

medicines
patent
pool

Medicines Patent Pool (MPP)

The promise of long acting injectables in Pakistan

2 May 2024 – Islamabad (virtual)

Presented by Dr Navneet Singh Tewatia

MEDICINESPATENTPOOL.ORG



About the Medicines Patent Pool

The Medicines Patent Pool (MPP) is a public health organization whose mission is to increase equitable access to innovative medicines and other health technologies through **public health-oriented voluntary licensing** and **technology transfer**.



MPP's is funded by Unitaid and the governments of France, Germany, Switzerland and Japan.



The MPP model: How it works in practice

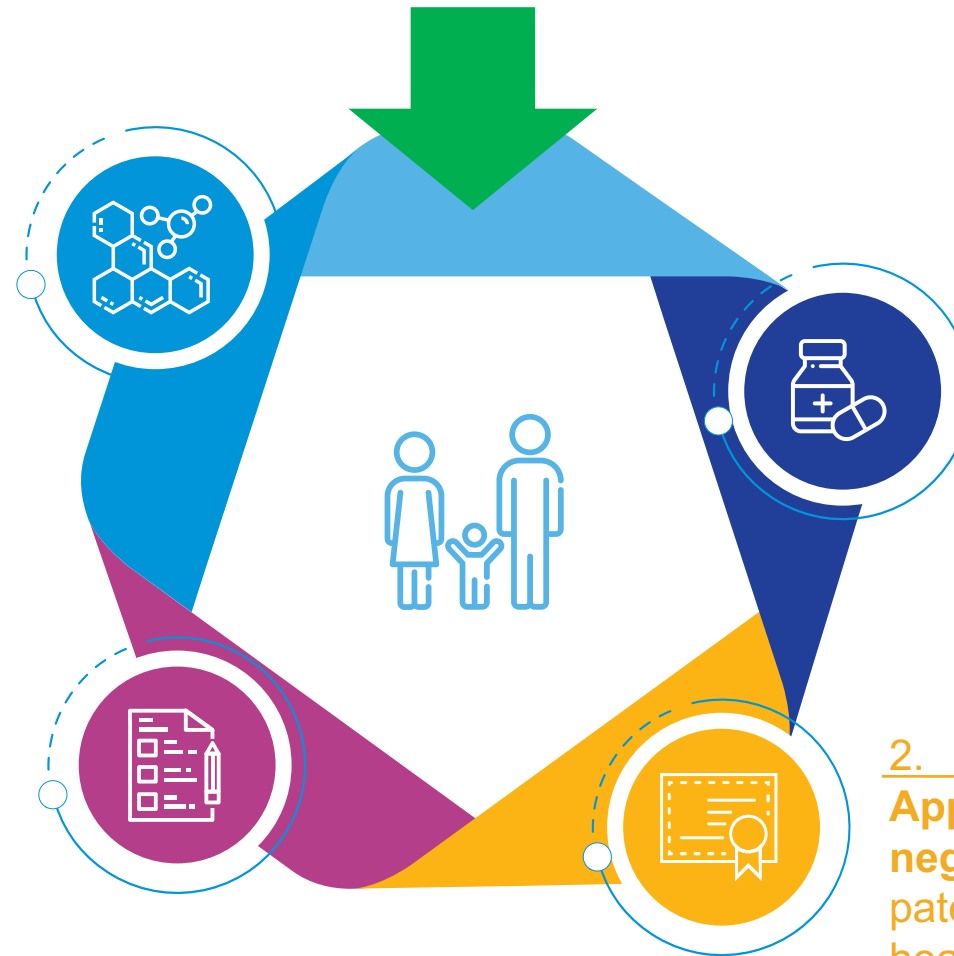
4. **Work with generic manufacturers** to accelerate the development and registration of adapted formulations for LMICs

