterinary medicinal products containing gentamicin for parenteral administration to horses • Gentamicin
Referral under Article 35 of Directive 2001/82/EC	• 10/10/2018	• Veterinary medicinal products containing paromomycin to be administered parenterally to pigs • Paromomycin
Referral under Article 35 of Directive 2001/82/EC	• 10/10/2018	• Veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep • Tylosin

Annex 19 – Budget summaries 2017–2018

The summarised comparative budget statements for 2017 and 2018 are as follows:

		2017 (final)[1]		2018 (budget)[2]		2018 (prov.)[3]	
		€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
	Revenue						
100	Fees and charges	278,813	*87.9%*	304,508	*90.2%*	284,157	*89.6%*
200	General EU contribution	2,438	*0.8%*	10,405	*3.1%*	10,503	*3.3%*
201	Special EU contribution for orphan medicinal products	13,268	*4.2%*	12,000	*3.6%*	11,857	*3.7%*
300	Contribution from EEA	60	*0.0%*	0	*0.0%*	0	*0.0%*
600	External assigned revenue	9,666	*3.0%*	148	*0.0%*	92	*0.0%*
700	Balance from previous year	12,767	*4.0%*	10,116	*3.0%*	10,231	*3.2%*
5+9	Other	348	*0.1%*	584	*0.2%*	240	*0.1%*
	TOTAL REVENUE	**317,360**	*100.0%*	**337,761**	*100.0%*	**317,081**	*100.0%*
	Expenditure						
	Staff						
11	Staff in active employment	99,892	*32.5%*	113,471	*33.6%*	104,130	*34.0%*
12	Staff recruitment	120	*0.0%*	545	*0.2%*	480	*0.2%*
13	Duty travel	861	*0.3%*	2,712	*0.8%*	1,761	*0.6%*
14	Socio-medical infrastructure	717	*0.2%*	1,983	*0.6%*	924	*0.3%*
15	Training	741	*0.2%*	900	*0.3%*	537	*0.2%*
16	Social welfare	4,365	*1.4%*	5,844	*1.7%*	4,581	*1.5%*
17	Representation expenses	97	*0.0%*	131	*0.0%*	106	*0.0%*
	Total Title 1	**106,793**	*34.7%*	**125,586**	*37.2%*	**112,518**	*36.7%*
	Building / equipment						
20	Investment in immovable property, renting of building and associated costs	22,736	*7.4%*	21,979	*6.5%*	21,723	*7.1%*
21	Expenditure on corporate data processing	21,201	*6.9%*	26,555	*7.9%*	23,731	*7.7%*
22	Movable property [..]	747	*0.2%*	726	*0.2%*	705	*0.2%*
23	Other administrative expenditure	594	*0.2%*	1,998	*0.6%*	1,325	*0.4%*
24	Postage	65	*0.0%*	107	*0.0%*	78	*0.0%*
25	Expenditure on other meetings	340	*0.1%*	375	*0.1%*	349	*0.1%*
26	Restaurant & catering	753	*0.2%*	877	*0.3%*	838	*0.3%*
27	Information & publishing	882	*0.3%*	1,288	*0.4%*	987	*0.3%*
28	Business consultancy & audit svcs.	2,046	*0.7%*	2,432	*0.7%*	1,562	*0.5%*
	Total Title 2	**49,364**	*16.0%*	**56,337**	*16.7%*	**51,298**	*16.7%*
	Operational expenditure						
300	Meetings	8,655	*2.8%*	8,317	*2.5%*	7,635	*2.5%*
301	Evaluation of medicines	114,725	*37.3%*	123,901	*36.7%*	114,144	*37.2%*
302	Translations	4,752	*1.5%*	4,994	*1.5%*	4,280	*1.4%*
303	Scientific studies & svcs.	3,471	*1.1%*	3,170	*0.9%*	2,864	*0.9%*
31	Expenditure on business related IT projects	20,064	*6.5%*	15,457	*4.6%*	13,798	*4.5%*
	Total Title 3	**151,667**	*49.3%*	**155,838**	*46.1%*	**142,721**	*46.6%*
	TOTAL EXPENDITURE	**307,824**	*100.0%*	**337,761**	*100.0%*	**306,537**	*100.0%*

