EMA/217810/2025
20 November 2025
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 and on the companies that have failed to comply with any of the obligations in this regulation

Year 2024

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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.[1]

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 the year 2024 and lists the companies benefiting from and infringing the regulation.

1.2. Data collection and methodology

In December 2024 the Agency contacted the national patent offices (NPOs) 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 2024.

The Agency received contributions from the following Member State NPOs: Austria, Belgium, Bulgaria, 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.

Developers of a medicinal product identified as potentially infringing the Paediatric Regulation in 2024, either by not completing a paediatric investigation plan (PIP) by the agreed date or by failing to submit an annual report on deferred measures by the due date, were given an opportunity to comment on these findings between April and November 2025 before publication of any identified infringement. All information received by 5 November 2025 was considered for finalisation of this report.

[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)
https://www.ema.europa.eu/en/human-regulatory-overview/paediatric-medicines-overview/paediatric-regulation

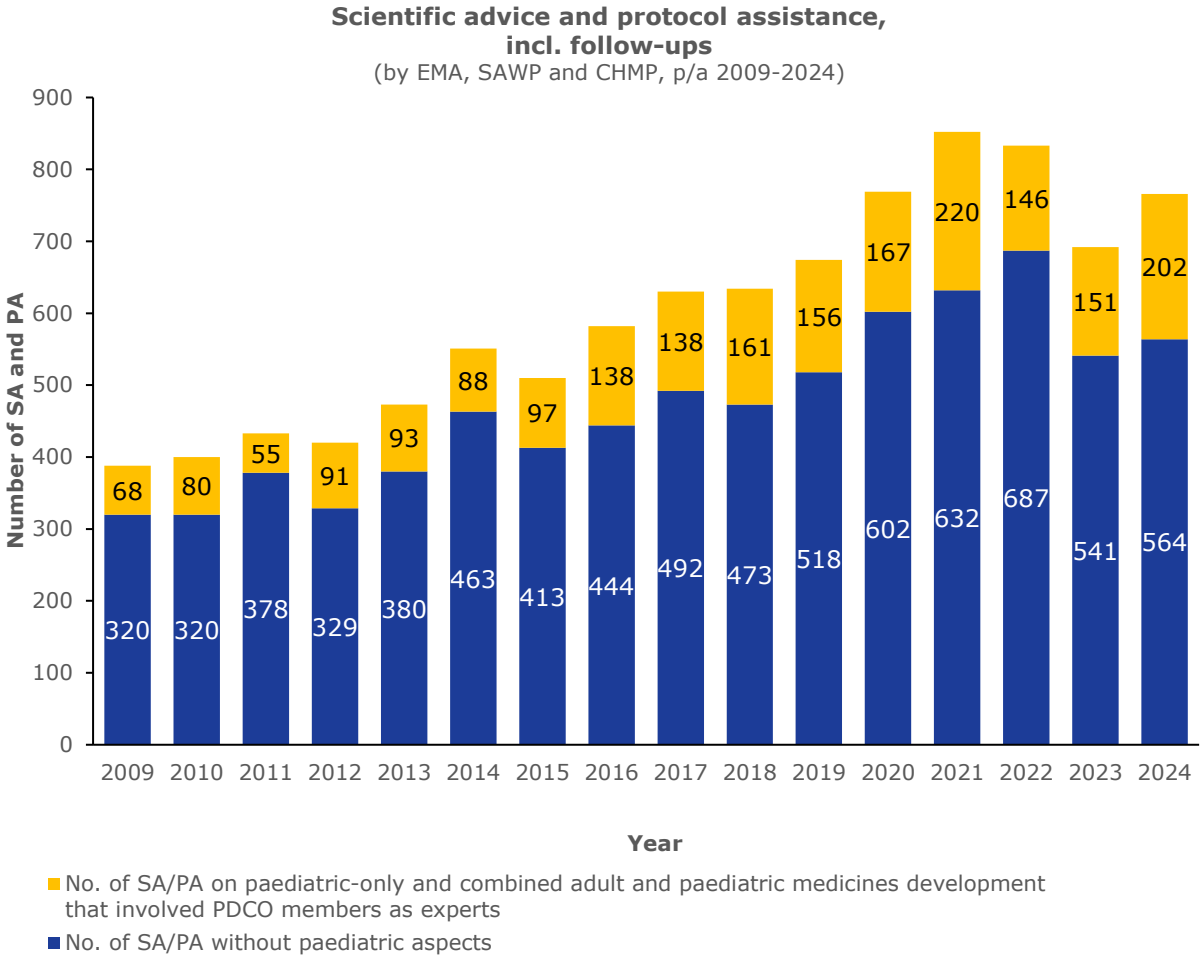
2. Companies and products that have benefited from the rewards and incentives in the regulation

