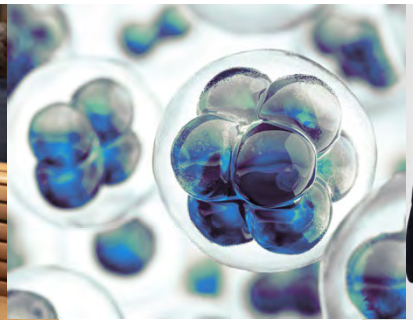
Europäisches Patentamt
European Patent Office
Office européen des brevets

SPC’s and Patent Term Extensions Series: protection beyond 20 years in Europe, in Japan, and in Korea and China


Jutta Haußer, Sofie Leplae, Jürgen Mühl

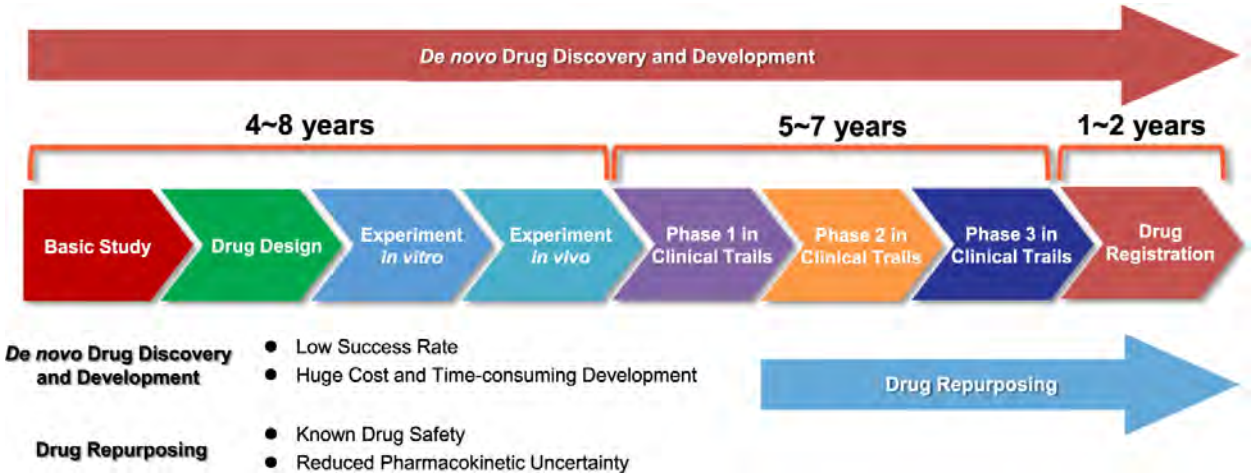
INTRODUCTION: Definition of Patent Term Extension

A Patent Term Extension/Supplementary Protection Certificate (SPC) is an intellectual property right that serves as an extension to a **patent** right.

It applies to specific pharmaceutical and plant protection products that have been authorised by regulatory authorities.

An SPC can extend a patent right for a maximum of five years.

INTRODUCTION: Drug Discovery Process



- Long
- Expensive
- Outcome uncertain

If successful, very successful

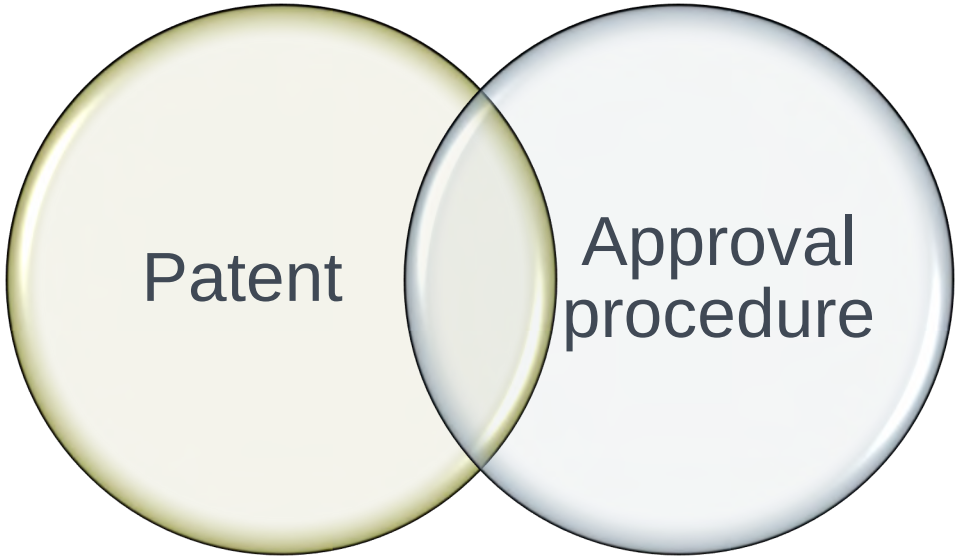
The top 20 drugs by worldwide sales in 2020

1. Humira (adalimumab) $20.39 billion
2. Keytruda (pembrolizumab) $14.38 billion
3. Revlimid (lenalidomide) $12.15 billion

Zhang, Z., Zhou, L., Xie, N. *et al.* Overcoming cancer therapeutic bottleneck by drug repurposing. *Sig Transduct Target Ther* **5,** 113 (2020). https://doi.org/10.1038/s41392-020-00213-8

INTRODUCTION: Patent Linkage System

Hybrid system: basic patent and regulatory marketing approval (Patent Linkage System)



INTRODUCTION:

Countries with Patent term extension

- EU, EEA (Iceland, Norway, Liechtenstein) and Switzerland, UK, Israel, US, Canada, Japan, Korea, Chinese Taipei, Australia, Russia, Singapore…

https://iiprd.wordpress.com/2019/07/04/patent-term-extension-in-different-countries/

INTRODUCTION:

Countries with Patent term extension

- EU, EEA (Iceland, Norway, Liechtenstein) and Switzerland, UK, Israel, US, Canada, Japan, Korea, Chinese Taipei, Australia, Russia, Singapore…

Countries without patent term extension laws

- Brazil, Mexico, …

https://iiprd.wordpress.com/2019/07/04/patent-term-extension-in-different-countries/

Content Online seminar Series

Today 26.5.2021 2 p.m.

- European Union

2.6.2021 2 p.m. (KL24-2021)

- Japan

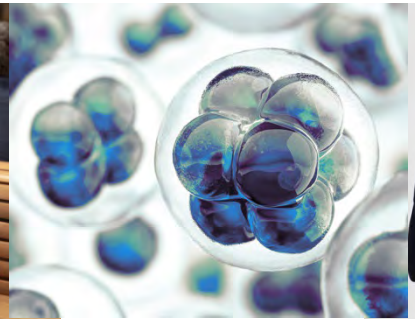
23.6.2021 2 p.m. (KL25-2021)

- Korea and China

Europäisches Patentamt
European Patent Office
Office européen des brevets

EU: Supplementary Protection Certificate (SPC)

EU regulation and national procedure


Today

1. EU Regulation and national law
2. Product approval procedure
3. Where to find SPC Information

1. EU Regulation and national law
2. Product approval procedure
3. Where to find SPC Information

EU: Purpose of the EU regulation

- putting EU industry on **equal level with US and Japan**
- preserving the **integrity** of the **common market**
  (Italy and France had developed own national law)
- adequate **protection** of pharmaceutical research
- **public health** interests
- **compensation** for long period between filing of patent and market authorization of a product

EU: EU regulation

- In 1992 creation of a supplementary protection certificate for **medicinal products**; entered into force in January 1993 (No 1768/92)
- In 1996 SPC for **plant protection products** (No 1610/96)
- In 2006 **Paediatric extension** of 6 months (No 1902/2006)
- In 2009 legislation was **codified** (No 469/2009)
- In 2019 **SPC manufacturing waiver** added (No 2019/933)
- In 2020 **Evaluation of Regulations**

EUR-Lex

Council regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products

Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products

Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 amending Regulation 1901/2006 on medicinal products for paediatric use (Text with EEA relevance)

Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version) (Text with EEA relevance)

Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (Text with EEA relevance.)

Evaluation of Regulations 469/2009 and 1610/96 concerning supplementary protection certificates

Summary: Supplementary protection certificates for medicines and plant protection products

EU: SPC and effects of the Brexit

Brexit transition – Stakeholder guidance on EU rules related to supplementary protection certificates for medicinal and plant protection products

Published on: 20/03/2020

Since 1 February 2020, the UK has withdrawn from the EU. The 'withdrawal agreement' provides for a transition period ending on 31 December 2020. As of 1 January 2021 there will be broad and far-reaching consequences, regardless of the outcome of ongoing Brexit negotiations. Stakeholders must make sure they are ready for them.

To assist, the European Commission is reviewing, and where necessary updating, the over 100 sector-specific stakeholder 'preparedness notices' it published during the Article 50 negotiations with the United Kingdom.

An updated so-called 'notice for readiness' for EU rules related to supplementary protection certificates for medicinal and plant protection products has been issued and can be found underneath.

All interested parties are reminded of the legal situation applicable as of the end of the transition period whether a future partnership agreement is concluded or not.

The notice also explains certain rules of the withdrawal agreement where relevant as well as the rules applicable to Northern Ireland as of the end of the transition period.

NOTICE TO STAKEHOLDERS

https://ec.europa.eu/growth/content/brexit-%E2%80%93-guidance-stakeholders-impact-field-supplementary-protection-certificates-medicinal_en

EU: SPC and Unitary Patent Package

- The 'patent package' that lays the ground for the creation of unitary patent protection in the EU does not explicitly provide for a 'unitary SPC'.

- To ensure that companies which choose unitary patent protection can benefit from the SPC extension, the European Commission is working on the articulation of unitary patent protection and SPC legislation.

