medicines patent pool

# Access to medicines for the global patient

## How can voluntary licensing improve access to innovative cancer medicines in low- and middle-income countries?

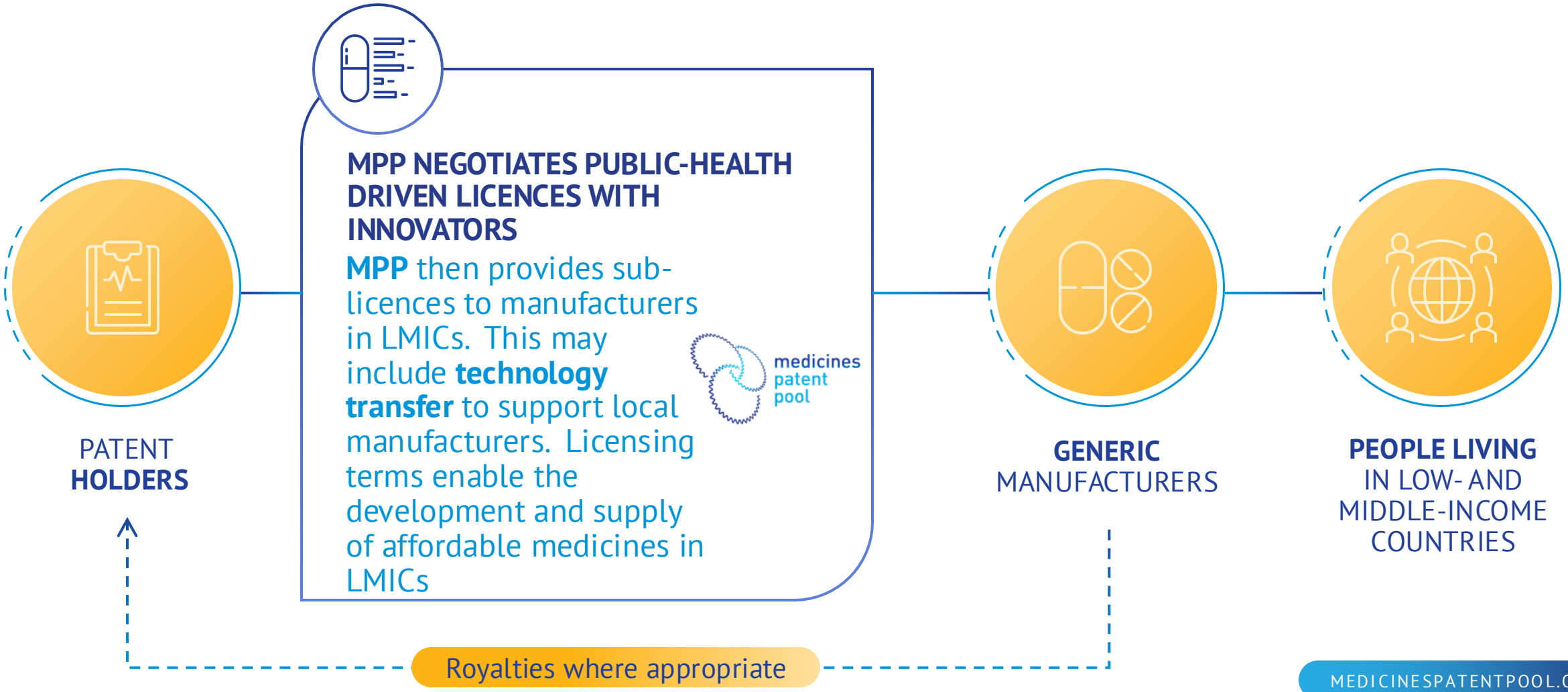
Giulia Segafredo, Medicines Patent Pool (MPP)

# Outline

- What is voluntary licensing? Brief introduction to MPP
- What have we achieved so far? Best practices?
- How can we integrate the voice of the patients in our daily activities?