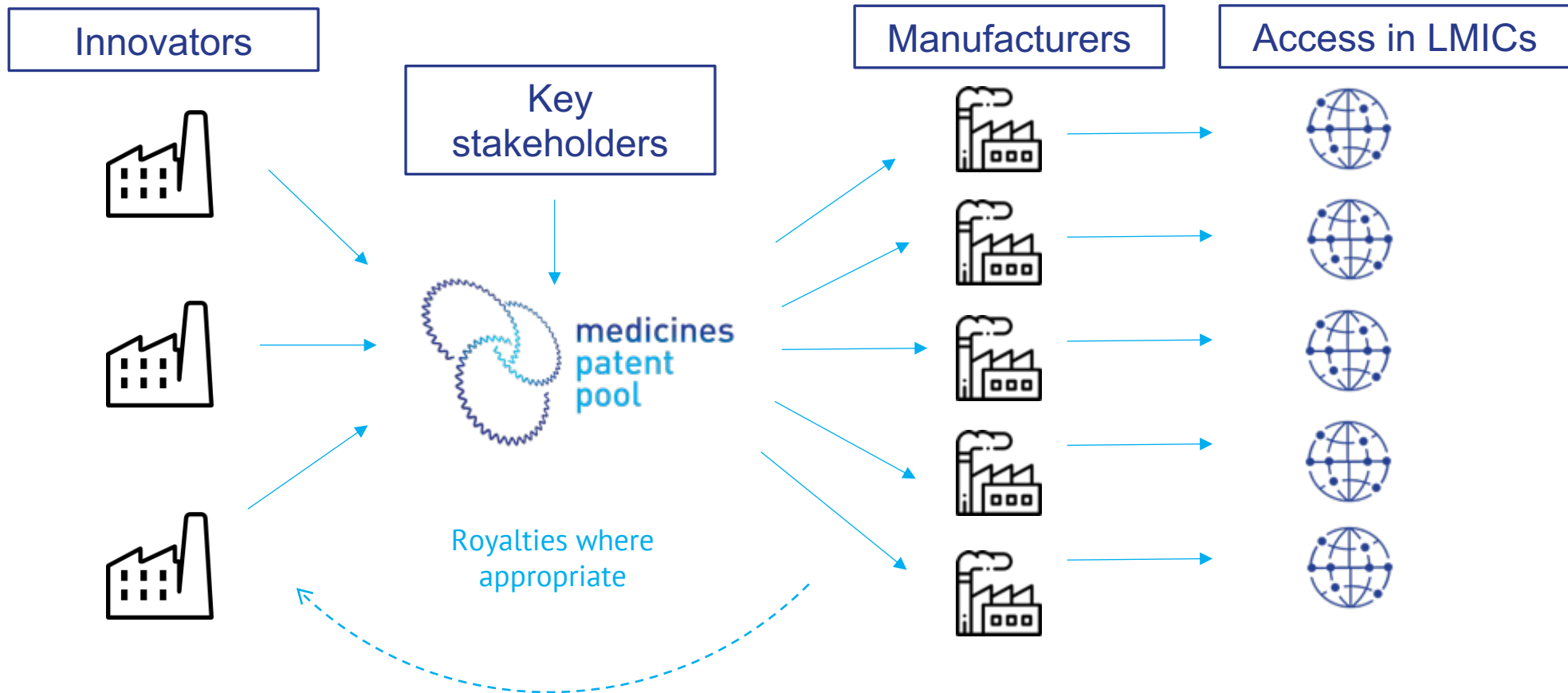
3. **Sublicense** to selected generic pharmaceutical companies committed to supplying LMICs

5. **Collaborate with various partners** to increase access to the medicines in LMICs

1. **Identify medicines and other health technologies** needed in low- and middle-income countries where licensing can improve access

2. **Approach innovators and negotiate licences** with patent holders from a public health perspective





Guiding Principles

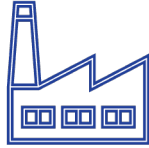
- | | | |
|------------------------|--|-----------------|
| ✓ Public health driven | ✓ Focus on accelerating access | ✓ Non-exclusive |
| ✓ Flexible | ✓ Facilitating innovation (where needed) | ✓ Voluntary |
| ✓ Bespoke | ✓ Complementary to other access mechanisms | ✓ Transparent |
| ✓ Collaborative | | |

BENEFITING ALL STAKEHOLDERS



PATENT HOLDERS

Effective and impactful way to make innovative products available in resource-limited settings; complements commercial strategy; reputational benefits; royalties



LOW-COST PRODUCERS

Accelerated approach to the development of affordable versions of health technologies needed in LMICs; where needed, possibility to develop products adapted to specific LMIC needs (e.g. new formulations of existing medicines)



GOVERNMENTS, TREATMENT PROVIDERS

Ability to stretch budgets to treat (prevent/diagnose) more people with improved products at more affordable prices



COMMUNITIES

Greater access to quality, appropriate, affordable and life-saving health technologies

What is MPP's scope of work?

In 2021, decision to create a **technology transfer team** at MPP initially focusing on COVID-19 mRNA vaccines

In 2020, expanded to health technologies relevant for **COVID-19**

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

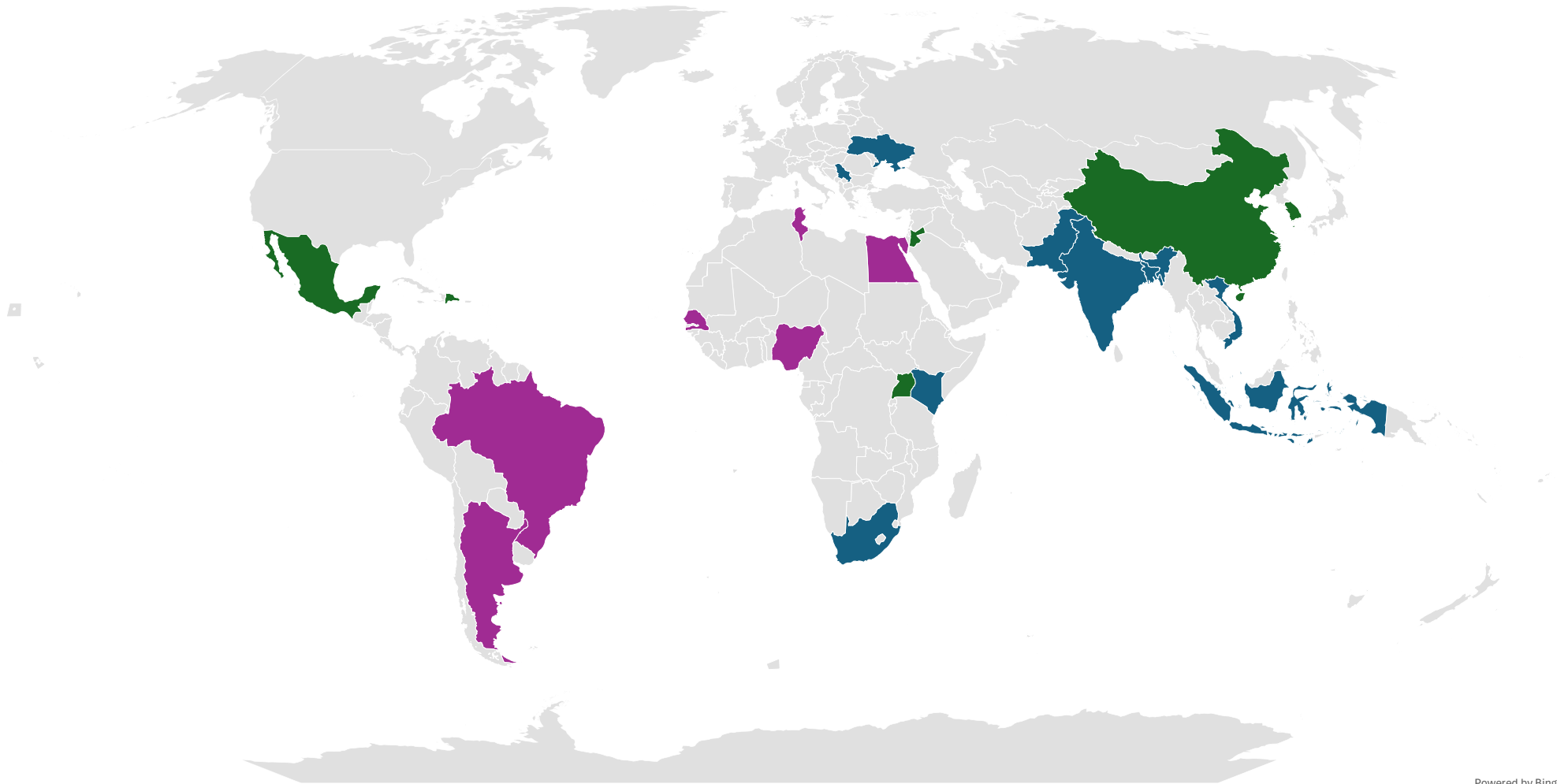
To increase access to new treatments for **HIV** through licensing of patented medicines

