

Medicines patents and licences database

www.medspal.org





- 1. Introduction to the Medicines Patent Pool
- 2. Background on MedsPaL
- 3. What patent information is included in MedsPaL?
- 4. What licensing and data exclusivity information is included in MedsPaL?
- 5. Demonstration
- 6. Next Steps



INTRODUCTION TO THE MEDICINES PATENT POOL



THE MEDICINES PATENT POOL: A PUBLIC HEALTH VOLUNTARY LICENSING ORGANIZATION

Founded in 2010 by



To increase **access** to new treatments for HIV

And facilitate **innovation** e.g. combinations and paediatrics

In 2015, expanded mandate to **Hepatitis C** and **Tuberculosis**





MPP'S OBJECTIVES

- Accelerate the availability of generic versions of new treatments
- Enable the development of new fixed-dose combinations (FDCs) particularly when patents are held by different entities
- Encourage the development of adapted formulations for children or for specific developing country needs (e.g., heat stable formulations)





HOW WE WORK







Facilitate access to affordable medicines for people in LMICs

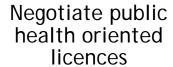


Approach patent holders





Facilitate development of needed formulations





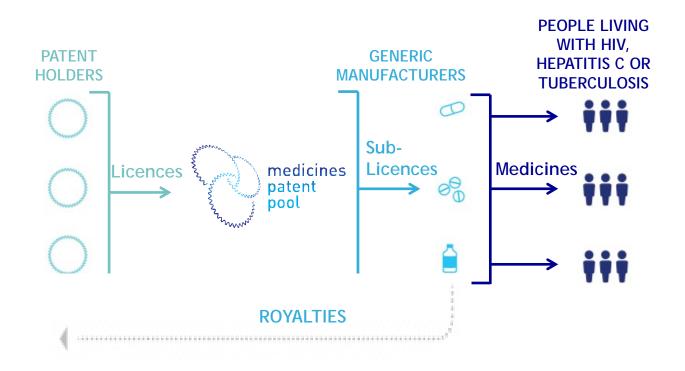
Sub-license to generics







First patent pool in public health





MPP LICENCES GEOGRAPHICAL COVERAGE (BASED ON WORLD BANK CLASSIFICATIONS)

Product(s) Licensed	LIC	LMIC	UMIC	ніс	Undefined	Total
Abacavir (paed.)	31	53	31	5	1	121 +
Atazanavir	31	52	32	3	3	122 +
Bictegravir	30	48	25	9	4	116
Cobicistat	30	48	25	9	4	116
Daclatasvir	31	46	30	2	3	112 +
Dolutegravir (paed.)	31	53	31	5	1	121 +
Dolutegravir	31	53	6	2	0	92 +
Elvitegravir	30	42	17	8	3	100
Lopinavir/Ritonavir (paed.)	31	50	19	2	0	102
Lopinavir/Ritonavir (Africa)	26	17	10	2	2	57 +
Raltegravir (paed.)	31	50	9	2	0	92
Ravidasvir	1	9	9	-	-	19#
Sutezolid (global)	31	53	56	78	0	218
TDF	30	48	25	9	4	116
TAF	30	48	25	9	4	116

⁺ Additional countries may be able to benefit

[#] Complements DNDi licence for a total of over 130 countries



MPP ACCOMPLISHMENTS



13 HIV medicines and 1 HIV technology platform licensed



130+
ongoing pharmaceutical development projects



2 hepatitis C direct-acting antivirals



14.6 million patient-years and 5.3 billion doses of treatments delivered through MPP's generic partners



1 tuberculosis treatment



391 million US dollars saved



EXPLORING EXPANSION INTO PATENTED ESSENTIAL MEDICINES

- The MPP is undertaking a feasibility study to assess the feasibility, desirability and potential public health impact of an MPP intervention on patented essential medicines
- A wide range of different stakeholders in governments, industry, academia and civil society are being consulted
- The study is being funded by the Swiss government
- The results of the study are expected to be available by Q2 2018





MPP IN RECENT UN STRATEGIES

UN Political Declaration on HIV/AIDS (2016), Paragraph 23:

"(...) welcome the broadening of the scope of work of the Medicines Patent Pool, hosted by UNITAID, to promote voluntary partnerships to address hepatitis C and tuberculosis, reflecting the importance of integrating the AIDS response into the broader global health agenda"

WHO Health Sector Strategy on HIV/AIDS 2016-21 (page 42)

"Strategies include fostering generic competition, including through, where appropriate, voluntary licences that include pro-access terms and conditions such as those negotiated by the Medicines Patent Pool"

World Health

UNAIDS 2016-21 Strategy (Page 83)

"Furthermore, UNAIDS will pursue additional collaboration with the Medicines Patent Pool, an initiative funded by UNITAID, to elaborate analyses on the patent landscape of HIV medicines and forecasting of newer HIV-related products."



