

COVID-19

NEW LICENCE AGREEMENTS DEMONSTRATE MPP'S READINESS FOR FUTURE PANDEMICS

The world's response to COVID-19 highlighted the shocking inequities that still exist in global health today. But that same response also drew attention to a range of mechanisms that could improve affordable access to health products in low- and middle-income countries. Pandemic preparedness and response (PPR) must above all avoid a repeat of past failures and prevent the devastation wreaked by COVID-19.

MPP HELPS WORLD PREPARE FOR NEXT PANDEMIC

Preparations for future pandemics are now underway, with new mechanisms being established. Discussions revolve around how best to streamline and accelerate access to diagnostics tools, vaccines and treatments for those living in low- and middle-income countries.

Preparation is coalescing around the following instruments:

- ✓ The newly created and WHO-led Intergovernmental Negotiating Body (INB) is negotiating a legally binding international 'pandemic accord'
- ✓ International Health Regulations are an existing PPR tool currently under review
- ✓ A review of WHO's Health Emergency pandemic preparedness and response architecture aims to address gaps in health emergency governance, systems and financing mechanisms
- ✓ The Pandemic Fund is managed by the World Bank and WHO. US\$1.6 billion has been raised since its inception in mid-2022, but there is still an estimated annual PPR funding gap of \$10billion
- ✓ The 100 Days Mission is an agenda to develop diagnostics, therapeutics and vaccines within the first 100 days of a pandemic threat being detected



MPP's urgent response to COVID-19 was invaluable experience for any future pandemic

- ✓ Advocated to try to ensure that all salient policies and initiatives incorporated licensing and technology transfer as mechanisms for achieving equitable access to medical countermeasures
- ✓ Made significant contributions to G7 and G20 processes for pandemic preparedness and response
- ✓ Undertook advocacy with governments and funding bodies
- ✓ Contributed to discussions at the INB meetings and other forums
- ✓ Initiated engagement with organisations developing antivirals against pathogens with pandemic potential
- ✓ Positioned the mRNA Technology Transfer Programme as vital tool for PPR

FOCUS ON PARTNERSHIP



We support the WHO's work in promoting efforts to enhance pandemic PPR governance, systems, and financing in accordance with member states. We recognize the role innovative and flexible partnerships in global health, such as Gavi, the Global Fund, CEPI, Unitaid, FIND, and the **Medicines Patent Pool**, can play in close collaboration with WHO, UNICEF and its Member States in building global health resilience and response capacity against future pandemic threats.

EXTRACT FROM G20 PRESIDENCY CHAIR'S SUMMARY

THE SECOND G20 JOINT FINANCE AND HEALTH MINISTERS' MEETING

Bali, Indonesia, 12 November 2022



Access to Covid Tools Accelerator framework accelerates access to COVID-19 response.

Contributions to the Access to Covid Tools Accelerator (ACT-A) framework formed a key plank of MPP's support for international pandemic response in 2022. ACT-A is a global collaboration that contributed to the development, production and access to COVID-19 tests, treatments and vaccines.

ACT-A's 2022 report recommended that: "To further strengthen pandemic preparedness it is important for WTO (World Trade Organization), WHO and Medicines Patent Pool (MPP) to build and strengthen strategies for generic licensing and technology transfer for therapeutics, including relevant TRIPS procedures, with input from industry partners and stakeholders. The aim of this is to accelerate access of novel products for all low- and middle-income countries and increase diversified manufacturing."

MPP EXPANDS REACH BY SIGNING FIRST EVER LICENCE WITH JAPANESE COMPANY

Throughout 2022, MPP remained steadfast in its commitment to the development and production of COVID-19 treatment by generic manufacturers in low- and middle-income countries. October saw us sign a licensing agreement with Shionogi, one of Japan's leading pharmaceutical companies, for their antiviral candidate ensitrelvir fumaric acid (S-217622). Following regulatory approval, Ensitrelvir will act as a COVID-19 treatment to be administered as an oral tablet taken once daily for five days.

Pending regulatory approval, MPP is now authorised to grant sublicences to manufacturers to develop generic versions of the product and supply ensitrelvir in 117 countries.



This means that many more people from low- and middle-income countries will have access to COVID-19 treatment.



27 generic manufacturers to supply 105 countries with oral COVID-19 treatment.

This news came on the heels of a series of notable MPP successes to combat COVID-19 in 2022.

