

PUBLIC CONTRACTS REVIEW BOARD

Case 2039 – CT 2171/2024 – Supplies – Tender for the Supply of Mek Inhibitor Tablets/Capsules and BRAF Inhibitor Tablets/Capsules

1st April 2025

The Board,

Having noted the call for remedies filed by Dr Steve Decesare, acting for Camilleri Preziosi Advocates, and for and on behalf of Pharma MT Limited (C42603), (hereinafter referred to as the appellant) filed on 17 July 2024;

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 (CPSU) (hereinafter referred to as the Contracting Authority) and Dr Audrey Marlene Buttigieg Vella (hereinafter referred to as the Department of Contracts (DOC)) filed on 23 July 2024;

Having heard and evaluated the testimony of the witness Dr Nick Refalo (Consultant Oncologist) as summoned by Dr Steve Decesare acting for Pharma MT Limited;

Having heard and evaluated the testimony of the witness Dr Dustin Balzan (Acting Director of the Directorate for Pharmaceutical Affairs (DPA)) as summoned by Dr Steve Decesare acting for Pharma MT Limited;

Having heard and evaluated the testimony of the witness Dr Alison Anastasi (Representative of the CPSU) as summoned by Dr Steve Decesare acting for Pharma MT Limited;

Having heard and evaluated the testimony of the witness Ms Julia Pirota (Representative of the CPSU) as summoned by Dr Alexia Farrugia Zrinzo acting for the CPSU;

Having heard and evaluated the testimony of the witness Mr Adrian Dalli (Director General at the DOC) as summoned by Dr Alexia Farrugia Zrinzo acting for the CPSU;

Having heard and evaluated the testimony of the witness Ms Antonia Formosa (Ex-Director of the DPA) as summoned by Dr Alexia Farrugia Zrinzo acting for the CPSU

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 21st November 2024, the second hearing held on the 13th February 2025, and the third hearing held on the 6th March 2025 hereunder-reproduced.

Minutes

Case 2039 – CT 2171/2024 – Supplies – Tender for the Supply of Mek Inhibitor Tablets/Capsules and BRAF Inhibitor Tablets/Capsules

Call for Remedies prior to the closing date of a Call for Competition

The tender was issued on the 26th June 2024, and the closing date was the 30th July 2024.

The estimated value of this tender, excluding VAT, was €2,970,297.

On the 17th July 2024, Pharma MT Ltd filed an application for remedies prior to the closing date of a call for competition in terms of Regulation 262 of the Public Procurement Regulations.

A deposit of €14,815.49 was paid.

On the 21st November 2024, the Public Contracts Review Board, composed of Mr. Kenneth Swain as Chairman, Mr. Lawrence Ancilleri, and Dr Ing. Damien Gatt as members, convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Pharma MT Ltd

Dr Steve Decesare	Legal Representative
Ms Elisa McKenna	Representative
Mr Stefan Cutajar	Representative
Mr Ljubo Dimitrovski	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Julia Pirootta	Representative
Dr Alison Anastasi	Representative

Interested Party – V J Salomone Pharma

Ms Louisann Caruana Scicluna	Representative
Ms Melanie Mercieca Decesare	Representative
Ms Tania Borg	Representative

Department of Contracts

Dr Audrey Marlene Buttigieg Vella	Legal Representative
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Mr. Kenneth Swain, Chairman of the Public Contracts Review Board, welcomed the parties and invited submissions.

Dr. Decesare requested that witnesses be heard.

Dr. Nick Refalo (512075M), called to testify by the appellant, stated on oath that he has served as a Consultant Oncologist for 15 years and for the last five years has been the Chairman of the Oncology Unit. The tender requirements cover medication for the treatment of melanoma and other lung cancers. He was not involved in the tender preparation. The types of lung cancers are not numerous - around less than five per year with around 10 to 20 cases of melanoma per year. A tender issued in

2020 for similar medication covered only one of the types mentioned in the 2024 tender. Since 2020, there have been advances in indications; hence, there is a constant change of combinations in the product. There are three combinations of BRAF and MEK inhibitors to meet the conditions in this tender – they are all equivalent in effectiveness in treatment, but there are variations in the side effects.

