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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 2019

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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)

Table of contents

Table of figures and tables

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 2019 and lists the companies benefiting from and infringing the regulation.

1.2. Data collection and methodology

In November 2020 the Agency contacted the national patent offices (NPO) of each Member State (MS) with regards to the medicinal products that had obtained a six-month extension of the supplementary protection certificate (SPC) in 2019.

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.

In November 2020, companies identified as potentially infringing the Paediatric Regulation in 2019 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 3 December 2020 was considered for finalisation of this report.

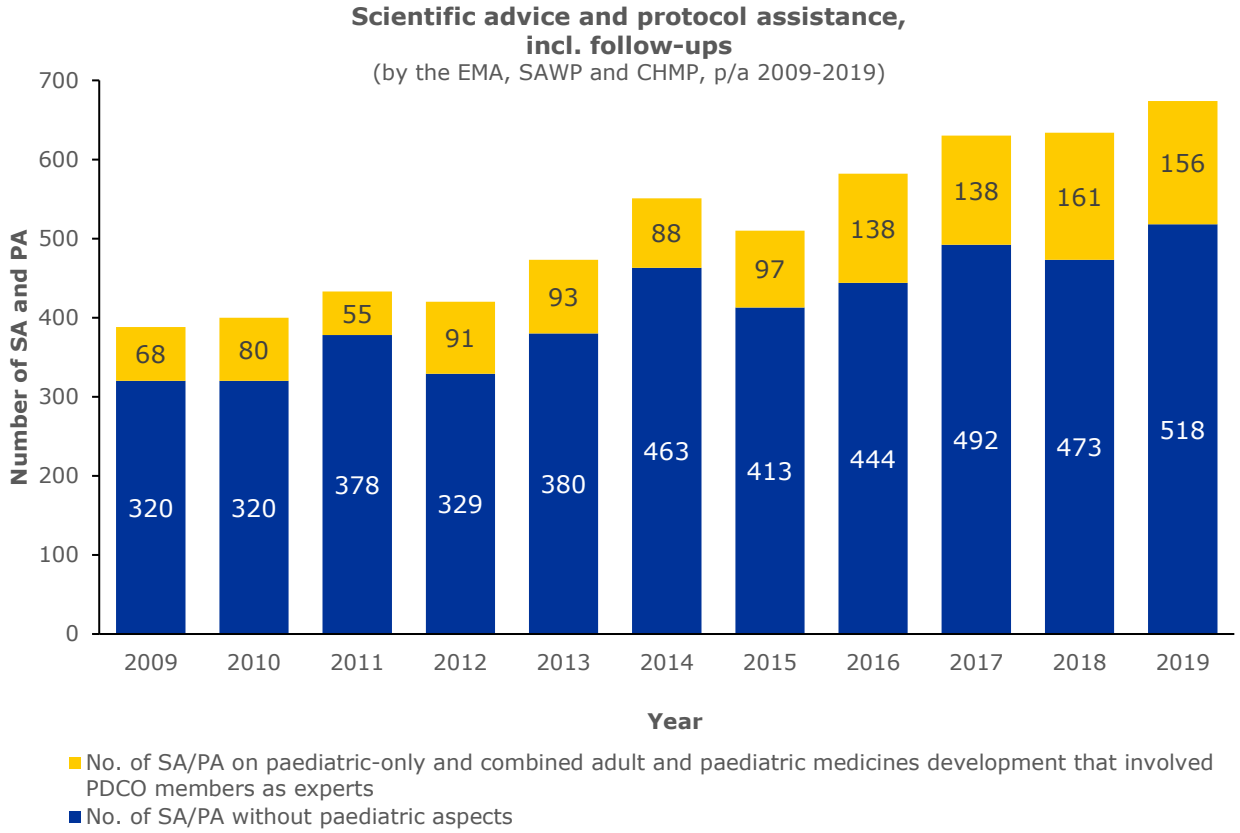
Data received from Cyprus on 5 February 2021 were added post hoc.

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 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 2019, 23% 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 and, in 2019, they were also involved in procedures that did 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 2009-2019)

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 2019, 33 active substances benefited from the six-month extension (see Table 1).

