EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Report to the European Commission

on companies and products that have benefited from any of the rewards and incentives in the Paediatric Regulation[1] and on the companies that have failed to comply with any of the obligations in this regulation

Year 2020

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[1] REGULATION (EC) No 1901/2006 of the EUROPEAN PARLIAMENT AND OF THE COUNCIL on medicinal products for paediatric use (Regulation (EC) No 1901/2006 and Regulation (EC) No 1902/2006)

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Acronyms, abbreviations

ASD	Autism spectrum disorder
CHMP	Committee for Medicinal Products for Human Use
CML	Chronic myelogenous leukaemia
EC	European Commission
EMA, the Agency	European Medicines Agency
HAE	Hereditary angioedema
INN	International non-proprietary name
MA	Marketing authorisation
MAH	Marketing authorisation holder(s)
MS	Member States
NCA	National Competent Authorities
NPO	National patent offices
PA	Protocol assistance
Paediatric Regulation	REGULATION (EC) No 1901/2006 of the EUROPEAN PARLIAMENT AND OF THE COUNCIL on medicinal products for paediatric use
PDCO	Paediatric Committee
PIP	Paediatric investigation plan
PUMA	Paediatric use marketing authorisation
SA	CHMP scientific advice
SAWP	Scientific Advice Working Party
SPC	Supplementary protection certificate
VKC	Vernal keratoconjunctivitis

1. Introduction

1.1. Scope of the report

REGULATION (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use (Paediatric Regulation) entered into force on 26 January 2007.

Article 50(1) states:

"*On the basis of a report from the Agency, and at least on an annual basis, the Commission shall make public a list of the companies and of the products that have benefited from any of the rewards and incentives in this Regulation and the companies that have failed to comply with any of the obligations in this Regulation. The Member States shall provide this information to the Agency.*"

This report covers year 2020 and lists the companies benefiting from and infringing the regulation.

1.2. Data collection and methodology

In January 2021 the Agency contacted the national patent offices (NPO) of each Member State (MS) with regard to the medicinal products that had obtained a six-month extension of the supplementary protection certificate (SPC) in 2020.

The Agency received contributions from the following Member State NPOs: Austria, Belgium, Bulgaria, the Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom[2].

In February 2021, companies identified as potentially infringing the Paediatric Regulation in 2020 with regard to non-completion of a paediatric investigation plan (PIP) by the agreed date and non-submission of an annual report on deferred measures by the due date, were given an opportunity to provide comments on the finding before publication of the identified infringement. All information received by 12 March 2021 was considered for finalisation of this report.

