PUBLIC CONTRACTS REVIEW BOARD

Case 1940 – CT2270/2022 – Supplies - Tender for the Supply of Oral Cyclin-Dependent Kinase 4/6 (CDK 4/6) Inhibitor

3rd January 2024

The Board,

Having noted the letter of objection filed Dr Mario de Marco and Dr Maria Margo Zammit Fiorentino acting for and on behalf of V.J. Salomone Pharma Limited, (hereinafter referred to as the appellant) filed on the 27th March 2023;

Having also noted the letter of reply filed by Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri acting for Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 6th April 2023;

Having also noted the letter of reply filed by Dr Clement Mifsud Bonnici and Dr Calvin Calleja on behalf of Ganado Advocates acting for and on behalf of Vivian Corporation Limited (hereinafter referred to as the Preferred Bidder) filed on the 13th April 2023;

Having heard and evaluated the testimony of the witness Ms Ruth Connaughton (Representative of Novartis) as summoned by Dr Mario de Marco acting for V.J. Salomone Pharma Limited;

Having heard and evaluated the testimony of the witness Ms Loukia Samata (Representative of Novartis) as summoned by Dr Mario de Marco acting for V.J. Salomone Pharma Limited;

Having heard and evaluated the testimony of the witness Dr Carmine de Angelis (Medical Oncologist & Assistant Professor at the University of Naples) as summoned by Dr Mario de Marco acting for V.J. Salomone Pharma Limited;

Having heard and evaluated the testimony of the witness Ms Edith Sciberras (Member of the Evaluation Committee) as summoned by Dr Leon Camilleri acting for Central Procurement and Supplies Unit;

Having heard and evaluated the testimony of the witness Dr Adrianos Liavas (Representative of Pfizer) as summoned by Dr Clement Mifsud Bonnici acting for Vivian Corporation Limited;

Having heard and evaluated the testimony of the witness Mr Kenneth Briffa (Representative of Pfizer) as summoned by Dr Clement Mifsud Bonnici acting for Vivian Corporation Limited;

Having taken cognisance and evaluated all the acts and documentation filed, as well as the submissions made by representatives of the parties;

Having noted and evaluated the minutes of the Board sitting of the 14th November 2023 hereunder-reproduced.

Minutes

Case 1940 – CT2270/2022 – Supplies – Tender for the Supply of Oral Cyclin-Dependent Kinase 4/6 (CDK 4/6) Inhibitor

The tender was issued on the 21st August 2022 and the closing date was the 20th September 2022.

The estimated value of this tender, excluding VAT, was € 6,922,260

On the 27th March 2023 V J Salomone Pharma Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds that their bid was deemed to be not financially compliant.

A deposit of € 34,611 was paid.

There were five bids.

On the 14th November 2023 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Dr Charles Cassar and Ms Stephanie Scicluna as members convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – V J Salomone Ltd

Dr Mario De Marco	Legal Representative
Dr Maria Margo Zammit Fiorentino	Legal Representative
Ms Louisann Caruana Scicluna	Representative
Ms Jacqui Mangion	Representative
Ms Vanessa Said Salomone	Representative (Online)
Ms Tania Borg	Representative
Mr Fabio Sperandei	Representative (Online)
Mr Jean Paul Buttigieg	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Leon Camilleri	Legal Representative
Dr Alexia Farrugia Zrinzo	Legal Representative
Ms Monica Sammut	Chairperson Evaluation Committee
Ms Julia Pirotta	Secretary Evaluation Committee
Ms Edith Sciberras	Evaluator

Recommended Bidder – Vivian Corporation

Dr Clement Mifsud Bonnici	Legal Representative
Dr Calvin Calleja	Legal Representative
Ms Denise Borg Manche	Representative
Mr Kenneth Briffa	Representative
Ms Victoria Grima	Representative
Ms Daniela Galea	Representative

Department of Contracts

Dr Mark Anthony Debono	Legal Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties and invited submissions.

