

**MINUTES OF MEETING HELD ON 30.09.2016 AT FDA BHAWAN,  
NEW DELHI UNDER THE CHAIRMANSHIP OF DCG (I) TO ADDRESS  
THE ISSUES REGARDING THE NON AVAILABILITY OF  
D-PENICILLAMINE IN THE COUNTRY**

A meeting regarding the non-availability of drug D-Penicillamine in India was held on 30.09.2016 at 02.00 PM under the chairmanship of Dr.G.N. Singh, Drugs Controller General (India).

The list of participants is annexed.

DCG (I) informed that, CDSCO has received many representations about the non-availability of D-Penicillamine Capsules in the country. He requested the representatives of the manufacturers/importers to give reasons and factual details regarding non-availability of the D-Penicillamine Capsules in the country.

The representatives of the various firms mentioned that because of small number of patients who requires Penicillamine Capsules in the country, the demand of the drug is low. It was also mentioned at present that the availability of Bulk drug is also an issue.

The factual status regarding the availability of the drug as mentioned by the representatives of the firms are as under -

**Panacea Biotec, New Delhi:-**

The firm informed that since 26<sup>th</sup> September 2016 they have resumed limited production of the drug and have released 69 thousand capsules through their distributors to cope with the temporary shortage of the drug. They have also delivered the drug to approximately 300 patients so far, who could reach them through various forums.

It was also mentioned that they have launched a website [www.cilamin.com](http://www.cilamin.com) for emergency supplies to patients and for access to latest information on its availability. They have also formed a WhatsApp Group Cilamin Support (+91-9350588528) of patients, Doctors, company executives and a Twitter Handler @Cilamin250 and facebook page <https://www.facebook.com/cilamin250> for support, monitoring and real time communications.

The firm also informed that they have registration for import of Bulk Penicillamine from China. However the registered site is not manufacturing the drug since last six months. Therefore, they have identified another bulk drug source in China but the same is not registered

in India. The firm requested for special consideration for import of the Bulk from the said source so that continuous supply of the Penicillamine Capsules can be ensured.

DCG (I) informed that once application along with the required documents for import registration is received, the same can be processed expeditiously for grant of import registration

**Fleming Laboratories, Hyderabad:**

They informed that at present they have a capacity to manufacture of about 200kg of Penicillamine bulk per month. They have already manufactured and supplied 23 kg of the bulk drug to M/s. Panacea Biotec. They also mentioned that manufacturing of 45 kg of Bulk Penicillamine is in their pipeline which may be manufactured within next 2-3 weeks time.

DCG (I) requested that they should focus and put all efforts by diverting resource from other activities to manufacture this drug to the full capacity on priority basis.

**VHB Life Sciences, Mumbai:**

They informed that they are not manufacturer. However, they market D-Penicillamine Capsules manufactured under third party agreement. They have marketed around 2.7 lakhs Capsules, manufactured in September 2014, of which around 1.36 lakhs Capsules remained unsold and expired on August 2016. Since, then they have not marketed the product. However they have a plan to market the product soon.

**Chandra Bhagat Pharma, Mumbai:**

The firm informed that they are involved in import of Bulk and manufacture of Penicillamine Capsule under third party agreement from West Coast Pharma, Ahmedabad. Since 2010, they have marketed approximately 17 lakhs of Penicillamine Capsules. They have already import registration for import of Penicillamine Bulk from China which is valid till 2018. However, they informed that the manufacturer in China is presently renovating their facilities and not in a position to manufacture the API.

**Biophore Pharmaceuticals, Hyderabad:**

They informed that they are not the manufacturer. However, they are involved in development of various bulk drugs including Penicillamine.

**German Remedies (A Division of Cadila Healthcare Limited), Ahmedabad:**

The firm informed that they are not manufacturing the drug since last 12 years.

DCG (I) requested the firms to take all necessary steps on urgent basis to ensure uninterrupted supply of the Penicillamine Capsules in the interest of our patients.

The meeting ended with vote of thanks to the Chair

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**From CDSCO:**

1. Dr. G N. Singh, Drugs Controller General (India).
2. Mr. A. K. Pradhan, Deputy Drugs Controller (India).
3. Mrs. Rubina Bose, Deputy Drugs Controller (India).

**Firms Representatives:**

1. Mr. K Ramesh, COO, M/s Biophore India Pharmaceuticals, Hyderabad.
2. Dr. S. Srinivasan, CSO, M/s Fleming Labs Limited, Hyderabad.
3. Mr. Kapil Sethi, M/s VHB Life Sciences Limited, Mumbai.
4. Mr. Manish Srivastava, M/s German Remedies (A Division of Cadila HealthCare Limited), Ahmedabad.
5. Mr. P.D.Karan, M/s Panacea Biotec, New Delhi.
6. Mr. Deepak Rastogi, M/s Panacea Biotec Limited, New Delhi.
7. Mr. Bhupathiragri V.S.S.R.K. Ragir, M/s Celon Laboratories Limited.
8. Mr. Pranav Bhagat, M/s Chandra Bhagat Pharma Private Limited, Mumbai.