

SEEPZ SPECIAL ECONOMIC ZONE

ANDHERI (EAST), MUMBAI.

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AGENDA FOR

28th MEETING OF THE APPROVAL COMMITTEE FOR SECTOR SPECIFIC SPECIAL ECONOMIC ZONE FOR PHARMACETICALS AND BIOTECHNOLOGY AT PUNE OF M/s. SERUM BIO PHARMA PARK.

VENUE : Conference Hall, BFC Building, 2nd Floor, Behind the Office of Development Commissioner, SEEPZ-SEZ, Andheri (East), Mumbai – 400 096.

DATE : 8th January, 2016.

TIME : 2.30 P.M.

28th MEETING OF THE APPROVAL COMMITTEE FOR SECTOR SPECIFIC SPECIAL ECONOMIC ZONE FOR PHARMACEUTICALS AND BIOTECHNOLOGY AT PUNE OF M/s. SERUM BIO PHARMA PARK, UNDER THE CHAIRMANSHIP OF DEVELOPMENT COMMISSIONER, SEEPZ-SEZ ON 8th JANUARY, 2016.

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Agenda Item No.	Subject
Agenda item No. 01: -	Confirmation of Minutes of the meeting held on 07.12.2015.
Agenda item No. 02 : -	Application for Providing Manufacturing Services to Bilthoven Biological B. V. Netherlands (BBio). - M/s. Serum Institute of India Private Limited. (SEZ Unit V).

Minutes of the 27th Meeting of the Approval Committee held under the Chairmanship of Development Commissioner for Sector Specific Special Economic Zone for Pharmaceuticals and Biotechnology at Pune of M/s. Serum Bio-Pharma Park SEZ, Pune on 07.12.2015.

1. Name of the SEZ : M/s. Serum Bio-Pharma Park.
2. Sector : Pharmaceuticals and Biotechnology
3. Meeting no : 27
4. Date : 07.12.2015

Members Present: -

1. Shri. C.L. Hedao
FTDO, Pune : Nominee of Joint.
DGFT, Pune.
2. Shri. K.L Rayappa
Asst. Commissioner : Nominee of Commissioner of
Central Excise & Customs, Thergaon
Division, Pune.
3. Smt. Meena Chavan
Income Tax Officer : Nominee of the Commissioner
of Income Tax, PCIT -3, Pune.

Special Invitees:

4. Shri. B. C. Sahu,
Specified Officer,
Pune.

Agenda Item No. 1: Confirmation of Minutes of the meeting held on 11.07.2014.

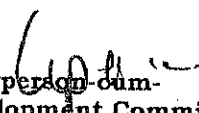
The Minutes of the 26th Meeting held on 11.07.2014 were confirmed.

Agenda Item No. 2: Application for Permission to do Subcontracting as per Provision of Rule 41 (3) of SEZ rules, 2006 to produce "Ready Mix Concrete (RMC)" for construction purpose. - M/s. Serum Bio-Pharma Park SEZ. (Developer)

The developer vide letter dated 07.11.2015 has requested to do Subcontracting as per Provision of Rule 41 (3) of SEZ Rules, 2006 to produce "Ready Mix Concrete (RMC)" for construction purpose. - M/s. Serum Bio-Pharma Park SEZ. (Developer)

After deliberation, the Committee approved the proposal for Sub-contracting as per Provision of Rule 41 (3) of SEZ Rules, 2006 to produce "Readymix Concrete (RMC)" for construction purpose in accordance with input-output norms of Chartered Engineer.

The meeting ended with the vote of thanks to the Chair.


Chairperson cum-
Development Commissioner

**GOVT. OF INDIA,
OFFICE OF THE DEVELOPMENT COMMISSIONER,
MINISTRY OF COMMERCE & INDUSTRY,
SEEPZ (SPECIAL ECONOMIC ZONE)
MUMBAI**

AGENDA NOTE FOR CONSIDERATION OF UNIT APPROVAL COMMITTEE

a) Proposal: -

Application of **M/s. Serum Institute of India Private Limited. (SEZ Unit V)** for Providing Manufacturing Services to **Bilthoven Biological B. V, Netherlands(BBio).**

b) Specific Issue on which decision of UAC is required: -

Permission for manufacturing of few batches of Polio Vaccine on behalf of **Bilthoven Biological B. V, Netherlands.**

c) Relevant provisions of SEZ, Act, 2005 & Rules:-

Rule 18 (6) of SEZ Rules, 2006 as under:-

Units may also be set up for providing services or manufacturing services to overseas Entities subject to following conditions, namely:-

(a) Capital goods, raw materials including consumables sub-assemblies, components, semi-finished goods shall be supplied by the overseas Entity free of cost.

