Annexes to the annual report of the European Medicines Agency 2021

Annex 1 – Members of the Management Board

Chair: Christa WIRTHUMER-HOCHE
EMA contact: Hilde BOONE

Members

• European Parliament	Matthias GROOTE, Anthony BORG
• European Commission	Sandra GALLINA, Patrick CHILD[1] (Alternates: Andrzej RYS, Irene NORSTEDT[2])
• Belgium	Xavier DE CUYPER (Alternate: Greet MUSCH)
• Bulgaria	Bogdan KIRILOV (Alternate: Svetlin SPIROV)
• Czech Republic	Irena STOROVÁ (Alternate: Jiří BUREŠ)
• Denmark	Lars BO NIELSEN[3] (Alternate: Mette AABOE HANSEN)
• Germany	Karl BROICH (Alternate: Lars - Christoph NICKEL)
• Estonia	Katrin KIISK[4] (Alternate: Alar IRS)
• Ireland	Lorraine NOLAN (Alternate: Rita PURCELL)
• Greece	Eleftherios PALLIS (Alternate: Awaiting nomination[5])
• Spain	María Jesús LAMAS DÍAZ (Alternate: César HERNÁNDEZ)
• France	Christelle RATIGNIER-CARBONNEIL[6] (Alternate: Jean-Pierre ORAND)
• Croatia	Siniša TOMIĆ [7] (Alternate: Danica KRAMARIĆ[8])
• Italy	Nicola MAGRINI (Alternate: Francesco TROTTA[9])
• Cyprus	Helena PANAYIOTOPOULOU (Alternate: Irini Chrysafi FANIDOU)
• Latvia	Awaiting nomination[10] (Alternate: Janis ZVEJNIEKS)
• Lithuania	Gytis ANDRULIONIS (Alternate: Awaiting nomination)
• Luxembourg	Anna CHIOTI[11] (Alternate: Marcin WISNIEWSKI[12])
• Hungary	Mátyás SZENTIVÁNYI (Alternate: Beatrix HORVATH)
• Malta	Anthony SERRACINO-INGLOTT (Alternate: John-Joseph BORG)

[1] Replaced Carlo PETTINELLI from June 2021
[2] Replaced Valentina SUPERTI from June 2021
[3] Previously vacant
[4] Replaced Kristin RAUDSEPP from December 2021
[5] Awaiting nomination
[6] Replaced Dominique MARTIN from February 2021
[7] Replaced Vili BEROS from December 2021
[8] Replaced Siniša TOMIĆ from December 2021
[9] Replaced Giuseppe AMATO from August 2021
[10] Awaiting nomination
[11] Replaced Laurent MERTZ from April 2021
[12] Replaced Françoise BERTHET from August 2021

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• Netherlands	Paula LOEKMEIJER[13] (Alternate: Christina LEGUIJT[14])
• Austria	Christa WIRTHUMER-HOCHE (Alternate: Thomas REICHHART)
• Poland	Grzegorz CESSAK (Alternate: Marcin KOLAKOWSKI)
• Portugal	Rui SANTOS IVO (Alternate: Susana GUEDES POMBO[15])
• Romania	Awaiting nomination[16] (Alternate: Andrei BACIU [17])
• Slovenia	Momir RADULOVIĆ (Alternate: Awaiting nomination)
• Slovakia	Zuzana BAŤOVÁ (Alternate: Judita HEDEROVA)
• Finland	Eija PELKONEN (Alternate: Johanna NYSTEDT[18])
• Sweden	Bjoern ERIKSSON[19] (Alternate: Asa KUMLIN HOWELL)
• Representatives of patients' organisations	Marco GRECO, Ioannis NATSIS
• Representative of doctors' organisations	Wolf-Dieter LUDWIG
• Representative of veterinarians' organisations	Nancy DE BRIYNE

Observers

• Iceland	Runa HAUKSDOTTIR (Alternate: Awaiting nomination[20])
• Liechtenstein	Vlasta ZAVADOVA (Alternate: Martin STRICKER)
• Norway	Audun HÅGÅ (Alternate: Awaiting nomination[21])

[13] Replaced Hugo HURTS from June 2021
[14] Replaced Hugo HURTS from September 2021
[15] Previously vacant
[16] Awaiting nomination
[17] Replaced Cristina RACOCEANU from March 2021
[18] Replaced Esa HEINONEN from February 2021
[19] Replaced Joakim BRANDBERG from June 2021
[20] Awaiting nomination
[21] Awaiting nomination

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

Chair: Harald ENZMANN

Members

• Andrea LASLOP (Austria)	Alternate: Daniela PHILADELPHY [1]
• Christophe FOCKE (Belgium)	Alternate: Karin JANSSEN VAN DOORN
• Ilko GETOV (Bulgaria)	Alternate: Velislava TODOROVA
• Margareta BEGO (Croatia)	Alternate: Selma ARAPOVIC DZAKULA
• Helena PANAYIOTOPOULOU (Cyprus)	Alternate: Emilia MAVROKORDATOU
• Ondrej SLANAR (Czechia)	Alternate: Tomas RADIMERSKY
• Sinan B. SARAC (Denmark)	Alternate: Thalia Marie Estrup BLICHER [2]
• Alar IRS (Estonia)	Alternate: Edward LAANE
• Outi MAKI-IKOLA (Finland)	Alternate: Johanna LAHTEENVUO
• Alexandre MOREAU (France)	Alternate: Jean-Michel RACE
• Martina WEISE (Germany)	Alternate: Janet KOENIG
• Konstantina ALEXOPOULOU (Greece) [3, 4]	Alternate: Anastasia MOUNTAKI [5]
• *Awaiting nomination* (Hungary)	Alternate: Agnes GYURASICS
• Hrefna GUDMUNDSDOTTIR (Iceland) [6, 7]	Alternate: Jan SJOBERG [8, 9]
• Jayne CROWE (Ireland)	Alternate: Peter KIELY
• Armando GENAZZANI (Italy)	Alternate: Nicola MAGRINI
• Elita POPLAVSKA (Latvia)	Alternate: *Awaiting nomination*
• Vlasta ZAVADOVA (Liechtenstein) [10]	Alternate: *Awaiting nomination*
• Romaldas MACIULAITIS (Lithuania)	Alternate: Silvijus ABRAMAVICIUS [11, 12]
• Martine TRAUFFLER (Luxembourg)	Alternate: Carola DE BEAUFORT
• John Joseph BORG (Malta)	Alternate: Helen VELLA
• Johann Lodewijk HILLEGE (Netherlands)	Alternate: Paula Boudewina VAN HENNIK

[1] Replaced Milena STAIN as of January 2021
[2] Replaced Kirstine Moll HARBOE as of November 2021
[3] Constantinos MARKOPOULOS's mandate expired as of October 2021
[4] Konstantina ALEXOPOULOU nominated as of December 2021
[5] Replaced Eleftheria NIKOLAIDI as of October 2021
[6] Kolbeinn GUDMUNDSSON's mandate ended in August 2021
[7] Hrefna GUDMUNDSDOTTIR nominated as of September 2021 with a swap of roles from alternate to member
[8] Hrefna GUDMUNSDOTTIR swapped roles from alternate to a member as of September 2021
[9] Jan SJOBERG nominated as of October 2021
[10] Nominated as of November 2021
[11] Simona STANKEVICIUTE resigned as of May 2021
[12] Silvijus ABRAMAVUCIUS nominated as of September 2021

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• Ingrid WANG (Norway) [13, 14]	Alternate: Eva SKOVLUND [15]
• Ewa BALKOWIEC-ISKRA (Poland)	Alternate: Grzegorz CESSAK [16]
• Bruno SEPODES (Portugal) *(Vice-Chair)*	Alternate: Fatima VENTURA
• Simona BADOI (Romania)	Alternate: Dana Gabriela MARIN
• Francisek DRAFI (Slovakia)	Alternate: Dorota DISTLEROVA
• Kristina NADRAH (Slovenia) [17, 18]	Alternate: Nevenka TRSINAR BRODT
• Maria Concepcion PRIETO YERRO (Spain)	Alternate: Blanca GARCIA-OCHOA
• Kristina DUNDER (Sweden)	Alternate: Filip JOSEPHSON

Co-opted members

- Christian GARTNER (Medical statistics (clinical-trial methodology / epidemiology))
- Blanka HIRSCHLEROVA (Quality (non-biologicals) and Pharmacokinetics)
- Jan MUELLER-BERGHAUS (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))
- Carla TORRE (Pharmaco-Epidemiology) [19]
- Sol RUIZ (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))

[13] Bjorg BOLSTAD's mandate ended in September 2021
[14] Ingrid WANG nominated as of November 2021 with a swap of roles from alternate member to a member
[15] Replaced Ingrid WANG as of November 2021
16 Replaced Marcin KOLAKOWSKI as of September 2021
[17] Rajko KENDA's mandate expired in March 2021
[18] Kristina NADRAH nominated as of October 2021
[19] Nominated as of February 2021

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Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: Sabine STRAUS

Members nominated by Member States

• Jan NEUHAUSER (Austria)	Alternate: Sonja HRABCIK
• Jean-Michel DOGNE (Belgium)	Alternate: Laurence DE FAYS
• Maria POPOVA-KIRADJIEVA (Bulgaria)	Alternate: Yuliyan EFTIMOV
• Nikica MIROSEVIC SKVRCE (Croatia)	Alternate: Zeljana MARGAN KOLETIC
• Elena KAISIS (Cyprus) [1, 2]	Alternate: Panagiotis PSARAS [3, 4]
• Eva JIRSOVA (Czechia)	Alternate: Jana LUKACISINOVA
• Anette STARK (Denmark)	Alternate: Hans Christian SIERSTED
• Maia UUSKULA (Estonia)	Alternate: Krõõt AAB [5]
• Kirsti VILLIKKA (Finland)	Alternate: Kimmo JAAKKOLA
• Tiphaine VAILLANT (France) [6]	Alternate: Nathalie GAULT [7, 8]
• Martin HUBER (Germany) *(Vice-Chair)*	Alternate: Brigitte KELLER-STANISLAWSKI
• Sofia TRANTZA (Greece) [9]	Alternate: Georgia GKEGKA [10]
• Melinda PALFI (Hungary) [11]	Alternate: Julia PALLOS [12]
• Gudrun STEFANSDOTTIR (Iceland)	Alternate: *Awaiting nomination* [13]
• Rhea FITZGERALD (Ireland)	Alternate: Ronan GRIMES
• Amelia CUPELLI (Italy) [14]	Alternate: Ilaria BALDELLI
• Zane NEIKENA (Latvia)	Alternate: Zane STADE
• Rugile PILVINIENE (Lithuania)	Alternate: *Awaiting nomination* [15]
• Nadine PETITPAIN (Luxembourg)	Alternate: Anne-Cecile VUILEMIN
• John Joseph BORG (Malta)	Alternate: Benjamin MICALLEF

[1] Panagiotis PSARAS replaced Helena PANAYIOTOPOULOU as from January 2021 with a swap of role from alternate to member
[2] Elena KAISIS replaced Panagiotis PSARAS as of November 2021
[3] Christina Sylvia CHRYSOSTOMOU replaced Panagiotis PSARAS as of January 2021 who swapped roles from alternate to member
[4] Panagiotis PSARAS replaced Christina Sylvia CHRYSOSTOMOU as of November 2021 with swap of roles from member to alternate
[5] Replaced Katrin KIISK as of July 2021
[6] Replaced Adrien INOUBLI as from August 2021 with a swap of role from alternate to member
[7] Tiphaine VAILLANT swapped roles from alternate to member as from August 2021 Nominated as of October 2021
[8] Nathalie GAULT nominated as of October 2021
[9] Replaced Agni KAPOU as of December 2021 with a swap of roles from alternate to member
[10] Replaced Sofia TRANTZA as of December 2021
[11] Swap of roles with Julia PALLOS as of July 2021
[12] Swap of roles with Melinda PALFI as of July 2021
[13] Gudrun Kristin STEINGRIMSDOTTIR resigned as of January 2021
[14] Amelia CUPELLI's mandate expired as of May 2021, re-nominated as of September 2021
[15] Ruta KERPAUSKIENE's mandate expired as of July 2021

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- Menno VAN DER ELST (Netherlands) Alternate: Liana GROSS-MARTIROSYAN
- David BENEE OLSEN (Norway) Alternate: Karen PERILLE HARG
- Adam PRZYBYLKOWSKI (Poland) Alternate: Katarzyna ZIOLKOWSKA
- Ana Sofia DINIZ MARTINS (Portugal) Alternate: Marcia SILVA
- Roxana DONDERA (Romania) [16] Alternate: Alexandra-Maria SPURNI
- Marek JURACKA (Slovakia) [17] Alternate: Anna MAREKOVA [18]
- Polona GOLMAJER (Slovenia) [19, 20, 21] Alternate: Milena RADOHA-BERGOC [22, 23]
- Eva SEGOVIA (Spain) Alternate: Maria del PINAR RAYON
- Ulla WANDEL LIMINGA (Sweden) Alternate: Annika FOLIN

Independent scientific experts nominated by the European Commission

- Annalisa CAPUANO [24]
- Daniel MORALES
- Hedvig NORDENG
- Patricia McGETTIGAN [25]
- Milou Daniel DRICI
- Teresa HERDEIRO [26]

Members representing healthcare professionals nominated by the European Commission

- Raymond ANDERSON Alternate: Roberto FRONTINI

Members representing patients' organisations nominated by the European Commission

- Cathalijne VAN DOORNE Alternate: Virginie HIVERT

[16] Replaced Roxana STROE as of January 2021
[17] Replaced Michal RADIK as of October 2021 with a swap of roles from alternate to member
[18] Replaced Marek JURACKA as of October 2021
[19] Gabriel JAZBEC resigned as from April 2021
[20] Petra Brina KOVACIC nominated as from July 2021 and resigned as from July 2021
[21] Polona GOLMAJER nominated as November 2021 with a swap of role from alternate to member
[22] Polona GOLMAJER replaced Jasmina KLOPIC as from July 2021
[23] Milena RADOHA-BERGOC replaced Polona GOLMAJER as of November 2021
[24] Replaced Birgitta GRUNDMARK as of July 2021
[25] Replaced Antoine PARIENTE as of July 2021
[26] Replaced Stefan WEILER as of July 2021

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

Chair: David MURPHY

Members and alternates

• Petra FALB (Austria)	Alternate: Manuela LEITNER
• Bruno URBAIN (Belgium)	Alternate: Frédéric KLEIN
• Svetoslav BRANCHEV (Bulgaria)	Alternate: *awaiting nomination*
• Frane BOŽIĆ (Croatia)	Alternate: Hrvoje PAVASOVIC
• Leona NEPEJCHALOVÁ[1] (Czechia)	Alternate: Jiří BUREŠ[2]
• Christodoulos PIPIS (Cyprus)	Alternate: Alia MICHAELIDOU-PATSIA
• Niels Christian KYVSGAARD (Denmark)	Alternate: Merete BLIXENKRONE-MØLLER
• Toomas TIIRATS (Estonia)	Alternate: *awaiting nomination*
• Minna LEPPÄNEN (Finland)[3]	Alternate: Tita-Maria MUHONEN[4]
• Sylvie LOUET (France)	Alternate: Christine MIRAS
• Esther WERNER (Germany)	Alternate: Andrea GOLOMBIEWSKI
• Spyridon FARLOPOULOS (Greece)	Alternate: Amalia PAPADAKI
• Gabor KULCSÁR (Hungary)	Alternate: Melinda NEMES-TERENYI
• J. Gabriel BEECHINOR (Ireland)	Alternate: Paul McNEILL
• Paolo PASQUALI (Italy)	Alternate: Antonio BATTISTI
• Zanda AUCE (Latvia)	Alternate: Santa ANSOSKA
• Snieguolė T. DZEKČIORIENĖ (Lithuania)	Alternate: Nijolė STANKEVIČIENĖ
• Marc SCHMIT (Luxembourg)	Alternate: Caroline CONER[5]
• Stephen SPITERI (Malta)	Alternate: Elena Maria VELLA[6]
• Jacqueline POOT (Netherlands)	Alternate: Kim BOERKAMP
• Anna WACHNIK-ŚWIĘCICKA (Poland)	Alternate: Ewa AUGUSTYNOWICZ
• João Pedro DUARTE DA SILVA (Portugal)	Alternate: Inês FLOR DIAS[7]
• Lollita TABAN (Romania)	Alternate: Gabriela TUCHILA
• Judita HEDEROVÁ (Slovakia)	Alternate: Eva CHOBOTOVÁ

[1] Nominated as of September 2021 meeting
[2] Nominated as of September 2021 meeting
[3] Replaced Tita-Maria MUHONEN as of February 2021
[4] Replaced Katariina KIVILAHTI-MANTYLA as of February 2021
[5] Nominated as of 14 September 2021
[6] Nominated as of 26 November 2021
[7] Replaced Cristina GONÇALVES SANTOS as of September 2021

- Katarina ŠTRAUS (Slovenia) Alternate: Boris KOLAR
- Cristina MUÑOZ MADERO (Spain) Alternate: Consuelo RUBIO MONTEJANO
- Frida HASSLUNG-WIKSTRÖM (Sweden) Alternate: Carina BERGMAN

EEA members

- Péter Zsolt Fekete (Iceland) Alternate: *awaiting nomination*
- Hanne BERGENDAHL (Norway) Alternate: Annelin Bjelland

Co-opted members

Co-opted member	**Expertise**
Keith BAPTISTE	Antimicrobials
Rory BREATHNACH	General clinical veterinary practice
G. Johan SCHEFFERLIE	MRLs/residues
Mary O'GRADY	Quality pharmaceuticals
Ricardo CARAPETO GARCÍA	Environmental risk assessment

Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Violeta STOYANOVA-BENINSKA

Members nominated by Member States

- Brigitte SCHWARZER-DAUM (Austria)
- Tim LEEST (Belgium)
- Lyubina Racheva TODOROVA (Bulgaria)
- Dinko VITEZIC (Croatia)
- Elli LOIZIDOU (Cyprus) [1]
- Lenka GAIDADZI (Czechia)
- Elisabeth PENNINGA (Denmark)
- Vallo TILLMANN (Estonia)
- Karri PENTTILA (Finland)
- Cecile DOP (France)
- Frauke NAUMANN-WINTER (Germany)
- George DIMOPOULOS (Greece) [2]
- Zsofia GYULAI (Hungary)
- *Awaiting nomination* (Iceland)
- Geraldine O'DEA (Ireland)
- Enrico COSTA (Italy) [3, 4]
- Irena ROGOVSKA (Latvia)
- Vlasta ZAVADOVA (Liechtenstein) [5]
- Ausra MATULEVICIENE (Lithuania)
- Michel HOFFMAN (Luxembourg)
- Robert NISTICO (Malta)
- Elisabeth ROOK (Netherlands)
- Maria Elisabeth KALLAND (Norway)
- Bozenna DEMBOWSKA-BAGINSKA (Poland)
- Dinah DUARTE (Portugal)

[1] Replaced Vasileios LOUTAS as of November 2021
[2] Replaced Nikolaos SYPSAS as of July 2021
[3] Armando MAGRELLI's mandate expired as of April 2021
[4] Enrico COSTA nominated as of May 2021
[5] Nominated as of October 2021

- Olimpia NEAGU (Romania)
- Eva MALIKOVA (Slovakia)
- Martin MOZINA (Slovenia)
- Gloria Maria PALOMO CARRASCO (Spain)
- Darius MATUSEVICIUS (Sweden)

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

- Ingeborg BARISIC
- Giuseppe CAPOVILLA
- Armando MAGRELLI [6, 7] *(Vice-Chair)*

Members representing patients' organisations nominated by the European Commission

- Marie Pauline EVERS
- Julian ISLA
- Ines ALVES [8]

[6] Nominated as of May 2021
[7] Elected as Vice-Chair as of June 2021
[8] Replaced Angelo Loris BRUNETTA as of July 2021

Annex 6 – Members of the Committee on Herbal Medicinal Products

Chair: Emiel VAN GALEN

Members nominated by Member States

• Reinhard LANGER (Austria)	Alternate: Astrid OBMANN
• Patricia BODART (Belgium)	Alternate: *Awaiting nomination*
• Iliana IONKOVA (Bulgaria)	Alternate: Valentin KOTEV [1, 2]
• Ivan KOSALEC (Croatia)	Alternate: Darko TRUMBETIC
• Antri KOUROUFEXI (Cyprus)	Alternate: Maria YIANNITSAROU
• Marketa PRIHODOVA (Czechia)	Alternate: Marie HEROUTOVA
• Steffen BAGER (Denmark)	Alternate: Rahat NAZMI
• *Awaiting nomination* (Estonia)	Alternate: *Awaiting nomination*
• Maria PAILE HYVARINEN (Finland)	Alternate: Sari KOSKI
• An LE (France)	Alternate: *Awaiting nomination*
• Jacqueline WIESNER (Germany)	Alternate: Susanne FLEMISCH
• Ioanna CHINOU (Greece)	Alternate: Stavroula MAMOUCHA
• Zsuzsanna BIRO-SANDOR (Hungary)	Alternate: Rita NEMETH
• *Awaiting nomination* (Iceland)	Alternate: *Awaiting nomination*
• Sarah KELLAGHAN (Ireland)	Alternate: Jacqueline MASTERSON [3]
• Alessandro ASSISI (Italy)	Alternate: Anna Maria SERRILLI
• Baiba JANSONE (Latvia)	Alternate: Evita SKUKAUSKA
• Jurate ANTANAVICIENE (Lithuania) [4]	Alternate: Asta KUBILIENE [5]
• Sven BACK (Luxembourg) [6, 7]	Alternate: Jane MURRAY [8]
• Everaldo ATTARD (Malta)	Alternate: Matthew CAMILLERI
• Burt H. KROES (Netherlands)	Alternate: Hilda KUIN
• *Awaiting nomination* (Norway) [9]	Alternate: Gro FOSSUM
• Wojciech DYMOWSKI (Poland)	Alternate: Katarzyna TOMASZEWSKA

[1] Dafna MARINKEVA resigned as of September 2021
[2] Valentin KOTEV nominated as of October 2021
[3] Nominated as of January 2021
[4] Replaced Rugile PILVINIENE as of March 2021
[5] Replaced Audronis LUKOSIUS as of March 2021
[6] Clemence VARRET resigned as of July 2021
[7] Sven BACK nominated as of September 2021
[8] Nominated as of February 2021
[9] Steinar MADSEN resigned as of July 2021

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- Ana Paula MARTINS (Portugal) Alternate: Eva MENDES
- Carmen PURDEL (Romania) Alternate: Ligia Elena DUTU
- Miroslava PETRIKOVA (Slovakia) Alternate: *Awaiting nomination* [10]
- Barbara RAZINGER (Slovenia) Alternate: *Awaiting nomination*
- Olga Maria PALOMINO (Spain) [11] Alternate: Olga Teresa ESTEBAN [12, 13]
- Erika SVEDLUND (Sweden)*(Vice-Chair)* Alternate: Malin Kyllikki HOBRO SODERBERG

Co-opted members

- Maria DA GRACA RIBEIRO CAMPOS (Clinical pharmacology) [14, 15]
- Heidi FOTH (Toxicology)
- Gert LAEKEMAN (Experimental/non-clinical pharmacology)
- Maria Helena PINTO FERREIRA (General and family medicine)
- Peter VOITL (Paediatrics) [16]

Observers

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

[10] Milan NAGY's mandate ended as of December 2021
[11] Replaced Adela NUNEZ VELAZQUEZ as of February 2021
[12] Cristina MARTINEZ GARCIA's mandate expired as of October 2021
[13] Olga Teresa ESTEBAN nominated as of October 2021
[14] Ewa BALKOWIEC ISKRA's mandated expired as of June 2021
[15] Maria DA GRACA RIBEIRO CAMPOS nominated as of July 2021
[16] Nominated as of May 2021

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Annex 7 – Committee for Advanced Therapies

Chair: Martina SCHUSSLER-LENZ

Members nominated from within the CHMP

- Jan MUELLER-BERGHAUS (Germany) Alternate: Egbert FLORY
- Romaldas MACIULAITIS (Lithuania) Alternate: Raimondas BENETIS
- John Joseph BORG (Malta) Alternate: Anthony SAMUEL
- Bruno SEPODES (Portugal) Alternate: Maria Isabel BORBA VIEIRA
- Sol RUIZ (Spain) Alternate: Marcos TIMON

Members nominated by Member States

- Ilona G. REISCHL (Austria) *(Vice-Chair)* Alternate: Silke DORNER
- Claire BEUNEU (Belgium) Alternate: Belaid SEKKALI
- Rozalina KULAKSAZOVA (Bulgaria) Alternate: Evelina SHUMKOVA
- Azra SELIMOVIC (Croatia) [1, 2] Alternate: Petra SOKOL
- Rafaella PONTOU (Cyprus) Alternate: Isavella KYRIAKIDOU
- Tomas BORAN (Czechia) [3] Alternate: Petr SOUKUP [4]
- *Awaiting nomination* (Denmark) [5] Alternate: Ebru KARAKOC MADSEN [6]
- Toivo MAIMETS (Estonia) Alternate: Pille SAALIK
- Heli SUILA (Finland) Alternate: Maija TARKKANEN [7, 8]
- Violaine CLOSSON CARELLA (France) Alternate: Jean-Michel RACE [9]
- Maria GAZOULI (Greece) [10] Alternate: Angeliki ROMPOTI
- Katalin LENGYEL (Hungary) Alternate: Balazs SARKADI
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- Maura O'DONOVAN (Ireland) Alternate: Niamh CURRAN
- Concetta QUINTARELLI (Italy) [11] Alternate: Barbara BONAMASSA [12]
- Una RIEKSTINA (Latvia) Alternate: *Awaiting nomination* [13]

[1] Mirna GOLEMOVIC's mandate ended as of January 2021
[2] Azra SELIMOVIC nominated as of February 2021
[3] Replaced Ivana HAUNEROVA as of September 2021 with a swap of role from alternate to member
[4] Replaced Tomas BORAN as of September 2021
[5] Anne PASTOFT's mandate ended as of October 2021
[6] Replaced Nanna Aaby KRUSE as of October 2021
[7] Olli TENHUNEN resigned as from May 2021
[8] Maija TARKKANEN nominated as of September 2021
[9] Nominated as of December 2021
[10] Replaced Asterios TSIFTSOGLOU as of January 2021
[11] Replaced Paolo GASPARINI as of March 2021
[12] Replaced Giulio POMPILIO as of March 2021
[13] Liga KUNRADE's mandate expired as of March 2021

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- Vlasta ZAVADOVA (Liechtenstein) [14] Alternate: *Awaiting nomination*
- Nancy DE BREMAEKER (Luxembourg) [15] Alternate: Guy BERCHEM [16]
- Carla HERBERTS (Netherlands) Alternate: Babs FABRIEK [17]
- Rune KJEKEN (Norway) Alternate: Maja SOMMERFELT GRØNVOLD
- Dariusz SLADOWSKI (Poland) Alternate: Marcin KOLAKOWSKI [18]
- Silviu ISTRATE (Romania) [19, 20] Alternate: Alexandrina PREDA [21]
- Lukas SLOVAK (Slovakia) Alternate: Alexandra PADOVA
- Metoda LIPNIK-STANGELJ (Slovenia) Alternate: Suzana VIDIC [22]
- Lisbeth BARKHOLT (Sweden) Alternate: Maria LUTTGEN

