Appendix G

# Model term sheet for Guarantee and Supply Agreement

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| **1. Parties:** | Funder(s) and one or more Designated Suppliers.[1] |
| **2. Purpose:** | Guarantee that the Designated Supplier(s) receive a specific price[2] for each sale of the Approved Vaccine[3] if the sale qualifies as a Qualified Sale (as defined below) and the Approved Vaccine is purchased for use in an Eligible Country (as defined below), provided that the Designated Supplier commits to supply the Approved Vaccine to Eligible Countries to meet their requirements.[4] |
| **3. Principal Responsibilities of Funder:** | Funder will, subject to Sections 7 and 13 below, irrevocably and unconditionally Guarantee that the gross price paid to a Designated Supplier shall be not less than the price set forth in Schedule A (the **"Guaranteed Price"**) for each Qualified Sale of the Approved Vaccine up to the maximum number of sales specified in Schedule A (the **"Approved Maximum"**);[5] provided that (a) the Base Price is not less than the amount specified in Schedule A, and (b) the Approved Vaccine is purchased for use in an Eligible Country. The **"Base Price"** is the amount actually paid, directly or indirectly, by the purchaser of the Approved Vaccine.[6] |
| **4. Principal Responsibilities of Designated Supplier:** | The Designated Supplier will (a) use commercially reasonable efforts to create awareness of the availability of the Approved Vaccine in the Eligible Countries in order to meet the public health requirements in the Eligible Countries,[7] (b) [use commercially reasonable efforts to] establish manufacturing capacity for the production of the Approved Vaccine that is sufficient to meet the public health requirements for the Approved Vaccine in the Eligible Countries,[8] (c) obtain and maintain World Health Organization (WHO) prequalification (or any substitute qualification determined by the Committee) for the Approved Vaccine,[9] and those facilities used in its production, as well as any local authorizations and approvals necessary to market and sell the Approved Vaccine in the Eligible Countries, including by complying with all adverse event reporting requirements and providing ongoing evidence of product and production safety and regulatory compliance, (d) provide the Committee with copies of all written communications to or from, including all filings or submissions to, and summaries of all oral communications with, the WHO or any other relevant regulatory agency with respect to the Approved Vaccine, (e) in connection with the marketing, distribution and sale of the Approved Vaccine, comply with the U.S. Foreign Corrupt Practices Act and all other applicable law,[10] (f) provide information as reasonably requested by the Committee from time to time in order to confirm ongoing compliance with the technical specifications and usability requirements set forth in Sections 8 and 9 of the Framework Agreement, (g) agree to be bound by decisions of the Committee acting within the scope of its authority,[11] and (h) continue to supply product to Eligible Countries to meet their requirements as provided in Section 8. |

# Notes

1. The Framework and Guarantee Agreement term sheets were designed to accommodate a variety of sponsors, despite the fact that there are substantial differences between governmental and nongovernmental organizations in areas such as funding capacity and ability to contractually commit to the Guarantee Agreement. There were discussions regarding mechanisms for ensuring that sponsors are and remain bound by their financial commitments under the Framework and Guarantee Agreements. In the end, the Working Group concluded that traditional commercial mechanisms for ensuring compliance, such as letters of credit or escrow arrangements, would be unattractive to potential Funders as they would result in increased transaction costs and unnecessarily tie up funds that could be made available for more immediate opportunities. Instead, the Working Group elected to implement a bilateral contract structure, which would permit the Developer to pursue standard contract remedies, such as money damages and specific performance, if the Funders fail to satisfy their financial commitments. The Guarantee Agreement term sheet would permit a single Funder, multiple Funders or a system where a lead Funder parcels out participations to sub-Funders. Some of the potential Funders considered by the Working Group include private foundations, developed country governments and international organizations.

2. The Guarantee Agreement is designed so that price for each Qualified Sale could vary. For example, a higher payment could be made in the early years to permit the Developer to recapture R&D costs and capital investments in manufacturing capacity more rapidly, with lower payments in the later years.

