

ANNOTATED DISTRIBUTION AND LICENSE AGREEMENT (VACCINES)¹

Section	Annotation
<p>This Distribution and License Agreement is entered into at the date of countersignature (the “Effective Date”) by and between [<i>insert company name, address and registration number (if applicable)</i>] (“Company”) and [<i>insert distributor name, address and registration number (if applicable)</i>] (“Distributor”). [*]</p>	<p>[*] Consider whether certain affiliates should be included within the definition of “Company” or “Distributor”</p>
<p style="text-align: center;">RECITALS</p> <p>WHEREAS, the Company has developed a prophylactic vaccine indicated for protection against [<i>insert indication/pathogen name, (the “Indication”)</i>] that is the subject of BB-IND # [<i>insert applicable number</i>] filed with the U.S. Food and Drug Administration on [<i>insert date</i>]; [*]</p> <p>WHEREAS, the Company intends to market and sell the Product to Governments other than the United States Government and to Non-Governmental Organizations;</p> <p>WHEREAS, the Distributor has developed an international sales force to market and make sales to Governments and Non-Government Organizations; and</p> <p>WHEREAS, the Distributor and Company acknowledge that the Product (as hereinafter defined) is not licensed in the Territory. Therefore, due to regulatory and liability reasons, the Product shall not be distributed in the private market under this Agreement. [*]</p> <p>NOW, THEREFORE, in consideration of the mutual agreements herein set forth and other valuable consideration, the Parties agree as follows:</p>	<p>[*] Useful to have more detailed information in the recitals in certain situations, including if you are dealing with clients that have many similar deals within an industry. Here, we have a description of the indication along with the relevant application number.</p> <p>[*] Another reason to have detailed recitals is if the transaction is complicated or somewhat atypical in order to give the reader an overview of key points.</p>
<p style="text-align: center;">ARTICLE 1</p> <p style="text-align: center;"><u>DEFINITIONS</u></p> <p>In this Agreement, the terms not already defined herein above shall have the following</p>	<p>[1] Having all defined terms listed in the main Definitions section can make lengthy agreements more accessible.</p>

¹ Note that because this is based on a real, negotiated agreement, certain provisions are not optimally drafted as pro-company or pro-distributor. The annotations point out certain of these provisions, but caution is advised if using this as a model.

meanings:

1.1 “**AE**” shall have the definition given in Section 9.1.

1.2 “**Agreement**” means this agreement, including all schedules, appendices, and attachments and amendments agreed to in writing by the Parties.

1.3 “**Affiliate**” means any company, partnership or other legal entity or person which directly or indirectly controls, is controlled by or is under common control with a Party.

1.4 “**Anti-Corruption Laws**” shall have the definition given in Section 2.1(j).

1.5 “**Company**” shall have the definition given in the Preamble.

1.6 “**Control**” means the ownership of more than 50% of the issued share capital or the legal power to direct or cause the direction of the Board or general management and policies of the entity in question.

1.7 “**Customer**” means any Governmental Authority (military or civilian) other than the United States Government, any third party acting on behalf of a Governmental Authority other than the United States Government, or a Non-Government Organization (NGO). Customer does not include a private individual, doctor, hospital, or physician supply house. The United States Government is not a Customer, whether purchasing the Product for its own use or for transfer to a third party.

1.8 “**Distributor**” shall have the definition given in the Preamble.

1.9 “**Effective Date**” shall have the definition given in the Preamble.

1.10 “**Embargoed Countries**” shall have the definition given in Section 2.1(i).

1.11 “**Excessive Orders**” shall have the definition given in Section 3.1(e).

1.12 “**FDA**” means the United States Food and Drug Administration and any successor agency

[1.7] Important to clearly define important concepts. Vagueness and ambiguity around important concepts are not helpful to either party.

thereto.

1.13 “**Forecasts**” shall have the definition given in Section 3.1(a).

1.14 “**Government**” means (a) any government of any country or territory, (b) any nation, state, province, county, city or other political subdivision thereof or (c) any supranational body.

1.15 “**Governmental Authority**” means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of a Government.

1.16 “**Indication**” shall have the definition given in the Recitals.

1.17 “**Marketing Authorizations**” means any and all authorizations required from any Regulatory Authority to officially market, distribute, or sell the Product.

1.18 “**Neglected Country**” shall have the definition set forth in Section 2.1(i).

1.19 “**Non-Government Organization**” means an organization which is independent from the state and is self-governing, non-profit/not-for-profit and established voluntarily by citizens or by legal entities other than State agencies (*i.e.*, organizations that exercise legislative, executive, and/or judicial powers) on the basis of their individual or social interests and opinions and are associated with organizations such as the United Nations. Examples of Non-Government Organizations are the World Health Organization and the Pan American Health Organization.

1.20 “**Orders**” shall have the definition given in Section 3.1(c).

1.21 “**Party**” means Company or Distributor, and “**Parties**” means Company and Distributor.

1.22 “**Product**” means the vaccine manufactured and tested as described in BB-IND [# ___], as amended from time to time.