Members representing clinicians nominated by the European Commission

- Bernd GANSBACHER Alternate: Frederic BERNARD
- Alessandro AIUTI Alternate: Alessandra RENIERI

Members representing patients' organisations nominated by the European Commission

- Kerstin SOLLERBRANT Alternate: Lydie MEHEUS
- Kieran BREEN Alternate: Roland POCHET

Observers

- *Awaiting nomination* (EDQM) Alternate: Catherine Milne (EDQM)

[14] Nominated as of October 2021
[15] Replaced Guy BERCHEM as of March 2021
[16] Replaced Anne-Cécile VUILEMIN as of March 2021 with a swap of role from member to alternate
[17] Replaced Johannes H. OVELGONNE as from January 2021
[18] Replaced Anna CIESLIK as of September 2021
[19] Felicia CIULU COSTINESCU resigned as from January 2021
[20] Silviu ISTRATE nominated as of February 2021
[21] Nominated as of February 2021
[22] Replaced Nevenka TRSINAR BRODT as of July 2021

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Annex 8 – Members of the Paediatric Committee

Chair: Koenraad NORGA

Members nominated from within the CHMP

- Agnes GYURASICS (Hungary) Alternate: *Awaiting nomination*
- Carola DE BEAUFORT (Luxembourg) Alternate: Martine TRAUFFLER
- Dana Gabriela MARIN (Romania) Alternate: Simona BADOI

Members nominated by Member States

- Karl-Heinz HUEMER (Austria) Alternate: Johanna WERNSPERGER
- Marleen RENARD (Belgium) Alternate: Karen VAN MALDEREN
- Dimitar ROUSSINOV (Bulgaria) Alternate: Vessela BOUDINOVA
- Milivoj NOVAK (Croatia) Alternate: Arnes RESIC
- Georgios SAVVA (Cyprus) Alternate: Elena KAISIS
- *Awaiting nomination* (Czechia) [1] Alternate: Tereza BAZANTOVA [2]
- Nanna BORUP JOHANSEN (Denmark) Alternate: *Awaiting nomination*
- Irja LUTSAR (Estonia) Alternate: Jana LASS
- Pauliina LEHTOLAINEN DALKILIC (Finland) [3] [4] Alternate: Anne PAAVOLA [5]
- Sylvie BENCHETRIT (France) Alternate: Dominique PLOIN
- Sabine SCHERER (Germany) *(Vice-Chair)* Alternate: Yuansheng SUN
- Eleni KATSOMITI (Greece) Alternate: Anastasia MOUNTAKI
- *Awaiting nomination* (Iceland) Alternate: *Awaiting nomination*
- Brian AYLWARD (Ireland) Alternate: *Awaiting nomination*
- Sara GALLUZZO (Italy) Alternate: *Awaiting nomination*
- Dina APELE-FREIMANE (Latvia) Alternate: *Awaiting nomination*
- Vlasta Zavadova (Liechtenstein) [6] Alternate: *Awaiting nomination*
- Dovile ZACHARKIENE (Lithuania) Alternate: Silvijus ABRAMAVICIUS
- John Joseph BORG (Malta) Alternate: Herbert LENICKER
- Roderick HOUWEN (Netherlands) [7] Alternate: Maaike VAN DARTEL

[1] Lucie KRAVACKOVA resigned as of April 2021
[2] Nominated as of February 2021
[3] Ann Marie TOTTERMAN resigned as of January 2021
[4] Pauliina LEHTOLAINEN DALKILIC nominated as of March 2021
[5] Nominated as of March 2021
[6] Nominated as of October 2021
[7] Nominated as of January 2021

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- Siri WANG (Norway) Alternate: Anette Solli KARLSEN
- Marek MIGDAL (Poland) Alternate: *Awaiting nomination*
- Helena FONSECA (Portugal) Alternate: Hugo TAVARES
- Peter SISOVSKY (Slovakia) Alternate: Peter SZITANYI
- Stefan GROSEK (Slovenia) Alternate: *Awaiting nomination*
- Fernando DE ANDRES TRELLES (Spain) Alternate: Maria Jesus FERNANDES CORTIZO
- Eva AGURELL (Sweden) Alternate: Sara VENNBERG

Members representing healthcare professionals nominated by the European Commission

- Johannes TAMINIAU [8] Alternate: Fabio MIDULLA [9]
- Fernando CABANAS Alternate: Doina PLESCA
- Francesca ROCCHI Alternate: Catherine CORNU

Members representing patients' organisations nominated by the European Commission

- Jaroslav STERBA Alternate: Milena STEVANOVIC
- Dimitrios ATHANASIOU Alternate: Tomasz GRYBEK
- Nora KRIAUZAITE Alternate: Michal ODERMARSKY

[8] Nominated as of January 2021 with a swap of roles from alternate to member
[9] Nominated as of January 2021

Annex 9 – Working parties and working groups

As part of the EMA business continuity plan, many working party meetings and expert groups were temporarily suspended or reduced in 2021.

When the mandate of a working party or experts group expired and no new chair election took place due to the business continuity plan, the records are marked "on hold" in the tables below.

Committee for Medicinal Products for Human Use (CHMP)

CHMP standing working parties

	Chair
Biologics Working Party	Sol RUIZ
Quality Working Party	Blanka HIRSCHLEROVA
Safety Working Party	Jan-Willem VAN DER LAAN / Susanne BRENDLER-SCHWAAB
Scientific Advice Working Party	Anja SCHIEL

CHMP temporary working parties

	Chair
Biosimilar Medicinal Products Working Party	Elena WOLFF-HOLZ
Biostatistics Working Party	Christian B. ROES
Blood Products Working Party	Jacqueline KERR
Cardiovascular Working Party	Kristina DUNDER
Central Nervous System Working Party	On hold
Infectious Diseases Working Party	Maria Jesús FERNÁNDES CORTIZO
Modelling and Simulation Working Party	Kristin KARLSSON
Oncology Working Party	Sinan B. SARAC
Pharmacogenomics Working Party	Marcus PAULMICHL
Pharmacokinetics Working Party	Henrike POTTHAST
Rheumatology/Immunology Working Party	On hold
Vaccines Working Party	Mair POWELL

CHMP scientific advisory groups

	Chair
Scientific Advisory Group on Cardiovascular Issues	Franz Xaver KLEBER
Scientific Advisory Group on Infectious Diseases	Emilia CERCENADO MANSILLA
Scientific Advisory Group on Neurology	Serge BAKCHINE
Scientific Advisory Group on Vaccines	Jean Daniel LELIEVRE

Other CHMP-associated groups

	Chair
(Invented) Name Review Group	EMA representative
Working Group on Quality Review of Documents	EMA representative
Geriatric Expert Group	On hold
Summary of Product Characteristics Advisory Group	EMA representative
Guidelines Consistency Group	Aranzazu SANCHO-LOPEZ
Good Manufacturing and Distribution Practice Inspectors Working Group	EMA representative
Good Clinical Practice Inspectors Working Group	EMA representative
Good Laboratory Practice Inspectors Working Group	EMA representative
Pharmacovigilance Inspectors Working Group	EMA representative
PAT Team	On hold

Committee for Medicinal Products for Veterinary Use (CVMP)

CVMP working parties

	Chair
CVMP Antimicrobial Working Party (AWP)	Christine SCHWARZ
CVMP Efficacy Working Party (EWP-V)	Cristina MUÑOZ MADERO
CVMP Environmental Risk Assessment (ERAWP)	Ricardo CARAPETO GARCÍA
CVMP Immunologicals Working Party (IWP)	Esther WERNER
CVMP novel Therapies and Technologies Working Party (NTWP)	Jaqueline POOT
CVMP Pharmacovigilance Working Party (PhVWP-V)	Els DEWAELE
CVMP Safety Working Party (SWP-V)	Carina BERGMAN
Quality Working Party	Blanka HIRSCHLEROVA
Scientific Advice Working Party (SAWP-V)	Frida HASSLUNG WIKSTRÖM

Other CVMP-associated groups

	Chair
CVMP Ad Hoc Group on Veterinary Novel Therapies (ADVENT)	Jean-Claude ROUBY
Good Manufacturing and Distribution Practice Inspectors Working Group	EMA representative
Pharmacovigilance Inspectors Working Group	EMA representative
PAT Team	On hold

Pharmacovigilance Risk Assessment Committee (PRAC)

	Chair
Signal Management Review Technical (SMART) Working Group work stream 1 (processes)	Menno van der ELST/EMA representative
Signal Management Review Technical (SMART) Working Group work stream 2 (methods)	Eugene van PUIJENBROEK/EMA representative
Granularity and Periodicity Advisory Group (GPAG)	Menno van der ELST

Committee for Orphan Medicinal Products (COMP)

COMP temporary working groups

	Chair
Protocol assistance working group	N/A
Non-clinical Working Group	N/A

Committee on Herbal Medicinal Products (HMPC)

HMPC working parties

	Chair
Working Party on European Union Monographs and European Union List	On hold

HMPC temporary drafting groups

	Chair
Organisational Matters Drafting Group	On hold
Quality Drafting Group	On hold

Other HMPC-associated groups

	Chair
Good Manufacturing Practice Inspection Services Group	EMA representative

Committee for Advanced Therapies (CAT)

CAT associated group

	Chair
European Medicines Agency / CAT and Medical Devices' Notified Body Collaboration Group	On hold

Paediatric Committee(PDCO)

PDCO working groups

	Chair
Formulation Working Group	Brian AYLWARD
Non-clinical Working Group	Karen VAN MALDEREN

Human Scientific Committees' Working Parties

	Chair
Patients' and Consumers' Working Party (PCWP)	EMA representative and Kaisa IMMONEN
Healthcare Professionals' Working Party (HCPWP)	EMA representative and Ulrich JÄGER

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

Other CMDh-associated groups

	Chair
Working Party on Pharmacovigilance Procedures Work Sharing	Maria Luisa CASINI
Non-Prescription Medicinal Products Task Force	Martin HUBER

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

	Chair
Document Management Working Group	CMDv member from Member State holding EU Presidency
Packaging and Labelling Working Group	Iveta OBROVSKA
Notice to Applicants Working Group	Paula KAJASTE
Autogenous Vaccines Working Group	Mariette SALERY
Borderline Products Working Group	Jose JONIS
Legislation Working Group	Dries MINNE
Working Group on Improvement of DCP/MRP	Mariette SALERY
TOPRA Working Party	Paula KAJASTE
Working Group on EU Network Training Centre	Laetitia LE LETTY
CMDv Brexit Working Group	Laetitia LE LETTY

Joint working parties, working groups and advisory groups

	Chair
Joint CHMP/CVMP Quality Working Party (QWP)	Blanka HIRSCHLEROVA
Joint CMDh-CMDv-EMA-EDQM Active Substance Master File Working Group	Nienke RODENHUIS
Joint CHMP/CVMP Working Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products	On hold
Inter-Committee Scientific Advisory Group on Oncology	
Working Group on Quality Review of Documents	EMA representative
Joint PRAC/PDCO working group	N/A
Joint CMDh-CMDv Variation Regulation Working Party	Susanne WINTERSCHEID
EMA/CMDh Working Party on Paediatric Regulation	Siri WANG
GCP Inspectors WG/CMDh Working Party	Jayne CROWE
Extrapolation working group	Koen NORGA
CTS Working Group	Dino SOUMPASIS

Annex 10 – CHMP opinions on initial evaluations and extensions of therapeutic indication in 2021

This annex is available in an Excel spread sheet here.

Annex 11 – Guidelines and concept papers adopted by CHMP

Biologics Working Party

Reference number	Document	Status	Date
EMA/CHMP/BWP/76987/2021	CHMP position statement on quality and safety assessment for the Plasma Master File (PMF) certification with regard to donor deferral criteria for sexual risk behaviour	Final Joint with BPWP	22 February 2021
EMA/CHMP/QWP/BWP/259165/2019	QWP/BWP Guideline on quality documentation for medicinal products when used in combination with a medical device	Final Joint with QWP	22 July 2021
EMA/246400/2021	Questions and answers on the Principles of GMPs for the manufacturing of starting materials of biological origin used to transfer genetic material for the manufacturing of ATMPs	Final Inspections Working Group - Lead	24 February 2021
EMA/CHMP/138502/2017	Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development	Final Joint with QWP BSWP - Lead	26 July 2021

Biosimilar Medicinal Product Working Party

Reference number	Document	Status	Date
None			

Biostatistics Working Party

Reference number	Document	Status	Date
EMA/CHMP/138502/2017	Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development	Final	22 July 2021

Blood Products Working Party

Reference number	Document	Status	Date
EMA/CHMP/BPWP/94038/ 2007 Rev. 6	Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg)	Final	16 December 2021
EMA/CHMP/BPWP/94033/ 2007 rev. 4	Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)	Final	16 December 2021

Cardiovascular Working Party

None, except for the work done by the CHMP in the Diabetes Drafting Group.

Committee for Advanced Therapies (CAT)

Reference number	Document	Status	Date
None			

Central Nervous System Working Party

Reference number	Document	Status	Date
None			

Diabetes Drafting Group

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 Guideline released for external consultation until 15 August 2018. The Group discussed the best way to incorporate external comments	

Excipients Drafting Group

Reference number	Document	Status	Date
None			

Gastroenterology Drafting Group

Reference number	Document	Status	Date
None			

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ICH

Reference number	Document	Status	Date
EMA/CHMP/ICH/272147/2021	ICH guideline S1B(R1) addendum on testing for carcinogenicity of pharmaceuticals	Draft for public consultation, step 2b	22 April 2021
EMA/CHMP/ICH/82260/2006	ICH Q3C (R8): Impurities: guideline for Residual Solvents	Adopted, step 5	20 May 2021
EMA/CHMP/ICH/544570/1998	ICH guideline E8(R1) on general considerations for clinical studies	Adopted, step 5	10 October 2021
EMA/CHMP/ICH/318372/2021	ICH guideline S12 on nonclinical biodistribution considerations for gene therapy products	Draft for public consultation, step 2b	24 June 2021
EMA/CHMP/ICH/24235/2006	ICH guideline Q9 (R1) on quality risk management	Draft for public consultation, step 2b	16 December 2021
EMA/CHMP/ICH/427817/2021	ICH guideline Q13 on continuous manufacturing of drug substances and drug products	Draft for public consultation, step 2b	22 July 2021
EMA/CHMP/ICH/272147/2021	ICH guideline M7 on assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk – addendum	Draft for public consultation, step 2b	16 September 2021

Infectious Diseases Working Party

Reference number	Document	Status	Date
None			

Modelling and Simulation Working Party

Reference number	Document	Status	Date
None			

Oncology Working Party

Reference number	Document	Status	Date
None			

Pharmacogenomics Working Party

Reference number	Document	Status	Date
None			

Pharmacokinetics Working Party

Reference number	Document	Status	Date
EMA/CHMP/257298/2018	Lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance	Final	22 April 2021
EMA/CHMP/472383/2020	Deferasirox, dispersible tablets (125 mg, 250 mg and 500 mg), film-coated tablets (90 mg, 180 mg, and 360 mg), and granules (90 mg, 180 mg, and 360 mg) product-specific bioequivalence guidance	Final	20 May 2021
EMA/CHMP/512475/2020	Acenocoumarol, tablet, 1 mg and 4 mg product-specific	Final	22 April 2021
EMA/CHMP/802679/2018 Rev.1	Palbociclib hard capsule 75 mg, 100 mg and 125 mg and film-coated tablet 75 mg, 100 mg and 125 mg product-specific bioequivalence guidance	Final	22 April 2021
EMA/CHMP/371445/2021	Ibrutinib hard capsules 140 mg and film-coated tablets 140, 280, 420 & 560 mg product-specific bioequivalence guidance	Draft for public consultation	11 November 2021
EMA/CHMP/371470/2021	Olaparib 100 mg & 150 mg film-coated tablets product-specific bioequivalence guidance	Draft for public consultation	11 November 2021
EMA/CHMP/371467/2021	Enzalutamide soft capsule 40 mg and film-coated tablet 40 mg & 80 mg product-specific bioequivalence guidance	Draft for public consultation	11 November 2021
EMA/CHMP/559889/2021	Liposomal amphotericin B powder for dispersion for infusion 50 mg product-specific bioequivalence guidance	Draft for public consultation	16 December 2021
EMA/CHMP/559890/2021	Ursodeoxycholic acid capsule 250 mg, film-coated tablet 150mg, 300 mg, 450 mg, 500 mg, 600 mg and suspension 50 mg/ml (250 mg/5 ml) product-specific bioequivalence guidance	Draft for public consultation	16 December 2021

Quality Working Party

Reference number	Document	Status	Date
EMA/CHMP/QWP/BWP/259165/2019	Guideline on quality documentation for medicinal products when used with a medical device	Final	22 July 2021
EMA/CHMP/QWP/31884/2021 (EMA/CHMP/QWP/545525/2017 Rev.2)	Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials	Draft for public consultation	24 June 2021
EMA/CHMP/138502/2017	Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development	Final Joint with BSWP BSWP - Lead	26 July 2021

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
None			

Safety Working Party

Reference number	Document	Status	Date
None			

Vaccines Working Party

Reference number	Document	Status	Date
None			

Annex 12 – CVMP opinions on medicinal products for veterinary use in 2021

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** • **Decision** • **Notification** • **Official Journal**
• Credelio Plus • Lotilaner / Milbemycin oxime	• Elanco GmbH	• Dogs • For use in dogs with, or at risk from, mixed infestations/infections of ticks, fleas, gastrointestinal nematodes, heartworm and/or lungworm.	• 20/11/2019 • 17/02/2021 • 209 • 246	• 14/04/2021 • 15/04/2021 • 28/05/2021
• Daxocox • Enflicoxib	• Ecuphar NV	• Dogs • For the treatment of pain and inflammation associated with osteoarthritis (or degenerative joint disease) in dogs.	• 19/02/2020 • 17/02/2021 • 209 • 155	• 20/04/2021 • 21/04/2021 • 27/08/2021
• Ultifend ND IBD • Newcastle disease, infectious bursal disease and Marek's disease vaccine (live recombinant)	• Ceva-Phylaxia Co. Ltd	• Chickens • For the active immunisation of one-day-old chicks or 18-day-old embryonated chickens eggs to reduce mortality, clinical signs and lesions caused by Newcastle disease virus (NDV) and to reduce virus shedding; to reduce mortality, clinical signs and bursa lesions	• 20/11/2019 • 17/02/2021 • 209 • 246	• 20/04/2021 • 22/04/2021 • 28/05/2021

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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 • Decision • Notification • Official Journal
		caused by very virulent infectious bursal disease virus (IBDV); to reduce mortality, clinical signs and lesions caused by classical Marek's disease virus (MDV).		
• Bonqat • Pregabalin	• Orion Corporation	• Cats • Alleviation of acute anxiety and fear associated with transportation and veterinary visits.	• 10/06/2020 • 12/05/2021 • 209 • 127	• 13/07/2021 • 14/07/2021 • 27/08/2021
• Tessie • Tasipimidine	• Orion Corporation	• Dogs • Short term alleviation of situational anxiety and fear in dogs triggered by noise or owner departure.	• 20/12/2019 • 17/06/2021 • 209 • 331	• 16/08/2021 • 17/08/2021 • 29/09/2021
• Fatrovax RHD • Rabbit haemorrhagic disease vaccine (inactivated, recombinant)	• Fatro S.p.A	• Rabbits • For active immunisation of rabbits from the age of 28 days to reduce mortality, infection, clinical signs and organ lesions of rabbit haemorrhagic disease caused by RHDV1 and RHDV2.	• 25/09/2019 • 17/06/2021 • 209 • 422	• 16/08/2021 • 17/08/2021 • 29/09/2021
• Strangvac • Streptococcus equi vaccine	• Intervacc AB	• Horses • For the active immunisation to reduce clinical	• 18/03/2020 • 17/06/2021 • 210 • 246	• 16/08/2021 • 17/08/2021 • 29/09/2021

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 • Decision • Notification • Official Journal
(recombinant proteins)		signs and number of abscesses in acute stage of infection with S. equi.		
• Felpreva • Tigolaner / Emodepside / Praziquantel	• Vetoquinol SA	• Cats • For cats with, or at risk from, mixed parasitic infestations.	• 08/07/2020 • 09/09/2021 • 210 • 218	• 11/11/2021 • Pending • Pending
• Imoxat • Imidacloprid / Moxidectin	• Chanelle Pharmaceuticals	• Dogs, Cats, Ferrets • For cats and ferrets suffering from, or at risk from, mixed parasitic infections. For dogs suffering from, or at risk from, mixed parasitic infections.	• 12/08/2020 • 07/10/2021 • 210 • 211	• Pending • Pending • Pending
• Zenalpha • Medetomidine hydrochloride / Vatinoxan hydrochloride	• Vetcare Oy	• Dogs • To provide restraint, sedation and analgesia during conduct of non-invasive, non-painful or mildly painful procedures and examinations intended to last no more than 30 minutes.	• 10/06/2020 • 07/10/2021 • 209 • 275	• 15/12/2021 • Pending • Pending
• Suiseng Diff/A • Clostridioides difficile and Clostridium perfringens	• Laboratorios Hipra, S.A.	• Pigs • For the passive immunisation of neonatal piglets by means of the active	• 12/08/2020 • 07/10/2021 • 210 • 211	• 07/12/2021 • Pending • Pending

Product • Invented name • INN/Common name	Marketing authorisation holder	Therapeutic area • Target species • Summary of indication	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Decision • Notification • Official Journal
vaccine (inactivated)		immunisation of breeding sows and gilts: - to prevent mortality and reduce clinical signs and macroscopic lesions caused by C. difficile. - to reduce clinical signs and macroscopic lesions caused by C. perfringens type A.		
• CircoMax • Porcine circovirus vaccine (inactivated recombinant)	• Zoetis Belgium SA	• Pigs • Active immunisation of pigs against Porcine Circovirus type 2.	• 08/07/2020 • 05/11/2021 • 210 • 275	• 11/01/2022 • Pending • Pending

Negative opinions

There were no negative opinions in 2021.

CVMP opinions in 2021 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
• Bambermycin	• Poultry	• 20/12/2019 • 15/07/2021 • 208 • 241	• 15/07/2021 • Pending • Pending
• Toltrazuril	• Poultry	• 08/07/2021 • 09/12/2021 • 154 • 0	• 09/12/2021 • Pending • Pending

Negative opinions

There were no negative opinions on establishment of MRLs in 2021.

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**
• Cortavance • hydrocortisone aceponate	• Virbac S.A.	• QD07AC • For symptomatic treatment of inflammatory and pruritic dermatoses in dogs. For alleviation of clinical signs associated with atopic dermatitis in dogs.	• 18/03/2021	• 20/04/2021
• Suvaxyn CSF Marker • bovine viral diarrhoea virus expressing classical swine fever virus, strain cp7_e2alf, live	• Zoetis Belgium SA	• QI09AD04 • For active immunisation of pigs from 7 weeks of age onwards to prevent mortality and reduce infection and disease caused by classical swine fever virus (CSFV) and for active immunisation of breeding females to reduce transplacental infection caused by CSFV.	• 15/07/2021	• 16/08/2021

Product • Brandname • INN	**Marketing authorisation holder**	**Therapeutic Area** • ATC Code • Summary of indication	**EMA/CVMP opinion**	**European Commission decision date**
• NexGard Combo • esafoxolaner / eprinomectin / praziquantel	• Boehringer Ingelheim Vetmedica GmbH	• QP54AA54 • For cats with, or at risk from mixed infections by cestodes, nematodes and ectoparasites. The veterinary medicinal product is exclusively indicated when all three groups are targeted at the same time.	• 07/10/2021	• 29/11/2021
• Bravecto • fluralaner	• Intervet International B.V.	• QP53BE02 • For the treatment of tick and flea infestations in cats and dogs	• 09/12/2021	• 01/02/2022
• Improvac • gonadotropin releasing factor analogue diptheria toxoid conjugate	• Zoetis Belgium SA	• QG03XA91 • Induction of antibodies against GnRF to produce a temporary immunological suppression of testicular function (males) and ovarian function (females)	• 09/12/2021	• 20/01/2022

Annex 13 – Guidelines and concept papers adopted by CVMP in 2021

CVMP Quality

Reference number	Document title	Status
EMA/CVMP/QWP/798401/2015	Guideline on Manufacture of the Veterinary Finished Dosage Form	Adopted July 2021
EMA/CVMP/QWP/485008/2019	Overview of comments received on the guideline on Manufacture of the Veterinary Finished Dosage Form (EMA/CVMP/QWP/798401/2015)	Adopted July 2021

CVMP Safety

Reference number	Document title	Status
EMA/CVMP/345237/2020	Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted February 2021 for consultation End of consultation: 15 May 2021
EMA/CVMP/345236/2020	Safety and residue data requirements for the establishment of Maximum Residue Limits in minor species	Adopted February 2021 for consultation End of consultation: 15 May 2021
EMA/CVMP/SWP/265238/2021	Concept paper for the revision of residues guidelines to align with the definitions for withdrawal periods provided in Regulation (EU) 2019/6	Adopted June 2021 for consultation End of consultation: 31 July 2021
EMA/CVMP/SWP/207500/2021	Concept paper on the development of a guideline on determination of the need for an MRL evaluation for biological substances	Adopted July 2021 for consultation End of consultation 30 September 2021
EMA/CVMP/345237/2020	Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted July 2021

Reference number	Document title	Status
EMA/CVMP/148001/2021	Overview of comments received on 'Guideline on safety and residue data requirements for applications for nonimmunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 (EMA/CVMP/345237/2020)	Adopted September 2021
EMA/CVMP/SWP/735325/2012 – Rev.2	Guideline on determination of withdrawal periods for edible tissues	Adopted October 2021 for consultation End of consultation: 17 December 2021
EMA/CVMP/SWP/735418/2012 – Rev.1	Guideline on determination of withdrawal periods for milk	Adopted October 2021 for consultation End of consultation: 17 December 2021
EMA/CVMP/SWP/185470/2004 – Rev.1	Guideline on injection site residue	Adopted October 2021 for consultation End of consultation: 17 December 2021

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/52665/2020	Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted February 2021 for consultation End of consultation: 15 May 2021
EMA/CVMP/EWP/165592/2021	Concept paper for the revision of the guideline on the summary of product characteristics for anthelmintics	Adopted April 2021 for consultation End of consultation: 31 May 2021
EMA/CVMP/EWP/170208/2005 - Rev.1	Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products	Adopted July 2021 for consultation End of consultation: 30 September 2021

