

Session 3: Access to Medicines and TB

What you Need to Know about Public-Health
Licensing and Access to Medicines in Africa

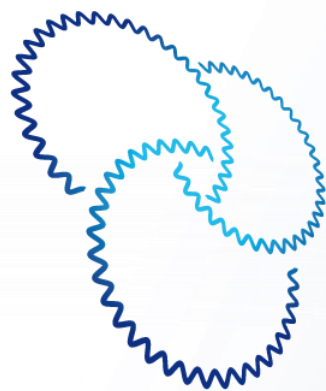
Sébastien Morin

Medicines Patent Pool,
Switzerland



What you need to know about public-health licensing and access to medicines in Africa

Presented by Sébastien Morin
Policy and Advocacy Manager
Medicines Patent Pool (MPP)
smorin@mppf.ch



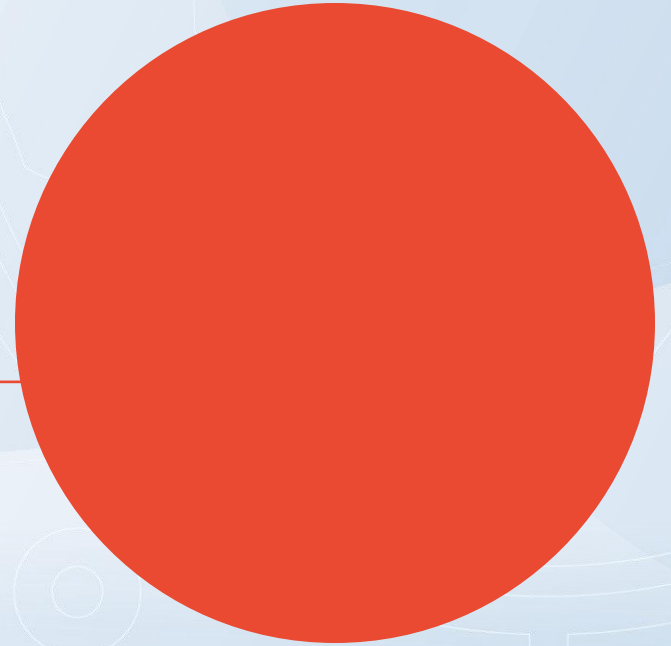
**medicines
patent
pool**

INTEREST 2020

Presentation outline

1. Access to medicines
2. Public-health licensing
3. Licences in action
4. Access to medicines tools
5. Moving forward

1. Access to medicines



Access to medicines is a multidimensional challenge



When can generic competition drive prices down?

Case 1.

If a product has not been patented in a given country



Example:

Some HIV medicines (e.g., raltegravir) not patented in many African countries

Case 2.

If patents on a product have expired (or been withdrawn or revoked)



Example:

Patents on older medicines on the WHO EML have expired (e.g., lamivudine)

Case 3.

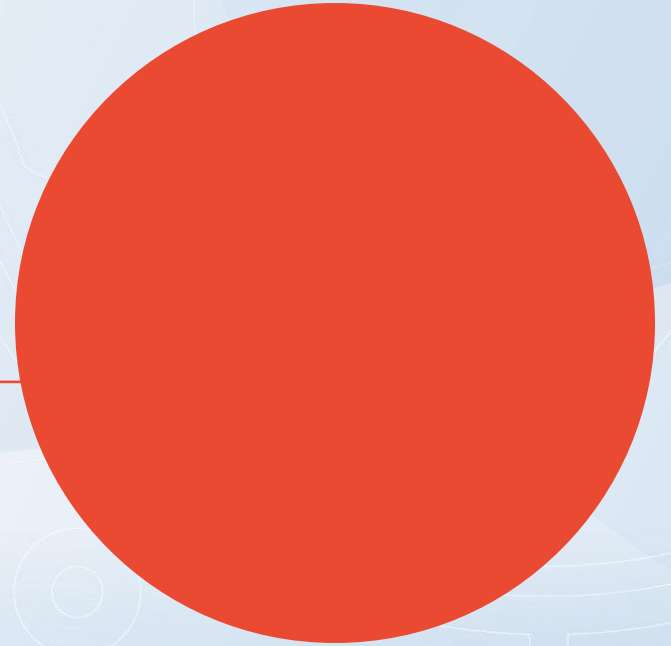
If licences have been granted that enable generics entry



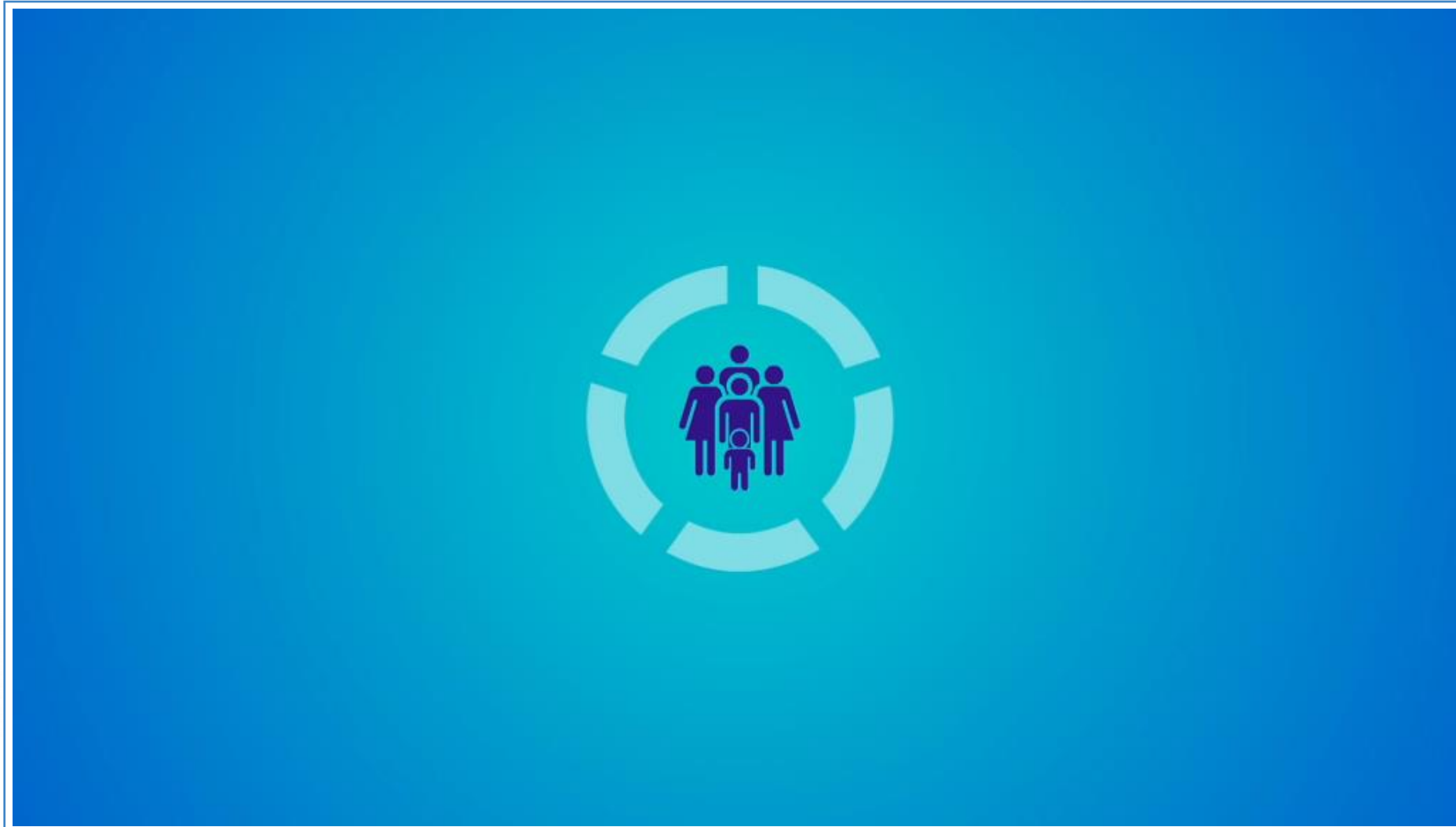
Example:

Public health voluntary MPP licences for patented WHO-recommended HIV and HCV medicines

