

MedsPal

THE MEDICINES PATENTS AND LICENCES DATABASE

Update on publicly accessible databases of patent status information concerning medicines and vaccines, WIPO 31st SCP, Geneva, December 3, 2019



- 1. Introduction to the Medicines Patent Pool
- 2. Background on MedsPaL
- 3. How is patent data collected
- 4. Demonstration
- 5. Latest developments/Updates
- 6. Feedback / Use



Introduction to the Medicines Patent Pool



The Medicines Patent Pool: a public health voluntary licensing organisation

Created in 2010 as first voluntary licensing and patent pooling mechanism in public health

to increase access to new treatments for HIV through licensing of patented medicines

and facilitate innovation
e.g. new fixed dose combinations and
paediatric formulations

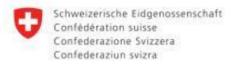
In 2015, expanded mandate to Hepatitis C and Tuberculosis

In 2018, decision to expand to other patented essential medicines



MPP's activities in HIV, HCV and TB are funded by:

MPP's expansion into patented essential medicines is undertaken with financial support from:



Swiss Agency for Development and Cooperation SDC





Background on MedsPaL



April 2011

Launch of the MPP Patent
Status Database, an
enhanced worksheet including
24 HIV medicines in 88
countries



October 2016

Launch of MedsPaL as the most comprehensive source of information on the patent and licensing status of medicines for HIV, TB, hepatitis C and other patented essential medicines in low- and middle-income countries







Most comprehensive FREE source of information on the patent and licensing status of **patented essential medicines** in low- and middle-income countries.

Patent status data on more than

8000

NATIONAL PATENT APPLICATIONS

from over 130 LMICs

Covering approximately

100

PRIORITY MEDICINES

(approx. 200 formulations)



10

With

information on

4U LICENCES

and other access agreements in LMICs

And data exclusivity information from

15
COUNTRIES

www.medspal.org

Widely endorsed by public health organisations:



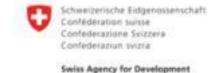












and Cooperation SDC



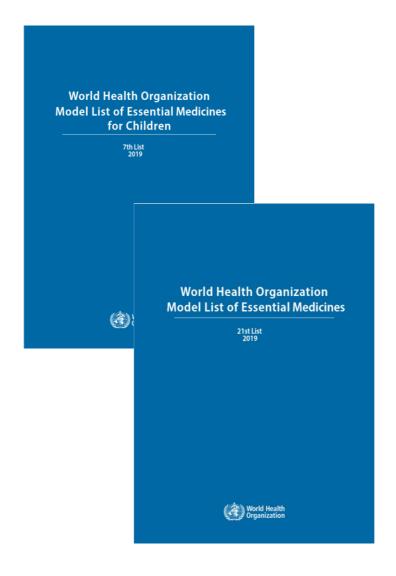


Patented medicines for the treatment of HIV, hepatitis C and tuberculosis that are (or were) included in WHO treatment guidelines

Patented medicines on WHO Essential Medicines list (EML)

Products in late stage development / Recent regulatory filings / Recommended treatment regimens





Possible future priority medicines as identified by WHO and other public health stakeholders



How is patent data collected



How is national/regional patent data obtained?

- USFDA Orange book $\stackrel{\bullet}{\blacksquare}$
- Health Canada patent register 🏰
- Publicly available licences
- Published patent landscapes (e.g. by WHO or UNITAID)

1- Identification of basic/relevant patents



Automated processes



1- Identification of basic/relevant patents

Search for the INN Dolutegravir in Health Canada Patent Register



Home > Drugs & Health Products > Drug Products > Patent Register

Search results for medicinal ingredient

From Health Canada

Search results for medicinal ingredient **DOLUTEGRAVIR SODIUM**

To view detailed patent and submission information select the link for the record you wish to view.

Filter items Showing 1 to 3 of 3 entries | Show 10 ventries

Medicinal ingredient search results

Medicinal ingredient ↑↓	Brand name ↑↓	Strength 🚹 👃	Dosage 🚹 👃	DIN 1	Patent 🚹 👃
dolutegravir sodium	TIVICAY	50 mg	tablet	02414945	<u>2606282</u>
dolutegravir sodium	TIVICAY	10 mg	tablet	02461218	<u>2606282</u>
dolutegravir sodium	TIVICAY	25 mg	tablet	02461226	<u>2606282</u>



1- Identification of basic/relevant patents

Search for the INN Dolutegravir in US FDA Orange Book



Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

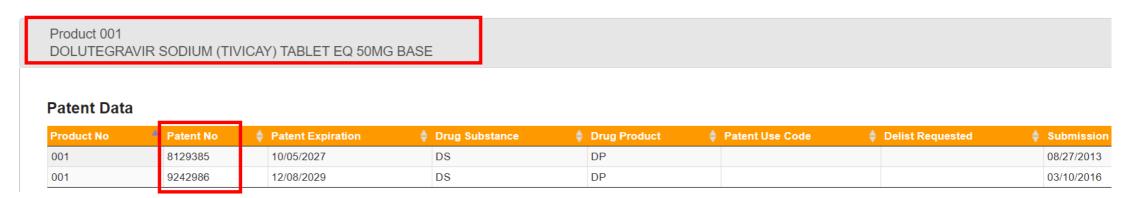


Home | Back to Product Details

Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53(d)(5).
- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specither the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that r NDA holder or patent owner.

Patent and Exclusivity for: N204790





1- Identification of basic/relevant patents

Patent data disclosed in publicly available licences e.g. MPP and ViiV Healthcare agreement on Dolutegravir

Appendix E, Part B: Non-Territory Patents in respect of the DTG Compound registered in countries which fall within Appendix C but do not fall within Appendix B (Territory):

Country	Application Number	Application Date	Patent Number
Albania	AL/P/2015/000276	24-Jan-2011	5403
Algeria	70738	28-Apr-2006	5531
	120523	24-Jan-2011	
Azerbaijan	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Belarus	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Bosnia and Herzegovina	11737484.3	24-Jan-2011	EP2531027
Brazil	PI0610030-9	28-Apr-2006	
	PI0923217-6	8-Dec-2009	
	BR1120120186701	24-Jan-2011	
Bulgaria	6758843.4	28-Apr-2006	1874117
	11737484.3	24-Jan-2011	EP2531027
China P.R.	2.00680022891.4	28-Apr-2006	ZL200680022891.4
	2.00980135216.6	23-Jul-2009	ZL200980135216.6
	201310734307.X	23-Jul-2009	ZL201310734307.X
	2.01510553862.2	2-Sep-2015	
	200980149670.7	9-Dec-2009	ZL200980149670.7
	201510071074.9	9-Dec-2009	
	200980149697.6	8-Dec-2009	ZL200980149697.6
	201180015114.8	24-Jan-2011	ZL201180015114.8
Colombia	07-115501	28-Apr-2006	1886
	12-125.933	24-Jan-2011	6085
Costa Rica	2012-423	24-Jan-2011	

How is national/regional patent data obtained?

