

## CORRIGENDUM -2

### Feedback on queries raised at the Pre-EOI Meeting held on 22.01.2021

**Time: 11:00 AM – 12:30 PM**

**Participants:**

1. Bharat Biotech International Limited, Hyderabad
2. Dr. Reddy's Laboratories
3. Reliance Lifesciences
4. Invex Health Pvt. Ltd.
5. Morepen Laboratories
6. SBI CAPS (Transaction Advisor to HLL)
7. HLL and HBL

Sl.No	Queries from the parties	Clarification from HLL
1	What is the timeline proposed by HLL for completing the process of EOI and selection of partners	HLL proposes to complete the process of shortlisting, selection of partner /partners by 31/03/2021. And hope to enter in to a workable agreement to start operation in April 2021
2	Requested for visit to HBL facility during the process of EOI	The visit to HBL facilities is allowed during the EOI process; parties can contact CEO, HBL in advance.
3	HBL is currently under MoHFW and have the benefits of PSU to get the supply orders; will the benefits of PSU under Ministry may continue or not when private party enter in to contract manufacturing/ leasing arrangements.	HBL will continue as Govt. of India PSU and benefits of PSU for supply of vaccines as per the captive status shall continue for the vaccines under UIP. For new vaccines including Covid -19, this captive status may not be applicable.
4	Is HBL looking to operationalize IVC with a single party or multiple parties?	HBL is looking forward for operationalizing the facilities already established, including formulation and filling facilities and bulk production facilities. The parties based on their requirement for bulk production and formulation and filling may submit their expression of interest and business/ operational plan.

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		Accordingly, HBL may select single or multiple parties as per the requirement and feasibility.
5	What is the financial model HBL is looking forward as part of the investment proposed by the partners - Is there any equity participation.	We are looking forward to select parties to complete the commissioning and validation of facilities as required and make them operational for production of one or more vaccines at this stage. The capital infusion requested now is not to be treated as an equity.
6	How long will it take to make ready the BVF and VVF facilities	The re-validation of BVF facility may require 2-4 months; Commissioning and validation of VVF facilities may require 4-6 months.
7	Approximate fund infusion required for operationalizing each facility	<ul style="list-style-type: none"> <li>• Liquid vaccine formulation facility (BVF) : Rs. 5 Cr.</li> <li>• Lyophilized vaccine Formulation facility (VVF) with 2 filling suites and lyophilizers : Rs. 15 Cr.</li> <li>• Tissue culture bulk production facility : 5 Cr</li> <li>• Bulk &amp; Formulation Block : 10.00-12.00 Cr</li> <li>• Multiple Bulk Block: 10.00-12.00 Cr</li> </ul>
8	Does HBL have the requisite manpower in place to manage the operation	HBL is having manpower in different disciplines for managing the operation; however, for the technical side, specific for vaccines, the manpower need to be strengthened by recruiting additional technical/ production based manpower. The partner can recruit/depute manpower for disciplines to augment the existing team.
9	Can the VVF facility handle two viral vaccines simultaneously	The viral vaccine facility is having two independent formulation and filling suites. As per requirement, parties can handle production of 2 different vaccines from this facility. The BVF Facility can handle only one vaccine at a time.
10	In incase a foreign company is interested to participate in the EOI, what is the procedure?	The foreign company shall participate through the Indian Joint venture partner.

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	Does the company require an Indian counterpart/partner to proceed	
11	Can the financial credentials of the foreign company produced as part of the EOI.	Yes. If any foreign collaborator is already, collaborating along with Indian partner for manufacture of Pharma/Vaccines then the partnership is acceptable and the partnership /Joint venture agreement need to be submitted along with the EOI.
12	Why the facility is not having R&D and pilot plant, which is a requirement for vaccine production process development.	R&D and Pilot plant facility is currently not available and this may be established as per the requirement in future.
13	The viral bulk production facility is completed with all infrastructure and equipment; however, the facility is not installed with bioreactors - any reason for the same.	The viral vaccine bulk production facility is planned for production of Rabies/ JE vaccines where the production process is based on tissue culture by using roller bottle/ cell factories. Bioreactors may be installed based on the production process requirement for new vaccines planned in the facility.
14	Before signing the MoU is there any due-diligence to be completed	All due diligence as per the requirement shall be done.
15	Is there any financial proposal to be submitted along with the EOI.	No Need to submit financial proposal along with EOI. However, parties shall submit the proposed business plan based on assumptions as deemed fit.
16	Vaccine manufacturing is a time driven process, so in that case short-term arrangements may not be beneficial. Hope the partnership model is for long term arrangements.	HLL is open for long-term partnership models as indicated in the Notification inviting Eoi.
17	How the EOI to be submitted; is it through only online platform.	EOI and supporting documents shall be uploaded in CPP portal as per the details provided and no hardcopies to be submitted.

Please Note: Relevant documents as required shall be shared to shortlisted parties.