2.1. Scientific advice or protocol assistance from 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) in 2024 is overall in the range of previous years. 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.

Figure 1. Scientific advice and protocol assistance, incl. follow-ups (by EMA, SAWP and CHMP, p/a 2009-2024)*



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

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 2024, 71 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 2024

Company/SPC holder	**Substance (INN as applicable)**	**SPC extension granted in 2024**
AbbVie Manufacturing Management Unlimited Company	pibrentasvir	Luxembourg
Actelion Pharmaceuticals Ltd.	macitentan	Finland Netherlands
Amgen Fremont Inc and Amgen Inc. And One Amgen Center Drive	denosumab	Austria Belgium
Amgen Inc.	evolocumab	Czech Republic Estonia Finland France Italy Luxembourg Poland Slovakia
Amgen K-A	romiplostim	Luxembourg
Astellas Pharma & Wakanuga Pharmaceutical	ceftolozane	Luxembourg
AstraZeneca AB	dapagliflozin	Luxembourg
AstraZeneca AB	ticagrelor	Luxembourg
Bayer Healthcare LLC	damoctocog alfa pegol	Germany
Bayer Healthcare LLC	octocog alfa	Italy

Biovex, INC	talimogene laherparepvec	Cyprus Finland Luxembourg Netherlands
Enanta Pharmaceuticals, Inc	glecaprevir	Luxembourg
Exelixis, Inc.	cobimetinib	France Lithuania Luxembourg Poland Slovakia Romania
Boehringer Ingelheim Pharma GmbH & Co. KG	afatinib	France Luxembourg
Boehringer Ingelheim International GmbH	idarucizumab	Luxembourg
Boehringer Ingelheim International GmbH	empagliflozin	Austria Belgium Bulgaria Czech Republic Denmark Finland Hungary Italy Latvia Netherlands Portugal Slovakia Slovenia Spain
Boehringer Ingelheim Pharma GmbH & Co. KG	linagliptin	Austria Bulgaria Cyprus Czech Republic

		Denmark Germany Italy Latvia Luxembourg Netherlands Portugal Slovakia Slovenia Spain
Boehringer Ingelheim PharmaGmbH & Co. KG	nintedanib	Cyprus Belgium Bulgaria Czech Republic Estonia Finland France Germany Luxembourg Poland Portugal Slovakia Spain
Bristol Myers Squibb Pharma EEIG	nivolumab/relatlimab	Italy
Bristol-Myers Squibb Company	relatlimab	Czech Republic France
Bristol-Myers Squibb Holdings Ireland Unlimited Company; Bristol-Myers Squibb/Pfizer EEIG (Spain)	apixaban	Estonia France Germany Italy Latvia Netherlands

		Romania Slovenia Spain Sweden
Chugai Seiyaku Kabushiki Kaisha	emicizumab	Czech Republic France Greece Luxembourg Slovakia Sweden
Daiichi Sankyo Company, Limited, Berlin Chemie AG (Spain)	edoxaban	Denmark Finland Germany Italy Netherlands Portugal Spain
Eisai R&D Management Co. Ltd	eribulin	Luxembourg
Eisai R&D Management Co. Ltd, Eisai GmbH (Spain)	lenvatinib	Austria Denmark Finland France Hungary Netherlands Portugal Spain
Eli Lilly and Company	dulaglutide	Cyprus Czech Republic Estonia France Greece Luxembourg Slovakia