(b) capital goods for setting up such facilities may also be supplied on loan or lease basis, provided the notional value of such capital goods shall be taken into account for calculation of Net Foreign Exchange Earnings under Rule 53,

(c) Finished goods shall be exported out of country or transferred to the customs Bonded Warehouse to be maintained by the overseas Entity. Provided that any supplies of finished goods shall be as per the instructions of the overseas Entity.

(d) the unit shall receive the consideration for its manufacturing services in convertible foreign exchange directly from the said overseas entity.

(e) in case the said manufacturing facility is used by the unit for carrying out production on its own account, separate accounts shall be maintained for the manufacturing and service activity.

d) Other Information:-

M/s. **Serum Institute of India Private Limited. (SEZ Unit V)** has been granted LOA No. SEEPZ/NEWSEZ/SERUM-PUNE/07/LOA-05/2009-10/11229, dated 23.10.2009 for manufacturing activities i.e. Vaccine for Human medicine (Freeze dried/Lyophilized Vaccines) in Single or Multi Doses at Bldg. No. 4, Ground Floor, 1st Floor and 2nd Floor, Serum Bio-Pharma Park SEZ, off Soli Poonawala Road, 212/2 Hadapsar, Pune - 411 028 in Serum Bio - Pharma Park SEZ. The LOA of the unit is valid upto 05.02.2018.

The unit has requested to grant one time permission to provide manufacturing services to Bilthoven Biologicals B.V (BBio) for manufacture of three batches of Polio Vaccine (total 26,670 vials approx).

The unit has informed that they have been approached by Bilthoven Biologicals B. V. (BBio), Netherlands, for manufacture of few batches of Polio Vaccine, on their behalf. BBio would supply bulk polio vaccine to them free of cost, which they have to fill in vials as per their requirement and export to the destinations abroad, as per advice, for conducting clinical trials. BBio shall pay them EUR 0.60 per vial towards processing charges. In addition, they shall also reimburse them freight, insurance and other charges in respect of export of the vaccine.

The unit has further stated that after conducting clinical trials and approval of the bulk for commercial production, they shall be importing the bulk polio vaccine from BBio for their commercial production and export.

The unit vide their letter dated.21.11.2015 has submitted the original overall process flow chart for manufacturing of Oral Polio Vaccine.

The unit vide letter dated **01.12.2015** has submitted the following:-

1. They need a **one time permission** to provide manufacturing service to Bilthoven Biologicals B. V. Netherlands, for manufacture of three batches of Polio Vaccine (total 26670 vials approx.). This will be done with the existing machinery in their unit.
2. Polio Vaccine is one of the Products approved for manufacturing in the Letter of Approval.
3. Bulk Polio Vaccine would be supplied to them by Bilthoven Biologicals, Netherlands on free of cost basis. Primary and secondary packing materials would also be provided by them.
4. Bilthoven Biologicals will pay to them EUR 0.60 per vial toward processing charges, in addition to reimbursement of freight, insurance and other charges at actual basis, for export of vaccines to them. **Hence, there is no foreign exchange outflow for providing the said manufacturing services.**

A copy of letters dated **10.10.2015, 21.11.2015 and 01.12.2015** are enclosed.

In view of the above, the proposal of the unit for providing the manufacturing services of Polio Vaccine on behalf of Bilthoven Biological B. V, Netherlands is placed before Approval Committee for Consideration.



SERUM INSTITUTE OF INDIA LTD.

Cyrus Poonawalla Group

(SEZ UNIT - V)

Serum Bio-Pharma Park SEZ

REGD. OFFICE AND LABORATORIES : 212/2, HADAPSAR, PUNE - 411028, INDIA. TEL. : +91 - 20 - 26602281

FAX: +91-20-26993974 / 26993921 ■ www.seruminstitute.com ■ E-mail : exim@seruminstitute.com

CIN - U80903PN1984PLC032945

October 10, 2015.

The Development Commissioner
SEEPZ Special Economic Zone
Andheri(E)
MUMBAI

Dear Sir,

Re: Manufacturing of Polio Vaccine on behalf of Bilthoven Biologicals B.V,
Netherlands.

Ref: Letter of Approval No. SEEPZ/NEWSEZ/SERUM-PUNE/07/LOA-05/2009-
10/11229, dated 23/10/2009, as amended.