# What is MPP and how does MPP model work?

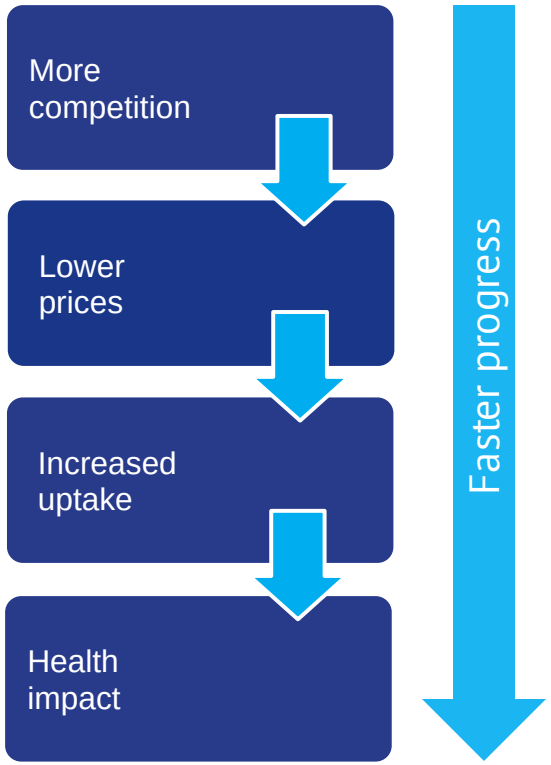
A UN-backed public health organization operating since 2010. MPP aims to improve access to medicines and health technologies, particularly in LMICs, and facilitate further innovation through non-exclusive voluntary licensing.

