

# Questionnaire

**Request for Information on Therapeutics Development**

**and Manufacturing for COVID-19**

**Reference:** **UNITAID/RFI/TDM/2020**

**Issue Date: 3 November 2020**

**Closing Date: 20 November 2020**

**Disclaimer Notice and Confidentiality**

This Request for Information (RfI) is issued by Unitaid, on behalf of the Access To COVID-19 Tools Accelerator (ACT-A) Therapeutics Partnership, solely for ACT-A’s planning purposes. It should not be regarded as a Call for Proposals or Request for Tender. Any information submitted in response to this RfI is provided to Unitaid on a voluntary basis. Neither Unitaid nor its ACT-A partners shall be under any obligation to procure any of the services or products described herein and the issuance of this RFI shall not be construed as a commitment by Unitaid or its ACT-A partners to enter into commercial or other business relations. Unitaid may use the information provided by respondents to the RfI to support strategic decisions and planning within ACT-A, or for its own internal purposes, including but not limited to, the design of future Calls for Proposal or other solicitations which may be issued by Unitaid or its ACT-A partners.

Any information submitted in response to this RfI that needs to be treated as “confidential” should be clearly marked as such on the completed form by the respondent. When information is marked confidential, Unitaid will take all reasonable measures to keep the information confidential and will not share it with other entities or individuals outside Unitaid without the respondent’s written authorization. However, this confidentiality commitment shall not apply if the information concerned, or any part of it: (a) was known to Unitaid prior to any disclosure by the respondent; or (b) was in the public domain at the time of disclosure by the respondent; or (c) becomes part of the public domain through no fault of Unitaid; or (d) becomes available to the Unitaid from a third party who is not in breach of any legal obligation of confidentiality to the respondent. Information not marked as confidential will nevertheless not be shared with other entities or individuals outside Unitaid without the respondent’s written authorization, unless that information has been anonymized or aggregated by Unitaid to deter identification of individual companies (e.g., used without specifying individual Company or Organization names, product names, geographical location). For the avoidance of doubt, the above restrictions on the sharing of both confidential and non-confidential information shall also apply with respect to any sharing of information with Unitaid’s ACT-A partners.

Table of Contents

[Questionnaire 1](#_Toc55249137)

[**Group 1: Novel Small molecules and Novel Biotherapeutics** 4](#_Toc55249138)

[**1.** **Organization profile** 4](#_Toc55249139)

[**2.** **Operational landscape** 4](#_Toc55249140)

[**3.** **Product scope** 5](#_Toc55249141)

[**4.** **Production capacity** 7](#_Toc55249142)

[**5.** **Commercialization and global access plans** 9](#_Toc55249143)

[**6.** **Potential Opportunities for collaboration** 10](#_Toc55249144)

[**7.** **Challenges and Constraints** 11](#_Toc55249145)

[**8.** **Potential Interventions and Innovation** 12](#_Toc55249146)

[**Group 2: Expansion of Biotherapeutics Manufacturing** 13](#_Toc55249147)

[**1.** **Organization Profile** 13](#_Toc55249148)

[**2.** **Operational landscape** 13](#_Toc55249149)

[**3.** **Product scope** 14](#_Toc55249150)

[**4.** **Production capacity** 16](#_Toc55249151)

[**5.** **Commercialization and global access plans** 17](#_Toc55249152)

[**6.** **Potential Opportunities for collaboration** 18](#_Toc55249153)

[**7.** **Challenges and Constraints** 19](#_Toc55249154)

[**8.** **Potential Interventions and innovations** 20](#_Toc55249155)

[**Group 3: Expansion of New/Experimental Small molecules Manufacturing** 21](#_Toc55249156)

[**1.** **Organization Profile** 21](#_Toc55249157)

[**2.** **Operational landscape** 21](#_Toc55249158)

[**3.** **Product scope** 22](#_Toc55249159)

[**4.** **Production capacity** 24](#_Toc55249160)

[**5.** **Commercialization and global access plans** 25](#_Toc55249161)

[**6.** **Potential opportunities for collaboration** 26](#_Toc55249162)

[**7.** **Challenges and constraints** 27](#_Toc55249163)

[**8.** **Potential Interventions and innovation** 28](#_Toc55249164)

[**Annex 1: Additional information on product development** 29](#_Toc55249165)

**General Information:** The questionnaire is divided into three groups as shown below. Please select the group that best suits your organization and complete relevant sections of the form.

