

# Novel medical technologies

## MPP'S EXCITING MOVE INTO A NEW AREA WITH THE POTENTIAL FOR LIFE-CHANGING MEDICINES

MPP's licensing model originally focused only on small molecules in oral formulations. Now, with more complex technologies emerging that could lead to significant improvements in public health, we have been developing ways to support efforts to make these long-acting technologies, biotherapeutics and mRNA vaccines available and affordable in low- and middle-income countries.

## CAB-LA TO EXPAND HIV PREVENTION OPTIONS FOR THE MOST VULNERABLE

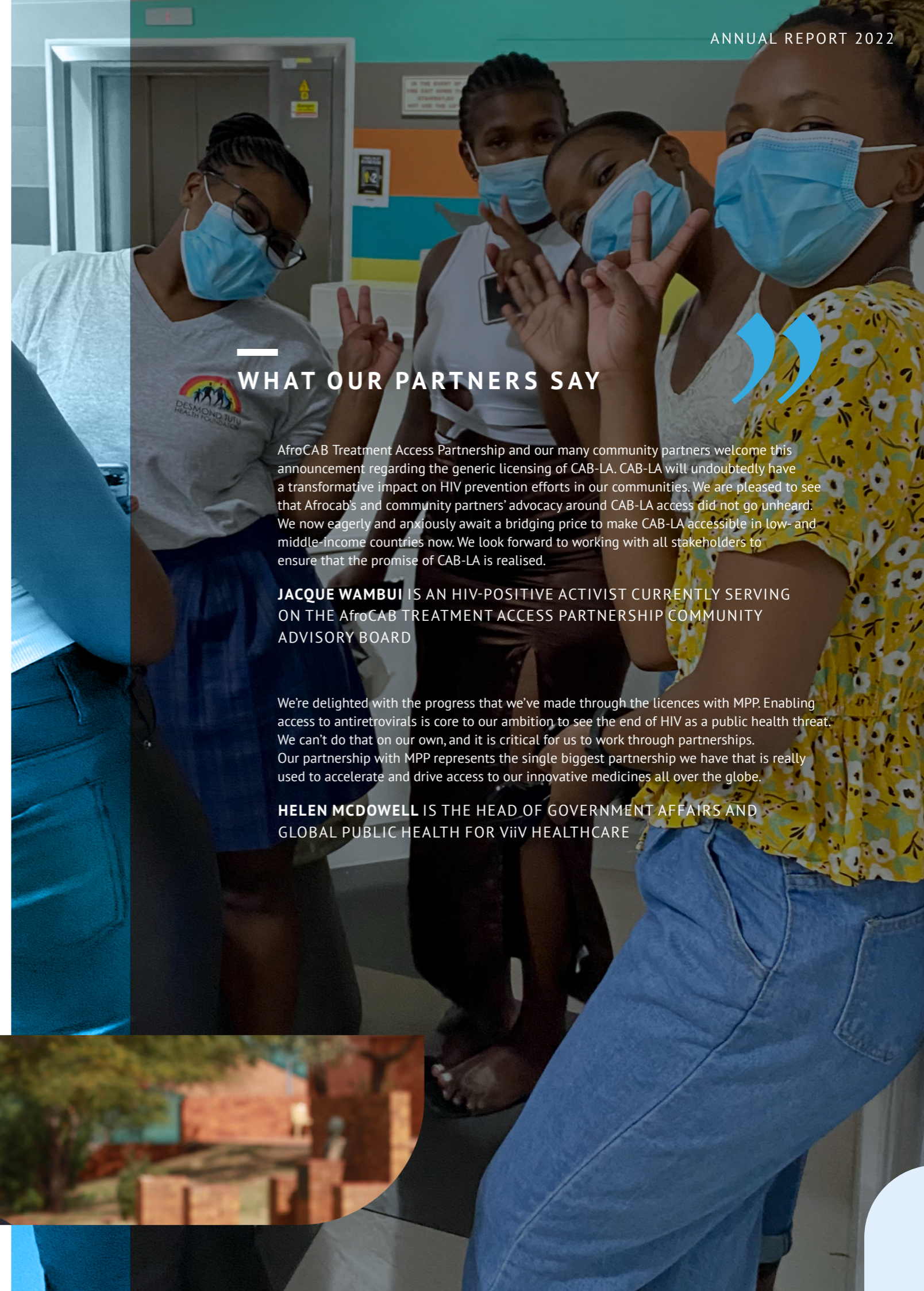
In July, MPP signed a voluntary licensing agreement with ViiV Healthcare for cabotegravir (CAB) long-acting (LA) for HIV Pre-Exposure Prophylaxis (PrEP). Subject to regulatory approvals, this bold move gives the go-ahead for manufacturers in at least 90 low- and middle-income countries to develop and supply CAB-LA to prevent HIV infection.

