

No. SEIAA: 6 : IND: 2013

**STATE LEVEL ENVIRONMENT IMPACT ASSESSMENT AUTHORITY,
KARNATAKA STATE**

(Constituted by Ministry of Environment & Forests, Government of India)

Department of Ecology and Environment
Room No.709, 7th Floor, IV-Gate,
M.S. Building, Bangalore-560 001,
Date: 3rd October 2013

To

M/s. Anthem Biosciences Pvt. Ltd.,
49, Canara Bank Road,
Bommasandra Industrial Area,
Phase-I, Hosur Road, Bangalore - 99.

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Sir,

Sub: Expansion of the existing R&D unit and production of drugs, dietary supplements & custom synthesis of organic compounds both from R&D and pilot plant at Plot No. 49, Bommasandra Industrial Area Phase-I, Hosur Road, Bangalore of M/s. Anthem Biosciences Pvt. Ltd. - Issue of Environmental Clearance- reg.

This has reference to your applications No. ABPL/SEIA/12-13 dated 15th January 2013 addressed to SEIAA, Karnataka and subsequent letters addressed to SEIAA/SEAC, Karnataka seeking prior environmental clearance for the above project under the EIA Notification, 2006. The proposal has been appraised as per prescribed procedure in the light of the provisions under the EIA Notification, 2006 on the basis of the mandatory documents enclosed with the application viz., the Application in Form 1, Risk Assessment Report, material balance of each proposed drug, project report for manufacture of proposed drugs and the additional clarifications furnished in response to the observations of the SEAC, Karnataka.

The proposal is for manufacturing the following drugs, dietary supplements & custom synthesis of organic compounds both from R&D and pilot plant:

Sl. No	Category	Products	Capacity Kgs/month
1	Custom research	Custom synthesis of organic compounds from R&D	15
2	Custom synthesis	Custom synthesis of organic compounds from pilot plant	1000
3	API	Phenoxy benzyl amine HCL	10

4	API	Pimozide	10
5	API	Tolcopone	100
6	API	L-Methyl Folate	50
7	Dietary supplement (DS)	Resargin	100
8	DS	MK-7	10
9	DS	Anatabine	150
10	API	Ibuprofen Piconol-	200
11	API	LevocloperastineFendizoate	500
12	DS	MK- 4	25
13	DS	PRO Q 10	500
14	API	Valganciclovir Hydrochloride	100
15	DS	Pyridoxal - 5 - Phosphate (P5P)	500
16	DS	Gamma-Glutamyl-cysteine (GGC)	500

It is, inter-alia, noted that M/s. Anthem Biosciences Pvt. Ltd., have proposed for expansion of existing R&D units by undertaking production of the above products. The total land area is 20,412.22 Sqm. No additional land is involved for the proposed expansion and the proposed expansion will be located in the existing infrastructure only. Total water consumption of 41 KLD will be met from KIADB, out of which 22 KLD for domestic purpose, 17 KLD is for process, 2 KLD is for cooling. Power requirement of 1980 KVA will be sourced from the BESCOM. The industry currently has 4 DG sets of capacity 2 X 500 KVA & 2 X 1010 KVA to meet the emergency power requirement and no additional DG sets are proposed. It is proposed to install 2 Lac Kilo calories per hour thermic fluid heater in addition to the existing 1 Lac Kilocalories per hour thermic fluid heater. Fuel for the heater is HSD. The total cost of the project is ₹ 20 Crores.

The wastewater generation after expansion will be 37 KLD of which 20 KLD will be the domestic sewage and 17 KLD will be the industrial effluent. The domestic sewage will be treated in existing ETP of capacity 25 KLD. The industrial effluent will be sent to Common Effluent Treatment Plant (CETP). The details of solid waste are paper, cardboard & wooden boxes of 1000 Kg/month will be disposal by sale, organic garbage of 47 Kg/day will be converted to soil conditioner and used as manure for green belt within the premises, inorganic garbage of 34 Kg/day will be disposed off to BBMP and STP sludge of 2 Kg/day will be used as manure for green belt within in the premises. The hazardous waste generated will be sold to authorized reprocessors/recyclers and the details of hazardous waste are HDPE bags of 1000 Kg/annum, Polythene bags of 200 kg/annum, PVC containers assorted sizes of 1000 Nos/annum, glass bottles of assorted sizes of 250 Nos/annum, M.S/Drums of raw materials of 100 Nos/annum and used oil/lubricant from DG sets & machinery of 2 KL/annum.