Dr Mario De Marco Legal Representative for V J Salomone Pharma Ltd (hereinafter referred to as VJS) said that the purpose of the tender was the supply of medicines to treat breast cancer for a period of three years extendable. The quantity offered was based on an annual round of treatment and the criteria for award was the cheapest bid. The relevant technical clauses were 2.3 regarding the dosage and 2.4 regarding the price. VJS put in an offer of €2.8 million and their Financial Bid indicated the quantity and price with a footnote stating that the price per patient was calculated according to the SmPC. The quantities could be reduced by reducing the number of packs. The packs offered by other offers required a certain quantity of medicine to go to waste. Since the medicine in question is taken in cycles of 28 days this meant that there are 13 cycles annually. A clarification was requested and VJS explained that if the instructions in the SPC (item 4.8) were followed 40% of patients will need a reduction of dosage during the course of treatment and a certain percentage will have the treatment discontinued completely leading to a reduction in the estimated volume of medication and no further purchases required. The SPCs of the products offered by the other bidders all suggest the same fall-off in dosage reduction. However a reduction in offers, other than that of VJS, is equivalent to an increase in dosage that needs to be acquired by the Authority and this point is worth considering. VJS was declared to be financially non-compliant as the bid was declared to be for an incomplete quantity and cannot be considered on the basis of dose adjustments.

The tender document states that the annual dosage is based on the SPC but one cannot use the starting dose as the beginning and the end of the story. Clause 4 of the SPC must be considered in full and the TEC appear to have ignored Item 4.8 and the undesirable effect the medication has on 8.7% of the patients and the reduction in dosage on 40%. Appellant satisfied the criteria as the 12 packs offered satisfy the recommended treatment. There is real world evidence that what Appellant proposed is realistic. Section 3 which states that adjudication is on an annual daily dose does not conform with reality and is not what realistically is needed. If the Tender Evaluation Committee (TEC) interprets the tender as not considering the recommendation regarding the reduction in quantities it will show lack of transparency and indicates that it is not considering the most advantageous offer and going against the reductions indicated in the Technical Specifications.

Dr Leon Camilleri Legal Representative for the Central Procurement and Supplies Unit said that the objection was not complicated and only simple quantities were involved. The Appellant based his bid on averages whilst the tender nowhere mentions averages, all it requires is a daily recommended dosage which is based on rule not on exception. The 40% reduction claimed is totally irrelevant. The principles of self-limitation and equal treatment were observed. The tender requested what the SPC indicated and that was followed. Conversely the quantity indicated in the Appellant's bid form was not what was requested and hence the bid was at fault.

Dr Mark Anthony Debono Legal Representative for the Department of Contracts referring to the appeal said that in anything quoted therein the Department was not involved. The tender document recommended certain dosage and if Appellant disagreed with this it had the right to use other procedures. It is up to the Appellant to prove that its offer meets the tender requirements and aqny ambiguity should have been resolved before the bid was submitted.

Dr Calvin Calleja Legal Representative for Vivian Corporation said that one must bear in mind the parameters of the tender, namely the cheapest price multiplied by patient's treatment on a daily dose based on one patient. The Appellant offered 12 packs, 756 tablets, which *ex admissis* is not enough. The financial bid indicates quantity for one patient. The reduction of dosage is up to the clinician and

not up to the bidder and all the studies quoted from various countries do not reflect the situation of patients in Malta. Appellant went for the lowest common denominator in its bid. If the CPSU were to revoke the decision they would be going against the principle of transparency. Clause 2.3 dealing with the dose reduction is there purely as a binary exercise to ascertain if the product fits the requirements.

Dr Clement Mifsud Bonnici Legal Representative for Vivian Corporation stated that he is convinced that this appeal is on a point of rights, this being the reservation by the Appellant when it decided to calculate the tender on the basis of average but maintained the full price per pack in the offer thus passing the issue of risk allocation to the Contracting Authority in case full treatment is required. Appellants claim is full of assumptions in their attempt to build a castle in the air. There were remedies available to the bidder if it did not like the terms of the tender and it would create a dangerous precedent if bidders are allowed to set their own terms. The CPSU foresaw this problem and issued a request for clarification.

