

LICENSE AGREEMENT

This LICENSE AGREEMENT (the “**Agreement**”) is made as of 13/01/2022 (the “**Effective Date**”) by and among the **Medicines Patent Pool**, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at rue de Varembe 7, Geneva 1202, Switzerland (“**MPP**”), and

BDR Pharmaceuticals Intl' Pvt Ltd a company registered under the laws of India, and having as principal place of business at 6, Engineering Center, 9 Mathew Rd, Opera House, Mumbai- 400004, (“**Licensee**”). Each of MPP and Licensee is referred to in this Agreement as a **Party** and collectively referred to in this Agreement as the **Parties**.

RECITALS

WHEREAS, in accordance with MSD-MPP Agreement (as hereinafter defined), MPP has been granted by MERCK SHARP & DOHME CORP, a New Jersey corporation, USA (“**MSD**”) the right to sublicense certain Patents (as hereinafter defined), and MSD Know-How regarding the Substance (as hereinafter defined) used in Product (as hereinafter defined) in furtherance of its policy of improving access to COVID-19 medicines in the countries set forth in Appendix 1 hereto;

WHEREAS, MPP is a non-profit organization with a mission to improve the health of people living in the developing world by increasing access to quality, safe, efficacious, and affordable medicines by facilitating access to intellectual property on these medicines;

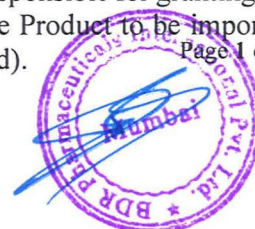
WHEREAS, the Licensee desires to obtain a licence from MPP to use the aforesaid Patents and MSD Know-How and MPP is willing to grant to the Licensee such a licence in accordance with the terms and subject to the conditions of this Agreement; and

WHEREAS, the intent of this Agreement is to provide a license to Patents and MSD Know-How as set forth herein, and not to create any contractual barriers except as otherwise provided in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants set forth herein and other good and valuable considerations, the receipt of which is hereby acknowledged, the Parties hereto mutually agree as follows:

1. DEFINITIONS

- 1.1 **Affiliate** shall mean in relation to a Party, any corporation, firm, partnership, or other entity which is directly or indirectly controlled by, in control of, or under common control of such Party. For the purposes of this definition “control” shall mean the ability of any corporation, firm, partnership, or other entity, whether through ownership of shares or otherwise, to ensure that the affairs of a Party hereto are conducted in accordance with the wishes of such corporation, firm, partnership, or other entity.
- 1.2 **Agency** shall mean any government regulatory authorities responsible for granting any health or pricing approvals or registrations necessary for the Product to be imported, promoted, and/or sold in the Territory (as hereinafter defined).



- 1.3 **Agreement Quarter** shall mean any period of three months ending on the last day of March or June or September, or December.
- 1.4 **Authorized Supplier** shall mean a Third Party that has entered into a written agreement with MSD regarding the right to supply Substance and/or Product to other (receiving) third parties who have also entered into a written license agreement with MSD regarding the right to supply Substance and/or Product.
- 1.5 **Business Day** shall mean a day (other than a Saturday or Sunday) on which the banks are open for normal business in New York, USA.
- 1.6 **Commercialization** or **Commercialize** shall mean sale, import, or export of the Product by the Licensee to an unrelated entity for the purposes of making the Product available in the Territory for use in the Field.
- 1.7 **Customer** shall mean the Third Party who is buying the Product from Licensee, but shall not include MSD, its Affiliates, an MPP Licensee, or the Authorized Suppliers.
- 1.8 **Field** shall mean the treatment of COVID-19 caused by SARS-CoV-2.
- 1.9 **Improvements** shall mean any (patentable or unpatentable) new or improved formulation, process, improvement, invention, development, or finding related to the Substance and/or the Product, or any (patentable or unpatentable) other pharmaceutical product using Substance, or any further invention (patentable or unpatentable) that relates to the manufacture or formulation of the Products and/or Substance or incorporate or are based on the Patents, developed by Licensee after the Effective Date.
- 1.10 **Key Approvals** shall mean local health Agency approval or authorization in the country of manufacture and/or local health Agency approval or authorization in any country in the Territory Licensee will export to or Commercialize the Product prior to exportation to or Commercialization in that country.
- 1.11 **Know-How** shall mean any and all confidential or proprietary information and materials, including discoveries, improvements, processes, methods, protocols, formulas, molecular constructs, reagents, assays, data, results, inventions, trade secrets, compositions of matter (including compounds), formulations, and findings, in each case, patentable or otherwise, and including any copyrights therein.
- 1.12 **MSD-MPP Agreement** shall mean the licence agreement entered into between MSD and MPP on _____ 2021.
- 1.13 **MSD Know-How** shall mean all Know-How, that: (i) directly relate to use in the Field of the Substance and/or the Product, (ii) are controlled by MSD or its Affiliates as of the execution date of this Agreement and, (iii) are not in the public domain or otherwise generally known. For avoidance of doubt, MSD Know-How shall not include any Know-How to the extent solely and directly related to any other MSD compound. Also, MSD Know-How includes only that Know-How, designated by MSD in its sole discretion, necessary for the manufacture, registration, and commercialization of the



Substance and/or the Product for use in the Field.

- 1.14 **MSD Trademarks** shall mean trademarks, service marks, Internet domain names, trade dress, trade names, and corporate names, now existing or hereafter adopted or acquired, whether registered or unregistered, including without limitation any applications or registrations therefor, and all goodwill connected with the use thereof and symbolized thereby, that are owned, controlled or used by MSD or its Affiliates.
- 1.15 **MPP Licensee(s)** shall mean any Third Party that has been licensed by MPP pursuant to the MSD-MPP Agreement.
- 1.16 **Net Sales** shall mean the gross amounts invoiced by Licensee or its Affiliate for sales of Products to Customers, less the sum of the following actual and customary deductions:
- (a) Cash, trade, quantity and other discounts, including chargebacks, retroactive price reductions, rebates (whether or not government mandated), and discounts in the form of wholesaler inventory management fees;
 - (b) Sales, value added (only to the extent of amounts actually paid and not refunded, reimbursed or credited), use, tariff, import/export duties or other excise taxes when included in the gross invoice price, but not value-added taxes assessed upon such sales that are not included in the gross invoice price or income taxes on income derived from such sales;
 - (c) Transportation and associated insurance, freight, packaging and customs charges when included in the gross invoice price;
 - (d) Allowances or credits to customers because of rejections, returns, or recalls; and
 - (e) Deductions for bad debts in accordance with generally accepted accounting principles, provided that such amounts will be included in Net Sales when recovered.

For purposes of calculating Net Sales, a sale to an Affiliate for end use by the Affiliate will be treated as a sale at list price. End use does not include: (a) use in a clinical trial if for no cost or for de minimis value, (b) charitable or compassionate use purposes if for no cost or for de minimis value, or (c) quantities provided for resale where royalties will be paid on the resale. For the avoidance of doubt, Net Sales shall not include consideration paid or owed to Licensee for any sale to MSD, an Affiliate, a MPP Licensee or the Authorized Suppliers that is not for end use by each of such parties. Net Sales and all deductions allowed in computing Net Sales shall be determined on an accrual basis in accordance with generally accepted accounting principles, consistently applied.

- 1.17 **Non-Territory Patents** shall mean any Patents, granted or pending, in any country that is not included in the Territory (as hereinafter defined). For the avoidance of doubt, to the extent international and regional patent applications are included in



Patents, such international and regional patent applications are Non-Territory Patents only with respect to countries that are not included in the Territory.

- 1.18 **Own Use** shall mean the act of Commercialization and/or the act of registration of the Product in the Territory for use in the Field.
- 1.19 **Patents** shall mean any unexpired letters patent or any pending patent applications as set forth in **Appendix 2** hereto, that are granted or pending, relating to the Substance and/or Product and made a part of this Agreement, including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, pediatric exclusivity, and the like of any such patents and patent applications, and international (i.e., WIPO), regional (e.g., EPO, EA), and foreign national equivalents of the foregoing.
- 1.20 **Product(s)** shall mean any pharmaceutical or biological composition or preparation (in any and all dosage forms, formulations and delivery modes) containing the Substance, including any Improvements to the foregoing, (i) for sale or use by prescription, over the counter or any other method, or (ii) for administration to, or use with, human patients in a human clinical trial ("**Clinical Trial**"). For purposes of calculating Net Sales, Product will refer to Product in final or bulk form when sold for Stockpiling purposes in a form other than final form. "**Stockpiling**" shall mean activities conducted by a governmental authority or Public Purchasers to address public health emergencies by purchasing and maintaining inventories of Product for distribution and use in responding to such emergencies. Stockpiling may apply to purchases of finished or bulk form pharmaceutical Products, or bulk forms of the Substance used to make such Products. For the avoidance of doubt, any sale of Products in bulk form or for a Clinical Trial may only take place if permitted and approved in advanced in writing by MSD.
- 1.21 **Public Purchasers** shall mean with respect to a country in the Territory (a) the following organizations to the extent that they are not for profit organizations and operate in such countries: (i) Non-Governmental Organizations to the extent that they are recognized by the applicable local government ministries from such country; (ii) UN-related organizations working for or in such country, including but not limited to UNDP and UNICEF; (iii) Not-for-profit organizations including without limitation, Médecins Sans Frontières, Save-the-Children, OXFAM and the International Committee of the Red Cross (ICRC) to the extent that they are recognized by the applicable local government ministries from such countries; (iv) programs funded by funding mechanisms, including without limitation, UNITAID, PEPFAR, USAID, and Global Fund; and agencies based outside of the Territory to the extent that they are supporting implementation of the organisations described in clauses (i) through (iii) above locally in such country, and (b) nominally for profit procurement organisations but only to the extent that such procurements are supporting not-for-profit programs in such country as described in (a) of this definition within the Territory.
- 1.22 **Retail** shall mean sale, import, or export of the Product by the Licensee to another



MPP Licensee or an Authorized Supplier for the purpose of making the Product available in the Territory for the MPP Licensee or an Authorized Supplier's Own Use.