Dana-Faber Cancer Institute, Inc.; Genetics Institute, LLC; F. Hoffmann-La Roche AG (Malta, Cyprus, Slovenia)	atezolizumab	Cyprus Hungary Luxembourg Malta Slovenia
F. Hoffman-La Roche AG	netupitant	Lithuania
F. Hoffman-La Roche AG	netupitant/palonosetron	Luxembourg
Gilead Pharmasset LLC (Germany); NuCana plc (Sweden France); Gilead Sciences Ireland UC (Spain)	sofosbuvir	France Germany Spain Sweden
Gilead Sciences, INC	cobicistat	Finland
Gilead Sciences, INC	tenofovir alafenamide	Poland
Glaxo Group Limited	fluticasone furoate/vilanterol	Czech Republic Estonia
GlaxoSmithKline Biologicals SA	HPV L1 VLPs 16 + 18 + 31	Belgium France
GlaxoSmithKline Biologicals SA	HPV L1 VLPs 16 + 18 + 45	Belgium France
GlaxoSmithKline Biologicals SA	HPV L1 VLPs 16, 18 and 52	Belgium France
GlaxoSmithKline Biologicals SA (Luxembourg); Merck Sharp & Dohme LLC (Luxembourg)	HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58	Luxembourg
GlaxoSmithKline Biologicals SA	*Neisseria meningitidis* group A conjugated to a tetanus toxoid carrier protein	Bulgaria Finland Germany Hungary Italy Latvia Netherlands Poland Portugal

		Slovenia
Glaxo Group Limited; GlaxoSmithKline (Ireland); Limited (Spain)	vilanterol	Austria Bulgaria Finland Hungary Latvia Netherlands Portugal Slovenia Spain
H. Lundbeck A/S	vortioxetine	Bulgaria Czech Republic Denmark Finland France Latvia Lithuania Luxembourg Netherlands Slovenia Spain
Janssen Pharmaceutica NV	rilpivirine	Bulgaria Czech Republic Finland Latvia Netherlands Portugal
Japan Tobacco, Inc	elvitegravir	Luxembourg Slovenia
Japan Tobacco Inc	elvitegravir/tenofovir alafenamid	Austria Bulgaria Estonia Finland

		Slovenia Sweden
Japan Tobacco Inc	elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide	Cyprus
Medimmune Limited	durvalumab	Austria Bulgaria Czech Republic Denmark Hungary Italy Estonia Finland Latvia Malta Netherlands Portugal Slovakia Slovenia
Merck Sharp & Dohme BV (Luxembourg); Ono Pharmaceutical Co. LTD and Honjo Tasuku (Luxembourg, Czech Republic, Italy); Ono Pharmaceutical Co. LTD (Greece)	pembrolizumab	Czech Republic Greece Italy Luxembourg
Merck Sharp & Dohme LLC	HPV 31 L1 protein	France
Merck Sharp & Dohme LLC	HPV 58 L1 protein	Belgium France Romania
Merck Sharp & Dohme LLC	HPV 45 L1 protein	Belgium France Lithuania Romania

Merck Sharp & Dohme LLC	HPV 52 L1 protein	Belgium France Lithuania Romania
Novartis AG	pazopanib	Belgium Luxembourg
Novartis AG	secukinumab	Luxembourg
Novo Nordisk A/S	insuline aspart	Luxembourg
Novo Nordisk A/S	insuline degludec	Cyprus Luxembourg Poland Slovakia
Novo Nordisk A/S	insulin degludec / insulin aspart	Bulgaria Czech Republic Denmark Italy Poland Portugal Romania Slovenia Sweden
N.V. Organon	corifollitropin alfa	France Luxembourg
ONO Pharmaceutical Co, Ltd, Honjo (Luxembourg, Italy); ONO Pharmaceuticals Co. Ltd (Estonia, Luxembourg, Greece, France, Germany, Slovakia, Cyprus); E.R.Squibb & Sons LLC (Estonia, Luxembourg, France, Germany, Slovakia, Cyprus)	nivolumab	Cyprus Estonia France Germany Greece Italy Luxembourg Slovakia

