GOVERNMENT OF INDIA
MINISTRY OF RAILWAYS
RAILWAY BOARD

No. 2015/H/4/1/Drug Procurement (Policy)/Bal Pharma New Delhi, dated: 06.06.2018

Principal Chief Medical Directors
All Indian Railways,

Chief Medical Officers
including PUs & RDSO
&
Prof. (Health), NAIR, Vadodara.

महाप्रबंधक का कार्यालय
GENERAL MANAGER'S OFFICE
13 JUN 2018
दक्षिण रेलवे/Southern Railway
चेन्नै/Chennai-600 003

Sub: Drug Procurement Policy – clarification regarding supply of sub-standard drugs.

Ref: Board's letter No. 2014/RS(G)/779/13 dated 04.06.2018.

*****

A copy of Board's letter cited under reference is forwarded herewith. It is desired that henceforth all cases of sub-standard Drugs/Pharmaceutical products should be dealt with accordingly.

(R.S. Shukla)
Joint Director (Health)
Railway Board
06/06/18

DA :- As Above

PCMD	Covering letter of Board. 8/6/18
CH	
ACMD / T	
Dy CMD / H&FW	

GOVERNMENT OF INDIA
MINISTRY OF RAILWAYS
RAILWAY BOARD

No. 2014/RS(G)/779/13 New Delhi, dated: 04.06.2018

The General Manager,
All Indian Railways/PUs, NF(C), CORE
The DG/RDSO/Lucknow & NAIR/Vadodara
CAOs, DMW/Patiala, WPO/Patna, COFMOW/NDLS.

Sub: Drug Procurement Policy - clarification regarding supply of sub-standard drugs.
Ref: Board's letter of even No. dated 14.05.2015.

The Drug Procurement Policy 2014 envisage supply of a salt (indigenously manufactured) by a manufacturing unit (MU) directly as a supplier or by a marketing unit + a manufacturing unit (MMU) wherein a marketing unit supplies the salt manufactured by another manufacturing unit. Subsequently, a detailed procedure was issued to deal with cases of supply of sub-standard quality of products vide Board's letter cited under reference. However, based on the field experience and the difficulty arising in implementation of the policy as also other issues thereafter, Health Directorate has desired certain amendments in the policy.

In view of above, the whole issue has been re-examined in consultation with Health & Finance Directorate of Ministry of Railways and it has been decided thus:

For all supplies made by MU/MMU, the process as indicated below will be followed in case sub-standard salts are discovered during usage in a railway hospital:-

i. The supply of a salt by a MU/MMU, if found sub-standard during usage, will be stopped forthwith in all Zonal Railways/PUs. The firm would be asked to replace the sub-standard batch by another batch. While replacing the batch, the firm will also submit a test report of a third party lab declaring the new batch as standard one alongwith the firm's own test report. Sample of this batch would also be sent to a Government Lab/Govt. approved NABL Lab for test by Zone/PU. However, supply of other salt(s) from that MU/MMU will continue. Further, if the registered firm has more than one MU duly inspected by a team of Railway officers on behalf of that firm, the salt (found sub-standard) would continue to be accepted if manufactured at the MU other than the one from which the sub-standard salt was manufactured.

ii. Information about the same will be sent by the ZR/PU to all ZRs/PUs, DG/RHS and also to the State Drug Controller in whose jurisdiction the manufacturing unit of the firm (where salt was manufactured) falls so that the salt manufactured at the unit from which the sub-standard batch was supplied, is not purchased by any other Railway Zone.

iii. It will thereafter be the responsibility of the MU/MMU to take clearance from State Drug Controller. Once, the clearance of State Drug Control Department is received, the MU/MMU will inform the PCMD/CMO of the concerned ZR/PU. Only on receipt of a satisfactory report of the Drug Control Department of the State Government, the supply of the salt (which was found sub-standard during usage) manufactured at that MU can re-commence. Clearance of the MU will be intimated by PCMD/CMO of the ZR/PU to all ZRs/PUs and DG/RHS.

iv. Two such instances of rejection of a particular salt (on all India basis) during usage will be permitted in one registration period.

v. If there are more than two such instances of a particular salt (on all India basis) from a MU/MMU being found sub-standard during one registration period and it is established that MU had manufactured sub-standard salt due to technical failure or failure to follow the laid down procedure, Railways will not accept *any salt* manufactured in that MU. However, the products of other MU, if inspected by a team of Railway officers on behalf of that firm, will continue to be accepted. Further order of any salt, manufactured at that MU, will not be placed on MU/MMU by any railway unit(s) till the expiry of 3 years period of its approval by DG/RHS or a period of one year whichever is later.

vi. Also, if there are more than two such instances of a particular salt (on all India basis) from a MU/MMU being found sub-standard during usage and it is established by Drug Control Department that the MU had manufactured sub-standard salt due to technical failure or failure to follow the laid down procedure, no P.O will be issued for purchase of *any product* manufactured at that premise till the expiry of 3 years period of its approval by DG/RHS or a period of one year, whichever is later. However, for products of other manufacturing units of the firm, if inspected on behalf of the firm, order will continue to be placed.

Example – If the MU/MMU was approved by DG/RHS in June 2010 and the third instance (on all India basis) of being found sub-standard during usage was reported in October 2012, then no order would be placed by any railway hospital for any salt manufactured at that MU after Oct., 2012 to Oct., 2013.

After October 2013, the firm will have to apply for a fresh inspection of the manufacturing unit in line with the procedure as suggested in Part I(A) of Drug Procurement Policy 2014 for all salt(s) as the manufacturing unit has essentially lost its approval status.

vii. Outstanding orders already placed on the MU/MMU for supply of any product manufactured at the premise of firm (after the 3rd instance of sub-standard salt during usage and it being established by Drug Control Department that the MU manufactured the sub-standard salt due to technical failure/failure to follow the laid down procedure), will be required to be cancelled.

viii. If more than two manufacturing units of a registered firm are defaulted by following above provisions, the registration of the firm would be suspended for a period of one year. Similarly, if the firm has only one manufacturing unit and a salt manufactured at that manufacturing unit is found sub-standard on more than two occasions, the firm would be suspended for a period of one year. Thereafter, the firm can be considered for resumption of registration only if all the clearances from State Drug Control Authority is submitted for satisfaction of DG(RHS) that the firm has all the legal papers to manufacture the salts, which were earlier found to be substandard.

This issues in consultation with Health Directorate and concurrence of Finance Directorate of Ministry of Railways.

(Anshu Malik)
Joint Director/RS(G)
Railway Board