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## Annex 1 – Members of the Management Board

Chair: Christa WIRTHUMER-HOCHE

EMA contact: Noël WATHION; Silvia FABIANI

### Members

- European Parliament Björn LEMMER, Tonio BORG
- European Commission Sandra GALLINA<sup>1</sup>, Kerstin JORNA<sup>2</sup>  
(Alternates: Andrzej RYS, Valentina SUPERTI<sup>3</sup>)
- Belgium Xavier DE CUYPER (Alternate: Greet MUSCH)
- Bulgaria Bogdan KIRILOV (Alternate: Svetlin SPIROV)
- Czech Republic Irena STOROVÁ (Alternate: Jiří BUREŠ)
- Denmark Thomas SENDEROVITZ (Alternate: Mette AABOE HANSEN)
- Germany Karl BROICH (Alternate: Lars-Christoph NICKEL)
- Estonia Kristin RAUDSEPP (Alternate: Alar IRS)
- Ireland Lorraine NOLAN (Alternate: Rita PURCELL)
- Greece Eleftherios Pallis (Alternate: Charalambos Kandiloros)
- Spain María Jesús LAMAS DÍAZ (Alternate: César HERNÁNDEZ)
- France Dominique MARTIN (Alternate: Jean-Pierre ORAND)
- Croatia Vili BEROS (Alternate: Siniša TOMIĆ)
- Italy Nicola MAGRINI<sup>4</sup> (Alternate: Giuseppe AMATO)
- Cyprus HELENA PANAYIOTOPOULOU<sup>5</sup>  
(Alternate: Iri Chrysafi FANIDOU)
- Latvia Svens HENKUZENS (Alternate: Janis ZVEJNIEKS)
- Lithuania Gytis ANDRULIONIS (Alternate: Awaiting nomination)
- Luxembourg Laurent MERTZ (Alternate: Françoise BERTHET)
- Hungary Mátyás SZENTIVÁNYI (Alternate: Beatrix HORVATH)
- Malta Anthony Serracino-Inglott (Alternate: John-Joseph BORG)
- Netherlands Hugo HURTS (Alternate: Constant VAN BELKUM)
- Austria Christa WIRTHUMER-HOCHE (Alternate: Thomas Reichhart)
- Poland Grzegorz CESSAK (Alternate: Marcin KOLAKOWSKI)
- Portugal Rui Santos Ivo (Alternate: Awaiting nomination)

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<sup>1</sup> Replaced Anne BUCHER from October 2020

<sup>2</sup> Replaced Carlo PETTINELLI from May 2020

<sup>3</sup> Replaced Stefano SORO from May 2020

<sup>4</sup> Replaced Luca LI BASSI from March 2020

<sup>5</sup> Replaced Loizos PANAYI as of December 2020

- Romania Andrei Baciu<sup>6</sup> (Alternate: Cristina Racoceanu<sup>7</sup>)
- Slovenia Momir Radulović (Alternate Awaiting nomination)
- Slovakia Zuzana Baťová (Alternate: Judita Hederova)
- Finland Eija Pelkonen (Alternate: Esa Heinonen)
- Sweden Catarina FORSMAN (Alternate: Asa Kumlin Howell<sup>8</sup>)

- 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: Einar MAGNUSSON)
- Liechtenstein Vlasta ZAVADOVA<sup>9</sup> (Alternate: Martin STRICKER)
- Norway Audun HÅGÅ (Alternate: Karen Marie ULSHAGEN)

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<sup>6</sup> Replaced Marius Daniel ŞIŞU as of June 2020

<sup>7</sup> Replaced Roxana STROE as of December 2020

<sup>8</sup> Replaced Sara ROSENMULLER as of February 2020

<sup>9</sup> Replaced Marc BÜRZLE as of February 2020

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

Chair: Harald ENZMANN

### Members

- |  |   |
|--|---|
| • Andrea LASLOP (Austria)                            | Alternate: Milena STAIN                             |
| • Christophe FOCKE (Belgium) <sup>1</sup>            | Alternate: Karin JANSSEN VAN DOORN <sup>2,3</sup>   |
| • Ilko GETOV (Bulgaria) <sup>4</sup>                 | Alternate: Velislava TODOROVA <sup>5</sup>          |
| • Margareta BEGO (Croatia)                           | Alternate: Selma ARAPOVIC DZAKULA                   |
| • Helena PANAYIOTOPOULOU (Cyprus) <sup>6</sup>       | Alternate: Emilia MAVROKORDATOU                     |
| • Ondrej SLANAR (Czechia)                            | Alternate: Tomas RADIMERSKY                         |
| • Sinan B. SARAC (Denmark)                           | Alternate: Kirstine Moll HARBOE <sup>7</sup>        |
| • Alar IRS (Estonia)                                 | Alternate: Edward LAANE <sup>8</sup>                |
| • Outi MAKI-IKOLA (Finland)                          | Alternate: Johanna LAHTEENVUO <sup>9</sup>          |
| • Alexandre MOREAU (France)                          | Alternate: Jean-Michel RACE                         |
| • Martina WEISE (Germany)                            | Alternate: Janet KOENIG                             |
| • Constantinos MARKOPOULOS (Greece)                  | Alternate: Eleftheria NIKOLAIDI                     |
| • <i>Awaiting nomination</i> (Hungary) <sup>10</sup> | Alternate: Agnes GYURASICS                          |
| • Kolbeinn GUDMUNDSSON (Iceland)                     | Alternate: Hrefna GUDMUNDSDOTTIR                    |
| • Jayne CROWE (Ireland)                              | Alternate: Peter KIELY                              |
| • Armando GENAZZANI (Italy) <sup>11</sup>            | Alternate: Nicola MAGRINI <sup>12</sup>             |
| • Elita POPLAVSKA (Latvia) <sup>13</sup>             | Alternate: <i>Awaiting nomination</i> <sup>14</sup> |
| • Romaldas MACIULAITIS (Lithuania)                   | Alternate: Simona STANKEVICIUTE <sup>15</sup>       |
| • Martine TRAUFLER (Luxembourg)                      | Alternate: Carola DE BEAUFORT                       |
| • John Joseph BORG (Malta)                           | Alternate: Helen VELLA                              |
| • Johann Lodewijk HILLEGE (Netherlands)              | Alternate: Paula Boudewina VAN HENNIK               |

<sup>1</sup> Replaced Bart VAN DER SCHUEREN as of May 2020 with swap of roles from alternate to member

<sup>2</sup> Bart VAN DER SCHUEREN replaced Christophe FOCKE as of May 2020 with swap of roles from member to alternate

<sup>3</sup> Replaced Bart VAN DER SCHUEREN as of July 2020

<sup>4</sup> Replaced Mila VLASKOVSKA as of October 2020

<sup>5</sup> Replaced Dariya DIMITROVA as of December 2020

<sup>6</sup> Replaced Loizos PANAYI as of December 2020

<sup>7</sup> Replaced Mark AINSWORTH as of June 2020

<sup>8</sup> Nominated as of March 2020

<sup>9</sup> Replaced Tuomo LAPVETELAINEN as of November 2020

<sup>10</sup> Melinda SOBOR (Hungary) resigned as of October 2020

<sup>11</sup> Replaced Daniela MELCHIORRI as of September 2020

<sup>12</sup> Replaced Guiseppa PISTRITTO as of September 2020

<sup>13</sup> Replaced Natalja KARPOVA as of September 2020 with a swap of roles from alternate to member

<sup>14</sup> Elita POPLAVSKA was nominated as of February 2020 and swapped roles from alternate to member as of September 2020

<sup>15</sup> Replaced Rugile PILVINIENE as of January 2020

- Bjorg BOLSTAD (Norway) Alternate: Ingrid WANG
- Ewa BALKOWIEC-ISKRA (Poland) Alternate: Marcin KOLAKOWSKI
- Bruno SEPODES (Portugal) (*Vice-Chair*) Alternate: Fatima VENTURA
- Simona BADOI (Romania) Alternate: Dana Gabriela MARIN
- Francisek DRAFI (Slovakia) Alternate: Dorota DISTLEROVA<sup>16</sup>
- Rajko KENDA (Slovenia) Alternate: Nevenka TRSINAR BRODT
- Maria Concepcion PRIETO YERRO (Spain) Alternate: Blanca GARCIA-OCHOA<sup>17,18</sup>
- 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))
- *Awaiting nomination*<sup>19</sup>
- Sol RUIZ (Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies))

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<sup>16</sup> Replaced Eva MALIKOVA as of May 2020

<sup>17</sup> Jorge CAMERERO JIMENEZ resigned as of May 2020

<sup>18</sup> Replaced Jorge CAMERERO JIMENEZ as of June 2020

<sup>19</sup> Koenraad NORGA (Pharmacology) resigned as of September 2020

## Annex 3 – Members of the Pharmacovigilance Risk Assessment Committee

Chair: Sabine STRAUS

### Members

- Jan NEUHAUSER (Austria) Alternate: Sonja HRABCIK
- Jean-Michel DOGNE (Belgium) Alternate: Laurence DE FAYS
- Maria POPOVA-KIRADJIEVA (Bulgaria) Alternate: Yuliyen EFTIMOV
- Nikica MIROSEVIC SKVRCE (Croatia) Alternate: Zeljana MARGAN KOLETIC
- Helena PANAYIOTOPOULOU (Cyprus) Alternate: Panagiotis PSARAS
- Eva JIRSOVA (Czechia) Alternate: Jana LUKACISINOVA
- Anette STARK (Denmark) Alternate: Hans Christian SIERSTED
- Maia UUSKULA (Estonia) Alternate: Katrin KIISK
- Kirsti VILLIKKA (Finland) Alternate: Kimmo JAAKKOLA
- Adrien INOUBLI (France)<sup>1</sup> Alternate: Tiphaine VAILLANT<sup>2</sup>
- Martin HUBER (Germany) (*Vice-Chair*) Alternate: Brigitte KELLER-STANISLAWSKI
- Agni KAPOU (Greece) Alternate: Sofia TRANTZA
- Julia PALLOS (Hungary) Alternate: Melinda PALFI
- Gudrun STEFANSDOTTIR (Iceland) Alternate: Gudrun Kristin STEINGRIMSDOTTIR
- Rhea FITZGERALD (Ireland) Alternate: Ronan GRIMES
- Amelia CUPELLI (Italy) Alternate: Iliaria BALDELLI
- Zane NEIKENA (Latvia) Alternate: Zane STADE
- Rugile PILVINIENE (Lithuania) Alternate: Ruta KERPAUSKIENE
- Nadine PETITPAIN (Luxembourg)<sup>3</sup> Alternate: Anne-Cecile VUILLEMIN
- John Joseph BORG (Malta) Alternate: Benjamin MICALLEF
- 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 STROE (Romania) Alternate: Alexandra-Maria SPURNI
- Michal RADIK (Slovakia) Alternate: Marek JURACKA<sup>4</sup>

<sup>1</sup> Replaced Ghania CHAMOUNI as of June 2020 with a swap of roles from alternate to member

<sup>2</sup> Replaced Adrien INOUBLI as of June 2020

<sup>3</sup> Replaced Marcel BRUCH as of October 2020; Marcel BRUCH resigned as of September 2020

<sup>4</sup> Replaced Tatiana MAGALOVA as of February 2020

- Gabriela JAZBEC (Slovenia) Alternate: Jasmina KLOPCIC
- Eva SEGOVIA (Spain) Alternate: Maria del PINAR RAYON
- Ulla WANDEL LIMINGA (Sweden) Alternate: Annika FOLIN

### ***Independent scientific experts nominated by the European Commission***

- Birgitta GRUNDMARK
- Daniel MORALES
- Hedvig NORDENG
- Antoine PARIENTE
- Milou Daniel DRICI<sup>5,6</sup>
- Stefan WEILER

### ***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

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<sup>5</sup> Livia PULJAK resigned as of April 2020

<sup>6</sup> Nominated as of July 2020

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

Chair: David MURPHY (vice-chair: G. J. SCHEFFERLIE)

### **Members and alternates**

- Petra FALB (Austria) Alternate: Manuela LEITNER<sup>1</sup>
- Bruno URBAIN (Belgium) Alternate: Frédéric KLEIN
- Svetoslav BRANCHEV (Bulgaria)<sup>2</sup> Alternate: *awaiting nomination*
- Frane BOŽIĆ (Croatia) Alternate: Hrvoje PAVASOVIĆ<sup>3</sup>
- Member: *awaiting nomination* Alternate: Leona NEPEJCHALOVÁ
- Christodoulos PIPIS (Cyprus)<sup>4</sup> Alternate: Alia MICHAELIDOU-PATSIA
- Niels Christian KYVSGAARD (Denmark) Alternate: Merete BLIXENKRONE-MØLLER
- Toomas TIIRATS (Estonia) Alternate: *awaiting nomination*
- Tita-Maria MUHONEN (Finland) Alternate: Katariina KIVILAHTI-MANTYLA
- Sylvie LOUET (France)<sup>5</sup> Alternate: Christine MIRAS<sup>6</sup>
- Esther WERNER (Germany)<sup>7</sup> Alternate: Andrea GOLOMBIEWSKI<sup>8</sup>
- Spyridon FARLOPOULOS (Greece)<sup>9</sup> Alternate: Amalia PAPADAKI<sup>10</sup>
- Gábor KULCSÁR (Hungary) Alternate: Melinda NEMES-TERÉNYI
- J. Gabriel BEECHINOR (Ireland) Alternate: Paul MCNEILL
- Paolo PASQUALI (Italy) Alternate: Antonio BATTISTI
- Zanda AUCE (Latvia) Alternate: Santa ANSOSKA<sup>11</sup>
- Snieguolė T. DZEKČIORIENĖ (Lithuania) Alternate: Nijolė STANKEVIČIENĖ
- Marc SCHMIT (Luxembourg) Alternate: *awaiting nomination*
- Stephen SPITERI (Malta) Alternate: *awaiting nomination*
- Jacqueline POOT (Netherlands)<sup>12</sup> Alternate: Kim BOERKAMP<sup>13</sup>
- Anna WACHNIK-ŚWIECICKA (Poland) Alternate: Ewa AUGUSTYNOWICZ
- João Pedro DUARTE DA SILVA (Portugal) Alternate: Cristina GONÇALVES SANTOS

<sup>1</sup> Replaced Ines LINDNER as of February meeting

<sup>2</sup> Replaced Emil Iliev KOZHUHAROV as of June meeting

<sup>3</sup> Replaced Svjetlana TERZIĆ as of October meeting

<sup>4</sup> Replaced Alia MICHAELIDOU-PATSIA as of February meeting

<sup>5</sup> Replaced Jean-Claude ROUBY as of February meeting

<sup>6</sup> Replaced Sylvie LOUET as of February meeting

<sup>7</sup> Replaced Gesine HAHN as of February meeting

<sup>8</sup> Replaced Esther WERNER as of February meeting

<sup>9</sup> Replaced Angeliki TSIGOURI as of July meeting

<sup>10</sup> Nominated 18 September 2020

<sup>11</sup> Nominated 1 December 2020

<sup>12</sup> Replaced Peter HEKMAN as of September meeting

<sup>13</sup> Replaced Jacqueline POOT as of September meeting



- Lollita TABAN (Romania) Alternate: Gabriela TUCHILA
- Judita HEDEROVÁ (Slovakia) Alternate: Eva CHOBOTOVÁ
- Katarina ŠTRAUS (Slovenia) Alternate: Boris KOLAR<sup>14</sup>
- Cristina MUÑOZ MADERO (Spain) Alternate: Consuelo RUBIO MONTEJANO
- Frida HASSLUNG-WIKSTRÖM (Sweden) Alternate: Carina BERGMAN<sup>15</sup>

### **EEA members**

- Member: Péter Zsolt Fekete<sup>16</sup> Alternate: *awaiting nomination*
- Hanne BERGENDAHL (Norway) Alternate: Annelin Bjelland<sup>17</sup>

### **Co-opted members**

#### **Co-opted member**

- Keith BAPTISTE
- Rory BREATHNACH
- G. Johan SCHEFFERLIE
- Mary O'GRADY
- Ricardo CARAPETO GARCÍA

#### **Expertise**

Antimicrobials and antimicrobial resistance  
 Clinical veterinary practice  
 Residue metabolism and pharmacokinetics  
 Quality  
 Environmental risk assessment

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<sup>14</sup> Replaced Maja TURK as of January meeting

<sup>15</sup> Replaced Eva LANDER PERSSON as of February meeting

<sup>16</sup> Nominated on 5 March 2020

<sup>17</sup> Replaced Tonje HØY as of April meeting

## Annex 5 – Members of the Committee on Orphan Medicinal Products

Chair: Violeta STOYANOVA-BENINSKA

### **Members**

- Brigitte BLOECHL-DAUM (Austria)
- Tim LEEST (Belgium)
- Lyubina Racheva TODOROVA (Bulgaria)
- Dinko VITEZIC (Croatia)
- Vasileios LOUTAS (Cyprus)<sup>1</sup>
- Lenka GAIDADZI (Czechia)<sup>2</sup>
- Elisabeth PENNINGA (Denmark)
- Vallo TILLMANN (Estonia)
- Karri PENTTILA (Finland)
- Cecile DOP (France)<sup>3</sup>
- Frauke NAUMANN-WINTER (Germany)
- Nikolaos SYPSAS (Greece)
- Zsofia GYULAI (Hungary)
- *Awaiting nomination* (Iceland)
- Geraldine O'DEA (Ireland)
- Armando MAGRELLI (Italy) (*Vice-Chair*)
- Irena ROGOVSKA (Latvia)
- Ausra MATULEVICIENE (Lithuania)
- Michel HOFFMAN (Luxembourg)
- Robert NISTICO (Malta)
- Elisabeth ROOK (Netherlands)
- Maria Elisabeth KALLAND (Norway)
- Bozenna DEMBOWSKA-BAGINSKA (Poland)
- Dinah DUARTE (Portugal)
- Olimpia NEAGU (Romania)
- Eva MALIKOVA (Slovakia)

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<sup>1</sup> Replaced Nectaroula COOPER as of January 2020

<sup>2</sup> Change of name (previous KOVAROVA) as of July 2020

<sup>3</sup> Replaced Annie LORENCE as of January 2020

- 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
- *Awaiting nomination*<sup>4</sup>

### ***Members representing patients' organisations nominated by the European Commission***

- Marie Pauline EVERS
- Julian ISLA
- Angelo Loris BRUNETTA

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<sup>4</sup> Bruno SEPODES resigned as of October 2020

## Annex 6 – Members of the Committee on Herbal Medicinal Products

Chair: Emiel VAN GALEN<sup>1</sup>

### Members

- |   |   |
|---|---|
| • Reinhard LANGER (Austria)                     | Alternate: Astrid OBMANN                              |
| • Patricia BODART (Belgium)                     | Alternate: <i>Awaiting nomination</i>                 |
| • Iliana IONKOVA (Bulgaria)                     | Alternate: Dafna MARINKEVA                            |
| • Ivan KOSALEC (Croatia)                        | Alternate: Darko TRUMBETIC                            |
| • Antri KOUROUFEXI (Cyprus) <sup>2</sup>        | Alternate: Maria YIANNITSAROU <sup>3</sup>            |
| • Marketa PRIHODOVA (Czechia) <sup>4</sup>      | Alternate: Marie HEROUTOVA <sup>5</sup>               |
| • Steffen BAGER (Denmark)                       | Alternate: Rahat NAZMI <sup>6,7</sup>                 |
| • <i>Awaiting nomination</i> (Estonia)          | Alternate: <i>Awaiting nomination</i>                 |
| • Maria PAILE HYVARINEN (Finland) <sup>8</sup>  | Alternate: Sari KOSKI                                 |
| • An LE (France)                                | Alternate: <i>Awaiting nomination</i> <sup>9,10</sup> |
| • Jacqueline WIESNER (Germany)                  | Alternate: Susanne FLEMISCH                           |
| • Ioanna CHINO (Greece)                         | Alternate: Stavroula MAMOUCHA <sup>11</sup>           |
| • Zsuzsanna BIRO-SANDOR (Hungary)               | Alternate: Rita NEMETH                                |
| • <i>Awaiting nomination</i> (Iceland)          | Alternate: <i>Awaiting nomination</i>                 |
| • Sarah KELLAGHAN (Ireland) <sup>12,13</sup>    | Alternate: <i>Awaiting nomination</i>                 |
| • Alessandro ASSISI (Italy) <sup>14,15</sup>    | Alternate: Anna Maria SERRILLI                        |
| • Baiba JANSONE (Latvia) <sup>16</sup>          | Alternate: Evita SKUKAUSKA <sup>17</sup>              |
| • Rugile PILVINIENE (Lithuania)                 | Alternate: Audronis LUKOSIUS                          |
| • Clemence VARRET (Luxembourg) <sup>18,19</sup> | Alternate: <i>Awaiting nomination</i>                 |

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<sup>1</sup> Elected as Chair as of March 2020

<sup>2</sup> Replaced Maria STAVROU as of January 2020

<sup>3</sup> Replaced Elli LOIZIDOU as of January 2020

<sup>4</sup> Replaced Marie HEROUTOVA as of March 2020 with a swap of roles from alternate to member

<sup>5</sup> Replaced Marketa PRIHODOVA as of March 2020 with a swap of roles from member to alternate

<sup>6</sup> Karoline Holm FELDING's mandate ended as of August 2020

<sup>7</sup> Nominated as of December 2020

<sup>8</sup> Replaced Eeva Sofia LEINONEN as of September 2020

<sup>9</sup> Michele BRUM nominated as of January 2020

<sup>10</sup> Michele BRUM resigned as of July 2020

<sup>11</sup> Replaced Zoe KARAMPOURMPOUNI as of September 2020

<sup>12</sup> Sheena KENNEDY resigned as of July 2020

<sup>13</sup> Nominated as of December 2020

<sup>14</sup> Alessandro ASSISI's mandate expired as of March 2020

<sup>15</sup> Nominated as of August 2020

<sup>16</sup> Replaced Evita SKUKAUSKA as of January 2020 with a swap of roles from alternate to member

<sup>17</sup> Replaced Baiba JANSONE as of January 2020 with a swap of roles from member to alternate

<sup>18</sup> Marcel BRUCH's mandate ended as of September 2020

<sup>19</sup> Nominated as of December 2020

- Everaldo ATTARD (Malta) Alternate: Matthew CAMILLERI
- Burt H. KROES (Netherlands)<sup>20,21</sup> Alternate: Hilda KUIN<sup>22,23</sup>
- Steinar MADSEN (Norway) Alternate: Gro FOSSUM
- Wojciech DYMOWSKI (Poland) Alternate: Katarzyna TOMASZEWSKA
- Ana Paula MARTINS (Portugal) Alternate: Eva MENDES
- Carmen PURDEL (Romania) Alternate: Ligia Elena DUTU
- Miroslava PETRIKOVA (Slovakia) Alternate: Milan NAGY
- Barbara RAZINGER (Slovenia) Alternate: *Awaiting nomination*
- Adela NUNEZ VELAZQUEZ (Spain) Alternate: Cristina MARTINEZ GARCIA
- Erika SVEDLUND (Sweden)(*Vice-Chair*)<sup>24</sup> Alternate: Malin Kyllikki HOBRO SODERBERG

### ***Co-opted members***

- Ewa BALKOWIEC ISKRA (Clinical pharmacology)
- Heidi FOTH (Toxicology)
- *Awaiting nomination*<sup>25</sup>
- Gert LAEKEMAN (Experimental/non-clinical pharmacology)
- Maria Helena PINTO FERREIRA (General and family medicine)

### ***Observers***

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

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<sup>20</sup> Emiel VAN GALEN elected as Chair as of March 2020

<sup>21</sup> Nominated as of May 2020 with a swap of roles from alternate to member

<sup>22</sup> Burt H. KROES became member as of May 2020

<sup>23</sup> Nominated as of November 2020

<sup>24</sup> Karin Erika SVEDLUND elected as Vice-Chair as of May 2020

<sup>25</sup> Silvia GIROTTO (Paediatric medicine) resigned as of June 2020

## Annex 7 – Committee for Advanced Therapies

Chair: Martina SCHUSSLER-LENZ

### Members

#### Members nominated from within the CHMP

- Jan MUELLER-BERGHAUS (Germany)                      Alternate: Egbert FLORY
- Romaldas MACIULAITIS (Lithuania)                      Alternate: Raimondas BENETIS<sup>1</sup>
- John Joseph BORG (Malta)                                      Alternate: Anthony SAMUEL
- Bruno SEPODES (Portugal)                                      Alternate: Maria Isabel BORBA VIEIRA<sup>2</sup>
- Sol RUIZ (Spain)    Alternate: Marcos TIMON

#### Members nominated by Member States

- Ilona G. REISCHL (Austria) (*Vice-Chair*)                      Alternate: Silke DORNER<sup>3</sup>
- Claire BEUNEU (Belgium)                                      Alternate: Belaid SEKKALI
- Rozalina KULAKSAZOVA (Bulgaria)                      Alternate: Evelina SHUMKOVA
- Mirna GOLEMOVIC (Croatia)                                      Alternate: Petra SOKOL
- Rafaella PONTOU (Cyprus)                                      Alternate: Isavella KYRIAKIDOU
- Ivana HAUNEROVA (Czechia)                                      Alternate: Tomas BORAN<sup>4</sup>
- Anne PASTOFT (Denmark)                                      Alternate: Nanna Aaby KRUSE
- Toivo MAIMETS (Estonia)                                      Alternate: Pille SAALIK
- Heli SUIILA (Finland)    Alternate: Olli TENHUNEN
- Violaine CLOSSON CARELLA (France)                      Alternate: *Awaiting nomination*<sup>5</sup>
- Asterios TSIFTSOGLU (Greece)                                      Alternate: Angeliki ROMPOTI
- Katalin LENGYEL (Hungary)                                      Alternate: Balazs SARKADI
- *Awaiting nomination* (Iceland)                                      Alternate: *Awaiting nomination*
- Maura O'DONOVAN (Ireland)                                      Alternate: Niamh CURRAN
- Paolo GASPARINI (Italy)    Alternate: Giulio POMPILIO
- Una RIEKSTINA (Latvia)    Alternate: Liga KUNRADE
- Guy BERCHEM (Luxembourg)                                      Alternate: Anne-Cécile VUILEMIN

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<sup>1</sup> Replaced Vitalis BRIEDIS as of October 2020

<sup>2</sup> Nominated as of January 2020

<sup>3</sup> Replaced Corina SPREITZER as of March 2020

<sup>4</sup> Replaced Ondrej PALAN as of October 2020

<sup>5</sup> Nathalie MORGENSZTEJN retired as of November 2020

- Carla HERBERTS (Netherlands) Alternate: Johannes H. OVELGONNE
- Rune KJEKEN (Norway) Alternate: Maja SOMMERFELT GRØNVOLD
- Dariusz SLADOWSKI (Poland) Alternate: Anna CIESLIK
- Felicia CIULU COSTINESCU (Romania)<sup>6,7,8</sup> Alternate: *Awaiting nomination*<sup>9</sup>
- Lukas SLOVAK (Slovakia) Alternate: Alexandra PADOVA<sup>10</sup>
- Metoda LIPNIK-STANGELJ (Slovenia) Alternate: Nevenka TRSINAR BRODT
- Lisbeth BARKHOLT (Sweden) Alternate: Maria LUTTGEN<sup>11</sup>

### **Members representing clinicians nominated by the European Commission**

- Bernd GANSBACHER Alternate: Frederic BERNARD<sup>12</sup>
- Alessandro AIUTI Alternate: Alessandra RENIERI

### **Members representing patients' organisations nominated by the European Commission**

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

### **Observers**

- *Awaiting nomination* (EDQM)<sup>13</sup> Alternate: Catherine Milne (EDQM)

<sup>6</sup> Alina MUSETESCU's mandate ended as of March 2020

<sup>7</sup> Simona BADOI nominated as of May 2020

<sup>8</sup> Replaced Simona BADOI as of August 2020

<sup>9</sup> Gianina-Nicoleta ANDREI's mandate ended as for October 2020

<sup>10</sup> Nominated as of January 2020

<sup>11</sup> Replaced Bjorn CARLSSON as of June 2020

<sup>12</sup> Nominated as of January 2020

<sup>13</sup> Karl-Heinz BUCHHEIT retired as of January 2020

## Annex 8 – Members of the Paediatric Committee

Chair: Koenraad NORGA

### **Members nominated from within the CHMP**

- Agnes GYURASICS (Hungary) Alternate: *Awaiting nomination*<sup>1</sup>
- Carola DE BEAUFORT (Luxembourg) Alternate: Martine TRAUFLER
- Dana Gabriela MARIN (Romania) Alternate: Simona BADOI

### **Members**

- Karl-Heinz HUEMER (Austria) Alternate: Johanna WERNSPERGER
- Marleen RENARD (Belgium)<sup>2</sup> Alternate: Karen VAN MALDEREN
- Dimitar ROUSSINOV (Bulgaria) Alternate: Vessela BOUDINOVA
- Milivoj NOVAK (Croatia) Alternate: Arnes RESIC
- Georgios SAVVA (Cyprus) Alternate: Elena KAISIS<sup>3</sup>
- Lucie KRAVACKOVA (Czechia)<sup>4</sup> Alternate: *Awaiting nomination*<sup>5</sup>
- Nanna BORUP JOHANSEN (Denmark)<sup>6</sup> Alternate: *Awaiting nomination*
- Irja LUTSAR (Estonia) Alternate: Jana LASS
- Ann Marie TOTTERMAN (Finland) Alternate: *Awaiting nomination*<sup>7</sup>
- 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*<sup>8</sup>
- Dovile ZACHARKIENE (Lithuania)<sup>9</sup> Alternate: Silvijus ABRAMAVICIUS<sup>10</sup>
- John Joseph BORG (Malta) Alternate: Herbert LENICKER
- *Awaiting nomination* (Netherlands)<sup>11</sup> Alternate: Maaïke VAN DARTEL

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<sup>1</sup> Melinda SOBOR resigned as of October 2020

<sup>2</sup> Nominated as of October 2020

<sup>3</sup> Replaced Eirini PERIKLEOUS as of December 2020

<sup>4</sup> Replaced Tereza BAZANTOVA as of February 2020

<sup>5</sup> Petra DOMINIKOVA resigned as of November 2020

<sup>6</sup> Replaced Kirstine Moll HARBOE as of July 2020

<sup>7</sup> Pia ANNUNEN resigned as of April 2020

<sup>8</sup> Kristine SUPE's mandate ended as of May 2020

<sup>9</sup> Replaced Sigita BUROKIENE as of December 2020

<sup>10</sup> Nominated as of December 2020

<sup>11</sup> Roel BOLT's mandate ended as of September 2020



- 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)<sup>12</sup> Alternate: Sara VENNBERG<sup>13,14</sup>

### ***Members representing healthcare professionals nominated by the European Commission***

- *Awaiting nomination*<sup>15,16</sup> Alternate: Johannes TAMINIAU<sup>17</sup>
- Fernando CABANAS Alternate: Doina PLESCA
- Francesca ROCCHI Alternate: Catherine CORNU

### ***Members representing patients' organisations nominated by the European Commission***

- Jaroslav STERBA<sup>18</sup> Alternate: Milena STEVANOVIC
- Dimitrios ATHANASIOU Alternate: Tomasz GRYBEK<sup>19</sup>
- Nora KRIAUAZAITE<sup>20,21</sup> Alternate: Michal ODERMARSKY<sup>22,23</sup>

<sup>12</sup> Replaced Ninna GULLBERG as of September 2020 with a swap of roles from alternate to member

<sup>13</sup> Eva AGURELL became a member as of September 2020

<sup>14</sup> Nominated as of December 2020

<sup>15</sup> Michael FRUEHWALD replaced Johannes TAMINIAU as of August 2020

<sup>16</sup> Michael FRUEHWALD resigned as of October 2020

<sup>17</sup> Replaced Jorrit GERRITSEN as of August 2020 with a swap of roles from member to alternate

<sup>18</sup> Replaced Michal ODERMARSKY as of August 2020

<sup>19</sup> Replaced Viviana GIANNUZZI as of August 2020

<sup>20</sup> Katrin CLAUS replaced Günter Karl-Heinz AUERSWALD as of August 2020 and resigned as of August 2020

<sup>21</sup> Replaced Katrin CLAUS as of November 2020 with a swap of roles from alternate to member

<sup>22</sup> Nora KRIAUAZAITE replaced Paola BAIARDI as of August 2020

<sup>23</sup> Replaced Nora KRIAUAZAITE as of November 2020

## Annex 9 – Working parties and working groups

As part of the EMA business continuity plan, most working party meetings and expert groups were temporarily suspended or reduced in 2020.

