THE MPP MODEL – HOW WE WORK

MPP licences enable multiple manufacturers to supply LMICs before patent expiry, facilitating competition, price reductions and supply security

1. Identify medicines needed in LMICs where licensing can improve access

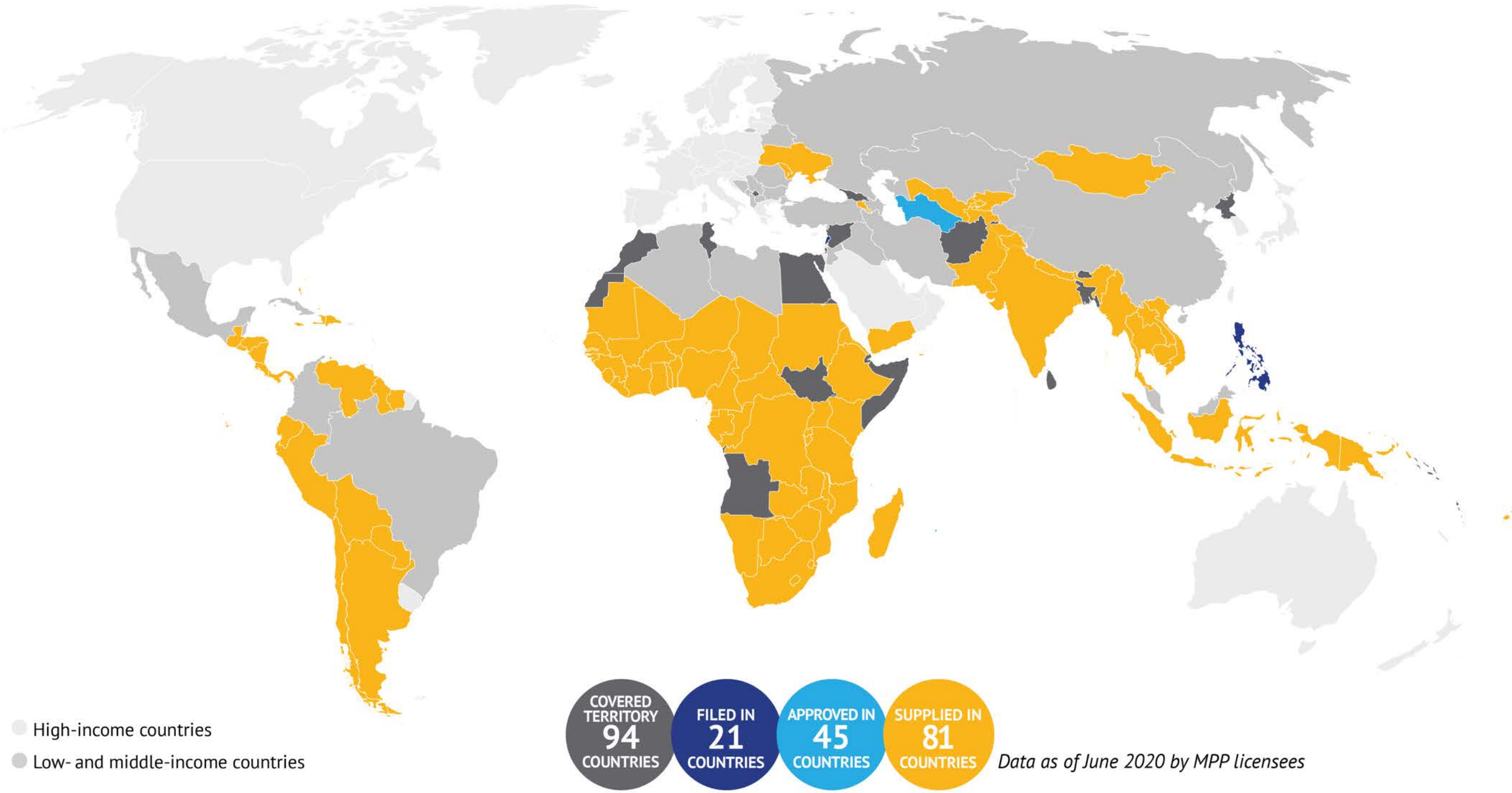
2. Negotiate licences with patent holders from a public health perspective

3. Sublicense to generic pharmaceutical companies committed to supplying LMICs

4. Accelerate development and work with partners to facilitate access to medicine in LMICs

Example: Licence on HIV medicine dolutegravir enabled development and supply of WHO's preferred 1st line regimen

Sales of TLD combination product have occurred in **81** countries in which **80.3%** of PLHIV reside globally#



Note: Sales may occur in countries in the absence of registration via procurement channels, registration waivers and/or exemptions
#: Estimated Global PLHIV population till Dec 2019 is 38M as per UNAIDS data http://aidsinfo.unaids.org/

Access to Medicines for COVID-19

On March 30, 2020, the MPP Board agreed to temporarily expand its mandate

"to include any health technology that could contribute to the global response to COVID-19 and where licensing could facilitate innovation and access.

With the support of Unitaid, this will allow MPP to offer its IP and licensing expertise to the World Health Organization (WHO) to assist the global effort in any way it can."