[1] Financial Year 2017: as per final accounts; rounded to nearest thousand Euro

[2] Financial Year 2018: as per final budget

[3] Financial Year 2018: as per provisional accounts; rounded to nearest thousand Euro

Annex 20 – European Medicines Agency Establishment Plan

Category and grade	TEMPORARY POSTS					
	POSTS 2018				POSTS 2019	
	Authorised		Actual as per 31.12.2018		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	0	-	0	-	0
AD 15	-	3	-	3	-	3
AD 14	-	7	-	6	-	7
AD 13	-	11	-	11	-	11
AD 12	-	43	-	42	-	43
AD 11	-	43	-	43	-	43
AD 10	-	41	-	41	-	43
AD 9	-	45	-	45	-	43
AD 8	-	59	-	59	-	59
AD 7	-	65	-	65	-	65
AD 6	-	23	-	23	-	37
AD 5	-	0	-	0	-	11
Total AD	**0**	**340**	**0**	**338**	**0**	**365**
AST 11	-	2	-	2	-	2
AST 10	-	7	-	7	-	7
AST 9	-	6	-	5	-	7
AST 8	-	16	-	16	-	16
AST 7	-	22	-	22	-	22
AST 6	-	42	-	39	-	27
AST 5	-	46	-	43	-	35
AST 4	-	57	-	57	-	57
AST 3	-	46	-	46	-	46
AST 2	-	7	-	60	-	7
AST 1	-	0	-	0	-	0
Total AST	**0**	**251**	**0**	**243**	**0**	**226**
Grand Total	**0**	**591**	**0**	**581**	**0**	**591**

Other staff	Planned (FTE[1]) 2018	Actual (FTE[1]) 2018	Actual headcount 31.12.2018	Planned (FTE[1]) 2019
CONTRACT AGENTS	**180**	**159**	**170**	**233**
NATIONAL EXPERTS	**39**	**32**	**30**	**30**

[1] FTE=Full Time Equivalent

Annex 21 – Access to documents requests in 2018

Requests received and pages released

Year	Number of requests received	Number of pages released
2018	822	441,720

Initial decisions on access in 2018[1]

Access given	
Yes	562
Partial	18
No	40
Not Applicable[2]	193
Total closed	**813**
Pending	267

Legal basis used for full or partial refusal

Legal basis	**Full**	**Partial**
4.1(a) – Protection of public interest	0	1
4.1(b) – Protection of privacy	1	0
4.2 1st ind – Protection of commercial interest	23	18
4.2 2nd ind – Protection of court proceedings	0	0
4.2 3rd ind – Protection of inspections	5	1
4.3 1st par – Protection of decision making process	12	4
4.3 2nd par – Protection of the Agency's decision making process	0	0
4.5 – Protection of Member States	0	0
Total	**41**	**24**

[1] Including initial requests received in previous years but closed in 2018
[2] Request became RFI / Document is not held by the Agency / Clarification is not received / Withdrawn

Decision on confirmatory applications in 2018[3]

Appeals	
Final refusal	2
Release	5
Partial	0
Not Applicable[4]	3
Total closed	**10**
Pending	0

Legal basis used for full or partial refusal

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

[3] Including appeals received in previous years but closed in 2018
[4] Withdrawn

Affiliation (per initial requests and appeals in 2018)

Affiliation	Number of requests received	In %	Number of pages released[5]	In %
Not-for-profit organisation	10	1	13,788	3
EU Institution (EC etc)	2	0	48	0
Regulator outside EU	1	0	0	0
EU NCA	0	0	17	0
Patients or Consumer	100	12	107,222	24
Healthcare professional	36	4	48,382	11
Academia/Research institute	63	8	103,587	23
Legal	70	9	21,402	5
Media	35	4	17,603	4
Pharmaceutical industry	385	47	111,130	25
Consultant	119	14	18,541	4
Other	1	0	0	0
Total	**822**	**100**	**441,720**	**100**

[5] Including initial requests and appeals received in previous years but closed in 2018

Annex 22 – Publications by Agency staff members and experts in 2018

Aartsma-Rus A, Mercuri E, Vroom E, Balabanov P.
Meeting report of the "Regulatory Exchange Matters" session at the 5th International TREAT-NMD Conference: Lessons in communication: How an early dialogue between patients, regulators and academics can further therapy development for neuromuscular disorders Freiburg, Germany, 27-29 November 2017.
Neuromuscul Disord. 2018 Jul;28(7):619-623. doi: 10.1016/j.nmd.2018.04.009. Epub 2018 Apr 20.