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
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

## Drafting groups

Chair	
Gastroenterology Drafting Group	Mark AINSWORTH <sup>1</sup>
Radiopharmaceuticals Drafting Group	On Hold
Respiratory Drafting Group	Karolina TORNEKE
Excipients Drafting Group	On hold

## CHMP scientific advisory groups

Chair	
Scientific Advisory Group on Cardiovascular Issues	N/A
Scientific Advisory Group on Anti-infectives	N/A
Scientific Advisory Group on Diabetes/Endocrinology	N/A
Scientific Advisory Group on HIV / Viral Diseases	N/A
Scientific Advisory Group on Neurology	Serge BAKCHINE
Scientific Advisory Group on Psychiatry	N/A
Scientific Advisory Group on Vaccines	N/A
Scientific Advisory Group on Oncology	Jonas BERGH <sup>2</sup>

## 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

<sup>1</sup> Until February 2020

<sup>2</sup> Until October 2020

Chair	
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 Pharmacovigilance Working Party (PhVWP-V)	Els DEWAELE
CVMP Safety Working Party (SWP-V)	Stefan SCHEID
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**

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

## ***Committee on Herbal Medicinal Products (HMPC)***

### **HMPC working parties**

<b>Chair</b>	
Working Party on European Union Monographs and European Union List	Ioanna CHINOUE

### **HMPC temporary drafting groups**

<b>Chair</b>	
Organisational Matters Drafting Group	Gert LAEKEMAN <sup>3</sup>
Quality Drafting Group	On hold

### **Other HMPC-associated groups**

<b>Chair</b>	
Good Manufacturing Practice Inspection Services Group	EMA representative

## ***Committee for Advanced Therapies (CAT)***

### **CAT associated group**

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

## ***Paediatric Committee (PDCO)***

### **PDCO working groups**

<b>Chair</b>	
Formulation Working Group	Brian AYLWARD
Non-clinical Working Group	Karen VAN MALDEREN

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<sup>3</sup> Until March 2020

## **Human Scientific Committees' Working Parties**

<b>Chair</b>	
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**

<b>Chair</b>	
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)**

<b>Chair</b>	
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**

	<b>Chair</b>
Joint CHMP/CVMP Quality Working Party (QWP)	Keith PUGH
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	Jonas BERGH <sup>4</sup> (until Oct 2020)
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

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<sup>4</sup> Until October 2020

## **Annex 10 – CHMP opinions on initial evaluations and extensions of therapeutic indication in 2020**

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
See CAT			

### *Biostatistics Working Party*

Reference number	Document	Status	Date
EMA/492010/2018	Questions and Answers on Data	Final	17 September 2020
EMA/CHMP/470185/2020	Monitoring Committees issues		

### *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	17 September 2020
EMA/CHMP/BPWP/94033/2007 rev. 4	Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)	Final	17 September 2020

### *Committee for Advanced Therapies (CAT)*

Reference number	Document	Status	Date
CHMP/CAT/GTWP/671639/2008 Rev.1	Quality, non-clinical and clinical requirements for medicinal products containing genetically modified cells	Final	12 November 2020

### *ICH*

Reference number	Document	Status	Date
EMA/CHMP/ICH/213867/2020	ICH Q3C (R8): Impurities: guideline for Residual Solvents	Draft for public consultation, step 2b	30 April 2020
EMA/CHMP/ICH/353369/2013	ICH guideline Q3D(R2) on elemental impurities	Draft for public consultation, step 2b	17 September 2020
EMA/CHMP/ICH/804273/2017	ICH guideline on Q12 on technical and regulatory considerations for pharmaceutical products lifecycle management	Adopted, step 5	30 January 2020

Reference number	Document	Status	Date
EMA/CHMP/ICH/544278/1998	ICH S5 (R3) guideline on reproductive toxicology: Detection of Toxicity to Reproduction for Human Pharmaceuticals	Adopted, step 5	30 January 2020
EMA/CHMP/ICH/616110/2018	ICH guideline S11 on nonclinical safety testing in support of development of paediatric pharmaceuticals	Adopted, step 5	26 March 2020
EMA/CHMP/ICH/436221/2017	ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials	Adopted, step 5	30 January 2020
EMA/CHMP/ICH/415588/2020	ICH guideline E14/S7B on clinical and nonclinical evaluation of QT/QTc interval prolongation and proarrhythmic potential - questions & answers	Draft for public consultation, step 2b	23 July 2020
EMA/CHMP/ICH/321999/2020	ICH M7 (R2) Addendum: Assessment of Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk - Questions and Answers on implementation	Draft for public consultation, step 2b	25 June 2020
EMA/CHMP/ICH/493213/2018	ICH M9 guideline on biopharmaceutics classification system-based biowaivers	Adopted, step 5	30 January 2020

### ***Oncology Working Party***

Reference number	Document	Status	Date
EMA/CHMP/205/95 Rev.6	Guideline on the clinical evaluation of anticancer medicinal products	Draft for public consultation	15 October 2020

### ***Pharmacokinetics Working Party***

Reference number	Document	Status	Date
EMA/CHMP/97470/2019	Etonogestrel and ethinylestradiol vaginal delivery system 0.12mg/0.015mg/day product-specific bioequivalence guidance	Final	27 February 2020
EMA/CHMP/176098/2020	Levothyroxine tablet 12.5 mcg, 25 mcg, 50 mcg, 75 mcg, 100 mcg and 200 mcg (and additional strengths within the range) product-specific bioequivalence guidance	Final	10 December 2020

Reference number	Document	Status	Date
EMA/CHMP/474712/2016 Rev.1	Abiraterone acetate tablets 250 mg and 500 mg product-specific bioequivalence guidance	Final	12 November 2020
EMA/CHMP/257298/2018	Lapatinib film-coated tablet 250 mg product-specific bioequivalence guidance	Draft for public consultation	25 June 2020
EMA/CHMP/675838/2014 Rev.1	Dasatinib film-coated tablets 20, 50, 70, 80, 100 & 140 mg and suspension 10 mg/ml product-specific bioequivalence guidance	Final	15 October 2020
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	Draft for public consultation	10 December 2020
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	Draft for public consultation	12 November 2020
EMA/CHMP/512475/2020	Acenocoumarol, tablet, 1 mg and 4 mg product-specific bioequivalence guidance	Draft for public consultation	15 October 2020

### **Quality Working Party**

Reference number	Document	Status	Date
EMA/CHMP/CVMP/QWP/496873/2018	Guideline on the quality of water for pharmaceutical use	Final	28 May 2020
EMA/CHMP/QWP/292439/2017	Reflection paper on the pharmaceutical development of medicines for use in the older population	Final	15 October 2020

## Annex 12 – CVMP opinions on medicinal products for veterinary use in 2020

### Positive opinions

<b>Product</b> <ul style="list-style-type: none"> <li>• <b>Invented name</b></li> <li>• <b>INN/Common name</b></li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>• <b>Target species</b></li> <li>• <b>Summary of indication</b></li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>• <b>Validation</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> <li>• <b>Clock stop</b></li> </ul>	<b>European Commission</b> <ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Transmission to EC</b></li> <li>• <b>Decision</b></li> <li>• <b>Notification</b></li> <li>• <b>Official Journal</b></li> </ul>
<ul style="list-style-type: none"> <li>• Tulaven</li> <li>• Tulathromycin</li> </ul>	<ul style="list-style-type: none"> <li>• Ceva Santé Animale</li> </ul>	<ul style="list-style-type: none"> <li>• Cattle, Pigs, Sheep</li> <li>• Cattle: Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni and Mycoplasma bovis susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. Treatment of infectious bovine keratoconjunctivitis (IBK) associated with Moraxella bovis susceptible to tulathromycin.</li> <li>• Pigs: Treatment and metaphylaxis of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis and Bordetella bronchiseptica susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. The product should only be used if pigs are expected to develop the disease within 2–3 days.</li> <li>• Sheep: Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent Dichelobacter nodosus requiring systemic treatment.</li> </ul>	<ul style="list-style-type: none"> <li>• 23/09/2019</li> <li>• 20/02/2020</li> <li>• 210</li> <li>• 127</li> </ul>	<ul style="list-style-type: none"> <li>• 20/02/2020</li> <li>• 18/03/2020</li> <li>• 24/04/2020</li> <li>• 27/04/2020</li> <li>• C 181 29/05/2020</li> </ul>

<b>Product</b> <ul style="list-style-type: none"> <li>Invented name</li> <li>INN/Common name</li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>Target species</li> <li>Summary of indication</li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>Validation</li> <li>Opinion</li> <li>Active time</li> <li>Clock stop</li> </ul>	<b>European Commission</b> <ul style="list-style-type: none"> <li>Opinion received</li> <li>Transmission to EC</li> <li>Decision</li> <li>Notification</li> <li>Official Journal</li> </ul>
<ul style="list-style-type: none"> <li>Tulissin</li> <li>Tulathromycin</li> </ul>	<ul style="list-style-type: none"> <li>Virbac S.A.</li> </ul>	<ul style="list-style-type: none"> <li>Cattle, Pigs, Sheep</li> <li>Treatment and metaphylaxis of bovine respiratory disease, treatment of infectious bovine keratoconjunctivitis, treatment and metaphylaxis of swine respiratory disease and treatment of the early stages of infectious pododermatitis in sheep.</li> </ul>	<ul style="list-style-type: none"> <li>23/01/2019</li> <li>20/02/2020</li> <li>209</li> <li>184</li> </ul>	<ul style="list-style-type: none"> <li>20/02/2020</li> <li>18/03/2020</li> <li>24/04/2020</li> <li>27/04/2020</li> <li>C 181 29/05/2020</li> </ul>
<ul style="list-style-type: none"> <li>Vectormune FP ILT + AE</li> <li>Fowlpox, avian infectious laryngotracheitis vaccine (live, recombinant) and avian encephalomyelitis vaccine (live)</li> </ul>	<ul style="list-style-type: none"> <li>Ceva-Phylaxia Co. Ltd</li> </ul>	<ul style="list-style-type: none"> <li>Chickens</li> <li>For active immunisation of chickens in order to reduce the clinical signs due to fowlpox, to reduce the clinical signs, mortality and tracheal lesions due to avian infectious laryngotracheitis and to prevent egg production losses due to avian encephalomyelitis.</li> </ul>	<ul style="list-style-type: none"> <li>18/12/2018</li> <li>20/02/2020</li> <li>210</li> <li>219</li> </ul>	<ul style="list-style-type: none"> <li>20/02/2020</li> <li>18/03/2020</li> <li>24/04/2020</li> <li>27/04/2020</li> <li>C 181</li> </ul>
<ul style="list-style-type: none"> <li>Lydaxx</li> <li>Tulathromycin</li> </ul>	<ul style="list-style-type: none"> <li>Vetoquinol S.A.</li> </ul>	<ul style="list-style-type: none"> <li>Cattle, Pigs, Sheep</li> <li>Cattle: Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni and Mycoplasma bovis susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. Treatment of infectious bovine keratoconjunctivitis (IBK) associated with Moraxella bovis susceptible to tulathromycin.</li> </ul>	<ul style="list-style-type: none"> <li>20/03/2019</li> <li>18/03/2020</li> <li>209</li> <li>155</li> </ul>	<ul style="list-style-type: none"> <li>18/03/2020</li> <li>17/04/2020</li> <li>18/05/2020</li> <li>19/05/2020</li> <li>C 213 26/06/2020</li> </ul>
<ul style="list-style-type: none"> <li>Prevexxion RN</li> <li>Marek's disease vaccine (live recombinant)</li> </ul>	<ul style="list-style-type: none"> <li>Boehringer Ingelheim Vetmedica GmbH</li> </ul>	<ul style="list-style-type: none"> <li>Chickens</li> <li>For active immunisation of one-day-old chicks to prevent mortality and clinical signs and reduce lesions caused by Marek's disease (MD) virus (including very virulent MD virus).</li> </ul>	<ul style="list-style-type: none"> <li>18/12/2018</li> <li>20/05/2020</li> <li>209</li> <li>310</li> </ul>	<ul style="list-style-type: none"> <li>20/05/2020</li> <li>17/06/2020</li> <li>20/07/2020</li> <li>23/07/2020</li> <li>C 285 28/05/2020</li> </ul>

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<b>Product</b> <ul style="list-style-type: none"> <li>• <b>Invented name</b></li> <li>• <b>INN/Common name</b></li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>• <b>Target species</b></li> <li>• <b>Summary of indication</b></li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>• <b>Validation</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> <li>• <b>Clock stop</b></li> </ul>	<b>European Commission</b> <ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Transmission to EC</b></li> <li>• <b>Decision</b></li> <li>• <b>Notification</b></li> <li>• <b>Official Journal</b></li> </ul>
<ul style="list-style-type: none"> <li>• Prevexxion RN+HVT+IBD</li> <li>• Infectious bursal disease and Marek's disease vaccine (live recombinant)</li> </ul>	<ul style="list-style-type: none"> <li>• Boehringer Ingelheim Vetmedica GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• Chickens</li> <li>• For active immunisation of one-day-old chicks to prevent mortality and clinical signs and reduce lesions caused by Marek's disease (MD) virus (including very virulent MD virus), and to prevent mortality, clinical signs and lesions caused by infectious bursal disease (IBD) virus.</li> </ul>	<ul style="list-style-type: none"> <li>• 18/12/2018</li> <li>• 20/05/2020</li> <li>• 209</li> <li>• 310</li> </ul>	<ul style="list-style-type: none"> <li>• 20/05/2020</li> <li>• 17/06/2020</li> <li>• 20/07/2020</li> <li>• 23/07/2020</li> <li>• C 285 28/05/2020</li> </ul>
<ul style="list-style-type: none"> <li>• Increxxa</li> <li>• Tulathromycin</li> </ul>	<ul style="list-style-type: none"> <li>• Elanco GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• Cattle, Pigs, Sheep</li> <li>• Cattle: Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni and Mycoplasma bovis susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. Treatment of infectious bovine keratoconjunctivitis (IBK) associated with Moraxella bovis susceptible to tulathromycin.</li> <li>• Pigs: Treatment and metaphylaxis of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis and Bordetella bronchiseptica susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. The product should only be used if pigs are expected to develop the disease within 2–3 days.</li> <li>• Sheep: Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent Dichelobacter nodosus requiring systemic treatment.</li> </ul>	<ul style="list-style-type: none"> <li>• 23/10/2019</li> <li>• 16/07/2020</li> <li>• 209</li> <li>• 58</li> </ul>	<ul style="list-style-type: none"> <li>• 16/07/2020</li> <li>• 11/08/2020</li> <li>• 16/09/2020</li> <li>• 17/09/2020</li> <li>• C 367 30/10/2020</li> </ul>

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<b>Product</b> <ul style="list-style-type: none"> <li>Invented name</li> <li>INN/Common name</li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>Target species</li> <li>Summary of indication</li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>Validation</li> <li>Opinion</li> <li>Active time</li> <li>Clock stop</li> </ul>	<b>European Commission</b> <ul style="list-style-type: none"> <li>Opinion received</li> <li>Transmission to EC</li> <li>Decision</li> <li>Notification</li> <li>Official Journal</li> </ul>
<ul style="list-style-type: none"> <li>Tulinovet</li> <li>Tulathromycin</li> </ul>	<ul style="list-style-type: none"> <li>VMD N.V.</li> </ul>	<ul style="list-style-type: none"> <li>Cattle, Pigs, Sheep</li> <li>Cattle: Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni and Mycoplasma bovis susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. Treatment of infectious bovine keratoconjunctivitis (IBK) associated with Moraxella bovis susceptible to tulathromycin.</li> <li>Pigs: Treatment and metaphylaxis of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis and Bordetella bronchiseptica susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. The product should only be used if pigs are expected to develop the disease within 2–3 days.</li> <li>Sheep: Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent Dichelobacter nodosus requiring systemic treatment.</li> </ul>	<ul style="list-style-type: none"> <li>10/07/2019</li> <li>16/07/2020</li> <li>209</li> <li>163</li> </ul>	<ul style="list-style-type: none"> <li>16/07/2020</li> <li>11/08/2020</li> <li>16/09/2020</li> <li>17/09/2020</li> <li>C 367 30/10/2020</li> </ul>
<ul style="list-style-type: none"> <li>Mhyosphere PCV ID</li> <li>Porcine circovirus and Mycoplasma hyopneumoniae vaccine</li> </ul>	<ul style="list-style-type: none"> <li>Laboratorios Hipra S.A.</li> </ul>	<ul style="list-style-type: none"> <li>Pigs</li> <li>For the active immunisation of pigs: <ul style="list-style-type: none"> <li>to reduce lung lesions associated with porcine enzootic pneumonia caused by Mycoplasma hyopneumoniae. Also, to reduce the incidence of these lesions (as observed in field studies).</li> <li>to reduce viraemia, virus load in lungs and lymphoid tissues and the duration of the</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>15/05/2019</li> <li>16/07/2020</li> <li>209</li> <li>155</li> </ul>	<ul style="list-style-type: none"> <li>16/07/2020</li> <li>12/08/2020</li> <li>18/09/2020</li> <li>21/09/2020</li> <li>C 213 30/10/2020</li> </ul>

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<b>Product</b> <ul style="list-style-type: none"> <li>Invented name</li> <li>INN/Common name</li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>Target species</li> <li>Summary of indication</li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>Validation</li> <li>Opinion</li> <li>Active time</li> <li>Clock stop</li> </ul>	<b>European Commission</b> <ul style="list-style-type: none"> <li>Opinion received</li> <li>Transmission to EC</li> <li>Decision</li> <li>Notification</li> <li>Official Journal</li> </ul>
		viraemic period associated with diseases caused by Porcine circovirus type 2 (PCV2). Efficacy against PCV2 genotypes a, b and d has been demonstrated in field studies. <ul style="list-style-type: none"> <li>to reduce culling rate and the loss of daily weight gain caused by Mycoplasma hyopneumoniae and/or PCV2 related diseases (as observed at 6 months of age in field studies).</li> </ul>		
<ul style="list-style-type: none"> <li>Innovax-ND-ILT</li> <li>Marek's disease vaccine, Newcastle disease vaccine &amp; infectious laryngotracheitis vaccine (live recombinant)</li> </ul>	<ul style="list-style-type: none"> <li>Intervet International B.V.</li> </ul>	<ul style="list-style-type: none"> <li>Chickens</li> <li>For active immunisation of one-day-old chicks or embryonated chicken eggs:               <ul style="list-style-type: none"> <li>to reduce mortality and clinical signs caused by Newcastle disease (ND) virus,</li> <li>to reduce mortality, clinical signs and lesions caused by avian infectious laryngotracheitis (ILT) virus and Marek's disease (MD) virus.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>07/08/2019</li> <li>16/07/2020</li> <li>209</li> <li>135</li> </ul>	<ul style="list-style-type: none"> <li>16/07/2020</li> <li>12/08/2020</li> <li>16/09/2020</li> <li>17/09/2020</li> <li>C 367 31/10/2020</li> </ul>
<ul style="list-style-type: none"> <li>Librela</li> <li>Bedinvetmab</li> </ul>	<ul style="list-style-type: none"> <li>Zoetis Belgium S.A.</li> </ul>	<ul style="list-style-type: none"> <li>Dogs</li> <li>For the alleviation of pain associated with osteoarthritis in dogs.</li> </ul>	<ul style="list-style-type: none"> <li>25/09/2019</li> <li>09/09/2020</li> <li>209</li> <li>141</li> </ul>	<ul style="list-style-type: none"> <li>09/09/2020</li> <li>08/10/2020</li> <li>10/11/2020</li> <li>11/11/2020</li> <li>C 453 30/12/2020</li> </ul>
<ul style="list-style-type: none"> <li>Ovugel</li> <li>Triptorelin acetate</li> </ul>	<ul style="list-style-type: none"> <li>Vetoquinol S.A.</li> </ul>	<ul style="list-style-type: none"> <li>Pigs</li> <li>For the synchronisation of ovulation in weaned sows to enable a single fixed-time artificial insemination.</li> </ul>	<ul style="list-style-type: none"> <li>12/06/2019</li> <li>09/09/2020</li> <li>208</li> <li>247</li> </ul>	<ul style="list-style-type: none"> <li>09/09/2020</li> <li>08/10/2020</li> <li>10/11/2020</li> <li>12/11/2020</li> <li>C 453 30/12/2020</li> </ul>



<b>Product</b> <ul style="list-style-type: none"> <li>• <b>Invented name</b></li> <li>• <b>INN/Common name</b></li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>• <b>Target species</b></li> <li>• <b>Summary of indication</b></li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>• <b>Validation</b></li> <li>• <b>Opinion</b></li> <li>• <b>Active time</b></li> <li>• <b>Clock stop</b></li> </ul>	<b>European Commission</b> <ul style="list-style-type: none"> <li>• <b>Opinion received</b></li> <li>• <b>Transmission to EC</b></li> <li>• <b>Decision</b></li> <li>• <b>Notification</b></li> <li>• <b>Official Journal</b></li> </ul>
<ul style="list-style-type: none"> <li>• CircoMax Myco</li> <li>• Porcine circovirus vaccine (inactivated, recombinant) and Mycoplasma hyopneumoniae vaccine (inactivated)</li> </ul>	<ul style="list-style-type: none"> <li>• Zoetis Belgium S.A.</li> </ul>	<ul style="list-style-type: none"> <li>• Pigs</li> <li>• Active immunisation of pigs against porcine circovirus type 2 to reduce viral load in blood and lymphoid tissues, fecal shedding and the lesions in lymphoid tissues associated with PCV2 infection.</li> <li>• Active immunisation of pigs against Mycoplasma hyopneumoniae to reduce the lung lesions associated with Mycoplasma hyopneumoniae infection.</li> </ul>	<ul style="list-style-type: none"> <li>• 25/09/2019</li> <li>• 07/10/2020</li> <li>• 209</li> <li>• 169</li> </ul>	<ul style="list-style-type: none"> <li>• 07/10/2020</li> <li>• 04/11/2020</li> <li>• 09/12/2020</li> <li>• 11/12/2020</li> <li>• C 33 29/01/2021</li> </ul>
<ul style="list-style-type: none"> <li>• Enteroporc Coli AC</li> <li>• Neonatal piglet colibacillosis (recombinant, inactivated) and Clostridium perfringens vaccine (inactivated)</li> </ul>	<ul style="list-style-type: none"> <li>• IDT Biologika GmbH</li> </ul>	<ul style="list-style-type: none"> <li>• Pigs</li> <li>• For the passive immunisation of progeny by active immunisation of pregnant sows and gilts to reduce clinical signs (severe diarrhoea) and mortality caused by Escherichia coli strains expressing the fimbrial adhesins F4ab, F4ac, F5 and F6.</li> </ul>	<ul style="list-style-type: none"> <li>• 15/05/2019</li> <li>• 08/10/2020</li> <li>• 210</li> <li>• 302</li> </ul>	<ul style="list-style-type: none"> <li>• 08/10/2020</li> <li>• 04/11/2020</li> <li>• 09/12/2020</li> <li>• 10/12/2020</li> <li>• C 33 29/01/2021</li> </ul>
<ul style="list-style-type: none"> <li>• Nobivac DP Plus</li> <li>• Canine distemper vaccine (live)and canine parvovirus vaccine (live, recombinant)</li> </ul>	<ul style="list-style-type: none"> <li>• Intervet International B.V.</li> </ul>	<ul style="list-style-type: none"> <li>• Dogs</li> <li>• For the active immunisation of puppies from 4 weeks of age onwards to prevent clinical signs and mortality of canine distemper virus infection and canine parvovirus infection and to prevent viral excretion following canine distemper virus infection and following canine parvovirus infection.</li> </ul>	<ul style="list-style-type: none"> <li>• 20/11/2019</li> <li>• 07/10/2020</li> <li>• 208</li> <li>• 114</li> </ul>	<ul style="list-style-type: none"> <li>• 07/10/2020</li> <li>• 03/11/2020</li> <li>• 09/12/2020</li> <li>• 10/12/2020</li> <li>• C 33 29/01/2021</li> </ul>
<ul style="list-style-type: none"> <li>• Vectormune FP ILT</li> <li>• Fowlpox and avian infectious laryngotracheitis vaccine (live, recombinant)</li> </ul>	<ul style="list-style-type: none"> <li>• Ceva-Phylaxia Co. Ltd.</li> </ul>	<ul style="list-style-type: none"> <li>• Chickens</li> <li>• For active immunisation of chickens from 8 weeks of age in order to reduce the skin lesions due to fowlpox and to reduce the clinical signs and tracheal lesions due to avian infectious laryngotracheitis.</li> </ul>	<ul style="list-style-type: none"> <li>• 19/02/2019</li> <li>• 07/10/2020</li> <li>• 179</li> <li>• 52</li> </ul>	<ul style="list-style-type: none"> <li>• 07/10/2020</li> <li>• 04/11/2020</li> <li>• 09/12/2020</li> <li>• 10/12/2020</li> <li>• C 33 29/01/2021</li> </ul>

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<b>Product</b> <ul style="list-style-type: none"> <li>Invented name</li> <li>INN/Common name</li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>Target species</li> <li>Summary of indication</li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>Validation</li> <li>Opinion</li> <li>Active time</li> <li>Clock stop</li> </ul>	<b>European Commission</b> <ul style="list-style-type: none"> <li>Opinion received</li> <li>Transmission to EC</li> <li>Decision</li> <li>Notification</li> <li>Official Journal</li> </ul>
<ul style="list-style-type: none"> <li>Rexxolide</li> <li>Tulathromycin</li> </ul>	<ul style="list-style-type: none"> <li>Dechra Regulatory B.V.</li> </ul>	<ul style="list-style-type: none"> <li>Cattle, Pigs, Sheep</li> <li>Cattle: Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni and Mycoplasma bovis susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. Treatment of infectious bovine keratoconjunctivitis (IBK) associated with Moraxella bovis susceptible to tulathromycin.</li> <li>Pigs: Treatment and metaphylaxis of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis and Bordetella bronchiseptica susceptible to tulathromycin. The presence of the disease in the herd should be established before metaphylactic treatment. The product should only be used if pigs are expected to develop the disease within 2–3 days.</li> <li>Sheep: Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent Dichelobacter nodosus requiring systemic treatment.</li> </ul>	<ul style="list-style-type: none"> <li>20/12/2019</li> <li>07/10/2020</li> <li>209</li> <li>78</li> </ul>	<ul style="list-style-type: none"> <li>07/10/2020</li> <li>30/10/2020</li> <li>03/12/2020</li> <li>09/12/2020</li> <li>C 33 29/01/2021</li> </ul>
<ul style="list-style-type: none"> <li>Nexgard Combo</li> <li>Esafoxolaner, Eprinomectin, Praziquantel</li> </ul>	<ul style="list-style-type: none"> <li>Boehringer Ingelheim Vetmedica GmbH</li> </ul>	<ul style="list-style-type: none"> <li>Cats</li> <li>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.</li> </ul>	<ul style="list-style-type: none"> <li>12/06/2019</li> <li>05/11/2020</li> <li>210</li> <li>302</li> </ul>	<ul style="list-style-type: none"> <li>05/11/2020</li> <li>01/12/2020</li> <li>06/01/2021</li> <li>07/01/2021</li> <li>C 67 26/02/2021</li> </ul>

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<b>Product</b> <ul style="list-style-type: none"> <li>Invented name</li> <li>INN/Common name</li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic area</b> <ul style="list-style-type: none"> <li>Target species</li> <li>Summary of indication</li> </ul>	<b>EMA/CVMP</b> <ul style="list-style-type: none"> <li>Validation</li> <li>Opinion</li> <li>Active time</li> <li>Clock stop</li> </ul>	<b>European Commission</b> <ul style="list-style-type: none"> <li>Opinion received</li> <li>Transmission to EC</li> <li>Decision</li> <li>Notification</li> <li>Official Journal</li> </ul>
<ul style="list-style-type: none"> <li>Enteroporc Coli</li> <li>Neonatal piglet colibacillosis vaccine (recombinant, inactivated)</li> </ul>	<ul style="list-style-type: none"> <li>IDT Biologika GmbH</li> </ul>	<ul style="list-style-type: none"> <li>Pigs</li> <li>For the passive immunisation of progeny by active immunisation of pregnant sows and gilts to reduce:</li> <li>Clinical signs (severe diarrhoea) and mortality caused by Escherichia coli strains expressing the fimbrial adhesins F4ab, F4ac, F5 and F6</li> <li>Clinical signs (diarrhoea during the first days of life) associated with Clostridium perfringens type A expressing alpha and beta 2 toxins</li> <li>Clinical signs and mortality associated with haemorrhagic and necrotising enteritis caused by Clostridium perfringens type C expressing beta1 toxin</li> </ul>	<ul style="list-style-type: none"> <li>12/06/2019</li> <li>05/11/2020</li> <li>210</li> <li>302</li> </ul>	<ul style="list-style-type: none"> <li>05/11/2020</li> <li>02/12/2020</li> <li>06/01/2021</li> <li>08/01/2021</li> <li>C 67 26/02/2021</li> </ul>
<ul style="list-style-type: none"> <li>Solensia</li> <li>Frunevetmab</li> </ul>	<ul style="list-style-type: none"> <li>Zoetis Belgium SA</li> </ul>	<ul style="list-style-type: none"> <li>Cats</li> <li>For the alleviation of pain associated with osteoarthritis in cats.</li> </ul>	<ul style="list-style-type: none"> <li>10/07/2019</li> <li>10/12/2020</li> <li>210</li> <li>309</li> </ul>	<ul style="list-style-type: none"> <li>10/12/2020</li> <li>25/01/2021</li> <li>17/02/2021</li> <li>18/02/2021</li> <li>C 105 26/03/2021</li> </ul>

## Negative opinions

There were no negative opinions in 2020.

## CVMP opinions in 2020 on establishment of MRLs

### Positive opinions

<b>Product</b> <ul style="list-style-type: none"><li>• <b>Substance</b></li></ul>	<b>Target species</b>	<b>EMA/CVMP</b> <ul style="list-style-type: none"><li>• <b>Validation</b></li><li>• <b>Opinion</b></li><li>• <b>Active time</b></li><li>• <b>Ck stop</b></li></ul>	<b>European Commission</b> <ul style="list-style-type: none"><li>• <b>Opinion received</b></li><li>• <b>Regulation</b></li><li>• <b>Official Journal</b></li></ul>
<ul style="list-style-type: none"><li>• Bupivacaine</li></ul>	<ul style="list-style-type: none"><li>• Pigs</li></ul>	<ul style="list-style-type: none"><li>• 11/07/2018</li><li>• 20/02/2020</li><li>• 210</li><li>• 379</li></ul>	<ul style="list-style-type: none"><li>• 20/02/2020</li><li>• 2020/1685</li><li>• L 379</li></ul>
<ul style="list-style-type: none"><li>• Ketoprofen</li></ul>	<ul style="list-style-type: none"><li>• Horses, Pigs, Cattle</li></ul>	<ul style="list-style-type: none"><li>• 20/02/2019</li><li>• 18/03/2020</li><li>• 207</li><li>• 185</li></ul>	<ul style="list-style-type: none"><li>• 20/02/2020</li><li>• N/a</li><li>• N/a</li></ul>
<ul style="list-style-type: none"><li>• Bupivacaine</li></ul>	<ul style="list-style-type: none"><li>• Cattle</li></ul>	<ul style="list-style-type: none"><li>• 15/05/2019</li><li>• 18/06/2020</li><li>• 208</li><li>• 192</li></ul>	<ul style="list-style-type: none"><li>• 18/06/2020</li><li>• 2020/1685</li><li>• L 379</li></ul>
<ul style="list-style-type: none"><li>• Lidocaine</li></ul>	<ul style="list-style-type: none"><li>• Pigs</li></ul>	<ul style="list-style-type: none"><li>• 26/09/2018</li><li>• 16/07/2020</li><li>• 209</li><li>• 450</li></ul>	<ul style="list-style-type: none"><li>• 16/07/2020</li><li>• 2020/1712</li><li>• L 384</li></ul>
<ul style="list-style-type: none"><li>• Lidocaine</li></ul>	<ul style="list-style-type: none"><li>• Cattle</li></ul>	<ul style="list-style-type: none"><li>• 15/05/2019</li><li>• 16/07/2020</li><li>• 209</li><li>• 219</li></ul>	<ul style="list-style-type: none"><li>• 16/07/2020</li><li>• 2020/1712</li><li>• L 384</li></ul>
<ul style="list-style-type: none"><li>• Imidacloprid</li></ul>	<ul style="list-style-type: none"><li>• Finfish</li></ul>	<ul style="list-style-type: none"><li>• 15/05/2019</li><li>• 09/09/2020</li><li>• 208</li><li>• 275</li></ul>	<ul style="list-style-type: none"><li>• 09/09/2020</li><li>• Pending</li><li>• Pending</li></ul>

### Negative opinions

There were no negative opinions on establishment of MRLs in 2020.

