medicines patent pool

AFROCAB AND TAC - TREATMENT OPTIMIZATION

GLOBAL SCENARIO, CHALLENGES AND OPPORTUNITIES TO ACCELERATE ACCESS TO TREATMENT IN THE REGION

Erika Dueñas

IAS - Paris, 27 juillet 2017

MEDICINES PATENT POOL

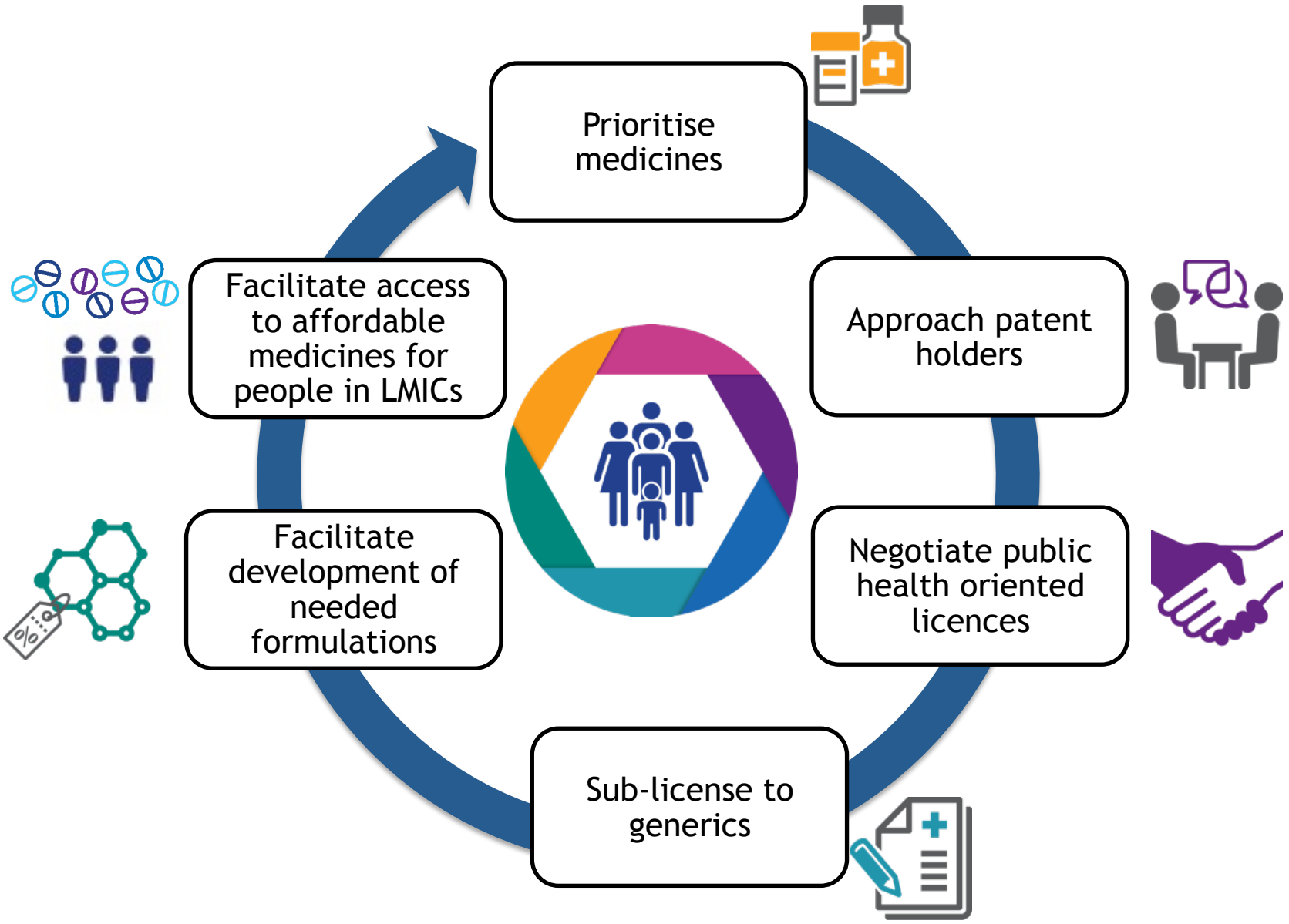
MPP created in 2010 to **increase access** to medicines for people living with **HIV** in developing countries