BACKGROUND ON MEDSPAL



- In order to prioritize medicines for in-licensing important to know which HIV medicines were patented where
- Through on-line searches and the support of WIPO and many patent offices, the MPP managed to obtain information for over 60 countries
- Many requests for data from public health stakeholders convinced us to make data public



HOW WE WORK







Facilitate access to affordable medicines for people in LMICs



Approach patent holders





Facilitate development of needed formulations

Negotiate public health oriented licences



Sub-license to generics





THE OLD MPP PATENT STATUS DATABASE (PREDECESSOR TO MEDSPAL)

Launched in April 2011 and regularly updated and expanded

Included patent status data for 24 HIV medicines in 88 countries

Most complete source of patent status data on HIV medicines in developing countries





FEEDBACK FROM STAKEHOLDERS (2012)



"The Medicines Patent Pool's Patent Status Database for Selected HIV Medicines takes an invaluable step towards furthering access to treatment of HIV/AIDS amassing information from numerous patent registries and jurisdictions into an easily navigable resource available to the public"

"The Medicines Patent Pool database is an essential impartial reference source for Global Fund Principal Recipients to understand the patent status of ARVs in their country - and it should be further expanded to include more countries."





"In the midst of a current patent regime that is at times not so transparent, this database is a great and valuable tool for players in the field, and one we regularly check as part of our procedures for determining a patent status. [It] ultimately allow[s] us to focus more of our energy into the actual delivery of HIV medicines to the ones who need it."

"The patent status database is an incredibly useful resource as it provides the most comprehensive pool of the available information on patent statuses, and combines this into one easy to use search engine."





RECENT MENTIONS IN WHO AND UNAIDS STRATEGIES

 The new WHO Global Health Sector Strategy for HIV (2016-2021), approved by all Member States, indicates that the WHO "collaborates with the Medicines Patent Pool, which maintains a database on patent status..."



• The UNAIDS 2016-21 strategy entitled "On the Fast-Track to End AIDS" states that "UNAIDS will pursue additional collaboration with the Medicines Patent Pool, an initiative funded by UNITAID, to elaborate analyses on the patent landscape of HIV medicines…"





MedsPal THE MEDICINES PATENTS & LICENCES DATABASE

MedsPaL provides information on the patent and licensing status of selected HIV, hepatitis C and tuberculosis medicines in low- and middle-income countries.

In October 2016, MPP launches MedsPaL as the most comprehensive source of information on the patent and licensing status of medicines for HIV, TB and hepatitis C in low- and middle-income countries



Patent status data from over 110 lowand middle-income countries



Data exclusivity information from 15 countries



Covering approx. 70 medicines (over 130 formulations)



Information on all relevant licences in LMICs



KEY FEATURES OF MEDSPAL



Enables search by name of medicine, formulation, country, etc.



Key IP data in one place: patent status, licences, data exclusivity



Information for more than 110 low and middle income countries



Provides links to additional information



Regularly updated including automated updates for some patent applications



Enables users to download patent status data for further analysis



Possibility to sign up to receive information on new features and updates



WHAT INFORMATION IS INCLUDED IN MEDSPAL?

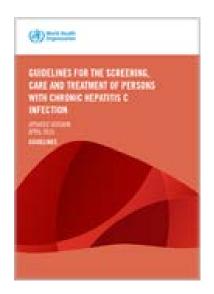


WHICH PRODUCTS ARE INCLUDED?

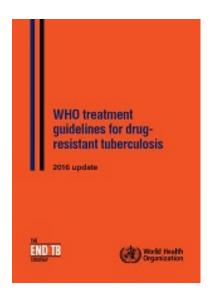
Patented medicines for the treatment of HIV, hepatitis C and tuberculosis that are (or were) included in WHO treatment guidelines



WHO HIV Treatment Guidelines



WHO Hepatitis C
Treatment
Guidelines



WHO MDR-TB
Treatment
Guidelines



NEW: EXPANDED TO INCLUDE OTHER PATENTED MEDICINES ON WHO ESSENTIAL MEDICINES LIST



WHO Model List of Essential Medicines (EML)

- Expanded today to include patented medicines on the WHO Essential Medicines List (WHO EML)
- In addition to HIV, HCV and TB, now patented cancer medicines also included
- Will be regularly updated as WHO EML is expanded

MedsPaL now includes a total of approximately 70 medicines with over 130 pharmaceutical formulations



HOW ARE PATENT FAMILIES IDENTIFIED?

