For information
on 13 July 2009

Legislative Council Panel on Health Services

Tender for the Procurement of Human Swine Influenza (HSI) Vaccine

PURPOSE

This paper briefs Members on the key conditions of the tender for the procurement of the Human Swine Influenza (HSI) vaccine.

BACKGROUND

2. At the meeting of the Finance Committee on 19 June 2009, Members approved, inter alia, a new commitment of $700 million for 2009-10 to cover the cost for the procurement of HSI vaccine and the related injection. Members requested the Administration to provide further information on the tender conditions for the procurement of HSI vaccine to the Panel on Health Services when they are available.

KEY CONDITIONS OF THE TENDER FOR HSI VACCINE

3. As explained to Members at the meeting of the Finance Committee, we will adhere to the usual open tender procedures in the procurement of HSI vaccine. We will include provisions in the tender documents to ensure the quality of the vaccine. Other relevant factors such as the payment schedule, delivery timetable and price would also be considered before deciding on the award of the tender. We will safeguard Government's interests during the procurement process.

4. In drawing up the tender conditions of the HSI vaccine, the Administration is building in several measures to protect Government's interests. In particular –

(a) the contractual quantity is being drawn up with such flexibility that the Administration is at liberty to purchase any quantity of the vaccine within plus 20% or minus 40% of the five million doses we plan to procure. As a result, the Administration could purchase

three million doses first, and make subsequent orders up to six million doses if necessary taking into account the latest developments in the HSI epidemic;

(b) we will also include a clause to the effect that any unused vaccines ordered and delivered could be returned to the manufacturer with refund;

(c) as an additional safeguard to ensure the safety, efficacy and quality of the vaccine procured, while the Administration will award the supplies contract to the successful tenderer following the completion of the tendering process to secure the availability of the vaccine, the vaccine will only be used after it has obtained regulatory approval by any one of the following authorities: the Food and Drug Administration of USA, the European Medicines Agency of the European Union, the Medicines and Healthcare Products Regulatory Agency of the UK, and the Therapeutic Goods Administration of Australia;

(d) the procurement contract will be conditional upon the vaccine being approved by any of the regulatory authorities mentioned in paragraph (c) above. If the tenderer eventually failed to obtain the necessary approval, the Administration will not be required to effect any payment; and

(e) to ensure that the tenderers are capable of producing vaccines of a good quality, we also require them to have a track record of securing marketing authorization from any of the authorities mentioned in paragraph (c) above in respect of influenza vaccines within the last five years.

5. The key conditions of the tender are as follows –

(a) General Terms

(i) ***Description of the vaccine*** : Human Swine Influenza A (H1N1) vaccine, containing antigen of the strain recommended by the World Health Organization.

(ii) ***Estimated quantity*** : five million doses, + 20% and – 40%

(iii) ***Contractual period*** : 12 months starting from October 2009

(iv) ***Delivery*** : to be delivered to any public or private facility, medical institution or hospital in Hong Kong, to be designated by the Administration, on an "as and when required" basis within 7 days from date of orders.

(v) ***Shelf-life*** : Not less than 10 months upon delivery.

(b) The Manufacturer

The manufacturer must comply with Good Manufacturing Practices as recommended by the World Health Organization, or equivalent, as indicated by –

(i) a certified true copy of the relevant Good Manufacturing Practices certificate issued by the national control authority of the country of origin of the manufacturer;

(ii) detailed information on the production and quality control facilities;

(iii) qualifications and experience of professional and technical personnel involved in production and quality control;

(iv) written permission from the manufacturer to allow representatives of the Department of Health to inspect the manufacturing facilities and processes as and when required.

(c) The Vaccine

(i) a certified true copy of the relevant document, issued by the Food and Drug Administration of U.S.A., the European Medicines Agency of the European Union, the Medicines and Healthcare Products Regulatory Agency of the UK, or the Therapeutic Goods Administration of Australia as evidence of the regulatory approval of the vaccine by any of these jurisdictions;

(ii) information on the registration status of the vaccine in other countries (if any);

(iii) copy of the complete master formula, method of assay, finished product specifications, stability data with recommended shelf-life and storage condition of the vaccine. Evidence showing compliance with appropriate current guidelines of the World Health Organization, where applicable, is required. If an adjuvant is contained in the vaccine, the amount is determined and shown to be within acceptable limits with respect to the expected amount.

(iv) a copy of the certificate of analysis of a representative batch of the product;

(v) information on the method of manufacture and quality control of the product, showing compliance with the current World Health Organization requirements or equivalent national requirements.

(vi) a copy of the batch release certificate of a representative batch issued by the manufacturer showing that the batch meets all the current quality and safety requirements of the World Health Organization or equivalent; and where applicable, certified true copy of a batch release certificate of a representative batch issued by the national control authority of the country of origin certifying that the batch meets all quality and safety requirements. All subsequent batches delivered must also be accompanied by their corresponding batch release certificates.

Note: If items (i), (ii), (iv) and (vi) above are not available at the time of tender submission, they must be submitted by the successful tenderer on or before a date as requested by the Administration.

6. All tenderers have to fulfill the requirements on the quality of the vaccine before their bids would be further considered in terms of price and other conditions. Based on past experience, it is not unusual for some tenderers to indicate that they may not be able to fulfill certain conditions and respond with alternative proposals.

7. The tender notice for the procurement will be gazetted on 17 July 2009 and the tender closing date will be 7 August 2009. We expect to award the tender in September/October 2009.

ADVICE SOUGHT

8. Members are invited to note the content of the paper.

Food and Health Bureau
Department of Health
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