



2000 Galloping Hill Road
Kenilworth, NJ 07033 U.S.A.
T: 908-740-4000
E: office.secretary@merck.com

[merck.com](https://www.merck.com)

**WITHOUT PREJUDICE
PRIVATE AND CONFIDENTIAL**

24 January 2022

Attention:

MEDICINES PATENT POOL FOUNDATION

7 rue de Varembeé
Geneva 1202, Switzerland

**NOTICE: WAIVER OF SECTION 3.2 OF THE FORM SUBLICENSE AGREEMENT (EXHIBIT C) OF THE
LICENSE AGREEMENT DATED 26 OCTOBER 2021**

Dear Mr. Park,

1. BACKGROUND:

- (A) We refer to Section 3.2 of the Form Sublicense Agreement (“**Sublicense**”), attached as Exhibit C to the License Agreement between Medicines Patent Pool Foundation (“**MPP**”) and Merck Sharp & Dohme Corp (“**Company**”) dated 26 October 2021 (“**Head License**”).
- (B) Under Section 3.2 of the Sublicense, a sublicensee of MPP (“**MPP Sublicensee**”) agrees that *“it will manufacture the Substance and the Product in a manner consistent with (i) WHO Pre-qualification standards; or (ii) the standards of any SRA. Licensee will not sell any Product without WHO Prequalification or SRA approval, or through any provisional or emergency use authorizations available through WHO or an SRA, and will comply with applicable regulatory requirements in the country of manufacturing and the country of sale.*
- (C) Unless otherwise defined, all capitalised terms used herein shall bear the same meanings as in the Sublicense.

2. RATIONALE FOR WAIVER:

As part of the discussion with MPP, the Company agrees that there may be situations where, subject to Section 2 of the Sublicense, a MPP Sublicensee is ready to make available the Product with the necessary regulatory approvals in the country of manufacture and sale, is manufacturing the Substance and Product in a manner consistent with WHO Pre-qualification or SRA standards, but has yet to receive either WHO Pre-qualification or SRA approval for the Product.

3. GRANTING OF THE WAIVER AND CONDITIONS:

- (A) Considering the above situation, Company agrees that it shall waive the requirements under Section 3.2 of the Sublicense and allow a MPP Sublicensee to make the Product available in accordance with Section 2 of the Sublicense if all conditions are met ("**Waiver**"):
- (i) The MPP Sublicensee certifies and represents to MPP and Company that it is manufacturing the Substance and Product in a manner consistent with WHO Pre-qualification or SRA standards.
 - (ii) **If Commercialization of the Product is intended in a country of sale ("COS")**, the MPP Sublicensee provides to MPP and Company documentary proof that the Product has been filed for WHO Pre-qualification (or Emergency Use Listing) or SRA Approval (or emergency use authorization ("**EUA**"), as applicable) (collectively, the "**Filings**").
 - (iii) **If Commercialization of the Product is intended in a country of manufacture ("COM")**, the MPP Sublicensee provides to MPP and Company written confirmation that the Filings shall be filed within 6 months of the grant of the Waiver ("**6-Month Requirement**").
 - (iv) Upon satisfying requirements (i) and (ii)/(iii) as applicable above, the MPP Sublicensee shall provide to MPP and Company documentary proof that it had complied with the applicable regulatory requirements in the COM and COS before making available the Product in accordance with Section 2 of the Sublicense. Specifically, if Commercialization of the Product takes place in the COM, there should be an EUA or an approval granted by the regulatory authorities of the COM and if the Commercialization of the Product is intended in any COS, the applicable authorization from the COS shall follow.
- (B) The MPP Sublicensee will agree in writing - prior to making the Product available under Section 2 of the Sublicense - that it will immediately cease selling the Product if either of the Filings are not approved within a reasonable timeframe as discussed and agreed between MPP and Company or if it breaches either or all of Sections 3(A)(i) to 3(A)(iv) of this Notice. On a case-by-case basis and with a minimum one-month prior notice, Company may, in its own discretion, provide a requesting MPP Sublicensee an extension to the 6-Month Requirement ("**Exemption**"). Any lapses of the 6-Month Requirement without a valid Exemption shall constitute a breach of Section 3(A)(iii).

- (C) **WE RESERVE THE RIGHT TO RESCIND OR CHANGE ANY REQUIREMENTS UNDER THIS WAIVER AT OUR SOLE DISCRETION.**
- (D) Notwithstanding the above, nothing contained in this Notice or otherwise shall be deemed to have waived or modified any of our rights under or in connection with the Head License or Sublicense. We hereby expressly reserve all such rights accordingly.
- (E) This Notice is not intended to amend any terms and conditions of the Head License or Sublicense except as mentioned above and shall supersede the notice dated 20 December 2021.
- (F) MPP may share this Notice with MPP Sublicensees on a strictly “need to” basis provided that it be considered and treated as Confidential Information under the terms of the Sublicense.

4. GENERAL:

- (A) Any references of “we”, “our” or “Company” shall refer to **MERCK SHARP & DOHME CORP.**
- (B) This Notice shall be governed by and construed in accordance with New York laws.

Yours Sincerely,

ON BEHALF OF MERCK SHARP & DOHME CORP.

Signature: *Kelly Grez*
Name: Kelly E.W. Grez
Title: Secretary