

Letter No. NGT-463/81-7-2024

From,

Devendra Singh Chauhan
Under Secretary,
Government of Uttar Pradesh

To,

The Registrar General,
Hon'ble National Green Tribunal,
Copernicus Marg, New Delhi.

**Environment, Forest and
Climate change Section-7,**

Lucknow: Dated: 16 August, 2024

**Sub: RESPONSE ON BEHALF OF RESPONDENT NO-5 THE STATE OF UTTAR
PRADESH IN COMPLIANCE TO ORDER DATED 06.05.2024 PASSED BY THE
HON'BLE NATIONAL GREEN TRIBUNAL, NEW DELHI IN O.A. NO. 497/2024
NEWS ITEM TITLED "IMPACT OF PHARMACEUTICAL TOXICITY ON THE
ENVIRONMENT AND ITS REGULATORY ASPECTS" APPEARING IN
CURRENT SCIENCE DATED 25.02.2024**

Sir,

That in Compliance of the order dated 06.05.2024 passed by Hon'ble Tribunal in O.A. No. 497/2024 News item titled "Impact of Pharmaceutical toxicity on the environment and its regulatory aspects" appearing in Current Science dated 25.02.2024, the response on behalf of the State of Uttar Pradesh is enclosed and filed herewith.

It is requested that the said response may be presented before the Hon'ble Tribunal for perusal and consideration.

Encl: As above

Your's Sincerely,

Signed by

Devendra Singh Chauhan
(Devendra Singh Chauhan)
Date: 14-08-2024 18:29:17
Under Secretary.

Copy to: Shri Bhanwar Pal Singh Jadon, Standing Counsel, State of UP,
Hon'ble NGT for information and further necessary action.

Response in the matter of OA 497/2024 on “Impact of Pharmaceutical toxicity on the environment and its regulatory aspects”

That, the Hon’ble NGT has passed order dated 06.05.2024 in OA 497 of 2024 involving matters pertaining to the News item titled "Impact of Pharmaceutical toxicity on the environment and its regulatory aspects" appearing in Current Science dated 25.02.2024, the relevant parts are as follows:-

“....10. Since, it is a PAN India issue, therefore, we deem it proper to implead the following as respondents in the matter:

.....(5). Chief Secretary, State of Uttar Pradesh.....(41). Member Secretary, Uttar Pradesh State Pollution Control Board....

11. Let notice be issued to the above respondents, except the CPCB who is already represented through the Counsel, for filing their response at least one week before the next date of hearing disclosing the compliance of the norms by the pharmaceutical company, the regulatory guidelines in force, number of pharmaceutical companies in each of the State and number of such companies complying with norms and number of companies against whom action is taken for violation of the norms as also the proposed action for prevention of environment from pharmaceutical toxicity...”

1. The Tribunal addressed concerns related to the environmental impact of pharmaceutical toxicity and regulatory measures discussed in the referenced news article. The news item discloses that pharmaceutical-induced environmental contamination needs urgent attention because around 43% of global rivers are facing risks from Active Pharmaceutical Ingredients (APIs). The continuous emissions are posing potential hazardous to the environment and human health. It also states that discussions on chemical waste reduction face limitations due to incomplete knowledge about their toxicity to humans. It discloses that pharmacies sometimes cannot filter all the chemicals used in



pharmaceutical production (e.g. solvents, active pharmaceutical ingredients (APIs), excipients, additives, by-products, intermediates, etc.). These chemicals cause ecosystem imbalances that give rise to chemical pollution in the environment.

2. **That as per the information provided by the Uttar Pradesh Pollution Control Board (UPPCB) the Regulatory guidelines and Compliance Norm for the sector are as follows:-**
- i. The Effluent and Emission Standards for Bulk Drug and Formulation (Pharmaceutical) have been notified in the schedule-I of The Environment (Protection) Rules, 1986 and are already in force. The Uttar Pradesh Pollution Control Board is monitoring on a monthly/quarterly basis.
 - ii. The Synthetic organic chemicals industry (dyes & dye intermediates; bulk drugs and intermediates excluding drug formulations; synthetic rubbers; basic organic chemicals, other synthetic organic chemicals, and chemical intermediates) has been notified in Activity 5 (f) of the Notification dated 14th September 2006 as amended issued by Ministry of Environment, Forest and Climate Change (MoEF&CC), Government of India. According to the provisions of this notification, Environment Clearance is issued by the Central Government and Uttar Pradesh State Environment Impact Assessment Authority (UP-SEIAA).
 - iii. The Drugs and Cosmetics Act, 1940; Manufacture, Sale and Distribution of Drugs and Cosmetics are mentioned in Chapter IV of the above-mentioned Act and its compliance is ensured by Food Safety and Drug Administration Department, UP.
3. **As per the information provided by UPPCB the Status of Active Pharmaceutical Ingredients (API) units is as follows:-**

There are 22 Operational Active Pharmaceutical Ingredients (API) units in the State of Uttar Pradesh. Out of these, 20 units are complying with



norms and 02 units are non-complying. Action is being taken by UPPCB against non-complying units. Details of the action taken are given below:

District	Total no. of industries	No. of industries closed by their own	No. of industries operational	No. of Industries having valid CTO	No. of industries complying with environmental standards	No. of industries non-complying with environmental standards	No. of industries against which action is taken for non-complying with environmental standards	
							Show cause notice issued	Closure directions issued
Ghaziabad	6	0	6	6	6	0	0	0
Greater Noida	7	0	7	7	7	0	0	0
Meerut	2	0	2	2	2	0	0	0
Muzaffarnagar	3	0	3	3	1	2	2	0
Bulandshahar	1	0	1	1	1	0	0	0
Varanasi	1	0	1	1	1	0	0	0
Amroha	1	0	1	1	1	0	0	0
Gorakhpur	1	0	1	1	1	0	0	0
Total	22	0	22	22	20	2	2	0

4. That UPPCB does regular inspections and if found complying, Consent to Operate (CTO) is granted. If any unit is found non complying actions is taken as per Air & Water act.
5. The Drug Licenses are issued to the pharmaceutical companies as per the provisions of the rules made under the Drugs and Cosmetics Act, 1940 by Food Safety and Drug Administration Department. Food Safety and Drug Administration Department, Government of UP has informed vide its letter dated 25.07.2024 that pharmaceutical companies obtain NOC from the Pollution Control Board regarding Pollution control and submit the same along with their applications. Emission and pollution from pharmaceutical companies are not regulated by the Food Safety and Drug Administration Department. The copy of the letter of Food Safety and Drug Administration Department dated 25.07.2024 is enclosed herewith as **Annexure-1**.

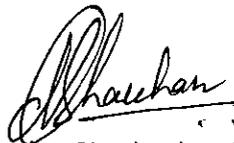


6. Prior Environmental Clearance has to be obtained by the Project Proponent interested in setting up of such units as per the notification of MoEF&CC dated 14th September 2006.

Therefore, the response of State of Uttar Pradesh is submitted before this Hon'ble Tribunal for perusal and kind consideration

Place : Lucknow

Dated : 16.08.2024


(Devendra Singh Chauhan) 16/08/24

Under Secretary,
DoEF&CC,
Govt. of U.P.

संख्या- 919 /अटठासी-1-2024

प्रेषक,

रेखा एस0 चौहान,
विशेष सचिव,
उ0प्र0 शासन।

सेवा में,

विशेष सचिव,
पर्यावरण, वन एवं जलवायु परिवर्तन विभाग,
उ0प्र0शासन।

खाद्य सुरक्षा एवं औषधि प्रशासन अनुभाग-1

लखनऊ: दिनांक 25 जुलाई, 2024

विषय:- आवेदन संख्या-497/2024 में नेशनल ट्रिव्यूनल, नई दिल्ली द्वारा पारित आदेश दिनांक 06.05.2024 के सम्बन्ध

महोदय,

उपर्युक्त विषयक आवेदन संख्या-497/2024 में नेशनल ट्रिव्यूनल, नई दिल्ली द्वारा पारित आदेश दिनांक 06.05.2024 का संदर्भ ग्रहण करने का कष्ट करें, जिसके द्वारा मा0 नेशनल ग्रीन ट्रिव्यूनल द्वारा आवेदन संख्या-497/2024 के सम्बन्ध में नोटिस निर्गत करते हुए फार्मास्युटिकल विषाक्तता से पर्यावरण की रक्षा हेतु निर्धारित मानको को पूर्ण नहीं करने वाली दवा कम्पनियों के विरुद्ध की गयी कार्यवाही से अगली सुनवाई दिनांक 20.08.2024 से पूर्व अवगत कराने की अपेक्षा की गयी है।

2- इस सम्बन्ध में अवगत कराना है कि औषधि एवं प्रसाधन सामग्री अधिनियम 1940 के अधीन बने नियमावली के प्राविधानानुसार फार्मास्युटिकल कंपनियों को औषधि लाइसेंस निर्गत किये जाते हैं। औषधि नियमावली के अंतर्गत प्रदूषण नियंत्रण के संबंध में यह उल्लिखित है, की संबंधित व्यक्ति/फर्म द्वारा प्रदूषण नियंत्रण से संबंधित कानून का अनुपालन किया जाएगा। उल्लेखनीय है कि फार्मास्युटिकल कंपनियों द्वारा प्रदूषण के संबंध में प्रदूषण नियंत्रण बोर्ड से अनापत्ति प्रमाण पत्र प्राप्त करके अपने आवेदन के साथ प्रस्तुत किया जाता है।

फार्मास्युटिकल कंपनियों के उत्सर्जन एवं प्रदूषण का नियंत्रण खाद्य सुरक्षा एवं औषधि प्रशासन द्वारा नहीं किया जाता है। प्रदेश में प्रदूषण नियंत्रण से संबंधित कार्यवाही उत्तर प्रदेश प्रदूषण नियंत्रण बोर्ड द्वारा किया जाता है।

3- इस सम्बन्ध में मुझे यह कहने का निदेश हुआ है कि आवेदन संख्या-497/2024 में नेशनल ट्रिव्यूनल, नई दिल्ली द्वारा पारित आदेश दिनांक 06.05.2024 के अनुक्रम में प्रकरण में अग्रेतर कार्यवाही कराने का कष्ट करें। प्रकरण में अगली सुनवाई दिनांक 20.08.2024 को नियत है।

भवदीया,
24/07
(रेखा एस0 चौहान)
विशेष सचिव।