(2002) 03 J&K CK 0007

In the Jammu And Kashmir High Court

Case No : Writ Petition (O) 26 of 2002 and CMP No's. 49, 62, 141 and 142 of 2002

Rohit Drugs and Others — APPELLANT

Vs

State and Others — RESPONDENT

Date of Decision : 04-03-2002

Acts Referred:
Drugs and Cosmetics Act, 1940 — Section 33
Drugs and Cosmetics Rules, 1945 — Rule 71

Citation : AIR 2002 J&K 127 : (2003) 2 JKJ 535

Hon'ble Judges : Tejinder Singh Doabia, J

Bench : Single Bench

Advocate : K.S. Johal, for the Appellant; S. Shehkhar, GA, A.V. Gupta and S. Hali, for the Respondent

Judgement

T.S. Doabia, J.—Admitted.

Petitioners in this petition are the licencees which licences have been issued to them under the Drugs and Cosmetics Act, 1940 and Drugs and

Cosmetics Rules, 1945. They want to participate in the process of tender issued by the respondent State. They are not being permitted to do so.

There is a condition in the tender notice that a person wanting to take part in this process must possess a Good Manufacturing Practice (WHO-

GMP) certificate. Petitioners do not possess this certificate and as indicated above, they are not being allowed to participate in the tender process.

According to the petitioners it is not necessary to have this certificate. It is this condition (condition No. 2), which is the subject-matter of challenge

in this petition. It would be apt to notice this condition. This is being reproduced below;-

Firms should be registered with the Director General of Quality Assurance (DGQA) Ministry of Defence, Government of India for manufacture

and supply of Drugs/Medicines/items Articles which comes under Drugs and Cosmetics Act quoted for Defence Services should be or having

Good Manufacturing Practice (WHO GMP) certificate issued by the Drug Controller of India or State Drug Controller in accordance with the

WHO recommendations strictly called as (WHO GMP), are authorized to tender directly or through their authorised Distributors in that case letter

of authority on the form enclosed as Annexure A shall have to be furnished by the Principal.

2. At this stage, it would be pertinent to notice that in para 1 of the terms and conditions, it has been mentioned that the ""original

suppliers/manufactures should have a valid Drug Licence in respect of items which come under Drugs and Cosmetics Act, 1940 from the Drug

Controller of India or State Drug Controller.....

3. As indicated above, the dispute is narrow; this is with regard to the stipulation that only those firms which are manufacturing medicines and drugs

and are possessing Good Manufacturing Practice (WHO GMP) certificate issued by the Drug Controller of India or State Drug Controller in

accordance with the WHO recommendations can take part in the process of tender, Unless and until this certificate is available, a tenderer cannot

participate in the tender process, Thus, the short question which is required to be gone into is as to whether the stipulation of this condition is a

condition which can be insisted upon by the respondents.

4. The learned counsel appearing for the petitioners submits that there is no requirement under the Drugs and Cosmetics Act of 1940 (here-in-after

referred to as the Act of 1940) or the Drug and Cosmetics Rules of 1945 (here-in-after referred as Rules) as amended from time to time to have a

certificate which is separate and distinct from the licence granted or the manufacture of medicines. The argument raised is that if a tenderer has a

valid licence under the Act and Rules, then a separate certificate as mentioned in the terms and conditions of the tender is not required.

5. The other argument which has been raised is that initially this was not the requirement and this condition, has been indicated later on, and

therefore, this cannot be looked into, it is urged that the only requirement which

was initially there was that the unit in question should be duly

registered with the Provincial Rate Contract Committee, Health and Medical Education Department, and if this was so, then, no further

requirement can be insisted upon later on. It is urged that respondent No. 4 was not competent to insist upon that a tenderer who is to make

supplies should possess the certificate in question.

6. So far as the last argument is concerned, this is merely noticed and rejected. If the requirement of Act of 1940 or the Rules of 1945 is that the

certain basic conditions are to be fulfilled then a tenderer who does not fulfil these conditions cannot insist that notwithstanding the fact that the

conditions are not being fulfilled, it being registered in the manner suggested in the petition has an absolute right. Therefore, a tenderer who wants

to take part in the process is to indicate that he possesses a licence in accordance with the Act of 1940 and also the rules framed thereunder.

7. As indicated above, the only question which is required to be gone into in this petition is as to whether respondents can insist on the possession

of certificate termed as ""Good Manufacturing Practice"" (WHO GMP) certificate.