Dr. Decesare requested witnesses from the CPSU be heard on the number of statements in their letter of reply.

Mr. Dustin Balzan (229880M), called to testify by the appellant, stated on oath that he is the Acting Director of the Directorate for Pharmaceutical Affairs (DPA) and that he did not have a direct role in the tender. The role of the DPA was to ensure that medicines were fit for requirements. The specifications in the tender have in common the mutation of BRAF 600, which follows the clinical protocol.

Questioned by Dr. Alexia Farrugia Zrinzo, Legal Representative for the CPSU, the witness said that he is a pharmacist by profession and went on to say that the DPA ensures that the correct cure is offered according to the agreed pathways. The protocol is the combined work of consultants, the Chief Medical Officer, and professionals. The DPA ensures that the specifications in the tender meet the medical requirements. The CPSU follows the DPA instructions, laid down by clinical people, in tender preparation.

Following a further question by Dr. Decesare, the witness said that the required combination of medicines follows a recommendation in 2022 and led to the present protocol developed in 2023, but the situation is constantly changing and developing at a very fast rate.

At this stage, Dr. Decesare requested that the testimony of individuals who drafted the tender specifications and the protocol be heard.

Dr. Farrugia Zrinzo said that the CPSU staff would testify on these points. She had requested the testimony of Ms. Tanya Formosa, who was the Director of the DPA when the tender was issued. Mr. Balzan had appeared instead.

Dr. Alison Anastasi (398380M), called to testify by the appellant, stated on oath that she only got involved in the tender when the appeal was filed. She is aware of the reasons for the addition of two medications in this call, and she tabled the DPA protocol for Dabrafenib capsules (Doc 1).

Dr. Anastasi was next called to testify by the Contracting Authority. She confirmed that she is a pharmacist and currently is the Head of Procurement Operations at the CPSU. She explained the process of how a tender is constructed. In this case, the DPA updated the specifications, and this process was completed before it reached the CPSU.

Dr. Audrey Marlene Buttigieg Vella, Legal Representative for the Department of Contracts, asked the witness why the clarification request of the 9th July 2024 was not replied to until the 17th July when it had been provided within the timeframe.

In reply to questions from Dr. Decesare, the witness said that she had no knowledge of the clarification response but was able now to give a reply based on the document just tabled listing the replies to the clarifications (Doc 2).

Ms. Julia Pirotta (496595M), called to testify by the Contracting Authority, stated on oath that she is a pharmacist by profession and currently Procurement Officer at CPSU. She was involved in the preparation of the tender document for publication, which was preceded by liaising with the DPA prior

to the drafting. The DOC alerted the CPSU that a number of clarifications had been sought, and these were referred to the DPA for reply. These replies were, in turn, forwarded to the DOC to enable them to reply to the clarifications. The person who dealt with these matters at the DPA was Ms. Doriella Cassar. DOC 3 was tabled backing the testimony given.

In reply to questions from Dr. Decesare, the witness said that the estimated value of the contract was based on the price the medication was last purchased. Three clarifications, replies 1, 2, and 3, were sent to the DoC on 15th July 2024. Clarification 4 did not reach the CPSU.

At this stage, Dr. Farrugia Zrinzo said it was essential that the testimony of Ms. Tanya Formosa, who at the time the tender was published was Director at the DPA, be heard and requested the Board to summon her at a further hearing.

The Chairman thanked the parties for their submissions and adjourned the hearing to the 7th January 2025 at 9.00 am.

End of Minutes of first hearing.

SECOND DAY OF HEARING – 13th February 2025

On the 13th February 2025, the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Mr Lawrence Ancilleri and Dr Ing. Damien Gatt as members convened a public hearing to consider further this call for remedy.

The attendance for this public hearing was as follows:

Appellant – Pharma MT Ltd

Dr Steve Decesare	Legal Representative
Ms Elisa McKenna	Representative
Mr Stefan Cutajar	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Julia Pirotta	Representative
Dr Alison Anastasi	Representative

Interested Party – V J Salomone Pharma

Ms Louisann Caruana Scicluna	Representative
Ms Melanie Mercieca Decesare	Representative

Department of Contracts

Dr Audrey Marlene Buttigieg Vella	Legal Representative
Ms Alicia Vella Lethridge	Representative

Mr. Kenneth Swain, Chairman of the Public Contracts Review Board, welcomed the parties and noted that at the previous hearing the Board had started hearing the witnesses called by the Contracting Authority.

