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Public Contracts Review Board
Department of Contracts
Notre Dame Ravelin
Floriana VLT2000

13 April 2023

Dear Sirs,

Re: TENDER FOR THE SUPPLY OF ORAL CYCLIN-DEPENDENT KINASE 4/6 (CDK 4/6 INHIBITOR) – Ref. CT2270/2022 (the "Tender")

1. We have been instructed by Vivian Corporation Limited (C-68) (the "**Recommended Bidder**") to lodge this reply in terms of Article 276 of the Public Procurement Regulations (the "**PPR**") in connection with the above-captioned Tender and in response to the appeal (the "**Appeal**") lodged by V.J. Salomone Pharma Limited (C-10268) (the "**Appellant**") which was served on the Recommended Bidder on 4 April 2023.

2. To expedite matters, the Recommended Bidder declares that it agrees with the factual matrix as described by the Central Procurement and Supplies Unit (the "**Contracting Authority**") in its reply to the Appeal.

3. The Appellant has filed a long-winded and convoluted Appeal in an effort, the Recommended Bidder respectfully submits, to compensate for the substance which it lacks. However, the Recommended Bidder is confident that this Honourable Board will see through the Appeal and hone in on the Appellant's true grievance: that the Appellant's failure to abide by the Tender conditions in the submission of its financial offer was a fatal error which forced the Contracting Authority's hand.

Rebuttal to First Ground*: *Wrong Reasons Given by Contracting Authority in Rejection Letter

4. By means of its first ground of appeal, the Appellant maintains that the Contracting Authority erroneously declared its bid to be divided into lots. It buttresses its grievance by alleging that its bid is for the whole of quantities required under the Tender, for the procurement of 756 KISQALI® tablets would satisfy the cancer treatment requirements of 180 patients over an annual period.

5. As shall be explained hereunder, this ground of appeal is unfounded in law and in fact. It is true that the product under procurement is based on an estimated 180 patients per year (Clause 1.1 of Section 1: Instructions to Tenderers). Furthermore, Clause 2.4 of Section 3: Specifications states that the cheapest offer "*will be established by comparing the annual cost based on the* ***recommended daily dosage regimen as per respective SPC***".

6. This is where the Appellant errs in its reasoning. It is amply clear from a reading of the Appeal itself, as well as the supporting documents attached to the Appeal, that the Appellant's financial bid form was based on considerations **other than** the "*recommended daily dosage regimen as per the respective SPC*".

7. The Appellant *ex admissis* acknowledges, and its entire appeal revolves around this premiss, that its financial bid form was based on the recommended daily dosage stated in Section 4.2 of the KISQALI® SPC under the heading "Posology" *as varied* by the second heading entitled "Dose Modifications" as well as Section 4.8 entitled "Undesirable Effects".

8. Whereas the Appellant calculated the amount of units required on the basis of the recommended daily dosage *after* taking into account other considerations such as dose modifications and dose discontinuations, the Recommended Bidder and potentially other tenderers simply adhered to the requirements imposed by the Contracting Authority.

9. The Contracting Authority strictly requested a financial bid form based on the "*recommended daily dosage regimen*" requested in Clause 2.4 of Section 3: Technical Specifications.

10. According to Section 4.2 of the Appellant's SPC under the heading "Posology": "*the recommended dose is 600 mg (three 200 mg film-coated tablets) of ribociclib once daily for 21 consecutive days followed by 7 days off treatment, resulting in a complete cycle of 28 days. The treatment should be continued as long as the patient is deriving clinical benefit from therapy or until unacceptable toxicity occurs*".

11. This means that a patient requires 63 KISQALI® tablets per cycle of 28 days (3 daily tablets for 21 days). 28 days translates into 13 cycles per year, which means that 819 KISQALI® tablets are required over an annual period (63 tablets multiplied by 13 cycles).

12. However, with reference to the latter's financial bid form (attached to the Appeal and marked as "**Appendix B**"), the quantity of units stated is "*12 packs (756 tablets)*". Perhaps invariably so, the missing cycle resulted in the Appellant's financial offer being the lowest received by the Contracting Authority in the amount of €2,894,162.40.

13. Furthermore, the Appellant was given the opportunity by the Contracting Authority to clarify its calculations, and to confirm that the reference to "*dose modifications*" in the former's financial bid form did not amount to "*conditions being imposed on the Contracting Authority*".

14. However, in its reply to the request for clarification, the Appellant confirmed the Contracting Authority's misgivings and reasserted that its financial bid form was based on the procurement of 12 cycles per patient instead of the required 13 cycles since it takes into account the dose modification sections of its product's SPC.

15. Consequently, the Appellant confirmed that its financial offer contained conditions being imposed on the Contracting Authority. This is a clear violation of Clause 9.4 of the General Rules Governing Tenders which obliges a tenderer to accept the Tender

conditions in their entirety whatever the tenderer's own corresponding conditions may be. This clause goes on to state that: "*No account can be taken of any reservation in the tender as regards the tender document; any disagreement, contradiction, alteration or deviation shall lead to the tender offer not being considered any further*".

16. The Contracting Authority could do little else other than to put aside the Appellant's offer given that its bid was in breach of the applicable rules and regulations.