The negotiation of the licence is an excellent example of MPP's continued commitment to making innovation available and affordable in low- and middle-income countries.



**The agreement also came just seven months after the first regulatory approval of CAB-LA for HIV PrEP anywhere in the world, by the USFDA.**

Although oral PrEP options are available in many countries, challenges with adherence and stigma have meant that these options have not had the impact they could have had. Long-acting technologies, on the other hand, open up a new dimension that could lead to greater uptake. By providing a much-needed additional option for those at risk, access to this prevention measure could significantly contribute towards the goal of ending the HIV epidemic.



## WHAT OUR PARTNERS SAY

AfroCAB Treatment Access Partnership and our many community partners welcome this announcement regarding the generic licensing of CAB-LA. CAB-LA will undoubtedly have a transformative impact on HIV prevention efforts in our communities. We are pleased to see that AfroCAB's and community partners' advocacy around CAB-LA access did not go unheard. We now eagerly and anxiously await a bridging price to make CAB-LA accessible in low- and middle-income countries now. We look forward to working with all stakeholders to ensure that the promise of CAB-LA is realised.

**JACQUE WAMBUI** IS AN HIV-POSITIVE ACTIVIST CURRENTLY SERVING ON THE AfroCAB TREATMENT ACCESS PARTNERSHIP COMMUNITY ADVISORY BOARD

We're delighted with the progress that we've made through the licences with MPP. Enabling access to antiretrovirals is core to our ambition to see the end of HIV as a public health threat. We can't do that on our own, and it is critical for us to work through partnerships. Our partnership with MPP represents the single biggest partnership we have that is really used to accelerate and drive access to our innovative medicines all over the globe.

**HELEN MCDOWELL** IS THE HEAD OF GOVERNMENT AFFAIRS AND GLOBAL PUBLIC HEALTH FOR ViiV HEALTHCARE



## FOCUS ON PARTNERSHIP: THE COALITION TO ACCELERATE ACCESS TO LONG-ACTING PRE- EXPOSURE PROPHYLAXIS

The Coalition to Accelerate Access to Long-Acting Pre-Exposure Prophylaxis (LA PrEP Coalition) is an initiative that brings together leading donors, agencies and advocates to further help combat HIV. Its purpose is simply to make longer-acting PrEP options accessible as quickly and as equitably as possible.

The Coalition is convened by Unitaid, WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), and the Global Fund, with AVAC as the secretariat. MPP's key contribution is through the licensing of novel long-acting PrEP products and technologies to enable the development and supply of generic versions in low-and middle-income countries. The Coalition's initial focus is on CAB-LA as a platform for next-generation options.



### Long-acting technology licence to help tackle scourge of malaria

September saw the signing of an MPP voluntary licence agreement for mdc-STM with French pharmaceutical company MedinCell. This long-acting injectable formulation may help tackle the transmission of malaria, which tragically remains endemic in 91 countries, home to 50 per cent of the world's population. According to WHO estimates, 247 million people were infected worldwide with malaria in 2021<sup>4</sup>, 95 per cent of them in Africa; this led to 627,000 deaths. Children under five are the most vulnerable, accounting for 80 per cent of deaths from the disease.



**Following this agreement, MPP can now identify suitable generic manufacturing companies to develop and commercialise this injectable version of ivermectin.**

Manufacturing can take place in any country worldwide for distribution in low- and middle-income countries.

The product is based on BEPO®, a MedinCell technology that enables the sustained release of ivermectin after a single injection. It is administered subcutaneously at the beginning of the malaria-transmission season to people living in malaria-endemic areas. Mosquitoes feeding on people who have received the ivermectin injection will be killed and thus prevent further malaria transmission.

If proven efficacious this may bring enormous benefits to the whole community by reducing the risk of transmission, especially in children.

<sup>4</sup> <https://beatmalaria.org/blog/world-malaria-report-2022-what-you-need-to-know/>

## WHAT OUR PARTNERS SAY

MPP was catalytic in obtaining the licence from ViiV. But we also need technology transfer, demand forecasts and a range of partnerships. I think what's critical is that the LA PrEP Coalition is bringing together all parties and recognising that no one element can deliver on its own. It's the wider ecosystem that is so essential and MPP is focused on other domains beyond just licensing. I'm thinking particularly of the mRNA platform and local manufacturing. MPP rightly focuses on encouraging manufacturing in as many countries as possible.

**MITCHELL WARREN IS THE EXECUTIVE DIRECTOR OF AVAC**

A huge proportion of the world's population are afflicted by the diseases we are working on at CELT. Long-acting medicines hold the promise to be transform treatment and prevention of infectious diseases.

