QORTI TAL-APPELL

IMĦALLFIN

S.T.O. PRIM IMĦALLEF MARK CHETCUTI
ONOR. IMĦALLEF JOSEPH R. MICALLEF
ONOR. IMĦALLEF TONIO MALLIA

Seduta ta' nhar l-Erbgħa, 30 ta' Marzu, 2022.

Numru 30

Rikors numru 348/21/1

Pharma.MT Limited (C42603)

v.

Direttur tal-Kuntratti; Central Procurement and Supplies Unit (CPSU); E.J. Busuttil Limited (C 10135) ghal kull interess li jista' jkollha

Il-Qorti:

1. Dan huwa appell imressaq mis-socjeta` rikorrenti Pharma.Mt Ltd fil-15 ta' Novembru, 2021, kontra decizjoni li ta l-Bord ta' Revizjoni dwar il-Kuntratti Pubblici (minn hawn 'il quddiem imsejjah "il-Bord") fil-25 ta' Ottubru, 2021, fir-rigward ta' sejha ghall-offerti b'referenza CT 2044/2021 (kaz numru 1639).

2. F'dan il-kaz is-Central Procurement and Supplies Unit (il-CPSU) harget sejha ghall-offerti ghax-xiri ta' "*Colchicine Tablets"*. Il-kriterju ta' selezzjoni kellu jkun il-prezz, bl-ghotja tas-sejha tinghata lill-offerent li jissottometti l-orhos offerta konformi mal-kriterji amministrattivi u teknici tas-sejha. L-offerta tas-socjeta` rikorrenti kienet ta' €136,572, filwaqt li l-offerta tas-socjeta` intimata E.J. Busuttil Ltd kienet ta' €138,510. Avolja din l-ahhar socjeta` tefghet offerta oghla minn dik tas-socjeta` rikorrenti, kienet hi li giet rakkomandata ghall-kuntratt wara li s-socjeta` rikorrenti giet skwalifikata. Hija kienet skwalifikata peress illi (i) ma tatx il-*Marketing Authorisation Details* tal-prodott, u (ii) inghad li l-prodott gie mill-Olanda, pero` il-letteratura tal-prodott kienet turi li gejja mill-Irlanda.

3. Is-socjeta` rikorrenti ma accettatx din l-iskwalifika u ressqet oggezzjoni ghal quddiem il-Bord. Dan il-Bord laqa' l-ewwel ilment tas-socjeta` rikorrenti peress illi l-istess dokumenti tas-sejha kienu jippermettu li d-dettalji relattivi setghu jinghataw lil CPSU "*within 90 days from signing of the contract*". Fil-fatt, fis-sezzjoni relattiva, is-socjeta` rikorrenti kienet qalet li l-prodott ikun registrat hawn Malta jekk tinghata l-kuntratt. Il-Bord, ghalhekk, qal li ma kienx hemm raguni ghala s-socjeta` attrici tigi skwalifikata minhabba din ir-raguni.

4. Il-Bord, pero`, ma laqax l-ispjegazzjoni li offriet is-socjeta` rikorrenti ghaliex il-*country of licensing* huwa ndikat bhala l-Olanda, waqt li s-*summary of product characteristics* (l-SPC) sottomessa minnha hija dik uzata fl-Irlanda. Is-sentenza tal-Bord hija s-segwenti:

"**Hereby resolves:**

The Board refers to the minutes of the Board sitting of the 19th October 2021.

Having noted the objection filed by Pharma.MT Ltd (hereinafter referred to as the Appellant) on 13th August 2021, refers to the claims made by the same Appellant with regards to the tender of reference CT 2044/2021 as case No. 1639 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Steve Decesare
Appearing for the Contracting Authority:	Dr Alexia Farrugia Zrinzo

Whereby, the Appellant contends that:

a) ***Disqualification due to missing information -*** The Department of Contracts ("DOC") letter states that Pharma's offer was disqualified since the *"Technical Offer form (not rectifiable as per tender conditions) has section 2.3 missing. Thus offer could not be validated"*. Therefore, the reason for disqualification is that the DOC considered that section 2.3 of Pharma's technical offer form is missing. This is entirely incorrect as a submission was made for section 2.3. It is evident therefore that Section 2.3 was not missing in Pharma's Technical Offer. Presumably, what is meant by this statement is that the MA/QL/PI/EU number was not indicated. If this is the case, the Marketing Authorisation number for the product in Malta is indeed missing, since the product (as permitted in the Tender Document) is not yet registered locally. In view of the above, Pharma stated in its technical offer that the "Product will be registered if tender is awarded". The Tender Document permits the registration of the medicinal product after award of the contract. It is obvious therefore that it is not possible for Pharma to specify an MA/QL/PI/EU number for the product being offered by Pharma in the Tender Procedure, as the relevant product is not yet registered locally.