Alteri E, Guizzaro L.
Be open about drug failures to speed up research
Nature. 2018 Nov;563(7731):317-319

Amaouche N, Casaert Salomé H, Collignon O, Santos MR, Ziogas C
Marketing authorisation applications submitted to the European Medicines Agency by small and medium-sized enterprises: an analysis of major objections and their impact on outcomes.
Drug Discov Today. 2018 Oct;23(10):1801-1805

Arlett P.
Rapid response to: Pandemrix vaccine: why was the public not told of early warning signs?
BMJ 2018;362:k3948

Bahri P, Castillon Melero M.
Listen to the public and fulfil their information interests – translating vaccine communication research findings into guidance for regulators
Br J Clin Pharmacol. 2018 Aug;84(8):1696-1705. doi: 10.1111/bcp.13587. Epub 2018 May 31.

Bec G, Strecenski I, Castelnovo T.
Marketing authorisation holder's compliance with post-authorisation obligations in the European Union: a 5-year review
Regulatory Rapporteur - Vol 15, No 11: 27-32

Blind E, Janssen H, Dunder K, de Graeff PA.
The European Medicines Agency's approval of new medicines for type 2 diabetes.
Diabetes Obes Metab. 2018 Sep;20(9):2059-2063. doi: 10.1111/dom.13349. Epub 2018 May 30.

Bonertz A, Roberts GC, Hoefnagel M, Timon M, Slater JE, Rabin RL, Bridgewater J, Pini C, Pfaar O, Akdis C, Goldstein J, Poulsen LK, van Ree R, Rhyner C, Barber D, Palomares O, Sheikh A, Pawankar R, Hamerlijnk D, Klimek L, Agache I, Angier E, Casale T, Fernandez-Rivas M, Halken S, Jutel M, Lau S, Pajno G, Sturm G, Varga EM, Gerth van Wijk R, Bonini S, Muraro A, Vieths S.
Challenges in the implementation of EAACI guidelines on allergen immunotherapy: A global perspective on the regulation of allergen products.
Allergy. 2018 Jan;73(1):64-76. doi: 10.1111/all.13266. Epub 2017 Aug 30.

Borysowski J, Saxena A, Bateman-House A, Papaluca M, Różyńska J, Wnukiewicz-Kozłowska A, Górski A.
Expanded access: growing importance to public health.
J Epidemiol Community Health. 2018 Jul;72(7):557-558. doi: 10.1136/jech-2017-210409. Epub 2018 Apr 7.

Cerreta, F., Padrão, A., Skibicka-Stepien, I. et al.
Medicines for older people. Assessment and transparency at the European Medicines Agency regarding cardiovascular and antithrombotic medicinal products
Eur Geriatr Med (2018) 9: 415. https://doi.org/10.1007/s41999-018-0071-1

Cilia M, Ruiz S, Richardson P, Salmonson T, Serracino-Inglott A, Wirth F, Borg JJ.
Quality Issues Identified During the Evaluation of Biosimilars by the European Medicines Agency's Committee for Medicinal Products for Human Use.
AAPS PharmSciTech. 2018 Feb;19(2):489-511

Collignon O, Koenig F, Koch A, Hemmings RJ, Pétavy F, Saint-Raymond A, Papaluca-Amati M, Posch M.
Adaptive designs in clinical trials: from scientific advice to marketing authorisation to the European Medicine Agency.
Trials. 2018 Nov 20;19(1):642. doi: 10.1186/s13063-018-3012-x.

Collignon O, Petavy F.
Statistical considerations about the design and endpoints of randomised clinical trials for children with irritable bowel syndrome
Neurogastroenterol Motil. 2018 May;30(5):

Day S, Jonker AH, Lau LPL, Hilgers RD, Irony I, Larsson K, Roes KC, Stallard N.
Recommendations for the design of small population clinical trials
Orphanet J Rare Dis. 2018 Nov 6;13(1):195. doi: 10.1186/s13023-018-0931-2.