In the event that a respondent company/organization/entity might be interested in responding to more than one category, this should be indicated as well. Any response previously indicated in another section should be clearly referenced as applicable.

[ ]  **Group 1: Novel Small Molecules and Novel Biotherapeutics Development**

**Target respondent:** Originator industry partners, academia and Product Development Partnerships (PDPs) that have **novel COVID-19** medicines (**small molecules and/or biotherapeutics)** currentlyin development.

[ ]  **Group 2: Expansion of Biotherapeutics Manufacturing**

**Target respondent:** Industry partners with experience in the development and manufacturing of quality-assured biotherapeutics with plans/interest in supporting development and production of **COVID-19 biotherapeutics (including similar or identical biotherapeutics)** **for LMICs.** This category may include CMOs and CDMOs.

[ ]  **Group 3: Expansion of New/Experimental Small molecules Manufacturing**

**Target respondent:** Industry partners with experience in the development and manufacturing of quality-assured small molecules medicineswith plans/interest in supporting development and production of **generics of new (and experimental) small molecules** medicines **for COVID-19 for LMICs**. These may include CMOs and CDMOs.

**Group 1: Novel Small molecules and Novel Biotherapeutics**

**Target respondent:** originator industry partners, academia and PDPs that have novel COVID-19 medicines (small molecules and/or biotherapeutics) in development.

1. **Organization profile**

Organization Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_

Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_

Phone Number(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_

Email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_

Contact person(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_

………………………………………………………………………………………………………………………………………………………………….

1. **Operational landscape**

Please identify which of the following are within your scope of operation and specify the mode of operation (in-house or outsourced).

|  | *In-house*  | *Outsourced* |
| --- | --- | --- |
| *Clinical development*  |
| [ ]  Phase I | [ ]   | [ ]   |
| [ ]  Phase II | [ ]   | [ ]   |
| [ ]  Phase III | [ ]   | [ ]   |
| *Product development* |  |  |
| [ ]  Drug substance development /Active Pharmaceutical Ingredient | [ ]   | [ ]   |
| [ ]  Process development  | [ ]   | [ ]   |
| [ ]  Formulation development | [ ]   | [ ]   |
| [ ]  Drug product development/Finished Pharmaceutical Product | [ ]   | [ ]   |
| [ ]  Analytical development and Quality Control Services | [ ]   | [ ]   |
| [ ]  Technology Transfer[[1]](#footnote-1) | [ ]   | [ ]   |
| [ ]  Other(s)……………………………………………..… (please specify)  | [ ]   | [ ]   |

|  | *In-house* | *Outsourced* |
| --- | --- | --- |
| *Commercial (Large/scale up) Manufacturing*  |
| [ ]  Drug product /Finished Pharmaceutical Product manufacturing | [ ]   | [ ]   |
| [ ]  Drug substance /Active Pharmaceutical Ingredient manufacturing | [ ]   | [ ]   |
| [ ]  Fill & Finish, packaging (biotherapeutics) | [ ]   | [ ]   |
| [ ]  Packaging (small molecules) | [ ]   | [ ]   |
| *Regulatory and licensing*  |
| [ ]  Marketing authorization submission | [ ]   | [ ]   |
| [ ]  Intellectual Property licensing  | [ ]   | [ ]   |
| [ ]  Other(s)…………………………………………………….. (please specify) | [ ]   | [ ]   |

