Case No 19

CT 2352/2003, Advertisement 253/2003, G.P.S.61.026.T.03.OT - Tender for the supply of DYNAMIC HIP SCREW (DHS) PLATES

The Government Pharmaceutical Services submitted a request on 23rd June 2003 to the Director of Contracts requesting the latter to formally issue a call for offers for the supply of Dynamic Hip Screw (DHS) Plates.

According to estimates the total value of the tender was not to exceed LM 83,882.

Following the publication of the call for offers in the Government Gazette on 5th September, 2003 five companies submitted their offer.

The Adjudication Board consisted of Ms M Dowling (Chairperson) with Mr D Darmanin and Ms D Gouder acting as the other members whilst Mr Esposito (Consultant Surgeon) was appointed Consultant to the Board.

The Board evaluated the offers submitted and on the 12th January, 2004 decided to recommend that the Director of Contracts award the tender to Messrs Pharma-Cos Ltd for a global price of Lm 54,279.

Following public notification of the award, Messrs Rodel Ltd lodged a formal objection on behalf of their principals Merete Medical GmbH against the Committee's decision on 25th March, 2004.

As a consequence, the Public Contracts Appeals Board (PCAB), consisting of Mr A Triganza (Chairman) and Messrs A Pavia and E Muscat respectively acting as the other members, convened a public hearing on 14 July 2004.

During the said hearing, Messrs Rodel Ltd. were represented by Dr N Vella. Pharma-Cos Limited were duly represented by Mr Marcel Mifsud (Director), Mr K Segerlund (Area Manager South East Asia – SYNTHES) and Doctors L Lombardi and A Tufigno who acted as the Company's legal advisers.

The Department of Health was represented by Ms M Dowling, Chairperson, Adjudication Board.

Consultants, Messrs F Zammit Maempel and A Bernard were summoned as witnesses.

The appellant, namely Dr Norman Vella, appearing on behalf of Messrs Rodel Ltd, was invited to give a resumè about the motivation of the Company's objection.

He started by stating that the offer of their principals, Merete Medical GmbH, was cheaper in price and that their product was according to specifications. He said that when comparing the prices of the recommended award of tender in favour of Pharma-Cos Ltd with that of Merete's offer, the difference was substantial – the first was about 83% more expensive than the latter.

He said that, although Mr Emanuel Anapliotis, Chairman and Chief Executive of Merete Medical GmbH, could not come to the public hearing, he sent a resumè of the argumentation that he would have submitted during this hearing. Dr Norman Vella read out the relevant documentation. In the first document he gave detailed technical and historical information

about the development of the AO/ASIF institution and AO-Osteosythesis principles. Those present were informed that '*AO*' stood for the initial letters of the German words *Arbeitsgemeinschaft für Osteosynthesefragen* which, when translated in English, stood for *Association for the Study of Internal Fixation.*

The second document dealt with the invention and concept of the Dynamic Hip Screw (DHS), Merete's and Mathys/Synthes Specifications, a list of number of clinics which were using their implant (DHS) and Merete's Quality Assurance and Quality Control Certificates.

At this stage Dr Vella proceeded by stating that Merete felt aggrieved due to the fact that Messrs Pharma-Cos Ltd and Mathys Synthes claimed that they were the only ones that manufactured this product according to AO/ASIF specifications.

He claimed that Merete itself, which pre-dated the establishment of some products by Synthes as approved by AO/ASIF, had already previously followed the recommendations and specifications of AO/ASIF. Dr Vella said that there were mainly two particular aspects which were quite anomalous, due to (a) the exclusivity basis under which Synthes operated and (b) the fact that Synthes had three representatives on the Board of AO/ASIF. As a direct consequence, Merete could never be in a position to compete with Synthes once they had to depend entirely on the recommendations and licensing by AO/ASIF. Yet, Dr. Vella reiterated that Merete's product was still being produced according to the standards recommended by AO/ASIF and this ever since the Company was formed. The Company was also covered with the latest quality control certificates. He said that Merete was not a member of the AO Foundation solely for reasons which were purely of a commercial nature emphasising in the process that this was definitely not due to Merete's product being inferior. In actual fact, Dr. Vella argued that Merete engaged the services of most of the same professors forming part of AO in order to design their products and duly patented under Merete.