3. The Working Group determined that a price Guarantee, rather than a minimum quantity Guarantee, would be the basis for the incentive. See chapter 4 for an explanation. The pricing structure can be designed to provide substantial insurance against demand risk for prospective vaccine developers so as to yield a net present value of revenue comparable with commercial products even under pessimistic uptake scenarios.

4. Sufficient vaccine must be made available to satisfy the requirements of all Eligible Countries. A Developer could not select a few Eligible Countries where it wishes to offer the vaccine or cease to supply vaccine once the price supplements cease to apply.

5. The Approved Maximum and the Guaranteed Price can be set to yield desired revenue. Price guaranties are on a per treatment basis—such as course of immunization—rather than a per dose basis.

6. A Base Price concept, similar to a co-payment, was introduced to create an incentive to help ensure that qualifying vaccines are not wasted and that payments are not made for unusable vaccines. If countries, or other donors, are required to make a minimum investment in an Approved Vaccine, then there is greater likelihood that appropriate quantities of the vaccine will be procured and that those quantities will be administered. This also provides an additional safeguard that donor funds will not be wasted on a vaccine for which there is no market. Especially for diseases for which the vaccine research is still at an early stage, the technical specifications in the Framework Agreement may be established many years in advance of identifying promising vaccine technology, or, for that matter, the delivery of an Approved Vaccine. Intervening events, such as improvements in sanitation or pesticide use, may render a technically adequate vaccine unnecessary. Similarly, unforeseen characteristics of an Approved Vaccine, such as medically harmless but culturally unacceptable side-effects, which would not have been addressed in the technical specifications, may render an otherwise safe vaccine unsuitable in certain countries. The co-payment requirement helps ensure that the advance market

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| **5. Qualified Sale:** | The sale of the Approved Vaccine for use in an Eligible Country shall be deemed a **"Qualified Sale"** if it meets the criteria set forth in Schedule B, as modified from time to time by the Independent Adjudication Committee. In the event of a conflict between Funder and the Designated Supplier over whether a particular sale of the Approved Vaccine satisfies the criteria for a Qualified Sale, the matter shall be referred to the Independent Adjudication Committee, whose decision shall be final and binding on the parties. |
| **6. Eligible Countries:** | Each of the countries listed in Schedule C shall be deemed **"Eligible Countries"**). Schedule C may be revised from time to time by the Independent Adjudication Committee in order to (a) add countries whose per capita GDP (as determined by [_____]) is less than [$____], or (b) remove countries whose per capita GDP (as determined by [_____]) is greater than [$____]. |
| **7. Cap on Total Commitment [and Termination of Commitment]:** | The total payment obligation of Funder pursuant to the Guarantee and Supply Agreement, including all payments and distributions to the initial Designated Supplier and any additional or replacement Designated Suppliers, shall (a) not exceed, in the aggregate, [$_____] (the **"Maximum Guaranteed Amount"**), and (b) be subject to termination or modification by the Independent Advisory Committee pursuant to Section 22 of the Framework Agreement. [Schedule C of the Framework Agreement sets forth the assumptions underlying the calculation of the Maximum Guaranteed Amount and the criteria for adjusting it if the number of Eligible Countries is materially reduced or a *force majeure* event occurs.] |
| **8. Supply** | The Designated Supplier shall supply all requirements of the Approved Vaccines in Eligible Countries during the Funding Term as provided herein and, thereafter, for a period of [10] years, or such longer period as the Designated Supplier may determine (the **"Supply Term"**), at a price not to exceed (a) if the Designated Supplier has received payments for the sale of the Approved Vaccine in Eligible Countries (the **"Gross Sales"**) in amounts, in the aggregate, greater than [$_____] (the **"Minimum Gross Sales Amount"**), then the lesser of [__]% of its fully burdened (without recapture of research and development) costs and expenses to manufacture the Approved Vaccine and [$___] per Dose (as defined in Schedule B), and (b) if the Designated Supplier has not received such payments in such amounts, then the per-Dose amount in clause (a) shall be increased by [__]% only until the aggregate Gross Sales for the Approved Vaccine equals the Minimum Gross Sales Amount, whereupon the increase in this clause (b) shall cease to apply.[12] |

commitment will be used for Approved Vaccines that actually meet the requirements of the Eligible Countries.