Reference number	Document title	Status
EMA/CVMP/52665/2020	Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted July 2021
EMA/CVMP/147926/2021	Overview of comments received on 'Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6' (EMA/CVMP/52665/2020)	Adopted September 2021
EMA/CVMP/EWP/170208/2005-Rev.1	Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products	Adopted December 2021
EMA/CVMP/EWP/524331/2021	Overview of comments received on "Draft guideline on the summary of product characteristics for antiparasitic veterinary medicinal products - Revision 1" (EMA/CVMP/EWP/170208/2005-Rev.1)	Adopted December 2021

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/10418/2009-Rev.12	VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted June 2021
EMA/CVMP/PhVWP/288284/2007 - Rev.13	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted June 2021

CVMP Antimicrobials

Reference number	Document title	Status
EMA/CVMP/179874/2020	CVMP strategy on antimicrobials 2021-2025	Adopted January 2021
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 February 2021
EMA/CVMP/383441/2005-Rev.1	Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances	Adopted June 2021
EMA/CVMP/143258/2021	Reflection paper on promoting the authorisation of alternatives to antimicrobial veterinary medicinal products in the EU	Adopted July 2021
EMA/CVMP/644209/2020	Overview of comments received on 'Reflection paper on promoting the authorisation of alternatives to antimicrobials in the EU' (EMA/CVMP/461776/2017)	Adopted July 2021
EMA/CVMP/AWP/266787/2021	Concept paper on an update to the CVMP's reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European Union: development of resistance and impact on human and animal health	Adopted October 2021 for consultation End of consultation: 31 January 2022

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/630533/2020	Concept paper for the development of a guideline on data requirements for authorisation of immunological veterinary medicinal products under exceptional circumstances	Adopted January 2021 for consultation. End of consultation: 31 March 2021

Reference number	Document title	Status
EMA/CVMP/IWP/674640/2020	Concept paper for the development of a guideline on data requirements for vaccine antigen master files (VAMF)	Adopted January 2021 for consultation. End of consultation: 31 March 2021
EMA/CVMP/IWP/582191/2020	Concept paper for the development of a guideline on data requirements for vaccine platform technology master files (PTMF)	Adopted January 2021 for consultation. End of consultation: 31 March 2021
EMA/CVMP/IWP/600275/2020	Concept paper for the revision of the guideline on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza (AI), Blue Tongue (BT) and Foot and Mouth Disease (FMD)	Adopted January 2021 for consultation. End of consultation: 31 March 2021
EMA/CVMP/IWP/671155/2020	Concept paper on the provision of field efficacy studies in support of marketing authorisation applications for immunological veterinary medicinal products and on indications for veterinary vaccines	Adopted January 2021 for consultation. End of consultation: 31 March 2021
EMA/CVMP/59531/2020	Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted February 2021 for consultation End of consultation: 15 May 2021
EMA/CVMP/IWP/251741/2015	CVMP reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products	Adopted May 2021 for consultation End of consultation: 23 July 2021
EMA/CVMP/IWP/105506/2007 - Rev. 2	Guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines	Adopted June 2021 for consultation End of consultation 30 September 2021
EMA/CVMP/IWP/258755/2021	Guideline on data requirements for vaccine antigen master files (VAMF)	Adopted June 2021 for consultation End of consultation 30 September 2021

Reference number	Document title	Status
EMA/CVMP/IWP/284316/2021	Concept paper for the revision of the guideline on requirements for production and control of immunological veterinary medicinal products	Adopted June 2021 for consultation End of consultation 30 September 2021
EMA/CVMP/IWP/315887/2017	Guideline on data requirements for adjuvants in vaccines for veterinary use	Adopted July 2021
EMA/CVMP/IWP/30398/2019	Overview of comments received on 'Guideline on the use of adjuvanted veterinary vaccines' (EMA/CVMP/IWP/315887/2017)	Adopted July 2021
EMA/CVMP/IWP/299554/2021	Guideline on data requirements for authorisation of immunological veterinary medicinal products under exceptional circumstances	Adopted July 2021 for consultation End of consultation 29 October 2021
EMA/CVMP/IWP/283631/2021	Guideline on data requirements for vaccine platform technology master files (vPTMF)	Adopted July 2021 for consultation End of consultation 29 October 2021
EMA/CVMP/IWP/260956/2021	Guideline on clinical trials with immunological veterinary medicinal products	Adopted July 2021 for consultation End of consultation 29 October 2021
EMA/CVMP/59531/2020	Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted July 2021
EMA/CVMP/IWP/251741/2015 Rev. 1	Reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products	Adopted September 2021

Reference number	Document title	Status
EMA/CVMP/147910/2021	Overview of comments received on 'Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6' (EMA/CVMP/59531/2020)	Adopted September 2021

CVMP environmental risk assessment

Reference number	Document title	Status
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 February 2021
EMA/CVMP/ERA/173026/2021	Concept paper on the development of a guideline on the environmental risk assessment of veterinary medicinal products intended to be used in aquaculture	Adopted July 2021 for consultation End of consultation: 31 October 2021
EMA/CVMP/ERA/622045/2020	Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6	Adopted September 2021 for consultation End of consultation: 17 December 2021
EMA/CVMP/ERA/87473/2021	Reflection paper on higher tier testing to investigate the effects of parasiticidal veterinary medicinal products on dung fauna	Adopted September 2021
EMA/CVMP/ERA/245311/2021	Reflection paper on the interpretation of Article 72 of Regulation (EU) 2019/6 – Environmental safety documentation and environmental risk assessment of certain veterinary medicinal products	Adopted October 2021 for consultation End of consultation: 31 January 2022

CVMP Novel therapies and technologies

Reference number	Document title	Status
EMA/CVMP/NTWP/706123/2020	Mandate, objectives and rules of procedure for the CVMP Veterinary Novel Therapies & Technologies Working Party (NTWP)	Adopted March 2021

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

None.

Regulation (EU) 2019/6 (Veterinary medicinal products)

[Topics covered by regular WPs are shown in the relevant thematic sections above]

Reference number	Document title	Status
EMA/635856/2020	Guideline on veterinary good pharmacovigilance practices (VGVP) Collection and recording of suspected adverse events for veterinary medicinal products	Adopted June 2021 for consultation End of consultation 5 September 2021
EMA/328998/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Controls and pharmacovigilance inspections	Adopted June 2021 for consultation End of consultation 5 September 2021
EMA/257136/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files	Adopted June 2021 for consultation End of consultation 5 September 2021
EMA/307620/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Signal management	Adopted June 2021 for consultation End of consultation 5 September 2021

Reference number	Document title	Status
EMA/63454/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Veterinary pharmacovigilance communication	Adopted June 2021 for consultation End of consultation 5 September 2021
EMA/118227/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Annex: Glossary	Adopted June 2021 for consultation End of consultation 5 September 2021
EMA/CMDv/7381/2021	Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations	Adopted May 2021
EMA/635856/2020	Guideline on veterinary good pharmacovigilance practices (VGVP) Collection and recording of suspected adverse events for veterinary medicinal products	Adopted November 2021
EMA/328998/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Controls and pharmacovigilance inspections	Adopted November 2021
EMA/257136/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files	Adopted November 2021
EMA/307620/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Signal management	Adopted November 2021

Reference number	Document title	Status
EMA/63454/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Veterinary pharmacovigilance communication	Adopted November 2021
EMA/CVMP/565615/2021	Question and answer document on requirements for pre-clinical studies submitted in support of a marketing authorisation application for a veterinary medicinal product	Adopted December 2021

General

Reference number	Document title	Status
EMA/CVMP/553776/2020	CVMP work plan 2021	Adopted January 2021
EMA/CVMP/235292/2020	Reflection paper on classification of a product as intended for a limited market and eligibility for authorisation according to Article 23 (Applications for limited markets)	Adopted February 2021 for consultation End of consultation: 15 May 2021
EMA/CVMP/235292/2020	Reflection paper on classification of a product as intended for a limited market and eligibility for authorisation according to Article 23 (Applications for limited markets)	Adopted July 2021
EMA/CVMP/147858/2021	Overview of comments received on 'Reflection paper on classification of a product as intended for a limited market according to Article 4(29) and/or eligibility for authorisation according to Article 23 (Applications for limited markets)' (EMA/CVMP/235292/2020)	Adopted July 2021
EMA/CVMP/272194/2021	Form for classification of a veterinary medicinal product intended for a limited market according to Article 4 (29) and for eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6	Adopted July 2021

Reference number	Document title	Status
EMA/CVMP/435071/2021	Concept paper on scientific guidelines for limited market products deemed not eligible for authorisation under Article 23 of Regulation 2019/6	Adopted October 2021 for consultation End of consultation: 15 December 2021
EMA/CVMP/299406/2021	Concept paper on the revision of the CVMP Recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products (EMEA/CVMP/248499/2007)	Adopted November 2021 for consultation End of consultation: 28 February 2022
EMA/127488/2021	Procedural advice for veterinary vaccine antigen master file (VAMF) certification	Adopted November 2021 for consultation End of consultation: 12 January 2022
EMA/CVMP/468877/2009 - Rev.3	Procedural advice on appointment and responsibilities of the CVMP rapporteur, co-rapporteur in accordance with Article 140(6) of Regulation (EU) 2019/6 and peer reviewer	Adopted December 2021
EMA/CVMP/476954/2021	CVMP Work plan 2022	Adopted December 2021

Annex 14 – COMP opinions on designation of orphan medicinal products in 2021

Positive COMP designation opinions

Case Subject	**Customer**	**Agreed Orphan Condition**	**EMA/COMP** • **Submission** • **Start date** • **Opinion** • **Active time**	**European Commission** • **Opinion received** • **Date of decision**
Adeno-associated virus vector serotype 2 expressing the human *MT-ND4* codon-optimised gene	IQVIA RDS Spain S.L. - Spain	Treatment of Leber's hereditary optic neuropathy	28/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
Adeno-associated virus serotype 9 expressing the human fukutin related protein and target sequence of the miR-208a	Atamyo Therapeutics – France	Treatment of Limb Girdle muscular dystrophy	28/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
N-sulfoglucosamine sulfohydrolase fused to a humanised monoclonal antibody Fab targeting the human transferrin receptor	Artemida Pharma Europe Limited – Ireland	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome)	28/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
5-((4'-(3,3-difluorocyclobutyl)-[1,1'-biphenyl]-4-yl)oxy)-1H-1,2,3-triazole-4-carboxylic acid	Voisin Consulting Life Sciences - France	Treatment of primary hyperoxaluria	28/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Sirolimus	Maxia Strategies-Europe Limited - Ireland	Treatment of bronchiolitis obliterans syndrome	28/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
Trans N-ethyl-2-((4-(7-((4-(ethylsulfonamido)cyclohexyl)methyl)-2,7-diazaspiro[3.5]nonan-2-yl)pyrimidin-5-yl)oxy)-5-fluoro-N-isopropylbenzamide sesquifumarate	Syndax Europe B.V. - Netherlands	Treatment of acute myeloid leukaemia	27/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
Azithromycin dihydrate	Vale Pharmaceuticals Limited - Ireland	Prevention of bronchopulmonary dysplasia	27/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
Insulin human	Sirius Regulatory Consulting EU Limited - Ireland	Prevention of retinopathy of prematurity	27/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
Melatonin	Worphmed S.r.l. - Italy	Treatment of pre-eclampsia	27/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
Navtemadlin	Yes Pharmaceutical Development Services GmbH - Germany	Treatment of Merkel cell carcinoma	27/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022

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Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Olorofim	F2G Biotech GmbH - Austria	Treatment of invasive *Scopulariopsis*	24/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
Fasudil hydrochloride	Granzer Regulatory Consulting & Services - Germany	Treatment of amyotrophic lateral sclerosis	23/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
5' moemC-(sp)-moemC-(p)-moeA-(p)-moemC-(p)-moeG-(p)-moeA-(p)-dmC-(sp)-dA-(sp)-dT-(sp)-dA-(sp)-dT-(sp)-dT-(sp)-dT-(sp)-dT-(sp)-dT-(sp)-dmC-(sp)-moeT-(p)-moeA-(sp)-moemC-(sp)-moeA 3'	Real Regulatory Limited - Ireland	Treatment of SCN2A developmental and epileptic encephalopathy	23/09/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
Gadolinium-chelated polysiloxane nanoparticles	NH Theraguix - France	Treatment of glioma	30/08/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022
Chimeric peptide of human glucagon-like peptide-1, glucagon and gastric inhibitory polypeptide analogues linked to a human immunoglobulin Fc fragment	JVM Europe B.V. - Netherlands	Treatment of primary biliary cholangitis	26/08/2021 14/09/2021 09/12/2021 (86 days/30 days)	15/12/2021 14/01/2022
mRNA encoding human glucose-6-phosphatase variant S298C	Moderna Biotech Spain S.L. - Spain	Treatment of glycogen storage disease type Ia	29/07/2021 26/10/2021 09/12/2021 (44 days/30 days)	15/12/2021 14/01/2022

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Efgartigimod alfa	Argenx - Belgium	Treatment of chronic inflammatory demyelinating polyneuropathy	29/06/2021 14/09/2021 09/12/2021 (86 days/30 days)	15/12/2021 14/01/2022
Copper (^{64}CU) chloride	Advanced Center Oncology Macerata - S.r.l. - Italy	Treatment of glioma	31/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
Troriluzole hydrochloride	Biohaven Pharmaceutical Ireland DAC - Ireland	Treatment of spinocerebellar ataxia	31/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
Retinol palmitate	Real Regulatory Limited - Ireland	Prevention of bronchopulmonary dysplasia	31/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
Allogenic fetal mesenchymal stem cells	Boost Pharma ApS - Denmark	Treatment of osteogenesis imperfecta	31/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioguanylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioadenylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioadenylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioadenylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioguanoylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioadenylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioguanylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioguanylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioadenylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioadenylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioguanylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioadenylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-uridine sodium salt	AdRes EU B.V. - Netherlands	Treatment of cystic fibrosis	31/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
N-[1-((5-cyanopyridin-2-yl)methyl)-1H-pyrazol-3-yl]-2-[4-(1-(trifluoromethyl)cyclopropyl) phenyl]acetamide	Neurocrine Therapeutics Limited - Ireland	Treatment of epileptic encephalopathy with continuous spike-and-wave during sleep	31/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
Crofelemer	Napo EU S.p.A. - Italy	Treatment of short bowel syndrome	30/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021

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Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Unesbulin	PTC Therapeutics International Limited - Ireland	Treatment of soft tissue sarcoma	30/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
Vatiquinone	PTC Therapeutics International Limited - Ireland	Treatment of Alpers-Huttenlocher syndrome	30/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
Octreotide acetate	Granzer Regulatory Consulting & Services - Germany	Treatment of idiopathic intracranial hypertension	30/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
Adeno-associated virus vector serotype 9 encoding the human *GRN* gene	Scendea (NL) B.V. - Netherlands	Treatment of frontotemporal dementia	27/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
Atrasentan	Voisin Consulting Life Sciences - France	Treatment of primary IgA nephropathy	26/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
3-(ethoxydifluoromethyl)-6-(5-fluoro-6-(2,2,2-trifluoroethoxy)pyridin-3-yl)-[1,2,4]triazolo[4,3-a]pyrazine	Real Regulatory Limited - Ireland	Treatment of SCN8A developmental and epileptic encephalopathy	25/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
3-(ethoxydifluoromethyl)-6-(5-fluoro-6-(2,2,2-trifluoroethoxy)pyridin-3-yl)-[1,2,4]triazolo[4,3-a]pyrazine	Real Regulatory Limited - Ireland	Treatment of SCN2A developmental and epileptic encephalopathy	25/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
Ribonucleoprotein complex composed of two sgRNA and a Cas9 nuclease targeting the human *COL7A1* gene	Branca Bunus Limited - Ireland	Treatment of epidermolysis bullosa	17/08/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
Garadacimab	Csl Behring GmbH - Germany	Treatment of hereditary angioedema	29/07/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
Norrin (25-133), Lys86Pro	Maxia Strategies-Europe Limited - Ireland	Treatment of familial exudative vitreoretinopathy	21/07/2021 14/09/2021 05/11/2021 (52 days/28 days)	12/11/2021 10/12/2021
6-(4-(tert-butyl)phenoxy)pyridin-3-amine	Yes Pharmaceutical Development Services GmbH - Germany	Treatment of acute lymphoblastic leukaemia	16/07/2021 12/08/2021 05/11/2021 (85 days/28 days)	12/11/2021 10/12/2021
Macitentan	Janssen-Cilag International N.V. - Belgium	Treatment of chronic thromboembolic pulmonary hypertension	16/07/2021 12/08/2021 05/11/2021 (85 days/28 days)	12/11/2021 10/12/2021

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Fusion protein of chimeric human glucagon-like peptide-1, glucagon and gastric inhibitory polypeptide analogues linked to a human immunoglobulin Fc fragment	JVM Europe B.V. - Netherlands	Treatment of primary sclerosing cholangitis	16/07/2021 12/08/2021 05/11/2021 (85 days/28 days)	12/11/2021 10/12/2021
Anti-(endothelin-1 receptor subtype A) IgG4 humanised monoclonal antibody	Gmax Biopharm Belgium - Belgium	Treatment of pulmonary arterial hypertension	16/07/2021 12/08/2021 05/11/2021 (85 days/28 days)	12/11/2021 10/12/2021
Cedazuridine, decitabine	Otsuka Pharmaceutical Netherlands B.V. - Netherlands	Treatment of acute myeloid leukaemia	15/07/2021 12/08/2021 05/11/2021 (85 days/28 days)	12/11/2021 10/12/2021
Autologous T cells ex vivo modified with a lentiviral vector encoding a chimeric antigen receptor specific for CD1a	Onechain Immunotherapeutics S.L. - Spain	Treatment of acute lymphoblastic leukaemia	15/07/2021 12/08/2021 05/11/2021 (85 days/28 days)	12/11/2021 10/12/2021
Fingolimod	Consorcio Centro de Investigación Biomédica en Red, M.P. - Spain	Treatment of adrenoleukodystrophy	16/07/2021 12/08/2021 07/10/2021 (56 days/24 days)	19/10/2021 12/11/2021
Soticlestat	Takeda Pharma A/S - Denmark	Treatment of Lennox-Gastaut syndrome	16/07/2021 12/08/2021 07/10/2021 (56 days/24 days)	19/10/2021 12/11/2021

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Adeno-associated viral vector serotype 9 containing the human *SURF1* gene	Raremoon Consulting Esp S.L. - Spain	Treatment of Leigh syndrome	15/07/2021 12/08/2021 07/10/2021 (56 days/24 days)	19/10/2021 12/11/2021
Olverembatinib	Ascentage Pharma Europe Limited - Ireland	Treatment of chronic myeloid leukaemia	15/07/2021 12/08/2021 07/10/2021 (56 days/24 days)	19/10/2021 12/11/2021
(14S)-8-[3-(2-{dispiro[2.0.24.13]heptan-7-yl}ethoxy)-1H-pyrazol-1-yl]-12,12-dimethyl-2lamba6-thia-3,9,11,18,23-penta-azatetracyclo[17.3.1.111,14.05,10]tetracosa-1(22),5,7,9,19(23),20-hexaene-2,2,4-trione calcium salt hydrate, deutivacaftor, tezacaftor	Vertex Pharmaceuticals (Ireland) Limited - Ireland	Treatment of cystic fibrosis	14/07/2021 12/08/2021 07/10/2021 (56 days/24 days)	19/10/2021 12/11/2021
Ibrexafungerp	Dlrc Pharma Services Limited - Ireland	Treatment of invasive candidiasis	13/07/2021 12/08/2021 07/10/2021 (56 days/24 days)	19/10/2021 12/11/2021
Paclitaxel, polyoligo(ethylene glycol)methacrylate-co-poly(vinylbenzyldithiodibutyric acid-gemcitabine)	Karma Oncology B.V. - Netherlands	Treatment of pancreatic cancer	13/07/2021 12/08/2021 07/10/2021 (56 days/24 days)	19/10/2021 12/11/2021

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Anti-CD38 IgG4 human monoclonal antibody	Encefa - France	Treatment of amyotrophic lateral sclerosis	08/07/2021 12/08/2021 07/10/2021 (56 days/24 days)	19/10/2021 12/11/2021
D-lactic acid, glycolic acid	Neurevo GmbH - Germany	Treatment of amyotrophic lateral sclerosis	06/07/2021 12/08/2021 07/10/2021 (56 days/24 days)	19/10/2021 12/11/2021
Cannabidiol, dronabinol	Tetra Bio-Pharma Europe Limited - Malta	Treatment of complex regional pain syndrome	25/06/2021 12/08/2021 07/10/2021 (56 days/24 days)	19/10/2021 12/11/2021
Mosunetuzumab	Roche Registration GmbH - Germany	Treatment of follicular lymphoma	25/06/2021 12/08/2021 07/10/2021 (87 days/24 days)	19/10/2021 12/11/2021
5-fluoro-4-(4-fluoro-2-methoxyphenyl)-N- {4-[(S-methylsulfonimidoyl)methyl] pyridin-2-yl}pyridin-2-amine	Vincerx Pharma GmbH - Germany	Treatment of diffuse large B-cell lymphoma	25/06/2021 12/08/2021 07/10/2021 (87 days/24 days)	19/10/2021 12/11/2021
Nadunolimab	Cantargia AB - Sweden	Treatment of pancreatic cancer	24/06/2021 12/08/2021 07/10/2021 (87 days/24 days)	19/10/2021 12/11/2021

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
2-[1-(3-{6-[(1E)-(hydroxyimino)methyl]-5-methyl-4-oxo-7-propyl-3H,4H-pyrrolo[2,1-f][1,2,4]triazin-2-yl}-4-propoxybenzenesulfonyl)piperidin-4-yl]ethyl nitrate	Topadur Pharma Deutschland GmbH - Germany	Treatment of systemic sclerosis	24/06/2021 12/08/2021 07/10/2021 (87 days/24 days)	19/10/2021 12/11/2021
Linerixibat	GlaxoSmithKline (Ireland) Limited - Ireland	Treatment of primary biliary cholangitis	23/06/2021 12/08/2021 07/10/2021 (87 days/24 days)	19/10/2021 12/11/2021
Rebastinib	Deciphera Pharmaceuticals (Netherlands) B.V. - Netherlands	Treatment of ovarian cancer	23/06/2021 12/08/2021 07/10/2021 (87 days/24 days)	19/10/2021 12/11/2021
Autologous CD34+ enriched cells transduced with a self-inactivating lentiviral vector containing the codon-optimized *RPS19* gene	Consorcio Centro de Investigación Biomédica en Red, M.P. - Spain	Treatment of Diamond-Blackfan anemia	22/06/2021 12/08/2021 07/10/2021 (87 days/24 days)	19/10/2021 12/11/2021
Udonitrectag lysine	Mimetech S.r.l. - Italy	Treatment of solid organ transplantation	12/05/2021 12/07/2021 07/10/2021 (87 days/24 days)	19/10/2021 12/11/2021
Psilocybine	Comac Medical Ltd. - Bulgaria	Treatment of fragile X syndrome	28/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021

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Encaleret sulfate	Voisin Consulting Life Sciences - France	Treatment of hypoparathyroidism	25/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021
Mocravimod	Priothera - France	Treatment of in haematopoietic stem cell transplantation	25/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021
Batiraxcept	Kinesys Consulting NL B.V. - Netherlands	Treatment of ovarian cancer	25/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021
Adeno-associated virus serotype rh10 containing the human *GALC* gene	Diamond Pharma Services Ireland Limited - Ireland	Treatment of Krabbe disease	25/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021
Idursulfase beta	Parexel International (Irl) Limited - Ireland	Treatment of mucopolysaccharidosis type II (Hunter's syndrome)	25/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021
Glofitamab	Roche Registration GmbH - Germany	Treatment of diffuse large B-cell lymphoma	24/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021

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Allogeneic umbilical cord mesenchymal cells-derived extracellular vesicles	Exo Biologics - Belgium	Prevention of bronchopulmonary dysplasia	23/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021
Selinexor	Karyopharm Europe GmbH - Germany	Treatment of glioma	22/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021
Allogeneic retinal pigment epithelial cells genetically modified with a non-viral vector to express human alpha-L-iduronidase	TMC Pharma (EU) Limited - Ireland	Treatment of mucopolysaccharidosis type I	22/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021
Autologous haematopoietic stem and progenitor cell population containing CD34+ cells transduced with a lentiviral vector encoding the TCIRG1 cDNA ex vivo expanded	Fondazione Telethon - Italy	Treatment of osteopetrosis	21/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021
Adeno-associated viral vector serotype 5 expressing the human cone-rod homeobox gene	Variant - France	Treatment of cone-rod dystrophy	11/06/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021
Ganaxolone	Marinus Pharmaceuticals Emerald Limited - Ireland	Treatment of tuberous sclerosis	20/05/2021 14/06/2021 09/09/2021 (87 days/28 days)	17/09/2021 15/10/2021

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Adeno-associated virus of serotype rh10 encoding Human MLC1 under the control of GFAP promoter	Consorcio Centro de Investigación Biomédica en Red, M.P. - Spain	Treatment of megalencephalic leukoencephalopathy with subcortical cysts	19/05/2021 14/06/2021 09/09/2021 (87 days/28 days)	17/09/2021 15/10/2021
Devimistat	IQVIA RDS Ireland Limited - Ireland	Treatment of Burkitt's lymphoma	18/05/2021 14/06/2021 09/09/2021 (87 days/28 days)	17/09/2021 15/10/2021
Humanised IgG1 monoclonal antibody against SEZ6 linked to N-acetyl-calicheamicin	AbbVie Deutschland GmbH & Co. KG - Germany	Treatment of small cell lung cancer	12/05/2021 12/07/2021 09/09/2021 (59 days/28 days)	17/09/2021 15/10/2021
Human IgG1 monoclonal antibody against Sortilin	Pharma Gateway AB - Sweden	Treatment of frontotemporal dementia	26/03/2021 14/06/2021 09/09/2021 (87 days/31 days)	17/09/2021 18/10/2021
Autologous CD34+ cell enriched population containing haematopoietic stem and progenitor cells transduced ex vivo with a lentiviral vector encoding the human *ADA2* gene	Fondazione Telethon - Italy	Treatment of adenosine deaminase 2 deficiency (DADA2)	21/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021
Adeno-associated virus serotype 9 encoding human *NGLY1* gene	Voisin Consulting Life Sciences - France	Treatment of NGLY1 deficiency	21/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021

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Autologous CD34+ haematopoietic stem and progenitor cells genetically modified with the lentiviral vector encoding for the human iduronate 2-sulfatase gene	University Of Padua - Italy	Treatment of mucopolysaccharidosis type II (Hunter's syndrome)	21/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021
Bardoxolone methyl	Pharma Gateway AB - Sweden	Treatment of autosomal dominant polycystic kidney disease	20/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021
Recombinant human apolipoprotein A-I	Abionyx Pharma - France	Treatment of lecithin-cholesterol acyltransferase deficiency	20/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021
Lurbinectedin	Pharma Mar S.A. - Spain	Treatment of malignant mesothelioma	20/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021
Adeno-associated viral vector serotype S3 containing codon-optimised expression cassette encoding human beta-glucocerebrosidase variant	Freeline Therapeutics (Ireland) Limited - Ireland	Treatment of Gaucher disease	19/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021
Talquetamab	Janssen-Cilag International N.V. - Belgium	Treatment of multiple myeloma	19/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021
Adeno-associated viral vector serotype 9 containing the human *MECP2* gene	Raremoon Consulting Esp S.L. - Spain	Treatment of Rett syndrome	19/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021