1. **Product scope**
2. Please specify which COVID-19 novel small molecules and/or novel biotherapeutics are currently in development by your organization.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Product Category* | Intended route of delivery  | *Product Name(s)* | *Development* | *Manufacturing* |
|  |  |  | ***In-house development***  | ***In-house*** | ***Contract*** |
| [ ]  Novel monoclonal antibodies (mAbs) | [ ]  IV[ ]  SC/IM[ ]  Others, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | [ ]  | [ ]  | [ ]  |
| [ ]  Novel Small Molecules | [ ]  Oral[ ]  IV[ ]  SC/IM[ ]  Others, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | [ ]  | [ ]  | [ ]  |
| [ ]  Others …………………………………(please specify) | [ ]  Oral[ ]  IV[ ]  SC/IM[ ]  Others, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | [ ]  | [ ]  | [ ]  |

1. Please specify if you are working on particular optimization activities for products on development (e.g. low-dose clinical trials).
2. Please describe any existing and/or in-process licensing agreement or technology transfer operation(s) for the product(s) in question.
3. **Production capacity**
	1. Please state the current and planned production capacity by geographic location for **novel biotherapeutics** product manufacturing. Please include notes on capacity that could be repurposed/assigned for COVID-19 biotherapeutics product(s) manufacturing.

|  |  |  |  |
| --- | --- | --- | --- |
| *By Geographic locations of manufacturing facility* | *Current annual production capacity**please specify* | *Planned production capacity**please specify* | Notes on potential spare capacity and capacity optimization |
| *Drug Substance* | *Drug Product* | *Drug Substance* | *Drug Product* |  |
| [ ]  Global  |  |  |  |  |  |
| [ ]  Africa |  |  |  |  |  |
| [ ]  Asia |  |  |  |  |  |
| [ ]  Oceania (incl. Australia and New Zealand) |  |  |  |  |  |
| [ ]  Europe(incl. Russian Federation and UK) |  |  |  |  |  |
| [ ]  North America |  |  |  |  |  |
| [ ]  South America |  |  |  |  |  |
| [ ]  Latin America and the Caribbean  |  |  |  |  |  |
| [ ]  Central America  |  |  |  |  |  |

* 1. Please state what is the current and planned production capacity by geographic location for **novel small molecules** product manufacturing. Please include notes on capacity that could be repurposed/assigned for novel COVID-19 small molecule product manufacturing.

|  |  |  |  |
| --- | --- | --- | --- |
| *By Geographic locations of manufacturing facility* | *Current annual production capacity**please specify* | *Planned production capacity**please specify* | Notes on potential spare capacity and capacity optimization |
| *API* | *FPP* | *API* | *FPP* |  |
| [ ]  Global  |  |  |  |  |  |
| [ ]  Africa |  |  |  |  |  |
| [ ]  Asia |  |  |  |  |  |
| [ ]  Oceania (incl. Australia and New Zealand) |  |  |  |  |  |
| [ ]  Europe(incl. Russian Federation and UK) |  |  |  |  |  |
| [ ]  North America |  |  |  |  |  |
| [ ]  South America |  |  |  |  |  |
| [ ]  Latin America and the Caribbean  |  |  |  |  |  |
| [ ]  Central America  |  |  |  |  |  |

* 1. Please provide details of the facilities that serve locations beyond their local markets (i.e., outside the same geographic territory as production).
1. **Commercialization and global access plans**
	1. Please provide summary of your commercialization plans for each of the COVID-19 pipeline products in development (novel small molecules and/or novel biotherapeutics), including regions (or countries) and timelines. **Information on plans for LMICs should be included.**
2. Please provide summary of any plans to ensure global access to the COVID-19 pipeline products (novel small molecules and or novel biotherapeutics), especially plans to ensure they are made widely available in LMICs, as quickly as possible and on a continuing basis, at an affordable and sustainable price and in sufficient quantities to meet the needs of LMICs. Include any specific plan to enable expanding supply (including licensing, tech transfer and, as relevant, access to cell lines, access to QC assays used in production, access to clinical data, etc.).

1. **Potential Opportunities for collaboration**
2. Would your organization be interested in or willing to collaborate in any initiative to ensure novel COVID-19 therapeutics (small molecules and/or biotherapeutics) are made widely available in LMICs, as quickly as possible and on a continuing basis, at an affordable and sustainable price and in sufficient quantities to meet the needs of LMICs? These may include interventions in development, manufacturing and commercialization.