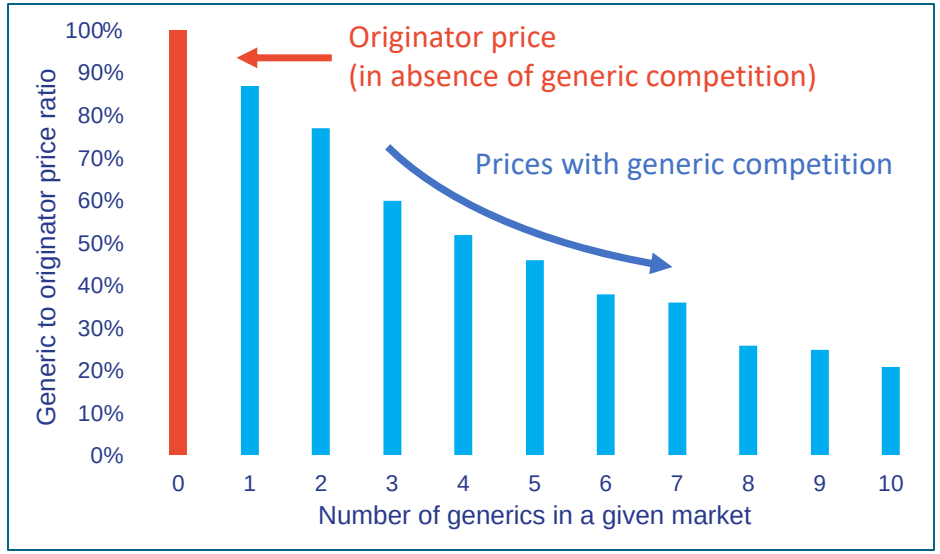


# The MPP model: Accelerated access and price reductions

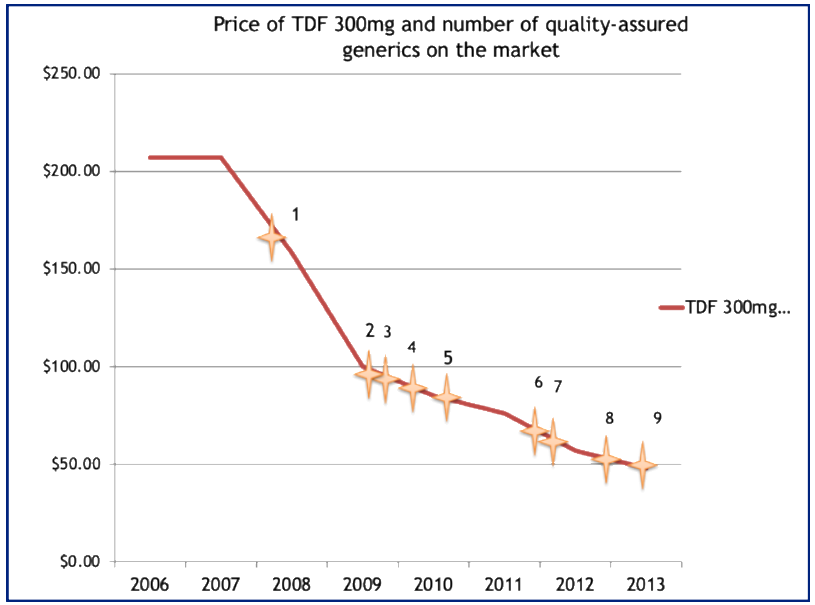
## Overview of the voluntary licensing model

- Driving prices down through generic competition
- Accelerating timelines for generic product availability BEFORE patent expiry




Generic competition induced pricing benchmarks: Dave et al. (2017) *NEJM*




Competition-induced price decay in practice

*More at: https://medicinespatentpool.org*

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# What is MPP's scope of work?

**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 combinations or paediatric formulations

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

**In 2018** decision to expand to **other patented essential medicines** and those with strong potential for future inclusion => **non-communicable diseases including cancer**

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

**In 2021** inclusion of **biotherapeutics** that are either on the WHO EML or have strong potential for future inclusion

**In 2021,** expansion to **technology transfer** with an initial focus on COVID-19 vaccines and pandemic preparedness

## HIV

**abbvie**
lopinavir
ritonavir
*(adults)*
lopinavir
ritonavir
*(paediatrics)*

**Boehringer Ingelheim**
nevirapine
*(non-assert)*

**Bristol Myers Squibb**
atazanavir

**GILEAD** Creating Possible
bictegravir
cobicistat
elvitegravir
emtricitabine
tenofovir alafenamide
tenofivir disoproxil

**janssen**
darunavir
*(paediatric; non-assert)*

**MSD**
raltegravir
*(paediatric)*

**NIH** National Institutes of Health
darunavir related

**ViiV Healthcare**
abacavir
*(paediatrics)*
cabotegravir long-acting *(for HIV PrEP)*
dolutegravir
*(paediatrics)*
dolutegravir *(adults)*

## VIRAL HEPATITIS

**abbvie**
glecaprevir/pibrentasvir

**Bristol Myers Squibb**
daclastavir

**PHARCO** CORPORATION
ravidasvir

## LONG-ACTING THERAPEUTICS

**MedinCell**
mdc-STM
*(malaria LAI)*

**THE UNIVERSITY of LIVERPOOL**
solid drug nanoparticles technology *(disease agnostic)*
ETFD LAI
*(TB, malaria, HCV)*

**UNIVERSITY of WASHINGTON**
abacavir *(paediatrics)*
cabotegravir long-acting *(for HIV PrEP)*
dolutegravir *(paediatrics)*
dolutegravir *(adults)*

**CSIC** Consejo Superior de Investigaciones Científicas
TLD LAI *(HIV)*

## CANCER

**NOVARTIS**
nilotinib

## TUBERCULOSIS

**Johns Hopkins University**
**Pfizer**
sutezolid

## COVID-19

**MSD**
molnupiravir

**Pfizer**
nirmatrelvir

**SHIONOGI INC.**
ensitrelvir fumaric acid

**SD BIOSENSOR**
rapid diagnostic testing (RDT) technology

## MATERNAL HEALTH

**FERRING** PHARMACEUTICALS
*heat-stable carbetocin*

# Access to MPP-licensed medicines

**Patent and licence information tools**

- To support procurement agencies, national programmes, and treatment advocates
- Fully public quarterly-updated country-by-country information