Challenge: A simple patent search using a product name can yield hundreds of results and would not include the main patent claiming the molecule itself



US FDA Orange Book (automated)



Health Canada Patent Register (automated)



Publicly available licences (e.g. MPP)



ALC MEE

Published patent landscapes (e.g. WHO or UNITAID)

Approach: Patent families disclosed by patent holders to the USFDA and Health Canada Patent Registry. Supplemented with patent families disclosed in licences and in patent landscapes of reputable organizations.

Over 210 patent families were identified and included in MedsPaL



HOW IS NATIONAL/REGIONAL PATENT DATA OBTAINED?

Automated data feeds from the EPO are supplemented with data collected from individual patent offices through on-line searches, direct collaboration with patent offices and via local experts; patent holder disclosures and WIPO PatentScope.



National /Regional Patent Offices



PATENT HOLDER DISCLOSURES

Automatic data feeds from Esp@acenet

Direct communication, MOUs, on-line searches

National patent collections on PatentScope

In licences or to patent offices

MedsPaL includes patent status data on over 6,800 national patents or patent applications.



MOUS WITH NATIONAL/REGIONAL PATENT OFFICES















The MPP has signed collaboration agreements (MOUs) with 7 patent offices and looks forward to expanding its network of collaborating patent offices



CONTENT OF THE MOUS WITH NATIONAL IP OFFICES

Key objective: maintain data in MedsPaL as up to date as possible through collaboration with patent offices

Nature of the collaboration:

- MPP requests legal status information on up to 30 patent applications every year
- Request usually includes national patent application number or international patent application + priority number
- Patent offices provide legal status information for these patents
- MPP includes information in MedsPaL

Note: Where patent office already has a public database with legal status information, or provides this regularly to Espacenet, requests may be limited to clarifications



WHAT LICENSING AND DATA EXCLUSIVITY INFORMATION IS INCLUDED IN MEDSPAL?



WHAT INFORMATION ON LICENCES IS INCLUDED IN THE DATABASE?

Types of Licences

Information in MedsPaL

Licences negotiated by the Medicines Patent Pool



Full information on the licences incl. links to summaries and full text

Bilateral licences between originators and generics



Information on countries, products, licensees (where public or provided by patent holder for public disclosure)

Commitments not to enforce patents on a given product



Information on countries and products

Compulsory licences



Based on publicly available information



HOW IS INFORMATION ON DATA EXCLUSIVITY OBTAINED?

- Data exclusivity: Some LMICs have adopted regulations providing for data exclusivity (DE) in relation to the submission of pharmaceutical test data to regulatory authorities for approval of new medicines
- Data on MedsPaL: data from 15 countries has been collected for HIV, TB and HCV medicines with expiry dates and will be supplemented further as data is gathered
- Source of data: National regulatory authorities (sometimes aided by patent office or local experts)
- Other essential medicines: Data on cancer medicines included in WHO EML is being collected for inclusion





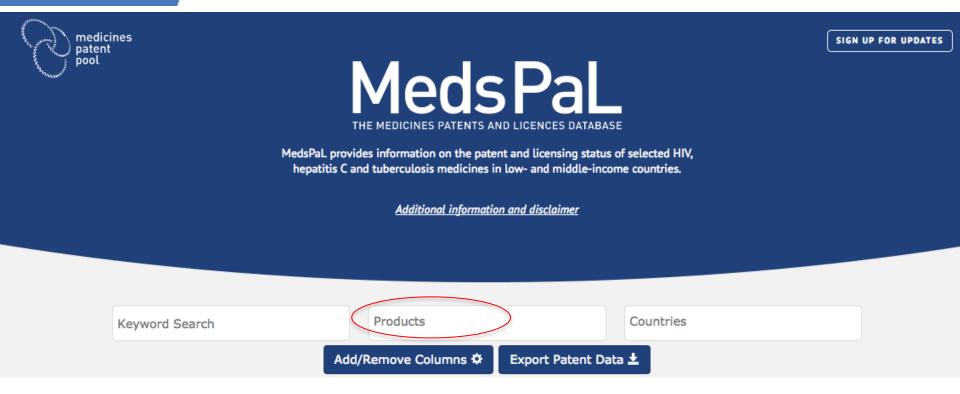
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• Free search by Keyword (e.g. patent number; brand name; country, etc.)