Why Licensing for COVID-19 treatments

What is needed for new COVID-19 treatments	How licensing helps
• Access, including in the poorest countries	• Leverages diverse geographical footprint of different manufacturers/suppliers
• Large volumes to meet large demand	• Leverage the manufacturing capacity of multiple suppliers
• Unprecedented speed	• Manufacturers are ready to start immediately on developing generics of new treatments
• Quality products	• MPP licensees are used to supplying quality assured products
• Affordable prices	• Competition key to keep prices low and ensure affordability

Specific Activities to Date: The Case of Lopinavir/ritonavir

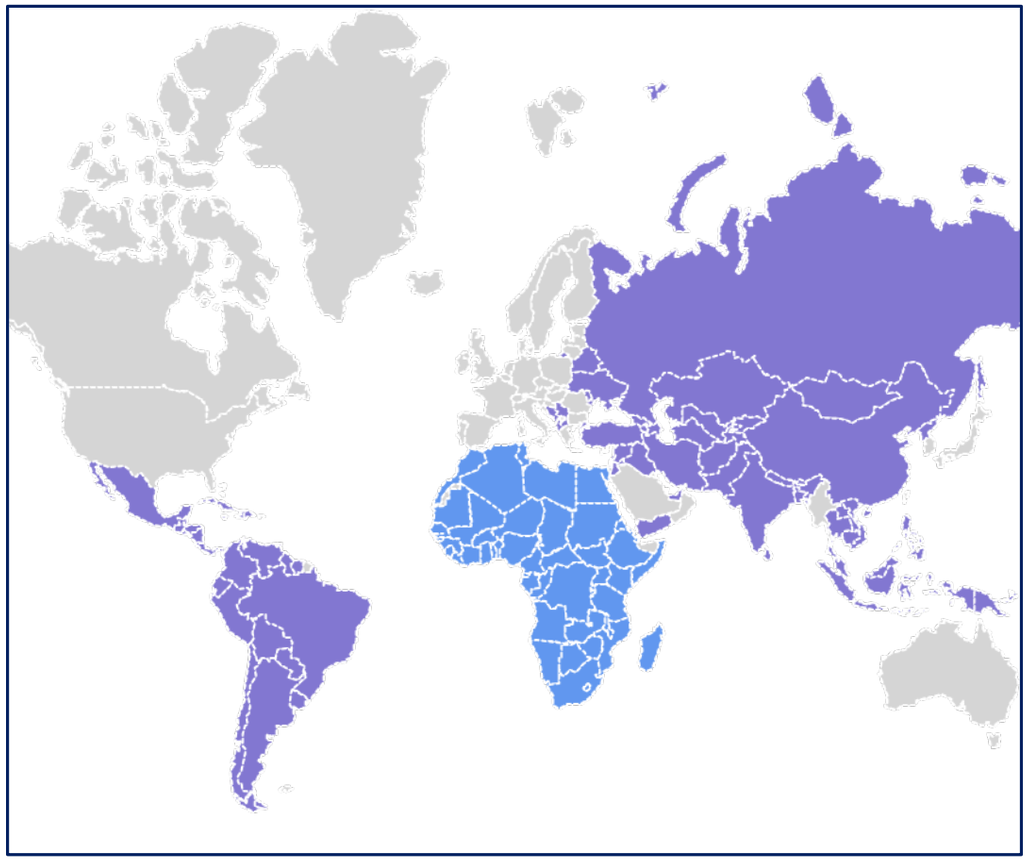
- In March, the patent holder for **lopinavir / ritonavir (LPV/r) (AbbVie)** informed MPP that it will no longer enforce its patents on LPV/r and allow sale of generics worldwide

- It is an **HIV medicine** for which MPP already had a licence covering Africa. It was considered a promising **COVID-19** treatment

- The WHO Solidarity Trial showed that LPV/r is **not effective against COVID-19 for hospitalized patients** – product has generally been deprioritized

- However, the announcement remains very relevant for HIV, enabling **affordable access to a standard second-line treatment**

Expansion of the licence as a consequence of the announcement



MPP involved in various International Initiatives against COVID-19

- **Access to Covid-19 Tools Accelerator (ACT-A)**:
  - Launched in April 2020
  - The ACT Accelerator, is a global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines.
  - Organized into 4 pillars: (1) Vaccines; (2) Treatments; (3) Diagnostics; and (4) Health Systems Strengthening
  - MPP actively contributing to pillar (2) focusing on treatments

- **Covid Technologies Access Pool (C-TAP)**
  - Launched in May 2020
  - C-TAP will compile, in one place, pledges of commitment to voluntarily share COVID-19 health technology related knowledge, intellectual property and data.
  - Will rely on existing mechanisms such as the MPP, for voluntary licensing of COVID-19 technology
  - Needs to step up efforts to engage constructively with industry

Some Observations and Challenges

- **Speed:** 3-4 years from innovator approval to global access was a record we were proud of in HIV - timelines need to be significantly accelerated for COVID. We believe it is possible through close collaboration with industry and other public health partners

- **Re-purposed medicines :** effective repurposed medicines, incl. those already licensed by MPP, could have significantly accelerated timelines for availability and access. But most have not proven effective, with some still awaiting definitive trials (exception: dexamethasone).

- **Biologics** : increasingly promising monoclonal antibodies (mAbs), but significant challenges and limited experience in rapidly scaling up and supplying mAbs in LMICs. Need to work on access strategies (including licensing!) for biologics. Important for COVID, but also beyond.

- **Collaboration**: there has been unprecedented collaboration between pharmaceutical companies for the development and manufacturing of new COVID products. This needs to be further leveraged to ensure access in LMICs.

Some Observations and Challenges (2)

- **Funding and incentives**: public funding for R&D has not been leveraged to ensure future access in LMICs, and there has been limited political appetite to introduce incentives for broad licensing of COVID treatments - this may limit the scope for licensing and its geographical reach

- **Access strategies:** access strategies being explored (e.g. contract manufacturing) can cover an immediate access gap but focuses on the short term – need to also think medium term and for more sustainable approaches (e.g. licensing)

- **Procurement**: important efforts under ACT-Accelerator to raise funds for future procurement of medicines for LMICs, but still far from meeting needs – efforts need to be stepped up

Thank you

www.medicinespatentpool.org