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

<b>Product</b> <ul style="list-style-type: none"> <li>• Brandname</li> <li>• INN</li> </ul>	<b>Marketing authorisation holder</b>	<b>Therapeutic Area</b> <ul style="list-style-type: none"> <li>• ATC Code</li> <li>• Summary of indication</li> </ul>	<b>EMA/CVMP opinion</b>	<b>European Commission decision date</b>
<ul style="list-style-type: none"> <li>• Aivlosin</li> <li>• tylvalosin</li> </ul>	ECO Animal Health Europe Limited	<ul style="list-style-type: none"> <li>• QJ01FA92</li> <li>• Treatment and prevention of Swine Enzootic Pneumonia caused by susceptible strains of Mycoplasma hyopneumoniae in pigs. At the recommended dose, lung lesions and weight loss are reduced but infection with Mycoplasma hyopneumoniae is not eliminated. Treatment of Porcine Proliferative Enteropathy (ileitis) caused by Lawsonia intracellularis in herds where there is a diagnosis based on clinical history, post-mortem findings and clinical pathology results. Treatment of clinical outbreaks of Swine Dysentery, caused by Brachyspira hyodysenteriae in herds where the disease has been diagnosed and prevention of further clinical cases. Treatment of respiratory disease associated with Mycoplasma gallisepticum in chickens</li> </ul>	<ul style="list-style-type: none"> <li>• 20/05/2020</li> </ul>	<ul style="list-style-type: none"> <li>• 24/06/2020</li> </ul>
<ul style="list-style-type: none"> <li>• Cytopoint</li> <li>• lokivetmab</li> </ul>	Zoetis Belgium SA	<ul style="list-style-type: none"> <li>• QD11AH91</li> <li>• Treatment of clinical manifestations of atopic dermatitis in dogs. Treatment of pruritus associated with allergic dermatitis in dogs</li> </ul>	<ul style="list-style-type: none"> <li>• 09/09/2020</li> </ul>	<ul style="list-style-type: none"> <li>• 04/11/2020</li> </ul>

## Annex 13 – Guidelines and concept papers adopted by CVMP in 2020

### CVMP Quality

Reference number	Document title	Status
<a href="#">EMA/CVMP/QWP/153641/2018</a>	Reflection paper on risk management requirements for elemental impurities in veterinary medicinal products	Adopted January 2020
<a href="#">EMA/CVMP/QWP/631010/2017-Rev.2</a>	Implementation of risk assessment requirements to control elemental impurities in veterinary medicinal Products	Adopted January 2020
<a href="#">EMA/CHMP/CVMP/QWP/496873/2018</a>	Guideline on the quality of water for pharmaceutical use	Adopted June 2020

### CVMP Pharmacovigilance

Reference number	Document title	Status
<a href="#">EMA/CVMP/PhVWP/33617/2020</a>	Veterinary Pharmacovigilance bulletin	Adopted March 2020
<a href="#">EMA/112926/2020</a>	Pharmacovigilance regulatory recommendations for centrally authorised veterinary medicinal products during 2020	Report publication adopted April 2020, updated on a regular basis
<a href="#">EMA/CVMP/PhVWP/10418/2009-Rev.11</a>	VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted May 2020
<a href="#">EMA/CVMP/PhVWP/288284/2007-Rev.12</a>	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted May 2020
<a href="#">EMA/CVMP/PhVWP/145186/2013 – Rev. 4</a>	Questions and answers on adverse event reporting	Adopted July 2020

### CVMP Antimicrobials

Reference number	Document title	Status
<a href="#">EMA/CVMP/179874/2020</a>	CVMP strategy on antimicrobials 2021-2025	Adopted for consultation June 2020  End of consultation 30 September 2020

### **CVMP Immunologicals**

Reference number	Document title	Status
<a href="#">EMA/CVMP/IWP/669993/2019</a>	Questions and Answers on management of extraneous agents in immunological veterinary medicinal products (IVMPs)	Adopted June 2020

### **CVMP environmental risk assessment**

Reference number	Document title	Status
<a href="#">EMA/CVMP/ERA/52740/2012</a>	Q&As in support of the guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products	Finalised January 2020
<a href="#">EMA/CVMP/ERA/55512/2020</a>	Concept paper for the development of a reflection paper on the environmental risk assessment for parasiticide veterinary medicinal products used in companion animals	Adopted for consultation April 2020 End of consultation 31 October 2020

### **CVMP Novel therapies**

Reference number	Document title	Status
<a href="#">EMA/CVMP/ADVENT/791717/2016</a>	Questions and Answers on Stem cell-based products for veterinary use: specific question on target animal safety to be addressed by ADVENT.	Adopted July 2020

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

Reference number	Document title	Status
<a href="#">EMA/CVMP/111028/2020</a>	Scientific recommendations for implementing measures under Article 77(6) of Regulation (EU) 2019/6 on veterinary medicinal products regarding good pharmacovigilance practice	Adopted May 2020

Reference number	Document title	Status
<a href="#">EMA/CVMP/123178/2019</a>	Scientific recommendation for implementing measures under Article 77(6) of Regulation (EU) 2019/6 on veterinary medicinal products regarding the pharmacovigilance system master file	Adopted May 2020
<a href="#">EMA/CVMP/586518/2019</a>	Advice on implementing measures under Article 57(4) of Regulation (EU) 2019/6 on veterinary medicinal products – Report on the format of the data to be collected on antimicrobial medicinal products used in animals	Adopted May 2020
<a href="#">EMA/567192/2019</a>	Advice on implementing measures under Article 99(6) of Regulation (EU) 2019/6 on veterinary medicinal products – Good distribution practices (GDP) for veterinary medicinal products	Adopted June 2020
<a href="#">EMA/87754/2020</a>	Advice on implementing measures under Article 95(8) of Regulation (EU) 2019/6 on veterinary medicinal products - Good distribution practices (GDP) for active substances used as starting materials in veterinary medicinal products	Adopted June 2020
<a href="#">EMA/CVMP/508559/2019</a>	Advice on implementing measures under Article 106 (6) of Regulation (EU) 2019/6 on veterinary medicinal products – scientific problem analysis and recommendations to ensure a safe and efficient administration of oral veterinary medicinal products via routes other than medicated feed	Adopted July 2020
<a href="#">EMA/CVMP/340959/2020</a>	Concept paper on criteria for the application of Article 40(5) of Regulation (EU) 2019/6	Adopted for consultation July 2020  End of consultation 21 September 2020



## General

Reference number	Document title	Status
<a href="#">EMA/CVMP/422/04 Rev. 2</a>	Revised CVMP rules of procedure	Adopted April 2020
<a href="#">EMA/CVMP/VICH/677723/2016</a>	VICH GL59 Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use	Adopted December 2020

## Annex 14 – COMP opinions on designation of orphan medicinal products in 2020

### Positive COMP designation opinions

Product INN	Sponsor	Indication	EMA/COMP Submission Start date Opinion Active time	European Commission  Opinion received Date of decision
Idursulfase	Shire Pharmaceuticals Ireland Limited - Ireland	Treatment of mucopolysacchari dosis type II (Hunter's syndrome)	28/09/2020 26/10/2020 03/12/2020 (38 days/30 days)	07/12/2020 06/01/2021
Alpha galactosidase A	Consejo Superior De Investigaciones Cientificas - Spain	Treatment of Fabry disease	28/09/2020 26/10/2020 03/12/2020 (38 days/30 days)	07/12/2020 06/01/2021
Humanised IgG1K monoclonal antibody against interferon beta	Pfizer Europe MA EEIG - Belgium	Treatment of dermatomyositis	25/09/2020 26/10/2020 03/12/2020 (38 days/30 days)	07/12/2020 06/01/2021
Celecoxib, ciprofloxacin	Morrison & Foerster - Belgium	Treatment of amyotrophic lateral sclerosis	24/09/2020 26/10/2020 03/12/2020 (38 days/30 days)	07/12/2020 06/01/2021
Cyclo-L-Glycyl-L-2-Allylproline	Dlrc Pharma Services Limited - Ireland	Treatment of Pitt-Hopkins syndrome	24/09/2020 26/10/2020 03/12/2020 (38 days/30 days)	07/12/2020 06/01/2021
Cyclo-L-Glycyl-L-2-Allylproline	Dlrc Pharma Services Limited - Ireland	Treatment of Phelan-McDermid syndrome	24/09/2020 26/10/2020 03/12/2020 (38 days/30 days)	07/12/2020 06/01/2021
Cyclo-L-Glycyl-L-2-Allylproline	Dlrc Pharma Services Limited - Ireland	Treatment of Angelman syndrome	23/09/2020 26/10/2020 03/12/2020 (38 days/30 days)	07/12/2020 06/01/2021
Sulindac	Aparito Netherlands B.V. - Netherlands	Treatment of fragile X syndrome	01/09/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
Adeno-associated virus serotype rh74 containing the human sarcoglycan beta gene	Sarepta Therapeutics Ireland Limited - Ireland	Treatment of limb-girdle muscular dystrophy	01/09/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
Riloncept	Granzer Regulatory Consulting & Services - Germany	Treatment of idiopathic pericarditis	01/09/2020 14/09/2020 05/11/2020 (52 days/30 days)	07/12/2020 06/01/2021
Perflubron	Boyd Consultants Limited - Ireland	Treatment of respiratory distress syndrome	01/09/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020

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<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
(R)-3-(1-(2,3-dichloro-4-(pyrazin-2-yl)phenyl)-2,2,2-trifluoroethyl)-1-methyl-1-(1-methylpiperidin-4-yl)urea fumarate	Helsinn Birex Pharmaceuticals Limited - Ireland	Treatment of Prader-Willi Syndrome	01/09/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
4-[(3S)-3-aminopyrrolidin-1-yl]-6-cyano-5-(3,5-difluorophenyl)-N-[(2S)-1,1,1-trifluoropropan-2-yl]pyridine-3-carboxamide	Scendea (NL) B.V. - Netherlands	Treatment of congenital hyperinsulinism	28/08/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
Erlotinib	Institut Des Maladies Genetiques - France	Treatment of patients with Olmsted syndrome	28/08/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
Allogeneic retinal pigment epithelial cells genetically modified with a non-viral vector to express beta-domain deleted human factor VIII	TMC Pharma (EU) Limited - Ireland	Treatment of haemophilia A	27/08/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
Synthetic oligonucleotide selectively targeting UBE3A antisense RNA transcripts	Roche Registration GmbH -Germany	Treatment of Angelman syndrome	27/08/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
Adeno-associated viral vector serotype 9 encoding human ATP7B	Ultragenyx Germany GmbH - Germany	Treatment of Wilson disease	27/08/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
2'-O-(2-methoxyethyl) phosphorothioate antisense oligonucleotide targeting CD49d RNA	Pharma Gateway AB -Sweden	Treatment of Duchenne muscular dystrophy	27/08/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
(S)-N-(5-(4-(1-(benzo[d][1,3]dioxol-5-yl)ethyl)piperazin-1-yl)-1,3,4-thiadiazol-2-yl)acetamide, hydrochloride salt	Granzer Regulatory Consulting & Services - Germany	Treatment of progressive supranuclear palsy	26/08/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
Calcium oxybate, Magnesium oxybate, Potassium oxybate, Sodium oxybate	Jazz Pharmaceuticals Ireland Limited - Ireland	Treatment of idiopathic hypersomnia	26/08/2020 14/09/2020 03/11/2020 (80 days/30 days)	07/12/2020 06/01/2021
Humanised IgG1 monoclonal antibody against the extracellular domain of receptor tyrosine kinase-like orphan receptor 1 coupled via a proteolytically cleavable maleimidocaproyl-valine-citrulline-para-aminobenzoate linker to monomethyl auristatin E	TMC Pharma (EU) Limited - Ireland	Treatment of Mantle cell lymphoma (MCL)	25/08/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
2'-O-(2-methoxyethyl) modified antisense oligonucleotide targeting glycogen synthase 1 pre-mRNA	Ionis Development (Ireland) Limited - Ireland	Treatment of progressive myoclonic epilepsy type 2 (Lafora disease)	25/08/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
Human laminin-111, recombinant	Maxia Strategies-Europe Limited - Ireland	Treatment of congenital muscular dystrophy	24/08/2020 14/09/2020 03/11/2020 (80 days/30 days)	07/12/2020 06/01/2021

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
Rezafungin acetate	Mundipharma Corporation (Ireland) Limited - Ireland	Treatment of invasive candidiasis	21/08/2020 26/10/2020 03/12/2020 (38 days/30 days)	07/12/2020 06/01/2021
Setanaxib	GenKyoTex S.A. - France	Treatment of primary biliary cholangitis	06/08/2020 14/09/2020 03/12/2020 (80 days/30 days)	07/12/2020 06/01/2021
Aspacytarabine	Granzer Regulatory Consulting & Services - Germany	Treatment of acute myeloid leukaemia	05/08/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
Dabrafenib mesylate	Novartis Europharm Limited - Ireland	Treatment of glioma	31/07/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
Trametinib dimethyl sulfoxide	Novartis Europharm Limited - Ireland	Treatment of glioma	31/07/2020 14/09/2020 05/11/2020 (52 days/26 days)	13/11/2020 09/12/2020
DNA plasmid encoding human transferrin gene	Eyeevensys S.A.S. - France	Treatment of Retinitis pigmentosa	16/07/2020 12/08/2020 08/10/2020 (57 days/30 days)	14/10/2020 13/11/2020
L-pyroglutamyl-L-asparaginyl-L-prolyl-D-tyrosyl-D-tryptophan amide	Neuropath Therapeutics Limited - Ireland	Treatment of amyotrophic lateral sclerosis	16/07/2020 12/08/2020 08/10/2020 (57 days/30 days)	14/10/2020 13/11/2020
Autologous bone marrow 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	16/07/2020 12/08/2020 08/10/2020 (57 days/30 days)	14/10/2020 13/11/2020
Autologous CD4+ and CD8+ T cells genetically modified with a lentiviral vector encoding a B-cell maturation antigen-specific chimeric antigen receptor	Celgene Europe B.V. - Netherlands	Treatment of multiple myeloma	15/07/2020 12/08/2020 05/11/2020 (85 days/26 days)	13/11/2020 09/12/2020
Autologous CD34+ cells transduced ex vivo with a lentiviral vector containing a modified gamma-globin gene	Clinical Technology Centre (Ireland) Limited - Ireland	Treatment of sickle cell disease	15/07/2020 12/08/2020 08/10/2020 (57 days/30 days)	14/10/2020 13/11/2020
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, Sodium chloride solution 4.2% (w/v)	EUDRAC GmbH - Germany	Treatment of primary ciliary dyskinesia	14/07/2020 12/08/2020 08/10/2020 (57 days/33 days)	14/10/2020 16/11/2020
Tremelimumab	AstraZeneca AB - Sweden	Treatment of hepatocellular carcinoma	14/07/2020 12/08/2020 05/11/2020 (85 days/26 days)	13/11/2020 09/12/2020

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
Human interleukin 12 fused with immunoglobulin G4 C-terminal Fc fragment	VH Regulatory Consulting GmbH & Co. KG - Germany	Treatment of glioma	13/07/2020 12/08/2020 05/11/2020 (85 days/26 days)	13/11/2020 09/12/2020
Triheptanoin	Ultragenyx Germany GmbH - Germany	Treatment of carnitine palmitoyltransferase I deficiency	10/07/2020 12/08/2020 08/10/2020 (57 days/30 days)	14/10/2020 13/11/2020
(R)-tetrahydrofuran-3-yl 4-(6-(5-(4-ethoxy-1-isopropylpiperidin-4-yl)pyridin-2-yl)pyrrolo[1,2-b]pyridazin-4-yl)piperazine-1-carboxylate sesquisuccinate	Ipsen Pharma - France	Treatment of fibrodysplasia ossificans progressiva	08/07/2020 12/08/2020 08/10/2020 (57 days/30 days)	14/10/2020 13/11/2020
Alisitol, retinol palmitate, zinc gluconate	Vanessa Research Magyarorszag Kft. - Hungary	Treatment of microvillus inclusion disease	26/06/2020 12/08/2020 08/10/2020 (57 days/30 days)	14/10/2020 13/11/2020
Highly branched poly(beta-amino ester) complexed with a nanoplasmid containing the human COL7A1 gene	Amryt Genetics Limited - Ireland	Treatment of epidermolysis bullosa	26/06/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2021
Adeno-associated virus serotype 5 containing the human RDH12 gene	MeiraGTx B.V. - Netherlands	Treatment of RDH12 mutation associated retinal dystrophy	26/06/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2021
Zanidatamab	Voisin Consulting - France	Treatment of gastric cancer	26/06/2020 15/07/2020 08/10/2020 (85 days/30 days)	14/10/2020 13/11/2020
Perflubron	Boyd Consultants Limited - Ireland	Treatment of congenital pulmonary hypoplasia	26/06/2020 15/07/2020 08/10/2020 (85 days/30 days)	14/10/2020 13/11/2020
Tislelizumab	BeiGene Ireland Limited - Ireland	Treatment of oesophageal cancer	26/06/2020 15 July 2020 08/10/2020 (85 days/30 days)	14/10/2020 13/11/2020
Adeno-associated viral vector serotype 9 expressing codon-optimized human GRN gene	PPD Bulgaria EOOD - Bulgaria	Treatment of frontotemporal dementia	25/06/2020 15/07/2020 08/10/2020 (85 days/30 days)	14/10/2020 13/11/2020
Sotatercept	IDEA Innovative Drug European Associates (Ireland) Limited - Ireland	Treatment of pulmonary arterial hypertension	25/06/2020 12/08/2020 05/11/2020 (85 days/26 days)	13/11/2020 09/12/2020
Poly(oxy-1,2-ethanediyl), alpha-hydro-omega-methoxy, ether with N-[[[2-[[[6-[[[1-[3-[[3-(2,3-dihydroxypropoxy)propyl]amino]-3-oxopropyl]-2,5-dioxo-3-pyrrolidinyl]thio]hexyl]amino]ethyl]amino]carbonyl]-2-methylalanyl-teriparatide (2:1)	Ascendis Pharma Bone Diseases A/S - Denmark	Treatment of hypoparathyroidism	25/06/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2020

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
Ribitol	Premier Research Group S.L. - Spain	Treatment of limb-girdle muscular dystrophy	25/06/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2020
Anti-(pancreatic adenocarcinoma upregulated factor) IgG1 humanised monoclonal antibody	Prestige Biopharma Belgium - Belgium	Treatment of pancreatic cancer	25/06/2020 15/07/2020 08/10/2020 (85 days/30 days)	14/10/2020 13/11/2020
Miglustat	Theranexus S.A.S. - France	Treatment of neuronal ceroid lipofuscinosis	24/06/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2020
Adeno-associated viral vector serotype 9 encoding a codon-optimised human aspartylglucosaminidase transgene	Real Regulatory Limited - Ireland	Treatment of aspartylglucosaminuria	24/06/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2020
Trehalose	Theranexus S.A.S. - France	Treatment of neuronal ceroid lipofuscinosis	24/06/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2020
Sparsentan	Retrophin Europe Limited - Ireland	Treatment of primary IgA nephropathy	23/06/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2020
Leniolisib	Pharming Group N.V. - Netherlands	Treatment of activated phosphoinositide 3-kinase delta syndrome (APDS)	23/06/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2020
Adeno-associated virus serotype hu68 containing the human GLB1 gene	Pharma Gateway AB - Sweden	Treatment of GM1 gangliosidosis	19/06/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2020
Poly(oxy-1,2-ethanediyl), alpha-(carboxymethyl)-omega-methoxy-, amide with cystathionine $\gamma$ -lyase [Pyridoxal 5'-phosphate cofactor] (synthetic engineered human), tetramer	Aeglea Biotherapeutics UK Limited - United Kingdom	Treatment of homocystinuria	18/06/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2020
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	Kite Pharma EU B.V. - Netherlands	Treatment of acute lymphoblastic leukaemia	23/05/2020 17/06/2020 10/09/2020 (85 days/31 days)	18/09/2020 19/10/2020
Human frataxin fused to TAT cell-penetrating peptide	YES Pharmaceutical Development Services GmbH - Germany	Treatment of Friedreich's ataxia	22/05/2020 17/06/2020 16/07/2020 (29 days/22 days)	30/07/2020 21/08/2020
Copper histidinate	CambPharma Solutions (CY) Limited - Cyprus	Treatment of Menkes Disease	22/05/2020 17/06/2020 16/07/2020 (29 days/22 days)	30/07/2020 21/08/2020

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
Venglustat	Genzyme Europe B.V. - Germany	Treatment of GM2 gangliosidosis	22/05/2020 17/06/2020 16/07/2020 (29 days/23 days)	29/07/2020 21/08/2020
1-(3-methylbutanoyl)-L-aspartyl-L-threonyl-L-histidyl-L-phenylalanyl-L-prolyl-(L-cystinyl-L-isoleucyl-[(N6-(S)-4-carboxy-4-palmitamidobutanoyl)-L-lysiny]-L-phenylalanyl-L-glutamyl-L-prolyl-L-arginyl-L-serinyl-L-lysiny-L-glyciny-L-cystinyl)-L-lysynamide, disulfide, acetate	Scendea (NL) B.V. - Netherlands	Treatment of polycythaemia vera	22/05/2020 17/06/2020 10/09/2020 (85 days/31 days)	18/09/2020 19/10/2020
Sodium (4-{(E)-3-(4-fluorophenyl)-3-[4-(3-morpholin-4-yl-prop1ynyl)phenyl]allyloxy}-2-methylphenoxy)acetate	Scendea (NL) B.V. - Netherlands	Treatment of long-chain 3-hydroxyacyl-coenzyme A deficiency	22/05/2020 17/06/2020 16/07/2020 (29 days/22 days)	30/07/2020 21/08/2020
Infigratinib	YES Pharmaceutical Development Services GmbH - Germany	Treatment of cholangiocarcinoma	21/05/2020 17/06/2020 16/07/2020 (29 days/23 days)	29/07/2020 21/08/2020
Adeno-associated viral vector serotype 3B encoding shortened human ATP7B	Vivet Therapeutics S.A.S. - France	Treatment of Wilson's disease	21/05/2020 17/06/2020 16/07/2020 (29 days/23 days)	29/07/2020 21/08/2020
Autologous CD34+ cells transduced with a lentiviral vector encoding glucosylceramidase beta	Clinical Technology Centre (Ireland) Limited - Ireland	Treatment of Gaucher disease	21/05/2020 17/06/2020 16/07/2020 (29 days/23 days)	29/07/2020 21/08/2020
Autologous CD34+ cells transduced with a lentiviral vector encoding galactosidase alpha	Clinical Technology Centre (Ireland) Limited - Ireland	Treatment of Fabry Disease	21/05/2020 17/06/2020 10/09/2020 (85 days/31 days)	18/09/2020 19/10/2020
6-((3S,4S)-4-methyl-1-(pyrimidin-2-yl-methyl)pyrrolidin-3-yl)-3-tetrahydropyran-4-yl-7H-imidazo(1,5-a)pyrazin-8-one	TMC Pharma (EU) Limited - Ireland	Treatment of Sickle cell disease	21/05/2020 17/06/2020 16/07/2020 (29 days/23 days)	29/07/2020 21/08/2020
Autologous T cells transduced with lentiviral vector containing a tandem chimeric antigen receptor directed against CD20 and CD19	Miltenyi Biomedicine GmbH - Germany	Treatment of diffuse large B cell lymphoma	20/05/2020 17/06/2020 16/07/2020 (29 days/23 days)	29/07/2020 21/08/2020
Pentosan polysulfate sodium	Paradigm Biopharmaceuticals (Ireland) Limited - Ireland	Treatment of mucopolysaccharidosis type VI (Maroteaux-Lamy syndrome)	20/05/2020 17/06/2020 16/07/2020 (29 days/23 days)	29/07/2020 21/08/2020
Retifanlimab	Incyte Biosciences Distribution B.V. - Netherlands	Treatment of anal cancer	20/05/2020 17/06/2020 10/09/2020 (85 days/31 days)	18/09/2020 19/10/2020
3-(((1S,2S,3R)-2,3-difluoro-1-hydroxy-7-(methylsulfonyl)-2,3-dihydro-1H-inden-4-yl)oxy)-5-fluorobenzonitrile	Merck Sharp & Dohme B.V. - Netherlands	Treatment of von Hippel-Lindau disease	20/05/2020 17/06/2020 16/07/2020 (29 days/22 days)	30/07/2020 21/08/2020

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<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
(S)-1-(5-((2,3-dihydro-[1,4]dioxino[2,3-b]pyridin-7-yl)sulfonyl)-3,4,5,6-tetrahydropyrrolo[3,4-c]pyrrol-2(1H)-yl)-3-hydroxy-2-phenylpropan-1-one	Clinipace GmbH - Germany	Treatment of sickle cell disease	20/05/2020 17/06/2020 10/09/2020 (85 days/31 days)	18/09/2020 19/10/2020
Teclistamab	Janssen-Cilag International N.V. - Belgium	Treatment of multiple myeloma	19/05/2020 17/06/2020 10/09/2020 (85 days/31 days)	18/09/2020 19/10/2020
Decitabine, tetrahydrouridine	Novo Nordisk A/S - Denmark	Treatment of sickle cell disease	19/05/2020 17/06/2020 10/09/2020 (85 days/31 days)	18/09/2020 19/10/2020
Allogeneic hepatoblastoma cells encapsulated in alginate, ex vivo expanded	ESPL Regulatory Consulting Limited - Ireland	Treatment of acute liver failure	18/05/2020 17/06/2020 16/07/2020 (29 days/23 days)	29/07/2020 21/08/2020
2-(2-(18F)fluoropyridin-4-yl)-9H-pyrrolo[2,3-b:4,5-c']dipyridine	Life Molecular Imaging GmbH - Germany	Diagnosis of corticobasal degeneration	18/05/2020 17/06/2020 10/09/2020 (85 days/31 days)	18/09/2020 19/10/2020
Trehalose	FGK Representative Service GmbH - Germany	Treatment of mucopolysacchari dosis type III (Sanfilippo syndrome)	18/05/2020 17/06/2020 16/07/2020 (29 days/23 days)	29/07/2020 21/08/2020
(4-((2S,4S)-4-ethoxy-1-[(5-methoxy-7-methyl-1h-indol-4-yl)methyl]piperidin-2-yl}benzoic acid-hydrogen chloride(1/1))	Novartis Europharm Limited - Ireland	Treatment of primary IgA nephropathy	17/04/2020 17/06/2020 10/09/2020 (85 days/31 days)	18/09/2020 19/10/2020
Dextran sulfate low molecular weight	TikoMed AB - Sweden	Treatment of amyotrophic lateral sclerosis	24/03/2020 23/04/2020 16/07/2020 (84 days/23 days)	29/07/2020 21/08/2020
Allogeneic umbilical cord tissue-derived mesenchymal stromal cells ex vivo expanded	MDTB Cells GmbH - Germany	Prevention of bronchopulmonary dysplasia	20/03/2020 23/04/2020 16/07/2020 (84 days/23 days)	29/07/2020 21/08/2020
Tinostamustine	Mundipharma Corporation (Ireland) Limited - Ireland	Treatment of T-cell prolymphocytic leukaemia	20/03/2020 23/04/2020 18/06/2020 (56 days/32 days)	25/06/2020 27/07/2020
Retinol palmitate	Provepharm S.A.S. - France	Prevention of bronchopulmonary dysplasia	20/03/2020 23/04/2020 18/06/2020 (56 days/32 days)	25/06/2020 27/07/2020
Imetelstat sodium	Parexel International GmbH - Germany	Treatment of myelodysplastic syndromes	20/03/2020 23/04/2020 18/06/2020 (56 days/32 days)	25/06/2020 27/07/2020
Bis-(3-deoxy-3-(4-(3-fluorophenyl)-1H-1,2,3-triazol-1-yl)-beta-D-galactopyranosyl) sulfane	Galecto Biotech AB - Denmark	Treatment of idiopathic pulmonary fibrosis	20/03/2020 23/04/2020 16/07/2020 (56 days/23 days)	29/07/2020 21/08/2020



<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
Sodium (4-{{E}}-3-(4-fluorophenyl)-3-[4-(3-morpholin-4-yl-propyl)phenyl]allyloxy}-2-methylphenoxy)acetate	Scendea (NL) B.V. - Netherlands	Treatment of mitochondrial encephalomyopathy, lactic acidosis and stroke-like episodes	20/03/2020 23/04/2020 16/07/2020 (56 days/23 days)	29/07/2020 21/08/2020
Fasudil hydrochloride	Aneuryst (Ireland) Limited - Ireland	Treatment of non-traumatic subarachnoid haemorrhage	20/03/2020 23/04/2020 18/06/2020 (56 days/32 days)	25/06/2020 27/07/2020
Allogeneic T-cell precursors, mobilised peripheral blood-derived, ex vivo cultured	Smart Immune - France	Treatment of haematopoietic stem cell transplantation	19/03/2020 23/04/2020 16/07/2020 (84 days/23 days)	29/07/2020 21/08/2020
Hemopexin, human	CSL Behring GmbH - Germany	Treatment of sickle cell disease	19/03/2020 23/04/2020 18/06/2020 (56 days/32 days)	25/06/2020 27/07/2020
Retigabine	FGK Representative Service GmbH - Germany	Treatment of KCNQ2 developmental and epileptic encephalopathy	19/03/2020 17/06/2020 10/09/2020 (85 days/31 days)	18/09/2020 19/10/2020
2-(2-(18F)fluoropyridin-4-yl)-9H-pyrrolo[2,3-b:4,5-c']dipyridine	Life Molecular Imaging GmbH - Germany	Diagnosis of progressive supranuclear palsy	19/03/2020 23/04/2020 16/07/2020 (84 days/23 days)	29/07/2020 21/08/2020
Maralixibat chloride	Granzer Regulatory Consulting & Services - Germany	Treatment of biliary atresia	19/03/2020 23/04/2020 18/06/2020 (56 days/23 days)	25/06/2020 27/07/2020
C-type natriuretic peptide conjugated to multi-arm polyethylene glycol carrier through a cleavable linker	Ascendis Pharma Growth Disorders A/S - Denmark	Treatment of achondroplasia	19/03/2020 23/04/2020 18/06/2020 (56 days/23 days)	25/06/2020 27/07/2020
Protein-based delivery vector carrying a DNA payload encoding an RNA-guided nuclease that targets stx genes of Shiga toxin-producing Escherichia coli	Eligo Bioscience - France	Prevention of haemolytic uraemic syndrome	18/03/2020 23/04/2020 16/07/2020 (84 days/23 days)	29/07/2020 21/08/2020
Humanised IgG1 monoclonal antibody against human eotaxin-2	Granzer Regulatory Consulting & Services - Germany	Treatment of primary sclerosing cholangitis	11/03/2020 23/04/2020 16/07/2020 (84 days/23 days)	29/07/2020 21/08/2020
Tipifarnib	TMC Pharma (EU) Limited - Ireland	Treatment of peripheral T-cell lymphoma	28/02/2020 15/07/2020 10/09/2020 (57 days/31 days)	18/09/2020 19/10/2020
Adeno-associated virus serotype HSC15 expressing human arylsulfatase A gene	YES Pharmaceutical Development Services GmbH - Germany	Treatment of metachromatic leukodystrophy	28/02/2020 25/03/2020 20/05/2020 (56 days/28 days)	29/05/2020 26/06/2020