2 -Collection of related patent family information

• INPADOC Patent family



- WIPO Patentscope
- Patent holder disclosures (e.g. to national patent offices; Pat-Informed, MPP licences)



Automated processes



2 - Collection of related patent family information

Search for equivalent patents/patent applications available in public databases such as Espacenet (European Patent Office):



Espacenet Patent search

Also published as:

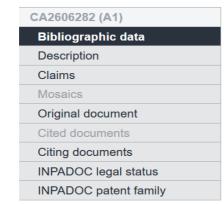
Deutsch English Français

Contact

Change country ▼

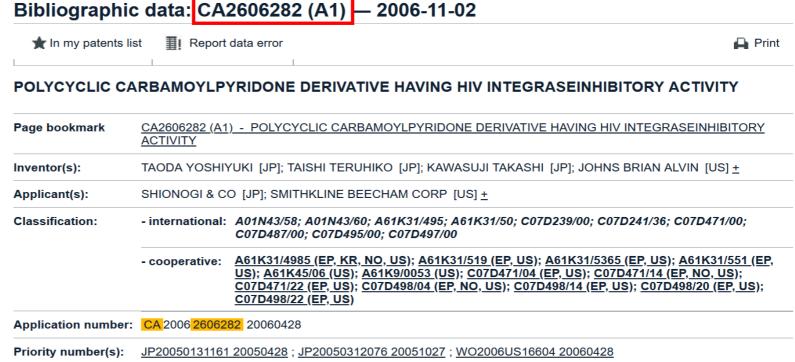


Refine search → Results → CA2606282 (A1)



Quick help

- → What is meant by high quality text as facsimile?
- → What does A1, A2, A3 and B stand for after a European publication number?
- → What happens if I click on "In my patents list"?
- → What happens if I click on the "Register" button?
- Why are some sidebar options deactivated for certain documents?
- → How can I bookmark this page?
- → Why does a list of documents with the heading "Also published as" sometimes appear, and what are these documents?
- → Why do I sometimes find the abstract of a corresponding document?
- → What happens if I click on the red "patent translate" button?
- → What is Global Dossier?



CA2606282 (C) AU2006239177 (A1) AU2006239177 (B2) AU2006239177 (B8) → BRPI0610030 (A2)

<u>HK1107227 (A1)</u> → <u>HK1172282 (A1)</u> □ <u>HUE037795 (T2)</u> → <u>HUS1400039 (I1)</u> □ <u>IL186555 (A)</u> → <u>IL225206 (A)</u>

KR101504998 (B1) □ KR101580310 (B1) □ KR101848819 (B1) → KR20080009733 (A) □ KR20130133061 (A)

MA29460 (B1) → MX2007013351 (A) → MX302718 (B) → MX312216 (B) □ NL300676 (I2) → NO20075165 (L)

NZ562339 (A) → PL3045206 (T3) □ PT1874117 (E) □ PT2465580 (E) □ PT3045206 (T) □ SI1874117 (T1) □

<u>US2017369509 (A1)</u> □ <u>US2019152990 (A1)</u> □ <u>US2019284208 (A1)</u> □ <u>US8129385 (B2)</u> □ <u>US8410103 (B2)</u> □ US8778943 (B2) □ US9051337 (B2) □ US9273065 (B2) → VN34404 (A1) □ WO2006116764 (A1) → less

→ <u>IL225207 (A)</u> <u>D JP2008540343 (A)</u> <u>D JP2009079058 (A)</u> <u>D JP4295353 (B2)</u> <u>D KR101363875 (B1)</u> <u>D</u>

□ KR20140097438 (A) □ KR20160003889 (A) → LT3045206 (T) → LT3284520 (T) → LU92446 (I2) □

NO20161315 (A1) → NO2017010 (I1) → NO2017010 (I2) NO339525 (B1) → NO340111 (B1)
 NO340111 (B1)

SI2465580 (T1) SI3045206 (T1) SI3284520 (T1) TW200716635 (A) TWI378931 (B) SI32809318421 (A1) SI3284520 (T1) SI

→ CY1115151 (T1) → CY1116331 (T1) → CY1120345 (T1) → DK1874117 (T3) D DK2465580 (T3) D

DK3045206 (T3) □ DK3284520 (T3) □ EA014162 (B1) □ EA200702080 (A1) → EP1874117 (A1) →

EP1874117 (A4) → EP1874117 (B1) → EP1874117 (B8) □ EP2465580 (A1) □ EP2465580 (B1) □

EP2527007 (A1) EP2527007 (B1) EP3045206 (A1) EP3045206 (B1) EP3187225 (A1) E

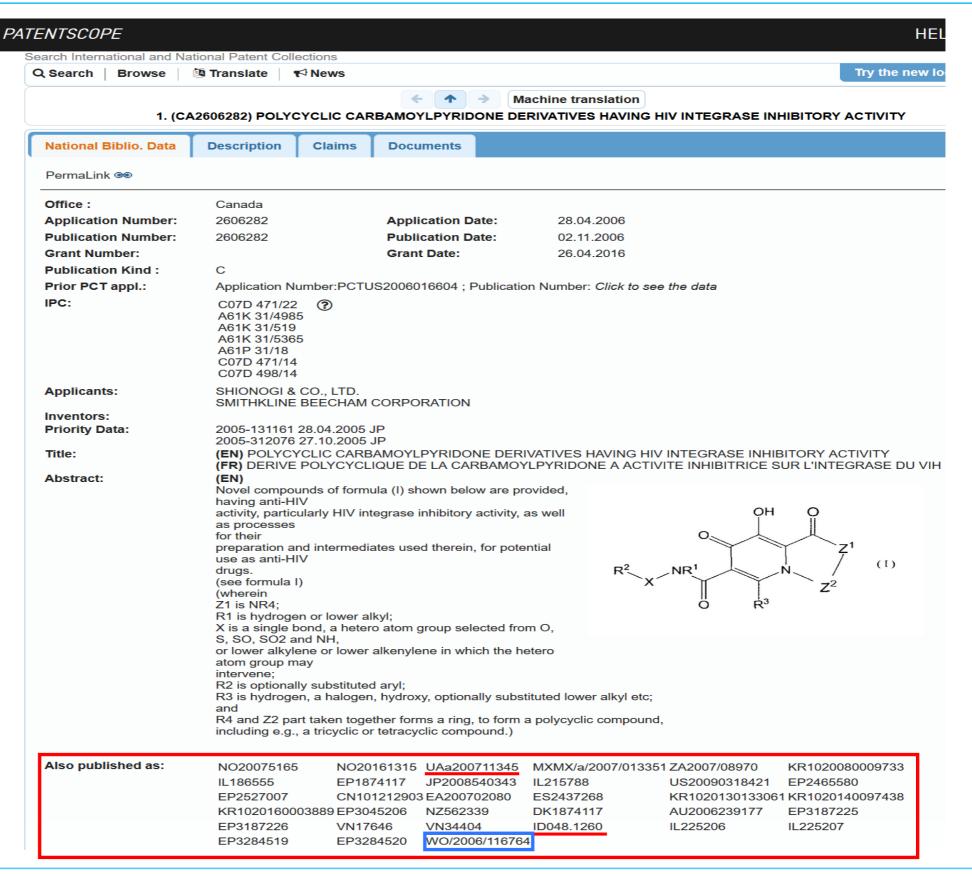
EP3372281 (A1) □ ES2437268 (T3) □ ES2446324 (T3) □ ES2567197 (T3) □ ES2667868 (T3) →

