

To: *Senator Omar Aziz*
Chairman of the Parliamentary Committee of Investigation on the Pandemic
SENADO FEDERAL – COCETI
Anexo II, Ala Senador Alexandre Costa, Sala 15, Subsolo
Postal Code 70165-900, Brasilia-Federal District

Reference: **Your Official Letter no. 2090/2021 – CIPANDEMIA dated 05th August 2021**

Subject: **Request for information – Request no. 1225/2021-CIPANDEMIA**
Reply from Bharat Biotech International Limited.

Hon'ble *Senator Omar Aziz*,

Greetings from Bharat Biotech International Limited (BBIL).

We write to you in response to your above referenced request for information.

At the outset, we would like to place on record our objection that the said request has not been submitted through established agency protocols that govern intercountry informational request, especially requests from governmental authorities as made therein. However, being a responsible corporate entity, we are providing our responses to the queries contained in the said request in good faith and without prejudice to our rights, contentions or ability to exercise the same subsequently. This reply does not constitute any formal acceptance by BBIL of the jurisdiction of the senate over BBIL nor does it constitute any admission / acceptance of any guilt or liability in addition thereto.

We would also like to inform you that the said letter request though dated 05th August, 2021, the same was received by us on email only on 11th August, 2021. We have noted that the time frame for reply thereto has been identified as 05 (five) days and are accordingly submitting our response within 05 (five) days from the date of receipt i.e 11th August 2021.

We would also like to bring to your kind notice that the said letter request was been sent to our business exports email address - exports02@bharatbiotech.com. You are requested to kindly address any and all queries to legal01@bharatbiotech.com.

Please find below, responses to your queries:

1. Request to provide a true copy of the agreement and/or other instruments and adjustments executed by the Brazilian company named Precisa - Comercialização de Medicamentos Ltda., related to the establishment of partnerships, memoranda of understanding, opportunity records, and representations, and, in particular, the documents that establish the participation

and payment of commissions for the sales of medicines, inputs, vaccines, etc., to the Brazilian Government, States, and Municipalities, emphasizing the particular importance of providing a copy of the documentation relating to the sale of the immunizer named COVAXIN to the Brazilian Ministry of Health, which gave rise to Agreement no. 29/2021 (Proceeding no. 25000.175250/2020-85), even though it has not been opened or signed.

BBIL Response: Please find attached the following:

- a. **Annexure A.** True Copy of the Memorandum of Understanding dated 24th November 2020 (“**MOU**”) executed between BBIL, Precisa Commercializacao de Medicamentos Ltda and Envixia Pharmaceuticals.
- b. **Annexure B.** True Copy of Quality Agreement dated 17th May, 2020 executed between BBIL and Precisa Commercializacao de Medicamentos Ltda.
- c. **Annexure C.** True Copy of Authorisation Certificate dated 05th October 2020 issued in favour of, Precisa Commercializacao de Medicamentos Ltda.
- d. **Annexure D.** True Copy of Letter of Authorisation dated 16th June, 2021 issued in favour of Precisa Commercializacao de Medicamentos Ltda.
- e. **Annexure E.** True Copy of termination and revocation notice dated 23rd July, 2021 whereby BBIL has terminated the MOU with Precisa Commercializacao de Medicamentos Ltda and Envixia Pharmaceuticals (“**Termination and Revocation Notice**”) as provided in point (a) above. All authorisations in favour of Precisa stand revoked.

2. if there was no formal contract besides the Memorandum of Understanding (MoU), what were the terms of the agreement with the company Precisa?

BBIL Response: Apart from the MOU, the Quality Agreement and a Non-Disclosure Agreement, there was no other formal contract between BBIL and Precisa.

3. What were the limits to its activities?

BBIL Response: The activities of Precisa are clearly identified in the MOU and Quality Agreement as appended herein.

4. What would be the compensation the company Precisa would be entitled to?

BBIL Response: No agreement was arrived at between BBIL and Precisa on the issue of compensation.

5. What were the contractual liabilities of the company Precisa?

BBIL Response: The contractual activities of Precisa were clearly identified in the MOU and Quality Agreement as appended herein.

6. What were the conditions for termination, and what were the consequences?

BBIL Response: BBIL terminated the MOU with Precisa for reasons quoted and in terms of the Termination and Revocation Notice appended as **Annexure E** hereto.

The consequences of such termination, apart from the fact that Precisa is no longer permitted to act on behalf of BBIL, are as under:

- a. ANVISA has since terminated the application for emergency use authorisation as filed by Precisa.
- b. The exceptional emergency use authorisation as granted for COVAXIN has since been terminated.
- c. The clinical trials for COVAXIN that were being conducted in Brazil have since been suspended.

Considering the confidentiality of the information disclosed herein, the same has been provided for the limited purpose of responding to the request for information as referenced above. The information shared herein is to be used solely by your office for the purpose of noted inquiry and not with a view to be disseminated to any other party including but not limited to the public at large. We request that the information as provided is accorded utmost confidentiality and should not be disclosed to any person other than those who require it strictly and solely for the Purpose. Any and all information that may be price sensitive and proprietary information is shared to respond, in good faith, upon your request, and sharing or making public this information would constitute a breach of assurance provided by Brazilian Law No. 12,527/2011, article 6, item III.

Further the disclosure of the said information by us is conditioned by the requirement that the same shall not under any circumstance be shared with Precisa Medicamentos.

For Bharat Biotech International Limited



Legal Associate
Legal Department

18.08.2021