[ ]  Yes

[ ]  No

[ ]  Undecided

1. If yes, please describe your organization’s interests in collaboration and resources available for such activities.

1. **Challenges and Constraints**
2. Please describe the challenges and constraints you are experiencing with the **development and commercial scale production** of novel therapeutics (small molecules and/or biotherapeutics) for COVID-19.
3. Please describe the primary challenges and constraints for **commercialization and global access** for LMICs for the novel therapeutics (small molecules and/or biotherapeutics) for COVID-19 (e.g regulatory approval, licensing agreements).
4. **Potential Interventions and Innovation**
	1. Please identify any additional resource(s) or interventions that your organization may require (if applicable) **to contribute effectively to equitable access** to COVID-19 therapeutics in LMICs.

[ ]  Visibility on market demand (models, granular demand forecasts)

[ ]  Demand generation, catalytic product introduction at country level

[ ]  Production capacity upgrade

[ ]  Incentives (volume guarantee, advance purchase commitment)

[ ]  Global regulatory and policy support

[ ]  WHO Prequalification

[ ]  Regulatory and registration support in countries

[ ]  Others (please specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. Provide any other **innovative approach or idea(s)** to improve the COVID-19 novel therapeutics (small molecules and/or biotherapeutics) development and landscape.

**Group 2: Expansion of Biotherapeutics Manufacturing**

**Target respondent:** Industry partners with experience in the development and/or manufacturing of quality-assured biotherapeutics with plans/interest in supporting development and production of **COVID-19 biotherapeutics (including similar or identical biotherapeutics) for LMICs**. This category may include CMOs and CDMOs.

1. **Organization Profile**

Organization Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_

Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_

Phone Number(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact person(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

………………………………………………………………………………………………………………………………………………………………….

1. **Operational landscape**
2. Please identify which of the following are within your scope of operation and specify the mode of operation (in-house or outsourced).

|  |  |  |
| --- | --- | --- |
|  | *In-house*  | *Outsourced* |
| *Product development*  |
| [ ]  Drug substance development  | [ ]   | [ ]   |
| [ ]  Process development  | [ ]   | [ ]   |
| [ ]  Formulation development | [ ]   | [ ]   |
| [ ]  Drug product development | [ ]   | [ ]   |
| [ ]  Analytical development and Quality Control Services | [ ]   | [ ]   |
| [ ]  Other(s)…………………… please specify  | [ ]   | [ ]   |
| *Commercial scale up Manufacturing*  |
| [ ]  Drug Product manufacturing | [ ]   | [ ]   |
| [ ]  Fill & Finish, packaging | [ ]   | [ ]   |
| *Regulatory and licensing*  |
| [ ]  Marketing authorization submission  | [ ]   | [ ]   |
| [ ]  Other(s)…………………… please specify | [ ]   | [ ]   |

1. **Product scope**
2. Please specify your experience with development or manufacturing of COVID-19 biotherapeutic products (similar or authentic biotherapeutics).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Product Category* | Intended route of delivery /administration | *Product Name(s)* | *Development* | *Manufacturing* |
|  |  |  | ***In-house development***  | ***In-house*** | ***Contract*** |
| [ ]  Monoclonal antibodies (mAbs) | [ ]  IV[ ]  SC/IM[ ]  Others, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | [ ]  | [ ]  | [ ]  |
| [ ]  Other biotherapeutics  | [ ]  Oral[ ]  IV[ ]  SC/IM[ ]  Others, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | [ ]  | [ ]  | [ ]  |
| [ ]  Others …………………………………(please specify) | [ ]  Oral[ ]  IV[ ]  SC/IM[ ]  Others, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | [ ]  | [ ]  | [ ]  |

1. Are you currently collaborating with an originator/developer of novel COVID-19 biotherapeutics to increase production capacity of any of the identified COVID-19 products above?

