

No. 31026/23/2016-PI.I
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Shastri Bhawan, New Delhi
Dated, the 21st December, 2016

To

1. Panacea Biotech Limited, B-1, Extn./A-27, Mohan Co-operative Industrial Estate, Mathura Road, New Delhi-110044.
(Email:companysec@panaceabiotec.com/
goutamghosh@panaceabiotec.com), Fax- 011-41679070.
2. Samarth Life Sciences Pvt. Ltd., Samarth House, Ram Mandir Road, Goregaon(W), Mumbai-400104.
(Email:- samarth@samarthlife.com/info@samarthlife.com Fax
022-56959185
3. VHB Life Sciences Limited, 50-AB, Government Industrial Estate, Charkop Naka, Kandivali West, Mumbai – 400067
(Email: sanjay.buch@vhbgroup.com/ kapil4vhb@gmail.com)
4. M/s. Fleming Laboratories, Hyderabad, 4th Floor, Madhupala Towers, Ameerpet, Hyderabad – 500 016, Telengana.
{Email: prakash@fleminglabs.com, hrd@fleminglabs.com}
Fax No. 040-23416779
5. M/s. Biophore India Pharmaceuticals Pvt. Ltd., Plot No. 23, 3rd Floor, TIE, 1st Phase, Balanagar, Hyderabad-500037.
Fax No. 040-40113218 (Email: info@biophore.com)

Subject:- Shortage of Pencillamine medicine used for treatment of Wilson's disease-Meeting Notice- regarding.

Sir,

I am directed to refer on the above mentioned subject and to say that the matter was reviewed by Secretary, D/o Pharmaceuticals in a meeting held on 6.12.2016 which was attended by Chairman, NPPA and DCGI. The manufacturers of formulations of D-Pencillamine who attended the meeting viz. M/s. Panacea Biotech Limited and VHB Life Sciences Pvt. Limited, were given an opportunity to explain the genesis of current shortages and their action plans to resume production and distribution of the said medicine.

2. After due deliberations on the current situation and alternatives available with the government to resume normal production and distribution of the medicine, it has been decided to invoke the powers of Section 3 (i) of DPCO, 2013 which provides as under:-

“The Government may,-(i) with a view to achieve adequate availability and to regulate the distribution of drugs, in case of emergency or in circumstances of urgency or in case of non-commercial use in public interest, direct any manufacturer of any active pharmaceutical ingredient or bulk drug or formulation to increase the production and to sell such active pharmaceutical ingredient or bulk drug to such other manufacturer(s) of formulations and to direct formulators to sell the formulations to institutions, hospitals or any agency as the case may be.”

3. The Companies manufacturing the API of D-Pencillamine medicine in India (M/s. Fleming Laboratories and M/s. Biophore Pharmaceuticals) are directed as under:-

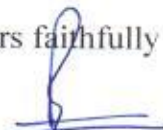
- (i) These companies will report the annual production and sale of the said API in the last three financial year to NPPA and DCGI;
- (ii) These companies will report the production plan and capacity for next three months to NPPA and DCGI and will follow their directions for production of the said API and sale to the manufacturers of the formulations;
- (iii) These Companies will give first right of refusal to buy the supply of said API to M/s Panacea Biotech and second right of refusal to buy the supply to M/s. VHB Life Sciences Pvt. Limited before selling or marketing to the other manufacturers;
- (iv) During the period of three months, these companies will submit a weekly report of delivery of API and the plan of production of the next week to NPPA;
- (v) Any proposal for sale of the said API besides these two companies referred to in point (iii) above will require written permission of NPPA during this period.

4. The Companies manufacturing the formulations of D-Pencillamine in India (M/s. Panacea Biotech and M/s. VHB Life Sciences Pvt. Limited) are directed as under:-

- (i) These companies will report the quarterly production and sale of the said medicine in India during last financial year to NPPA and DCGI;
- (ii) These companies will report the production plan and capacity for next three months to NPPA and DCGI and will follow their directions for production of these medicines at the average level of the previous financial year;
- (iii) These Companies will source their supply of API D-Pencillamine from M/s Fleming Laboratories and M/s. Biophore Pharmaceuticals who are also being directed under the present order to supply the API;

- (iv) During the period of three months, these companies will submit a weekly report of delivery of API received, formulations produced and formulations distributed. They will also submit a weekly production plan for the next week to NPPA and DCGI;
 - (v) They will also submit a weekly report about the efforts made to reach out to the patients and hospitals for ensuring accessibility to the medicine;
 - (vi) These companies will simultaneously make effort to tie up the supply of D-Pencillamine API for normal business operations after expiry of three months period from the date of this order.
5. NPPA and DCGI are also empowered to extend these directions to any other producers of API D-Pencillamine or formulations in India during this three months period.
6. This order will be valid for next three months and NPPA and DCGI will recommend withdrawal or extension as the case may be, two weeks before the expiry of the period.
7. This issues with the approval of Hon'ble Minister for Chemicals & Fertilizers.

Yours faithfully



(Raj Kumar)

Under Secretary to the Govt. of India

Phone: 23071162

E-mail: uspi3-pharma@nic.in

Copy for compliance and reporting:-

1. Chairman, NPPA, YMCA Building, New Delhi. He is requested to focus on regular monitoring of Availability/Production of all important drugs in the market and ensure their availability. NPPA will set up a system for such 'alerts' & monitoring so that such situations are avoided in future.
2. DCGI, FDA Bhawan, ITO, Kotla Road, New Delhi.

Copy for information to:-

1. PMO (Kind Attn:- Shri Mayur Maheshwari, DS), South Block, New Delhi
2. Secretary, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi.
3. Secretary, Department of Commerce, Udyog Bhawan, New Delhi.