MedsPaL
THE MEDICINES PATENTS AND LICENCES DATABASE

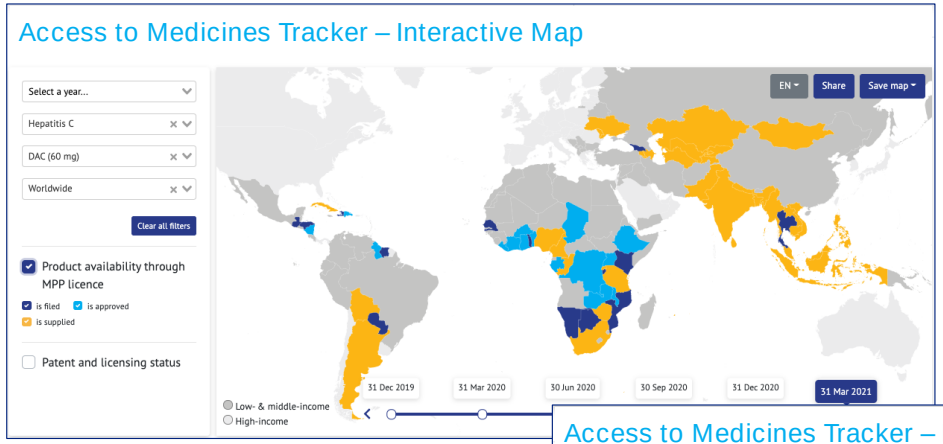
www.medspal.org

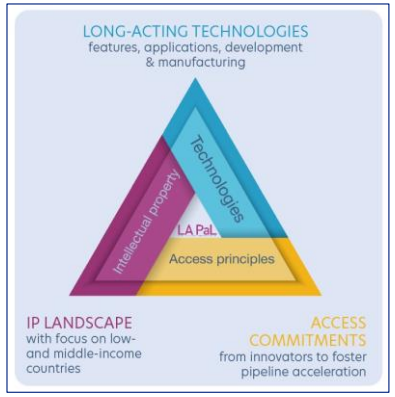
VaxPaL
COVID-19 VACCINES PATENT LANDSCAPE