WIPO FOR OFFICIAL USE ONLY



2 - Collection of related patent family information

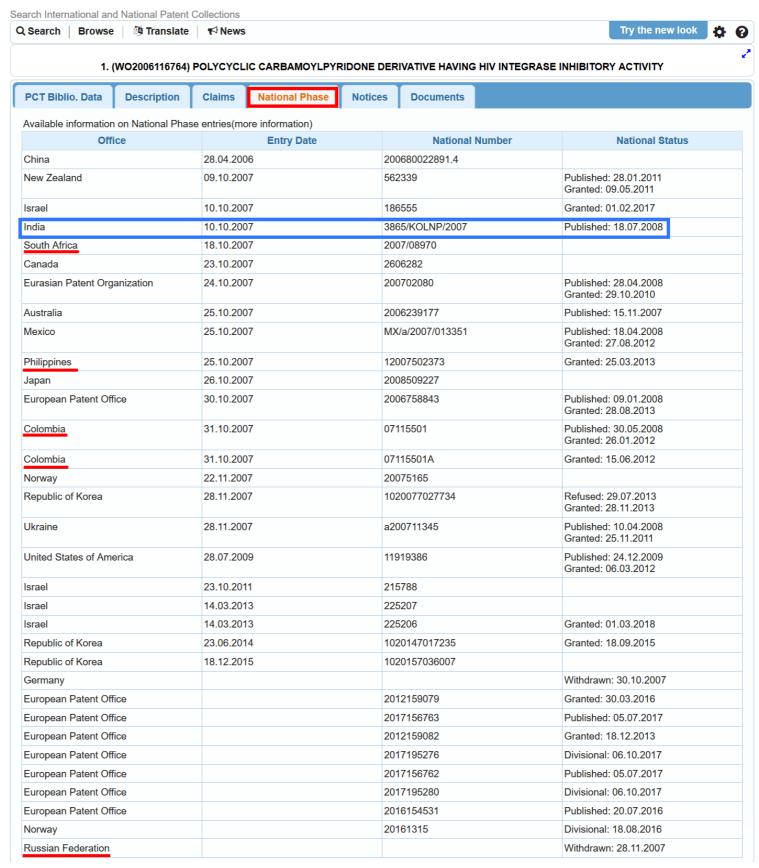
Search for equivalent patents/patent applications in public databases such as Patentscope (WIPO)





Search for equivalent patents/patent applications in public databases such as Patentscope (WIPO):
National phase tab of the corresponding international application

2 - Collection of related patent family information





2 - Collection of related patent family information

Patent holder disclosures e.g. to patent offices





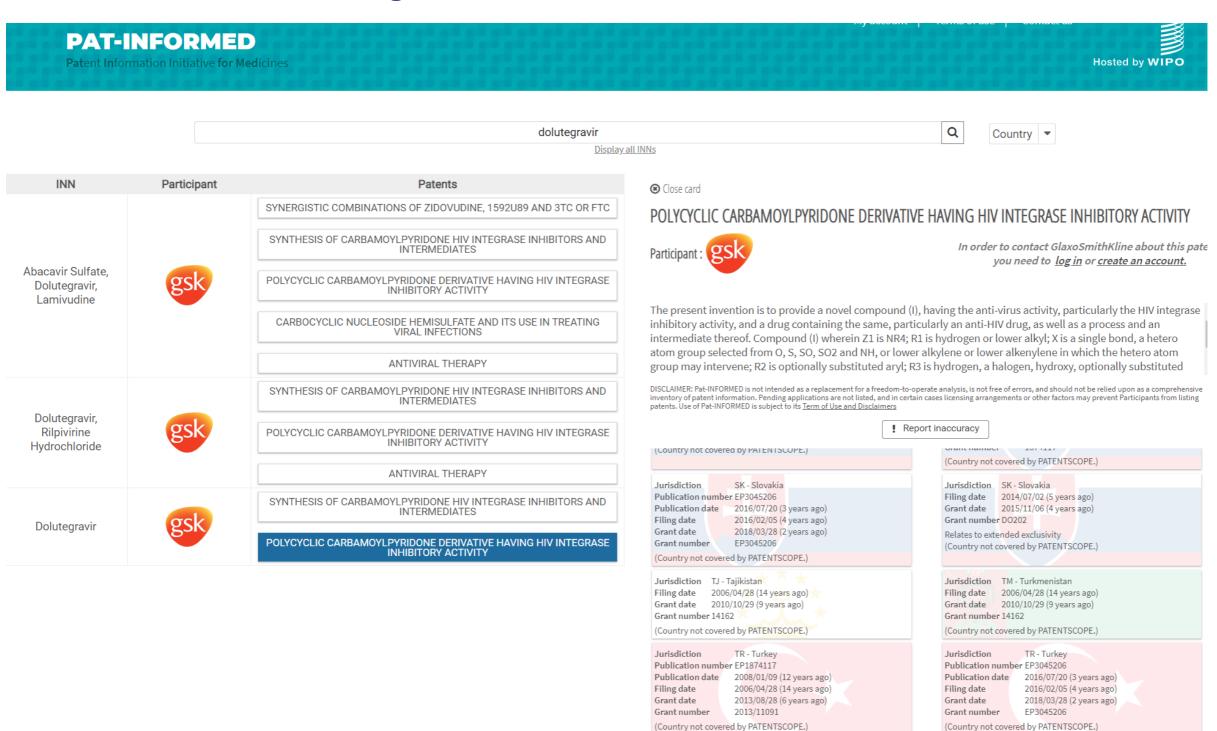
40	03 DIV 21	10/400,373	renumg	Inone	INOILE	NOTE	163	01-03-2013		unuci examination
50										
51	Algeria	070738	Patented	None	None	5531	No	28-04-2006	12-05-2010	granted
52										
53	Australia	2006239177	Patented	None	None	2006239177	No	28-04-2006	02-02-2012	granted
54										

	Α	В	C	D	E	F	G	Н	1	J	K
55			Litigation Analysis -	Phillips Ormonde							
56											
57	Brazil	PI 0610030-9	Pending	None	None	None	No	28-04-2006			opposition pending
58											
59	Opposition 1	BLANVER	Pending								
60											
61	Canada	2606282	Patented	None	None	2606282	Yes After	28-04-2006		26-04-2016	granted
62							File Request				
63											
64											
65	China	200680022891.4	Patented	None	None	ZL200680022891.4	No	28-04-2006	101212903	24-07-2013	granted
66											
67	Columbia	07-115.501	Patented	None	None	1886	No	28-04-2006	592	16-04-2012	granted
68											
69	Columbia DIV	07-115.501A	Patented	None	None	1887	No	28-04-2006		05-07-2012	granted
70											
71	Egypt	PCT 1167/2007	Pending	None	None	None	Yes	28-04-2006			under examination
72											
	1			1	1		1				



2 - Collection of related patent family information

Patent holder disclosures e.g. in Pat-INFORMED



How is national/regional patent data obtained?

