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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 2021

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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

CHMP	Committee for Medicinal Products for Human Use
EC	European Commission
EMA, the Agency	European Medicines Agency
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

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 2021 and lists the companies benefiting from and infringing the regulation.

1.2. Data collection and methodology

In December 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 2021.

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 and Sweden.

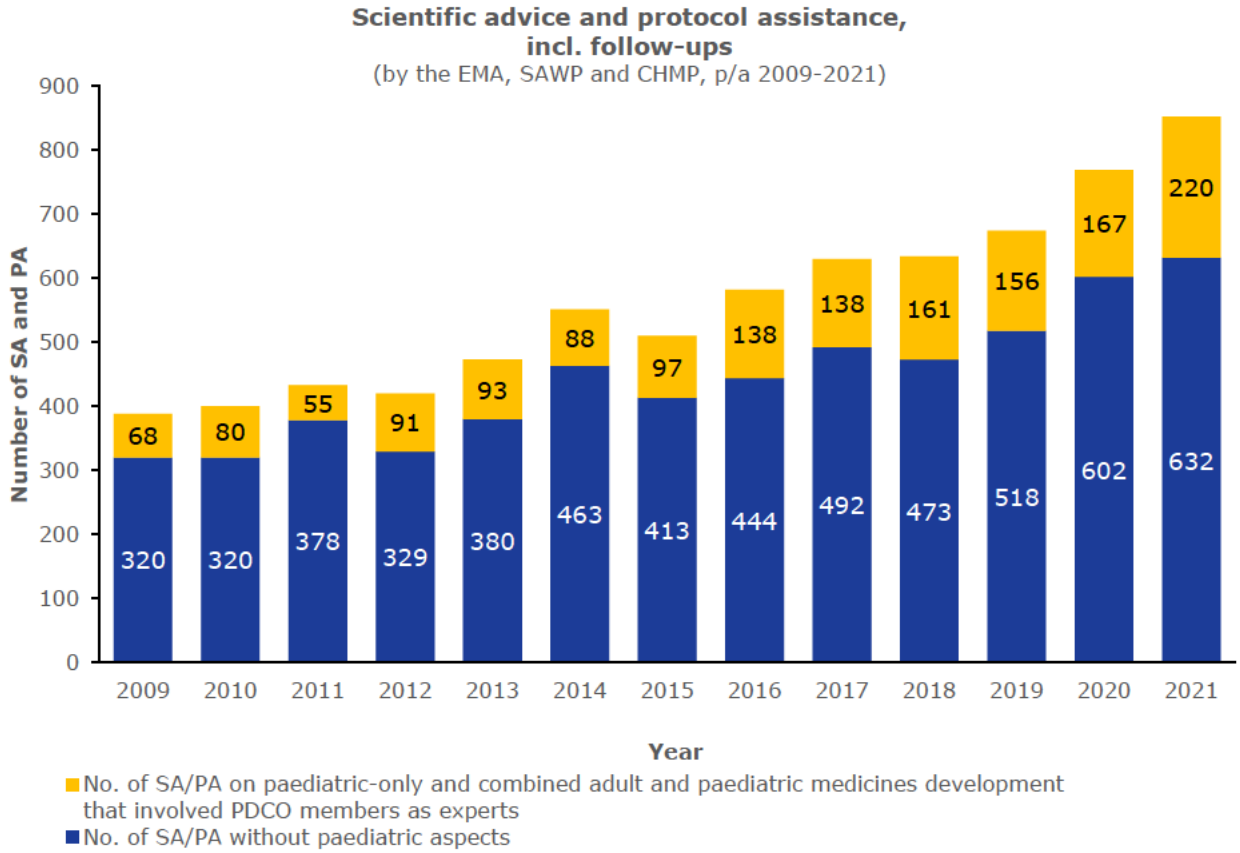
In February 2022, companies identified as potentially infringing the Paediatric Regulation in 2021 with regard to non-completion of a paediatric investigation plan (PIP) by the agreed date and non-submission of an annual report on deferred measures by the due date, were given an opportunity to provide comments on the finding before publication of the identified infringement. All information received by 04 April 2022 was considered for finalisation of this report.

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 2021, 26% of the requests for SA or PA were of paediatric relevance, with an observed increase comparing to 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 2009-2021)

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 2021, 39 active substances including fixed-dosed combinations (FDC) benefited from the six-month extension (see Table 1).