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
Triheptanoin	Ultragenyx Germany GmbH - Germany	Treatment of carnitine- acylcarnitine translocase deficiency	28/02/2020 25/03/2020 18/06/2020 (85 days/32 days)	25/06/2020 27/07/2020
Stiripentol	Biocodex - France	Treatment of Primary hyperoxaluria	27/02/2020 25/03/2020 20/05/2020 (56 days/28 days)	29/05/2020 26/06/2020
Onfekafusp alfa	Philogen S.p.A. - Italy	Treatment of glioma	27/02/2020 25/03/2020 20/05/2020 (56 days/28 days)	29/05/2020 26/06/2020
Nomacopan	Akari Malta Limited - Malta	Treatment of bullous pemphigoid	27/02/2020 25/03/2020 20/05/2020 (56 days/28 days)	29/05/2020 26/06/2020
Axicabtagene ciloleucel	Kite Pharma EU B.V. - Netherlands	Treatment of marginal zone lymphoma	25/02/2020 25/03/2020 20/05/2020 (56 days/28 days)	29/05/2020 26/06/2020
Adeno-associated viral vector expressing acid alpha-glucosidase gene	Audentes Therapeutics Netherlands B.V. - Netherlands	Treatment of glycogen storage disease type II (Pompe's disease)	21/02/2020 25/03/2020 18/06/2020 (85 days/32 days)	25/06/2020 27/07/2020
Pegylated adrenomedullin	Bayer AG - Germany	Treatment of acute respiratory distress syndrome (ARDS)	18/02/2020 25/03/2020 18/06/2020 (85 days/32 days)	25/06/2020 27/07/2020
Adeno-associated virus serotype 2/8 vector containing the human PDE6A gene	Institute For Ophthalmic Research - Germany	Treatment of retinitis pigmentosa	29/01/2020 23/04/2020 16/07/2020 (84 days/23 days)	29/07/2020 21/08/2020
Adeno-associated virus serotype 9 containing the human ASPA gene	Raremoon Consulting Limited - United Kingdom	Treatment of Canavan Disease	27/01/2020 25/02/2020 23/04/2020 (58 days/30 days)	05/05/2020 04/06/2020
Autologous CD4+ and CD8+ T cells transduced with a lentiviral vector encoding an affinity enhanced T cell receptor specific to MAGE-A4	Adaptimmune Limited - United Kingdom	Treatment of soft tissue sarcoma	26/01/2020 25/02/2020 23/04/2020 (58 days/30 days)	05/05/2020 04/06/2020
Viltolarsen	Medpace Finland Oy - Finland	Treatment of Duchenne muscular dystrophy	24/01/2020 25/02/2020 23/04/2020 (58 days/30 days)	05/05/2020 04/06/2020
Ile-Ala-Leu-Ile-Leu-Glu-Pro-Ile-Cys- Cys-Gln-Glu-Arg-Ala-Ala-(discrete- polyethylene glycol)24	Clinipace GmbH - Germany	Treatment of neonatal encephalopathy	24/01/2020 25/02/2020 23/04/2020 (58 days/30 days)	05/05/2020 04/06/2020
(4-{{(2S,4S)-4-ethoxy-1-[(5- methoxy-7-methyl-1H-indol-4- yl)methyl]piperidin-2-yl}}benzoic acid-hydrogen chloride(1/1))	Novartis Europharm Limited - Ireland	Treatment of paroxysmal nocturnal haemoglobinuria	24/01/2020 25/02/2020 23/04/2020 (58 days/30 days)	05/05/2020 04/06/2020

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
Lys40(NODAGA-68Ga)NH2-exendin-4	Stichting Katholieke Universiteit - Netherlands	Diagnosis of insulinoma	24/01/2020 25/02/2020 20/05/2020 (85 days/28 days)	29/05/2020 26/06/2020
(+)-epicatechin	MWB Consulting S.A.R.L. - France	Treatment of Becker muscular dystrophy	24/01/2020 25/02/2020 20/05/2020 (85 days/28 days)	29/05/2020 26/06/2020
Sodium phenylbutyrate, tauroursodeoxycholic acid	Drug Development and Regulation S.L. - Spain	Treatment of amyotrophic Lateral Sclerosis	23/01/2020 25/02/2020 23/04/2020 (58 days/30 days)	05/05/2020 04/06/2020
1-((2S,4S)-2-(((S)-(4-bromophenoxy)((S)-1-oxo-1-((S)-pentan-2-yl)oxy)propan-2-yl)amino)phosphoryl)oxy)methyl)-1,3-dioxolan-4-yl)-2-oxo-1,2-dihydropyrimidin-4-aminium chloride	Medivir AB - Sweden	Treatment of hepatocellular carcinoma	23/01/2020 25/02/2020 23/04/2020 (58 days/30 days)	05/05/2020 04/06/2020
Rilzabrutinib	Scendea (NL) B.V. - Netherlands	Treatment of immune thrombocytopenia	23/01/2020 25/02/2020 23/04/2020 (58 days/30 days)	05/05/2020 04/06/2020
Magrolimab	Granzer Regulatory Consulting & Services - Germany	Treatment of myelodysplastic syndromes	23/01/2020 25/02/2020 20/05/2020 (85 days/28 days)	29/05/2020 26/06/2020
Lumacaftor	Qanatpharma GmbH - Germany	Treatment of non-traumatic subarachnoid haemorrhage	23/01/2020 25/02/2020 23/04/2020 (58 days/30 days)	05/05/2020 04/06/2020
Sodium cromoglicate	IQVIA RDS Spain S.L. - Spain	Treatment of idiopathic pulmonary fibrosis	22/01/2020 25/02/2020 20/05/2020 (85 days/28 days)	29/05/2020 26/06/2020
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)-1-oxopropan-2-yl)amino)-1-oxopropan-2-yl)adipamide	ImmunoGen BioPharma (Ireland) Limited - Ireland	Treatment of blastic plasmacytoid dendritic cell neoplasm	21/01/2020 25/02/2020 20/05/2020 (85 days/28 days)	29/05/2020 26/06/2020
Adeno-associated viral vector serotype 3B encoding human multidrug resistance protein 3A	Vivet Therapeutics S.A.S. - France	Treatment of progressive familial intrahepatic cholestasis	05/12/2019 27/01/2020 19/03/2020 (52 days/26 days)	27/03/2020 22/04/2020
Glucagon analogue linked to a human immunoglobulin Fc fragment	JVM Europe B.V. - Netherlands	Treatment of insulin autoimmune syndrome	05/12/2019 27/01/2020 19/03/2020 (52 days/26 days)	27/03/2020 22/04/2020

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<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
Florbetaben (18F)	Life Molecular Imaging GmbH - Germany	Diagnosis of AL amyloidosis	05/12/2019 27/01/2020 19/03/2020 (52 days/26 days)	27/03/2020 22/04/2020
Adeno-associated virus vector serotype hu37 encoding human factor VIII	Bayer AG - Germany	Treatment of haemophilia A	05/12/2019 27/01/2020 19/03/2020 (52 days/26 days)	27/03/2020 22/04/2020
Lutetium (177Lu) lilotomab satetraxetan	Nordic Nanovector ASA - Norway	Treatment of marginal zone lymphoma	04/12/2019 27/01/2020 23/04/2020 (87 days/30 days)	05/05/2020 04/06/2020
Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human B cell maturation antigen with 4-1BB and CD3-zeta intracellular signalling domains	FGK Representative Service GmbH - Germany	Treatment of multiple myeloma	04/12/2019 27/01/2020 23/04/2020 (87 days/30 days)	05/05/2020 04/06/2020
Anti-(integrin beta-3) human monoclonal antibody	FGK Representative Service GmbH - Germany	Prevention of fetal and neonatal alloimmune thrombocytopenia due to human platelet antigen-1a incompatibility	04/12/2019 27/01/2020 19/03/2020 (52 days/26 days)	27/03/2020 22/04/2020
Cusatuzumab	Janssen-Cilag International N.V. - Belgium	Treatment of acute myeloid leukaemia	29/11/2019 27/01/2020 19/03/2020 (52 days/26 days)	27/03/2020 22/04/2020
Mitapivat sulfate	Agios Netherlands B.V. - Netherlands	Treatment of pyruvate kinase deficiency	27/11/2019 27/01/2020 19/03/2020 (52 days/26 days)	27/03/2020 22/04/2020
Rozanolixizumab	UCB Pharma - Belgium	Treatment of myasthenia gravis	22/11/2019 03/01/2020 19/03/2020 (76 days/26 days)	27/03/2020 22/04/2020
DNA plasmid encoding IL-12 p35 and p40 genes	FGK Representative Service GmbH - Germany	Treatment of ovarian cancer	22/11/2019 03/01/2020 19/03/2020 (76 days/26 days)	27/03/2020 22/04/2020
Haematopoietic stem cells and blood progenitors umbilical cord-derived expanded with (1R, 4R)-N1-(2-benzyl-7-(2-methyl-2H-tetrazol-5-yl)-9H-pyrimido[4,5-b]indol-4-yl)cyclohexane-1,4-diamine dihydrobromide dihydrate	CATS Consultants GmbH - Germany	Treatment of treatment in haematopoietic stem cell transplantation	21/11/2019 03/01/2020 19/03/2020 (76 days/26 days)	27/03/2020 22/04/2020
Trifarotene	Premier Research Group S.L. - Spain	Treatment of autosomal recessive congenital ichthyosis	20/11/2019 03/01/2020 20/02/2020 (48 days/29 days)	24/02/2020 24/03/2020

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
Tislelizumab	BeiGene Ireland Limited - Ireland	Treatment of hepatocellular carcinoma	20/11/2019 03/01/2020 19/03/2020 (76 days/26 days)	27/03/2020 22/04/2020
Losmapimod	Pharma Gateway AB - Sweden	Treatment of facioscapulothoracic muscular dystrophy	18/11/2019 03/01/2020 20/02/2020 (48 days/29 days)	24/02/2020 24/03/2020
Methotrexate	Helio Vision Germany GmbH - Germany	Treatment of retinal detachment	07/11/2019 27/01/2020 23/04/2020 (87 days/30 days)	05/05/2020 04/06/2020
Adeno-associated virus serotype 8 containing the human RdCVF sequence and the human RdCVFL sequence	SparingVision - France	Treatment of inherited retinal dystrophies	25/10/2019 26/11/2019 22/01/2020 (57 days/28 days)	31/01/2020 28/02/2020
Sintilimab	Parexel International GmbH - Germany	Treatment of peripheral T-cell lymphoma	25/10/2019 26/11/2019 22/01/2020 (57 days/28 days)	31/01/2020 28/02/2020
Sutimlimab	Celerion Austria GmbH - Austria	Treatment of immune thrombocytopenia	25/10/2019 26/11/2019 22/01/2020 (57 days/28 days)	31/01/2020 28/02/2020
Adeno-associated viral vector serotype S3 encoding human alpha-galactosidase A cDNA	Freeline Therapeutics (Ireland) Limited - Ireland	Treatment of Fabry disease	25/10/2019 26/11/2019 22/01/2020 (57 days/28 days)	31/01/2020 28/02/2020
Allogeneic multi-virus specific T lymphocytes targeting BK virus, cytomegalovirus, human herpesvirus-6, Epstein-Barr virus and adenovirus	TMC Pharma (EU) Limited - Ireland	Treatment of in haematopoietic stem cell transplantation	25/10/2019 26/11/2019 20/02/2020 (86 days/29 days)	27/02/2020 24/03/2020
2-((4S)-6-(4-chlorophenyl)-1-methyl-4H-benzo[C]isoxazolo[4,5-e]azepin-4-yl)acetamide monohydrate	IQVIA RDS Ireland Limited - Ireland	Treatment of myelofibrosis	24/10/2019 26/11/2019 22/01/2020 (57 days/28 days)	31/01/2020 28/02/2020
Fosgemcitabine palabenamide	Pharma Gateway AB - Sweden	Treatment of biliary tract cancer	24/10/2019 26/11/2019 20/02/2020 (86 days/29 days)	24/02/2020 24/03/2020
Adeno-associated virus serotype rh74 containing the human micro-dystrophin gene	Sarepta Therapeutics Ireland Limited - Ireland	Treatment of Duchenne muscular dystrophy	23/10/2019 26/11/2019 22/01/2020 (57 days/28 days)	31/01/2020 28/02/2020
Luspatercept	Celgene Europe B.V. - Netherlands	Treatment of myelofibrosis	23/10/2019 26/11/2019 22/01/2020 (57 days/28 days)	31/01/2020 28/02/2020
2-hydroxy-N,N,N-trimethylethan-1-aminium (Z)-4-(5-((3-benzyl-4-oxo-2-thioxothiazolidin-5-ylidene)methyl)furan-2-yl)benzoate	MWB Consulting S.A.R.L. - France	Treatment of pancreatic cancer	23/10/2019 26/11/2019 20/02/2020 (86 days/29 days)	24/02/2020 24/03/2020

<b>Product INN</b>	<b>Sponsor</b>	<b>Indication</b>	<b>EMA/COMP Submission Start date Opinion Active time</b>	<b>European Commission Opinion received Date of decision</b>
Autologous human T cells genetically modified ex-vivo with a lentiviral vector encoding a chimeric antigen receptor for B-cell maturation antigen	Janssen-Cilag International N.V. - Belgium	Treatment of multiple myeloma	21/10/2019 26/11/2019 22/01/2020 (57 days/28 days)	31/01/2020 28/02/2020
Asciminib	Novartis Europharm Limited - Ireland	Treatment of chronic myeloid leukaemia	21/10/2019 26/11/2019 20/02/2020 (86 days/29 days)	24/02/2020 24/03/2020
Artesunate	YES Pharmaceutical Development Services GmbH - Germany	Treatment of malaria	10/10/2019 26/11/2019 22/01/2020 (57 days/28 days)	31/01/2020 28/02/2020
Reldesemtiv	Pharma Gateway AB - Sweden	Treatment of amyotrophic lateral sclerosis	27/09/2019 29/10/2019 22/01/2020 (86 days/28 days)	31/01/2020 28/02/2020
Combination of three adeno-associated viral vectors of serotype 8 containing the 5'-, the body- and the 3'- coding sequences of human CEP290 fused to inteins	Fondazione Telethon - Italy	Treatment of inherited retinal dystrophies	27/09/2019 29/10/2019 22/01/2020 (85 days/28 days)	31/01/2020 28/02/2020
Autologous skin equivalent graft composed of keratinocytes and fibroblasts genetically corrected by CRISPR/Cas9-mediated excision of mutation-carrying COL7A1 exon 80	Consortio Centro de Investigación Biomédica en Red, M.P.- Spain	Treatment of epidermolysis bullosa	27/09/2019 29/10/2019 22/01/2020 (85 days/28 days)	31/01/2020 28/02/2020

### ***Negative COMP designation opinions***

<b>Product INN</b>	<b>Sponsor</b>	<b>Summary of indication</b>	<b>EMA/COMP • Submission • Start date • Opinion • Active time</b>	<b>European Commission • Opinion received • Date of decision</b>
Benzyl benzoate, beta-caryophyllene, cineole, cinnamaldehyde, cinnamyl acetate, linalool, trans-2-methoxycinnamaldehyde	Septeos S.A.S. - France	Treatment of eumycetoma	21/10/2019 26/11/2019 19/03/2020 114/144	23/03/2020 10/08/2020
Melatonin	Worphmed S.r.l. - Italy	Treatment of intracerebral haemorrhage	21/10/2019 26/11/2019 19/03/2020 114/134	06/07/2020 31/07/2020

## Annex 15 – HMPC European Union herbal monographs in 2020

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

### **European Union herbal monographs - Final**

Reference number	Document title	Adoption / Outcome*
<b>First Assessment</b>		
EMA/HMPC/554043/2018	Herniariae herba	08/07/2020 / TU
EMA/HMPC/44543/2018	Species amarae	18/11/2020 / TU
EMA/HMPC/438183/2017	Species sedativae	18/11/2020 / TU
<b>Revision</b>		
EMA/HMPC/638242/2018	Hippocastani semen	15/01/2020 / TU + WEU
EMA/HMPC/522410/2013	Menthae piperitae aetheroleum	15/01/2020 / TU + WEU
EMA/HMPC/572705/2014	Menthae piperitae folium	15/01/2020 / TU
EMA/HMPC/376416/2019	Millefolii herba	23/09/2020 / TU
EMA/HMPC/726270/2016	Rhamni purshianae cortex	06/05/2020 / WEU
EMA/HMPC/113700/2019	Rhei radix	06/05/2020 / WEU
EMA/HMPC/48715/2017	Tanacetii parthenii herba	08/07/2020 / TU
EMA/HMPC/59032/2017	Thymi aetheroleum	08/07/2020 / TU

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

Reference number	Document title	Adoption *
<b>First Assessment</b>		
	none	
<b>Revision</b>		
EMA/HMPC/679997/2013	Menthae piperitae aetheroleum	15/01/2020 / TU + WEU
EMA/HMPC/376417/2019	Millefolii herba	23/09/2020 / TU

### **European Union herbal monographs - Draft**

Reference number	Document title	Adoption / Outcome*
<b>First Assessment</b>		
EMA/HMPC/376770/2019	Aloysiae citriodoraе folium	06/05/2020 / TU
EMA/HMPC/637833/2018	Menyanthes trifoliata folium	23/09/2020 / TU
EMA/HMPC/44543/2018	Species amarae	06/05/2020 / TU
EMA/HMPC/438183/2017	Species sedativae	06/05/2020 / TU
<b>Revision</b>		

Reference number	Document title	Adoption / Outcome*
	none	

### ***Monograph/ list entry reviews***

Reference number	Document title	Adoption / Outcome
<b>Final decision</b>		
EMA/HMPC/13144/2020	Absinthii herba	04/03/2020 / no revision
EMA/HMPC/509409/2019	Arctii radix	15/01/2020 / no revision
EMA/HMPC/351955/2020	Carvi aetheroleum	18/11/2020 / no revision
EMA/HMPC/351955/2020	Carvi fructus	18/11/2020 / no revision
EMA/HMPC/475451/2020	Caryophyllii floris aetheroleum	18/11/2020 / no revision
EMA/HMPC/439694/2020	Chamomillae romanae flos	18/11/2020 / no revision
EMA/HMPC/232764/2020	Filipendulae ulmariae flos	06/05/2020 / no revision
EMA/HMPC/595722/2019	Filipendulae ulmariae herba	06/05/2020 / no revision
EMA/HMPC/616091/2019	Juniperi aetheroleum	23/09/2020 / no revision
EMA/HMPC/4369/2020	Juniperi pseudo-fructus	23/09/2020 / revision required
EMA/HMPC/487303/2020	Lavandulae aetheroleum	18/11/2020 / revision required
EMA/HMPC/487394/2020	Lavandulae flos	18/11/2020 / no revision
EMA/HMPC/7199/2020	Pelargonii radix	06/05/2020 / revision required
EMA/HMPC/489234/2020	Solani dulcamarae stipites	18/11/2020 / no revision



## Annex 16 – PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2020

### 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
(2S)-2-[[2-[(4S)-4-(difluoromethyl)-2-oxo-oxazolidin-3-yl]-5,6-dihydroimidazo[1,2-d][1,4]benzoxazepin-9-yl]amino]propanamide	not available at present	W	Oncology	Roche Registration GmbH	18/03/2020	P/0113/2020
5%-Δ9-Tetrahydrocannabinol standardised Cannabis extract (VER-01)	not available at present	W	Pain	Vertanical GmbH	18/03/2020	P/0077/2020
6 fluoro-7-(2-fluoro-6-hydroxyphenyl)-(1M)-1-[4-methyl-2-(propan-2-yl)pyridin-3-yl]-4-[(2S)-2-methyl-4-(prop-2-enoyl)piperazin-1-yl]pyrido[2,3-d]pyrimidin-2(1H)-one (Common name: AMG 510)	not available at present	W	Oncology	Amgen Europe BV	18/03/2020	P/0091/2020
Allogeneic,non-expanded,umbilical cord blood-derived,haematopoietic mature myeloid and lymphoid cells (NF) / Allogeneic,ex vivo expanded,umbilical cord blood-derived,haematopoietic CD34+progenitor cells (CF)	NiCord	P	Immunology- Rheumatology- Transplantation	Gamida Cell Ltd	18/03/2020	P/0099/2020
Alogliptin benzoate (as alogliptin)	Vipidia	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Takeda Development Centre Europe Ltd	18/03/2020	P/0078/2020
Anti-neonatal Fc receptor human monoclonal antibody	not available at present	P	Other	Momenta Pharmaceuticals, Inc.	18/03/2020	P/0117/2020
Autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding for the human Beta 2 Integrin/CD18 gene	not available at present	P	Immunology- Rheumatology- Transplantation	Rocket Pharmaceuticals, Inc.	20/03/2020	P/0106/2020
Avapritinib	not available at present	W	Oncology / Haematology- Haemostaseology	Blueprint Medicines (Netherlands) B.V.	18/03/2020	P/0083/2020
Avatrombopag maleate	Doptelet	P	Haematology- Haemostaseology	Dova Pharmaceuticals Ireland Limited	18/03/2020	P/0096/2020

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Berotrastat	not available at present	P	Pneumology - Allergology	BioCryst UK	10/02/2020	P/0061/2020
Brolucizumab	Beovu	W	Ophthalmology	Novartis Europharm Limited	20/03/2020	P/0112/2020
Burosumab	Crysvita	PM	Other	Kyowa Kirin Holdings B.V.	18/03/2020	P/0093/2020
CD34+enriched cells from patients with Fanconi anemia subtype A (FA-A) transduced ex vivo with lentiviral vector carrying the FANCA gene, PGKFANCA-WPRE	not available at present	P	Haematology-Haemostaseology	Rocket Pharmaceuticals, Inc.	18/03/2020	P/0114/2020
Cannabidiol	Epidyolex	P	Neurology	GW Pharma (International) B.V	18/03/2020	P/0095/2020
Eftilagimod alpha	not available at present	W	Oncology	Immutep SAS	27/03/2020	P/0118/2020
Eluxadoline	Truberzi	PM	Gastroenterology-Hepatology	Allergan Pharmaceuticals International Limited	18/03/2020	P/0107/2020
Entrectinib	Rozlytrek	PM		Roche Registration GmbH	18/03/2020	P/0092/2020
Ezetimibe / Rosuvastatin	Rosuvastatin/Ezetimibe Elpen "and associated names"	W	Cardiovascular Diseases	ELPEN Pharmaceutical Co. Inc.	18/03/2020	P/0079/2020
Gefapixant citrate salt	not available at present	W	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme (Europe), Inc.	18/03/2020	P/0100/2020
Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / 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 UK Limited	18/03/2020	P/0084/2020
Ixekizumab	Taltz	PM	Dermatology	Eli Lilly Nederland B.V.	18/03/2020	P/0087/2020
Live, attenuated, chimeric dengue virus, serotype 4 / Live, attenuated, chimeric dengue virus, serotype 3 / Live, attenuated, chimeric dengue virus, serotype 2 / Live, attenuated, chimeric dengue virus, serotype 1	Dengvaxia	PM	Vaccines	Sanofi Pasteur	21/02/2020	P/0065/2020

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Meloxicam / Bupivacaine	Zynrelef	PM	Pain	Heron Therapeutics B.V.	18/03/2020	P/0088/2020
Nemolizumab	not available at present	W	Dermatology	Galderma International S.A.	20/03/2020	P/0119/2020
Nemolizumab	not available at present	<b>Negative</b>	Dermatology	Galderma International S.A.	N/A <sup>1</sup>	
Nirsevimab (MEDI8897, anti-respiratory syncytial virus human IgG1κ monoclonal antibody)	Nirsevimab	PM	Infectious Diseases	AstraZeneca AB	18/03/2020	P/0082/2020
PF-05221304-82 Tris(hydroxymethyl)aminomethane Trihydrate	not available at present	P	Gastroenterology-Hepatology	Pfizer Europe MA EEIG	18/03/2020	P/0098/2020
Parsaclisib	not available at present	W	Oncology	Incyte Biosciences Distribution B.V.	18/03/2020	P/0067/2020
Perampanel	Fycompa	PM	Neurology	Eisai Europe Limited	18/03/2020	P/0072/2020
Recombinant anti-human CD20 and anti-human CD3 monoclonal antibody (RO7082859; CD20 CD3 TCB).	not available at present	P	Oncology	Roche Registration GmbH	18/03/2020	P/0094/2020
Risdiplam	Not available at present	PM	Neurology	Roche Registration GmbH	18/03/2020	P/0089/2020
Sodium zirconium cyclosilicate	Lokelma	PM	Endocrinology-Gynaecology-Fertility-Metabolism	AstraZeneca AB	18/03/2020	P/0069/2020
Sonidegib	Odomzo	PM	Oncology	Sun Pharmaceutical Industries Europe B.V.	20/03/2020	P/0111/2020
Soticlestat	not available at present	P	Neurology	Takeda Pharma A/S	18/03/2020	P/0115/2020
Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain	not available at present	PM	Vaccines	Sanofi Pasteur	20/02/2020	P/0064/2020
Tenofovir alafenamide	Vemlidy	PM	Infectious Diseases	Gilead Sciences International Ltd.	20/02/2020	P/0063/2020

<sup>1</sup> procedure withdrawn after adoption of opinion

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Vosoritide	Not available at present	PM	Other	BioMarin International Limited	10/02/2020	P/0060/2020
avacopan	Vynpenta	PM	Immunology- Rheumatology- Transplantation	ChemoCentryx Ireland Ltd.	20/03/2020	P/0103/2020
baricitinib	Olumiant	P	Immunology- Rheumatology- Transplantation	Eli Lilly and Company Limited	18/03/2020	P/0070/2020
bezlotoxumab	Zinplava	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	20/03/2020	P/0104/2020
carbidopa / levodopa	Not available at present	W	Neurology	Neuroderm Ltd	18/03/2020	P/0068/2020
dapagliflozin	Forxiga	PM	Endocrinology- Gynaecology-Fertility- Metabolism	AstraZeneca AB	18/03/2020	P/0086/2020
daratumumab	Darzalex	W	Oncology	Janssen-Cilag International N.V.	18/03/2020	P/0116/2020
denosumab	Xgeva, Prolia	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Amgen Europe B.V.	20/03/2020	P/0102/2020
dupilumab	Dupixent	P	Gastroenterology- Hepatology	Regeneron Ireland DAC	10/02/2020	P/0059/2020
eculizumab	Soliris	PM	Neurology	Alexion Europe SAS	21/03/2020	P/0075/2020
efgartigimod alfa	not available at present	P	Neurology	argenx BVBA	18/03/2020	P/0097/2020
eftrenonacog alfa	ALPROLIX	PM	Haematology- Haemostaseology	Swedish Orphan Biovitrum AB (publ)	18/03/2020	P/0071/2020
eladocagene exuparvovec	Upstaza	PM	Neurology	PTC Therapeutic International Limited	18/03/2020	P/0080/2020
emapalumab	Gamifant	PM	Immunology- Rheumatology- Transplantation	Novimmune BV	20/03/2020	P/0109/2020
evinacumab	not available at present	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Regeneron Ireland DAC	18/03/2020	P/0105/2020
idasanutlin	not available at present	PM	Oncology	Roche Registration GmbH	18/03/2020	P/0081/2020

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inotuzumab ozogamicin	Besponsa	PM	Oncology / Haematology-Haemostaseology	Pfizer Europe MA EEIG	10/02/2020	P/0062/2020
mosunetuzumab	not available at present	P	Oncology	Roche Registration GmbH	20/03/2020	P/0108/2020
posaconazole	Noxafil	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	18/03/2020	P/0101/2020
timrepigene emparvovec	not available at present.	P	Ophthalmology	Nightstar Europa Limited	20/03/2020	P/0085/2020
vadadustat	Vafseo	PM	Haematology-Haemostaseology	Akebia Therapeutics, Inc.	21/03/2020	P/0074/2020
verdiperstat	not available at present	W	Neurology	Biohaven Pharmaceuticals, Inc.	18/03/2020	P/0110/2020
zolbetuximab	not available at present	W	Oncology	Astellas Pharma Europe B.V.	18/03/2020	P/0090/2020
zoliflodacin	not available at present	P	Infectious Diseases	Entasis Therapeutic Inc.	21/03/2020	P/0073/2020
(S)-(2-(5-chloro-4-methyl-1H-benzo[d]imidazol-2-yl)-2-methylpyrrolidin-1-yl)(4-methoxy-2-(2H-1,2,3-triazol-2-yl)phenyl)methanone hydrochloride (daridorexant)	not available at present	P	Psychiatry	Idorsia Pharmaceuticals Deutschland GmbH	15/04/2020	P/0131/2020
1-[4-bromo-5-[1-ethyl-7-(methylamino)-2-oxo-1,2-dihydro-1,6-naphthyridin-3-yl]-2-fluorophenyl]-3-phenylurea	not available at present	W	Oncology	Deciphera Pharmaceuticals LLC	18/03/2020	P/0122/2020
2-[[[2-ethyl-6-[4-[2-(3-hydroxyazetid-1-yl)-2-oxoethyl]piperazin-1-yl]-8-methylimidazo[1,2-a]pyridin-3-yl](methyl)amino]-4-(4-fluorophenyl)-1,3-thiazole-5-carbonitrile (GLPG1690)	not available at present	P	Pneumology - Allergology	Galapagos NV	18/04/2020	P/0148/2020
3-(((1S,2S,3R)-2,3-difluoro-1-hydroxy-7-(methylsulfonyl)-2,3-dihydro-1H-inden-4-yl)oxy)-5-fluorobenzonitrile	not available at present	W	Oncology	Merck, Sharp & Dohme (Europe) Inc	17/04/2020	P/0154/2020
4-[4-({4-[(2-[(3S)-2,6-dioxopiperidin-3-yl]-1-oxo-2,3-dihydro-1H-isoindol-4-yl)oxy]methyl}phenyl)methyl]piperazin-1-yl]-3-fluorobenzonitrile	not available at present	W	Oncology	Celgene Europe B.V.	17/04/2020	P/0153/2020
Ad26.ZEBOV	not available at present	PM	Vaccines	Janssen Cilag International NV	17/04/2020	P/0155/2020
Alpha1-proteinase inhibitor (human) (A1-PI)	not available at present	P	Immunology-Rheumatology-Transplantation	CSL Behring GmbH	15/04/2020	P/0134/2020

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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)	not available at present	PM	Oncology	Kite Pharma EU B.V.	18/04/2020	P/0142/2020
Axicabtagene ciloleucel	Yescarta	PM	Oncology	Kite Pharma EU B.V.	15/04/2020	P/0132/2020
Bintrafusp alfa	not available at present	P	Oncology	Merck Europe B.V.	18/04/2020	P/0150/2020
Blinatumomab	Blinzto	PM	Oncology	Amgen Europe B.V.	18/04/2020	P/0143/2020
Clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins	Xeomin (and associated names), Bocouture	PM	Ophthalmology / Neurology	Merz Pharmaceuticals GmbH	30/03/2020	P/0125/2020
Dihomo- $\gamma$ -linolenic acid (D5107)	not available at present	P	Dermatology	DS Biopharma Ltd.	15/04/2020	P/0129/2020
Etrolizumab	not available at present	PM	Gastroenterology- Hepatology	Roche Registration GmbH	30/04/2020	P/0168/2020
Galcanezumab	Emgality	PM	Neurology	Eli Lilly and Company Limited	15/04/2020	P/0136/2020
Ladarixin	not available at present	P	Endocrinology- Gynaecology- Fertility- Metabolism	Dompé farmaceutici SpA	24/03/2020	P/0124/2020
Lanadelumab	Takhzyro	W	Other	Shire Pharmaceuticals Ireland Limited (a Takeda company)	18/04/2020	P/0140/2020
Lazertinib (mesylate)	not available at present	W	Oncology	Janssen-Cilag International N.V.	15/04/2020	P/0127/2020
Lebrikizumab	not available at present.	P	Dermatology	Dermira Inc.	17/04/2020	P/0151/2020
Lenadogene nolparvovec (GS010)	Lumevoq	P	Neurology	GenSight-Biologics	24/04/2020	P/0166/2020
Linaclotide	Constella	PM	Gastroenterology- Hepatology	Allergan Pharmaceuticals International Limited	15/04/2020	P/0135/2020
MVA-BN-Filo	not available at present	PM	Vaccines	Janssen Cilag International NV	17/04/2020	P/0138/2020