b) ***The note in DOC Letter re MA number -*** Separately from the reason for disqualification, the DOC Letter also notes the following: *"Also section 2.2 details that the country of licensing is Netherlands but the SmPC submitted details an MA number which relates to Ireland".* This does not relate to the technical offer form and does not appear to be a reason for disqualification. In any case, Pharma is clarifying this note. The DOC correctly notes that the country of licensing of the product is the Netherlands. However, the Tender Document also required in Section 2.1 of Section 3, that a Summary of Product Characteristics ("SmPC" or "SPC") of the product being offered. An SPC is a specific legal document which is approved as part of the market authorisation of each medicine. It can be found on the European Medicines Agency ("EMA") and the Malta Medicines Authority website. The SPC acts as a basis of information on the use of medicines and forms part of the Marketing authorization of every medicine, the structure of which is defined by European Pharmaceutical legislation. In particular, the SPC includes reference to i) Marketing Authorisation Holder ii) Marketing Authorisation Number iii) Date of First Authorisation / Renewal of the Authorisation. In view of the fact that an SPC has not been issued for the product in Malta, as the product is not yet registered in Malta and no Market Authorisation has been issued in favour of the relevant proposed Market Authorisation Holder in Malta. Pharma (or any other tenderer submitting a tender with a product which is not yet registered, as expressly permitted in the Tender Document as explained above) was not in a position to submit an SPC showing a Market Authorisation number from the Malta Medicines Authority. Since an SPC for the product, in the English language, was required Pharma submitted the SPC used by Tiofarma B.V. for the same product in Ireland, which is one of the EU Member States in which Tiofarma B.V. has a Market Authorisation. The reason for this is obvious; the SPC used in Ireland is in English, one of the official Languages of Malta, and therefore abides by the requirements in Section 2.1 of Section 3 of the Tender Document, as herein mentioned. Therefore, while the DOC's statement that "section 2.2 details that the country of licensing is Netherlands but the SmPC submitted details an MA number which relates to Ireland" is factually correct, this does not result in any breach of the requirements in the Tender Document.

c) ***Duty to seek clarifications*** - While Pharma contends that, on the basis of the above, there is no room for any ambiguity or uncertainty on Pharma's reply in Section 2.3 of its Technical Offer form and the SPC, it submitted that should the Contracting Authority have had any doubt on the same, it had an obligation to seek a clarification from Pharma in these circumstances. Pharma notes that both the Technical Offer form and the SPC are indicated in the Tender Document as being Note 3, meaning that while no rectification may be made in their respect, the Contracting Authority is allowed to make clarifications thereon.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 19th August 2021 and its verbal submission during the virtual hearing held on 19th October 2021, in that:

a) ***Disqualification due to missing information -*** Referring to the first reason, that being that Section 2.3 of the Technical Offer Form is missing. CPSU contend that the Technical Offer Form was clear and unambiguous, wherein it clearly stated "MA/OU/PI/EU No _____". The Appellant instead opted to indicate "product will be registered if is awarded" therefore referring to the process where a product may be registered within 90 days from signing of the Contract. Evidently, the appellant in his appeal is insisting on this line of argument, however the appellant fails to note that the Technical Offer Form did not request the Maltese MA number, but merely requested "MA/QL/PI/EU No". Therefore, although the Tender stipulates that an unregistered product may be submitted as long as it is registered within 90 days from the date of signing of the Contract the Technical Offer Form did not request the Market Authorisation Number for Malta, but merely requested a Market Authorisation Number. In view of this, the argument being raised by the appellant is entirely unfounded at fact and at law.

b) ***The note in DOC Letter re MA number -*** Moreover, the second reason as to why the offer was rejected is that the Country of Licensing is indicated as Netherlands in the Technical Offer Form whilst the SmPC indicates Ireland as the Country of Licensing. CPSU contend that the SmPC is the official document of the product, which Product outlines all the characteristics of the product as well as the licensed country of the product. Therefore, if the Country of Licensing is listed as Ireland in the SmPC, then the objector ought to have indicated Ireland as the Country Of Licensing in the Technical Offer Form, and not Netherlands. The argument being brought by the appellant that they submitted the Irish SmPC due to being published in the English Language can never justify this mistake on the part of the objector. The Contracting Authority must always act in line with the provisions of the law and in the best interest of the patient Moreover. the Evaluation Committee is bound by the principle of Self-Limitation. Therefore, the Evaluation Committee must carry out its Evaluation on the documentation and information as submitted at tendering stage. In evaluating the Technical Offer Form and the SmPC of the product being offered, the Evaluation Committee noticed that the Country of Licensing listed in the Technical Offer Form and that listed in the SmPC of the product as submitted, differed from each other. Therefore, the information given in the Technical Offer Form and that resulting from the SmPC submitted did not corroborate with each other. Consequently, for the reason outlined above, and due to the fact that the Technical Offer Form is a Note 3 Document (Non-rectifiable as per tender conditions), the Evaluation Committee could not validate the offer as submitted.