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Sabatolimab	Novartis Europharm Limited - Ireland	Treatment of myelodysplastic syndromes	18/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021
Cemdisiran	Alnylam Netherlands B.V. - Netherlands	Treatment of primary IgA nephropathy	14/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021
Adeno-associated virus serotype PTC3 expressing the human *UBE3A* gene	PTC Therapeutics International Limited - Ireland	Treatment of Angelman syndrome	05/05/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021
Autologous CD34+ cells transfected with a lentiviral vector containing codon optimised *RPS19* gene	Premier Research Group S.L. - Spain	Treatment of Diamond-Blackfan anaemia	20/04/2021 14/06/2021 15/07/2021 31 days/25 days)	26/07/2021 20/08/2021
Loncastuximab tesirine	FGK Representative Service GmbH - Germany	Treatment of diffuse large B-cell lymphoma	22/03/2021 19/04/2021 15/07/2021 (87 days/25 days)	26/07/2021 20/08/2021
Humanised IgG1 monoclonal antibody against TfR1 conjugated to double stranded siRNA oligonucleotide against DMPK via a non-cleavable linker	MWB Consulting S.A.R.L. - France	Treatment of myotonic disorders	20/03/2021 19/04/2021 15/07/2021 (87 days/25 days)	26/07/2021 20/08/2021

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Human keratinocytes	Dizg Deutsches Institut Für Zell- Und Gewebeersatz gGmbH - Germany	Treatment of partial deep dermal and full thickness burns	17/03/2021 14/06/2021 15/07/2021 (31 days/25 days)	26/07/2021 20/08/2021
Adeno-associated viral vector serotype 9 containing the human *HEXA* and *HEXB* genes	Raremoon Consulting Esp S.L. - Spain	Treatment of GM2 gangliosidosis	12/03/2021 19/04/2021 15/07/2021 (87 days/25 days)	26/07/2021 20/08/2021
Adeno-associated viral vector serotype 9 containing the human *SLC13A5* gene	Raremoon Consulting Esp S.L. - Spain	Treatment of SLC13A5-epileptic encephalopathy deficiencies	22/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
Synthetic double-stranded siRNA oligonucleotide directed against apolipoprotein C-III mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues	Pharma Gateway AB - Sweden	Treatment of familial chylomicronaemia syndrome	22/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
Recombinant human ectonucleotide pyrophosphatase/phosphodiesterase 1 fused to the Fc fragment of IgG1	Inozyme Pharma Ireland Limited - Ireland	Treatment of adenosine triphosphate binding cassette transporter protein subfamily C member 6 deficiency	22/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
Zanidatamab	Voisin Consulting Life Sciences - France	Treatment of biliary tract cancer	22/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021

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Adeno-associated viral vector serotype Anc80 containing the 3' portion of human *OTOF* gene, Adeno-associated viral vector serotype Anc80 containing the 5' portion of human *OTOF* gene	Boyd Consultants Limited - Ireland	Treatment of otoferlin gene-mediated hearing loss	22/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
Autologous CD34+ hematopoietic stem and progenitor cells genetically modified with the lentiviral vector encoding for the human palmitoyl-protein thioesterase 1 gene	University Of Padua - Italy	Treatment of neuronal ceroid lipofuscinosis	22/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
humanised IgG2k Fc-modified bispecific monoclonal antibody against CD3 and BCMA	Pfizer Europe MA EEIG - Belgium	Treatment of multiple myeloma	22/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
3,5-diiodothyropropionic acid	Raremoon Consulting Esp S.L. - Spain	Treatment of Allan-Herndon-Dudley syndrome	19/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
Adeno-associated virus vector serotype 1 containing the human *GRN* gene	Pharma Gateway AB - Sweden	Treatment of frontotemporal dementia	19/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
Infigratinib	Yes Pharmaceutical Development Services GmbH - Germany	Treatment of achondroplasia	19/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021

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mRNA encoding the human glycogen debranching enzyme	Ultragenyx Germany GmbH - Germany	Treatment of glycogen storage disease type III	19/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
1-(4-(6-chloropyridazin-3-yl)piperazin-1-yl)-2-(4-cyclopropyl-3-fluorophenyl)ethan-1-one	Premier Research Group S.L. - Spain	Treatment of pantothenate kinase-associated neurodegeneration	18/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
1-(4-(6-chloropyridazin-3-yl)piperazin-1-yl)-2-(4-cyclopropyl-3-fluorophenyl)ethan-1-one	Premier Research Group S.L. - Spain	Treatment of propionic acidaemia	19/03/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
Tisagenlecleucel	Novartis Europharm Limited - Ireland	Treatment of follicular lymphoma	25/02/2021 25/03/2021 17/06/2021 (84 days/25 days)	24/06/2021 19/07/2021
Pridopidine hydrochloride	Prilenia Therapeutics B.V. - Netherlands	Treatment of amyotrophic lateral sclerosis	25/02/2021 25/03/2021 17/06/2021 (84 days/25 days)	24/06/2021 19/07/2021
Sirolimus	Yes Pharmaceutical Development Services GmbH - Germany	Treatment of perivascular epithelioid cell tumours	25/02/2021 25/03/2021 17/06/2021 (84 days/25 days)	24/06/2021 19/07/2021

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Saroglitazar magnesium	Zydus France - France	Treatment of primary biliary cholangitis	25/02/2021 25/03/2021 17/06/2021 (84 days/25 days)	24/06/2021 19/07/2021
Eftansomatropin alfa	Parexel International (Irl) Limited - Ireland	Treatment of growth hormone deficiency	24/02/2021 25/03/2021 17/06/2021 (84 days/25 days)	24/06/2021 19/07/2021
Lutetium (^{177}Lu) omburtamab barzuxetan	Y-Mabs Therapeutics A/S - Denmark	Treatment of medulloblastoma	24/02/2021 25/03/2021 17/06/2021 (84 days/25 days)	24/06/2021 19/07/2021
Melatonin	Worphmed S.r.l. - Italy	Treatment of non-traumatic spontaneous intracerebral haemorrhage	22/02/2021 25/03/2021 17/06/2021 (84 days/25 days)	24/06/2021 19/07/2021
Vodobatinib	Sun Pharmaceutical Industries Europe B.V. - Netherlands	Treatment of chronic myeloid leukaemia	19/02/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021
Itolizumab	Biocon Pharma Ireland Limited - Ireland	Treatment of graft-versus-host disease	26/01/2021 19/04/2021 17/06/2021 (59 days/25 days)	24/06/2021 19/07/2021

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Adeno-associated viral vector LK03 encoding human methylmalonyl-CoA mutase	Parexel International (Irl) Limited - Ireland	Treatment of methylmalonic acidaemia	26/02/2021 25/03/2021 12/05/2021 (48 days/27 days)	25/05/2021 21/06/2021
Allogenic placenta-derived mesenchymal stromal cells secretome	Corion Biotech S.r.l. - Italy	Treatment of pre-eclampsia	26/02/2021 25/03/2021 12/05/2021 (48 days/27 days)	25/05/2021 21/06/2021
Humanised monoclonal antibody derivative against fibroblast growth factor receptor 3	Genzyme Europe B.V. - Netherland	Treatment of achondroplasia	25/02/2021 25/03/2021 12/05/2021 (48 days/27 days)	25/05/2021 21/06/2021
Adeno-associated virus serotype 9 containing the human *FXN* gene isoform 1	Novartis Gene Therapies EU Limited - Ireland	Treatment of Friedreich's ataxia	24/02/2021 25/03/2021 12/05/2021 (48 days/27 days)	25/05/2021 21/06/2021
Adeno-associated virus serotype 9 expressing human CLN5	Real Regulatory Limited - Ireland	Treatment of neuronal ceroid lipofuscinosis	22/02/2021 25/03/2021 12/05/2021 (48 days/27 days)	25/05/2021 21/06/2021
Hydrocortisone hydrogen succinate	Laboratoire Aguettant - France	Prevention of bronchopulmonary dysplasia	22/02/2021 25/03/2021 12/05/2021 (48 days/27 days)	25/05/2021 21/06/2021

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Humanised IgG2 monoclonal antibody against TNFSF13	Otsuka Pharmaceutical Netherlands B.V. - Netherlands	Treatment of primary IgA nephropathy	22/02/2021 25/03/2021 12/05/2021 (48 days/27 days)	25/05/2021 21/06/2021
H-D-valyl1-D-alanyl-D-glutamyl-D-alanyl-D-arginyl5-D-glutamyl-D-glutamyl-D-leucyl-D-glutamyl-D-arginyl10-D-leucyl-D-glutamyl-D-alanyl-D-arginyl-D-leucyl15-glycyl-D-glutaminyl-D-alanyl-D-arginyl-glycyl20-D-glutamyl-D-leucyl-D-lysyl-D-lysyl-D-tryptophyl25-D-lysyl-D-methionyl-D-arginyl-D-arginyl-D-asparaginyl30-D-glutaminyl-D-phenylalanyl-D-tryptophyl-D-leucyl-D-lysyl35-D-leucyl-D-glutaminyl-D-arginine	Sapience Therapeutics Limited - Ireland	Treatment of glioma	19/02/2021 25/03/2021 12/05/2021 (48 days/27 days)	25/05/2021 21/06/2021
(S)-5-amino-3-(4-((5-fluoro-2-methoxybenzamido)methyl)phenyl)-1-(1,1,1-trifluoropropane-2-yl)-1H-pyrazole-4-carboxamide	Eli Lilly Nederland B.V. - Netherlands	Treatment of mantle cell lymphoma	18/02/2021 25/03/2021 12/05/2021 (48 days/27 days)	25/05/2021 21/06/2021
Melatonin	Worphmed S.r.l. - Italy	Prevention of retinopathy of prematurity	26/01/2021 25/03/2021 12/05/2021 (48 days/27 days)	25/05/2021 21/06/2021
Tislelizumab	BeiGene Ireland Limited - Ireland	Treatment of nasopharyngeal cancer	21/01/2021 12/02/2021 12/05/2021 (89 days/27 days)	25/05/2021 21/06/2021

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Imatinib	MDC RegAffairs GmbH - Germany	Treatment of pulmonary arterial hypertension	21/01/2021 12/02/2021 12/05/2021 (89 days/27 days)	25/05/2021 21/06/2021
Bomedemstat ditosilate	Imago Biosciences B.V. - Netherlands	Treatment of essential thrombocythaemia	20/01/2021 12/02/2021 12/05/2021 (89 days/27 days)	25/05/2021 21/06/2021
L-ergothioneine	Consorcio Centro de Investigación Biomédica en Red, M.P. - Spain	Treatment of cystinuria	21/12/2020 12/02/2021 12/05/2021 (89 days/27 days)	25/05/2021 21/06/2021
Dantrolene sodium, hemiheptahydrate	Norgine B.V. - Netherlands	Treatment of malignant hyperthermia	25/02/2021 25/03/2021 15/04/2021 (21 days/24 days)	26/04/2021 20/05/2021
Eflornithine	Brancaster Pharma Ireland Limited - Ireland	Treatment of neuroblastoma	21/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021
Begelomab	Adienne S.r.l. - Italy	Treatment of dermatomyositis	21/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021

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Trehalose	FGK Representative Service GmbH - Germany	Treatment of amyotrophic lateral sclerosis	21/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021
Adeno-associated virus serotype 9 expressing the cDNA for human MECP2	Novartis Gene Therapies EU Limited - Ireland	Treatment of Rett syndrome	21/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021
Elamipretide	Scendea (NL) B.V. - Netherlands	Treatment of Barth syndrome	21/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021
2-amino-6-[(2S)-2-hydroxypropanoyl]-7,8-dihydro-1H-pteridin-4-one	PTC Therapeutics International Limited - Ireland	Treatment of hyperphenylalaninemia	20/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021
2-[4-[3-(methylamino)-1-phenylpropoxy]phenyl]ethanol hydrochloride	Connecta Therapeutics S.L. - Spain	Treatment of fragile X syndrome	20/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021
Macitentan	Janssen-Cilag International N.V. - Belgium	Treatment of functional single ventricle congenital heart disease	20/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021

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Adeno-associated viral vector serotype 5 expressing the human cone-rod homeobox gene	Variant - France	Treatment of Leber's congenital amaurosis	20/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021
Autologous mobilised peripheral blood-derived CD34+ cells transduced ex vivo with a self-inactivating lentiviral vector containing a normal version of the coding region of the *IL2RG* gene	Real Regulatory Limited - Ireland	Treatment of X-linked severe combined immunodeficiency	19/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021
Zanubrutinib	BeiGene Ireland Limited - Ireland	Treatment of marginal zone lymphoma	19/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021
Melatonin	Worphmed S.r.l. - Italy	Treatment of retinitis pigmentosa	18/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021
Synthetic 2′-O-(2-methoxyethyl)-modified antisense oligonucleotide linked to a triantennary cluster of N-acetyl galactosamine sugars targeting transmembrane protease, serine 6 mRNA	Ionis Development (Ireland) Limited - Ireland	Treatment of beta thalassemia intermedia and major	12/01/2021 12/02/2021 15/04/2021 (62 days/24 days)	26/04/2021 20/05/2021
6-Amino-5-chloro-N-((1R)-1-(5-(((5-chloro-4-(trifluoromethyl)-2-pyridinyl)amino)carbonyl)-2-thiazolyl)ethyl)-4-pyrimidinecarboxamide	Parexel International (Irl) Limited - Ireland	Treatment of glioma	07/12/2020 25/01/2021 15/04/2021 (80 days/24 days)	26/04/2021 20/05/2021

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Human IgG1 monoclonal antibody against alpha-synuclein	H. Lundbeck A/S - Denmark	Treatment of multiple system atrophy	03/12/2020 25/01/2021 15/04/2021 (80 days/24 days)	26/04/2021 20/05/2021
Adeno-associated viral vector serotype 2.5T encoding the human cystic fibrosis transmembrane conductance regulator with a partial deletion in the R domain	Raremoon Consulting Esp S.L. - Spain	Treatment of cystic fibrosis	02/12/2020 25/01/2021 15/04/2021 (80 days/24 days)	26/04/2021 20/05/2021
Ganglioside GM1	3R Pharma Consulting GmbH - Germany	Treatment of amyotrophic lateral sclerosis	04/12/2020 25/01/2021 18/03/2021 (52 days/20 days)	24/03/2021 13/04/2021
S-[5-(omega-methoxypoly(oxyethylene)-2-oxopentyl)]-L-cysteinylglycyl-L-serinylglycylgylcyl-L-isoleucyl-L-lysyl-L-glutamyl-L-phenylalanyl-L-leucyl-L-glutaminyl-L-arginyl-L-phenylalanyl-L-isoleucyl-L-histyl-L-isoleucyl-L-valyl-L-glutaminyl-L-serinyl-L-isoleucyl-L-isoleucyl-L-asparaginyl-L-threonyl-L-serinamide, acetate salt	Almirall S.A. - Spain	Treatment of cutaneous T-cell lymphoma	23/11/2020 04/01/2021 18/03/2021 (73 days/20 days)	24/03/2021 13/04/2021
Cevostamab	Roche Registration GmbH - Germany	Treatment of mulitple myeloma	20/11/2020 04/01/2021 18/03/2021 (73 days/20 days)	24/03/2021 13/04/2021

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Vatiquinone	PTC Therapeutics International Limited - Ireland	Treatment of Friedreich's ataxia	11/01/2021 04/01/2021 18/02/2021 (45 days/29 days)	25/02/2021 26/03/2021
Lorcaserin hydrochloride	Premier Research Group S.L. - Spain	Treatment of Dravet syndrome	24/11/2020 23/11/2020 18/02/2021 (87 days/29 days)	25/02/2021 26/03/2021
Lefitolimod	Molecular Biology And Integral Biomathics - Germany	Treatment of small cell lung cancer	20/11/2020 04/01/2021 18/02/2021 (45 days/29 days)	25/02/2021 26/03/2021
Alpelisib	Novartis Europharm Limited - Ireland	Treatment of PIK3CA related overgrowth spectrum	20/11/2020 04/01/2021 18/02/2021 (45 days/29 days)	25/02/2021 26/03/2021
Alpha-L-iduronidase fused to Fab fragment of a humanised monoclonal antibody targeting human transferrin receptor	Artemida Pharma Europe Limited - Ireland	Treatment of mucopolysaccharidosis type I	19/11/2020 04/01/2021 18/02/2021 (45 days/29 days)	25/02/2021 26/03/2021
Herpes simplex virus 1 expressing the human *CFTR* gene	IDEA Innovative Drug European Associates (Ireland) Limited - Ireland	Treatment of cystic fibrosis	16/11/2020 04/01/2021 18/02/2021 (45 days/29 days)	25/02/2021 26/03/2021

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
5-fluoro-4-(7'-fluoro-2'-methylspiro[cyclopentane-1,3'-indol]-5'-yl)-N-(5-(1-methylpiperidin-4-yl)pyridin-2-yl)pyrimidin-2-amine	Rapport Global Strategic Services Ireland Limited - Ireland	Treatment of glioma	09/11/2020 04/01/2021 18/02/2021 (45 days/29 days)	25/02/2021 26/03/2021
Messenger RNA encoding Cas9, single guide RNA targeting the human *TTR* gene	Voisin Consulting Life Sciences - France	Treatment of ATTR amyloidosis	26/10/2020 23/11/2020 18/02/2021 (87 days/29 days)	25/02/2021 26/03/2021
Ilixadencel	Immunicum AB - Sweden	Treatment of gastrointestinal stromal tumours	23/10/2020 23/11/2020 18/02/2021 (87 days/29 days)	25/02/2021 26/03/2021
Adeno-associated virus serotype hu68 containing the human *GALC* gene	Pharma Gateway AB - Sweden	Treatment of Krabbe disease	21/10/2020 23/11/2020 18/02/2021 (87 days/29 days)	25/02/2021 26/03/2021
Adeno-associated virus serotype 5 containing the human *NR2E3* gene	Ocugen Limited - Ireland	Treatment of retinitis pigmentosa	26/10/2020 23/11/2020 21/01/2021 (59 days/23 days)	27/01/2021 19/02/2021
Adeno-associated virus serotype 5 containing the human *NR2E3* gene	Ocugen Limited - Ireland	Treatment of Leber's congenital amaurosis	26/10/2020 23/11/2020 21/01/2021 (59 days/23 days)	27/01/2021 19/02/2021

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Adeno-associated viral vector serotype 9 expressing codon-optimized human *GBA* gene	PPD Bulgaria EOOD - Bulgaria	Treatment of Gaucher disease	26/10/2020 23/11/2020 21/01/2021 (59 days/23 days)	27/01/2021 19/02/2021
18-(p-[131I]-iodophenyl)octadecyl phosphocholine	Scendea (NL) B.V. - Netherlands	Treatment of lymphoplasmacytic lymphoma	26/10/2020 23/11/2020 21/01/2021 (59 days/23 days)	27/01/2021 19/02/2021
Gly-Arg-Lys-Lys-Arg-Arg-Gln-Arg-Arg-Arg-Cys-Asp-Met-Ala-Glu-His-Thr-Glu-Arg-Leu-Lys-Ala-Asn-Asp-Ser-Leu-Lys-Leu-Ser-Gln-Glu-Tyr-Glu-Ser-Ile-NH2	Raremoon Consulting Esp S.L. - Spain	Treatment of spinal cord injury	23/10/2020 23/11/2020 21/01/2021 (59 days/23 days)	27/01/2021 19/02/2021
2-[6-(6,7-Dimethoxyquinolin-3-yl)pyridin-3-yl]-N-[3-(1,1,1-trifluoro-2-methylpropan-2-yl)-1,2-oxazol-5-yl]acetamide	Southwood Research Limited - Netherlands	Treatment of medullary thyroid carcinoma	22/10/2020 23/11/2020 21/01/2021 (59 days/23 days)	27/01/2021 19/02/2021
Dodecyl creatine ester, Dodecyl creatine ester hydrochloride	Ceres Brain Therapeutics S.A.S. - France	Treatment of creatine deficiency syndromes	15/10/2020 23/11/2020 21/01/2021 (59 days/23 days)	27/01/2021 19/02/2021
Autologous CD34+ hematopoietic stem and progenitor cells transfected with zinc finger nuclease mRNAs SB-mRENH1 and SB-mRENH2	Genzyme Europe B.V. - Netherland	Treatment of sickle cell disease	28/09/2020 26/10/2020 21/01/2021 (87 days/23 days)	27/01/2021 19/02/2021

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Autologous CD34+ cells transduced with a lentiviral RNA vector that results in integrated cDNA encoding for functional cystinosin	Clinical Technology Centre (Ireland) Limited - Ireland	Treatment of cystinosis	28/09/2020 26/10/2020 21/01/2021 (87 days/23 days)	27/01/2021 19/02/2021
Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human claudin 18.2 antigen with CD28 and CD3-zeta intracellular signalling domains	ICON Clinical Research Limited - Ireland	Treatment of gastric cancer	27/09/2020 26/10/2020 21/01/2021 (87 days/23 days)	27/01/2021 19/02/2021
(2S)-2-[(2S)-4-cyclohexyl-2-{[(2S)-1-(4-fluorobenzoyl)pyrrolidin-2-yl]formamido}butanamido]-N-(1-{[(1S)-1-{[(1S)-1-({1-[(1-{[2-({1-[(dimethylamino)methyl]cyclobutyl}carbamoyl)ethyl]carbamoyl}-1-methylethyl)carbamoyl]-1-methylethyl}carbamoyl)-3-methylbutyl]carbamoyl}-3-methylbutyl]carbamoyl}-1-methylethyl)-4-methylpentanamide acetate	Biopharma Excellence GmbH - Germany	Treatment of leishmaniasis	25/09/2020 26/10/2020 21/01/2021 (87 days/23 days)	27/01/2021 19/02/2021
2'-O-methyl phosphorothioate RNA oligonucleotide, 5'-m5CUGm5CUGm5CUGm5CUGm5CUGm5CUGm5CUG-3'	Vico Therapeutics B.V. - Netherlands	Treatment of spinocerebellar ataxia	25/09/2020 26/10/2020 21/01/2021 (87 days/23 days)	27/01/2021 19/02/2021
(1R,3S,5R)-2-(2-(3-acetyl-5-(2-methylpyrimidin-5-yl)-1H-indazol-1-yl)acetyl)-N-(6-bromo-3-methylpyridin-2-yl)-5-methyl-2-azabicyclo[3.1.0]hexane-3-carboxamide	Alexion Europe S.A.S. - France	Treatment of paroxysmal nocturnal haemoglobinuria	25/09/2020 26/10/2020 21/01/2021 (87 days/23 days)	27/01/2021 19/02/2021

Case Subject	Customer	Agreed Orphan Condition	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
2-(2-{[2-(1H-benzimidazol-2-yl)ethyl]amino}ethyl)-N-[(3-fluoropyridin-2-yl)methyl]-1,3-oxazole-4-carboxamide trihydrochloride	Vifor France - France	Treatment of sickle cell disease	24/09/2020 26/10/2020 21/01/2021 (87 days/23 days)	27/01/2021 19/02/2021
Rintatolimod	Hemispherx Biopharma Europe - Belgium	Treatment of pancreatic cancer	22/09/2020 26/10/2020 21/01/2021 (87 days/23 days)	27/01/2021 19/02/2021
Anti-SIGLEC8 IgG1 humanised monoclonal antibody	Turnkey Pharmaconsulting Ireland Limited - Ireland	Treatment of eosinophilic gastroenteritis	14/09/2020 26/10/2020 21/01/2021 (87 days/23 days)	27/01/2021 19/02/2021
Tebentafusp	Pharma Gateway AB - Sweden	Treatment of uveal melanoma	19/05/2020 17/06/2020 21/01/2021 (218 days/23 days)	27/01/2021 19/02/2021

Negative

Product INN	Sponsor	Summary of indication	EMA/COMP • Submission • Start date • Opinion • Active time	European Commission • Opinion received • Date of decision
Enterovirus B, Echovirus 7, Live	Latima SIA - Latvia	Treatment of uveal melanoma	18/05/2021 14/06/2021 09/09/2021 (87 days/34 days)	08/12/2021 11/01/2022
Amivantamab	Janssen-Cilag International N.V. - Belgium	Treatment of non-small cell lung cancer with EGFR alterations	23/11/2020 04/01/2021 01/04/2021 (87 days/42 days)	17/05/2021 28/06/2021

Annex 15 – HMPC European Union herbal monographs in 2021

Abbreviations: TU – traditional use

WEU – well established use

European Union herbal monographs - Final

Reference number	Document title	Adoption / Outcome
First Assessment		
EMA/HMPC/637833/2018	Menyanthidis trifoliatae folium	05/05/2021 / TU
EMA/HMPC/475726/2020	Taraxaci officinalis radix	24/11/2021 / TU
EMA/HMPC/376770/2019	Verbenae citriodorae folium	13/01/2021 / TU
Revision		
EMA/HMPC/486551/2020	Orthosiphonis folium	22/09/2021 / TU
EMA/HMPC/179591/2018	Trigonellae foenugraeci semen	24/11/2021 / 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 for consultation

Reference number	Document title	Adoption / Outcome
First Assessment		
EMA/HMPC/489142/2020	Centellae asiaticae herba	22/09/2021 / TU
EMA/HMPC/180400/2018	Species digestivae	07/07/2021 / TU
EMA/HMPC/475726/2020	Taraxaci officinalis radix	05/05/2021 / TU
EMA/HMPC/49135/2017	Vaccinii macrocarpi fructus	05/05/2021 / TU
Revision		
EMA/HMPC/114726/2021	Agropyri repentis rhizoma	07/07/2021 / TU
EMA/HMPC/486551/2020	Orthosiphonis folium	13/01/2021 / TU
EMA/HMPC/179591/2018	Trigonellae foenugraeci semen	03/03/2021 / TU
EMA/HMPC/7695/2021	Hyperici herba	03/03/2021 / WEU + TU

European Union List entries – Draft for consultation

Reference number	Document title	Adoption
First Assessment		
	none	
Revision		
	none	

Monograph/ list entry review reports

Reference number	Document title	Adoption / Outcome
Final decision		
EMA/HMPC/351447/2020	Agropyri repentis rhizoma	13/01/2021 / revision required*
EMA/HMPC/601695/2020	Cinnamomi corticis aetheroleum	03/03/2021 / no revision
EMA/HMPC/601683/2020	Cinnamomi cortex	03/03/2021 / no revision
EMA/HMPC/357351/2020	Colae semen	05/05/2021 / no revision
EMA/HMPC/367273/2021	Cucurbitae semen	24/11/2021 / no revision
EMA/HMPC/583991/2020	Fumariae herba	05/05/2021 / revision required*
EMA/HMPC/515836/2021	Grindeliae herba	24/11/2021 / no revision
EMA/HMPC/500504/2021	Levistici radix	24/11/2021 / no revision
EMA/HMPC/502105/2021	Lichen islandicus	24/11/2021 / no revision
EMA/HMPC/599113/2020	Mate folium	05/05/2021 / no revision
EMA/HMPC/3845/2021	Plantaginis lanceolatae folium	05/05/2021 / revision required*
EMA/HMPC/602132/2020	Rosmarini aetheroleum	07/07/2021 / revision required*
EMA/HMPC/602135/2020	Rosmarini folium	07/07/2021 / revision required*
EMA/HMPC/602363/2019	Sabalis serrulatae fructus	07/07/2021 / no revision
EMA/HMPC/637909/2018	Solidaginis virgaureae herba	22/09/2021 / no revision
EMA/HMPC/488970/2020	Urticae herba	24/11/2021 / revision required*
EMA/HMPC/472964/2020	Violae herba cum flore	05/05/2021 / no revision
EMA/HMPC/509849/2019	Zingiberis rhizoma	24/11/2021 / revision required*

* When revision is required, the review report is not published.