1.23 “**Proprietary Information**” shall have

<p>the definition set forth in Section 11.1.</p> <p>1.24 “Regulatory Authority” means any authority having jurisdiction to regulate the manufacture, sale, or distribution of the Product.</p> <p>1.25 “Seller” means the Party that sells the Product to a Customer. For sales of Product for delivery to Customers within the Territory, the Seller shall be the Distributor or one of its affiliated companies or subsidiaries. For sales of Product for delivery to Customers outside the Territory, the Seller shall be the Company or its designated agent(s).</p> <p>1.26 “Term” shall have the definition given in Section 12.1.</p> <p>1.27 “Territory,” as such term relates to sales to a government authority (military or civilian) or any third party acting on behalf of a government authority, means all countries worldwide, excluding the United States (and its territorial possessions) and the United Kingdom. “Territory”, as such term relates to sales to Non-Government Organizations, shall mean all countries throughout the world.</p>	
<p style="text-align: center;">ARTICLE 2</p> <p style="text-align: center;"><u>DISTRIBUTORSHIP</u></p> <p>2.1 <u>Grant of Distributor Rights in the Territory.</u></p> <p>(a) Subject to the terms and conditions of this Agreement, during the Term, the Company hereby appoints the Distributor as the Company's exclusive distributor in the Territory for the sole purposes of marketing, promoting, soliciting customers for, distributing, and selling (or otherwise disposing of) the Product to Customers for delivery in the Territory, and the Distributor accepts such appointment. The Distributor may not assign or otherwise transfer its distributorship rights, with the exception as to affiliated companies or subsidiaries. The Distributor shall not actively sell or distribute the Product to any entity other than Customers within the Territory. The Parties may however agree on a case-by-case basis that the Distributor uses a local distributor if required by local law, regulations, or</p>	<p>[2.1] The usual reason for entering into a distribution agreement is that the distributor has a better sales force or relationships in the territory than the supplier, so it is more efficient for the supplier to sell through the distributor even if the supplier has its own sales and marketing staff.</p> <p>[2.1(a)] This section includes standard language giving the Distributor relevant rights in the Territory and prohibiting the Distributor from distributing outside the Territory.</p>

<p>Government request.</p> <p>(b) The Distributor shall not, during the Term, appoint any other person, firm, company or other entity as (i) its distributor for the marketing, promotion, or sale of the Product to Customers in the Territory; (ii) its distributor for the solicitation of Customers for the Product to be delivered in the Territory; or (iii) agent or reseller of the Product to Customers in the Territory.</p> <p>(c) The Company shall not, during the Term, market, promote or solicit Customers for, or actively sell or distribute, the Product outside the Territory without the prior written consent of the Distributor (such consent not to be unreasonably withheld or delayed). However, this provision does not restrict the Company from selling the Product outside the Territory to persons who are located within the European Union, who are not solicited by the Company and who approach the Company on their own initiative.</p> <p>(d) The Distributor shall coordinate each potential Customer order with the Company. Prior to signing any agreement or contract for the sale of a Product, the Distributor shall inform the Company (in writing and in English) of the material features of such agreement or contract, including but not limited to: Customer name, price for the Product, whether the Customer is providing indemnity and the terms of such indemnity, payment terms, which Product is being ordered, the Company's proposed manufacturing and delivery schedule, contractual consequences of delivery delays, potential Marketing Authorization requirements that are indispensable to the Customer, any regulatory requirements of the Customer or the competent Regulatory Authority(ies) and any special labeling requirements.</p> <p>(e) Each Customer order must be approved by the Company prior to the Distributor, its affiliated companies or its subsidiaries signing any agreement or contract for the sale of Product, such approval not to be unreasonably withheld and shall be compliant with applicable laws and regulations. The Company agrees to actively cooperate with the Distributor and to use all commercially reasonable efforts to pursue with such approval.</p> <p>(f) [The Distributor shall inform</p>	<p>[2.1(b)] Distributor's rights are further circumscribed by prohibiting "sub-distributors" other than affiliates/subsidiaries.</p> <p>[2.1(c)] Whether arrangement like this is appropriate will depend on the business case.</p> <p>[2.1(d)] It is important for the Company to have detailed information because of the industry. In less heavily regulated industry, the Distributor would likely have fewer or possibly no obligation to report this level of detail for Customers.</p> <p>[2.1(f)] The specific circumstances of this agreement call for this language.</p>
--	--

each Customer in the Territory that the Product:
(i) prior to licensure, is intended for emergency use only and is not a licensed product in the Territory; and
(ii) until such time that the Product receives licensure from the FDA, is not licensed in the United States.]

(g) [The Company has provided the Distributor with a recommendation with regard to Customer prices for the Product in the Territory, which is attached to this Agreement as Attachment A (the price recommendations in Attachment A reflect the prices for Customers providing Attachment B indemnity). The Distributor shall, however, not be obliged to follow such recommendations.]

(h) The Distributor shall not make or give any promises, warranties, guarantees or representations concerning the Product other than those contained in BB-IND #[] and/or in the Company's product literature and shall provide the Customer with a detailed outline description of the qualities and specifications of the Product. The Distributor shall market the Product only for the Indication [authorized] by the FDA and, if applicable, only for those Indications as authorized by the competent Regulatory Authority(ies) in the Territory. The Distributor shall market the Company's vaccine as the Company's and not represent or otherwise give the appearance to a Customer that the Company's Product is the Distributor's Product.

(i) If the Company believes that the Distributor is not using all reasonable efforts to market and promote the Product in a country of the Territory or is not otherwise complying with its obligations under this Agreement in a country in the Territory (the "**Neglected Country**"), the Company may provide written notice thereof to the Distributor, specifying the basis of its belief and any additional commercial activities the Distributor should reasonably undertake. Within thirty (30) days of such notification, the Parties shall meet and discuss in good faith the steps the Distributor is taking to market and promote the Product and any such additional activities the Distributor should commercially reasonably undertake. In the event that the Parties are unable to agree on such additional activities or if the Distributor does not undertake agreed upon remedial steps to remedy any default within 60 days of notice, the Company may terminate the assignment of the Distributor being the exclusive distributor as set forth

[2.1(g)] Optional if there is a strong reason for giving price guidance.

