World Health Organization
REGIONAL OFFICE FOR South-East Asia

License agreements for COVID-19 therapeutics

1. Therapeutics and COVID-19 : WHO Guide

The WHO Therapeutics and COVID-19: living guideline contains the Organization's most up-to-date recommendations for the use of therapeutics in the treatment of COVID-19.1 The treatment with molnupiravir is conditional to those at highest risk of hospitalization. COVID-19 therapeutics that are currently under consideration by WHO include molnupiravir, fluvoxamine, nirmatrelvir/ritonavir, colchicine and anticoagulants.2 The Medicines Patent Pool (MPP) was the first patent pool with a clear public health mandate that was established by Unitaid in 2010. MPP operates as a non-profit voluntary licensing mechanism through partnerships with originator pharmaceutical companies and generic manufacturers that facilitate access and promote innovation.3 The therapeutics nirmatrelvir/ritonavir by Pfizer and molnupiravir by Merck have agreements with Medicines Patent Pool to promote manufacturing.

Table 1. *License Agreements with MPP- Pfizer and Merck*

Pfizer–MPP agreement	Merck–MPP agreement
License agreement effective date - November 15, 2021	**License agreement effective date - 26 October 2021**
◈ November 2021, Pfizer and the MPP signed a license agreement to facilitate affordable access of Pfizer's oral COVID-19 antiviral treatment candidate nirmatrelvir in combination with low dose ritonavir. ◈ License covers 95 countries.	◈ October 2021 - MPP signed a license agreement with Merck Sharp & Dohme (MSD) for molnupiravir, an oral COVID-19 antiviral medicine. ◈ In November 2021, MSD provided an update on the results from the MOVe-OUT study where molnupiravir reduced the risk of hospitalization or death from 9.7% in the placebo group (68/699) to 6.8% (48/709) in the molnupiravir group, with a relative risk reduction of 30%. ◈ In December 2021, MSD received U.S. FDA Emergency Use Authorization for molnupiravir. ◈ The license covers 105 countries.

1 Therapeutics and COVID-19: living guideline, https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.2 3 March 2022

2 Therapeutics and COVID-19: living guideline, https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.2 3 March 2022

3 Medicines Patent Pool, https://medicinespatentpool.org/what-we-do/licensing-for-public-health

2. Key features of MPP agreements are:

(1) The agreements allows for the manufacturing of the active pharmaceutical ingredients formulations anywhere in the world.

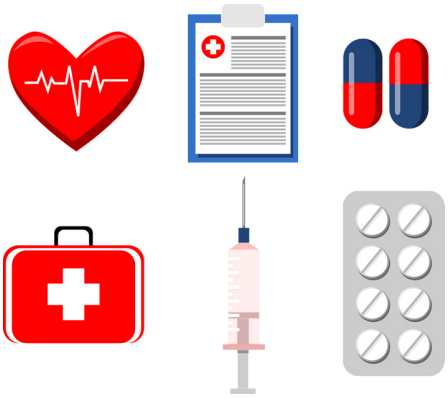
(2) The agreements are mostly royalty free and ensures quality as it makes it mandatory for the licensees to obtain approval from WHO pre-qualification, or a stringent authority. Where such approval is not yet available, temporary approval from a WHO expert review panel may be obtained.

(3) Data exclusivity is waived in countries with such form of protection, thus facilitating regulatory approval of generics.

(4) The license discloses the list of all pending and granted patents at the time of signing the license.

(5) All Indian and South African sublicensees benefit from a one-time technology transfer.

(6) The licensees have the right to terminate the agreement at any time on a product by product basis and can challenge any of the licensed patents.[4]



Comparative tables on the License and sub license terms of Pfizer and Merck with MPP are placed below for easy reference.

Table 2. *License terms of Pfizer and Merck with the Medicines Patent Pool*

Clauses	Pfizer	Merck
License grant	Non-exclusive, non-transferable, sublicensable (solely to sublicensees through one tier), royalty-bearing right and license under the territory Patents and licensed knowhow to grant licenses to Sublicensees.	Non-exclusive, non-transferable license under the Territory Patents and MSD knowhow to enter into Sublicenses with sublicensees for the latter to manufacture the product at a facility that is in the territory and that is approved by a stringent regulatory authority or prequalified by the World Health Organization.
License restrictions	No rights are granted under this agreement for any other purpose, and MPP agrees that it will not use the patents or licensed knowhow itself or grant sublicenses to: (a) to entities or persons other than Sublicensees; (b) other than in the form of the Sublicense.	No rights are hereby granted for any other purpose, and MPP agrees that it will not use the patents or MSD knowhow itself or grant sublicenses.