Mr. Adrian Dalli (480479M), called to testify by the Contracting Authority, stated on oath that there were a number of clarifications on different dates on this tender, to which the Authority replied to on the 15th July. These replies were vetted on the 16th July, and as approval had not been given by the statutory date, the Department of Contracts was prepared to extend the closing date when the request for remedy was received, resulting in the tender's suspension.

Ms. Antonia Formosa (373667M), called to testify by the Contracting Authority, stated on oath that when the tender was issued, she served as Director for Pharmaceutical Affairs (DPA), which entity is responsible for drawing up specifications for tenders following approval by specific committees. The process for this tender began in October 2017 when the combination medication received approval, funds were allocated, and the item was included in the formulary. At that time, the specifications stated a combination of Dabrafenib and Trametinib as the request from the supplier was for this combination. At that time, this was to be used solely for the treatment of metastatic melanoma. As soon as the tender was issued, objections were raised through the PCRb claiming that there were other medicines of similar class that have the same indications. As a result, the specifications were changed to MEK inhibitor tablets or capsules and BRAF inhibitor tablets or capsules for treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation to be used in combination according to the SPC.

The witness continued that at that time, there were three combinations: Dabrafenib and Trametinib, Vemurafenib and Cobimetinib, and Encorafenib and Binimetinib. The tender stated that the cheapest combination should be recommended. At that stage, the protocol was altered, and Trametinib, which was the originator, was included in the formulary. Over time, further indications were approved with others in the pipeline. Oncologists expressed feeling "morally uncomfortable" that they could offer the treatment but were restricted to metastatic melanoma cases. An application was therefore made to treat patients through the exceptional route (the named patient route), but this was rejected on the basis that since the medication was included in the formulary, the exceptional route should not be used. For affected patients, no alternatives existed due to the medication's cost, except applying to the Malta Community Chest Fund, which would not assist per an agreement with the Government. Unless patients paid privately, they received no treatment. This issue was repeatedly referred to the Chief Medical Officer and the Ombudsman.

The witness further testified that an audit was carried out to find out how the medication had been used over a number of years. It resulted that doctors were prescribing the medicine for other conditions in spite of the fact that this was not according to the existing protocol. The matter was referred to the Chief Medical officer, and it was decided that other conditions would be included in the formulary with the necessary adjustments to the protocol. In March 2023, the specifications and the protocol were adjusted accordingly. Up to the present time, only one combination of MAK and BRAF inhibitors is licensed to meet the indication specifications on the protocol as per product SPCs.

Responding to Dr. Decesare's questions, the witness explained that policy requires suppliers to submit applications for formulary inclusion—V J Salomone was the only applicant for Dabrafenib and Trametinib. The initial indication for metastatic melanoma was eventually expanded to include Stage III melanoma and lung cancer. The audit covering 2017-2022 showed 20% of stock was used for lung cancer, but records couldn't determine the breakdown of the remaining 80% of melanoma cases. Witness further replied that on matters involving these medications, the DPA dealt with the Head of

the Department of Oncology, Dr. Nick Refalo. Referred to the protocol issued by DPA, witness confirmed that the indications on the protocol were specific to Dabrafenib 75 mg and Trametinib 2mg.

When questioned by Dr. Farrugia Zrinzo, the witness stated that the specifications are drafted by the DPA which makes sure that it covers all requirements. The PCRB had directed that 'open tenders' had to be issued.

Replying to further questions from Dr. Decesare, Ms. Formosa, the witness, said that indications in tender documents are sometimes superseded by new indications through the time intervals between the issuing of a tender, completion of the process, and obtaining supplies. Therefore, the DPA attempts to anticipate developments in the pipeline for the subsequent three years. While Novartis currently produces the licensed product, the DPA considers overall licensed indications for MEK and BRAF inhibitors. Specifications must incorporate future conditions if the medication's use is expanded to cover additional treatments.