Dr Vella insisted that the tender specifications and conditions stated only that the product had to be according to AO/ASIF and did not require a branded product of Synthes and alleged that whoever drafted the specifications knew that only Synthes were licensed by AO/ASIF. Merete had confirmed that all their implants were made strictly according to AO/ASIF specifications in respect of both dimensions and design and the material used for the manufacturing of their implants was stainless steel type AISI316L. He tabled two copies of Merete Medical GmbH's Certificates Nos. G1 03 07 32007 008 and Q1N 04 06 32007 010.

Dr Lombardi, commenced her intervention by reading out from the tender specifications and conditions which stated that:

'Dynamic Hip Screw (DHS) Plates 135 of stainless steel material of type AIS1316L having tolerances regarding chemical composition, impurity content, mechanical stress, shape and design according to AO/ASIF.'

She argued that it was stated that Merete's '*implants are directly comparable to so called AO implants*' and that they were so similar that surgeons were not able to see the difference. Dr Lombardi stressed that the tender's specifications stipulated that the product, which was a foreign fixation, had to be according to AO/ASIF and not *similar* or *equivalent.* She claimed that the only approved products in the world were those manufactured under the trademark 'Synthes' products and thus no other products apart from 'Synthes' products could claim to be made according to AO/ASIF. Therefore any products claiming to be similar or equivalent were not AO/ASIF approved. She emphasised that the technical committee of AO had to approve every single product that the manufacturer developed, produced, sold and distributed, otherwise it would not be considered to be AO/ASIF approved product.

It was stated that there were three exclusive manufacturers of the original "Synthes" implants for bone surgery, namely Mathys Medical Ltd, Synthes Stratec and Synthes Inc., all of them licensed to produce for AO/ASIF.

She concluded by stating that AO/ASIF implants should not be combined with products of other manufacturers. Implants from various manufacturers could be of different material, construction and quality. The compatibility of instruments and implants was taken into account during development and production. Manufacturing under their production tolerances guaranteed the compatibility with the correspondent SYNTHES instruments. These were also guaranteed whenever their products were modified. The research in this institution was continuous. The use of implants and instruments of different origin instigated the risk of inadequate fixation, increased corrosion and technical complications. National and international standards might limit the risk but could not exclude it. Responsibility for implant material and construction could not be assumed if they were used in conjunction with implants from other manufacturers.

On his part, Dr Tufigno, explained how the AO Foundation had its own Institutes for Research, Development, International and Clinical Investigation & Documentation. In order to emphasise his point he quoted the following from the Foundation's official website, namely

'Alongside these is the Technical Commission (TK) which monitors the development of new implants and tools and gives the final AO approval necessary for bringing a product to market under the "Synthes" brand.'

With regard to the Management Boards of AO it was stated that:

'The Board of Directors implements the Academic Council's goals and proposals. Its 11 members include 3 representatives of the licensed manufacturers of SYNTHES® products.'

As far as the AO Quality Assurance was concerned, it was stated that *'It establishes and maintains the technical commission's guidelines for new surgical methods and devices according to the decisions of the OATK, the AO Board of Directors (AOVA), and the contracts between Synthes AG, Chur and the Synthes producers.'*

He insisted that only "Synthes Products" were authorised to sell products which were certified by AO/ASIF. It was an International Association for the Study of Internal Fixation, the members of which were medical doctors who were experts in this field and who usually followed what was dictated by AO/ASIF - which was the international standard.

When addressing those present, Mr K Segerlund said that AO was a Foundation which followed all international laws regarding research. Many companies sold their implant products. If they produced a screw and a plate, the tolerance level between them and the instruments was guaranteed. They could not guarantee quality assurance if products of different origin were mixed. Tolerance level was important because products had to be compatible with each other. Synthes would not have been allowed to produce, sell or commercialise such implants without the sanction of AO Group, which was composed of a number of scientists and researchers.

Taking the witness stand, Mr Zammit Maempel, Chairman Orthopaedics Department at St.Luke's Hospital, declared that the decision to award the tender to Messrs Pharma-Cos was taken unanimously by the Department of Orthopaedics' consultant surgeons. Specifications were usually drafted on the advice of the end users. He pointed out that in medicine emphasis was put on care of the patients and not on the price as this was considered irrelevant. He insisted that the end users had to be satisfied with the implants that Government provided

them with, since otherwise, if they were ordered to stick an implant against their advice, they would not shoulder any responsibility if something went wrong with their patients. The call for offers was resorted to in order to ensure transparency in procedure.

