



OFFICE OF THE MISSION DIRECTOR
NATIONAL HEALTH MISSION, ASSAM

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No. NHM-18017/16/2018-PROC-NHM/ECF-70586/ 33022

Dated:- 03/03/2020

To,

Kwality Pharmaceuticals Limited.
6th Mile Stone, Village Nag Kalan,
Majitha Road, Amritsar-143601, India.

Sub: Product debarment of Tablet Pantoprazole 40 mg for supplying of Not of Standard Quality- NSQ batches as per the analytical report of Govt. of India Lab (CDL-Kolkata & RDTL-Guwahati).

Ref: 1. Test reportS of RDTL- Regional Drug Testing Laboratory, Guwahati (Govt. of India Lab), Sixmile, Guwahati. (Report. RDTL/2688/2019-20, Date. 9/7/2019 & RDTL/4053/2019-20, date.19/02/2020 and RDTL/4054/2019-20, date.19/02/2020).

2. Report of CDL-Central Drug Laboratory (Govt. of India), Kolkata. (Report No. CDSCO-Guwahati/NSQ/PJD/2019/0540, Date. 12/4/2019 & CDSCO-Guwahati/NSQ/PJD/2019/0178-0918, Date. 4/2/2020

3. Tender under reference vide no. NHM/PROC/ RC-DRUG/NEW-EDL/3040/2016-17/22420, DT:- 20.03.2017.

4. Several Show cause notices on supply of NSQ batches of Tablet Pantoprazole 40 mg issued from NHM, Assam to Kwality Pharmaceutical Limited on 20/4/2019 and 31.07.2019.

5. Reply received from Kwality Pharmaceuticals Limited via mail on 19/2/2020 against the final show cause served to them.

6. Final show cause notices served from NHM, Assam to Kwality Pharmaceutical Limited on 17/2/2020 & and again on 24/2/2020 for supply of NSQ batches of Tablet Pantoprazole 40 mg.

Sir

With reference to the subject cited above, you were served several show cause notices on 20/4/2019 and 31.07.2019 and lastly final show cause notices on 17/2/2020 & on 24/2/2020 as already 4 batches of your supplied drug Tablet Pantoprazole 40 mg has been declared as “**NSQ- Not of Standard Quality**” as per analytical report (NABL report) of RDTL, Guwahati & CDL, Kolkata which has been communicated by Central Drug Standard Control Organization-CDSCO, Govt. of India as well as Drug Control Deptt. Govt. of Assam. All your show cause notices were as per tender clause no. 25 “**QUALITY CONTROL DEDUCTION & OTHER PENALTIES**” and clause no. 26 “**BLACKLISTING**”.

These batches which were declared as NSQ are the Batch No. T-7164, Mfg. Date:- Oct/2018 & Exp. Date:- Sept/2020 & Batch No. T-6988, Mfg. Date:- Aug/2018 & Exp. Date:- July/2020 and Batch no. T-7159, Mfg. Date:-Oct/2018 & Exp. Date:-Sep/2020 and lastly Batch no. T-7156, Mfg. Date:-Oct/2018 & Exp. Date:-Sep/2020.

Hence, considering the above situation and to retain the trust of public in Govt. supplied medicines, NHM-Assam has decided to Bann your manufactured Tablet Pantoprazole 40 mg from further use in Govt. hospitals of the state and hence your company will not eligible to participate in tenders of the Tender Inviting Authority for supply of the said Drug for a period of five subsequent years as per the tender clause no. 26 “**BLACKLISTING**”, point no. C.

Please be noted that as per the said tender Clause No. 22 "Quality Testing-Pt.no-A", NHM, Assam will not accept any further supply of Tablet Pantoprazole 40 mg from your company. Also, the Batch No. T-7164, Mfg. Date:- Oct/2018 & Exp. Date:- Sept/2020 & Batch No. T-6988, Mfg. Date:- Aug/2018 & Exp. Date:- July/2020 and Batch no. T-7159, Mfg. Date:-Oct/2018 & Exp. Date:-Sep/2020 and lastly Batch no. T-7156, Mfg. Date:-Oct/2018 & Exp. Date:-Sep/2020 of Tablet Pantoprazole 40 mg are treated as rejected batch as per the referred tender Clause No. 22 "Quality Testing-Pt.no-C".

Hence, as per tender Clause no. 25 "Quality Control deduction & other penalties Pt. no-A", you are asked to take back the goods of the said 4 batches within a period of 30 days from the date of issue of this letter without fail at your own cost from the District Drug Store as well as Medical College Drug Store and submit all details with documentary evidence or else demurrage charges will be levied at the rate of 2% per week on the value of the items declared NSQ.

Please be noted that the penalty will be recovered against the said 4 batches declared as "Not of Standard Quality" as per tender Clause No. 22 "Quality Testing-Pt. no-B" & also the security deposit submitted from your end will be forfeited if valid or else the same amount will be recovered from any of your outstanding bill yet to be cleared by NHM, Assam.

[Handwritten signature]
2/3/2020

Mission Director, NHM, Assam

Memo No. NHM-18017/16/2018-PROC-NHM/ECF-70586/ 33023-35 Dated: - 03/03/2020
Copy forwarded for information to the: -

1. Principal Secretary, Health and FW Deptt. GoA for kind information.
2. Managing Director, Assam Medical Services Corporation Limited, Assam.
3. Director Health Services, Assam for information.
4. Director Medical Education, Assam for information.
5. Executive Director, NHM, Assam for kind information.
6. Drug Controller of Assam for information and necessary action.
7. Deputy Drugs Controller (India), O/o The Assistant Drugs Controller (India), CDSCO Sub-Zone, Guwahati for information and necessary action.
8. Principal cum Chief Superintendent/ Superintendent, All Medical College Hospitals to stop all kind of distribution/use of Tablet Pantoprazole 40 mg manufactured by Kwaliti Pharmaceuticals Limited.
9. Jt. DHS, All Districts for information and to direct the I/C of the Govt. Hospitals under their districts to stop all kind of distribution/use of Tablet Pantoprazole 40 mg manufactured by Kwaliti Pharmaceuticals Limited.
10. Director Finance, NHM, Assam for information and needful.
11. MIS-Manager/ SFM/ DSM-SHQ/ Accounce Manager (R.H)/ Programmer (G.T)- NHM, Assam for information & needful.
12. DPM/DDSM/M.O i/c CMS/Block Pharmacist/Store Pharmacist. He/She is directed to stop all kind of distribution/use of Tablet Pantoprazole 40 mg manufactured by Kwaliti Pharmaceuticals Limited.
13. P.S to Hon'ble Minister, Health and FW Deptt. GoA for kind information of the Hon'ble Minister.

[Handwritten signature]
2/3/2020

Mission Director, NHM, Assam