This concluded the testimony of Ms. Formosa.

Following Ms. Formosa's testimony, Dr. Decesare said that the Board needs to recall Dr. Refalo since the witness indicated certain facts that did not come out in his testimony. According to his testimony, Dr. Refalo indicated, when specifically asked, that he was not involved in the preparation of the tender. The Board has now heard that the advice of the Head of Oncology was sought.

Dr. Farrugia Zrinzo suggested Dr. Refalo's statement about non-involvement might have referred specifically to the actual drafting of the tender, depending on how the question was phrased.

Dr. Decesare pointed out that Ms. Formosa in her testimony stated that the oncologists were 'morally uncomfortable'. If that was the case, Dr. Refalo would surely have mentioned it in his testimony, and that is the reason why he needs to be recalled. One must also ask if it was Dr. Refalo who agreed to the bundling.

The Chairman indicated that the Board would have a short recess to consider the request made.

On resumption, the Chairman stated the following:

"The Board, having heard the testimony of Mrs. Antonia Formosa, which indicated that there might be a discrepancy between her testimony and that of Dr. Refalo, has no objection to Dr. Refalo giving further testimony.

At this stage, the Board expects that such testimony be used to clarify why the three indications have been bundled together.

The hearing is adjourned to the 6th March 2025 at 9.00 am."

The Chairman thanked the parties and declared the hearing adjourned.

End of Minutes of Second Hearing

THIRD DAY OF HEARING- 6th March 2025

On the 6th March 2025, the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Dr Ing. Damien Gatt and Mr Richard Matrenza as members convened a public hearing to consider the appeal.

This was the third sitting.

The attendance for this public hearing was as follow:

Appellant: Pharma MT

Dr Steve Decesare	Legal Representative
Ms Elisa Mc Kenna	Company Representative
Mr Stephen Cutajar	Company Representative

Contracting Authority: Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Julia Pirotta	Chairperson

Interested Party – V J Salomone Pharma

Ms Melenie Mercieca Decesare	Representative
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Department of Contracts

Dr Audrey Marlene Buttigieg Vella	Legal Representative
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Administrative Matters

The Chairperson announced that Mr. Harry Fenech resigned from his position as PCRB secretary, and Mr. Lawrence Ancilleri was temporarily assigned to the role until a replacement is found. Due to Mr. Ancilleri being unable to serve concurrently as both tribunal member and secretary, Mr. Matrenza was appointed to replace him on the tribunal. All parties agreed to the Board configuration.

Witness Testimony

The Chairperson asked Dr. Nicholas Refalo to present his evidence as requested by the appellant.

Dr. Refalo (ID 512075), Chairman of the Oncology Unit for the past five years, testified under oath in response to Dr. Decesare's questions that he had not been consulted during the formulation of the tender document specification.

In response to the questions of Dr. Farrugia Zrinzo, representing the CPSU, Dr. Refalo stated that clinicians had long identified the need for these medications and had requested them from the relevant authorities. He indicated that there had been no direct communication between his team and the Directorate for Pharmaceutical Affairs (DPA) regarding specific product requirements. Dr. Refalo clarified that while the products in question belonged to the same class, they had different

varieties and indications, with only metastatic breast cancer being a common indication among all products under consideration.

Final Submissions

Appellant's Submissions (Dr. Decesare)

Case Overview

Dr. Decesare provided a summary of the case and hearings, explaining that the tender requested BRAF and MEK inhibitors, which are classes of products used in combination to treat certain cancer indications. The tender was intended to treat 60 patients over three years (with an optional six-month extension), at an estimated value of €2,970,297.

Previous Testimony

Dr. Refalo outlined three combinations of products suitable for the specified indications:

1. Dabrafenib and Trametinib (Novartis products, currently supplied by V.J. Salamone) - can treat all three indications specified in the tender.
2. Encorafenib and Binimetinib (appellant's products) - can treat metastatic melanoma and lung cancer.
3. Vemurafenib and Cobimetinib - restricted to metastatic melanoma treatment only.