www.vaxpal.org

LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

https://lapal.medicinespatentpool.org

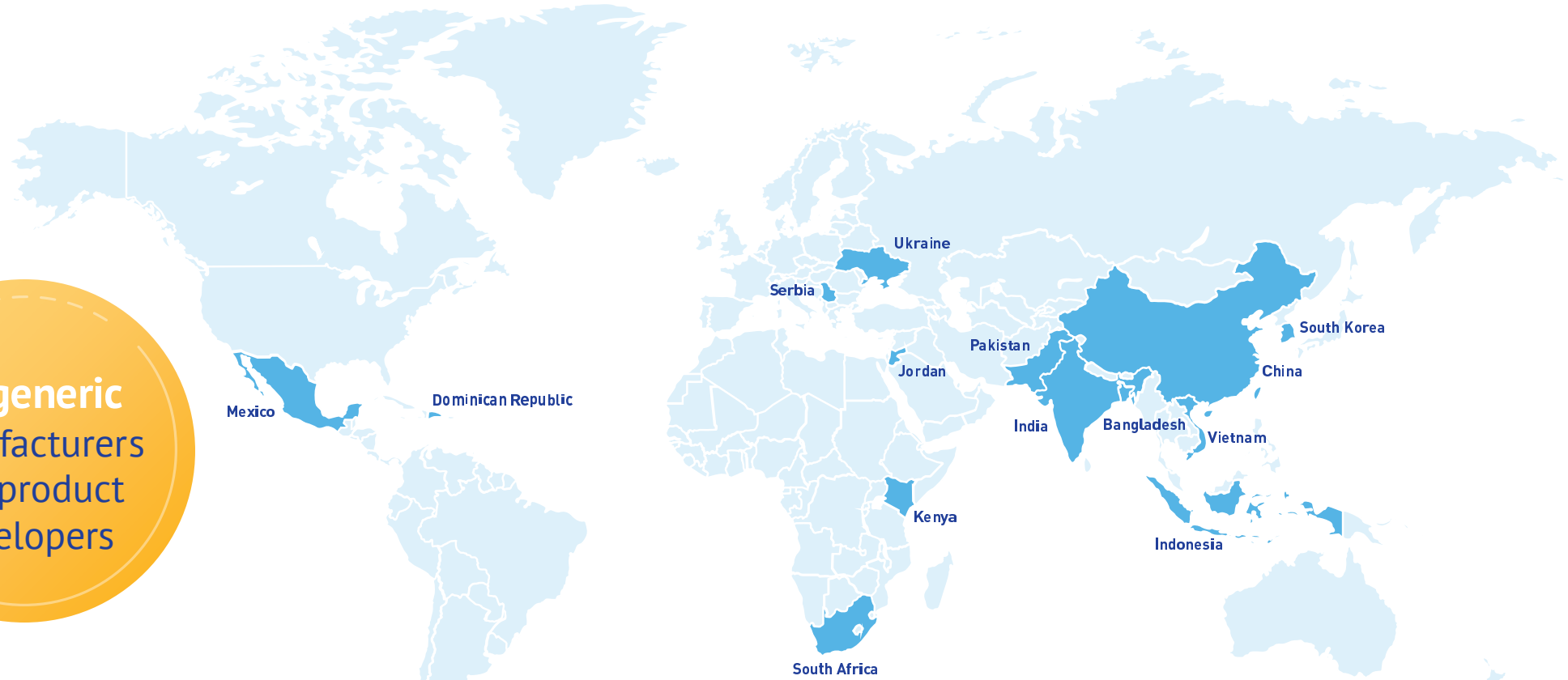




*More at:* https://medicinespatentpool.org/what-we-do/medspal
https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker

# MPP's network of generic manufacturers and product developers are in 14 countries ensuring the importance of local production




**55 generic** manufacturers and product developers

**Bangladesh**
Incepta

**China**
Apeloa
Aurisco
Biochem
BrightGene
Desano
Fosun
Jiuzhou
Huahai
Langhua
Lonzeal

**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
Viatris
Zydus
Cadila

**Indonesia**
Kimia Farma

**Jordan**

**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

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# 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

