

F.N. J-11011/23/2014-IA.II(I)  
Government of India  
Ministry of Environment & Forests

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To

Dated: 23<sup>rd</sup> July 2014

Shri KVS R Seshu Kumar,  
Director,  
**M/s Emmennar Pharma Pvt. Ltd.,**  
Plot No. 203, H.No.5-36/203,  
Prashanti Nagar, IDA,  
Kukatpally, HYDERABAD – 500072.

**Sub:** Expansion of Intermediate Bulk Drug Manufacturing Unit of **M/s Emmennar Pharma Pvt.Ltd.** at Survey Nos.334 & 335, Turkhal Khanpur Village Hatnoora Mandal Medak District Andhra Pradesh (**TOR**)

Sir,

This is with reference to your letter No. Nil dated 04.12.2013 along with project documents including Form-I, Pre-feasibility Report seeking 'Terms of Reference' (TOR) on the aforesaid project as per the EIA Notification, 2006. Based on the documents furnished, it is noted that M/s Emmennar Pharma Pvt. Ltd. (Unit – II) has proposed to change their chemical manufacturing facility to bulk drug and intermediate manufacturing facility without increasing the production capacity at Survey Nos.334 & 335, TurkhalKhanpur Village Hatnoora Mandal Medak District Andhra Pradesh. Total plot area is 61671 m<sup>2</sup> of which greenbelt will be developed in 20351 m<sup>2</sup>. The cost of modernization is Rs. 911.33 crores.

2. All Synthetic Organic Chemicals Industry (Bulk Drugs & Intermediates) located outside the notified industrial area/estate are listed at S.N. 5(f) under category 'A' and appraised by Expert Appraisal Committee (I).

3. The following products will be manufactured:

S.N	Products	Quantity (MTPM)
1	Meta Chloro Nitro Benzene	300
2	Meta chloro Anisole	240
3	Diethyl-D Tartarate	60
4	Triphenyl Phosphine	90
5	Metformin Hydrochloride	450
6	Butaphosphan	120
7	Ciprofloxacin Hydrochloride	90
8	By-Products	Quantity (MTPD)
9	P-Chloro Nitro Benzene	1.243
10	O-Chloro Nitro Benzene	1.243
11	Hydrochloric Acid	8.264
12	Sodium Hydroxide	4.92
13	Phosphorous Oxy Chloride	2.076

4. Bagfilter will be provided to coal fired (TPH) boiler. Scrubber will be provided to control process emissions. Total fresh water requirement from ground water will be 195.6 m<sup>3</sup>/day. Total effluent generation will be 96.93 m<sup>3</sup>/day. Industrial wastewater will be segregated into High TDS/COD and Low TDS/COD effluent streams. High TDS/COD effluent stream will be treated through steam stripper followed by multiple effect evaporator (MEE) and agitated thin film drier (ATFD). Low TDS effluent stream will be treated in ETP followed by RO. No effluent will be discharged outside the plant premises. Process organic residue, solvent residue and spent carbon will be sent to TSDF/cement industries. Process Inorganic residue, evaporation salts and ETP sludge will be sent to TSDF. Fly ash will be sent to brick manufacturers. Existing DG sets (250 + 1000 KVA) will be continued.

5. The aforesaid proposal was considered by the Reconstituted Expert Appraisal Committee (Industry) (EAC (I)) in its 17<sup>th</sup> Meeting held on 18<sup>th</sup>-19<sup>th</sup> March 2014. The project authorities and their Consultant (Righsource Industrial Solutions Pvt. Ltd.) gave a detailed presentation on the salient features of the project and proposed environmental protection measures to be undertaken along with the draft Term of References for the preparation of EIA-EMP. After detailed deliberations, the Expert Appraisal Committee prescribed the Generic TORs at Annexure-1 read with Additional TORs at Annexure-2 read with the following additional conditions for preparation of EIA-EMP report:

- (i) Zero-discharge
- (ii) Develop good plantation within the project site using tree species with broad canopy

6. The Ministry of Environment & Forests on the basis of the aforesaid recommendations hereby accords the aforesaid TORs as given in the attached Annexure for preparation of the EIA-EMP Report.

(Dr.T.Chandini)  
Director

Copy to: Chairman, Andhra Pradesh State Pollution Control Board, Paryavaran Bhawan, A-3 Industrial Estate, Sanatnagar, Hyderabad – 500038.

