GROUNDS FOR THE JUDGEMENT OF THE MARKET COURT

Procurement procedure

Compliance of the winning tender with the call for tenders

Subsection 1 of section 46 of the Act on Public Contracts[1] requires a tenderer to show in the tender that the tendered goods, services, or construction contract comply with the requirements of the call for tenders. Tenders that do not fulfil the terms of the call for tenders or competitive tendering procedure must be excluded from the competitive tendering. The legislative history of the provision (Government Bill no. 50 of 2006, page 91) states that the exclusion of a tender should be evaluated precisely from the perspective of equitable treatment of tenderers.

The call for tenders in question begins with the following definition of the subject of the tendering procedure: "We invite you to tender for the following vaccine supply:
1. Pneumococcal conjugate vaccine (PCV) in the National Vaccination Programme for basic immunisation of infants with a 2 + 1 dose schedule."

It is the view of the Market Court that this introductory paragraph, and the subsequent more detailed terms of the same content, unambiguously state that tenders have been requested for a vaccine that will be used in a national vaccination programme for children with a dose schedule of 2 + 1.

The essential issue in this case is whether the Synflorix vaccine in the GSK tender is designed for use with the 2 + 1 dose schedule presented in the call for tenders.

The Market Court finds that according to the call for tenders, the selection criterion was the best overall value for money. The award criteria for this were price with a 74 percent weighting and quality with a 26 percent weighting. The stated basis of quality assessment was the amount of various pneumococcal serotypes in the vaccine.

GSK stated the following in the first and second paragraphs of its tender: "Thank you for your letter dated 25.11.2009 inviting us to tender for pneumococcal conjugate vaccine (PCV) to be included in the National Vaccination Programme for basic immunisation of infants with a 2 + 1 dose schedule.

We are pleased to offer you Synflorix (PCV) vaccine as per the conditions below as requested in the official THL vaccine tender invitation."

Based on this declaration in its tender, GSK must be considered to have committed to the terms of the call for tenders unless the company otherwise indicated later in its tender. The Market Court finds that GSK makes no further references in the actual tender document to the dose schedule used.

Based on the report presented, the summary of product characteristics and the package leaflet of the vaccine offered were appended to the GSK tender.

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[1] *Laki julkisista hankinnoista*, no. 348 of 2007 ("the Public Procurement Act")

The following observation was included in section 4.1 "Therapeutic indications" of the summary of product characteristics: "The use of Synflorix should be determined on the basis of official recommendations taking into consideration the impact of invasive disease in different age groups as well as the variability of serotype epidemiology in different geographical areas."

The *"*Posology*"* subsection of section 4.2."Posology and method of administration" in the summary of product characteristics states the following: "The immunisation schedules for Synflorix should be based on official recommendations." The said subsection also states the following under the heading "Infants from 6 weeks to 6 months of age": "The primary vaccination schedule consists of three doses of 0.5 ml with an interval of at least 1 month between doses. A booster dose is recommended at least 6 months after the last priming dose and preferably between 12 and 15 months of age."

Subsection 3 "Additional immunogenicity data" of section 5.1 "Pharmacodynamic properties" in the summary of product characteristics includes the observation that in addition to the primary vaccination schedule, the immunogenicity of Synflorix has been evaluated in a 2-dose primary vaccination schedule in subjects under 6 months of age. To ensure optimal immunisation, a three-dose primary vaccination schedule has been recommended for infants under the age of 6 months. A clinical study had found that with infants aged 7 to 11 months, the immune responses with the 2 + 1 dose schedule were usually similar to those of children who had received three primary doses before the age of 6 months.

Section 3 "How Synflorix is given" of the package leaflet appended to the GSK tender includes the observation that "Usually, your child will receive a course of 3 injections according to official recommendations or an alternative schedule may be used by the health care professional."

The Market Court finds that the call for tenders imposes no condition for the approval of tenders that requires a tenderer to provide, for example, instructions on the dosage of the vaccine in an attachment to the tender. Neither the summary of product characteristics for Synflorix nor any other part of the GSK tender states that the medicinal product in question could not be administered with a 2 + 1 dose schedule.

The National Institute for Health and Welfare (THL) is formally competent to assess that the GSK vaccine is suitable for administration in the manner required by the call for tenders.

On the foregoing grounds, it is the view of the Market Court that in its tender GSK offered the vaccine for administration under the dose schedule presented in the call for tenders.

Petition on the financial subsidy received by the tenderer from the contracting authority

Under Section 64 of the Act on Public Contracts[2], if the contracting authority has granted or will grant the tenderer a financial subsidy, then when comparing tenders the contracting authority shall take into account the factors that have a *de facto* impact on the price of the tender paid by the contracting authority, such as the financial subsidy in question.

[2] *Laki julkisista hankinnoista*, no. 348 of 2007 ("the Public Procurement Act")

The legislative history of this provision (Government Bill no. 50 of 2006, page 109) states that if the contracting authority supports a tenderer outside of its organisation, then the requirement of impartial treatment would require any subsidy of this kind to be taken into account when comparing tenders in accordance with case law principles. The duty to take a subsidy into account would only apply to financial subsidies that the tenderer had received from the contracting authority unit that affect the tender price.

