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 this 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.

Acronyms

ACT-A	Access To COVID-19 Tools Accelerator
API	Active Pharmaceutical Ingredient
BTP	Biotherapeutics Product
CDMO	Contract Development and Manufacturing Organization
CMO	Contract Manufacturing Organization
CRO	Clinical Research Organization
DP	Drug Product
DS	Drug Substance
FPP	Finished Pharmaceutical Product
GBT	WHO Global Benchmarking Tool
IM	Intramuscular
IND	Investigational New Drug
IV	Intravenous
LMICs	Low and Middle-income Countries
mAbs	Monoclonal Antibodies
PDP	Product Development Partnership
PEP	Post-Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
RFI	Request for Information
SBP	Similar Biotherapeutic products
SC	Subcutaneous
WHO	World Health Organization
WLA L4	WHO Listed Authority Level 4
WLA	WHO Listed Authority

Table of contents

Background

COVID-19 is a human, social, and economic tragedy that, as of 23 September 2020, has cost more than 960,000 lives globally and will contract global GDP by $US 7 trillion in 2020[1]. In the face of a growing COVID-19 pandemic, a race for the discovery of diagnostics, therapeutics and vaccines has begun across the world. The research and development landscape include many therapeutic agents[2] with potential to prevent infection and/or slow the progression of the disease.

While the development of lifesaving products is essential, equitable access is key. Affordable quality-assured, safe, and effective COVID-19 therapeutics must reach those who may benefit, in a timely manner, irrespective of geography and/or socioeconomic status. There is a crucial need to understand the market and supply dynamics, potential access barriers, constraints and challenges that could hinder the development and ability to timely bring to scale accessible COVID-19 therapeutics.

The Access To COVID-19 Tools Accelerator (ACT-A) was formed to accelerate the development, production and equitable access to COVID-19 diagnostics, therapeutics and vaccines. Unitaid, as co-lead of the ACT-A Therapeutics Partnership, is interested in understanding industry partners' interest, capabilities, activities and plans to develop and commercialize COVID-19 therapeutics.

About this RFI

This request for Information (RfI) is issued to provide an opportunity for interested organizations or groups of organizations to provide information, opinions, and recommendations on the development and production of COVID-19 therapeutics.

This RfI is issued solely for information-gathering and planning purposes. This is not a Request for Proposals and is not to be construed as a commitment by Unitaid or any ACT-A partners to award a contract or enter into any collaborative agreement or relations based on this RfI. No payment will be made by Unitaid, nor any of its ACT-A partners, for any of the information voluntarily submitted in response to this request. Information submitted in response to this RfI may be used to inform potential support or interventions that the ACT-A Therapeutics partnership and/or Unitaid may undertake in future.

About ACT-A

ACT-Accelerator (ACT-A) was launched on 24 April 2020, with the vision of creating a global solution to expedite the end of the COVID-19 pandemic. Uniquely, ACT-Accelerator combines public and private sector expertise and institutions from around the world to accelerate the development, regulatory approval, scale-up, delivery and equitable allocation of COVID-19 tests, treatments and vaccines. ACT-Accelerator has ambitious targets: to provide 2 billion vaccine doses to the world by the end of 2021, 245 million courses of treatment and 500 million diagnostic tests to low and middle-income countries (LMICs) in 2021.

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[1] World Bank, Global Economic Prospects – Pandemic, Recession: The Global Economy in Crisis, June 2020

[2] Therapeutics for COVID-19 might include medicines across all the use cases from prophylaxis, prevention, and/or treatment of mild, moderate and severe cases of COVID-19. Candidate therapeutics for COVID-19 under clinical evaluation include small molecules (repurposed, experimental or novel small molecules) or biotherapeutics (including monoclonal antibodies, repurposed or novel targeting SARS-CoV2). For more details on the focus of this RfI, please, see section "Target respondents and products".

ACT-Accelerator is an end-to-end global solution to expedite the end of the COVID-19 pandemic by developing, scaling and enabling equitable global access to tests, treatments and vaccines needed to reduce mortality and severity of the disease, restoring full societal and economic activity globally in the near term, and facilitating high-level control of COVID-19 pandemic in the medium term.

The ACT-A Therapeutics Partnership's role is to gather evidence on therapeutics, engage in market preparedness and catalyze manufacturing, and facilitate procurement and deployment of eligible, safe, effective and quality-assured therapeutics to countries across the world. The ACT-A Therapeutics partnership is co-convened by Unitaid and the Wellcome Trust.

Learn more at https://www.who.int/initiatives/act-accelerator

About Unitaid

Unitaid is an international organization that invests in innovations for the prevention, diagnosis and treatment of HIV and coinfections/comorbidities, tuberculosis and malaria more quickly, affordably and effectively, enabling their scaled-up use in low and middle-income countries. Unitaid's investments establish the viability of health innovations, allowing partner organizations to make them widely available. Unitaid is a hosted partnership of the World Health Organization (WHO).

Keep updated on all Unitaid actions against #COVID19 on our dedicated website: https://unitaid.org/covid-19/#en. Learn more at www.unitaid.org.

Target respondents and products

The RfI is targeted at stakeholders that fit into the following categories:

1. Originator[3] industry partners, academia and Product Development Partnerships (PDPs) that have **novel COVID-19 medicines (small molecules[4] or biotherapeutics[5])** currently in development.