- 1.23 **Stringent Regulatory Authority (SRA)** shall mean a regulatory authority which is: (a) a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or (b) an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).
- 1.24 **Substance** shall mean Molnupiravir, {(2R,3S,4R,5R)-3,4-Dihydroxy-5-[(4Z)-4-(hydroxyimino)-2-oxo-3,4-dihydropyrimidin-1(2H)-yl]oxolan-2-yl}methyl 2-methylpropanoate, which has the molecular formula C₁₃H₁₉N₃O₇, and has the chemical structure [either insert or reference an Appendix]. For clarity, Substance includes all forms of {(2R,3S,4R,5R)-3,4-Dihydroxy-5-[(4Z)-4-(hydroxyimino)-2-oxo-3,4-dihydropyrimidin-1(2H)-yl]oxolan-2-yl}methyl 2-methylpropanoate, including but not limited to, mono-, di, and triphosphate forms, isomers, stereoisomers, tautomers, pharmaceutically acceptable salts, esters, hydrates, solvates, crystal forms including crystalline forms and co-crystalline forms, amorphous forms, free acid form, free base form, polymorphs, chelates, optically active forms, metabolites, and prodrugs thereof. Additionally, Substance includes all deuterated forms.
- 1.25 **Territory** shall mean those countries set forth in Appendix 1.
- 1.26 **Territory Patents** shall mean any Patents, granted or pending, in any country within the Territory. For the avoidance of doubt, to the extent international and regional patent applications are included in Patents, such international and regional patent applications are Territory Patents only with respect to countries within the Territory.
- 1.27 **Third Party(ies)** shall mean any party other than a Party to this Agreement.
- 1.28 **Valid Claim** means a claim of any issued and unexpired patent or pending patent application whose validity, enforceability, or patentability has not been affected by any of the following: (a) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (b) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding, or decision being final and unappealable or unappealed within the time allowed for appeal.
- 1.29 **Vend** shall mean sale, import, or export of the Substance by the Licensee to another Licensee or an Authorized Supplier for the purpose of manufacturing the Product for its Own Use.



2. SCOPE OF THE GRANT

2.1 **Within the Territory.** Subject to the terms and conditions of this Agreement, MPP hereby grants to Licensee a non-exclusive, non-transferable, non-sublicensable license under the Territory Patents and MSD Know-How to manufacture the Product at a facility that is in the Territory (excluding any Sanctions Targets as defined in Section 6.3) and that is approved by a SRA or prequalified by the World Health Organization:

- (a) To Commercialize the Product by itself or through its Affiliates in the Territory for use in the Field;
- (b) To Retail the Product to other MPP Licensees or Authorized Suppliers for their Own Use within the Territory;
- (c) to register the Product in the Territory by itself or through its Affiliates for use in the Field for (a) and (d); and
- (d) to sell the Product to Public Purchasers for the sole purpose of enabling the Public Purchasers to supply the Product in the Territory for use in the Field.

2.2 **Within the Territory.** Subject to the terms and conditions of this Agreement, MPP hereby grants to Licensee a non-exclusive, non-transferrable, non-sublicensable license under the Territory Patents and MSD Know-How to manufacture the Substance at a facility that is in the Territory (excluding any Sanctions Targets as defined in Section 6.3) and that is approved by a SRA or prequalified by the World Health Organization;

- (a) to manufacture the Product in accordance with Section 2.1; and
- (b) to Vend the Substance.

2.3 **Outside the Territory.** Subject to the terms and conditions of this Agreement, MPP hereby grants to Licensee a non-exclusive, non-transferable, non-sublicensable license under the Non-Territory Patents and MSD Know-How manufacture the Product at a facility that is in a non-Territory country (excluding any Sanctions Targets as defined in Section 6.3) and that is approved by a SRA or prequalified by the World Health Organization;

- (a) to export the Product to the Territory for its Own Use;
- (b) to Retail the Product in the Territory to other MPP Licensees or Authorized Suppliers for their Own Use; and
- (c) to sell the Product to Public Purchasers for the sole purpose of enabling the Public Purchasers to supply the Product in the Territory for use in the Field.



- 2.4 **Outside the Territory.** Subject to the terms and conditions of this Agreement, MPP hereby grants to Licensee a non-exclusive, non-transferrable, non-sublicensable license under the Non-Territory Patents and MSD Know-How to manufacture the Substance at a facility that is in a non-Territory country (excluding any Sanctions Targets as defined in Section 6.3.) and that is approved by a SRA or prequalified by the World Health Organization;
- (a) to manufacture the Product in accordance with Section 2.3; and
 - (b) to Vend the Substance.
- 2.5 No license or right is granted by implication or otherwise with respect to the Substance and/or Product, except as expressly granted herein. Subject to the above and except as permitted by statute, the Licensee shall not be entitled to manufacture, use, Commercialize, Retail, Vend, register with regulatory agencies, and/or sell the Substance and/or the Product for any other purpose or in combination with any other substance, product, intermediate, and/or active pharmaceutical ingredient (whether co-packaged, co-formulated or otherwise) ("**Combination**") unless prior written approval had been provided by MSD in its sole discretion.
- For the avoidance of doubt, Parties agree that any approval of the Combination by MSD shall be subject to separate terms and conditions which shall be negotiated independently of this Agreement.
- 2.6 For the avoidance of doubt, nothing in this Agreement shall be construed to prevent the Licensee from engaging in activities inside or outside the Territory where such activities would not (1) infringe the Patents and/or any other intellectual property rights; and/or (2) misappropriate MSD Know-How. Licensee acknowledges that MSD has expressly reserved all its rights under the Patents, except as expressly set forth in the MSD-MPP Agreement, and under any additional patents and/or patent applications owned or controlled by MSD. Licensee also acknowledges that MSD does not waive any applicable statutory and/or regulatory exclusivities owned or controlled by MSD, except as expressly set forth in the MSD-MPP Agreement. Nothing in this Agreement shall provide a right to commercialize outside the Territory.
- 2.7 Except as otherwise provided and solely in the manner permissible under this Agreement, the license granted is solely for the stated Territory. Licensee and its Affiliates agree not to sell the Substance and/or the Product to any Third Party outside the Territory or to sell Substance and/or Product to any Third Party that Licensee or its Affiliates have reason to believe will resell the Substance and/or the Product outside of the Territory in breach of this Agreement. Licensee shall (a) include language on the packaging of such Product indicating that such Product is "not for resale" outside of the initial country of sale and (b) implement a system of batch control and tracing which will enable the identification and batch tracing of any such Product which are subsequently reexported outside the Territory. In



addition, Licensee shall use its best efforts, including but not limited to including provisions in its customer contracts and purchase orders, to ensure that all of its customers and any subsequent purchasers of the Product in all countries of the Territory shall not sell the Product or offer the Product for sale outside of the initial country of sale. If MPP or MSD becomes aware of any Commercialization of Product outside the Territory in breach of this Agreement, MPP or MSD (through MPP) shall provide the relevant information to Licensee, and Licensee shall promptly take all possible steps to prevent any further re-exports through the distribution channel or channels identified in such information.

- 2.8 If Licensee wishes to Commercialize or sell the Product through an Affiliate of the Licensee acting on Licensee's behalf, Licensee shall first provide prior written notification to MPP and MSD. Upon MPP's or MSD's request, Licensee will provide MPP or MSD with a written copy of Licensee's agreement(s) with such Affiliate and will certify to MPP and MSD in writing that such agreement(s) is/are consistent with the terms and conditions of this Agreement. MPP and MSD have the right to review all such agreements to verify consistency with the terms and conditions of this Agreement. In the event that any inconsistency is found which had not been specifically discussed with, and agreed to in writing by MSD, MPP or MSD shall have the right to require Licensee to amend such agreement with such Affiliate to be consistent with the terms and conditions of this Agreement. Licensee shall be held responsible for the actions of any of its Affiliates or any other permitted assignees/transferees in connection with this Agreement, and all obligations of Licensee under this Agreement in connection with the sale and Commercialization of the Product in the Territory will be deemed to apply to such activities conducted by any of its Affiliates and permitted assignees/transferees.
- 2.9 The license granted under Sections 2.1 to 2.4 above does not include a license to other intellectual property that MSD may possess with respect to the Substance and/or the Product, other than the Territory Patents, the Non-Territory Patents, and MSD Know-How, as expressly provided herein. For clarity, license granted under Sections 2.1 to 2.4 above does not include a license to processes or procedures for the manufacture, production, packaging, labeling, warehousing, and quality control testing of the Substance and/or the Product that are not included in the Patents and/or MSD Know-How.
- 2.10 Except as expressly set forth in this Agreement, (1) MPP does not grant any license to Licensee under any of MSD intellectual property rights (including, without limitation, patents or rights to any MSD proprietary compounds or drug substances other than the Substance), and (2) Licensee shall not take any action which would constitute an infringement of any of the Patents.