Table 1 - List of companies / products receiving six-month SPC extension in 2019

Company / SPC holder	**INN**	**SPC extension granted in 2019**
Amgen Fremont Inc.; Amgen Inc.	denosumab	Denmark
Bayer Healthcare LLC	damoctocog alfa pegol	Denmark Luxembourg Netherlands Slovenia
Biogen	natalizumab	Germany
Bristol-Myers Squibb Company	abatacept	Hungary
Bristol-Myers Squibb Holding Unlimited Company	dasatinib	Poland
Chugai Seiyaku Kabushiki Kaysha (& Tadamitsu Kishimoto)	tocilizumab	Belgium Finland Luxembourg Netherlands
E. R. Squibb & Sons; Medarex Inc. (Cyprus)	ipilimumab	Belgium Cyprus France Greece Luxembourg
Genentech	bevacizumab	France Germany
Genentech	ranibizumab	Cyprus Denmark Portugal Slovenia
Genzyme Corporation	colesevelam	France

Company / SPC holder	INN	SPC extension granted in 2019
Gilead Sciences	emtricitabine / tenofovir disoproxil	Ireland Luxembourg Portugal Spain United Kingdom
Gilead Sciences	tenofovir disoproxil	Germany
Gilead Sciences	cobicistat	France Germany Hungary Lithuania
GlaxoSmithKline	mepolizumab	Austria Belgium Cyprus France Germany Greece Hungary Ireland Luxembourg Poland Sweden
Janssen Biotech	golimumab	Hungary
Merck Sharp & Dohme; Medimmune (Luxembourg)	human papillomavirus vaccine [types 6, 11, 16, 18]	Austria Belgium Finland Ireland Latvia Luxembourg Netherlands Portugal Slovenia Sweden United Kingdom
Merck Sharp & Dohme	human papillomavirus [Type 6, 11] L1 protein	Denmark
Merck Sharp & Dohme; University of Rochester ur ventures (Luxembourg)	human papillomavirus [Type 16] L1 protein	Denmark Luxembourg
Merck Sharp & Dohme	human papillomavirus [Type 6, 11, 16] L1 protein	Denmark

Company / SPC holder	INN	SPC extension granted in 2019
Merck Sharp & Dohme	human-papillomavirus Typ 18 L1-Protein	Austria Denmark Finland Ireland Netherlands Sweden
Merck Sharp & Dohme	fosaprepitant	France Germany Spain United Kingdom
Novartis	atazanavir	Germany United Kingdom
Novartis	deferasirox	Austria France Greece Hungary Romania Spain
Novartis	eltrombopag	Czech Republic Denmark Finland Latvia Portugal Slovenia
Novo Nordisk	insulin degludec	Hungary
Novo Nordisk A/S, Bagsvaerd (NO); Novo Nordisk A/S	liraglutide	Austria Denmark Finland Ireland Portugal

Company / SPC holder	INN	SPC extension granted in 2019
Pharmacia & Upjohn Company LLC; Sugen, Inc.; Pfizer Europe (Spain)	sunitinib	Czech Republic Denmark Finland France Germany Hungary Ireland Italy Latvia Lithuania Luxembourg Netherlands Poland Portugal Slovenia Spain Sweden United Kingdom
Sanofi Pasteur (Hungary); The Henry M. Jackson foundation for the advancement of military medicine	meningococcal group A, C, W-135 and Y conjugate vaccine	Hungary Germany United Kingdom
Sanofi Pasteur	diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus type b conjugate vaccine (adsorbed)	Belgium France Luxembourg
Shire-NPS Pharmaceuticals	cinacalcet	Germany Luxembourg
Shire International GmbH; Movetis N.V. (Slovenia)	prucalopride	Belgium Czech Republic Denmark Luxembourg Slovenia
The Henry M. Jackson foundation for the advancement of military medicine, Inc	neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein	France

Company / SPC holder	INN	SPC extension granted in 2019
Theramex HQ UK Limited	nomegestrol / estradiol	Hungary France Luxembourg

Source: NPO survey 2020

2.2.2. Orphan market exclusivity extension

In 2019, one orphan medicinal product has benefited from a two-year extension of their respective market exclusivity:

- Mozobil (plerixafor) for the treatment of lymphoma or solid malignant tumours in children from 1 to less than 18 years of age.

