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GlaxoSmithKline Oy

PNEUMOCOCCAL VACCINE TENDER – COURT PROCEEDINGS

**1
INTRODUCTION**

This memorandum discusses certain procedural questions relating to the appeal to the Market Court by Pfizer Oy ("Pfizer") on 29 January 2010 against the decision of the Finnish National Institute for Health and Welfare ("THL") of 15 January 2010 choosing GlaxoSmithKline Oy ("GSK") as the winner of the tender for pneumococcal conjugate vaccines.

In its appeal, Pfizer requests the Market Court to

- immediately discontinue the procurement process and prohibit THL from concluding a procurement contract with GSK during the proceedings;
- annul THL's procurement decision choosing GSK as the supplier of pneumococcal conjugate vaccines;
- order THL to organize a new procurement process in which it disregards GSK's offer as contrary to the tender invitation; and
- order THL to compensate Pfizer's legal fees.

According to information from THL's outside counsel, the Market Court has requested THL to give its reply at the latest on 12 February 2010.

**2
PFIZER'S APPEAL**

In its appeal, Pfizer claims that the procurement procedure was unlawful since the winning tender does not correspond with the tender invitation, primarily on two grounds. Pfizer believes it would have won the tender if the procedure had been correct.

Firstly, Pfizer claims, with reference to the Summary of Product Characteristics of the Synflorix vaccine, that GSK has offered vaccines for infants from 6 weeks to 6 months of age with a 3 + 1 dose schedule even though, according to the tender invitation, vaccines should be supplied with a 2 + 1 dose schedule. Pfizer also states that GSK's price

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calculations are incorrect since the prices have been calculated on a 2 + 1 schedule instead of a 3 + 1 schedule.

Secondly, Pfizer refers to the cooperation between THL and GSK in relation to the FinIP-trial referred to in GSK's tender and claims that due to the existing cooperation THL favored GSK and thus discriminated against Pfizer. According to the appeal, GSK has received financial support from THL in connection with the FinIP-trial which should have been taken into account when comparing the tenders.

In addition, Pfizer claims that the procurement procedure should be suspended due to public interest. Pfizer refers to the assessment report of the European Medicines Agency concerning the Synflorix vaccine and states that according to the report the 2-dose schedule cannot be recommended.

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THL'S UNDERTAKING

On 2 February 2010, THL gave to the Market Court an undertaking not to implement the procurement decision during the Market Court proceedings. According to the Market Court notary, the Market Court will send a request for statement to GSK shortly with respect to THL's undertaking.

In the undertaking, THL states that it will be possible to procure the necessary vaccines by means of alternative arrangements during the spring of 2010. THL notes, however, that it is necessary to conclude a procurement agreement as soon as possible for a period of at least one year in order to secure the availability of vaccines and comply with security stocking requirements.

Following THL's undertaking, the procurement process will be suspended until the Market Court has given its decision in the matter. Due to the undertaking, the Market Court will not consider the issue of whether it would be appropriate to issue an interim order prohibiting the contracting authority from implementing the procurement decision.

From the contracting authority's perspective, the advantage of an undertaking of this kind is that, in agreeing to refrain from implementing the procurement decision, the contracting authority avoids the risk of being ordered to pay a compensation fee to the applicant in case the appeal is successful.

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It is likely to be possible for the contracting authority to cancel the undertaking if the Market Court proceedings are delayed or it otherwise becomes necessary to implement the procurement. If the contracting authority cancels its undertaking, the Market Court may consider whether it would be appropriate to prohibit the implementation of the procurement decision through an interim order.

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TIMETABLE FOR COURT PROCEEDINGS

In general, the handling of public procurement matters at the Market Court currently takes approximately six months. However, in matters which the Market Court considers as urgent, which is likely to be the case here, a decision may be rendered somewhat more quickly. In the present case, it might therefore be realistic to expect the Market Court to render its decision within three to five months.

The decision of the Market Court may be appealed to the Supreme Administrative Court. The proceedings there usually take longer than at the Market Court, usually at least a year. The decision of the Market Court must be followed despite the appeal unless the Supreme Administrative Court orders otherwise.

3 February 2010
JPM, EAI