First, in January, we signed agreements with 27 generic manufacturing companies to produce the oral COVID-19 antiviral molnupiravir for supply in 105 low- and middle-income countries. These sublicense agreements were the result of the voluntary licensing agreement signed the previous October by MPP and MSD, a trade name of Merck & Co.

As with all our non-exclusive sublicences, the agreement allows generic manufacturers to produce both the raw ingredients for molnupiravir or the finished drug itself. The companies offered the sublicense were obliged to meet MPP's requirements for regulatory compliance, as well as international standards for quality-assured medicines. The companies span 11 countries: Bangladesh, China, Egypt, India, Indonesia, Jordan, Kenya, Pakistan, South Africa, South Korea and Vietnam.





27 sublicences signed with MPP for molnupiravir



- Raw ingredients
- Finished drugs
- Raw ingredients and finished drugs



A FURTHER 38 GENERIC MANUFACTURERS TO HELP SUPPLY COVID-19 TREATMENT TO 53% OF WORLD POPULATION

Then in March, MPP signed agreements with 35 companies to manufacture the generic version of Pfizer's oral COVID-19 treatment nirmatrelvir. In combination with a low dose of ritonavir, this can be supplied in 95 low- and middle-income countries and was the result of a voluntary licensing agreement between MPP and Pfizer in November 2021. Overall, this will help enable the supply of these vital medicines to 53 per cent of the world's population.

Six companies will focus on producing the drug substance, nine will develop the product itself and the remainder will do both. The companies cover 12 countries: Bangladesh, Brazil, China, Dominican Republic, Jordan, India, Israel, Mexico, Pakistan, Serbia, Republic of Korea and Vietnam.

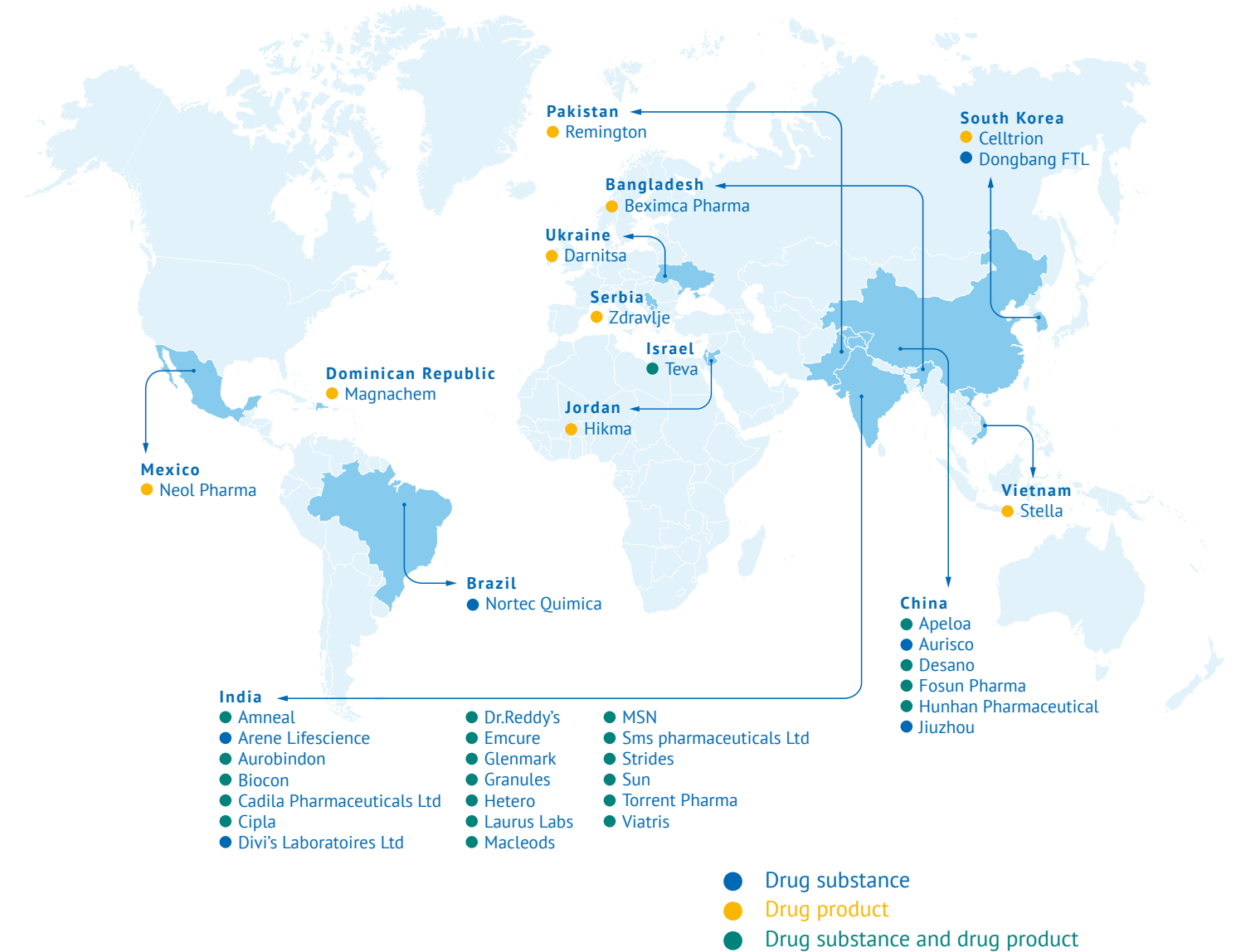
Darnitsa, a Ukrainian company, was unable to sign the initial agreement because of the sudden onset of the war with Russia. Later in the month, however, MPP was delighted to announce that the company had also become one of the sublicensees. This therefore brought the number of signatory companies to 36, and the total number of countries to 13.