3. DEVELOPMENT AND REGISTRATION

- 3.1 As of the Effective Date and subject always to MSD's retained rights to the Patents, the Licensee shall have full control, responsibility (financial and otherwise) and authority over development, registration, importation, manufacture, and



commercialisation of the Products to be sold or supplied by the Licensee in the Territory under this Agreement.

- 3.2 Licensee 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.
- 3.3 Licensee shall submit a complete file for WHO Pre-qualification or any SRA approval within 36 months from the Effective Date for any existing formulation of the Products, or within a period to be agreed among MSD, MPP and Licensee for any new formulation of the Product. Licensee will diligently pursue such applications following submission. The Licensee agrees, where applicable and to the extent that it is able: (a) to not seek; and (b) to waive, regulatory exclusivity in the Territory in relation to any data relating to the Products.
- 3.4 For the period beginning from the Effective Date, within 10 Business Days following the end of each Agreement Quarter, Licensee shall provide MPP with a quarterly written report covering all its activities related to the development and testing of all Products and/or Substance (as permitted and to the extent applicable) and the obtaining of necessary governmental approvals; these shall include (but is not limited and to the extent applicable and permitted) to its (a) Products and/or Substance in its development pipeline, (b) status of development of each Product and/or Substance in development, (c) regulatory filing plan for WHO Pre-qualification Programme and/or a Stringent Regulatory Authority for each Product, (d) a list of regulatory authorities, including as applicable the FDA, WHO and authorities in the countries within the Territory for which such regulatory approvals or authorizations have been filed and/or obtained for any Product, (e) summary of work completed and in progress, (f) current schedule of anticipated events and milestones, (g) anticipated market introduction dates and (h) its activities, if applicable. Licensee will also report to MPP the date of first commercial sale of each Product within five (5) business days thereafter.
- 3.5 The Parties agree to meet on a quarterly basis or as reasonably requested by the MPP, to review development and filing status and also regarding such reports concerning Products and/or Substance. MPP agrees that information contained in quarterly and other such reports shall be treated as Confidential Information; provided, however, that such information may be shared with MSD (with MSD treating such reports as Confidential Information); and that aggregated data may be publicly disclosed by MPP. Licensee shall, at its own expense and using its own resources, and using all due care in accordance with the prevailing standard of professional competence in a regulatory function in the pharmaceutical industry, obtain, maintain and operate in compliance with (a) the Key Approvals and (b) all other authorizations, licenses, permits, registrations, and regulations which may from time to time be required by any Agency for Licensee to import, manufacture, promote, and sell the Product in the Territory. Licensee will not sell Product in any country in the Territory prior to obtaining both



local health Agency approval or authorization in the country where the Product is manufactured and/or local health Agency approval or authorization in the country in the Territory where the Product is sold and Commercialized. Licensee shall provide quarterly written reports to MPP notifying MPP about the registration process and providing MPP with any other information in this regard that MPP may reasonably require. Licensee shall not transfer, assign, or otherwise convey any of the authorizations, registrations, or permits related to the Product, as set forth above in this Section, to any Affiliate without the prior written notice to MPP and MSD.

- 3.6 Licensee will manufacture and sell the Substance and Products in accordance with all laws and regulations relevant to the manufacture and sale of the Substance and Products and in accordance with good industry practice in addition to provisions contained in 3.2.
- 3.7 Licensee shall not transfer, assign, or otherwise convey any of the authorizations, registrations, or permits related to the Product, as set forth above in this Section, to any Third Party without the prior permission of MPP, and which may be withheld at MPP's sole discretion in the case of a proposed transfer to a Third Party.
- 3.8 Licensee shall promote, Commercialize and sell the Product in strict adherence to regulatory, professional, and legal requirements in the Territory and shall do nothing which would jeopardize the good will or reputation of MPP or MSD or the reputation of the Product.
- 3.9 This Section 3 shall always be subject to the provisions of Section 3B. Where there is any inconsistency between the two Sections, Section 3B shall prevail.

3A. TRADEMARKS

- 3A.1 No rights in any MSD Trademarks are granted to Licensee under this Agreement, and Licensee shall not appropriate or otherwise use or register any MSD Trademarks in connection with the Product in the Territory, including without limitation in connection with the sale, distribution, promotion, or marketing of the Product. A complete description of any trademark proposed to be used or registered by Licensee in connection with the sale of the Product in the Territory shall be submitted to MPP for MSD's written approval prior to use or filing an application to register such trademark. MPP shall promptly review such request and refer it to MSD. The Licensee shall provide any additional information required by MPP in relation to such request. The response to the Licensee for any request for approval shall be given within 30 days of receipt by MSD from MPP of all relevant documentation necessary to consider the Licensee's request. Such approval may be withheld if the subject trademark is determined by MSD, in its sole discretion, to be identical to or confusingly similar to any MSD Trademark, however any such approval shall not waive any rights with respect to the MSD Trademarks.
- 3A.2 In addition to the foregoing, for the avoidance of doubt, Licensee agrees that it shall not: (i) register or, in connection with the sale of any Product, use any trademark or



trade name which is identical to or confusingly similar (as MSD shall determine in its sole discretion) to any MSD Trademark; (ii) use trade dress, packaging (both internal and external), or labeling which is the same as or similar to (as MSD shall determine in its sole discretion) that of MSD or any Affiliate of MSD in connection with the sale of any Product; and (iii) give the impression to the public, to physicians or to the trade that the Product is manufactured by or in any way connected with MSD or any of its Affiliates.

3B. PURCHASE OF SUBSTANCE OR PRODUCT

- 3B.1 Licensee hereby agrees to supply the Substance and/or the Product, as requested by MSD in writing, to MSD or its Affiliates at the actual cost of goods (verifiable via Third Party audit) plus a reasonable markup (to be negotiated) under a supply agreement containing such other reasonable and customary terms and conditions as are agreed by the Parties in good faith.
- 3B.2 If Licensee wishes to obtain Substance and/or Product from a Third Party source, Licensee shall notify MSD through MPP of the intended source prior to making any commitments to purchase the Substance and/or Product. MSD will determine at its sole discretion whether and on what terms to grant a license to the intended source to produce the Substance and/or Product or inform Licensee whether such license already exists.
- 3B.3 Subject to Sections 3B.2 and 3B.4 below, the Licensee shall have the right to source the Substance and/or Product in its finished form from an Authorized Supplier or MPP Licensee. Licensee's Commercialization of any Product sourced from an Authorized Supplier or MPP Licensee shall be subject to the terms and conditions of this Agreement and be royalty-bearing in accordance with Section 5A of this Agreement.
- 3B.4 Licensee shall not enter into any agreements with an Authorized Supplier or MPP Licensee with respect to Substance and/or Product without providing prior notice to MSD through MPP. All terms of the agreement between Licensee and Authorized Supplier or MPP Licensee must be consistent with this Agreement or written approval needs to be obtained by MSD. Licensee shall certify to MSD through MPP in writing that its arrangement(s) with each Authorized Supplier with respect to Substance and/or Product is consistent with the terms and conditions of this Agreement. MSD shall have the right to review all such agreements to verify consistency with the terms and conditions of this Agreement. If any inconsistency is found which had not been specifically discussed and agreed with MSD, MSD shall have the right to require Licensee to terminate its agreement(s) with such Authorized Supplier.
- 3B.5 Licensee shall not be obliged to disclose to MPP the financial terms of its agreement(s) with Authorized Suppliers, but shall provide MPP with quarterly reports in accordance with Section 5A of the Agreement that shall include the quantities of Substance and/or Product being supplied to Licensee by each Authorized Supplier (on an Authorized Supplier-by-Authorized Supplier basis), which will be shared by MPP with MSD.



- 3B.6 Licensee's right to source from/ sell to Substance and/or Product a particular Authorized Supplier hereunder shall remain in effect solely for so long as such Authorized Supplier remains compliant with the terms and conditions of the agreement between such Authorized Supplier and MSD, and provided that such agreement between such Authorized Supplier and MSD has not expired or been terminated.
- 3B.7 The Licensee hereby grants MPP the right to disclose its contact information to MSD, an Authorized Supplier or an MPP Licensee for the fulfilment of Section 3B of this Agreement ("**Disclosure Right**"). Licensee shall receive reciprocal information of other Authorized Supplier or MPP Licensee to the extent that the Disclosure Right had been similarly granted by such Authorized Suppliers or an MPP Licensee.
- 3B.8 The Licensee confirms and warrants that it shall not engage in any anti-competitive behavior if it exercises its rights under this Section 3B and shall be fully compliant of all applicable laws.

4. NON-DIVERSION

- 4.1 Diversion. Licensee shall not, directly or indirectly, divert Substance and/or Product outside the Territory. Without limitation of the foregoing, except to the extent provided under this Agreement, the Licensee shall not, directly or indirectly, sell, or supply:
- (a) Products or Substance outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent;
 - (b) Substance to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Substance outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent; and/or
 - (c) Products to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Products outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent.
- 4.2 Product Labelling. The labelling of all Products sold or offered for sale under this Agreement shall expressly state that
- (a) the Product is manufactured under a license from the Medicines Patent Pool; and
 - (b) any other use, beyond the Field, is not authorized.
- 4.3 Notice to Third Parties. The Licensee shall give written notice, prior to the first sale of Products, to any Third Party to which it sells Products of the restrictions contained in this Clause 4 and the Licensee shall use its best endeavors, without prejudice to any other provision of this Agreement, to ensure that such Third Parties will undertake to



abide by the restrictions contained in this Clause 4 and will assist the MPP and MSD in securing compliance with this Clause 4 and the restrictions which it contemplates.

