PUBLIC CONTRACTS REVIEW BOARD

Case 1337 – CT 2379/2018 – Tender for the Supply of Various Vaccines (Lot 1)

The publication date of the call for tenders was the 9th January 2019 whilst the closing date of the call for tenders was 12th February 2019. The estimated value of the tender (exclusive of VAT) on Lot 1 was € 241,554.

On the 17th May 2019 Associated Drug Co Ltd filed an appeal against the Central Procurement and Supplies Unit, as the Contracting Authority contesting the decision to disqualify them as their bid was technically non-compliant. A deposit of € 1,208 was paid.

There were two (2) bidders.

On 6th August 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Mr Carmel Esposito and Mr Richard Matrenza as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – Associated Drug Co Ltd

Dr Clement Mifsud Bonnici	Legal Representative
Mr Chris Grech	Representative
Mr David Caruana	Representative
Ms Kimberley Vella	Representative

Recommended Bidder – Alfred Gera & Sons Ltd

Mr Mario Sciberras	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Ms Denise Dingli	Chairperson Evaluation Committee
Ms Tracy West	Secretary Evaluation Committee
Dr Ian Ellul	Member Evaluation Committee
Dr Alison Anastasi	Representative

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

Dr Clement Mifsud Bonnici Legal Representative for Associated Drug Co Ltd said that his clients' offer was deemed to be technically non-compliant although it offered a savings of € 80,000 on the preferred bid. The tender was for five lots but only the decision on Lot 1 was being contested, which product was being refused as it is claimed that it contained human albumen. The second point contested regarding the mode of propagation was settled prior to the hearing since it is not an issue.

There are two products that are very similar, manufactured by Glaxo and Merck and are therapeutically equivalent. The technical specifications were very specific – the product could not contain human albumen. His clients' product MMRVaxPro contained minute traces of human albumen, which presented no risk and its use was authorised by the European Medicines Agency (EMA).

Dr Marco Woods Legal Representative for the Central Procurement and Supplies Agency (CPSU) said that there were remedies available to Appellants before tendering, and this claim should not have been raised at this point since they have accepted the tender terms. The point of the appeal was the difference between human albumen and human serum albumen.

The Chairman stated that the Board would like to establish clearly the difference between the tender specifications and what the Appellants were offering and asked for technical witnesses to assist in this respect.

Dr Ian Ellul (296980M) called as a witness by the PCRB testified on oath that he was the technical evaluator on the evaluation committee. By profession he was a Pharmacist and a Doctor in Regulatory Medicine. The tender specifications clearly stated that the product must not contain human albumen but what Appellants were offering did contain traces of human recombinant albumen – this was due to pure human albumen being used in the process of creating the culture for the vaccine.

On being questioned he agreed that the traces of human albumen were minute – something like one part in a million parts. The product was approved by the EMA as the risk is extremely low. He confirmed that he is aware that Priorex and MMRVaxPro are equivalent in their effectiveness.

Dr Oliver Wicht called as a witness by Associated Drug Co Ltd testified on a solemn declaration that he had a M.Sc. in Infection Immunity from Heidelberg University and a Ph.D. from the University of Utrecht in Virology. He then worked for three years at the Dutch Public Health Institute and is currently a Senior Scientist at the Chemicals Manufacturing and Controls Regulatory Affairs in the UK. His focus is on human vaccines. There are two vaccines for the treatment of measles and rubella on the market which he referred to by name.

Witness testified that human albumen refers to a protein which is derived from the human blood.

Thanks to scientific research in the last decade it is now possible to produce the protein in yeast. This is made by a recombinant process so that it is recombinant human albumen. MMRVaxPro is practically free of human albumen as it does not contain any products derived from the human body so ensuring safety to the patient. Witness explained how very tiny drops of human serum albumen are used at the beginning of the manufacturing process in the vaccine and this is massively diluted (which he equated to a tiny dot on the whole area of the Island of Malta). According to the witness this process meets the tender specifications as the manufacturers are using the recombinant version of human albumen and the vaccine is therefore free of human blood products – this is confirmed by the EMA in their scientific advice, and is in use in some 25 European countries, apart from the World Health Organisation (WHO). In support of this statement a document headed –'MMRVaxPro acceptance in Europe' was tabled (Doc 1). Further scientific papers were tabled listed as Docs ADC 8, 9 and 12 confirming that both MMRVaxPro and Priorex are manufactured without the use of human serum albumen.

