PUBLIC CONTRACTS REVIEW BOARD

Case 1228 – CT 2189/2018 – Tender for the Supply of Tenofovir 245mg Tablets

Call for Remedies before the Closing Date for Competition

The publication date of the call for tenders was the 14th September 2018 whilst the closing date of the call for tenders was 2nd October 2018. The estimated value of the tender (exclusive of VAT) was € 1,643,405.40

On the 1st October 2018, V J Salomone Pharma Ltd filed a Call for Remedy against the Central Procurement and Supplies Unit as Contracting Authority on the grounds that clauses in the tender were discriminatory.

On 1st November 2018 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – V J Salomone Pharma Ltd

Ms Jackie Mangion	Representative
Mr Charles Treeby Ward	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Mr Mark Zammit	Representative

Dr Anthony Cassar, Chairman of the Public Contracts Review Board, welcomed the parties and invited submissions.

Ms Jackie Mangion, Representative of V J Salomone Pharma Ltd, stated that a clause in the Tender regulated the supply of medicines to be in blister packs, and that pack formulation takes precedence irrelevant of price. Whilst this could apply in instances where treatment might be for a relatively short period of time, Tenofovir was a long term treatment where it was in order to deliver a months' supply (30 tablets x 1 daily) in a bottle. Contrary to what the CPSU were claiming stability was not an issue, and there was no silica gel tablet in the 30 tablet bottle as the silica was incorporated in the bottle top. Portability and ease of dispensing where not such

important factors that they should take precedence over price. The originators of the medicine in question supplied it in both blister packs and bottles and this principle should be adhered to in all tenders.

Mr Mark Zammit (425874M) called as a witness by the CPSU, testified on oath that he was an Advanced Pharmacy Practitioner at the CPSU. The clause to which Appellants were objecting has been in use since 2015. He tabled several documents outlining comments favouring the use of blister packs:

- Health Compliance Packaging Council – advantage of increase in adherence in following prescribed treatment on daily basis; ensures and assists in taking right doses
- World Health Organisation Expert Committee – preference for blister packs in particulate formation; problem of opening bottles for arthritis sufferers
- Usability Study among Health Workers – difficulty of opening screw cap bottles leading to decanting tablets into another container making them unusable as stable only if properly stored. Evidence that overdosing reduced by blister packaging
- Human and Experimental Toxicology Report - severe overdoses where halved through blister packs. Empirical evidence of reduction in amount of tablets taken by persons in unstable mental condition.

Witness also tabled documents giving examples of various range of medicines marketed in blister packs which do not reduce competition. In blister option there were many advantages to the patients benefit.

Ms Mangion said that adherence is not a big factor as not something very common; popping tablets out of a blister pack can be just as difficult as opening a bottle, whilst the overdosing argument is specious.

The Chairman said that the principle of open competition must be observed, and the point should be amplified and clearly specified that preference to blister packs will be given provided prices with bottled tablets are comparable. He then thanked both parties for their submissions and declared the hearing closed.

This Board,

having noted this Call for Remedies filed by VJ Salomone Pharma Limited, (also referred to as the Appellants) before the Closing date for Competition on 1 October 2018 referring to the contentions made by the same Appellants with

regard to the issue of Tender of Reference CT 2189/2018 by the Central Procurement and Supplies Unit, (also referred to as the Contracting Authority), and listed as Case No 1228 in the records of the Public Contracts Review Board.

Appearing for the Appellants: **Ms Jackie Mangion**

Appearing for the Contracting Authority: **Dr Marco Woods**

Whereby, the Appellants contend that:

a) **a clause in the Tender Document regulated that the supply of medicines will be given preference if presented in "*blister packs*". In this regard, the medicine being requested consists of medical treatment of quite a long duration and the use of tablet bottles is more appropriate for use by the patient. However, such a mode of packaging is not being accepted so that, the Appellants are being disadvantaged from participation in the Tender.**

This Board has also noted the Contracting Authority's "*Letter of Reply*" dated 8 October 2018 and its verbal submissions during the Public Hearing held on 1 November 2018, in that:

a) **The Central Procurement and Supplies Unit maintain that there are various advantages which are beneficial to the patient through having**

the requested medicine packed in "*blister pack*" mode. Such benefits take into consideration the well being of the patients' medical condition whilst at the same time, minimise the risk and incidence of the incorrect and unhealthy abuse of the same medicine.

This Board has also noted the testimony of the witness, namely Mr Mark Zammit who was duly summoned by the Central Procurement and Supplies Unit.

This same Board has also noted the documents submitted by Mr Mark Zammit which consisted of literature which show various medicines marketed in "*Blister Packs*".

This Board, after having examined the relevant documentation to the Appellants' concern and heard the submissions made by all interested parties, including the testimony of the technical witness, opines that the issues which merit consideration are twofold namely,

i) **The Mode of Packaging;**
ii) **The Advantages of "*Blister Pack*" Mode**

i) **<u>The Mode of Packaging</u>**

With regards to this issue, this Board would refer to Clauses 1.2.1 of the Technical Specifications of the Tender Document, as follows:

"*1.2.1 Medicinal products and food supplements*

i) In case of solid oral dosage forms (tablets/capsules), medicinal products and food supplements must be supplied in the following containers and these will considered in the following sequence order as follows:

a) Pack size of 120 units or less in blister packs;

b) Pack size of 120 units or less in any other container type;

c) Pack size of 120 units or less, in blister packs repackaged from a larger pack size, provided that the re-packaged product is registered as per clause 9.11 [Registration with Medicines

Authority (Medicinal Products)] of the Special Conditions in this Tender Dossier.

d) Pack size of 120 units or less in any other container type, repackaged from a larger pack size, provided that the re-packaged product is registered as per clause 9.11 (Registration of Medicinal Products) of the Special Conditions in Section 3 of this tender dossier.