- SPC information for unitary patens will be made available in the EP Register

EU: Regulation - content

- IP right

- Pharmaceutical, veterinary and plant protection products

Vibrance® Gold

EU: EU Regulation - content

Conditions for obtaining an SPC:

1. Product must be protected by a **basic patent**

2. Valid market authorisation must already exist

3. SPC for the product cannot already exist

4. The **valid market authorisation** is the **first place to place the product on the market**

EU: EU Regulation - content

- **SPC only granted to patent holder(s)** of basic patent (at the time of SPC grant), NOT to different authorisation holder or licensee

- **More than one SPC** per patent can be requested

EU: EU Regulation - content

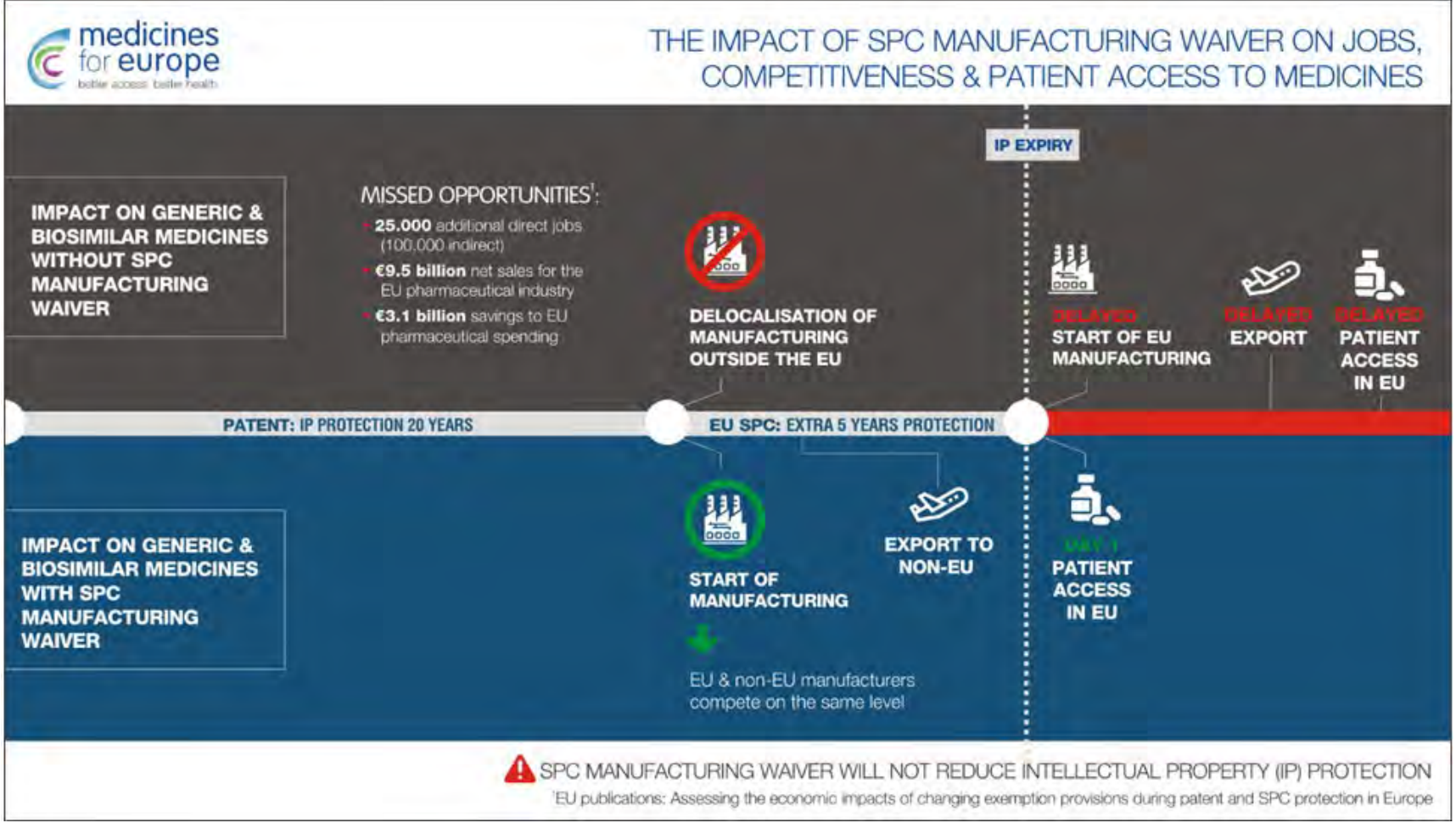
- **Paediatric extension:**
  - **IP right**
  - **6 months of additional protection**
  - Only if an SPC is granted
  - Agreed completed Paediatric Investigation Plan

Key facts	
Invented name	Comirnaty
Active substance	highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2)
Therapeutic area	Vaccines
Decision number	P/0179/2021
PIP number	EMEA-002861-PIP02-20-M01
Pharmaceutical form(s)	Concentrate for solution for injection
Condition(s) / indication(s)	Prevention of Coronavirus disease 2019 (COVID-19)
Route(s) of administration	Intramuscular use
Contact for public enquiries	BioNTech Manufacturing GmbH E-mail: ruben.rizzi@biontech.de Tel. +49 61319084-7593
Decision type	PM: decision on the application for modification of an agreed PIP

EU: Manufacturing and stockpiling Waiver

- In force since 1 July 2019
- **manufacture a generic or biosimilar version of an SPC-protected drug**, if done exclusively for **exporting** out of the EU to markets where IP protection for the drug has expired or never existed.
- right to **stockpile** in country of manufacture for release on to the EU market upon SPC expiry during the last six months of the validity of the SPC

> The new regulation will enable generics manufacturers based within the EU to compete with non-EU manufacturers on equal terms. It will create high-value jobs and boost the availability of generic medicines in the EU.
>
> — Niculae BĂDĂLĂU, Romanian Minister of economy



http://www.spcwaiver.com/en

EU: Third party observations, opposition and appeal

- Majority of countries allow for third party observations (not in GR, LT, CH) *
- With the exception of Denmark, no country allows for opposition to SPCs.
- Appeals:

Article 18

Appeals

The decisions of the authority referred to in Article 9(1) or of the bodies referred to in Articles 15(2) and 16(2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version) (Text with EEA relevance)

* Source: Study on the legal aspects of supplementary protection certificates in the EU, European Commission, EU publication, 2018

EU: SPC fee structure – national law

20.2.16 Payment of fees (EURO)

Country	Filing an SPC application	1st year	2nd year	3rd year	4th year	5th year	Request for extension of duration	Additional information
Austria	363	2,611	3,029	3,448	3,864	4,282	258	
Croatia*	Adm. fee 20 + coverage charges 400	1,500	2,000	2,400	2,800	3,200	330	In case of late payment (grace period 6 months), the specified amounts double
Czech Republic *	191	994	1,070	1,147	1,223	1,299	-	
Denmark *	403 Paed. ext. – 336	685	685	685	685	685	403 (re-establishment fee)	Fee for appeal: 537; fee for administrative re-examination: 2,012
Finland	500	900	900	900	900	900	500	Decision fee under section 71a of the Finnish Patents Act: 450 and annual fee for each year or part of it: 900
France	520	940	940	940	940	940	470	
Germany	300	2,650	2,940	3,290	3,650	4,120	100 (if filed with SPC request) 200 (if filed separately)	6th year (extension) – 4520
Greece	250	1,200	1,300	1,400	1,500	1,800		Filing fees for duration of the validity of an SPC for paediatric medicines 6 months extension – 1200

Source: Table 20.2.16 in:Study on the legal aspects of supplementary protection certificates in the EU, European Commission, EU publication, 2018

EU: SPC Numbers 1990-2015

Table 19: SPCs by country

Country	Total Patents	SPC Applications	SPC Grants	SPC Refusals
Austria	2,636	774	618	78
Belgium	2,671	752	496	91
Bulgaria	863	181	105	20
Croatia	506	79	19	1
Czech Republic	1,146	272	165	33
Denmark	2,411	742	596	126
Estonia	628	145	121	6
Finland	1,853	571	385	19
France	2,845	775	582	135
Germany	2,923	942	560	219
Greece	2,308	531	455	23
Hungary	1,218	338	177	60
Iceland	363	101	66	8
Ireland	2,211	669	486	100
Italy	2,692	771	722	55
Latvia	967	211	155	15
Lithuania	911	201	119	11
Luxembourg	2,484	658	656	7
Netherlands	2,648	782	668	134
Norway	978	387	324	32
Poland	931	213	74	41
Portugal	2,137	542	421	68
Romania	1,167	234	126	15
Slovak Republic	1,020	203	147	21
Slovenia	1,120	282	254	26
Spain	2,709	643	535	165
Sweden	2,632	770	630	117
Switzerland	2,717	631	539	66
UK	2,797	807	566	134
Total	52,492	14,207	10,767	1,826

Kyle, Margaret. “Economic Analysis of Supplementary Protection Certificates in Europe”. 2017, table 19 page 24.

Overview of this presentation

1. EU Regulation and national law
2. Product approval procedure
3. Where to find SPC Information

EU: Authorisation of medicinal products

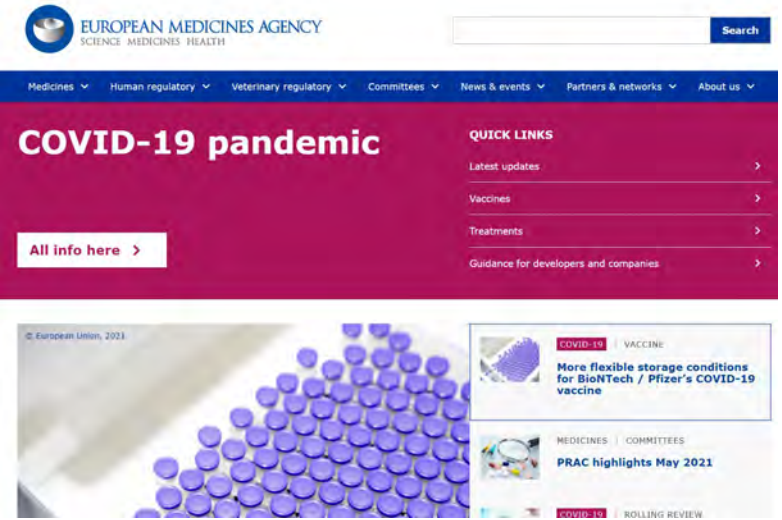
- **Centralised** procedure

  “European Medicines Agency” (EMA) gives advice; European commission decides.