Ecker A, Mariz S, Naumann-Winter F, Norga K, Barisic I, Girard T, Tomasi P, Mentzer D, Sepodes B.
Comparative analysis of the scope of European Union paediatric investigation plans with corresponding orphan designations.
Arch Dis Child. 2018 May;103(5):427-430. doi: 10.1136/archdischild-2017-313352. Epub 2017 Oct 31.

Eichler HG, Barker R, Bedlington N, Bouvy JC, Broekmans AW, Bucsics A, Cerreta F, Corriol-Rohou S, Granados A, Le Cam Y, Schuurman A.
The evolution of adaptiveness: balancing speed and evidence.
Nat Rev Drug Discov. 2018 Dec;17(12):845-846. doi: 10.1038/nrd.2018.90. Epub 2018 Jul 6.

Eichler HG, Sweeney F.
The evolution of clinical trials: Can we address the challenges of the future?
Clin Trials. 2018 Feb;15(1_suppl):27-32.

Gerven J van, Bonelli M.
Commentary on the EMA Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products.
Br J Clin Pharmacol. 2018 Jul;84(7):1401-1409. doi: 10.1111/bcp.13550. Epub 2018 May 30.

Goedecke T, Morales D, Pacurariu A, Kurz X.
Measuring the impact of medicines regulatory interventions – Systematic review and methodological considerations
Br J Clin Pharmacol. 2018 Mar;84(3):419-433

Goedecke T, Morales D, Pacurariu A, Kurz X.
Response to Comment on `Measuring the impact of medicines regulatory interventions – Systematic review and methodological considerations`
Br J Clin Pharmacol. 2018 Sep;84(9):2169-2170. doi: 10.1111/bcp.13664. Epub 2018 Jul 3.

Hofer MP, Hedman H, Mavris M, Koenig F, Vetter T, Posch M, Vamvakas S, Regnstrom J, Aarum S.
Marketing authorisation of orphan medicines in Europe from 2000 to 2013.
Drug Discov Today. 2018 Feb;23(2):424-433

Hwang TJ, Tomasi PA, Saint-Raymond A, Bourgeois FT.
Availability of paediatric information in European Medicines Agency approvals.
Lancet Child Adolesc Health. 2018 May;2(5):e9. doi: 10.1016/S2352-4642(18)30101-9. Epub 2018 Apr 12.

Hwang TJ, Tomasi PA, Bourgeois FT.
Delays in completion and results reporting of trials under the Paediatric Regulation in the European Union: cohort study
PLoS Med. 2018 Mar 1;15(3)

Ioannou F, Burnsteel C, Mackay DKJ, Gay CG.
Regulatory pathways to enable the licencing of alternatives to antibiotics
Biologicals. 2018 May;53:72-75. doi: 10.1016/j.biologicals.2018.03.003. Epub 2018 Mar 31.

Kälviäinen R, Straus S, Dogne JM, Bakchine S, Haas M.
Reducing valproate use in women with epilepsy
vaccine.2018.11.082

Kondo H, Saint-Raymond A, Yasuda N.
What to Know About Medicines With New Active Ingredients Approved in FY 2016 / 2016 in Japan and EU: A Brief Comparison of New Medicines Approved in Japan and the EU in 2016.
Ther Innov Regul Sci. 2018 Mar;52(2):214-219. doi: 10.1177/2168479017720248. Epub 2017 Jul 21.

Kurz X, Perez -Gutthann S, the ENCePP Steering Group.
Strengthening standards, transparency, and collaboration to support medicine evaluation: Ten years of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP).
Pharmacoepidemiol Drug Saf. 2018 Mar;27(3):245-252

Mazzaglia G, Straus SMJ, Arlett P, da Silva D, Janssen H, Raine J, Alteri E.
Study Design and Evaluation of Risk Minimization Measures: A Review of Studies Submitted to the European Medicines Agency for Cardiovascular, Endocrinology, and Metabolic Drugs.
Drug Saf. 2018 Feb;41(2):191-202

McCarthy D, Bahri P, Barnes J, Delumeau JC, Edwards B, Harrison-Woolrych M.
An Update on ISoP Special Interest Groups (SIGs)
Drug Saf. 2018 Jan;41(1):1-6

Moellenhoff K, Dette H, Kotzagiorgis E, Volgushev S, Collignon O.
Regulatory assessment of drug dissolution profiles comparability via maximum deviation
Statistics in Medicine. 2018;1–14.

