No. 31015/61/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
……..

A- Wing, Shastri Bhawan,
New Delhi 110 001

Subject: **Review application of M/s Sun Pharmaceutical Industries Ltd. against price fixation of "Sodium Valproate Tablet 200mg" vide NPPA order No. S.O. 1569(E), dated 15.05.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

Ref: **1) Review application dated 05.06.2017**
2) NPPA notification under review S.O. 1569(E), dated 15.05.2017
3) Record Note of discussions held in the personal hearing held in the matter on 27.06.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Ltd. (hereinafter called the petitioner) against notification S.O. No.1569(E), dated 15.05.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Sodium Valproate Tablet 200mg

2. The petitioner has contended as under:-

I. The said notification NPPA S.O. No. 1569 (E) dated 15.05.2017 came with suppression of previous notification S.O. 1039(E) dated 01.04.2017. However, in the notification NPPA S.O. No. 1569 (E) footnote (i) was included- "The formulation of Sodium Valproate includes combination of Sodium Valproate and Valproic Acid both together corresponding to Sodium Valproate of the stated strength." With inclusion of this footnote, the notified ceiling price became applicable for products containing combination of Sodium Valproate and Valproic Acid corresponding to Sodium Valproate 200 mg including their product **Encorate Chrono 200**.

II. **However, the notification S.O. 2195(E) dated 23.06.2016, prior to S.O. 1039(E) dated 01.04.2017 on Sodium Valproate 200 mg tablets does not include any such footnote. Including molecules/variants other than what is included in Schedule-I, is not as per provision of DPCO.**

III. The company's product **Encorate Chrono 200** contains both Sodium Valproate and Valproic Acid. Combination of Sodium Valproate and Valproic Acid (equivalent to Sodium Valproate 200 mg) is not included in DOP S.O. 701(E) dated 10.03.2016 and thus, is not a scheduled product.

IV. Ceiling price notified for Sodium Valproate 200 mg Tablet vide NPPA S.O. No. 1569 (E) dated 15.05.2017 should not get applicable for product with

combination of Sodium Valproate and Valproic Acid corresponding to Sodium Valproate 200 mg including **Encorate Chrono 200**.

V. In view of the above, company requested this Department to issue necessary directives to NPPA to exclude foot note (i) of NPPA S.O. 1569(E) for the said formulation.

3. **Comments of NPPA:**

Ceiling price of Sodium Valporate Tablet 200mg was notified as Rs. 2.93 per tablet vide S.O. 1569(E) dated 15.05.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

II. The company has raised objection to the footnote (i) of the above notification. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:**-**

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has challenged footnote (i) of S.O. 1569(E) by stating that subject notification came with supersession of S.O. 1039(E) dated 01.04.2017 where such footnote was not included. Inclusion of such footnote in S.O. 1569(E) is against the provisions of DPCO, 2013. With inclusion of this footnote, their product Encorate Chrono 200mg tablet containing Sodium Valporate 133.33 mg + Valproic Acid 58 mg became a scheduled formulation. Company has also stated that ceiling price notified for Sodium Valporate 200mg tablet vide S.O. 1569(E) dated 15.05.2017 should not applicable for their product Encorate Chrono 200mg tablet.	Company's request is not acceptable as Sodium Valporate 200 mg tablet was included in NLEM 2011 as well as in NLEM 2015. DPCO does not differentiate the API used in manufacturing pharmaceuticals products. Valproic Acid, its salts and esters are used in the treatment of various type of epilepsy. Manufacturer may use API Sodium Valporate 200mg or Sodium Valporate 133mg + API Valproic Acid 58mg to manufacture Sodium Valporate tablet 200mg. The footnote is for clarification only. Even if the footnote is not in notification the ceiling price is applicable.
		Detail of trade margin based on AIOCD-AWACS data as on August 2015:- Trade Margin from PTS level of:- Sodium Valporate 200mg (Encorate 200mg tablet) – 10's - 37% Sodium Valporate 200mg (Encorate Chrono 200mg tablet) – 10's - 37% Sodium Valporate 200mg (Epival EC 200mg tablet) – 10's - 37%