Too often, there is insufficient consideration of low- and middle-income needs and the collaboration with MPP ensures that this is considered upfront in our development programmes. MPP fulfil an incredibly important role in global healthcare equity by removing IP barriers and facilitating partnership between stakeholders to help ensure there is a roadmap for product introduction. As a research centre, CELT doesn't have the know-how and resources to fulfil this role and MPP have been critical global health partners for us for over a decade.

MPP's role means that we are able to address these factors which are so important to us, while being able to concentrate on what we are good at, safe in the knowledge that other elements are being addressed.

**ANDREW OWEN IS A PROFESSOR OF PHARMACOLOGY AND THE DIRECTOR OF THE CENTRE OF EXCELLENCE IN LONG-ACTING THERAPEUTICS (CELT) AT THE UNIVERSITY OF LIVERPOOL**



THE FOLLOWING IS A SUMMARY OF MPP'S ACTIVITIES IN THE LONG-ACTING FIELD:



**3**

**licences**

for investigational long-acting technologies and their applications in the field of **HIV, TB and Malaria**

**1**

**licence**

for an approved long-acting injectable to prevent **HIV (CAB-LA)**

**1**

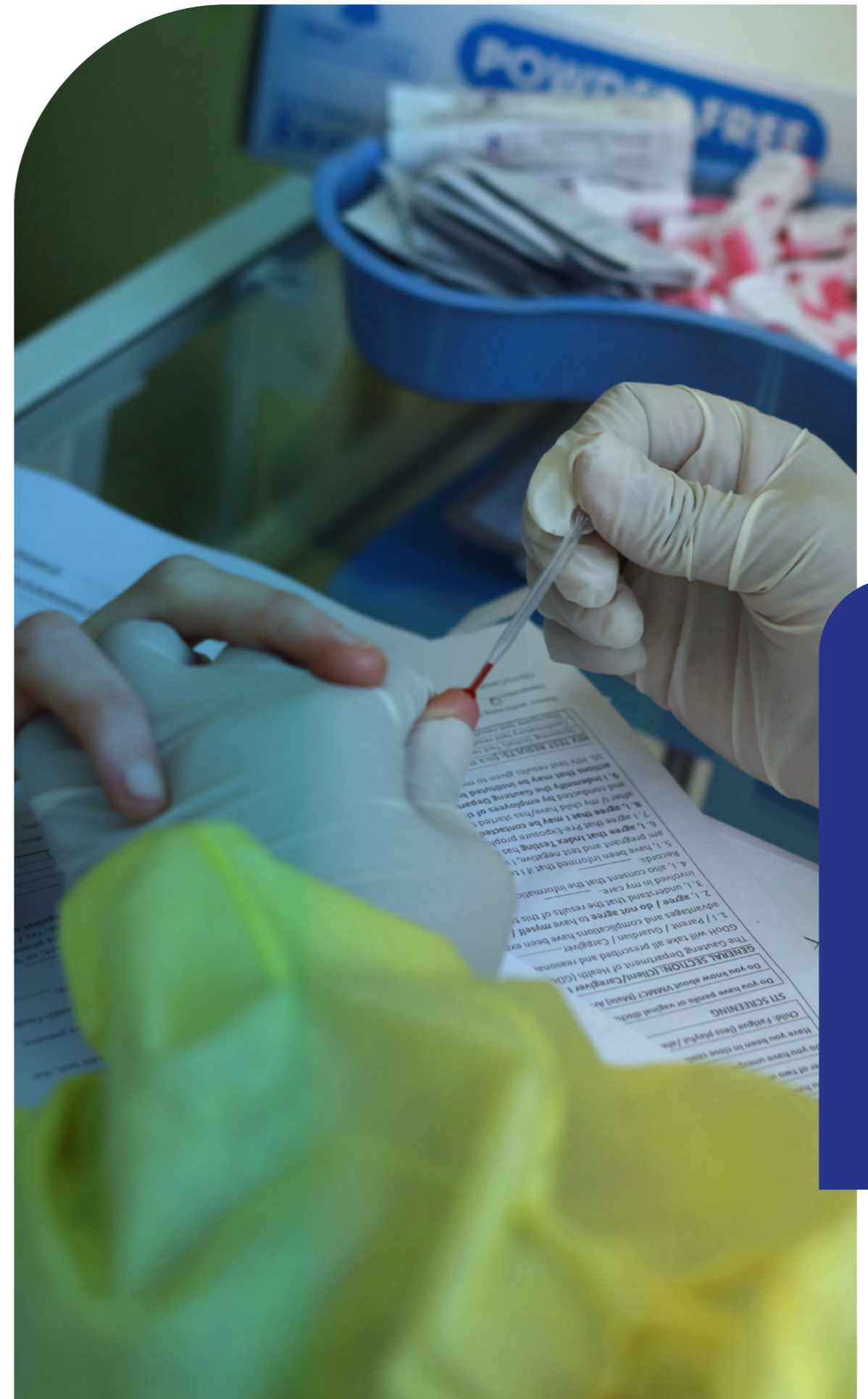
**dedicated website**

**LAPaL**  
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

for a selection of long-acting therapeutics patents and licences

In May-June 2022 a series of roundtables meetings took place about long-acting, in the context of the Industry Liaison Forum led by IAS. MPP co-hosted the third roundtable.