5. INTELLECTUAL PROPERTY

- 5.1 Licensee shall disclose, promptly and in English, to MPP and MSD, without charge, any Improvements. As to any such Improvements (including any patents or patent applications that may be filed by Licensee relating to such Improvements), Licensee shall grant to MSD, its Affiliates, and MPP a world-wide, royalty-free, non-exclusive, sublicensable license to any Improvements ("**Improvement License**") for any and all purposes in the Field, including the rights to make, have made, use, and/or sell the Substance and/or the Product or any other pharmaceutical product using the Substance. For the avoidance of doubt, the Improvement License shall not affect the Licensee's ownership of any Improvements. MPP shall not sublicense the Improvement License to any Third Party or to another MPP Licensee without the consent of the Licensee.
- 5.2 Further to Section 5.1, Licensee shall grant to MSD and/or its Affiliates the right to sublicense the Improvement License to a Third Party ("**Third-Party Sublicense**") as follows, and Licensee shall negotiate and agree with MSD and/or its Affiliates in good faith a royalty and development fee to be paid to the Licensee for such Third-Party Sublicense:
- (i) contract manufacturers for use in connection with the commercialization of MSD products; or
 - (ii) a Third Party in compliance with any contractual obligations that MSD or its Affiliates has with such Third Party.
- 5.3 Licensee shall grant to MSD and its Affiliates an option and right of first refusal to obtain a sole, sublicensable, world-wide, royalty-bearing license to the Improvements in the Field, for any use outside the Field ("**Out-of-Field License**") including the rights to make, have made, use, and/or sell the Substance and/or the Product or any other pharmaceutical product using the Substance outside the Field. MSD shall negotiate and agree with Licensee in good faith a royalty and development fee to be paid to the Licensee for the Out-of-Field License. For the avoidance of doubt, the Out-of-Field License shall not affect the Licensee's ownership of any Improvements to the Products.
- 5.4 The Licensee shall have no rights in relation to the conduct of any matter relating to the Patents, including the filing, prosecution, and maintenance thereof.
- 5.5 If Licensee becomes aware of a possible infringement of the Patents by a Third Party in any country, Licensee will notify MSD, through MPP, immediately. The decision on whether any legal action is necessary or appropriate shall belong to MSD.
- 5.6 In the event that MSD institutes an action at its expense against alleged third-party infringers with respect to Substance or any Product, or takes action to defend the



Patents, Licensee agrees to cooperate in good faith with MSD in such action, upon the request of MSD and at MSD's cost. Any recovery obtained by MSD as a result of such a proceeding or other action shall be retained by MSD.

5A. ROYALTY AND TAXES

5A.1 Licensee will pay to MSD an earned royalty at the rate of five percent (5%) of aggregate Net Sales of Products sold by Licensee or its Affiliates to a governmental entity or Public Purchasers in the Territory in each calendar year, and ten percent (10%) of aggregate Net Sales of Products sold by Licensee or its Affiliates to a commercial entity in the Territory in each calendar year and be recorded in the manner further described in Appendix 3 of this Agreement.

5A.2 Royalty Term. On a country-by-country and Product-by-Product basis, royalty payments in the Territory shall commence upon the first commercial sale of such Product in such country in the Territory and would terminate upon the later of: (a) the expiration, invalidation or abandonment date of the last Patent that includes a Valid Claim that covers such Product in such country in the Territory; (b) ten (10) years from first commercial sale of such Product in such country in the Territory; or (c) expiration of regulatory exclusivity of such Product in such country in the Territory (the "Royalty Term").

5A.3 Royalties accruing to MSD will be paid to MSD quarterly within 45 days after the end of each calendar quarter. Licensee will make all payments under this Agreement by check or wire transfer to an account of MSD designated by written notice from MSD. All royalties due to MSD will be payable in United States dollars. When Products are sold for monies other than United States dollars, the earned royalties will first be determined in the foreign currency of the country in which the sale was made and then converted into equivalent United States funds. The exchange rate will be that rate quoted in The Wall Street Journal on the last Business Day of the reporting period. Licensee shall bear the expense of any bank charges or any other transaction costs incurred in connection with payment under this Section 5A.1 and will effect payment of such amount that will result in MSD receiving the full amount calculated under the first sentence of this Section 5A.1 with no deduction of any type. Each royalty payment shall be accompanied by a statement setting forth the elements and calculation of the royalty amount in the format specified by MSD. It is clarified that any sale of Substance and/or Product between Licensee and Authorized Suppliers or MPP Licensee(s) shall be exempt from any royalty payment.

5A.4 Notwithstanding the aforesaid, the license provided under Section 2 of this Agreement is royalty-free until the end of the month in which the World Health Organization (WHO) declares the end of the Public Health Emergency of International Concern regarding COVID-19.

5A.5 Payments due for sales occurring in any country outside the United States will not be reduced by any fees or other charges imposed by the government of such country on



the remittance of royalty income, provided that if laws or regulations require that taxes be withheld with respect to any royalty payments by Licensee to MSD under this Agreement, Licensee will: (a) deduct those taxes from the remittable payment, (b) pay the taxes to the proper taxing authority, (c) send evidence of the obligation together with proof of tax payment to MSD on a reasonable and timely basis following that tax payment, and (d) Licensee will reasonably assist MSD in seeking an exemption to such withholding to the extent available.

5A.6 To comply with contractual obligations that MSD or its Affiliates has with a Third Party, if monies owed to MSD under this Agreement are not received by MSD when due, Licensee will pay to MSD interest charges at a rate of three percent (3%) above the WSJ rate up to a maximum of ten percent (10%) per annum. Such interest will be calculated from the date payment was due until actually received by MSD. Such accrual of interest will be in addition to, and not in lieu of, enforcement of any other rights of MSD related to such late payment. Acceptance of any late payment will not constitute a waiver under Article 10.9 of this Agreement.

6. REPRESENTATIONS, WARRANTIES, AND COVENANTS

6.1 Ability to Perform. Each of the Parties hereby represents and warrants that:

- (a) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of their incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
- (b) this Agreement has been duly executed and delivered, and constitutes a legal, valid, and binding obligation, enforceable against it in accordance with the terms hereof; and
- (c) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party.
- (d) it has not and will not employ or otherwise use in any capacity the services of any person or entity debarred under 21 U.S.C. § 335a (or equivalent foreign provisions) in performing any activities under this Agreement. Each Party shall notify the other Party, in writing, immediately if any such debarment occurs or comes to its attention, and shall, with respect to any person or entity so debarred, promptly remove such person or entity from performing any further activities under this Agreement, as applicable.
- (e) shall comply with all applicable laws, regulations and codes relating to data privacy, personal data, trans-border data flow, and data protection involved in handling any personal data and information related to each other and their representatives. It shall be the duty of MPP and the Licensee to ensure that no



personally identifiable information that permits the identity of an individual to whom the information applies to be reasonably inferred by either direct or indirect means is shared with each other under any circumstances without complying with applicable privacy laws. This obligation shall survive the expiry of this Agreement.

6.2 Law and Compliance

- (a) General. Licensee covenants and agrees that it shall perform all activities under this Agreement in accordance with all applicable laws and regulations, including, without limitation, with respect to anti-competition, recalls, safety and reporting requirements and export controls and sanctions, and shall obtain, have and maintain all necessary regulatory approvals, marketing authorizations, export licenses, and other permits and licenses, at Licensee's expense for the manufacture and sale of the Substance and/or Product and any other Licensee activities contemplated hereby. Licensee further agrees that it shall not export, re-export, transfer, transmit, or release (including to a foreign national within the United States and Germany) any goods, materials, software, or technology (including technical data) without first obtaining all necessary authorizations from the relevant government agencies. Notwithstanding anything herein to the contrary, any delay or failure to perform any part of this Agreement by either Party resulting from a denial, delay, or withdrawal of any required export authorization shall not constitute a breach of this Agreement nor expose either Party to liability hereunder.
- (b) Conflicts. None of the Parties shall be required to take any action or perform any obligation under this Agreement to the extent that such action or obligation is in direct conflict with any applicable law, rule, or regulation.

- 6.3 OFAC. Licensee represents that neither Licensee nor, to the knowledge of Licensee, any director, officer, employee, or agent of Licensee, is an individual or entity ("**Person**") that is, or is 50% or more owned or controlled by Persons that are: (i) the target of any sanctions administered or enforced by the U.S. Government, including by the Department of Treasury's Office of Foreign Assets Control ("**OFAC**"), or by the governments of Switzerland, the EU, or the United Kingdom ("**Sanctions**") or listed on any denied party lists maintained by OFAC, the U.S. Commerce Department or on the European Union's Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions, or (ii) located, organized or resident in a country or territory that is, or whose government is, the target of Sanctions (including, without limitation, Cuba, Iran, North Korea, Crimea, Venezuela, and Syria). [(i) and (ii) collectively, "**Sanctions Targets**")].

Licensee further warrants that in relation to this Agreement it will not, directly or indirectly, use, transfer, lend, contribute or otherwise make available the any rights (including intellectual property rights) to any Sanctions Target, nor to any Person to engage in any activities or business of or with any Sanctions Target or in any country or territory, that, at the time of such transfer or other transaction, is, or whose



government is, the target of Sanctions (including, for the avoidance of doubt, any country listed in Appendix 1,) without prior written approval from MPP and MSD. Licensee covenants that it shall notify MPP and MSD in writing immediately if any of the preceding representations and warranties becomes incorrect during the term of this Agreement. In case of an inaccuracy or breach in the representations, warranties or covenants in this Section 6.3 during the term of this Agreement, MPP shall be entitled to terminate this Agreement immediately and without penalty to MPP.