MPP **promotes innovation** through the development of FDCs and paediatric formulations

MPP expanded in 2015 to include **hepatitis C and tuberculosis**

The MPP is funded by Unitaid Innovation in Global Health

HOW WE WORK


Prioritise medicines
Approach patent holders
Negotiate public health oriented licences
Sub-license to generics
Facilitate development of needed formulations
Facilitate access to affordable medicines for people in LMICs

ACCELERATING AVAILABLITY OF QUALITY ASSURED GENERICS

HISTORICAL TIMELINES FROM APPROVAL TO GENERIC COMPETITION

LPV/r : 8 years 5 months

TDF: 7 years and 6 months

DRV: 8 years and four months

TIMELINES WITH THE MPP*

DTG: ~ 3.5 years

TAF/FTC : ~ 2.5 years

- Estimates based on current information. May change depending on complexity of molecule, WHO guidance, market forecasts and time taken for regulatory review. May vary depending on whether, when and in which formulations TAF is approved by regulatory authority

KEY FEATURES OF MPP LICENCES

- Broad geographical scope – including 55 to 80% of MICs
- Transparent – all licences are public
- Non-exclusive and non-restrictive to encourage competition
- Ability to develop fixed dose combinations
- Strict quality assurance
- Compatible with TRIPS flexibilities

MPP LICENCES GEOGRAPHICAL COVERAGE

Product(s) Licensed	LIC	LMIC	UMIC	HIC	Undefined	Total
Abacavir (paed.)	31	53	31	5	1	121 +
Atazanavir	**31**	**52**	**32**	**3**	**3**	**122 +**
Cobicistat	30	42	18	9	4	103
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	46	23	9	4	112
TAF	30	46	23	9	4	112

NEW: EXPANSION OF ATAZANAVIR LICENCE

- This week we announced the expansion of our licence with Bristol Myers Squibb (BMS) on WHO recommended 2nd line medicine atazanavir from 110 to 122 countries

- New countries: **Algeria, Morocco, Tunisia, Egypt*, Indonesia*, Malaysia*, Philippines*, Vietnam, Equatorial Guinea, Cook Islands, Niue, Ukraine***

- These countries are home to 1.4 million people living with HIV

** Countries where ATV is patented, with patents expiring in late 2018 / early 2019*

IMPACT OF MPP AGREEMENTS

9 patent holders with signed agreements

125 countries receiving treatment from MPP generic partners

12 ARVs for HIV + 2 antiviral for HCV + 1 TB drug candidate licensed to the MPP

USD 239 million saved by international community from MPP licences

16 generic manufacturers and developpers working with the MPP

79 new countries benefitted from generic competition through MPP agreements

10.9 mn patient years serviced by MPP licensees between Jan 2012-June 2016

USD 2.2 billion expected savings from HIV licences over coming years

medicines patent pool

AN IMPORTANT TOOL FOR ALL PUBLIC HEALTH ACTORS

MedsPaL

THE MEDICINES PATENTS AND LICENCES DATABASE

A free, easy-to-use online database that **governments, procurement agencies, civil society and pharmaceutical producers** can use to understand the intellectual property status of medicines for **HIV, TB, and hepatitis C** for over **110 countries**.