- Online national and regional PO registers
- National patent collections on WIPO PatentScope
- INPADOC Legal Status data



- Direct communications with patent offices, local experts
- MOUs with patent offices

3 - Status check & updates



Automated processes



3 - Status check & updates

National Patent Registers e.g. China





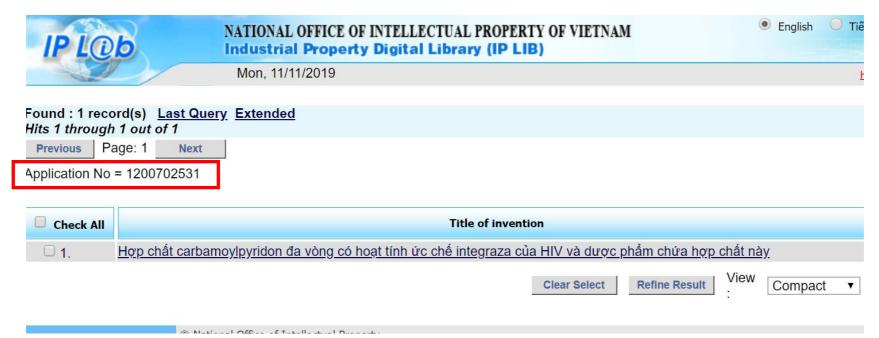
Polycyclic carbamoyl pyridone derivative having HIV integrase inhibitory activity

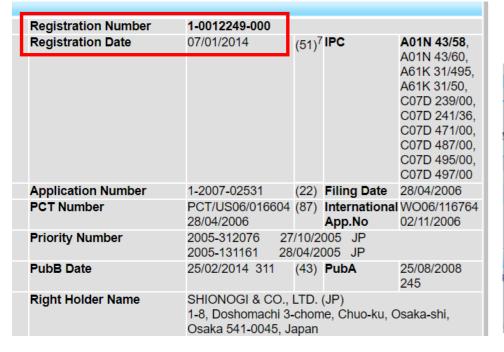
Application (patent) number	2006800228914					
Transaction data announcement day	2013.07.31 Change of name or address of pa					
Change of the name	or address of the patentee					
IPC (Main Category):	A01N43/58					
Change : Before the o	change of the patentee					
: Smith Klein Bicham	Company					
changed: GlaxoSmith	Kline Klein limited liability					
Change of company	:					
Before the change of	address:					
After the change of P	Pennsylvania, USA : Change of Pennsylvania, I	USA				
:						
Before the change of	patentee :					
	anyeyi Pharmaceutical Co., Ltd.: Yanyeyi Pha					

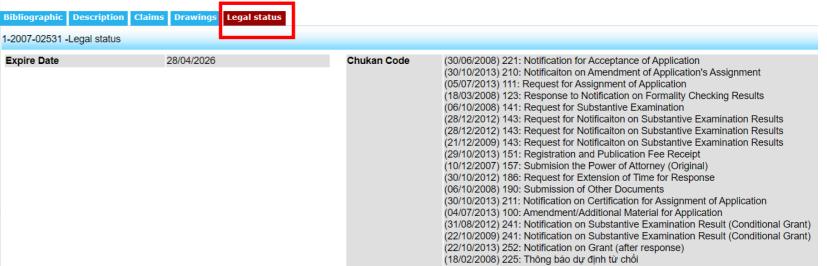


3 - Status check & updates

National Patent Registers e.g. Vietnam









3 - Status check & updates

Regional

African Regional IP Organisation



Eurasian Patent Office



European Patent Office



National





Brazil



Chile





Ecuador







Peru



South Africa



El Salvador

13 patent offices have signed MoUs with the MPP committing to share data

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- Publicly available licences
- Published patent landscapes (e.g. by WHO or UNITAID)

1- Identification of basic/relevant patents

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INPADOC Patent family



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- National patent collections on WIPO PatentScope
- INPADOC Legal Status data