Notwithstanding anything to the contrary in this Agreement, including Appendix 1: Territory, the Parties acknowledge that the grant of any rights under this Agreement through MSD in the MSD-MPP Agreement relating to the Substance or Product for, in, or to the Sanctions Targets require prior authorization from OFAC. Accordingly, nothing in this Agreement, including Appendix 1: Territory shall be construed as a grant of rights under this Agreement with respect to Sanctions Targets, except as noted below. MPP shall require that MSD use commercially reasonable efforts to submit to OFAC a request for authorization for MSD to grant the rights contemplated under this under the MSD-MPP Agreement (and consequently under this Agreement) as they relate to the relevant Sanctions Targets. For the avoidance of doubt, MPP shall and shall ensure that the Licensee shall, to the extent required, comply with applicable trade and export controls.

In accordance with OFAC Iran General License N, Syria General License No. 21, and Venezuela General License No. 39 (the "**General Licenses**"), the Territory includes Iran, Syria, and Venezuela as provided for in Appendix A: Territory until June 16, 2022 (or, if the General Licenses are extended, until the applicable expiration date of the General Licenses). Any and all licenses granted for Iran, Syria, and Venezuela automatically expire as of June 16, 2022 (or, if the General Licenses are extended, as of the applicable expiration date of the General Licenses). Licensee warrants that it will ensure that (i) any rights (including intellectual property rights), Substance, Product or rights under this Agreement will be made available or supplied to Iran, Syria, or Venezuela after June 16, 2022 (or, if the General Licenses are extended, after the applicable expiration date of the General Licenses), and (ii) any supply of the Substance of the Product to Iran, Syria, or Venezuela will take place in compliance with the conditions and requirements of the General Licenses, including no involvement by any persons designated on, or owned by 50% or more by any persons designated on, OFAC's List of Specially Designated Nationals or by any military, intelligence, or law enforcement purchasers or importers.

6.4 Ethical Business Clause.

- (a) By signing this Agreement, Licensee agrees to conduct the business contemplated herein in a manner which is consistent with both law and good business ethics.
- (b) Specifically, Licensee warrants that none of the employees, agents, officers, or other members of the management of the Licensee or its Affiliates or permitted assignees/transferees are or will become during the term of this Agreement



officials, officers, agents, or representatives of any government or political party having governmental authority to make or participate in any decisions regarding the Product in the Territory. Licensee shall not make any payment or promise of payment, either directly or indirectly, of money or any other thing of value, including but not limited to any compensation derived from this Agreement (hereinafter collectively referred to as a "**Payment**"), to government or political party officials, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred to as "**Officials**") where such Payment would constitute a violation of any law. In addition, regardless of legality, Licensee shall not make any Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of the Licensee's, MPP's or MSD's business.

- (c) Licensee shall comply with, and will not cause each other and their Affiliates, associates, directors, officers, shareholders, employees, representatives, or agents worldwide to be in violation with any applicable anti-corruption regulation and notably without limiting the foregoing to any provision of the United States Foreign Corrupt Practices Act (the "**FCPA**") and U.K. Bribery Act 2010. In light of the aforementioned, Licensee shall not, directly or indirectly, pay any money to, or offer or give anything of value to, any "Government Official" as that term is used in the FCPA, in order to obtain or retain business or to secure any commercial or financial advantage for Licensee, MSD or the MPP or any of their respective Affiliates. Licensee undertakes not to bribe government officials or any private companies or individuals, bribes having the following definition: offering, promising, or giving a financial or other advantage to another person where: (i) it is intended to bring about the improper performance of a relevant function or activity, or to reward such "Improper Performance" (as that term is used in the FCPA); or (ii) acceptance of the advantage offered, promised or given in itself constitutes improper performance of a relevant function or activity.
- (d) Licensee will maintain proper and accurate books, records, and accounts which accurately and fairly reflect any and all payments made, expenses incurred and assets disposed of in connection with its performance of this Agreement, and will maintain an internal accounting controls system to ensure the proper authorization, recording and reporting of all transactions and to provide reasonable assurances that any breaches of this Section 6.4 will be prevented, detected and deterred.
- (e) Licensee further acknowledges that no employee of MSD and MPP or their respective Affiliates shall have the authority to give any direction, either written or oral, relating to any Payment by the Licensee or its agents, employees, officers, sub-contractors, sub-licensees, or Affiliates, to any Third Party in violation of this Agreement.



- (f) The Licensee represents and warrants that it respects the human rights of its staff and does not employ child labor, forced labor, unsafe working conditions, or cruel or abusive disciplinary practices in the workplace and that it does not discriminate against any workers on any ground (including race, religion, disability, gender, sexual orientation or gender identity) and aims to achieve greater equity along those lines in the workplace; and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the laws on working hours and employment rights in the countries in which it operates.
- (g) MPP may, in the event that it determines that Licensee has breached any provision of this Section 6.4, provide written notice to Licensee of its intention to terminate this Agreement, along with any evidence supporting its claim of breach ("**Breach**") to the extent that it is possible to provide. The Parties will discuss any mitigation plans to the Breach but in the event that no consensus can be reached, MPP shall have the sole right to terminate the Agreement. These measures are in addition and without prejudice to any other remedies that may be available.
- (h) In addition to all other remedies and indemnities provided for in this Agreement, the Licensee and its Affiliates shall indemnify and hold MPP and MSD and any of its Affiliates harmless from and against any and all liabilities (including all costs and reasonable attorneys' fees associated with defending against such claims) that may arise by reason of the acts or omissions of the Licensee or Third Parties acting on the Licensee's behalf which would constitute a violation of this Section 6.4.
- 6.5 EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, MPP AND MSD (IN THE MPP-MSD AGREEMENT) MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE PATENTS OR ANY LICENSE GRANTED BY MPP AND MSD (IN THE MPP-MSD AGREEMENT) HEREUNDER, OR WITH RESPECT TO THE SUBSTANCE OR THE PRODUCTS, OR ANY OTHER MATTER. FURTHERMORE, NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A WARRANTY THAT ANY PATENT OR OTHER PROPRIETARY RIGHTS INCLUDED IN THE PATENTS IS VALID OR ENFORCEABLE OR THAT THE MPP'S OR LICENSEE(S)'S USE OF THE PATENTS, SUBSTANCE OR PRODUCT AS CONTEMPLATED HEREUNDER WILL NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY. MPP AND MSD (IN THE MPP-MSD AGREEMENT) ALSO DOES NOT GIVE ANY WARRANTY, EXPRESS OR IMPLIED, WITH REGARD TO THE SAFETY OR EFFICACY OF THE SUBSTANCE OR THE PRODUCT AND IT SHALL BE THE SOLE RESPONSIBILITY OF THE LICENSEE TO ENSURE SUCH SAFETY OR EFFICACY.



7. QUALITY CONTROL, REGULATORY COMPLIANCE, LIABILITY, AND INDEMNITY

- 7.1 Licensee agrees that the Product sold by it and the processes for manufacturing, storage and handling of such Product shall strictly comply with all applicable laws, guidelines (including current good manufacturing practices), regulations, and Licensee's manufacturing standards relating to any operations involved in the manufacture, packaging, labeling, quality control, testing, receipt, storage of, warehousing, and shipping, of Product, including but not limited to regulations for protection of worker health and safety. If at any time, during the term of this Agreement, MPP is made aware of any action (including any official notifications or communications) taken by any Agency in the Territory in connection with Licensee's failure to meet the standards set forth in this Section 7.1 for the manufacture and handling of the Product, MPP shall promptly provide Licensee with a notice of the same and the Licensee shall within a period of thirty (30) days from receipt of such notice, provide MPP with a plan for remedying the same within a mutually agreed timeline. If Licensee is unable to remedy the same within the mutually agreed timeline, MPP may, after giving Licensee written notice, terminate this Agreement at its sole discretion and without prejudice to any other remedies that may be available to MPP; provided however, that in the event that Licensee has already received a prior notice of any such violation, then MPP shall have the right to terminate this Agreement immediately without any notice.
- 7.2 Neither MSD nor MPP shall not be responsible to Licensee or to any Third Party for any damages or losses resulting from Licensee's or its Affiliates' or permitted assignees/transferees' manufacture, packaging, labeling, receipt, shipping, handling, storage, use, importation, marketing, or sale of the Product or any other acts or omissions of Licensee arising out of this Agreement.
- 7.3 Licensee shall defend MPP, MSD, its Affiliates and its directors, officers, employees, and agents, and inventors of any patents and patent applications within the Patents (each and collectively a "**Indemnified Party**"), at Licensee's cost and expense, and shall indemnify and hold any Indemnified Party harmless from and against any and all liabilities, losses, costs, damages, fees, or expenses (including reasonable legal expenses and attorneys' fees incurred by a Indemnified Party) arising out of any claim, action, lawsuit or other proceeding brought against such Indemnified Party by a Third Party resulting directly or indirectly from the manufacture, packaging, labeling, receipt, shipping, handling, storage, use, importation marketing, Commercialization, or sale of Product or Substance or any other activity under this Agreement by Licensee or permitted assignees/transferees relating to: (a) any breach of this Agreement by Licensee or its Affiliates, or (b) the gross negligence, willful misconduct, or violation of applicable law by or of Licensee, its Affiliates or their respective directors, officers, employees or agents or any of them in performing under this Agreement; except, in each case, to the extent caused by the negligence, willful misconduct, violation of applicable law, or breach of this Agreement of or by MPP, MSD, its Affiliates, or any of the other Indemnified Parties. Licensee shall immediately notify MPP and MSD of any such suits and shall confer with MPP and MSD prior to the settlement of such



claims.