(Dr.T.Chandini)  
Director

**GENERIC TERMS OF REFERENCE (TOR)**

1. Executive summary of the project along with justification for the project.
2. Photographs of the proposed and existing (if applicable) plant site.
3. A line diagram/flow sheet for the process and EMP.
4. In case of existing projects seeking expansion, (i) A certified copy of the Monitoring Report of the Regional Office of the Ministry of Environment and Forests as per circular dated 30<sup>th</sup> May, 2012, on the status of compliance of the conditions stipulated in the environmental clearance and (ii) Status of compliance of Consent to Operate for the ongoing existing operation of the project from SPCB, which shall include data on AAQ, water quality, solid waste etc. shall be submitted.
5. A toposheet of the study area and site location map on Indian map of 1:10, 00,000 scale followed by 1:50,000/1:25,000 scale on an A3/A2 sheet of a circle of radius of 10 kms and further 10 kms on A3/A2 sheets with proper longitude/latitude/heights with minimum 100/200m contours shall be included. A 3-D view i.e. DEM (Digital Elevation Model) for the area in 10 km radius from the proposal site. MRL details of project site and RL of nearby sources of water shall be indicated.
6. High-resolution satellite image data having 1m-5m spatial resolution like quickbird, Ikonos, IRS P-6 pan sharpened etc. for the 10 Km radius area from proposed site. The same shall be used for land use/land-cover mapping of the area. Present land use – agricultural land, forestland, wasteland, water bodies, settlements, etc shall be prepared based on satellite imagery.
7. Topography of the area shall be given clearly indicating whether the site requires any filling. If so, details of filling, quantity of fill material required, its source, transportation etc. shall be given. In case the site is located on a hilly terrain, a 3-dimensional view of the location vis-à-vis major land use features and locations such as Critically Polluted Area(s) and Eco-sensitive Area(s) found within the study area, indicating shortest distance from the site shall be provided.
8. Map showing location of Eco-sensitive Areas such as National Parks/Wildlife Sanctuary/Reserve Forests within 10 km. radius (study area) shall specifically be mentioned. A map showing land use/land cover, reserved forests, wildlife sanctuaries, national parks, tiger reserve etc in 10 km of the project site and shortest (aerial) distance from critically/severely polluted area(s) and Eco-sensitive Areas.
9. Project site layout plan to scale using AutoCAD of the project site showing Plant details, raw materials, fly ash and other storage plans, ash pond and water harvesting structures, bore well or water storage, aquifers (within 1 km.), dumping, waste disposal, green belt (areas), water bodies, rivers/drainage passing through/near the project site shall be included.
10. Coordinates of the plant site with topo sheet co-ordinates shall also be included.
11. Details and classification of total land (identified and acquired) shall be included.
12. A copy of the mutual agreement for land acquisition signed with land owners.
13. Proposal shall be submitted to the Ministry for environment clearance only after acquiring total land. Necessary documents indicating acquisition of land shall be included.
14. Permission and approval for the use of forest land (forestry clearance), if any, and recommendations of the State Forest Department, in case the project involves forestland.
15. If the project falls within 10km of an eco-sensitive area, present status/approval from the Standing Committee on Wildlife of the NBWL shall be furnished.
16. Rehabilitation & Resettlement (R & R) shall be as per the R&R Policy of the State Govt. and a detailed action plan shall be included.
17. A list of major industries with name and type within study area (10km radius) shall be incorporated.
18. List of raw material required, analysis of all the raw materials and source along with mode of transportation shall be included. All the trucks for raw material and finished product transportation must be “Environmentally Compliant”.
19. Action plan for excavation and muck disposal during construction phase.