www.medspal.org

HIV, TB, hepatitis C

35 priority medicines

>4000 national patent applications

38 licenses available

data exclusivity information for **15** countries

E.G. MEDSPAL SEARCHES – NIGERIA, RWANDA

Keyword Search | × Abacavir/Dolutegravir/Lamivudine 6 | × Nigeria × Rwanda

Add/Remove Columns | Export Patent Data

Showing result 1 out of 1 total results

Country	Product Name	Patent Description	Patent Status	Patent Application Number	Expected Expiry Date (dd/mm/yyyy)
Nigeria	Abacavir/Dolutegravir/Lamivudine 600/50/300 mg	Abacavir hemisulfate salt	Granted	NG164.98	14/05/2018
		Dolutegravir compound	Filed	NG2007/12/473	28/04/2026
		Dolutegravir in combination with ABC and 3TC	Filed	NG/C/2012/444	24/01/2031
	Licence(s): MPP licence on adult formulations of dolutegravir (DTG) and DTG/ABC combinations				
Rwanda	Abacavir/Dolutegravir/Lamivudine 600/50/300 mg	Dolutegravir compound	Not Filed		
	Licence(s): MPP licence on adult formulations of dolutegravir (DTG) and DTG/ABC combinations				

E.G. MEDSPAL SEARCHES – KENYA

Keyword Search | × Abacavir/Dolutegravir/Lamivudine 6 | × Kenya | × Zambia

Add/Remove Columns | Export Patent Data

Showing result 1 out of 1 total results

Country	Product Name	Patent Description	Patent Status	Patent Application Number	Expected Expiry Date (dd/mm/yyyy)
Kenya	Abacavir/Dolutegravir/Lamivudine 600/50/300 mg	Abacavir compound	Expired	AP8900129	26/06/2009
		Emtricitabine/lamivudine compounds family	Expired	AP9000163	08/02/2010
		Abacavir compound	Expired	AP9000234	21/12/2010
		Lamivudine crystal forms	Expired	AP9200395	02/06/2012
		ABC/3TC, ABC/FTC combinations with or without ZDV	Granted	AP9701089	28/03/2016
		Abacavir hemisulfate salt	Granted	AP9901688	14/05/2018
		Abacavir enzyme for intermediate process	Granted	AP9901721	20/08/2018
		Abacavir manufacturing process	Granted	AP200001790	14/10/2018
		Dolutegravir in combination with ABC and 3TC	Granted	AP201206445	24/01/2031
		Dolutegravir compound	Not Filed		

Licence(s):

MPP licence on adult formulations of dolutegravir (DTG) and DTG/ABC combinations

E.G. MEDSPAL SEARCHES – SOUTH AFRICA

Keyword Search | × Abacavir/Dolutegravir/Lamivudine 6 | × South Africa

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)
South Africa	Abacavir/Dolutegravir/Lamivudine 600/50/300 mg	Emtricitabine/lamivudine compounds family	Expired	ZA8902645	11/04/2009
		Abacavir compound	Expired	ZA8904837	26/06/2009
		Emtricitabine/lamivudine compounds family	Granted	ZA9000943	08/02/2010
		Abacavir compound	Expired	ZA9010365	21/12/2010
		Lamivudine crystal forms	Expired	ZA9204007	02/06/2012
		ABC/3TC, ABC/FTC combinations with or without ZDV	Granted	ZA9602477	02/03/2016
		Abacavir hemisulfate salt	Withdrawn	ZA9804083	14/05/2018
		Abacavir hemisulfate salt	Granted	ZA9804085	14/05/2018
		Abacavir manufacturing process	Granted	ZA9809338	13/10/2018
		Dolutegravir compound	Granted	ZA200708970	28/04/2026
		Dolutegravir in combination with ABC and 3TC	Granted	ZA201205586	24/01/2031

Licence(s):

MPP licence on adult formulations of dolutegravir (DTG) and DTG/ABC combinations

E.G. MEDSPAL SEARCHES – BOTSWANA

Keyword Search | × Abacavir/Dolutegravir/Lamivudine 6 | × Botswana

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)
Botswana	Abacavir/Dolutegravir/Lamivudine 600/50/300 mg	Abacavir compound	Expired	AP8900129	26/06/2009
		Emtricitabine/lamivudine compounds family	Expired	AP9000163	08/02/2010
		Abacavir compound	Expired	AP9000234	21/12/2010
		Lamivudine crystal forms	Expired	AP9200395	02/06/2012
		Dolutegravir in combination with ABC and 3TC	Granted	AP201206445	24/01/2031
		Dolutegravir compound	Not Filed		

Licence(s):

MPP licence on adult formulations of dolutegravir (DTG) and DTG/ABC combinations