Pfizer Ireland Pharmaceuticals	meningococcal group A, C, W-135 and Y conjugate vaccine	Austria Czech Republic Finland France Germany Italy Luxembourg Poland Portugal Romania
Pfizer Products Inc	tremelimumab	Austria Denmark Finland Hungary Lithuania Slovakia Slovenia
Pharming Intellectual Property B.V	conestat alfa	Belgium
Pharmacyclics LLC	ibrutinib	Bulgaria
Ratiopharm GMBH	lipegfilgrastim	Austria Bulgaria Czech Republic Denmark Finland France Hungary Italy Luxembourg Malta Netherlands Poland Portugal

		Romania Slovenia
Regeneron Pharmaceuticals, INC	aflibercept	Ireland Luxembourg
Regeneron Pharmaceuticals, INC	alirocumab	Austria Bulgaria Cyprus Czech Republic Denmark Estonia Finland Hungary Italy Latvia Lithuania Malta Netherlands Portugal Slovenia Sweden
Regeneron Pharmaceuticals, INC	dupilumab	Estonia Luxembourg Slovakia
Sanofi Pasteur Limited	diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed)	Germany

Shionogi & CO., LTD and ViiV Healthcare company (Austria, France, Czech Republic, Finland, Latvia, Slovakia, Sweden, Bulgaria, Cyprus); ViiV Healthcare company (Greece, Spain)	dolutegravir	Austria Bulgaria Cyprus Czech Republic Finland France Germany Greece Hungary Latvia Slovakia Spain Sweden
Takeda Pharmaceutical Company Limited; Takeda Pharma A/S (Spain)	alogliptin	Finland Germany Hungary Italy Latvia Portugal Spain
UCB Biopharma SRL	brivaracetam	Belgium Czech Republic France Germany Greece Hungary Poland Sweden
Warner Lambert	palbociclib	Netherlands
Wyeth Holdings LLC	bosutinib	Romania

Source: NPO survey 2024

2.2.2. Orphan market exclusivity extension

In 2024, seven orphan medicinal products benefited from a two-year extension of their respective market exclusivity:

- Altuvoct (efanesoctocog alfa) for the treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).
- Blincyto (blinatumomab) for the treatment of acute lymphoblastic leukaemia.
- Cerdelga (eliglustat) for the treatment of Gaucher disease.
- Cresemba (isavuconazole) for the treatment of invasive aspergillosis and the treatment of mucormycosis.
- Filsuvez (birch bark extract) for the treatment of epidermolysis bullosa.
- Spexotras (trametinib) for the treatment of low-grade and high-grade glioma.
- Upstaza (eladocagene exuparvovec) for the treatment of aromatic L-amino acid decarboxylase deficiency.

2.3. Paediatric-use marketing authorisation

One new paediatric-use marketing authorisation (PUMA) was granted in 2024:

- Neoatricon (dopamine hydrochloride) by BrePco Biopharma Limited received a positive CHMP opinion in March 2024 for the treatment of hypotension in haemodynamically unstable neonates, infants and children less than 18 years of age. The EC decision was adopted in May 2024.

2.4. Placing on the market

The Paediatric Register 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.

Please refer to the following link: Paediatric register (PIPs, waivers), including Art. 33 register · IRIS

The register includes a column titled *'Placement on the market (info from MAH)'* which indicates the requirement to market the product in all applicable Member States by the established deadline. The information on whether this requirement has been fulfilled is provided by the 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 developers of a medicinal product to submit applications for agreement on a waiver or a PIP no later than upon completion of the human pharmacokinetic (PK) studies in adults as specified in Section 5.2.3 of Part I of Annex I to Directive 2001/83/EC, except when duly justified. Recital 10 of the Regulation states that paediatric investigation plans should be submitted early during product development, in time for studies to be conducted in the paediatric population, where appropriate, before marketing-authorisation applications are submitted.