2. 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 Contract Manufacturing Organizations (CMOs) and Contract Development and Manufacturing Organizations (CDMOs).

3. Industry partners with experience in the development and or manufacturing of quality-assured small molecule therapeutics with plans/interest in supporting development and production of **generics of new (and experimental) small molecule medicines for COVID-19 for LMICs.** This category may

[3] Originator, for the purpose of this RFI, are manufacturers or product developers whose product was first authorized worldwide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization by a WHO Listed Authorities L4 (previously called Stringent Regulatory Authority).

[4] Multiple small molecules are being evaluated for prevention or treatment of COVID-19 from multiple therapeutic classes. This RfI focuses only on experimental or novel small molecules. Several repurposed small molecules for COVID-19 are currently under clinical evaluation and, should they be able to prove safety and efficacy for prevention or treatment of COVID-19, large supplies would be needed to meet future demand. However, these are not currently in scope of this RFI. A separate solicitation may later be issued for repurposed small molecules for COVID-19 if it becomes necessary.

[5] Biologic products (biotherapeutics) in scope include monoclonal antibodies and other biologics now being evaluated for COVID-19, with the exclusion of hyperimmunoglobulin and convalescent plasma.

include Contract Manufacturing Organizations (CMOs) and Contract Development and Manufacturing Organizations (CDMOs).

How to Submit a Response

This RFI will be open from the date of release through **20th November 2020** at 17:00 Geneva Local time. Please send all responses to this RFI via email to Unitaid-RFI@who.int. An electronic confirmation acknowledging receipt of each response will be made upon submission.

Responses should be provided by completing relevant sections of the *"Questionnaire"* provided as a separate document. Responses should be typewritten and saved in a pdf format using the naming convention Unitaid_RFI_TDM_[Organization name] before sending to the designated email address. Additional information limited to the respondents' corporate or organizational capability statement, updated product development landscape etc., may be included in the Annex or as a separate attachment to the submission. Please do not submit full proposals, resumes or promotional materials, at this stage. Contact details of respondents (email address, telephone and contact addresses) should be provided as part of the RFI response.

Costs of preparing documents

All costs associated with responding to this request will be solely at the respondent's expense.

Questionnaire

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)** currently in 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 medicines with 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): _____

……

2. 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[6]	☐	☐
☐ Other(s)…… (please specify)	☐	☐

[6] Technology transfer might include process scale-up and process validation, tech transfer to external parties, analytical and manufacturing method transfer.

	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)	☐	☐

3. Product scope

a. 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 _____		☐	☐	☐

b. Please specify if you are working on particular optimization activities for products on development (e.g. low-dose clinical trials).

c. Please describe any existing and/or in-process licensing agreement or technology transfer operation(s) for the product(s) in question.

4. Production capacity

a. 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**					

b. 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**					

c. Please provide details of the facilities that serve locations beyond their local markets (i.e., outside the same geographic territory as production).

5. Commercialization and global access plans

a. 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.**

b. 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.).

6. Potential Opportunities for collaboration

a. 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

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

7. Challenges and Constraints

a. 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.

b. 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).

8. Potential Interventions and Innovation

a. 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):_____

b. 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): _____

……

2. Operational landscape

a. 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	☐	☐

3. Product scope

a. 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 _____		☐	☐	☐

b. 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

c. 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[7]
Injectables ready for use	☐	☐		
Lyophilized powder for reconstitution	☐	☐		
Others (please specify) _____	☐	☐		

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

[7] 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/

4. Production capacity

a. 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**					

b. Please provide details of the facilities that serve locations beyond their local markets (i.e., outside the same geographic territory as production).

5. Commercialization and global access plans

a. 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.

b. 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.

6. Potential Opportunities for collaboration

a. 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

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

7. Challenges and Constraints

a. Please describe the challenges and constraints you are experiencing with the **development and commercial scale production** of biotherapeutics for COVID-19.

b. Please describe potential primary challenges and constraints to **commercialization and global access** to biotherapeutics for COVID-19 for LMICs.

8. Potential Interventions and innovations

a. 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):_____

b. 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): _____

……

2. 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[8]	☐	☐
☐ Other(s)…… please specify	☐	☐

[8] Technology transfer might include process scale-up and process validation, tech transfer to external parties, analytical and manufacturing method transfer.

	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	☐	☐

3. Product scope

a. Please specify your experience with development or manufacturing of <u>new or experimental</u> 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 _____		☐	☐	☐

b. 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[9]
Injectables	☐	☐		
Lyophilized powder for reconstitution	☐	☐		
Solid dosage form	☐	☐		

c. 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

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

[9] 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/

4. Production capacity

a. 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**					

b. Please provide details of the facilities that serve locations beyond their local markets (i.e., outside the same geographic territory as production).

5. Commercialization and global access plans

a. 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.

b. 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.

6. Potential opportunities for collaboration

a. 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

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

7. Challenges and constraints

a. Please describe potential challenges and constraints to **development and manufacturing** of generic (novel or experimental) small molecules for COVID-19.

b. Please describe potential challenges and constraints to **commercialization and global access** to generic (new /experimental) small molecules for COVID-19.

8. Potential Interventions and innovation

a. 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): _____

b. 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