Public statements

Reference number	Document title	Adoption
Drafts		
EMA/HMPC/509931/2019	Salviae miltiorrhizae radix et rhizoma	13/01/2021
EMA/HMPC/483588/2020	Saccharomyces cerevisiae CBS 5926	05/05/2021

Reference number	Document title	Adoption
Final		
EMA/HMPC/483588/2020	Saccharomyces cerevisiae CBS 5926	24/11/2021

Annex 16 – PDCO opinions and EMA decisions on paediatric investigation plans and waivers in 2021

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

P: PIP agreed, RP: PIP refused, PM: PIP Modification agreed, RPM: PIP Modification refused, W: product specific waiver agreed, RW: product specific waiver refused

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Denosumab	Xgeva, Prolia	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Amgen Europe B.V.	05/01/2021	P/0001/2021
Autologous peripheral blood T cells CD4- and CD8-selected and CD3- and CD28-activated transduced with retroviral vector expressing anti-CD19 CD28/CD3-zeta chimeric antigen receptor and cultured (KTE-X19)		P	Oncology	Kite Pharma EU B.V.	05/01/2021	P/0002/2021
COVID-19 Vaccine (ChAdOx1-S [recombinant])		P	Vaccines	AstraZeneca AB	05/01/2021	P/0003/2021
(S)-6-hydroxy-2,5,7,8-tetramethyl-N-((R)-piperidin-3-yl)chroman-2-carboxamide hydrochloride (KH176)		P	Other	Khondrion BV	14/01/2021	P/0004/2021
Lenacapavir		P	Infectious Diseases	Gilead Sciences International Ltd.	15/01/2021	P/0005/2021
Lorlatinib	Lorviqua	W	Oncology	Pfizer Europa MA EEIG	15/01/2021	P/0006/2021
Cobicistat	Tybost	PM	Infectious Diseases	Gilead Sciences International Ltd.	15/01/2021	P/0007/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Betibeglogene autotemcel	Zynteglo	PM	Haematology-Hemostaseology	bluebird bio (Netherlands) B.V.	15/01/2021	P/0008/2021
Tofacitinib	Xeljanz	PM	Gastroenterology-Hepatology	Pfizer Europe MA EEIG	15/01/2021	P/0009/2021
Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage)	Efluelda	PM	Vaccines	Sanofi Pasteur	18/01/2021	P/0010/2021
18-(p-[131I]-iodophenyl)octadecyl phosphocholine		W	Oncology	Cellectar Biosciences, Inc.	28/01/2021	P/0011/2021
Arimoclomol citrate		P	Neurology	Orphazyme A/S	28/01/2021	P/0012/2021
Brentuximab vedotin	Adcetris	PM	Oncology	Takeda Pharma A/S	28/01/2021	P/0013/2021
Siponimod (hemifumarate)		PM	Neurology	Novartis Europharm Ltd	28/01/2021	P/0014/2021
Heparin Sodium		W	Cardiovascular Diseases / Haematology-Hemostaseology	YES Pharmaceutical Development Services GmbH	29/01/2021	P/0015/2021
Carfilzomib	Kyprolis	P	Oncology / Haematology-Hemostaseology	Amgen Europe BV	27/01/2021	P/0016/2021
Allopurinol / verinurad		P	Uro-nephrology	AstraZeneca AB	29/01/2021	P/0017/2021
3-((1R,3s,5S)-3-((7-((5-methyl-1H-pyrazol-3-yl)amino)-1,6-naphthyridin-5-yl)amino)-8-azabicyclo[3.2.1]octan-8-yl)propanenitrile (TD-1473)		P	Gastroenterology-Hepatology	Theravance Biopharma Ireland Limited	27/01/2021	P/0018/2021
Dexmedetomidine (hydrochloride)		P	Psychiatry	BioXcel Therapeutics, Inc.	29/01/2021	P/0019/2021

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Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Esketamine hydrochloride		P	Psychiatry	Celon Pharma S.A.	27/01/2021	P/0020/2021
Sparsentan		P	Uro-nephrology	Travere Therapeutics Ireland Ltd.	27/01/2021	P/0021/2021
Autologous tumour-infiltrating lymphocytes (LN-144/LN-145)		P	Oncology	Iovance Biotherapeutics, Inc.	27/01/2021	P/0022/2021
Retinol (Vitamin A)		P	Neonatology - Paediatric Intensive Care	orphanix GmbH	28/01/2021	P/0023/2021
Sparsentan		P	Uro-nephrology	Travere Therapeutics Ireland Ltd.	27/01/2021	P/0024/2021
Reldesemtiv		W	Neurology	Cytokinetics, Inc.	28/01/2021	P/0025/2021
darvadstrocel	Alofisel	PM	Gastroenterology-Hepatology	Takeda Pharma A/S	27/01/2021	P/0026/2021
ceftazidime / Avibactam	Zavicefta	PM	Infectious Diseases	Pfizer Europe MA EEIG	27/01/2021	P/0027/2021
Aztreonam (ATM) / Avibactam (AVI)		PM	Infectious Diseases	Pfizer Europe MA EEIG	29/01/2021	P/0028/2021
Baloxavir marboxil		PM	Infectious Diseases	Roche Registration GmbH	29/01/2021	P/0029/2021
3-({5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl}methyl)-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-c]pyridin-2-one) (JNJ-53718678)		PM	Infectious Diseases	Janssen-Cilag International NV	27/01/2021	P/0030/2021
Eliapixant		W	Pneumology - Allergology	Bayer AG	27/01/2021	P/0031/2021
Vortioxetine	Brintellix	PM	Psychiatry	H. Lundbeck A/S	27/01/2021	P/0032/2021
Cannabidiol	Epidyolex	PM	Neurology	GW Pharma (International) B.V.	29/01/2021	P/0033/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Tenofovir alafenamide / Emtricitabine	Descovy	PM	Infectious Diseases	Gilead Sciences International Ltd.	27/01/2021	P/0034/2021
Alpha1-Proteinase Inhibitor (Human)		W	Pneumology - Allergology / Haematology-Hemostaseology	Baxalta Innovations GmbH (owned by Takeda)	27/01/2021	P/0035/2021
Crizotinib	Xalkori	PM	Oncology	Pfizer Europe MA EEIG	27/01/2021	P/0036/2021
Luspatercept	Reblozyl™	PM	Haematology-Hemostaseology	Bristol-Myers Squibb Pharma EEIG	27/01/2021	P/0037/2021
Tenofovir alafenamide / Emtricitabine / Bictegravir	Biktarvy	PM	Infectious Diseases	Gilead Sciences International Ltd.	27/01/2021	P/0038/2021
Risankizumab	Skyrizi	PM	Immunology-Rheumatology-Transplantation	AbbVie Ltd	27/01/2021	P/0039/2021
Eribulin	Halaven	PM	Oncology	Eisai GmbH	27/01/2021	P/0040/2021
Obeticholic acid	Ocaliva	PM	Gastroenterology-Hepatology	Intercept Pharma International Ltd.	27/01/2021	P/0041/2021
Ofatumumab		PM	Neurology	Novartis Ireland Limited	29/01/2021	P/0042/2021
In vitro expanded autologous human articular chondrocytes		PM	Other	TETEC Tissue Engineering Technologies AG	27/01/2021	P/0043/2021
Umbralisib tosylate		W	Oncology	TG Therapeutics, Inc	28/01/2021	P/0044/2021
Rosuvastatin (calcium) / acetylsalicylic acid		W	Cardiovascular Diseases	Neopharmed Gentili S.p.A.	27/01/2021	P/0045/2021
Ublituximab		W	Oncology	TG Therapeutics, Inc	27/01/2021	P/0046/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
daprodustat		PM	Uro-nephrology / Haematology-Hemostaseology	GlaxoSmithKline Trading Services Limited	27/01/2021	P/0047/2021
Fosdenopterin (ORGN001)		PM	Other	Origin Biosciences, Inc.	27/01/2021	P/0048/2021
Cobicistat / darunavir	Rezolsta	PM	Infectious Diseases	Janssen-Cilag International NV	27/01/2021	P/0049/2021
Obinutuzumab	Gazyvaro	P	Immunology-Rheumatology-Transplantation	Roche Registration GmbH	28/01/2021	P/0050/2021
Human Thrombin / Human Fibrinogen	Evarrest, Evicel	PM	Other	Omrix Biopharmaceuticals N.V.	27/01/2021	P/0051/2021
Human Thrombin / Human Fibrinogen	Veraseal	PM	Other	Instituto Grifols, S.A.	27/01/2021	P/0052/2021
catumaxomab		W	Oncology	Lindis Biotech GmbH	27/01/2021	P/0053/2021
Acetylcysteine / Ibuprofen (sodium dihydrate)		W	Pneumology - Allergology / Oto-rhino-laryngology	E-Pharma Trento S.p.A.	27/01/2021	P/0054/2021
Paracetamol / nefopam (hydrochloride)		W	Pain	Aptys Pharmaceuticals	27/01/2021	P/0055/2021
Lasmiditan		PM	Neurology	Eli Lilly and Company Limited	29/01/2021	P/0056/2021
Pitolisant	Wakix	PM	Neurology	Bioprojet Pharma	27/01/2021	P/0057/2021
Docosahexaenoic Acid		W	Ophthalmology	Natac Pharma S.L.	12/02/2021	P/0058/2021
COVID-19 vaccine (Ad26.COV2-S (recombinant))		P	Vaccines / Infectious Diseases	Janssen-Cilag International N.V.	05/02/2021	P/0059/2021
Remdesivir	Veklury	PM	Infectious Diseases	Gilead Sciences International Ltd.	05/02/2021	P/0060/2021
Recombinant humanised monoclonal immunoglobulin		W	Neurology	UCB Pharma S.A.	12/02/2021	P/0061/2021

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Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
G4, with specificity for human tau (UCB0107)						
baricitinib	Olumiant	P	Immunology-Rheumatology-Transplantation	Eli Lilly and Company Limited	05/02/2021	P/0062/2021
Rimegepant		P	Neurology	Biohaven Pharmaceuticals, Inc.	18/02/2021	P/0063/2021
Exenatide	Bydureon, Byetta	PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	18/02/2021	P/0064/2021
Deucravacitinib		PM	Dermatology	Bristol-Myers Squibb International Corporation	19/02/2021	P/0065/2021
Ponesimod		PM	Other / Neurology	Janssen-Cilag International NV	18/02/2021	P/0066/2021
Ozanimod hydrochloride	Zeposia	PM	Gastroenterology-Hepatology	Celgene Europe B.V.	18/02/2021	P/0067/2021
Idecabtagene vicleucel		W	Oncology	Celgene Europe B.V.	19/02/2021	P/0068/2021
Evinacumab		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Regeneron Ireland DAC	17/03/2021	P/0069/2021
Nivolumab / relatlimab		PM	Oncology	Bristol-Myers Squibb International Corporation	17/03/2021	P/0070/2021
Synthetic double-stranded siRNA oligonucleotide directed against lactate dehydrogenase A mRNA and containing four modified nucleosides which form a ligand cluster of four N-		PM	Uro-nephrology	Dicerna Ireland Limited	17/03/2021	P/0071/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
acetylgalactosamine residues (DCR-PHXC)						
efgartigimod alfa		PM	Neurology	argenx BV	17/03/2021	P/0072/2021
Islatravir / doravirine		PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	17/03/2021	P/0073/2021
Eladocagene exuparvovec		PM	Neurology	PTC Therapeutic International Limited	17/03/2021	P/0074/2021
Canakinumab	Ilaris	W	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	17/03/2021	P/0075/2021
Larotrectinib	Vitrakvi	PM	Oncology	Bayer AG	17/03/2021	P/0076/2021
Larotrectinib	Vitrakvi	PM	Oncology	Bayer AG	17/03/2021	P/0077/2021
Bimekizumab		P	Immunology-Rheumatology-Transplantation / Dermatology	UCB Biopharma SRL	17/03/2021	P/0078/2021
seltorexant [(3aR,6aS)-5-(4,6-dimethylpyrimidin-2-yl)hexahydropyrrolo[3,4-c]pyrrol-2(1H)-yl][2-fluoro-6-(2H-1,2,3-triazol-2-yl)phenyl]methanone		P	Psychiatry	Janssen-Cilag International NV	17/03/2021	P/0079/2021
Vamorolone		PM	Other	ReveraGen BioPharma Ltd	17/03/2021	P/0080/2021
Olpasiran		W	Cardiovascular Diseases	Amgen Europe B.V.	17/03/2021	P/0081/2021
Autologous CD4+ and CD8+ T cells genetically modified with a lentiviral vector encoding a B cell maturation antigen-specific chimeric antigen receptor (JCARH125)		W	Oncology	Celgene Europe B.V.	19/03/2021	P/0082/2021

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Ustekinumab	Stelara	PM	Gastroenterology-Hepatology	Janssen-Cilag International NV	19/03/2021	P/0083/2021
Ustekinumab	Stelara	PM	Gastroenterology-Hepatology	Janssen-Cilag International NV	19/03/2021	P/0084/2021
Hydrochlorothiazide / Amlodipine / Ramipril		W	Cardiovascular Diseases	Sandoz GmbH	19/03/2021	P/0085/2021
Midostaurin	Rydapt	PM	Oncology	Novartis Europharm Limited	19/03/2021	P/0086/2021
Anti-C1s Humanized IgG4 Monoclonal Antibody (BIVV020)		W	Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology / Neurology	Genzyme Europe B.V.	17/03/2021	P/0087/2021
Linagliptin	Trajenta	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	19/03/2021	P/0088/2021
Empagliflozin	Jardiance	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	19/03/2021	P/0089/2021
Bintrafusp alfa		PM	Oncology	Merck Europe B.V.	17/03/2021	P/0090/2021
Palbociclib	Ibrance	PM	Oncology	Pfizer Europe MA EEIG	17/03/2021	P/0091/2021
Vilanterol / fluticasone (furoate)	Relvar ellipta	PM	Pneumology - Allergology	Glaxo Group Limited	19/03/2021	P/0092/2021
Enalapril maleate		PM	Cardiovascular Diseases	Proveca Pharma Limited	17/03/2021	P/0093/2021
Glycopyrronium bromide / Formoterol fumarate dihydrate / Beclometasone dipropionate	Riarify, Trimbow, Trydonis	PM	Pneumology - Allergology	Chiesi Farmaceutici S.p.A.	17/03/2021	P/0094/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Edaravone		W	Neurology	Mitsubishi Tanabe Pharma GmbH	17/03/2021	P/0095/2021
Interferon beta-1a		PM	Pneumology - Allergology	Faron Pharmaceuticals Ltd.	17/03/2021	P/0096/2021
Telitacicept		P	Immunology-Rheumatology-Transplantation	RemeGen, Ltd.	19/03/2021	P/0097/2021
Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein		P	Vaccines	GlaxoSmithKline Biologicals SA	19/03/2021	P/0098/2021
Imetelstat		P	Oncology	Geron Corporation	19/03/2021	P/0099/2021
Rozibafusp alfa		P	Immunology-Rheumatology-Transplantation	Amgen Europe B.V.	17/03/2021	P/0100/2021
Tacrolimus		P	Immunology-Rheumatology-Transplantation	Proveca Pharma Limited	17/03/2021	P/0101/2021
(S)-2-(5-((3-ethoxypyridin-2-yl)oxy)pyridin-3-yl)-N-(tetrahydrofuran 3 yl) pyrimidine-5-carboxamide (PF-06865571)		P	Gastroenterology-Hepatology	Pfizer Europe MA EEIG	17/03/2021	P/0102/2021
Roxadustat		PM	Haematology-Hemostaseology	Astellas Pharma Europe B.V.	17/03/2021	P/0103/2021
Crinecerfont		P	Endocrinology-Gynaecology-Fertility-Metabolism	Neurocrine Therapeutics Ltd	17/03/2021	P/0104/2021
Cariprazine (hydrochloride)	Reagila	**RPM**	Psychiatry	Gedeon Richter Plc.	17/03/2021	P/0105/2021
Durvalumab	Imfinzi	PM	Oncology	AstraZeneca AB	17/03/2021	P/0106/2021
Tremelimumab		PM	Oncology	AstraZeneca AB	17/03/2021	P/0107/2021
Delgocitinib		P	Dermatology	LEO Pharma A/S	17/03/2021	P/0108/2021
Isopropyl alcohol / Povidone-iodine		W	Other	BD Switzerland Sàrl	17/03/2021	P/0109/2021

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Gilteritinib (as fumarate)	Xospata	PM	Oncology / Haematology-Hemostaseology	Astellas Pharma Europe B.V.	17/03/2021	P/0110/2021
Secukinumab	Cosentyx	W	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	17/03/2021	P/0111/2021
Secukinumab	Cosentyx	P	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	17/03/2021	P/0112/2021
Bupivacaine		PM	Pain	Pacira Ltd	17/03/2021	P/0113/2021
Sarilumab	Kevzara	PM	Immunology-Rheumatology-Transplantation	sanofi-aventis recherche & développement	17/03/2021	P/0114/2021
Agomelatine	Valdoxan, Thymanax	PM	Psychiatry	Les Laboratoires Servier	17/03/2021	P/0115/2021
Lamivudine / Abacavir / Dolutegravir	Triumeq	PM		ViiV Healthcare UK Limited	17/03/2021	P/0116/2021
Ibrutinib	Imbruvica	PM	Oncology	Janssen-Cilag International N.V.	17/03/2021	P/0117/2021
Cabotegravir		PM	Infectious Diseases	ViiV Healthcare UK Limited	17/03/2021	P/0118/2021
Cobimetinib	Cotellic	PM	Oncology	Roche Registration GmbH	17/03/2021	P/0119/2021
Tildrakizumab		PM	Dermatology	Almirall, S.A	17/03/2021	P/0120/2021
Dupilumab	Dupixent	W	Oto-rhino-laryngology	sanofi-aventis recherche & développement	17/03/2021	P/0121/2021
Alpelisib	Piqray	W	Oncology	Novartis Europharm Limited	17/03/2021	P/0122/2021
Eptinezumab		W	Neurology	H. Lundbeck A/S	17/03/2021	P/0123/2021
Crovalimab		P	Haematology-Hemostaseology	Roche Registration GmbH	17/03/2021	P/0124/2021

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Linear single strand of deoxyribonucleic acid (encoding human retinitis pigmentosa GTPase regulator [RPGR]) packaged in a recombinant adeno-associated virus protein capsid of serotype 5 (AAV5-hRKp.RPGR)		P	Ophthalmology	MeiraGTx UK II Ltd	17/03/2021	P/0125/2021
Severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) / matrix-M1 adjuvant		P	Vaccines	Novavax, Inc.	15/03/2021	P/0126/2021
Fluoride 18-labelled Prostate-Specific Membrane Antigen-1007 ([18F]PSMA-1007)		W	Diagnostic / Oncology	ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH	26/03/2021	P/0127/2021
Adeno-associated virus, serotype 9 (AAV9)-based non-replicating, self-complementary recombinant vector containing an expression cassette for the human ASPA transgene (scAAV9-CB6-hASPAopt)		P	Neurology	Aspa Therapeutics, Inc.	14/04/2021	P/0128/2021
Sepofarsen		P	Ophthalmology	ProQR Therapeutics	14/04/2021	P/0129/2021
Talazoparib	Talzenna	W	Oncology	Pfizer Europe MA EEIG	14/04/2021	P/0130/2021
A phosphorothioate oligonucleotide targeted to apolipoprotein C-III [ISIS 304801]	Volanesorsen, Waylivra	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Akcea Therapeutics	14/04/2021	P/0131/2021

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Defatted powder of peanuts		PM	Pneumology - Allergology	Aimmune Therapeutics Inc	14/04/2021	P/0132/2021
(4R,5R)-1-[[4-[[4-[3,3-Dibutyl-7-(dimethylamino)-2,3,4,5-4- hydroxy-1,1-dioxido-1-benzothiepin-5-yl] phenoxy] methyl] phenyl] methyl]-4-aza-1-azoniabicyclo[2.2.2]octane Chloride		PM	Gastroenterology-Hepatology	Mirum Pharmaceuticals	14/04/2021	P/0133/2021
Potassium chloride / Sodium chloride / Citric acid (as citric acid anhydrous) / Sodium citrate / Simeticone / Sodium sulphate (as sodium sulfate anhydrous) / Macrogol 4000		PM	Gastroenterology-Hepatology	Alfasigma S.p.A.	14/04/2021	P/0134/2021
Humanised recombinant IgG4, Anti-PD-1 monoclonal antibody (CS1003)		W	Oncology	CStone Pharmaceuticals (Suzhou) CO., Ltd.	16/04/2021	P/0135/2021
Anti-(alpha-synuclein) human monoclonal antibody		W	Neurology	H. Lundbeck A/S	16/04/2021	P/0136/2021
2-((4S)-6-(4-chlorophenyl)-1-methyl-4H-benzo[C]isoxazolo[4,5-e]azepin-4-yl) acetamide monohydrate		W	Oncology	Constellation Pharmaceuticals Inc.	14/04/2021	P/0137/2021
Tavapadon		W	Neurology	Cerevel Therapeutics, LLC	16/04/2021	P/0138/2021
Sintilimab		W	Oncology	Eli Lilly and Company Limited	16/04/2021	P/0139/2021
Encequidar		W	Oncology	Athenex Inc.,	16/04/2021	P/0140/2021
Paclitaxel		W	Oncology	Athenex Inc.,	14/04/2021	P/0141/2021
Surufatinib		P	Oncology	Hutchison MediPharma Ltd	14/04/2021	P/0142/2021
Zilucoplan		P	Other / Neurology	UCB Pharma SA	14/04/2021	P/0143/2021

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Ladarixin		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Dompé farmaceutici S.p.A	16/04/2021	P/0144/2021
Ruxolitinib (phosphate)		P	Dermatology	Incyte Biosciences Distribution B.V.	16/04/2021	P/0145/2021
Sutimlimab		W	Haematology-Hemostaseology	Genzyme Europe B.V.	14/04/2021	P/0146/2021
Ritlecitinib		P	Dermatology	Pfizer Europe MA EEIG	14/04/2021	P/0147/2021
Valoctocogene roxaparvovec		PM	Haematology-Hemostaseology	BioMarin International Limited	16/04/2021	P/0148/2021
Nadofaragene firadenovec		W	Oncology	Ferring Pharmaceuticals A/S	16/04/2021	P/0149/2021
Pioglitazone hydrochloride / Spironolactone / Metformin hydrochloride		P	Endocrinology-Gynaecology-Fertility-Metabolism	Katholieke Universiteit Leuven (KUL) Research & Development	16/04/2021	P/0150/2021
Gadopiclenol		PM	Diagnostic	Guerbet	16/04/2021	P/0151/2021
Gadopiclenol		PM	Diagnostic	Guerbet	16/04/2021	P/0152/2021
Dupilumab	Dupixent	P	Dermatology	sanofi-aventis recherche & développement	16/04/2021	P/0153/2021
Oritavancin (diphosphate)	Orbactiv	PM	Infectious Diseases	Menarini International Operations Luxembourg S.A.	16/04/2021	P/0154/2021
Mometasone (furoate) / Indacaterol (acetate)	Atectura Breezhaler and its duplicate authorization Bemrist Breezhaler	PM	Pneumology - Allergology	Novartis Europharm Limited	16/04/2021	P/0155/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Tenofovir (disoproxil fumarate)	Viread	PM	Infectious Diseases	Gilead Sciences International Limited	14/04/2021	P/0156/2021
Golimumab	Simponi	PM	Gastroenterology-Hepatology	Janssen Biologics B.V.	14/04/2021	P/0157/2021
Azilsartan medoxomil	Edarbi	PM	Cardiovascular Diseases	Takeda Development Centre Europe Ltd	14/04/2021	P/0158/2021
Chikungunya Virus Virus-Like Particle Vaccine		P	Vaccines	Emergent Netherlands B.V.	16/04/2021	P/0159/2021
Dermatophagoides farinae / Dermatophagoides pteronyssinus	ACARIZAX and associated names	PM	Pneumology - Allergology	ALK-Abelló A/S	16/04/2021	P/0160/2021
Landiolol (hydrochloride)	Rapibloc, Raploc, Landiobloc, Runrapic	PM	Cardiovascular Diseases	AOP Orphan Pharmaceuticals AG	16/04/2021	P/0161/2021
Hydroxypropyl-β-cyclodextrin		P	Endocrinology-Gynaecology-Fertility-Metabolism	Cyclo Therapeutics Inc	14/04/2021	P/0162/2021
Anti-IL-7Rα monoclonal antibody (S95011/ OSE-127)		W	Immunology-Rheumatology-Transplantation	Les Laboratoires Servier	14/04/2021	P/0163/2021
Sabatolimab		W	Oncology	Novartis Europharm	14/04/2021	P/0164/2021
Ensartinib		W	Oncology	Xcovery Holdings, Inc.	14/04/2021	P/0165/2021
Upadacitinib	Rinvoq	PM	Immunology-Rheumatology-Transplantation / Dermatology	AbbVie Ltd	14/04/2021	P/0166/2021
Upadacitinib	Rinvoq	PM	Immunology-Rheumatology-Transplantation	AbbVie Ltd	14/04/2021	P/0167/2021
Bimekizumab		PM	Dermatology	UCB Biopharma SRL	14/04/2021	P/0168/2021