The timing of submission should not be later than the end of healthy participant or patient pharmacokinetic (PK) studies, which may coincide with initial tolerability studies, or the initiation of the adult phase II (proof-of-concept) studies. If a phase II study in adults has already been completed by the time of the PIP submission, the submission is generally considered delayed unless a valid justification is provided. Submitting a first application for a new active substance during confirmatory or phase-III trials in adults, or after starting clinical trials in children, is likely to be considered unjustified. Late submissions have been reported since 2011 (Table 2) for applications with a delay greater than six months. 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 PIP or product-specific waiver application. Since 2014 only those deemed unjustified by the PDCO are being reported.

For further information on the timing of a PIP application please refer to guidance published on the EMA website (Q 1.2).

Table 2. Number of PIP and waiver procedures with a submission delay of greater than six months.

Procedure type	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
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%)	43 (33.3%)	46 (35.9%)	47 (39.5%)
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%)	37 (32.7%)	46 (33.6%)	37 (30.1%)

Source: EMA Paediatric database (PedRA)

In 2024, a total of 119 PIPs received a positive opinion, and 123 full product-specific waivers were granted. In recent years, an increasing trend has been observed in the late submission of PIP and waiver applications. The list of unjustified late submissions of PIP and waiver applications is presented in Annex I.

3.2. Completion of PIPs

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

For the analysis of timely completion, the PIPs with an agreed completion date up to 30 June 2024 were reviewed. This cut-off date was chosen because applicants must submit the completed study

reports within six months of completion (art. 46 of the Paediatric Regulation). Studies and PIPs completed after June 2024 may not have yet been subjected to a final compliance check.

In total, 817 PIPs were scheduled to be completed by 30 June 2024. Of these, 429 (52%) were completed. Among the remaining 388 that have not been completed, 215 were discontinued or a full waiver was granted in a subsequent modification. For 26 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 2024 EMA received 215 annual reports on deferred measures. All MAHs except five submitted their annual report on deferred measures due in 2024.

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	2022	2023	2024
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						
Bristol-Myers Squibb International Corporation													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													1
Ipsen Pharma								1						
Janssen-Cilag International N.V.	1				1									
Jazz Pharmaceuticals Ireland Limited														1
Kowa Pharmaceutical Europe Company Ltd	1	1	4											
Merck Sharp & Dohme (Europe) Inc.	2	1	2											
Navidea Biopharmaceuticals Europe Limited														1

Noden Pharma DAC														1
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							1		
Seqirus S.r.l.						1								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	10	8	3	3	0	0	0	1	1	5

Source: EMA Paediatric 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 2024.

The table below lists the agreed PIPs or waivers submitted in 2024 that were significantly delayed by at least 6 months for which no or an unacceptable justification (as determined by the PDCO) was provided.

Company	**Substance (INN as applicable)**	**Application type**
Agenus Inc	balstilimab	PIP
Agenus Inc	botensilimab	PIP
Integrative Research Laboratories AB	mesdopetam	Waiver
Gilead Sciences Ireland Unlimited Company	sacituzumab govitecan	Waiver
Propharma Group The Netherlands B.V.	relacorilant	Waiver
Transcrip Ireland Limited	ulixacaltamide (hydrochloride)	Waiver
Tourmaline Bio Inc	pacibekitug	Waiver
Adamed Pharma S.A.	amlodipine, ramipril, rosuvastatin	Waiver
Italfarmaco S.p.A.	sacituzumab govitecan	Waiver
Pharma Gateway AB	tenapanor	Waiver
Serum Life Science Europe GmbH	inbakicept, nogapendekin alfa	Waiver
Freya Pharma Solutions Holding B.V.	sildenafil citrate, testosterone	Waiver
Gilead Sciences International Limited (GSIL)	lenacapavir sodium	PIP
Taiho Pharma Netherlands B.V.	zipalertinib	Waiver
Telix Innovations S.A.	zirconium (89Zr) girentuximab senvedoxam	Waiver
BeyondSpring Pharmaceuticals, Inc	plinabulin	Waiver
Rocket Pharmaceuticals, B.V.	Adeno-associated virus serotype 9 vector containing the human LAMP2 isoform B transgene	PIP
Abliva AB	2-isopropyl-3H-naphtho[1,2-d]imidazole-4,5-dione	PIP