Ms Ruth Connaughton (Irish Passport TG 3174419) called to testify by the Appellant stated on oath that she has been working for Novartis Ireland for seven years and is a trained scientist with a Ph.D. in molecular science. Since 2021 she has been working on the treatment of breast cancer. Witness was asked to explain the functions of an SPC and with the aid of a screen shot she explained product characteristics; clinical characteristics; administration of medication and comparison in the dose adjustments when administering cyclin-dependent kinase 4/6 inhibitors. Witness also referred to Real World Clinical Evidence Studies on the frequency of dose adjustments in Sweden, Brazil and the UK and to Items 4.2 and 4.8 of the SPC which indicates that due to adverse reaction dose interruption, reduction or discontinuation of treatment may be required. The recommended daily dose on an annual basis may change but this has no impact in the case of Kisqali as there is no need to use another pack and therefore there is no waste.

In reply to questions from Dr Camilleri, witness said that adjustments in treatment may or may not be required. She was not familiar with the tender call nor was she involved in the Appellant's tender submission.

Questioned by Dr Mifsud Bonnici, witness stated that treatment was on a 28 day cycle which meant that 13 annual cycles have to be provided for. It was very unusual, but not unheard of, that the full 13 cycles were administered. 60% of patients do not need a reduction in their treatment and 13 packs have to be provided for these. The UK Clinical study was funded by Novartis with the collaboration fo the University of Edinburgh Cancer Research Centre.

Ms Loukia Samata (PP KOO 380724) called to testify by the Appellant stated on oath that she is a qualified Pharmacist with a Masters Degree and has been employed by Novartis for 16 years with responsibility for the Cyprus and Malta sector. She stated that she is familiar with the tender in question but was not involved in its submission. She confirmed that she is familiar with the SPC on the product offered by the Appellant and explained the staged dosages recommended in that case and the management of the side effects by the reduction of the dosage. This is detailed in Section 4.4 of the SPC. Item 4.8 of the SPC, said the witness, states that dose reduction due to adverse events occurred in 39.5% of patients and permanent discontinuation in 8.7% of cases. These dose adjustments were evidenced in different countries and there is a large data of evidence that reduction of dosage happens – the data is recognised by the WHO. There are unique benefits in having single strength product packages and this is clearly noticeable when compared to the different dosage packages of the other products offered as this leads to waste upon changing the strength of a dose. Asked to explain the basis of calculation in offering only 12 packs instead of 13 witness stated that

this is accounted for by the percentage of patients affected by reduction in their treatment. The different tables showing these calculations were illustrated by screenshots.

In reply to questions from Dr Camilleri, witness said that not all patients require dose reduction; that she has been working in the Malta sector since April 2023 but was not part of the team which submitted the tender offer although she was aware of the tender prior to its submission.

Dr Carmine de Angelis (Italian PP YB 6225399) called as a witness by the Appellant stated on oath that he is a Medical Oncologist, Assistant Professor at the University of Naples and specialist on breast cancer treatment. He has been working for 15 years on the treatment of breast cancer during which he has used Kisqali, on which he has ran trials, and other drugs. These trials included real life clinical studies and collecting data in real life settings. Randomised trials have shown a reduction in the risk of progression of the disease and better survival rates. The fact that Kisqali is an innovative leader in the treatment of breast cancer is recognised by the Italian Medicines Agency. In dealing with this disease there is the need to manage the common side effects and therefore the starting dosage of 600mg daily is reduced gradually if side effects are noticed by 200mg at a time. The packaging of Kisqali makes it easier to adjust a reduction in dosage The side effects, and therefore the reduction in dosage, usually appear after some six cycles on average and only 40 to 50% stay on the full dosage with the other 50% requiring reductions. All the inhibitors offered in this tender produce common side effects which are very similar in all of them in different forms. Usually the dosage is reduced by different amounts in each of these different products with higher consumption in the case of the other two. Treatment with these medications are usally undertaken at the patient's home.