2. Public-health licensing

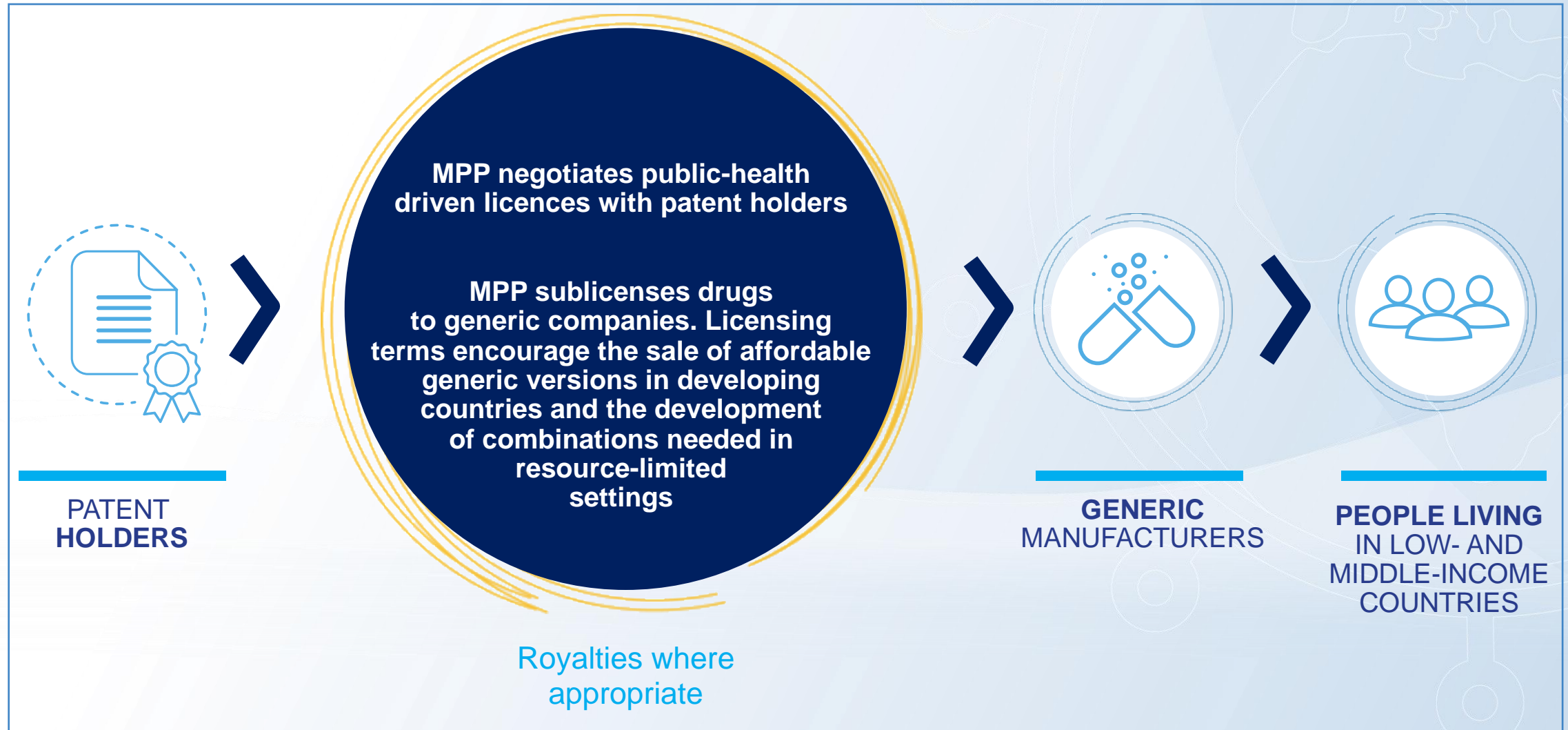


Public-health licensing through MPP (short video)



The Medicines Patent Pool is the first and only medicine patent pool with a public health mandate, established by Unitaid in 2010 and operating as a non-profit voluntary, public health licensing mechanism in partnership with originators and generics to facilitate access and promote innovation in LMICs

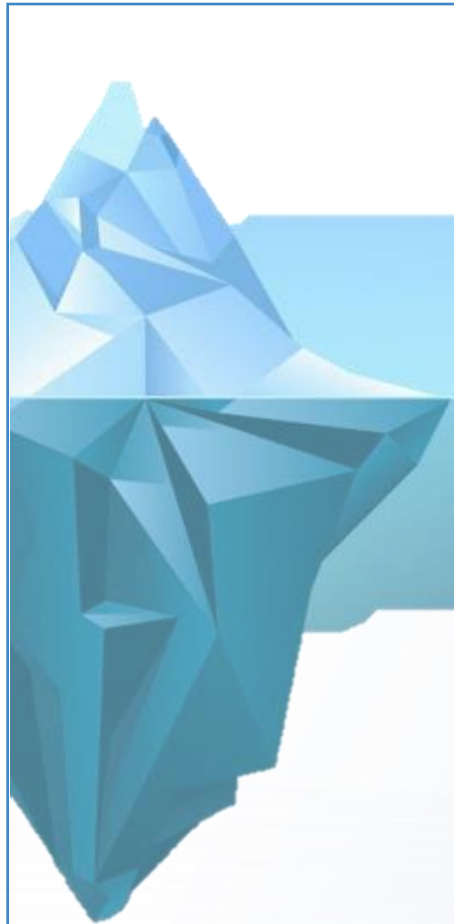
Public-health licensing – The MPP model



Public-health licences – What they look like

<p>WIDE GEOGRAPHICAL SCOPE <i>Over 130 countries have been able to benefit</i></p>	<p>NON-EXCLUSIVE <i>Licences are non-exclusive to promote competition</i></p>	<p>TRANSPARENT <i>Licences are published on MPP's website</i></p>	<p>QUALITY ASSURANCE <i>Strict quality assurance policies</i></p>
<p>COMPLEMENTARY <i>to other mechanisms and tools to facilitate access to treatments</i></p>	<p>LICENCE MANAGEMENT <i>to monitor compliance with all terms and conditions</i></p>	<p>WAIVERS <i>for data exclusivity</i></p>	<p>TECHNOLOGY TRANSFER <i>Can be included to accelerate development of generic versions</i></p>

Managing licences for access



Selecting manufacturers through an Expression of Interest process

Supporting development of API, formulations, technology transfer, data packages

Supporting investment prioritisation and API make or buy decisions by licensees

Monitoring, supporting and reporting on regulatory filings

Ensuring compliance of all licensing terms (e.g., packaging and trade dress, potential royalties)

Tracking issues with quality when raised by partners

Licence management helps build stronger competition faster

Undertaking quarterly review meetings and monitoring sales reports

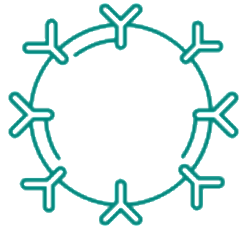
GOVERNMENTS, TREATMENT PROVIDERS

Ability to stretch budgets to treat more people with WHO-recommended medicines

COMMUNITIES

Greater access to quality, appropriate, affordable and life-saving treatments

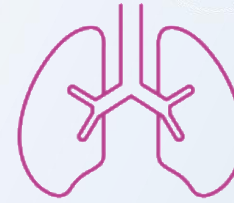
Building a public-health licence pool



HIV



Hepatitis C



Tuberculosis

13 HIV
antiretrovirals and
1 HIV technology
platform licensed

3 hepatitis C
direct-acting
antivirals licensed

1 tuberculosis
treatment licensed



Building a pharmaceutical manufacturer network

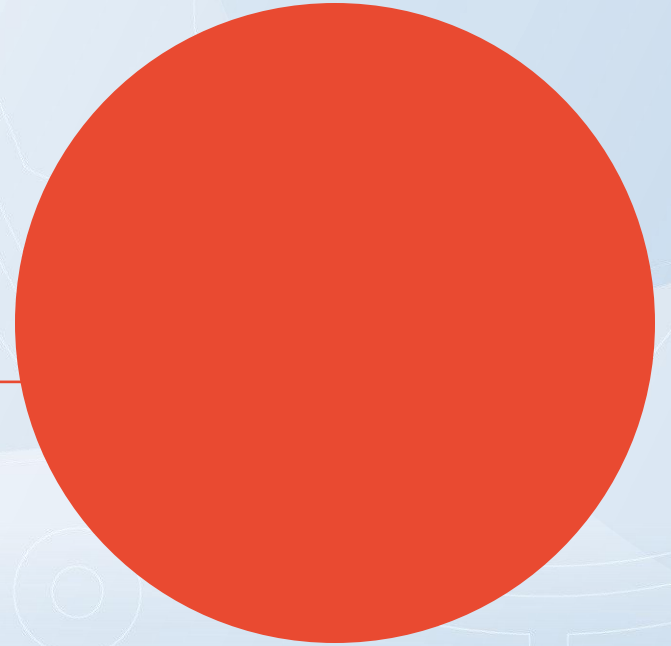
Manufacturer	Drug	adcock ingram	BC	Amne Lifesciences Limited	AUROBINDO	BEXIMCO PHARMA	CELLTRION	Cipla	DESANO	Emcure	HETERO	LOOVZ	LAURIUS LABS	LUPIN	RAKLEODS	COSECO	MICRO LABS LIMITED	Mylan	MATCO	Strides Shasun	SUN PHARMA	TB ALLIANCE	Zydus Cadila		
abbvie	lopinavir, ritonavir (LPV/r)	●	●	●					●	●	●			●								●			8
	lopinavir, ritonavir (LPV/r) paed							●			●														2
	glecaprevir, pibrentasvir (G/P)																		●						1
	atazanavir (ATV)				●			●	●	●	●								●						6
Bristol-Myers Squibb	daclatasvir (DAC)					●		●			●		●					●	●					●	7
GILEAD	bictegravir (BIC)	●	●	●	●				●	●			●	●	●										9
	cobicistat (COBI)	●	●	●					●	●				●	●										7
	elvitegravir	●	●	●											●										5
	emtricitabine (FTC)	●	●	●	●				●	●			●	●	●		●		●						11
	tenofovir alafenamide (TAF)	●	●	●	●				●	●		●	●	●	●		●		●						12
	tenofovir disoproxil fumarate (TDF)	●	●	●																					3
MSD	raltegravir (RAL) paed										●		●												2
	abacavir – paed (ABC)				●																				1
ViiV Healthcare	dolutegravir – adult (DTG)	●	●	●	*	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	17
	dolutegravir – paed	●	●		*	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	14
JOHNS HOPKINS UNIVERSITY	sutezolid																						●		1
	TOTAL	9	8	8	6	1	2	5	8	8	7	2	6	8	7	1	4	5	3	2	3	1	1		