In 2018 decision to expand to **other patented essential medicines** including in **non-communicable diseases**

In 2021 inclusion of **biotherapeutics** that are either on the WHO EML or have strong potential for future inclusion (including monoclonal antibodies)

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

MPP's manufacturing partners across all regions

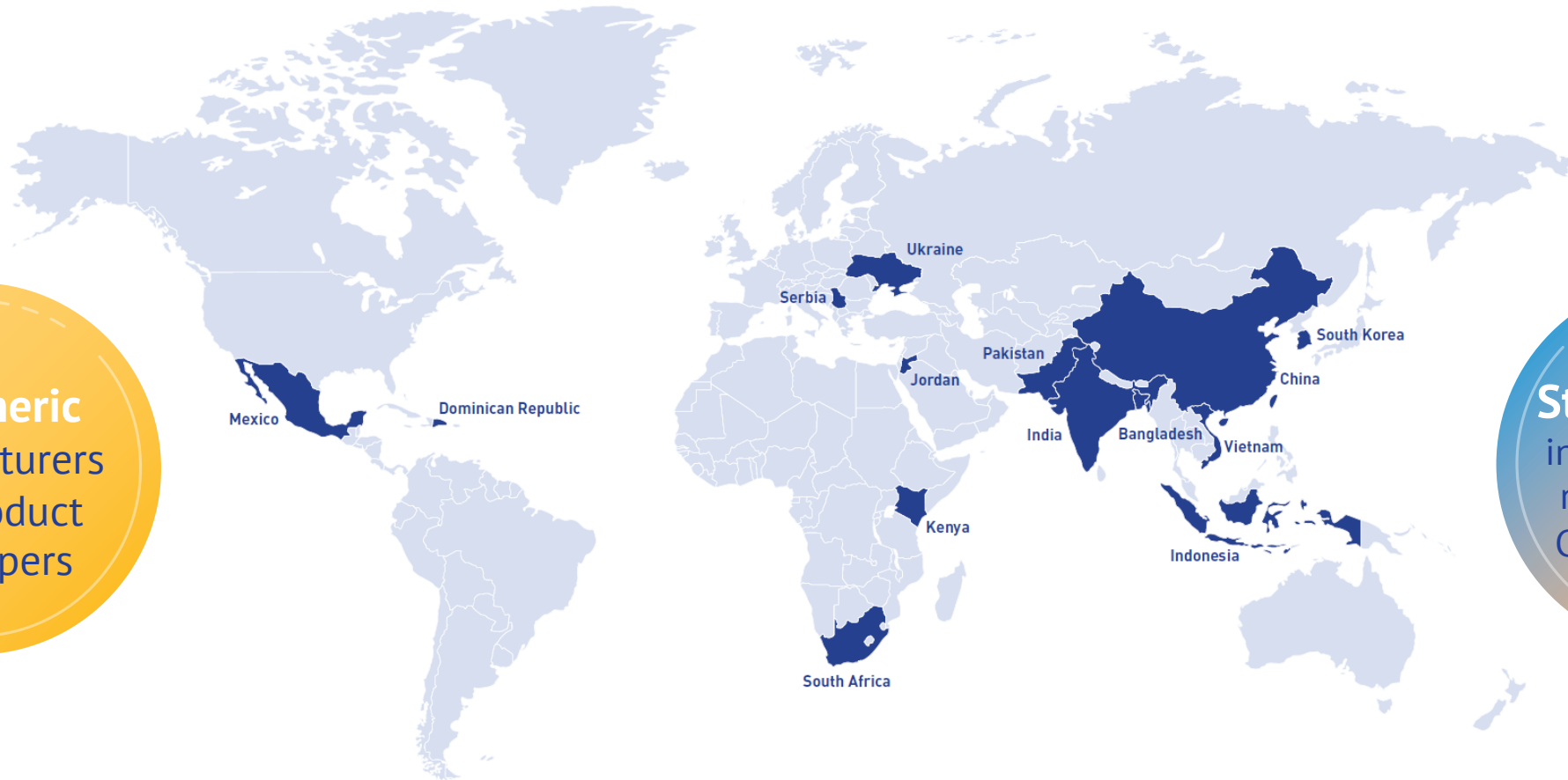


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- MPP's licensee / licensee's subsidiary & mRNA Technology Transfer partners
- MPP's licensee / licensee's subsidiary
- mRNA Technology Transfer programme partners