- **Mutual recognition** procedure

- **National** authorisation procedure
  - mutual recognition procedure in EEA (including Switzerland)
  - decentralised procedure

EU: Medicines (human and veterinary)– centralised procedure "European Medicines Agency" (1995)



https://www.ema.europa.eu/en

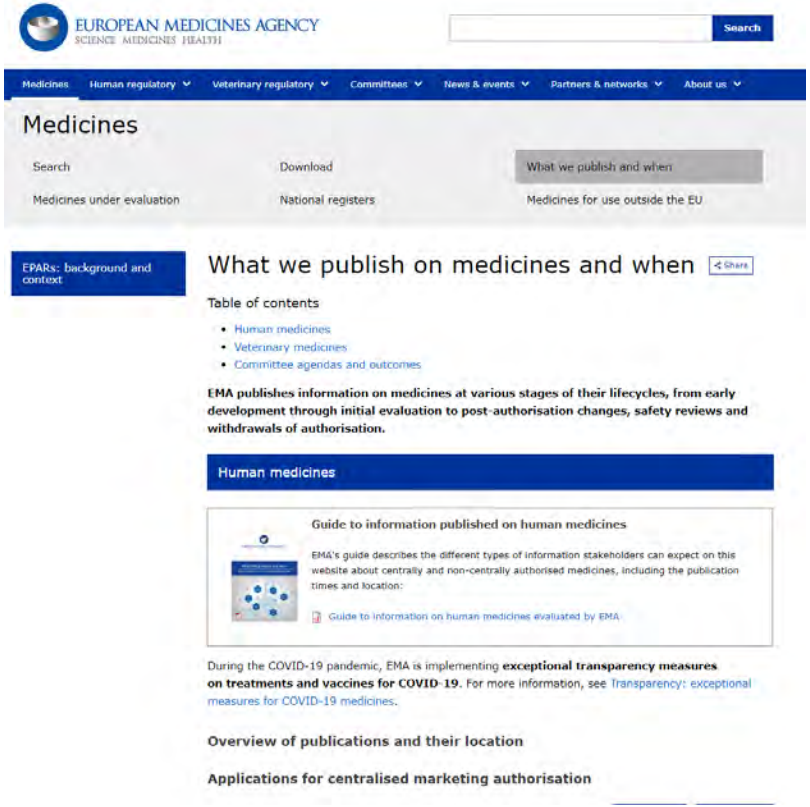
The European Medicines Agency (EMA) is a decentralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.

Centralised Procedure: single marketing authorisation.

Compulsory for:

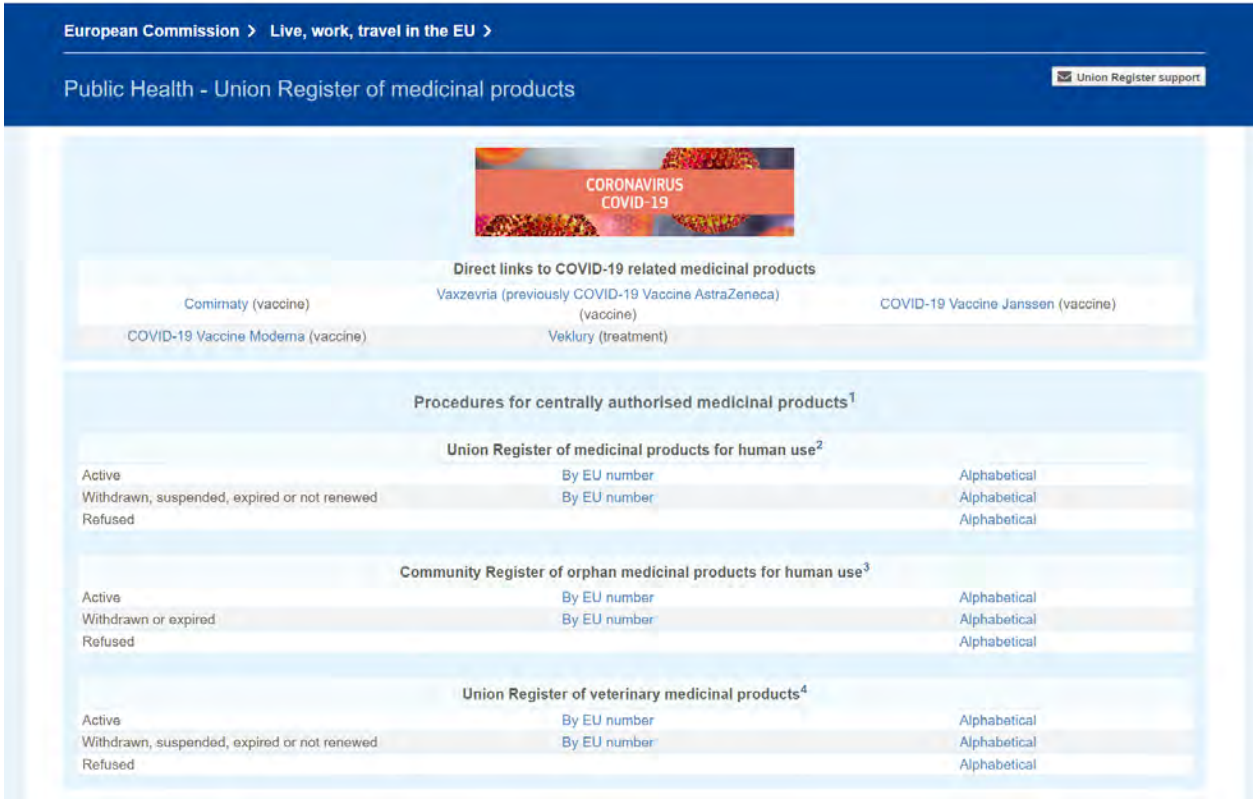
- human medicines containing a new active substance to treat: human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS); cancer; diabetes; neurodegenerative diseases; auto-immune and other immune dysfunctions; viral diseases.
- medicines derived from biotechnology processes, such as genetic engineering;
- advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;
- orphan medicines (medicines for rare diseases);
- veterinary medicines for use as growth or yield enhancers.

EU: European Medicines Agency



https://www.ema.europa.eu/en/medicines/what-we-publish-medicines-when

EU: Community Register



EU: Union Register

Union Register of medicinal products for human use

Search:

EU #	Brand name	Marketing Authorisation Holder
EU/1/14/944	Abasaglar	Eli Lilly Nederland B.V.
EU/1/20/1515	Abevmy	Mylan IRE Healthcare Limited
EU/1/04/276	Abilify	Otsuka Pharmaceutical Netherlands B.V.
EU/1/13/882	ABILIFY MAINTENA	Otsuka Pharmaceutical Netherlands B.V.
EU/1/20/1512	Abiraterone Accord	Accord Healthcare S.L.U.
EU/1/07/428	Abraxane	Bristol-Myers Squibb Pharma EEIG
EU/1/07/412	Abseamed	Medice Arzneimittel Pütter GmbH & Co KG
EU/1/14/946	Accofil	Accord Healthcare S.L.U.
EU/1/05/308	Aclasta	Novartis Europharm Limited
EU/1/13/817	Actelsar HCT	Actavis Group PTC ehf.
EU/1/00/150	Actos	Takeda Pharma A/S
EU/1/02/229	Actraphane	Novo Nordisk A/S
EU/1/02/230	Actrapid	Novo Nordisk A/S

Product information

Product name:	Comirnaty ACTIVE
EU number:	EU/1/20/1528
Active substance:	COVID-19 mRNA Vaccine (nucleoside modified)
Indication:	Comirnaty is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older. The use of this vaccine should be in accordance with official recommendations.
Marketing Authorisation Holder:	BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Deutschland
ATC:	Anatomical main group: J - General antiinfectives for systemic use Therapeutic subgroup: J07 - Vaccines Pharmacological subgroup: J07B - Viral vaccines Chemical subgroup: J07BX - Other viral vaccines Chemical substance: J07BX03 - covid-19 vaccines (See WHO ATC Index)
Links to EMA website:	EMA - Comirnaty

https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

EU: National authorities

https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human
https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-veterinary

National competent authorities (human)

Share

Table of contents

- List of national competent authorities in the EEA
- Information on coronavirus disease (COVID-19)

The European Medicines Agency works closely with the national competent authorities of the Member States of the European Union (EU) and the European Economic Area (EEA) responsible for human medicines.

The national competent authorities are primarily responsible for the authorisation of medicines available in the EU that do not pass through the centralised procedure.

They also supply thousands of European experts who serve as members of the Agency's scientific committees, working parties or in assessment teams supporting their members.

For more information on how EMA works together with the national competent authorities, see European medicines regulatory network.

List of national competent authorities in the EEA

Country	Name	Contact details
Austria	Austrian Agency for Health and Food Safety	Spargelfeldstraße 191 1220 Wien Austria Tel. +43 5 0555-0 Fax +43 5 0555-22019 www.ages.at
Belgium	Federal Agency for Medicines and Health Products	Eurostation building, block 2 place Victor Horta, 40/ 40 1060 Brussels Belgium Tel. +32 2 524 7111 E-mail: info.medicines@fagg-afmps.be www.fagg-afmps.be/
Bulgaria	Bulgarian Drug Agency	8 Damyan Gruev Str. Sofia 1303 Bulgaria Tel. +359 2 890 35 55 Fax +359 2 890 34 34 E-mail: bda@bda.bg www.bda.bg

National competent authorities (veterinary)

Share

The European Medicines Agency works closely with the national competent authorities of the Member States of the European Union (EU) and the European Economic Area (EEA) responsible for veterinary medicines.