The petitioner has stated that GSK received a financial subsidy from THL associated with its participation in the FinIP vaccine trial, which had affected the price of the GSK tender, without further itemising how the subsidy had been paid.

According to THL, the trial in question collects clinical evidence on the immunity against blood poisoning, meningitis, and pneumonia provided by GSK's new vaccine, using the two vaccine doses that are already widely applied. The study is a co-financed effort, in which both THL and GSK defray the costs of the research and the findings are shared between the parties according to which party achieves them. According to the contracting authority, the trial had no effect on the procurement in question or on the price comparison.

GSK has denied receipt of any financial subsidy in connection with the FinlP trial, arguing that implementation of the FiniP trial is a supplementary condition of the marketing authorisation for the Synflorix vaccine agreed with the European Medicines Agency.

Based on the report presented, it is the view of the Market Court that the joint vaccine trial between GSK and the contracting authority does not mean that GSK received a financial subsidy from the contracting authority that would affect the tendering price in the sense of section 64 of the Act on Public Contracts.

Equitable treatment of tenderers

According to subsection 2 of section 1 of the Act on Public Contracts[3], the Act seeks to achieve more efficient use of public funds, to promote high quality procurement, and to safeguard equal opportunities for enterprises and other corporations in offering goods, services and construction contracts under competitive tendering for public procurement.

Subsection 1 of section 2 of the Act requires contracting authorities to make use of existing competitive conditions, to ensure equitable and non-discriminatory treatment of all participants in the procurement procedure, and to act in a transparent manner that meets the requirements of proportionality.

GSK has argued that in the competitive tendering in question it offered the vaccine at an affordable price, as GSK has estimated that parents could have been less willing to participate in the ongoing FinIP trial if the GSK vaccine had not been selected for the national vaccination programme.

The Market Court finds that other co-operation between a tenderer and the contracting authority during the tendering process may arouse suspicion as to whether all tenderers will be treated equally. Such

[3] *Laki julkisista hankinnoista*, no. 348 of 2007 ("the Public Procurement Act")

suspicions are further supported in this case by the fact that GSK specifically stated in its tender that the vaccine trial had affected the price of the tender.

Generally speaking, regular long-term collaboration between THL and a privately owned enterprise may, in the field in question, cause problems in terms of ensuring the equitable and non-discriminative treatment of tenderers in a procurement procedure.

Even though collaboration may have certain problematic features of the foregoing kind, it is the view of the Market Court that the comparison criteria (best overall value for money) in the call for tenders now under review were by nature non-discriminatory, tangible, and objectively measurable.

No other indications of any conflict between the procedure of the contracting authority and the requirement for equal treatment of tenderers have emerged in the case based on the participation of GSK in the vaccine trial.

Conclusion concerning the procurement procedure

On the foregoing grounds, the procedure of the National Institute for Health and Welfare (THL) in selecting the tender of GlaxoSmithKline Oy as the winner of the competitive tendering did not conflict with the legal rules on public procurement in the sense of subsection 1 of section 76 of the Act on Public Contracts[4] The petition must therefore be dismissed.

Legal costs

Subsection 1 of section 74 of the Administrative Judicial Procedure Act[5] provides that a party shall be liable to compensate the other party for its legal costs in full or in part if, especially having regard to the outcome of the case, it is unreasonable to require the latter party to bear its own costs.

Having regard to the outcome of this case and to the foregoing provision, the petitioner must bear its own legal costs. By contrast, it would be unreasonable for the contracting authority and for GlaxoSmithKline Oy, as a party issuing an opinion, to be required to bear their legal costs in full. The petitioner is therefore ordered to reimburse the legal costs of the contracting authority and GlaxoSmithKline Oy in the amounts considered reasonable by the Market Court.

JUDGEMENT OF THE MARKET COURT

The Market Court dismisses the petition.

The Market Court orders Pfizer Oy to pay EUR 6,000 to THL in compensation for legal costs. Delay penalty interest shall be payable on the legal costs at the annual rate indicated in subsection 1 of section 4 of the Interest Act[6] after one month has elapsed from the date on which this judgement was made available to the concerned parties.

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[4] *Laki julkisista hankinnoista*, no. 348 of 2007 (“the Public Procurement Act”)
[5] *Hallintolainkäyttölaki*, no. 586 of 1996
[6] *Korkolaki*, no. 633 of 1982

The Market Court orders Pfizer Oy to pay EUR 20,000 to GlaxoSmithKline Oy in compensation for legal costs. Delay penalty interest shall be payable on the legal costs at the annual rate indicated in subsection 1 of section 4 of the Interest Act[7] after one month has elapsed from the date on which this judgement was made available to the concerned parties.

AMENDMENT

Amendment to this judgement may be sought by appeal to the Supreme Administrative Court. The judgement of the Market Court shall be binding, notwithstanding any appeal, unless otherwise ordered by the Supreme Administrative Court.

Appeal instructions are attached.

Chief Judge
Kimmo Mikkola

The case was decided by the following learned members of the Market Court: Kimmo Mikkola, Jaakko Ritvala, and Sami Rautiainen.

DISTRIBUTION

Pfizer Oy, general fee for legal proceedings: EUR 223
GlaxoSmithKline Oy: no fee
National Institute for Health and Welfare (THL): no fee

[7] *Korkolaki*, no. 633 of 1982