+150

Ongoing pharmaceutical development projects to produce affordable medicines for LMICs

3. Licences in action

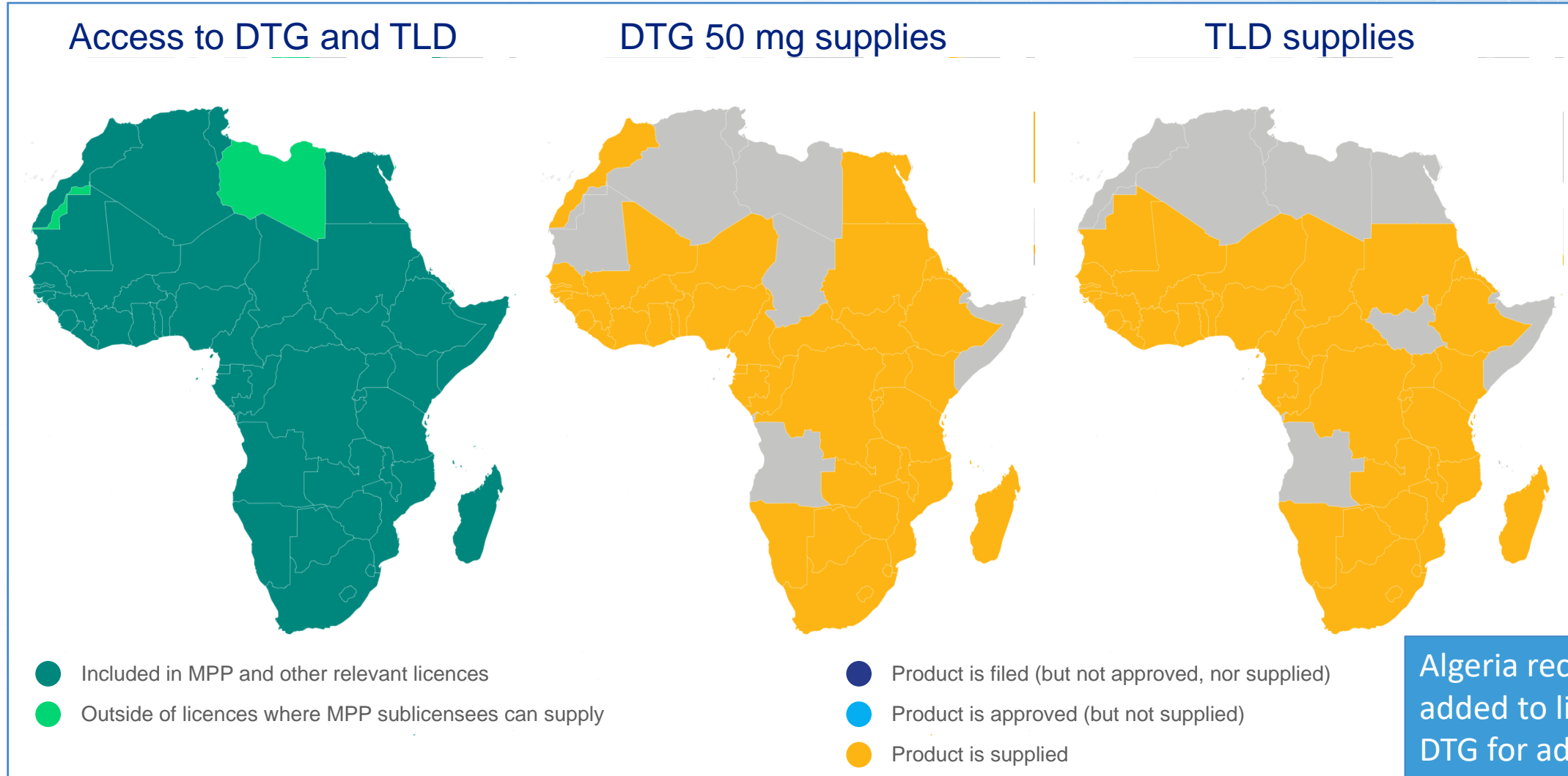


Case study 1: Access to generic DTG products

2013	2014	2015	2016	2017	2018	2019	2020
<p>AUGUST USFDA approves DTG for HIV treatment</p>	<p>APRIL MPP signs a licence with ViiV Healthcare which covers countries home to 94% of people living with HIV in LMICs</p>	<p>DECEMBER Four MPP licensees are already developing products containing DTG</p>	<p>JUNE WHO guidelines recommend DTG in first line treatment</p>	<p>AUGUST 1st MPP licensee receives USFDA approval for fixed dose combination TLD</p> <p>SEPTEMBER Multiple partners announce an annual price of USD 75 – an 83% price reduction from originator</p>	<p>JUNE Six quality-assured generic manufacturers are ready to supply TLD to people living with HIV in LMICs</p>	<p>MARCH DTG 50mg is commercialised in 61 countries and TLD in 37 countries. In all, seven MPP manufacturing partners are ready to supply DTG and its combinations</p>	<p>JUNE ViiVs DTG 10mg dispersible for paediatric use is FDA approved. Two generics are awaiting SRA, 2 more are in development</p> <p>DTG 50mg is available at \$5.30 a pack in certain countries</p> <p>OCTOBER Algeria gains inclusion to the DTG adult licence</p>

Just four years after FDA approval of new HIV medicine DTG, MPP licensees had developed the fixed-dose combination TLD for use in LMICs