17. It is also respectfully submitted by the Recommended Bidder that the Contracting Authority acted correctly in declaring the Appellant's offer to be financially non-compliant. The letter of rejection is also in line with the correct application of the principle of self-limitation. The Contracting Authority requested a clarification from the Appellant in line with Note 3 of Clause 5 as it was entitled to do so, and proceeded to declare the Appellant's bid as "financially non-compliant" following the receipt of the clarification itself.

18. As this Honourable Board is aware, each bid is composed of a technical offer and a financial offer. If a tenderer's financial offer falls shorts of the Tender requirements, consequentially this has to be declared as "financially non-compliant".

19. In view of the foregoing, the Recommended Bidder invites this Honourable Board to reject the Appeal in its entirety and to confirm the decision of the Contracting Authority in the recommendation of award.

Rebuttal to Second Ground: Misapplication of Financial Non-Compliance

20. By means of its second ground of appeal, the Appellant maintains that its bid was financially compliant, and that the Contracting Authority misapplied its own requirements in rejecting the former's bid. In support of its grievance, the Appellant relies on Clause 2.3 of Section 3: Technical Specifications for the "*same active ingredient [to] be available in all marketed doses to treat all patients and allow for any required dose adjustments*".

21. This clause espouses a mandatory technical requirement which must be present in the product on offer. In other words, it was not possible for the Appellant or any other tenderer to bid with a product which is not capable of addressing dose adjustment needs.

22. The objective of the foregoing requirement is to determine whether a tenderer's product is technically-compliant or otherwise—it was not relevant for the purposes of financial bid form and its financial compliance.

23. The Appellant should not have included additional factors such as "*dose adjustments*" not asked for in the Tender in its financial offer, and the Contracting Authority was equally bound to ignore such additional factors.

24. Had the Contracting Authority done otherwise and considered the qualified financial bid submitted by the Appellant, it would have failed in its duty to treat all tenderers equally, fairly and with transparency. Such conduct would have been in violation of Regulation

39 of the PPR, for the Appellant would have been given the opportunity to qualify its financial bid unilaterally whereas the Recommended Bidder and potentially other tenderers would have simply complied with the tender requirements – as is their duty.

25. Furthermore, one cannot but fail to mention, that dose modifications are not a state of fact but a *possibility* that may or may not materialise. Even the clauses of its product's SPC as cited by the Appellant are couched in uncertain terms: "*management of severe or intolerable adverse reactions (ARs) **may require** temporary dose interruption, reduction or discontinuation of Kisqali. **If dose reduction is required**, the recommended dose reduction guidelines are listed in Table 1*".

26. The one certain and foreseeable event is that the Contracting Authority strictly required treatment for 180 patients based on the daily recommended dosage on each product's SPC.

27. In view of the foregoing, the Recommended Bidder invites this Honourable Board to reject the Appeal in its entirety and to confirm the decision of the Contracting Authority in the recommendation of award.

Rebuttal to Third Ground: Ambiguity in Tender Specifications

28. By means of its third ground of appeal, the Appellant maintains that the application and interpretation of the "*recommended daily dosage regime as per respective SPC*" requirement by the Contracting Authority has led to a distortion of competition and has unfairly prejudiced the Appellant's product as against other products.

29. First of all, the Recommended Bidder wishes to reiterate that the Appellant's allegations are unfounded. Such distortion of competition and unequal treatment between bidders would have occurred had the Contracting Authority decided to recommend the Appellant's bid for award. While the latter unilaterally altered the parameters of its financial offer in its favour to procure a cheaper price, the Recommended Bidder and potentially other bidders adhered to the tender conditions for the submission of their financial offer, invariably resulting in higher prices.

30. Furthermore, the Appellant's claim of "misinterpretation" and "misapplication" by the Contracting Authority of its own criteria is a smokescreen for the real issue which has aggrieved the Appellant.

31. For the purposes of determining the true nature of this third ground, it is important to note two uncontested facts which chronologically precede the submission by the Appellant of its bid: (a) the tender requirements with particular reference to Clause 2.4 of Section 3: Technical Specifications, that is, the "*recommended daily dosage regime*" and (b) the SPC of the Appellant's product.

32. These two facts have been known to the bidders since the publication of the tender on ePPS. Therefore, the proper remedies for the Appellant to remove or rectify ambiguous tender clauses, including clauses that could have been allegedly interpreted differently, were either requests for clarification in terms of Regulation 38, or the pre-contractual remedy in terms of Regulation 262, of the PPR.

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33. The Appellant attempts to found this misinterpretation grievance on the allegation that the Contracting Authority excluded its product "*because of particular characteristics of the product*". It then proceeds to make an even more spurious allegation where the Appellant alleges that the technical specifications were based on product characteristics with the outcome of excluding its product. While this allegation remains unproven and, the Recommended Bidder submits, cannot be proven given that it is false, this remains a moot issue because the allegation should have been, if at all, raised prior to the closing date for the submission of bids.

34. In view of the foregoing, the Recommended Bidder invites this Honourable Board to reject the Appeal in its entirety and to confirm the decision of the Contracting Authority in the recommendation of award.

Yours Sincerely,
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