All three combinations could effectively treat metastatic melanoma, which represents the majority of cases (10-20 patients per year, compared to 2-3 patients with lung cancer). He noted that in 2010, a similar tender was restricted to unresectable metastatic melanoma only, which would have allowed all three combinations to participate if the tender was published for the same scope today..

Dr. Decesare noted that in the previous session, Ms. Tanja Formosa stated she consulted Dr. Refalo regarding this tender, but today he could not recall this. Mr. Dustin Balzan, Acting Director of DPA, had stated that the specifications were based on a DPA protocol of the existing product (supplied by VJ Salamone of Novartis). Mr Balzan mentioned that the current specifications reflected the DPA's existing protocol, noting that this combination was licensed for three indications over time, while other combinations are not licensed for the same number of indications.

Dr. Anastasi, head of operations and procurement, confirmed that CPSU relies on specifications provided by the DPA. When presented with the protocol published by DPA, she mentioned that it directly specifies Dabrafenib and Trametinib manufactured by Novartis. Ms. Julia Pirota of CPSU confirmed that the estimated contract value was based on products acquired from the existing Novartis tender.

Legal Arguments

Dr. Decesare addressed several legal issues:

- **Estimated Tender Value:** According to Regulation 28, the Contracting Authority must determine the tender contract value based on the moment of issuance of the tender or contract notice. According to Ms. Pirota, this was not done, as it was based on the existing Novartis tender without comprehensive market research or appropriate financial analysis.
- **Division into Lots:** Regulation 34 stipulates that tenders of certain financial value must be divided into lots. For tenders under Regulation 9. (1) (b) exceeding €140,000, the Contracting Authority must divide the tender into lots or explain why this is not done. No valid objective

reason was provided why the tender was not divided into lots; the only reason specified in the tender was that only one combination was being requested.

- **Previous Tender:** A 2020 tender for the same inhibitors with the same number of patients was restricted to unresectable or metastatic melanoma. This allowed broader participation. When Novartis added new indications, the tender specifications began following Novartis's specifications.

Reference was made to a decision by the PCRB on June 5th, 2019, case 1315 (CT2042/2019) was referred to. The tender was for blood collection tubes. It included both adult and paediatric. It was requested that the adult and paediatric are divided separately. As the tender was drafted, for 4 or 5 % of the paediatric demand, one was limiting the market for those bidders who supply both adult and paediatric.

- **Clarification Issues:** The tender document required clarifications to be answered 6 days before closing, by July 17. The appellant requested clarification about dividing the tender into lots, but never received a reply, leading to this appeal.
- **Discriminatory Specifications:** Preamble 74 of the directive states that tenders must be drafted to avoid narrowing competition by favouring specific operators or mirroring key characteristics of supplies. In this case, the indications mirror the DPA protocol and limit the market to Novartis products.

Relevant Case Law

Dr. Decesare cited several precedents:

- **PCRB Case 1397:** A tender for Dabrafenib and Trametinib (Novartis products) was challenged. The PCRB stated that "*The technical specifications as stipulated in the RFP promote the supply of a product that can be obtained from one manufacturer only and such eventuality limits the scope of open competition*". The Board noted that "*the formulary list should not override the main principle in Public Procurement*" and that the Authority "*must never allow restriction in the participation of bidders in open competition.*" This appeal was upheld and the specifications had to be open for competition.
- **PCRB Case 1361:** Similar circumstances where DPA dictated specifications to CPSU. The PCRB ruled that "*the formulary list should not be a hindrance for the application of a type of treatment not presently included in such a list and at the same instance, promoting a breach in public procurement by defying the scope for competition.*"
- **PCRB Case 1135:** Supply of Sunitinib Preparations. The Board stated that "*the tender document specifies the specifications of a particular brand of product without inviting equivalent products to compete, thus limiting the scope of competition.*"
- **EU Case T668/15:** Jema Energy vs Enterprise - the court declared that public contracts must always be open to the widest possible competition in the interest of Union law.

Court of Appeal Precedents

Dr. Decesare cited two Court of Appeal cases regarding the burden of proof for showing anti-competitive intent:

- **Krypton Chemists vs CPSU (538/23/1):** The Court ruled that regulations should be interpreted broadly, not narrowly, and that to demonstrate artificially reduced competition, the economic operator need not prove the contracting authority acted dishonestly.