[2.1(h)] Heavily regulated industry, and regulations control what can or cannot be said about the product, so important to have Distributor covenants to this effect.

[2.1(i)] Diligence requirement of some sort for Distributor is standard. Here, Company can terminate country-by-country for diligence failure. If there are specific diligence requirements, it's important to have strong reporting obligations in the agreement to allow Company to track diligence.

in Section 2.1(a) of this Agreement in the Neglected Country and such Country shall be excluded from the Territory.

(j) The Distributor shall not promote, make sales or otherwise engage in negotiations related to the Product (i) to any country that is subject to an embargo by the U.S. Government (collectively, the “**Embargoed Countries**”); (ii) to any instrumentality, agent, entity, or individual that is acting on behalf of, or directly or indirectly owned or controlled by, any governmental entity of any Embargoed Country; (iii) to a national of an Embargoed Country; or (iv) engage in any transactions or dealings with any organization, entity, or individual identified on the List of Specially Designated Nationals and Blocked Persons or the Foreign Sanctions Evaders List, which are both maintained by the Office of Foreign Assets Control of the U.S. Treasury Department, or the Entity List, Denied Persons List, or Unverified List, which are maintained by the Bureau of Industry and Security of the U.S. Commerce Department.

(k) The Distributor shall not act in any fashion or take any action in the performance of its obligations under this Agreement which will render Company liable for a violation of the U.S. Foreign Corrupt Practices Act, UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism (“**Anti-Corruption Laws**”), which prohibits the offering, giving or promising to offer or give, directly or indirectly, money or anything of value to any official of a government, political party or instrumentality thereof in order to assist the Distributor or the Company in obtaining or retaining business. The Company shall have the right to terminate this Agreement immediately if the Distributor takes any action in violation of any Anti-Corruption Laws. The Distributor shall indemnify and hold the Company harmless from and against all losses, liabilities, damages and expenses (including reasonable attorneys’ fees and costs) relating to Distributor’s breach of this Section 2.1(k).

(l) Should during the term of this Agreement or thereafter the Company decide to market the Product to private individuals or entities outside the United States or its territories, then the

[2.1(j) and 2.1(k)] Standard covenants to give Company some protection against Distributors’ breaking laws.

[2.1(l)] Here, the parties envision the potential for expanding their arrangement. Whether language like this is included depends on the

<p>Parties shall enter into good faith discussions as to whether it might be agreeable to use the Distributor as a potential distributor.</p> <p>2.2 <u>Marketing Authorizations.</u></p> <p>(a) The Company shall initially have the right to file for any Marketing Authorization(s) with respect to the Product. Should the Company decide, in its sole discretion, to apply for and obtain a Marketing Authorization in a country or region, then the Company will be responsible for filing and maintaining the Marketing Authorization(s) for the Product and shall bear all related costs. If (i) the Company decides to not apply for or obtain a Marketing Authorization in a specific country or region or (ii) the Distributor is required by law or government request to apply for a Marketing Authorization in any country, then the Company and the Distributor shall consult to jointly decide if a Marketing Authorization in this particular country is commercially justified from a business perspective. The Company shall not unreasonably refuse to file and maintain the Marketing Authorization(s) for the Product, nor shall it unreasonably refuse to allow the Distributor to file for a Marketing Authorization under the circumstances of (ii) above.</p> <p>(b) If obtaining a Marketing Authorization for a certain country or region is not commercially justified from a business perspective and the Company elects not to file for such Authorization, the Distributor may apply for and obtain such Marketing Authorization(s) and shall bear all related costs. The Distributor shall provide all documents to the Company required for the Distributor to apply for and obtain such Marketing Authorization(s). The Company shall not be required to provide any document or information that is not in its possession or that the Company is not entitled to disclose to the Distributor.</p> <p>(c) No Marketing Authorization has been issued for the Product inside the Territory or outside the Territory. The Company shall inform the Distributor on a continuous basis about the status of Marketing Authorizations for the Product in the US, Canada, and Europe (through the EMA). Should the Company grant the Distributor the right to hold a Marketing Authorization for Product under Sections 2.2(a) or 2.2(b) above, the Distributor shall</p>	<p>business case and the parties' relative strengths. Can be removed for a more arms'-length arrangement; can also be strengthened depending on the deal.</p> <p>[2.2(a) and (b)] Important for regulatory purposes. Because Territory is worldwide, and different countries have different regulatory regimes, Distributor needs ability to get appropriate authorizations.</p> <p>[2.1(c)] Because this deal contemplates an arrangement where the Product is not yet approved by FDA or other regulatory agencies, what can be done with the Product is limited.</p>
---	---