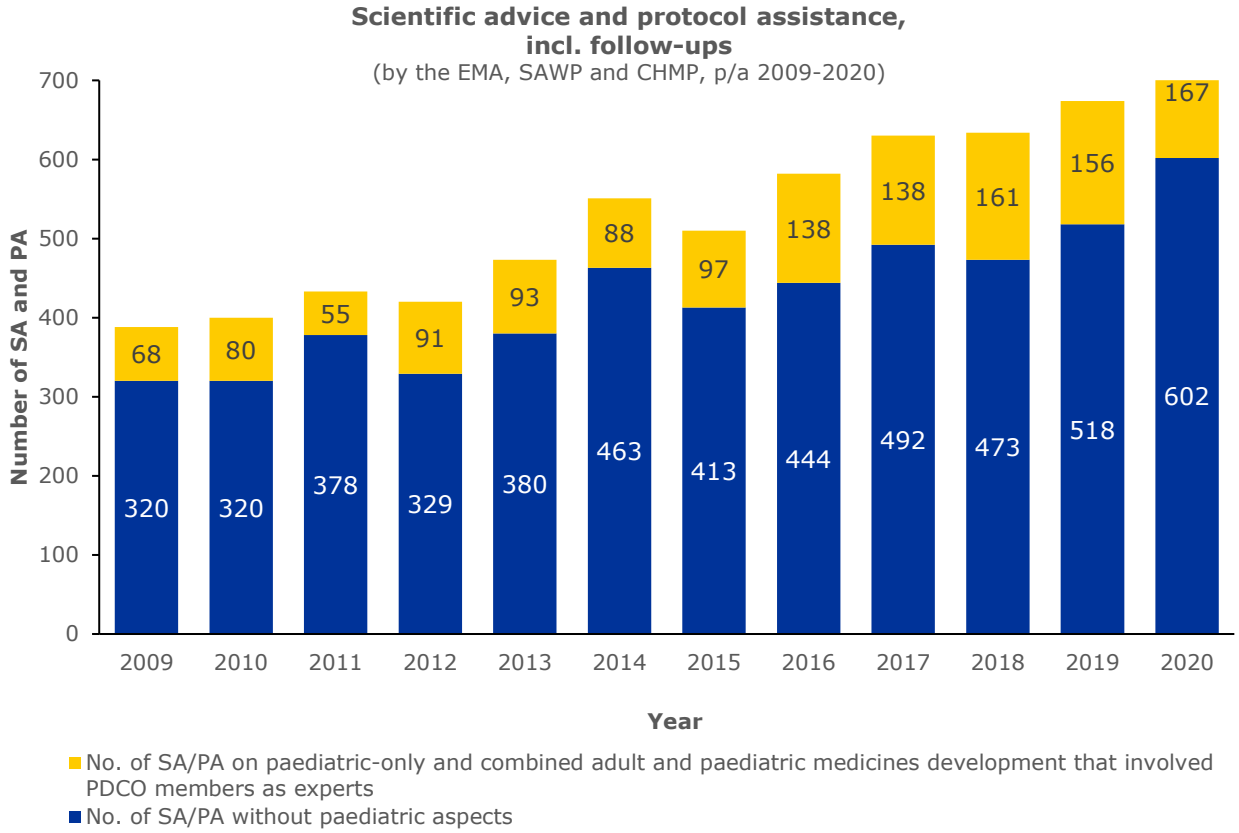
[2] Data from the United Kingdom (UK) are included in this report as EU Law continued to apply in the UK until 31 December 2020.

2. Companies and products that have benefited from the rewards and incentives in the regulation

2.1. Scientific advice or protocol assistance from the EMA

In accordance with Article 26 of the Paediatric Regulation, the Agency provides free scientific advice (SA) or protocol assistance (PA) on any question related to paediatric development of a medicinal product. The advice is prepared by the Scientific Advice Working Party (SAWP) and is adopted by the Committee for Medicinal Products for Human Use (CHMP). For the requests on paediatric development, members of the Paediatric Committee (PDCO) routinely contribute as experts to the provision of scientific advice through the SA/PA procedures (Figure 1).

The number of SA/PA procedures including paediatric questions (paediatric only advice and advice concerning adult and paediatric medicines development) has generally been increasing since the implementation of the Paediatric Regulation. In 2020, 22% of the requests for SA or PA were of paediatric relevance remaining at a similar level as in the previous year. PDCO members are involved in procedures relating to paediatric development as well as in procedures that do not directly include paediatric questions but where paediatric development could be affected.



Source EMA databases. *from 2017: includes also parallel consultation with regulators and health technology assessment

Figure 1 Scientific advice and protocol assistance, incl. follow-ups (by the EMA, SAWP and CHMP, p/a 2009-2020)

2.2. Rewards

2.2.1. Extensions of the supplementary protection certificate

Extensions of the supplementary protection certificate (SPC) are granted by National Patent Offices (NPO) therefore the data provided in this report relies on the information provided by these offices. This report provides data only for SPC extensions that have been granted, unlike in years prior to 2015 when pending SPC extensions were also reported. Furthermore, products may be mentioned in annual reports of several years because SPC expiration (and therefore extension) may not be simultaneous in all EU countries, and hence a product may obtain SPC extension in different years in the various countries. In 2020, 29 active substances benefited from the six-month extension (see Table 1).