Table 1 - List of companies / products receiving six-month SPC extension in 2021

Company / SPC holder	**Substance (INN as applicable)**	**SPC extension granted in 2021**
AbbVie Bahamas Ltd., Nassau (BS)	pibrentasvir	Austria Italy Latvia Lithuania Malta Netherlands Portugal Slovenia Sweden
Amgen Fremont Inc. (FR, LU); Amgen Inc. (FR, LV, LU, SI, RO); Amgen Europe B.V. (ES); Immunex Coorporation (BE, FI, GR, IT, IE, LU, SE)	denosumab	Belgium Finland France Greece Ireland Italy Latvia Luxembourg Romania Slovenia Spain Sweden
AstraZeneca AB	rosuvastatin (calcium)	Malta
Bayer Healthcare LLC;	damoctocog alfa pegol	Bulgaria France Lithuania Romania

Company / SPC holder	Substance (INN as applicable)	SPC extension granted in 2021
Bayer Intellectual Property GmbH	rivaroxaban	Bulgaria Czech Republic Denmark Estonia Finland Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Netherlands Portugal Slovenia Sweden
Bioverativ Therapeutics Inc.	efmoroctocog alfa	Austria Bulgaria Cyprus Czech Republic France Germany Greece Lithuania Luxembourg Romania

Company / SPC holder	Substance (INN as applicable)	SPC extension granted in 2021
Boehringer Ingelheim Pharma GmbH & Co. KG	dabigatran etexilate	Austria Belgium Czech Republic Denmark Estonia Finland France Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Netherlands Portugal Romania Slovakia Slovenia Spain Sweden
Chiesi Farmaceutici S.p.A.	beclomethazone / formoterol	Greece Lithuania Luxembourg Portugal
E. R. Squibb & Sons, L.L.C.	ipilimumab	Czech Republic Hungary
Enanta Pharmaceuticals, Inc.	glecaprevir	Italy Latvia Lithuania Malta Netherlands Portugal Slovakia Slovenia Sweden
Genentech, Inc.	ranibizumab	Germany Luxembourg Romania

Company / SPC holder	Substance (INN as applicable)	SPC extension granted in 2021
Gilead Pharmasset LLC; Gilead Science Ireland (ES).	ledipasvir	Austria Czech Republic Estonia Finland France Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Malta Netherlands Slovakia Slovenia Spain Sweden
Gilead Pharmasset LLC; Gilead Science International LTD (MT).	sofosbuvir	Austria Cyprus Estonia Hungary Italy Latvia Lithuania Malta Netherlands Portugal Slovenia Sweden
Gilead Pharmasset LLC	ledipasvir / sofosbuvir	Cyprus Germany
GlaxoSmithKline, L.L.C.	mepolizumab	Slovakia
Human Genome Sciences Inc.	belimumab	Germany Luxembourg

Company / SPC holder	Substance (INN as applicable)	SPC extension granted in 2021
Janssen Pharmaceutica N.V.; Janssen Cilag International NV (ES).	etravirine	Bulgaria Czech Republic Cyprus Finland Germany Greece Hungary Ireland Italy Latvia Lithuania Netherlands Poland Romania Slovakia Slovenia Spain Sweden
Janssen Biotech, Inc.	golimumab	Germany
Janssen Biotech, Inc.	ustekinumab	Cyprus France Greece Luxembourg
Merck Sharp & Dohme Corp.	human papillomavirus vaccine [types 6, 11, 16, 18]	Cyprus France Luxembourg
Merck Sharp & Dohme Corp.	humanpapillomavirus vaccine [Type 18]	France
Merck Sharp & Dohme Corp.; Astellas Pharma Europe B.V. (ES)	fidaxomicin	Bulgaria Finland France Germany Greece Hungary Luxembourg Slovakia Spain Sweden

Company / SPC holder	Substance (INN as applicable)	SPC extension granted in 2021
Merck Sharp & Dohme.	sitagliptin	Austria Belgium Bulgaria Cyprus France Greece Hungary Lithuania
Merck Sharp & Dohme BV	pembrolizumab	Italy Portugal Slovenia
MSD Italia S.r.l.	raltegravir	Austria Belgium France Greece Luxembourg
Novartis AG	canakinumab	Germany Hungary
Novartis AG	eltrombopag	Luxembourg
Novartis AG	pazopanib	Netherlands
Novo Nordisk A/S	liraglutide	Belgium Hungary
N.V. Organon	corifollitropin alfa	Belgium
Pharmacia & Upjohn Company LLC; Sugen, Inc.	sunitinib	Austria
Pharming Intellectual Property	conestat alfa	Austria Finland France Greece Ireland Italy Portugal Spain Sweden

Company / SPC holder	Substance (INN as applicable)	SPC extension granted in 2021
Phivco-1 LLC; ViiV Healthcare UK Limited (ES)	maraviroc	Belgium Bulgaria Estonia Finland France Germany Greece Hungary Luxembourg Poland Romania Spain Sweden
Research Corporation Technologies, Inc.	lacosamide	Austria Belgium France
Royalty Pharma Collection Trust, US.	alogliptin	Romania
Royalty Pharma Collection Trust, US.	linagliptin	Romania
Royalty Pharma Collection Trust, US.	saxagliptin	Romania
Takeda Pharmaceutical Company Limited; Pfizer Ireland Pharmaceuticals (ES)	ceftaroline fosamil	Finland France Germany Greece Luxembourg Spain
Theramex HQ UK Ltd.	nomegestrol acetate / estradiol	Belgium Germany

Source: NPO survey 2022

2.2.2. Orphan market exclusivity extension

No orphan medicinal products benefited from a two-year extension of their respective market exclusivity in 2021.