The national competent authorities are primarily responsible for the authorisation of medicines available in the EU that do not pass through the centralised procedure.

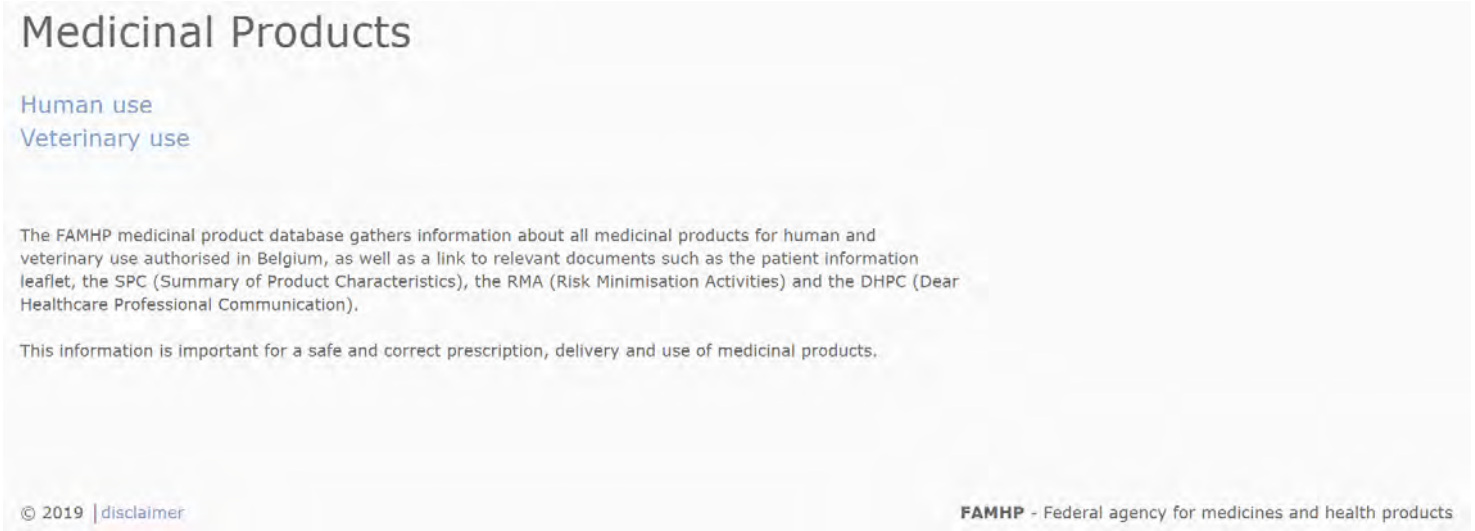
They also supply thousands of European experts who serve as members of the Agency's scientific committees, working parties or in assessment teams supporting their members.

For more information on how EMA works together with the national competent authorities, see European medicines regulatory network.

List of national competent authorities in the EEA

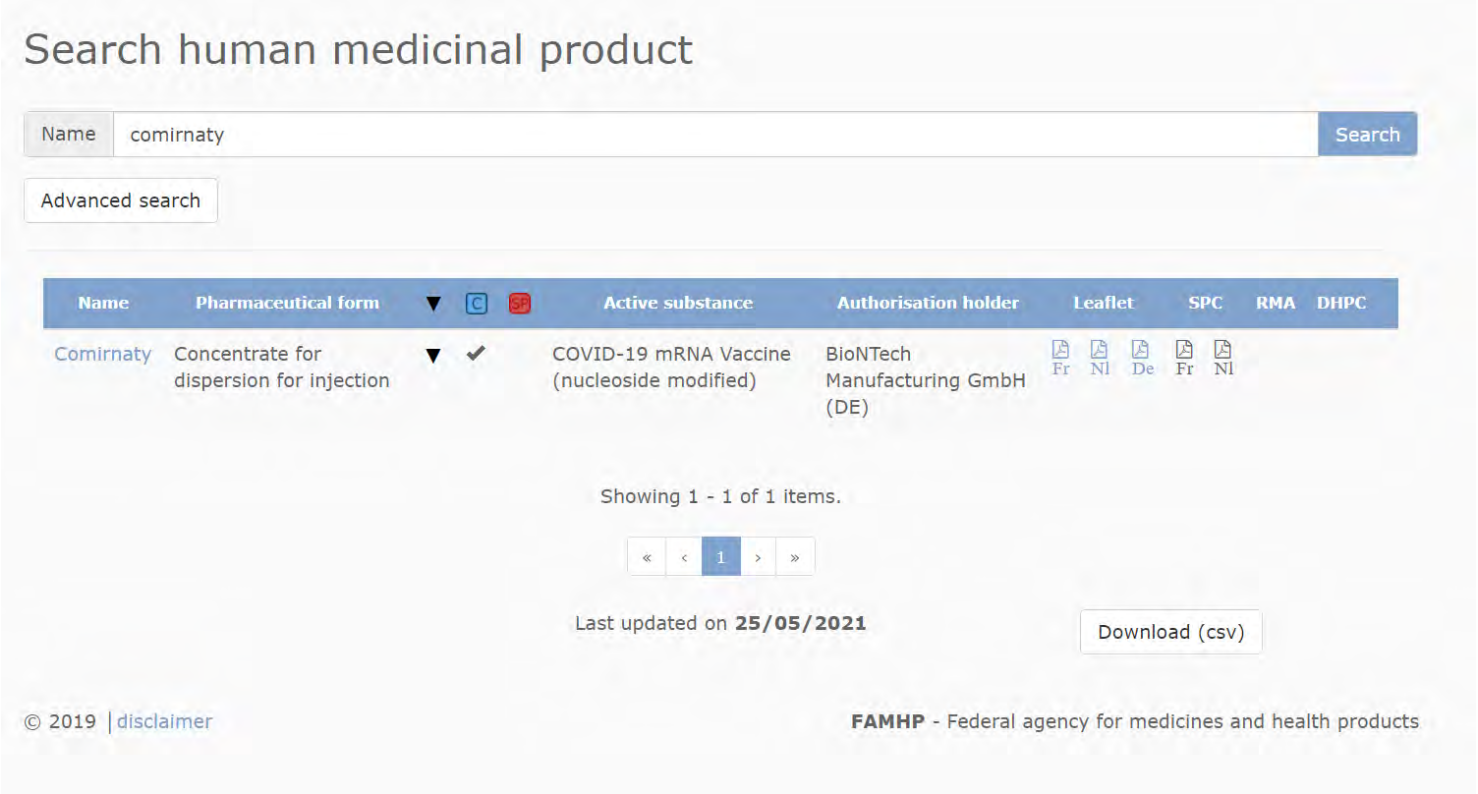
Country	Name	Contact details
Austria	Austrian Agency for Health and Food Safety	Spargelfeldstraße 191 220 Wien Austria Tel. +43 5 0555-0 Fax: +43 5 0555-22019 www.ages.at
Belgium	Federal Agency for Medicines and Health Products	Eurostation building, block 2 place Victor Horta, 40/ 40 1060 Brussels Belgium Tel. +32 2 524 7111 E-mail: info.medicines@fagg-afmps.be www.fagg-afmps.be/
Bulgaria	Bulgarian Food Safety Authority	15A Pencho Slaveikov blvd. 1606 Sofia Bulgaria Tel. +359 2 9159820 Fax: +359 2 9549593 E-mail: bfsa@bfsa.bg www.babh.government.bg/ www.babh.government.bg/en/

EU: National authority: example Belgium



https://banquededonneesmedicaments.afmps-fagg.be/#/

EU: National authority: example Belgium



Search human medicinal product

Name | comirnaty | Search

Advanced search

Name	Pharmaceutical form	▼ C SP	Active substance	Authorisation holder	Leaflet	SPC	RMA	DHPC
Comirnaty	Concentrate for dispersion for injection	▼ ✔	COVID-19 mRNA Vaccine (nucleoside modified)	BioNTech Manufacturing GmbH (DE)	Fr Nl De	Fr Nl		

Showing 1 - 1 of 1 items.

« ‹ 1 › »

Last updated on **25/05/2021**

Download (csv)