Table 1 - List of companies / products receiving six-month SPC extension in 2020

Company / SPC holder	**INN**	**SPC extension granted in 2020**
Amgen Fremont Inc. (CY, FI, DE, GR, IE, IT, NL, PL, PT, SE); Amgen Inc. (CY, FI, DE, GR, IE, PL, PT, SE); Amgen Europe B.V. (ES); Immunex (NL, PT)	denosumab	Cyprus Finland Germany Greece Ireland Italy Netherlands Poland Portugal Spain Sweden
Bayer Healthcare LLC; Bayer AG (ES)	damoctocog alfa pegol	Austria Czech Republic Cyprus Estonia Greece Ireland Latvia Spain Sweden
Bioverativ Therapeutics Inc.; Biogen Idec Limited (ES); Biogen Hemophilia Inc (SE)	efmoroctocog alfa	Estonia Finland Ireland Italy Latvia Netherlands Portugal Slovakia Slovenia Spain Sweden
Bristol-Myers Squibb Holding Unlimited Company	dasatinib	Czech Republic

Company / SPC holder	INN	SPC extension granted in 2020
Chiesi Farmaceutici S.p.A.	beclomethazone / formoterol	Belgium Romania
E. R. Squibb & Sons	ipilimumab	Romania Slovakia
Genentech; Novartis Europharm Limited (ES)	ranibizumab	Austria Belgium Finland France Greece Ireland Italy Latvia Netherlands Spain Sweden
Gilead Sciences	cobicistat	Czech Republic Slovakia
Gilead Pharmasset LLC	ledipasvir	Portugal
GlaxoSmithKline	mepolizumab	Finland
Human Genome Sciences Inc.; GlaxoSmithKline (ES)	belimumab	Austria Belgium Cyprus Denmark Finland France Greece Ireland Italy Netherlands Portugal Spain Sweden

Company / SPC holder	INN	SPC extension granted in 2020
Janssen Biotech; Janssen-Cilag International NV (ES); Centocor Ortho Biotech INC (RO)	ustekinumab	Austria Denmark Finland Hungary Ireland Italy Latvia Lithuania Netherlands Portugal Romania Slovenia Spain Sweden
Merck Sharp & Dohme; Medimmune (BE); Sanofi Pasteur MSD (ES)	human papillomavirus vaccine [types 6, 11, 16, 18]	Belgium Greece Italy Lithuania Romania Spain
Merck Sharp & Dohme	human papillomavirus [Type 6, 16]	Germany
Merck Sharp & Dohme	human papillomavirus [Type 16]	Germany
Merck Sharp & Dohme	human-papillomavirus [Type 18]	Germany Greece
Merck Sharp & Dohme	fidaxomicin	Czech Republic Cyprus Denmark Estonia Ireland Italy Netherlands Portugal Slovenia United Kingdom

Company / SPC holder	INN	SPC extension granted in 2020
Merck Sharp & Dohme; Merck & Co., INC. (PL, UK)	sitagliptin	Czech Republic Denmark Estonia Finland Germany Ireland Latvia Luxembourg Netherlands Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom
MSD Italia S.r.l.; Merck Sharp & Dohme Limited (ES)	raltegravir	Bulgaria Czech Republic Denmark Estonia Finland Germany Hungary Ireland Italy Latvia Lithuania Netherlands Portugal Romania Slovakia Slovenia Spain Sweden
Novartis	canakinumab	Czech Republic United Kingdom
Novartis	deferasirox	Belgium Finland Germany Slovakia United Kingdom