He declared that 25 years ago the Health Authorities decided to get AO implants for internal fixation of bones (plates, material etc). The tender stipulated that the DHS plates' specifications had to be according to AO/ASIF because all the equipment they had was AO certified and AO was the flagship in this field. It was issued to replenish only a part (DHS plates) of a whole system because it was out of stock. They would consider other products if it was certified that they would fit with all their equipment.

He said that they had to be convinced that Merete's products were interchangeable and mixable with products of other manufacturers. Furthermore he said that they were not going to put a plate of a different company they had never heard of before. He insisted that when there was doubt about a product they would not take risks. In such instances they had to safeguard the patients' interests first because, if something went wrong, it was they who would have to face the consequences.

When cross-examined, Mr Bernard, another Consultant, stated that the product had to be according to AO/ASIF because this Foundation had the highest quality products. Also, they took into account the continued research and development, education and product improvement. He maintained that once it was disclosed that such Synthes products were not interchangeable and mixable, they would not take that risk. In actual fact this was one of the reasons why they decided to continue using this system. Apart from this, AO was recognised throughout the world as an authority on internal fixation.

In his concluding remarks, Dr Vella presented and read out Merete's reply to Dr Lombardi's letter dated 5th April, 2004 and to Mathys/Synthes' letter dated 1st April, 2004 which, in general, rebutted all claims of its inability to meet tender specifications.

Dr Tufigno said that Mr Bernard and Mr Zammit Maempel had declared that an entire system of Synthes products were being used in Government Hospital. It was stated that it was dangerous to combine Synthes products AO certified with products that were not AO certified and that different items produced from different chemical compositions could lead to some problems. Neither Messrs Rodel nor Messrs Merete had ever guaranteed that their product did have AO/ASIF specifications but only stated that the quality was comparable. He said that the technical people who adjudicated the tender had vetted the specifications and had decided that Merete's product was not according to AO/ASIF.

Mr Keneth Segurland emphasised that their instruments were specifically made to fit implants produced by SYNTHES. They could not guarantee the tolerance level of several instruments used with another implant. The supplier of implants should also supply the instruments.

Following a thorough deliberation of all facts and documentation submitted, and

a. having considered the lack of propensity by the end user to change existing supplier;

b. having noted the contents of the '*Recommendation Report*' submitted by the Adjudication Board;

c. having noted both the Adjudications Board's and the Consultants' insistence for offers to be in accordance with AO / ASIF specifications which practically rules out the possible procurement of D.H.S. plates from other sources since it is evidently clear that the number of companies who can manufacture the requested

product according to AO / ASIF specifications are very few and that Synthes thereby apparently enjoys a near monopoly;

d. having in consideration of (a) and (c) above,

the Board deemed the process of this call for offers as having been futile as well as exceptionally costly to the Government's coffers.

the PCAB,

i. not being in a position to justify the rightful reason for this call for offer when, '*ab initio*', it would have been more beneficial to all those involved, directly or indirectly, for such purchase to be conducted via a '*direct order*';

ii. not being, in consideration of the reason given above, in a position to determine the justification or not for the local public coffers to be burdened with an additional financial commitment of approximately Lm 24,000, or rather the difference between the global price of the offer awarded the tender and the cheaper offer as submitted by Messrs Rodel Limited;

concludes that the call for offers should be *annulled* and the procedure conducted by way of a '*direct order'*.

The Board, not being technically qualified, cannot possibly comment on whether the decision to restrict the choice to AO approved products only, that is practically products made by Synthes, is correct or not. We recommend, however, that in view of the substantial savings which could be made through procurement from other companies, the question should be looked at carefully by those who possess the necessary technical qualifications.

Finally, this Board rules that Messrs Rodel Ltd should be reimbursed the amount of Lm 839 (Eight Hundred and Thirty None Liri) being the amount paid by appellant to lodge objection.

Alfred R. Triganza	**Anthony Pavia**	**Edwin Muscat**
Chairman	Member	Member

Date: 10th August, 2004