IN THE PUBLIC CONTRACTS REVIEW BOARD

6th April 2023

Re: Objection - CT2270/2022- Tender for the Supply of Oral Cyclin- Dependent Kinase 4/6 (CDK 4/6) Inhibitor

Reply of the **Central Procurement and Supplies Unit** (CPSU) on behalf of the Department of Health to the reasoned application lodged by V.J. Salamone Pharma Limited (the objector).

On the 21st of August 2022 a call for tenders for the supply of Oral Cyclin- Dependent Kinase 4/6 (CDK 4/6) Inhibitor was published. This medication is used in the treatment of cancer and will be introduced on the Government formulary list. A number of bids were submitted, an evaluation process was carried out and the offer of Vivian Corporation Limited (the Preferred Bidder) was recommended for award.

The sole award criterion was the price. Clause 6 of the Instruction to Tenderers provided that *"The contract will be awarded to the tenderer submitting the cheapest priced offer satisfying the administrative and technical criteria."*

The Estimated Quantity as stipulated in the Tender Document Section 1 – Instruction to Tenderers – General Provisions clause 1.1 was: *"Based on annual patient treatment as per SPC of product/s on offer to cater for a total of 180 patient treatments."*

Tender Document Section 3 – Specifications clause 1.1.2.4 clearly stipulated that: *For adjudication purposes, the cheapest acceptable offer will be established by comparing the annual cost based on the recommended daily dosage regimen as per respective SPC.*

The Objector was disqualified for financial incompliance for the below reason:

"Since the Bidder had confirmed the mandatory requirement in Part 1 Section 2.4 of the submitted Technical Offer Form: 'For adjudication purposes, the cheapest acceptable offer will be established by comparing the annual cost based on the recommended daily dosage regimen as per respective SPC.', and stated that this is being shown in the "SmPC Section 4.2- Posology and method of administration, page 1", the Bidder was asked to indicate where, in the submitted Financial Bid Form, the quantity (based on annual patient treatment i.e for one patient for one (1) year), conforms to the recommended dose as specified in Section 4.2 of the SmPC i.e. "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". (This amounts to 3 tablets x 21 days x 13 cycles = 819 tablets annually or 13 packs of 63 tablets each).

In his reply, the Bidder:

1. stated that "We have submitted our financial bid as per Section 1 - Article 1.1 of the tender specifications –"Estimated Quantity is based on annual patient treatment as per SPC of product/s on offer to cater for a total of 180 patient treatments.";

2. confirmed that the full dose regime as per SmPC Section 4.2 is 13 packs per year per patient, (13 x 63 tablets =819 tablets);

3. gave workings to explain the quantity of 756 tablets (12 packs x 63 tablets each) declared in the submitted Financial Bid Form, and stated that the average number of packs for 180 patients/year works out at 12 packs per patient per year, (12 x 63 tablets = 756 tablets) when taking into consideration the reduction of dose/discontinuation of treatment, as per SmPC section 4.8.: "Taking into consideration the full dose regime as perSmPC Section 4.2 (13 packs per year per patient)" "and the reduction of dose/ discontinuation of treatment, as per SmPC section 4.8 as explained above, the average number of packs for 180 patients / year works out at 12 packs per patient per year, as per our financial bid submitted.";*

4. remarked that "It is VERY important to note that any dose adjustment with Kisqali® (Bidder's product) does not involve any further purchases by CPSU, unlike does adjustments with other products in this Class. Patients treated with other products will require CPSU to purchase a different pack accordingly to the new dose prescribed. For Kisqali® a lower number of tablets will need to be administered to the patient.

The purpose of this declaration on the financial bid "Price per patient is calculated as per the SmPC 4.2 Table 1. Please note that dose modifications do not require the use of a new pack, thereby reducing wastage of unused product and reduction of cost." is to highlight that with Kisqali®, any dose adjustment can be managed with the same pack as supplied - Kisqali® 200mg x 63 tablets. The patient will only need to take less tablets per day if dose is reduced. For other products in this Class, the purchase of other packs with a different dose will be necessary when dose modification is needed. This comes as an extra cost (and wastage) for CPSU. In practice, this means that it will cost CPSU more when dose adjustments are done for products in this Class, except with Kisqali®.

We can confirm that this statement is not a condition being imposed on CPSU, but rather a point which we believe should be taken into consideration when evaluating the financial bid."