# Best practice: dolutegravir (DTG) preferred 1st line HIV regimen

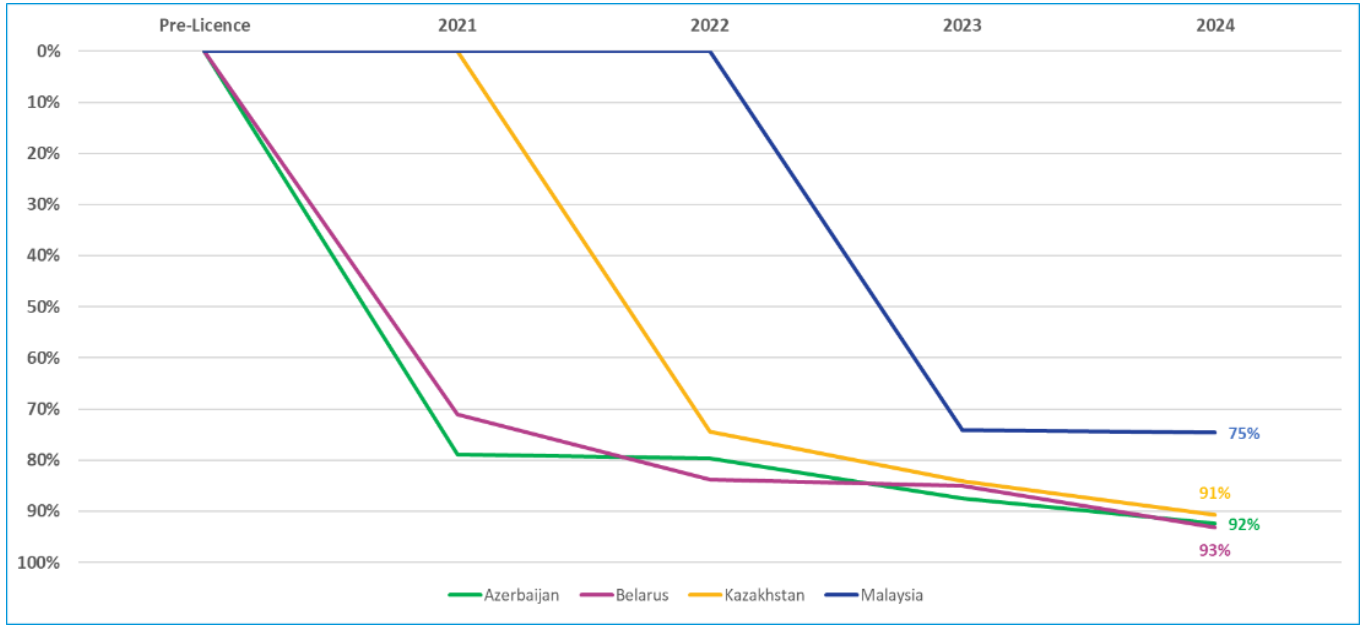

- Dolutegravir (DTG) was approved by USFDA in 2013[1] for HIV treatment and include in the WHO guidelines in 2016.
- ViiV Healthcare/GSK holds the patent for DTG, which is set to expire in **2026**.[2]
- Having only one DTG supplier could have been an issue in terms of availability and affordability.

**MPP Approach**

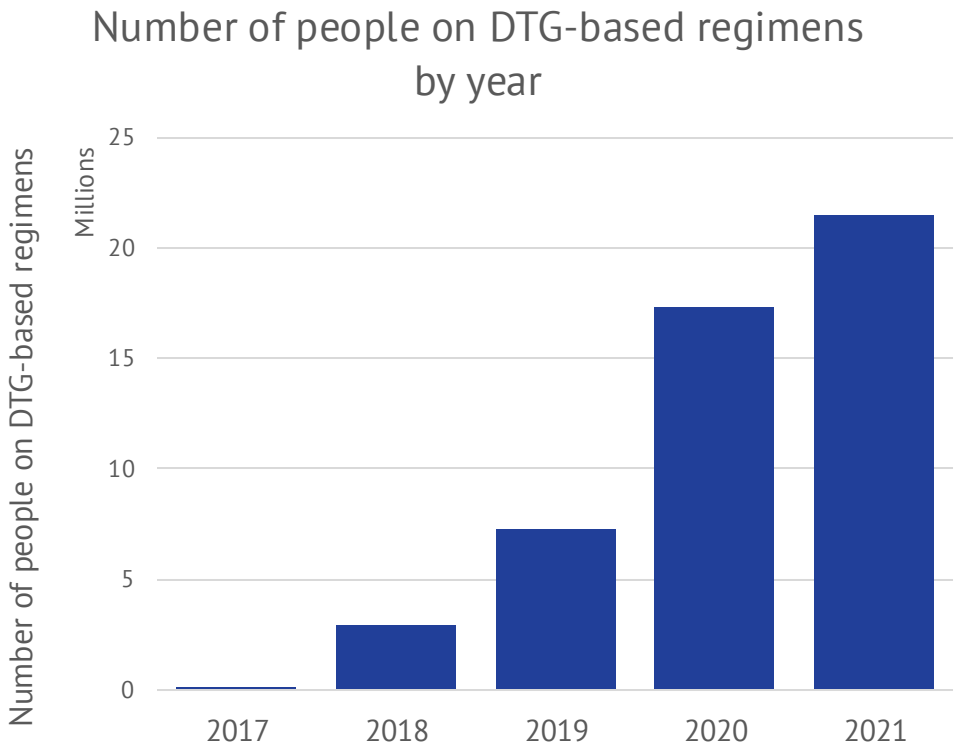
- In 2014, MPP signed **two voluntary licence** agreements with **Viiv Healthcare/GSK** for both **adult**[3] and **peadaitric**[4] formulations of DTG.
- These agreements covered at least **95 countries** for **adult DTG** and **123 countrie**s for **pediatric DTG**
- To date **14 generic manufacturers** are producing and supplying low-cost versions of DTG to patients in these countries increasing the availability and access of DTG.[5]