[ ]  Yes

[ ]  No

[ ]  Not applicable

1. Please specify experience with different dosage forms (mark x as applicable).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Dosage form | Yes | No | If yes,No of years of experience | Example of products with WHO PQ or WHO Listed Authorities Level 4[[2]](#footnote-2) |
| Injectables ready for use | [ ]   | [ ]   |  |  |
| Lyophilized powder for reconstitution | [ ]   | [ ]   |  |  |
| Others (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]   | [ ]   |  |  |

1. Please describe any existing/in-process licensing agreement and/or technology transfer process for the products listed above.

1. **Production capacity**
2. Please specify current and planned production capacity by geographic location for **biotherapeutics** product manufacturing. Please include notes on current capacity that could be assigned/repurposed for COVID-19 biotherapeutics product manufacturing.

|  |  |  |  |
| --- | --- | --- | --- |
| *By Geographic locations of manufacturing facility* | *Current annual production capacity**please specify* | *Planned production capacity**please specify* | Notes on potential spare capacity and capacity optimization |
| *Drug Substance* | *Drug Product* | *Drug Substance* | *Drug Product* |  |
| [ ]  Global  |  |  |  |  |  |
| [ ]  Africa |  |  |  |  |  |
| [ ]  Asia |  |  |  |  |  |
| [ ]  Oceania (incl. Australia and New Zealand) |  |  |  |  |  |
| [ ]  Europe(incl. Russian Federation and UK) |  |  |  |  |  |
| [ ]  North America |  |  |  |  |  |
| [ ]  South America |  |  |  |  |  |
| [ ]  Latin America and the Caribbean  |  |  |  |  |  |
| [ ]  Central America  |  |  |  |  |  |

1. Please provide details of the facilities that serve locations beyond their local markets (i.e., outside the same geographic territory as production).
2. **Commercialization and global access plans**
	1. Please provide summary of your commercialization plans for each of the COVID-19 pipeline products in development (biotherapeutics), including regions (or countries) and timelines. Information on plans for LMICs should be included.

* 1. Please provide summary of any plans to ensure global access to the COVID-19 pipeline products (biotherapeutics), especially plans to ensure they are made widely available in LMICs, as quickly as possible and on a continuing basis, at an affordable and sustainable price and in sufficient quantities to meet the needs of LMICs. Include any specific plan to enable expanding supply.

1. **Potential Opportunities for collaboration**
2. Would your organization be interested in or willing to collaborate in any initiative to ensure COVID-19 biotherapeutics are made widely available in LMICs, as quickly as possible and on a continuing basis, at an affordable and sustainable price and in sufficient quantities to meet the needs of LMICs? These may include interventions in development, manufacturing and commercialization.

[ ]  Yes

[ ]  No

[ ]  Undecided

1. If yes, please describe your organization’s interests in collaboration and resources available for such activities.
2. **Challenges and Constraints**
	1. Please describe the challenges and constraints you are experiencing with the **development and commercial scale production** of biotherapeutics for COVID-19.
	2. Please describe potential primary challenges and constraints to **commercialization and global access** to biotherapeutics for COVID-19 for LMICs.
3. **Potential Interventions and innovations**
4. Please identify any additional resource(s) or interventions that your organization may require (if applicable) to **contribute effectively to equitable access** to COVID-19 therapeutics in LMICs

[ ]  Visibility on market demand (models, granular demand forecasts)

[ ]  Demand generation, catalytic product introduction at country level

[ ]  Production capacity upgrade

[ ]  Incentives (volume guarantee, advance purchase commitment)

[ ]  Global Regulatory and Policy support

[ ]  WHO Prequalification

[ ]  Regulatory and registration support in countries

[ ]  Others (please specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Any other **innovative approach or idea(s)** to improve the COVID-19 biotherapeutics development and manufacturing landscape?

**Group 3: Expansion of New/Experimental Small molecules Manufacturing**

**Target respondent:** Industry partners with experience in the development and manufacturing of quality-assured therapeutics with plans/interest in supporting development and production of **generics of new (and experimental) small molecules** **for COVID-19** for LMICs. These may include CMOs and CDMOs.