Pre-determined search by Products (e.g. Abacavir 300mg)





Pre-determined search by Countries (e.g. Chile, South Africa, Vietnam)





MedsPaL provides information on the patent and licensing status of selected HIV, hepatitis C and tuberculosis medicines in low- and middle-income countries.

Additional information and disclaimer

Keyword Search × Bedaquiline 100 mg × Brazil × Ecuador

Add/Remove Columns 🌣

Export Patent Data 👤

Showing results 1 through 3 out of 3 total results

Count	ry	Product Name	Patent Description	Patent Status	Patent Application Number	Expected Expiry Date (dd/mm/y)
	Argentina	Bedaquiline 100 mg	Bedaquiline fumarate salt	Rejected	ARP070105442	31/01/2014
			Bedaquiline to treat MDR TB	Withdrawn	ARP050102200	20/10/2014
			Bedaquiline to treat latent TB	Withdrawn	ARP050105140	13/11/2014
			Bedaquiline compounds family	Granted	ARP030102655	24/07/2023
(Brazil	Bedaquiline 100 mg	Bedaquiline compounds family	Filed	BR0312927	18/07/2023
			Bedaquiline to treat MDR TB	Filed	BRPI0510414	24/05/2025
			Bedaquiline to treat latent TB	Filed	BRPI0506400	08/12/2025
			Bedaquiline process	Filed	BRPI0611166	22/05/2026
			Bedaquiline fumarate salt	Filed	BRPI0719693	03/12/2027
O	Ecuador	Bedaquiline 100 mg	Bedaquiline compounds family	Not Filed		
			Bedaquiline to treat MDR TB	Not Filed		
	South Africa	Bedaquiline 100 mg	Bedaquiline compounds family	Granted	ZA200500680	24/01/2025
			Bedaquiline to treat MDR TB	Granted	ZA200609899	27/11/2026
			Bedaquiline to treat latent TB	Granted	ZA200705160	22/06/2027
			Bedaquiline process	Granted	ZA200710150	26/11/2027
			Bedaquiline fumarate salt	Granted	ZA200903907	04/06/2029





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			Bedaquiline to treat MDR TB	Not Filed		
	South Africa	Bedaquiline 100 mg	Bedaquiline compounds family	Granted	ZA200500680	24/01/2025
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			Bedaquiline fumarate salt	Granted	ZA200903907	04/06/2029

medicines patent pool		Patent Card ×		SIGN UP FOR UPDATES
		Country:	South Africa	
		Patent Application Number:	ZA200500680	
		Patent Status:	Granted	
		Patent Application Date (dd/mm/yyyy):	24/01/2005	
		Expected Expiry Date (dd/mm/yyyy):	24/01/2025	
	Keyword Search	Patent Description:	Bedaquiline compounds family	azil × Ecuador
	Reyword Search	Invention Title:	Quinoline Derivatives And Their Use As Mycrobacterial Inhibitors	
	_	Patent Family Identification:	US FDA	
у	Product Name	Publication / Grant Number(s):	ZA200500680B	Expected Expiry Date (dd/mm/yy)
Argentina	Bedaquiline 100 mg			31/01/2014
		Priority Number(s):	US39871102	20/10/2014
		Patent Applicant(s):	Janssen Pharmaceutica N.V	13/11/2014
		PCT Related	WO2004011436A1	24/07/2023
Brazil	Bedaquiline 100 mg	Application(s):		18/07/2023
		Patent Status Source:	National Patent Office	24/05/2025
		Last Updated (dd/mm/yyyy):	05/10/2016	08/12/2025
				22/05/2026
				03/12/2027
Ecuador	Bedaquiline 100 mg	Print 🖶 Copy Link 🔗	Close	
		Redaquiline to treat MDR TR	Not Filed	



EXAMPLE 2



MedsPaL

MedsPaL provides information on the patent and licensing status of selected HIV, hepatitis C and tuberculosis medicines in low- and middle-income countries.