Company / SPC holder	INN	SPC extension granted in 2020
Novartis; Novartis Europharm Limited (ES)	eltrombopag	Austria Belgium Bulgaria Cyprus Estonia France Germany Greece Hungary Ireland Italy Lithuania Netherlands Poland Romania Slovakia Spain Sweden United Kingdom
Novo Nordisk A/S	liraglutide	Czech Republic France Greece Italy Netherlands Poland Spain Sweden
Pharmacia & Upjohn Company LLC; Sugen, Inc.	sunitinib	Belgium Bulgaria Greece Romania Slovakia
Pharming Intellectual Property	conestat alfa	Netherlands
Phivco-1 LLC	maraviroc	Austria Czech Republic Denmark Ireland Italy Latvia Lithuania Netherlands Portugal Slovenia

Company / SPC holder	INN	SPC extension granted in 2020
Research Corporation Technologies, Inc.; UCB Pharma S.A. (ES)	lacosamide	Denmark Finland Ireland Italy Netherlands Portugal Spain Sweden United Kingdom
Shire International GmbH; Shire Pharmaceuticals Ireland Ltd (ES); Shire-Movetis N.V. (UK)	prucalopride	Finland France Germany Ireland Italy Netherlands Latvia Portugal Romania Slovakia Spain United Kingdom
Takeda Pharmaceutical Company Limited	ceftaroline fosamil	Austria Cyprus Denmark Ireland Italy Netherlands Portugal Sweden

Source: NPO survey 2021

2.2.2. Orphan market exclusivity extension

In 2020, two orphan medicinal product benefited from a two-year extension of their respective market exclusivity:

- Dacogen (decitabine) for the treatment of acute myeloid leukaemia in children from 28 days to less than 18 years of age;
- Cablivi (nanobody directed towards the human A1 domain of von Willebrand factor) for the treatment of thrombotic thrombocytopenic purpura.

2.3. Paediatric use marketing authorisation

No paediatric use marketing authorisation (PUMA) was granted in 2020.

2.4. Placing on the market

The "Register of deadlines to put a medicinal product on the market" (Article 33 of the Paediatric Regulation) lists the two-year timelines by which marketing authorisation holders (MAHs) have to place their medicinal products on the market following completion of an agreed PIP and obtaining a paediatric indication. The register includes information on the fulfilment of this requirement provided by NCAs and MAHs.

3. Failure to comply with the obligations set out in the Paediatric Regulation

3.1. Submission of PIP and waiver applications to the PDCO

Article 16 of the Paediatric Regulation requires pharmaceutical companies to submit applications for a PIP and a waiver no later than upon completion of the human pharmacokinetic (PK) studies in adults specified in Section 5.2.3 of Part I of Annex I to Directive 2001/83/EC, except when duly justified.

Late submissions are being reported since 2010 (Table 2) for applications with a delay greater than six months. From 2014 only those considered by the PDCO as not justified are being reported.

Table 2 – Number of procedures with a time lag six months or longer between completion of adult PK studies and submission of PIP or waiver application

Procedure type	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
PIPs (% of total granted)	65 (74%)	44 (59%)	34 (39%)	18 (20%)	12 (13%)	7 (10%)	20 (23%)	24 (28%)	9 (16%)	26 (25%)	38 (26%)
Full waivers (% of total granted)	26 (59%)	13 (42%)	11 (23%)	6 (11%)	4 (8%)	4 (8%)	14 (27%)	14 (16%)	9 (20%)	25 (25%)	26 (24%)

Source: EMA Paediatric database

In 2020, a total of 148 PIPs received a positive opinion and 107 full product-specific waivers were granted by the PDCO.

The list of unjustified late submissions of PIPs is presented in Annex I.

3.2. Completion of PIPs

The EMA decisions on PDCO opinions contain the expected date of PIP completion.

For the analysis of timely completion, the PIPs with an expected completion date until 30 June 2020 were reviewed. This cut-off date was chosen to account for the fact that applicants must submit the completed study reports within six months of completion (Art. 46) and studies (and PIPs) completed after June 2020 may not have yet been subjected to a final compliance check.