Furthermore, Licensee shall indemnify and hold harmless the upstream licensors of MSD, inventors of any patents and patent applications within the Patents, their Affiliates and their respective directors, officers, employees and agents, students, their heirs, executors, administrators, successors, legal representatives and agents and their respective successors and assigns (each a "**Third Party Indemnified Party**" and collectively the "**Third Party Indemnified Parties**"), from, against and in respect of any and all liabilities, losses, costs and expenses (including reasonable attorneys' and experts' fees and costs and expenses), damages, fines, penalties or amounts paid in settlement, in each case, payable to Third Parties ("**Losses**"), in each case to the extent resulting from any claim, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), arbitration or other proceedings brought or asserted by any Third Party (including any regulatory agencies) against a Party (or any other Third Party Indemnified Party) and to the extent such Losses are incurred or suffered by the Third Party Indemnified Parties or any of them as a result of, arising out of or directly or indirectly relating to: (a) any breach of this Agreement by Licensee or its Affiliates, or (b) the gross negligence, wilful misconduct or violation of applicable laws by or of Licensee, its Affiliates or their respective directors, officers, employees or agents or any of them in performing under this Agreement; except, in each case, to the extent caused by the negligence, wilful misconduct, violation of applicable or breach of this Agreement of or by either of the Third Party Indemnified Parties.

Licensee shall immediately notify MPP and MSD of any such suits and shall confer with MPP and MSD prior to the settlement of such claims.

- 7.4 Notwithstanding anything expressed or implied to the contrary in this clause, the amount of any losses subject to indemnification shall be reduced by the amount of any insurance proceeds received by the indemnified Party with respect to such Losses; and there shall be no obligation under this Agreement to indemnify such indemnified Party for the amount of losses so reduced.
- 7.5 NOTWITHSTANDING ANY PROVISION IN THIS AGREEMENT TO THE CONTRARY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OR LOST OR IMPUTED PROFITS OR ROYALTIES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION.

8. INSURANCE

- 8.1 Licensee, at its sole cost and expense, shall insure its activities in connection with this Agreement and obtain, keep in force, and maintain comprehensive or commercial form general liability insurance (contractual liability included) with limits as follows:
- (a) Each occurrence \$500,000



- (b) Products/completed operations aggregate \$1,000,000
- (c) Personal and advertising injury \$500,000
- (d) General aggregate (commercial form only) \$1,000,000

8.2 Notwithstanding the foregoing, no later than sixty (60) days before the first use of any Product in or on a human, Licensee, at its sole cost and expense, shall insure its activities in connection with the work under this Agreement and obtain, keep in force, and maintain comprehensive or commercial form general liability insurance (contractual liability included) with limits as follows:

- (a) Each occurrence \$10,000,000
- (b) Products/completed operations aggregate \$10,000,000
- (c) Personal and advertising injury \$1,000,000
- (d) General aggregate (commercial form only) \$5,000,000

8.3 Notwithstanding the foregoing, no later than sixty (60) days before the anticipated date of market introduction of any Product, Licensee, at its sole cost and expense, shall insure its activities in connection with the work under this Agreement and obtain, keep in force, and maintain comprehensive or commercial form general liability insurance (contractual liability included) with limits as follows:

- (a) Each occurrence \$10,000,000
- (b) Products/completed operations aggregate \$50,000,000
- (c) Personal and advertising injury \$5,000,000
- (d) General aggregate (commercial form only) \$10,000,000

8.4 If the above insurance is written on a claims-made form, it shall continue for three (3) years following termination or expiration of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the Effective Date of this Agreement.

8.5 The coverage and limits referred to in Sections 8.1 to 8.3 above will not in any way limit the liability of Licensee under this Agreement. Upon the execution of this Agreement, subsequently at the time of each of the further triggers stated above requiring increased coverage, Licensee will furnish MPP with certificates of insurance evidencing compliance with all requirements herein. Licensee will promptly notify MPP of any material modification of the insurance coverages or cancellation notice it receives of any such insurance policies.

8.6 All insurance coverage required under this Agreement shall be primary to any coverage carried by MSD or MPP. MSD, the MPP and their respective Affiliates, and their respective directors, officers, agents, and employees will be named as loss payees under such commercial general liability and product liability insurance. Upon request by MPP or MSD, Licensee shall provide to MSD and MPP evidence of its insurance coverage.

9. STATEMENTS, REPORTING AND RIGHT TO AUDIT



- 9.1 Licensee will keep full, true, and accurate books and records containing all particulars that may be necessary for the purpose of showing the amount of royalties payable to MSD and Licensee's compliance with other obligations under this Agreement and applicable laws. Said books and records will be kept at Licensee's principal place of business or the principal place of business of the appropriate division of Licensee to which this Agreement relates. Said books and records and the supporting data will be open at all reasonable times during normal business hours upon at least fifteen (15) days' advance written notice, for three (3) years following the end of the calendar year to which they pertain, to the inspection and audit (on site if Licensee so requests) by independent certified public accountants hired by MSD and MPP, individually or together and reasonably acceptable to Licensee for the purpose of verifying Licensee's royalty reports or compliance in other respects with this Agreement and applicable laws. Such certified public accountants will be bound to hold all information in confidence except as necessary to communicate Licensee's non-compliance with this Agreement to MSD and/or MPP.

The fees and expenses of the certified public accountants performing such an examination will be borne by MSD and/or MPP. However, if an error in underpaid royalties to MSD of more than five percent (5%) of the total royalties due for any year is discovered, then the fees and expenses of these representatives will be borne by Licensee.

- 9.2 After the first sale anywhere in the Territory, within 20 Business Days following the end of each Agreement Quarter, the Licensee shall deliver to MPP a statement accounting for, *inter alia*, all royalties calculations, Products and/or Substance (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under this Agreement during such Agreement Quarter in the Reporting Template as set forth in Appendix 3. MPP agrees that information contained in quarterly and other such reports shall be treated as Confidential Information, provided, however, that such information may be shared with MSD (with MSD treating such reports as Confidential Information); and that aggregated data may be publicly disclosed by MPP.

10. TERM AND TERMINATION

- 10.1 Term. Unless otherwise terminated by the operation of law or by acts of the parties in accordance with the terms of this Agreement, this Agreement will be in force from the Effective Date and will remain in effect until expiration of all of Licensee's obligations to pay royalties to MSD pursuant to Article 5A.
- 10.2 Termination for Breach. A Party ("**non-breaching party**") shall have the right to terminate this Agreement in the event the other Party ("**breaching party**") is in material breach of any of its material obligations under this Agreement. The non-breaching party shall provide written notice to the breaching party. The breaching party shall have a period of 30-days after such written notice is provided to cure such



breach, or to provide a timeline to cure such breach to the satisfaction of the non-breaching party. If such breach is not cured within the 30-day period or in accordance with the timeline, the non-breaching party shall have the right to terminate this Agreement immediately in the sole discretion. Any termination pursuant to this Section 10.2 will not (1) relieve either Party of any obligation or liability accrued; (2) impair any accrued rights of either Party (3) or rescind anything done by either Party hereunder prior to the time of such termination becoming effective. In the case where the breaching party is Licensee, such termination shall not relieve Licensee of its obligation to pay any royalty or other fees owing at the time of such termination.

10.3 MPP Right to Terminate. MPP shall have the right to terminate this Agreement, either in whole or in relation to a particular Patent, with immediate effect by notice in writing to Licensee if:

- (a) Licensee breaches any of the anti-diversion provisions of Section 4;
- (b) MPP becomes aware of any action (including any official notifications or communications) taken by any regulatory authority involving a determination of Licensee's failure to comply with good manufacturing practices as prescribed in the applicable legal or regulatory standards in connection with for the manufacture and handling of the Products, or otherwise reasonably determines that, due to material deficiencies in Licensee's compliance, or repeated failure to comply, with the quality requirements of Section 3.2, Licensee is unable to reliably and consistently manufacture Substance or Product in accordance with such quality requirements;
- (c) Licensee fails to comply with the obligations contained in Section 3.3 of this Agreement;
- (d) Licensee repeatedly fails to comply with or to timely provide MPP with the reports contemplated under Sections 3.4 and 9.2 of this Agreement; or
- (e) Licensee fails to file for WHO Pre-Qualification of the Product within six months of a WHO Expression of Interest for the Product or such other time as may be mutually agreed between the Parties.
- (f) The legal or beneficial ownership of Licensee or any of its Affiliates changes in such a manner as MPP after consulting with Licensee reasonably determines to be significant and adversely impacts the ability of the Parties to achieve the objectives of this Agreement.
- (g) if Licensee, its subsidiaries or Affiliates challenges the validity, enforceability or scope of any claim within the Patent in a court or other governmental agency of competent jurisdiction, including in a re-examination or opposition proceeding, or as a defense to enforcement of this Agreement or the terms of this Agreement, including applicable payment obligations. The Parties understand that this right of termination is required pursuant to MSD's upstream contractual



obligations. To the extent that this Section 10.3(g) is deemed invalid or unenforceable in any jurisdiction, this Section 10.3(g) is intended to be severable without affecting the validity of the rest of this Agreement.

