SEEPZ SPECIAL ECONOMIC ZONE
PHASE-III HINJEWADI, PUNE.

AGENDA FOR

MEETING OF THE APPROVAL COMMITTEE FOR SECTOR SPECIFIC SPECIAL ECONOMIC ZONE FOR BIO TECHNOLOGIES AT PUNE OF M/S. SEZ BIOTECH SERVICES PVT. LTD. -SEZ.

VENUE : Conference Hall, Ground Floor, Office of Zonal Development Commissioner' SEEPZ-SEZ, Sub Office of Joint Development Commissioner Pune Cluster, SEZ Bhawan, Plot No. 6/1, MIDC, Phase – III, Hinjewadi, Pune-411057.

DATE : 18.10.2019

TIME : 10.00 A.M.

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MEETING OF THE APPROVAL COMMITTEE FOR SECTOR SPECIFIC SPECIAL ECONOMIC ZONE FOR IT/ITES AT PUNE, UNDER THE CHAIRMANSHIP OF DEVELOPMENT COMMISSIONER, SEEPZ-SEZ ON 19.08.2019.

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<td>Confirmation of the Minutes of the meeting held on 21.08.2018</td>
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<td>Agenda Item No. 02 :-</td>
<td>Application for change in manufacturing items of M/s. Serum Institute of India Pvt. Ltd.(PBP-I)</td>
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Minutes of the 15th Meeting of the Approval Committee held under the Chairmanship of Development Commissioner SEEPZ - SEZ for sector Specific Special Economic Zone for Bio - Technology M/s. SEZ Biotech Services Pvt. Ltd. - SEZ, held on 21.08.2018 at Wipro Ltd. SEZ, Phase - I, Hinjewadi, Pune.

1. Name of the SEZ : M/s. SEZ Biotech Services Pvt. Ltd.
2. Sector : Bio - Technology
3. Meeting No. : 15th
4. Date : 21 August 2018.

Member Present:

1. Shri Pravin Chandra JDC : Pune Cluster SEZ, Pune
2. Dr. Arvind S Dhapate : Nominee of MPCE, Pune
3. Shri B. P. Nawale, Supdt. : Nominee of GST

Special Invitees:

5. Shri. B.S. Chauhan, Specified Officer.

Agenda No. 1: Confirmation of Minutes of the meeting held on 17.05.2018

The Minutes of the 14th Meeting held on 17.05.2018 were confirmed.
Agenda Item No.02: Approval of list of items for authorized operations of M/s. SEZ Biotech Services Pvt. Ltd. [Developer].

After deliberation, the Committee approved the list of material required for their authorized operation duly certified by Chartered Engineer Mr. S.G. Purshet (Registration No. M/038153), having value of Rs. 3008/- Lakhs for the development of processing area and value of Rs. 670/- Lakhs for the development of non-processing area in terms of Rule 12(2) of SEZ Rules, 2006 & Instruction No. 50 issued by MOChI dated 15.03.2010.

The committee also noted the submitted declaration submitted by the developer in regard to infrastructure/other facilities in non-processing area which will be use by SEZ entities only.

Meeting ended with a vote of thanks to the Chair.

Chairperson - cum - Development Commissioner
AGENDA NOTE FOR CONSIDERATION OF UNIT APPROVAL COMMITTEE

a) Proposal:

- Application of M/s. Serum Institute of India Pvt. Ltd. (SEZ Unit PBP-1) for change in item of manufacture i.e. instead of manufacture of Dengue Vaccine manufacture of Erythropoietin (EPO) and Polysialylated Erythropoietin (PSA-EPO)

b) Specific issue on which decision of UAC is required:

- Approval of change in item of manufacture i.e. instead of manufacture of Dengue Vaccine manufacture of Erythropoietin (EPO) and Polysialylated Erythropoietin (PSA-EPO) as detailed below:

  - Approval of additional list of raw material / chemicals

<table>
<thead>
<tr>
<th>Sl.No. in LOA</th>
<th>Product Description</th>
<th>ITCHS</th>
<th>Production capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Dengue vaccine in single and Multi doses or in Bulk form</td>
<td>30022019</td>
<td>100 million</td>
</tr>
</tbody>
</table>

the following product be added in LOA

<table>
<thead>
<tr>
<th>Sl.No. in LOA</th>
<th>Product Description</th>
<th>Metric</th>
<th>ITCHS</th>
<th>Production capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3(a)</td>
<td>Erythropoietin (EPO) Injection (multi strength)</td>
<td>Vials</td>
<td>30045010</td>
<td>20 lakhs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PFS</td>
<td></td>
<td>20 lakhs</td>
</tr>
<tr>
<td>3(b)</td>
<td>Polysialylated Erythropoietin (PSA-EPO) Multi strength</td>
<td>PFS</td>
<td>30045010</td>
<td>17.5 lakhs</td>
</tr>
</tbody>
</table>

The unit has submitted the following reason for change in item of manufacture:

- that Dengue Vaccine being a new vaccine will take additional time to commercialize, and they wish to defer, since it is a preventive medicine, they have to consider the stains suitable at the given time of administering and the current strain may not be efficient, hence they wish to delete this item from the list of items approved for manufacture.

- they have got enquiries for a product viz. Erythropoietin (EPO) and Polysialylated Erythropoietin (PSA-EPO a combination product) which can be manufactured in their facility at Manjri PBP-1. Their R&D unit has already completed and finished Phase III trial for this product and they can commercialize it in next few months; that all the capital goods which they have already installed can be used to produce EPO and PSA-EPO, and they will be able to export his product during the year 2020-21 as the infrastructure is ready and available except that certain specific raw material is required which will be used in the place of the raw material which was approved for Dengue vaccine.

- they have not procured any raw material / chemicals for Dengue vaccine and the packing material and reagents approved for the Dengue vaccine can also be used for the new product; that instead of raw material for Dengue vaccine, they will procure raw material for EPO and hence, there will no escalation in procurement cost.
the cost of the raw material / chemicals required for production of EPO and PSA-EPO is Rs. 5039128/- per year as compared to Rs. 6057765/- per year required for Dengue vaccine

- Erythropoietin (EPO) is a hormone produced by the kidney and its promotes the formation of RBC by the bone marrow and EPO major function is to promote the development of RBCs. The global EPO drugs market size was valued at Rs. 7.4 billion in 2016 and is expected to witness CAGR of 11.5%. Considering increase in chronic disease viz. end-stage renal diseases, cancer and HIV, demand for EPO stimulating agents is expected to accelerate as these diseases may cause anemia.

- Cost of raw material / chemical required per year is as below :

<table>
<thead>
<tr>
<th>Product</th>
<th>Cost of R/m per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw material for EPO 20 Kg. batch</td>
<td>Rs. 1490555.28</td>
</tr>
<tr>
<td>Raw material for PSA-EPO 2.5 l batch</td>
<td>Rs. 3548552.82</td>
</tr>
<tr>
<td>TOTAL</td>
<td>Rs. 5039128.10</td>
</tr>
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c) Relevant provisions: -

As per 1st proviso to Rule 19(2)

"PROVIDED that the Approval Committee may also approve proposals for broad-banding, diversification, enhancement of capacity of production, change in the items of manufacture or services activity, if it meets the requirements of rule 18;"

d) Other Information:
- M/s. Serum Institute of India Pvt. Ltd. SEZ Unit PBP-I is located at Manjari Bk., Tal. Haveli, Pune 412 307
- LOA No. SEEPZ-SEZ/NEWSEZ/SITPL-SBSPL/03/2015-16 dated 10-03-2016
- DCP - Not yet Commenced
- Since they have not yet commenced operation and considering the fact that there is only change in item of manufacture with marginal change in requirement of raw material / chemicals required for manufacture of EPO / PSA-EPO as compared to Dengue vaccine, there is no change in procurement value as well as change in projection.

e) ADC's recommendation:-
- Proposal for change in item of manufacture resubmitted for consideration of UAC.