<p>inform the Company on a continuous basis about the status of the Marketing Authorizations of the Product in those countries where the Distributor holds or is seeking a Marketing Authorization.</p> <p>(d) The Company will be responsible for performing the regulatory activities required by the Regulatory Authorities with respect to the manufacture, marketing, sale and use of the Product. The Distributor shall provide regulatory support to assist the Company in meeting the requirements of the non-US Regulatory Authorities. Such support will include, but is not limited to advice and assistance in obtaining and maintaining European product Marketing Authorization(s) in obtaining and maintaining product Marketing Authorizations in other non-US countries, and meeting all regulatory requirements and performing the required regulatory activities as set forth by the non-US Regulatory Authorities.</p> <p>(e) At the conclusion or termination of this Agreement, the Distributor shall transfer all Product Marketing Authorizations acquired under this Section and all materials obtained from the Company hereunder to the Company. Such transfer shall be at no charge to the Company except that the Company shall reasonably compensate the Distributor for its transfer activities relating to transferring the Marketing Authorization(s) from the Distributor's name to the Company's name.</p>	<p>[2.1(d)] Clarification of Parties' respective rights with respect to Product. The Company is responsible and retains its rights, even though Distributor may hold Marketing Authorization in certain countries.</p> <p>[2.1(e)] Ensures Company recovers all of its rights in countries after the Agreement ends.</p>
<p style="text-align: center;">ARTICLE 3</p> <p style="text-align: center;"><u>SUPPLY AND DELIVERY</u></p> <p>3.1 Forecasts and Orders.</p> <p>(a) In order to ensure timely receipt of the Products, the Distributor may notify the Company in writing, by completing the Company's annual forecasting form, of the Distributor's non-binding forecast of the number of the Products (indicating types of Product) which the Distributor expects to purchase from the Company for the subsequent twelve (12) month period ("Forecasts"). The Distributor shall endeavor to submit Forecasts that are reasonably accurate and shall notify the Company of any event likely to make Forecasts</p>	<p>[3.1 and 3.2] Specifics of these sections are business considerations, not really legal concerns. Here are some standard terms for a basic supply/delivery arrangement. This will be negotiated by the parties and may differ substantially based on the particulars of the deal.</p>

materially inaccurate.

(b) Without prejudice to Section 3.1(e), the Company shall ensure at all times that the Company has available sufficient quantities of the Products to meet the Distributor's requirements as set out in the Forecasts.

(c) The Distributor shall place firm orders for Products from time to time ("**Orders**"). Subject to Section 3.1(e), the Company shall accept in writing all Orders submitted by the Distributor within seven (7) days unless there is a manifest error on the face of the Order in which case the Company shall inform the Distributor of the error within seven (7) days and give the Distributor an opportunity to rectify such error. Notwithstanding the foregoing, where the Company fails to notify the Distributor of acceptance or rejection of an Order within seven (7) days such Order shall be deemed to have been accepted by the Company. The Distributor may cancel any Order prior to [its acceptance or deemed acceptance/delivery].

(d) The Distributor shall be responsible to the Company for ensuring the accuracy of the terms of any Order and for giving the Company any necessary information relating to the Products within a sufficient time to enable the Company to perform its obligations under this agreement.

(e) Where an Order is for in excess of [two hundred per cent (200%)] of the greatest of: (i) the latest forecast for the period concerned; (ii) the Order for the corresponding period in the previous year; and (iii) the Order for the previous period (an "**Excessive Order**"), the Company shall only be bound to accept such Order for the amount not in such excess.

3.2 Delivery.

(a) Except where the Company notifies the Distributor otherwise, delivery of the Products shall be made DDP to the Distributor's notified delivery address (as that term is defined in Incoterms 2000) ("**Delivery**").

(b) All Products shall be delivered by the date agreed between the parties which shall be stated on the order confirmation form. If no such date is stated on the order confirmation form, the relevant

<p>Products shall be delivered within [fourteen (14) days] of the date of the Order.</p> <p>(c) Without prejudice to any other rights and remedies the Distributor may have, the Distributor shall notify the Company of any failure to deliver the Products in accordance with any Order or of any short delivery or of any damage in the delivered Products promptly on such failure or short delivery coming to its attention.</p> <p>(d) Title and risk in the Products shall pass to the Distributor on Delivery unless payment is made prior to delivery in which case title shall pass on payment.</p>	
<p style="text-align: center;">ARTICLE 4</p> <p style="text-align: center;"><u>PAYMENT AND PAYMENT AMOUNT</u></p> <p>4.1 Payment from the Customer shall be made under the terms in the agreement between the Customer and the Seller.</p> <p>4.2 The Company shall invoice the Distributor for Products ordered on or at any time after the Products concerned are delivered. The Company's invoices are due net thirty (30) days from the date of the Company's invoice.</p> <p>4.3 The prices payable for the Products shall be as set out in Appendix A. The prices as so set out are inclusive of all delivery charges which shall be included on the invoice concerned. All Orders accepted before the date of a price increase shall be at the price at the date on which the Order was accepted.</p> <p>4.4 If the Distributor fails to pay the charges within thirty (30) days of the due date for payment under this agreement (other than in the case of a bona fide dispute), the Company shall be entitled to charge the Distributor interest on the unpaid charges for the period from and including the due date of payment up to the date of actual payment. The interest shall be paid at the rate of [two per cent (2%)] above the base rate from time to time of the Bank of England.</p> <p>4.5 If the Distributor disputes the whole or</p>	<p>[4] Specifics of this are business considerations, not really legal concerns. Here are some standard terms for a basic supply/delivery arrangement. This will be negotiated by the parties and may differ substantially based on the particulars of the deal.</p> <p>[4.3] Pricing details are usually separate from main text of the agreement.</p>