And by July, the total number had risen to 38 companies across the world.



38 sublicences signed with MPP for nirmatrelvir (update July 2022)



Record approval time for MPP-enabled generic formulation

subsequent approval under the MPP nirmatrelvir licence, but the approval took place in record time.

Of the 18 COVID-19 products filed by generic companies in 2022, Hetero's nirmatrelvir/ritonavir was approved on 25 December 2022 by WHO-PQ.

Just 300 days elapsed between MPP's signing the sub-licence agreement with Hetero and final approval, and a mere 165 days between filing and approval. On average, it takes between 18 to 24 months for a product to be approved by the WHO-PQ or a Stringent Regulatory Authority after filing.

MPP AND COVID-19: KEY FACTS AND STATS FOR 2022

The success of the COVID-19 licence agreements secured in 2021 meant that MPP signed an unprecedented number of sublicense agreements in 2022.

- ✔ The geographical spread of MPP's sub-licensees has expanded from six to 16 countries, demonstrating that manufacturers on every continent are able to meet MPP's stringent and highest-quality requirements and thus contribute to health security
- ✔ Two agreements were signed with the United States National Institutes of Health (NIH) for 11 innovative therapeutics, early-stage vaccines and diagnostic tools
- ✔ One agreement was signed with Shionogi for ensitrelvir fumaric acid, an oral antiviral
- ✔ By the end of the year, 27 and 38 generic manufacturers respectively had signed sub-licence agreements with MPP to develop products under the molnupiravir and nirmatrelvir licences
- ✔ Out of these 59 sub-licensees, 38 are companies which MPP has never worked with before
- ✔ By the end of 2022, 52 COVID-19 products were under development as a result of the therapeutics' licences secured in 2021
- ✔ Of these 52 products, 18 were filed last year with WHO-PQ or the US Food and Drug Administration (USFDA), with 34 to follow
- ✔ Of the 18 filed in 2022, Hetero's nirmatrelvir/ritonavir was approved in December 2022 by WHO-PQ
- ✔ With an average approval time by a Stringent Regulatory Authority of anywhere between 18-24 months, this particular approval took place in record time, just 165 days or five-and-a-half months
- ✔ Exceptionally, in 2022 four molnupiravir licensees supplied 548,051 treatments' courses in India and Guatemala.



WHAT OUR PARTNERS SAY

What we at Hetero find most useful is the support we receive from MPP's Indian office, this can be on the industry landscape reports with the market share and regulatory approvals of licensed products or providing clarity on the patent situation in different markets. This sharing of scientific and commercial updates gives us a better understanding of the market and our positioning. The MPP team also helps resolve technical issues which may arise in product development and filing with regulatory authorities. What appeals to us in MPP licences is that it ensures a level playing field for all the sublicensees with the terms and conditions, territory, and timelines common to all.

BHAVESH SHAH IS THE DIRECTOR OF INTERNATIONAL MARKETING FOR HETERO, A GENERIC PHARMACEUTICAL COMPANY BASED IN INDIA