With reference to the above, this is to inform you that we have been approached by Bilthoven Biologicals B.V. (BBio), Netherlands, for manufacture of few batches of Polio Vaccine, on their behalf. BBio would supply bulk polio vaccine to us free of cost, which we have to fill in vials as per their requirement and export to the destinations abroad, as per their advice, for conducting clinical trials. BBio shall pay us EUR 0.60 per vial towards processing charges. In addition, they shall also reimburse us freight, insurance and other charges in respect of export of the vaccine.

Please note that after conducting clinical trials and approval of the bulk for commercial production, we shall be importing the bulk polio vaccine from BBio for our commercial production and export.

In view of the above, kindly grant us permission for providing the manufacturing services to BBio, as per the provisions of sub-rule (6) of Rule 18 of SEZ Rules, 2006, as early possible.

Thanking you,

Yours faithfully,

For SERUM INSTITUTE OF INDIA LTD. (SEZ UNIT-V)

P. C. NAMBIAR
DIRECTOR (GROUP EXIM)

10/10/15

12/10/15



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SERUM INSTITUTE OF INDIA LTD.

Cyrus Poonawalla Group

(SEZ UNIT - V)

Serum Bio-Pharma Park SEZ

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CIN - U80903PN1984PLC032945

November 21, 2015

The Development Commissioner
SEEPZ Special Economic Zone,
Andheri (E), Mumbai.

Dear Sir,

**Sub: Manufacturing of Polio Vaccine on behalf of Bilthoven Biologicals B.V,
Netherlands.**

**REF: Letter of Approval No.SEEPZ/NEWSEZ/SERUM-PUNE/07/LOA-05/2009-
10/11229, dated 23/10/2009, as amended.**

With further reference to our letter dated 10.10.15, we are submitting herewith the original overall process flow chart for manufacturing of Oral Polio Vaccine.

In view of the above, kindly grant us permission for providing the manufacturing services to BBio, as per provision of sub-rule (6) of Rule 18 of SEZ Rules, 2006 as early as possible.

Thanking You,

Yours faithfully,
For **SERUM INSTITUTE OF INDIA LTD (SEZ UNIT-V)**


**HARISH RADHAKRISHNAN
GENERAL MANAGER**

12481

23.11.15



SERUM INSTITUTE OF INDIA LTD.

Cyrus Poonawalla Group

(SEZ UNIT - V)

Serum Bio-Pharma Park SEZ

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CIN - U80903PN1984PLC032945

December 1, 2015.

The Development Commissioner
SEEPZ Special Economic Zone
Andher (E)
MUMBAI

Dear Sir,

Re: Manufacturing of Polio Vaccine on behalf of Bilthoven Biologicals B.V, Netherlands, as per the provisions of sub-rule (6) of Rule 18 of SEZ Rules, 2006.

Ref: Letter of Approval No. SEEPZ/NEWSEZ/SERUM-PUNE/07/LOA-05/2009-10/11229, dated 23/10/2009, as amended.

With further reference to our letter dated October 10, 2015 and November 21, 2015, on the above mentioned subject, we would like to state as under :-

1. We need a one time permission to provide manufacturing service to Bilthoven Biologicals B.V. Netherlands, for manufacture of three batches of Polio Vaccine (total 26,670 vials approx.). This will be done with the existing machinery in our unit.
2. Polio Vaccine is one of the products approved for manufacturing in our above mentioned Letter of Approval.
3. Bulk Polio Vaccine would be supplied to us by Bilthoven Biologicals, Netherlands on free of cost basis. Primary and secondary packing materials would also be provided by them.
4. Bilthoven Biologicals will pay to us EUR 0.60 per vial towards processing charges, in addition to reimbursement of freight, insurance and other charges at actual basis, for export of vaccines to them. Hence, there is no foreign exchange outflow for providing the said manufacturing service.

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2-12-15



SERUM INSTITUTE OF INDIA LTD.

Cyrus Poonawalla Group

(SEZ UNIT - V)

Serum Bio-Pharma Park SEZ

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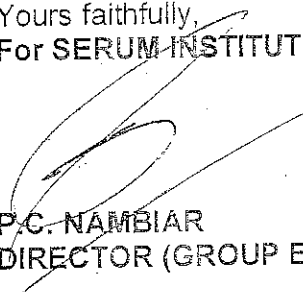
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In view of the above, kindly grant us one time permission for providing the manufacturing services to Biihoven Biologicals, Netherlands, as per the provisions of sub-rule (6) of Rule 18 of SEZ Rules, 2006, as early as possible.

Thanking you,

Yours faithfully,

For **SERUM INSTITUTE OF INDIA LTD. (SEZ UNIT-V)**


P.C. NAMBIAR
DIRECTOR (GROUP EXIM)