***In the case that none of the offers received are in line or within the Last Purchased Price through open tender procedure, other pack sizes may be considered*.”**

The above mentioned clause does indicate the preferred mode of packaging, however, at the same time, it is also allowing the Contracting Authority to consider other packaging methods, so that, there are no restrictions for prospective Bidders to participate with offers having a different packaging mode other than that of “*Blister Packs*”

At this stage of consideration, this Board would respectfully point out that, the Contracting Authority has every right to dictate technical specifications which are attainable and have measurable objectives and yet, at the same instance, affording equivalent features; in this particular case being the mode of packaging of the medicines. This Board would however amplify the issue of the main objective of this procurement in that, it is the medicine which must be procured and the packaging mode being preferred by the Contracting Authority should not restrict competition, or create undue advantages as long as the packaging mode of the medicine itself is medically justified or renders benefits to the patient.

With regards to the Appellants' contention that Clause 1.2.1 of the technical specifications does create an advantage to offers in "*Blister Packing*" modes, and this Board confirms that the clause does state that there is an order of preference in the consideration of the offers, however, one must analyse and establish whether the benefits derived from a "*Blister Pack*" mode is justified, in the medical sense.

ii) <u>The Benefits of "*Blister Pack*" mode</u>

The Contracting Authority is insisting that apart from the fact that, such a clause has been in use since 2015 in similar Tenders, it has been scientifically proved that such mode of packing does render the following advantages:

- **There is less risk that the patient will not take the correct dose;**

- **"*Blister Pack*" modes allow easier handling to patients suffering from arthritis;**

- **Studies indicate that medicine is more protected for usage through "*Blister Packs*";**

- **There is less incidence of abuse of an overdose by persons having a medical condition;**

In this regard, this Board would respectfully point out that through the documentation and literature presented by the witness, it is evidently

clear that there are credible medical reasons as to why "*Blister Packing*" mode is preferred and in this respect, this Board refers to an extract from the testimony of the witness, as follows:

"***Pero' fil-verita' hemm ħafna options ta'prodotti li huma available bħala blister packs ta'dan il-prodott partikolari li qed nitkellmu fuqu llum. Fil-fatt dawn huma.... SPCs tal-prodotti u jekk taraw għamilt bil-highlighter u anke b'dik l-isticky note, so għandek at least six different options li jidher li huma made in blister packs. Ifisser li meta' qed nitkellmu li għandek six possible options ta'prodotti li huma available in blister packs. Minbarra hekk qatt m'hu qed nagħlqu l-bibien għal HDPE bottles in any case u m'aħniex ser nagħlqu l-bibien qatt għaliex xorta l-HDPE bottles għadhom jistgħu jikkompetu u hemm ħafna medicine li jiġu in HDPE bottles fejn m'hemmx alternattiva ta'blister packs. Pero' fejn hemm alternattiva għal blister packs, żgur l-evidenza kollha, scientific studies, parir tal-WHO u ħafna organisations juru b'mod ċar li hemm ħafna vantaġġi tagħhom. Allura kemm għall-vantaġġ tal-pazjent, vantaġġ ta'compliance, vantaġġ ta'portability, iktar garanzija ta'stability, vantaġġ li nnaqqsu l-potential overdoses, huwa ċar. L-HDPE xort agħadhom b'ċans li jiġu considered u żgur m'għalaqniex il-bibien għall-HDPE pero'***

***jien inħossni hands on heart, fil-kuxjenza tiegħi, naf li għal dan il-prodott żgur li hemm competition, a healthy competition u naf li hemm vantaġġi distinti tal-blister packs*"**

Furthermore, this Board was made aware of the importance that medicine is stored in the right condition to remain effective so that medicine which is packed in "*Blister Packs*" mode is more protected and will contain its maximum efficiency level once packed in this mode. In this respect, this Board would again refer to an extract from the testimony of the technical witness, which highlights this issue as follows:

"*Kif taf, hemm ħafna mediċini li huma suxxettibbli. Jien semmejt l-Amoprazole għax huwa mediċina komuni. Pero' jeżistu mijiet ta'mediċini. Anke Tenofovir huwa suxxettibbli. Kull mediċina speċjalment fit-temp ta' Malta iva huma suxxettibbli. Ifisser din hija standard f'kollox. Il-fatt li inti prodott ikun fi blister pack, fejn għandek protection tablet, dik qed tagħti protezzjoni superjuri irrespective mill-pazjent jekk ser iżomm il-prodott fil-bott. U dwar tal-overdoses, Tenefovir huwa ukoll very serious in overdose. U ħafna pazjenti li huma*

***HIV positive, hemm ħafna issues oħrajn. Anke psychiatric issues. U severity in overdose, huwa punt validu f'kull mediċina.*"**

This Board also noted that the medicine being packed in "*Blister Pack*" mode can be supplied from more than five suppliers, so that, in this respect, there is no restriction in open competition and at the same instance, the credible advantages and benefits to the patients, in general, has to be taken into consideration.

In view of the above, this Board,

i) **does not uphold VJ Salomone Pharma Limited's contention that Clause 1.2.1. restricts competition;**

ii) **upholds the Central Procurement and Supplies Unit's arguments and instructs the latter to continue the tendering process.**

Dr Anthony Cassar Chairman	Dr Charles Cassar Member	Mr Lawrence Ancilleri Member

15th November 2018