Curium Pet France	copper (64Cu) oxodotreotide	Waiver
Daiichi Sankyo Europe GmbH	ifinatamab deruxtecan	Waiver
Soleno Therapeutics Europe Ltd.	diazoxide choline	PIP
Adaptimmune B. V.	letetresgene autoleucel	PIP
Adlai Nortye USA, Inc.	buparlisib	Waiver
Sato Pharmaceutical Co., Ltd.	luliconazole	PIP
BioNTech SE	Immunoglobulin G1 (Trastuzumab), anti-(human tyrosine kinase receptor Erb B2), thioether with (1R,3R)-3-(((7S)-7-benzyl-20-(3-mercapto-2,5-dioxopyrrolidin-1-yl)-3,6,9,12,15-pentaoxo-2,5,8,11,14-pentaazaicosyl)oxy)-N-((1S,9S)-9-ethyl-5-fluoro-9-hydroxy-4-methyl-10,13-dioxo-2,3,9,10,13,15-hexahydro-1H,12H-benzo[de]pyrano[3',4':6,7]indolizino[1,2-b]quinolin-1-yl)cyclobutane-1-carboxamide	Waiver
Adamed Pharma S.A.	indapamide / ramipril	Waiver
Sanofi Winthrop Industrie	teplizumab	PIP
Almirall, S.A	tildrakizumab	PIP
Elevar Therapeutics Inc.	rivoceranib	Waiver
Acadia Pharmaceuticals Inc.	trofinetide	PIP
Netherlands Cancer Institute (NKI)	autologous viable CD45+CD3+ T-cells isolated and expanded from a melanoma metastasis	PIP
Verisfield Single Member SA	rosuvastatin / ezetimibe	Waiver
Abbisko Therapeutics., Co., Ltd.	3,3-Dimethyl-N-(6-methyl-5-{[2-(1-methyl-1H-pyrazol-4-yl)pyridine-4-yl]oxy}pyridine-2-yl)-2-oxopyrrolidine-1-carboxamide hydrochloride hydrate	PIP
Althera Laboratories Ltd	sitagliptin / dapagliflozin	Waiver
Merz Pharmaceuticals GmbH	*Clostridium botulinum* neurotoxin type A (150 kD), free from complexing proteins	Waiver
Visus Therapeutics, Inc.	carbachol / brimonidine tartrate	Waiver
Shionogi BV	olorofim	PIP
Laminar Pharmaceuticals SA	idroxioleic acid	PIP
Luzsana Biotechnology Europe AG	camreluzimab	Waiver
Inhibrx, Inc.	human alpha-1-proteinase inhibitor immuno-globulin G fusion protein, recombinant	Waiver