Replying to questions from Dr Camilleri, witness confirmed that some patients have to have the full dose throughout and reductions in dosage are on medical advice. He was not familiar with the tender n or its submissions.

Ms Edith Sciberras (360068M) called to testify by the Contracting Authority stated on oath that she is a Principal Pharmacist and has been in Government employment for 25 years and was one of the evaluators in this tender. The tender was adjudged on the basis of the SPC according to the tender and awarded to the cheapest offer. In reply to Specification 2.4 in the tender which was mandatory Appellant had stated 'yes' and referred to Item 4.2 Table 1 of the SPC which states that the requirement is for 13 cycles. However the Financial Bid Form indicated 12 packs with footnotes indicating dose modification. This conflicting mismatch in the submission and the doubt that Appellant was imposing a condition on the Authority required a clarification to be sought. Appellant confirmed that calculation was based on 12 packs but that full dose is 13 packs and that they had calculated use on an average and that they were not imposing a condition on their bid. The offer could thus not be accepted as the quantity offered did not tally with the tender requisites. The footnote added by VJS on the Financial Bid Form was not part of the original tender document.

Questioned by Dr De Marco, witness agreed that in Product Specification Clause 2.4 neither the word 'full' nor 'starting' are mentioned; that calculation is based on 'annual cost' and that the SPC refers to all products. Referred to the SPC, witness concurred that Kisqali mentions three different doses and that these are from 600mg to 200mg. graded and the same SPC mentions under 'Undesirable effects' a dose reduction of 39.5% and permanent discontinuation of 8.7%. As regards the offer of Appellant, witness said that in the reply to the clarification note VJS had stated that packages do not have to be changed or additional purchases made on change of dosage, and that this feature is different to the other offers. Witness was not certain that treatment is always carried out at patient's home but agreed that variable quantity packs meant discarding the unused packs as they are not returnable and that dose reduction might mean needing 14 or 15 packs of medicine in actual fact.

Dr Adrianos Liavas (Greek ID AN 635205) testifying at the request of Vivian Corporation stated on oath that he is a medical representative for Pfizer and specialised in Oncology for more than five years. His firm manufactured the medication offered by the Vivian Corporation in this tender. The recommended daily dosage regimen recommends one tablet for 21 days in every 28 days cycle. In some patients it may be found necessary to reduce the dosage if adverse effects are noticed but it was impossible to predict this or to determine how reduction or stopping treatment would work. Witness explained the difference between real life experience and randomised trials. The latter are complimentary to clinical trials to fill the knowledge gap. Monitoring requirements for both Kisqal and Ibrance were detailed – both require blood counts prior to the start of treatment and at the beginning of each cycle; this was the only regular monitoring for Ibrance. Kisqali requires additional monitoring for liver function, electrocardiogram before treatment and then at regular intervals leading to additional costs.

Questioned by Dr DeMarco witness confirmed that Ibrance comes in three packs in different sizes each containing 21 tablets and that 125 mgs for 21 days is the recommended starting dose.

Mr Kenneth Briffa (418675M) called to testify by Vivian Corporation stated on oath that he was the representative for Pfizer in Malta and had collaborated with the tender department to ensure that the tender submissions were all in order. The tender did not request dosage adjustments or modifications in the medication which was used for the treatment of breast cancer and the products offered in this tender all deal with this condition.

Dr De Marco referred the witness to the SPC for Ibrance who agreed that in Table 1 modifications in dosage were mentioned. Witness further agreed that packs, holding 21 tablets, have to be changed when treatment is reduced. Referred to Item 4.8 he agreed that there were modifications of around 38% reductions and 5% permanent discontinuance in patients being treated with Ibrance. Witness did not agree that on a change of dosage more medication would be needed since according to him the reduction may take place after a particular pack is exhausted or the decision to reduce is taken on completion of a pack. Witness admitted that reduction may take place in the middle of a cycle and in that case two packs are used.