Case study 1: Access to generic DTG products

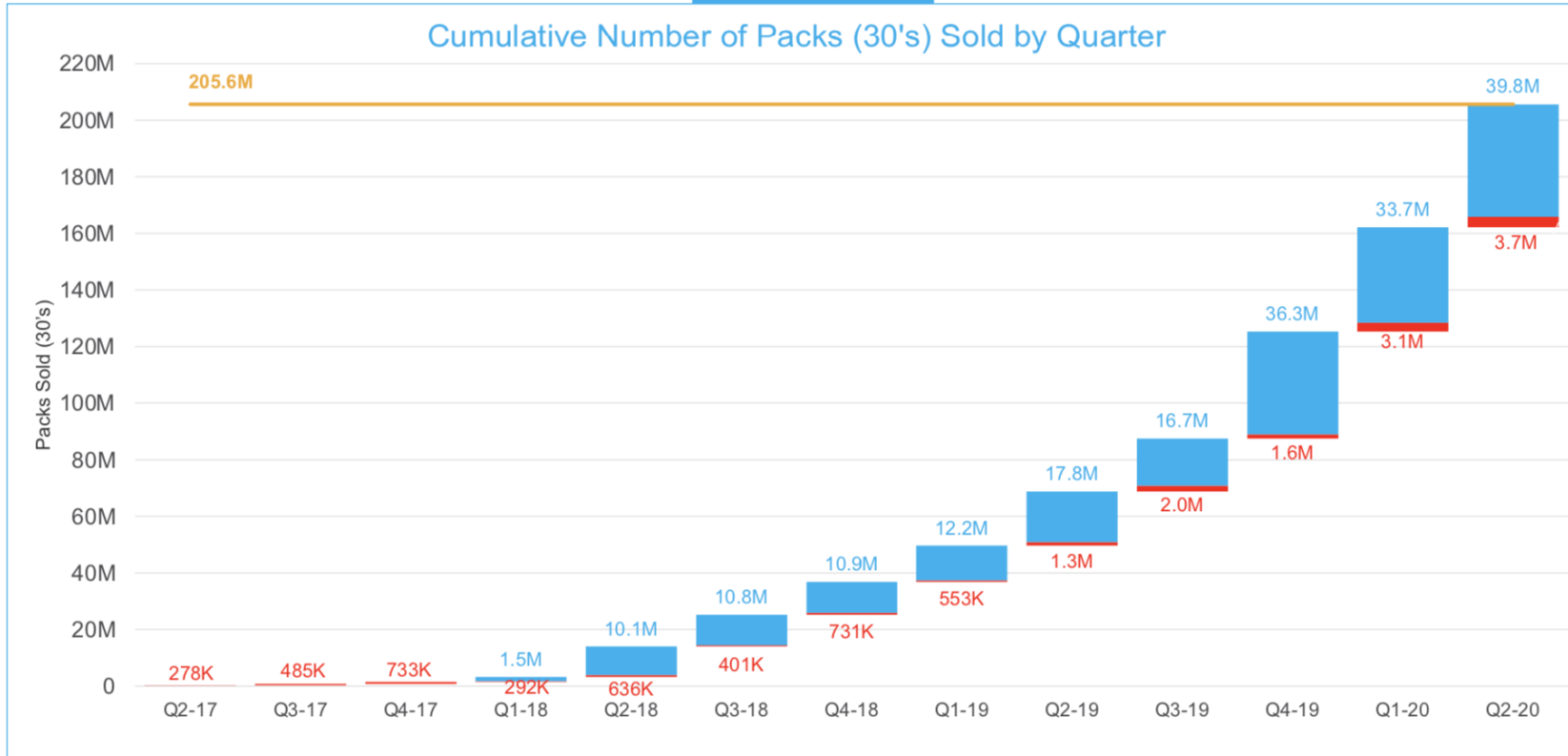


Algeria recently added to licence for DTG for adult use

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Case study 1: Access to generic DTG products

189.8 million packs of TLD and 15.8 million packs of DTG 50mg sold till June 2020



Source: confidential sales data by MPP licensees

● DTG 50mg ● TLD ● Total Packs

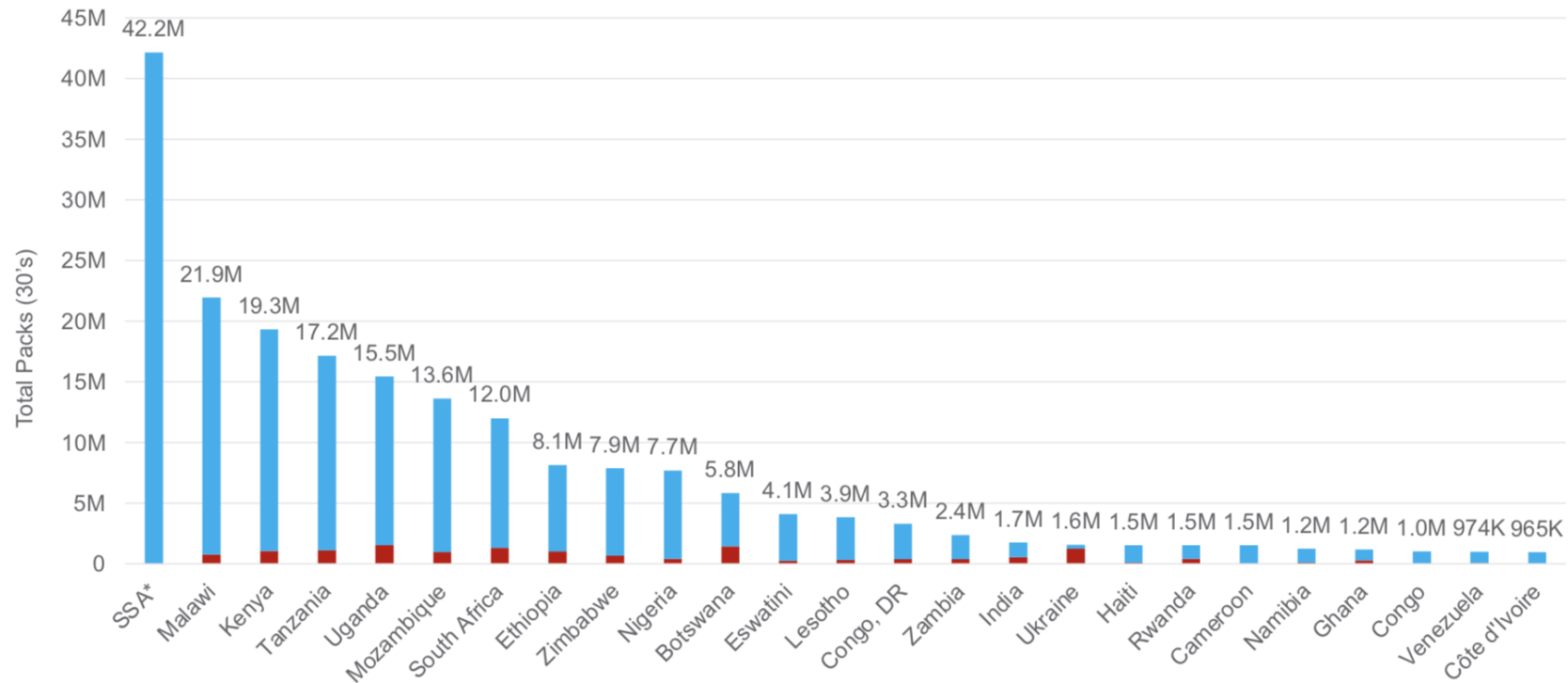
Supply data as of June 2020

Scale up of DTG 50 mg and TLD 300/300/50 mg is accelerating

Case study 1: Access to generic DTG products

Top 10 countries comprise 82% of the TLD Market in LMICs (by volume)
DTG 50mg is largely being used for TB-coinfection and/or 2L ART

Sale of DTG-Based HIV Treatment Through MPP Licensees By Country (TLD & DTG)



All top 14 volume countries scaling up of DTG 50 mg and TLD 300/300/50 mg are in the African region

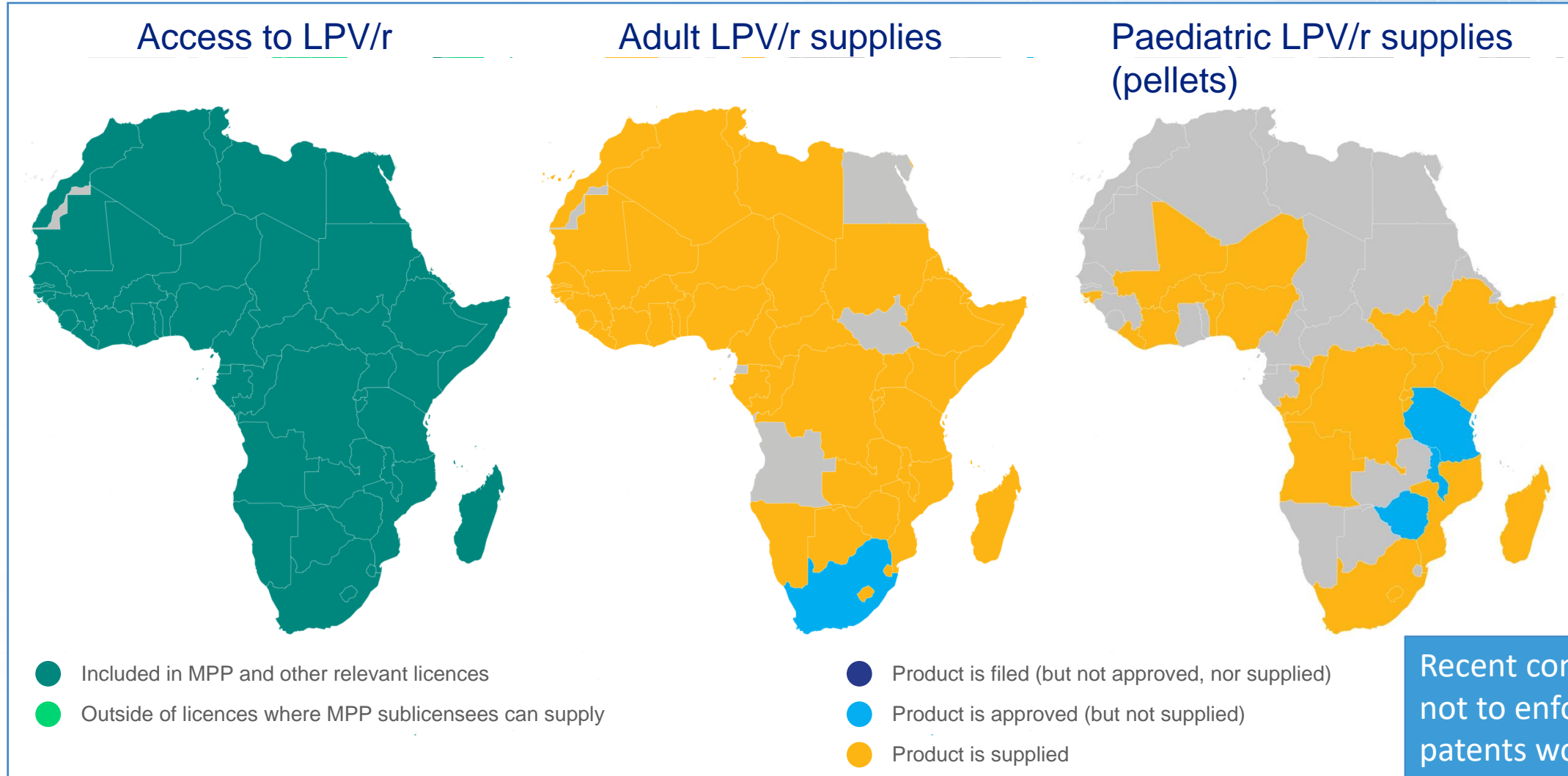
Source: confidential sales data by MPP licensees

