



**BEFORE THE NATIONAL GREEN TRIBUNAL
WESTERN ZONE, BENCH, PUNE**

Original Application No.31/2023(WZ)

Prasad M.Mulye

---Applicant



Vs

M/s.Bharat Serums and Vaccines Ltd & Ors

---Respondent(s)

**Affidavit on behalf of Respondent No.2 -Maharashtra Pollution
Control Board.**

I, L. S. Bhad , Age-adult , Occupation -Service , the Regional Officer of the Maharashtra Pollution Control Board at Kalyan , having my office address at Siddhivinayak Sankul, 3rd Floor, Near Oak Baug, Station Road, Kalyan – 421 301, do hereby state on solemn affirmation as under:-

1. I am filing this Affidavit in compliance of this Hon'ble Tribunal order dated 30/5/2023 on behalf of the Respondent No.2 i.e. Maharashtra Pollution Control Board before this Hon'ble Tribunal.
2. The instant application is filed against Respondent No.1 - M/s.Bharat Serums and Vaccines Ltd., which is engaged in the manufacturing of bio-pharmaceutical products having its plant at Plot No.K-27 , K 27/part, K 27/1, Additional MIDC, Ananad Nagar , Ambernath (East), Thane, which is generating huge hazardous waste in close proximity of Chikhloli dam and



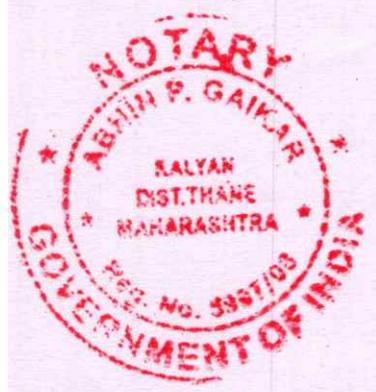
incorrectly categorized in an 'Orange' Category instead of 'Red'.

3. I say and submit that earlier the Respondent -Board had granted Consent to Operate to Respondent No.1-M/s.Bharat Serums & Vaccines Ltd at Plot No. K-27 & K-27/1, Jambhivali Village, Additional MIDC, Ananad Nagar , Ambernath (East), Thane in 'Orange' Category, as under :

Sr. No.	Date of Consent to Operate	Manufacturing activity	Valid upto
1.	27/9/2002	For manufacture of INJ Propavan, INJ Anphollp, INJ Fruseuide I.P. (Only formulation activity),	29/9/2004
2.	Amendment to Consent dtd.26/6/2003 for Condition No.3- For daily quantity of effluent from the factory shall not exceed 35 M ³ and the daily quantity of sewage effluent from the factory shall not exceed 12 M ³ .	--	--
3.	21/07/2004	For manufacture of Injections & Vaccines (Only formulation)	30/6/2014
4.	30/1/2015	For manufacture of Injections & Vaccines (Only formulation)	30/6/2016
5.	23/1/2017	For manufacture of Injections & Vaccines (Only formulation)	30/6/2022
6.	6/4/2018	For manufacture of :	30/6/2022



		1. Injections & Vaccines (Only formulation) 2. Analytical Testing and R & D Activity.	
7.	1 st Consent to Operate for expansion dated 8/4/2021	For the manufacturing of 1. Injection & Vaccines 2. r-FSH (Recombinant - Follicle Stimulating Hormone), 3. r-HCG (Recombinant-Human Chronic Gonadotropin, 4. mAnti-D (Monoclonal Anti Rho-D Immunoglobulin), 5. rAnti-D (Recombinant Anti Rho-D Immunoglobulin), 6. Analytical Testing and R & D Activity.	30/6/2022
8.	Combined Consent to Operate and BMW Authorization for Bio-Pharmaceuticals & small animal testing facility dated 28/01/2022	For the manufacturing of 1. Injection & Vaccines, 2. r-FSH (Recombinant - Follicle Stimulating Hormone), 3. r-HCG (Recombinant-Human Chronic Gonadotropin, 4. mAnti-D (Monoclonal Anti Rho-D Immunoglobulin), 5. rAnti-D (Recombinant Anti Rho-D Immunoglobulin), 6. Analytical Testing and R & D Activity.	30/6/2022
9.	Renewal of Consent dated 13/1/2023	For manufacture of : 1. Analytical Testing and R & D Activity, 2. r-FSH (Recombinant - Follicle Stimulating Hormone),	30/6/2026