In reply to a question from Dr Mifsud Bonnici witness said that the majority of patients complete the maximum dose with no reductions and there are patients who have been receiving treatment for as long as two years.

This concluded the testimonies.

Dr De Marco said that there is no one size fits all formula and yet that is what the Contracting Authority expected in its interpretation. A careful perusal of the tender requires otherwise – this was not a question of a rate per pack and the cheapest bidder wins but specifically for annual patient treatment according to the SPC of a product on offer for 180 patient treatment for three years. One cannot treat 180 patients alike and this notion flies against the basic concept of Public Procurement Regulations which demand the most economically advantageous bid. In treating 180 patients one cannot ignore what the SPC states that for all products 40% of patients require a dose reduction. This is not a margin of error of some 5% but a significant figure and one cannot ignore the circumstances of one in every two patients.

The product offered by both parties require reduction to a high percentage. Clause 2.4 of the Technical Specifications request comparison of annual cost as recommended in the SPC and one cannot isolate treatment on the starting dose and a three year basis when it is certain that there is going to be a reduction. This point is important for two reasons – since a reduction is required in 40% of patients this will lead to an increase, not decrease, in the number of packages required in the preferred bidder's

offer. There is therefore extra costs involved when the dosage is reduced due to change of packaging and instead of 13 at least 14, if not 15, packets are required on dose reduction. The cost of each packet is over € 1,000 which with 180 patients at 40% reduction amounts to a significant amount.

Conversely, continued Dr De Marco, in the VJS offer reduced dosage equals reduced tablets, equals reduced costs. This offer is realistic as it reflects a real situation and the reduction is across the board on all offers. According to the calculations made the offer of 12 packs is realistic over 180 patient treatments and the Authority has not disproven these facts and reductions. What is stated in the SPC is corroborated by real world evidence. The financial bid is based on the total cost for three years for 180 patients and the determining factor was the three year cost and this is what was published not the price per pack. The VJS offer was transparent and fully correct. Witness Ms Sciberras stated that the words 'full' or 'starting dose' do not appear in Section 2.4 and were introduced by the Authority to be merely restrictive. More than one witness confirmed that there would be wastage on change of dosage in one offer. In this case it would be more likely that the Health Authorities would be required to supplement the offer by direct order as not enough funds were provided in the tender. The guiding principle must be what is the best deal for the Government and what makes common sense.

Dr Calleja said that on the point that an adverse event will result Section 4.2 of the Kisqali SPC states that interruption may occur – the fact is purely hypothetical and cannot be banked upon in preparing the tender and no clinician can forecast it. If as claimed the tender is perceived as one size fits all, one would ask why no remedy was sought? This option was not taken up and once a bid is submitted it indicates that the bidder agreed with the terms. Clause 9.4 of the General Rules Governing Tenders requires offers to be for the whole of supplies whilst the financial bid form refers to price for one patient. In the Technical Form Appellant submitted 12 packs and the Authority had no alternative but to disqualify.

Dr Mifsud Bonnici stated that if the Appellant is confident that there is a 40% reduction why has the risk been put on the Government when they could easily have reduced the price per pack instead of reducing the averages. What happens if the reductions do not happen? In that case the Authority has to be asked for more funds as the funds allocated to the tender have been exhausted. The reservation in the Financial Bid should not have been accepted and ultimately there is only a hope that a reduction in dosage will happen. There are many assumptions made that the number of packs will need to increase if treatment is curtailed when administering Ibrance. The Authority has chosen the lowest common denominator and the formula ensures equal treatment. If there was a problem accepting the terms of the tender remedies were available.