2.3. Paediatric use marketing authorisation

No paediatric use marketing authorisation (PUMA) was granted in 2021.

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 until the end of 2021.

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	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
PIPs (% of total granted)	44 (59%)	34 (39%)	18 (20%)	12 (13%)	7 (10%)	20 (23%)	24 (28%)	9 (16%)	26 (25%)	38 (26%)	31 (22%)
Full waivers (% of total granted)	13 (42%)	11 (23%)	6 (11%)	4 (8%)	4 (8%)	14 (27%)	14 (16%)	9 (20%)	25 (25%)	26 (24%)	23 (20%)

Source: EMA Paediatric database

In 2021, a total of 140 PIPs received a positive opinion and 113 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 2021 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 2021 may not have yet been subjected to a final compliance check.

In total, 512 PIPs were scheduled to finish by 30 June 2021 of those, 268 (52.3%) were completed; of the remaining 244 that have not been completed, 122 were discontinued or a full waiver was granted in subsequent modification. For 24 PIPs a valid justification for the delayed completion has not been provided or found (e.g. a modification to amend the date of completion is pending/ongoing or development has been discontinued), these are listed 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 2021 the EMA received 267 annual reports on deferred measures. All MAHs submitted their annual report on deferred measures due in 2021.

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

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	2021
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								
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						

Company	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
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	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 2021.

The below table shows the agreed PIPs or waivers submitted in 2021 with a significant delay of at least 6 months 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.

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

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**
1A Pharma GmbH	amlodipine (besilate) / ramipril	Waiver
ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH	fluoride 18-labelled prostate-specific membrane antigen-1007 ([18F]PSMA-1007)	Waiver
Acceleron Pharma	sotatercept	PIP
ADC Therapeutics SA	loncastuximab tesirine	PIP
Alector, Inc.	immunoglobulin G1 anti-SORT1 human monoclonal antibody	Waiver
Allakos Inc	recombinant monoclonal antibody to sialic acid-binding Ig-like lectin 8 (AK002)	PIP
Alexion Europe SAS	ravulizumab	Waiver
Amgen Europe B.V.	human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (KHK4083)	PIP
Aravive, Inc	batiraxcept	Waiver
Ascendis Pharma Bone Diseases A/S	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) (TransCon PTH)	PIP

Company	**Substance** (INN as applicable)	**Application type**
AstraZeneca AB	savolitinib	Waiver
Biohaven Pharmaceuticals, Inc.	rimegepant	PIP
CambPharma Solutions (CY) Ltd	ublituximab	PIP
Chemo Research	ethinylestradiol / dienogest	PIP
CStone Pharmaceuticals (Suzhou) CO., Ltd.	humanised recombinant IgG4, Anti-PD-1 monoclonal antibody (CS1003)	Waiver
Dr. Franz Köhler Chemie GmbH	3,4-Dimethoxy-N-methylbenzohydroxamic acid / Deferoxamine mesylate / Alpha-ketoglutaric acid / Arginine / Alanine / Glycine / Aspartic acid / Tryptophan / N-acetyl-histidine (monohydrate) / Histidine / Calcium chloride (dihydrate) / Magnesium chloride (hexahydrate) / Potassium chloride / Sodium chloride	PIP
Eli Lilly and Company Limited	sintilimab	Waiver
Eli Lilly and Company Limited	etesevimab	PIP
Evofem, Inc.	potassium bitartrate / citric acid / L-lactic acid	PIP
FibroGen, Inc	pamrevlumab	Waiver
Geron Corporation	imetelstat	PIP
GlaxoSmithKline Biologicals SA	respiratory syncytial virus (RSV) preF3 recombinant fusion protein/AS01	PIP
Hutchison MediPharma Ltd	surufatinib	PIP
Idorsia Pharmaceuticals Deutschland GmbH	selatogrel	Waiver
Insmed Netherlands B.V.	brensocatib	PIP
Jazz Pharmaceuticals Ireland Ltd.	crisantaspase	PIP
Kamada Ireland Limited	human alpha1-proteinase inhibitor	Waiver
Karyopharm Europe GmbH	selinexor	Waiver