In total, 453 PIPs were scheduled to finish by 30 June 2020 of those, 360 (79%) were completed; of the remaining 93 that have not been completed, 35 did not provide a valid justification (e.g. a modification to amend the date of completion is pending/ongoing or development has been discontinued). The detailed list is provided in Annex II.

3.3. Annual reports on deferrals

According to Article 34.4 of the Paediatric Regulation, MAHs should submit an annual report to the Agency providing an update on progress of deferred paediatric studies in accordance with the EMA decision agreeing the PIP and granting a deferral. In 2020 the EMA received 253 annual reports on deferred measures. All MAHs submitted their annual report on deferred measures due in 2020.

The list of companies that did not submit one or more annual reports since 2011 is included in Table 3.

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Table 3 - List of companies not submitting annual reports on deferred measures in due time

Company	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Aastrom Biosciences DK Aps					1					
Actelion Registration Ltd						1	1			
Aegerion Pharmaceuticals						1	1			
AMAG Pharmaceuticals, Inc.					1		1	1		
Amgen Europe B.V.			1							
APEIRON Biologics AG								1		
Clinigen Healthcare Ltd						1				
Clinuvel (UK) Limited					1					
Eisai Ltd.	1					1				
Forest Laboratories Limited				1	1					
Genzyme Europe B.V.	1									
GlaxoSmithKline	1									
Ipsen Pharma								1		
Janssen-Cilag International N.V.	1				1					
Kowa Pharmaceutical Europe Company Ltd	1	1	4							
Merck Sharp & Dohme (Europe) Inc.	2	1	2							
Novartis (Europharm Limited, Vaccines and diagnostics)		2	1							

Company	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Novo Nordisk A/S	1	1	2							
N.V. Organon						1				
Nycomed Danmark ApS						1				
Omrix Biopharmaceuticals SA			1		1					
Pfizer Limited	2									
Pharmaxis Pharmaceuticals Limited					1					
Roche Registration Limited	1	1	1		1					
Seqirus S.r.l.						1				
Sigma-Tau SpA		1	1		1					
Takeda Global Research and Dev. Centre (Europe) Ltd		1			1					
Teva Pharma GmbH						1				
Theravance, Inc.		1	1							
Total p/a:	11	9	14	1	11	8	3	3	0	0

Source: EMA database (PedRA)

Annex I. List of non-justified late submissions of applications for PIPs or waivers

This list includes only applications for which a decision on a PIP or a waiver was adopted by the European Medicines Agency in 2020.

The number of months of delay is calculated from the date of the completion of PK studies in adults as declared by the applicant in the application for a PIP or a product-specific waiver request.

The below table shows the agreed PIPs or waivers submitted in 2020 with a significant delay for which none or unacceptable (by the PDCO) justification was provided. The timing of submission should not be later than the end of healthy subject or patient PK, which can coincide with the initial tolerability studies, or the initiation of the adult phase II studies (proof-of-concept studies). In cases where a phase II study in adults is already completed by the time of the PIP submission, the submission is in principle considered delayed unless justified. Further information on the timing of a PIP application can be found on the EMA website (Q 1.1).

Company	**Substance** (INN as applicable)	**Application type**
Abeona Therapeutics Inc.	rebisufligene etisparvovec	PIP
Adamed Pharma S.A.	sitagliptin (hydrochloride monohydrate) / metformin (hydrochloride)	Waiver
AlgiPharma AS	Sodium alginate oligosaccharide	PIP
Amicus Therapeutics Europe Limited	Recombinant human acid alpha-glucosidase	PIP
Amivas Ireland Ltd	artesunate	PIP
Aptys Pharmaceuticals	nefopam (hydrochloride) / paracetamol	Waiver
Arena Pharmaceuticals, Inc.	etrasimod L-arginine	PIP
argenx BVBA	efgartigimod alfa	PIP
ARS Pharmaceuticals IRL, Limited	adrenaline	PIP
Arvelle Therapeutics Netherlands B.V.	cenobamate	PIP
Ascendis Pharma Endocrinology Division A/S	lonapegsomatropin	PIP
AstraZeneca AB	monalizumab	Waiver