# Price reduction and increase in uptake of volumes

% of price reduction of DTG compared to originator prices at the start of licence negotiations in 4 UMICs




Prices of DTG 50mg & TLD considered




- In 2020, in response to feedback from the HIV community and government stakeholders, MPP signed an expanded license agreement with ViiV, extending coverage to **four UMICs—Azerbaijan, Belarus, Kazakhstan, and Malaysia**.
- With a price of under **US 45 per patient per year**,[2] up to **1.5 billion doses** have been supplied and approximately **24 million** people on HIV (including children) currently on DTG-based regimens
- MPP collaborates with various stakeholders (governments, communities, civil society, WHO, Global Fund, procurement agencies and many others) to ensure uptake of quality assured DTG

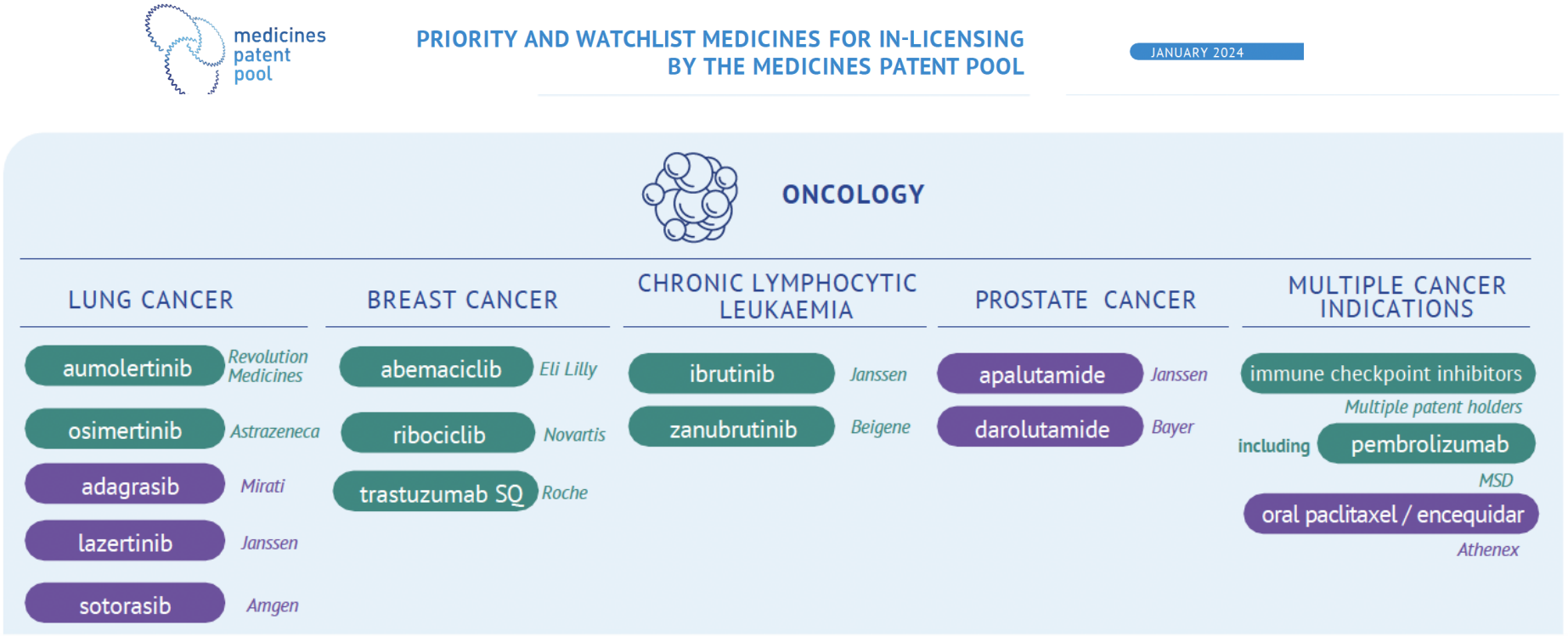
# Nilotinib for treatment of CML with Novartis