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Ethinyl estradiol / Dienogest		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Chemo Research	14/04/2021	P/0169/2021
Bumetanide		PM	Neurology	Les Laboratoires Servier	09/04/2021	P/0170/2021
Ganaxolone		PM	Neurology	Marinus Pharmaceuticals Inc.	09/04/2021	P/0171/2021
Ruxolitinib (phosphate)	Jakavi	PM	Oncology	Novartis Europharm Limited	09/04/2021	P/0172/2021
Brivaracetam	Briviact	PM	Neurology	UCB Pharma S.A.	09/04/2021	P/0173/2021
Brivaracetam	Briviact	PM	Neurology	UCB Pharma S.A.	09/04/2021	P/0174/2021
Ticagrelor	Brilique	PM	Cardiovascular Diseases / Haematology-Hemostaseology	AstraZeneca AB	09/04/2021	P/0175/2021
Tenofovir disoproxil (fumarate) / lamivudine / doravirine		PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	12/04/2021	P/0176/2021
Doravirine		PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	12/04/2021	P/0177/2021
Spesolimab		PM	Dermatology	Boehringer Ingelheim International GmbH	19/04/2021	P/0178/2021
BNT162b2	Comirnaty	PM		BioNTech Manufacturing GmbH	23/04/2021	P/0179/2021
Remimazolam		PM	Anaesthesiology	PAION Deutschland GmbH	10/05/2021	P/0180/2021
Avacopan		PM	Immunology-Rheumatology-Transplantation	ChemoCentryx Ireland Ltd.	10/05/2021	P/0181/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Meloxicam (HTX-011) / Bupivacaine	Zynrelef	PM	Pain	Heron Therapeutics B.V.	10/05/2021	P/0182/2021
(S)-N-(1-amino-4-(dimethylamino)-1-oxobutan-2-yl)-5-(2,4-difluorophenoxy)-1-isobutyl-1H-indazole-6-carboxamide		W	Cardiovascular Diseases	Pfizer Europe MA EEIG	10/05/2021	P/0183/2021
Niraparib (tosylate monohydrate)	Zejula	PM	Oncology	GlaxoSmithKline (Ireland) Limited	10/05/2021	P/0184/2021
Isatuximab	Sarclisa	PM	Oncology	Sanofi-Aventis Recherche & Développement	10/05/2021	P/0185/2021
vedolizumab	Entyvio	P	Gastroenterology-Hepatology	Takeda Pharma A/S	10/05/2021	P/0186/2021
Oxygen / Argon		W	Neurology	Air Liquide Santé International	07/05/2021	P/0187/2021
Reparixin		RW	Infectious Diseases	Dompé farmaceutici S.p.A.	07/05/2021	P/0188/2021
Concentrate of proteolytic enzyme enriched in bromelain	Nexobrid	PM	Other	MediWound Germany GmbH	10/05/2021	P/0189/2021
3,4-Dimethoxy-N-methylbenzohydroxamic acid (Custodiol-N) / Deferoxamine (mesylate) / Alpha-ketoglutaric acid / Arginine / Alanine / Glycine / Aspartic acid / Tryptophan / N-acetyl-histidine (monohydrate) / Histidine / Calcium chloride (dihydrate) / Magnesium chloride (hexahydrate) / Potassium chloride / Sodium chloride		P	Cardiovascular Diseases	Dr. Franz Köhler Chemie GmbH	10/05/2021	P/0190/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Brexpiprazole	Rxulti	PM	Psychiatry	Otsuka Pharmaceutical Development & Commercialisation Europe GmbH	10/05/2021	P/0191/2021
Pembrolizumab / quavonlimab		W	Oncology	Merck, Sharp & Dohme (Europe) Inc	10/05/2021	P/0192/2021
Pegunigalsidase alfa		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Chiesi Farmaceutici S.p.A.	10/05/2021	P/0193/2021
rAAV8 viral vector encoding the human UGT1A1 transgene (rAAV8-hUGT1A1)		P	Endocrinology-Gynaecology-Fertility-Metabolism	GENETHON	10/05/2021	P/0194/2021
Ataluren	Translarna	PM	Neurology	PTC Therapeutics International, Limited	10/05/2021	P/0195/2021
Obinutuzumab	Gazyvaro	W	Oncology	Roche Registration GmbH	10/05/2021	P/0196/2021
(S)-5-amino-3-(4-((5-fluoro-2-methoxybenzamido)methyl)phenyl)-1-(1,1,1-trifluoropropane-2-yl)-1H-pyrazole-4-carboxamide		W	Oncology	Eli Lilly and Company	10/05/2021	P/0197/2021
Tenofovir alafenamide / emtricitabine / cobicistat / darunavir	Symtuza	PM	Infectious Diseases	Janssen-Cilag International NV	10/05/2021	P/0198/2021
Human anti-interleukin-15 (IL-15) monoclonal antibody		W	Immunology-Rheumatology-Transplantation	Provention Bio, Inc.	10/05/2021	P/0199/2021
Anti-CD40L humanized monoclonal antibody (SAR441344)		W	Immunology-Rheumatology-Transplantation	Sanofi-aventis recherche & développement	10/05/2021	P/0200/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
SARS-CoV2 prefusion spike delta TM (CoV-2 preS dTM) adjuvanted with AS03		P	Vaccines	Sanofi Pasteur	10/05/2021	P/0201/2021
Respiratory Syncytial Virus Stabilised Prefusion F Subunit Vaccine (RSVpreF, PF-06928316)		P	Vaccines	Pfizer Europe MA EEIG	10/05/2021	P/0202/2021
Edaravone		W	Neurology	Treeway B.V.	10/05/2021	P/0203/2021
Cipaglucosidase alfa		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Amicus Therapeutics Europe Limited	10/05/2021	P/0204/2021
Lenvatinib	Kisplyx, Lenvima	PM	Oncology	Eisai GmbH	10/05/2021	P/0205/2021
Pegfilgrastim (Recombinant human granulocyte colony stimulating factor coupled with recombinant human albumin fusion protein)	Pelgraz Junior	P	Haematology-Hemostaseology	Accord Healthcare S.L.U.	10/05/2021	P/0206/2021
Birch pollen extract (Betula verrucosa)	Itulazax	PM	Pneumology - Allergology	ALK-Abelló A/S	10/05/2021	P/0207/2021
Naproxen sodium / Sumatriptan		W	Neurology	Orion Corporation	10/05/2021	P/0208/2021
Rilpivirine / Dolutegravir	Juluca	PM	Infectious Diseases	ViiV Healthcare UK Limited	10/05/2021	P/0209/2021
Pegcetacoplan		PM		Swedish Orphan Biovitrum AB (Publ)	10/05/2021	P/0210/2021
Dostarlimab		PM	Oncology	GlaxoSmithKline (Ireland) Limited	10/05/2021	P/0211/2021
Zorecimeran		P	Vaccines / Infectious Diseases	CureVac AG	17/05/2021	P/0212/2021
Denosumab	Prolia, Xgeva	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Amgen Europe B.V.	21/05/2021	P/0213/2021
Etesevimab		P	Infectious Diseases	Eli Lilly and Company Limited	09/06/2021	P/0214/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Setmelanotide		PM	Nutrition	Rhythm Pharmaceuticals, Inc	08/06/2021	P/0215/2021
Linaclotide	Constella	PM	Gastroenterology-Hepatology	Allergan Pharmaceuticals International Limited	08/06/2021	P/0216/2021
Venetoclax	Venclyxto	PM	Oncology / Haematology-Hemostaseology	AbbVie Ltd	09/06/2021	P/0217/2021
Synthetic hypericin		W	Oncology	Soligenix NL B.V	08/06/2021	P/0218/2021
Immunoglobulin G4 [449-cysteine], anti-(human vascular endothelial growth factor A) (human-Mus musculus monoclonal OG1950 gamma-4-chain), disulfide with human-Mus musculus monoclonal OG1950 kappa-chain, (232 - 232'),(235 - 235')-bis(disulfide) with immunoglobulin G4 anti-(human vascular endothelial growth factor A) (human-Mus musculus monoclonal OG1950 gamma-4-chain) disulfide with human-Mus musculus monoclonal OG1950 kappa-chain, 449-thioether with 1,1'-[2-[11,11-bis[15-bromo-11,11-bis[(2-bromo-2-methyl-1-oxopropoxy)methyl]-15-methyl-3,7,14-trioxo-9,13-dioxa-2,6-diazahexadec-1-yl]-44-(3-mercapto-2,5-dioxo-1-pyrrolidinyl)-		W	Ophthalmology	Kodiak Sciences Inc.	09/06/2021	P/0219/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
4,8,26,42-tetraoxo-2,13,16,19,22,29,32,35,38-nonaoxa-5,9,25,41-tetraazatetratetracont-1-yl]-2-[(2-bromo-2-methyl-1-oxopropoxy)methyl]-1,3-propanediyl] bis(2-bromo-2-methylpropanoate) core 9-arm star compd. with 4-hydroxy-N,N,N,10-tetramethyl-9-oxo-3,5,8-trioxa-4-phosphaundec-10-en-1-aminium inner salt 4-oxide homopolymer (KSI-301)						
Liquid ethalonic 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 HEALHCARE	09/06/2021	P/0220/2021
bamlanivimab		P	Infectious Diseases	Eli Lilly and Company Limited	09/06/2021	P/0221/2021
Iscalimab		P	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	08/06/2021	P/0222/2021
Erdafitinib		P	Oncology	Janssen-Cilag International N.V.	08/06/2021	P/0223/2021
Talazoparib	Talzenna	P	Oncology	Pfizer Europe MA EEIG	09/06/2021	P/0224/2021
Human plasma derived C1-inhibitor (OCTA-C1-INH)		P	Immunology-Rheumatology-Transplantation	Octapharma Pharmazeutika Produktionsges.m.b.H	09/06/2021	P/0225/2021

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Sotagliflozin	Zynquista	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Guidehouse Germany GmbH	08/06/2021	P/0226/2021
Sotatercept		P	Cardiovascular Diseases	Merck Sharp & Dohme B.V.	08/06/2021	P/0227/2021
3,4-Dimethoxy-N-methylbenzohydroxamic acid / Deferoxamine mesylate / Alpha-ketoglutaric acid / Arginine / Alanine / Glycine / Aspartic acid / Tryptophan / N-acetyl-histidine (monohydrate) / Histidine / Calcium chloride (dihydrate) / Magnesium chloride (hexahydrate) / Potassium chloride / Sodium chloride		P	Cardiovascular Diseases	Dr. Franz Köhler Chemie GmbH	09/06/2021	P/0228/2021
Atropine sulfate		P	Ophthalmology	Nevakar Inc.	08/06/2021	P/0229/2021
Ravulizumab	Ultomiris	P	Neurology	Alexion Europe SAS	08/06/2021	P/0230/2021
Savolitinib		W	Oncology	AstraZeneca AB	08/06/2021	P/0231/2021
Betibeglogene autotemcel	Zynteglo	PM	Haematology-Hemostaseology	bluebird bio (Netherlands) B.V.	16/06/2021	P/0232/2021
Ozanimod (hydrochloride)	Zeposia	PM	Gastroenterology-Hepatology	Celgene Europe B.V.	08/06/2021	P/0233/2021
Regdanvimab		P	Infectious Diseases	Celltrion Healthcare Hungary Kft.	08/06/2021	P/0234/2021
Cilgavimab (AZD1061)		P	Infectious Diseases	AstraZeneca AB	08/06/2021	P/0235/2021
Tixagevimab (AZD8895)		P	Infectious Diseases	AstraZeneca AB	08/06/2021	P/0236/2021
Nivolumab	Opdivo	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	14/06/2021	P/0237/2021
Ravulizumab	Ultomiris	PM	Uro-nephrology / Haematology-Hemostaseology	Alexion Europe SAS	17/06/2021	P/0238/2021

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Ravulizumab	Ultomiris	PM	Uro-nephrology / Haematology-Hemostaseology	Alexion Europe SAS	17/06/2021	P/0239/2021
Sotrovimab		P	Infectious Diseases	GlaxoSmithKline (Ireland) Ltd	17/06/2021	P/0240/2021
Oseltamivir (phosphate)	Tamiflu	PM	Infectious Diseases	Roche Registration GmbH	25/06/2021	P/0241/2021
Macitentan	Opsumit	P	Cardiovascular Diseases	Janssen-Cilag International N.V.	07/07/2021	P/0242/2021
Finerenone		P	Cardiovascular Diseases	Bayer AG	09/07/2021	P/0243/2021
Ralinepag		P	Cardiovascular Diseases	United Therapeutics Corporation	09/07/2021	P/0244/2021
(4R,5R)-1-[[4-[[4-[3,3-dibutyl-7-(dimethylamino)-2,3,4,5-tetrahydro-4-hydroxy-1,1-dioxido-1-benzothiepin-5-yl]phenoxy]methyl]phenyl]methyl]-4-aza-1-azoniabicyclo[2.2.2]octane chloride		P	Gastroenterology-Hepatology	Mirum Pharmaceuticals Inc.	09/07/2021	P/0245/2021
odevixibat		P	Gastroenterology-Hepatology	Albireo AB	09/07/2021	P/0246/2021
Allogeneic skin-derived ATP-binding cassette, sub-family B, member 5 (ABCB5)-positive mesenchymal stem cells (allo-APZ2-EB)		P	Dermatology	RHEACELL GmbH & Co. KG	09/07/2021	P/0247/2021
ibalizumab		PM	Infectious Diseases	Theratechnologies Europe Limited	09/07/2021	P/0248/2021
Dapagliflozin (propanediol monohydrate) / Zibotentan		W	Other	AstraZeneca AB	09/07/2021	P/0249/2021

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Guselkumab	Tremfya	PM	Immunology-Rheumatology-Transplantation	Janssen-Cilag International NV	09/07/2021	P/0250/2021
Human Papilloma Virus Type 16 E6 001-032/Human Papilloma Virus Type 16 E6 019-050/Human Papilloma Virus Type 16 E6 041-065/Human Papilloma Virus Type 16 E6 055-080/Human Papilloma Virus Type 16 E6 085-109/Human Papilloma Virus Type 16 E6 091-122/Human Papilloma Virus Type 16 E6 127-158 / Human Papilloma Virus Type 16 E6 071-095/Human Papilloma Virus Type 16 E6 109-140/Human Papilloma Virus Type 16 E7 001-035/Human Papilloma Virus Type 16 E7 022-056/Human Papilloma Virus Type 16 E7 064-098		W	Oncology	ISA Therapeutics B.V.	09/07/2021	P/0251/2021
Anti-C1s Humanized IgG4 Monoclonal Antibody		W	Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology / Neurology	Genzyme Europe B.V.	09/07/2021	P/0252/2021
Nemolizumab		PM	Dermatology	Galderma International S.A.	09/07/2021	P/0253/2021
Cobicistat / darunavir	Rezolsta	PM	Infectious Diseases	Janssen-Cilag International NV	09/07/2021	P/0254/2021
Romosozumab	Evenity	PM	Endocrinology-Gynaecology-Fertility-Metabolism	UCB Pharma S.A.	09/07/2021	P/0255/2021

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Vupanorsen		W	Cardiovascular Diseases	Pfizer Europe MA EEIG	09/07/2021	P/0256/2021
Peramivir	Alpivab	PM	Infectious Diseases	BioCryst Ireland Limited	07/07/2021	P/0257/2021
[18F]CTT1057		W	Oncology	Advanced Accelerator Applications SA	09/07/2021	P/0258/2021
Datopotamab deruxtecan		W	Oncology	Daiichi Sankyo Europe GmbH	09/07/2021	P/0259/2021
Vaborbactam / meropenem (trihydrate)	Vaborem	PM	Infectious Diseases	Menarini International Operations Luxembourg S.A.	09/07/2021	P/0260/2021
Bis-choline tetrathiomolybdate (ALXN1840)		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Alexion Europe S.A.S.	07/07/2021	P/0261/2021
Mannitol		W	Gastroenterology-Hepatology	NTC Srl	07/07/2021	P/0262/2021
Selatogrel		W	Cardiovascular Diseases	Idorsia Pharmaceuticals Deutschland GmbH	07/07/2021	P/0263/2021
Lanadelumab	Takhzyro	PM	Other	Takeda Pharmaceuticals International AG Ireland Branch	07/07/2021	P/0264/2021
Autologous selected renal cells		P	Uro-nephrology	ProKidney	07/07/2021	P/0265/2021
COVID-19 Vaccine (ChAdOx1-S [recombinant])	Vaxzevria	PM	Vaccines	AstraZeneca AB	07/07/2021	P/0266/2021
Dolutegravir	Tivicay	PM	Infectious Diseases	ViiV Healthcare UK Limited	09/07/2021	P/0267/2021
Canagliflozin	Invokana	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Janssen-Cilag International NV	09/07/2021	P/0268/2021

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Tenofovir alafenamide	Vemlidy	PM	Infectious Diseases	Gilead Sciences International Ltd.	09/07/2021	P/0269/2021
Cotadutide		PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	09/07/2021	P/0270/2021
Pralsetinib		P	Oncology	Roche Registration GmbH	09/07/2021	P/0271/2021
Rilzabrutinib		PM	Immunology-Rheumatology-Transplantation	Principia Biopharma, Inc.	08/07/2021	P/0272/2021
Cotadutide		PM	Immunology-Rheumatology-Transplantation	AstraZeneca AB	08/07/2021	P/0273/2021
Garadacimab		PM	Haematology-Hemostaseology	CSL Behring GmbH	08/07/2021	P/0274/2021
Trastuzumab deruxtecan	Enhertu	W	Oncology	Daiichi Sankyo Europe GmbH	08/07/2021	P/0275/2021
Patritumab deruxtecan		W	Oncology	Daiichi Sankyo Europe GmbH	08/07/2021	P/0276/2021
Recombinant monoclonal antibody to sialic acid-binding Ig-like lectin 8 (AK002)		P	Gastroenterology-Hepatology	Allakos Inc	08/07/2021	P/0277/2021
DTX401 (AAV8G6PC)		P	Endocrinology-Gynaecology-Fertility-Metabolism	Ultragenyx Germany GmbH	08/07/2021	P/0278/2021
Datopotamab deruxtecan		W	Oncology	Daiichi Sankyo Europe GmbH	16/07/2021	P/0279/2021
Bardoxolone methyl		P	Uro-nephrology	Reata Pharmaceuticals Inc.	16/07/2021	P/0280/2021
Quizartinib		PM	Oncology	Daiichi Sankyo Europe GmbH	16/07/2021	P/0281/2021
cabozantinib	Cometriq, Cabometyx	PM	Oncology	Ipsen Pharma	19/07/2021	P/0282/2021

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Empagliflozin	Jardiance	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	29/10/2021	P/0283/2021
Human Immunoglobulin G1 constant region – human ectodysplasin-A1 receptor-binding domain fusion protein (ER004)		P	Dermatology	EspeRare Foundation	28/07/2021	P/0284/2021
Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid (MenACYW)	Menquadfi	PM	Vaccines	Sanofi Pasteur	29/07/2021	P/0285/2021
Lebrikizumab		PM	Dermatology	Eli Lilly and Company Limited	11/08/2021	P/0286/2021
Fasinumab		PM	Pain	Regeneron Ireland D.A.C.	12/08/2021	P/0287/2021
Gemcitabine (hydrochloride)		W	Oncology	Janssen-Cilag International NV	13/08/2021	P/0288/2021
Cetrelimab		W	Oncology	Janssen-Cilag International NV	11/08/2021	P/0289/2021
Bentracimab		W	Cardiovascular Diseases	PhaseBio Pharmaceuticals Inc.	11/08/2021	P/0290/2021
Seltorexant [(3aR,6aS)-5-(4,6-dimethylpyrimidin-2-yl)hexahydropyrrolo[3,4-c]pyrrol-2(1H)-yl][2-fluoro-6-		PM	Psychiatry	Janssen-Cilag International NV	13/08/2021	P/0291/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
(2H-1,2,3-triazol-2-yl)phenyl]methanone						
Tralokinumab		PM	Dermatology	LEO Pharma A/S	11/08/2021	P/0292/2021
Cemiplimab	Cemiplimab	PM	Oncology	Regeneron Ireland DAC	12/08/2021	P/0293/2021
Aldafermin		W	Gastroenterology-Hepatology	NGM Biopharmaceuticals, Inc.	11/08/2021	P/0294/2021
Xylitol / Procaine (hydrochloride) / Magnesium (sulphate heptahydrate) / Potassium (chloride)		PM	Other	MIT Gesundheit GmbH	11/08/2021	P/0295/2021
Anti-respiratory syncytial virus human IgG1κ monoclonal antibody (MEDI8897)		PM	Vaccines	AstraZeneca AB	11/08/2021	P/0296/2021
Hydrochlorothiazide / Amlodipine / Ramipril		W	Cardiovascular Diseases	Swyssi AG	11/08/2021	P/0297/2021
Finerenone		PM	Uro-nephrology	Bayer AG	11/08/2021	P/0298/2021
Immunoglobulin G1 anti-SORT1 human monoclonal antibody		W	Neurology	Alector, Inc.	11/08/2021	P/0299/2021
cenobamate		PM	Neurology	A.C.R.A.F. SpA	13/08/2021	P/0300/2021
Phenobarbital		PM	Neurology	Proveca Pharma Limited	13/08/2021	P/0301/2021
Rurioctocog alfa pegol	Adynovi	PM	Haematology-Hemostaseology	Baxalta Innovations GmbH	11/08/2021	P/0302/2021
Tocilizumab	Roactemra	PM	Immunology-Rheumatology-Transplantation	Roche Registration GmbH	13/08/2021	P/0303/2021
Hepatitis B (rDNA) surface antigen adjuvanted	Heplisav b	PM	Vaccines	Dynavax GmBH	11/08/2021	P/0304/2021

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Ocrelizumab	Ocrevus	PM	Neurology	Roche Registration GmbH	13/08/2021	P/0305/2021
Empagliflozin	Jardiance	W	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	14/09/2021	P/0306/2021
Monovalent, live, recombinant, replication-incompetent adenoviral serotype 26 vectored vaccine expressing the full length glycoprotein of the Ebola virus Mayinga variant [Ad26.ZEBOV]	Zabdeno	PM	Vaccines	Janssen Cilag International NV	12/08/2021	P/0307/2021
Ligelizumab		PM	Dermatology	Novartis Europharm Limited	11/08/2021	P/0308/2021
Liraglutide	Saxenda	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	13/08/2021	P/0309/2021
Vortioxetine	Brintellix	PM	Psychiatry	H. Lundbeck A/S	13/08/2021	P/0310/2021
Baricitinib	Olumiant	PM	Dermatology	Eli Lilly and Company Limited	11/08/2021	P/0311/2021
Semaglutide / insulin icodec		W	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	11/08/2021	P/0312/2021
Temelimab		W	Neurology	GeNeuro SA	12/08/2021	P/0313/2021
Lactobacillus reuteri (IBP-9414)		PM	Other / Neonatology - Paediatric Intensive Care / Gastroenterology-Hepatology	Infant Bacterial Therapeutics AB	11/08/2021	P/0314/2021
In vitro expanded autologous human articular chondrocytes		W	Other	TETEC Tissue Engineering Technologies AG	12/08/2021	P/0315/2021

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Ferric maltol	Feraccru	PM	Haematology-Hemostaseology	Norgine BV	11/08/2021	P/0316/2021
Ublituximab		P	Neurology	TG Therapeutics, Inc	11/08/2021	P/0317/2021
Vatiquinone		P	Neurology	PTC Therapeutics International Limited	11/08/2021	P/0318/2021
Fenebrutinib		P	Immunology-Rheumatology-Transplantation	Roche Registration GmbH	13/08/2021	P/0319/2021
Human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (KHK4083)		P	Dermatology	Amgen Europe B.V.	13/08/2021	P/0320/2021
Allogeneic anti-CD19 CAR T cells produced using CRISPR/Cas9 to disrupt the T cell receptor alpha constant (TRAC) and β2-microglobulin (B2M) genomic loci and a recombinant adeno-associated viral vector to deliver donor template for insertion of the anti-CD19 CAR expression cassette into the TRAC locus (CTX110)		P	Oncology	CRISPR Therapeutics AG	11/08/2021	P/0321/2021
Iptacopan		P	Other / Haematology-Hemostaseology	Novartis Europharm Limited	12/08/2021	P/0322/2021
Afamitresgene autoleucel		P	Oncology	Adaptimmune Ltd	12/08/2021	P/0323/2021
(1R,3S,5R)-2-(2-(3-acetyl-5-(2-methylpyrimidin-5-yl)-1H-indazol-1-yl)acetyl)-N-(6-bromo-3-methylpyridin-2-yl)-5-methyl-2-		P	Haematology-Hemostaseology	Alexion Europe SAS	11/08/2021	P/0324/2021

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azabicyclo[3.1.0]hexane-3-carboxamide (ALXN2050)						
Deucravacitinib		P	Immunology-Rheumatology-Transplantation	Bristol-Myers Squibb International Corporation	12/08/2021	P/0325/2021
Sivopixant		W	Pneumology - Allergology	Shionogi B.V.	13/08/2021	P/0326/2021
Sacubitril/valsartan	Entresto, neparvis	PM	Cardiovascular Diseases	Novartis Europharm Ltd.	13/08/2021	P/0327/2021
Selexipag	Uptravi	PM	Other	Janssen-Cilag International NV	13/08/2021	P/0328/2021
Dupilumab	Dupixent	PM	Dermatology	Regeneron Pharmaceuticals, Inc	11/08/2021	P/0329/2021
Zidebactam / cefepime		P	Neonatology - Paediatric Intensive Care / Infectious Diseases / Uro-nephrology	Wockhardt Bio AG	11/08/2021	P/0330/2021
Infigratinib		P	Endocrinology-Gynaecology-Fertility-Metabolism	QED Therapeutics Inc.	13/08/2021	P/0331/2021
Giroctocogene fitelparvovec		PM	Haematology-Hemostaseology	Pfizer Europe MA EEIG	05/08/2021	P/0332/2021
Tocilizumab	Roactemra	P	Immunology-Rheumatology-Transplantation	Roche Registration GmbH	27/07/2021	P/0333/2021
Multivalent, live, recombinant, non-replicating in human cells, Modified Vaccinia Ankara vectored vaccine, expressing the EBOV Mayinga glycoprotein, the	Mvabea	PM	Vaccines	Janssen Cilag International NV	19/08/2021	P/0334/2021

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Sudan virus Gulu GP, the Marburg virus Musoke GP, and the Taï Forest virus nucleoprotein [MVA-BN-Filo]						
gabapentin		W	Pain / Neurology	Alvogen Malta Out-licensing Ltd.	12/08/2021	P/0335/2021
Sirolimus		PM	Ophthalmology	Santen Incorporated	11/08/2021	P/0336/2021
Ibrutinib	Imbruvica	PM	Oncology	Janssen-Cilag International N.V.	11/08/2021	P/0337/2021
Remdesivir	Veklury	PM	Infectious Diseases	Gilead Sciences International Ltd.	09/08/2021	P/0338/2021
Baricitinib	Olumiant	P	Immunology-Rheumatology-Transplantation	Eli Lilly and Company Limited	09/08/2021	P/0339/2021
Bumetanide		PM	Neurology	Les Laboratoires Servier	09/08/2021	P/0340/2021
Selumetinib		PM	Oncology	AstraZeneca AB	12/08/2021	P/0341/2021
Bupivacaine	Exparel liposomal	PM	Pain	Pacira Ltd	09/08/2021	P/0342/2021
Pneumococcal Polysaccharide Serotype 33F - Diphtheria CRM197 Conjugate (15-valent pneumococcal polysaccharide conjugate vaccine [V114]) / Pneumococcal Polysaccharide Serotype 23F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19F - Diphtheria		PM	Vaccines	Merck Sharp & Dohme (Europe), Inc.	09/08/2021	P/0343/2021