8. The learned counsel for the State submits that the requirement to possess the certificate is mandatory. It is submitted that the drugs which are to

be supplied are going to be used in Government Hospitals; if these are of sub-standard quality and are manufactured in premises which do not

conform to the standards indicated in the Act or the Rules or if these are not as per the standard of World Health Organisation, then, these cannot

be purchased. It is submitted that any purchase of sub-standard quality medicines would endanger the life of the patients who are going to get the

treatment in various Government hospitals.

9. It be noticed that it is not only from the point of view of hospitals but the larger question as to whether a medicine which is not fit for hospital can

be permitted to be sold to the general public is also required to be gone into. It is this aspect of the matter which should also attract the attention of

the Government. For reasons best known, this aspect of the matter has not been taken note of by the respondents. The only concern which has

been shown is for the Government hospitals and not for the general public. This is a matter which would be examined by the State Government at

its own level.

10. Before dealing with the question as involved in this case, the other argument which has been urged by the respondent State is that it is well

within its rights to purchase the medicine or for that matter any other commodity required by it from any source it chooses and no mandamus can

be issued either to change its policy or to effect purchases from a particular supplier.

11. With the above proposition, there can be no dispute. Such was the view expressed by the Supreme Court way back in 1959 in the case

reported as C.K. Achuthan Vs. The State of Kerala and Others, and has been reiterated time and again. The later decision on which reliance is

being placed by the State is reported as Krishnan Kakkanth Vs. Government of Kerala and ohters,

12. No doubt, these decisions have been given but in the intervening period, one decision given by the Supreme Court in the case reported as

Ramana Dayaram Shetty Vs. International Airport Authority of India and Others, , is also required to be taken note of. It is in this decision the

view expressed was that the State and its functionaries while entering into contractual obligations are also supposed to act in fair manner. The

provisions of Article 14 were made applicable to the State contracts also. Therefore, to say that the State is at absolute liberty to enter into a

contract without giving any regard to the concept of Article 14 is an argument which cannot be accepted.

13. At this stage, it would be apt to notice the Scheme of Act of 1940. The manufacture, sale and distribution of drugs and cosmetics is regulated

by Chapter IV of the Act of 1940. The standard of quality which a manufacturer is supposed to maintain is mentioned in Section 16. It is,

however, the Rules which deal in detail with regard to the method and grant of licence and also the terms and conditions which are supposed to be

complied with by a licensee. A licence is issued in Form 25. The conditions for the grant and renewal of the licence are indicated in Rule 71. Rule

71(1) deals with the persons who are supposed to supervise the manufacturing unit. The qualifications required and the institution from which these

qualifications are to be acquired have been indicated. So far as the condition of the factory premises where the drugs are to be manufactured is the

subject-matter of Rule 71(2). This entry makes it apparent that the factory premises should be as per the conditions prescribed in Schedule M. It is

Sub-rule (3) which makes mention that a licencee must have adequate plant and equipment for the manufacturing operations. Sub-rule (4) lays

down that licencee is to provide and maintain adequate staff, premises and bottling equipment for carrying out its operations at the testing unit.

Sub-rule (7) makes mention of the fact that the licencee shall comply with the requirement of good manufacturing practise. At this stage, Schedule

M may also be noticed in brief:

14. The locality and surrounding, the nature of building from where the operations can be carried out, the requirement for sterile products, working

space and storage area, health clothing and sanitation of workers, type of equipment required, the requirement to have Master Formula Records,

Batch Manufacturing Records, Manufacturing Operations and Control and precautions to be taken against contamination and mix up have been

indicated. How the reprocessing and recovery is to be done, how the labels and other printed materials are to be used and distribution records are

to be maintained have again been indicated in Schedule M, Part II deals with the requirement of Plant and Equipment. It makes mention of the

various equipment which are required to be maintained. The granulating section, Tableting section, Coating Section and other conditions which are

required to be followed have been indicated. Paragraph 12 of the Schedule also makes mention of the steps which are to be taken for filling and

sealing, sterilisation and testing. Unless and until the conditions stipulated in Schedule M are fulfilled, a person applying for the licence in Form 25 is

not to be granted the licence and if it is granted, then it is not to be renewed if somebody is found not observing the conditions enumerated in

Schedule M.