On further questioning witness said that making statements regarding human serum albumen in products is outdated but confirmed that there are minute traces down to undetectable level of human serum albumen in the manufacture of the product.

Dr Mifsud Bonnici said that one of the principles of Public Procurement Regulations (PPR) was that terms should be clear and understandable and the specifications did not consider certain scientific points (highlighted in ADC 8 and 9) in the drafting of the tender. These scientific papers confirm that the use of human albumen was theoretical and there were no safety concerns. The composition of a product should not be taken out of context and the aspect of proportionality must apply. PPR 53 (1) lays down the characteristics required in the technical specifications and on this point alone the Board is invited to set aside the specifications in this tender. The CPSU have been aware since 2013 that there is another similar product on the market and they are in breach of PPR as these two products are the same – the clause they have inserted is merely there to deter the competition. On the technical aspect it has been made clear that the matter of minute traces of human serum is a non-issue, and poses absolutely no risk and is EMA approved.

Dr Woods re-iterated that Appellants had remedies prior to submitting their offer. The specifications were very clear and any ambiguity could have been dealt with at that early stage. By bidding Appellants had agreed to abide by the terms and conditions of the tender, and they cannot now claim that the specifications are discretionary and at the least they should have sought clarification (reference to Court of Appeal case 291/2018). The Appellants' own technical witness had confirmed that there are traces of human serum in the product they were offering.

Dr Mifsud Bonnici said that it seemed that the aim of the CPSU was to exclude Appellants. Since there was no risk of safety to the patients the technical specifications need to be set aside. The PPR are clear and unambiguous that competition should be encouraged not frustrated. He concluded by referring to the document ADC 9 particularly to the part that stated that the Merck is the only

vaccine licensed in the United States that it is human serum albumen free vaccine and any interruption in it availability would pose a critical public health risk.

Dr Woods referred again to the remedies available to the Applicant under regulation 262 of the PPR.

The Chairman thanked the parties for their submissions and declared the hearing closed.

This Board,

having noted this objection filed by Associated Drug Co Ltd (herein after referred to as the Appellants) on 17 May 2019, refers to the claims made by the same Appellants with regard to the tender of reference CT 2379/2018 listed as case no 1337 in the records of the Public Contracts Review Board, awarded by Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).

Appearing for the Appellants: Dr Clement Mifsud Bonnici

Appearing for the Contracting Authority: Dr Marco Woods

Whereby, the Appellants contend that:

a) Their offer was discarded due to the fact that they offered a vaccine which, it is being claimed by the Authority, contains human albumen. In this regard, Appellants maintain that the human albumen content is negligible and insignificant, and it does not contain any product derived from the human, thus ensuring safety to patients.

This Board also noted the Contracting Authority's 'Letter of Reply' dated 12 June 2019 and its verbal submissions during the hearing held on 6 August 2019, in that:

a) **The Authority insists that, Appellants objection refers to issues which should have been raised prior to the closing date of submissions of offers. In this regard, Appellants had accepted all the conditions stipulated in the tender document by submitting their offer, knowing well that the vaccine should not contain human albumen.**

This same Board also noted the testimony of the witnesses namely,

Dr Ian Ellul, duly summoned by the Public Contracts Review Board

Dr Oliver Wicht, duly summoned by Associated Drug Co Ltd

This Board has also taken note of the documents submitted by Associated Drug Co Ltd which consisted of:

1. **Document showing acceptance of 'MMRVaxpro' in Europe.**
2. **Scientific papers, Doc 8, 9 and 12, confirming that MMRVaxpro and Priorex are human serum albumen free.**

This Board, after having examined the relevant documentation to this appeal and heard submissions made by the parties concerned, including the testimony of the witnesses duly summoned, opines that the issue that merits consideration refers to the content of human albumen in Appellants' product.

1. **First and foremost, this Board would point out that, Appellants, at this particular tendering stage, cannot claim that the technical specifications were uncompetitive, as such a concern should have been raised through remedies available, prior to the closing date of submissions and not through an objection before this Board, after the announcement of the award.**

2. **However, at the same instance, this Board felt the need to establish the technical difference in the specifications, between Appellants' product and those stipulated in the tender dossier, so that, it was decided to treat Appellants' objection in its own merits.**

3. **The tender's 'Product Specifications' clearly stipulated that:**

"Tenders are to clearly specify the mode of propagation and preparation of the viruses for the vaccine and only vaccines that do not use or contain human

albumin or other human blood products will be considered unless no such product is an offer.