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Automated processes



Demonstration



SIGN UP FOR UPDATES



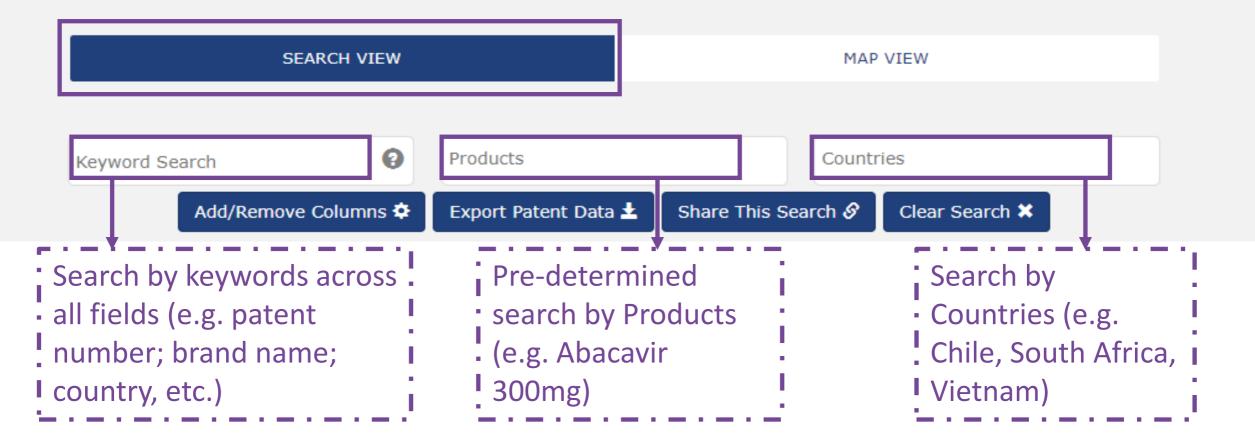


MedsPaL

THE MEDICINES PATENTS AND LICENCES DATABASE

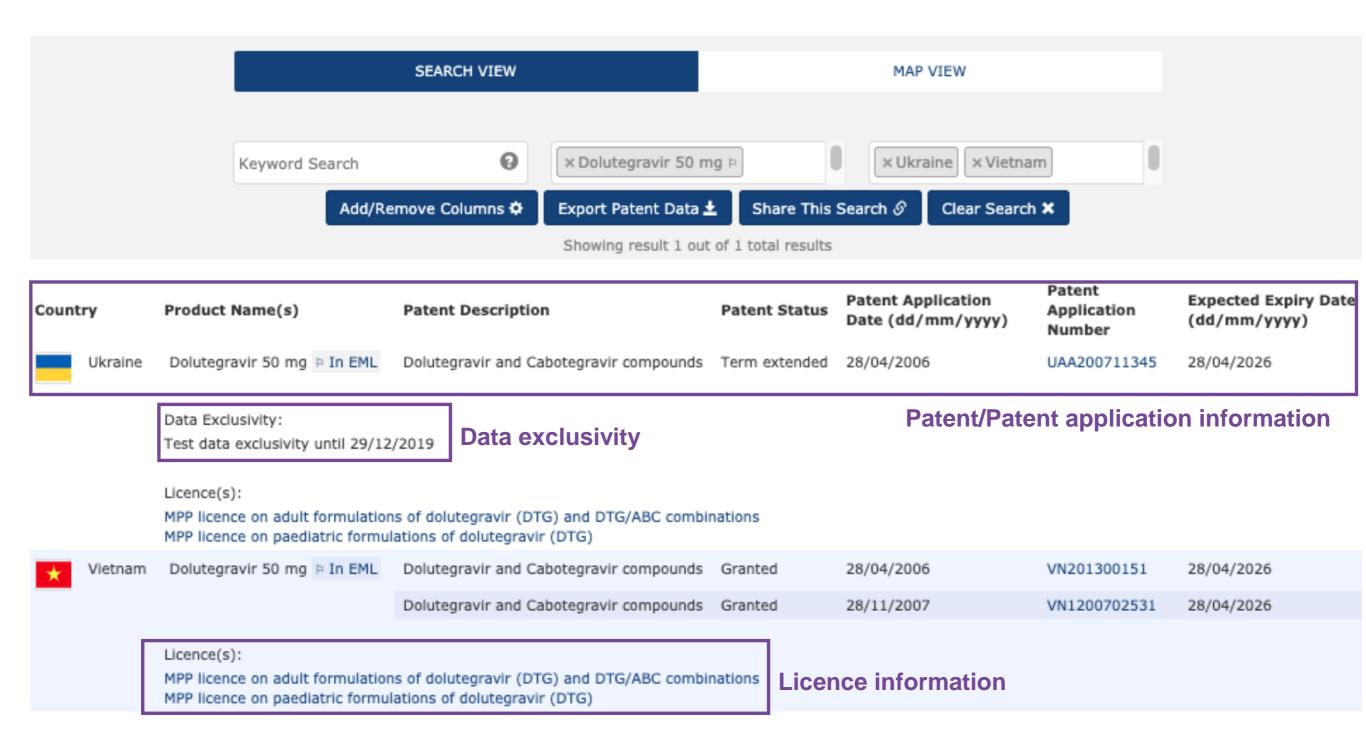
MedsPaL provides information on the patent and licensing status of selected HIV, hepatitis C, tuberculosis and other patented essential medicines in low-and middle-income countries. For more detailed and up-to-date information on a given patent application, MedsPaL users are encouraged to contact the national patent office or consult legal counsel.

