

JAMMU AND KASHMIR MEDICAL SUPPLIES CORPORATION LTD.

Public Sector Undertaking of the Government of Jammu and Kashmir



**Proposed Policy
for
Blacklisting/Debarring
of
Product or Company**

PROPOSED POLICY FOR BLACK LISTING/DEBARRING OF PRODUCT OR COMPANY

1. ON SUBMISSION OF FALSE, FORGED OR FABRICATED DOCUMENTS OR CONCEALING OF FACTS:

1.1. The tenderer who submits false, forged or fabricated documents or conceals facts with intention to win over the tender or procure purchase order; EMD of such tenderer firm shall be forfeited and firm shall be liable for blacklisting for a period of not Less than 2 years. The firm shall also be liable for Legal action depending on the facts & circumstances of the case.

2. ON ACCOUNT OF FAILURE TO ENTER INTO AGREEMENT OR WITHDRAWL AFTER AGREEMENT OR REFUSAL / FAILURE TO SUPPLY:

2.1. The successful tenderer fails to execute the agreement after being declared as L-1, L-2 or L-3 etc. to perform the obligations under the tender conditions, EMD of such tenderer firm shall be forfeited and firm shall be liable for blacklisting for a period of not less than 2 years or the period specified in tender document.

2.2. The successful tenderer after entering into an agreement withdraw or fail to honour commitments as per tender conditions, Security Deposit of such tenderer firm will be forfeited and firm will be liable for blacklisting for a period of not Less than 2 years.

3. ON ACCOUNT OF NON-SUPPLY:

3.1. The supplier shall start to supply according to tender condition from the date of purchase order and shall complete the supplies within 60/90 days as mentioned in Purchase Order or as stated in tender condition.

3.2. JKMSCL will be at liberty to accept or reject the supply made belatedly as per the terms and conditions of the tender documents. In the event of acceptance of delayed supply the liquidated damages shall be imposed at the rate stipulated in conditions of the tender document.

3.3. If the supplier fails to execute the purchase order and informs JKMSCL about its inability to execute the order and non-compliance of the purchase order due to act of vis-majeure, then the Managing Director, JKMSCL will issue appropriate order on merits of case.

3.4. If the supplier fails to execute atleast 60% of the quantity of item mentioned in purchase order and such failure in supply continues for three purchase orders, then supplier firm will be liable for blacklisting for a period of not Less than 2 years. As a result such supplier will be ineligible to participate in any of the tenders for particular item(s) of drugs / medicines for a period of not less than 2 years or the period specified in tender document.

4. ON ACCOUNT OF QUALITY FAILURE OF DRUGS & MEDICINES:

- 4.1. The drugs supplied by the suppliers to the District Drug Warehouses are quarantined and samples of each and every batch of drugs /medicines are drawn on random basis and forwarded to Quality Control Wing of JKMSCL at the headquarter. The samples shall then be sorted; common batches pooled, required number of samples taken at random from total batch and sent to the empanelled laboratories for quality control test as per the QC Policy of JKMSCL.
- 4.2. Samples of all sterile surgicals & sutures items falling in the categories of drugs shall also be drawn as per above policy and all of them shall be subjected essentially for sterility testing.
- 4.3. If such samples **pass** quality test in all respects, JKMSCL shall instruct its Warehouses to issue items of drugs to various hospitals / institutions.
- 4.4. If the sample fails in quality test and report is received certifying that sample is **not of standard quality**, the drugs of the batch shall not qualified for issue and supplier shall be informed to take back stocks of such batch, which failed the quality test and other consequences would follow as per the conditions in the tender documents.
- 4.5. If **two batches of a particular item** supplied under a tender tenure by the supplier are declared as **Not of Standard Quality** by an empanelled lab or Govt. Lab in **grossly substandard** and such failures are further confirmed by another empanelled lab / Govt. Lab, then the particular item of the drug shall be liable for blacklisting for a period of not less than 2 years.
- 4.6. If **three batches of a particular item** supplied under a tender tenure by the supplier are declared as **Not of Standard Quality** during its entire shelf life by an empanelled lab or Govt. Lab in **test for assay and / or in any other parameter(s)** and if such failures are further confirmed by another empanelled lab or Govt. Lab during its entire shelf life, the particular item of the drug shall be liable for blacklisting for a period of not Less than 2 years.
- 4.7. In case **three products of a company/supplier are blacklisted** for supply made during a tender duration, the **Supplier / Company** shall be liable for blacklisting for a period of not Less than 2 years.
- 4.8. In case, any sample (even one batch) is declared as **Spurious or Adulterated** by an empanelled lab or Govt. Lab and if such failure is further confirmed by Govt. Lab during its entire shelf life, the **Product** shall be liable for blacklisting for a period of not less than 3 years.

4.9. If any statutory sample of JKMSCL supply drug is drawn by Drugs Control Officer on suo-moto basis or on complaint and if it fails in quality parameters, the report is conclusive till it is challenged by supplier / company. If it is challenged then the report of Director, C.D.L., Kolkata/ or any authorised Lab by the Govt. shall be conclusive and action as contemplated in foregoing paragraphs will be initiated in the matter of blacklisting of product or company. However if failure is of such nature, wherein Controller, Drug and Food Control Organization of State grants prosecution sanction under Drugs & Cosmetics Act, 1940 & as amended from time to time, then even failure of such one batch shall be considered adequate for blacklisting the product for not less than 2 years and in case of involvement of three different products, the **Supplier/Company** as a whole shall be liable for blacklisting for a period of not Less than 3years.