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N-(3-{6-Amino-5-[2-(N-methylprop-2-enamido)ethoxy]pyrimidin-4-yl}-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide (LOU064)	not available at present	P	Dermatology	Novartis Europharm Limited	17/04/2020	P/0158/2020
PRACINOSTAT	not available at present	P	Oncology	Helsinn Birex Pharmaceuticals limited	03/04/2020	P/0126/2020
Palovarotene	Sohonos	PM	Other	Ipsen Pharma	15/04/2020	P/0144/2020
Pegcetacoplan	not available at present	P	Haematology-Haemostaseology	Apellis Ireland Limited	17/04/2020	P/0149/2020
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 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	not available at present	P	Vaccines	Pfizer MA EEIG	17/04/2020	P/0159/2020

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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 5 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype						
Pneumococcal polysaccharides individually biotinylated and complexed with a carrier protein (recombinant fusion construct of rhizavidin and Streptococcus pneumoniae derived proteins), 24-valent	not available at present	P	Vaccines	Astellas Pharma Europe, B.V.	18/04/2020	P/0146/2020
Polymyxin B	not available at present	P	Infectious Diseases	The GARDP Foundation	17/04/2020	P/0157/2020
Regorafenib	Stivarga	PM	Oncology	Bayer AG	17/04/2020	P/0141/2020
Temozolomide	not available at present	P	Oncology	Accord Healthcare S.L.U.	17/04/2020	P/0147/2020
boceprevir	not available at present	W	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc	17/04/2020	P/0156/2020
cenobamate	not available at present	P	Neurology	Aziende Chimiche Angelini Francesco - A.C.R.A.F. S.p.A	18/03/2020	P/0120/2020
copanlisib	Aliqopa	PM	Oncology	Bayer AG	15/04/2020	P/0133/2020
elafibranor	Obdiela	PM	Gastroenterology- Hepatology	GENFIT SA	17/04/2020	P/0139/2020
leriglitzone	not available at present	P	Neurology	Minoryx Therapeutics S.L.	18/04/2020	P/0152/2020
mirikizumab	not available at present	PM	Dermatology / Gastroenterology- Hepatology	Eli Lilly and Company	15/04/2020	P/0130/2020
natalizumab	Tysabri	W	Neurology	Biogen Idec Limited	18/03/2020	P/0123/2020
semaglutide	Ozempic	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Novo Nordisk A/S	18/04/2020	P/0137/2020

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tenofovir disoproxil (as fumarate)	Viread	PM	Infectious Diseases	Gilead Sciences International Limited	20/03/2020	P/0121/2020
tralokinumab	not available at present	PM	Dermatology	LEO Pharma A/S	15/04/2020	P/0145/2020
urea / Glycerol /	not available at present	W	Dermatology	ACO Hud Nordic AB	15/04/2020	P/0128/2020
18-(p-[131I]-iodophenyl)octadecyl phosphocholine	not available at present	W	Oncology	Collectar Biosciences, Inc.	13/05/2020	P/0169/2020
2-iminobiotin	not available at present	PM	Neonatology - Paediatric Intensive Care	Neurophyxia BV	15/05/2020	P/0192/2020
Afatinib	Giotrif	PM	Oncology	Boehringer Ingelheim International GmbH	13/05/2020	P/0184/2020
Alicaforsen (sodium salt)	Camligo	PM	Gastroenterology- Hepatology	Atlantic Healthcare Europe B.V.	15/05/2020	P/0180/2020
Arfollitoxin	Arfollitoxin powder for solution for injection 100 mg	P	Oncology	Isofol Medical AB	13/05/2020	P/0182/2020
Avalglucosidase alfa	not available at present	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Genzyme Europe B.V.	13/05/2020	P/0174/2020
Crisaborole	Staquis	PM	Dermatology	Pfizer Europe MA EEIG	16/04/2020	P/0162/2020
Cyclophosphamide	not available at present	P	Oncology	Accord Healthcare S.L.U.	15/05/2020	P/0191/2020
Difelikefalin	not available at present	P	Other	Vifor Fresenius Medical Care Renal Pharma France	13/05/2020	P/0172/2020
Dimethyl fumarate	Tecfidera	PM	Neurology	Biogen Idec Ltd.	15/05/2020	P/0177/2020
Dulaglutide	Trulicity	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Eli Lilly and Company	13/05/2020	P/0175/2020
Hydrocortisone (acetate) / Benzocaine	Hemorrane Plus	W	Gastroenterology- Hepatology	FAES FARMA, S.A.	13/05/2020	P/0181/2020
Ibrexafungerp	not available at present	P	Infectious Diseases	SCYNEXIS, Inc.	17/04/2020	P/0164/2020
Imatinib	not available at present	P	Oncology	Accord Healthcare S.L.U.	13/05/2020	P/0171/2020

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Influenza virus surface antigens - A/turkey/Turkey/1/05 (H5N1)	Aflunov	PM	Vaccines	Seqirus S.r.l.	15/05/2020	P/0189/2020
Isoflurane	IsoConDa	PM	Neonatology - Paediatric Intensive Care	Sedana Medical AB	15/05/2020	P/0190/2020
Livoretide	not available at present	P	Endocrinology- Gynaecology-Fertility- Metabolism	Millendo Therapeutics SAS	13/05/2020	P/0176/2020
Macimorelin	Macimorelin Aeterna Zentaris	PM	Endocrinology- Gynaecology-Fertility- Metabolism / Diagnostic	Aeterna Zentaris GmbH	06/04/2020	P/0076/2020
Methoxyflurane	Penthrox	PM	Pain	Medical Developments UK Ltd	13/05/2020	P/0178/2020
Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	Foclivia	PM	Vaccines	Seqirus S.r.l.	15/05/2020	P/0188/2020
Pitolisant	Wakix	PM	Neurology	BIOPROJET PHARMA	27/04/2020	P/0167/2020
Propan-2-yl 2-[5-( acryloylamino )-4-{ [2-( dimethylamino )ethyl] ( methyl)amino }-2-methoxyanilino ]-4- ( 1 methyl-1 H-indol-3-yl)pyrimidine-5-carboxylate (TAK-788)	not available at present	W	Oncology	Takeda Pharma A/S	16/04/2020	P/0161/2020
Rolapitant	Varuby	W	Other	Tesaro Bio Netherlands B.V.	15/05/2020	P/0194/2020
Rosuvastatin calcium/fenofibrate	not available at present	W	Endocrinology- Gynaecology-Fertility- Metabolism / Cardiovascular Diseases	Accord Healthcare S.L.U.	13/05/2020	P/0170/2020
Setmelanotide	not available at present	PM	Nutrition	Rhythm Pharmaceuticals, Inc	15/05/2020	P/0179/2020
Spesolimab	not available at present	P	Dermatology	Boehringer Ingelheim International GmbH	15/05/2020	P/0195/2020
Talimogene laherparepvec	Imlygic	PM	Oncology	Amgen Europe B.V.	13/05/2020	P/0187/2020
Tezacaftor / ivacaftor	Symkevi	PM	Pneumology - Allergology	Vertex Pharmaceuticals (Europe) Ltd.	15/05/2020	P/0193/2020
Tiragolumab	not available at present	W	Oncology	Roche Registration GmbH	13/05/2020	P/0186/2020
Tofacitinib	XELJANZ	PM	Gastroenterology- Hepatology	Pfizer Europe MA EEIG	24/04/2020	P/0165/2020

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Volanesorsen	Volanesorsen, Waylivra	PM	Endocrinology-Gynaecology-Fertility-Metabolism	Akcea Therapeutics	13/05/2020	P/0185/2020
gilteritinib (as fumarate)	Xospata	PM	Oncology / Haematology-Haemostaseology	Astellas Pharma Europe B.V.	13/05/2020	P/0173/2020
idasanutlin	not available at present	P	Oncology	Roche Registration GmbH	15/05/2020	P/0196/2020
ivacaftor	Kalydeco	PM	Other	Vertex Pharmaceuticals (Ireland) Ltd	17/04/2020	P/0163/2020
romosozumab	Evenity	PM	Endocrinology-Gynaecology-Fertility-Metabolism	UCB Pharma S.A.	15/05/2020	P/0183/2020
roxadustat	not available at present	PM	Haematology-Haemostaseology	Astellas Pharma Europe B.V.	16/04/2020	P/0160/2020
Adeno-associated viral vector serotype 8 containing the human RPGR gene	not available at present	P	Ophthalmology	Biogen Netherlands B.V.	17/06/2020	P/0229/2020
Adeno-associated virus serotype 2 (AAV2) encoding human aromatic L-amino acid decarboxylase (hAADC)	not available at present	W	Neurology	Neurocrine Therapeutics, Ltd.	16/06/2020	P/0205/2020
Adenovirus encoding vascular endothelial growth factor C (AdAptVEGF-C)	Lymfactivin	W	Other	Herantis Pharma Plc	19/06/2020	P/0230/2020
Allogeneic haptenised and irradiated cell lysates derived from glioma	Sitoiganap	P	Oncology	ERC Belgium	17/06/2020	P/0224/2020
Allogeneic haptenised and irradiated cells derived from glioma	Sitoiganap	P	Oncology	ERC Belgium	17/06/2020	P/0225/2020
Atropine (sulphate)	not available at present	P	Ophthalmology	Fondazione Per La Ricerca Farmacologica Gianni Benzi Onlus	17/06/2020	P/0237/2020
Autologous CD34+ cells transduced with lentiviral vector encoding the human beta-globin gene	not available at present	PM	Haematology-Haemostaseology	Orchard Therapeutics (Europe) Ltd	12/06/2020	P/0236/2020
Autologous haptenised and irradiated cell lysates derived from glioma	Sitoiganap	P	Oncology	ERC Belgium	17/06/2020	P/0223/2020
Autologous haptenised and irradiated cells derived from glioma	Sitoiganap	P	Oncology	ERC Belgium	17/06/2020	P/0226/2020
Betahistine (dihydrochloride)	not available at present	W	Oto-rhino-laryngology / Neurology	Auris Medical Ltd.	17/06/2020	P/0228/2020

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Bilastine	Bilaxten and associated names	<b>RW</b>	Dermatology / Pneumology - Allergology / Oto-rhino-laryngology	FAES FARMA, S.A.	17/06/2020	P/0219/2020
Bis-choline tetrathiomolybdate (ALXN1840)	not available at present	P	Endocrinology- Gynaecology-Fertility- Metabolism	Alexion Europe S.A.S.	19/06/2020	P/0234/2020
Chloroprocaine (hydrochloride)	Ampres	W	Anaesthesiology	Sintetica GmbH	17/06/2020	P/0216/2020
Dexamethasone (sodium phosphate) encapsulated in human autologous erythrocytes	Not available at present	P	Neurology	EryDel S.p.A	16/06/2020	P/0211/2020
Elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide	Genvoya	PM	Infectious Diseases	Gilead Sciences International Ltd.	27/05/2020	P/0202/2020
Eptinezumab	Vyepti	PM	Neurology	H. Lundbeck A/S	16/06/2020	P/0209/2020
Erenumab	Aimovig	PM	Neurology	Novartis Europharm Limited	19/06/2020	P/0233/2020
Ezetimibe / Atorvastatin	not available at present	W	Cardiovascular Diseases	ELPEN Pharmaceutical Co. Inc.	16/06/2020	P/0215/2020
Gepotidacin	not available at present	P	Infectious Diseases	GlaxoSmithKline Trading Services Limited	16/06/2020	P/0213/2020
Gepotidacin	not available at present	P	Infectious Diseases	GlaxoSmithKline Trading Services Limited	16/06/2020	P/0212/2020
Human fibrinogen concentrate (BT524)	not available at present	PM	Haematology- Haemostaseology	Biotest AG	19/06/2020	P/0232/2020
IMG-2789	not available at present	W	Haematology- Haemostaseology	Imago Biosciences BV	16/06/2020	P/0220/2020
Ligelizumab	not available at present	PM	Dermatology	Novartis Europharm Limited	16/06/2020	P/0208/2020
Lucerastat	not available at present	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Idorsia Pharmaceuticals Deutschland GmbH	17/06/2020	P/0221/2020
Maralixibat chloride	not available at present	PM	Gastroenterology- Hepatology	Mirum Pharmaceuticals	25/05/2020	P/0200/2020

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Monovalent, recombinant, replication-incompetent human adenovirus serotype 26-vectored vaccine encoding the pre-fusion conformation-stabilised F protein derived from the RSV A2 strain	not available at present	PM	Vaccines / Infectious Diseases	Janssen-Cilag International NV	20/05/2020	P/0197/2020
Ribociclib (succinate)	Kisqali	W	Oncology	Novartis Europharm Limited	17/06/2020	P/0218/2020
Satralizumab	Enspryng	PM	Neurology	Roche Registration GmbH	16/06/2020	P/0204/2020
Sodium alginate oligosaccharide	Not available at present	P	Pneumology - Allergology	AlgiPharma AS	19/06/2020	P/0235/2020
Tofacitinib	Xeljanz	PM	Immunology- Rheumatology- Transplantation	Pfizer Europe MA EEIG	17/06/2020	P/0227/2020
Upadacitinib	Rinvoq	PM	Immunology- Rheumatology- Transplantation / Dermatology	AbbVie Ltd	17/06/2020	P/0214/2020
apixaban	Eliquis	PM	Cardiovascular Diseases	Bristol-Myers Squibb / Pfizer EEIG	20/05/2020	P/0198/2020
apixaban	Eliquis	PM	Cardiovascular Diseases	Bristol-Myers Squibb / Pfizer EEIG	20/05/2020	P/0199/2020
darvadstrocel	Alofisel	PM	Gastroenterology- Hepatology	Takeda Pharma A/S	16/06/2020	P/0207/2020
fidanacogene elaparvovec	Not available at present	P	Haematology- Haemostaseology	Pfizer Europe MA EEIG	17/06/2020	P/0222/2020
lenvatinib	Kispalyx, Lenvima	P	Oncology	Eisai GmbH	16/06/2020	P/0210/2020

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meningococcal group Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein (MenABCWY) / recombinant Neisseria meningitis group B Protein 961c / recombinant Neisseria meningitis group B Protein 287- 953 / meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / meningococcal group A oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein / recombinant Neisseria meningitis group B Protein 936-741 / Outer Membrane Vesicles (OMV) from N. meningitidis Strain NZ 98/254	not available at present	PM	Vaccines	GSK Vaccines s.r.l.	19/06/2020	P/0231/2020
monalizumab	not available at present	W	Oncology	AstraZeneca AB	16/06/2020	P/0206/2020
ticagrelor	Brilique	PM	Cardiovascular Diseases / Haematology- Haemostaseology	AstraZeneca AB	17/06/2020	P/0217/2020
remdesivir	not available at present	P	Infectious Diseases	Gilead Sciences International Ltd.	19/05/2020	P/0201/2020
Alemtuzumab	Lemtrada	W	Neurology	Genzyme Europe B.V.	17/07/2020	P/0269/2020
Alogliptin benzoate (as alogliptin)	Vipidia	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Takeda Development Centre Europe Ltd	15/07/2020	P/0257/2020
Brivaracetam	Briviact (in Italy: Nubriveo)	PM	Neurology	UCB Pharma S.A.	12/06/2020	P/0203/2020
Drospirenone / Estetrol monohydrate	not available at present	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Estetra SPRL	15/07/2020	P/0256/2020
Eravacycline	Xerava	PM	Infectious Diseases	Tetraphase Pharmaceuticals, Inc.	15/07/2020	P/0255/2020
Ezetimibe / Rosuvastatin	Coroswera	W	Cardiovascular Diseases	Krka, d.d., Novo mesto	15/07/2020	P/0251/2020
Factor VIII Fc – von Willebrand factor – XTEN fusion protein (rFVIII Fc-VWF-XTEN)	not available at present	PM	Haematology- Haemostaseology	Bioerativ Therapeutics, Inc., a Sanofi Company	16/06/2020	P/0238/2020
Fostemsavir (tromethamine)	Rukobia	PM	Infectious Diseases	ViiV Healthcare UK Ltd	17/07/2020	P/0268/2020

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Human Fibrinogen	not available at present	W	Haematology- Haemostaseology	Instituto Grifols, S.A.	15/07/2020	P/0260/2020
Humanised Antibody Targeting the Inducible T cell Co-Stimulatory receptor	not available at present	W	Oncology	GlaxoSmithKline (Ireland) Limited	17/07/2020	P/0259/2020
Icosasodium{26-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]-14,14-bis{[(3-{6-[(2-acetamido-2-deoxy-β-D-galactopyranosyl)oxy]hexyl}amino)-3-oxopropoxy]methyl}-8,12,19-trioxo-16-oxa-7,13,20-triazahexacosyl}2'-O-(2-methoxyethyl)-(3'→5')-[2'-O-(2-methoxyethyl)guanylyl-(3'→5')-2'-O-(2-methoxyethyl)-5-methylcytidylyl-(3'→5')-2'-O-(2-methoxyethyl)-5-methyluridylyl-(3'→5')-2'-O-(2-methoxyethyl)-5-methylcytidylyl-(3'→5')-2'-deoxy-5-methyl-P-sulfidocytidylyl-(3'→5')-2'-deoxy-P-sulfidoguanilyl-(3'→5')-P-sulfidothymidylyl-(3'→5')-P-sulfidothymidylyl-(3'→5')-2'-deoxy-P-sulfidoguanilyl-(3'→5')-2'-deoxy-P-sulfidoguanilyl-(3'→5')-P-sulfidothymidylyl-(3'→5')-2'-deoxy-P-sulfidoguanilyl-(3'→5')-2'-deoxy-5-methyl-P-sulfidocytidylyl-(3'→5')-P-sulfidothymidylyl-(3'→5')-2'-O-(2-methoxyethyl)-5-methyluridylyl-(3'→5')-2'-O-(2-methoxyethyl)guanylyl-(3'→5')-2'-O-(2-methoxyethyl)-5-methyl-P-sulfidouridylyl-(3'→5')-2'-O-(2-methoxyethyl)-5-methyl-P-sulfidouridylyl-(3'→5')-2'-O-(2-methoxyethyl)-5-methylcytidine]-5-methyl-P-sulfidouridylyl-5'-yl phosphate (TQJ230)	not available at present	W	Cardiovascular Diseases	Novartis Europharm Ltd.	15/07/2020	P/0245/2020
Insulin 287	not available at present	W	Endocrinology- Gynaecology-Fertility- Metabolism	Novo Nordisk A/S	15/07/2020	P/0263/2020
Metformin hydrochloride / Sitagliptin hydrochloride monohydrate	not available at present	W	Endocrinology- Gynaecology-Fertility- Metabolism	Adamed Pharma S.A.	15/07/2020	P/0247/2020
Olaparib	Lynparza	PM	Oncology	AstraZeneca AB	15/07/2020	P/0250/2020
Ondansetron Hydrochloride	not available at present	P	Other / Neurology	Adial Pharmaceuticals	15/07/2020	P/0248/2020
Pegzilarginase	not available at present	P	Endocrinology- Gynaecology-Fertility- Metabolism	Aeglea BioTherapeutics, Inc.	15/07/2020	P/0252/2020

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Ravagalimab	not available at present	P	Immunology- Rheumatology- Transplantation	AbbVie Ltd	25/06/2020	P/0241/2020
Rozanolixizumab	not available at present	P	Neurology	UCB Pharma S.A.	19/06/2020	P/0240/2020
Rucaparib (camsylate)	Rubraca	W	Oncology	Clovis Oncology Ireland Ltd.	22/06/2020	P/0242/2020
Sutimlimab	not available at present	W	Immunology- Rheumatology- Transplantation / Haematology- Haemostaseology	Genzyme Europe B.V.	15/07/2020	P/0265/2020
Tapentadol	Palexia, Yantil, Tapentadol	PM	Pain	Grünenthal GmbH	15/07/2020	P/0258/2020
Tecovirimat monohydrate	Tpoxx	P	Infectious Diseases	SIGA Technologies, Inc.	17/07/2020	P/0274/2020
Tominersen	not available at present	P	Neurology	Roche Registration GmbH	15/07/2020	P/0264/2020
Trimetazidine dihydrochloride / Bisoprolol fumarate	not available at present	W	Cardiovascular Diseases	Les Laboratoires Servier	17/07/2020	P/0261/2020
Vortioxetine	Brintellix	PM	Psychiatry	H. Lundbeck A/S	15/07/2020	P/0271/2020
abiraterone (acetate) / niraparib (tosylate monohydrate)	not available at present	W	Oncology	Janssen Research & Development	15/07/2020	P/0244/2020
anifrolumab	not available at present	PM	Immunology- Rheumatology- Transplantation	AstraZeneca AB	16/06/2020	P/0239/2020
bempegaldesleukin	not available at present	PM	Oncology	Nektar Therapeutics	15/07/2020	P/0273/2020
bosutinib	Bosulif	PM	Oncology	Pfizer Europe MA EEIG	17/07/2020	P/0270/2020
brentuximab vedotin	Adcetris	PM	Oncology	Takeda Pharma A/S	22/06/2020	P/0243/2020
doravirine	Pifeltro	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	15/07/2020	P/0254/2020
neratinib	Nerlynx	W	Oncology	Pierre Fabre Médicament	15/07/2020	P/0246/2020

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otilimab	Not available at present	PM	Immunology- Rheumatology- Transplantation	GlaxoSmithKline Trading Services Limited	15/07/2020	P/0266/2020
ravagalimab	not available at present	W	Immunology- Rheumatology- Transplantation	AbbVie Ltd	15/07/2020	P/0249/2020
recombinant human IgG1λ monoclonal Fab antibody	not available at present	RW	Cardiovascular Diseases	PhaseBio Pharmaceuticals Inc.	15/07/2020	P/0262/2020
tenofovir disoproxil fumarate / lamivudine / doravirine	Delstrigo	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	15/07/2020	P/0253/2020
vaborbactam / meropenem	Vaborem	PM	Infectious Diseases	Menarini International Operations Luxembourg S.A.	15/07/2020	P/0267/2020
(R)-1-(1-acryloylpiperidin-3-yl)-4-amino-3-(4-phenoxyphenyl)-1H-imidazo[4,5-c]pyridin-2(3H)-one	not available at present	P	Neurology	Genzyme Europe B.V.	14/08/2020	P/0310/2020
Balixafortide	not available at present	W	Oncology	Polyphor Deutschland GmbH	12/08/2020	P/0297/2020
Ceftobiprole medocaril sodium	Zevtera and associated names	PM	Infectious Diseases	Basilea Pharmaceutica International Ltd.	14/08/2020	P/0311/2020
Crisaborole	Staquis	PM	Dermatology	Pfizer Europe MA EEIG	15/07/2020	P/0276/2020
Dermatophagoides pteronyssinus / Dermatophagoides farinae	Acarizax and associated names	PM	Pneumology - Allergology	ALK-Abelló A/S	15/07/2020	P/0278/2020
Dupilumab	Dupixent	W	Dermatology	Regeneron Ireland DAC	12/08/2020	P/0304/2020
Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)	Ervebo	PM	Vaccines	Merck Sharp & Dohme (Europe), Inc.	14/08/2020	P/0316/2020
Efpeglenatide	not available at present	PM	Endocrinology- Gynaecology-Fertility- Metabolism	JVM Europe B.V	12/08/2020	P/0300/2020
Ezetimibe / Pravastatin sodium	not available at present	W	Cardiovascular Diseases	Laboratoires SMB S.A.	12/08/2020	P/0286/2020
Glycopyrronium bromide / Formoterol fumarate dihydrate / Beclometasone dipropionate	Riarity, Trimbow, Trydonis	PM	Pneumology - Allergology	Chiesi Farmaceutici S.p.A.	14/08/2020	P/0313/2020
Guselkumab	Tremfya	P	Gastroenterology- Hepatology	Janssen-Cilag International N.V.	12/08/2020	P/0293/2020

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Half-life extended bispecific T-cell engager (BiTE) antibody construct that binds to prostate-specific membrane antigen and cluster of differentiation 3, with a single chain fragment crystallizable moiety	not available at present	W	Oncology	Amgen Europe BV	12/08/2020	P/0303/2020
Lasmiditan	not available at present	PM	Neurology	Eli Lilly and Company Limited	12/08/2020	P/0299/2020
Lonapegsomatropin	not available at present	P	Endocrinology- Gynaecology-Fertility- Metabolism	Ascendis Pharma Endocrinology Division A/S	15/07/2020	P/0275/2020
Marstacimab	not available at present	P	Haematology- Haemostaseology	Pfizer Europe MA EEIG	12/08/2020	P/0292/2020
Oportuzumab monatox	not available at present	W	Oncology	Sesen Bio, Inc	12/08/2020	P/0287/2020
Perampanel	Fycompa	PM	Neurology	Eisai Europe Limited	12/08/2020	P/0296/2020
Pitolisant	Wakix	PM	Neurology	Bioprojet PHARMA	12/08/2020	P/0298/2020
Purified Rabies virus, WISTAR PM/WI 38-1503-3M strain (inactivated)	Verorabvax	PM	Vaccines	Sanofi Pasteur	12/08/2020	P/0319/2020
Reslizumab	Cinqaero	W	Pneumology - Allergology	Teva Pharmaceuticals Europe	12/08/2020	P/0305/2020
Rilzabrutinib	not available at present	P	Immunology- Rheumatology- Transplantation	Principia Biopharma, Inc.	12/08/2020	P/0306/2020
Ritonavir / Darunavir	not available at present	P	Infectious Diseases	PharOS - Pharmaceutical Oriented Services Ltd	12/08/2020	P/0308/2020
Sasanlimab	not available at present	W	Oncology	Pfizer Europe MA EEIG	12/08/2020	P/0290/2020
Soticlestat	not available at present	P	Neurology	Takeda Pharma A/S	12/08/2020	P/0317/2020
Synthetic double-stranded siRNA oligonucleotide directed against antithrombin mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues	Fitusiran	PM	Haematology- Haemostaseology	Genzyme Europe B.V.	12/08/2020	P/0302/2020
belatacept	Nulojix	PM	Immunology- Rheumatology- Transplantation	Bristol-Myers Squibb Pharma EEIG	15/07/2020	P/0277/2020

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benralizumab	Fasenra	W	Dermatology	AstraZeneca AB	14/08/2020	P/0314/2020
brincidofovir	not available at present	PM	Infectious Diseases	Chimerix IRL Limited	12/08/2020	P/0320/2020
cilofexor	not available at present	P	Gastroenterology- Hepatology	Gilead Sciences International Ltd.	12/08/2020	P/0294/2020
concentrate of proteolytic enzyme enriched in bromelain	NexoBrid	PM	Other	MediWound Germany GmbH	12/08/2020	P/0282/2020
dasabuvir sodium	Exviera	W	Infectious Diseases	AbbVie Ltd	12/08/2020	P/0289/2020
derivative of 4H-pyrazolo[3,4-d]pyrimidin-4-one	not available at present	<b>RP</b>	Psychiatry	Boehringer Ingelheim International GmbH	14/08/2020	P/0312/2020
elafibranor	not available at present	W	Gastroenterology- Hepatology	Genfit SA	12/08/2020	P/0295/2020
fasinumab	not available at present	P	Pain	Regeneron Ireland D.A.C.	12/08/2020	P/0307/2020
glucagon	Baqsimi	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Eli Lilly and Company	12/08/2020	P/0301/2020
ladarixin	Not available at present	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Dompé farmaceutici S.p.A	12/08/2020	P/0284/2020
nivolumab	Opdivo	W	Oncology	Bristol-Myers Squibb Pharma EEIG	20/07/2020	P/0280/2020
olenasufigene relduparvec	Not available at present	PM	Neurology	LYSOGENE	12/08/2020	P/0283/2020
palonosetron / fosnetupitant	Akynzeo	PM	Other	Helsinn Birex Pharmaceuticals Limited	13/07/2020	P/0272/2020
recombinant human glutamic acid decarboxylase (rhGAD65)	Diamyd	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Diamyd Medical AB	12/08/2020	P/0318/2020
relebactam monohydrate / cilastatin sodium / imipenem monohydrate	Recarbrio	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	24/07/2020	P/0279/2020
resamirigene bilparvec	not available at present	P	Other	Audentes Therapeutics, Inc.	14/08/2020	P/0309/2020
rilpivirine (hydrochloride)	Edurant	PM	Infectious Diseases	Janssen-Cilag International NV	12/08/2020	P/0291/2020

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rimegepant	not available at present	W	Neurology	Biohaven Pharmaceuticals, Inc.	12/08/2020	P/0285/2020
ritonavir / paritaprevir / ombitasvir	Viekirax	W	Infectious Diseases	AbbVie Ltd	12/08/2020	P/0288/2020
sacubitril/valsartan	Entresto, Neparvis	W	Cardiovascular Diseases	Novartis Europharm Ltd.	14/08/2020	P/0315/2020
ustekinumab	Stelara	PM	Gastroenterology-Hepatology	Janssen-Cilag International NV	12/08/2020	P/0321/2020
ustekinumab	Stelara	PM	Gastroenterology-Hepatology		12/08/2020	P/0281/2020
(4S,7aR,9aR,10S,11E,14S,15R)-6'-chloro-10-methoxy-14,15-dimethyl-3',4',7a,8,9,9a,10,13,14,15-decahydro-2'H,7H-spiro[1,19-ethenocyclobuta[i][1,4]oxazepino[3,4-f][1,2,7]thiadiazacyclohexadecine-4,1'-naphthalen]-18(17H)-one 16,16-dioxide	not available at present	P	Oncology	Amgen Europe BV	24/08/2020	P/0331/2020
Acetylsalicylic acid / Rosuvastatin calcium	not available at present	W	Cardiovascular Diseases	IBSA Farmaceutici Italia s.r.l.	09/09/2020	P/0348/2020
Anti-neonatal Fc receptor human monoclonal antibody	not available at present	P	Other	Momenta Pharmaceuticals, Inc.	09/09/2020	P/0363/2020
Artesunate	Artesunate Amivas	P	Infectious Diseases	Amivas Ireland Ltd	14/08/2020	P/0328/2020
BAY 1747846	not available at present	P	Diagnostic	Bayer AG	23/10/2020	P/0371/2020
Bedaquiline (fumarate)	Sirturo	PM	Infectious Diseases	Janssen-Cilag International NV	09/09/2020	P/0373/2020
Bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts	not available at present	P	Dermatology	CUTISS AG	09/09/2020	P/0364/2020
Bisoprolol fumarate / Ramipril	not available at present	W	Cardiovascular Diseases	Adamed Pharma S.A.	16/10/2020	P/0390/2020
Brivaracetam	Briviact (in Italy: Nubriveo)	PM	Neurology	UCB Pharma S.A.	12/08/2020	P/0324/2020
Cabotegravir	Vocabria	PM	Infectious Diseases	ViiV Healthcare UK Limited	09/09/2020	P/0354/2020
Cannabidiol	Epidyolex	PM	Neurology	GW Pharma (International) B.V.	09/09/2020	P/0350/2020