- 10.4 Failure to Promote Access. If, in the reasonable opinion of the MPP, the Licensee fails to promote access or appears in MPP's reasonable opinion, will fail to promote access to the Products in the Territory in accordance with this Agreement, the MPP shall give notice to the Licensee requiring it to cure such failure. If, in the reasonable opinion of the MPP, the Licensee fails to present an acceptable plan within 60 days and report reasonable progress within 180 days after receiving written notice with respect to the default, the MPP shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee. In making such determination of reasonable progress, the MPP shall take into account the period within which the relevant authorities provide the necessary approvals and normal development lead time for the Products, and progress reported by Licensee in its quarterly reports and meetings provided under Section 3.4 of this Agreement.
- 10.5 Misrepresentations in Expression of Interest. Licensee acknowledges that it was offered to enter into this Agreement on the basis of certain representations and projections that it made through MPP's Expression of Interest system. In the event that MPP discovers any material misrepresentations made therein, or if Licensee fails to substantially meet its projections, MPP shall have the right, upon 30 days' notice, to terminate this Agreement.
- 10.6 Conversion to Direct Licence with MSD. Subject always to the termination provisions of the MSD-MPP Agreement, in the event that the MSD-MPP Agreement is terminated prior to its Term, this Agreement shall be converted into a direct licence between MSD and Licensee, provided that Licensee is not in breach of this Agreement.
- 10.7 Termination by Licensee. Licensee may terminate this Agreement at any time by providing 30 days written notice to MPP. Any termination pursuant to this Section 10.7 by the Licensee will not relieve Licensee of any obligation or liability accrued hereunder prior to such termination or rescind anything done by Licensee or any payments made to MSD hereunder prior to the time such termination becomes effective, and such termination will not affect in any manner any rights of MPP arising under this Agreement prior to such termination.
- 10.8 Insolvency. Either Party may terminate this Agreement in the event that the other Party becomes insolvent, makes an assignment to the benefit of creditors, or has a petition in bankruptcy filed for or against it.
- 10.9 Waiver. No waiver by any Party in one or more instances of any of the provisions of this Agreement or the breach thereof shall establish a precedent for any other instance with respect to the same or any other provision. Furthermore, in case of waiver of a particular provision, all other provisions of this Agreement shall continue in full force and effect.



10.10 Rights on Termination. Any termination of this Agreement will not relieve Licensee of its obligations to pay any monies due or owing at the time of such termination and will not relieve any obligations, of either to the other Party, established prior to termination.

10.11 Survival. Sections 3A, 7.3, 8, 10.5, 11, and 12 shall survive termination or expiry of this Agreement.

11. EXCHANGE OF INFORMATION, CONFIDENTIALITY AND PUBLICATIONS

11.1 Licensee may conduct studies or basic research or pre-clinical, clinical, or other trials with the Substance and/or the Product, provided that Licensee has obtained MSD's prior written consent through MPP, which may be withheld at MSD's sole discretion. A response by MSD should be provided within 90 business days after receiving the suggested study protocol from the Licensee. In the event MSD approves any such studies or trials in accordance with this Section 11, then, at the option of MSD, MSD may have its representative monitor any approved studies or trials.

11.2 In the event that any such studies or trials have been approved by MSD, Licensee will pay for any necessary supplies and, upon completion of such studies or trials, Licensee shall furnish free of charge to MSD and its Affiliates in the English language all data and information, especially any adverse drug experiences, derived from any such studies, pre-clinical or clinical trials carried out by Licensee relating to the Product, in such detail and at such times as MSD may reasonably request for non-commercial and internal use and disclosure to any Third Party in compliance with the contractual obligations of MSD and its Affiliates. Any such Affiliates which are recipients of such information pursuant to the foregoing shall be under the same obligation of confidentiality as set forth in this Section. If MSD and its Affiliates want to use the data and information for any other purpose, the Licensee and MSD shall negotiate in good faith.

11.3 Each Party hereto agrees to keep secret and confidential any and all business information, Know-How, quarterly reports, technology, or any other confidential information disclosed by one Party ("**Confidential Information**") to the other Party pursuant to this Agreement (including any discussions or correspondence relating to the preparation of this Agreement), and not to disclose such information to any Third Party other than to (i) MSD in order to comply with the MSD-MPP Agreement; and (ii) any Agency as may be required by applicable law or regulations. For the avoidance of doubt, MSD shall have the right to such Confidential Information and wherever MSD has a contractual obligation towards a Third Party to disclose information regarding the Product or Substance, MSD may disclose Confidential Information to that Third Party under obligations of confidentiality no less stringent than contained herein. The obligations imposed by this Section 11.3 shall not apply to any information:



- (a) which, at the time of disclosure, is in the public domain; or
- (b) which, after disclosure, becomes part of the public domain by publication or otherwise, through no fault of the receiving Party; or
- (c) which, at the time of disclosure, is already in the receiving Party's possession from a source owing no obligation of confidentiality to the disclosing Party, and such possession can be properly demonstrated by the receiving Party; or
- (d) which is rightfully made available to the receiving party from sources independent of the disclosing Party; or
- (e) which is developed independently without the use or reference to the information received from the receiving Party and without making reference to Substance and/or Product.

11.4 Licensee will keep MSD Know-How confidential subject to Section 11.3 above.

11.5 Within 30 days after any expiration or termination of this Agreement, either Party shall destroy (and certify to the other Party such destruction) or return all Confidential Information provided by the other Party except as otherwise set forth in this Agreement. One copy of the other Party's Confidential Information may be retained solely for archival purposes as a means of determining any continuing or surviving obligations under this Agreement.

11.6 The obligations of confidentiality set forth in this Section 11 shall survive for a period of 10 years after the expiration, cancellation, or other termination of this Agreement.

11.7 Subject always to MPP's obligations under the MSD-MPP Agreement, MPP and Licensee agree that no public release or announcement concerning the Agreement shall be issued without the prior written consent of MPP and to the extent applicable, MSD, except if such release or announcement may be required by law (including without limitation information to any Agency), in which case the Licensee shall allow MSD reasonable time to comment on such release or announcement in advance of such issuance.

11.8 Save as otherwise provided in this Agreement, the Parties agree that MSD shall not be required to provide any technical support or technical assistance to Licensee for any reason. MSD and its Affiliates make no representations that Licensee or its Affiliates will be able to obtain or maintain marketing authorizations, licenses, permits, or registration for the Product in the Territory or that the Licensee will be able to manufacture the Product.

12. MISCELLANEOUS

12.1 Third Party Beneficiary. The Parties hereto acknowledge that MSD and Drug



Innovation Ventures At EMORY, a fully-owned subsidiary of EMORY University ("DRIVE"), an upstream licensor of MSD are intended to be and constitute a third party beneficiary of the representation, warranties, covenants, and agreements of Licensee, and MSD and DRIVE are entitled to enforce the terms and provisions of this Agreement on its own behalf to the same extent as MPP.

12.2 Agency. Neither Party is, nor will be deemed to be, an employee, agent or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party shall have the authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

12.3 Entire Understanding. This Agreement embodies the entire understanding of the Parties with respect to the subject matter hereof and supersedes all previous communications, representations or understandings, and agreements, whether oral or written, between the Parties relating to the subject matter hereof.

12.4 Severability. The Parties hereby expressly state that it is not their intention to violate any applicable rule, law, or regulation. If any of the provisions of this Agreement are held to be void or unenforceable with regard to any particular country by a court of competent jurisdiction, then, to the extent possible, such void or unenforceable provision shall be replaced by a valid and enforceable provision which will achieve as far as possible the economic business intentions of the Parties. The provisions held to be void or unenforceable shall remain, however, in full force and effect with regard to all other countries. All other provisions of this Agreement shall remain in full force and effect.

12.5 Notices

- (a) Any legal notice or other communication to be given under this Agreement, unless otherwise specified, shall be in writing and shall be deemed to have been provided when delivered to the addressee at the address listed below (i) on the date of delivery if delivered in person or email (receipt confirmed) or (ii) three days after mailing by registered or certified mail, postage paid:

In the case of MPP:

Medicines Patent Pool
Rue de Varembe 7
Geneva 1202
Switzerland
Attention: General Counsel
E-mail: legal@medicinespatentpool.org

In the case of Licensee:



BDR Pharmaceuticals Intl' Pvt Ltd.
6, Engineering Center, 9 Mathew Road,
Opera House, Mumbai -400004
Attention: Mr. Dheer Shah
E-mail: dheershah@gmail.com

- (b) Any Party may change its address for communications by a notice in writing to the other Party in accordance with this Section.

12.6 Language; Governing Law. This Agreement is entered into and will be governed by and construed in accordance with the English language. This Agreement is made in accordance with and shall be governed and construed under the laws of New York, without regard to its choice of law principles.

12.7 Dispute Resolution.

- (a) The Parties agree that in the event of a dispute they shall first attempt in good faith to resolve such dispute. In the even that such dispute is not resolved on an informal basis, either Party may refer the dispute to the Executive Director of the MPP, and to Director mentioned under caluse 12.5 (a) of the Licensee (together, the Designated Officers). If such dispute is not resolved by the Designated Officers within 30 days, the Parties shall submit such dispute to mediation in accordance with the WIPO Mediation Rules. In the event that the dispute remains outstanding after 60 days from the date when it was first discussed (in any manner) between the Parties, either Party may commence court proceedings. The foregoing however shall not prevent any person from seeking and obtaining injunctive relief at any time.
- (b) Subject to paragraph (a) of this Section, the New York courts have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement (including a dispute relating to any non-contractual obligations arising out of or in connection with this Agreement) and the Parties submit to the exclusive jurisdiction of the New York courts.
- (c) Without prejudice to the foregoing, nothing in this Agreement shall prevent or restrict MPP or MSD from electing to bring proceedings in relation to patent infringement or from applying for injunctive relief in any country outside the United States, to which election MPP and the Licensee hereby agrees.