		3. r-HCG (Recombinant-Human Chronic Gonadotropin, 4. mAnti-D (Monoclonal Anti Rho-D Immunoglobulin), 5. rAnti-D (Recombinant Anti Rho-D Immunoglobulin), 6. Injection & Vaccines.	
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4. I say and submit that the Central Pollution Control Board has issued Guidelines dated 7/3/2016 for categorization of industries into Green, Orange and Red category depending upon the pollution load. As per the said categorization, at Final Sr.No.74 and Original Sr.No.50, Pharmaceutical Formulation and for R & D Purpose (for sustained release/extended release of drugs only and not for commercial purpose), the Respondent No.1-Industry falls under 'Orange' Category.
5. I say and submit that on the basis of non-compliance of consent conditions observed during the visit of the official of the Board at Kalyan on 6/6/2017, the Respondent-Board had issued closure directions to the Respondent No.1-Industry on 13/6/2017 with the directions to the competent Authorities to disconnect water / electricity supply. A copy of the closure direction dated 13/6/2017 is annexed as an Annexure -C to the said application.
6. I say and submit that the Respondent No.1- Industry vide reply dated 15/6/2017 requested not to disconnect the electric supply as the industry is manufacturing Life Saving injection



and vaccines, which are to be preserved and stored below 10°C, which require continuous refrigeration and cooling, as the said products are very sensitive. The Respondent -Board had considered the request of the Respondent No.1- Industry and accordingly granted Temporary Reconnection of water and electricity supply to Respondent No.1- Industry vide letter dated 20/6/2017 subject to condition that they shall not charge fresh batch of manufacturing till further orders. A copy of the letter dated 20/6/2017 is enclosed herewith and marked as an **Exhibit-I**.



7. I say and submit that the Respondent Board has extended an opportunity of personal hearing to the Respondent No.1- Industry on 3/8/2020 and as decided in the said hearing, the Respondent-Board had issued conditional restart directions on 21/8/2020 to the Respondent No.1-Industry, subject to certain terms & conditions. A copy of the conditional restart directions dated 21/8/2020 is enclosed herewith and marked as an **Exhibit-II**.
8. I say and submit that in order to verify the present status, the Officials of the Respondent Board at Kalyan visited to the Respondent No.1-Industry on 19/6/2023 and observed as under :
 - (i) During visit, the Industry was found operational, engaged in manufacture of bio-pharmaceuticals and small animal testing facility.
 - (ii) Production quantity found within consented limit.

- (iii) The industry has provided primary, secondary & tertiary treatment facility for the treatment of trade effluent. During visit, the ETP was found in operation.
- (iv) The industry is recycling the treated effluent—to utilities i.e. cooling tower to achieve zero liquid discharge.
- (v) The industry has provided STP for the treatment of sewage.
- (vi) The treated domestic effluent is recycled for toilet flushing and remaining used on land for gardening.
- (vii) During visit, no discharge of effluent observed outside the factory premises.
- (viii) During visit, the representative of the Respondent-Industry informed they are manufacturing bio-pharmaceuticals products etc.
- (ix) The industry is having PNG /LDO fired boiler, during visit, the boiler was found in operation on PNG.
- (x) The industry has provided ladder, sampling point and platform to the stack.
- (xi) The industry is a Member of CHWTSDF and is regularly disposing hazardous waste to MWML, Taloja etc..
- (xii) The industry has also obtained membership of CBMWTDF and regularly disposing bio-medical to MWML-Taloja etc.

A copy of the visit report dated 19/6/2023 is enclosed herewith and marked as an **Exhibit-III**.



9. I say and submit that as per the Classification of Industrial Sectors issued by the Central Pollution Control Board, the Respondent Board has issued Consents to the Respondent No.1-Industry in 'Orange' Category from time to time.

Solemnly affirmed on this 25th day of July, 2023 at Kalyan

For and on behalf of Maharashtra Pollution Control Board,

(L. S. Bhad)

Regional Officer-Kalyan



ABHIN P. GAIKAR
B.A., LL.B.
ADVOCATE & NOTARY

Mrunal Niwas, Dawadi Road,
Golavali, Tal. Kalyan, Dist. Thane.

