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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

Date of Decision: 15th September, 2023

+ W.P.(C) 12134/2023 & CM APPLs. 47694/2023, 47695/2023

RUSAN PHARMA LIMITED

..... Petitioner

Through: Mr. Shailendra Babbar, Mr. Avinash
Das and Mr. Shubham Chauhan,
Advocates.

versus

CENTRAL MEDICAL SERVICES SOCIETY (CMSS) & ORS.

..... Respondents

Through: Ms. Aakansha Kaul, Ms. Rhea
Borkotoky, Ms. Versha Singh,
Advocates for R-1.
Mr. Vikram Jetly, CGSC with
Ms. Shreya Jetly, Advs and
Mr. Siddhant Gupta, GP.
Mr. Rohit Goel, Advocate for R-4.

CORAM:

HON'BLE THE CHIEF JUSTICE

HON'BLE MR. JUSTICE SANJEEV NARULA

JUDGMENT

SANJEEV NARULA, J. (Oral):

1. The Petitioner, a pharmaceutical company with expertise in addiction treatment and pain management through a broad spectrum of products, participated in a tender floated by Respondent No. 1, the Central Medical Services Society (“**CMSS**”), an autonomous body operating under the aegis of Ministry of Health and Family Welfare, Government of India. However,



CMSS rejected the bid as technically non-responsive. This decision was predicated on the Petitioner's failure to submit crucial documents i.e., a valid Certificate of Pharmaceutical Product ("**COPP**"), which is awarded under World Health Organization–Good Manufacturing Practices ("**WHO-GMP**") certification scheme, and a corresponding WHO-GMP Certificate. Aggrieved by this adverse decision, the Petitioner has filed the present writ petition impugning their disqualification, seeking revocation of the award of work pertaining to the tender in-question, and consequently, a fresh evaluation of the bids.

FACTS AND PETITIONER'S SUBMISSIONS

2. The facts and submissions set forth by the Petitioner's Counsel, are as under:

2.1. CMSS issued invitation to bid through Tender No. CMSS/PROC/2022-23/NACO/029, dated 14th February, 2023, (*hereinafter referred to as the "**Tender**"*). The objective of this tender was to facilitate procurement of specified drugs: Buprenorphine 2 mg, Buprenorphine 0.4 mg, and Buprenorphine-Naloxone 2/0.5 mg for the National AIDS Control Program for the year 2022-23.

2.2. The Tender set out the "Eligibility Criteria" with emphasis on the requisite COPP and WHO-GMP Certificate, which are delineated in Clauses 4(b) and 6.2(y) as follows:

"4. ELIGIBILITY CRITERIA

xx .. xx .. xx

b) Tenderer shall be a manufacturer of quoted product and having valid own manufacturing license in the indicated pharmacopeia (in technical specification at Annexure IA) and Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/BP/USP. The manufacturing license & COPP should be valid on the date of tender opening packet 1. In case of failure to submit the same, the bid shall not be



considered any further.

xx .. xx .. xx

6. TECHNICAL BID – “PACKET 1”

xx .. xx .. xx

6.2. ...

xx .. xx .. xx

(y) A valid Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any pharmacopeia IP/BP/USP and a valid WHO-GMP shall be submitted by the bidder.”

2.3. The Petitioner submitted both, technical and financial bids on 24th April, 2023, accompanied with all requisite documents, including COPP and WHO-GMP Certificate. These certificates were valid until 12th April, 2023. Foreseeing their impending expiration, the Petitioner had proactively applied for renewals to the Drug Licensing & Controlling Authority, Shahastradhara Road, Dehradun, Uttarakhand, on two occasions: first on 28th January, 2023 and subsequently, on 13th March, 2023. A copy of the application dated 13th March, 2023 was enclosed with the bid documents.

2.4. CMSS opened the technical bids on 25th April, 2023. Upon review of the documents submitted, CMSS called for certain clarifications, which the Petitioner promptly provided. Notably, at this juncture, no questions or discrepancies were raised in respect of Petitioner’s COPP/ WHO-GMP Certificate. However, later on 19th May, 2023, CMSS sought additional clarifications regarding Petitioner's technical bid, with the following remarks:

“Your offer against Tender No. CMSS/PROC/2022-23/NACO/029 is under evaluation. Following documents/clarifications which would not change the substance of the bid may be submitted:

- 1. COPP certificate not valid on the date of tender opening i.e., 25.04.2023*
- 2. WHO-GMP expired on the date of tender opening i.e., 25.04.2023*
- 3. Copies of audit report not readable.*



4. The local content declaration is to be submitted by cost auditor of the firm.

You are requested to submit the above mentioned documents by 22.05.2023 till 5 p.m., after which the evaluation will be finalized based on the documents available.”

