

AMENDED AND RESTATED QUALITY AGREEMENT

This **Amended and Restated Quality Agreement** is made on May 17, 2021 between:

Bharat Biotech International Limited, a company incorporated as per the Companies Act, 1956, having its registered office situated at Genome Valley, Shameerpet, Hyderabad – 500 078, Telangana, India, (which term shall include its successors, and permitted assigns) [Hereinafter referred to as “BBIL”], of the FIRST PART;

and

Precisa Comercialização de Medicamentos Ltda, a company incorporated under the laws of Brazil, having its registered office Av. Portugal, 1100 - Rua 5 Parte A 14 A-Itapevi, SP Cep: 06696-060, (hereinafter referred to as “PRECISA”), which term shall include its successors, affiliates, subsidiaries and permitted assigns of the SECOND PART.

WHEREAS, the Parties have entered into a MOU dated 24th November for Supply of Covaxin pursuant to which the parties entered into a Quality Agreement to govern the Quality related aspects of the supply.

WHEREAS the Parties desire to amend and restate the Quality Agreement as set forth herein to reflect the significant changes that have occurred in the quality operations of the Parties since the effective date of the Quality Agreement.

NOW, THEREFORE, for and in consideration of the mutual covenants contained in this Agreement, the parties hereto hereby agree to amend and restate the Quality Agreement as follows:

This agreement is valid for 3 years from the date of the last approval signature.

Responsibilities of BBIL and PRECISA

Item	Responsibilities	
	Bharat Biotech International Limited	Precisa Comercialização de Medicamentos Ltda
1. Communication / Site Contacts	1.1 Identify key personnel to ensure responsible individuals are contacted for the resolution of quality issues. 1.2 Provide all communication in writing, if direct contact is required, such contact must be followed-up and/or confirmed in writing when possible.	
2. Compliance	2.1 To ensure that all manufacturing facilities, manufacturing process and personnel of BBIL's	2.1 Responsible to ensure all GDP activities are compliant with Precisa's SOPs, local regulations,

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	<p>manufacturing facilities or BBIL and its subcontractors, if any, shall comply with GMP and GDP of Food and Drugs Administration of India and any other authorities where the facilities are located in.</p> <p>2.2 Responsible to ensure that manufacturing and supply of the Product as listed in annex 2 in accordance with the Product dossier approved by Brazil Regulatory Authority.</p>	<p>and applicable regulatory requirements.</p>
3. Regulatory Inspections and Audits	<p>3.1 Perform the self-inspection periodically to ensure that the activities of BBIL's manufacturing facilities or BBIL including its subcontractors comply with the GMP and GDP requirement.</p>	<p>3.1 Reserves the right to request and receive (if need be redacted), copies from BBIL and any subcontractor(s), stemming from regulatory agency inspection or audit reports and corresponding responses related to the Product.</p> <p>3.2 Responsible to notify BBIL as soon as they became aware of any regulatory inspections or inspection notices of their facilities and any other relevant subcontracted facility that may be relevant to ancillary supporting systems or the Product.</p>
4 CAPA (Corrective Action and Preventive Action) System	<p>4.1 The CAPA process shall be in place that requires a clear and complete description of the investigation that took place.</p> <p>4.2 The CAPA process shall be in place that requires root cause to be determined and a</p>	<p>4.1 Evaluate the impact of the CAPA in the product commercialized in Brazil and decided by their approval together with BBIL.</p> <p>4.2. Submission of the CAPA report for any issues related to the Product in case of a request by Brazil authority.</p>

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	<p>description of how root cause was identified.</p> <p>4.3 Corrective actions and preventive actions shall be documented along with defined owners and the due dates for completion of each action plan.</p> <p>4.4 Verification that all corrective actions and preventive actions have been implemented and found to be effective shall be documented.</p> <p>4.5 Target time frames for identification of root cause and closure of action plans shall be established.</p> <p>4.6 CAPA report shall be provided to Precisa and for submission to Brazil authority if required.</p>	
5. Artwork	<p>5.1 Responsible to provide artwork proofs to Precisa for printed packaging materials to obtain Precisa's approval.</p> <p>5.2 Responsible to maintain the artwork in conjunction with applicable regulatory requirements and will inform Precisa, in a timely manner, of any necessary changes, keeping the control of versions.</p> <p>5.3 Responsible to implement changes upon Precisa's approval.</p>	<p>5.1 Responsible to inform BBIL, in a timely manner, about any required changes regarding printed packaging material and artwork, by competent authorities or Precisa, as well as timelines for implementation of changes.</p> <p>5.2 Responsible for the approval of artwork proofs in accordance with the currently Brazilian regulations.</p>