In addition, two orphan medicinal products benefited from a two-year extension of their respective market exclusivity in 2018 which were not included in the previous report:

- Coagadex (human coagulation factor X) for the treatment and prophylaxis of bleeding episodes and for perioperative management in patients of all age groups with hereditary factor X deficiency.
- Spinraza (nusinersen) for the treatment of 5q spinal muscular atrophy.

2.3. Paediatric use marketing authorisation

No paediatric use marketing authorisation (PUMA) was granted in 2019.

2.4. Placing on the market

The update of the "Register of deadlines to put a medicinal product on the market" (Article 33 of the Paediatric Regulation), established in 2012 is pending and planned for 2021. It lists the two-year deadlines 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 either by NCAs and/or 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
PIPs (% of total granted)	65 (74%)	44 (59%)	34 (39%)	18 (20%)	12 (13%)	7 (10%)	20 (23%)	24 (28%)	9 (16%)	26 (25%)
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%)

Source: EMA Paediatric database

In 2019, a total of 108 PIPs received a positive opinion and 102 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 2019 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 2019 may not have yet been subjected to a final compliance check.

In total, 384 PIPs were scheduled to finish by 30 June 2019; of those, 307 (79%) were completed; of the remaining 77 that have not been completed, 43 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 2019 the EMA received 251 annual reports on deferred measures. All MAHs submitted their annual report on deferred measures due in 2019.

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
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				
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

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 2019.

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 2019 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.

Company	**Substance** (INN as applicable)	**Application type**
Janssen-Cilag International NV	guselkumab	PIP
Global Alliance for TB Drug Development	pretomanid	PIP
Myovant Sciences Ireland Limited	norethisterone / estradiol / relugolix	waiver
Eli Lilly and Company Limited	abemaciclib	PIP
Bayer AG	rogaratanib	waiver
Aurinia Pharmaceuticals Ltd.	voclosporin	PIP
GUERBET	gadopiclenol	PIP
Soligenix UK Limited	dusquetide	PIP
Chiesi Farmaceutici S.p.A.	glycopyrronium bromide / formoterol / beclometasone	PIP
SymbioVaccin GmbH	Inactivated patient's own (autologous) microorganism (Escherichia coli, Candida spp., Enterococcus spp., Streptococcus spp., Staphylococcus spp., Prevotella intermedia, Fusobacterium nucleatum and others)	waiver
BioMarin International Limited	Adeno-associated viral vector serotype 5 containing a B domain deleted variant of human coagulation factor VIII gene	PIP
Ocular Therapeutix, Inc.	dexamethasone	PIP

Company	**Substance** (INN as applicable)	**Application type**
Pluristem Ltd.	emiplacel	waiver
Trasis S.A.	Glu-NH-CO-NH-Lys-(Ahx)-[N,N9-bis[2-hydroxy-5-(carboxyethyl) benzyl]ethylenediamine-N,N9-diacetic acid (PSMA11-HBED-CC)	waiver
Vakzine Projekt Management GmbH	bordetella pertussis antigen: pertactin / bordetella pertussis antigen: filamentous Haemagglutinin / bordetella pertussis antigen: pertussis toxoid / tetanus toxoid / diphtheria toxoid	waiver
Bausch Health Ireland Limited	brimonidine	waiver
NTC srl	dexamethasone / Levofloxacin	waiver
Abbott Laboratories Limited	ezetimibe / rosuvastatin	waiver
B. Braun Melsungen AG	heparin	waiver
AstraZeneca AB	moxetumomab pasudotox	waiver
Bristol-Myers Squibb International Corporation	6-cyclopropaneamido-4-{[2-methoxy-3-(1-methyl-1H-1,2,4 triazol-3-yl)phenyl]amino}-N-(2H3)methylpyridazine-3-carboxamide (BMS-986165)	PIP
Sun Pharmaceutical Industries Europe BV	ciclosporin	waiver
Krystal Biotech, Inc.	Genetically modified replication-incompetent herpes simplex virus-1 expressing collagen VII	PIP
Aclaris Therapeutics Inc.	hydrogen peroxide	PIP
Myovant Sciences Ireland Limited	norethisterone / estradiol / relugolix	PIP
Roche Registration GmbH	baloxavir marboxil	PIP
QED Therapeutics	infigratinib	waiver
Chemo Research, S.L.	levonorgestrel	PIP
Nektar Therapeutics	aldesleukin	PIP
Bristol-Myers Squibb International Corporation	PEGylated-fibroblast growth factor 21 (BMS-986036)	PIP