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Cefiderocol	Fetroja	PM	Infectious Diseases	Shionogi B.V.	18/09/2020	P/0382/2020
Dronabinol	not available at present	W	Other / Neurology	Bionorica Ethics GmbH	09/09/2020	P/0344/2020
Emixustat (hydrochloride)	not available at present	P	Ophthalmology	Kubota Pharmaceutical Holdings Co. Limited	09/09/2020	P/0369/2020
Exenatide	Bydureon, Byetta	PM	Endocrinology- Gynaecology-Fertility- Metabolism	AstraZeneca AB	09/09/2020	P/0353/2020
Faricimab	not available at present	W	Ophthalmology	Roche Registration GmbH	28/08/2020	P/0332/2020
Faricimab	not available at present	W	Ophthalmology		28/08/2020	P/0333/2020
Fruquintinib	not available at present	W	Oncology	Hutchison MediPharma Ltd	09/09/2020	P/0360/2020
Giroctocogene fitelparvovec	not available at present	P	Haematology- Haemostaseology	Pfizer Europe MA EEIG	09/09/2020	P/0362/2020
Hydrocortisone	Not available at present	PM	Neonatology - Paediatric Intensive Care	LABORATOIRE AGUETTANT	09/09/2020	P/0358/2020
Icosabutate	NST-4016	W	Gastroenterology- Hepatology	NorthSea Therapeutics BV	09/09/2020	P/0338/2020
Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / 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)	Fluad Tetra	PM	Vaccines	Seqirus Netherlands B.V.	09/09/2020	P/0355/2020
Iodine (131-I) murine IgG1 monoclonal antibody against B7-H3 (131I-omburtamab)	not available at present	PM	Oncology	Y-mAbs Therapeutics A/S	10/08/2020	P/0322/2020
Lamivudine / Dolutegravir	Dovato	PM	Infectious Diseases	ViiV Healthcare UK Limited	09/09/2020	P/0372/2020
Lenadogene nolparvovec	Lumevoq	PM	Ophthalmology	GenSight-Biologics	14/08/2020	P/0327/2020
Lerodalcibep	Lerodalcibep	P	Endocrinology- Gynaecology-Fertility- Metabolism	LIB Therapeutics, LLC	09/09/2020	P/0370/2020

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Linerixibat	not available at present	W	Gastroenterology- Hepatology	GlaxoSmithKline (Ireland) Ltd	09/09/2020	P/0337/2020
Live attenuated poliovirus type 3 / Live attenuated poliovirus type 1	BB-OPV	W	Vaccines	Bilthoven Biologicals	09/09/2020	P/0357/2020
Maribavir	not available at present	PM	Infectious Diseases	Shire Pharmaceuticals Ireland Limited	31/08/2020	P/0335/2020
Mitapivat sulfate	not available at present	P	Haematology- Haemostaseology	Agios Netherlands B.V.	09/09/2020	P/0365/2020
Oseltamivir phosphate	Tamiflu	PM	Infectious Diseases	Roche Registration GmbH	09/09/2020	P/0341/2020
Ozanimod	Zeposia	PM	Neurology	Celgene Europe B.V.	13/08/2020	P/0325/2020
PROLGOLIMAB	not available at present	W	Oncology	JSC "BIOCAD"	13/08/2020	P/0323/2020
Potassium chloride / Sodium chloride / Citric acid (as citric acid anhydrous) / Sodium citrate / Simeticone / Sodium sulfate (as sodium sulfate anhydrous) / Macrogol 4000	Clensia	PM	Gastroenterology- Hepatology	Alfasigma S.p.A.	09/09/2020	P/0339/2020
Pretomanid	not available at present	PM	Infectious Diseases	Global Alliance for TB Drug Development	09/09/2020	P/0340/2020
Quizartinib	Vanflyta	PM	Oncology	Daiichi Sankyo Europe GmbH	09/09/2020	P/0343/2020
Rilpivirine (RPV) / Dolutegravir (DTG)	Juluca	PM	Infectious Diseases	ViiV Healthcare UK Limited	09/09/2020	P/0359/2020
Synthetic double-stranded siRNA oligonucleotide directed against lactate dehydrogenase A mRNA and containing four modified nucleosides which form a ligand cluster of four N-acetylgalactosamine residues (DCR-PHXC)	not available at present	PM	Uro-nephrology	Dicerna Ireland Limited	09/09/2020	P/0342/2020
Tenofovir alafenamide / Emtricitabine / Bictegravir	Biktarvy	PM	Infectious Diseases	Gilead Sciences International Ltd.	24/08/2020	P/0334/2020
Tofacitinib	Xeljanz	PM	Gastroenterology- Hepatology	Pfizer Europe MA EEIG	09/09/2020	P/0380/2020
Treosulfan	Trecondi	PM	Immunology- Rheumatology- Transplantation / Oncology	medac Gesellschaft für klinische Spezialpräparate mbH	09/09/2020	P/0346/2020

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Upadacitinib	Rinvoq	PM	Immunology- Rheumatology- Transplantation	AbbVie Ltd	09/09/2020	P/0347/2020
VIB4920	not available at present	W	Immunology- Rheumatology- Transplantation	Viela Bio Inc	09/09/2020	P/0352/2020
Venetoclax	Venclyxto	PM	Oncology / Haematology- Haemostaseology	AbbVie Ltd	09/09/2020	P/0375/2020
alpelisib	not available at present	P	Other	Novartis Europharm Limited	17/08/2020	P/0329/2020
andexanet alfa	Ondexxya	PM	Other	Alexion Europe SAS	09/09/2020	P/0349/2020
cenicriviroc	not available at present	PM	Gastroenterology- Hepatology	Allergan Pharmaceuticals International Limited	09/09/2020	P/0356/2020
diroximel fumarate	Vumerity	P	Neurology	Biogen Netherlands B.V.	09/09/2020	P/0381/2020
ixazomib	Ninlaro	PM	Oncology	Takeda Pharm A/S	09/09/2020	P/0351/2020
lacosamide	Vimpat	PM	Neurology	UCB Pharma S.A.	21/08/2020	P/0330/2020
nivolumab / relatlimab	not available at present	P	Oncology	Bristol-Myers Squibb International Corporation	14/08/2020	P/0326/2020
odevixibat	not available at present	P	Gastroenterology- Hepatology	Albireo AB	09/09/2020	P/0368/2020
odevixibat	not available at present	PM	Gastroenterology- Hepatology	Albireo AB	11/09/2020	P/0377/2020
onasemnogene abeparvovec	Zolgensma	PM	Neurology	AveXis EU Limited	09/09/2020	P/0379/2020
ranibizumab	not available at present	W	Ophthalmology	Roche Registration GmbH	09/09/2020	P/0345/2020
rebisufligene etisparvovec	not available at present	P	Endocrinology- Gynaecology-Fertility- Metabolism	Abeona Therapeutics Inc.	09/09/2020	P/0366/2020
relamorelin	not available at present	P	Gastroenterology- Hepatology	Allergan Pharmaceuticals International Limited	09/09/2020	P/0367/2020

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retifanlimab (proposed INN pending WHO approval)	not available at present	W	Oncology	Incyte Biosciences Distribution B.V.	09/09/2020	P/0336/2020
tadalafil	Cialis, Adcirca	PM	Cardiovascular Diseases	Eli Lilly and Company Ltd	11/09/2020	P/0376/2020
tezepelumab	not available at present	W	Oto-rhino-laryngology	AstraZeneca AB	09/09/2020	P/0378/2020
triphenylacetic acid - 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol / fluticasone furoate	Relvar Ellipta	PM	Pneumology - Allergology	Glaxo Group Limited	09/09/2020	P/0374/2020
(2S,4S)-2-(4-Carboxyphenyl)-4-ethoxy-1-[(5-methoxy-7-methyl-1H-indol-4-yl)methyl]piperidin-1-ium chloride—water (1/1) (LNP023)	not available at present	P	Other	Novartis Europharm Limited	23/10/2020	P/0417/2020
(2S,4S)-2-(4-Carboxyphenyl)-4-ethoxy-1-[(5-methoxy-7-methyl-1H-indol-4-yl)methyl]piperidin-1-ium chloride—water (1/1) (LNP023)	not available at present	P	Other		23/10/2020	P/0415/2020
Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human B cell maturation antigen with 4-1BB and CD3-zeta intracellular signalling domains (CT053)	not available at present	W	Oncology	CARsgen Therapeutics Corporation	23/10/2020	P/0411/2020
Birch bark extract	Filsuvez	PM	Dermatology	Amryt Research Limited	22/10/2020	P/0425/2020
Brolucizumab	Beovu	W	Ophthalmology	Novartis Europharm Limited	23/10/2020	P/0408/2020
Colchicine	not available at present	W	Cardiovascular Diseases	Disphar International B.V.	23/10/2020	P/0422/2020
Dabrafenib	not available at present	P	Oncology	Novartis Europharm Limited	23/10/2020	P/0423/2020
Dabrafenib	Tafinlar	PM	Oncology	Novartis Europharm Limited	23/10/2020	P/0410/2020
Doravirine / Islatravir	not available at present	P	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	23/10/2020	P/0395/2020
Dupilumab	Dupixent	W	Dermatology	sanofi-aventis recherche & développement	23/10/2020	P/0394/2020
Edoxaban (tosylate)	Lixiana film coated tablets	PM	Cardiovascular Diseases / Haematology- Haemostaseology	Daiichi Sankyo Europe GmbH	23/10/2020	P/0393/2020

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Etripamil	not available at present	PM	Cardiovascular Diseases	Milestone Pharmaceuticals, Inc.	23/10/2020	P/0406/2020
Fenofibrate / Ezetimibe / Pravastatin sodium	not available at present	W	Cardiovascular Diseases	Laboratoires SMB S.A.	22/10/2020	P/0405/2020
Filgotinib	not available at present	PM	Gastroenterology- Hepatology	Gilead Sciences International Ltd.	25/09/2020	P/0386/2020
Glycopyrronium bromide	not available at present	P	Dermatology	Dr. August Wolff GmbH & Co. KG - Arzneimittel	23/10/2020	P/0420/2020
Lenvatinib	Kisplyx, Lenvima	PM	Oncology	Eisai GmbH	21/10/2020	P/0427/2020
Mepolizumab	Nucala	PM	Haematology- Haemostaseology	GSK Trading Services Limited	23/09/2020	P/0384/2020
Mixture of 2 synthetic double-stranded N-acetyl-galactosamine conjugated siRNA oligonucleotides that are directed against the hepatitis B virus	not available at present	P	Infectious Diseases	Janssen-Cilag International NV	23/10/2020	P/0426/2020
N-(3-cyano-4-fluorophenyl)-1-methyl-4-[[[(2S)-1,1,1-trifluoro-2-propanyl]sulfonyl]-1H-pyrrole-2-carboxamide	not available at present	P	Infectious Diseases	Janssen-Cilag International NV	22/10/2020	P/0418/2020
Peanut Allergen Extract	not available at present	PM	Pneumology - Allergology	DBV Technologies S.A.	02/10/2020	P/0389/2020
Pegylated-fibroblast growth factor 21 (BMS-986036)	not available at present	PM	Gastroenterology- Hepatology	Bristol-Myers Squibb International Corporation	01/10/2020	P/0387/2020
Plasma kallikrein inhibitor	not available at present	P	Haematology- Haemostaseology	KalVista Pharmaceuticals Ltd	23/10/2020	P/0416/2020
Recombinant human granulocyte colony-stimulating factor – human immunoglobulin Fc fusion protein (rhG-CSF-Fc)	not available at present	P	Oncology	Generon (Shanghai) Corporation	23/10/2020	P/0414/2020
Recombinant humanised monoclonal antibody (IgG1, Kappa) to IL-5	not available at present	W	Pneumology - Allergology	GlaxoSmithKline (Ireland) Limited	23/10/2020	P/0396/2020
The whole range of unmanipulated autologous mononuclear cells derived from human umbilical cord blood (Hau-UCB-mnc)	not available at present	P	Neonatology - Paediatric Intensive Care	BrainRepair UG (haftungsbeschränkt)	25/09/2020	P/0385/2020
Tiragolumab	not available at present	W	Oncology	Roche Registration GmbH	23/10/2020	P/0412/2020
Tiragolumab	not available at present	W	Oncology		22/10/2020	P/0409/2020

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Trametinib	Mekinist	PM	Oncology	Novartis Europharm Limited	23/10/2020	P/0392/2020
Trametinib	not available at present	P	Oncology	Novartis Europharm Limited	23/10/2020	P/0424/2020
Velmanase alfa	Lamzede	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Chiesi Farmaceutici S.p.A.	23/10/2020	P/0407/2020
alpha-R-lipoic acid choline ester tosilate	not available at present	W	Ophthalmology	Novartis Europharm Limited	23/10/2020	P/0413/2020
copanlisib	Aliqopa	PM	Oncology	Bayer AG	22/10/2020	P/0402/2020
danicopan	not available at present	P	Haematology- Haemostaseology	Alexion Europe SAS	22/10/2020	P/0403/2020
daratumumab	Darzalex	PM	Oncology	Janssen-Cilag International NV	22/10/2020	P/0421/2020
dupilumab	Dupixent	PM	Pneumology - Allergology	sanofi-aventis recherche & développement	22/10/2020	P/0404/2020
eculizumab	Soliris	PM	Neurology	Alexion Europe SAS	29/09/2020	P/0388/2020
ivacaftor / tezacaftor / elexacaftor	Kaftrio	PM	Other / Pneumology - Allergology	Vertex Pharmaceuticals (Ireland) Limited	23/10/2020	P/0397/2020
ozanimod hydrochloride	Zeposia	PM	Gastroenterology- Hepatology	Celgene Europe B.V.	24/09/2020	P/0383/2020
rAAVrh74.MHCK7.microdystrophin	not available at present	P	Neurology	Roche Registration GmbH	22/10/2020	P/0419/2020
ravulizumab	Ultomiris	PM	Uro-nephrology / Haematology- Haemostaseology	Alexion Europe SAS	23/10/2020	P/0400/2020
ravulizumab	Ultomiris	PM	Uro-nephrology / Haematology- Haemostaseology		23/10/2020	P/0399/2020
sacituzumab govitecan	Trodelyv	W	Oncology	Immunomedics GmbH	23/10/2020	P/0398/2020
vadadustat	Vafseo	PM	Haematology- Haemostaseology	Akebia Therapeutics, Inc.	23/10/2020	P/0401/2020

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zanamivir	Dectova, Relenza	PM	Infectious Diseases	GlaxoSmithKline Trading Services Limited	23/10/2020	P/0391/2020
vedolizumab	Entyvio	PM	Gastroenterology- Hepatology	Takeda Pharma A/S	05/10/2020	P/0361/2020
(1R,2R,3S,4S,5R,6S)-cyclohexane-1,2,3,4,5,6-hexayl-hexakis (dihydrogen phosphate)	not available at present	W	Other	Sanifit Therapeutics S.A.	01/12/2020	P/0472/2020
2-(6-azaspiro[2.5]octan-6-yl)-N-[2-(4,4-difluoropiperidin-1-yl)-6-methylpyrimidin-4-yl]- 4- [(2-hydroxyethanesulfonyl)amino]benzamide hydrochloride	not available at present	W	Oncology / Haematology- Haemostaseology	Amgen Europe BV	01/12/2020	P/0448/2020
2-(6-azaspiro[2.5]octan-6-yl)-N-[2-(4,4-difluoropiperidin-1-yl)-6-methylpyrimidin-4-yl]- 4- [(2-hydroxyethanesulfonyl)amino]benzamide hydrochloride	not available at present	W	Oncology / Haematology- Haemostaseology		01/12/2020	P/0447/2020
Adrenaline (epinephrine)	not available at present	P	Pneumology - Allergology	ARS Pharmaceuticals IRL, Limited	05/11/2020	P/0431/2020
Allogeneic BCMA-directed chimeric antigen receptor T Cell	not available at present	W	Oncology	CRISPR Therapeutics AG	01/12/2020	P/0438/2020
Allogeneic bone marrow derived mesenchymal stromal cells, ex-vivo expanded (MC0518)	Obnitix	P	Immunology- Rheumatology- Transplantation	medac Gesellschaft für klinische Spezialpräparate mbH	01/12/2020	P/0453/2020
Alpha1-proteinase inhibitor (human)	not available at present	P	Immunology- Rheumatology- Transplantation	CSL Behring GmbH	01/12/2020	P/0442/2020
Apremilast	Otezla	PM	Immunology- Rheumatology- Transplantation	Amgen Europe B.V.	01/12/2020	P/0469/2020
BI 425809	not available at present	P	Psychiatry	Boehringer Ingelheim International GmbH	01/12/2020	P/0473/2020
BILASTINE	Bilaxten and associated names	PM	Dermatology Oto-rhino-laryngology Pneumology-allergology	Faes Farma S.A.	01/12/2020	P/0466/2020
Bimekizumab	not available at present	P	Immunology- Rheumatology- Transplantation	UCB Biopharma SRL	01/12/2020	P/0456/2020
Birch pollen extract (Betula verrucosa)	Itulazax	PM	Pneumology - Allergology	ALK-Abelló A/S	06/11/2020	P/0434/2020

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Bispecific antibody binding to clotting factor IX and X	not available at present	P	Haematology- Haemostaseology	Novo Nordisk A/S	01/12/2020	P/0450/2020
Canagliflozin (1s)-1,5-anhydro-1-[3-[[5-(4-fluorophenyl)-2-thienyl]methyl]-4-methylphenyl]-D-glucitol hemihydrate	Invokana	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Janssen-Cilag International NV	01/12/2020	P/0464/2020
Chimeric fibrin-reactive IgG1k monoclonal antibody 11-1F4	not available at present	W	Endocrinology- Gynaecology-Fertility- Metabolism	Real Regulatory Limited	01/12/2020	P/0449/2020
Drospirenone / Estetrol	not available at present	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Estetra SPRL	01/12/2020	P/0478/2020
Ezetimibe / Atorvastatin	not available at present	W	Cardiovascular Diseases	Sandoz B.V.	04/12/2020	P/0445/2020
Garadacimab	not available at present	P	Haematology- Haemostaseology	CSL Behring GmbH	01/12/2020	P/0451/2020
Guselkumab	Tremfya	P	Gastroenterology- Hepatology	Janssen-Cilag International N.V.	04/12/2020	P/0461/2020
Humanised anti-IL-6 receptor (IL-6R) monoclonal antibody (INN: satralizumab)	Enspryng	PM	Neurology	Roche Registration GmbH	01/12/2020	P/0477/2020
Lanadelumab	Takhzyro	P	Other	Shire Pharmaceuticals Ireland Limited (a Takeda company)	01/12/2020	P/0476/2020
Live attenuated, chimeric dengue virus, serotype 4 / Live, attenuated, chimeric dengue virus, serotype 1 / Live, attenuated, chimeric dengue virus, serotype 3 / Live, attenuated dengue virus, serotype 2	not available at present	PM	Vaccines	Takeda Vaccines, Inc.	30/10/2020	P/0429/2020
Lixisenatide	Lyxumia	W	Endocrinology- Gynaecology-Fertility- Metabolism	sanofi-aventis R&D	01/12/2020	P/0443/2020
Lurbinectedin	Zepzelca	W	Oncology	Pharma Mar, S.A.	01/12/2020	P/0446/2020
Olipudase alfa	Xenpozyme	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Genzyme Europe B.V.	01/12/2020	P/0459/2020
Palovarotene	Sohonos	PM	Other	Ipsen Pharma	01/12/2020	P/0441/2020
Perindopril arginine / Indapamide / Amlodipine besilate	Not available at present	W	Cardiovascular Diseases	Teva B.V.	04/12/2020	P/0470/2020

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Potassium chloride / Sodium chloride / Ascorbic acid / sodium sulfate / Sodium ascorbate / Polyethylene Glycol 3350	PLENVU	PM	Gastroenterology- Hepatology	Norgine Limited	01/12/2020	P/0458/2020
Recombinant human acid alpha-glucosidase (ATB200)	not available at present	P	Endocrinology- Gynaecology-Fertility- Metabolism	Amicus Therapeutics Europe Limited	01/12/2020	P/0474/2020
Serplulimab	not available at present	W	Oncology	Shanghai Henlius Biotech, Inc.	01/12/2020	P/0471/2020
Teduglutide	Revestive	PM	Gastroenterology- Hepatology	Shire Pharmaceuticals Ireland Limited	01/12/2020	P/0479/2020
Tenofovir (disoproxil fumarate)	Viread	PM	Infectious Diseases	Gilead Sciences International Limited	20/11/2020	P/0437/2020
Tenofovir Alafenamide / Emtricitabine / Cobicistat / Elvitegravir	Genvoya	PM	Infectious Diseases	Gilead Sciences International Ltd.	13/11/2020	P/0435/2020
Veliparib	not available at present	PM	Oncology	AbbVie Ltd	04/12/2020	P/0465/2020
concentrate of proteolytic enzyme enriched in bromelain	NexoBrid	PM	Other	MediWound Germany GmbH	05/11/2020	P/0430/2020
cotadutide	not available at present	P	Immunology- Rheumatology- Transplantation	AstraZeneca AB	01/12/2020	P/0452/2020
dapagliflozin	Forxiga	W	Other	AstraZeneca AB	01/12/2020	P/0444/2020
dapirolizumab pegol	not available at present	P	Immunology- Rheumatology- Transplantation	UCB Biopharma SRL	01/12/2020	P/0439/2020
fasudil hydrochloride	not available at present	W	Neurology	Aneuryst (Ireland) Limited	01/12/2020	P/0468/2020
fenfluramine hydrochloride	Fintepla	PM	Neurology	Zogenix International Ltd	01/12/2020	P/0475/2020
inebilizumab	Uplizna	PM	Neurology	Viela Bio, Inc	28/10/2020	P/0428/2020
nivolumab	Opdivo	PM	Oncology	Bristol-Myers Squibb Pharma EEIG	05/11/2020	P/0432/2020
nivolumab	Opdivo	PM	Oncology		05/11/2020	P/0433/2020

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recombinant parathyroid hormone: rhPTH (1-84)	Natpar	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Shire Pharmaceuticals Ireland Limited	04/12/2020	P/0460/2020
taniborbactam / cefepime	Not available at present	P	Infectious Diseases	Venatorx Pharmaceuticals, Inc.	04/12/2020	P/0455/2020
tazobactam / ceftolozane	Zerbaxa	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	13/11/2020	P/0436/2020
tedizolid	Sivextro	PM	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	01/12/2020	P/0462/2020
tralokinumab	not available at present	PM	Dermatology	LEO Pharma A/S	01/12/2020	P/0440/2020
ustekinumab	Stelara	PM	Immunology- Rheumatology- Transplantation	Janssen-Cilag International NV	01/12/2020	P/0467/2020
venglustat	not available at present	P	Endocrinology- Gynaecology-Fertility- Metabolism / Neurology	Genzyme Europe B.V.	04/12/2020	P/0457/2020
vonicog alfa	Veyvondi	PM	Haematology- Haemostaseology	Baxalta Innovations GmbH	04/12/2020	P/0463/2020
vonoprazan fumarate	not available at present	P	Infectious Diseases / Gastroenterology- Hepatology	Phathom Pharmaceuticals, Inc.	04/12/2020	P/0454/2020
(R)-2-(1-(6-Amino-5-chloropyrimidine-4- carboxamido)ethyl)-N-(5-chloro-4- (trifluoromethyl)pyridin- 2-yl)thiazole-5-carboxamide	not available at present	P	Oncology	DOT Therapeutics-1 Inc	22/12/2020	P/0500/2020
Avatrombopag maleate	Doptelet	PM	Haematology- Haemostaseology	Swedish Orphan Biovitrum AB (publ)	09/12/2020	P/0482/2020
Aztreonam	Cayston	PM	Infectious Diseases	Gilead Sciences International Ltd.	21/12/2020	P/0494/2020
Brigatinib	ALUNBRIG	PM	Oncology	Takeda Pharm A/S	09/12/2020	P/0483/2020
Burosumab	Crysvita	PM	Other	Kyowa Kirin Holdings B.V.	21/12/2020	P/0491/2020
Calcifediol	Royaldee	PM	Uro-nephrology	Vifor Fresenius Medical Care Renal Pharma France	22/12/2020	P/0503/2020
Captopril	not available at present	PM	Cardiovascular Diseases	Proveca Pharma Limited	22/12/2020	P/0507/2020

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Cholera vaccine, live attenuated, oral (Strain CVD 103-HgR)	Vaxchora	PM	Vaccines	Emergent Netherlands B.V.	22/12/2020	P/0509/2020
Cotadutide	not available at present	PM	Endocrinology- Gynaecology-Fertility- Metabolism	AstraZeneca AB	22/12/2020	P/0502/2020
Docosahexaenoic Acid	Retriacyl	W	Ophthalmology	Natac Pharma S.L.	12/02/2021	P/0058/2021
Eltrombopag	Revolade	PM	Haematology- Haemostaseology	Novartis Europharm Limited	22/12/2020	P/0516/2020
Etrasimod L-arginine	not available at present	P	Gastroenterology- Hepatology	Arena Pharmaceuticals, Inc.	22/12/2020	P/0487/2020
Levofloxacin hemihydrate	Quinsair	W	Pneumology - Allergology	Chiesi Farmaceutici S.p.A.	22/12/2020	P/0511/2020
N-[(1R)-1-(1H-indol-3-ylmethyl)pentyl]-2-(4-methylpiperazin-1-yl)thiazole-5-carboxamide (UCB0599)	not available at present	W	Neurology	UCB Pharma S.A.	21/12/2020	P/0484/2020
Naloxegol	Moventig	PM	Gastroenterology- Hepatology	Kyowa Kirin Pharmaceutical Development Limited	22/12/2020	P/0513/2020
Obinutuzumab	Gazyvaro	<b>RW</b>	Immunology- Rheumatology- Transplantation	Roche Registration GmbH	22/12/2020	P/0512/2020
Olinciguat	not available at present	P	Haematology- Haemostaseology	Cyclerion Therapeutics Inc.	22/12/2020	P/0501/2020
Ramipril / bisoprolol (fumarate)	not available at present	W	Cardiovascular Diseases	Egis Pharmaceuticals PLC	22/12/2020	P/0497/2020
Tabelecleucel	not available at present	P	Oncology	Atara Biotherapeutics, Inc.	21/12/2020	P/0490/2020
Tauroursodeoxycholic acid / Sodium phenylbutyrate	not available at present	W	Neurology	Drug Development and Regulation SL	22/12/2020	P/0495/2020
Testosterone	Natesto	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Acerus Biopharma Inc.	22/12/2020	P/0508/2020
Tipifarnib	not available at present	W	Oncology	Kura Oncology, Inc.	22/12/2020	P/0496/2020
Voxelotor	Oxbryta	P	Haematology- Haemostaseology	Synteract GmbH	21/12/2020	P/0489/2020

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avelumab (recombinant human monoclonal IgG1 antibody directed against Programmed Death Ligand-1 (anti-PD-L1); company code:MSB0010718C)	Bavencio	PM	Oncology	Merck Healthcare KGaA	22/12/2020	P/0504/2020
cobicistat / atazanavir sulphate	Evotaz	PM	Infectious Diseases	Bristol-Myers Squibb Pharma EEIG	22/12/2020	P/0510/2020
dapagliflozin	Forxiga	W	Cardiovascular Diseases	AstraZeneca AB	22/12/2020	P/0515/2020
delolimogene mupadenorepvec	not available at present	W	Oncology	Lokon Pharma AB	21/12/2020	P/0485/2020
eculizumab	Soliris	PM	Neurology	Alexion Europe SAS	22/12/2020	P/0514/2020
efgartigimod alfa	not available at present	W	Dermatology	argenx BV	22/12/2020	P/0488/2020
etranacogene dezaparvovec	not available at present	P	Haematology-Haemostaseology	uniQure biopharma B.V.	02/01/2021	P/0517/2020
fluciclovine (18F)	Axumin	<b>RW</b>	Diagnostic / Oncology	Blue Earth Diagnostics Ireland Ltd	22/12/2020	P/0492/2020
fully human IgG1 RB-1 YTE anti-RSV F monoclonal antibody (MK-1654)	not available at present	P	Infectious Diseases	Merck Sharp & Dohme (Europe), Inc.	22/12/2020	P/0486/2020
ivacaftor / lumacaftor	Orkambi	PM	Other	Vertex Pharmaceuticals (Europe) Ltd	22/12/2020	P/0506/2020
ocrelizumab	Ocrevus	PM	Neurology	Roche Registration GmbH	22/12/2020	P/0493/2020
sulbactam / durlobactam	not available at present	P	Infectious Diseases	Entasis Therapeutics Inc.	22/12/2020	P/0499/2020
venglustat	not available at present	P	Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology	Genzyme Europe B.V.	22/12/2020	P/0505/2020
ziltivekimab	not available at present	W	Cardiovascular Diseases	Novo Nordisk A/S	22/12/2020	P/0498/2020
COVID-19 mRNA Vaccine BioNTech (BNT162b2)	COVID-19 mRNA Vaccine BioNTech	P	Infectious Diseases	BioNTech Manufacturing GmbH	27/11/2020	P/0480/2020
CX-024414 - mRNA that encodes for the pre-fusion stabilized Spike glycoprotein of 2019-novel Coronavirus	not available at present	P	Vaccines	ModernaTX, Inc.	30/11/2020	P/0481/2020
(S)-6-hydroxy-2,5,7,8-tetramethyl-N-((R)-piperidin-3-yl)chroman-2-carboxamide hydrochloride (KH176)	not available at present	P	Other	Khondrion BV	14/01/2021	P/0004/2021

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Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
18-(p-[131I]-iodophenyl)octadecyl phosphocholine	not available at present	W	Oncology	Collectar Biosciences, Inc.	28/01/2021	P/0011/2021
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)	not available at present	P	Gastroenterology- Hepatology	Theravance Biopharma Ireland Limited	27/01/2021	P/0018/2021
3-({5-chloro-1-[3-(methylsulfonyl)propyl]-1Hindol-2-yl}methyl)-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-C]pyridin-2-one) (JNJ-53718678)	Rilematovir	PM	Infectious Diseases	Janssen-Cilag International NV	27/01/2021	P/0030/2021
Acetylcysteine / Ibuprofen (sodium dihydrate)	not available at present	W	Pneumology - Allergology / Oto-rhino-laryngology	E-Pharma Trento S.p.A.	27/01/2021	P/0054/2021
Adeno-associated viral vector serotype 9 containing the human mini-dystrophin gene (PF-06939926)	not available at present	P	Neurology	Pfizer Europe MA EEIG	21/12/2020	P/0518/2020
Alpha1-Proteinase Inhibitor (Human)	not available at present	W	Pneumology - Allergology / Haematology- Haemostaseology	Baxalta Innovations GmbH (owned by Takeda)	27/01/2021	P/0035/2021
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)	not available at present	P	Oncology	Kite Pharma EU B.V.	05/01/2021	P/0002/2021
Autologous tumour-infiltrating lymphocytes (LN-144/LN-145)	not available at present	P	Oncology	Iovance Biotherapeutics, Inc.	29/01/2021	P/0022/2021
Aztreonam / Avibactam	Not yet available	PM	Infectious Diseases	Pfizer Europe MA EEIG	29/01/2021	P/0028/2021
Baloxavir marboxil	Xofluza	PM	Infectious Diseases	Roche Registration GmbH	29/01/2021	P/0029/2021
COVID-19 Vaccine (ChAdOx1-S [recombinant])	COVID-19 Vaccine AstraZeneca	P	Vaccines	AstraZeneca AB	05/01/2021	P/0003/2021
Cannabidiol	Epidyolex	PM	Neurology	GW Pharma (International) B.V.	29/01/2021	P/0033/2021
Carfilzomib	Kyprolis	P	Oncology / Haematology- Haemostaseology	Amgen Europe BV	27/01/2021	P/0016/2021
Cobicistat	Tybost	PM	Infectious Diseases	Gilead Sciences International Ltd.	15/01/2021	P/0007/2021
Denosumab	Xgeva, Prolia	PM	Endocrinology- Gynaecology-Fertility- Metabolism	Amgen Europe B.V.	05/01/2021	P/0001/2021