<p>any portion of the amount claimed in an invoice submitted by the Company, the Distributor may notify the Company in writing within a reasonable period of receipt of the invoice together with reasons for disputing the invoice. For the avoidance of doubt, failure to pay the charges in the case of a bona fide dispute is not a breach of this agreement.</p> <p>4.6 All prices and any other charges quoted by the Company under this agreement are [exclusive/inclusive] of any applicable VAT and any customs duties imposed or levied in the Territory.</p> <p>4.7 The exchange rate applicable to all payments under this Agreement shall be the exchange rate published in the London Financial Times in effect on the date the Seller receives payment for the Product from a Customer.</p> <p>4.8 Payment to the Company shall be submitted to: [_____]</p>	
<p style="text-align: center;">ARTICLE 5</p> <p style="text-align: center;"><u>EXPORT/IMPORT REQUIREMENTS</u></p> <p>5.1 If Product will be exported from the United States, the Party responsible for distribution of the Product shall obtain, at its own risk and expense, any export license or other official authorization and carry out, where applicable, all customs formalities for the export of Product from the US under this Agreement and the import of such Product. The Party not responsible for exporting the Product shall use all reasonable efforts to assist the exporting Party in obtaining such import license or other authorizations necessary for the export of Product.</p> <p>5.2 If the Product will be exported from a country other than the United States, the Distributor shall be required to obtain, at its own risk and expense, any export license or other official authorization and carry out, where applicable, all customs formalities for the export of Product and the import of such Product. The Company shall use all reasonable efforts to assist the Distributor in obtaining such import license or other authorizations necessary for the export of Product.</p> <p>5.3 The Party responsible for obtaining the</p>	<p>[5] Not always a separate section, and the details will differ based on the particulars of the deal.</p>

<p>export license or other official authorization as set forth in this Section Article 5 shall also be responsible for insuring compliance with export requirements, including but not limited to these requirements of the Bureau of Export Administration and the Bureau of Industry and Security of the U.S. Department of Commerce.</p>	
<p style="text-align: center;">ARTICLE 6</p> <p style="text-align: center;"><u>LICENSE & NON-COMPETE</u></p> <p>6.1 <u>License.</u></p> <p>(a) For the duration of this Agreement, the Company grants to the Distributor a non-exclusive royalty-free license, to use the Company's intellectual property rights (including any and all trademarks, logos and other markings used by the Company) that are reasonably necessary to promote the sale of the Product to Customers within the Territory. Intellectual property rights licensed from the Company to the Distributor used or embodied in the Product remain as the sole property of the Company. The Distributor shall not apply for registration of or register any intellectual property rights that claim the Product or improvements thereof without the prior written consent of the Company, nor shall the Distributor oppose any action taken by the Company with respect to registering such rights for the benefit of the Company..</p> <p>(b) The Distributor agrees that it will (i) use the trademarks of the Company only in a manner from time to time approved by the Company accompanied by an acknowledgment that the same are the trademarks of the Company, (ii) not use the trademarks of the Company in relation to any other products or in any way which might prejudice their distinctiveness or validity or the goodwill of the Company therein; (iii) not use any other trademarks so resembling the trademarks of the Company as to be likely to cause confusion or deception; and (iv) not use the trademarks of the Company in combination with any other trademark or other names or logos other than trademarks of the Company, except with the prior written consent of the Company. The Distributor agrees that the use of the trademarks of the Company and all goodwill associated therewith,</p>	<p>[6.1] The IP licensed here is limited to trademarks. Because this deal is set up as one in which Distributor is simply sold Product by Company and resells to Customers, patents are exhausted and license is not required. Company retains ownership of all IP rights related to the Product.</p> <p>[6.1(b)] Trademark-specific protections are included here to ensure no dilution, confusion, etc.</p>

<p>shall inure to the benefit of the Company.</p> <p>(c) The grant of the licenses from the Company to the Distributor under this Agreement shall be free of any charges whatsoever.</p> <p>6.2 <u>Non-Compete</u>. The Distributor and its affiliates shall not sell or market any vaccine product designed to confer immunity against the Indication other than the Product inside or outside of the Territory during the term of this Agreement.</p>	<p>[6.2] A non-compete like this is common in conjunction with exclusive distribution rights.</p>
<p style="text-align: center;">ARTICLE 7</p> <p style="text-align: center;"><u>AUDITS AND REPORTS</u></p> <p>7.1 The Distributor shall inform the Company about the progress of its sales and marketing activities of the Product in the Territory at least on a monthly basis. The Company shall provide the Distributor with manufacturing updates, including but not limited to information on any event or difficulty that may have a potential impact on the delivery schedules agreed upon or negotiated between Sellers and Customers.</p> <p>7.2 Additionally, the Distributor shall submit quarterly reports to the Company detailing:</p> <p>(a) Potential and actual sales in and outside the Territory;</p> <p>(b) Current and planned marketing efforts in and outside the Territory;</p> <p>(c) A list of current contracts for the sale of Product to Customers and the price for the Product in such contracts; and</p> <p>(d) Anticipated payment dates for outstanding Product to be delivered to a Customer; if known.</p> <p>7.3 The Company and the Distributor shall keep proper records and books of account and all proper entries therein relating to the Product sold to Customers for delivery in the Territory and for delivery outside the Territory and the amounts paid by Customers and shall maintain such records for seven years after the expiration of the Term or termination of this Agreement. The Company and the Distributor</p>	<p>[7] Fairly standard obligations here. Reporting requirements are lighter or more stringent based on the business relationship of the parties and the specifics of the deal (are there ongoing royalties; are there diligence obligations?).</p>