Dr Camilleri said that the Authority denies that it acted irresponsibly as it adhered to the Public Procurement Regulations throughout. Price should not be the only guiding principle and one cannot accept that one size fits all limits self-limitation as at the end of it all there must be parameters. One cannot argue if it is outside these parameters. The Appellant is only contesting the compliance of their offer and therefore the Authority will not deal with other submissions. Dose reductions was not one of the criteria of the tender and no clinician is going to forecast if there will be any reductions. The tender asked for the cheapest offer on annual patient treatment and if 180 treatments were asked for it was expected that 180 treatments would be offered in full. A tender cannot be issued on a 'what may be' basis. Statistics are hypothetical and not part of the tender. Section 4.2 of the SPC states the recommended dose and leads to the need for 13 packs and belies the claim that 12 packs are enough. Modification is not part of the tender and the available remedies were not availed of. The decision of the Authority should be honoured.

Dr De Marco said the tender requested annual treatment and the law of averages should be taken into consideration over a three year period. The statistics quoted were very widely carried out and treating all bids equally does not mean that anyone is disadvantaged.

Dr Mifsud Bonnici said that the starting point is wrong. The recommended dose is the case in the majority of cases and the reduction is the minority. Witnesses agreed that the use of 12 packs is a wrong statement. The reduction of dosage is a misnomer.

Dr Camilleri concluded by saying that the tender refers to a recommended dose for one year not three and the evaluation correctly worked on this.

There being no further submissions the Chairman thanked the parties and declared the hearing closed.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 14th November 2023.

Having noted the objection filed by V.J. Salomone Pharma Limited (hereinafter referred to as the Appellant) on 27th March 2023, refers to the claims made by the same Appellant with regard to the tender of reference CT2270/2022 listed as case No. 1940 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Mario de Marco & Dr Maria Margo Zammit Fiorentino
Appearing for the Contracting Authority:	Dr Leon Camilleri & Dr Alexia Farrugia Zrinzo
Appearing for the Preferred Bidder:	Dr Clement Mifsud Bonnici & Dr Calvin Calleja

Whereby, the Appellant contends that:

a) Appellant's Bid is not Divided in Lots, is for the whole of the quantities and for complete quantities. -

The DoC has erroneously declared Appellant's bid to be a bid divided into lots and not being for the whole of quantities indicated or for incomplete quantities. A tender bid divided into lots is one which would require the product of the procurement to be, acquired by using a number of separate contracts. Contracts Circular No 05/2021, of 23 March 2021 *"each lot is deemed as-a separate contract. Therefore, the requirements, characteristics, criteria and deliverables shall be defined per lot."* This confirms that for a tender and consequently for a corresponding bid to be considered to be one which includes lots, the bid must be such that would require the contracting authority to enter into different

contracts each with its own requirements, characteristics, criteria and deliverables. In no manner does Appellant bid refer to different contracts with different requirements, characteristics, criteria and deliverables. Appellant's bid is for the making available to the authority of one product, Kisqali®, under one single contract. The bid can in no manner be understood as requiring the authority to enter into separate contracts. In this respect the bid is clear. Appellants bid is also one that represents the whole of quantities and for complete quantities, as sought for in the Tender. As the sections indicated by the Evaluation Committee in its letter for clarification show, the product quantity was to cover a total of 180 patient treatments which are calculated on the basis of the product's characteristics indicated in its SPC: The Summary of Product Characteristics for Kisqali® clearly establishes the total annual number of treatment packs that the authority would need to cover 180 patient treatments. With the use of Kisqali®, the authority would cover 180 patient treatments with the- use of 756 tablets annually. Therefore Appellant's bid is compliant with this criterion and is a bid that represents the whole of the quantity and the complete quantity required by the authority.

That furthermore, nothing in the SPC indicates, suggests or recommends that the supply of Kisqali® is being offered in incomplete quantities and that the offer was being proposed into lots. The DoC effectively failed to take into account what is further stated in SPC, ie. that the Product characteristics provide for 'Recommended dose modification guidelines, which dose modifications, comprise the whole quantities of the Product. Instead, the Doc wrongfully interpreted the offer for 756 tablets per patient per year as being incomplete, failing to take account of the stated: dosage guidelines pertinent to the. characteristics of the product.