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Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Dexmedetomidine (hydrochloride)	not available at present	P	Psychiatry	BioXcel Therapeutics, Inc.	29/01/2021	P/0019/2021
Eliapixant	not available at present	W	Pneumology - Allergology	Bayer AG	27/01/2021	P/0031/2021
Eribulin	Halaven	PM	Oncology	Eisai GmbH	27/01/2021	P/0040/2021
Esketamine (hydrochloride)	not available at present	P	Psychiatry	Celon Pharma S.A.	27/01/2021	P/0020/2021
Heparin Sodium	not available at present	W	Cardiovascular Diseases / Haematology- Haemostaseology	YES Pharmaceutical Development Services GmbH	29/01/2021	P/0015/2021
Human Thrombin / Human Fibrinogen	Evarrest, Evicel	PM	Other	Omxix Biopharmaceuticals N.V.	27/01/2021	P/0051/2021
Human thrombin (component 2) / Human fibrinogen (component 1)	VeraSeal	PM	Other	Instituto Grifols, S.A.	27/01/2021	P/0052/2021
In vitro expanded autologous human articular chondrocytes	Artobend	PM	Other	TETEC Tissue Engineering Technologies AG	27/01/2021	P/0043/2021
Lasmiditan	Reyvow	PM	Neurology	Eli Lilly and Company Limited	29/01/2021	P/0056/2021
Lenacapavir	not available at present	P	Infectious Diseases	Gilead Sciences International Ltd.	15/01/2021	P/0005/2021
Luspatercept	Reblozyl	PM	Haematology- Haemostaseology	Bristol-Myers Squibb Pharma EEIG	27/01/2021	P/0037/2021
Obinutuzumab	Gazyvaro	P	Immunology- Rheumatology- Transplantation	Roche Registration GmbH	28/01/2021	P/0050/2021
Ofatumumab	Kesimpta	PM	Neurology	Novartis Europharm Limited	29/01/2021	P/0042/2021
Pitolisant	Wakix	PM	Neurology	Bioprojet Pharma	27/01/2021	P/0057/2021
Recombinant humanised monoclonal immunoglobulin G4, with specificity for human tau (UCB0107)	not available at present	W	Neurology	UCB Pharma S.A.	12/02/2021	P/0061/2021
Reldesemtiv	not available at present	W	Neurology	Cytokinetics, Inc.	28/01/2021	P/0025/2021
Retinol (Vitamin A)	not available at present	P	Neonatology - Paediatric Intensive Care	orphanix GmbH	28/01/2021	P/0023/2021

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Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Risankizumab	Skyrizi	PM	Immunology- Rheumatology- Transplantation	AbbVie Ltd	27/01/2021	P/0039/2021
Rosuvastatin (calcium) / acetylsalicylic acid	not available at present	W	Cardiovascular Diseases	Neopharmed Gentili S.p.A.	27/01/2021	P/0045/2021
Siponimod (hemifumarate)	Mayzent	PM	Neurology	Novartis Europharm Ltd	28/01/2021	P/0014/2021
Sparsentan	not available at present	P	Uro-nephrology	Traverse Therapeutics Ireland Ltd.	27/01/2021	P/0021/2021
Sparsentan	not available at present	P	Uro-nephrology		27/01/2021	P/0024/2021
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
Tenofovir alafenamide / Emtricitabine	Descovy	PM	Infectious Diseases	Gilead Sciences International Ltd.	27/01/2021	P/0034/2021
Tenofovir alafenamide / Emtricitabine / Bictegravir	Biktarvy	PM	Infectious Diseases	Gilead Sciences International Ltd.	27/01/2021	P/0038/2021
Tofacitinib	Xeljanz	PM	Gastroenterology- Hepatology	Pfizer Europe MA EEIG	15/01/2021	P/0009/2021
Ublituximab	not available at present	W	Oncology	CambPharma Solutions (CY) Ltd	27/01/2021	P/0046/2021
Umbralisib tosylate	not available at present	W	Oncology	CambPharma Solutions (CY) Ltd	28/01/2021	P/0044/2021
Vortioxetine	Brintellix	PM	Psychiatry	H. Lundbeck A/S	27/01/2021	P/0032/2021
Allopurinol / verinurad	not available at present	P	Uro-nephrology	AstraZeneca AB	29/01/2021	P/0017/2021
Arimoclomol (citrate)	not available at present	P	Neurology	Orphazyme A/S	28/01/2021	P/0012/2021
Betibeglogene autotemcel	Zynteglo	PM	Haematology- Haemostaseology	bluebird bio (Netherlands) B.V.	15/01/2021	P/0008/2021
Brentuximab vedotin	Adcetris	PM	Oncology	Takeda Pharma A/S	28/01/2021	P/0013/2021
Catumaxomab	Remun	W	Oncology	Lindis Biotech GmbH	27/01/2021	P/0053/2021

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Active substance(s)	Invented Name	PDCO Opinion	Therapeutic area(s)	Applicant	Decision date	Decision Number
Ceftazidime / Avibactam	Zavicefta	PM	Infectious Diseases	Pfizer Europe MA EEIG	27/01/2021	P/0027/2021
Cobicistat / darunavir	Rezolsta	PM	Infectious Diseases	Janssen-Cilag International NV	27/01/2021	P/0049/2021
Crizotinib	Xalkori	PM	Oncology	Pfizer Europe MA EEIG	27/01/2021	P/0036/2021
Daprodustat	not available at present	PM	Uro-nephrology / Haematology- Haemostaseology	GlaxoSmithKline Trading Services Limited	27/01/2021	P/0047/2021
Darvadstrocel	Alofisel	PM	Gastroenterology- Hepatology	Takeda Pharma A/S	27/01/2021	P/0026/2021
Fosdenopterin	Nulybry	PM	Other	Origin Biosciences, Inc.	27/01/2021	P/0048/2021
Lorlatinib	Lorviqua	W	Oncology	Pfizer Europa MA EEIG	15/01/2021	P/0006/2021
Obeticholic acid	Ocaliva	PM	Gastroenterology- Hepatology	Intercept Pharma International Ltd.	27/01/2021	P/0041/2021
Paracetamol / nefopam (hydrochloride)	Metapain	W	Pain	Aptys Pharmaceuticals	27/01/2021	P/0055/2021

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

Active substance(s)	Therapeutic area(s)	Applicant	PDCO opinion date
Adjupanrix: Purified antigen fractions of inactivated split virion influenza A/VietNam/1194/2004 (H5N1) like strain used (NIBRG-14) / Prepandrix: Purified antigen fractions of inactivated split virion influenza A/Indonesia/05/2005 like strain used (PR8-IBCDC-RG2)	Vaccines	GlaxoSmithKline Biologicals SA	31/01/2020
Lubiprostone	Gastroenterology-Hepatology	Sucampo AG	28/02/2020
Mepolizumab	Pneumology - Allergology	GSK Trading Services Limited	28/02/2020
Sitagliptin phosphate	Endocrinology-Gynaecology-Fertility-Metabolism	Merck Sharp & Dohme (Europe), Inc.	28/02/2020

<b>Active substance(s)</b>	<b>Therapeutic area(s)</b>	<b>Applicant</b>	<b>PDCO opinion date</b>
Olopatadine hydrochloride / Mometasone furoate (as the monohydrate)	Oto-rhino-laryngology	Glenmark Pharmaceuticals Europe Ltd.	27/03/2020
Romiplostim	Haematology-Haemostaseology	Amgen Europe B.V.	27/03/2020
lonafarnib	Other	EigerBio Europe Limited	27/03/2020
Adalimumab	Gastroenterology-Hepatology	AbbVie Limited	30/04/2020
Lipegfilgrastim	Oncology	UAB "Sicor Biotech"	30/04/2020
Zoledronic acid	Endocrinology-Gynaecology-Fertility-Metabolism	Novartis Europharm Limited	30/04/2020
Live, attenuated, chimeric dengue virus, serotype 3 / Live, attenuated, chimeric dengue virus, serotype 4 / Live, attenuated, chimeric dengue virus, serotype 1 / Live, attenuated, chimeric dengue virus, serotype 2	Vaccines	Sanofi Pasteur	29/05/2020
Clostridium Botulinum neurotoxin type A (150 kD), free of complexing proteins	Neurology	Merz Pharmaceuticals GmbH	24/07/2020
Delamanid	Infectious Diseases	Otsuka Pharmaceutical Development & Commercialisation Europe GmbH	24/07/2020
Idarucizumab	Cardiovascular Diseases / Haematology-Haemostaseology	Boehringer Ingelheim International GmbH	24/07/2020
Eftrenonacog alfa	Haematology-Haemostaseology	Swedish Orphan Biovitrum AB (publ)	24/07/2020
Glucarpidase	Oncology	Protherics Medicines Development BV	24/07/2020
Pazopanib	Oncology	Novartis Europharm Limited	24/07/2020
Spheroids of human autologous matrix-associated chondrocytes	Other	CO.DON AG	24/07/2020
Eptacog beta (activated)	Haematology-Haemostaseology	LFB SA	04/09/2020
Influenza virus surface antigens (haemagglutinin and neuraminidase) of the following strains: A/(H1N1), A/(H3N2), B/Yamagata lineage, B/Victoria lineage	Vaccines	Abbott Biologicals B.V.	04/09/2020

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<b>Active substance(s)</b>	<b>Therapeutic area(s)</b>	<b>Applicant</b>	<b>PDCO opinion date</b>
elivaldogene autotemcel	Neurology	bluebird bio (Netherlands) B.V.	04/09/2020
lonapegsomatropin	Endocrinology-Gynaecology-Fertility-Metabolism	Ascendis Pharma Endocrinology Division A/S	04/09/2020
Sofosbuvir / Voxilaprevir / Velpatasvir	Infectious Diseases	Gilead Sciences Ireland UC	16/10/2020
Human normal immunoglobulin for subcutaneous administration	Immunology-Rheumatology-Transplantation	Grifols Therapeutics LLC	13/11/2020
Dapagliflozin	Endocrinology-Gynaecology-Fertility-Metabolism	Astrazeneca AB	11/12/2020
Idursulfase	Endocrinology-Gynaecology-Fertility-Metabolism	Shire Human Genetic Therapies AB	11/12/2020
Riociguat	Cardiovascular Diseases	Bayer AG	11/12/2020
Elbasvir / grazoprevir	Infectious Diseases	Merck Sharp & Dohme B.V.	11/12/2020

## Annex 17 – Referral procedures overview 2020 – 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
Angiotensin-II-receptor antagonists (sartans) containing a tetrazole group (candesartan, irbesartan, losartan, olmesartan, valsartan)	16/07/2018	12/11/2020 <sup>1</sup>	Article 31 of Directive 2001/83/EC
Fosfomycin-containing medicinal products (fosfomycin calcium, fosfomycin disodium, fosfomycin sodium, fosfomycin trometamol)	13/12/2018	26/03/2020	Article 31 of Directive 2001/83/EC
Direct oral anticoagulants (DOACs) (direct oral anticoagulants (DOACs))	31/01/2019	26/03/2020	Article 5(3) of Regulation (EC) No 726/2004
Methocarbamol/paracetamol-containing medicinal products (methocarbamol/paracetamol)	29/05/2019	26/03/2020	Article 31 of Directive 2001/83/EC
Nitrosamine impurities in human medicinal products (various)	19/09/2019	26/06/2020	Article 5(3) of Regulation (EC) No 726/2004
Ranitidine-containing medicinal products (ranitidine)	19/09/2019	17/09/2020 <sup>2</sup>	Article 31 of Directive 2001/83/EC
Budesonide SUN and associated names (budesonide)	17/10/2019	25/06/2020 <sup>3</sup>	Article 29(4) of Directive 2001/83/EC
Yondelis (trabectedin)	27/02/2020	23/07/2020	Article 20 of Regulation (EC) No 726/2004
Medicinal products which have been authorised or are pending approval based on clinical trials performed at Panexcell Clinical Laboratories Priv. Ltd. (various)	27/02/2020	23/07/2020	Article 31 of Directive 2001/83/EC
Carbamazepin Tillomed 200 and 400 mg prolonged-release tablets and associated names (carbamazepine)	26/03/2020	30/04/2020	Article 29(4) of Directive 2001/83/EC
Ibuprofen Kabi 400 mg Infusionslösung and associated names (ibuprofen)	26/03/2020	23/07/2020	Article 29(4) of Directive 2001/83/EC
Varilrix and associated names (live attenuated varicella virus (OKA strain))	25/06/2020	ongoing	Article 30 of Directive 2001/83/EC
Dexamethasone use in hospitalised patients with COVID-19 (dexamethasone)	23/07/2020	17/09/2020	Article 5(3) of Regulation (EC) No 726/2004

<sup>1</sup> Revised opinion regarding the impact of the Article 5(3) scientific opinion on nitrosamines. CHMP initiated a review during its October 2020 plenary meeting

<sup>2</sup> CHMP opinion after re-examination

<sup>3</sup> CHMP opinion after re-examination

## Referrals made to the PRAC

Procedure name (international non-proprietary name (INN) or common name)	Start of procedure	End of procedure	Type of referral
Fluorouracil and related substances containing medicinal products (fluorouracil, capecitabine, tegafur, flucytosine)	15/03/2019	30/04/2020	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Estradiol-containing (0.01% w/w) medicinal products for topical use (estradiol)	11/04/2019	30/01/2020 <sup>4</sup>	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Leuprorelin-containing depot medicinal products (leuprorelin)	14/06/2019	24/06/2020	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Cyproterone-containing medicinal products (cyproterone)	11/07/2019	26/03/2020	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Picato (ingenol mebutate)	05/09/2019	30/04/2020	Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data
Ulipristal acetate 5mg (ulipristal acetate)	12/03/2020	12/11/2020	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data
Ifosfamide-containing solutions (ifosfamide)	12/03/2020	ongoing	Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

<sup>4</sup> CMDh position after re-examination



## Annex 18 – Arbitrations and referrals in 2020 – veterinary medicines

Type of procedure	Date <ul style="list-style-type: none"> <li>• Clock start</li> <li>• CVMP opinion</li> </ul>	Product <ul style="list-style-type: none"> <li>• Product name</li> <li>• INN</li> </ul>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>• 20/02/2019</li> <li>• 16/07/2020</li> </ul>	<ul style="list-style-type: none"> <li>• Betamox LA 150 mg/ml Suspension for Injection and its associated names, and generic products thereof</li> <li>• Amoxicillin</li> </ul>
Referral under Article 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>• 17/07/2019</li> <li>• 10/12/2020</li> </ul>	<ul style="list-style-type: none"> <li>• Adjusol and its associated names</li> <li>• Sulfadiazine and trimethoprim</li> </ul>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>• 11/09/2019</li> <li>• 18/06/2020</li> </ul>	<ul style="list-style-type: none"> <li>• Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection, and associated names and generic products thereof</li> <li>• Dinoprost tromethamine</li> </ul>
Referral under Article 34 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>• 11/09/2019</li> </ul>	<ul style="list-style-type: none"> <li>• Ronaxan and its associated names</li> <li>• Doxycycline hyclate</li> </ul>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>• 09/10/2019</li> <li>• 16/07/2020</li> </ul>	<ul style="list-style-type: none"> <li>• Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof</li> <li>• Azaperone</li> </ul>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>• 06/11/2019</li> <li>• 09/09/2020</li> </ul>	<ul style="list-style-type: none"> <li>• Veterinary medicinal products containing tiamulin hydrogen fumarate presented as premix for medicated feeding stuff and oral powder for in-feed use to be administered to pigs</li> <li>• Tiamulin hydrogen fumarate</li> </ul>
Procedure under Article 45 of Regulation (EC) No 726/2004	<ul style="list-style-type: none"> <li>• 07/11/2019</li> <li>• 20/05/2020</li> </ul>	<ul style="list-style-type: none"> <li>• Suvaxyn PRRS MLV lyophilisate and solvent for suspension for injection for pigs</li> <li>• Porcine respiratory and reproductive syndrome (PRRS) virus vaccine (live)</li> </ul>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>• 19/02/2020</li> <li>• 05/11/2020</li> </ul>	<ul style="list-style-type: none"> <li>• Valbazen 100 mg/ml Total Spectrum Wormer oral suspension and associated names, including its generic/hybrid products</li> <li>• Albendazole</li> </ul>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>• 15/07/2020</li> </ul>	<ul style="list-style-type: none"> <li>• Injectable veterinary medicinal products containing vitamin A for use in food producing species</li> <li>• Vitamin A (retinol and its esters)</li> </ul>

<b>Type of procedure</b>	<b>Date</b>	<b>Product</b>
Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none"> <li>• <b>Clock start</b></li> <li>• <b>CVMP opinion</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Product name</b></li> <li>• <b>INN</b></li> </ul>
	<ul style="list-style-type: none"> <li>• 15/07/2020</li> </ul>	<ul style="list-style-type: none"> <li>• Modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines</li> <li>• Porcine respiratory and reproductive syndrome virus vaccine (live)</li> </ul>

## Annex 19 – Budget summaries 2019–2020

The summarised comparative budget statements for 2019 and 2020 are as follows:

		2019 (final) <sup>1</sup>		2020 (budget) <sup>2</sup>		2020 (prov.) <sup>3</sup>	
		€ `000	% of total	€ `000	% of total	€ `000	% of total
<b>Revenue</b>							
100	Fees and charges	293,953	89.1%	310,595	84.0%	316,889	84.2%
200	General EU contribution	9,326	2.8%	33,704	9.1%	33,704	9.0%
201	Special EU contribution for orphan medicinal products	11,703	3.5%	11,374	3.1%	11,374	3.0%
600	External assigned revenue	95	0.0%	0	0.0%	0	0.0%
700	Balance from previous year	14,468	4.4%	13,803	3.7%	13,803	3.7%
5+9	Other	193	0.1%	273	0.1%	476	0.1%
	<b>TOTAL REVENUE</b>	<b>329,738</b>	<b>100.0%</b>	<b>369,749</b>	<b>100.0%</b>	<b>376,246</b>	<b>100.0%</b>
<b>Expenditure</b>							
<b>Staff</b>							
11	Staff in active employment	106,654	31.2%	105,095	28.4%	104,979	28.7%
12	Staff recruitment	310	0.1%	300	0.1%	199	0.1%
13	Duty travel	1,197	0.4%	219	0.1%	138	0.0%
14	Socio-medical infrastructure	2,928	0.9%	1,997	0.5%	1,695	0.5%
15	Training	247	0.1%	720	0.2%	556	0.2%
16	Social welfare	3,935	1.2%	7,039	1.9%	7,001	1.9%
17	Representation expenses	116	0.0%	78	0.0%	66	0.0%
	<i>Total Title 1</i>	<b>115,387</b>	<b>33.8%</b>	<b>115,448</b>	<b>31.2%</b>	<b>114,634</b>	<b>31.4%</b>
<b>Building/equipment</b>							
20	Investment in immovable property, renting of building and associated costs	50,932	14.9%	42,944	11.6%	41,541	11.4%
21	Expenditure on corporate data processing	22,522	6.6%	32,628	8.8%	32,334	8.8%
22	Movable property [..]	795	0.2%	1,231	0.3%	1,222	0.3%
23	Other administrative expenditure	5,460	1.6%	1,126	0.3%	887	0.2%
24	Postage	123	0.0%	48	0.0%	35	0.0%
25	Expenditure on other meetings	304	0.1%	279	0.1%	270	0.1%
26	Restaurant & catering	1,925	0.6%	1,843	0.5%	1,703	0.5%
27	Information & publishing	1,000	0.3%	1,274	0.3%	1,241	0.3%
28	Business consultancy & audit svcs.	673	0.2%	3,701	1.0%	3,693	1.0%
	<i>Total Title 2</i>	<b>83,734</b>	<b>24.5%</b>	<b>85,074</b>	<b>23.0%</b>	<b>82,927</b>	<b>22.7%</b>
<b>Operational expenditure</b>							
300	Meetings	6,499	1.9%	1,354	0.4%	1,309	0.4%
301	Evaluation of medicines	121,590	35.6%	134,009	36.2%	133,571	36.6%
302	Translations	3,964	1.2%	5,077	1.4%	5,047	1.4%
303	Scientific studies & svcs.	2,978	0.9%	7,926	2.1%	7,490	2.0%
31	Expenditure on business related IT projects	7,617	2.2%	20,861	5.6%	20,455	5.6%
	<i>Total Title 3</i>	<b>142,648</b>	<b>41.7%</b>	<b>169,227</b>	<b>45.8%</b>	<b>167,872</b>	<b>45.9%</b>
90	Provisional appropriation	0	0.0%	0	0.0%	0	0.0%
	<i>Total Title 9</i>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>
	<b>TOTAL EXPENDITURE</b>	<b>341,769</b>	<b>100.0%</b>	<b>369,749</b>	<b>100.0%</b>	<b>365,433</b>	<b>100.0%</b>
<sup>1</sup> Financial Year 2019: as per final accounts; rounded to nearest thousand Euro <sup>2</sup> Financial Year 2020: as per final budget <sup>3</sup> Financial Year 2020: as per provisional accounts; rounded to nearest thousand Euro							

## Annex 20 – European Medicines Agency establishment plan

Category and grade	TEMPORARY POSTS					
	POSTS 2020				POSTS 2021	
	Authorised		Actual as per 31.12.2020		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	0	-	0	-	0
AD 15	-	3	-	3	-	3
AD 14	-	8	-	8	-	9
AD 13	-	12	-	12	-	13
AD 12	-	44	-	44	-	45
AD 11	-	47	-	47	-	51
AD 10	-	44	-	44	-	51
AD 9	-	46	-	46	-	55
AD 8	-	66	-	66	-	71
AD 7	-	76	-	76	-	94
AD 6	-	46	-	46	-	65
AD 5	-	3	-	3	-	15
<b>Total AD</b>	<b>0</b>	<b>395</b>	<b>0</b>	<b>395</b>	<b>0</b>	<b>472</b>
AST 11	-	2	-	2	-	2
AST 10	-	7	-	7	-	7
AST 9	-	8	-	8	-	9
AST 8	-	19	-	19	-	10
AST 7	-	15	-	15	-	19
AST 6	-	15	-	15	-	20
AST 5	-	39	-	39	-	38
AST 4	-	52	-	52	-	46
AST 3	-	44	-	44	-	32
AST 2	-	0	-	0	-	2
AST 1	-	0	-	0	-	0
<b>Total AST</b>	<b>0</b>	<b>201</b>	<b>0</b>	<b>201</b>	<b>0</b>	<b>185</b>
<b>Grand Total</b>	<b>0</b>	<b>596</b>	<b>0</b>	<b>596</b>	<b>0</b>	<b>657</b>

Other staff	Planned (FTE <sup>1</sup> ) 2020	Actual (FTE <sup>1</sup> ) 2020	Actual headcount 31.12.2020	Planned (FTE <sup>1</sup> ) 2021
<b>CONTRACT AGENTS</b>	<b>228</b>	<b>199</b>	<b>197</b>	<b>226</b>
<b>NATIONAL EXPERTS</b>	<b>30</b>	<b>28</b>	<b>32</b>	<b>30</b>

<sup>1</sup> FTE=Full Time Equivalent

## Annex 21 – Access to documents requests

### *Requests received and pages released*

Year	Number of requests received	Number of pages released
<b>2020</b>	597	110,995

### *Initial decisions on access in 2020<sup>1</sup>*

Access given	
Yes	294
Partial	14
No	13
Not Applicable <sup>2</sup>	191
<b>Total closed</b>	<b>512</b>
Pending <sup>3</sup>	354

### *Legal basis used for full or partial refusal*

Legal basis	Full	Partial
4.1(a) – Protection of public interest	0	0
4.1(b) – Protection of privacy	0	0
4.2 1 <sup>st</sup> ind – Protection of commercial interest	9	14
4.2 2 <sup>nd</sup> ind – Protection of court proceedings	0	0
4.2 3 <sup>rd</sup> ind – Protection of inspections	0	0
4.3 1 <sup>st</sup> par – Protection of decision making process	4	0
4.3 2 <sup>nd</sup> par – Protection of the Agency’s decision making process	0	0
4.5 – Protection of Member States	0	0
<b>Total</b>	<b>13</b>	<b>14</b>

<sup>1</sup> Including initial requests received in previous years but closed in 2020

<sup>2</sup> Request became RFI / Document is not held by the Agency / Clarification is not received / Withdrawn

<sup>3</sup> Requests ongoing (currently processed) and in queue (not started)

*Decision on confirmatory applications in 2020<sup>4</sup>*

Appeals	
Final refusal	3
Release	2
Partial	0
Not Applicable <sup>5</sup>	1
<b>Total closed</b>	<b>6</b>
Pending <sup>6</sup>	2

*Legal basis used for full or partial refusal*

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

<sup>4</sup> Including appeals received in previous years but closed in 2020

<sup>5</sup> Withdrawn

<sup>6</sup> Requests ongoing (currently processed) and in queue (not started)

### **Affiliation (per initial requests and appeals in 2020)**

Affiliation	Number of requests received	In %	Number of pages released <sup>7</sup>	In %
Not-for-profit organisation	18	3	2,187	2
EU Institution (EC etc)	0	0	0	0
Regulator outside EU	1	0	0	0
EU NCA	1	0	0	0
Patients or Consumer	33	6	21,897	20
Healthcare professional	23	4	8,779	8
Academia/Research institute	53	9	18,632	17
Legal	42	7	6,754	6
Media	11	2	1,612	1
Pharmaceutical industry	331	55	45,912	41
Consultant	84	14	5,222	5
Other	0	0	0	0
<b>Total</b>	<b>597</b>	<b>100</b>	<b>110,995</b>	<b>100</b>

<sup>7</sup> Including initial requests and appeals received in previous years but closed in 2020

## Annex 22 – Publications by Agency staff members and experts in 2020

**Ali S, Camarero J, Hennik P, Bolstad B, Sommerfelt Grønvold M, Syvertsen C, Oddvar Strøm B, Ökvist M, Josephson F, Keller-Stanislawski B, Zafiroopoulos N, Pean E, Bergh J, da Rocha Dias S, Pignatti F**

European Medicines Agency extension of indication to include the combination immunotherapy cancer drug treatment with nivolumab (Opdivo) and ipilimumab (Yervoy) for adults with intermediate/poor-risk advanced renal cell carcinoma.

ESMO Open. 2020 Nov;5(6):e000798. doi: 10.1136/esmoopen-2020-000798. PMID: 33188050; PMCID: PMC7668381.

**Ali S, Dunmore HM, Karres D, Hay JL, Salmonsson T, Gisselbrecht C, Sarac SB, Bjerrum OW, Hovgaard D, Barbachano Y, Nagercoil N, Pignatti F**

The EMA Review of Mylotarg (Gemtuzumab Ozogamicin) for the Treatment of Acute Myeloid Leukemia. *Oncologist*. 2019 May;24(5):e171-e179. doi: 10.1634/theoncologist.2019-0025. Epub 2019 Mar 21. PMID: 30898889; PMCID: PMC6516123.

**Ali S, Kjekken R, Niederlaender C, Markey G, Saunders TS, Opsata M, Moltu K, Bremnes B, Grønevik E, Muusse M, Håkonsen GD, Skibeli V, Kalland ME, Wang I, Buajordet I, Urbaniak A, Johnston J, Rantell K, Kerwash E, Schuessler-Lenz M, Salmonson T, Bergh J, Gisselbrecht C, Tzogani K, Papadouli I, Pignatti F**

The European Medicines Agency Review of Kymriah (Tisagenlecleucel) for the Treatment of Acute Lymphoblastic Leukemia and Diffuse Large B-Cell Lymphoma.

*Oncologist*. 2020 Feb;25(2):e321-e327. doi: 10.1634/theoncologist.2019-0233. Epub 2019 Oct 16. PMID: 32043764; PMCID: PMC7011647.

**Ali S, Moreau A, Melchiorri D, Camarero J, Josephson F, Olimpier O, Bergh J, Karres D, Tzogani K, Gisselbrecht C, Pignatti F**

Blinatumomab for Acute Lymphoblastic Leukemia: The First Bispecific T-Cell Engager Antibody to Be Approved by the EMA for Minimal Residual Disease.

*Oncologist*. 2020 Apr;25(4):e709-e715. doi: 10.1634/theoncologist.2019-0559. Epub 2019 Nov 14. PMID: 32297447; PMCID: PMC7160312.

**Arlett P et al**

CSPS/Health Canada, R. W. D. W. G. (2020). Health Canada & Canadian Society for Pharmaceutical Sciences - Use of Real World Data/Evidence to Inform Regulatory Decision Making.

*Journal of Pharmacy & Pharmaceutical Sciences*, 23(1), 1s–47s. <https://doi.org/10.18433/jpps31051>

**Arlett P, Straus S, Rasi G**

Pharmacovigilance 2030.

*Clin Pharmacol Ther*. 2020 Jan;107(1):89-91. doi: 10.1002/cpt.1689. Epub 2019 Nov 22

**Arlett P**

Measuring the impact of risk communications: Robust analytical approaches are key.

*Br J Clin Pharmacol*. 2020 Apr;86(4):635-636. doi: 10.1111/bcp.14222. Epub 2020 Feb 16. PMID: 32064646; PMCID: PMC7098862.

**Armstrong TS, Dirven L, Arons D, Bates A, Chang SM, Coens C, Espinasse C, Gilbert MR, Jenkinson D, Kluetz P, Mendoza T, Rubinstein L, Sul J, Weller M, Wen PY, van den Bent MJ, Taphoorn MJB**

Glioma patient-reported outcome assessment in clinical care and research: a Response Assessment in Neuro-Oncology collaborative report.

*Lancet Oncol*. 2020 Feb;21(2):e97-e103. doi: 10.1016/S1470-2045(19)30796-X. PMID: 32007210.

**Barrett JS, Bucci-Rechtweg C, Amy Cheung SY, Gamalo-Siebers M, Haertter S, Karres J, Marquard J, Mulugeta Y, Ollivier C, Strougo A, Yanoff L, Yao L, Zeitler P**

Pediatric Extrapolation in Type 2 Diabetes: Future Implications of a Workshop.

*Clin Pharmacol Ther*. 2020 Jul;108(1):29-39. doi: 10.1002/cpt.1805. Epub 2020 Mar 16. PMID: 32017043; PMCID: PMC7383960.



**Bell SC, Mall MA, Gutierrez H, Macek M, Madge S, Davies JC, Burgel PR, Tullis E, Castañós C, Castellani C, Byrnes CA, Cathcart F, Chotirmall SH, Cosgriff R, Eichler I, Fajac I, Goss CH, Drevinek P, Farrell PM, Gravelle AM, Havermans T, Mayer-Hamblett N, Kashirskaya N, Kerem E, Mathew JL, McKone EF, Naehrlich L, Nasr SZ, Oates GR, O'Neill C, Pypops U, Raraigh KS, Rowe SM, Southern KW, Sivam S, Stephenson AL, Zampoli M, Ratjen F**

The future of cystic fibrosis care: a global perspective.

Lancet Respir Med. 2020 Jan;8(1):65-124. doi: 10.1016/S2213-2600(19)30337-6. Epub 2019 Sep 27.

Erratum in: Lancet Respir Med. 2019 Dec;7(12):e40. PMID: 31570318.

**Candore G, Hedenmalm K, Slattery J, Cave A, Kurz X, Arlett P**

Can we rely on results from IQVIA Medical Research Data UK converted to the Observational Medical Outcome Partnership Common Data Model?

Clin Pharmacol Ther. 2020 Apr;107(4):915-925. doi: 10.1002/cpt.1785. Epub 2020 Mar 2. PMID:

31956997; PMCID: PMC7158210.

**Cavaller Bellaubi M, Harvey Allchurch M, Lagalice C, Saint-Raymond A**

The European Medicines Agency facilitates access to medicines in low and middle-income countries.

Expert Rev Clin Pharmacol. 2020 Mar;13(3):321-325. doi: 10.1080/17512433.2020.1724782. Epub

2020 Feb 13. PMID: 32053756.

**Cave A, Brun NC, Sweeney F, Rasi G, Senderovitz T; HMA-EMA Joint Big Data Taskforce**

Big Data - How to Realize the Promise.

Clin Pharmacol Ther. 2020 Apr;107(4):753-761. doi: 10.1002/cpt.1736. Epub 2020 Jan 27. PMID:

31846513; PMCID: PMC7158218.

**Cerreta F, Ritzhaupt A, Metcalfe T, Askin S, Duarte J, Berntgen M, Vamvakas S**

Digital Technologies for Medicines: Shaping a Framework for Success.

Nat Rev Drug Discov. 2020 Sep;19(9):573-574. doi: 10.1038/d41573-020-00080-6. PMID: 32398879.

**Cohen AF, van Gerven J, Burgos JG, de Boer A, Foucher RAM, Flore H, Teitelbaum Z, van Eden W, Webb A, Cremers S**

COVID-19 vaccines: the importance of transparency and fact-based education

Br J Clin Pharmacol. 2020 Nov;86(11):2107-2110. doi: 10.1111/bcp.14581. Epub 2020 Oct 14. PMID:

33464636; PMCID: PMC7576612.