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 consider Appellant's grievances, as follows:

a) ***Disqualification due to missing information –*** The Board makes reference to Section 4 of the Tender Dossier, whereby Marketing Authorisation (MA) is defined as follows: "is the licence for medicinal products to be placed on the market in Malta granted by the Medicines Authority in accordance with the Medicines Act, 2003 (Act No III of 2003 and subsidiary legislation) and for
Centrally Authorized products, by the European Medicines Agency (EMA)……". Reference is also made to the fact that 'if a product is not registered in Malta a copy of the registration must be submitted within 90 days'. Therefore, the Appellant is not deemed to have breached his Technical Offer submission of Section 1 Sub-section 2.3 when he declared "Product will be registered if tender is awarded".

This Board upholds Appellant's first grievance.

b) ***The note in DOC Letter re MA number –*** In relation to this specific grievance, the Board notes that the:

i. Technical Offer (Note 3 document) of the Appellant company stated in Section 1 Sub-section 2.2 – "Country of licensing Netherlands".

ii. Summary of Product Characteristics (SPC) provided within the tender bid, which was requested as per the Tender Document paragraph 2.1 of Section 3, refers to an Irish SPC.

The Board also notes that the respective European Union Directive has within it a 'template' for SPCs' which has as one of its main objectives, that of harmonisation. As per testimony under oath of Dr Ian Ellul, *"SPC relates to each particular country and had a particular number. European regulations insist on harmonisation of products and the product and authorisation should be from the same country. There might be some small differences between SPCs from different countries but following harmonisation they basically follow the same template."* Therefore, it is the specific and respective country SPC which is the official document upon which one has to base his / her evaluation. Therefore, this Board opines when the Appellant listed "Netherlands" in Section 1 Sub-section 2.2 – Country of licensing, within the Technical Offer, then he should have substantiated his technical documentation with an SPC from the Netherlands. This to be duly translated into an approved language of Malta. It is further noted, that the Evaluation Committee, in this instance, correctly observed the principle of 'Self-Limitation'.

This Board does not uphold Appellant's second grievance.

The Board,

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

a) To uphold the Appellant's concerns with regards to the first grievance entiteld "Disqualification due to missing information" but does not uphold Appellant's concerns with regards to the second grievance (and second reason for technical non-compliance) entitled "The note in DoC Letter re MA number" ;

b) Upholds the Contracting Authority's decision in the recommendation for the award of the tender,

c) Directs that the half the deposit paid by Appellant to be reimbursed."

5. Is-socjeta` rikorrenti hassitha aggravata bit-tieni parti tad-decizjoni tal-Bord, u ressqet appell ghar-riforma tad-decizjoni tal-Bord biex tigi revokata l-parti fejn il-Bord ma laqax l-ispjegazzjoni li tat ghal dik id-diskrepanza b'mod li kkonferma l-iskwalifika taghha. L-aggravju principali tas-socjeta` issa appellanti huwa marbut mal-fatt li l-offerta taghha kienet konformi mas-sejha li riedet li l-SPC tinghata f'wahda mil-lingwi ufficjali ta' Malta, u cioe`, bl-Ingliz jew bil-Malti. Gie spjegat li peress li l-letteratura tal-prodott kienet bil-lingwa Olandiza, offrew letteratura tal-istess prodott mahruga mill-Irlanda, li ovvjament kienet bl-Ingliz.

6. Wara li semghet lid-difensuri tal-partijiet u rat l-atti kollha tal-kawza u d-dokumenti esebiti, din il-Qorfti sejra tghaddi ghas-sentenza taghha.

