

F. N.: BMSIC/40025/27-2014/ 976

Date: 23/06/2016

**Order**

BMSICL vide its order contained in Letter no. BMSIC/40025/27-2014/29 dated 06.04.2015 blacklisted M/s Laborate Pharmaceutical Pvt. Ltd for two years. M/s Laborate Pharmaceutical Pvt. Ltd filed writ petition (CWJC No. 6886 of 2015) in the Hon'ble High Court Patna, for quashing of BMSICL Order dated 06.04.2015 vide which the firm was blacklisted. The petitioner submitted that the order dated 06.04.2015 was in violation of fundamental principles of natural justice as the petitioner was not served a copy of the report of the enquiry committee headed by Sri Anand Kishor which was referred to in the BMSICL order dated 06.04.2015.

2. In the above matter, the Hon'ble High Court, Patna vide its Order dated 03.12.2015 quashed the BMSICL order dated 06.04.2015. The excerpt of operative part of the Order of Hon'ble High Court is reproduced below:

*“--the impugned order dated 06.04.2015 is quashed with liberty to the respondents to pass orders afresh in accordance with law after supplying a copy of the 2<sup>nd</sup> enquiry report of the committee headed by Sri Anand Kishore and after grant of reasonable opportunity to the petitioner. It is made clear that the writ petition is being disposed of without considering the merits of the matter.”*

3. In compliance of the above order of the Hon'ble High Court, Patna, BMSICL vide its letter no. 2787 dated 21<sup>st</sup> January 2016, provided copy of the 2<sup>nd</sup> enquiry report of Shri Anand Kishor to the petitioner. Post receipt of the enquiry report, Laborate submitted its reply dated 4<sup>th</sup> February 2016 vide which it rejected the grounds based on which it was blacklisted by BMSICL.

4. During pendency of the CWJC No. 6886 of 2015 in the Hon'ble High Court, Patna, the in-house Quality Control (QC) section of BMSICL conducted a detailed analysis of the test report of the two batches (BAAJI002 and BAAJI003) of the drug Aminophylline which had earlier been declared as Not of Standard Quality. As per the detailed calculation of variation in assay content done by the QC section, the variation in assay content for the ingredient

Ethylenediamine in the product Aminophylline in batch no. BAAJI002 was found to be 8.64%, while for batch no. BAAJI003 it was 13.95%. Since, the variation in Assay content of the batch no. BAAJI003 is more than 10%, hence this invites penal action as per clause 1 A (c) of the Annexure X of the tender which is quoted as below:

*"If variation in assay content is more than 10% in any of the batch of the drug/product, the firm shall be blacklisted for five year"*

5. In light of the above fact, M/s Laborate Pharmaceutical Pvt. Ltd was served Show Cause Notice vide BMSICL letter no. BMSIC/40025/27-2014/53 dated 06.04.2016 to explain why action should not be taken against the firm as per clause 1 A (c) of the Annexure X of the tender and the firm be blacklisted for five years.

6. Laborate submitted its reply to the Show cause notice vide its letter dated 25.04.2016. The main points raised in their reply are as follows:

- i. BMSICL is under obligation to issue show cause notice only with regard to reason for which order dated 06.04.2015 had been passed and for such subsequent events for which penalty of blacklisting has been provided for in the NIT.
- ii. Laborate has reaffirmed the calculation of variation in Assay content as technically correct. Hence, according to laborate, for both batches the variation is 2.54% and 4.11% respectively which is below 5%.
- iii. Test reports dated 10.7.2014 and 12.7.2014 issued by M/s Shree Krishna Analytical Services have reported both batches to be of Standard Quality.
- iv. Test reports dated 14.8.2015 issued by M/s Standard Analytical Laboratory Pvt. Ltd., which is the same laboratory which issued the impugned test reports, also certified subject to be of standard quality.
- v. Laborate has already suffered punishment for variation in assay content vide BMSICL office order dated 2.1.2015. They have already lifted the goods of the subject batches and not received payment.
- vi. Laborate has already been penalised and suffered harassment by getting blacklisted twice without justified reasons.