Morales DR, Slattery J, Evans S, Kurz X.
Antidepressant use during pregnancy and risk of autism spectrum disorder and attention deficit hyperactivity disorder: systematic review of observational studies and methodological considerations
BMC Med. 2018 Jan 15;16(1):6.

Morales DR, Slattery J, Pinheiro L, Kurz X, Hedenmalm K.
Indications for Systemic Fluoroquinolone Therapy in Europe and Prevalence of Primary Care Prescribing in France, Germany and the UK: Descriptive Population Based Study
Clin Drug Investig. 2018 Oct;38(10):927-933. doi: 10.1007/s40261-018-0684-7.

Newbould V, Le Meur S, Goedecke T, Kurz X.
Correction to: Medication Errors – a characterisation of spontaneously reported cases in EudraVigilance
Drug Saf. 2018 Dec;41(12):1439-1440. doi: 10.1007/s40264-018-0700-0

Nordenmalm S, Tomasi P, Pallidis C.
More medicines for children – impact of the EU Paediatric Regulation
Arch Dis Child. 2018 Jun;103(6):557-564. doi: 10.1136/archdischild-2017-313309. Epub 2018 Feb 28.

O'Sullivan J, Ponzano S, Bonelli M.
Safety Pharmacology Study Results and their Impact on the Design of First-in-human Trials for Authorised Oncology Therapies.
Pharmaceutical Medicine, 32(5), 335-341, 2018

Pacurariu A, Plueschke K, McGettigan P, Morales DR, Slattery J, Vogl D, Goedecke T, Kurz X, Cave A.
Electronic healthcare databases in Europe: characterisation and assessment of usefulness for benefit-risk evaluation of medicines
BMJ Open 2018;8:e023090. doi: 10.1136/bmjopen-2018-023090

Pacurariu A, Plueschke K, Olmo CA, Kurz X.
Imposed registries within the European postmarketing surveillance system: Extended analysis and lessons learned for regulators
Pharmacoepidemiol Drug Saf. 2018 Jul;27(7):823-826. doi: 10.1002/pds.4449. Epub 2018 May 11.

Pacurariu AC, Hoeve CE, Arlett P, Genov G, Slattery J, Sturkenboom MCJM, Straus SMJM.
Is patient exposure pre and post-approval a determinant of the timing and frequency of occurrence of safety issues?
Pharmacoepidemiol Drug Saf. 2018 Feb;27(2):168-173

Peschel W, Monedero Alvarez B
Harmonised European standards as basis for the safe use of herbal medicinal products and their marketing authorisation in EU member states
Pharmaceutical Medicine; August 2018, Volume 32, Issue 4, pp 275–293

Pinheiro LC, Candore G, Zaccaria C, Slattery J, Arlett P.
An algorithm to detect unexpected increases in frequency of reports of adverse events in EudraVigilance.
Pharmacoepidemiol Drug Saf. 2018 Jan;27(1):38-45

Plueschke K, McGettigan P, Pacurariu A, Kurz X, Cave A.
EU-funded initiatives for real world evidence: descriptive analysis of their characteristics and relevance for regulatory decision-making
BMJ Open. 2018 Jun 14;8(6):e021864. doi: 10.1136/bmjopen-2018-021864.

Pomba C, Catry B, Edo JT, Jukes H.
Licensing and Approval of Antimicrobial Agents for Use in Animals
Microbiol Spectr. 2018 Aug;6(4). doi: 10.1128/microbiolspec.ARBA-0016-2017.

Ponzano S, Blake K, Bonelli M, Enzmann H; European Medicines Agency Committee for Human Medicinal Products "First-in-Human Guideline Drafting Group".
Promoting Safe Early Clinical Research of Novel Drug Candidates: A European Union Regulatory Perspective.
Clin Pharmacol Ther. 2018 Apr;103(4):564-566

Ponzano S, Nigrelli G, Fregonese L, Eichler I, Bertozzi F, Bandiera T, Galietta LJV, Papaluca M.
A European regulatory perspective on cystic fibrosis: current treatments, trends in drug development and translational challenges for CFTR modulators.
Eur Respir Rev. 2018 Apr 13;27(148). pii: 170124. doi: 10.1183/16000617.0124-2017. Print 2018 Jun 30.