Taking into consideration the dose regime as per SPC Section 4.2 with the guidelines for dosage or discontinuation of treatment as specified in the Product's: SPC, the average number of packs works out at 12 packs per patient per year equivalent to 756 tablets per patient per year, in accordance with the Appellant's bid. Since the authority did not declare the bid to be technically non-compliant, and could not do so, then Appellant's bid with the product Kisqali® is compliant with the Tender specifications and cannot be rejected as being "financially non-compliant"

b) Misapplication of Financial Non-Compliance

The Authority has assumed that because the product's SPC calculates the required annual treatment for 180 patients differently to other productson the market, then Appellant's bid is financially non-compliant. It did so in a way that contradicts its own acceptance of the bid being technically compliant. A bid that is technically compliant because it is offering the product for a quantity that is based on annual treatment according to its SPC, cannot then be punished as being financially non-compliant for following its SPC.

In this case, with the use of the product Kisqali® in line with its SPC, the annual-cost of procurement for the authority is that quoted for in the Applicant's bid. This means that the total price quoted in the bid, that of €2,894,162.40c reflects the total annual treatment for 180 patient treatments.

c) Ambiguity in Tender Specifications

The Tender provided for two mandatory requirements which included that: *"a, the same active ingredient must be available in all marketed doses to treat all patients and allow for any required dose adjustments; And b. the cheapest offer is established on the annual cost based on the recommended daily dosage regimen as per respective SPC."* This within the context that the procurement was for 180 annual patient treatments.

Considering the manner in which the Evaluation Committee and the Department of Contracts has interpreted the combination of these criteria, the Tender requirements place Applicant's product at a disadvantage, containing criteria which discriminate against Appellant's product, and favour the product of other bidders, thereby also distorting competition.

Furthermore, the second reason that DoC indicated in its letter of 17 March 2023 was that the evaluation, process could not take into consideration dose adjustments. Yet Section 3, article 1.1.2.3 makes it a mandatory requirement for the product to be available in all marketed doses and to allow for any required dose adjustments. It is therefore, at best, a misapplication of the Tender specifications and. requirements for the Department of Contracts to conclude that dose, adjustment in patient treatment *"cannot be taken into consideration for evaluation purposes since the only requirement in the published specifications addressing dose adjustments is in Section 3 Article. 1.1.2.3"*

At best, that the Tender failed to reflect its mandatory technical specifications in its cost specifications thereby rendering the Tender one which is ambiguous, and consequently misleading to the extent that it cannot be determined. However, in adopting its interpretation and in Its application of these criteria, the 7 Authority has also placed Appellant at a disadvantage, favouring the products of other bidders by distorting competition.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 6th April 2023 and its verbal submission during the hearing held on 14th November 2023, in that:

a) On the Request for Clarification

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 ie 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:

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.

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."*

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.

b) 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)

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

The above is being stated and summitted (sic) 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.

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"*. 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)..."*.

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.

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.

c) On the Grievance entitled: Appellant's Bid is not Divided in Lots, is for the whole of the quantities and for complete quantities

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: *"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.

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.

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.

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.

d) On the Grievance entitled: Misapplication of Financial Non-Compliance

This grievance is, with respect to the objectors, totally unfounded and an attempt of (sic) 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. 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. 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.

e) On the Grievance entitled: Ambiguity in Tender Specifications

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 (sic) 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 (sic) 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.

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. 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. 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.

This Board also noted the Preferred Bidder's Reasoned Letter of Reply filed on 13th April 2023 and its verbal submission during the hearing held on 14th November 2023, in that:

a) Rebuttal to First Ground: Wrong Reasons Given by Contracting Authority in Rejection Letter -

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.

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"*

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"*. 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".

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. 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.

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". 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).