<p>and their respective auditors, shall have the right to inspect such books and records (upon reasonable, prior written notice, during regular business hours), for the sole purpose of verifying the reports, information and payments provided or due hereunder and verifying compliance with the material terms and conditions of this Agreement. If such audit should disclose any underpayment, the underpaying Party shall be given a reasonable time to assess the situation and provide the other party with a counter statement, and, if the underpayment is substantiated, promptly pay the amount due, together with interest thereon at a rate of one and one-half percent (1.5%) per month from the date such amount was due until fully paid. If the Parties fail to reach an agreement upon such underpayment, an independent third party shall be mutually identified by the Company and the Distributor in order to decide upon the alleged underpayment. If the amount of such underpayment exceeds ten percent (10%) of the total amount due from that sale, the underpaying Party shall immediately reimburse the expenses associated with such audit.</p>	
<p style="text-align: center;">ARTICLE 8</p> <p style="text-align: center;"><u>LIMITATIONS OF LIABILITY</u></p> <p>8.1 EXCEPT AS EXPLICITLY SET OUT IN THIS AGREEMENT, ALL CONDITIONS, WARRANTIES, AND REPRESENTATIONS, EXPRESS OR IMPLIED BY STATUTE OR OTHERWISE, IN RELATION TO THE PRODUCT ARE EXCLUDED TO THE EXTENT POSSIBLE UNDER THE APPLICABLE LAWS.</p> <p>8.2 To the extent possible under the applicable laws, and except with respect to damages (other than lost profits) arising out of or relating to breaches of this Agreement, the Company is not liable to the Distributor, whether for negligence, tort, breach of contract, misrepresentation or otherwise, for:</p> <p style="padding-left: 40px;">(a) loss or damage incurred as a result of third party claims;</p> <p style="padding-left: 40px;">(b) loss of profit, goodwill, business opportunity or anticipated saving;</p> <p style="padding-left: 40px;">(c) indirect or consequential loss</p>	<p>[8] This section is very Company-favorable given that the Company is supplying the Product.</p> <p>[8.1] Warranties are disclaimed.</p> <p>[8.2] Unilateral limitation of liability.</p>

<p>or damage;</p> <p>(d) property damage; or</p> <p>(e) death or personal injury.</p>	
<p style="text-align: center;">ARTICLE 9</p> <p style="text-align: center;"><u>NOTIFICATION PROCEDURES FOR PHARMACOVIGILANCE & RECALL</u></p> <p>9.1 <u>Adverse Events/Adverse Experiences.</u></p> <p>The Parties shall promptly inform each other of all reports of adverse experiences/adverse events (“AE’s”) in respect of the Product coming to the knowledge of either party. Serious AE’s shall be communicated promptly to the other Party. Any AE that involves a death shall be reported within twenty-four (24) hours and any serious AE shall be reported within forty-eight (48) hours according to a standard operating procedure to be agreed upon between the Company and the Distributor within three months of the execution date of this Agreement. Prior to licensure, each Party shall cooperate with the other to allow the holder of the pre-licensure application to report and manage any AE’s as required by the applicable Regulatory Authority(ies). For Products sold to Customers in the Territory, after applying for and receiving a Marketing Authorization, the Marketing Authorization holding Party shall be solely responsible for investigating and evaluating each AE in order to meet legal, regulatory, and contractual requirements for risk assessment or proper reporting to the authorities. The non Marketing Authorization holding Party shall reasonably support the holder of the Marketing Authorization in such activities. The Company and the Distributor shall jointly agree on a fair schedule on compensation for the regulatory support of the non Marketing Authorization holding Party under this Section.</p> <p>9.2 <u>Recalls.</u></p> <p>(a) Product recalls involving any Product for which the Company has applied for or obtained an Investigational New Drug (IND) application or a Biological License Application (BLA) under United States law or a non-United States Marketing Authorization, that is sold to a Customer in</p>	<p>[9.1 and 9.2] Very detailed reporting requirements here due to industry regulations. Standard language for this industry.</p>

<p>the Territory shall be carried out in accordance with a standard operating procedure to be agreed upon between the Company and the Distributor within three months of the execution date of this Agreement.</p> <p>(b) For the recalls addressed in Section 9.2(a), the Distributor shall provide reasonable assistance to the Company in any recall of such Product distributed by the Distributor in the Territory. The Company and the Distributor shall jointly develop and execute any such recall in accordance with a recall procedure which is compliant with the requirements of the relevant Regulatory Authority(ies) having jurisdiction. The Companies and the Distributor shall jointly agree on a fair schedule on compensation for the Distributor's regulatory support under this Section.</p> <p>9.3 <u>SOP.</u></p> <p>(a) Consistent with the above, the Company and the Distributor shall jointly develop certain procedures with regard to Pharmacovigilance & Field Corrective Actions (including Recall) within three months of the execution date of this Agreement.</p>	<p>[9.3] Very typical to have an ancillary agreement further detailing these matters in this industry.</p>
<p style="text-align: center;">ARTICLE 10</p> <p style="text-align: center;"><u>INDEMNITY & INSURANCE</u></p> <p>10.1 Due to the unknown risks of the Product, the Seller of the Product shall use all reasonable efforts to obtain complete indemnification for all Parties under this Agreement from the Government Authority of Customer's country according to the guidelines agreed upon in Attachment B. <u>In the event a Customer refuses to provide complete indemnity consistent with Attachment B, the Seller shall promptly notify the other Party and no contract shall be executed until the other Party agrees in writing.</u> When a Government Authority of a Customer's nation provides indemnification, the Selling Party shall conduct due diligence to verify that such indemnification is valid and enforceable.</p> <p>10.2 The Distributor agrees to defend, indemnify and hold free and harmless the Company and its affiliates, directors, officers and employees from any and all claims or damages (including</p>	<p>[10] Fairly typical language EXCEPT for pass-through indemnity requirement, which is very unusual. Specifics of this deal (unapproved vaccine being used for emergency outbreak) make it sensible to get indemnity from Government customer before moving forward.</p>

litigation expenses and attorneys' fees and costs) of every kind or nature whatsoever arising from acts and/or omissions of the Distributor in the course of this Agreement including, without limitation, any and all claims arising from third parties in relation to any activity under the control or in the responsibility of the Distributor. This indemnity shall not apply however, to the extent any such claims are (a) caused by any act or omission under the Company's responsibility, including but not limited to any act or omission of third parties under contractual control of the Company or (b) indemnified by Customer according to Section 10.1.