15. The learned counsel for the State was pointedly asked to indicate as to what are the different parameters prescribed in the Scheme known as

WHO-GMP certificate. The learned counsel was further asked to indicate as to under which statutory provision, the Good Manufacturing Practice

(WHO-GMP) certificate can be related to. All that has been said is that a General proforma is available. This proforma is virtually a replica of

what is contained in Schedule M, Paragraph 1 deals with the personnel, their qualification and experience. Paragraph 2 deals with the training of

personnel. Paragraph 3 and its sub-paras make mention as to what steps are to

be taken in this regard by those who are attending to the various

processes being undertaken by the concern, Clothing, clean uniforms, hair covering, foot wears and special uniforms for those who are working in

such areas and whether there is adequate staff are some of the matters which are dealt with in paragraph 3. What is contained in paragraph 3 is

found mentioned in para 3 of Schedule M. So far as paragraph 4 of WHO Scheme is concerned, this deals with the premises. The corresponding

provision in Schedule M is paragraph 1. This deals with the buildings, water supply and disposal of waste, Paragraph 5 deals with storage. Para 6

deals with the production area. Paragraph 7 deals with the materials which are to be used. Paragraph 10 deals with packing; paragraph 11 deals

with quality control, paragraph 12 deals with inspection. As indicated above, whatever is contained in the Scheme is found correspondingly

mentioned in the various clauses contained in Schedule M. Therefore, what is contained in the Scheme is part and parcel of Schedule M. Therefore

to say that what is contained in the Scheme is over and above what is contained in Part I and Part II of Schedule M is an argument which is not

based on factual realities.

16. As indicated above, Schedule M has a heading ""Good Manufacturing Practices Factory Premises"", therefore, it can safely be presumed that if

a particular manufacturing unit is conforming to the conditions prescribed in Schedule M, then, it would be presumed that the concern is conforming

to Good Manufacturing Practices, Independently of this, there is no separate certificate. As a matter of fact, in the tender notice, this requirement

to have Good manufacturing practices is not absolute. A firm which is duly registered with the Director General of Quality Assurance (DGQA),

Ministry of Defence, Government of India, for manufacture and supply of Drugs/ medicines/items which come under Drugs and Cosmetics Act

quoted for Defence services has been found to be good. Therefore, to say that a Good Manufacturing Practice (WHO-GMP) certificate is sine-

qua-non for a concern if it wants to participate in any exercise initiated by the State in the tender process would not be a correct way of looking at

the matter. As a matter of fact, a manufacturing unit which fulfils the conditions enumerated in Schedule M would be deemed to be conforming to

all those conditions which are treated as Good Manufacturing Practices,

Independently of this, as indicated above, there is no requirement either

under the Act or under the Rules.

17. The learned counsel for the State submits that some of the concerns are not adhering to practices enumerated in Schedule M. It is stated that

notices have been issued to various concerns calling upon them to conform to these conditions. It is stated that in the event of non-compliance,

their licences are likely to be cancelled. In this regard, the file pertaining to M/s Rohit Drugs and Pharmaceuticals, who figures as petitioner No. 1

in this petition, has been made available. This file does contain a copy of licence which was issued in favour of this petitioner concern. This is dated

25th Nov. 1986. This was valid upto 31st Dec. 1987. A licence, as per the State remains in force unless and until a specific order to the contrary

is passed in terms of Rules 72 and 78, thus a licensee can carry on the manufacturing process till the licence is cancelled.

18. At this stage, it would be apt to notice Rule 72, This reads as under:

An original licence or a renewed licence in Form 25, Form 25-B or Form 25-F unless sooner suspended or cancelled shall be valid upto the 31st

December of the year following the year in which it is granted or renewed:

Provided that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry

after payment of additional fee, the licence shall continue to be in force until orders are passed on the application and the licence shall be deemed

to have expired if the application for its renewal is not made within six months of its expiry.

19. A perusal of the above makes it apparent that the application for renewal of licence if made before its expiry or if the application is made within

six months of expiry after payment of additional fee, the licence continues to be in force until orders to the contrary are passed otherwise the

licence shall be deemed to have expired or cancelled if the application for renewal is not made within a period of six months of expiry. Thus a

licence so granted under the Rules shall remain valid if any application is made within a period of six months of its expiry and in case, there is no

specific order on the application regarding rejection, the same shall continue to be in force. It is not the case of the State that there is any order

passed by the concerned authority by which steps have been taken with a view

to cancel the licence. All that is said is that the premises were

inspected from time to time and the concern was found deficient in certain parameters and the notices have not been complied with and now

further action in accordance with the law would be taken.

The above aspect of the matter be also examined.