- **Medina Health Care vs CPSU (86/2024/1):** The Court stated that the fact that the conditions serve no purpose other than giving advantage to one party and disadvantage to another is sufficient evidence of anti-competitive intention. This is objective evidence that does not require proof of subjective dishonesty or deceit.

Requested Remedy

Dr. Decesare concluded that the Contracting Authority designed the tender for only one product, with the estimated contract value based on currently supplied products and specifications limited to the product being purchased today. The appellant requested that the Board order the Contracting Authority to either amend the tender by dividing it into three lots for each indication or cancel this tender and publish another that is open to the market.

Contracting Authority's Submissions (Dr. Farrugia Zrinzo)

Dr. Farrugia Zrinzo referred to Medina Health Care vs. CPSU, emphasizing that specifications are made by the Contracting Authority to their requirements and should not create unjustified obstacles. She explained that DPA provided specifications based on protocols seen with clinicians who use this product. CPSU publishes specifications as requested by DPA.

She emphasized that a combination of products was being requested, which is why the tender was not divided into lots, as the products are to be used together. She noted there was no element of multiple awards, and referred to Article 262 (pre-contractual), stating the appellant needed to prove PPR rules were broken, which she contended had not been proven.

Dr. Farrugia Zrinzo cited PCRB case 967 (May 26, 2014), where it was declared that the Contracting Authority ensures each call is open to the greatest number of bidders to secure the best product at the lowest possible price for its needs and patients.

Final Clarification

Dr. Decesare clarified that the appellant was not objecting to combining of BRAF and MEK inhibitors in the tender specifications but rather to requiring a combination that must target all three of the same indications simultaneously.

The Chairman thanked both parties and declared the submissions closed.

End of minutes of third hearing.

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 21st November 2024, the second hearing held on the 13th February 2025 and the third hearing held on the 6th March 2025.

Having noted the call fall remedies filed by Pharma MT Limited (C42603) (hereinafter referred to as the Appellant) on 17th July 2024, refers to the claims made by the same Appellant with regard to the tender of reference CT 2171/2024 listed as case No. 2039 in the records of the Public Contracts Review Board.

Appearing for the Appellant: Dr Steve Decesare

Appearing for the Contracting Authority: Dr Alexia J Farrugia Zrinzo & Dr Leon Camilleri

Appearing for the Department of Contracts: Dr Audrey Marlene Buttigieg Vella

Whereby, the Appellant contends that:

- a) In this case, the Contracting Authority required - as a mandatory requirement - that the relevant products supplied are licensed for treatment of three (3) separate and distinct indications. The Contracting Authority, by doing so, has limited the Tender Procedure to particular products, to the exclusion of other products which are suitable to treat multiple indications but not all the indications arbitrarily bundled together by the Contracting Authority. The manner in which the Contracting Authority has formulated the technical specifications favours specific economic operators / manufacturers, and at the same time prejudices other economic operators / manufacturers who are precluded from competing in this Tender Procedure. In addition, by requiring the relevant products to be licensed for treatment of the indications referred to in the Tender Document, the Contracting Authority is restricting the products available to clinicians which could be prescribed for the better treatment of the specific indication of patients, and at the same time not obtaining best value for money due to the fact that only one (or, at most, a very limited number) supplier / manufacturer could compete for this Tender Procedure. Indeed, the products which meet the requirements of the Tender Document are not the most effective products available on the market for treating patients suffering from certain indications referred to therein.
- b) The principle of "*divide or explain*" is a general principle. The reason for this is simple: by bundling one or more indications into one contract, a contracting authority is favouring those economic operators which can offer a product which is suitable for all those indications and prejudicing (effectively excluding) all those operators which may offer a product which would be suitable for only one or more of those indications but not all, and in some cases several other indications which the Contracting Authority chose to omit.