Additional information and disclaimer

Keyword Search

Licence(s):

MPP licence on daclatasvir (DCV)

× Daclatasvir 60 mg

× India × South Africa

Add/Remove Columns ❖

Export Patent Data 👱

Showing result 1 out of 1 total results

Count	ry	Product Name	Patent Description	Patent Status	Patent Application Number	Expected Expiry Date (dd/mm/yyyy)
•	India	Daclatasvir 60 mg	Daclatasvir compound family	Filed (opposed)	IN853/DELNP/09	09/08/2027
			Daclatasvir crystalline forms	Filed (opposed)	IN806/DELNP/2010	31/07/2028
			Daclatasvir intermediate manufacturing process	Filed (opposed)	IN3999/CHENP/2012	02/11/2030
		Licence(s):				
		MPP licence on dad	clatasvir (DCV)			
	South Africa	Daclatasvir 60 mg	Daclatasvir compound family	Granted	ZA200900962	09/08/2027
			Daclatasvir crystalline forms	Granted	ZA201000843	31/07/2028



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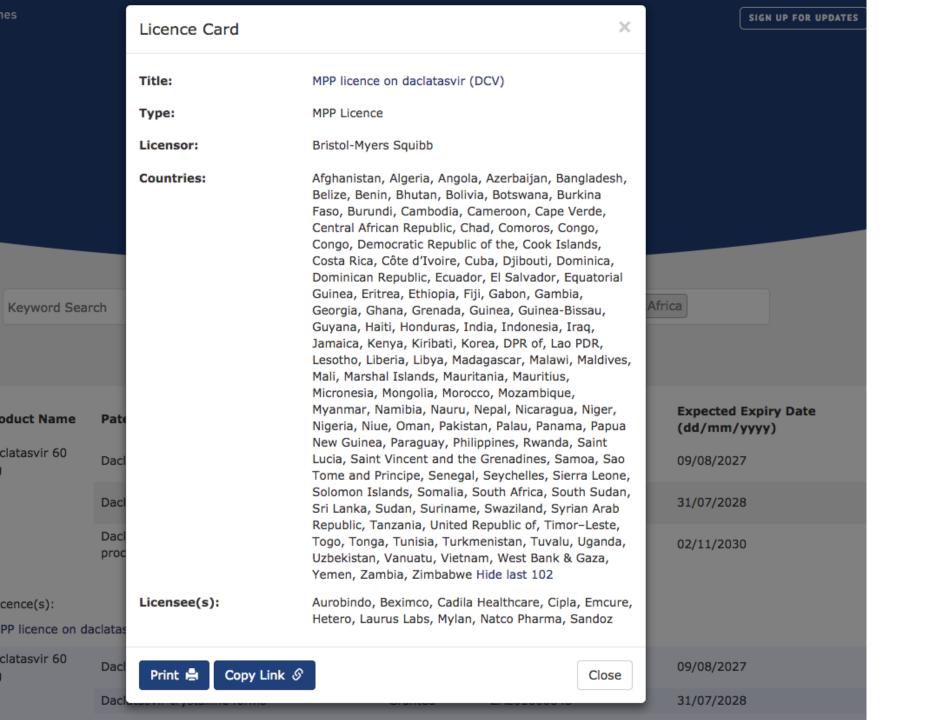
× India × South Africa

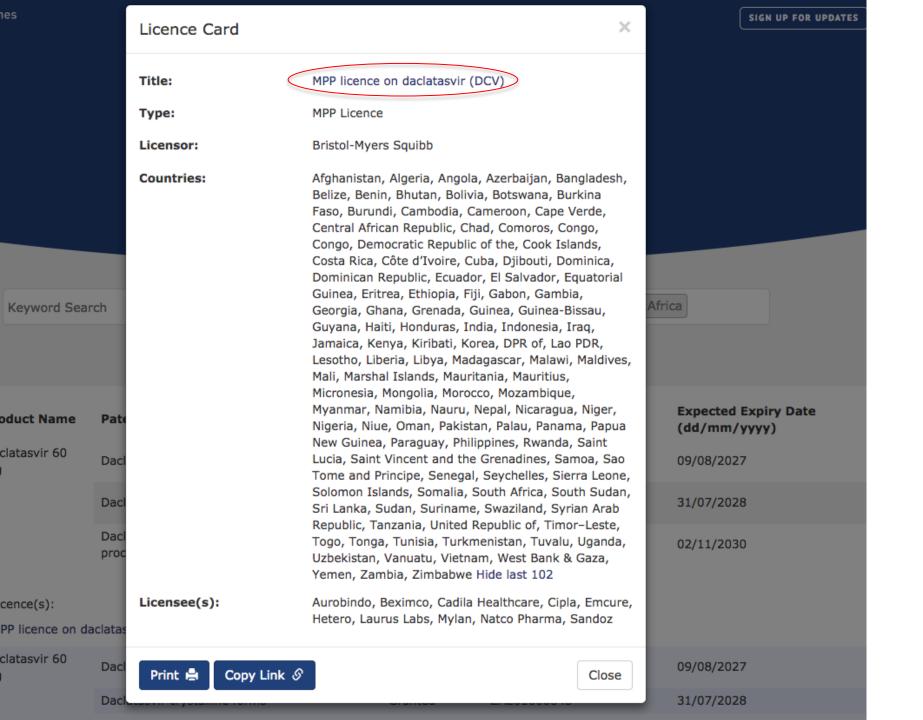
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LICENCE SUMMARIES AND FULL TEXT OF MPP LICENCES