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CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 18C - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 14 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9V - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6B - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 5 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 4 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 3 - Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 1 - Diphtheria CRM197 Conjugate						
Epcoritamab		P	Oncology	AbbVie Ltd	12/08/2021	P/0344/2021
Molnupiravir		P	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	12/08/2021	P/0345/2021

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Pegylated-fibroblast growth factor 21 (BMS-986036)		PM	Gastroenterology-Hepatology	Bristol-Myers Squibb International Corporation	18/08/2021	P/0346/2021
Casirivimab (REGN10933)		P	Infectious Diseases	Regeneron Ireland DAC	16/08/2021	P/0347/2021
Imdevimab (REGN10987)		P	Infectious Diseases	Regeneron Ireland DAC	16/08/2021	P/0348/2021
Lacosamide	Vimpat	PM	Neurology	UCB Pharma S.A.	20/08/2021	P/0349/2021
Aztreonam (ATM) / Avibactam (AVI)		PM	Infectious Diseases	Pfizer Europe MA EEIG	08/09/2021	P/0350/2021
Entrectinib	Rozlytrek	PM		Roche Registration GmbH	08/09/2021	P/0351/2021
Florbetaben (18F)	Neuraceq	W		Life Molecular Imaging GmbH	08/09/2021	P/0352/2021
Berotralstat		PM	Pneumology - Allergology	BioCryst Ireland Limited	08/09/2021	P/0353/2021
Ociperlimab		W	Oncology	BeiGene Ireland Limited	08/09/2021	P/0354/2021
Ligelizumab		P	Dermatology	Novartis Europharm Limited	08/09/2021	P/0355/2021
Rubidium Rb-82 Chloride	Ruby-fill (82sr/82rb Generator)	PM	Diagnostic	Jubilant DraxImage Inc., dba Jubilant Radiopharma	08/09/2021	P/0356/2021
Pevonedistat		PM	Oncology	Takeda Pharma A/S	08/09/2021	P/0357/2021
Amikacin sulfate		PM	Pneumology - Allergology	Insmed Netherlands B.V.	08/09/2021	P/0358/2021
Prasterone / levonorgestrel / ethinylestradiol		W	Endocrinology-Gynaecology-Fertility-Metabolism	Gedeon Richter Plc.	08/09/2021	P/0359/2021

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Avalglucosidase alfa		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Genzyme Europe B.V.	08/09/2021	P/0360/2021
Dupilumab	Dupixent	PM	Gastroenterology-Hepatology	Regeneron Ireland DAC	08/09/2021	P/0361/2021
Mometasone (furoate) / Glycopyrronium (bromide) / Indacaterol (acetate)	Enerzair Breezhaler and its duplicate authorization Zimbus Breezhaler	PM	Pneumology - Allergology	Novartis Europharm Limited	08/09/2021	P/0362/2021
Autologous tumor-infiltrating lymphocytes (LN-144/LN-145)		PM	Oncology	Iovance Biotherapeutics, Inc.	08/09/2021	P/0363/2021
Selinexor	Nexpovio	W	Oncology	Karyopharm Europe GmbH	08/09/2021	P/0364/2021
Mexiletine (hydrochloride)		PM	Other	Lupin Europe GmbH	08/09/2021	P/0365/2021
Bisoprolol (fumarate) / amlodipine / indapamide / perindopril (arginine)		W	Cardiovascular Diseases	Les Laboratoires Servier	08/09/2021	P/0366/2021
Patiromer calcium	Veltassa	PM	Other	Vifor Fresenius Medical Care Renal Pharma France	08/09/2021	P/0367/2021
Bosutinib	Bosulif	PM	Oncology	Pfizer Europe MA EEIG	08/09/2021	P/0368/2021
Recombinant parathyroid hormone	Natpar	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Takeda Pharmaceuticals International AG Ireland Branch	08/09/2021	P/0369/2021
Narsoplimab		PM	Haematology-Hemostaseology	Omeros Ireland Limited	08/09/2021	P/0370/2021
Concizumab		P	Haematology-Hemostaseology	Novo Nordisk A/S	08/09/2021	P/0371/2021
Ligelizumab		P	Pneumology - Allergology	Novartis Europharm Limited	08/09/2021	P/0372/2021

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Multivalent pneumococcal polysaccharide conjugate to carrier protein (SP0202)		P	Vaccines	Sanofi Pasteur	08/09/2021	P/0373/2021
Recombinant Clostridioides difficile toxoid A / recombinant Clostridioides difficile toxoid B		PM	Vaccines	Pfizer Europe MA EEIG	08/09/2021	P/0374/2021
Cendakimab		P	Gastroenterology-Hepatology	Celgene Europe B.V.	08/09/2021	P/0375/2021
Prednisolone		W	Oncology	Alfred E. Tiefenbacher (GmbH & Co. KG)	08/09/2021	P/0376/2021
Sodium chloride solution 4.2% (P-1037 inhalation solution) / 3,5-diamino-6-chloro-N-(N-(4-(4-(2-(hexyl((2S,3R,4R,5R)-2,3,4,5,6-pentahydroxyhexyl)amino)ethoxy)phenyl)butyl)-carbamimidoyl)pyrazine-2-carboxamide		P	Pneumology - Allergology	Parion Sciences, Inc.	02/09/2021	P/0377/2021
Potassium Bitartrate / Citric Acid / L-Lactic Acid		W	Infectious Diseases	Evofem, Inc.	08/09/2021	P/0378/2021
Naldemedine		PM	Gastroenterology-Hepatology	Shionogi B.V.	08/09/2021	P/0379/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Pneumococcal polyssacharide serotype 33F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 12F conjugated to		PM	Vaccines	Pfizer Europe MA EEIG	08/09/2021	P/0380/2021

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CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 7F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 6A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 1 conjugated to CRM197 carrier protein and adsorbed on aluminium						

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phosphate / Pneumococcal polyssacharide serotype						

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Azithromycin		P	Neonatology - Paediatric Intensive Care	Aspire Pharma Limited	08/09/2021	P/0381/2021
Fidanacogene elaparvovec		PM	Haematology-Hemostaseology	Pfizer Europe MA EEIG	08/09/2021	P/0382/2021
Tolvaptan	Samsca, Jinarc	PM	Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology	Otsuka Pharmaceutical Netherlands B.V.	08/09/2021	P/0383/2021
Atezolizumab	Tecentriq	W	Oncology	Roche Registration GmbH	08/09/2021	P/0384/2021
Eliglustat	Cerdelga	PM	Other	Genzyme Europe B.V.	08/09/2021	P/0385/2021
Brodalumab		PM	Dermatology	LEO Pharma A/S	08/09/2021	P/0386/2021
Ribitol		P	Other	Premier Research Group S.L.	08/09/2021	P/0387/2021
Benralizumab	Fasenra	P	Gastroenterology-Hepatology	AstraZeneca AB	08/09/2021	P/0388/2021
Metreleptin	Myalepta	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Amryt Pharmaceuticals DAC	08/09/2021	P/0389/2021
Bupropion (hydrochloride) / Naltrexone (hydrochloride)		PM	Other	Orexigen Therapeutics Ireland Limited	08/09/2021	P/0390/2021
Single chain urokinase plasminogen activator (scuPA)		P	Pneumology - Allergology	Lung Therapeutics, Inc.	08/09/2021	P/0391/2021
Efgartigimod alfa		P	Neurology	argenx BV	08/09/2021	P/0392/2021
Dasiglucagon		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Zealand Pharma A/S	08/09/2021	P/0393/2021
Solriamfetol		PM	Neurology	Jazz Pharmaceuticals Ireland Limited	08/09/2021	P/0394/2021

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Rezafungin acetate		PM		Mundipharma Corporation (Ireland) Limited	08/09/2021	P/0395/2021
BNT162b2 / Tozinameran	Comirnaty	PM	Infectious Diseases	BioNTech Manufacturing GmbH	25/08/2021	P/0396/2021
Human Thrombin / Human Fibrinogen	Evicel, evarrest	PM	Other	Omrix Biopharmaceuticals N.V.	08/09/2021	P/0397/2021
Selpercatinib	Retsevmo	PM	Oncology	Eli Lilly and Company	30/09/2021	P/0398/2021
Ravulizumab	Ultomiris	P	Uro-nephrology / Haematology-Hemostaseology	Alexion Europe SAS	30/09/2021	P/0399/2021
Loncastuximab tesirine		P	Oncology	ADC Therapeutics SA	01/10/2021	P/0400/2021
5'-capped mRNA encoding HPV16 oncoprotein E6 and E7 / 5'-capped mRNA encoding HPV16 oncoprotein E6 and E7		W	Oncology	BioNTech SE	30/09/2021	P/0401/2021
mirabegron	Betmiga	PM	Uro-nephrology	Astellas Pharma Europe B.V.	01/10/2021	P/0402/2021
Brensocatib		P	Pneumology - Allergology	Insmed Netherlands B.V.	01/10/2021	P/0403/2021
ganaxolone		PM	Neurology	Marinus Pharmaceuticals Inc.	01/10/2021	P/0404/2021
Brigatinib	Alunbrig	PM	Oncology	Takeda Pharm A/S	01/10/2021	P/0405/2021
Ivacaftor / tezacaftor	Symkevi	PM	Other / Pneumology - Allergology	Vertex Pharmaceuticals (Ireland) Limited	30/09/2021	P/0406/2021
Islatravir		P	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	08/10/2021	P/0407/2021

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Acalabrutinib	Calquence	PM	Oncology	Acerta Pharma, BV	08/10/2021	P/0408/2021
Dulaglutide	Trulicity	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Eli Lilly and Company	29/10/2021	P/0409/2021
Pyridoxine (hydrochloride) / doxylamine (succinate)	Bonjesta	W	Endocrinology-Gynaecology-Fertility-Metabolism	EXELTIS HEALTHCARE S.L.	29/10/2021	P/0410/2021
Ezetimibe / rosuvastatin	Lipocomb, Rosulip Plus, Cholecomb, Liporosa, Rosuvastatin/ezetimibe EGIS, Delipid Plus, Ridutrin, Rosulip, Ayadont	W	Cardiovascular Diseases	Egis Pharmaceuticals PLC	29/10/2021	P/0411/2021
Leriglitazone		PM	Neurology	Minoryx Therapeutics S.L.	29/10/2021	P/0412/2021
Ravulizumab	Ultomiris	W	Neurology	Alexion Europe SAS	29/10/2021	P/0413/2021
Recombinant Human A Disintegrin and Metalloprotease with Thrombospondin Type-1 Motifs 13		PM	Haematology-Hemostaseology	Baxalta Innovations GmbH	29/10/2021	P/0414/2021
ozanimod (hydrochloride)	Zeposia	PM	Neurology	Celgene Europe B.V.	29/10/2021	P/0415/2021
Ivacaftor / Tezacaftor / Elexacaftor	Kaftrio	PM	Other / Pneumology - Allergology	Vertex Pharmaceuticals (Ireland) Limited	29/10/2021	P/0416/2021
Depemokimab		W	Pneumology - Allergology	GlaxoSmithKline Trading Services Limited	29/10/2021	P/0417/2021
Temozolomide		PM	Oncology	Accord Healthcare S.L.U.	29/10/2021	P/0418/2021
Anti-neonatal Fc receptor human monoclonal antibody		W	Neurology	Janssen-Cilag International NV	29/10/2021	P/0419/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
B cell maturation antigen antibody-drug conjugate comprised of an immunoglobulin G1 humanized antibody conjugated covalently to the dibenzocyclooctyne noncleavable linker maytansinoid warhead (BMS-986352)		W	Oncology	Bristol-Myers Squibb International Corporation	29/10/2021	P/0420/2021
Alnuctamab		W	Oncology	Bristol-Myers Squibb International Corporation	29/10/2021	P/0421/2021
Rusfertide		W	Haematology-Hemostaseology	Protagonist Therapeutics, Inc.	29/10/2021	P/0422/2021
Edoxaban (tosylate)	Lixiana film coated tablets	PM	Cardiovascular Diseases / Haematology-Hemostaseology	Daiichi Sankyo Europe GmbH	29/10/2021	P/0423/2021
Imatinib (as imatinib mesylate)		PM	Oncology	Accord Healthcare S.L.U.	29/10/2021	P/0424/2021
Anti-CD123 IgG1 humanised monoclonal antibody conjugated to N1-(2-(2,5-dioxo-2,5-dihydro-1H-pyrrol-1-yl)ethyl)-N6-((S)-1-(((S)-1-((3-((((S)-8-methoxy-6-oxo-11,12,12a,13-tetrahydro-6H-benzo[5,6][1,4]diazepino[1,2-a]indol-9-yl)oxy)methyl)-5-((((S)-8-methoxy-6-oxo-12a,13-dihydro-6Hbenzo[5,6][1,4]diazepino[1,2-a]indol-9-yl)oxy)methyl)phenyl)amino)-		W	Oncology	Immunogen BioPharma (Ireland) Limited	29/10/2021	P/0425/2021

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1-oxopropan-2-yl)amino)-1-oxopropan-2-yl)adipamide						
palbociclib	Ibrance	PM	Oncology	Pfizer Europe MA EEIG	29/10/2021	P/0426/2021
Remimazolam	Byfavo	PM	Anaesthesiology	PAION Deutschland GmbH	29/10/2021	P/0427/2021
Pralsetinib		W	Oncology	Roche Registration GmbH	29/10/2021	P/0428/2021
Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)		PM	Vaccines	Merck Sharp & Dohme (Europe), Inc.	29/10/2021	P/0429/2021
Fostemsavir (tromethamine)	Rukobia	PM	Infectious Diseases	ViiV Healthcare UK Ltd	29/10/2021	P/0430/2021
Batiraxcept		W	Oncology	Aravive, Inc	29/10/2021	P/0431/2021
izaflortaucipir (18F)		W	Neurology	Life Molecular Imaging GmbH	29/10/2021	P/0432/2021
Lutetium (177Lu) chloride		W	Other	Eckert & Ziegler Radiopharma GmbH	29/10/2021	P/0433/2021
Anti-C1s Humanized IgG4 Monoclonal Antibody		W	Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology / Neurology	Genzyme Europe B.V.	29/10/2021	P/0434/2021
Perflubutane		**RW**	Diagnostic / Oncology	GE Healthcare AS	22/11/2021	P/0435/2021

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amlodipine / zofenopril (calcium)		W	Cardiovascular Diseases	Menarini Ricerche S.p.A.	29/10/2021	P/0436/2021
Humanized monoclonal antibody of igg1 sub-type targeting the human SEMA3A polypeptide		W	Ophthalmology	Boehringer Ingelheim International GmbH	29/10/2021	P/0437/2021
Nintedanib	Vargatef, Ofev	PM	Pneumology - Allergology / Oncology	Boehringer Ingelheim International GmbH	29/10/2021	P/0438/2021
Abemaciclib	Verzenios	PM	Oncology	Eli Lilly and Company Limited	29/10/2021	P/0439/2021
Abemaciclib	Verzenios	PM	Oncology	Eli Lilly and Company Limited	29/10/2021	P/0440/2021
Recombinant human glutamic acid dexarboxylase (rhGAD65)		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Diamyd Medical AB	29/10/2021	P/0441/2021
Fluocinolone acetonide	Iluvien 190 micrograms intravitreal implant in applicator and associated names	PM	Ophthalmology	Alimera Sciences Limited	29/10/2021	P/0442/2021
Efgartigimod alfa		W	Neurology	argenx BV	29/10/2021	P/0443/2021
Single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2	Spikevax	PM	Vaccines / Infectious Diseases	MODERNA BIOTECH SPAIN, S.L.	22/11/2021	P/0444/2021
Senaparib		W	Oncology	IMPACT Therapeutics US, Inc.	29/10/2021	P/0445/2021
linagliptin	Trajenta	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Boehringer Ingelheim International GmbH	29/10/2021	P/0446/2021

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Oxalobacter formigenes Strain HC-1		PM	Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology	OxThera AB	29/10/2021	P/0447/2021
Ofloxacin / dexamethasone (sodium phosphate)		W	Ophthalmology	Laboratório Edol - Produtos Farmacêuticos S.A.	29/10/2021	P/0448/2021
Galcanezumab		PM	Neurology	Eli Lilly and Company Limited	29/10/2021	P/0449/2021
Terbinafine (hydrochloride)		P	Infectious Diseases	Moberg Pharma AB	29/10/2021	P/0450/2021
Drospirenone	Slinda and associated names	W	Endocrinology-Gynaecology-Fertility-Metabolism	Chemo Research, S.L.	29/10/2021	P/0451/2021
2-[(4-{6-[(4-cyano-2-fluorobenzyl)oxy]pyridin-2-yl}piperidin-1-yl)methyl]-1-[(2S)-oxetan-2-ylmethyl]-1H-benzimidazole-6-carboxylic acid tris(hydroxymethyl)aminomethane salt (1:1) (PF-06882961)		P	Endocrinology-Gynaecology-Fertility-Metabolism	Pfizer Europe MA EEIG	29/10/2021	P/0452/2021
Crisantaspase		P	Oncology	Jazz Pharmaceuticals Ireland Ltd.	29/10/2021	P/0453/2021
Adalimumab conjugated with (4S)-4-[2-(2-bromoacetamido)acetamido]-5-{3-[(4-{(4aR,4bS,5S,6aS,6bS,8R,9aR,10aS,10bS)-5-hydroxy-4a,6a-dimethyl-2-oxo-6b-[(phosphonooxy)acetyl]-4a,4b,5,6,6a,6b,9a,10,10a,10b,11,12-dodecahydro-2H,8H-		P	Immunology-Rheumatology-Transplantation	AbbVie Ltd	29/10/2021	P/0454/2021

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naphtho[2',1':4,5]indeno[1,2-d][1,3]dioxol-8-yl}phenyl)methyl] anilino}-5-oxopentanoic acid; (ABBV-154)						
Glepaglutide		P	Gastroenterology-Hepatology	Zealand Pharma A/S	29/10/2021	P/0455/2021
Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein/AS01		P	Vaccines	GlaxoSmithKline Biologicals SA	29/10/2021	P/0456/2021
LR 2006-OPY1 delta 5nsP3		P	Vaccines	Valneva Austria GmbH	29/10/2021	P/0457/2021
Pritelivir (mesylate monohydrate)		P	Infectious Diseases	AiCuris Anti-infective Cures AG	29/10/2021	P/0458/2021
Thienopyrimidine Derivative		P	Pneumology - Allergology	Boehringer Ingelheim International GmbH	29/10/2021	P/0459/2021
Oteseconazole		PM	Infectious Diseases	Gedeon Richter Plc.	29/10/2021	P/0460/2021
Semaglutide	Ozempic	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Novo Nordisk A/S	29/10/2021	P/0461/2021
Ezetimibe / Rosuvastatin		W	Cardiovascular Diseases	Qualipharmacon Kft.	29/10/2021	P/0462/2021
Propan-2-yl (2S)-2-{[(S)-({(2R,3R,4R,5R)-5-[2-amino-6-(methylamino)-9H-purin-9-yl]-4-fluoro-3- hydroxy-4-methyloxolan-2-yl}methoxy)(phenoxy)phosph		P	Infectious Diseases	Atea Pharmaceuticals, Inc.	29/10/2021	P/0463/2021

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oryl]amino}propanoate; sulfuric acid (2:1) (AT-527 / RO7496998)						
Semaglutide	Ozempic	P	Gastroenterology-Hepatology	Novo Nordisk A/S	29/10/2021	P/0464/2021
AZD8233 sodium, PCSK9-targeted, antisense oligonucleotide (ASO)		P	Cardiovascular Diseases	AstraZeneca AB	29/10/2021	P/0465/2021
Tocilizumab	Roactemra	**RW**	Immunology-Rheumatology-Transplantation	Roche Registration GmbH	29/10/2021	P/0466/2021
Pyridine-3-carboxamide derivative (K-161)		W	Ophthalmology	Kowa Pharmaceuticals Europe AG	29/10/2021	P/0467/2021
Sotrovimab		PM	Infectious Diseases	GlaxoSmithKline Trading Services Ltd	12/11/2021	P/0468/2021
Ezetimibe / Rosuvastatin		W	Cardiovascular Diseases	Sandoz s.r.o.	19/11/2021	P/0469/2021
Risdiplam	Evrysdi	PM	Neurology	Roche Registration GmbH	26/11/2021	P/0470/2021
Ofranergene obadenovec		W	Oncology	Vascular Biogenics Ltd. (VBL Therapeutics)	03/12/2021	P/0471/2021
Otenaproxesul		W	Pain	Antibe Therapeutics Inc.	03/12/2021	P/0472/2021
Neisseria meningitidis serogroup B Protein-based active substance / Recombinant Neisseria meningitidis serogroup B protein 1 / Recombinant Neisseria meningitidis		P	Vaccines	Sanofi Pasteur	03/12/2021	P/0473/2021

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serogroup B protein 3 / Recombinant Neisseria meningitidis serogroup B protein 2						
Ravulizumab	Ultomiris	P	Neurology	Alexion Europe SAS	21/12/2021	P/0474/2021
Erenumab	Aimovig	PM	Neurology	Novartis Europharm Limited	03/12/2021	P/0475/2021
Vericiguat		PM	Cardiovascular Diseases	Bayer AG	03/12/2021	P/0476/2021
Sodium zirconium cyclosilicate	Lokelma	PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	03/12/2021	P/0477/2021
Inotuzumab ozogamicin	Besponsa	PM	Oncology / Haematology-Hemostaseology	Pfizer Europe MA EEIG	03/12/2021	P/0478/2021
Isavuconazonium (sulfate)	Cresemba	PM	Infectious Diseases	Basilea Pharmaceutica International Ltd.	03/12/2021	P/0479/2021
Macitentan	Opsumit	PM	Cardiovascular Diseases	Janssen-Cilag International NV	03/12/2021	P/0480/2021
Marzeptacog alfa (activated)		P	Haematology-Hemostaseology	Catalyst Biosciences, Inc.	03/12/2021	P/0481/2021
Marzeptacog alfa (activated)		P	Haematology-Hemostaseology	Catalyst Biosciences, Inc.	03/12/2021	P/0482/2021
Severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine/ matrix-M1 adjuvant (NVX-CoV2373)		PM	Vaccines	Novavax CZ, a.s.	03/12/2021	P/0483/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
3,4-Dimethoxy-N-methylbenzohydroxamic acid / Deferoxamine mesylate / Alfa-ketoglutaric acid / Arginine / Alanine / Glycine / Aspartic acid / Tryptophan / N-acetyl-histidine (monohydrate) / Histidine / Calcium chloride (dihydrate) / Magnesium chloride (hexahydrate) / Potassium chloride / Sodium chloride		PM	Cardiovascular Diseases	Dr. Franz Köhler Chemie GmbH	03/12/2021	P/0484/2021
vibostolimab / pembrolizumab		W	Oncology	Merck, Sharp & Dohme (Europe) Inc	03/12/2021	P/0485/2021
Baloxavir marboxil	Xofluza	PM	Infectious Diseases	Roche Registration GmbH	03/12/2021	P/0486/2021
Larotrectinib	Vitrakvi	PM	Oncology	Bayer AG	03/12/2021	P/0487/2021
Furosemide / Eplerenone		W	Cardiovascular Diseases	Przedsiębiorstwo Farmaceutyczne LEK-AM Sp. z o.o.	03/12/2021	P/0488/2021
Inactivated poliovirus: type 3 (Saukett strain) / Inactivated poliovirus: type 2 (MEF-1 strain) / Inactivated poliovirus: type 1 (Mahoney strain) / Bordetella pertussis antigen: Pertactin / Bordetella pertussis antigen: Filamentous Haemagglutinin / Bordetella pertussis antigen: Pertussis toxoid / Tetanus toxoid / Diphtheria toxoid		W	Vaccines / Infectious Diseases	Vakzine Projekt Management GmbH	03/12/2021	P/0489/2021
Cyclophosphamide		PM	Oncology	Accord Healthcare S.L.U.	03/12/2021	P/0490/2021

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Soticlestat		PM	Neurology	Takeda Pharma A/S	03/12/2021	P/0491/2021
Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) [QIVc] / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)	Flucelvax tetra	PM	Vaccines	Seqirus Netherlands	03/12/2021	P/0492/2021
Naloxegol	Moventig	PM	Gastroenterology-Hepatology	Kyowa Kirin Pharmaceutical Development Limited	03/12/2021	P/0493/2021
Vonicog alfa	Veyvondi	PM	Haematology-Hemostaseology	Baxalta Innovations GmbH	03/12/2021	P/0494/2021
Regorafenib	Stivarga	PM	Oncology	Bayer AG	03/12/2021	P/0495/2021
Tecovirimat (monohydrate)		PM	Infectious Diseases	SIGA Technologies, Inc.	03/12/2021	P/0496/2021
Benralizumab	Fasenra	W	Pneumology - Allergology	AstraZeneca AB	03/12/2021	P/0497/2021
Oritavancin (diphosphate)	Orbactiv	PM	Infectious Diseases	Menarini International Operations Luxembourg S.A.	03/12/2021	P/0498/2021
Human alpha1-proteinase inhibitor		W	Pneumology - Allergology	Kamada Ireland Limited	03/12/2021	P/0499/2021

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Peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain (BI 456906)		P	Gastroenterology-Hepatology	Boehringer Ingelheim International GmbH	03/12/2021	P/0500/2021
Human normal immunoglobulin		P	Immunology-Rheumatology-Transplantation	Octapharma Pharmazeutika Produktionsges.m.b.H	03/12/2021	P/0501/2021
Fenfluramine (hydrochloride)		PM	Neurology	Zogenix International Ltd	02/12/2021	P/0502/2021
Lutetium (177Lu) oxodotreotide	Lutathera	P	Oncology	Advanced Accelerator Applications	03/12/2021	P/0503/2021
2'-O-(2-methoxyethyl) phosphorothioate antisense oligonucleotide targeting CD49d RNA (ATL1102)		P	Other	Antisense Therapeutics Limited	03/12/2021	P/0504/2021
Lumasiran (ALN-GO1)	Oxlumo	PM	Uro-nephrology	Alnylam UK Limited	03/12/2021	P/0505/2021
Cotadutide		W	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	03/12/2021	P/0506/2021
Pretomanid		PM	Infectious Diseases	Global Alliance for TB Drug Development	03/12/2021	P/0507/2021
Pamrevlumab		P	Oncology	FibroGen, Inc	03/12/2021	P/0508/2021
Molgramostim		PM	Pneumology - Allergology	Savara Aps	03/12/2021	P/0509/2021
Upadacitinib	Rinvoq	PM	Immunology-Rheumatology-Transplantation	AbbVie Ltd	03/12/2021	P/0510/2021
Adagrasib		W	Oncology	Mirati Therapeutics, Inc.	03/12/2021	P/0511/2021
Adavosertib		W	Oncology	AstraZeneca AB	03/12/2021	P/0512/2021
amlodipine (besilate) / Ramipril		W	Cardiovascular Diseases	1A Pharma GmbH	03/12/2021	P/0513/2021