20. The file which has been made available regarding Petitioner concern was called upon to get the premises white washed wherever it was

required. Further directions were given to develop its own testing facilities, to provide exhaust fan in finished goods store, to provide proper colour

codes for labelling of raw material and maintain quarantine and to maintain complete records of the production activities. As to whether these were

complied with or not and what happened after this communication is not apparent from the file. The factory premises was again was inspected on

9th Aug. 2000. What is conveyed in this regard is contained in communication dated 3rd Oct. 2000. The petitioner concern was again called upon

to update the Analytical laboratory and test the items of raw material and finished goods. It was further directed that unit be got white washed and

painted to make the walls of oral liquid section washable, to get repaired the seepage in washing section, to provide exhaust fan in finished goods

store, to conduct fresh medical examination of workers, to submit a letter of consent from the State Pollution Control Board and to update the

wash and change room. Thereafter the petitioner concern is said to have made a prayer for renewal of licence, This is dated 26th Dec. 2001.

Thereafter, again a notice was issued in Feb. 2002. In this communication which is dated 7th Feb. 2002, the petitioner concern has been called

upon to observe Good Manufacturing Practices as per Schedule M, referred to above. The observations made in this communication are as under:

You will ensure that the conditions so prescribed under Schedule M of the Drugs and Cosmetics Rules, 1945 are strictly adhered to and

compliance in this regard be now communicated to this office within a period of 3 months, failing which this applications received by this

organisation will not be considered for renewal of your Drug Manufacturing licences.

21. A perusal of above communication as also communication dated 3rd Oct. 2000 makes it apparent that petitioner concern was called upon to

comply with certain conditions, As to whether these were complied with or not is not apparent from the file, A perusal of communication dt. 7th

Feb. 2002 makes it apparent that it is a general notice which does not disclose as to on what basis, the same has been issued. These facts have

been taken on record to indicate as to now much seriousness was displayed by the State on earlier occasions while dealing with a subject which

has been said to be a very sensitive one and for which now a very serious concern for the health of the citizens of this State has been projected to.

22. Shri Hali, learned counsel appearing for respondents 8 to 10 submits that in pursuance of the Notice Inviting Tender, they have made the

supplies.

23. Shri A.V. Gupta, learned counsel who has put in appearance for M/s Jay Aar Agencies, submits that this concern is not a party to this petition.

It is stated that supplies have also been made this concern. He further submits that the drugs regarding which supplies have been made are not

being manufactured by the petitioner concern, and therefore, so far as his clients are concerned, petitioner has no competition with this concern.

24. After having heard learned counsel for the parties, I am of the opinion that the questions which are ultimately required to be answered can be

formulated as under;

(i) Whether the requirement in the Notice Inviting Tender that a manufacturer must have Good Manufacturing Practice (WHO-GMP) certificate is

a statutory requirement?

(ii) That even if there is no statutory requirement, can a condition indicated in the Tender notice be said to be good or bad in writ jurisdiction?

(iii) Whether the conditions which are supposed to exist before a certificate known as 'Good Manufacturing Practices' can be granted is something

which is distinct and different from the conditions which have been mentioned in Rules of 1945 i.e., Rule 71 and Schedule M attached with the

Rules;

(iv) Whether the requirement insisted upon by the State calling upon the manufacturers to go by Good Manufacturing Practices is to be insisted vis-

a-vis purchased and supplies which are made to the Government hospitals and not when the supply is made by these manufacturers in the open

market?

(v) Whether the action taken by the State by issuing various notices including notice dt, 7th Feb. 2002, noticed above, which has been issued to

petitioner No. 1 is good and sufficient to prohibit this concern form taking part in the tender process?

25. The above issues have been considered.

I am of the opinion that there is no statutory requirement either in the Act or in the Rules to have a certificate known as ""Good Manufacturing

Practices"", As to what this certificate should contain and what are its contents have not been indicated by the State. As a matter of fact, as to what

matters are to be considered before graining this certificate is a matter on which no stand has been taken by the State. I am of the opinion that this

certificate is nothing but a requirement of what is contained in Schedule M. If a particular manufacturer is complying with Schedule M, then, it

would be presumed that he is complying with the conditions known as Good Manufacturing Practices. This becomes apparent from the perusal of

Schedule M and heading given to this Schedule. Again, if a manufacturer is not complying with these conditions then his licence is liable to be

cancelled and, in any case, the respondents can with-held the renewal thereof. Therefore, I am of the opinion that the requirement of having a

certificate of the kind aforementioned is not specified anywhere in the Rules, and therefore, if a particular concern is complying with the stipulations

contained in Schedule M, then, as indicated above, it would be presumed that he is adhering to good Manufacturing Practices as per the conditions

mentioned in Schedule M. If he is not doing so, then the respondents can cancel his licence. As a matter of fact, the State would be under a legal

obligation not only to cancel the licence but to see that the drugs manufactured by such a concern are destroyed not permitted to be sold in the

open market. What is not good for Government hospitals cannot be said to be good for the general public also.