Company	**Substance** (INN as applicable)	**Application type**
Atara Biotherapeutics, Inc.	tabelecleucel	PIP
Auris Medical Ltd.	betahistine (dihydrochloride)	Waiver
Baxalta Innovations GmbH	Alpha1-Proteinase Inhibitor (Human)	Waiver
Bayer AG	BAY 1747846	PIP
BioCryst UK	berotralstat	PIP
Biogen Netherlands B.V.	diroximel fumarate	PIP
Biohaven Pharmaceuticals, Inc.	rimepegant	PIP
Boehringer Ingelheim International GmbH	BI 425809	PIP
CambPharma Solutions (CY) Ltd	ublituximab	Waiver
CambPharma Solutions (CY) Ltd	umbralisib (tosylate)	Waiver
Cellectar Biosciences, Inc.	18-(p-[131I]-iodophenyl)octadecyl phosphocholine	Waiver
CUTISS AG	Bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts	PIP
Cytokinetics, Inc.	reldesemtiv	Waiver
Disphar International B.V.	colchicine	Waiver
Drug Development and Regulation SL	Tauroursodeoxycholic acid / sodium phenylbutyrate	Waiver
Eli Lilly and Company Limited	baricitinib	PIP
Entasis Therapeutic Inc.	zoliflodacin	PIP
ERC Belgium	Allogeneic haptenised and irradiated cell lysates derived from glioma	PIP
ERC Belgium	Allogeneic haptenised and irradiated cells derived from glioma	PIP
ERC Belgium	Autologous haptenised and irradiated cell lysates derived from glioma	PIP
ERC Belgium	Autologous haptenised and irradiated cells derived from glioma	PIP
EryDel S.p.A	dexamethasone (sodium phosphate) encapsulated in human autologous erthrocytes	PIP

Company	**Substance** (INN as applicable)	**Application type**
Gamida Cell Ltd	Allogeneic,ex vivo expanded,umbilical cord blood-derived,haematopoietic CD34+progenitor cells (CF) / Allogeneic,non-expanded,umbilical cord blood-derived,haematopoietic mature myeloid and lymphoid cells (NF)	PIP
Generon (Shanghai) Corporation	Recombinant human granulocyte colony-stimulating factor – human immunoglobulin Fc fusion protein (rhG-CSF-Fc)	PIP
Genfit SA	elafibranor	Waiver
Gilead Sciences International Ltd.	cilofexor	PIP
GlaxoSmithKline Trading Services Limited	gepotidacin	PIP
GlaxoSmithKline Trading Services Limited	gepotidacin	PIP
Helsinn Birex Pharmaceuticals limited	pracinostat	PIP
Immunomedics GmbH	sacituzumab govitecan	Waiver
Immutep SAS	eftilagimod alpha	Waiver
Incyte Biosciences Distribution B.V.	parsaclisib	Waiver
Isofol Medical AB	arfolitixorin	Waiver
Merck Sharp & Dohme (Europe), Inc.	Fully human IgG1 RB-1 YTE anti-RSV F monoclonal antibody	PIP
Merck, Sharp & Dohme (Europe) Inc	3-(((1S,2S,3R)-2,3-difluoro-1-hydroxy-7-(methylsulfonyl)-2,3-dihydro-1H-inden-4-yl)oxy)-5-fluorobenzonitrile	Waiver
Millendo Therapeutics SAS	livoletide	PIP
Neuroderm Ltd	levodopa/carbidopa	Waiver
Nightstar Europa Limited	timrepigene emparvovec	PIP
Pfizer Europe MA EEIG	sasanlimab	Waiver
Pharma Mar, S.A.	lurbinectedin	Waiver
Real Regulatory Limited	Chimeric fibril-reactive IgG1k monoclonal antibody 11-1F4	Waiver