MPP's network of manufacturing partners are in 14 countries

58 generic
manufacturers
and product
developers



Steep increase
in manufacturing
network during
Covid-19 across
LMICs

58 generic manufacturers and product developers

Bangladesh

Beximco
Incepta

China

Apeloa
Aurisco

Biochem
BrightGene
Desano
Fosun
Jiuzhou
Huahai
Langhua

Dominican Republic

Magnachem

India

Amneal

Arene
Aurobindo
BDR
Biocon
Biophore
Cadila

Cipla
Divi's
Dr Reddy's
Emcure
Glenmark
Granules

Hetero
Laurus
Lupin
Macleods
Mangalam
Micro Labs

MSN
Natco
SMS Pharma
Strides
Sun
Torrent

USV
Viatrix
Zydus
Cadila

Indonesia

Kimia Farma
Brightgene

Jordan

Hikma

Kenya

UCL

Mexico

Neolpharma

Pakistan

Remington

Serbia

FHI Zdravlje

South Africa

Adcock
Ingram
Biotech
CPT

South Korea

Celltrion
Dongbang

Ukraine

Darnitsa

Vietnam

Stella

Product developers

TB Alliance
Gates MRI

MPP has signed licences with 18 innovators

PATENT HOLDERS	HIV	HCV	HBV	TB	MALARIA	COVID-19	CANCER
AbbVie	●	●					
Bristol Myers Squibb	●	●					
Boehringer Ingelheim	●						
Gilead Sciences	●		●				
Janssen	●						
Johns Hopkins University				●			
Merck Sharp & Dohme	●					●	
MedinCell					●		
Novartis							●
Pfizer				●		●	
Pharco		●					
Spanish National Research Council						●	
Shionogi						●	
Tandem Nano		●		●	●		
ViiV Healthcare	●						
University of Liverpool	●						
University of Washington	●						
National Institutes of Health	●					●	

Licensing and sublicensing agreements, and other agreements on specific products with partners: **Pakistan**



Cancer

- NILOTINIB



HIV

- ABACAVIR – PAEDIATRICS (ABC)
- ATAZANAVIR (ATV)
- BICTEGRAVIR (BIC)
- COBICISTAT (COBI)
- DOLUTEGRAVIR - ADULT (DTG)
- DOLUTEGRAVIR - PAEDIATRICS (DTG)
- **ELVITEGRAVIR (EVG)**
- EMTRICITABINE (FTC)
- LOPINAVIR, RITONAVIR (LPV/r)
- LOPINAVIR, RITONAVIR (LPV/r) PAEDIATRICS
- RALTEGRAVIR (RAL) PAEDIATRICS
- SOLID DRUG NANOPARTICLE TECHNOLOGY
- TENOFOVIR ALAFENAMIDE (TAF)
- TENOFOVIR DISOPROXIL FUMARATE (TDF)



COVID-19

COVID-19 antivirals

- ENSITRELVIR FUMARIC ACID
- MOLNUPIRAVIR (MOL)
- NIRMATRELVIR



Long-Acting
Therapeutics

- CABOTEGRAVIR LONG-ACTING (LA) FOR HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)
- LONG-ACTING INJECTABLE HIV DRUG COMBINATION TECHNOLOGY
- LONG-ACTING TECHNOLOGIES FOR HCV, TB, AND MALARIA TREATMENT
- LONG-ACTING TECHNOLOGY FOR MALARIA VECTOR CONTROL



Viral
Hepatitis

- DACLATASVIR (DAC)
- GLECAPREVIR/PIBRENTASVIR (G/P)