* SSA stands for non-identified sub-Saharan African countries supplied through procurement agents

Supply data as of June 2020

● DTG 50mg ● TLD ⊕ DTG + TLD

Case study 2: Access to generic LPV/r products



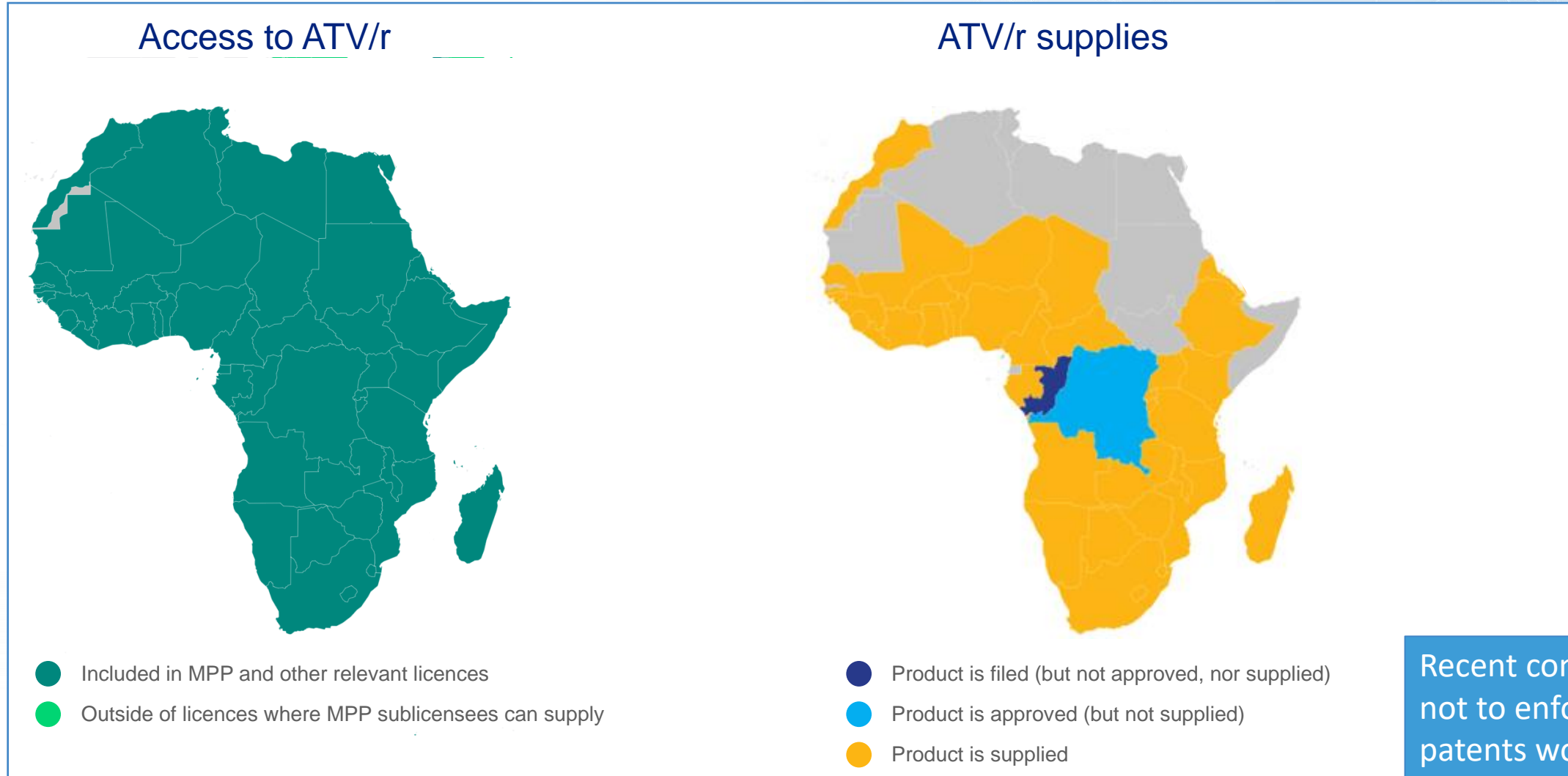
Patent and licence data as of October 2020

Supply data as of June 2020

Recent commitment not to enforce LPV/r patents worldwide

Slide 19

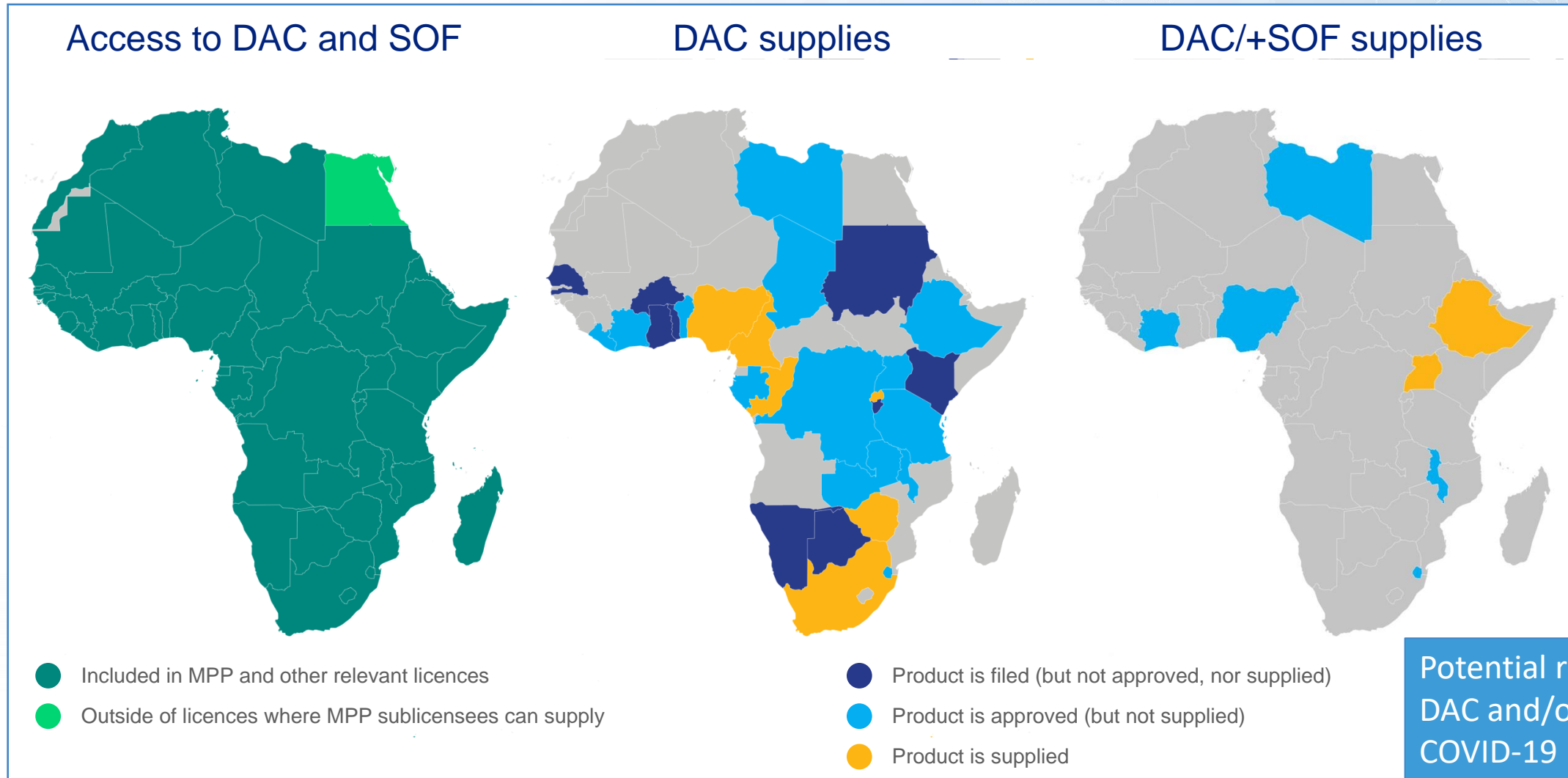
Case study 3: Access to generic ATV/r products