From the licence card, users can access further information on MPP licences

This includes a summary of key features and full text of MPP licences

Links to information about other licences also included where available

ATAZANAVIR (ATV)

COMPANY: BRISTOL-MYERS SQUIBB DATE: DECEMBER 2013



In December 2013, the MPP announced an agreement with biopharmaceutical company Bristol-Myers Squibb to increase access to a key HIV medicine, atazanavir (ATV), part of the WHO-preferred second-line treatment for adults and children. In July 2017, the MPP signed an extension of its licence agreement to include 12 additional countries, namely, Algeria, Cook Islands, Egypt, Equatorial Guinea, Indonesia, Malaysia, Morocco, Niue, the Philippines, Tunisia, Ukraine and Vietnam. The licence allows generic manufacture of ATV for sale in at least 122 countries that together are home to 89% of people living with HIV in low- and middle-income countries.



- LICENCE AGREEMENT



- SUBLICENCE AGREEMENT - FORM



KEY FEATURES



PRESS RELEASE



CHAIRMAN'S SUMMARY



ADVISORY GROUP REPORT



COUNTRY



EXAMPLE DATA EXCLUSIVITY



MedsPal

THE MEDICINES PATENTS AND LICENCES DATABASE

MedsPaL provides information on the patent and licensing status of selected HIV, hepatitis C and tuberculosis medicines in low- and middle-income countries.

Additional information and disclaimer

Keyword Search

× Dolutegravir 50 mg

× Chile

Add/Remove Columns 🌣

Export Patent Data 🕹

Showing result 1 out of 1

Country

Product Name

Patent Description

Patent Status

Patent Application Number

Expected Expiry Date (dd/mm/yyyy)

SIGN UP FOR UPDATES

__ c

Chile

Dolutegravir 50 mg

Dolutegravir compound

Not Filed

Data Exclusivity:

Test data exclusivity until 20/11/2018



EXAMPLE DATA EXCLUSIVITY



MedsPaL THE MEDICINES PATENTS AND LICENCES DATABASE

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Additional information and disclaimer

Keyword Search

× Dolutegravir 50 mg

× Chile

Add/Remove Columns *

Export Patent Data ±

Showing result 1 out of 1

Country

Product Name

Patent Description

Patent Status

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SIGN UP FOR UPDATES

Dolutegravir 50 mg

Dolutegravir compound

Not Filed

Data Exclusivity:

Test data exclusivity until 20/11/2018





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



NEXT STEPS





- Additional features will be added to MedsPaL over time including:
 - Possibility to visualize search results via maps and brief search reports on pre-defined queries
- Addition of additional patented EML medicines



Establish collaboration with additional patent offices



ESTABLISH COLLABORATION WITH ADDITIONAL PATENT OFFICES

 MedsPaL is a public resource that is being widely used by the public health community. Its usefulness is directly linked to accuracy of the data

 Establishing formal collaborations with as many national patent offices is crucial to maintaining the data up to date

MOUs have already been signed with 7
national/regional patent offices and more are under
discussion

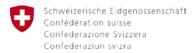


ACKNOWLEDGEMENTS

The MPP's HIV, TB and hepatitis C activities, including MedsPaL, are fully funded by **UNITAID**:



Funding provided by the **Swiss Agency for Development and Cooperation** (SDC) for MPP's feasibility study on the potential expansion of its licensing activities into patented essential medicines made the upgrade of MedsPaL to include other essential medicines possible.



Swiss Agency for Development and Cooperation SDC



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