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Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Evinacumab	Evkeeza	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Regeneron Ireland DAC	03/12/2021	P/0514/2021
Vamorolone		PM	Other	ReveraGen BioPharma Ltd	03/12/2021	P/0515/2021
Marstacimab		PM	Haematology-Hemostaseology	Pfizer Europe MAA EEIG	03/12/2021	P/0516/2021
Etranacogene dezaparvovec		P	Haematology-Hemostaseology	CSL Behring GmbH	02/01/2021	P/0517/2020
Evenamide		P	Psychiatry	Newron Pharmaceuticals SpA	03/12/2021	P/0517/2021
Perampanel	Fycompa	PM	Neurology	Eisai Europe Limited	03/12/2021	P/0521/2021
Dalbavancin hydrochloride	Xydalba	PM	Infectious Diseases	Allergan Pharmaceuticals International Limited	03/12/2021	P/0522/2021
Verdiperstat		W	Neurology	Biohaven Pharmaceutical Ireland DAC	03/12/2021	P/0523/2021
Rilpivirine / Dolutegravir	Juluca	PM	Infectious Diseases	ViiV Healthcare UK Limited	03/12/2021	P/0524/2021
Methoxyflurane	Penthrox	PM	Pain	Medical Developments UK Ltd	03/12/2021	P/0525/2021
Bilastine	Bilaxten and associated names	PM		Faes Farma S.A.	03/12/2021	P/0526/2021
Ruxolitinib (phosphate)	Jakavi	PM	Oncology	Novartis Europharm Limited	03/12/2021	P/0527/2021
Tenofovir alafenamide / Emtricitabine / Bictegravir	Biktarvy	PM	Infectious Diseases	Gilead Sciences International Ltd.	03/12/2021	P/0528/2021

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Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Ceftobiprole medocaril (sodium)	Zevtera and associated names	PM	Infectious Diseases	Basilea Pharmaceutica International Ltd.	03/12/2021	P/0529/2021
Azilsartan medoxomil	Edarbi	PM	Cardiovascular Diseases	Takeda Development Centre Europe Ltd	03/12/2021	P/0530/2021
Magrolimab		P	Oncology	Gilead Sciences International Ltd	03/12/2021	P/0531/2021
Satralizumab		P	Neurology	Roche Registration GmbH	03/12/2021	P/0532/2021
Crizanlizumab	Adakveo	PM	Haematology-Hemostaseology	Novartis Europharm Limited	09/12/2021	P/0533/2021
Pembrolizumab	Keytruda	PM	Oncology	Merck Sharp & Dohme (Europe), Inc.	03/12/2021	P/0534/2021
Eribulin	Halaven	PM	Oncology	Eisai GmbH	06/12/2021	P/0535/2021
Alpelisib	Piqray	PM	Other	Novartis Europharm Limited	03/12/2021	P/0536/2021
Exebacase		P	Infectious Diseases	ContraFect Corporation	09/12/2021	P/0537/2021
Efgartigimod alfa		W	Dermatology	argenx	31/12/2021	P/0538/2021
2'-O-(2-methoxyethyl) modified antisense oligonucleotide targeting glial fibrillary acidic protein pre-mRNA (ION373)		P	Neurology	Ionis Pharmaceuticals	31/12/2021	P/0539/2021
Tirzepatide		PM	Endocrinology-Gynaecology-Fertility-Metabolism	Eli Lilly and Company Ltd	31/12/2021	P/0540/2021
Nedosiran (DCR-PHXC)		PM	Uro-nephrology	Dicerna Ireland Limited	31/12/2021	P/0541/2021

Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Repotrectinib		P	Oncology	Premier Research SLU	31/12/2021	P/0542/2021
Vatiquinone		P	Neurology	PTC Therapeutics International	31/12/2021	P/0543/2021
Plitidepsin		W	Infectious Diseases	Pharma Mar, S.A.	31/12/2021	P/0544/2021
Avelumab	Bavencio	PM	Oncology	Merck Healthcare KGaA	31/12/2021	P/0546/2021
Tozinameran	Comirnaty	PM	Infectious Diseases	BioNTech Manufacturing GmbH	31/12/2021	P/0547/2021
Autologous CD34+ hematopoietic stem cells with a CRISPR-edited erythroid enhancer region of the BCL11A gene		P	Haematology-Hemostaseology	Vertex Pharmaceuticals (Ireland) Limited	31/12/2021	P/0548/2021
Autologous CD34+ hematopoietic stem cells with a CRISPR-edited erythroid enhancer region of the BCL11A gene		P	Haematology-Hemostaseology	Vertex Pharmaceuticals (Ireland) Limited	31/12/2021	P/0549/2021
Alirocumab	Praluent	PM	Endocrinology-Gynaecology-Fertility-Metabolism	sanofi-aventis recherche & développement	31/12/2021	P/0550/2021
Romosozumab	Evenity	PM	Endocrinology-Gynaecology-Fertility-Metabolism	UCB Pharma S.A.	31/12/2021	P/0551/2021
Vedolizumab	Entyvio	PM	Gastroenterology-Hepatology	Takeda Pharma A/S	31/12/2021	P/0552/2021
Molnupiravir		P	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	31/12/2021	P/0553/2021
Fully human igg1 RB-1 YTE anti-RSV F monoclonal antibody (MK-1654)		PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	31/12/2021	P/0554/2021
Leniolisib		P	Immunology-Rheumatology-Transplantation	Pharming Group N.V.	31/12/2021	P/0556/2021

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Active substance(s)	Invented name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Phenylephrine / Acetylcysteine / Paracetamol		W	Infectious Diseases / Oto-rhino-laryngology	HEXAL AG	31/12/2021	P/0557/2021
lisocabtagene maraleucel		PM	Oncology	Bristol-Myers Squibb Pharma EEIG	31/12/2021	P/0558/2021
COVID-19 Vaccine (ChAdOx1-S [recombinant])	Vaxzevria	PM	Vaccines	AstraZeneca AB	27/12/2021	P/0559/2021
Secukinumab	Cosentyx	W	Immunology-Rheumatology-Transplantation	Novartis Europharm Limited	31/12/2021	P/0560/2021
Estetrol / drospirenone	Lydisilka	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Estetra SRL	31/12/2021	P/0561/2021
Palovarotene		PM	Other	Ipsen Pharma	31/12/2021	P/0562/2021
Tosatoxumab		P	Infectious Diseases / Pneumology - Allergology	Aridis Pharmaceuticals Inc	31/12/2021	P/0563/2021
Humanised IgG2k Fc-modified bispecific antibody against CD3 and BCMA (PF-06863135)		W	Oncology	Pfizer Europe MA EEIG	31/12/2021	P/0564/2021
Glycopyrronium bromide		PM	Dermatology	Dr. August Wolff GmbH & Co. KG - Arzneimittel	21/12/2021	P/0565/2021
(1R,2S,5S)-N-((1S)-1-Cyano-2-((3S)-2-oxopyrrolidin-3-yl)ethyl)-3-((2S)-3,3-dimethyl-2-(2,2,2-trifluoroacetamido)butanoyl)-6,6-dimethyl-3-azabicyclo[3.1.0]hexane-2-carboxamide		P	Infectious Diseases	Pfizer Europe MA EEIG	21/12/2021	P/0566/2021

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

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Afatinib	Oncology	Boehringer Ingelheim International GmbH	23/04/2021
Aflibercept	Ophthalmology	Bayer AG	15/10/2021
Brentuximab vedotin	Oncology	Takeda Pharma A/S	25/06/2021
Ceftolozane / tazobactam	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	25/06/2021
Cerliponase alfa	Other / Neurology	BioMarin International Limited	26/02/2021
Cobimetinib	Oncology	Roche Registration GmbH	25/06/2021
Corifollitropin alfa	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme B.V.	29/01/2021
Dimethyl fumarate	Neurology	Biogen Idec Ltd	14/06/2021
Dolutegravir (DTG)	Infectious Diseases	ViiV Healthcare UK Limited	15/10/2021
Elvitegravir / Cobicistat / emtricitabine / Tenofovir alafenamide	Infectious Diseases	Gilead Sciences International Ltd.	25/06/2021
Enalapril maleate	Cardiovascular Diseases	Proveca Pharma Limited	25/06/2021
Exenatide	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	21/05/2021
Fosdenopterin	Other	Comharsa Life Sciences Limited	15/10/2021
Lonoctocog alfa	Haematology-Hemostaseology	CSL Behring GmbH	10/09/2021
Nivolumab / relatlimab	Oncology	Bristol-Myers Squibb International Corporation	10/09/2021
Octocog alfa	Haematology-Hemostaseology	Bayer AG	23/07/2021
Oseltamivir (phosphate)	Infectious Diseases	Roche Registration GmbH	15/10/2021
Peramivir	Infectious Diseases	BioCryst Ireland Limited	17/12/2021

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
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 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])	Vaccines	Merck Sharp & Dohme (Europe), Inc.	17/12/2021
Secukinumab	Dermatology	Novartis Europharm Ltd	20/04/2021
Secukinumab	Immunology-Rheumatology-Transplantation	Novartis Europharm Ltd	25/06/2021

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Simeticone / Macrogol 4000 / Potassium chloride / Sodium sulphate, anhydrous / Sodium chloride / Citric acid, anhydrous / Sodium citrate	Gastroenterology-Hepatology	Alfasigma S.p.A.	17/12/2021
Simoctocog alfa	Haematology-Hemostaseology	Octapharma Pharmazeutika Produktionsges.m.b.H.	26/03/2021
Sofosbuvir / velpatasvir	Infectious Diseases	Gilead Sciences Ireland UC	26/02/2021
Teduglutide	Gastroenterology-Hepatology	Takeda Pharmaceuticals International AG	26/03/2021
Ticagrelor	Cardiovascular Diseases / Haematology-Hemostaseology	AstraZeneca AB	25/06/2021
Turoctocog alfa pegol	Haematology-Hemostaseology	Novo Nordisk A/S	23/07/2021
Velmanase alfa	Endocrinology-Gynaecology-Fertility-Metabolism	Chiesi Farmaceutici S.p.A	23/04/2021

Annex 17 – Referral procedures overview 2021 – 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
Varilrix and associated names (live attenuated varicella virus (OKA strain))	25/06/2020	25/02/2021	Article 30 of Directive 2001/83/EC
Regeneron Ireland DAC use of casirivimab and imdevimab for the treatment of COVID-19 (casirivimab and imdevimab)	04/02/2021	25/02/2021	Article 5(3) of Regulation (EC) No 726/2004
Eli Lilly and Company Limited use of bamlanivimab and etesevimab for the treatment of COVID-19 (bamlanivimab and etesevimab)	04/02/2021	04/03/2021	Article 5(3) of Regulation (EC) No 726/2004
Celltrion use of regdanvimab for the treatment of COVID-19 (regdanvimab)	03/03/2021	25/03/2021	Article 5(3) of Regulation (EC) No 726/2004
Lidocain/Prilocain IDETEC and associated names (lidocaine/prilocaine)	25/03/2021	ongoing1	Article 29(4) of Directive 2001/83/EC
Vaxzevria (chimpanzee Adenovirus encoding the SARS-CoV-2 Spike glycoprotein (ChAdOx1-S))	14/04/2021	16/09/2021	Article 5(3) of Regulation (EC) No 726/2004
GlaxoSmithKline use of sotrovimab (VIR-7831/GSK4182136) for the treatment of COVID-19 (sotrovimab)	15/04/2021	20/05/2021	Article 5(3) of Regulation (EC) No 726/2004
Etifoxine-containing medicinal products (etifoxine)	24/06/2021	ongoing	Article 31 of Directive 2001/83/EC
Nasolam and associated names (midazolam)	14/10/2021	ongoing	Article 29(4) of Directive 2001/83/EC
Molnupiravir_COVID19-MSD (molnupiravir)	08/11/2021	19/11/2021	Article 5(3) of Regulation (EC) No 726/2004
Paxlovid use for the treatment of COVID-19 (PF-07321332/ritonavir)	19/11/2021	16/12/2021	Article 5(3) of Regulation (EC) No 726/2004

[1] Re-examination procedure started on 30/11/2021

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Referrals made to the PRAC

Procedure name (international non-proprietary name (INN) or common name)	Start of procedure	End of procedure	Type of referral
Ifosfamide-containing solutions (ifosfamide)	12/03/2020	21/04/2021	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Amfepramone-containing medicinal products (amfepramone)	11/02/2021	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Zynteglo (betibeglogene autotemcel)	11/03/2021	22/07/2021	Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data
Medicinal products containing nomegestrol or medicinal products containing chlormadinone (nomegestrol or chlormadinone)	30/09/2021	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Annex 18 – Arbitrations and referrals in 2021 – veterinary medicines

Type of procedure	**Date** • **Clock start** • **CVMP opinion**	**Product** • **Product name** • **INN**
Referral under Article 34 of Directive 2001/82/EC	• 11/09/2019 • 17/06/2021	• Ronaxan and its associated names • Doxycycline hyclate
Referral under Article 35 of Directive 2001/82/EC	• 15/07/2020 • 12/05/2021	• Injectable veterinary medicinal products containing vitamin A for use in food producing species • Vitamin A (retinol and its esters)
Referral under Article 35 of Directive 2001/82/EC	• 15/07/2020 • 15/04/2021	• Modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines • Porcine respiratory and reproductive syndrome virus vaccine (live)

Annex 19 – Budget summaries 2020-2021

The summarised comparative budget statements for 2020 and 2021 are as follows:

		2020 (final)[1]		2021 (budget)[2]		2021 (prov.)[3]	
		€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
	Revenue						
100	Fees and charges	316,889	*84.2%*	338,931	*89.4%*	341,638	*89.4%*
200	General EU contribution	33,704	*9.0%*	23,259	*6.1%*	25,450	*6.7%*
201	Special EU contribution for orphan medicinal products	11,374	*3.0%*	14,378	*3.8%*	12,187	*3.2%*
600	External assigned revenue	0	*0.0%*	0	*0.0%*	0	*0.0%*
700	Balance from previous year	13,803	*3.7%*	0	*0.0%*	0	*0.0%*
5+9	Other	476	*0.1%*	2,660	*0.7%*	2,881	*0.8%*
	TOTAL REVENUE	**376,246**	*100.0%*	**379,228**	*100.0%*	**382,156**	*100.0%*
	Expenditure						
	Staff						
11	Staff in active employment	104,979	*28.7%*	111,697	*29.5%*	106,812	*29.2%*
12	Staff recruitment	199	*0.1%*	300	*0.1%*	211	*0.1%*
13	Duty travel	138	*0.0%*	350	*0.1%*	25	*0.0%*
14	Socio-medical infrastructure	1,695	*0.5%*	2,115	*0.6%*	1,647	*0.5%*
15	Training	556	*0.2%*	650	*0.2%*	649	*0.2%*
16	External services	7,001	*1.9%*	17,063	*4.5%*	16,084	*4.4%*
17	Representation expenses	66	*0.0%*	125	*0.0%*	54	*0.0%*
	Total Title 1	**114,634**	*31.4%*	**132,300**	*34.9%*	**125,482**	*34.3%*
	Building/equipment						
20	Investment in immovable property, renting of building and associated costs	41,541	*11.4%*	15,861	*4.2%*	14,813	*4.1%*
21	Expenditure on corporate data processing	32,334	*8.8%*	28,482	*7.5%*	26,269	*7.2%*
22	Movable property [..]	1,222	*0.3%*	604	*0.2%*	588	*0.2%*
23	Other administrative expenditure	887	*0.2%*	3,732	*1.0%*	1,025	*0.3%*
24	Postage	35	*0.0%*	54	*0.0%*	31	*0.0%*
25	Expenditure on other meetings	270	*0.1%*	320	*0.1%*	342	*0.1%*
26	Restaurant & catering	1,703	*0.5%*	1,061	*0.3%*	602	*0.2%*
27	Information & publishing	1,241	*0.3%*	2,567	*0.7%*	2,028	*0.6%*
28	Business consultancy & audit svcs.	3,693	*1.0%*	2,850	*0.8%*	2,060	*0.6%*
	Total Title 2	**82,927**	*22.7%*	**55,531**	*14.6%*	**47,758**	*13.1%*
	Operational expenditure						
300	Meetings	1,309	*0.4%*	450	*0.1%*	143	*0.0%*
301	Evaluation of medicines	133,571	*36.6%*	140,848	*37.1%*	143,176	*39.2%*
302	Translations	5,047	*1.4%*	5,684	*1.5%*	4,773	*1.3%*
303	Scientific studies & svcs.	7,490	*2.0%*	13,315	*3.5%*	14,707	*4.0%*
31	Expenditure on business related IT projects	20,455	*5.6%*	31,100	*8.2%*	29,452	*8.1%*
	Total Title 3	**167,872**	*45.9%*	**191,397**	*50.5%*	**192,251**	*52.6%*
90	Provisional appropriation	0	*0.0%*	0	*0.0%*	0	*0.0%*
	Total Title 9	**0**	*0.0%*	**0**	*0.0%*	**0**	*0.0%*
	TOTAL EXPENDITURE	**365,433**	*100.0%*	**379,228**	*100.0%*	**365,491**	*100.0%*

[1] Financial Year 2020: as per final accounts; rounded to nearest thousand Euro

[2] Financial Year 2021: as per final budget

[3] Financial Year 2021: as per provisional accounts; rounded to nearest thousand Euro

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Annex 20 – European Medicines Agency Establishment Plan

Category and grade	TEMPORARY POSTS					
	POSTS 2021				POSTS 2022	
	Authorised		Actual as per 31.12.2021		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	0	-	0	-	0
AD 15	-	3	-	2	-	3
AD 14	-	9	-	9	-	10
AD 13	-	13	-	11	-	13
AD 12	-	45	-	42	-	50
AD 11	-	51	-	49	-	52
AD 10	-	51	-	47	-	50
AD 9	-	55	-	54	-	62
AD 8	-	71	-	71	-	77
AD 7	-	94	-	94	-	97
AD 6	-	65	-	65	-	60
AD 5	-	15	-	15	-	3
Total AD	**0**	**472**	**0**	**459**	**0**	**477**
AST 11	-	2	-	2	-	2
AST 10	-	7	-	7	-	7
AST 9	-	9	-	9	-	10
AST 8	-	10	-	10	-	13
AST 7	-	19	-	19	-	19
AST 6	-	20	-	20	-	26
AST 5	-	38	-	38	-	43
AST 4	-	46	-	46	-	42
AST 3	-	32	-	32	-	23
AST 2	-	2	-	0	-	0
AST 1	-	0	-	0	-	0
Total AST	**0**	**185**	**0**	**185**	**0**	**185**
Grand Total	**0**	**657**	**0**	**662**	**0**	**662**

Other staff	Planned (FTE[1]) 2021	Actual (FTE[1]) 2021	Actual headcount 31.12.2021	Planned (FTE[1]) 2022
CONTRACT AGENTS	**226**	**200**	**206**	**223**
NATIONAL EXPERTS	**30**	**26**	**28**	**30**

[1] FTE=Full Time Equivalent

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Annex 21 – Litigation activities of EMA in 2021

Actions before the Court of Justice of the European Union that are directed against EMA (pending or concluded in 2021)

1. Case T-549/18, *Hexal v EMA*

By Order of 10 February 2021, the case was removed from the register and the applicant was ordered to pay its own costs and those incurred by EMA.

2. Case T-611/18, *Pharmaceutical Works Polpharma v EMA*

By its Judgment of 5 May 2021, the General Court annulled a decision of EMA to not validate an application for a generic medicinal product.

3. Case T-628/19, *Teva v Commission and EMA*

By Order of 27 October 2021, the case was removed from the register and the applicant was ordered to pay its own costs and those incurred by the European Commission and EMA.

4. Case T-556/20, *D&A Pharma v Commission and EMA*

On 4 September 2020, the applicant brought an action against the European Commission and EMA in connection with the decision of the European Commission to refuse the grant of a conditional marketing authorisation for a medicinal product for human use.

5. Case T-570/20, *Kedrion v EMA*

On 11 September 2020, the applicant brought an action against the decision of EMA to refuse access, pursuant to Regulation (EC) No 1049/2001 to a document related to blood plasma centres in Italy, which had been submitted by another pharmaceutical company.

6. Case T-653/20, *Mylan Ireland v EMA*

On 28 October 2020, the applicant brought an action against the decision of EMA to not validate an application for a generic medicinal product.

7. Case T-703/20, *Mylan Ireland v EMA*

On 27 November 2020, the applicant brought an action against the decision of EMA to not validate an application for a generic medicinal product.

8. Case T-381/21, *D&A Pharma v EMA*

On 5 July 2021, the applicant brought an action against the decision of EMA to not renew the mandate of a scientific advisory group.

9. Case T-418/21, *Alauzun and Others v Commission and EMA*

On 12 July 2021, a group of natural persons brought an action against the European Commission and EMA in connection with the decision of the European Commission extending the indication of an authorised COVID-19 vaccine to persons of 12 years of age and older.

10. Case C-440/21 P, *EMA v Pharmaceutical Works Polpharma*

On 15 July 2021, EMA brought an appeal against the Judgment of the General Court of 5 May 2021 in Case T-611/18, *Pharmaceutical Works Polpharma v EMA*. Appeals were also submitted by the interveners in the first instance.

11. Case T-713/21, *Agentur für Globale Gesundheitsverantwortung v EMA*

On 5 November 2021, the applicant brought an action against the decision of EMA to grant partial access, pursuant to Regulation (EC) No 1049/2001, to a document containing information on a study relating to a COVID-19 vaccine.

Actions before the Court of Justice of the European Union that are not directed against EMA, but concern EMA's scientific assessments (pending or concluded in 2021)

12. Case T-303/16, *Mylan IRE Healthcare v Commission*

On 14 June 2016, an action was brought against the decision of the European Commission, adopted in the framework of Article 29 of Directive 2001/83/EC, concerning a number of marketing authorisations of nationally authorised medicinal products for human use.

13. Case T-223/20, *Orion v Commission*

On 23 April 2020, an action was brought against the decision of the European Commission to grant a marketing authorisation for a generic medicinal product for human use.

14. Joined Cases C-6/20 P and C-16/21 P, *Germany and Estonia v Pharma Mar and Commission*

On 17 September 2021, EMA was granted leave to intervene in support of the forms of order sought by two Member States in their respective appeals against the Judgment of the General Court of 28 October 2020 in Case T-594/18, *Pharma Mar v Commission*.

15. Case T-96/21, *Amort and Others v Commission*

By Order of 9 November 2021, the General Court rejected as inadmissible an action for annulment against a decision of the European Commission relating to the grant a conditional marketing authorisation for a COVID-19 vaccine.

16. Case T-136/21, *Amort and Others v Commission*

By Order of 9 November 2021, the General Court rejected as inadmissible an action for annulment against a decision of the European Commission relating to the grant of a conditional marketing authorisation for a COVID-19 vaccine.

Case T-138/21, *Virbac v Commission*

On 4 March 2021, the applicant brought an action against the decision of the European Commission to grant a marketing authorisation for a medicinal product for veterinary use.

17. Case T-165/21, *Amort and Others v Commission*

By Order of 9 November 2021, the General Court rejected as inadmissible an action for annulment against a decision of the European Commission relating to the grant of a conditional marketing authorisation for a COVID-19 vaccine.

18. Case T-267/21, *Amort and Others v Commission*

By Order of 9 November 2021, the General Court rejected as inadmissible an action for annulment against a decision of the European Commission relating to the grant of a conditional marketing authorisation for a COVID-19 vaccine.

19. Case T-464/21, *Faller and Others v Commission*

On 30 July 2021, a group of natural persons brought an action against the decision of the European Commission extending the indication of an authorised COVID-19 vaccine to persons of 12 years of age and older.

Annex 22 – Access to documents requests

Requests received and pages released

Year	Number of requests received	Number of pages released
2021	710	165,943

Initial decisions on access[1]

Access given	
Yes	319
Partial	15
No	19
Document is not held by the Agency	43
Request became RFI	88
Clarification is not received/ Withdrawn by requester	186
Total closed	**670**
Pending[2]	436

Legal basis used for full or partial refusal

Legal basis	Full	Partial
4.1(a) – Protection of public interest	1	0
4.1(b) – Protection of privacy	2	0
4.2 1st ind – Protection of commercial interest	13	14
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	3	2
4.3 2nd par – Protection of the Agency's decision making process	0	0
4.5 – Protection of Member States	1	0
Total	**19**	**15**

[1] Including initial requests received in previous years but closed in 2021
[2] Requests ongoing (currently processed) and in queue (not started)

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Decision on confirmatory applications in 2021[3]

Appeals	
Final refusal	6
Release	4
Partial	0
Request became RFI	1
Withdrawn by requester	1
Total closed	**12**
Pending[4]	4

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	2	0
4.2 1st ind – Protection of commercial interest	4	0
4.2 2nd ind – Protection of court proceedings	0	0
4.2 3rd ind – Protection of inspections	1	0
4.3 1st par – Protection of decision making process	0	0
4.3 2nd par – Protection of the Agency's decision making process	0	0
4.5 – Protection of Member States	0	0
Total	**6**	**0**

[3] Including appeals received in previous years but closed in 2021
[4] Requests ongoing (currently processed) and in queue (not started)

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Affiliation (per initial requests and appeals in 2021)

Affiliation	**Number of requests received**	**In %**	**Number of pages released[5]**	**In %**
Not-for-profit organisation	16	2	18066	11
EU Institution (EC etc)	0	0	0	0
Regulator outside EU	0	0	0	0
EU NCA	1	0	0	0
Patients or Consumer	88	12	17480	11
Healthcare professional	18	3	5235	3
Academia/Research institute	46	6	26277	16
Legal	57	8	11241	7
Media	32	5	10415	6
Pharmaceutical industry	324	46	60273	36
Consultant	116	16	16933	10
Other	12	2	23	0
Total	**710**	**100**	**165 943**	**100**

[5] Including initial requests and appeals received in previous years but closed in 2021

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Annex 23 – Clinical Data Publication[1]

NUMBER OF DOCUMENS PUBLISHED

Year	Number of documents published	Number of pages published
2021	215	79.325

Documents and Pages published per module

MODULE	Documents	Pages
Module 2.5	13	1.503
Module 2.7	14	1.674
Module 5	188	76.148

Number of procedures published by procedure type

Initial MAA	7
Extension of Indication	1
Renewal	1
Type II Variation	1
Post Authorisation Recommendation (REC)	1

Anonymisation Risk Assessment Approach

Approach	Number of Procedures
Qualitative[2]	7
Quantitative[3]	1
Mixed[4]	1
Not Applicable[5]	2

[1] Only Covid-19 related procedures were published during 2021
[2] Qualitative approach: calculate the level of risk (e.g. high, medium, low) based on the characteristics of the source data (e.g. prevalence of the disease, trial sample size, number of sites) . External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency (europa.eu)
[3] Quantitative approach: calculate the probability of uniquely identifying an individual (the risk of re-identification is defined as a numerical value obtained through the *analysis of the clinical* data to be disclosed.) External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency (europa.eu)
[4] Mixed: a combination of the two.
[5] No anonymisation needed as no private personal data (PPD) was present in the documents

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Annex 24 – Publications by Agency staff members and experts in 2021

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