20. Studies for fly ash, muck, slurry, sludge material disposal and solid waste generated from the plant operations and processes and environmental control measures. If the raw materials used have trace elements, an environment management plan shall also be included.
21. Manufacturing process details shall be included.
22. Mass balance for the raw material and products shall be included.
23. Energy balance data for all the components of steel plant including proposed power plant shall be incorporated.
24. One season site-specific micro-meteorological data using temperature, relative humidity, hourly wind speed and direction and rainfall and AAQ data (except monsoon) shall be collected. The monitoring stations shall take into account the pre-dominant wind direction, population zone and sensitive receptors including reserved forests.
25. One season data for gaseous emissions other than monsoon season is necessary.
26. Ambient air quality monitoring at 8 locations within the study area of 10 km, aerial coverage from project site with one AAQMS in downwind direction shall be carried out.
27. Suspended particulate matter present in the ambient air must be analysed for source analysis – natural dust/generated from plant operations (for eg. Cement dust)/flyash/etc. The SPM shall also be analysed for presence of poly-aromatic hydrocarbons (PAH), i.e. Benzene soluble fraction, where applicable. Chemical characterization of RSPM.
28. Determination of atmospheric inversion level at the project site and assessment of ground level concentration of pollutants from the stack emission based on site-specific meteorological features. In case the project is located on a hilly terrain/elevation, the AQIP Modelling shall be done using inputs of the specific terrain characteristics of the project for determining the potential impacts of the project on the AAQ.
29. Action plan to implement National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16<sup>th</sup> November, 2009 shall be included.
30. Ambient air quality modelling along with cumulative impact shall be included for the day (24 hrs) for maximum GLC along with following :
  - i) Emissions (g/second) with and without the air pollution control measures
  - ii) Meteorological inputs (wind speed, m/s), wind direction, ambient air temperature, cloud cover, relative humidity & mixing height) on hourly basis
  - iii) Model input options for terrain, plume rise, deposition etc.
  - iv) Print-out of model input and output on hourly and daily average basis
  - v) A graph of daily averaged concentration (MGLC scenario) with downwind distance at every 500 m interval covering the exact location of GLC.
  - vi) Details of air pollution control methods used with percentage efficiency that are used for emission rate estimation with respect to each pollutant
  - vii) Applicable air quality standards as per LULC covered in the study area and % contribution of the proposed plant to the applicable Air quality standard. In case of expansion project, the contribution shall be inclusive of both existing and expanded capacity.
  - viii) No. I-VII are to be repeated for fugitive emissions and any other source type relevant and used for industry
  - ix) Graphs of monthly average daily concentration with down-wind distance
  - x) Specify when and where the ambient air quality standards are exceeded either due to the proposed plant alone or when the plant contribution is added to the background air quality.
  - xi) Fugitive dust protection or dust reduction technology for workers within 30 m of the plant active areas.
31. A plan for the utilisation of waste/flue gases (if applicable) for generating power shall be presented.
32. Impact of the transport of the raw materials and end products on the surrounding environment shall be assessed and provided. The alternate method of raw material and end product transportation shall also be studied and details included.
33. An action plan to control and monitor secondary fugitive emissions from all the sources as per the latest permissible limits issued by the Ministry vide G.S.R. 414(E) dated 30<sup>th</sup> May, 2008.
34. Presence of aquifer(s) within 1 km of the project boundaries and management plan for recharging the aquifer shall be included.
35. If the site is within 1 km radius of any major river, Flood Hazard Zonation Mapping is required at 1:5000 to 1:10,000 scale indicating the peak and lean River discharge as well as flood occurrence frequency.