TB

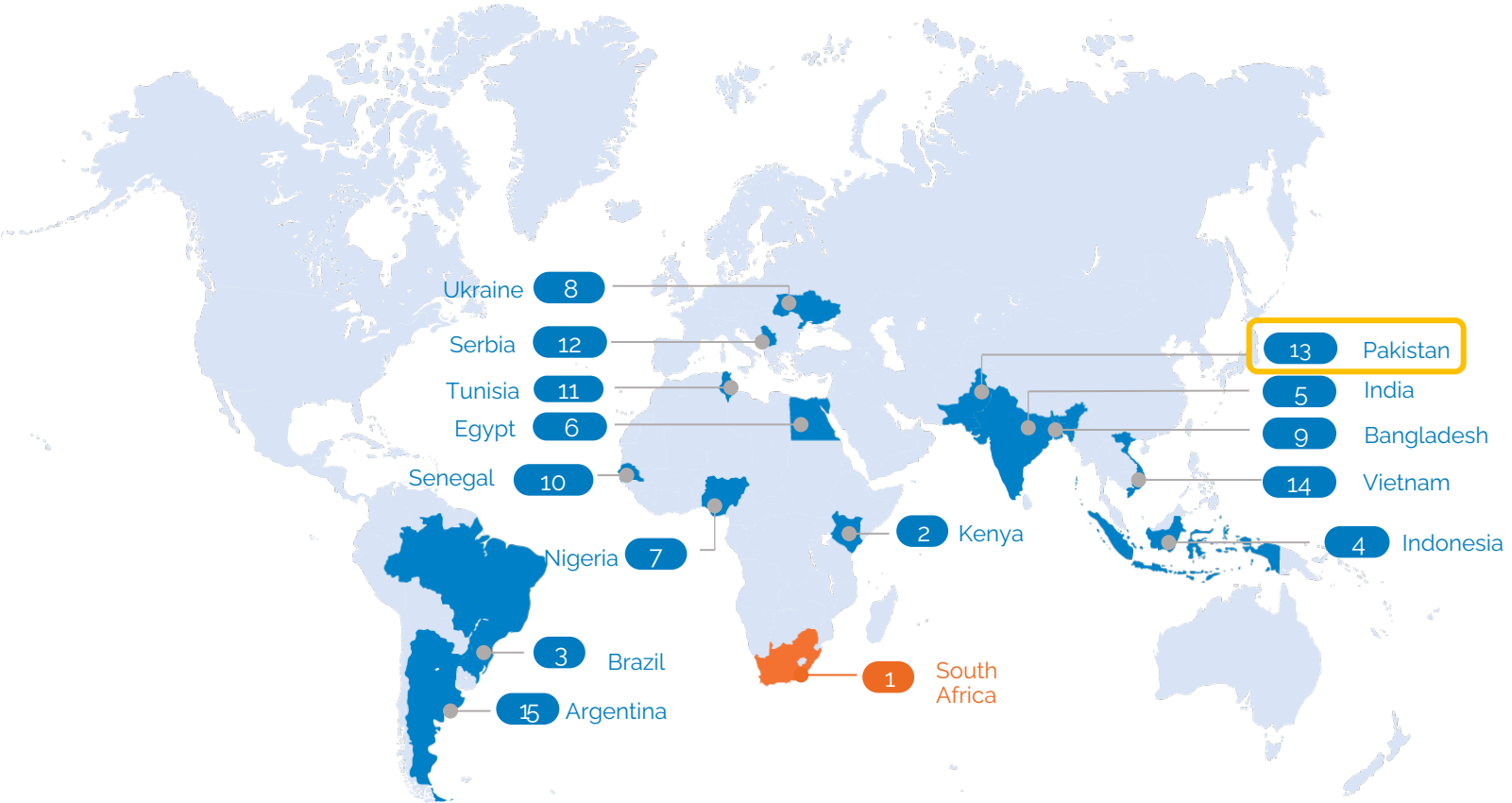
- SUTEZOLID - Johns Hopkins University



- **Products supplied in Pakistan through MPP licences:**
 - **HIV**
 - Atazanavir/ritonavir (300/100 mg)
 - Dolutegravir (50 mg)
 - Tenofovir/lamivudine/dolutegravir (TLD) (300/300/50 mg)
 - **Hepatitis C**
 - Daclatasvir (60 mg)
- **Manufacturing partners in Pakistan:**
 - Pakistan company [Remington](#) is a licensee of MPP and has entered into agreements for the manufacturing of **molnupiravir** and **nirmatrelvir** (for COVID-19) and **glecaprevir/pibrentasvir** (for hepatitis C)
- **mRNA Technology Transfer Hub Programme:**
 - The Pakistan **National Institute of Health** is one of the recipients of mRNA technology from the WHO/MPP mRNA technology transfer programme, a global initiative that aims to improve countries' mRNA manufacturing capabilities in low- and middle-income countries (more details in next slide).
- **Cancer:**
 - Pakistan is one of the countries included in the MPP's first licence on a cancer medicine: **nilotinib**

15 Manufacturing Partners have been selected in Feb-Apr 2022 in LMICs to receive the technology from Afrigen

- 1 Afrigen mRNA technology development and training
- 2 Biovac 1st Partner
- 3 Biovax
- 4 Bio-Manguinhos
- 5 Biofarma
- 6 BiologicalE
- 7 BioGeneric Pharma
- 8 Biovaccines Nigeria
- 9 Darnitsa
- 10 Incepta Vaccine
- 11 Institut Pasteur de Dakar
- 12 Institut Pasteur de Tunis
- 13 Institut Torlak
- 14 National Institute of Health
- 15 Polyvac
- 16 Sinergium Biotech