**Cole S, Kerwash E, Andersson A**

A summary of the current drug interaction guidance from the European Medicines Agency and considerations of future updates.

Drug Metab Pharmacokinet. 2020 Feb;35(1):2-11. doi: 10.1016/j.dmpk.2019.11.005. Epub 2020 Jan

8. PMID: 31996310.

**Collignon O, Gartner C, Haidich AB, James Hemmings R, Hofner B, Pétavy F, Posch M, Rantell K, Roes K, Schiel A**

Current Statistical Considerations and Regulatory Perspectives on the Planning of Confirmatory Basket, Umbrella, and Platform Trials.

Clin Pharmacol Ther. 2020 May;107(5):1059-1067. doi: 10.1002/cpt.1804. Epub 2020 Apr 1. PMID:

32017052.

**Correia Pinheiro L, Durand J, Dogné JM**

An application of machine learning in pharmacovigilance: estimating likely patient genotype from phenotypical manifestations of fluoropyrimidine toxicity.

Clin Pharmacol Ther. 2020 Apr;107(4):944-947. doi: 10.1002/cpt.1789. Epub 2020 Feb 27. PMID:

31955411; PMCID: PMC7158217.

**De Jong WH, Borges T, Ion RM, Panagiotakos D, Testai E, Vermeire T, Bernauer U, Rousselle C, Bégué S, Kopperud HM, Milana MR, Schmidt T, Pignatti F, Stoyanova E, Volk K, Bertolini R, De Voogt P, Duarte-Davidson R, Hoet P, Kraetke R, Proykova A, Samaras T, Scott M, Slama R, Vighi M, Zacharo S**

Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties.

Regul Toxicol Pharmacol. 2020 Mar;111:104546. doi: 10.1016/j.yrtph.2019.104546. Epub 2019 Dec 9.

PMID: 31830500.

**Ehmann F, Aerssens J, Blanchard R**

Commentary on ICH Guideline on Genomic Sampling and Data Management-Enabling Opportunities in Drug Development and Patient Treatment.

Br J Clin Pharmacol. 2020 Aug;86(8):1454-1464. doi: 10.1111/bcp.14305. Epub 2020 May 18. PMID: 32307727; PMCID: PMC7373702.

**Eichler HG, Cavaleri M, Enzmann H, Scotti F, Sepodes B, Sweeney F, Vamvakas S, Rasi G**

Clinical trials for Covid-19: can we better use the short window of opportunity?

Clin Pharmacol Ther. 2020 Oct;108(4):730-733. doi: 10.1002/cpt.1891. Epub 2020 Jun 12. PMID: 32407539; PMCID: PMC7272975.

**Eichler HG, Koenig F, Arlett P, Enzmann H, Humphreys A, Pétavy F, Schwarzer-Daum B, Sepodes B, Vamvakas S, Rasi G**

Are Novel, Nonrandomized Analytic Methods Fit for Decision Making? The Need for Prospective, Controlled, and Transparent Validation.

Clin Pharmacol Ther. 2020 Apr;107(4):773-779. doi: 10.1002/cpt.1638. Epub 2019 Oct 1.

**Eichler HG, Rasi G**

Clinical trial publications: A sufficient basis for healthcare decisions?

Eur J Intern Med. 2020 Jan;71:13-14. doi: 10.1016/j.ejim.2019.11.022. Epub 2020 Jan 14.

**Fabrega J, Carapeto R**

Regulatory review of the environmental risk assessment of veterinary medicinal products in the European Union, with particular focus on the centralised authorisation procedure.

Environ Sci Eur 32, 99 (2020). <https://doi.org/10.1186/s12302-020-00374-x>

**Flynn R, Hedenmalm K, Murray-Thomas T, Pacurariu A, Arlett P, Shepherd H, Myles P, Kurz X**

Ability of Primary Care Health Databases to Assess Medicinal Products Discussed by the European Union Pharmacovigilance Risk Assessment Committee.

Clin Pharmacol Ther. 2020 Apr;107(4):957-965. doi: 10.1002/cpt.1775. Epub 2020 Feb 12. PMID: 31955404; PMCID: PMC7158204.

**Gonzalez-Quevedo R, Wolff-Holz E, Carr M, Garcia Burgos J**

Biosimilar medicines: Why the science matters.

Health Policy and Technology (2020), Vol 9 (2), 129-133, [doi.org/10.1016/j.hlpt.2020.03.004](https://doi.org/10.1016/j.hlpt.2020.03.004).

**Greco M, Bere N**

Patients' emotions matter in the regulation of medicines.

Blog: [bmjopinion](https://www.bmj.com/blog/2020/08/11/patients-emotions-matter-in-the-regulation-of-medicines), 11 August 2020

**Guizzaro L, Morgan DDV, Falco A, Gallo C**

Hamilton scale and MADRS are interchangeable in meta-analyses but can disagree at trial level.

J Clin Epidemiol. 2020 Aug;124:106-117. doi: 10.1016/j.jclinepi.2020.04.022. Epub 2020 May 6. PMID: 32387423.

**Hay JL, O'Sullivan J, Kerwash E, Ilie AR, Cole SM**

A review of clinical pharmacology deficiencies of European centralised drug marketing authorisation applications.

Regul Toxicol Pharmacol. 2020 Dec;118:104804. doi: 10.1016/j.yrtph.2020.104804. Epub 2020 Oct 10. PMID: 33049309.

**Herold R**

Real-World-Evidence – rascherer Fortschritt für Krebsarzneimittel?

Onko360

**Hines PA, Gonzalez-Quevedo R, Lambert AIOM, Janssens R, Freischem B, Torren Edo J, Claassen IJTM, Humphreys AJ**

Regulatory Science to 2025: An Analysis of Stakeholder Responses to the European Medicines Agency's Strategy.

Front Med (Lausanne). 2020 Sep 23;7:508. doi: 10.3389/fmed.2020.00508. PMID: 33072771; PMCID: PMC7540226.

**Hines PA, Guy RH, Brand A, Humphreys AJ, Papaluca-Amati M**

Regulatory Science and Innovation Programme for Europe (ReSciPE): a proposed model. Br J Clin Pharmacol. 2020 Dec;86(12):2530-2534. doi: 10.1111/bcp.14099. Epub 2019 Oct 17. PMID: 31426120; PMCID: PMC7688530.

**Hines PA, Janssens R, Gonzalez-Quevedo R, Lambert AIOM, Humphreys AJ**

A future for regulatory science in the European Union: the European Medicines Agency's strategy. Nat Rev Drug Discov. 2020 May;19(5):293-294. doi: 10.1038/d41573-020-00032-0.

**Holtkamp F, Gudmundsdottir H, Maciulaitis R, Benda N, Thomson A, Vetter T**

Change in Albuminuria and Estimated GFR as End Points for Clinical Trials in Early Stages of CKD: A Perspective From European Regulators. Am J Kidney Dis. 2020 Jan;75(1):6-8. doi: 10.1053/j.ajkd.2019.07.019. Epub 2019 Oct 28.

**Jamei M, Abrahamsson B, Brown J, Bevernage J, Bolger MB, Heimbach T, Karlsson E, Kotzagiorgis E, Lindahl A, McAllister M, Mullin JM, Pepin X, Tistaert C, Turner DB, Kesisoglou F**

Current status and future opportunities for incorporation of dissolution data in PBPK modeling for pharmaceutical development and regulatory applications: OrBiTo consortium commentary. Eur J Pharm Biopharm. 2020 Oct;155:55-68. doi: 10.1016/j.ejpb.2020.08.005. Epub 2020 Aug 8. PMID: 32781025.

**Karres D, Ali S, van Hennik PB, Straus S, Josephson F, Thole G, Glerum PJ, Herberts C, Babae N, Herold R, Papadouli I, Pignatti F**

EMA Recommendation for the Pediatric Indications of Plerixafor (Mozobil) to Enhance Mobilization of Hematopoietic Stem Cells for Collection and Subsequent Autologous Transplantation in Children with Lymphoma or Malignant Solid Tumors. Oncologist. 2020 Jun;25(6):e976-e981. doi: 10.1634/theoncologist.2019-0898. Epub 2020 Mar 10. PMID: 32154610; PMCID: PMC7288649.

**Karres D, Lesa G, Ligas F, Annunen P, van Dartel M, Demolis P, Galluzzo S, Herold R, van Criekingen OK, Stoyanova-Beninska V, Norga K**

Can a Multistakeholder Prioritization Structure Support Regulatory Decision Making? A Review of Pediatric Oncology Strategy Forums Reflecting on Challenges and Opportunities of this Concept. Clin Pharmacol Ther. 2020 Sep;108(3):553-556. doi: 10.1002/cpt.1939. Epub 2020 Jul 8. PMID: 32559312.

**Kashoki M, Hanaizi Z, Yordanova S, Veselý R, Bouygués C, Llinares J, Kweder SL**

A comparison of EMA and FDA decisions for new drug marketing applications 2014-2016: concordance, discordance and why. Clin Pharmacol Ther. 2020 Jan;107(1):195-202. doi: 10.1002/cpt.1565. Epub 2019 Aug 14.

**Kush RD, Warzel D, Kush MA, Sherman A, Navarro EA, Fitzmartin R, Pétavy F, Galvez J, Becnel LB, Zhou FL, Harmon N, Jauregui B, Jackson T, Hudson L**

FAIR Data Sharing: The Roles of Common Data Elements and Harmonization. J Biomed Inform. 2020 Jul;107:103421. doi: 10.1016/j.jbi.2020.103421. Epub 2020 May 12. PMID: 32407878.

**Manolis E, Musuamba FT, Karlsson KE**

Regulatory Considerations for Building an In Silico Clinical Pharmacology Backbone by 2030. Clin Pharmacol Ther. 2020 Apr;107(4):746-748. doi: 10.1002/cpt.1772. Epub 2020 Feb 3. PMID: 32010966.

**Mariz S, Westermark K, Sepodes B**

Designation of orphan conditions in Europe: regulatory observations and considerations after implementation of regulation 141/2000. Expert Opinion on Orphan Drugs, DOI: 10.1080/21678707.2020.1784720

**McAllister M, Flanagan T, Boon K, Pepin X, Tistaert C, Jamei M, Abend A, Kotzagiorgis E, Mackie C**

Developing Clinically Relevant Dissolution Specifications for Oral Drug Products—Industrial and Regulatory Perspectives.  
Pharmaceutics. 2019 Dec 23;12(1):19. doi: 10.3390/pharmaceutics12010019. PMID: 31878006; PMCID: PMC7022466.

**Michaleas S, Penninga E, Hovgaard D, Dalseg AM, Rosso A, Sarac SB, Jimenez JC, Fernández LL, Fernández CP, Mangas-SanJuan V, Garcia I, Payares-Herrera C, Sancho-López A, Enzmann H, de Castro Lopes Silva MSS, Duarte S, Pignatti F**

EMA Review of Daratumumab (Darzalex) for the Treatment of Adult Patients Newly Diagnosed with Multiple Myeloma.  
Oncologist. 2020 Dec;25(12):1067-1074. doi: 10.1002/onco.13554. Epub 2020 Oct 16. PMID: 33026700.

**Mitroiu M, Oude Rengerink K, Teerenstra S, Pétavy F, Roes KCB**

A narrative review of estimands in drug development and regulatory evaluation: old wine in new barrels?  
Trials. 2020 Jul 23;21(1):671. doi: 10.1186/s13063-020-04546-1. PMID: 32703247; PMCID: PMC7376663.

**Monnier AA, Tacconelli E, Årdal C, Cavaleri M, Gyssens IC**

A case study on Staphylococcus aureus bacteraemia: available treatment options, antibiotic R&D and responsible antibiotic use strategies.  
JAC-Antimicrobial Resistance, Volume 2, Issue 2, June 2020, dlaa034, <https://doi.org/10.1093/jacamr/dlaa034>

**Morales DR, Pacurariu A, Slattery J, Kurz X**

Association between hydrochlorothiazide exposure and different incident skin, lip and oral cavity cancers: A series of population-based nested case-control studies.  
Br J Clin Pharmacol. 2020 Jul;86(7):1336-1345. doi: 10.1111/bcp.14245. Epub 2020 Mar 2. PMID: 32068906; PMCID: PMC7319007.

**Moscetti L, Hennik P, Bolstad B, Camarero J, Josephson F, Melchiorri D, Sommerfelt Grønvold M, Sjoberg J, Botezatu M, Mulder J, Meulendijks D, Trullas Jimeno A, Zafiroopoulos N, Bergh J, Enzmann H, Pignatti F**

Combinations in the first-line treatment of patients with advanced/metastatic renal cell cancer: regulatory aspects.  
ESMO Open. 2020 Aug;5(4):e000856. doi: 10.1136/esmoopen-2020-000856. PMID: 32847837; PMCID: PMC7451283.

**Moseley J, Vamvakas S, Berntgen M, Cave A, Kurz X, Arlett P, Acha V,, Bennett S, Cohet C, Corriol-Rohou S, Du Four E, Lamoril C, Langeneckert A, Koban M, Pasté M, Sandler S, Van Baelen K, Cangini A, García S, Obach M, Gimenez Garcia E, Varela Lema L, Jauhonen HM, Rannanheimo P, Morrison D, Van De Castele M, Strömngren A, Viberg A, Makady A, Guilhaume C**

Regulatory and health technology assessment advice on postlicensing and postlaunch evidence generation is a foundation for lifecycle data collection for medicines.  
Br J Clin Pharmacol. 2020 Jun;86(6):1034-1051. doi: 10.1111/bcp.14279. Epub 2020 Apr 24. PMID: 32162368; PMCID: PMC7256124.

**Nambiar S, Cavaleri M, Sato J**

Achieving Regulatory Alignment for Anti-Infective Clinical Trials.  
ACS Infect Dis. 2020 Jun 12;6(6):1308-1310. doi: 10.1021/acsinfecdis.0c00270.

**Orsini LS, Berger M, Crown W, Daniel G, Eichler HG, Goettsch W, Graff J, Guerino J, Jonsson P, Lederer NM, Monz B, Mullins CD, Schneeweiss S, Brunt DV, Wang SV, Willke RJ**

Improving Transparency to Build Trust in Real-World Secondary Data Studies for Hypothesis Testing—Why, What, and How: Recommendations and a Road Map from the Real-World Evidence Transparency Initiative.  
Value Health. 2020 Sep;23(9):1128-1136. doi: 10.1016/j.jval.2020.04.002. PMID: 32940229.

**Oude Rengerink K, Mitroiu M, Teerenstra S, Pétavy F, Roes KCB**

Rethinking the intention-to-treat principle: one size does not fit all.

J Clin Epidemiol. 2020 Sep;125:198-200. doi: 10.1016/j.jclinepi.2020.04.023. Epub 2020 May 4. PMID: 32380178.

**Papadouli I, Mueller-Berghaus J, Beuneu C, Ali S, Hofner B, Petavy F, Tzogani K, Miermont A, Norga K, Kholmanskikh O, Leest T, Schuessler-Lenz M, Salmonson T, Gisselbrecht C, Garcia JL, Pignatti F**

EMA Review of Axicabtagene Ciloleucel (Yescarta) for the Treatment of Diffuse Large B-Cell Lymphoma.

Oncologist. 2020 Oct;25(10):894-902. doi: 10.1634/theoncologist.2019-0646. Epub 2020 Apr 27. PMID: 32339368; PMCID: PMC7543293.

**Pearson AD, Stegmaier K, Bourdeaut F, Reaman G, Heenen D, Meyers ML, Armstrong SA, Brown P, De Carvalho D, Jabado N, Marshall L, Rivera M, Smith M, Adamson PC, Barone A, Baumann C, Blackman S, Buenger V, Donoghue M, Duncan AD, Fox E, Gadbaw B, Hattersley M, Ho P, Jacobs I, Kelly MJ, Kieran M, Lesa G, Ligas F, Ludwinski D, McDonough J, Nikolova Z, Norga K, Senderowicz A, Taube T, Weiner S, Karres D, Vassal G**

Paediatric Strategy Forum for medicinal product development of epigenetic modifiers for children: ACCELERATE in collaboration with the European Medicines Agency with participation of the Food and Drug Administration.

Eur J Cancer. 2020 Nov;139:135-148. doi: 10.1016/j.ejca.2020.08.014. Epub 2020 Sep 26. PMID: 32992153.

**Pearson ADJ, Karres D, Reaman G, DuBois SG, Knox L, Scobie N, Vassal G**

The RACE to accelerate drug development for children with cancer.

Lancet Child Adolesc Health. 2020 Oct;4(10):714-716. doi: 10.1016/S2352-4642(20)30247-9. Epub 2020 Aug 18. PMID: 32822672.

**Pearson ADJ, Rossig C, Lesa G, Diede SJ, Weiner S, Anderson J, Gray J, Georger B, Minard-Colin V, Marshall LV, Smith M, Sondel P, Bajars M, Baldazzi C, Barry E, Blackman S, Blanc P, Capdeville R, Caron H, Cole PD, Jiménez JC, Demolis P, Donoghue M, Elgadi M, Gajewski T, Galluzzo S, Ilaria R Jr, Jenkner A, Karres D, Kieran M, Ligas F, Lowy I, Meyers M, Oprea C, Peddareddigari VGR, Sterba J, Stockman PK, Suenart P, Tabori U, van Tilburg C, Yancey T, Weigel B, Norga K, Reaman G, Vassal G**

ACCELERATE and European Medicines Agency Paediatric Strategy Forum for Medicinal Product Development of checkpoint inhibitors for use in combination therapy in paediatric patients.

Eur J Cancer. 2020 Mar;127:52-66. doi: 10.1016/j.ejca.2019.12.029. Epub 2020 Jan 24.

**Pearson ADJ, Zwaan CM, Kolb EA, Karres D, Guillot J, Kim SY, Marshall L, Tasian SK, Smith M, Cooper T, Adamson PC, Barry E, Benettaib B, Binlich F, Borgman A, Brivio E, Capdeville R, Delgado D, Faller D, Fogelstrand L, Fraenkel PG, Hasle H, Heenen D, Kaspers G, Kieran M, Klusmann JH, Lesa G, Ligas F, Mappa S, Mohamed H, Moore A, Morris J, Nottage K, Reinhardt D, Scobie N, Simko S, Winkler T, Norga K, Reaman G, Vassal G**

Paediatric Strategy Forum for medicinal product development for acute myeloid leukaemia in children and adolescents: ACCELERATE in collaboration with the European Medicines Agency with participation of the Food and Drug Administration.

Eur J Cancer. 2020 Sep;136:116-129. doi: 10.1016/j.ejca.2020.04.038. Epub 2020 Jul 17. PMID: 32688206; PMCID: PMC7789799.

**Pétavy F, Guizzaro L, Antunes Dos Reis I, Teerenstra S, Roes KCB**

Beyond "Intent-to-treat" and "Per protocol": Improving assessment of treatment effects in clinical trials through the specification of an estimands.

Br J Clin Pharmacol. 2020 Jul;86(7):1235-1239. doi: 10.1111/bcp.14195. Epub 2020 Mar 27. PMID: 31883123; PMCID: PMC7319001.

**Pignatti F, Péan E**

Regulatory and Evidence Requirements and the Changing Landscape in Regulation for Marketing Authorisation.

Recent Results Cancer Res. 2019;213:169-187. doi: 10.1007/978-3-030-01207-6\_11. PMID: 30543013.

**Pilarska A, Zimmermann A, Piątkowska K, Jabłoński T**

Patient safety culture in EU legislation.  
Healthcare (Basel). 2020 Oct 19;8(4):410. doi: 10.3390/healthcare8040410. PMID: 33086596;  
PMCID: PMC7711468.

**Pottegård A, Kurz X, Moore N, Christiansen CF, Klungel O**

Considerations for pharmacoepidemiological analyses in relation to the SARS-CoV-2 pandemic.  
Pharmacoepidemiol Drug Saf. 2020 Aug;29(8):825-831. doi: 10.1002/pds.5029. Epub 2020 May 21.  
PMID: 32369865.

**Potts J, Genov G, Segec A, Raine J, Straus S, Arlett P**

Improving the Safety of Medicines in the European Union: From Signals to Action.  
Clin Pharmacol Ther. 2020 Mar;107(3):521-529. doi: 10.1002/cpt.1678. Epub 2019 Dec 6.

**Radawski CA, Hammad TA, Colilla S, Coplan P, Hornbuckle K, Freeman E, Smith MY, Sobel RE, Bahri P, Arias AE, Bennett D**

The utility of real-world evidence for benefit-risk assessment, communication, and evaluation of pharmaceuticals: Case studies.  
Pharmacoepidemiol Drug Saf. 2020 Dec;29(12):1532-1539. doi: 10.1002/pds.5167. Epub 2020 Nov 17. PMID: 33146901.

**Reaman G, Karres D, Ligas F, Lesa G, Casey D, Ehrlich L, Norga K, Pazdur R**

Accelerating the Global Development of Pediatric Cancer Drugs: A Call to Coordinate the Submissions of Pediatric Investigation Plans and Pediatric Study Plans to the European Medicines Agency and US Food and Drug Administration.  
J Clin Oncol. 2020 Dec 20;38(36):4227-4230. doi: 10.1200/JCO.20.02152. Epub 2020 Sep 18. PMID: 32946356.

**Reginster JY, Beaudart C, Al-Daghri N, Avouac B, Bauer J, Bere N, Bruyère O, Cerreta F, Cesari M, Rosa MM, Cooper C, Cruz Jentoft AJ, Dennison E, Geerinck A, Gielen E, Landi F, Laslop A, Maggi S, Prieto Yerro MC, Rizzoli R, Sundseth H, Sieber C, Trombetti A, Vellas B, Veronese N, Visser M, Vlaskovska M, Fielding RA**

Update on the ESCEO recommendation for the conduct of clinical trials for drugs aiming at the treatment of sarcopenia in older adults.  
Aging Clin Exp Res. 2020 Jul 31. doi: 10.1007/s40520-020-01663-4.

**Ritzhaupt A, Hayes I, Ehmann F**

Implementing the EU in vitro diagnostic regulation - a European regulatory perspective on companion diagnostics.  
Expert Rev Mol Diagn. 2020 Jun;20(6):565-567. doi: 10.1080/14737159.2020.1720653. Epub 2020 Jan 28. PMID: 31976775.

**Saint-Raymond A, Sato J, Kishioka Y, Teixeira T, Hasslboeck C, Kweder SL**

Remdesivir emergency approvals: a comparison of the US, Japanese and EU systems.  
Expert Rev Clin Pharmacol. 2020 Oct;13(10):1095-1101. doi: 10.1080/17512433.2020.1821650. Epub 2020 Sep 29. PMID: 32909843.

**Santoro A, Caplanusi I, Sweeney F, Cappelli B, Nolan L, Straus S, Arlett P**

Navigating stormy waters: 10 years of operation of the European Union Regulatory Network Incident Management Plan for Medicines for Human Use.  
Pharmacoepidemiol Drug Saf. 2020 Nov;29(11):1343-1352. doi: 10.1002/pds.5133. Epub 2020 Sep 21. PMID: 32954565; PMCID: PMC7756214.

**Schanberg LE, Ramanan AV, De Benedetti F, Beukelman T, Eakin GS, Del Gaizo V, Ringold S, Vesely R, Schrandt S, Jaki T, Bili A, Chung JB, De Bono S, Douglass W, Enejosa JV, Kanik KS, Knobe K, Kunder R, Leite-Schnell JC, Suehiro RM, Wong RL, Mieszkalski KL, Marrow LC, Siebenaler K, Fraulo E, Kimura Y**

Toward Accelerated Authorization and Access to New Medicines for Juvenile Idiopathic Arthritis.  
Arthritis Rheumatol. 2019 Dec;71(12):1976-1984. doi: 10.1002/art.41043. Epub 2019 Nov 1. PMID: 31313532.



**Schuessler-Lenz M, Enzmann H, Vamvakas S**

Regulators' Advice Can Make a Difference: European Medicines Agency Approval of Zynteglo for Beta Thalassemia.

Clin Pharmacol Ther. 2020 Mar;107(3):492-494. doi: 10.1002/cpt.1639. Epub 2019 Nov 8. PMID: 31705534; PMCID: PMC7027974.

**Sheean ME, Malikova E, Duarte D, Capovilla G, Fregonese L, Hofer MP, Magrelli A, Mariz S, Mendez-Hermida F, Nistico R, Leest T, Sipsas NV, Tsigkos S, Vitezic D, Larsson K, Sepodes B, Stoyanova-Beninska V**

Nonclinical data supporting orphan medicinal product designations in the area of rare infectious diseases.

Drug Discov Today. 2020 Feb;25(2):274-291. doi: 10.1016/j.drudis.2019.10.015. Epub 2019 Nov 5.

**Slater R, Moultrie F, Bax R, van den Anker J, Bhatt A**

Preterm health: time to bridge the evidence gap.

Lancet. 2020 Sep 26;396(10255):872-873. doi: 10.1016/S0140-6736(20)31977-2. PMID: 32979963.

**Slattery J, Kurz X**

Assessing strength of evidence for regulatory decision making in licensing: What proof do we need for observational studies of effectiveness?

Pharmacoepidemiol Drug Saf. 2020 Oct;29(10):1336-1340. doi: 10.1002/pds.5005. Epub 2020 Apr 16. PMID: 32301230; PMCID: PMC7687174.

**Strampelli A, Cerreta F, Vučić K**

Medication use among older people in Europe: Implications for regulatory assessment and co-prescription of new medicines.

Br J Clin Pharmacol. 2020 Oct;86(10):1912-1920. doi: 10.1111/bcp.14462. Epub 2020 Jul 26. PMID: 32644249; PMCID: PMC7495283.

**Sturkenboom M, Bahri P, Chiucchiuini A, Grove Krause T, Hahné S, Khromava A, Kokki M, Kramarz P, Kurz X, Larson HJ, de Lusignan S, Mahy P, Torcel-Pagnon L, Titievsky L, Bauchau V; ADVANCE consortium**

Why we need more collaboration in Europe to enhance post-marketing surveillance of vaccines.

Vaccine. 2020 Dec 22;38 Suppl 2:B1-B7. doi: 10.1016/j.vaccine.2019.07.081. Epub 2019 Oct 31. PMID: 31677952.

**Tambuyzer E, Vandendriessche B, Austin CP, Brooks PJ, Larsson K, Needleman KIM, Valentine J, Davies K, Groft SC, Preti R, Oprea TI, Prunotto M**

Publisher Correction: Therapies for rare diseases: therapeutic modalities, progress and challenges ahead.

Nat Rev Drug Discov. 2020 Apr;19(4):291. doi: 10.1038/s41573-019-0059-7. Erratum for: Nat Rev Drug Discov. 2020 Feb;19(2):93-111. PMID: 31913355.

**Teixeira T, Kweder SL, Saint-Raymond A**

Are EMA, FDA and other international regulators talking to each other?

Clin Pharmacol Ther. 2020 Mar;107(3):507-513. doi: 10.1002/cpt.1617. Epub 2019 Oct 24.

**Tenhunen O, Lasch F, Schiel A, Turpeinen M**

Single-Arm Clinical Trials as Pivotal Evidence for Cancer Drug Approval: A Retrospective Cohort Study of Centralized European Marketing Authorizations Between 2010 and 2019.

Clin Pharmacol Ther. 2020 Sep;108(3):653-660. doi: 10.1002/cpt.1965. PMID: 32578196.

**Tervonen T, Angelis A, Hockley K, Pignatti F, Phillips LD**

Quantifying Preferences in Drug Benefit-Risk Decisions.

Clin Pharmacol Ther. 2019 Nov;106(5):955-959. doi: 10.1002/cpt.1447. Epub 2019 Apr 24. PMID: 30929257.

**Tervonen T, Pignatti F, Postmus D**

From Individual to Population Preferences: Comparison of Discrete Choice and Dirichlet Models for Treatment Benefit-Risk Tradeoffs.

Med Decis Making. 2019 Oct;39(7):879-885. doi: 10.1177/0272989X19873630. Epub 2019 Sep 9. PMID: 31496357; PMCID: PMC6843605.

**Tzogani K, Penttilä K, Lapveteläinen T, Hemmings R, Koenig J, Freire J, Márcia S, Cole S, Coppola P, Flores B, Barbachano Y, Roige SD, Pignatti F**

EMA Review of Daunorubicin and Cytarabine Encapsulated in Liposomes (Vyxeos, CPX-351) for the Treatment of Adults with Newly Diagnosed, Therapy-Related Acute Myeloid Leukemia or Acute Myeloid Leukemia with Myelodysplasia-Related Changes.  
Oncologist. 2020 Sep;25(9):e1414-e1420. doi: 10.1634/theoncologist.2019-0785. Epub 2020 Apr 13. PMID: 32282100

**Tzogani K, Røshol H, Olsen HH, Aas IB, Dalhus ML, Håkonsen GD, Nilssen LS, Lindberg V, Økvist M, Bolstad B, Rogovska I, Karpova N, Enzmann H, Gisselbrecht C, Pignatti F**

The European Medicines Agency Review of Gilteritinib (Xospata) for the Treatment of Adult Patients with Relapsed or Refractory Acute Myeloid Leukemia with an FLT3 Mutation.  
Oncologist. 2020 Jul;25(7):e1070-e1076. doi: 10.1634/theoncologist.2019-0976. Epub 2020 Mar 10. PMID: 32154636; PMCID: PMC7356782.

**Tzogani K, Yu Y, Meulendijks D, Herberts C, Hennik P, Verheijen R, Wangen T, Dahlseng Håkonsen G, Kaasboll T, Dalhus M, Bolstad B, Salmonson T, Gisselbrecht C, Pignatti F**

European Medicines Agency review of midostaurin (Rydapt) for the treatment of adult patients with acute myeloid leukaemia and systemic mastocytosis.  
ESMO Open. 2019 Nov;4(6):e000606. doi: 10.1136/esmoopen-2019-000606. PMID: 32392175; PMCID: PMC7001097.

**Vreman RA, de Ruijter AS, Zawada A, Tafuri G, Stoyanova-Beninska V, O'Connor D, Naumann-Winter F, Wolter F, Mantel-Teeuwisse AK, Leufkens HGM, Sidiropoulos I, Larsson K, Goettsch WG**

Assessment of significant benefit for orphan medicinal products by European Regulators may support subsequent relative effectiveness assessments by HTA organizations.  
Drug Discov Today. 2020 Jul;25(7):1223-1231. doi: 10.1016/j.drudis.2020.04.012. Epub 2020 Apr 25. PMID: 32344040.

**Vreman RA, Heikkinen I, Schuurman A, Sapede C, Garcia JL, Hedberg N, Athanasiou D, Grueger J, Leufkens HGM, Goettsch WG**

Unmet Medical Need: An Introduction to Definitions and Stakeholder Perceptions.  
Value Health. 2019 Nov;22(11):1275-1282. doi: 10.1016/j.jval.2019.07.007. Epub 2019 Sep 6. PMID: 31708064.

**Wieringa FP, Sheldon MI, Hidalgo Simon A**

Regulatory approaches to stimulate innovative renal replacement therapies.  
Nat Rev Nephrol. 2020 Oct;16(10):546-547. doi: 10.1038/s41581-020-0275-8. PMID: 32242124.

**Wilking N, Bucsics A, Kandolf Sekulovic L, Kobelt G, Laslop A, Makaroff L, Roediger A, Zielinski C**

Achieving equal and timely access to innovative anticancer drugs in the European Union (EU): summary of a multidisciplinary CECOG-driven roundtable discussion with a focus on Eastern and South-Eastern EU countries.  
ESMO Open. 2019 Nov 13;4(6):e000550. doi: 10.1136/esmoopen-2019-000550. PMID: 31798977; PMCID: PMC6863652.

**Zafiropoulos N and the Desmoid Tumor Working Group**

The management of desmoid tumours: A joint global consensus-based guideline approach for adult and paediatric patients.  
Eur J Cancer. 2020 Mar;127:96-107. doi: 10.1016/j.ejca.2019.11.013. Epub 2020 Jan 28. PMID: 32004793.