Additional information and disclaimer



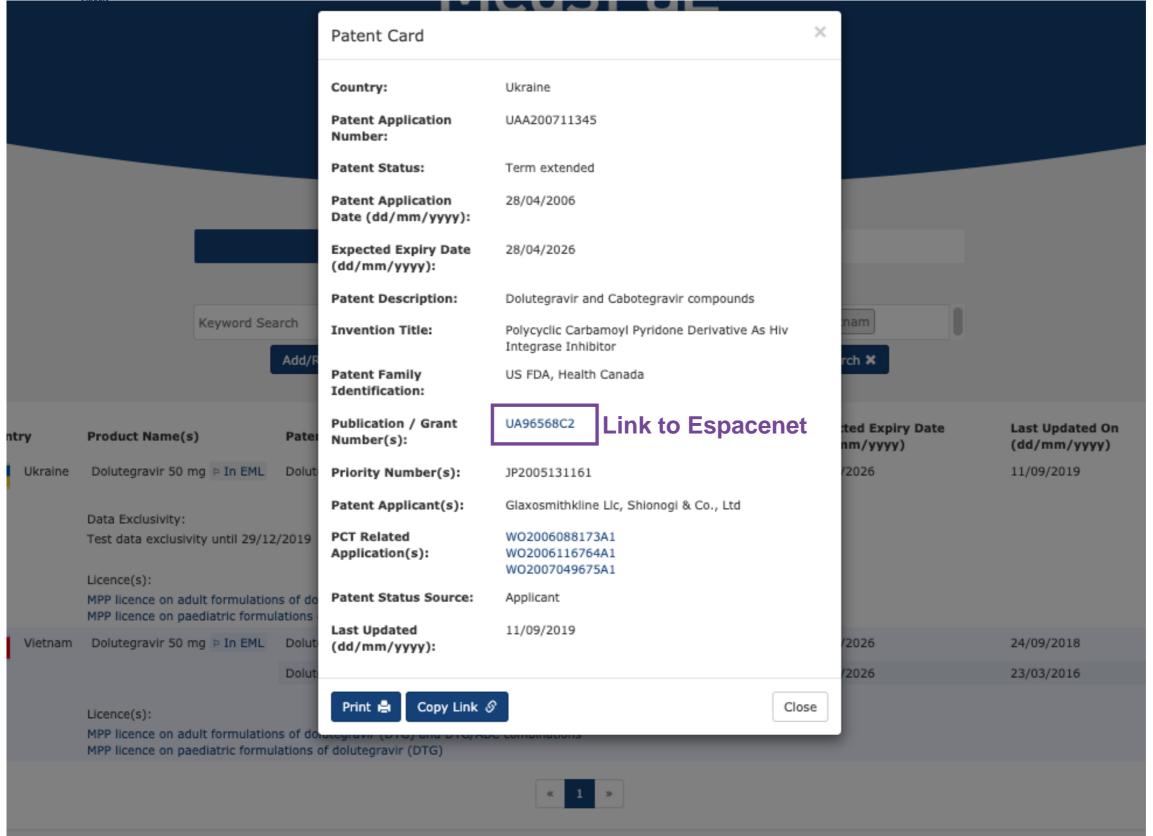






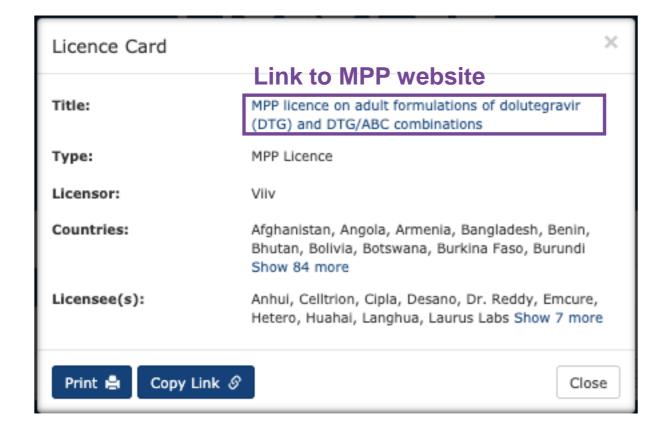








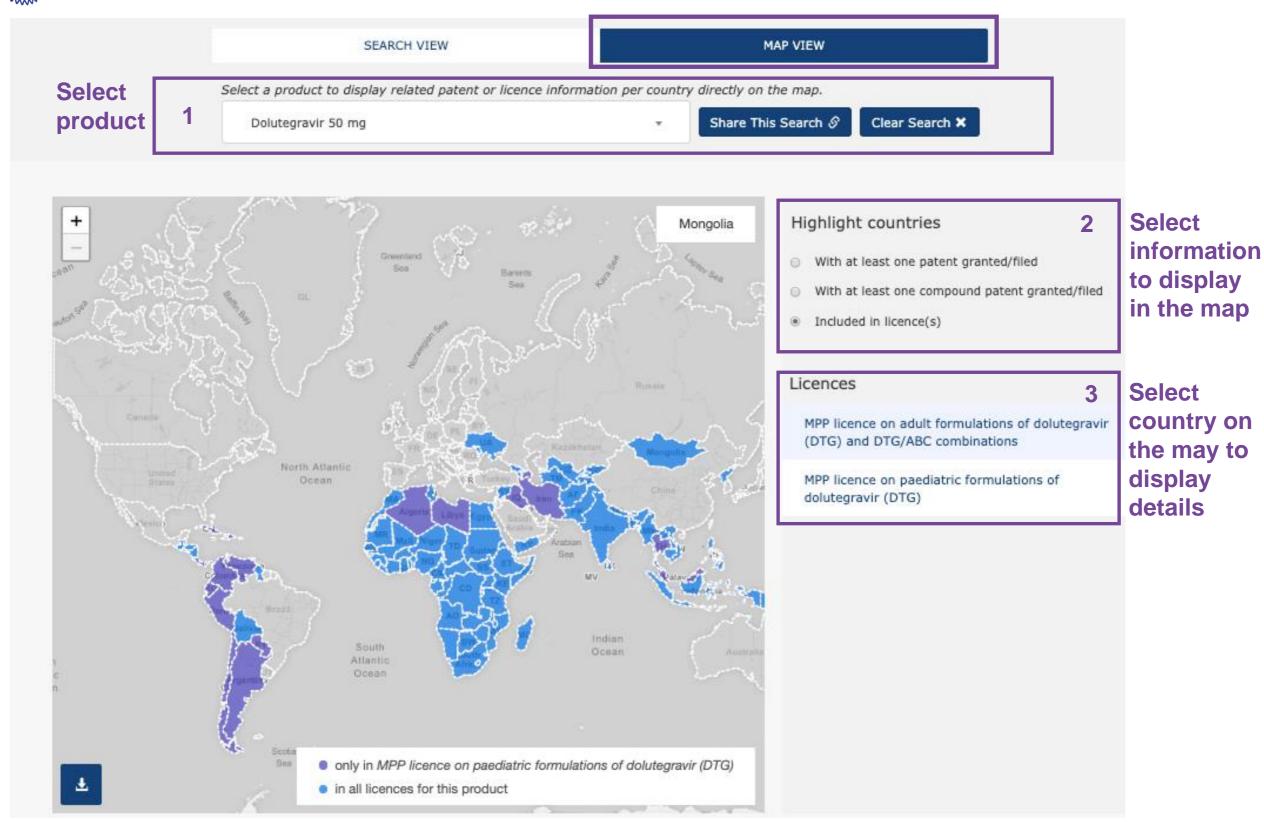
Licence cards













Latest developments/Updates



In October 2019, the MPP included 18 small molecules that were recently added to the WHO Model List of Essential Medicines to MedsPaL

Medicines (INN)	Indications
ceftazidime+avibactam meropenem+vaborbactam plazomicin	Antibiotics
apixaban dabigatran edoxaban rivaroxaban	Atrial fibrillation
tiotropium	Chronic obstructive pulmonary disease
telmisartan+amlodipine	Hypertension
telmisartan + hydrochlorothiazide	Hypertension
afatinib erlotinib, gefitinib	Lung cancer
bortezomib lenalidomide	Multiple myeloma
aprepitant	Nausea
carbetocin (heat-stable formulation)	Post-partum haemorrhage
abiraterone	Prostate cancer



Products in late stage development / Recent regulatory filings / Recommended treatment regimens

Medicines (INN)	Indications
Rifapentine (RPT)/Isoniazid (INH)	Latent tuberculosis infection
Bedaquiline+Pretomanid+Linezolid	Highly treatment-resistant tuberculosis
Cabotegravir	HIV (NDA submitted to the US FDA in 2019)



Latest additions – Licences

Licence Card

Title: Bilateral Licence on Delamanid (Mylan)

Type: Bilateral Licence

Licensor: Otsuka

Countries: Afghanistan, Albania, Algeria, Angola, Bangladesh,

Belize, Benin, Bhutan, Bolivia, Bosnia and Herzegovina

Show 106 more

Licensee(s): Mylan

Licence Card

Title: Bilateral Licence on Delamanid (R-Pharm)

X

Type: Bilateral Licence

Licensor: Otsuka

Countries: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyz

Republic, Moldova, Republic of, Russian Federation,

Tajikistan, Turkmenistan, Ukraine Show 1 more

Licensee(s): R-Pharm



Latest additions – Licences

Licence Card

Title: Bilateral Licence on BDQ

Type: Bilateral Licence

Licensor: Janssen

Countries: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan,

Kyrgyz Republic, Moldova, Republic of, Russian Federation, Tajikistan, Turkmenistan Show 2 more

Licensee(s): Pharmstandard

BPaL and BPaMZ regimens

Type: Bilateral Licence

Licence Card

Title:

Licensor: TB Alliance

Countries: Afghanistan, Albania, Algeria, American Samoa,

Andorra, Angola, Antigua and Barbuda, Argentina,

TB Alliance/Mylan licence on pretomanid for use in the

Armenia, Aruba Show 204 more

Licensee(s): Mylan

Licence Card

Title: TB Alliance/Macleods non-exclusive licence on

pretomanid for use in the BPaL regimen

Type: Bilateral Licence

Licensor: TB Alliance

Countries: Afghanistan, Albania, Algeria, American Samoa,

Angola, Argentina, Armenia, Azerbaijan, Bangladesh,

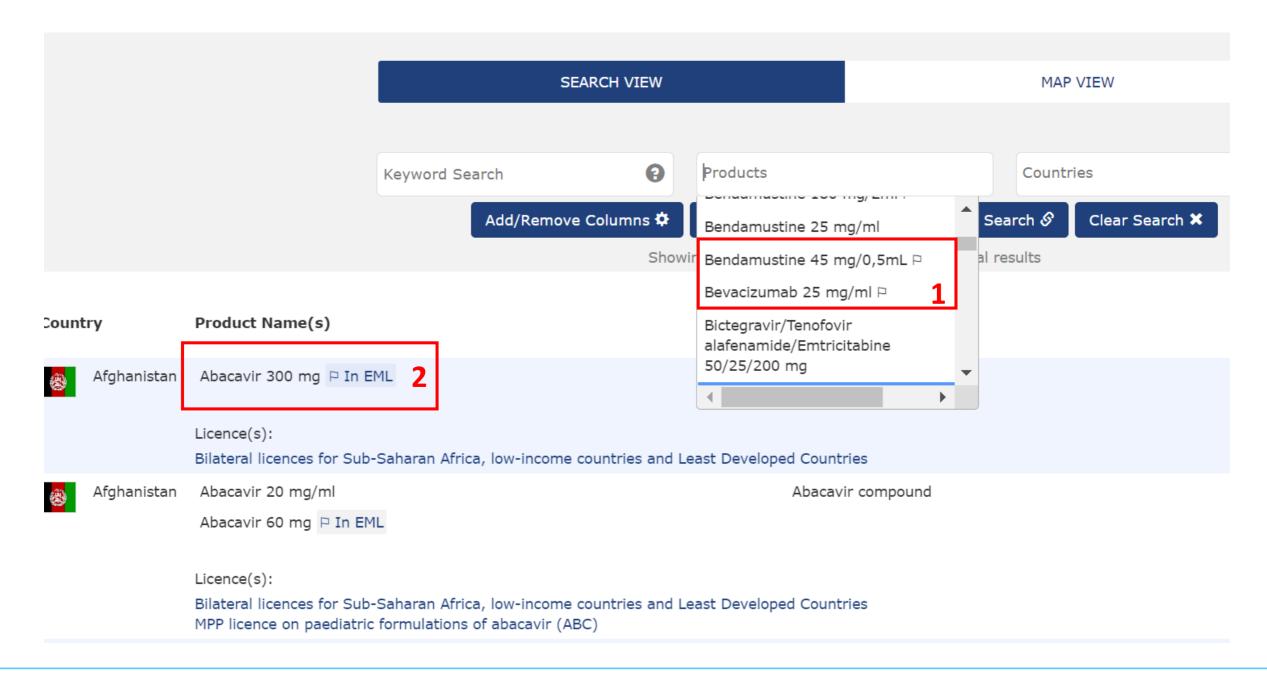
Belarus Show 133 more

Licensee(s): Macleods



Medicines and formulations that are listed in the EML are now flagged as follows:

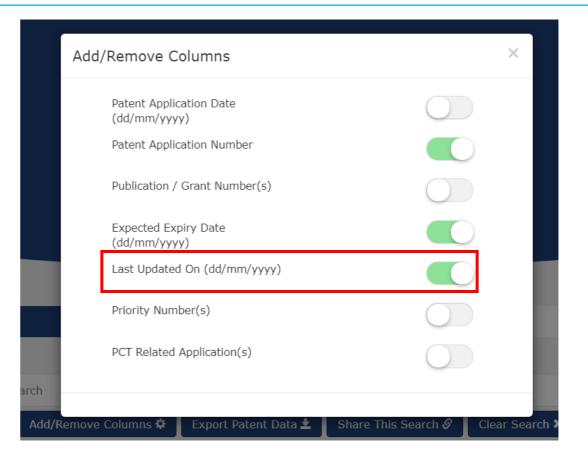
- 1 in the products search box drop-down list with a flag (1)
- 2 in the results list with a flag and the mention "In EML" (2)





Easier access to information on when data was last updated

The "last updated on" information corresponds to the date when the most recent legal event was added to the application or the date when the patent status was confirmed.









Regional









European Patent Office



National





Brazil



Chile





Ecuador





El Salvador



Peru



South Africa



13 patent offices have signed MoUs with the MPP committing to share data



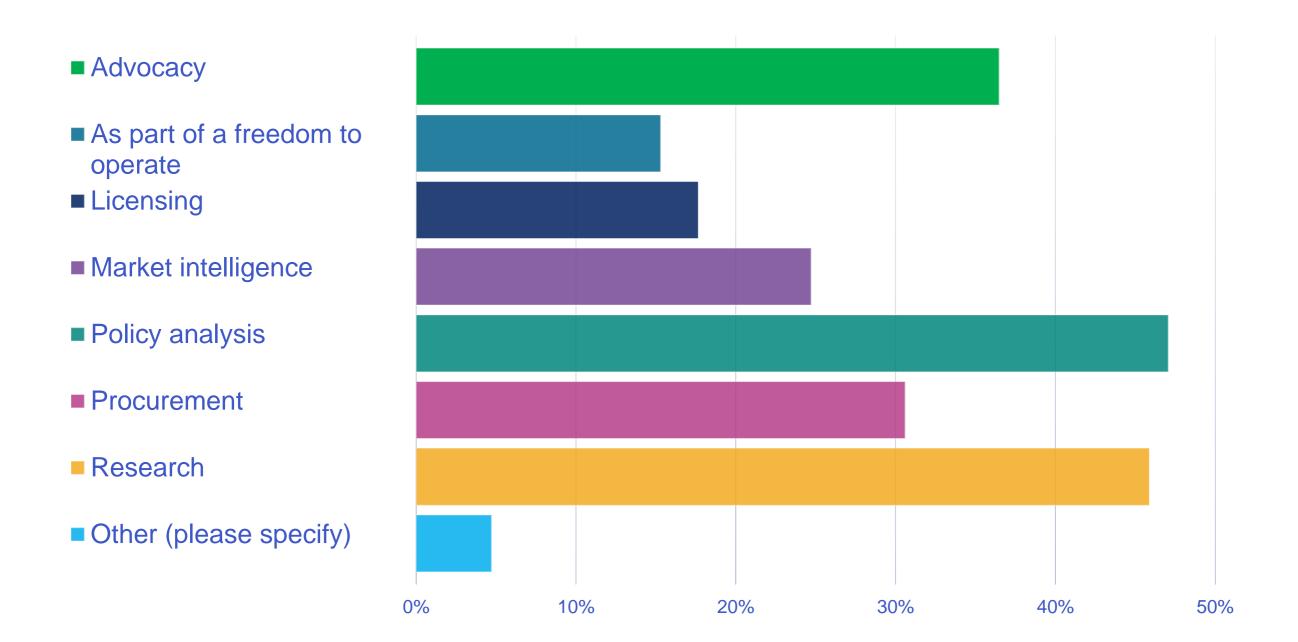
- Complement patent data with data exclusivity data for the new additions
- Add some of the **biologics** that were recently added to the WHO EML and some of the WHO-recommended **vaccines**
- Consider implementing some of the recommendations made during recent User Survey (e.g. user alerts for specific products/patents? Direct links to national patent offices?)
- Explore ways to better classify pharmaceutical patents, in a manner to better guide users on the likely strength and relevance of specific patents or patent families