36. Details of water requirement, water balance chart for new unit or for existing unit as well as proposed expansion (if expansion). Measures for conservation water by recycling and reuse to minimize the fresh water requirement.
37. Source of water supply and permission of withdrawal of water from Competent Authority.
38. Water balance data including quantity of effluent generated, recycled and reused and discharged is to be provided. Methods adopted/to be adopted for the water conservation shall be included. Zero discharge effluent concepts to be adopted.
39. Source of surface/ground water level, site (GPS), cation, anion (Ion Chromatograph), metal trace element (as above) chemical analysis for water to be used. If surface water is used from river, rainfall, discharge rate, quantity, drainage and distance from project site shall also be included. Information regarding surface hydrology and water regime shall be included.
40. Ground water analysis with bore well data, litho-logs, drawdown and recovery tests to quantify the area and volume of aquifer and its management.
41. Ground water monitoring minimum at 8 locations and near solid waste dump zone, Geological features and Geo-hydrological status of the study area are essential as also. Ecological status (Terrestrial and Aquatic) is vital.
42. Ground water modelling showing the pathways of the pollutants shall be included
43. Action plan for rainwater harvesting measures at plant site shall be submitted to harvest rainwater from the roof tops and storm water drains to recharge the ground water and also to use for the various activities at the project site to conserve fresh water and reduce the water requirement from other sources. Rain water harvesting and groundwater recharge structures may also be constructed outside the plant premises in consultation with local Gram Panchayat and Village Heads to augment the ground water level. Incorporation of water harvesting plan for the project is necessary, if source of water is bore well.
44. A note on the impact of drawl of water on the nearby River particularly during lean season. Permission of competent authority for withdrawal of river/groundwater.
45. Surface water quality of nearby River (60 m upstream and downstream) and other surface drains at eight locations to be provided in and around the project site.
46. A note on treatment of wastewater from different plants, recycle and reuse for different purposes shall be included. Complete scheme of effluent treatment. Characteristics of untreated and treated effluent to meet the prescribed standards.
47. Provision of traps and treatment plants are to be made, if water is getting mixed with oil, grease and cleaning agents.
48. If the water is mixed with solid particulates, proposal for sediment pond before further transport shall be included. The sediment pond capacity shall be 100 times the transport capacity.
49. Wastewater characteristics (heavy metals, anions and cations, trace metals, PAH) from any other source shall be included.
50. The pathways for pollution via seepages, evaporation, residual remains are to be studied for surface water (drainage, rivers, ponds, and lakes), sub-surface and ground water with a monitoring and management plans.
51. Action plan for solid/hazardous waste generation, storage, utilisation and disposal from all the sources and fly ash. EMP shall include the concept of waste-minimization, recycle/reuse/recover techniques, Energy conservation, and natural resource conservation.
52. Details of evacuation of ash, details regarding ash pond impermeability and whether it would be lined, if so details of the lining etc. need to be addressed. Copies of MOU regarding utilisation of ash shall also be included.
53. End use of solid waste and its composition shall be covered. Toxic metal content in the waste material and its composition shall also be incorporated.
54. All stock piles will have to be on top of a stable liner to avoid leaching of materials to ground water.
55. Action plan for the green belt development plan in 33 % area i.e. land with not less than 1,500 trees per ha. Giving details of species, width of plantation, planning schedule etc. shall be included. The green belt shall be around the project boundary and a scheme for greening of the roads used for the project shall also be incorporated. All rooftops/terraces shall have some green cover.
56. Detailed description on flora and fauna (terrestrial and aquatic) exists in the study area shall be given with special reference to rare, endemic and endangered species. If Schedule-I fauna are found within the study area, a Wildlife Conservation Plan shall be prepared and furnished.

57. Risk Assessment and Disaster (Emergency) Preparedness and Management Plan including damage control needs to be addressed and included.
58. Occupational health:
  - a. Details of existing Occupational & Safety Hazards. What are the exposure levels of above mentioned hazards and whether they are within Permissible Exposure level (PEL). If these are not within PEL, what measures the company has adopted to keep them within PEL so that health of the workers can be preserved,
  - b. Details of exposure specific health status evaluation of worker. If the workers' health is being evaluated by pre designed format, chest x rays, Audiometry, Spirometry, Vision testing (Far & Near vision, colour vision and any other ocular defect) ECG, during pre placement and periodical examinations give the details of the same. Details regarding last month analyzed data of abovementioned parameters as per age, sex, duration of exposure and department wise.
  - c. Annual report of health status of workers with special reference to Occupational Health and Safety.
  - d. Action plan for the implementation of OHS standards as per OSHAS/USEPA.
  - e. Plan and fund allocation to ensure the occupational health & safety of all contract and sub-contract workers.
59. Corporate Environment Policy
  - i. Does the company have a well laid down Environment Policy approved by its Board of Directors? If so, it may be detailed in the EIA report.
  - ii. Does the Environment Policy prescribe for standard operating process / procedures to bring into focus any infringement / deviation / violation of the environmental or forest norms / conditions? If so, it may be detailed in the EIA.
  - iii. What is the hierarchical system or Administrative order of the company to deal with the environmental issues and for ensuring compliance with the environmental clearance conditions? Details of this system may be given.
  - iv. Does the company have system of reporting of non compliances / violations of environmental norms to the Board of Directors of the company and / or shareholders or stakeholders at large? This reporting mechanism shall be detailed in the EIA report
60. Details regarding infrastructure facilities such as sanitation, fuel, restroom etc. to be provided to the labour force during construction as well as to the casual workers including truck drivers during operation phase.
61. Impact of the project on local infrastructure of the area such as road network and whether any additional infrastructure needs to be constructed and the agency responsible for the same with time frame.
62. Environment Management Plan (EMP) to mitigate the adverse impacts due to the project along with item wise cost of its implementation. Total capital cost and recurring cost/annum for environmental pollution control measures shall be included.
63. Plan for the implementation of the recommendations made for the Sector in the CREP guidelines must be prepared.
64. At least 5 % of the total cost of the project shall be earmarked for the initial 5 years towards the Enterprise Social Commitment and 2% of retain profit thereafter for life of the project towards CSR based on public hearing issues and item-wise details along with time bound action plan shall be included. Socio-economic development activities need to be elaborated upon.
65. A note on identification and implementation of Carbon Credit project shall be included.
66. Any litigation pending against the project and/or any direction/order passed by any Court of Law against the project, if so, details thereof shall also be included. Has the unit received any notice under the Section 5 of Environment (Protection) Act, 1986 or relevant Sections of Air and Water Acts? If so, details thereof and compliance/ATR to the notice(s) and present status of the case.
67. A tabular chart with index for point wise compliance of above TORs.
68. The questionnaire for industry sector (available on MOEF website) shall be submitted while submitting EIA-EMP.
69. 'TORs' prescribed by the Expert Appraisal Committee (Industry) shall be considered for preparation of EIA-EMP report for the project in addition to all the relevant information as per the 'Generic Structure of EIA' given in Appendix III and IIIA in the EIA Notification, 2006. Where the documents provided are in a language other than English, an English translation shall be provided. The draft EIA-EMP report shall be submitted to the State Pollution Control Board of the concerned State for conduct of Public Hearing. The SPCB shall conduct the Public