Recent commitment not to enforce RTV patents worldwide

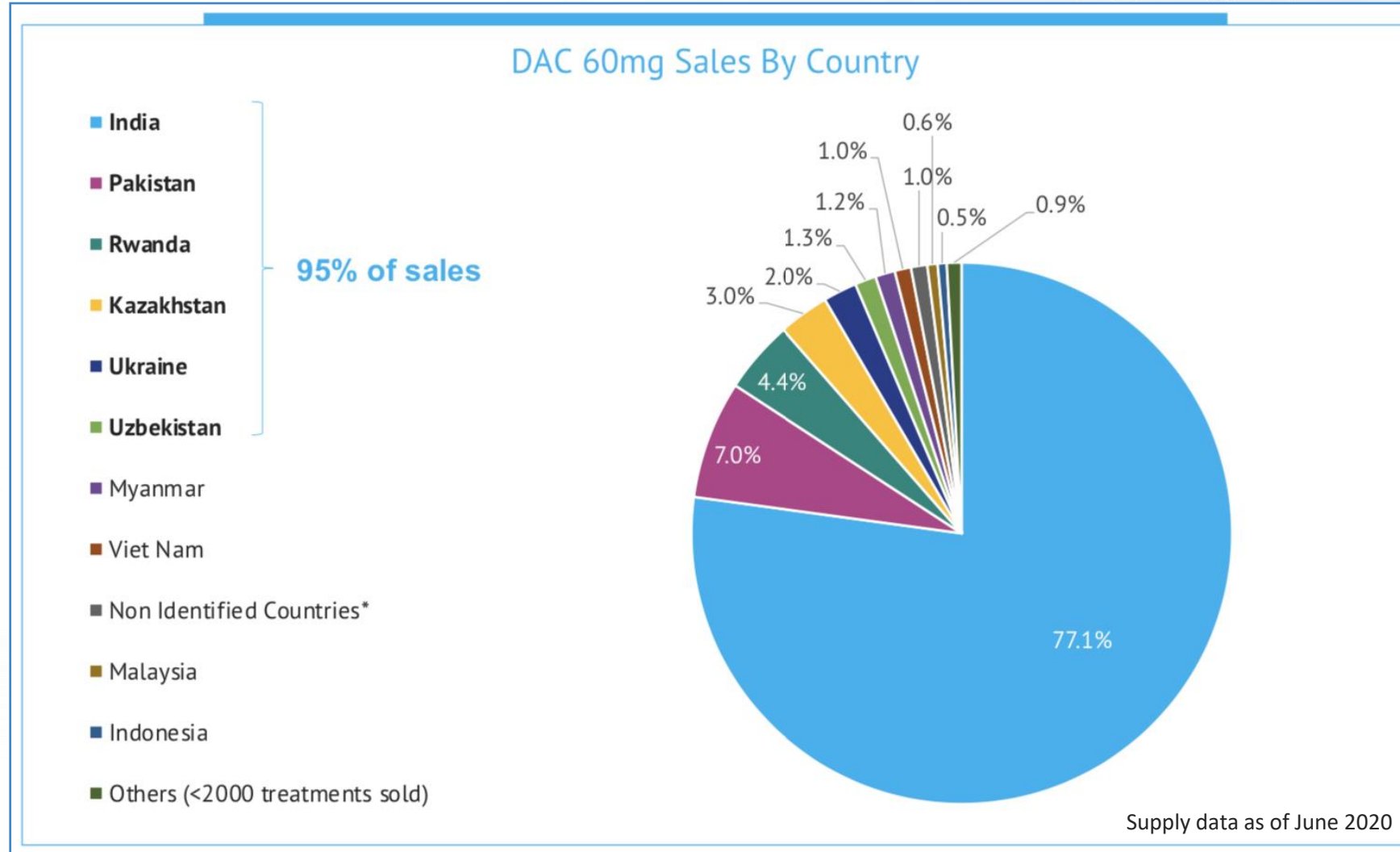
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Case study 4: Access to generic DAC products



Potential role for
DAC and/or SOF in
COVID-19

Case study 4: Access to generic DAC products



Uptake of DAC products remains limited in the African region

But opportunities to benefit from low, negotiated prices and procure from international agencies (Global Fund, IDA Foundation, UNDP, GPRO) exist...

Case study 5: Access to TB treatments

- MPP has one licence for candidate TB medicine sutezolid (currently in phase 2 studies)
- MPP has also prioritized MDR-TB medicine bedaquiline (BDQ) for in-licensing; this medicine is now WHO-recommended as the backbone for all-oral MDR-TB treatment, and access to quality, affordable generics could have major economic and public health impact

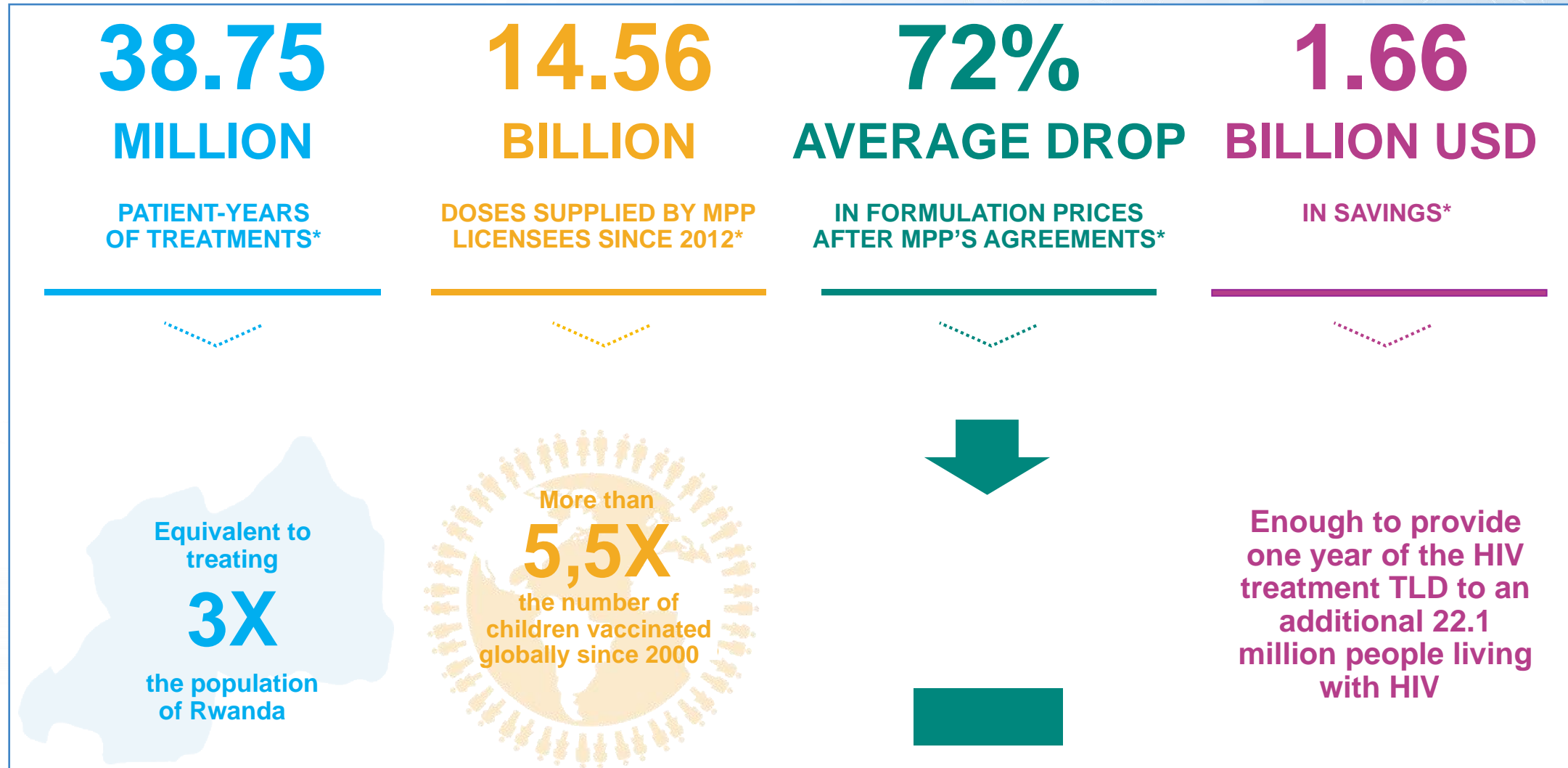
Licensing through the MPP of patented essential medicines for the treatment of tuberculosis (e.g. bedaquiline) would also be a welcome contribution to improving access.