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6 Notification of Changes	<p>6.1 BBIL must notify Precisa in a timely manner for the decommissioning/ commissioning of manufacturing facilities expansion or relocation of API, drug product and its diluent in a documental manner (change control) that must be previously approved by Precisa.</p> <p>6.2 Responsible to inform Precisa in a timely manner for any changes made to the Product.</p> <p>6.3 Responsible to perform the correspondent calibration, qualification and/or validation required for this change.</p> <p>6.4 Provide all documents required to update the MA when necessary.</p>	<p>6.1 Evaluate the proposal change control to approve it if applicable.</p> <p>6.2 Evaluate the impact of the change in the MA, if applicable.</p> <p>6.3 To inform Brazil authority if such changes related to the Product and required for submission as per local regulation.</p>
7. Deviations and Out of Specifications (OOS)	<p>7.1 Responsible for notifying Precisa if there are any deviations or OOS results that may adversely affect the safety, integrity, strength, purity and quality of the Product.</p> <p>7.2 The shipment of the product to Brazilian market can only be carried out after Precisa's approval</p>	<p>7.1 Evaluate and decide by the approval and the impact of the deviation or OOS in the Brazilian product.</p> <p>7.2 To inform Brazilian authority if such deviations and OOS results related to the Product and BBIL asked for submission to Brazil authority, if applicable.</p>
8. Batch Release and Distribution	<p>8.1 Process with the batch release and provide the supportive documents for the shipment delivery to Precisa in a timely manner.</p>	<p>8.1 Process with all local activities as per Brazil regulation and Precisa quality system for the Product importation and distribution, as per: importation process, local distributors qualification, evaluate the shipment temperature (data loggers), actions to be taken in case of excursion of temperature</p>

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		<p>out of specification and inform BBIL.</p> <p>8.2 Process with the local redressing to make the product complied with Brazilian health authorities regulation (if required) and maintain the records of such activities.</p> <p>8.3 Responsible to release the product for Brazilian market.</p> <p>8.4 Responsible for the distribution of the Product to the end user.</p>
9 Storage and Transportation	<p>9.1 Responsible for transporting the released Product as per INCOTERMS FCA.</p> <p>9.2 The shipment under transportation shall be properly controlled as per GMP/GDP requirement.</p> <p>9.3 Responsible to ensure that the Product shall be transported in cool containers/refrigerated countainers, fully qualified.</p>	<p>9.1 Responsible for incoming shipment inspection, storing, transporting and distribution of the Product under the recommended controlled environmental conditions and as per their SOPs in the territory.</p>
10. Record Retention	<p>10.1 BBIL will retain all executed batch documentation and reference samples for a period stated in their controlled system.</p> <p>10.2 BBIL must keep the traceability for all commercialized products.</p>	<p>10.1 Responsible for ensuring that batch release documents and distribution records are retained for every batch processed as per their local regulations and internal quality system.</p> <p>10.2 Precisa will retain retention samples, when applicable, under controlled conditions as per internal SOP's.</p> <p>10.3 Precisa must keep the traceability for all commercialized products.</p>
11. Subcontracting	<p>11.1 Committed to ensure that all subcontractors in the present and those it will employ in the future will meet or exceed the standard as outlined in this quality</p>	<p>11.1 Responsible to control and check the qualification of the subcontractors to be used in the territory.</p> <p>11.2 Responsible to ratify and maintain an up to date quality</p>

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	<p>agreement and this supplementary.</p> <p>11.2 Responsible for ensuring subcontractor's qualification status, through audits, remains acceptable as per BBIL applicable SOPs.</p> <p>11.3 Responsible for qualifying and performing audits of subcontractors in accordance with applicable regulatory requirements and internal SOPs, prior to using their services for the Product.</p> <p>11.4 Responsible to ratify and maintain an up to date quality agreement with all subcontractors detailing the mutual quality and compliance roles and responsibilities.</p> <p>11.5 Keep Precisa informed about all contracted services and the respective status.</p>	<p>agreement with all subcontractors detailing the mutual quality and compliance roles and responsibilities.</p>
12 Return/Destruction	<p>12.1 Provide the instructions for the actions to be done for the return or destruction to be done as per BBIL requests.</p>	<p>12.1 Responsible for the handling of any returned and destructible product done as per BBIL requests, as agreed between the parties.</p> <p>12.2 Responsible for destruction as per their SOPs, as agreed between the parties.</p>
13 Complaints	<p>13.1 In the event of customer complaints with regards to the Product and that complaints relate to the activities done by BBIL or BBIL's manufacturing</p>	<p>13.1 Precisa shall receive and maintain a record of all complaints it receives with respect to the Product regardless of whether the complaint pertains to the use of the Product within or outside of</p>