Company	**Substance** (INN as applicable)	**Application type**
Laboratório Edol - Produtos Farmacêuticos S.A.	ofloxacin / Dexamethasone (sodium phosphate)	Waiver
Les Laboratoires Servier (LLS)	vorasidenib (as hemicitrate, hemihydrate salt)	PIP
Lung Therapeutics, Inc.	single chain urokinase Plasminogen Activator (scuPA)	PIP
MeiraGTx UK II Ltd	linear single strand of deoxyribonucleic acid (encoding human retinitis pigmentosa GTPase regulator [RPGR]) packaged in a recombinant adeno-associated virus protein capsid of serotype 5 (AAV5-hRKp.RPGR)	PIP
Merck, Sharp & Dohme (Europe) Inc	vibostolimab / pembrolizumab	Waiver
NTC Srl	mannitol	Waiver
Orion Corporation	naproxen (sodium) / sumatriptan	Waiver
Parion Sciences, Inc.	sodium chloride solution 4.2% (P-1037 inhalation solution) / 3,5-diamino-6-chloro-N-(N-(4-(4-(2-(hexyl((2S,3R,4R,5R)-2,3,4,5,6-pentahydroxyhexyl)amino)ethoxy)phenyl)butyl)-carbamimidoyl)pyrazine-2-carboxamide	PIP
Pharmascience International Limited	colchicine	Waiver
Pharming Group N.V.	leniolisib	PIP
PhaseBio Pharmaceuticals Inc.	bentracimab	PIP
ProKidney	autologous selected renal cells	PIP
ProQR Therapeutics	sepofarsen	PIP
PTC Therapeutics International	vatiquinone	PIP
QED Therapeutics Inc.	infigratinib	PIP
Reata Pharmaceuticals Inc.	bardoxolone methyl	PIP
Roche Registration GmbH	gantenerumab	Waiver
Shionogi B.V.	sivopixant	Waiver

Company	**Substance** (INN as applicable)	**Application type**
Soligenix NL B.V	synthetic hypericin	Waiver
Swyssi AG	ramipril / amlodipine / hydrochlorothiazide	Waiver
Theravance Biopharma Ireland Limited	izencitinib	PIP
UCB Biopharma SRL	bimekizumab	PIP
United Therapeutics Corporation	ralinepag	PIP
Vascular Biogenics Ltd. (VBL Therapeutics)	ofranergene obadenovec	Waiver
Xcovery Holdings, Inc.	ensartinib	Waiver
Zealand Pharma A/S	glepaglutide	PIP

Source: EMA database PedRA

Annex II. List of PIPs not completed by the agreed date until 30 June 2021

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.

The following list includes all PIPs due to be completed by 30 June 2021 without sufficient justification for the delay.

Procedure number	**Substance**	**Invented Name**	**Company**
EMEA-002266-PIP01-17	recombinant human acid ceramidase	N/A	Aceragen Inc.
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-000814-PIP01-09	birch/alder/hazel pollen Extract	POLLINEX Quattro 1.0 mL Birch/Alder/Hazel	Allergy Therapeutics (UK) Ltd
EMEA-000988-PIP01-10	ciclosporin	N/A	APT Pharmaceuticals Inc
EMEA-000973-PIP01-10-M03	recombinant human N-acetylgalactosamine-6-sulfatase	Vimizim (Elosulfase Alfa)	Biomarin Europe Limited
EMEA-001369-PIP01-12	exon 45 specific phosphorothioate oligonucleotide	N/A	Biomarin International Limited
EMEA-001374-PIP01-12	exon 53 specific phosphorothioate oligonucleotide’	N/A	BioMarin International Limited

Procedure number	Substance	Invented Name	Company
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-000786-PIP01-09-M02	autologous CD34+ cells transduced with lentiviral vector containing the human Wiskott Aldrich Syndrom Protein gene	N/A	Genethon
EMEA-001175-PIP01-11-M04	albiglutide	Eperzan	Glaxo Group Limited
EMEA-000532-PIP01-09	sodium bituminosulphonate / clindamycin phosphate	Ichthoseptal N	Ichthyol -Gesellschaft Cordes, Hermanni & Co. (GmbH & Co.) Kg
EMEA-000093-PIP01-07-M01	sotrastaurin acetate	N/A	Novartis Europharm Limited
EMEA-001310-PIP01-12-M03	gabapentin	N/A	Pharm Srl
EMEA-000580-PIP01-09	dalcetrapib	N/A	Roche Registration Limited
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-000977-PIP01-10	house dust mites allergen extract from Dermatophagoides pteronyssinus and Dermatophagoides farinae (50/50)	STALORAL Mites	STALLERGENES S.A.
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