PC No 3234 Date 25 JUL 2023

MPCB. order

MAHARASHTRA POLLUTION CONTROL BOARD

Tel: 24010437/24020781/24014701

Fax: 24024068 / 24023516

Website: <http://mpcb.gov.in>E-mail: psa@mpcb.gov.in

No. MPCB/PSO/Restart/B- 2469

Kalpataru Point, 2nd - 4th Floor

Opp. Cine Planet Cinema,

Near Sion Circle, Sion (E)

Mumbai-400 022.

Date: 20.06.2017.

To,
M/s Bharat Serums and Vaccines Ltd,
Plot No- K27 and K27/1,
MIDC Addl Ambarnath
Dist- Thane

- Sub: Temporary Re-connection of the Water and Electricity supply of M/s Bharat Serums and Vaccines Ltd, Plot No- K27 and K27/1, MIDC Addl Ambarnath.
- Ref: 1. Closure Directions issued by RO Kalyan dated 13.06.2017
2. Industry letter dated 15.06.2017
3. Office Note approved by MS, MPCB on 15.06.2017

With reference to above referred letter at Sr. No.1, Regional Officer, Kalyan issued Closure Directions for non- compliance observed and not obeying the directions of the Board time to time.

Vide your letter dated 15.06.2017, it is requested to not to disconnect the electric supply, as the industry is manufacturing Life Saving injections and vaccines which are to be preserved and stored below 10° C which require continuous refrigeration and cooling being these products are very sensitive.

It is to inform you that Board has considered your request and decided to grant temporary permission for not to disconnect the electricity and water supply, subject to condition that, you shall not charge fresh batch of manufacturing till further orders.

This is issued with approval of the Member Secretary of the Board.

(Dr. A. R. Supate)

Principal Scientific Officer

Copy submitted for information to:

Member Secretary, MPCB, Sion, Mumbai-22

Copy to:

1. Regional Officer, MPCB, Kalyan – for information and n.a.
2. Sub-Regional Officer, MPCB, Kalyan-II- for further necessary follow up and report compliance to Regional Officer.

Copy to:

1. Executive Engineer, MIDC, Division Ambarnath- He is directed to restore the water supply of the said unit, immediately.
2. Executive Engineer, MSEDCL, Ambarnath- He is directed to restore the Electric supply of the said unit, immediately.

MAHARASHTRA POLLUTION CONTROL BOARD

Tel: (0251) 2310167/2310212
 Fax: (0251) 2310192
 Website: <http://mpcb.mah.nic.in>
 E-mail: rokalyan@mpcb.gov.in



Siddhivinayak Sankul,
 3rd Floor, Near Oak Baug,
 Station Road,
 Kalyan (West) - 421 301.

No. MPCB/RESTART/2008210001

Date: 21/08/2020.

To,
 M/s. Bharat Serums & Vaccines Ltd.,
 Plot No. K - 27, K - 27/1, MIDC Addl. Ambernath,
 Dist. Thane.

Sub: - Conditional Restart Direction u/s 33A of the Water (Prevention & Control of Pollution) Act, 1974 and/or u/s 31A of the Air (Prevention & Control of Pollution) Act, 1981.

- Ref:** - 1. Consent to Operate granted by the Board vide no. MPCB/19/466/1909000025 dtd. 03/09/2019.
 2. Closure Direction issued by the Board vide dtd. 13/06/2017.
 3. Temporary permission issued by the Board for not to disconnect water & electricity supply on 20/06/2017.
 4. Request letter to restart the unit submitted by you vide dtd. 19/08/2019.
 5. Personal hearing extended on 03/08/2020.
 6. Minutes of the personal hearing approved on 21/08/2020.

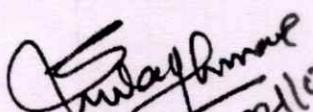
This refers to the Closure Direction issued by the Board vide under ref. no. 2 to your unit due to using treated effluent on land for gardening and causing environmental pollution problems. This also refers to the temporary permission issued by the Board for not to disconnect water & electricity supply on 20/06/2017.

Considering your request letter submitted by you vide under ref. no. 4, minutes of the personal hearing received from authorities it was decided to allow industry to continue their production activity with following terms and conditions -

1. Industry shall submit concrete proposal of sewage treatment plant along with time bound program, within a period of 15 days and shall complete the same on or before 31/12/2020.
2. Industry shall strictly comply with Consent conditions and directions issued by the Board from time to time.
3. In case of failure of any pollution control system, you shall voluntarily suspend the related manufacturing activity and report to the Board, immediately.