The project proposal has been considered by SEAC and ToRs were issued on 3rd April 2013 for conducting Environment Impact Assessment Study. EIA has been conducted by M/s. Rightsource Industrial Solutions Pvt. Ltd., Plot No.203, H.No.5-36/203, Prashanthi Nagar, Kukatpally, Hyderabad- 500072 who is NABET, QCI accredited. The EIA report has been submitted vide letter dated 26.08.2013.

Based on the information submitted by you, presentation made by you and your consultant, M/s. Rightsource Industrial Solutions Pvt. Ltd., Plot No.203, H.No.5-36/203, Prashanthi Nagar, Kukatpally, Hyderabad- 500072, the State Level Expert Appraisal Committee (SEAC) examined the proposal in the meeting held on 15th - 16th March 2013 & 20th, 21st & 23rd September 2013 and has recommended for issue of Environmental Clearance.

The State Environmental Impact Assessment Authority (SEIAA) Karnataka has considered the project in its meeting held on 30th September 2013 and after due consideration of the relevant documents submitted by the project proponent and additional clarifications furnished in response to its observations and the appraisal and recommendation of the SEAC, have accorded environmental clearance as per the provisions of Environmental Impact Assessment Notification-2006 and its subsequent amendments, subject to strict compliance of the terms and conditions as follows:-

Part A- SPECIFIC CONDITIONS

1. National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended time to time shall be followed by the unit.
2. The industrial effluent generation shall be sent to common effluent treatment plant (CETP). The domestic sewage shall be treated in the existing ETP.
3. The project authorities shall maintain daily logbook of the quantity and quality trade effluent generated and dispatched to the CETP.
4. Total water requirement from KIADB water supply shall not exceed 41 KLD and prior permission shall be obtained from the concerned Authority. No ground water shall be used.
5. The process emissions from the boiler shall be dispersed through stack of adequate height as per CPCB /Karnataka State Pollution Control Board standards. The gaseous emissions from the DG set shall be dispersed through stack height as per CPCB standards shall be provided. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.
6. Ambient air quality data shall be collected as per NAAQES standards notified by the Ministry vide G.S.R. No. 826(E) dated 16th September, 2009. The levels of PM₁₀, SO₂, NO_x, VOC and HCl shall be monitored in the ambient air and emissions from the stacks and displayed at a convenient location near the main gate of the company and at important public places. The company shall upload the results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MoEF, Bangalore, SEIAA, Karnataka, the respective Zonal office of CPCB and the Karnataka State Pollution Control Board.
7. The company shall upload the status of compliance of the stipulated environmental clearance conditions, including results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MoEF, Bangalore, SEIAA, Karnataka, the respective Zonal office of CPCB and the Karnataka State Pollution Control Board. The levels of SPM, RSPM, SO₂, NO_x and VOC (ambient levels) and emissions from the stacks shall be monitored and displayed at a convenient location near the main gate of the company and at important public places.

8. The Company shall obtain Authorization for collection, storage and disposal of hazardous waste under the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008 for management of hazardous wastes and prior permission from KSPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. The concerned company shall undertake measures for fire fighting facilities in case of emergency.
9. In plant control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, multi cyclone separator and water sprinkling system. Dust suppression system including water sprinkling system shall be provided at loading and unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits stipulated by the KSPCB.
10. Hazardous chemicals shall be stored in tanks in tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.
11. The company shall undertake following Waste Minimization measures :-
 - a. Metering and control of quantities of active ingredients to minimize waste.
 - b. Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
 - c. Use of automated filling to minimize spillage.
 - d. Use of Close Feed system into batch reactors.
 - e. Venting equipment through vapour recovery system.
 - f. Use of high pressure hoses for equipment clearing to reduce wastewater generation.
12. For control of fugitive emission following steps shall be followed:
 - a. Closed handling system shall be provided for chemicals.
 - b. Reflux condenser shall provided over reactor.
 - c. System of leak detection and repair of pump/pipeline based on preventive maintenance.
 - d. The acids shall be taken from storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap receiver and condenser operated on chilled water.
 - e. Cathodic protection shall be provided to the underground solvent storage tanks.
13. Solvent management shall be as follows:
 - a. Solvent used in the process shall be completely recovered and reused.
 - b. Reactor shall be connected to chilled brine condenser system.
 - c. Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - d. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery
 - e. Solvents shall be stored in a separate space specified with all safety measures.
 - f. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - g. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.