Company	**Substance** (INN as applicable)	**Application type**
PTC Therapeutic International Limited	Recombinant adeno-associated viral vector serotype 2 carrying the gene for the human aromatic L-amino acid decarboxylase protein	PIP
Alder BioPharmaceuticals Limited	eptinezumab	PIP
Egis Pharmaceuticals PLC	ramipril / rosuvastatin	waiver
Curium Netherlands BV	2-(3-(1-carboxy-5-[(6-[18F]fluoropyridine-3-carbonyl)-amino]-pentyl)-ureido)-pentanedioic acid	waiver
Eisai Ltd	7-(2-Methoxy-3,5-dimethylpyridin-4-yl)-1-[(3S)-tetrahydrofuran-3-yl]-1,5-dihydro-4H-pyrazolo[4,3-c]quinolin-4-one maleate	waiver
Emalex Biosciences, Inc.	ecopipam	PIP
Advanced Nuclear Medicine Ingredients (ANMI)	(3S,7S)-22-(3-(((2-((5-(2-Carboxyethyl)-2-hydroxybenzyl)(carboxymethyl)amino)ethyl)(carboxymethyl)amino)methyl)-4-hydroxyphenyl)-5,13,20-trioxo-4,6,12,19-tetraazadocosane-1,3,7-tricarboxylic acid (PSMA-11)	waiver
Ipsen Pharma	177Lu-satoreotide tetraxetan	waiver
Verastem, Inc.	duvelisib	waiver
ELPEN Pharmaceutical Co. Inc	ezetimibe / atorvastatin	waiver
Marinus Pharmaceuticals Inc.	ganaxolone	PIP
AstraZeneca AB	savolitinib	waiver
Cancer Prevention Pharma (Ireland) Limited	sulindac / eflornithine	PIP
Pfizer Europe MA EEIG	crizotinib	PIP
Agios Pharmaceuticals, Inc.	ivosidenib	PIP
BeiGene Ireland, Ltd	zanubrutinib	PIP
Eli Lilly and Company Limited	abemaciclib	PIP
Pfizer Europe MA EEIG	aztreonam / avibactam	PIP
AB Science	masitinib mesylate	waiver

Company	**Substance** (INN as applicable)	**Application type**
Immunomedics GmbH	sacituzumab govitecan	waiver
Johnson and Johnson	benzocaine	waiver

Source: EMA database PedRA

Annex II. List of PIPs not completed by the agreed date until 30 June 2019

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-000532-PIP01-09	sodium bituminosulphonate / clindamycin phosphate	Ichthoseptal N	Ichthyol -Gesellschaft Cordes, Hermanni & Co. (GmbH & Co.) Kg
EMEA-000436-PIP01-08	mannitol	Bronchitol	Pharmaxis Pharmaceuticals Limited
EMEA-000651-PIP01-09-M02	cholic acid	N/A	Fgk Representative Service GmbH
EMEA-000487-PIP01-08	Bromocriptine	Cycloset	Veroscience Eu Ltd
EMEA-000288-PIP01-08-M02	moxifloxacin	Avalox, Avelox, Havelox, Izilox, Octegra, Proflox, Actimax and Actira.	Bayer Schering Pharma
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-000337-PIP01-08	Grass pollen preparation	N/A	Allergopharma J. Ganzer KG
EMEA-000898-PIP01-10-M02	meropenem	N/A	NeoMero Consortium
EMEA-001134-PIP01-11	Chimeric monoclonal anti-shiga toxin (Stx) antibodies Cαstx1 and Cαstx2	Shigamabs	Albany Regulatory Consulting Limited
EMEA-001145-PIP01-10	azithromycin	N/A	Ixodes AG
EMEA-001324-PIP01-12-M01	glibenclamide	Glibentek	Ammtek