* + 1. **Organization Profile**

Organization Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone Number(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact person(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

…………………………………………………………………………………………………………………………………….……………………………

* + 1. **Operational landscape**

Please identify which of the following are within your scope of operation and specify the mode of operation (in-house or outsourced).

|  |  |  |
| --- | --- | --- |
|  | *In-house* | *Outsourced* |
| *Product development* |  |  |
| [ ]  Active Pharmaceutical Ingredient | [ ]   | [ ]   |
| [ ]  Process development  | [ ]   | [ ]   |
| [ ]  Formulation development | [ ]   | [ ]   |
| [ ]  Finished Pharmaceutical Product | [ ]   | [ ]   |
| [ ]  Analytical development and Quality Control Services | [ ]   | [ ]   |
| [ ]  Technology Transfer[[3]](#footnote-3) | [ ]   | [ ]   |
| [ ]  Other(s)…………………… please specify  | [ ]   | [ ]   |

|  |  |  |
| --- | --- | --- |
|  | *In-house* | *Outsourced* |
| *Commercial (Large/ scale up) Manufacturing*  |
| [ ]  Finished Pharmaceutical Product manufacturing | [ ]   | [ ]   |
| [ ]  Active Pharmaceutical Ingredient manufacturing | [ ]   | [ ]   |
| [ ]  Packaging  | [ ]   | [ ]   |
| *Regulatory and licensing*  |
| [ ]  Marketing authorization submission  | [ ]   | [ ]   |
| [ ]  Other(s)…………………… please specify | [ ]   | [ ]   |

* + 1. **Product scope**
1. Please specify your experience with development or manufacturing of new or experimental small molecules for COVID-19.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Product Category* | Intended route of delivery  | *Product Name(s)* | *Development* | *Manufacturing* |
|  |  |  | ***In-house development***  | ***In-house*** | ***Contract*** |
| [ ]  Generics of Novel small molecules  | [ ]  Oral [ ]  IV[ ]  SC/IM[ ]  Others, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | [ ]  | [ ]  | [ ]  |
| [ ]  Generics of Experimental small molecules  | [ ]  Oral[ ]  IV[ ]  SC/IM[ ]  Others, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | [ ]  | [ ]  | [ ]  |
| [ ]  Others …………………………………(please specify) | [ ]  Oral[ ]  IV[ ]  SC/IM[ ]  Others, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | [ ]  | [ ]  | [ ]  |

1. Please specify experience with different dosage forms (mark x as applicable).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Dosage form | Yes | No | If yes,No of years of experience | Example of products with WHO PQ or WHO Listed Authorities Level 4[[4]](#footnote-4) |
| Injectables  | [ ]   | [ ]   |  |  |
| Lyophilized powder for reconstitution | [ ]   | [ ]   |  |  |
| Solid dosage form | [ ]   | [ ]   |  |  |

1. Are you currently collaborating with an originator/developer of novel or experimental small molecules for COVID-19 to increase production capacity?

[ ]  Yes

[ ]  No

[ ]  Not applicable

1. Please describe any existing/in-process licensing agreement or technology transfer process for **any COVID-19 product.**

* + 1. **Production capacity**
1. Please specify current and planned production capacity by geographic location for small molecules product manufacturing. Please include notes on current capacity that could be assigned to small molecules product manufacturing.

|  |  |  |  |
| --- | --- | --- | --- |
| *By Geographic locations of manufacturing facility* | *Current annual production capacity**please specify* | *Planned production capacity**please specify* | Notes on potential spare capacity and capacity optimization |
| *API* | *FPP* | *API* | *FPP* |  |
| [ ]  Global  |  |  |  |  |  |
| [ ]  Africa |  |  |  |  |  |
| [ ]  Asia |  |  |  |  |  |
| [ ]  Oceania (incl. Australia and New Zealand) |  |  |  |  |  |
| [ ]  Europe(incl. Russian Federation and UK) |  |  |  |  |  |
| [ ]  North America |  |  |  |  |  |
| [ ]  South America |  |  |  |  |  |
| [ ]  Latin America and the Caribbean  |  |  |  |  |  |
| [ ]  Central America  |  |  |  |  |  |

1. Please provide details of the facilities that serve locations beyond their local markets (i.e., outside the same geographic territory as production).
2. **Commercialization and global access plans**
	1. Please provide summary of your commercialization plans for each of the COVID-19 pipeline products in development (small molecules) including regions (or countries) and timelines. Information on plans for LMICs should be included.