- h. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits imposed by KSPCB.
14. No effluent shall be discharged outside the factory premises and "Zero" discharge concept shall be adopted.
 15. Multi-cyclone followed by bag filter shall be provided to the boilers to control particulate emissions within 100 mg/Nm³. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/APPCB guidelines.
 16. Two stage chilled water/caustic scrubber shall be provided to process vents to control HCl. Two stage scrubbers with caustic lye media solution shall be provided to process vents to control SO₂. The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. At no time, the emission levels shall go beyond the prescribed standards.
 17. As proposed, process organic residue and spent carbon shall be sent to cement industries. ETP sludge, process (inorganic) & evaporation salt shall be disposed off to the TSDF. The ash from boiler shall be sold to brick manufacturers.
 18. Boiler ash shall be stored separately as per CPCB guidelines so that it shall not adversely affect the air quality, becoming air borne by wind or water regime during rainy season by flowing along with the storm water. Direct exposure of workers to fly ash & dust shall be avoided.
 19. During transfer of materials, spillages shall be avoided and garland drains be constructed to avoid mixing of accidental spillages with domestic waste and storm drains.
 20. The Company shall harvest surface as well as rainwater from the rooftops of the buildings and storm water drains to recharge the ground water and use the same water for the various activities of the project to conserve fresh water.
 21. The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire fighting system shall be as per the OISD 117 norms.
 22. Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.
 23. Usage of PPEs by all employees/ workers shall be ensured.
 24. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
 25. Green belt shall be developed in at least 33% of area with suitable species of the plants as per the CPCB guidelines to mitigate the effects of fugitive emissions. Selection of plant species shall be as per the CPCB guidelines.
 26. The adequate financial provisions shall be made in the budget of the project for implementation of the above suggested environmental safeguards. Fund so earmarked shall not be diverted for any other purposes.
 27. The company shall comply with the recommendations made in the EIA/EMP/Risk assessment report. Risk assessment shall be included in the safety Manual.
 28. Provision shall be made for the housing for the construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile sewage treatment plant, safe drinking water, medical health care,

- crèche etc. The housing may be in the form of temporary structure to be removed after the completion of the project. All the construction wastes shall be managed so that there is no impact on the surrounding environment.
29. The proponent shall recover salts including Lithium to be addressed and documented.
 30. The proponent shall be use custom synthesis only for research and not for commercial purpose.
 31. The proponent shall adopt good management practices and green chemistry.
 32. The proponent shall adopt zero discharge technology.
 33. Custom synthesis of organic compounds production from R&D unit and pilot plant shall involve the reaction processes like hydrogenation, esterification, BOC protection, chlorination and nitration only. The organic compounds manufactured from R&D and pilot plant shall not deviate from the above mentioned reaction processes that have been considered for Environment Impact Assessment.
 34. The project authorities shall spend ₹ 2 Lakhs towards the corporate social responsibility made during the SEAC dated 21.09.2013 and report be submitted to the Authority.
 35. The Project authorities also shall earmark at least 5 % of the total cost of the project towards the corporate social responsibility and item-wise details along with time bound action plan shall be prepared and submitted to the Authority.


B. GENERAL CONDITIONS:

1. The project authorities shall strictly adhere to the stipulations made by the Karnataka State Pollution Control Board (KSPCB).
2. At no time, the emissions shall exceed the prescribed limits. In the event of failure of any pollution control system adopted by the unit, the unit shall be immediately put out of operation and shall not be restarted until the desired efficiency has been achieved.
3. No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA/Ministry of Environment and Forests as the case may be. In case of deviations or alterations in the project proposal from those submitted to this Authority for clearance, a fresh reference shall be made to the Authority to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
4. The gaseous emissions (NO_x, SO₂ and SPM) and Particulate matter along with RSPM levels from various process units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system(s) adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency. Stack monitoring for SO₂, NO_x and SPM shall be carried.
5. The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended in October 1994 and January 2000. all transportation of Hazardous Chemicals shall be as per the MVA, 1989. Authorization from the KSPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes.