Offer is not acceptable for the following reason:

"The Bidder stated that "We have submitted our financial bid as per Section 1 – Article 1.1 of the tender specifications – "Estimated Quantity is based on annual patient treatment as per SPC of product/s on offer to cater for a total of 180 patient treatments." In Section 3 – Specifications Article 1.1.2.4 of the published Tender Document it is also stipulated that "For adjudication purposes, the cheapest acceptable offer will be established by comparing the annual cost based on recommended daily dosage regimen as per respective SPC.", without making any reference to the reduction of dose/discontinuation of treatment that was mentioned by the Bidder in the

clarification response. Thus, since the Bidder's offer was for 756 tablets (12 packs x 63 tablets) per patient per year instead of "the full dose regime as per SmPC Section 4.2 (13 packs per year per patient)" (i.e. 13 packs x 63 tablets = 819 tablets per patient per year), the offer cannot be recommended in line with Section 1 – Article 3.1 of the Tender Document, which states that "This tender is not divided into lots, and tenders must be for the whole of quantities indicated. Tenders will not be accepted for incomplete quantities"*

The objector feels aggrieved with the decision of the evaluation committee and has filed the present objection.

CPSU respectfully disagrees and is filing the below submissions.

Submissions

<u>On the Request for Clarification</u>

1. It is being submitted that at the stage when the request for clarification was sent to the Objector, shortcomings were already noted, however the evaluation committee acted responsibly and exercised their discretion to request the objector to clarify his position with regards to 2 points which can be summarised as below:

   - Bidder was asked to indicate where, in the submitted Financial Bid Form, the quantity (based on annual patient treatment i.e for one patient for one (1) year) conforms to the recommended dose as specified in Section 4.2 of the SmPC i.e. "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, since in the submitted Technical Offer Form, he had confirmed this mandatory requirement and stated that this is being shown in the SmPC Section 4.2- Posology and method of administration, page 1.

   - Bidder was asked to confirm that the following statements:
     *"*Price per patient is calculated as per the SmPC 4.2 Table 1. Please note that dose modifications do not require the use of a new pack, thereby reducing wastage of unused product and reduction of cost."*
     were not conditions being imposed on the Contracting Authority and that he will be satisfying to all tender conditions:

2. With regards to the first point for clarification, the objector gave an explanation on how it arrived at the 12 packs annually considering the percentage of patients which require reduction and the percentage of patients that would discontinue the treatment;

3. With regards to the second point of clarification, the objector clarified that with regards to the product it is offering dose modification can be done with the same tablets from the same pack and that the statement *"is not a condition being imposed on CPSU, but rather a point which we believe should be taken into consideration when evaluating the financial bid."*

4. These answers were not to the satisfaction of the Evaluation Committee and thus the offer was rejected for the reason cited in the first part of this reasoned letter of reply.

<u>On the Reason for Rejection (On the Grievances entitled: Reasons given by Department of Contract for Rejecting Appellant's bid; and Relevant Provisions of the Tender Document)</u>

5. In reply to clause 13 in general CPSU submits that there were numerous other conditions on which this tender was adjudicated, but the present objection and this reasoned letter of reply deals only with the grounds for refusal which in a nut shell is that an incomplete quantity (less than requested) was stipulated by objector in the financial bid form and re-confirmed in the clarification response;

6. In its objection letter, paragraph 13.a. the objector states that *"the bid was to be for the provision of a medicinal product in such an estimated quantity that its Summary of Product Characteristics (..) indicates for an annual patient treatment where the number of patients is that of 180 patient treatments"*

7. The above is factually incorrect because clause 1.1.2.4 of the Specifications provides that: *For adjudication purposes, the cheapest acceptable offer will be established by comparing the annual cost based on the* ***recommended daily dosage*** *regimen as per respective SPC;*

8. The tender document thus requested **a recommended daily dosage for 180 patients and not an average as incorrectly stated by the objector**;

9. The above is being stated and summitted as the tender document has to be read as a whole document and each clause interpreted in line with the rest of the clauses. The tender document is crystal clear in this regards and is seeking to procure a total of 180 patient treatments and this has to be in line with the recommended daily dosage regimen of the SPC;

10. The SPC of the objector's product in clause 4.2 Page 1 clearly states that:

    "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"* emphasis added

11. Each pack of the objector's product has 63 tablets, which is one whole cycle. A calendar year (365 days) of treatments therefore has 13 cycles of 28 days each. Thus a total of 13 packs were required for the offer to be for a whole year of treatment in line with the recommended daily dosage regimen in the SPC. This was confirmed by the objector himself in the clarification response *"Taking into consideration the full dose regime as per SmPC Section 4.2 (13 packs per year per patient)...."*;

12. What the objector did was to work out a formula by means of which it has taken into consideration the discontinuation of treatment to certain patients for some reason or other and dose adjustments of treatment to certain patients for some reason or other to end up with an average quantity for 180 patients. This is not what the tender requested as the tender requested **the full recommended dose** and not an average.