2.5 The Petitioner addressed the aforementioned clarifications by submitting a reply on 22nd May, 2023. The response included a letter dated 06th May, 2023, issued by the Drug Controller, Food Safety & Drugs Administration Authority in Dehradun (“**FSDA Dehradun**”) which testified to the extended validity of the COPP and WHO-GMP Certificate, commencing from the date of issuance of the letter i.e., 06th May, 2023 till 05th November, 2023 (*hereinafter referred to as “**Extension Letter**”*). Subsequent to this, following inspection of the Petitioner’s manufacturing plant by the FSDA Dehradun, the Petitioner received a fresh WHO-GMP Certificate dated 04th July, 2023. This development was communicated to CMSS on 05th July, 2023. Despite submission of these documents, CMSS rejected Petitioner’s technical bid for all three specified drugs. The Technical Evaluation Summary, which was made public on 07th July, 2023, articulated the reasons as under:

“Reason:

COPP and WHO GMP certificates submitted along with the technical bid were expired on 12/04/2023, hence, clarifications were asked. After clarification M/s Rusan Pharmaceuticals. Ltd. have submitted a certificate from FDA, Uttarakhand that "the validity of COPP granted under WHO-GMP certification scheme & WHO-GMP certificate is further extended from 06/05/2023 to 05/11/2023 for six month". However, extended COPP certificate & WHO- GMP not submitted.

It is also noted that the extension is done from 06/05/2023 and the previous certificate WHO-GMP & COPP were valid till 12/04/2023, the tender was opened on 25/04/2023, Hence, it is evident that on the date of tender opening i.e. 25/04/2023, the certificate i.e. WHO-GMP & COPP were not valid even if extension letter is taken into consideration.

Following tender clauses will apply:

Clause 6.1 (a) states that “Those indenting to participate in the tender (herein



called Tenderer) should first ensure that they fulfil all the eligibility criteria and All documents should be valid on the date of tender opening packet 1"

And

clause 8.1 states that "Documents issued after the date of tender opening will not be accepted."

Hence, the bid of M/s Rusan Pharma Ltd. Will not be considered."

2.6. Petitioner reached out to CMSS to contest the disqualification. However, CMSS opened the price bid on 10th July, 2023, whereupon Respondent No. 3, Concern Pharma Limited and Respondent No. 4, Verve Human Care Laboratories, emerged as the lowest bidders. Persisting for reconsideration, the Petitioner dispatched written representations to 13th July, 2023 and again on 20th July, 2023, to CMSS emphasizing a potential misinterpretation of the WHO-GMP/ COPP certification scheme by the CMSS.

2.7. The World Health Organization (WHO), in its guidelines, does not specify a fixed validity period for the COPP. In the Indian context, WHO-GMP/COPP certificates are conventionally granted a three-year validity, with provisions for two extensions of six months each. As per established protocol, certificate holders can directly approach the Certifying Authority to seek a six-month extension. Notably, when granted, the extension commences from the date the original certificate expired, rather than the date on which the extension letter is issued. In light of this, the Extension Letter indicating the COPP and WHO-GMP certificate's validity as extending from 06th May, 2023 to 05th November, 2023, appears to be misaligned with standard practices concerning the starting date of the validity period. Thus, CMSS ought to have recognized the certificates as being valid from 12th April, 2023, when the technical bid was opened.

2.8. The framework allowing for the extension of WHO-GMP/COPP



certificates has been meticulously devised to address the challenges faced by manufacturers, especially in the context of product registration/export and their active participation in both international and domestic tenders. This provision recognizes the inherent delays and the typical timeframe required by the relevant authority to carry out inspections of manufacturing sites.

2.9. The Petitioner possesses the requisite licenses, in accordance with the Drugs and Cosmetics Act, 1945, to produce various products, tablets, and medicines, and has been diligently adhering to these guidelines in its manufacturing operations. Notwithstanding the Petitioner's claim of holding valid COPP and WHO-GMP certificates, it is wholly unnecessary to mandate these certificates for products which are aimed for use only in the domestic market. As such, the contested decision is clearly unreasonable and arbitrary.

2.10. Clause 8.6 of the Tender stipulates that the purchaser reserves the right to overlook any minor discrepancies, non-conformities, or irregularities in a bid, as long as they do not amount to significant deviations. The absence of an active COPP and WHO-GMP Certificate should benefit from this provision.

2.11. The Petitioner is the principal manufacturer of both, the product, Buprenorphine, and its core active pharmaceutical ingredient (API). This sets the Petitioner apart from Respondents No. 3 and 4, as well as other formulators. Consequently, the Petitioner is uniquely positioned to fulfil the entire demand for the specified drugs.

2.12. The rejection of Petitioner's bid is not just unfounded but also carries significant financial repercussions for the public exchequer. Had the Petitioner's financial bid been evaluated, they would have emerged as the most cost-effective bidder (L-1). Thus, the rejection translates to a potential



loss of around INR 6,98,74,321.82/-. In this context, reliance is placed upon to the Supreme Court's verdict in *Michigan Rubber (India) Limited v. State of Karnataka & Ors.*¹, to argue for a judicial review of the tender process, especially considering its adverse implications on public interest.