Kiniksa Pharmaceuticals (UK) Ltd	rilonacept	PIP
Incyte Biosciences Distribution B.V.	povorcitinib	Waiver
Kamada Ireland Limited	human rabies immune globulin	PIP
Merck Sharp & Dohme B.V.	tulisokibart	PIP
ArriVent Biopharma, Inc.	N-(2-((2-(dimethylamino)ethyl)(methyl) amino)-5-((4-(1-methyl-1H-indol-3-yl)pyrimidin-2-yl)amino)-6-(2,2,2-trifluoroethoxy)pyridin-3-yl)acrylamide methanesulfonate	Waiver
Roche Registration GmbH	humanized IgG4 Monoclonal Antibody against FIXa and FX	PIP
Jazz Pharmaceuticals Ireland Ltd	suvecaltamide hydrochloride	Waiver
Zaklady Farmaceutyczne Polpharma S.A.	nebivolol / ramipril	Waiver
AstraZeneca AB	volrustomig	Waiver
Senju Pharmaceutical Co., Ltd.	motugivatrep	Waiver
Exelixis, Inc.	zanzalintinib	Waiver
CEL-SCI Corporation	interleukin-2/interleukin-1 beta, human/granulocyte colony-stimulating factor/ tumour necrosis factor-alpha/interferon gamma	Waiver
Springworks Therapeutics Ireland Limited	mirdametinib	PIP
Merus N.V.	zenocutuzumab	Waiver
Dr. Falk Pharma GmbH	methyl (E,6S)-7-[[1-[2-(2-ethylbutylamino)-2-oxoethyl]-2-oxopyridin-3-yl]amino]-6-[(3-methylimidazole-4-carbonyl)amino]-7-oxohept-2-enoate	PIP
Sanofi B.V.	venglustat	PIP
Sanofi Winthrop Industrie	belumosudil	PIP
Sanofi Pasteur	Live attenuated respiratory syncytial virus (RSV)	PIP
Immedica Pharma AB	Iodine (131I) apamistamab	PIP
Novo Nordisk A/S	etavopivat	PIP
Disc Medicine B.V.	bitopertin	PIP
GRIN Therapeutics, Inc.	radiprodil	PIP
Regeneron Ireland DAC	garetosmab	PIP

Pfizer Europe MA EEIG	borrelia outer surface protein A (OspA) sero-types (ST1-6) lipidated, fusion protein vaccine	PIP
FGK Representative Service GmbH	laruparetigene zovaparvovec	PIP
Laboratorios Salvat, S.A.	clobetasol propionate	PIP
Myrtelle,Inc.	Rrecombinant adeno-associated virus olig001 containing human aspartoacylase cDNA	PIP
Orphix Consulting GmbH	mometasone furoate	PIP
Fulcrum Therapeutics, Inc.	losmapimod	PIP
Seagen B.V	disitamab vedotin	PIP
Marinus Pharmaceuticals, Inc.	ganaxolone	PIP
PTC Therapeutics International Limited	sepiapterin	PIP
Sanofi Winthrop Industrie	belumosudil	PIP
Moderna Biotech Spain, S.L.	CX-000359 mRNA encoding the UL128 protein in the CMV glycoprotein complex pentamer / CX- 000594 mRNA encoding the gL protein in the CMV glycoprotein complex pentamer / CX- 000712 mRNA encoding the UL130 protein in the CMV glycoprotein complex pentamer / CX-005128 mRNA encoding the UL131A protein in the CMV glycoprotein complex pentamer / CX-005282 m-RNA encoding the gH protein in the CMV glycoprotein complex pentamer / CX-000667 mRNA encoding CMV gB (mRNA-1647)	PIP
FGK Representative Service GmbH Germany	sevasemten	PIP
Zynerba Pharmaceuticals, Inc.	cannabidiol	PIP
AstraZeneca AB	tozorakimab	PIP
Longboard Pharmaceuticals, Inc.	bexicaserin	PIP
Belite Bio, Inc	tinlarebant	PIP
X4 Pharmaceuticals (Austria) GmbH	mavorixafor	PIP
Arrowhead Pharmaceuticals, Inc.	synthetic double-stranded siRNA oligonucleotide directed against apolipoprotein C-III mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues (ARO-APOC3)	PIP

Nuvalent, Inc	(R)-9-Chloro-11-ethyl-21-fluoro-4-methyl-19-methyl-18-oxa-3,4,10,11,15-pentaazapentacyclo[18.3.1.1 13,17 .02,6 .08,12]pentacosa-1(23),2,5,8(12),9,13,15,17(25),20(24),21-decaen-16-ylamine	Waiver
Nuvalent, Inc	zidesamtinib	Waiver
Grunenthal GmbH	resiniferatoxin	Waiver

Source: EMA database (PedRA, IRIS)

Annex II. List of PIPs not completed by the agreed date until 30 June 2024

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

The following list includes all PIPs due to be completed by 30 June 2024 without sufficient justification for the delay.