Hearing/public consultation, district-wise, as per the provisions of EIA notification, 2006. The issues raised in the Public Hearing and during the consultation process and the commitments made by the project proponent on the same shall be included separately in EIA-EMP Report in the form of tabular chart with financial budget (capital and revenue) along with time-schedule of implementation for complying with the commitments made. The final EIA report shall be submitted to the Ministry for obtaining environmental clearance.

70. The TORs prescribed shall be valid for a period of two years for submission of the EIA-EMP reports along with Public Hearing Proceedings (wherever stipulated).

The following general points shall be noted:

- i. All documents shall be properly indexed, page numbered.
- ii. Period/date of data collection shall be clearly indicated.
- iii. Authenticated English translation of all material in Regional languages shall be provided.
- iv. The letter/application for environmental clearance shall quote the MOEF file No. and also attach a copy of the letter.
- v. The copy of the letter received from the Ministry shall be also attached as an annexure to the final EIA-EMP Report.
- vi. The index of the final EIA-EMP report must indicate the specific chapter and page no. of the EIA-EMP Report
- vii. While preparing the EIA report, the instructions for the proponents and instructions for the consultants issued by MoEF vide O.M. No. J-11013/41/2006-IA.II (I) dated 4<sup>th</sup> August, 2009, which are available on the website of this Ministry shall also be followed.
- viii. The consultants involved in the preparation of EIA-EMP report after accreditation with Quality Council of India (QCI) /National Accreditation Board of Education and Training (NABET) would need to include a certificate in this regard in the EIA-EMP reports prepared by them and data provided by other organization/Laboratories including their status of approvals etc.

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## **ANNEXURE-2**

### **ADDITIONAL TORs FOR SYNTHETIC ORGANIC CHEMICALS INDUSTRY**

1. Manufacturing process details along with the chemical reactions and process flow chart.
2. Name of all the solvents to be used in the process and details of solvent recovery system.
3. Design details of ETP, incinerator, if any along with boiler, scrubbers/bag filters etc.
4. The details of solid and hazardous wastes generation, storage, utilisation and disposal particularly related to the hazardous waste calorific value of hazardous waste and detailed characteristic of the hazardous waste. Action plan for the disposal of fly ash generated from boiler shall be included.
5. Precautions to be taken during storage and transportation of hazardous chemicals shall be clearly mentioned and incorporated.
6. Material Safety Data Sheet for all the Chemicals are being used/will be used. CAS No./RTECS No./DOT/UN etc to be mentioned against each chemicals.
7. Authorization/Membership for the disposal of solid/hazardous waste in TSDF.
8. Risk assessment for storage for chemicals/solvents. Action plan for handling & safety system.
9. Details of occupational health programme.
  - i) To which chemicals, workers are exposed directly or indirectly.
  - ii) Whether these chemicals are within Threshold Limit Values (TLV)/ Permissible Exposure Levels as per ACGIH recommendation.
  - iii) What measures company have taken to keep these chemicals within PEL/TLV.
  - iv) How the workers are evaluated concerning their exposure to chemicals during pre-placement and periodical medical monitoring.
  - v) Liver function tests (LFT) during pre-placement and periodical examination.
10. A Toxic management Plan shall be prepared.
11. A write up on "Safe Practice" followed for handling, storage, transportation and unloading of chemicals to be submitted.
12. What are onsite and offsite emergency plan during chemical disaster.
13. A write up on "Treatment of workers affected by accidental spillage of chemicals".