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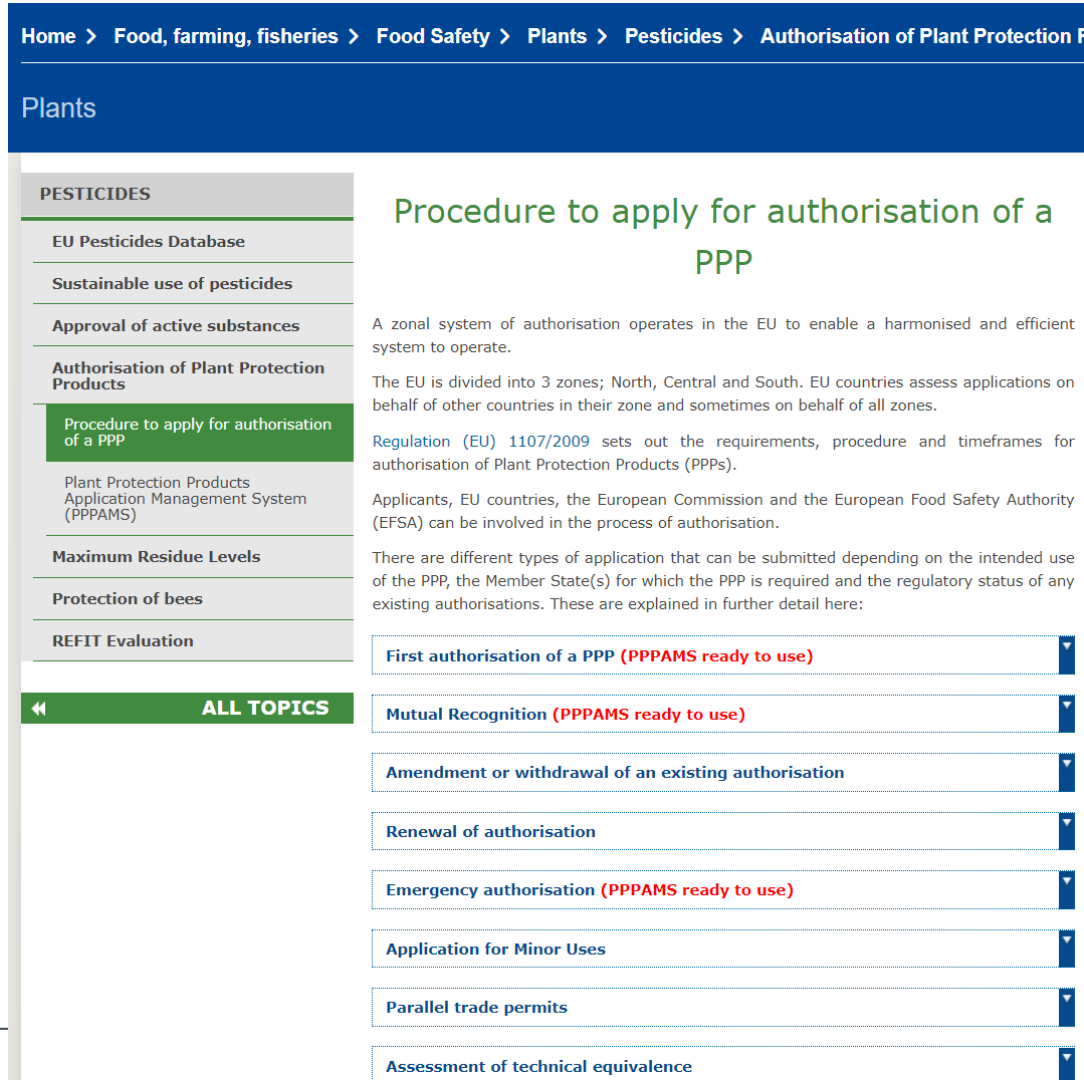
FAMHP - Federal agency for medicines and health products

EU: Authorisation of Plant Protection Products (PPP)



https://ec.europa.eu/food/plant/pesticides_en

EU: Authorisation of Plant Protection Products (PPP)

PPPs (also referred to as 'pesticides') are

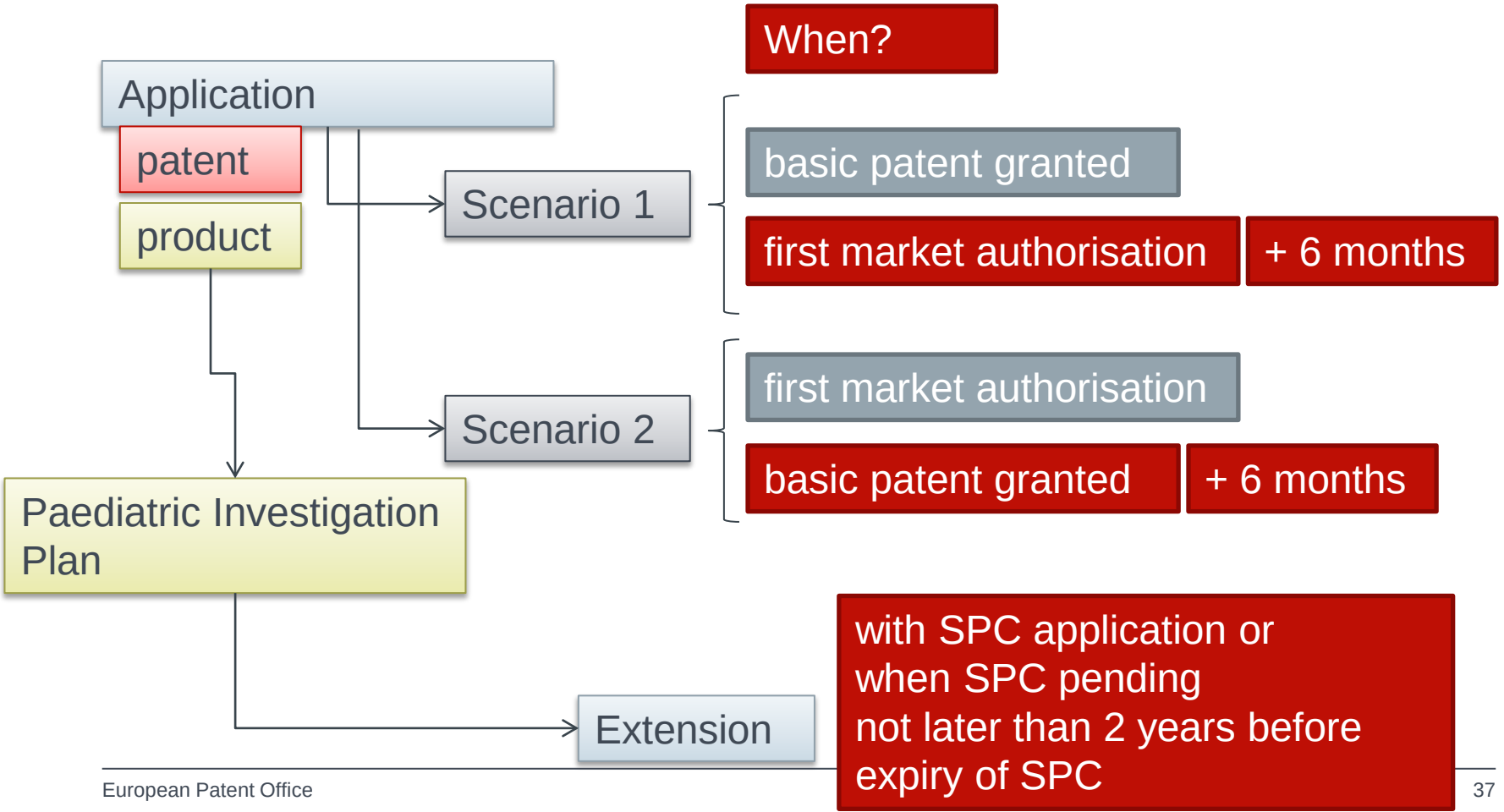
- products **in the form in which they are supplied** to the user
- **consisting of, or containing** active substances, safeners or synergists
- **intended for one of the following uses**: protecting plants or plant products, influencing the life processes of plants, preserving plant products, destroying undesired plants or parts of plants, …
- contain **at least one approved active substance**
- must be **authorised** in the EU country concerned (Regulation (EC) No 1107/2009)

EU: Authorisation of Plant Protection Products (PPP) - references

Arunasalam and De Corte: Supplementary protection certificates for plant protection products: the story of “The Ugly Duckling”, Journal of Intellectual Property Law & Practice, Volume 11, Issue 11, pages 833-840.

The importance of Supplementary Protection Certificates in protecting the EU PPP market from generic competition (by Nigel Uttley from Enigma Marketing research)

EU: Procedure



EU: Procedure

Manufacturing Waiver

The manufacturer must

- inform the relevant patent office and the SPC owner about his intended activities 3 months before they begin making the product for export (Article 5(2)(b)).

Example:

https://www.ipoi.gov.ie/en/types-of-ip/supplementary-protection-certificates/spc-waiver-notifications

SPC Waiver Notifications Received

Notifications filed in accordance with Article 5(2) (b) or (c) of Regulation EC No. 469/2009 (as amended)

Date of Notification	Name & Address of Maker	Purpose of Making	SPC No.	Notification

EU: Procedure

Manufacturing Waiver

The manufacturer must

- indicate on the packaging of the product that the product is for export only, by affixing the new EU export only logo (Article 5(2)(d)).

EU: Procedure

Stockpiling provision

- permits the manufacturer to make a product covered by an SPC, within the period 6 months before the expiry of the SPC, for the purpose of storing the product within the EU
- enables generics and biosimilar manufacturers to launch the product in Europe on day-1 of the expiry of the SPC, with the aim of improving patient access to medicines

http://patentblog.kluweriplaw.com/2019/06/11/spc-manufacturing-waiver-enters-into-force-in-july-2019/

EU: Duration of an SPC

Duration of SPC protection: maximum of 5 years

=

date of first Market Authorisation in the EEA*

- date of filing of corresponding patent
- 5 years

maximum of 15 years of exclusivity from the time the product gets the market authorization

EU: Expiry date of SPC

Country	Filing of the basic patent	Expiry date basic patent	Start date SPC	Latest expiry date SPC	Latest expiry date SPC paediatric extension
Austria, Croatia, Czech Republic, Denmark, Finland, Germany, Hungary, Latvia, Lithuania, Portugal, Romania, Spain, Sweden	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Greece	15.10.2015	16.10.2035	17.10.2035	16.10.2040	16.04.2041
Ireland, Netherlands	15.10.2015	14.10.2035	15.10.2015	14.10.2015	14.04.2041
Italy	15.10.2015	15.10.2035 (excluded)	15.10.2035	15.10.2040 (excluded)	15.04.2041
Poland	15.10.2015	15.10.2035	15.10.2035	15.10.2040	15.04.2041
Serbia	15,10.2015	15.10.2035 (included)	16.10.2035	15.10.2040 (included)	15.04.2041
Slovak Republic	15.10.2015	15.10.2035	16.10.2035	16.10.2040	16.04.2041
Switzerland	15.10.2015	14.10.2035 at midnight	15.10.2035	-	-

Source: **Study on the legal aspects of supplementary protection certificates in the EU. Final report – Study.** Published: 2018-05-31
https://publications.europa.eu/en/publication-detail/-/publication/6845fac2-6547-11e8-ab9c-01aa75ed71a1