13. What if none of the 180 patients would require discontinuation or adjustment of the treatment? What if patients in Malta would be able to continue with the recommended medication more than the average as calculated by objector? The offer as submitted would effectively mean that the contract will not cover 180 full year treatments for our patients.

<u>On the Grievance entitled: Appellant's Bid is not Divided in Lots, is for the whole of the quantities and for complete quantities</u>

14. The Evaluation committee did not declare that the appellants bid was divided into lots. They simply cited in the reason for refusal clause 3.1 of the Instructions to Tenderers which states:

    *3.1 This tender is not divided into lots, and **tenders must be for the whole of quantities indicated. Tenders will not be accepted for incomplete quantities.** Tender is not divided in lots since tender requirements do not merit division in lots.*

    The above clause was only quoted since the tender of the objector was submitted for incomplete quantities.

15. The objector did not bid with the complete requested quantities since the tender requested a yearly treatment of the recommended dose. The discontinuations and the reductions are only undesired exceptions and should not be taken as an advantage by the objector to bid with a cheaper price when the tender requested a recommended dose and not an average quantity for 180 patient treatment.

16. CPSU submits that there might be patients on any type of medication which might be required to stop the treatment or to change the dose, however that would be a specific recommendation as an exception to that particular patient and not the general recommendation of how the medicinal product should be administered. Such medication requiring dose reduction, treatment interruption or treatment discontinuation includes other anti-cancer drugs such as MEK inhibitor tablets/capsules and BRAF inhibitor tablets/capsules, but the reduction is not the general recommendation but specific to particular patients.

17. The way that the objector arrived to the quantity indicated in its Financial Bid Form, has led the objector to come up with an offer which was only cheaper on paper because had it been for the full recommended quantity as requested it would have been different and more expensive. Such approach (to which CPSU is strongly objecting) would also be incentivising medicinal products with higher

discontinuation and reduction rates, something which is surely not desired as ideally all patients continue their treatment for as long as needed.

On the Grievance entitled: Misapplication of Financial Non-Compliance

18. This grievance is, with respect to the objectors, totally unfounded and an attempt of plot twisting. The objector was not penalised as its annual treatment is calculated differently than that of other economic operators, but simply because it did not bid with the recommended quantity as requested.

19. Moreover, dose adjustment is only mentioned in the tender document in clause 1.1.2.3 of the technical specifications which states that: *The same active ingredient must be available in all marketed doses to treat all patients and allow for any required dose adjustments.*

20. The above clause is intended to ensure that lower doses are available for the patient should they be required during treatment. **This does not mean that dose adjustment should have been taken into consideration in recommendation of the quantities to be offered.**

On the Grievance entitled: Ambiguity in Tender Specifications

21. CPSU submits that this grievance is also unfounded and incorrect as it is implying that the tender document was drafted in a way as to give some bidders an advantage over others. The tender was drafted in a way that included all the necessary clauses to ensure that the CPSU is buying the product it wants in the best interest of patients, but it wanted to leave competition as open as possibly and did so by refraining from stipulating any quantities or any doses so that these could be determined by the bidder in line with the SPC of its product. What CPSU requested in terms of quantities were only 180 times of the recommended dose for a period of 1 year and the rest was up to the bidder to provide in line with its SPC. The main point and what the objector is avoiding is the difference between the recommended quantity and a form of average calculated by the objector for 180 patients.

22. Without prejudice to the above, CPSU submits that if the objector had any difficulties with the specifications and requirements, the remedy at law for such difficulties was that contemplated in regulation 262 of the Public Procurement Regulations (PPR) which should have been filed before closing time for offers.

23. The bidder has up till the first two third of the period open for submissions to file for such a remedy in line with article 262 of the PPR.

24. Since the objector did not file for the remedy above referred to, the specifications and tender conditions were being accepted as published and cannot now

complain on the specifications as published which according to the objector, let to its disqualification.

On the Requests

25. Whilst holding firm to its position that the objection should be rejected and the evaluation committee's recommendation confirmed, CPSU submits that should this honourable board uphold the appeal, the third request should in no case be accepted and the bids would thus need to be re-evaluated in line with constant jurisprudence of this Honourable Board.

26. Moreover CPSU sees no reason why a tender, the conditions of which have been unchallenged and which has clear terms and is intended to introduce in Malta a new cancer treatment should be cancelled because the objector chose to be creative in its bid in breach of clear and unchallenged mandatory tender conditions.

CPSU is hereby reserving its right to present further evidence both written and orally to further their submissions in relation to this objection.

In view of the above, the objection lodged by the objector ought to be rejected in full, whilst the decision of the Contracting Authority and the Evaluation Board confirmed, and the relevant deposit forfeited.

CPSU will however not object to the refund of the deposit if the objection is withdrawn prior to the sitting.

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