OFFICE OF THE DIRECTOR GENERAL: DRUGS & COPYRIGHTS
DRUGS CONTROL ADMINISTRATION, VENGALARAONAGAR, HYDERABAD
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Circular Rc No.24 /DG/Drugs/2013 **Dated: 8-03-2013**

Sub: Drugs & Cosmetics Act 1940 and Rules made thereunder NSQ/spurious drug reports - investigation / procedure / recall - procedure to be adopted in the investigation and recall on the drugs declared as NSQ - certain instructions issued – reg.

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For speedy withdrawal of the Not of Standard Quality Drugs from the market and quick completion of the investigation on Not of Standard Quality drug reports, all the Drugs Inspectors/AD's/DD's in the state are instructed to follow and comply with the following procedures/instructions subject to the provisions of Section 25 and other related provisions under Drugs & Cosmetics Act 1940 and rules made thereunder.

1. On receipt of the Government Analyst report in Form 13, the Drugs Inspector concerned, shall serve a copy of the said report on the person from whom the sample was taken on the same day of the receipt of the report.
2. After service of such report in Form-13, the Drugs Inspector concerned shall forthwith send the details of the subject drug such as name of the drug(including brand name if any), Batch No:, Mfg.dt; Exp.dt; Name of the manufacturer/marketer; by SMS to all DIs/ ADs / DDs/JDs and also Director/Director General on the same day.
3. The DI shall inform the details to all the chemists in his / her jurisdiction for immediate recall of the drug on the same day.
4. If the manufacturer is located within the state of Andhra Pradesh, on the same day the DI shall inform the details to the concerned area manufacturing DI and the AD/DD concerned.
5. The area manufacturing DI and AD/DD concerned shall take immediate necessary steps to recall the unsold drug in the market and obtain the distribution details from the manufacturer and communicate the same to all concerned DIs/ADs where the drug was distributed.
6. If the manufacturer is located outside the state, the DI shall inform the details to the Head Quarters requesting to address the concerned State Drug Controller for taking necessary action to recall the drug at their end.
7. If the supplier(s) of the drug is /are located within the area of the DI concerned, he/she shall proceed forthwith to the place(s) for further investigation.
8. If the supplier(s) is/are located in other than the concerned DI's jurisdiction, the DI shall forthwith proceed for further investigation to the place(s) with the area DI with due information to the concerned ADs.
9. The DI shall immediately communicate the complete distribution details of the drug thus obtained during investigation to all the concerned DI/AD marking copies to DDs/JDs and the Director.
10. The DI shall also simultaneously proceed for investigation at the manufacturing premises with the area DI, in case the said manufacturer is located within the state of A.P duly taking the permission of the Licensing & Controlling Authority concerned and Director General.
11. The above steps have to be completed within 10 working days of the receipt of the NSQ report.

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12. All ADs/DDs on receipt of the NSQ drug information shall ensure total withdrawal of the drug from the circulation in their respective jurisdictions and a consolidated report to the concerned JDs and Director shall be submitted within fortnight.
13. If the manufacturer is located outside of the state of A.P , the DI after obtaining the necessary permission from the Director General shall proceed to the place of manufacturer for investigation.
14. The DI shall complete the investigation and submit detailed report to Head Quarters through concerned AD/DD within 30 days, if the manufacturer is located within the state of Andhra Pradesh and within 45 days if the manufacturer is located outside the state of Andhra Pradesh and seek necessary orders from D.G.
15. On receipt of the detailed report from the DI, the concerned AD/DD shall submit their remarks on the report of the DI within 5 working days suggesting the course of action to be taken in the subject case to the Head Quarters.
16. In case the subject drug is of 'Spurious' in nature the DI shall devote full time towards investigation on the above lines and report to the concerned AD on daily basis. The AD shall review the progress of the case and issue guidance and instructions for speedy completion of investigation.
17. The DD concerned shall review the progress of all such cases on weekly basis and ensure that the complaints are filed in the court as expeditiously as possible.
18. The DD shall recommend for issuance of commendation letters by Director General for all the good work done by the DI/AD in their respective zones through the JDs and Director.

Further whenever any drug of a manufacturer has been declared as Not of Standard Quality, the available drugs of the same manufacturer and the person from whom such NSQ drugs are identified must be closely kept under observation.

These instructions shall come into force with immediate effect.

DIRECTOR GENERAL
DRUGS & COPYRIGHTS
DRUGS CONTROL ADMINISTRATION

To
All Drugs Inspectors / Assistant Directors / Deputy Directors in the State
Copy to Joint Directors (Enforcement)
Copy to Director