Section A: Applicant Information

A1. Details of individual submitting the application on behalf of the company

Name

Responsibility

Email

Company Name

Section B: Health Products Expertise

B1. Describe your experience in the manufacturing of in vitro diagnostics (IVDs); specify whether your assays are based on lateral flow, ELISA, PCR, or other technology.

B2. Describe your experience in the manufacturing of other health products *for example: Biological Materials for IVDs, Medical Devices, Medicines, etc. (mention only the product categories).*

B3. Which of the following best describes your entity.

- Small or Medium Enterprise ☐
- Large Enterprise ☐
- Institution ☐
- Other ☐

Other

B4. **How many production and quality system staff does your entity have?**

B5. **Describe the scope of current manufacturing activities (e.g. packaging and assembly, reagent manufacture, strips manufacture, full manufacture, etc.)**

Section C: Manufacturing Capacity

C1. **If you are an established IVD manufacturer, indicate (for all IVDs) the quantity of IVDs sold for use in LMICs in the last year.**

C2. **If you are an established IVD manufacturer, indicate (for all IVDs) the number of kits/tests sold for use in LMICs in the last year.**

Section D: Geographical Presence

D1. **List the LMICs where you have registered IVDs with Regulatory Authorities.**

D2. **List LMICs where you actively sell IVDs, if applicable.**

D3. **Please identify any public health procurement agencies you are currently working with. Please list the product categories sold to such agencies.**

Section E: Manufacturer's Quality Management System certification status

E1. **Are you certified ISO 13485:2016 ?**

Yes [Specify scope of certification and the certifying body/authority in the comment box.] ☐

No ☐

E2. **Are you certified ISO 9001:2015?**

Yes [Specify the certifying body/authority for your certification] ☐

No ☐

E3. **Other certifications, e.g. GMP (please specify the regulatory authority)?**

E4. **Attach all relevant documents and certifications for each site.**

Section F: Product Regulatory Approvals

F1. **Provide details of any IVDs you manufacture that are prequalified by WHO.**

F2. **Provide details of any IVDs you manufacture that have been granted a regulatory approval by a Regulatory Authority (please specify) or a CE Certification by a designated EU Notified Body.**

F3. **Provide details of any IVD biological starting material you manufacture and the details of any regulatory approvals obtained.**

F4. **Provide details of any medical devices (other than IVDs) you manufacture, and the details of any regulatory approvals obtained.**

F5. **Provide details of any medicines manufactured and any regulatory approvals obtained.**

Section G: Manufacturer's Regulatory Capacity

G1. **Do you have responsibility for all key manufacturing and regulatory activities, including outsourced activities?**

G2. **Provide a detailed description of your own facility(ies) or shared facilities, i.e., premises, laboratories, equipment, staff etc..**

G3. **Does your company currently undertake post market surveillance and vigilance reporting?**

G4. **In the last two years, were there any Field Safety Corrective Actions, recalls of your products, and has your company received any warning letters or any inspection designated as OAI (Official Action indicated) by USFDA, or a similar action by other Regulatory Authorities or Accredited Certification Body?**

G5. **Does your company currently use a Unique Device Identification system (UDI)?**

Yes ☐

No [explain your plans to beings begin employing UDI] ☐

Section H: Innovation

H1. **Do you have any examples of innovative and cost-effective processes that you have developed?**

Yes ☐

No ☐

H2. **Indicate IVD type (e.g. lateral flow, ELISA, PCR, etc.) and specific IVD and/or biological starting material produced for the manufacture of specific IVD(s).**

H3. **What types of cost reductions were you able to achieve (indicative)?**

H4. **Did you develop and register any intellectual property? [Provide a detailed description]**

Section I: Financials

I1. **Provide your three-year financial history (please include Consolidated Balance Sheet, Income Statement, Cash Flow Statement, Manufacturing expenditure, and R&D expenditure).**

I2. **What percent share of your net revenue from all products is from LMICs?**

I3. **What percent share of your net revenue is from IVDs?**

I4. **Indicate the specific financial investment you plan to make for the development and/or manufacturing of the RDT (in this call for applications).[Please indicate if you do not envisage any new investment.]**

Section J: Details of existing manufacturing facilities

Please complete the information requested below for your current manufacturing facilities for IVDs

J1. **Name of facility.**

J2. **Location (Country, City, Area).**

J3. **Type of IVD (e.g. lateral flow, ELISA, PCR, etc.) facility.**

J4. **Type of biological material facility (if manufactured).**

J5. **Estimated annual IVD manufacturing capacity.**

Section K: Details of new manufacturing facility

Please complete the information requested below for your planned manufacturing facilities for IVDs

K1. **Name of facility.**

K2. **Location (Country, City, Area).**

K3. **Planned annual IVD manufacturing capacity.**

K4. **Expected timelines (please provide all that apply below):**

Facility Completion.

K5. **First expected commercial production date.**

Section L: Product Strategy and Timelines

L1. **What is your intended use for this sublicence ?**

- [ ] Manufacture, sell and distribute IVDs
- [ ] Manufacture, sell and distribute IVDs and biological products
- [ ] Other

Other

L2. **What is your organisation's approach to sourcing biological starting materials for the IVDs covered by this sublicense (own biological starting materials, outsourced biological starting materials, etc.)?**

L3. **Which RDT(s) covered by this license are you interested in manufacturing.**

- [ ] COVID-19
- [ ] HIV
- [ ] HIV/Syphilis
- [ ] Hepatitis
- [ ] Malaria
- [ ] Other

Other

L4. **Indicate your current status of development.**

L5. **Estimated timelines for development.**

L6. **Proposed dossier submission date (mm/yy) to WHO or another Regulatory Authority (please specify), after signing of the sublicense.**

L7. **List LMICs where you propose to file and distribute the IVDs using this sublicense, including an average estimated filing timeline from your submission date.**

L8. **Describe key milestones such as design locked date, validation batches, stability data analysis, external laboratory evaluation and dossier submission.**

L9. **Provide a three-year forecast from the date of receipt of the IVD sublicense, including timelines based on the ramp-up of capacity and the quantity of IVD you plan to manufacture annually, including the number of individual tests.**

L10. **Explain your plans for manufacturing, distribution, and marketing in the short- and mid-term for the IVD being considered. Describe how it fits with the strategy of your company.**

L11. **Upload any additional supporting information that compliments information provided in the application.**

Thank you for completing the call for application form.

For any queries send an email to HTAPsublicenses@who.int