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	<p>facilities and its subcontractor, if any, BBIL undertakes to provide sufficient support, to conduct a thorough investigation.</p> <p>13.2 Responsible to provide Precisa with an investigation report of the complaint, composed of an interdisciplinary team, adequately trained to manage investigations in order to mainly reduce risks inherent to quality deviations.</p>	<p>the Territory. Precisa shall notify any complaint pertaining to quality of the Product or with regulatory implications received by it in sufficient detail and within 3 business days after receipt of such complaint to the contact person as listed in annex 1.</p> <p>13.2 Precisa shall notify the customers within the decision made by BBIL, providing an official report following the action defined by the manufacturer.</p>
14. Recall	<p>14.1 Responsible to notify Precisa immediately a recall or any quality deviation lead to the suspension of the Product registered or marketed in the Territory, within 24 hours after the deviation detection.</p> <p>14.2 Discussion and make a decision together with Precisa how to handle with recalled product.</p>	<p>14.1 Responsible to implement retrieval of all impacted product from the market, according to the traceability records.</p> <p>14.2 To inform Brazil authority for a recall (ANVISA and others) including any issues related to the suspension of the Product and requested by BBIL, stating the reason for the deviation, classification of risk, health problem or consequence, among other information pertinent to the detected quality deviation, in accordance with the local regulation RDC 55/2005.</p> <p>14.3 Submit to ANVISA the recall notification and periodically reports, following the category and timeline defined in the RDC 55/2005.</p>
15. Adverse Drug Event	<p>14.4 Responsible to provide investigation report for identification of root cause of any adverse drug event related to the use of the Product.</p>	<p>15.1 Shall promptly provide the adverse drug event information received from the field to the contact person as listed in Annex 1 of BBIL.</p> <p>15.2 To submit the report for the adverse drug event to the health</p>

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		authority as per the regulated timeline, in accordance with RDC 406/2020.
16. Indemnification	16.1 BBIL will indemnify Precisa and its Affiliates, agents, directors, officers and employees (the “Precisa Indemnities”) from and against any and all suits, claims, actions, demands, liabilities, expenses and/or losses (collectively “Losses”) resulting directly due to defect in the quality of product ex-factory, as determined by competent Independent testing laboratory, as mutually agreed upon by the Parties. Such indemnification is subject to the upper limit of the product liability insurance coverage maintained by BBIL.	16.1 Precisa hereby agrees to Indemnify BBIL and its Affiliates, agents, directors, officers and employees (the “BBIL Indemnities”) from and against any and all Losses resulting directly or indirectly from commercialization, marketing, improper handling, storage and distribution of the product or suffered by BBIL as a result of enforcement of this Agreement and/or failure to comply with any law applicable in the Territory.
17. Jointly and Severally Responsibility	17.1 BBIL will provide all the support to help Precisa maintain the quality, safety and efficacy of the products to the final consumer.	17.2. Precisa, as a registry holder, it is jointly and severally responsible for maintaining the quality, safety and efficacy of the products to the final consumer, in order to avoid risks and adverse health effects.
18. Insurance	18.1 BBIL will maintain product liability insurance during the term of the agreement.	18.2 Precisa will maintain sufficient insurance to cover any and all claims arising out of or in connection with the activities under this Agreement. Precisa will provide a copy of such insurance to BBIL as and when demanded in writing by BBIL.

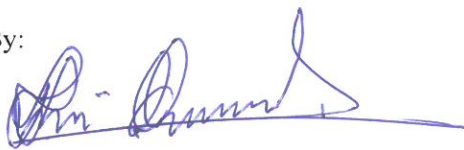
This Agreement constitutes the whole and entire agreement between the parties hereto and supersedes any prior agreement, undertaking, declarations, commitments or representations, verbal or oral, in respect of the subject matter hereof.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement with effect as of the date first above written.

Bharat Biotech International Limited

Genome Valley, Shameerpet, Hyderabad – 500 078,
Telangana, India

By:



Name: Sai D. Prasad

Title: Executive Director

Date: 17.05.2021

Precisa Comercialização de Medicamentos Ltda

Av. Portugal, 1100 - Rua 5 Parte A 14 A-Itapevi,
SP Cep: 06696-060

By:

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Date: 2021.05.17 12:29:08
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Name: Ms. Emanuela Medrades

Title: Executive Director

Date: _____

Annex 1: List of contact person

Items	Bharat Biotech International Limited	Precisa Comercialização de Medicamentos Ltda
Complaints	Mr. U. Rama Rao Manager – Regulatory Affairs Operations ramarao2488@bharatbiotech.com	Amanda Santo Regulatory Affairs qualidade@precisamedicamentos.com.br
Pharmacovigilance	Dr. Bhargav Reddy Pharmacovigilance Officer In charge – Medical Affairs feedback@bharatbiotech.com	Daniele Constantino Pharmacovigilance qualidade@precisamedicamentos.com.br
Quality issues	Dr.Nagarjuna Akula Senior Vice President – Quality Operations nagarjuna4432@bharatbiotech.com	Leandro Santos Quality Assurance Manager – Technical Responsible. Leandro.santos@precisamedicamentos.com.br

Annex 2: List of product handled as per this agreement

No.	Trade Name	Manufacturing site	Storage and transport condition
1	COVAXIN®	Bharat Biotech International Ltd. Sy. No. 230, 231 & 235, Genome Valley, Turkapally, Shamirpet Mandal, Medchal-Malkajgiri District - 500 078, Telangana, India	Store at 2-8°C