Rajasthan Medical Services Corporation

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।।सर्वे सन्तु निरामयाः।।
(Government of Rajasthan undertaking)

F.5/RMSC/QC/Test/2018-19/952 Date: 28.08.18

GUIDELINES FOR BLACK LISTING/DEBARRING OF PRODUCT OR COMPANY

(Ref: Clause No. 13, 16 & 19 of Tender Document)

The existing guidelines for Black listing/Debarring of Product or Company is hereby substituted by the following, namely:

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 intent to win over the tender or procure purchase order; EMD of such tenderer firm will be forfeited and firm will be liable for debarring for a period of not Less than 2 years. The firm will 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 bidder fails to execute the agreement after being declared as L-1, L-2 or L-3 etc. to perform the obligations under the bid conditions, Bid Security Deposit of such Bidder firm shall be forfeited.

If an LoA for more than one products is issued to a successful bidder and he/she/it fails to execute agreement for few items, in such case, a penalty of Rs. 2.00 Lac and in case of MSME of the State of Rajasthan Rs. 50,000 shall be imposed on successful bidder and the product for which agreement is not executed shall be debarred for a period of not less than 3 years."]

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 debarring 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 45/60 days as mentioned in Purchase Order or as stated in tender condition.

3.2 RMSC 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 RMSC about its inability to execute the order and non-compliance of the purchase order due to

act of vis-majeure, then the Managing Director, RMSC will issue appropriate order on merits of case.

3.4 If the supplier fails to execute atleast 50% of the quantity mentioned in single purchase order and such failure in supply continues for three purchase orders, then supplier firm will be liable for debarring 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 RMSC at the headquarter. The samples are then sorted; common batches pooled, coded and are sent to the empanelled laboratories for quality control test as per the QC Policy of RMSC.

4.2 Samples of all sterile surgicals & sutures items falling in the categories of drugs will also be drawn as per above policy and all of them will be subjected essentially for sterility testing.

4.3 If such samples pass quality test in all respects, RMSC will 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 will 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.

Minor defects

***[4.5 (1) If **one batch of a particular item supplied** during contract period fails in any of the quality test conducted by the tender inviting authority and/or by the Drugs Control Department, then Penalty of not less than **5.0%** of Purchase Order value of that particular item shall be levied."]

*4.5 (2) If **two batches of a particular item supplied** during contract period fail in any of the quality tests conducted by the tender inviting authority and/or by the Drugs Control Department, then that particular product of that firm will be blacklisted for a period up to 3 years but not less than 06 months in any case.

(*Tablets/Capsules failing in dissolution test and active contents found 70% and above for thermo labile products and upto 5% less than the prescribed limits for thermo stable products.)

Grossly substandard

4.6 (1) If **any batch of a particular item** supplied under a tender tenure by the supplier is declared as **Not of Standard Quality** by an empanelled lab or Govt. Lab which falls in **grossly substandard** category and such failure is further confirmed by another empanelled lab / Govt. Lab, then the product shall be liable for debarring for a period of not Less than one (1) years.

*[(2) If **two or more batches** supplied under a tender tenure by the supplier is declared as **Not of Standard Quality** by an empanelled lab or Govt. Lab, which falls in **grossly substandard** and such failure is further confirmed by Govt. Lab, then the **Product** shall be liable for debarring for a period of not less than two (2) years.]

*[4.7 If the supplier supplied **more than one drug** (subject to a minimum of 6 drugs) during a tender duration and 50% of such drugs are blacklisted, the **firm** is liable to be blacklisted for a period of **2 years** from the date of intimation after observing the procedure.]

Spurious or Adulterated

*[4.8 In case, any sample (even one batch) is declared as **Not of Standard Quality** by an empanelled lab or Govt. Lab which falls in **Spurious or Adulterated** category and if such failure is further confirmed by Govt. Lab during its entire shelf life, the **Company** shall be liable for debarring for a period **of not less than 5 years.**]

4.9 If any statutory sample of RMSC 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 shall be conclusive and action as contemplated in foregoing paragraphs will be initiated in the matter of debarring of product or company. However if failure is of such nature wherein Drugs Controller of State grants prosecution sanction under Drugs & Cosmetics Act, 1940, then even failure of such one batch shall be considered adequate for debarring 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 debarring 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 will 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 / DDC's.

5.2 Warehouse In-charge will 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 its lifting 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 by QC Cell.

5.4 The supplier shall be informed immediately about the test results and instructions be issued to lift the entire stock at supplier's expenses of such batch no. Drug 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, one of drug warehouse In-charge will be directed to contact the District Drugs Control officer for drawing statutory sample of such batch as per Act. The DDW In-charge 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 the procedure given in sub-Para 5.2 will be followed in respect of stock available with the warehouse. In respect of stock already issued and drug warehouse In-charge 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 will 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 will 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 RMSC 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 will 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 RMSC

6.1 Each & every case of submission of false documents, failure to execute agreement, non-supply or quality failure, etc. Will be referred to disciplinary committee of RMSC 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 will be placed before the Managing Director, RMSC 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 Debarring 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 will not be eligible for participating in any of the tenders for the particular item floated by RMSC for the specified period. For such purpose period of debarring will be counted from date of issue of order and it will 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 will 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 RMSC will 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 debarring order to the Principal Health Secretary, Medical & Health Department, Govt. of Rajasthan who shall decide the same.

9. **SAVINGS :**

The debarring of particular product or supplier / firm will 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. RMSC will display names of such blacklisted products and companies on its website and also circulate the same among all stakeholders viz. PSME, DM&HS, DC 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 Jaipur City only or Hon'ble Rajasthan High Court, Bench at Jaipur.

11. **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."

**[To be added in 11(ii):-

On the basis of quantitative analysis (Assay), the NOSQ drug shall be distinguished in the following manner :-

Category of NOSQ drugs	Active ingredient content (Assay)	
	Thermo stable	Thermolabile
Minor	Upto 5% less than the prescribed lower limit	Above 70% to the prescribed lower limit
Grossly Substandard	Below 5% of the prescribed lower limit to 50%	70% to 40%
Spurious	Below 50%	Below 40%

]

(iii) Purchase Orders, if any, already issued before taking any debarring 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.

The above provisions shall be deemed to have come into force with effect from 28th August, 2018 i.e. the date of issue of minutes of meeting of Board of Directors' held on 10th August, 2018 and administrative approval has also been sought from competent level.

28.8.18

(Mahavir Prasad Sharma)
Managing Director

@ Substituted w.e.f. 13.03.2018
*** Substituted w.e.f. 13.12.2017**
**** Inserted w.e.f. 07.08.2015**
***** Inserted w.e.f. 28.08.2018**

Copy forwarded to the following for information and necessary action:-

1. PS to Additional Chief Secretary, M&H and Chairperson, RMSC, Jaipur.
2. PA to MD, RMSC, Jaipur.
3. Executive Director, Quality Control, RMSC, Jaipur.
4. OSD, RMSC, Jaipur.
5. Executive Director, Procurement, RMSC, Jaipur with the request to kindly incorporate the amended provisions of existing policy in Tender Documents.
6. Executive Director, Finance, RMSC, Jaipur.
7. Drug Controller, Rajasthan, Jaipur.
8. Company Secretary, RMSC, Jaipur.
9. Guard file.

Executive Director (QC)