African Vaccine Manufacturing Accelerator (AVMA):

application for in-principle eligibility

**1. Application to AVMA[[1]](#footnote-2)**

**Applicant Information**

|  |  |
| --- | --- |
| Applicant Name/Legal Entity |  |
| Please confirm that Applicant is the WHO prequalification holder of the Qualifying Vaccine |  |

**Applicant Group**

|  |  |
| --- | --- |
| Please provide a corporate structure chart incorporating all the companies in the Applicant’s group (with company registration numbers). The chart should include all companies controlled by the Applicant and companies controlling the Applicant, and companies under common control with the Applicant. |  |
| Has any company controlled by the Applicant, under the control of Applicant or under common control with Applicant benefited from any AVMA payment? (Yes/No).If "Yes", please provide details. |  |
| Please explain how the management and decision-making of any manufacturing facilities used by the Applicant are controlled, whether by the Applicant or another third party. |  |

**Product Profile**

|  |  |
| --- | --- |
| Vaccine Name(s): |  |
| Presentation(s): |  |
| Formulation(s):  |  |
| Name of Marketing Authorisation holder on which WHO prequalification is based |  |
| Name of National Regulatory Authority on which WHO prequalification is based |  |
| Product or Drug Substance licensor(s) (if relevant) |  |

**Manufacturing Locations**

|  |  |
| --- | --- |
| Manufacturing site locations listed in the WHO PQ application |  |
| Site(s) of antigen(s) Drug Substance manufacturing |  |
| Site(s) of Fill and Finish manufacturing |  |

**Milestone Application (AVMA Priority vaccines and AVMA Priority technology platforms)**

|  |  |
| --- | --- |
| Has the Applicant had their final WHO prequalification site inspection? (Yes/No) |  |
| Detailed description of all manufacturing step(s) performed by Applicant (i.e. Fill and Finish or Drug Substance) |  |
| If Drug Substance is manufactured, technology platform used to manufacture the Drug Substance |  |
| Legal entities other than Applicant performing Fill and Finish or Drug Substance manufacturing for the product/platform |  |

**Accelerator Application**

|  |  |
| --- | --- |
| Legal entities other than Applicant performing Fill and Finish or Drug Substance manufacturing for the product |  |

*The manufacturer is required to inform Gavi of any changes to the information submitted in this application form which arise at any time prior to Milestone payment or UNICEF tender award (as the case may be).*

*In addition to the information provided in this application form, manufacturers who receive a positive assessment of in-principle eligibility may be requested from time to time to participate in monitoring, learning and evaluation exercises over the lifespan of AVMA and contribute information, learning and perspectives through these exercises*.

**2. AVMA Eligibility Justification**

Please provide below a detailed description of product eligibility for AVMA with reference to both **Vaccine Type** and **Manufacturing Type**, as those terms are defined within the AVMA Guidance for Manufacturer (<https://www.gavi.org/news/document-library/AVMA-Guidance-for-Manufacturers>). This written justification should comprehensively address all of the eligibility criteria. Gavi reserves the right to ask for additional information in relation to the description provided by the Applicant or any other information provided within this Application.

*(maximum 1000 words)*

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1. In case any information contained in this Application Form is inconsistent with the information provided in the AVMA Guidance for Manufacturers, please refer to the AVMA Guidance for Manufacturers. Additional definitions for capitalised terms are also available in the AVMA Guidance for Manufacturers. [↑](#footnote-ref-2)