6. The project authorities must strictly comply with the rules and regulations with regard to handling and disposal of hazardous wastes in accordance with the Hazardous Wastes (Management and Handling) Rules, 2003. Authorization from the KSPCB must be obtained for collection/treatment/ storage/disposal of hazardous wastes.
7. Application of solar energy should be incorporated for illumination of common areas, lighting for gardens and street lighting in addition to provision for solar water heating. A hybrid system or fully solar system for lighting and heating should be provided. Details in this regard should be submitted to the SEIAA.
8. The overall noise levels in and around the plant area shall be kept well within the standards (85 dBA) by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, Rules, 1989 viz. DBA (day time) and 70 dBA (night time).
9. The project proponent shall also comply with all the environmental protection measures and safeguards as per the information provided.
10. The implementation of the project vis-à-vis environmental action plans shall be monitored by MoEF, Regional Office at Bangalore / KSPCB/ CPCB and the Department of Environment & Ecology, Bangalore. A six monthly compliance status report shall be submitted to monitoring agencies.
11. The project proponent shall inform the public that the project has been accorded environmental clearance by the SEIAA and copies of the clearance letter are available with the KSPCB and may also be seen at Website of the Authority at <http://www.seiaa.kar.nic.in>. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the MoEF Regional Office at Bangalore / KSPCB/ CPCB and the Department of Environment & Ecology, Bangalore.
12. The project authorities shall inform the MoEF Regional Office at Bangalore / KSPCB/ CPCB and the Department of Ecology and Environment, Bangalore, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.
13. The SEIAA, Karnataka may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
14. The SEIAA, Karnataka reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.
15. The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 Hazardous Wastes (Management and Handling) Rules, 2003 and the Public Liability Insurance Act, 1991 along with their amendments and rules.
16. The issue of Environment Clearance doesn't confer any right to the project proponent to operate / run the project without obtaining statutory clearances / sanctions from all other concerned Authorities.
17. Concealing factual data or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of Environmental (Protection) Act, 1986.

18. Any appeal against this environmental clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.
19. Officials from the Department of Environment and Ecology, Bangalore/ Regional Office of MoEF, Bangalore who would be monitoring the implementation of Environmental safeguards should be given full cooperation, facilities and documents/ data by the project proponents during their inspection. A complete set of all the documents submitted to MoEF / SEIAA should be forwarded to the CCF, Regional Office of MoEF, Bangalore/ Department of Ecology and Environment, Bangalore/ Regional Officer, KSPCB Bangalore.
20. In the case of any change(s) in the scope of the project, the project would require a fresh appraisal by this Authority.
21. The Authority reserves the right to add additional safeguard measures subsequently, if found necessary, and to take action including revoking of the environment clearance under the provisions of the Environment (Protection) Act, 1986, to ensure effective implementation of the suggested safeguard measures in a time bound and satisfactory manner.
22. All other statutory clearances such as the approvals for storage of diesel from Chief Controller of Explosives, Fire Department, Civil Aviation Department, Forest Conservation Act, 1980 and Wildlife (Protection) Act, 1972 etc. shall be obtained, as applicable by project proponents from the competent authorities.
23. These stipulations would be enforced among others under the provisions of water (Prevention and Control of Pollution) Act, 1974, the Air (Prevention and Control of Pollution) act 1981, the Environment (Protection) Act, 1986, the Public Liability (Insurance) Act, 1991 and EIA Notification, 2006.
24. Under the provisions of Environment (Protection) Act, 1986, legal action shall be initiated against the project proponent if it is found that construction of the project has been started without obtaining environmental clearance.

Yours Faithfully,


(RAMACHANDRA)
Member Secretary,
SEIAA.

Copy to:

- 1) The Secretary, Ministry of Environment & Forests, Government of India, Paryavaran Bhavan, CGO Complex, Lodi Road, New Delhi-110003.
- 2) The Member Secretary, Karnataka State Pollution Control Board, Bangalore.
- 3) The CCF, Regional Office, Ministry of Environment & Forests (SZ), Kendriya Sadan, IV Floor, E & F wings, 17th Main Road, Koramangala II Block, Bangalore-560 034.
- 4) Guard File.