- c) The consequence of this is that - contrary to the PPR and the Directive which seek to ensure that public purchases ensure fair competition (respecting the principles of equal treatment and non-discrimination) and to ensure that contracting authorities get the best value for taxpayers' money - the competition is reduced drastically (or eliminated completely).
- d) The Contracting Authority has an obligation to promote competition for the contract and ensure that competition in the market is not distorted - particularly by avoiding the configuration of contracts which result in potentially competitors, with equivalent market experience and products conforming to the technical specifications for a significant number of indications, from being excluded.
- e) The default position in terms of the PPR is that division into lots (particularly when the products are being procured for multiple indications) is preferable to one lot which bundles different indications together.
- f) The bundling of requirements into lot/s with select design characteristics has a detrimental effect on competition for those contracts in the market concerned. The bundling of essentially independently available requirements in the manner set out above restricts the number of potential bidders and, therefore, generates anticompetitive effects and alters the structure of the markets.?
- g) Stating that these were bundled together into one contract because "only one combination of MEK Inhibitor Tablets/Capsules and BRAF Inhibitor Tablets/Capsule is being requested" is not a justification, let alone a sufficient justification, since the indications listed are separate and distinct indications for which different products may be supplied, some more effective than others in treating certain indications.

This Board also noted the Contracting Authority's & Department of Contract's Reasoned Letter of Reply filed on 23rd July 2024 and its verbal submission during the hearing held on 21st November 2024, the second hearing held on the 13th February 2025 and the third hearing held on the 6th March 2025, in that:

- a) CPSU and DOC submit that the claim of the objector stating that failure to split the indications into lots is a clear breach of the PPR, is unfounded in fact and at law. The applicant bases its argument in regulation 39(3) of the PPR and quotes this sub paragraph. The applicant chooses to emphasise the phrase '*artificially narrowing competition*' however conveniently falls to emphasise also the phrase '*(.) made with the intention of unduly favouring or disadvantaging certain economic operators*'
- b) CPSU and DOC submit that in line with general principles of law, the person who alleges, must prove its claim. It is being respectfully submitted that in its application the applicant did not prove any intention of unduly favouring or disadvantaging certain economic operators, consequently that there was any artificial narrowing of competition caused by the specifications as published.
- c) CPSU and DOC submit that based on the technical and clinical reasons as indicated by Directorate Pharmaceutical Affairs (DPA) and shall be proven was necessary that the specifications are published in the manner published in the Tender document, due to the manner in which these items are used.

- d) CPSU and DOC rebut to this grievance since the conditions which were stipulated in the tender document are necessary for the proper administration of medication as will be further explained in the viva voce testimony.

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 witness duly summoned, will now consider Appellant's grievances as follows in their entirety.

Grievance 1: Artificially Narrowing of Competition

In determining this grievance, the Board shall analyse the following legal issues:

1. Whether the technical specifications requiring products licensed for three specific indications constitutes an undue restriction of competition in contravention of Regulation 39(3) of the PPR
2. Whether the Contracting Authority's failure to divide the tender into separate lots corresponding to distinct indications violates Regulation 34 of the PPR.
and
3. The applicable legal standard for determining anti-competitive intention in the context of public procurement, in light of relevant Court of Appeal jurisprudence.

1. The requirement for products licensed for three specific indications in the technical specifications

- The Appellant contends that by requiring products to be licensed for three separate and distinct indications, the Contracting Authority has limited competition to specific products, effectively excluding other products suitable for multiple (but not all) indications. The Appellant further claims that the specifications mirror Novartis's product characteristics, thereby favouring its supplier (V.J. Salomone Pharma) and excluding competitors.
- The Board notes that the specifications were drafted based on the existing protocol provided by the Directorate for Pharmaceutical Affairs (DPA), which reflected the current clinical requirements. However, it is evident from the testimony of Ms. Antonia Formosa and Dr. Nicholas Refalo that only one combination of MEK and BRAF inhibitors (Dabrafenib and Trametinib) currently meets all three indications specified in the tender.
- The Board finds this approach restrictive by favouring a single supplier, which does not align with the principles of equal treatment and non-discrimination enshrined in public procurement regulations.
- This position is consistent with PCRB Case 1397, which involved the same products (Dabrafenib and Trametinib), where the Board clearly stated:

"The technical specifications as stipulated in the RFP promote the supply of a product that can be obtained from one manufacturer only and such eventuality limits the scope of open competition."