5. PROCEDURE IN THE EVENT OF QUALITY FAILURE WILL INVOLVE THE FOLLOWING STEPS:

- 5.1. On receipt of adverse quality test report from empanelled lab or Govt. Lab of a quarantined stock, instructions shall be issued immediately through e-mail to the concerned District Drug Warehouses to not to release such stock and entries be made by QC Cell at headquarter in e-aushadhi software for batch rejection i.e. not to be released for distribution to institutions / DDCs (Drug Distribution Centres).
- 5.2. Warehouse Incharge shall take appropriate measures immediately to segregate such stock and label all cartons as “**NOSQ Drugs-Not for release**” and shift it from quarantine area to Non-Release / Rejected Drugs Area (which is under lock & key) till it is lifted by the supplier.
- 5.3. Immediately on receipt of NOSQ report, the second sample should be sent to another empanelled lab/Govt. Lab by the QC Cell of JKMSCL.
- 5.4. The supplier shall be informed immediately about the test results and instructions be issued to lift the entire stock/ batch at supplier's expenses which is declared as “NOSQ” by the empanelled lab / Govt. Lab. However, in case of serious quality failure i.e. if drug is declared or adjudged spurious, adulterated or grossly substandard, Quality Control Cell of JKMSCL shall contact the District Drugs Control officer for drawing statutory sample/s of such batch/s as per Act. The DDW Incharge has to keep adequate quantity of such drug for statutory sampling by Drugs Control officer.
- 5.5. In case of drug declared as **Not of Standard Quality** on subsequent sampling after the batch was released including actual ingredient below 95% during the shelf life of drug the procedure given in sub-para 5.2 shall be followed in respect of stock available with the warehouse. In respect of stock already

issued and drug warehouse incharge will take immediate steps to RETRIEVE the unused stock of such drugs from all such institutions and D.D.C.s by all possible mode and means and he/she will ensure that no such NOSQ drug is further distributed to the patients and ensure effective recall.

- 5.6. On receipt of test report from empanelled lab / Govt. Lab, show cause notice shall be issued immediately to the concerned supplier calling for explanation within 3 days from the date of receipt of notice in respect of quality failure of concerned batches of drug. The supplier shall be required to submit the batch manufacturing record, batch analysis report, raw material purchase record & raw material test reports etc. Opportunity for personal hearing, if desired by supplier, may also be accorded.
- 5.7. On confirmation of the test result by the second laboratory, the case will be referred to the disciplinary committee of JKMSCL for further action.
- 5.8. In case when the second report is contradictory to the first report, the statutory sample will be sent to Govt. Lab, whose report shall be final and if the sample has been tested by the Govt. Lab at any stage, its report will be conclusive & final unless challenged as per provisions of Drugs & Cosmetics Act, 1940.

6. EXAMINATIONS OF ISSUES BY DISCIPLINARY COMMITTEE OF JKMSCL:

- 6.1. Each & every case of submission of false documents, failure to execute agreement, non-supply or quality failure, etc. shall have to be referred to disciplinary committee of JKMSCL to be constituted by Managing Director, JKMSCL for examination on a case to case basis for making appropriate technical recommendation to Managing Director for further appropriate action.
- 6.2. The recommendations of disciplinary committee shall be placed before the Managing Director, JKMSCL who shall take appropriate action which may deem fit in the light of facts & circumstances of the case by way imposing penalty or debarring or Blacklisting of the particular product or supplier/company.
- 6.3. If, the quality failure is of such nature that a particular product has been blacklisted according to the procedure stated above, the supplier shall not be eligible for participating in any of the tenders for the particular item floated by JKMSCL for the specified period. For such purpose period of blacklisting shall be counted from date of issue of order and it shall deemed to be over on completion of the period and as such no fresh orders will normally be required for re-eligibility purpose. Similarly if the supplier /company is blacklisted the supplier shall not be eligible for participating in any of the tenders for any of the items during blacklisted period.

7. POWER OF REVIEW:

Subsequent to the action taken on the basis of available facts if some new facts & evidences such as reversal of test results findings by Appellate Laboratories etc. are brought to the notice of the corporation, the Managing Director of JKMSCL shall have the right to review the earlier action. He may seek advice from the disciplinary committee in such matters.

8. RIGHT TO APPEAL:

Any supplier / company against whom the above action is taken may prefer an appeal within 30 days of date of blacklisting order to the Administrative Secretary, Health & Medical Education Department, Govt. of J&K who shall decide the same.

9. SAVINGS:

The blacklisting of particular product or supplier / firm shall be done without prejudice to other penalty which may be imposed as per the conditions of tender documents and also to other actions which may be initiated under Drugs and Cosmetics Act 1940 or any other law of land. JKMSCL shall display names of such blacklisted products and companies on its website and also circulate the same among all stakeholders viz. Principal GMC J&K, DHS Jammu/ Kashmir etc. including respective State Drug Controllers where the supplier / company is located.

10. JURISDICTION:

In the event of any dispute arising out of the orders and implementation thereof, such dispute shall be subject to the jurisdiction of the Courts of Jammu & Kashmir City only or Honøble J&K High Court, Bench at Jammu/ Srinagar (Jammu and Kashmir).

EXPLANATIONS:

- (i) Increase in the cost of raw materials, power cut, Labour strike, insolvency, closure of the factory would not be considered as act of vis-majeure.
- (ii) The Spurious, Adulterated, Grossly sub-standard drug shall have the explanation as per guidelines issued by Govt. of India for taking action on "Not of Standard quality drugs.ö
- (iii) Purchase Orders, if any, already issued before taking any blacklisting action or replacement orders given in past will not be affected in view of action taken as per above guidelines but all strict quality checks shall be observed for each supply of products.
- (iv) The action proposed as above is not in conflict to any express conditions laid down in corresponding tender and in case of any overlapping, the tender condition will prevail.