In July 2022, MPP-IAS co-chaired satellite symposium at AIDS 2022 conference in Montreal: "Accessing long-acting HIV prevention & treatment innovations: Landscape, service delivery & pathways."



## MPP's focus on biologics opens new front to lower disease burden

Biotherapeutics such as recombinant proteins and monoclonal antibodies (mAbs) have become mainstays in the treatment of many diseases. The proportion of biotherapeutics among new drug approvals has significantly increased in recent years, as has the number of biotherapeutics included in WHO's Essential Medicines List.

However, a combination of health system challenges, higher prices and barriers to market entry have hindered broad access to biotherapeutics. This is especially the case in low- and middle-income countries. For example, just one per cent of mAbs are currently being supplied in Africa.



**MPP is now working to develop a model to facilitate equitable access to biotherapeutics in low- and middle-income countries through licensing and technology transfer.**



### Significant MPP article published in 'The Lancet Global Health'

In 2022, MPP published an important paper in a leading public health journal, *Lancet Global Health*. Following a request by WHO's Essential Medicines Expert Committee, we investigated how licensing could improve both affordability and timely access to biotherapeutics in low- and middle-income countries. It was the findings of this investigation that were published by *The Lancet Global Health*.

This research saw MPP leveraging expert consultations, literature and data analysis, and internal technical knowledge. **As a result, various salient elements were identified to encourage greater access to affordable biosimilars in low- and middle-income countries:**

- ✓ Prioritising potential biotherapeutic targets according to their potential for public health impact
- ✓ Supporting biosimilar product and clinical development, including through technology transfer to expedite regulatory approval
- ✓ Facilitating biosimilars' entry and use in low- and middle-income countries by meeting procurement, supply chain and health system requirements

## FOCUS ON PARTNERSHIP

The Access to Medicine Foundation's research has found that MPP has been the gold standard on voluntary licensing arrangements between originator pharmaceutical companies and generic medicine manufacturers, enabling broad access to people worldwide with a range of treatments. I believe more opportunities exist to use this model for the years to come, saving more lives. We incentivize companies to expand access using methods such as voluntary licensing, and without the MPP, the scale and scope of access will be limited to benefit only a few patients worldwide.

**JAYASREE K. IYER** IS CEO OF THE ACCESS TO MEDICINE FOUNDATION

We are very much philosophically aligned with MPP in terms of the goals of creating important lifesaving innovations to be available to all people who need them. Monoclonal antibody technology is one area that IAVI has recently been very active in terms of research and development.

MPP serves a very important role in access to innovative health products and its track record has been very positive. The licensing mechanism is very important. I think that makes MPP a partner who can be trusted by different sectors and who may have previously looked at these kind of initiatives around access and IP licensing with some scepticism. There's really no other organisation that has the specific focus that MPP does. MPP is an important partner because it's very clear that no one organisation can solve these challenges by itself. The global health ecosystem would be significantly worse off if MPP did not exist.

**DR. MARK FEINBERG** IS PRESIDENT AND CEO OF THE INTERNATIONAL AIDS VACCINE INITIATIVE (IAVI)

## FOCUS ON PARTNERSHIP: GATES MRI AND SUTEZOLID

Gates MRI is member of the Project to Accelerate New Treatments for Tuberculosis collaboration. The collaboration aims to identify novel regimens that could treat both drug-susceptible and drug-resistant forms of TB in a much shorter duration than the currently used treatment regimens.

A key drug in the proposed regimen is sutezolid, a promising antibiotic drug candidate. In combination with other drugs, it could potentially be used as an all-oral, shortened regimen for all forms of TB, including DR-TB. In December 2020, MPP and Gates MRI signed an agreement to advance the development of this investigational drug for use in low- and middle-income countries.

We very much welcome MPP's work to facilitate the development of medicines for low- and middle-income countries and enables access to such medicines. This licensing of medicines and vaccines serves the underserved, a critically important role. We look forward to MPP continuing to be an integrator and collaborator – as well as a negotiator and problem-solver – by establishing further opportunities to facilitate market access for life-saving medicines.

**DR. CHARLES WELLS** IS THE HEAD OF THERAPEUTICS DEVELOPMENT AT THE BILL AND MELINDA GATES RESEARCH INSTITUTE