7. Although the Designated Supplier has responsibility for generating awareness of the availability of Approved Vaccines in Eligible Countries, the Working Group, as noted above, recognized that the Funders must also share in this responsibility.

8. It is critical that the Designated Supplier have adequate manufacturing capacity to meet all of the requirements of the Eligible Countries, not just the Approved Maximum amount of product. The Guarantee Agreement requires that the Designated Supplier use commercially reasonable efforts in this regard, but a higher standard, such as best efforts or an absolute obligation, may be preferable in certain circumstances. In addition, as noted below, consideration needs to be given to the contract remedy if the Designated Supplier fails to establish adequate manufacturing capacity, or otherwise to meet its supply requirements, under the Guarantee Agreement, particularly once the Guaranteed Price commitment has been exhausted.

9. The Working Group recognized that it would be extremely costly to create an Independent Adjudication Committee that was fully capable of evaluating, approving and monitoring the Eligible Vaccines and their ongoing production. Accordingly, the Guarantee Agreement permits the Independent Adjudication Committee to rely on third parties and their procedures, such as the WHO and its prequalification process.

10. Compliance with the Foreign Corrupt Practices Act was imposed to alleviate concern that illegal payments might be used to generate demand. Obviously, the purpose of the advance market commitment is to generate orders for vaccines that will be used, not to simply to generate orders for vaccines.

11. The Working Group recognized the tension between the need for certainty in the determinations of the Independent Adjudication Committee and the need for some review. Court review was deemed impractical in most circumstances. Instead, the goal is to create an IAC that would be viewed as independent by all participants in the Framework, but that is subject to review if it exceeds or abuses its authority, and with respect to certain critical decisions such as a decision to alter or terminate the Funder's payment obligation in the face of a force majeure event, as discussed in note 15 below.

12. The Guarantee Agreement requires that the Designated Supplier continue to make Approved Vaccines available even after the Funding Period expires on a cost-plus basis subject to a cap. If there are multiple Designated Suppliers, the cap will be increased for a limited time for any Designated Supplier that does not receive a certain minimum percentage of the Maximum Guaranteed Amount during the Funding Term, which amount is defined as the Minimum Gross Sales Amount. The increase will cease to be effective, and the cap will return to the predetermined amount, once the Designated Supplier's aggregate sales equal the Minimum Gross Sales Amount. The Minimum Gross Sales Amount is intended to be a rough proxy for a return on the Developer's investment in the Eligible Product, but cannot exceed 100% of the Maximum Guaranteed Amount. For simplicity, the term sheet includes a cost-plus formula, subject to a cap, for determining the ongoing supply price, but it is possible to include more complex hybrid options. For example, a formula could be employed that would allow the Designated Supplier to share in the benefits of reducing the cost of production. In any event, setting the ongoing supply price is a critical component of the advance market commitment.