Postigo R, Brosch S, Slattery J, van Haren A, Dogné JM, Kurz X, Candore G, Domergue F, Arlett P.
EudraVigilance Medicines Safety Database: Publicly Accessible Data for Research and Public Health Protection
Drug Saf. 2018 Jul;41(7):665-675. doi: 10.1007/s40264-018-0647-1.

Postmus D, Richard S, Bere N, van Valkenhoef G, Galinsky J, Low E, Moulon I, Mavris M, Salmonsson T, Flores B, Hillege H, Pignatti F.
Individual Trade-Offs Between Possible Benefits and Risks of Cancer Treatments: Results from a Stated Preference Study with Patients with Multiple Myeloma.
Oncologist. 2018 Jan;23(1):44-51

Sharma RA, Fumi L, Audisio RA, Denys A, Wood BJ, Pignatti F.
Commentary: How will interventional oncology navigate the "valleys of death" for new medical devices?
Br J Radiol. 2018 Feb;91(1083):20170643

Sheean ME, Stoyanova-Beninska V, Capovilla G, Duarte D, Hofer MP, Hoffmann M, Magrelli A, Mariz S, Tsigkos S, Shaili E, Polsinelli B, Ricciardi M, Bonelli M, Balabanov P, Larsson K, Sepodes B.
Nonclinical data supporting orphan medicinal product designations: lessons from rare neurological conditions
Drug Discov Today. 2018 Jan;23(1):26-48

Slattery J, Morales D, Pinheiro L, Kurz X.
Cohort Study of Psychiatric Adverse Events Following Exposure to Levonorgestrel Containing Intrauterine Devices in UK General Practice
Drug Saf. 2018 Oct;41(10):951-958. doi: 10.1007/s40264-018-0683-x.

Slikker W Jr, de Souza Lima TA, Archella D, de Silva JB Junior, Barton-Maclaren T, Bo L, Buvinich D, Chaudhry Q, Chuan P, Deluyker H, Domselaar G, Freitas M, Hardy B, Eichler HG, Hugas M, Lee K, Liao CD, Loo LH, Okuda H, Orisakwe OE, Patri A, Sactitono C, Shi L, Silva P, Sistare F, Thakkar S, Tong W, Valdez ML, Whelan M, Zhao-Wong A.
Emerging technologies for food and drug safety.
Regul Toxicol Pharmacol. 2018 Oct;98:115-128. doi: 10.1016/j.yrtph.2018.07.013. Epub 2018 Jul 23.

Smith MY, Russell A, Bahri P, Mol PGM, Frise S, Freeman E, Morrato EH.
The RIMES Statement: A Checklist to Assess the Quality of Studies Evaluating Risk Minimization Programs for Medicinal Products.
Drug Saf. 2018 Apr;41(4):389-401. doi: 10.1007/s40264-017-0619-x.

Suarez-Sharp S, Cohen M, Kesisoglou F, Abend A, Marroum P, Delvadia P, Kotzagiorgis E, Li M, Nordmark A, Bandi N, Sjögren E, Babiskin A, Heimbach T, Kijima S, Mandula H, Raines K, Seo P, Zhang X.
Applications of clinically relevant dissolution testing: workshop summary report
AAPS J. 2018 Aug 27;20(6):93. doi: 10.1208/s12248-018-0252-3.

Sullivan JO, Blake K, Berntgen M, Salmonson T, Welink J; Pharmacokinetics Working Party.
Overview of the European Medicines Agency's Development of Product-Specific Bioequivalence Guidelines.
Clin Pharmacol Ther. 2018 Sep;104(3):539-545. doi: 10.1002/cpt.957. Epub 2018 Jan 9.