Company	**Substance** (INN as applicable)	**Application type**
Roche Registration GmbH	rAAVrh74.MHCK7.microdystrophin	PIP
Rocket Pharmaceuticals, Inc.	Autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding for the human Beta 2 Integrin/CD18 gene	PIP
Rocket Pharmaceuticals, Inc.	CD34+enriched cells from patients with Fanconi anaemia subtype A (FA-A) transduced ex vivo with lentiviral vector carrying the FANCA gene, PGKFANCA-WPRE	PIP
Sanifit Therapeutics S.A.	(1R,2R,3S,4S,5R,6S)-cyclohexane-1,2,3,4,5,6-hexayl-hexakis (dihydrogen phosphate)	Waiver
Scynexis, Inc.	ibrexafungerp	PIP
Sesen Bio, Inc	oportuzumab monatox	Waiver
Shanghai Henlius Biotech, Inc.	serplulimab	Waiver
SIGA Technologies, Inc.	tecovirimat monohydrate	PIP
Takeda Pharma A/S	Propan-2-yl 2-[5-(acryloylamino)-4-{[2-(dimethylamino)ethyl] (methyl)amino}-2-methoxyanilino]-4-(1methyl-1 H-indol-3-yl)pyrimidine-5-carboxylate	Waiver
Theravance Biopharma Ireland Limited	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	PIP
Vertanical GmbH	5%-Δ9-Tetrahydrocannabinol standardised cannabis extract	Waiver
Viela Bio Inc	CD40-ligand antagonist comprising two identical Tn3 modules fused to human serum albumin, with each Tn3 module being an engineered form of the third fibronectin type III protein domain of human Tenascin C	Waiver

Source: EMA database PedRA

Annex II. List of PIPs not completed by the agreed date until 30 June 2020

It should be noted that this list does not specify if the development of the medicinal product has been discontinued or not, as the EMA may not have been informed by the company accordingly.

For the purpose of this analysis, a PIP is considered completed if the PDCO adopted a positive final compliance opinion.

Procedure number	**Substance**	**Invented Name**	**Company**
EMEA-002402-PIP02-18	artesunate	Malacef	ACE Pharmaceuticals BV
EMEA-000488-PIP02-11	rubidium-82	Cardiogen-82	Advanced Accelerator Applications
EMEA-001134-PIP01-11	Chimeric monoclonal anti-shiga toxin (Stx) antibodies Cαstx1 and Cαstx2	Shigamabs	Albany Regulatory Consulting Limited
EMEA-000337-PIP01-08	Grass pollen preparation	N/A	Allergopharma J. Ganzer KG
EMEA-000284-PIP01-08-M04	Modified Grass pollen extract	N/A	Allergy Therapeutics (UK) Limited
EMEA-001324-PIP01-12-M01	glibenclamide	Glibentek	Ammtek
EMEA-001314-PIP01-12	dinutuximab beta / chimeric anti-disialoganglioside (GD2) Monoclonal Antibody (Ch14.18/CHO)	N/A	Apeiron Biologics Ag
EMEA-000988-PIP01-10	ciclosporin	N/A	APT Pharmaceuticals Inc
EMEA-000661-PIP01-09-M07	trenonacog alfa (coagulation factor IX, recombinant)	IXINITY	Aptevo Europe Limited
EMEA-000753-PIP02-16	susoctocog alfa	Obizur	Baxalta Innovations GmbH
EMEA-000288-PIP01-08-M02	moxifloxacin	Avalox, Avelox, Havelox, Izilox, Octegra, Proflox, Actimax and Actira.	Bayer Schering Pharma
EMEA-000973-PIP01-10-M03	Recombinant human N-acetylgalactosamine-6-sulfatase	Vimizim (Elosulfase Alfa)	Biomarin Europe Limited
EMEA-001369-PIP01-12	2'-O-methyl-uridylyl-(3'→5'O,O-	N/A	Biomarin International Limited