Each dose of MMR should only contain traces of neomycin."

Appellants, themselves, confirm that a minute particle of human albumen is used in the manufacturing of the vaccine, yet, so insignificant that it was authorised by the European Medicines Agency (EMA) and considered as 'Risk Free' to the patient.

4. **In this regard, this Board takes into consideration the testimony of technical medical witnesses namely, Dr Ian Ellul, a chemist by profession and a doctor in 'Regulatory Medicine' who confirmed that, Appellants' product did contain traces of human recombinant albumen to one of 'One Part in a Million Parts'. Dr Ellul also confirmed that the product was approved by the European Medicines Agency and the risk of the dose of the product is 'Extremely Low'. The witness affirmed that both the Appellants' and the Preferred Bidders' product, are equivalent in their effectiveness.**

5. **At this particular stage of consideration, this Board notes that the issue of the content of the insignificant amount of human albumen in**

Appellants' product, is whether such a minute content of the human albumen, poses any risk to the patient, as Appellants' product effectiveness, is equivalent to that of the Preferred Bidder.

6. **This Board would also refer to the testimony of Dr Oliver Wicht, who explained in detail how such a protein is produced and an extract from such testimony will amplify the process in a more scientific description of the process itself, as follows:**

"Witness : *So human albumen to me refers to a protein that is albumen which is derived from the human body basically. In that sense albumen is a protein that everybody has, all mammals have it. It is in the blood. It works like a lubricant to your blood, carrier protein for lot of other things and it is needed for vaccine production and historically it has been derived from blood. People donated blood and they removed the protein from the blood and used it in manufacturing and of course why we are here today, that has changed in the last decade of scientific research, we are able to produce this proteins in yeast, which is actually baker yeast, the same yeast of bread that you and I eat, produces now that protein, the albumen. And they are different*

albumens from chicken and cow and you know, if we would produce the human version of it, we call it human albumen. But I think in the sense of the tender, if I can extend on that, it says human albumen or other blood derived products. So it clearly indicates that they actually mean albumen that is derived from human blood"

This Board notes that the process of the protein in appellants' vaccine is not derived from human materials, as duly explained further on, during Dr Wicht's testimony, as follows:

"Lawyer : *You just referred to this process relating to yeast. What does that refer to? The component which is purely based on yeast*

Witness : *So that is made by recombinant processes so that is recombinant human albumen*

Lawyer : *And what do you say that the recombinant process is free from the human element from plasma derived?*

Witness : *Exactly. So yeast is grown in a fermenter like beer basically and we do not make beer, we make protein from it. So there is a little bit of sugar, a little bit of nutrients but there are no human components in there and it all relates back to the safety of the product in the end. So if you can make something without using any human materials, it will be safe to humans.*

Lawyer : *Now let us turn to MMRVaxpro. If someone were to ask you whether it contains human albumen, what would you say in your expert opinion?*

Witness : *To me MMRVaxpro is practically human albumen free because it does not contain any products that are derived from the human body. So there is no risk to safety. There is no risk of any diseases that could be spread."*

7. **This Board, after having heard the submissions made by the interested parties and the technical witnesses, can only establish that Appellants' product has an extremely low risk factor, although such a minimal risk**

was not described or established, and that Appellants' product has an equivalent effectiveness.

In conclusion, this Board opines that:

a) **The technical specifications, as duly stipulated in the tender dossier are clear and does not limit, in any particular way, the scope of participation for such a procurement,**

b) **it has been established that Appellants' product has the equivalent effectiveness, as that of the product of the Preferred Bidder,**

c) **with regard to risks towards the well being of the patient, this Board cannot arrive at a decision, as no evidence as to the nature and level of the 'Extremely Low' risk which the patient might incur, was produced by the Authority.**

In view of the above, this Board,

i) cancels the Contracting Authority's decision in the award of the tender,

ii) directs the Authority to reintegrate Appellants' offer and establish whether there are any risks to the well-being of the patient, from the application of Appellants' product and deliberate accordingly, always taking into consideration as a priority, any real risks to the patient,

iii) directs that the deposit paid by Appellant should be refunded.

Dr Anthony Cassar	Mr Carmel Esposito	Mr Richard A. Matrenza
Chairman	Member	Member

30 August 2019