Procedure number	Substance	Invented Name	Company
EMEA-002402-PIP02-18	artesunate	Malacef	ACE Pharmaceuticals BV
EMEA-002266-PIP01-17	recombinant humanacid ceramidase	N/A	Aceragen Inc.
EMEA-000488-PIP02-11	rubidium-82	Cardiogen-82	Advanced Accelerator Applications
EMEA-001535-PIP01-13-M01	potassium hydrogen carbonate / Potassium citrate monohydrate	N/A	Advicenne
EMEA-001571-PIP01-13	N-{2-(2,3-Difluorobenzylthio)-6-[(2R,3S)-3,4-dihydroxybut-2-yloxy]pyrimidin-4-yl}azetidine-1-sulfonamide	N/A	AstraZeneca AB
EMEA-001369-PIP01-12	exon 45 specific phosphorothioate oligonucleotide	N/A	Biomarin Interna-tionalLimited
EMEA-001374-PIP01-12	exon 53 specific phosphorothioate oligonucleotide	N/A	BioMarin Interna-tionalLimited
EMEA-001485-PIP01-13-M01	(1aR,12bS)-8-Cyclohexyl-N-(dimethylsulfamoyl)-11-methoxy-1a-(((1R,5S)-3-methyl-3,8-diaza bicyclo[3.2.1]oct-8-yl)carbonyl)-1,1a,2,12b-tetrahydrocyclopropa [d]indolo[2,1-a][2]benzazepine-5-carboxamide hydrochloride (company code BMS-791325) / asunaprevir / daclatasvir dihydrochloride	N/A	Bristol-Myers Squibb International Corporation
EMEA-001860-PIP04-16	galcanezumab (LY2951742)	N/A	Eli Lilly and Company Limited
EMEA-001513-PIP01-13	estetrol / levonorgestrel	N/A	Estetra S.A.
EMEA-001175-PIP01-11-M04	albiglutide	Eperzan	Glaxo Group Limited

EMEA-001568-PIP03-14	ceftriaxone /sulbactam	Elores	Venus Pharma GmbH
EMEA-000044-PIP01-07	TGplPTH1-34	N/A	Kuros Biosurgery International AG
EMEA-000362-PIP01-08-M04	Aliskiren hemifumarate	Rasilez	Noden Pharma
EMEA-002537-PIP02-19	darunavir / ritonavir	N/A	PharOS - Pharmaceutical Oriented Services Ltd
EMEA-000880-PIP02-11-M04	sonidegib	Odomzo	Sun Pharmaceutical Industries Europe B.V.
EMEA-001909-PIP01-15	Cathine hydrochloride (D-Norpseudoephedrine hydrochloride)	Alvalin Riemser, 40 mg/g, Tropfen zum Einnehmen, Lösung	Schuck GmbH
EMEA-002051-PIP02-16	allopregnanolone	N/A	Sage Therapeutics Inc
EMEA-001453-PIP01-13-M01	zuretinol acetate	N/A	Retinagenix LLC
EMEA-001434-PIP01-13-M03	etrolizumab	N/A	Roche Registration GmbH
EMEA-002138-PIP01-17-M01	carotuximab (TRC105)	N/A	TRACON Pharma International Limited
EMEA-001568-PIP03-14	sulbactam (in the form of sodium salt) / ceftriaxone (in the form of sodium salt)	Elores	Venus Pharma GmbH
EMEA-001255-PIP01-11-M03	tilmanocept	Lymphoseek	Navidea Biopharmaceuticals Europe Ltd.
EMEA-001288-PIP01-12	1-(2R,5R)-5-ethynyl-5-(hydroxymethyl)-2,5-dihydro-2-furanyl)-5-methyl-2,4(1H,3H)-pyrimidinedione (BMS-986001)	N/A	Oncolys BioPharma Inc
EMEA-001895-PIP01-15-M01	lactobacillus reuteri	IBP-9414	Infant Bacterial Therapeutics AB
EMEA-002867-PIP01-20	afamitresgene autoleucel	N/A	Adaptimmune Ltd