Procedure number	Substance	Invented Name	Company
	phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-		

Procedure number	Substance	Invented Name	Company
	phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-cytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2’-O-methyl-guanosine sodium salt		
EMEA-001374-PIP01-12	2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-5-methylcytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-5-	N/A	BioMarin International Limited

Procedure number	Substance	Invented Name	Company
	methylcytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-5-methylcytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-5-methylcytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-5-methylcytidylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-adenosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-		

Procedure number	Substance	Invented Name	Company
	methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-guanosylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-uridylyl-(3'→5'O,O-phosphorothioyl)-2'-O-methyl-5-methylcytidylyl sodium salt		
EMEA-001267-PIP01-12	[N-{4-Chloro-2-[(1-oxido-4-pyridinyl)carbonyl]phenyl}-4-(1,1-dimethylethyl) benzenesulfonamide, sodium salt	N/A	ChemoCentryx, Inc.
EMEA-001352-PIP01-12-M01	metformin	N/A	Effrx Pharmaceuticals Sa
EMEA-001513-PIP01-13	estetrol / levonorgestrel	N/A	Estetra S.A.
EMEA-000651-PIP01-09-M02	cholic acid	N/A	Fgk Representative Service GmbH
EMEA-000736-PIP01-09	Culture expanded autologous chondrocytes	Hyalograft C autograft	Fidia Advanced Biopolymers S.r.l.
EMEA-000786-PIP01-09-M02	Autologous CD34+ cells transduced with lentiviral vector containing the human Wiskott Aldrich Syndrom Protein gene	N/A	Genethon
EMEA-000969-PIP01-10-M05	cobicistat	Tybost	Gilead Sciences International Ltd.

Procedure number	Substance	Invented Name	Company
EMEA-001359-PIP01-12-M03	retosiban	N/A	GlaxoSmithKline Trading Services Limited
EMEA-000532-PIP01-09	sodium bituminosulphonate / clindamycin phosphate	Ichthoseptal N	Ichthyol -Gesellschaft Cordes, Hermanni & Co. (GmbH & Co.) Kg
EMEA-000360-PIP01-08	carisbamate	Comfyde	Janssen Cilag NV International
EMEA-000044-PIP01-07	Tgplpth1-34	N/A	Kuros Biosurgery International Ag
EMEA-001016-PIP01-10	Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis	N/A	Lofarma S.P.A.
EMEA-000550-PIP02-10-M01	cilengitide	N/A	Merck KGaA
EMEA-001310-PIP01-12-M03	gabapentin	N/A	Pharm Srl
EMEA-001627-PIP01-14	efinaconazole	N/A	PharmaSwiss Česká republika
EMEA-000436-PIP01-08	mannitol	Bronchitol	Pharmaxis Pharmaceuticals Limited
EMEA-001634-PIP01-14	Recombinant human heparan N-sulfatase	N/A	Shire Human Genetic Therapies AB
EMEA-000976-PIP01-10	Grass pollen allergen extract from Cocksfoot (Dactylis glomerata L.)/ Sweet vernal grass (Anthoxanthum odoratum L.)/ Rye grass (Lolium perenne L.)/ Meadow grass (Poa pratensis L.)/ Timothy (Phleum pratense L.)	Staloral 5 Grasses	Stallergenes S.A.

Procedure number	Substance	Invented Name	Company
EMEA-001354-PIP01-12	2,6-Bis-{(1-napthalenyl-3,6-disulfonic acid)-oxyacetamido}-2,6-bis-2,6-bis-2,6-bis-(2,6-diamino-hexanoylamino)-2,6-diamino-hexanoic acid (diphenylmethyl)-amide, polysodium salt	Vivagel	Starpharma Pty Ltd
EMEA-001568-PIP03-14	ceftriaxone / sulbactam	Elores	Venus Pharma GmbH
EMEA-000487-PIP01-08	bromocriptine	Cycloset	Veroscience Eu Ltd