Report from the 22nd WHO Expert Committee on the Selection and Use of Essential Medicines - April 2019

“To ensure equitable access to bedaquiline in LMICs and sufficient and stable manufacturing capacity, we call on J&J to issue non-exclusive voluntary licenses for bedaquiline via the MPP.”

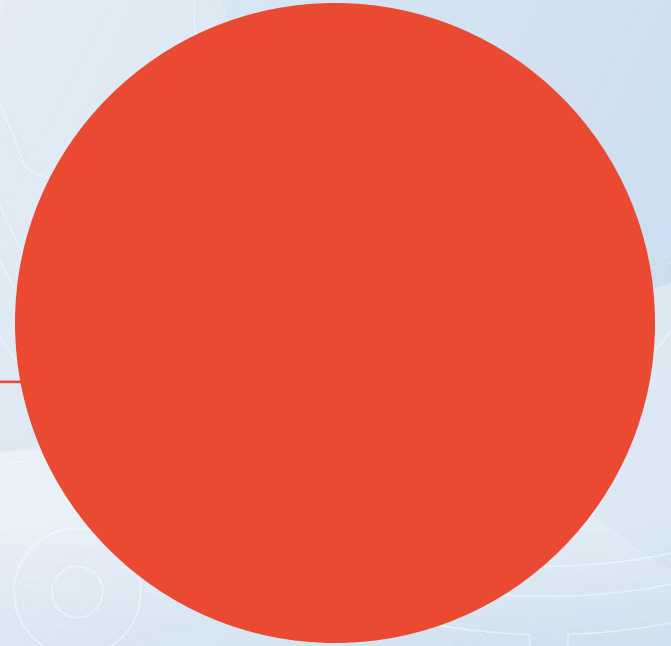
TB CAB Access Considerations Statement Regarding Johnson & Johnson Announcement of Bedaquiline Price Reduction - July 2020

Impact of public-health licensing



* Impact of MPP agreements (HIV + HCV products) as of June 2020 (source: KPMG)

4. Access to medicines tools



Medicines patents and licences database – MedsPaL

Patent status data on more than

8500

NATIONAL PATENT APPLICATIONS

from over 130 LMICs

Covering approximately

110

PRIORITY MEDICINES

(approx. 220 formulations)



With information on

50

LICENCES

and other access agreements in LMICs

And data exclusivity information from

15

COUNTRIES

www.medspal.org

Most comprehensive open-access source of information on patent and licensing status of patented essential medicines in LMICs

Now also includes COVID-19 candidate medicines having reached phase 3 clinical trials

MedsPaL
THE MEDICINES PATENTS AND LICENCES DATABASE

Collaborations in Africa

African Regional Intellectual Property Organization (ARIPO)



Egyptian Patent Office (EGPO)





South Africa's Companies and Intellectual Property Commission (CIPC)




MPP access to medicines tracker – Table

Interactive Table

Key ■ HIV ■ Hepatitis C ■ Tuberculosis

Filter table rows by product  

PRODUCTS	COMPANIES DEVELOPING THE PRODUCT	PENDING APPROVAL		READY TO SUPPLY			COUNTRIES WHERE		
		WHO-PQ*	USFDA**	WHO-PQ* APPROVED	USFDA** APPROVED	ERP*** APPROVED	PRODUCT IS FILED	PRODUCT IS APPROVED	PRODUCT IS SOLD
<p>DTG 50mg</p> <p>Licensed from ViiV Healthcare</p> 	12	3	2	<p>Cipla</p> <p>Emcure</p> <p>HETERO</p> <p>LAURUS Labs</p> <p>Mylan</p> <p>SUN PHARMA</p>	<p>AUROBINDO</p> <p>Cipla</p> <p>LAURUS Labs</p> <p>MICRO LABS LIMITED</p> <p>Mylan</p>		Benin, Bolivia (Plurinational State of), Burkina Faso, Burundi, Cameroon, Chile, Dominican Republic, Ecuador.	Anguilla, Antigua and Barbuda, Bahamas, Barbados, Botswana, Cambodia, Congo, democratic Republic of the, Conao.	Afghanistan, Albania, Anguilla, Antigua and Barbuda, Argentina, Armenia, Azerbaijan, Bahamas, Barbados, Benin, Bermuda.
TLD (TDF/3TC/DTG)	15	5	5	7	6		21	45	81

Information on progress and uptake of MPP-licensed generic products

Updated quarterly

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MPP access to medicines tracker – Map

Interactive Map

HIV x v

DRV/r (400/50 mg) x v

Worldwide x v

Clear all filters

Product availability

Patent and licensing status

Included in MPP and other relevant licences

Outside of licences where MPP sublicensees can supply

Outside of licences with granted compound

Low- & middle-income

High-income

Save map v

Worldwide

DRV/r (400/50 mg) – darunavir/ritonavir:

- Fixed-dose combination antiretroviral regimen recommended by WHO as part of an alternative treatment of HIV. [More](#)

Product availability

DRV/r (400/50 mg)

- is filed in 10 countries *
- is approved in 0 country
- is supplied in 0 country

**For confidentiality purposes, countries will be disclosed when approval from a stringent regulatory authority (SRA) for this product will have been granted to more than one licensee.*

Patent and licensing status

12 Oct 2020

Covers MPP-licensed HIV and HCV drugs

Is access possible?

- Patent and licensing status

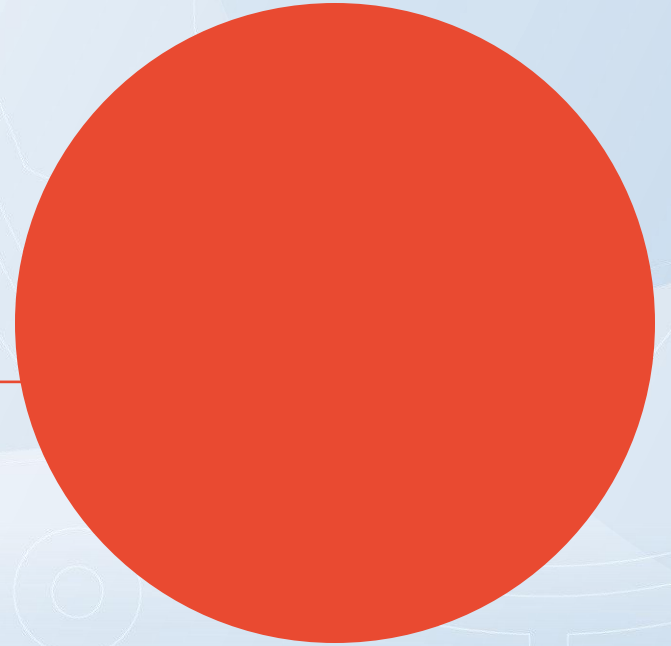
Is the drug getting into the country?

- Registration and supply status

Possibility to explore across geographies and over time

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5. Moving forward



MPP mandate – Essential medicines and COVID-19



Perspectives

Patent pooling to increase access to essential medicines

Esteban Burrone,^a Dzintars Gotham,^a Andy Gray,^b Kees de Joncheere,^c Nicola Magrini,^d Yehoda M Martei,^e Charles Gore^a & Marie Paule Kieny^a

[News & Publications](#) » [News & Press Releases](#) » [News](#)