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. 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'.*

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. 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"*

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. 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.

b) Rebuttal to Second Ground: Misapplication of Financial Non-Compliance

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." 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. 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. 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. 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.

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"* 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.

c) Rebuttal to Third Ground: Ambiguity in Tender Specifications

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.

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.

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. 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,

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.

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.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties including the testimony of the witnesses duly summoned, will now consider Appellant's grievances in their entirety.

a) **On the issue of 'Lots' -** The Contracting Authority, in its rejection letter never attributed a reason for rejection on the grounds that the appellant's bid was divided into lots. The appellant's submission was not accepted due to 'incomplete quantities' offered. This is the main bone of contention and what will be duly analysed and decided upon by this Board.

b) **On the issue of 'Ambiguity' -** A principle which is deemed crucial to this appeal is that of equal treatment (reference to regulation 39 of the Public Procurement Regulations "PPR"). It impinges on the Contracting Authority, that to fully observe such an important principle the evaluation and eventual award is done in accordance with the specifications as issued in the tender document. Once that no clarifications were sought on the technical and / or financial parameters by the appellant (reference to regulation 38 of the PPR) and the timeframes for the application of a call for remedies in accordance with regulation 262 of the Public Procurement Regulations have elapsed, it is to be deemed that economic operators participating in the tendering process have accepted to duly abide by such specifications included therein. The 'goal posts' / evaluation criteria are to be then considered shut.

c) **On compliance –** The tender document was clear and unambiguous when it stated *"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****"*. (bold emphasis added)

i. Therefore, in the opinion of this Board, what the tender document required was a supply, for 180 patients, in accordance with the recommended daily dosage of the respective SPC, and not a calculation based on averages.

ii. *Ex admissis* it is the same appellant that states that since the medicine is taken in cycles of 28 days each, on an annual basis there will be 13 distinct cycles. It was also the same witness called to testify by the appellant, Ms Loukia Samata that when asked to explain the basis of calculation in offering only 12 packs instead of 13, she stated that this is accounted for by the percentage of patients affected by reduction in their treatment.

iii. Even though, such reasoning seems to be based and follows proper economic logic, especially due to the fact that most probably it will mean less wastage more so in the context that Kisqali is dispensed by 1 tablet of 200mg which is different to the other offers made by other economic operators, the tender document was specific in what it required.

iv. It is certainly not up to individual economic operators to change the specifications imposed on them as drafted in the tender document. Other tools, as already mentioned in the section *"On the issue of 'Ambiguity'"*, were duly available to the appellant but they were not utilised by them. Once the tender specifications as drafted and accepted by the economic bidders by the submission of their bid, it is the Contracting Authority's duty and responsibility to manage the evaluation process on the remit provided to it. It is only by following those specifications as drafted that the evaluation committee can fully adhere to the principles of self-limitation and to obtain an equal level playing field between **all** economic operators participating in the tendering process.

v. Finally, it is the opinion of this Board that the rejection letter dated 17th March 2023 was correctly drafted to state *"…. was found to be financially non compliant….."*. This since the issue identified related to the incomplete quantities as listed in the Financial Bid Form. Reference is made to the testimony under oath of Ms Edith Sciberras who when questioned on the submission of the appellant stated *"In reply to Specification 2.4 in the tender which was mandatory Appellant had stated 'yes' and referred to Item 4.2 Table 1 of the SPC which states that the requirement is for 13 cycles. However the Financial Bid Form indicated 12 packs with footnotes indicating dose modification."*

Therefore, this Board cannot but reject and does not uphold the Appellant's grievances.

The Board,

Having evaluated all the above and based on the above considerations, concludes and decides:

a) Does not uphold Appellant's Letter of Objection and contentions,
b) Upholds the Contracting Authority's decision in the recommendation for the award of the tender,
c) Directs that the deposit paid by Appellant not to be reimbursed.

Mr Kenneth Swain **Chairman**	**Dr Charles Cassar** **Member**	**Ms Stephanie Scicluna Laiviera** **Member**