Furthermore, in that same decision, it was emphasized that:

"This Board would respectfully point out that the formulary list should not override a main principle in Public Procurement i.e. the duty and obligation of the Contracting Authority, in its stipulated technical specifications in a particular tender, must never allow a restriction in the participation of bidders in an open competition."

- The Board refers to other cases where similar restrictive specifications were deemed anti-competitive. In PCRB Case 1361, the Board stated that *"the formulary list should not be a hindrance for the application of a type of treatment not presently included in such a list and at the same instance, promoting a breach in public procurement by defying the scope for competition."*

2. Failure to Divide the Tender into Lots

- The Appellant argues that the tender should have been divided into three lots, each corresponding to a separate indication, as required by Regulation 34 of the Public Procurement Regulations (PPR).
- The Board notes that dividing tenders into lots is a default principle under PPR to promote competition unless justified otherwise. In this case, no valid justification was provided in the tender document for bundling all three indications into a single lot. The testimony confirms that different combinations of MEK and BRAF inhibitors are effective for different indications, supporting the feasibility of dividing the tender into lots.
- The Board agrees with the Appellant that failure to divide the tender into lots has artificially narrowed competition and limited market access for other suppliers. This position aligns with EU jurisprudence, specifically Case T-668/15, Jema Energy vs Enterprise, where it is stated that *"the EU Courts have held that one of the objectives of EU rules on public procurement is to open up to the widest possible competition and that it is in the interest of EU law to ensure the widest possible participation of tenderers in a call for tenders."*

3. On the Burden of Proof Regarding Intention to Limit Competition

- The Contracting Authority argued that the Appellant failed to prove any intention by the Authority to limit the market.
- However, as established in the Court of Appeal Case Krypton Chemists vs CPSU (538/23/1) dated February 15, 2024:

"Fil-fehma tal-Qorti dan ir-regolament ghandu jigi interpretat f'sens wiesgha u mhux f'sens dejjaq, kif x'aktarx interpretat il-Bord ta' Reviżjoni dwar Kuntratti Pubbliċi."

This means that Regulation 39(3) of the Public Procurement Regulations should be interpreted broadly, not narrowly. The Court further clarified that to show artificial restriction of competition, the economic operator does not need to prove that the contracting authority acted dishonestly.

- This principle was reinforced in the more recent Court of Appeal case Medina Health Care vs. CPSU (86/2024/1) of June 24, 2024, which specified that:

" Kif senwa jinghad fil-każ ta' Krypton, [M]hux mehtieg l-prova tad-disonestà jew tal-qerq, ghax il-fatt li l-kondizzjonijiet tas-sejba ma jservu ghal xejn iżjed blief illi jaghtu vantaġġ lil parti u żvantaġġ lil parti ohra jkun prova biżżejjed tal-intenzjoni antikompetitiva."

- The Board determines that, consistent with these Court of Appeal judgments, the Appellant is not required to prove subjective dishonesty or deceit on the part of the Contracting Authority.

Based on the above reasons the Board upholds the Appellant's grievance.

The Board,

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

- a) Uphold Appellant's Letter of Objection and contentions,
- b) Directs the Contracting Authority to (either Option A **or** Option B):

Option A:

- 1) Divide the current Tender Document into 3 separate lots, one lot for each of the following indications:
 - i. unresectable or metastatic melanoma with a BRAF V600 mutation, for use in combination as per SPC
 - ii. Stage III melanoma with a BRAF V600 mutation as adjuvant treatment following complete resection, for use in combination as per SPC and
 - iii. Advanced NSCLC with a BRAF V600 mutation, for use in combination as per SPC

And

- 2) To amend the '*Closing Date of the Call for Tenders*' to the 4th May 2025.

Or

Option B:

- 1) To cancel the current Tender Procedure and re-issue a new tender with the indications divided into 3 separate lots, as detailed above.

For Both Options: REQUIRES division of quantities per lot be based on supported clinical data and research.

- c) Directs that the deposit paid by Appellant to be reimbursed in full.

Mr Kenneth Swain
Chairman

Mr Richard A. Matrenza
Member

Dr Ing. Damien Gatt
Member