12.8 Assignment. Neither Party is entitled to transfer or assign this Agreement or the rights and obligations under this Agreement without the other Party's prior written consent except that MSD shall have the right, to the extent possible, assign, or transfer the benefits, rights and obligations under this Agreement or any part thereof to an Affiliate without consent subject to Section 12.1 of this Agreement.

12.9 Amendment. No amendment or modification hereof shall be valid or binding upon the



Parties unless made in writing and signed by all of the Parties.

- 12.10 Entire Agreement. This Agreement contains the entire agreement between the Parties hereto in respect of the subject matter hereof, and supersedes and cancels all previous agreements, negotiations, commitments, and writings in respect of the subject matter hereof, except that any previous confidentiality agreements shall remain in full force and effect. This Agreement may not be changed or modified in any manner, or released, discharged, abandoned, or otherwise terminated orally or otherwise, unless in writing and signed by the duly authorized officers or representatives of the Parties.
- 12.11 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument. Signature pages of this Agreement may be exchanged by facsimile, pdf, or through DocuSign, and that any such e-signature shall be given the same legal force and effect as the physical delivery of this Agreement, bearing original handwritten signatures without affecting the validity thereof.

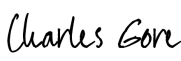
[signatures appear on following page]



IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the Effective Date.

MEDICINES PATENT POOL:

Medicines Patent Pool

DocuSigned by:

By 4713D0E59C13482
Name: Charles Gore
Title: Executive Director

LICENSEE:

BDR Pharmaceuticals Intl' Pvt Ltd

By 

Name: Mr. Dheer Shah
Title: Director (Finance)



Appendix 1 - Countries in the Territory

LIC : Low Income Country
 LDC : Least Developed Country (UN Classification)
 SSA : Sub-Saharan Africa
 LMIC : Lower Middle-Income Country
 UMIC : Upper Middle-Income Country

LIC+LDC+SSA		
#	Country	Channels in scope of Agreement
1	Afghanistan	All
2	Angola	All
3	Bangladesh	All
4	Benin	All
5	Bhutan	All
6	Botswana	All
7	Burkina Faso	All
8	Burundi	All
9	Cabo Verde	All
10	Cambodia	All
11	Cameroun	All
12	Central African Republic	All
13	Chad	All
14	Comoros	All
15	Congo, Dem Rep.	All
16	Congo, Rep.	All
17	Côte d'Ivoire	All
18	Djibouti	All
19	Equatorial Guinea	All
20	Eritrea	All
21	Eswatini	All
22	Ethiopia	All
23	Gabon	All
24	Gambia, The	All
25	Ghana	All
26	Guinea	All
27	Guinea-Bissau	All
28	Haiti	All
29	Kenya	All
30	Kiribati	All
31	Korea, Dem. People's Rep.	All
32	Lao PDR	All
33	Lesotho	All
34	Liberia	All
35	Madagascar	All
36	Malawi	All
37	Mali	All
38	Mauritania	All
39	Mauritius	All
40	Mozambique	All
41	Myanmar	All
42	Namibia	All



43	Nepal	All
44	Niger	All
45	Nigeria	All
46	Rwanda	All
47	São Tomé and Príncipe	All
48	Senegal	All
49	Seychelles	All
50	Sierra Leone	All
51	Solomon Islands	All
52	Somalia	All
53	South Africa	Public Sector Only
54	South Sudan	All
55	Sudan	All
56	Syrian Arab Republic	All
57	Tajikistan	All
58	Tanzania	All
59	Timor-Leste	All
60	Togo	All
61	Tuvalu	All
62	Uganda	All
63	Vanuatu	All
64	Yemen, Rep.	All
65	Zambia	All
66	Zimbabwe	All

LMIC (Ex-SSA)

#	Country	Channels in scope of Agreement
67	Algeria	All
68	Bolivia	All
69	Egypt, Arab Rep	All
70	El Salvador	All
71	Honduras	All
72	India	All
73	Micronesia, Federated States	All
74	Moldova	All
75	Mongolia	All
76	Morocco	All
77	Nicaragua	All
78	Pakistan	All
79	Papua New Guinea	All
80	Philippines	All
81	Sri Lanka	All
82	Tunisia	All
83	Uzbekistan	All
84	Vietnam	All



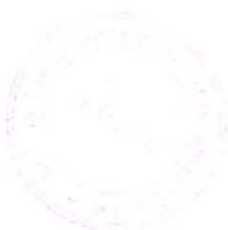
UMIC (Ex-SSA, ex-LDC)		
#	Country	Channels in scope of Agreement
85	Belize	All
86	Cuba	All
87	Dominica	All
88	Fiji	All
89	Grenada	All
90	Guatemala	All
91	Guyana	All
92	Indonesia	All
93	Iran, Islamic Rep	All
94	Iraq	All
95	Jamaica	All
96	Libya	All
97	Maldives	All
98	Marshall Islands	All
99	Paraguay	All
100	Samoa	All
101	St. Lucia	All
102	St. Vincent and the Grenadines	All
103	Suriname	All
104	Tonga	All
105	Venezuela, RB	All



Appendix 2

Patents

Patents and Patent Applications				
Ref.	Country	Application No.	Int'l Filing Date	Title
A	Australia	2015370004	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	Australia	2021203840	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	Brazil	BR1120170138581	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	Brazil	BR1220210157006	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	Canada	2,972,259	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	China	201580076718.1	Dec. 16, 2015	N4-Hydroxycytidine And Derivative And Relative Anti-Viral Uses
A	Eurasian Patent Office	201791460	Dec. 16, 2015	N4-Hydroxycytidine And Related Derivatives And Options For Anti-Virus Application
A	European Patent Office	15874145.4	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	European Patent Office	21178364.2	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	India	201717025098	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	Israel	279663	Jun. 19, 2017	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	Israel	252997	Jun. 19, 2017	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	Japan	2017-534192	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Related Antiviral Applications
A	Singapore	10202105371Y	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	South Africa	2017/04291	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	South Korea	10-2017-7020692	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	US	16/921,359	Jul. 6, 2020	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	US	15/537,087	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
A	WO	PCT/US2015/066144	Dec. 16, 2015	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Australia	2018378832	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Australia	2021206866	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Brazil	BR1120200105813	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Brazil	BR 12 2021 0126275	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Canada	3,082,191	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto



Patents and Patent Applications				
Ref.	Country	Application No.	Int'l Filing Date	Title
B	China	201880073278.8	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Eurasian Patent Office	202091005	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	European Patent Office	18886104.1	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Hong Kong	62021026723.8	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Hong Kong	62021026557.0	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	India	202017019418	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Indonesia	P00202003494	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Israel	274155	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Israel	284100	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Japan	2020-524817	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Japan	2020-195927	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Mexico	MX/a/2020/005392	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Philippines	1-2020-550607	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Russian Federation	2020116571	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Saudi Arabia	520412305	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	Singapore	11202004403Q	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	South Africa	2020/02849	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	South Korea	10-2021-7012910	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	South Korea	10-2020-7014737	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	United Kingdom	GB2020498.8	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	United Kingdom	GB2008628.6	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	US	16/755,779	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	US	17/170,172	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
B	WO	PCT/US2018/064503	Dec. 7, 2018	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
C	Argentina	P210100320	Feb. 8, 2021	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
C	Jamaica		Feb. 9, 2021	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
C	Lebanon			N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
C	Pakistan	115/2021	Feb. 8, 2021	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto



Patents and Patent Applications				
Ref.	Country	Application No.	Int'l Filing Date	Title
C	Taiwan	110104831	Feb. 8, 2021	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
C	US	17/170172	Feb. 8, 2021	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
C	Venezuela	2021-000027	Feb. 8, 2021	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
C	WO	PCT/US2021/016984	Feb. 7, 2021	N4-Hydroxycytidine And Derivatives And Anti-Viral Uses Related Thereto
D	WO	PCT/US2021/048054	Aug. 27, 2021	Novel Forms Of Antiviral Nucleosides



Appendix 3

Quarterly Reporting Template

Each Reporting Template shall include the following but may be subject to change from time to time:

Reporting Template for Royalties

Country	Local Currency (LC)	Customer	Gross revenue from sale of Products (in LC)	Allowable Deductions (in LC)	Net Sales pursuant to Section 1.16 of the License Agreement, itemized detail of details against gross sales to compute net sales (LC)	Exchange Rate (USD per LC)	Net Sales pursuant to Section 1.16 of the License Agreement, itemized detail of details against gross sales to compute net sales (LC)	Royalty Rate	Total Royalties due to MSD
E.g. India	INR	Gov. Entities/Public Purchasers	80,000,000	5,000,000	75,000,000	0.0133	1,000,000	5%	50,000
	INR	Commercial Entities	20,000,000	1,000,000	19,000,000	0.0133	253,333.33	10%	25,333.33



Reporting Template for Products

Country	Product manufactured and sold	Strength	Formulation (Tablet/granules /liquid/powder for suspension)	Pack Size	Quantity (number of packs)	Total Value in USD (FOB)*	Country of Origin

* Please mention FOB (Free on Board) price basis country of origin

Note: this format is to be filled and sent to MPP on a quarterly basis, 10 Business days from end of each calendar quarter.

Reporting Template for Substances

Month	Country	Purchaser	Product	Quantity (kg)	Total Value (USD)