* 1. Please provide summary of any plans to ensure global access to COVID-19 pipeline products listed above, especially plans to ensure they are made widely available in LMICs, as quickly as possible and on a continuing basis, at an affordable and sustainable price and in sufficient quantities to meet the needs of LMICs. Include any specific plan to enable expanding supply.

1. **Potential opportunities for collaboration**
	1. Would your organization be interested in or willing to collaborate on any equitable access initiative, aimed at ensuring COVID-19 small molecules are made widely available in LMICs, as quickly as possible and on a continuing basis, at an affordable and sustainable price and in sufficient quantities to meet the needs of LMICs through interventions in development, manufacturing and commercialization?

[ ]  Yes

[ ]  No

[ ]  Undecided

* 1. If yes, please describe your organization’s interests in collaboration and resources available for such activities.
1. **Challenges and constraints**
	1. Please describe potential challenges and constraints to **development and manufacturing** of generic (novel or experimental) small molecules for COVID-19.
	2. Please describe potential challenges and constraints to **commercialization and global access** to generic (new /experimental) small molecules for COVID-19.
2. **Potential Interventions and innovation**
	1. Please identity any additional resource(s) or interventions that your organization may require (if applicable) to **contribute effectively to equitable access** to COVID-19 therapeutics in LMICs

[ ]  Visibility on market demand (models, granular demand forecasts)

[ ]  Demand generation, catalytic product introduction at country level

[ ]  Production capacity upgrade

[ ]  Incentives (volume guarantee, advance purchase commitment)

[ ]  Global regulatory and policy support

[ ]  WHO Prequalification

[ ]  Regulatory and registration support in countries

[ ]  Others (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. Any other **innovative approach or idea(s)** to improve the COVID-19 small molecules development and manufacturing landscape?

**Annex 1: Additional information on product development**

Please, as relevant, provide an updated summary of your product(s) in development.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Product in development | Product category(e.g monoclonal antibodies, small molecules etc.) | Proposed indications (e.g PrEP, PEP, mild, moderate, severe COIVD-19 cases) | Mode of action  | Stage in development (e.g preclinical, clinical phase, formulation development) | Estimated read out date for ongoing clinical trials  | Existing evidence summary |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

1. Technology transfer might include process scale-up and process validation, tech transfer to external parties, analytical and manufacturing method transfer. [↑](#footnote-ref-1)
2. WHO Listed Authorities (WLA), which replaced the concept of a Stringent Regulatory Authority (SRA), is a transparent and evidence-based global framework for evaluating, designating and publicly listing regulatory authorities which meet WHO and other international recognized standards and practices. WHO Listed Authorities Level 4 (WLA 4) are regulatory systems operating at advanced level of performance and continuous improvement as benchmark against WHO Global Benchmarking Tool (GBT). For more information please visit: <https://www.who.int/medicines/regulation/wla_introduction/en/> [↑](#footnote-ref-2)
3. Technology transfer might include process scale-up and process validation, tech transfer to external parties, analytical and manufacturing method transfer. [↑](#footnote-ref-3)
4. WHO Listed Authorities (WLA), which replaced the concept of a Stringent Regulatory Authority (SRA), is a transparent and evidence-based global framework for evaluating, designating and publicly listing regulatory authorities which meet WHO and other international recognized standards and practices. WHO Listed Authorities Level 4 (WLA 4) are regulatory systems operating at advanced level of performance and continuous improvement as benchmark against WHO Global Benchmarking Tool (GBT). For more information please visit: <https://www.who.int/medicines/regulation/wla_introduction/en/> [↑](#footnote-ref-4)