26. Independently if the above, I am of the opinion that merely because a particular concern has been granted this certificate in the shape of a

licence in the beginning of the year can also be re-examined by the State and if for a particular batch or for a particular period, a concern has not

been adhering to the conditions contained in Schedule M, even then the State would be well within its rights to cancel the licence or at least to not

to have the supplies from that concern.

27. In view of the above, it is held that there is no stipulation that a manufacturer should have a separate certificate as has been mentioned in the

Tender notice i.e ""Good Manufacturing Practices"" certificate. A manufacture who as indicated above, complies with the conditions mentioned in

Schedule M would be deemed to adhering to these practices. If it is not doing so, then its licence can always be cancelled, in any case, even if the

State comes to a conclusion that a particular manufacturer is adhering to Good Manufacturing Practices as per Schedule M, and a licence has not

been cancelled, even then, the State would be at liberty to not to accept the drugs manufactured by it if at the time of supply it is found to be

deficient in any manner. To repeat, there is no statutory proforma on which this certificate is to be issued. As a matter of fact, such being not the

statutory requirement, therefore, a manufacturer who is sticking to Good Manufacturing Practices as per Schedule M would be deemed to be

following Good Manufacturing Practices and would be eligible to take part in the process of tender initiated by the State.

28. In view of the above discussions, it is concluded:-

(i) That a licencee under the Act and Rules, referred to above has necessarily to adhere to Good Manufacturing Practices as indicated in the Rule

71 and Schedule M appended with the Rules. The heading in the Schedule reads as Good Manufacturing Practices and Requirements of Premises,

Plant and Equipment. Therefore, a licencee as indicated above, has to adhere to the conditions stipulated in the Act and more particularly in

Schedule M;

(ii) That there is no statutory provision requiring the possession of a Good Manufacturing Practice certificate. As to what are its contents and under

what circumstances, this is to be issued has not been laid down anywhere;

(iii) That the guidelines given by the World Health Organisation are replica of the conditions as contained in Schedule M;

(iv) That any licencee having a valid licence under the above Act and Rules would be deemed to be adhering to Good Manufacturing Practices as

indicated in Schedule M. Once he is a licencee, he need not to have any other certificate. It would be presumed that he is adhering to Good

Manufacturing Practices;

(v) That mere possession of a licence would not ipso factor confer a benefit on the manufacturer to take part in the process of tender. The State

authorities can still examine the premises and if on any particular occasion, it is found that any licencee is not adhering to any of the conditions, then

notwithstanding the fact that a licence is in existence, the respondent-State may still hold that as the licencee is not adhering to Good Manufacturing

Practices, therefore, the medicines manufactured by the said licencee are not acceptable. But in doing so, such a licencee is to be afforded a

reasonable opportunity;

(vi) That the requirement to stick to Good Manufacturing Practices as mentioned in the Act. Rules and Schedule M is necessary not only when the

medicines are supplied to the general hospitals but also when these are made available to the public at large in the open market;

(vii) That the proceedings initiated against petitioner No. 1 regarding which file was made available and reliance on communication dt. 7th Feb.

2002, is of no consequence. This notice is not only vague but it has also not been pursued to its logical end. Till a positive finding is recorded one

way or the other the petitioner No. 1 and other licencees cannot be put to a disadvantageous position i.e. unless and until a finding is recorded that

a licencee is not adhering to Good Manufacturing Practices, such a licencee cannot be debarred from taking part in the tender process. As no such

order has been passed in the case of the petitioners, therefore, they are held entitled to take part in the tender process.

29. So far as the dealers represented by Sh A.V. Gupta, Senior Advocate are concerned, the stand taken is that they have made the supplies of

those medicines, which are not being manufactured by the petitioners. Therefore, it is directed that the State would not with-hold the payment so

far as this concern is concerned.

30. The claims of the petitioners would be considered accordingly. If they are entitled to any price preference in terms of industrial policy, then that

aspect of the matter would also be taken note of.

31. So far as the dealers who are within the State of Jammu and Kashmir and who have made the supplies are concerned, their payment be also

released in terms of the supplies made by them but in doing so, the minimum price quoted by the tenderers including the petitioners would be taken

note and it is only the minimum price which is quoted and ultimately accepted which would form the basis for release of the payment.

32. These petitions are accordingly disposed of in terms of observations made above along with connected Civil Miscellaneous petitions.