III. Company has not challenged any notification in respect of **Sodium Valporate Tablet 200mg** in the Court.

4. During the personal hearing, the representatives of the company made the following further submissions –

1. Company is having a product, namely Encorate Chrono 200 containing combination of Sodium Valproate and Valproic Acid. NLEM 2015 covers only Sodium Velproate tablet 200mg and not the combination with Valproic Acid. However, in the notification NPPA SO No. 1569(E) footnote (i) was included- "The formulation of Sodium Valproate includes combination of Sodium Valproate and Valproic Acid both together corresponding to Sodium Valproate of the stated strength." With inclusion of this footnote, the notified ceiling price became applicable for products containing combination of Sodium Valproate and Valproic Acid corresponding to Sodium Valproate 200 mg including our product **Encorate Chrono 200**.
2. Further, the first notification under NLEM 2015, vide SO 2195(E) dated 23.06.2016, on Sodium Valproate 200 mg tablets does not include any such footnote.
3. There are separate monographs for products containing Sodium Valproate and Valproic Acid in Indian Pharmacopoeia (for example, Sodium Valproate tablets, Valproic Acid capsules).
4. Ceiling price notified for Sodium Valproate 200 mg Tablet vide NPPA S.O. No. 1569(E) dated 15.05.2017 should not get applicable for product with combination of Sodium Valproate and Valproic Acid corresponding to Sodium Valproate 200 mg including **Encorate Chrono 200**.
5. While going through the working sheet of ceiling price, it has been observed that there is no product captured with the combination of Sodium Valproate and Valproic Acid, including Enrorate Chrono 200. This confirms that combination of Sodium Valproate and Valproic Acid are not covered under ceiling price. Hence, footnote (i) of SO 1569(E), dated 15.05.2017 should be deleted.
6. Company has already submitted copy of price list in Form V of DPCO 2013 of the captioned ceiling price of **Encorate Chrono 200** with the Review Application**.**
7. For the comments given by NPPA in the brief of hearing about detail of trade margin based on AIOCD-AWACS data as on August, 2015, the company representative submitted that they are giving margin to retailers and wholesalers as per the existing standard trade practice prevalent in the pharmaceutical industry.

NPPA representative submitted that DPCO, 2013 does not differentiate the API used in manufacturing pharmaceuticals products. Manufacturer may use API Sodium Valporate 200mg or Sodium Valporate 133mg + API Valporic Acid 58mg to manufacture Sodium Valporate tablet 200mg.

5. Examination:

The ceiling price of the formulation Sodium valporoate tablet 200mg was earlier fixed vide SO 2195(E), dated 23.6.2016 which was revised vide SO No.1569(E), dated 15th May, 2017 in compliance to DoP Review Order No.31015/71/2016-PI.I., dated 30.01.2017. In the said notification, NPPA has inserted a footnote (i), which reads as ***"The formulation of Sodium Valproate includes combination of Sodium Valproate and Valproic Acid both together corresponding to Sodium Valproate of the stated strength."*** This footnote was not included in the earlier SO 2195(E), dated

23.6.2016. The inclusion of the said footnote resulted into one formulation Encorate Chrono 200mg tablet, (which contains both Sodium Valporate 133.33mg + Valproic Acid 58mg) of the petitioner company becoming a scheduled formulation. In support of the footnote, the NPPA clarified that Valproic Acid, its salts and esters are used in the treatment of various type of epilepsy. Manufacturer may use API Sodium Valporate 200mg or Sodium Valporate 133mg + API Valproic Acid 58mg to manufacture Sodium Valporate tablet 200mg. and the footnote is only for clarification. NPPA also stated that DPCO does not differentiate the API used in the manufacturing pharmaceuticals products.

The Explanation Notes (4) & (5) of SO 701(E), dated 10.3.2016 issued by DoP vide which Schedule-I was revised, states as under :-

"(4) In general, medicines have been mentioned with respect to their active moieties, without mentioning the salts and, in case where there is significant difference between the salts, the medicine finds mention as its specific salt.
(5) In cases where an active moiety is available as different isomers or analogues or derivatives, they are considered as separate entities, and inclusion of one does not imply inclusion of all isomers or analogues or derivatives."

NPPA has not submitted any expert opinion in support of their claim that Valproic Acid, its salts and esters are used in the treatment of various type of epilepsy and the product containing API Sodium Valporate 200mg or Sodium Valporate 133mg + API Valproic Acid 58mg also comes under the purview of scheduled drug. In view of Explanation Notes (4)&(5) of SO 701(E), mentioned above, it is proposed that NPPA may obtain the opinion of Committee of Experts to take a view on merit whether footnote (i) of SO 1569(E), dated 15.5.2017 is in order, by virtue of which formulation Encorate Chrono 200mg tablet of the company containing Sodium Valporate 133.33mg + Valproic Acid 58 mg also comes under the purview of scheduled drug.

Government Decision:

"NPPA is hereby directed to obtain the opinion of Committee of Experts on whether the inclusion of formulation Encorate Chrono 200mg tablet of the company containing Sodium Valporate 133.33mg + Valproic Acid 58 mg under the purview of scheduled drug, is in order? And based on such opinion, the price fixation be done."

Issued on this date, the 11th day of January, 2018.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

To

1. M/s. Sun Pharma Laboratories Ltd.,
   Sun House, Plot No.201 B/I,
   Western Express Highway, Goregaon (E),
   Mumbai-400 063.
2. The Member Secretary,
   National Pharmaceutical Pricing Authority,
   YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department's Website