Procedure number	Substance	Invented Name	Company
EMEA-000044-PIP01-07	Tgplpth1-34	N/A	Kuros Biosurgery International Ag
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-001238-PIP01-12	alpha tocotrienol quinone	Vincerinone	Edison Orphan Pharma Bv
EMEA-001352-PIP01-12-M01	metformin	N/A	Effrx Pharmaceuticals Sa
EMEA-000281-PIP01-08-M02	Recombinant human monoclonal antibody to the Insulin-like growth factor-1 receptor (Humab IGF-1R – A)	N/A	Roche Registration Limited
EMEA-000488-PIP02-11	rubidium-82	Cardiogen-82	Advanced Accelerator Applications
EMEA-001314-PIP01-12	dinutuximab beta / chimeric anti-disialoganglioside (GD2) Monoclonal Antibody (Ch14.18/CHO)	N/A	Apeiron Biologics Ag
EMEA-000649-PIP01-09	taspoglutide	N/A	Ipsen Pharma
EMEA-000665-PIP01-09	taspoglutide	N/A	Ipsen Pharma
EMEA-000973-PIP01-10-M03	Recombinant human N-acetylgalactosamine-6-sulfatase	Vimizim (Elosulfase Alfa)	Biomarin Europe Limited
EMEA-000389-PIP01-08-M01	N-[4-(3-Amino-1H-Indazol-4 Yl) Phenyl]-N1- (2-Fluoro-5-Methylphenyl) urea	N/A	Abbvie Ltd
EMEA-000360-PIP01-08	carisbamate	Comfyde	Janssen Cilag NV International
EMEA-001460-PIP01-13-M02	eelvitegravir / cobicistat / emtricitabine / tenofovir alafenamide	Genvoya	Gilead Sciences

Procedure number	Substance	Invented Name	Company
EMEA-000284-PIP01-08-M04	Modified Grass pollen extract	N/A	Allergy Therapeutics (UK) Limited
EMEA-000736-PIP01-09	Culture expanded autologous chondrocytes	Hyalograft C autograft	Fidia Advanced Biopolymers S.r.l.
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.
EMEA-001203-PIP02-14-M02	Coagulation factor VIIa (recombinant)	N/A	LFB SA
EMEA-001627-PIP01-14	efinaconazole	N/A	PharmaSwiss Česká republika
EMEA-001568-PIP03-14	ceftriaxone / sulbactam	Elores	Venus Pharma GmbH
EMEA-000471-PIP01-08-M02	sitagliptin	Xelevia	Merck Sharp and Dohme (Europe), Inc.
EMEA-000472-PIP01-08-M02	stagliptin	Tesavel	Merck Sharp and Dohme (Europe), Inc.
EMEA-001333-PIP02-13	pradigastat	N/A	Novartis Europharm Limited
EMEA-000550-PIP02-10-M01	cilengitide	N/A	Merck KGaA
EMEA-001475-PIP02-13	maralixibat	N/A	Mirum Pharmaceuticals
EMEA-000800-PIP01-09-M01	ombrabulin	N/A	Sanofi-aventis recherche & developpement
EMEA-001881-PIP01-15	Ragweed pollen extract	N/A	ALK Abelló A/S
EMEA-001359-PIP01-12-M03	retosiban	N/A	GlaxoSmithKline Trading Services Limited
EMEA-000637-PIP02-10-M06	lanthanum carbonate hydrate	Fosrenol / Foznol	Shire Pharmaceuticals Ireland Limited
EMEA-001634-PIP01-14	Recombinant human heparan N-sulfatase	N/A	Shire Human Genetic Therapies AB
EMEA-001244-PIP01-11-M02	elivaldogene autotemcel	N/A	bluebird bio (Netherlands) B.V.

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.