- According to the Global Burden of disease study, in 2021 there were approximately 63,728 prevalent cases of CML globally[1] out of which 20-25% are resistant to the current generic first-line treatment.[1] The global patient population eligible for treatment with nilotinib can be estimated at 12,745-15,932 patients.[2]
- There is limited accessibility of 2nd and 3rd line treatment for CML in LMICs due to lack of **affordability**.[3] This is partly due to existing **IP barriers**, of these therapies.
- In **October 2022**, MPP and Novartis AG, in collaboration with the **Access To Oncology Medicine (ATOM)** Coalition, signed a voluntary licensing agreement to increase access to **nilotinib** indicated as second line treatment of **chronic myeloid leukaemia (CML)**
- The agreement includes a territory of **44 countries**, including **seven** countries **Egypt, Guatemala, Indonesia, Morocco, Pakistan, the Philippines,** and **Tunisia**, in which Novartis has its secondary patents granted or filed
- Licence includes **royalties** set at **5% of net sales**, due only for the sales in **Patent Territory**, and payable to **ATOM** for further investment in accordance with the ATOM mission.
- To date **four generic manufacturers** have been selected as sublicencees with **first supply** planned for early 2025
- **MPP** is collaborating with various stakeholders including national governments, CML patient groups, IDA foundation, the Max foundation to increase access and availability of quality assured generic nilotinib for CML patients in LMICs

# How can we integrate the voice of the patients in our daily activities?

## 1. Informing priorities

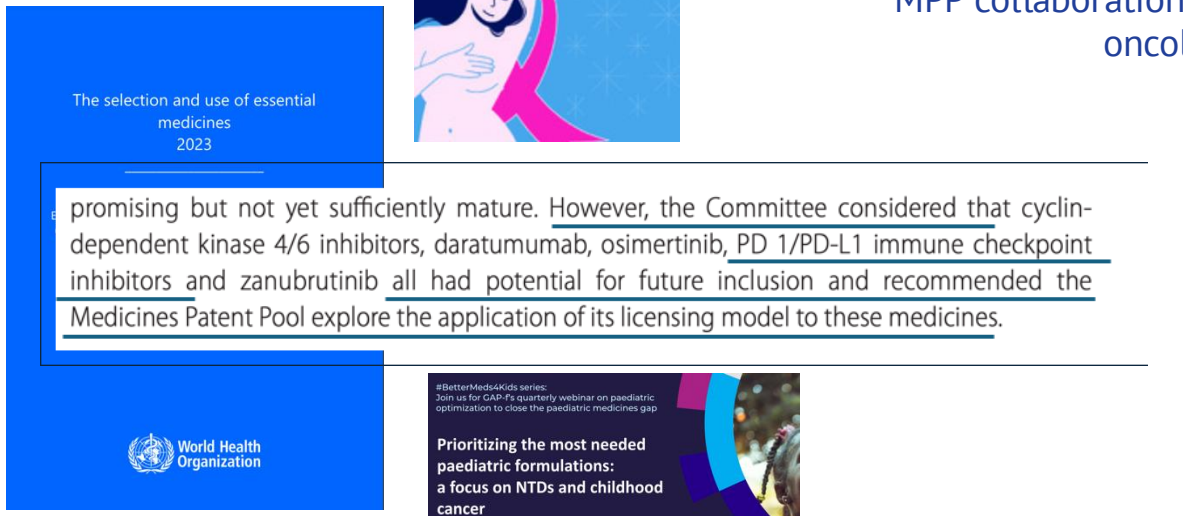
- MPP seeks to monitor innovation in terms of new MoA and new formulations (e.g. heat stabile and/or oral formulations) => additional candidates you consider relevant?



# How can we integrate the voice of the patients in our daily activities?

## Create an enabling environment for in-licensing

- Patients voice, especially coming from LMICs
- Collaboration on advocacy activities?





Access to cancer medicines in LMICs requires multi-stakeholder partnerships

MPP collaboration and interactions in the oncology space

Currently exploring:

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# Thank you

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Innovation in Global Health

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Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Agency for Development and Cooperation SDC

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