EU: EP national entry sources at the EPO

				Bibliographic information			Legal information			
	Country code	EPC member state	EPC member since	New document number for translation of entry to national phase publication	EPO's kind code for translation publication	Translation publication available in DOCDB/patent family	Legal status INPADOC for national entry publication available in	Post-grant information available in EP Register	Federated register service available in EP Register	NEW: Date of exact EXPIRATION OF PROTECTION (20 years from filling: on, before or after)
1	AL	Albania	01 May 2010		no	no	no	yes	no	anniversary of filling
2	AT	Austria	01 May 1979	yes	T1-T9	yes **	EP application	yes	yes 01.2016	anniversary of filling
3	BE	Belgium	07 October 1977	only EP/BE ****	T1, T2****	yes**** **	EP application	yes	yes 11.2017	anniversary of filling
4	BG	Bulgaria	01 July 2002		no	no	no	yes	yes 05.2017	anniversary of filling
5	CH	Switzerland	07 October 1977	only EP/CH ****	no	yes	EP application	yes	yes 02.2016	1 day before anniversary
6	CY	Cyprus	01 April 1998	yes	T1, T2	yes ***	no	yes	no	anniversary of filling
7	CZ	Czech Republic	01 July 2002		no	no	no	yes	yes	anniversary of filling
8	DE	Germany	07 October 1977	*only EP/DE****	* T1-T9	* yes	EP application	yes	yes 08.2018	anniversary of filling
9	DK	Denmark	01 January 1990	only EP/DK*	T1-T7	yes	EP application	yes	no	anniversary of filling
10	EE	Estonia	01 July 2002	yes	B1-B9	yes	EP application	yes	no	1 day before anniversary
11	ES	Spain	01 October 1986	yes	T1-T9	yes	ES record	yes	yes 09.2016	anniversary of filling
12	FI	Finland	01 March 1996	yes	T3	yes	no	yes	yes 03.2016	anniversary of filling
13	FR	France	07 October 1977	*only EP/FR****	* T	* yes	EP application	yes	yes 10.2019	1 day before anniversary

https://www.epo.org/searching-for-patents/data/coverage/regular.html

EU: Example Liraglutide (Novo Nordisk)

★ **EP0944648A1** GLP-1 DERIVATIVES

Bibliographic data | **Description** | **Claims** | **Drawings** | **Original document** | **Citations** | **Legal events**

Register ↗ ⓘ **Global Dossier** ↗

Applicants	NOVO NORDISK AS [DK] +
Inventors	KNUDSEN LISELOTTE BJERRE [DK]; NIELSEN PER FRANKLIN [DK]; SOERENSEN PER OLAF [DK] +
Classifications	
IPC	***A61K31/00; A61K38/00; A61K38/26; A61K38/28; A61K47/48; A61P3/00; A61P3/04; A61P3/10; A61P5/50; C07K14/00; C07K14/605;*** (IPC1-7): A61K38/26; C07K14/605;
CPC	**A61K38/26 (EP); A61K38/28 (EP); A61K47/542 (EP); A61P3/00 (EP); A61P3/04 (EP); A61P3/08 (EP); A61P3/10 (EP); A61P5/50 (EP); C07K14/605 (EP);**
C-sets	**A61K38/28, A61K2300/00 (EP);**
Priorities	DK125996A·1996-11-08; DK147096A·1996-12-20; DK93196A·1996-08-30;
Application	EP97935509A·1997-08-22
Publication	EP0944648A1·1999-09-29

https://www.novonordisk.com/about-novo-nordisk/perspectives/mother-of-molecules.html

EU: Example SPC procedure at the national offices: Belgium

The procedure

How to obtain the certificate?

To obtain a supplementary protection certificate for a **medicine**, a request form (DOC, 109.5 Kb) must be filed with the Office for Intellectual Property.

To obtain a supplementary protection certificate for a **phytopharmaceutical product**, a request form (DOC, 106 Kb) must be filed with the Office for Intellectual Propert.

The request may be filed in French, Dutch or German.

Content of the request

The request file must contain:

1. The request form for a SPC addressed to the relevant Minister (2 copies);
2. A copy of the market authorisation (MA) issued in Belgium which identifies the product, the number and the date of the authorisation as well as a summary of the product characteristics as of the date on which the SPC request was filed;
3. If the MA was issued in Belgium prior to another market authorisation in the European Union, information on the identity of the product for which authorisation was issued and the legal basis of this authorisation as well as a copy of the publication of the authorisation in the Official Journal;
4. Where applicable, the proxy authorisation given to a representative of the requesting party (accredited patent agent, attorney, employee etc.).

Most of the data listed above may be provided after the request is filed. However, a **filing date for the request** may not be attributed unless the following minimum data and documents have been provided:

- A declaration of the request for a certificate;
- Information on the requesting party's identity;
- Information on the basic patent.

Cost

Official taxes must be paid for an SPC request and for its continuance.

economie

Home › Themes › Intellectual property › Patents › Supplementary protection certificates

Supplementary protection certificates (SPC) for medicines and phytopharmaceutical products

ROYAUME DE BELGIQUE
SERVICE PUBLIC FEDERAL ECONOMIE, P.M.E., CLASSES MOYENNES ET ENERGIE
DIRECTION GENERALE DE LA REGLEMENTATION ECONOMIQUE
OFFICE DE LA PROPRIETE INTELLECTUELLE

REQUETE EN DELIVRANCE D'UN CERTIFICAT COMPLEMENTAIRE DE PROTECTION POUR LES MEDICAMENTS

REQUETE AU MINISTRE DE L'ECONOMIE

LE(S) SOUSSIGNE(S) REQUIER(EN)T QUE LA PRESENTE DEMANDE DE CERTIFICAT COMPLEMENTAIRE DE PROTECTION POUR LES MEDICAMENTS (OU CERTIFICAT), Y COMPRIS UNE EVENTUELLE PROROGATION, SOIT TRAITEE CONFORMEMENT AU REGLEMENT (C.E.) N° 469/2009 DU PARLEMENT EUROPEEN ET DU CONSEIL DU 6 MAI 2009 CONCERNANT LE CERTIFICAT COMPLEMENTAIRE DE PROTECTION POUR LES MEDICAMENTS ET AU TITRE 2 « CERTIFICATS COMPLEMENTAIRES DE PROTECTION » DU LIVRE XI DU CODE DE DROIT ECONOMIQUE ET A SES ARRETES D'EXECUTION

- Les emplacements entourés d'un cadre épais sont réservés à l'Office de la Propriété Intellectuelle (OPRI)
- Mettre une croix dans les cases ☐ lorsque c'est nécessaire

DEMANDE DE CERTIFICAT : N°

DATE DE RECEPTION :

DATE DE DEPOT :

Référence du demandeur ou du représentant (15 caractères au maximum)

I. DEMANDEUR ☐ Les autres demandeurs sont mentionnés à la rubrique V.

Nom :		Numéro d'entreprise / de registre national :
Forme juridique :		Numéro de téléphone :
Adresse :		Numéro du fax :
Ville :		E-mail :

national rules

economie

FEDERAL PUBLIC SERVICE
Economy, S.M.E.s., Self-employed & Energy

Intellectual Property Office

SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS AND FOR PLANT PROTECTION PRODUCTS

CIRCULAR ON THE DATE OF THE AUTORISATION TO PLACE THE PRODUCT ON THE MARKET

This circular establishes the rules applicable before the Intellectual Property Office for determining the date of the authorisation to place a medicinal product or a plant protection product on the market. The purpose of this circular is to simplify and harmonize the different authorization regimes. As from 01/06/2016, these provisions apply to all current and future SPC applications.

The concept of 'the date of the authorisation to place the product on the market' occurs in Articles 7 and 13 of the Regulation (EC) n° 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products and in Articles 7 and 13 of the Regulation (EC) n°1610/96 of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

Article 7, §1, stipulates that : « *The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market [as a medicinal product] [as a plant protection product] was granted.* ».

Article 13, § 1, stipulates that: « *The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.* ».

The date taken into account for the different authorisations to place the product on the market (MA) is the following:

1. **Date of MA for a medicinal product granted by the European Commission**

   The date of the MA is the date of notification of the decision granting the marketing authorisation. This date is published in the Official Journal of the European Union.

2. **Date of MA for a medicinal product granted by the Federal Agency for medicines and health products (FAMHP)**

   The date of the MA is either the starting date of the validity period of the marketing authorisation, or the date of signature of the MA, if this date is later.

3. **Date of MA for a plant protection product granted by the Federal Public Service Health**

   The date of the MA is either the starting date of the validity period of the marketing authorisation, or the date of signature of the MA, if this date is later.

The circular of 22 September 2003 on the SPC grant procedures for medicinal products and for plant protection products is repealed at the date of 1 June 2016.

Brussels, 07/04/2016,

Stefan DRISQUE
Advisor

EU: Example Liraglutide (Novo Nordisk)

EP 0944648
Filed 22.08.1997
Granted 14.03.2007

First marketing authorization date
30/06/2009 - EU/1/09/529/001

Federated Register

GLP-1 DERIVATIVES

Application No.	Publication No.	Applicant	IPC
EP97935509	EP0944648	NOVO NORDISK A/S	C07K14/605 A61K38/26

Only designated contracting states, extension states and validation states providing the Federated Register Service are listed below