ANALYSIS AND FINDINGS

3. The crux of the issue raised in the present petition is the Petitioner's technical disqualification on account of non-submission of a valid COPP and WHO-GMP Certificate. When the Petitioner submitted both technical and price bids on 24th April, 2023, the COPP and WHO-GMP Certificate were no longer valid. Moreover, these certificates were not renewed by the time the technical bids were opened on 25th April, 2023.

4. Petitioner's challenge to its disqualification is premised on a misinterpretation of the tender provisions pertaining to the validity of submitted documents. For convenience, the relevant clauses on this aspect, Clauses 6(a) and 8.1 of the Tender are reproduced herein, as under:

"6. TECHNICAL BID – "PACKET 1"

(a) Those indenting to participate in the tender (herein called Tenderer) should first ensure that they fulfil all the eligibility criteria and All documents should be valid on the date of tender opening packet 1:

6.1 The Tenderer should electronically submit the soft copies of following documents in Technical Bid "Packet 1". (All the documents submitted should bear signature and stamp of Tenderer)

xx .. xx .. xx

8. OPENING OF "PACKET 1" i.e. 'TECHNICAL BID AND "PACKET 2" i.e. FINANCIAL BID' OF TENDER:

8.1 To assist in the examination, evaluation and comparison of bids, the purchaser may, at his discretion ask the bidder for the clarification in its bid. The request for the clarification and response shall be in writing. However, no post bid clarification at the initiative of the bidder shall be entertained. Documents issued after the date of tender opening will not be accepted."

[Emphasis Supplied]

¹ (2012) 8 SCC 216.



5. It is imperative to note that the Extension Letter, which extended the validity of Petitioner's COPP and WHO-GMP Certificate, was effective from 06th May, 2023. The requirement as per Clauses 6(a) and 4(b) of the Tender, is explicit; the certificates of the Bidder must be valid "on the date of tender opening packet 1" i.e., date of opening of the technical bid – 25th April, 2023. Therefore, the Extension Letter does not meet the stipulated criteria. The later issued WHO-GMP Certificate, dated 04th July, 2023, only compounds this issue. Its issuance date is significantly after the tender's opening date, and its inclusion explicitly violates Clause 8.1 of the Tender, which strictly disallows the introduction of documents post the tender's opening. Additionally, the nature of the Extension Letter requires examination. Being essentially a communication, it does not carry the formal authority of an authentic certificate. This viewpoint is categorically recorded by CMSS in their Technical Evaluation Summary, emphasizing that a mere Extension Letter cannot substitute an official, valid certificate. In summation, the Petitioner's assertions of technical compliance, heavily reliant on the Extension Letter, diverge from the clear guidelines of the Tender.

6. Moreover, the mere act of applying for the renewal of the COPP/WHO-GMP Certificate does not automatically equate to meeting the requirement of possessing a valid certificate at the relevant time of technical bid opening. A clear distinction exists between initiating a renewal process and actually receiving the renewed certificate. Just applying for a certificate does not automatically grant a compliant status or replace the need for the renewed certificate. The Petitioner's notion that acquiring a certification later can retroactively rectify prior non-compliance is not tenable.

7. The Petitioner has failed to convincingly demonstrate that the



certificates' validity should commence from their expiration on 12th April, 2023, instead of the date mentioned in the Extension Letter, which is 06th May, 2023. As such, this argument cannot be upheld. In our opinion, furnishing a valid COPP and WHO-GMP Certificate is an essential requirement as specified in the "Eligibility Criteria" itself – in Clauses 4(b) and Clause 6.2(y) of the Tender. Thus, the absence of valid certificates is surely not a minor procedural lapse. The WHO-GMP Certificate validates that a manufacturing facility meets the standards set down by the WHO. The COPP is provided for a manufacturing facility for a specific product under the WHO-GMP certification scheme itself, after thorough inspections. Both certifications act as essential benchmarks ensuring the quality and safety of pharmaceutical products procured by the CMSS. Given CMSS's role in sourcing quality health products for public consumption, the absence of valid certifications raises significant concerns about quality assurance. CMSS' strict adherence to this stipulation aligns with public interest and is thus, neither unreasonable nor arbitrary.

8. Emphasizing the stringent requirements of a tender is crucial; they ensure procedural integrity and fairness for all contenders. Deviating from essential criteria would undermine the tender's objective of establishing an equitable platform for all participants. Considering the prevailing legal stance, which prescribes limited judicial intrusion in tender or contractual affairs unless clear arbitrariness or irrationality is evident, we see no justifiable reason to intervene in the current case.

9. During the hearing, the Petitioner levelled accusations against the award of work under the tender to Respondent No. 3 and 4, suggesting that CMSS showed undue bias in their favour. Even if such an allegation is found



to be true, it would certainly not aid the Petitioner in succeeding in the tender process. Therefore, the Petitioner is at liberty to submit a formal complaint regarding this issue to CMSS, which should then be assessed on its individual merits. We have made no observations on this issue.

10. Dismissed.

SANJEEV NARULA, J

SATISH CHANDRA SHARMA, CJ

SEPTEMBER 15, 2023

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