These Directions are issued under the power conferred upon me by Board under section 33 A of the Water (Prevention & Control of Pollution) Act, 1974 and under Section 31 A of the Air (Prevention & Control of Pollution) Act, 1981. These Directions shall followed scrupulously, in case of any non-compliance the Board is constrained to take stringent legal action including forfeiture of bank guarantee and closure of unit, which may please be noted.

This is issued with the approval of competent authority.


 Regional Officer, Kalyan. 21/08/2020

Copy Submitted to:

- 1) Member Secretary, MPC Board, Sion, Mumbai.
- 2) Principal Scientific Officer, MPCB, Sion, Mumbai.
- 3) Law officer, MPCB Sion, Mumbai; -for information.

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Copy f. w. cs to:

- 1) The Executive Engineer, MIDC Badlapur area, Badlapur, Dist. Thane - for Information.
- 2) The Executive Engineer/ Addl. Engineer, MSEDCL, Badlapur, Dist. Thane - for Information.

Copy to:

- 1) Sub Regional Officer, MPC Board, Kalyan-II- He is directed to monitor the compliance made by the industry and submit report of the same.
- 2) Master File.

Handwritten signature and date: 21/08/2020

Inspection Report.

- Industry - M/s. Bharat Serruno f Vaccines Ltd
 Plot No. K-27, K-27/P + K-27/11,
 Addl. MIDC, Anandnagar, Ambernath (E)
 Dist. Thane.

- Date of visit - 19/01/2023.

- Industry Rep - Ms. Kakasabheb ~~Patil~~ Lonkar - ^{Senior} GM
 - 7738168311

Observations -

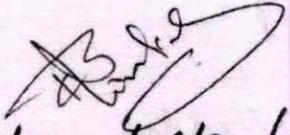
- ① During visit industry found operational engaged in manufacturing of Bio-Pharmaceuticals and small animal testing facility.
- ② Production quantities found within consented limits (Verified against previous form - V)
- ③ Consented water consumption of the industry is 243.0 CMD. Actual water consumption of the industry is about 200.0 to 205.0 CMD.
- ④ Consented trade effluent generation is 108.0 CMD. However, actual effluent generation is about 105 CMD.
- ⑤ Consented sewage generation is 40.0 CMD. However,

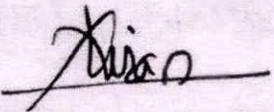
- actual generation from the industry is about 350 cu
- ⑥ Industry has provided ETP comprising of primary, secondary, tertiary treatment facility for treatment of trade effluent.
 - ⑦ During ~~visit~~ visit ETP found operational.
 - ⑧ Industry is recycling treated effluent back to utilities i.e. cooling towers to achieve ZLD.
 - ⑨ Industry has provided STP for treatment of sewage. Treated domestic effluent is being recycled for toilet flushing and remaining is used on land for gardening.
 - ⑩ During visit no discharge of effluent observed outside factory premises.
 - ⑪ ~~At~~ A sample ^{of treated domestic effluent.} is collected for analysis.
 - ⑫ Industry representative informed that they are manufacturing Bio-Pharmaceuticals by way of fermentation which does not involve any chemicals, solvents.

- ⑬ Industry has obtained combined consent valid up to 30/6/2026.
- ⑭ Industry is having PNA/LDO fired boiler.
During visit boiler found operational on PNG.
- ⑮ Industry has provided ladder, sampling point + platforms to the stack.
- ⑯ Industry is member of CHWTSDF and regularly disposing H.W. to mumbai, Talaja.
- ⑰ Industry has filed online returns of H.W. in form -IV for the previous year & latest year.
- ⑱ Industry has also filed Environmental statement for previous year.
- ⑲ Industry has also obtained membership of CBMWTSDF. and regularly disposing BMW to mumbai, Talaja.
- ⑳ Industry has submitted BAs of 10 lakhs, 5 lakhs + 3 lakhs.

21) Industry has planted 1101 nos of trees
around factory premises.




(Kulkarni) (Kulkarni)
Sr. GM


(K.G. Malbhage)
F.O. Kalyan - II