	Status	Application No.	Publication No.	Proprietor	Invalidation date	Not in force since	Renewal fees last paid	Record last updated
AT	Patent expired	EP97935509	EP944648	NOVO NORDISK A/S	12.09.2017	22.08.2017	—	—
BE	Patent expired	EP97935509	EP0944648	NOVO NORDISK A/S	22.08.2017	22.08.2017	20.07.2016	18.10.2020
CH/LI	Patent not in force	EP97935509	EP0944648	NOVO NORDISK A/S	21.08.2017	21.08.2017	—	28.08.2017
DE	Patent not in force	EP97935509	EP944648	Novo Nordisk A/S, 2880 Bagsvaerd, D...	—	—	—	30.10.2018
ES	Patent lapsed	E97935509	ES2283025	NOVO NORDISK A/S	29.11.2017	23.08.2017	27.07.2016 Latest annual fee paid: 20	—
FI	Patent expired	EP97935509	EP0944648	NOVO NORDISK A/S	—	22.08.2017	21.07.2016	25.05.2021
FR	Patent not in force	EP97935509	EP0944648	NOVO NORDISK A/S	—	—	20.07.2016 Latest annual fee paid: 20	21.05.2021
GB	Patent expired	EP97935509	EP0944648	NOVO-NORDISK A/S	—	21.08.2017	26.07.2016 Latest annual fee paid: 20	—
GR	Patent expired	EP97935509	GR3061947	NOVO NORDISK A/S	06.09.2017	23.08.2017	25.07.2016	06.09.2017
IE	Patent expired	EP97935509	EP0944648	NOVO NORDISK A/S	28.09.2017	28.09.2017	21.07.2016	04.11.2019
LT	Patent not validated	EP97935509	EP0944648	NOVO NORDISK A/S	—	—	—	18.04.2016

https://register.epo.org/application?number=EP97935509&lng=en&tab=federated

Authorisation details

Product details

Name	Victoza
Agency product number	EMEA/H/C/001026
Active substance	Liraglutide
International non-proprietary name (INN) or common name	Liraglutide
Therapeutic area (MeSH)	Diabetes Mellitus, Type 2
Anatomical therapeutic chemical (ATC) code	A10BJ02

Publication details

Marketing-authorisation holder	Novo Nordisk A/S
Revision	20
Date of issue of marketing authorisation valid throughout the European Union	30/06/2009
Contact address	Novo Allé DK-2880 Bagsvaerd Denmark

https://www.ema.europa.eu/en/medicines/human/EPAR/victoza

EU: Example Liraglutide (Novo Nordisk)

EP 0944648
Filed 22.08.1997
Granted 14.03.2007

First marketing authorization date
30/06/2009 - EU/1/09/529/001

SPC application in Belgium
2009C/050
Filing 23/10/2009
Grant 02/02/2010
Expiration date 22/02/2023
http://bpp.economie.fgov.be/fo-eregister-view/search/detailsType/2009CSLASH050/SPC

SPC application in the UK
SPC/GB09/058
Filing 11/12/2009
Grant 11/03/2011
Expiration date 21/08/2022
https://www.ipo.gov.uk/p-find-spc-bypatent-results.htm?number=EP0944648

SPC application in the Netherlands
300422
Filing 22/10/2009
Grant 16/02/2010
Expiration date 21/02/2023
http://mijnoctrooi.rvo.nl/fo-eregister-view/search/detailsType/300422/SPC

SPC application in the CH/LI C00944648/01
Filing 21/05/2010
Grant 31/10/2012
Expiration date 21/08/2022
https://www.swissreg.ch/srclient/faces/jsp/spc/sr300.jsp?language=en&section=spc&id=C00944648%2F01

EU: Paediatric investigation plan (PIP)

Medicines

Search | Download | What we publish and when

Medicines under evaluation | National registers | Medicines for use outside the E

victoza

For help on how to get the results you want, see our search tips.

Categories

Human (8)

Medicine name

Active substance / international non-proprietary name (INN) / common name

Medicine

European public assessment reports (EPAR) (7)

Paediatric investigation plans (1)

8 results

KEYWORD victoza

Sort by Relevance

Opinion/decision on a Paediatric investigation plan (PIP): Victoza, liraglutide

Decision type: PM: decision on the application for modification of an agreed PIP
Therapeutic area: Endocrinology, -gynacology-fertility-metabolism
PIP number: EMEA-000128-PIP01-07-M08, Route(s) of administration: Subcutaneous use, Pharmaceutical form(s): Solution for injection (in prefilled pen)
Decision date: 09/08/2017, Last updated: 29/09/2017, Compliance check: X

Investigation plan for liraglutide (**Victoza**), (EMEA-000128-PIP01-07-M08 … investigation plan for liraglutide (**Victoza**), (EMEA-000128-PIP01-07-M08 … investigation plan for liraglutide (**Victoza**), (EMEA-000128-PIP01-07-M08 …

Human medicine European public assessment report (EPAR): Victoza

Liraglutide, Diabetes Mellitus, Type 2

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/459439/2017

European Medicines Agency decision
P/0218/2017

of 9 August 2017

on the acceptance of a modification of an agreed paediatric investigation plan for liraglutide (Victoza), (EMEA-000128-PIP01-07-M08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

Overview of this presentation

1. EU Regulation and national law
2. Product approval procedure
3. Where to find SPC Information

EU: Where to find data on Patents and SPC's?

- National intellectual property registers: all EU members, Norway and Switzerland
- INPADOC worldwide legal event data available in Espacenet and GPI
- PAT-INFORMED (WIPO-IFPMA) (https://www.wipo.int/patinformed/)
- Commercial databases: for e.g. Cabinet Alice de Pastor (CAP) database, acquired by ENIGMA marketing research (for PPP products)

EU: National Patent Registers – Federated Register

Federated register: EP0944648

Refine search | ST36 | Espacenet | Submit observations | Report error | Print

GLP-1 DERIVATIVES

Application No.	Publication No.	Applicant	IPC
EP97935509	EP0944648	NOVO NORDISK A/S	C07K14/605 A61K38/26

Only designated contracting states and extension states providing the Federated Register Service are listed below.

	Status	Application No.	Publication No.	Proprietor	Invalidation date	Not in force since	Renewal fees last paid	Record last updated
AT	Patent expired	EP97935509	EP944648	NOVO NORDISK A/S	12.09.2017	22.08.2017	---	---
BE	---	EP97935509	EP0944648	NOVO NORDISK A/S	22.08.2017	22.08.2017	20.07.2016	07.02.2018
CH/LI	Patent not in force	EP97935509	EP0944648	NOVO NORDISK A/S	21.08.2017	21.08.2017	---	28.08.2017
DE	Patent not in force	EP97935509	EP944648	Novo Nordisk A/S, 2880 Bagsvaerd, D...	---	---	---	24.08.2017
ES	Patent lapsed	E97935509	ES2283025	NOVO NORDISK A/S	29.11.2017	23.08.2017	27.07.2016 Latest annual fee paid: 20	---
FI	Patent expired	EP97935509	EP0944648	NOVO NORDISK A/S	---	22.08.2017	21.07.2016	31.10.2018
GB	Patent expired	EP97935509	EP0944648	NOVO-NORDISK A/S	---	21.08.2017	26.07.2016 Latest annual fee paid : 20	---

EU: National Patent Registers

CC	SPC Number (for EP0944648)	First authorisation (Product: Liraglutide – Victoza)	filed	grant	Paediatric extension	max validity
AT	SPC 48/2009	EU/1/09/529/001 bis EU/1/09/529/005	23/11/2009	19/12/2014	Granted	22/02/2023
BE	2009C/050	EU/1/09/529/001-005 30/06/2009	23/10/2009	02/02/2010	Granted	22/02/2023
CH/LI	C00944648/01	SWISSMEDIC 59329 11/12/2009	21/05/2010	31/10/2012	No information	21/08/2022
DE	122009000079.6	EU/1/09/529/001-005 30/06/2009	27/05/2010	16/06/2011	Requested	22/08/2022
DK	CA 2009 00041	EU/1/09/529/001-5	29/10/2009		Granted	22-02-2023
ES	C200900054	EU/1/09/529/001-005 30/06/2009	06/11/2009	18/04/2011	Granted	22/08/2022
FI	C20090043	EU/1/09/529/001-005 30/06/2009	29/12/2009	27/04/2012	Granted	22/02/2023
FR	FR09C0054	EU/1/09/529/001-005 30/06/2009	23/10/2009	01/04/2011	granted	21/02/2023
GB	SPC/GB09/058	EU/1/09/529/001-005 30/06/2009	11/12/2009	11/03/2011	No information	21/08/2022
GR	20090800031	EU/1/09/529/001-005 30/06/2009	22/10/2009	27/04/2010	No information	23/08/2022
IE	2009/034	EU/1/09/529/001-005 30/06/2009	02/11/2009	27/10/2010	granted	21/02/2023
IT	132009901790907	EU/1/09/529/001-005 30/06/2009	07/12/2009	17/03/2010	granted	22/02/2023
LU	No information					
NL	300422	EU/1/09/529/001-005 30/06/2009	22/10/2009	16/02/2010	granted	21/02/2023
PT	383	EU/1/09/529/001-005 30/06/2009	26/10/2009	04/06/2010		22/02/2023
SE	SE 0990038-2	EU/1/09/529/001-005 30/06/2009	04/11/2009	02/02/2010	granted	22/02/2023

EP0944648A1 GLP-1 DERIVATIVES

EU: Espacenet

Available in

Bibliographic data | Description | Claims | Drawings | Original document | Citations | Legal events | Patent family

Data originating from sources other than the EPO may not be accurate, complete, or up to date.

Event indicator	Category	Event description	Countries	Event date	Effective date	Details
						NO/DATE: EU/1/09/529/001-005 20090630
AT SPCZ	G: Protection beyond IP right term	GRANT OF EXTENSION FOR AN SPC (PAEDIATRIC MEDICAMENT)		2019-12-15	2019-12-15	**Reference document** Country: AT Number: 356830 Kind: T
DE R420	G: Protection beyond IP right term	REQUEST FOR TERM EXTENSIONS (CHILDREN'S MEDICINES)		2019-12-17		**Reference document** Country: DE Number: 69737479 SPC information
FR SPCZ	G: Protection beyond IP right term	EXTENSION OF A SUPPLEMENTARY PROTECTION CERTIFICATE GRANTED [PAEDIATRIC EXTENSION]		2020-03-06		**SPC information** Number: 09C0054 Filing date: 2009-10-23 ExtensionDate: 2023-02-
NL SPCZ	G: Protection beyond IP right term	GRANT OF EXTENSION OF A SUPPLEMENTARY PROTECTION CERTIFICATE		2020-03-11	2020-03-05	**SPC information** Number: 300422 Filing date: 2009-10-22 Expiry date underlying patent: 2017-08-21 Details: PRODUCT NAME: LIRAGLUTIDE; REGISTRATION

Europe

EU: INPADOC legal status – events on SPC filing (GPI)

G	Protection beyond IP right term	This category covers legal events related to the protection of an IP right beyond its term.	Means of protection rights beyond IP right term covered include: • patent term adjustment (PTA) • term extension of a patent or utility model • supplementary protection certificate (SPC) • extension of a supplementary protection certificate (paediatric extension (PE). Events covered include: • protection beyond IP right term requested • protection beyond IP right term not requested • request found admissible • request refused • request withdrawn or deemed to be withdrawn • protection beyond IP right term not granted • protection beyond IP right term granted or registered. Events occurring after the protection right beyond IP right term was granted or registered are covered in other categories. E.g., the discontinuation of a granted supplementary protection certificate is covered in category H.