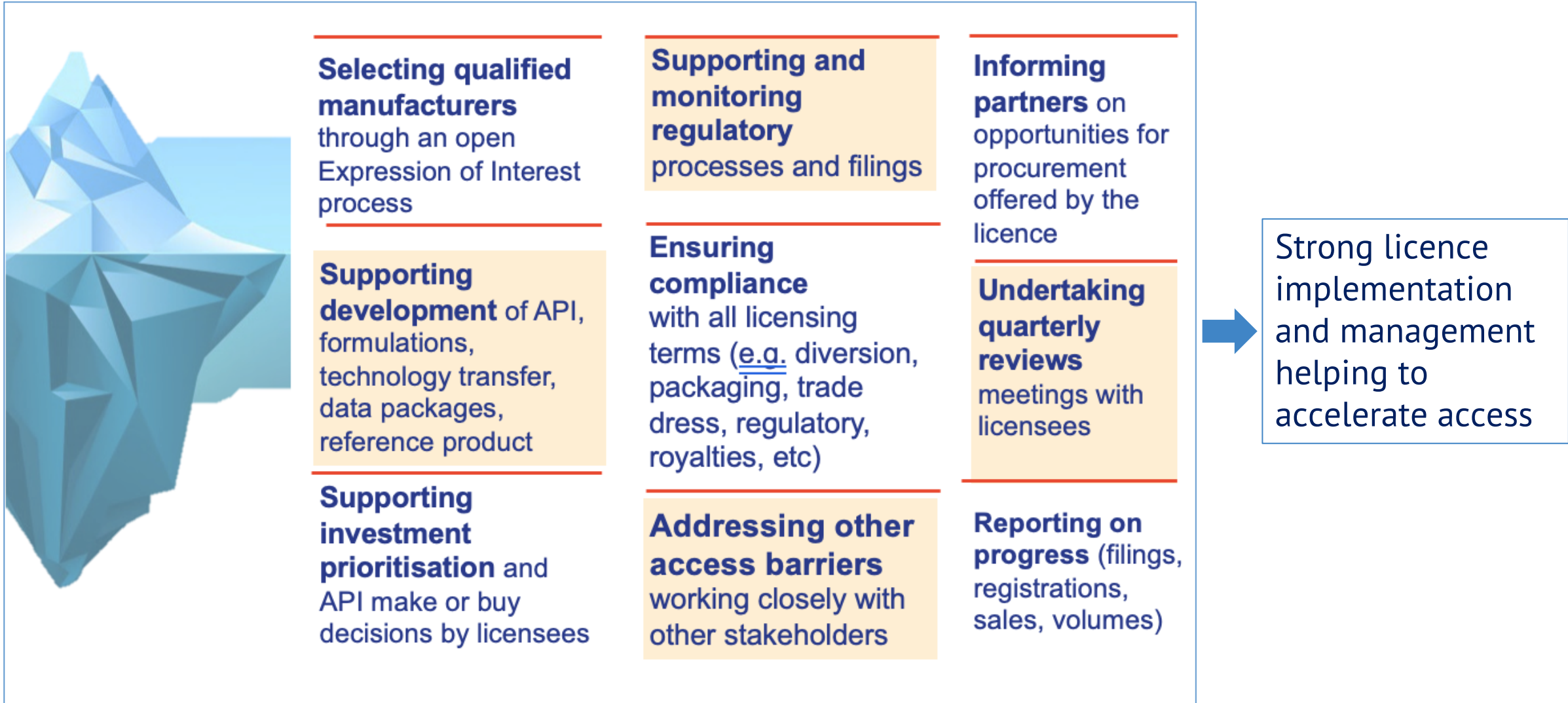


MPP licences “provide the highest level of flexibility and broadest geographical scope,” and licensing terms are “transparent” and “pro-access.”



Access to Medicines Index reports

Licensing is the tip of the iceberg



Our footprint – MPP’s impact

Data based on methodology described in peer-reviewed paper: Morin et al “The economic and public health impact of intellectual property licensing of medicines for low-income and middle-income countries: a modelling study” **The Lancet Public Health**, 2021

**34.69
Bn**

doses of
treatment
supplied
(2010 - 2022)



**USD
1.5 Bn**

dollars saved
through
MPP’s licences
(2010 - 2022)



By 2030

170,000

projected
deaths
averted



148

countries have
benefited from
access to MPP’s
products



**93.89
million**

patient years of
treatment
through MPP’s
generic partners
(2010 - 2021)



By 2030

**USD
3.8 Bn**

projected
savings



Long-acting products: the next frontier

July 2022, ViiV Healthcare for patents relating to cabotegravir long-acting (LA) for HIV pre-exposure prophylaxis (PrEP) to help enable access in 90 countries.

Dec 2021, the University of Washington (UW) for a long-acting injectable (LAI) drug combination candidate.

Currently at a pre-clinical stage, it has the potential to transform the WHO-recommended daily oral dosage of TLD (tenofovir/lamivudine/dolutegravir) into a simple subcutaneous monthly injection.



Long-Acting
Therapeutics

- CABOTEGRAVIR LONG-ACTING (LA) FOR HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)
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- LONG-ACTING TECHNOLOGY FOR MALARIA VECTOR CONTROL

Sep 2021, Tandem Nano Ltd. for [University of Liverpool's Unitaid-funded project LONGEVITY long-acting technologies](#).

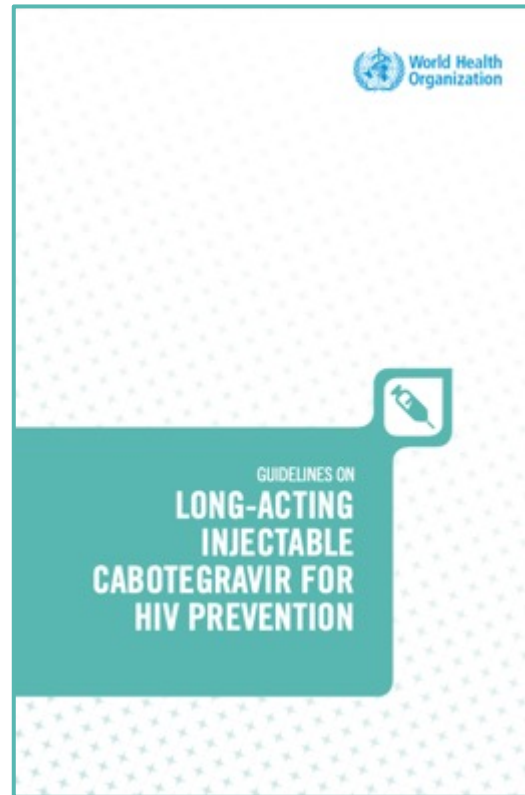
If proven safe and effective could help achieve optimal dosing regimens for malaria chemoprophylaxis, tuberculosis prevention, and hepatitis C cure.