10.3 The Company agrees to defend, indemnify and hold free and harmless the Distributor and its affiliates, directors, officers and employees from any and all claims or damages (including litigation expenses and attorneys' fees and costs) of every kind or nature whatsoever arising from acts and/or omissions of the Company in the course of this Agreement including, without limitation, any and all claims arising from third parties in relation to any activity under the control or in the responsibility of the Company. This indemnity shall not apply however, to the extent any such claims are (a) caused by any act or omission under the Distributor's control, including but not limited to any act or omission of third parties under contractual control of the Distributor, or (b) indemnified by the Customer according to Section 10.1.

10.4 The Company and the Distributor shall maintain insurance in appropriate amounts and terms to cover their potential liability with respect to personal injury or product liability claims related to or arising out of the Product, including any such insurance as may be required by any Regulatory Authority(ies) or other law or regulation.

10.5 The rights and obligations of the Parties under this clause shall survive the Agreement's termination, expiration or completion. Each Party shall promptly notify the other of any claim in respect of which the notifying Party intends to claim indemnification under this Section Article 10. The Party seeking Indemnification will not enter into any settlement, which would admit any fault of the other or place any blame on the Product without the prior written consent of the other Party. Both Parties shall cooperate fully in the investigation of any action, claim

<p>or liability covered by this indemnification, shall be given opportunity to assume their own defense, including but not limited to the option to be represented in any such action or proceeding.</p>	
<p style="text-align: center;">ARTICLE 11</p> <p style="text-align: center;"><u>CONFIDENTIALITY</u></p> <p>11.1 Each Party may have acquired or may acquire during the course and conduct of activities under this Agreement certain proprietary or confidential information disclosed by the other Party (“Proprietary Information”). Except to the extent as may be authorized in writing, each Party agrees that, during the term of this Agreement and for a period of five (5) years following its termination or completion, it shall (a) use any Proprietary Information disclosed to it only for the purpose of performance under this Agreement, (b) not disclose Proprietary Information to any third party, or to any employee who does not have a need-to-know such information, and (c) employ the same standard of care it uses to protect its own Proprietary Information (but, in all events, no less than due care). To be considered “Proprietary Information” under this clause, the information must be (i) disclosed in written or tangible form and appropriately marked as proprietary, or (ii) if disclosed orally or visually, clearly identified as proprietary at the time of disclosure and summarized in writing within thirty (30) calendar days after such disclosure. Information shall not be deemed to be proprietary if such information is already known without restriction to a receiving party; or is rightfully received without restriction by the receiving Party from a third party having the right to disclose the information; or becomes publicly available through no wrongful act of the receiving Party; or is hereafter routinely furnished by the disclosing Party without a similar restriction on disclosure; or is independently developed by the receiving Party without breach of this Agreement. The receiving Party shall not be liable for inadvertent disclosure or use of the information received hereunder if, upon discovery of such, it shall take reasonable steps to prevent any further inadvertent disclosure or unauthorized use. The receiving Party may make disclosures required by operation of law; <i>provided</i> that the receiving Party shall give the disclosing Party reasonable advance notice to provide the disclosing Party an opportunity to contest the</p>	<p>[11.1] Fairly standard language, not specific to the particulars of any deal.</p> <p>There should be no loss of protection for information that is disclosed in an isolated instance without NDA so long as it has not become publicly available.</p>

<p>requirement of disclosure. No license is either granted or implied by the conveyance of Proprietary Information by either Party. The Parties further agree that the obligations set forth above shall survive termination or completion of this Agreement.</p> <p>11.2 Notwithstanding Sections 14.9 and 14.10, either party may seek injunctive relief in any court of competent jurisdiction for a violation of Section 11.2 without posting bond or other security.</p> <p>11.3 The terms of the above confidentiality provisions supersede and replace the Confidential Disclosure Agreement signed by the Parties and executed on <i>[insert date]</i>.</p>	<p>[11.2] Very common to have a CDA in place for initial discussions that will be superseded by language in the final negotiated agreement</p>
<p style="text-align: center;">ARTICLE 12</p> <p style="text-align: center;"><u>TERM AND TERMINATION</u></p> <p>12.1 This Agreement shall come into force on the Effective Date and, unless earlier terminated, shall remain in force for a period of five (5) years.</p> <p>12.2 Notwithstanding termination rights stated in other sections of this Agreement, either Party may terminate this Agreement forthwith by giving a notice to the other Party in any of the following events:</p> <p style="padding-left: 40px;">(a) In the event that a Party commits a material breach or default of this Agreement and fails to take action to remedy such breach or default within thirty (30) days after receipt of written notice from the other Party.</p> <p style="padding-left: 40px;">(b) In the event that a Party files or consents to the filing of any petition of bankruptcy or for other relief under any bankruptcy law for the relief of its creditors, is adjudicated insolvent or bankrupt, is dissolved or liquidated, or makes any assignment to its creditors, or a receiver or similar person is appointed for or in relation to such a Party or a substantial part of its assets or undertaking.</p> <p>12.3 <u>Effects of Termination.</u></p> <p style="padding-left: 40px;">(a) Upon expiration or termination of this Agreement, the Distributor and/or any affiliated company shall return to the Company (without charge) all materials in its possession to which the</p>	<p>[12.1 and 12.2] Fairly generic and barebones termination language here.</p> <p>[12.3(a)] Important to provide for disposition of materials at the end of Agreement.</p>