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| **9. Intellectual Property:** | The Designated Supplier shall own all right, title and interest in and to the Approved Vaccine; provided, however, if the Designated Supplier fails to supply Approved Vaccine in the Eligible Countries as required in Section 8 during the Funding Term or the Supply Term and, in any event, within 2 years prior to the expiration of the Supply Term, the Designated Supplier shall grant Funder, or its designee, a non-exclusive, irrevocable, perpetual, license (with the right to sublicense) solely to make, have made, use, sell, offer for sale and import the Approved Vaccine in any Eligible Country, but Funder shall not have rights to any other products and shall have no rights outside the Eligible Countries, except the right to make and have made Approved Vaccine for use in Eligible Countries. The license grant shall be royalty-free, unless the Designated Supplier has not been paid the Minimum Gross Sales Amount, in which case such grant shall be subject to a royalty of [__]% of net sales until such time as the aggregate royalty payments to the Designated Supplier equal the product of (a) [__]%, multiplied by (b) the amount, if any, by which the Minimum Gross Sales Amount exceeds the aggregate Gross Sales of the Approved Vaccine, whereupon such vaccine will be fully paid and no further royalties shall be due.[13] |
| **10. Representation and Warranties:** | [TBD] |
| **11. Indemnification:** | The Designated Supplier will defend and indemnify the Funder and the members of the Independent Adjudication Committee from all claims and losses arising out of or related to (a) the use of the Approved Vaccine, including claims and losses for physical or mental injury (including death) and (b) infringement or misappropriation of intellectual property.[14] |
| **12. Term:** | The Guarantee and Supply Agreement shall begin on the date that the Committee designated the first Approved Vaccine and continue through such time as the Maximum Guaranteed Amount has been paid (the **"Funding Term"**), and, thereafter, until the end of the Supply Term, unless earlier terminated pursuant to Section 13. |
| **13. Termination:** | The Guarantee and Supply Agreement may be terminated by either party in the event of a material breach that is not cured within 30 days of notice thereof from the non-breaching party.<br>In addition, Funder shall have the right to terminate the Guarantee and Supply Agreement (a) with respect to a particular Designated Supplier in the event the Independent Adjudication Committee determines that the Approved Vaccine of that Designated Supplier no longer satisfies the technical specifications and usability requirements set forth in Sections 8 and 9 of the Framework Agreement, or (b) in the event of a *force majeure* event as determined by the Independent Advisory Committee as set forth in Section 22 of the Framework Agreement.[15] |

13. If the Designated Supplier of an Approved Vaccine fails to meet its supply requirements under the Guarantee Agreement, it would be required to grant the Funder, or its designee, a non-exclusive, royalty-free (except as necessary to provide the Designated Supplier with the Minimum Gross Sales Amount, as described above) license to exploit the Approved Vaccine only in Eligible Countries. Although less than ideal, this is intended to make the relevant technology available to the Funder if the Designated Supplier breaches its obligations under the Guarantee Agreement. However, because this provision may not provide much of an incentive not to breach, especially if a Designated Supplier has already received the Maximum Guaranteed Amount and because, even with this license, there could be a disruption of supply, potential Funders may wish to consider other penalties that would disincentivize a Designated Supplier from breaching, such as liquidated damages provisions.

14. Indemnification was deemed to be particularly important to attract qualified members to serve on the Independent Adjudication Committee. It is contemplated that this indemnification would be similar to that which is provided for directors and officers of corporations.

15. A *force majeure* provision permitting the Funder to alter the Guarantee Agreement based upon extraordinary events has been included. The *force majeure* clause would permit the Independent Adjudication Committee to void or alter the Guarantee Agreement in the event of major changes to technology or disease epidemiology that render a vaccine either inappropriate or unnecessary. For example, if advances in pesticides substantially reduced the incidence of malaria in Eligible Countries, then the Funder's financial obligation would be reduced accordingly. As noted in Section 7 of the Guarantee Agreement term sheet, Schedule C would include criteria, such as assumptions underlying the Framework Agreement, to guide the Independent Adjudication Committee in taking any such extraordinary action, which, as noted in the Framework Agreement term sheet, would be subject to review.

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| **14. Addition of New Designated Suppliers:** | If the Independent Adjudication Committee determines (by a 2/3 vote of its members and using the standards specified in Schedule B of the Framework Agreement) that a newly developed vaccine is superior to the previously selected Approved Vaccine, whether for certain target populations or epidemiological conditions or otherwise, and the Developer of the newly developed vaccine elects to become a party to the Guarantee Agreement, the Developer of the new vaccine shall be deemed a "Designated Supplier", the new vaccine shall be deemed an "Approved Vaccine" and the new Designated Supplier shall have the right to compete with the original Designated Supplier to make Qualified Sales of the new Approved Vaccine in the Eligible Countries under the Guarantee Agreement.[16] The addition of new Designated Suppliers and Approved Vaccines shall, in each case, be subject to the cap on Sponsor's total commitment set forth in Section 7. |
| **15. Remedies in the Event of Breach:** | [TBD] |
| **16. Dispute Resolution:** | [Arbitration under AAA rules in NY, NY]. |
| **17. Governing Law:** | [New York law]. |
| **18. Waiver of Immunity:** | If the Funder is a sovereign, it will (a) acknowledge that the transactions are subject to private commercial law, and (b) waive sovereign immunity. |
| **19. Other Provisions:** | Other covenants, terms and provisions as requested by legal counsel to Funder or the Designated Supplier. |