4 https://medicinespatentpool.org/what-we-do/strategy

Clauses	Pfizer	Merck
Regulatory exclusivity waivers	Pfizer shall provide, upon MPP's written request, a Sublicensee with regulatory exclusivity waivers to the extent required by the applicable agencies in order for such sublicensee to manufacture or sell licensed product in the territory in accordance with the terms of the applicable Sublicense.	MSD shall provide, upon MPP's request, a Sublicensee with regulatory exclusivity waivers to the extent required by the applicable regulatory authorities in order to manufacture or sell the product in the territory in accordance with the terms of the Sublicense.
Trademarks	No rights in any Pfizer trademarks are granted to MPP or Sublicensees under this agreement.	No rights in any MSD trademarks are granted to MPP or sublicensees under this agreement.
License purpose	MPP acknowledges that the licenses granted are solely under and with respect to the patents and licensed knowhow for the sole purpose of final supply of the licensed products in the territory.	MPP acknowledges that the license granted solely under and with respect to patents and MSD knowhow for the purposes of final supply of the products in the territory.
Patent prosecution; enforcement and defense	Pfizer shall have the sole right (but not the obligation) to file, prosecute and maintain the Patents in the territory in Pfizer's name and at Pfizer's own cost and expense.	MSD institute sanction at its expense against alleged third-party infringers with respect to substance or any product, or takes action to defend the patents, MPP agrees to cooperate in good faith with MSD and at MSD's cost.

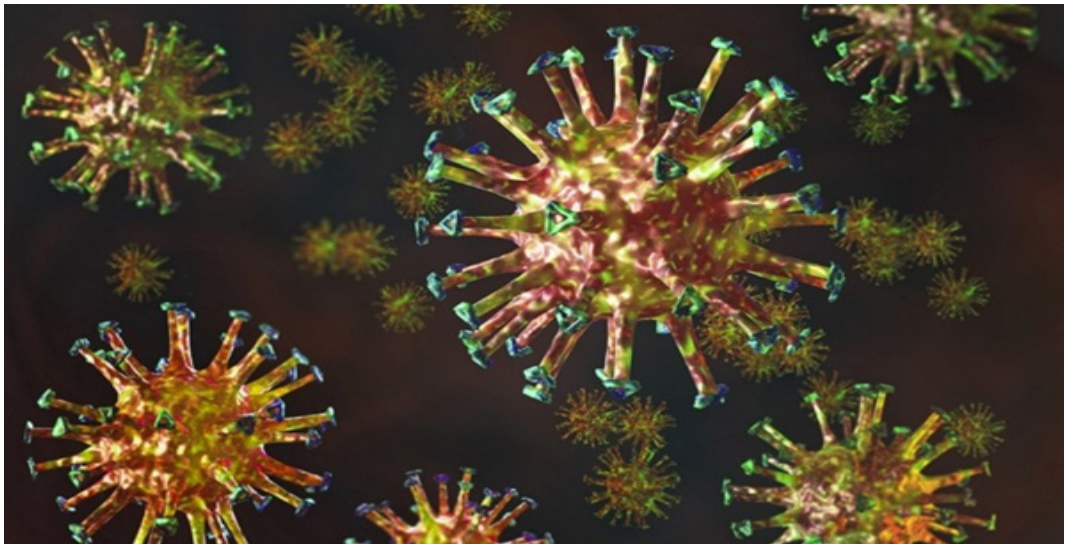


Table 3. *Sublicense terms of Pfizer and Merck with the Medicines Patent Pool*

Pfizer	Merck
Identification of Sublicensees. MPP may grant sublicenses to any entity (a) with demonstrated commitment, ability and readiness to develop, manufacture and Commercialize Licensed Product and/or Compound in accordance with the Sublicense to be granted and (b) satisfying certain other criteria to be jointly established by the Parties.	**Identification of Sublicensees.** MPP may grant Sublicenses to any entity with demonstrated commitment, ability and readiness to develop and commercialize Product and/or Substance in the form of Sublicense.
Pfizer's consent. Pfizer shall have the right of approval over each proposed Sublicensee, such approval not to be unreasonably withheld. Pfizer's response will be provided within thirty (30) business days following MPP's initial written notice of intent to sign a Sublicense with a proposed Sublicensee, such notice to include reasonably detailed information regarding the proposed Sublicensee to permit Pfizer to assess the proposed Sublicensee's compliance.	**MSD's consent.** MSD shall have the right of approval over any proposed Sublicensee, such approval not to be unreasonably withheld. MSD's response will be provided within 30 days of MPP's initial written notice of intent to sign a Sublicense with a proposed Sublicensee, such notice to include reasonably adequate information regarding the proposed Sublicensee to permit MSD to assess the proposed Sublicensee's compliance.
Insurance. MPP shall cause Sublicensees to purchase and maintain appropriate insurance as per the terms in the form of Sublicense.	**Insurance.** MPP shall cause Sublicensees to purchase and maintain appropriate insurance as per the terms of the Sublicense.
Waivers. MPP shall not waive any obligations or liabilities of a Sublicensee under a Sublicense without the express prior written consent of Pfizer.	-
Data package. Following the Effective Date, Pfizer shall assemble a discrete data package related to the Compound, the contents of which shall be determined by Pfizer in its sole discretion. A Sublicensee shall submit any request for access to the data package to MPP in writing.	-
Third-party beneficiary rights under the sublicense. Pfizer shall be a third party beneficiary of each Sublicense and shall have the right to exercise any rights of MPP under the Sublicense, including, without limitation, any right that MPP may have to terminate a Sublicense.	-