Tacconelli E, Carrara E, Savoldi A, Harbarth S, Mendelson M, Monnet DL, Pulcini C, Kahlmeter G, Kluytmans J, Carmeli Y, Ouellette M, Outterson K, Patel J, Cavaleri M, Cox EM, Houchens CR, Grayson ML, Hansen P, Singh N, Theuretzbacher U, Magrini N; WHO Pathogens Priority List Working Group.
Discovery, research, and development of new antibiotics: the WHO priority list of antibiotic-resistant bacteria and tuberculosis.
Lancet Infect Dis. 2018 Mar;18(3):318-327

Tafuri G, Lucas I, Estevão S, Moseley J, d'Andon A, Bruehl H, Gajraj E, Garcia S, Hedberg N, Massari M, Molina A, Obach M, Osipenko L, Petavy F, Petschulies M, Pontes C, Russo P, Schiel A, Van de Casteele M, Zebedin-Brandl EM, Rasi G, Vamvakas S.
The impact of parallel regulatory-health technology
assessment scientific advice on clinicaldevelopment. Assessing the uptake of regulatory and health technology assessment recommendations.
Br J Clin Pharmacol. 2018 May;84(5):1013-1019. doi: 10.1111/bcp.13524. Epub 2018 Mar 5.

Thanarajasingam G, Minasian LM, Baron F, Cavalli F, De Claro RA, Dueck AC, El-Galaly TC, Everest N, Geissler J, Gisselbrecht C, Gribben J, Horowitz M, Ivy SP, Jacobson CA, Keating A, Kluetz PG, Krauss A, Kwong YL, Little RF, Mahon FX, Matasar MJ, Mateos MV, McCullough K, Miller RS, Mohty M, Moreau P, Morton LM, Nagai S, Rule S, Sloan J, Sonneveld P, Thompson CA, Tzogani K, van Leeuwen FE, Velikova G, Villa D, Wingard JR, Wintrich S, Seymour JF, Habermann TM.
Beyond maximum grade: modernising the assessment and reporting of adverse events in haematological malignancies.
Lancet Haematol. 2018 Nov;5(11):e563-e598. doi: 10.1016/S2352-3026(18)30051-6. Epub 2018 Jun 18.

Tsigkos S, Hofer MP, Sheean ME, Mariz S, Larsson K, Naumann-Winter F, Fregonese L, Sepodes B.
Establishing rarity in the context of orphan medicinal product designation in the European Union
Drug Discov Today. 2018 Mar;23(3):681-686

Tzogani K, Penninga E, Schougaard Christiansen ML, Hovgaard D, Sarac SB, Camarero Jimenez J, Garcia I, Lafuente M, Sancho-López A, Salmonson T, Gisselbrecht C, Pignatti F.
EMA Review of Daratumumab for the Treatment of Adult Patients with Multiple Myeloma.
Oncologist. 2018 May;23(5):594-602. doi: 10.1634/theoncologist.2017-0328. Epub 2018 Jan 25.

Tzogani K, van Hennik P, Walsh I, De Graeff P, Folin A, Sjöberg J, Salmonson T, Bergh J, Laane E, Ludwig H, Gisselbrecht C, Pignatti F.
The European Medicines Agency Review of Panobinostat (Farydak) for the Treatment of Adult Patients with Relapsed and/or Refractory Multiple Myeloma.
Oncologist. 2018 May;23(5):631-636. doi: 10.1634/theoncologist.2017-0301. Epub 2017 Nov 30.
Erratum in: Oncologist. 2018 Jul;23(7):870.

Vannice KS, Wilder-Smith A, Barrett ADT, Carrijo K, Cavaleri M, de Silva A, Durbin AP, Endy T, Harris E, Innis BL, Katzelnick LC, Smith PG, Sun W, Thomas SJ, Hombach J.
Clinical development and regulatory points for consideration for second-generation live attenuated dengue vaccines.
Vaccine. 2018 Jun 7;36(24):3411-3417. doi: 10.1016/j.vaccine.2018.02.062. Epub 2018 Mar 7.

Vatzaki E, Straus S, Dogne HM, Garcia Burgos J, Girard T, Martelletti P.
Latest clinical recommendations on valproate use for migraine prophylaxis in women of childbearing age: overview from European Medicines Agency and European Headache Federation
J Headache Pain. 2018 Aug 14;19(1):68. doi: 10.1186/s10194-018-0898-3.