16. The Working Group devoted considerable discussion to the question of whether more than one Developer would be permitted to receive payments under the Guarantee Agreement. On the one hand, the Working Group felt that it was important to preserve incentives for product improvements and that it would be important to use superior products should they be developed. On the other hand, the Working Group was concerned companies might be less willing to risk large investments in early research if they faced the prospect of entry of "me too" products offering no significant advance over the original vaccine. However, many of the industry participants interviewed by the Working Group indicated that they would prefer to have multiple suppliers over a winner-takes-all approach. Recognizing that independent research may lead to the development of substantially similar products, another option would be to permit any qualifying vaccines, whether or not superior, that are tendered within a window (*e.g.,* one year) after the approval of the initial Approved Vaccine to be accepted without showing superiority, provided that the second vaccine resulted from independent research and is not simply a generic copy.

## Schedule A to model term sheet for Guarantee and Supply Agreement

### Base Price, Guaranteed Price and Approved Maximum

A. Base Price. The minimum Base Price shall be an amount not less than [$__] per Dose (as defined in Schedule B).

B. Guaranteed Price.

C. Approved Maximum (quantity of vaccine in Doses).

## Schedule B to model term sheet for Guarantee and Supply Agreement

### Criteria for Qualified Sales

#### A. Buyer Criteria.

1. Buyers Included. Qualified Buyer include (a) UNICEF, (b) WHO, (c) Pan American Health Organization, (d) any individual Eligible Country that is purchasing for the benefit of the public sector or local nonprofits, and (e) and any other buyer approved by the Independent Adjudication Committee.

2. Buyers Excluded. A pharmaceutical company, acting directly or indirectly thorough one or more intermediaries, shall not qualify as a Qualified Buyer.

#### B. Sales Criteria.

1. Course of Treatment. A single course of treatment, regardless of the number of individual immunizations, required to provide the desired efficacy and duration of protection shall be deemed a single "Dose" and shall constitute a single sale. For example, if 3 immunizations over a period of 2 years are required to achieve the desired efficacy and duration of protection, then the sale of all 3 immunizations, one Dose, shall be required to constitute a Qualified Sale.

2. Bundled Sales. In the event that the Designated Supplier bundles the sale of the Approved Vaccine to a purchaser with the sale or licensing of another product or service of the Designated Supplier or its affiliates, the Designated Supplier shall reasonably assign prices to (allocate revenue amounts between) the Approved Vaccine and such other products or services sold or licensed by the Designated Supplier or its affiliates to the purchaser, in accordance with the terms set forth in Exhibit B1 in order to ensure that the Designated Supplier has attributed a reasonable and equitable portion of that sale to the Approved Vaccine.

3. No Top Up. The Designated Supplier shall not seek or receive any additional compensation or value for the sale of the Approved Vaccine in an Eligible Country other than compensation from the purchaser in the form of the Base Price and the compensation from the Funder under the terms of the

Guarantee and Supply Agreement; provided, however, that the Designated Supplier may seek and receive additional compensation or value if (a) additional Funders are added to the Guarantee and Supply Agreement by amendment, or (b) approved by the Independent Adjudication Committee in writing.

4. Use in an Eligible Country. If the Approved Vaccine is purchased for use in a particular Eligible Country, the Designated Supplier must have a reasonable expectation that the Approved Vaccine will actually be used in such Eligible Country. For purposes of illustrating the foregoing, if UNICEF, as it presently operates, certifies that a country has certain requirements for the Approved Vaccine, then the Designated Supplier will have a reasonable expectation that such requirements of the Approved Vaccine will actually be used in such country.

### C. Other Criteria.

[*TBD*]

## Schedule C to model term sheet for Guarantee and Supply Agreement

### Eligible Countries

[*Insert e.g. Vaccine Fund–eligible countries.*]