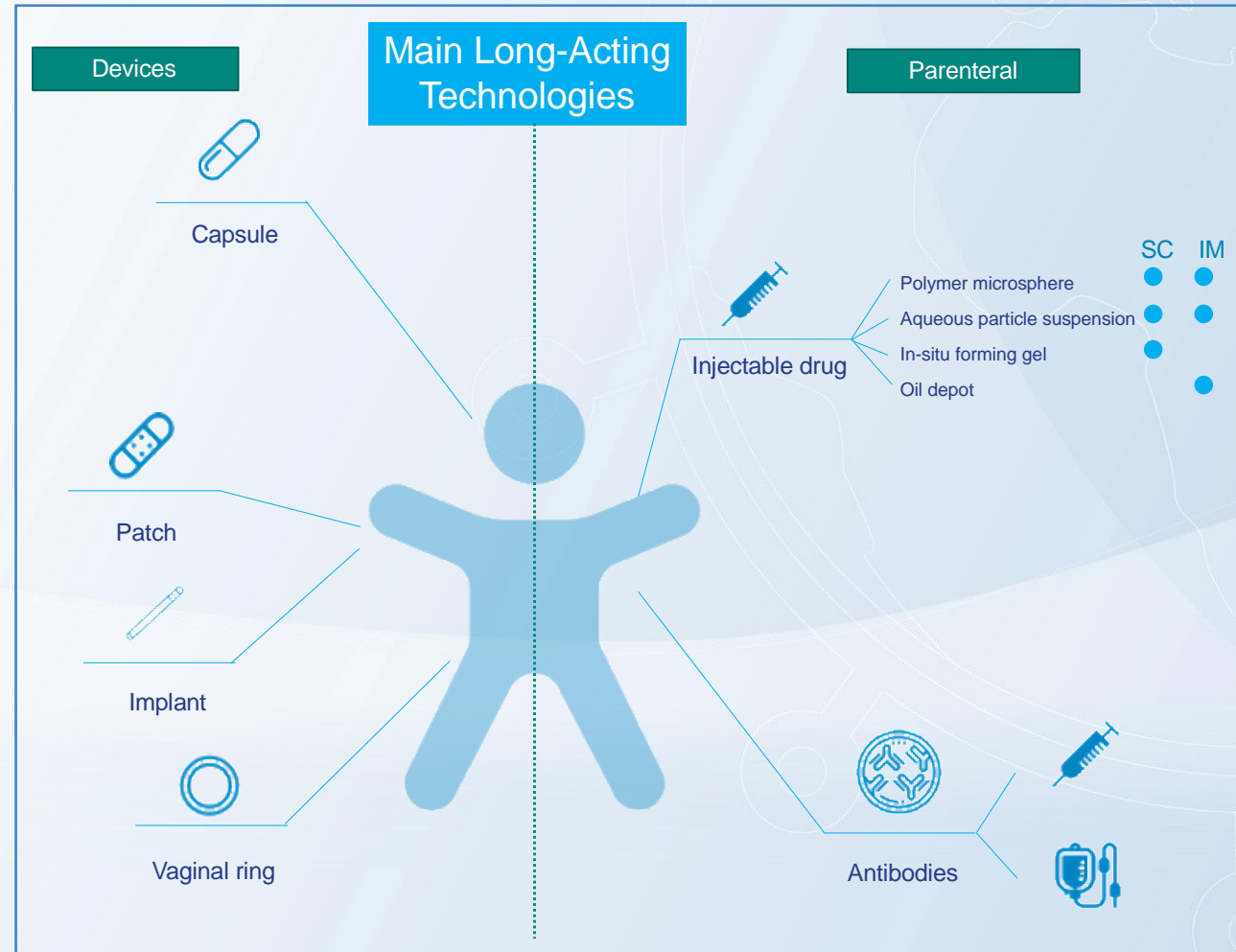
The Medicines Patent Pool and Unitaid respond to access efforts for COVID-19 treatments and technologies

31 March 2020

The MPP mandate now covers :

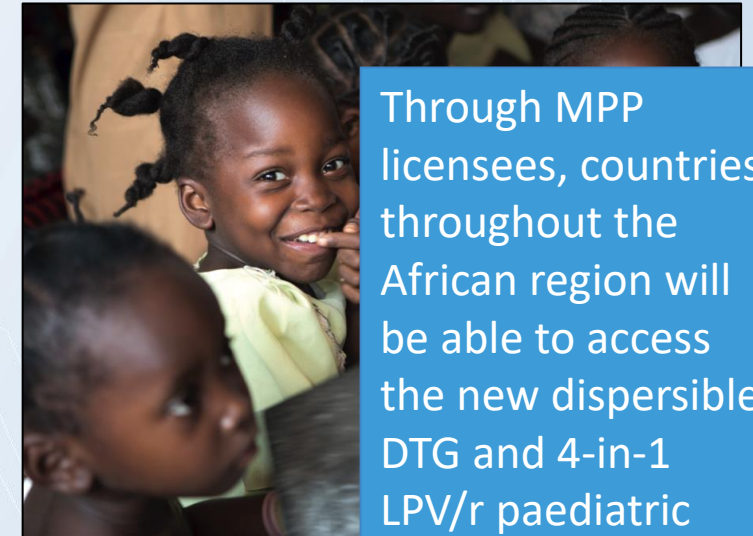
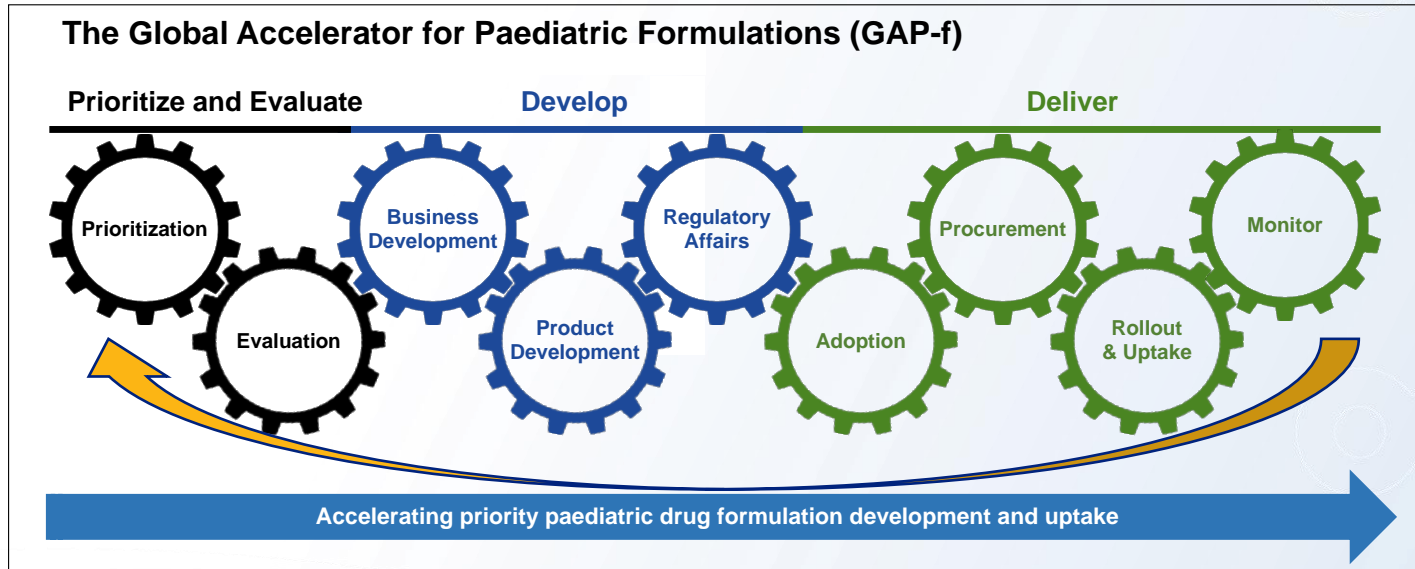
- HIV medicines
- HCV medicines
- TB medicines
- Medicines included in the WHO Model List of Essential Medicines
- Medicines with strong potential for future inclusion in the WHO EML
- COVID-19 health technologies (with a focus on therapeutics)

The next frontier – Long-acting treatments



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Addressing children's needs



Through MPP licensees, countries throughout the African region will be able to access the new dispersible DTG and 4-in-1 LPV/r paediatric drug formulations

POLICY BRIEF – JULY 2020

CONSIDERATIONS FOR INTRODUCING NEW ANTIRETROVIRAL DRUG FORMULATIONS FOR CHILDREN



MPP is a proud partner of the Global Accelerator for Paediatric Formulations WHO Network, with CHAI, EGPAF and PENTA-ID as co-founding members

MPP contributes to efficient coordination with innovator and generic pharmaceutical companies around prioritized paediatric drug formulations

MPP licences are royalty-free when it comes to paediatric use of licensed medicines

MPP can support you – Get in touch!

You can contact us to:

- Get information on **access opportunities** regarding MPP-licensed medicines in your country
- Inform us of your interest to start **rolling out MPP-licensed medicines**, or the need to increase generic competition, in your country
- Let us know of **stock outs, quality or other issues** for MPP-licensed medicines in your country
- Express your interest in **accessing new products** through potential future MPP licences (in particular for MPP-prioritized products and disease areas)
<https://medicinespatentpool.org/what-we-do/prioritising-medicines-for-licensing/>

Your point of contact for engagement in the African region:

Sébastien Morin – Policy and Advocacy Manager, MPP, smorin@mppf.ch

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Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

**Swiss Agency for Development
and Cooperation SDC**