Ikkunsidrat:

7. Trattat l-appell din il-Qorti tosserva li l-awtorita` kontraenti u l-Bord kienu ftit puntiljuzi meta skwalifikaw lis-socjeta` appellant fuq din it-teknikalita`. L-offerta riedet letteratura bl-Ingliz jew bil-Malti, u din is-socjeta` ressqet letteratura bl-Ingliz tal-istess prodott li gej mill-Irlanda. Is-socjeta` appellanti kienet sejra ggib il-prodott mill-Olanda u rat li l-SPC ta' dak il-prodott kien l-istess bhal prodott li johrog mill-Irlanda. Il-prodott taz-zewg pajjizi huwa l-istess u t-tnejn ghandhom kontenut tekniku identiku ghaliex il-kontenut huwa ddettat mir-regolamenti Ewropej u t-*templates* tal-agenzija Ewropea tal-medicina.

8. L-awtorita` kontraenti tinsisti li darba l-prodott gie mill-Olanda, il-letteratura kellha tigi minn dak il-pajjiz, u jekk ma kenitx bil-Malti jew bl-Ingliz, issir traduzzjoni ghal wahda minn dawk il-lingwi. Is-sejha ghall-offerti ma tghidx li kienet tkun sodisfatta bi traduzzjoni izda tghid biss li l-SPC ghandha tkun bil-Malti jew bl-Ingliz. Is-socjeta` appellanti hasset li jekk tressaq traduzzjoni ma tkunx konformi mal-htigijiet tas-sejha, u, ghalhekk, offriet dokument bl-Ingliz originali mahrug minn pajjiz iehor li juza dik il-lingwa. L-SPC huwa dokument illi huwa wzat sabiex jelenka informazzjoni important fuq medicina partikolari u jifforma parti mill-awtorizzazzjoni ghat-tqeghid fis-suq ta' kull medicina, bil-kontenut u l-istruttura tkun definita mil-legislazzjoni Ewropea fuq il-farmacewtici.

F'dan il-kaz, l-istess prodott johrog ukoll mill-Irlanda, li huwa wiehed mill-istati membri tal-Unjoni Ewropea li fihom Tioforma B.V., is-socjeta` produttrici, ghandha awtorizzazzjoni ghat-tqeghid fis-suq tal-prodott in kwistjoni.

9. Apparti dan, din il-Qorti tara li dan hu kaz car fejn l-awtorita` kontraenti messha talbet kjarifika. Dan tista' taghmlu bis-sahha tar-regolamenti in materja. Huwa veru li r-regolament jghid illi l-awtorita` kontraenti tista' titlob kjarifika fejn, per ezempju, l-offerta ma tkunx kompleta jew tkun zbaljata. Din il-Qorti tara li dan hu kaz fejn kien jimmerita spjegazzjoni mill-offerent, u kienet tkun talba mehtiega u xierqa fic-cirkostanzi. B'talba simili u bl-ispjegazzjoni ma kinitx sejra tinbidel l-offerta li oggettivament kienet sejra tibqa' l-istess. Fuq kollox, skont l-esigenzi tal-Unjoni Ewropea, l-informazzjoni teknika fil-prodott ghandha tkun identika irrispettivament mill-pajjizi li fihom il-prodott ikun licenzjat sabiex jitpogga fis-suq.

10. Din il-Qorti thoss, jew ahjar, ghandha suspett, li xi hadd x'imkien ried iwarrab lis-socjeta` appellanti ghall-kwalunkwe skuza jew ried jagevola lis-socjeta` E.J. Busuttil Ltd. Dan jinghad ghax ir-raguni principali ghall-iskwalifika kienet palesament hazina ghax marret kontra dak espressament provdut fis-sejha, filwaqt li t-tieni raguni setghet u

kellha tigi ccarata minghajr ma jintrifes il-principju ta' proporzjonalita` u trasparenza li jirregolaw il-materja.

Ghaldaqstant, ghar-ragunijiet premessi, tiddisponi mill-appell tas-socjeta` Pharma.MT Ltd., billi tilqa' l-istess u tirriforma d-decizjoni tal-Bord ta' Revizjoni dwar il-Kuntratti Pubblici tal-25 ta' Ottubru, 2021, billi tirrevoka u tannulla d-decizjoni limitatament fir-rigward tat-tieni aggravju, u minflok tilqa' l-istess u thassar id-decizjoni tal-awtorita` kontraenti li skwalifikat lis-socjeta` appellanti, u tordna r-reintegrazzjoni tal-offerta tas-socjeta` appellanti fis-sejha.

Id-depozitu li ressqet din is-socjeta` appellanti biex setghet tressaq oggezzjoni quddiem il-Bord ghandu jigi rifuz kollu lill-istess socjeta` appellanti, waqt li dawk marbuta ma' dan l-appell jithallsu mic-Central Procurement and Supplies Unit.

Mark Chetcuti Prim Imħallef	Joseph R. Micallef Imħallef	Tonio Mallia Imħallef

Deputat Reġistratur
gr