Feedback / Use



N: 85 Q5: What do you use it for? (You can select more than one option)



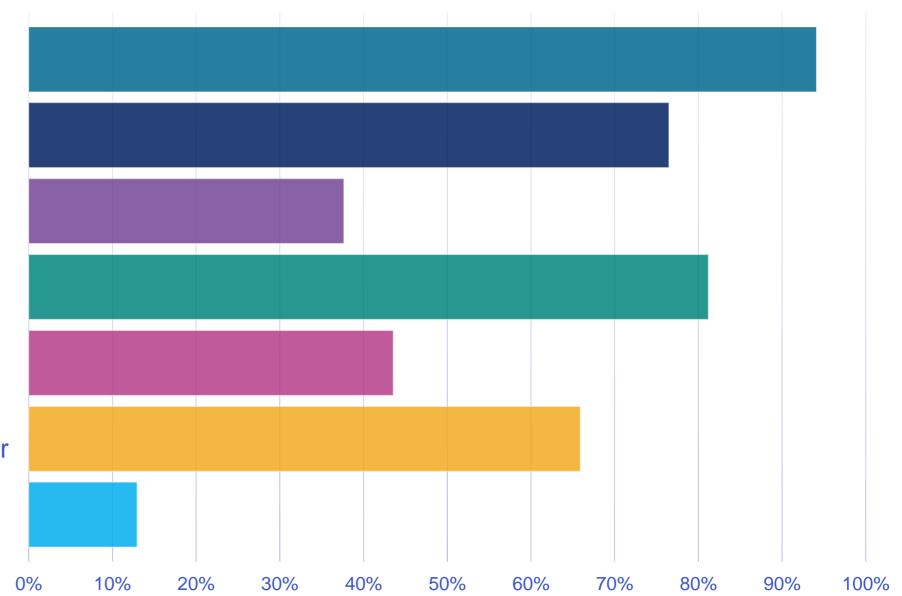
Follow-up interviews with 7 procurement agencies to gain further insights on how it's used and how it could be improved



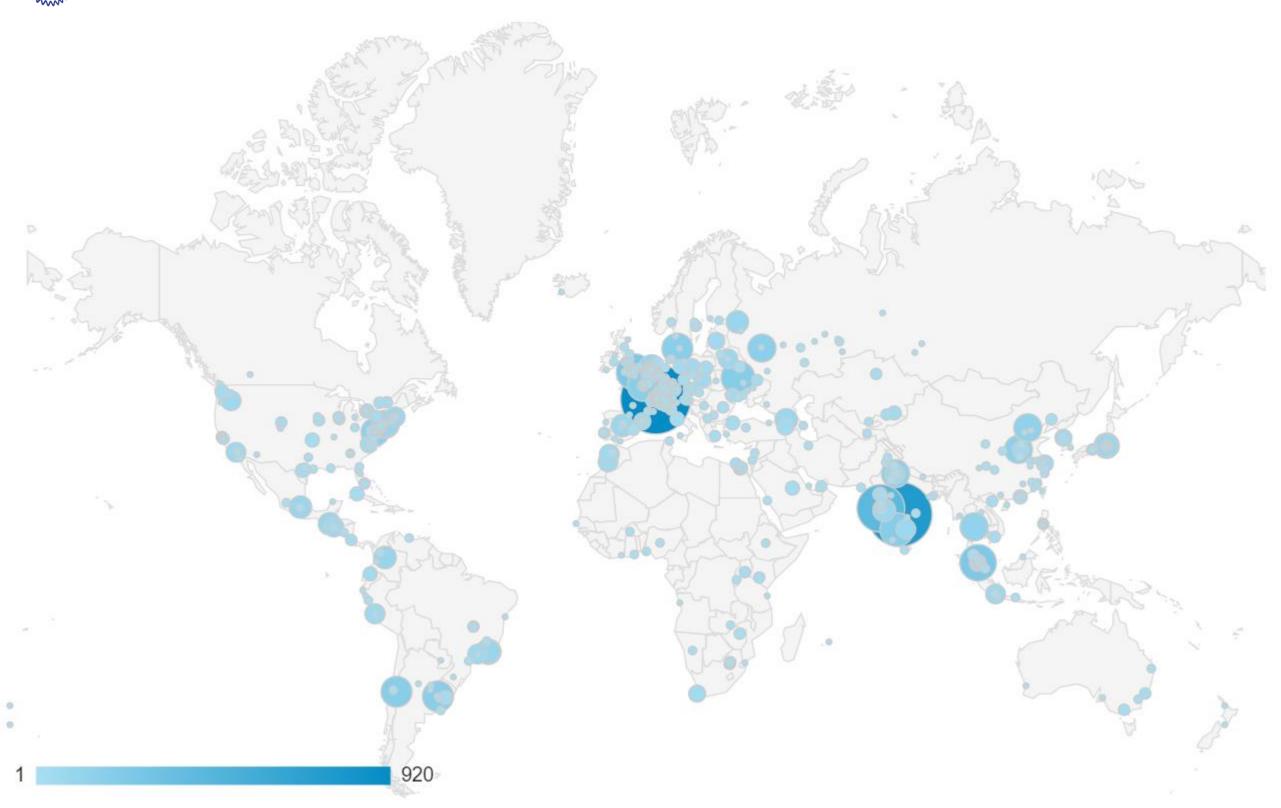
N: 85 Q7: What information are you most interested in? (You can select more than one option)



- Patent expiry dates
- Patent numbers (application, publication, grant)
- Countries covered by the licences
- Names of licensees
- Data exclusivity protection for specific products
- Other (please specify)







Source: Google analytics, period from 1.10.2016 - 1.12.2019



MedsPaL should not be considered a complete and authoritative source of patent information and is not meant to provide a 'freedom-to-operate' analysis. It only provides a snapshot at a particular point in time, based on the information that was available to the Medicines Patent Pool

Interested users are advised to contact the relevant national/regional patent office, or to consult local patent counsel, to obtain up to date information on any given patent application identified in MedsPaL

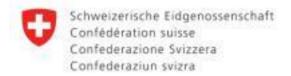
Users are also invited to submit information on any data that requires updating to the MPP at medspal@medicinespatentpool.org



MPP's HIV, TB and hepatitis C activities are funded by:



MPP'S EXPANSION INTO PATENTED ESSENTIAL MEDICINES IS UNDERTAKEN WITH FINANCIAL SUPPORT FROM:



Swiss Agency for Development and Cooperation SDC





THANK YOU

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WWW.MEDSPAL.ORG

eburrone@medicinespatentpool.org amaillard@medicinespatentpool.org