INPADOC classification scheme v. 1.0

EU: Legal status codes and categories

Authority	Event Code	Regional	First Date Filed	Last Application			Last Date Filed	No. Events	Date Created	Influence	Description ENG	Last Update ENG	Description ORI	Last Update ORI	Category (INPADOC classification scheme)	Category Description (INPADOC classification scheme)
BE	CCPV	EP	05-12-1991	EP	97105021	A	05-12-1991	1	20040206	+	GRANT OF A SUPPLEMENTARY PROTECTION CERTIFICATE	20180924	DELIVRANCE D'UN CERTIFICAT COMPLEMENTAIRE DE PROTECTION	20040206	G	PROTECTION BEYOND IP RIGHT TERM
BE	SPCD	EP	14-09-1994	EP	06820561	A	18-12-2006	22	20180919	-	SUPPLEMENTARY PROTECTION CERTIFICATE REJECTED	20180919	[NO DESCRIPTION IN ORIGINAL LANGUAGE]	20180919	G	PROTECTION BEYOND IP RIGHT TERM
BE	SPCE	EP	04-06-1992	EP	07836007	A	06-07-2007	51	20180919		FILING FOR A PAEDIATRIC EXTENSION OF A SUPPLEMENTARY PROTECTION CERTIFICATE	20180919	[NO DESCRIPTION IN ORIGINAL LANGUAGE]	20180919	G	PROTECTION BEYOND IP RIGHT TERM
BE	SPCF	EP	21-09-1994	EP	14800179	A	03-10-2014	498	20180919		SUPPLEMENTARY PROTECTION CERTIFICATE FILED	20180919	[NO DESCRIPTION IN ORIGINAL LANGUAGE]	20180919	G	PROTECTION BEYOND IP RIGHT TERM
BE	SPCG	EP	14-09-1994	EP	05823930	A	21-12-2005	122	20040219	+	SUPPLEMENTARY PROTECTION CERTIFICATE GRANTED	20180919	DELIVRANCE DE CERTIFICAT COMPLEMENTAIRE	20040219	G	PROTECTION BEYOND IP RIGHT TERM
BE	SPCZ	EP	04-06-1992	EP	01946365	A	15-06-2001	35	20180919	+	GRANT OF PAEDIATRIC EXTENSION OF A SUPPLEMENTARY PROTECTION CERTIFICATE	20180919	[NO DESCRIPTION IN ORIGINAL LANGUAGE]	20180919	G	PROTECTION BEYOND IP RIGHT TERM
CH	SPCF		15-03-1973	CH	364791	A	11-12-1991	179	20060206		SUPPLEMENTARY PROTECTION CERTIFICATE FILED	20060206	ZERTIFIKATSANMELDUNG	20060206	G	PROTECTION BEYOND IP RIGHT TERM
CH	SPCF	EP	28-06-1978	EP	14825154	A	23-12-2014	1163	20060206		SUPPLEMENTARY PROTECTION CERTIFICATE FILED	20060206	ZERTIFIKATSANMELDUNG	20060206	G	PROTECTION BEYOND IP RIGHT TERM
CH	SPCG		15-03-1973	CH	364791	A	11-12-1991	118	19700101	+	SUPPLEMENTARY PROTECTION CERTIFICATE GRANTED	20020206	ZERTIFIKATSERTEILUNG	20020206	G	PROTECTION BEYOND IP RIGHT TERM
CH	SPCG	EP	28-06-1978	EP	14802502	A	28-10-2014	958	19700101	+	SUPPLEMENTARY PROTECTION CERTIFICATE GRANTED	20020206	ZERTIFIKATSERTEILUNG	20020206	G	PROTECTION BEYOND IP RIGHT TERM
CH	SPCR		06-12-1973	CH	383887	A	02-10-1987	17	19700101		SUPPLEMENTARY PROTECTION CERTIFICATE REJECTED	20020206	ZERTIFIKATSANMELDUNG ZURUECKGEWIESEN	20020206	G	PROTECTION BEYOND IP RIGHT TERM

PAT-INFORMED: how to link patents to products?

The **Pat**ent **In**formation Initiative **for Med**icines (Pat-INFORMED)

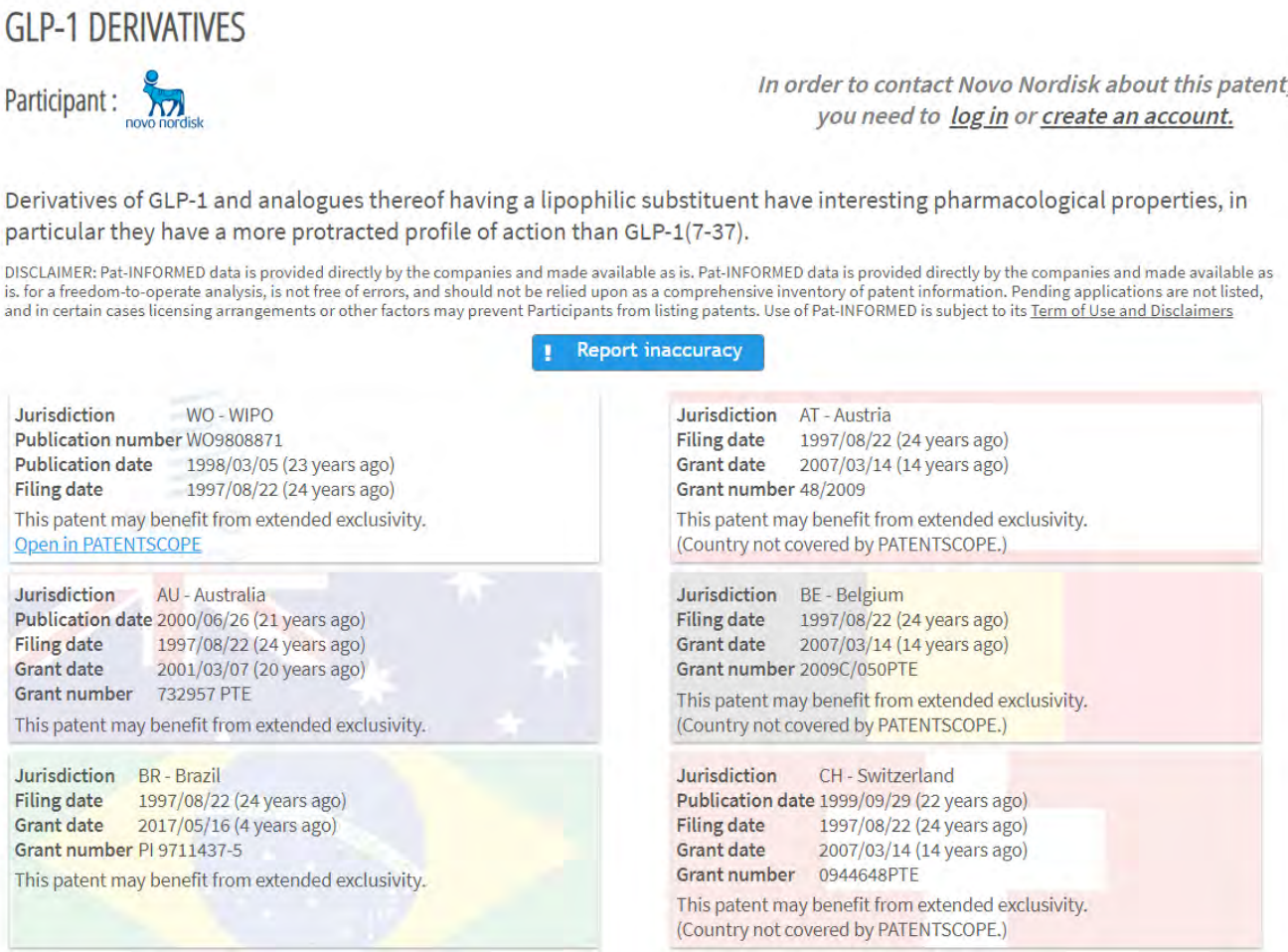
- Pat-INFORMED provides information about key patents on medicines. So far, Pat-INFORMED houses information on over 14,000 individual patents, for 600 patent families and 160 distinct products.
- At this time, the scope of the database covers medicines in six therapeutic areas, plus a number of other patented products belonging to the World Health Organization Essential Medicines List. As the project moves forward, it will likely be expanded to additional therapeutic areas.

https://www.wipo.int/pat-informed/en

PAT-INFORMED: Liraglutide

INN	Participant	Patents
Liraglutide Recombinant	novo nordisk	LIRAGLUTIDE IN CARDIOVASCULAR CONDITIONS
		GLP-1 DERIVATIVES
		PROPYLENE GLYCOL-CONTAINING PEPTIDE FORMULATIONS WHICH ARE OPTIMAL FOR PRODUCTION AND FOR USE IN INJECTION DEVICES
		STABLE FORMULATION OF MODIFIED GLP-1
Semaglutide	novo nordisk	PROPYLENE GLYCOL-CONTAINING PEPTIDE FORMULATIONS WHICH ARE OPTIMAL FOR PRODUCTION AND FOR USE IN INJECTION DEVICES
		STABLE FORMULATION OF MODIFIED GLP-1

PAT-INFORMED: how to link patents to products?



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Patent Data Services team: patentdata@epo.org

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