<p>Company has exclusive title under this Agreement and which were provided to the Distributor by the Company under this Agreement.</p> <p>(b) The Distributor shall be entitled to, at its discretion (i) sell any Products it has in stock at the date of termination or expiration or which it receives after termination or expiration pursuant to Orders placed before termination or expiration or (ii) destroy remaining inventory.</p> <p>(c) Termination or expiration of this Agreement shall not affect the rights or liabilities of either Party accrued prior to termination or expiration or any terms intended expressly or by implication to survive termination or expiration.</p>	<p>[12.3(b)] Important to clearly state what Distributor is permitted to do with Product at end of Agreement.</p>
<p style="text-align: center;">ARTICLE 13</p> <p style="text-align: center;"><u>INTELLECTUAL PROPERTY</u></p> <p>13.1 Neither Party shall knowingly do anything to infringe upon or harm the intellectual property rights of the other Party. Each Party shall promptly notify the other Party of any and all infringements, limitations, illegal use or misuse, of the other Party's intellectual property rights of which it becomes aware.</p> <p>13.2 The Distributor may refer to the Product by the associated Company trademarks applicable to such Product and include such in advertising, marketing, and promotional materials; <i>provided</i> that such reference is not misleading. Subject to the preceding sentence and other than the license granted under Section 6.1 of this Agreement, the Distributor is granted no right, title, or license to, or interest in, any trademarks of the Company. The Distributor acknowledges the Company's rights in its trademarks and agrees that any use of such trademarks shall inure to the benefit of the Company.</p>	<p>[13.1] Because no patents or know-how are at issue here, the Parties' obligations are fairly limited. This section would typically be much more detailed if a wider scope of IP were being licensed/exploited.</p>
<p style="text-align: center;">ARTICLE 14</p> <p style="text-align: center;"><u>GENERAL</u></p> <p>14.1 Except as stated otherwise in this Agreement, neither this Agreement nor any right or obligations hereunder shall be assignable by either Party hereto without the prior written approval of the other Party, and any assignment without such prior</p>	

written consent shall be null and void. In the case of an assignment to an affiliate of a Party, such consent shall not be unreasonably withheld or delayed.

14.2 The invalidity, illegality or unenforceability of the whole or part of any provision of this Agreement does not affect or impair the continuation in force of the remainder of this Agreement. All Attachments are an integrated part of this Agreement.

14.3 No waiver of a breach of any provision of this Agreement shall constitute a waiver of any other breach of such provision. Failure of either Party to enforce at any time, or from time to time, any provision of this Agreement shall not be construed as a waiver thereof.. The remedies herein shall be cumulative and additional to any other remedies in law or in equity.

14.4 This Agreement and the other agreements referenced herein contain the entire understanding of the Parties hereto with respect to the sale of Product to Customers, and supersedes all prior discussions, agreements, understandings with respect to its subject matter, and no condition, definition, warranty or representation other than those expressly provided for herein shall be binding upon either Party. Any amendments, modification, change or alteration of this Agreement shall be made in writing which expressly refers to this Agreement and which is signed by a duly authorized officer or representative of each of the Parties hereto. All Attachments to this Agreement are an integrated part of this Agreement.

14.5 Nothing in this Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein. There are no express or implied third party beneficiaries hereunder.

14.6 Any delay or failure in the performance of any obligation under this Agreement by either Party hereto shall be excused if and to the extent caused, directly or indirectly, by occurrences beyond such party's reasonable control. If as a result of force majeure, any Party hereto is precluded from receiving any benefit to which it is entitled hereunder, the

Parties shall review the terms hereof so as to restore them to the same relative positions as those previously obtained hereunder. The Party affected by force majeure shall promptly inform the other Party of the occurrence of such force majeure.

14.7 The Distributor shall comply with all applicable laws and regulations inside and outside of the Territory that from time-to-time apply to this Agreement or the transactions and activities contemplated by this Agreement. The Distributor shall not knowingly take any action, which will cause the Company to be in violation of any law of any jurisdiction inside or outside of the Territory.

14.8 A notice under or in connection with this Agreement shall be in writing and shall be delivered personally or sent by first class post pre-paid recorded delivery (and airmail if overseas) to the relevant party as follows:

(a) If to the Company: [_____]

(b) If to the Distributor: [_____]

14.9 All disputes arising out of or in connection with this Agreement shall be, if not settled amicably between the involved parties, will be referred to the Chief Executive Officer of the Company and the Chief Executive Officer of the Distributor, for good faith resolution, for a period of at least ninety (90) days. During such period, both Parties shall in good faith explore resolution of the dispute using alternative dispute resolution techniques before pursuing other remedies. If such dispute is not resolved by the end of such period (or extension thereto as agreed upon by the Parties), the Parties shall be free to pursue the legal or equitable remedies available to them before the ordinary courts of [*insert venue*].

14.10 This Agreement is governed by, and shall be construed in accordance with, the laws of [____]. The Parties irrevocably decree that the Courts of [____] have exclusive jurisdiction and venue to decide and settle any dispute or claim arising out of or in connection with this Agreement except as otherwise provided in section 11.2.

The headings in this Agreement do not affect its interpretation.

Signed by: _____ For and on behalf of the Company: _____ Name: _____ Date: _____ Signed by: _____ For and on behalf of the Distributor: _____ Name: _____ Date: _____	
Appendix A PRICING	
Appendix B SAMPLE INDEMNIFICATION TEMPLATE	