Sep 2022, MedinCell for a candidate long-acting drug formulation.
This could be used to fight malaria in low- and middle-income countries.

CAB-LA as one HIV prevention option

CAB-LA for PrEP is:

- ✓ Recommended by WHO
- ✓ Effective, well tolerated, safe
- ✓ Taken as an injection every 2 months
- ✓ Patented until 2031 but licensed to MPP



Prévention

- Oral PrEP (TDF/XTC)

Patents expired

- **CAB-LA**

MPP licence

- Dapivirine vaginal ring

Population Council

MPP-ViiV licence for CAB-LA for PrEP

- **Manufacturers:** licence enables MPP to provide licences to up to 3 manufacturers for the development and supply of generic versions of CAB-LA for PrEP
- **Supply:** licensees can supply the licence territory (similar to DTG licence territory)
- **Quality assurance:** licensees need to obtain approval from WHO PQ or Stringent Regulatory Authority (and national approvals or waivers)
- **Transfer of technical knowhow:** ViiV is providing technical knowhow to manufacturers; MPP supporting development

ViiV Healthcare and the Medicines Patent Pool sign new voluntary licensing agreement to expand access to innovative long-acting HIV prevention medicine

28 July 2022



Medicines Patent Pool signs sublicences with Aurobindo, Cipla and Viatris to produce generic versions of ViiV Healthcare's innovative long-acting HIV prevention medicine

30 March 2023

- Licences should enable potentially millions of people living in areas most impacted by HIV to access this innovative prevention medicine through low-cost generic manufacturers
- Announcement includes potential for large scale manufacturing on the continent of Africa



MPP licence for CAB-LA for PrEP

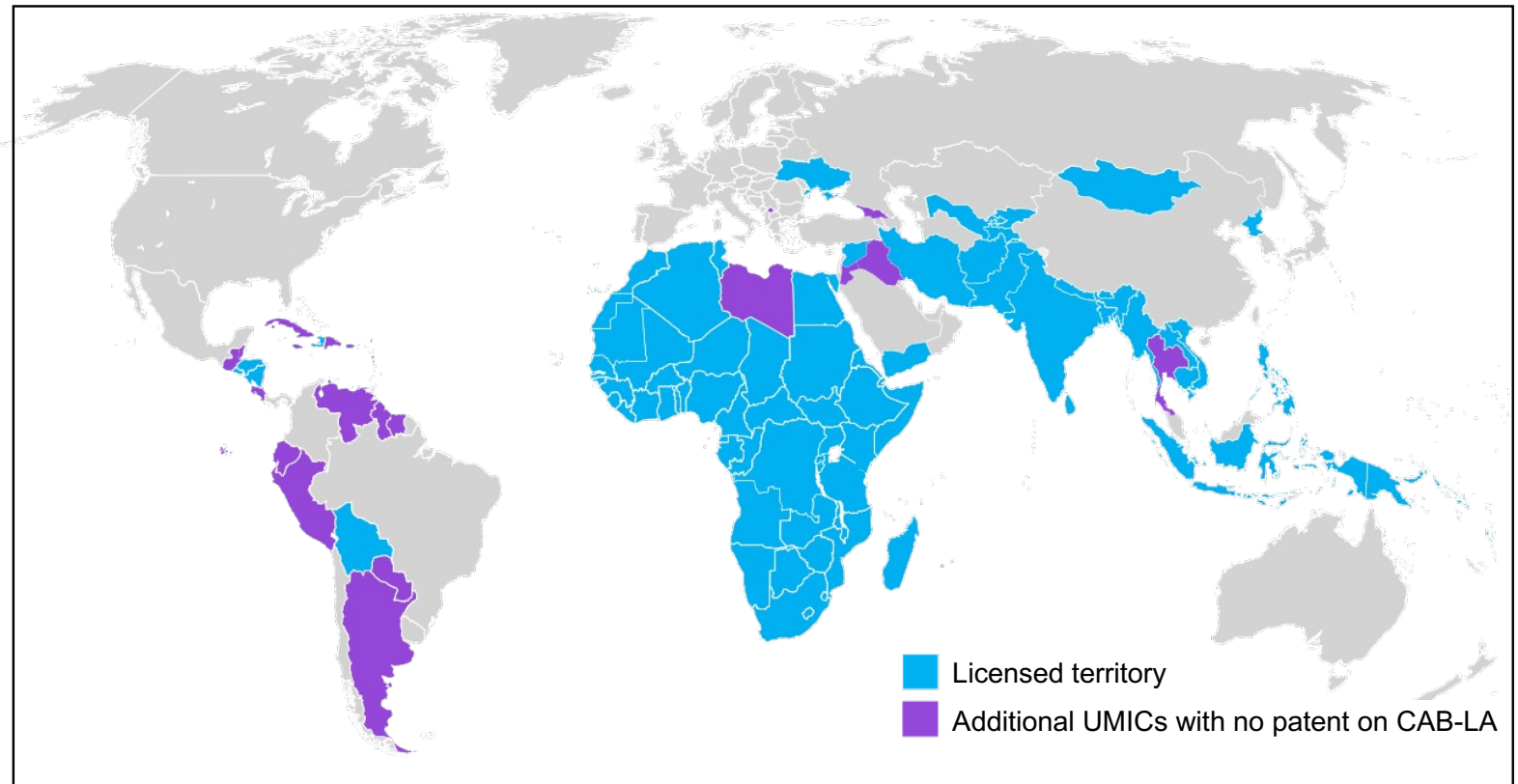
The effective licence territory covers: all countries listed + countries without patents and where supply may be possible

Countries listed (90)

- All low-income countries
- All lower middle-income countries
- All sub-Saharan African countries
- All least-developed countries

Countries without patents and where supply may be possible

- Based on data from MedsPaL (www.medspal.org)

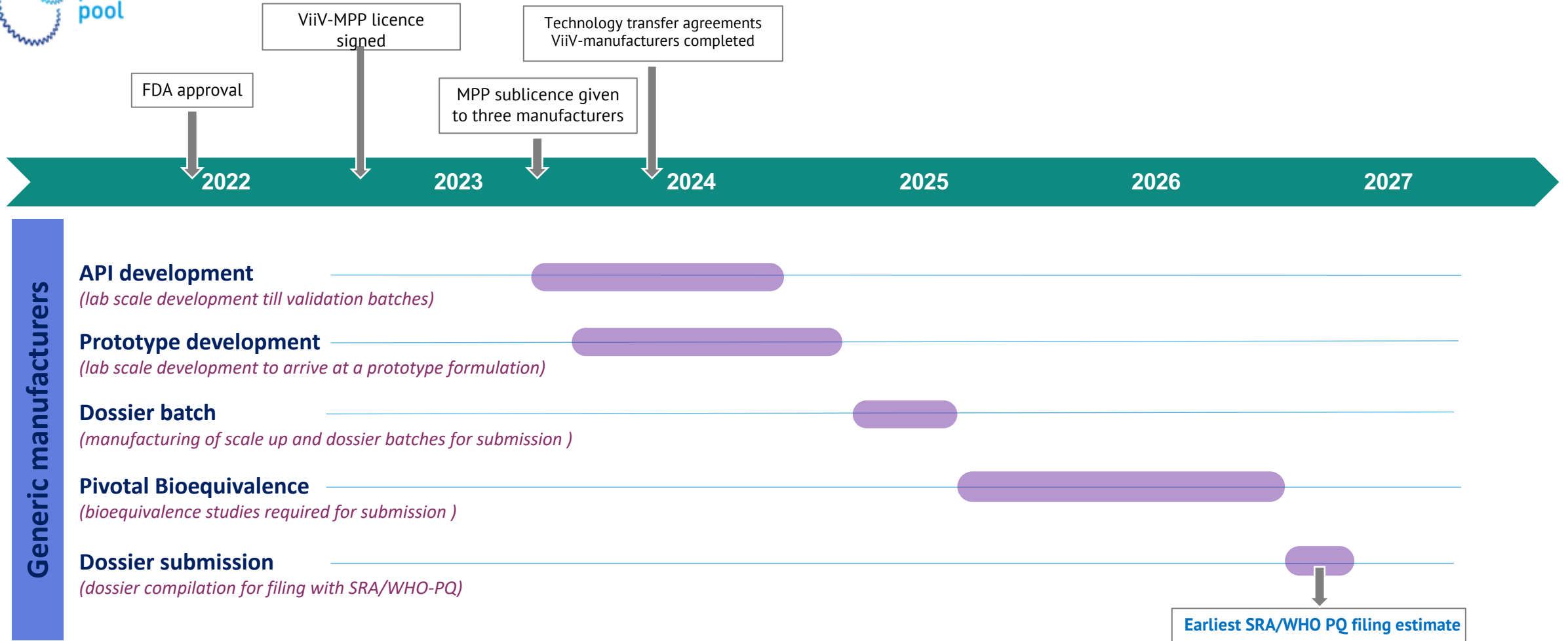


Source: Beatriz Grinsztejn, Long-acting PrEP implementation: Fostering access and equity, AIDS 2022

More at: <https://medicinespatentpool.org/licence-post/cabotegravir-long-acting-la-for-hiv-pre-exposure-prophylaxis-prep>
<https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker>

Generic CAB-LA for PrEP: Tentative development timeline

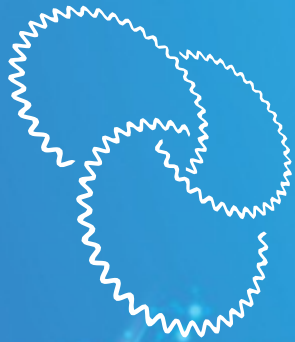
Tentative timeline as of
February 2024



- These timelines are not specific to any generic company; these are averages of the timelines required for different activities as shared by MPP licensees.
- The earliest possible timelines for filing is **H2 2026** based on the current estimation by MPP.
- Due to the uncertainty associated with product development, especially for such long-acting products, the timelines quoted here are tentative and can change during development of the product.

- Pakistan is included in majority of MPP voluntary licences.
- High quality WHO Prequalified generic drugs are available for procurement to facilitate access to WHO recommended treatment for people in need.
- Long-acting injectable PrEP can be a game changer to prevent new HIV infections especially in key populations.
- Advocate for regulatory approval and in-country adoption of CAB LA for PrEP guidelines.
- Strengthening community education is critical to raise awareness about HIV prevention
- Collaborate to create advocacy strategies and continue to integrate civil society towards building demand.





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Thank you

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