STATENS SERUM INSTITUT

SSI's procurement of COVID Vaccines

Invitation to market consultation

1. PURPOSE AND OBJECT OF THE PROCUREMENT

Statens Serum Institut (SSI) is under the auspices of the Danish Ministry of Health. The main duty of SSI is to ensure preparedness against infectious diseases and biological threats as well as control of congenital disorders.

The COVID outbreak has necessitated a vaccine strategy to protect the public health in Denmark through prevention of infection in the population. The purposes of the procurement are to ensure supply of a COVID vaccine that is safe, effective (high degree of protection), and developed to meet future mutations of the virus on a continuous basis, as well as to increase security of supply of vaccines to the Danish population through the establishment of vaccine production in Denmark.

The contract will be awarded after the conduct of a public procurement procedure under udbudsloven (the Danish act on public procurement).[1]

In the procurement procedure, SSI must observe the principles of equal treatment and transparency. The tender documents, including the draft contract, shall form the basis of the procedure and shall be completed by the tender in order to form the final contractual basis between the parties. The contract shall specify all terms and condition and to the extent possible allow for changes in clear, precise, and unequivocal amendment clauses. The possibility for amening or renegotiating the contract after signing are very limited.[2]

[1] Lov nr. 1564 af 15. december 2015, as amended (the Danish act on public procurement implements Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC, OJ 2014 L 94/65). The Procurement Act is available in English at: https://www.kfst.dk/media/54435/the-public-procurement-act.pdf. There are no official translations of the amendments to the Act.

[2] See section 178-184 of the Danish act on public procurement.

The details of the procurement procedure that will be initiated after the market consultation have not yet been decided. SSI is considering to initiate either an open tender or a negotiated or dialogue-based procedure.

The Ministry of Health and the Ministry of Industry, Business and Financial Affairs are cooperating with SSI on the procurement and participate in the process.

2. MARKET CONSULTATION

The market consultation will provide a basis for decisions on key elements in the planning and design of the procurement procedure, the tender terms, and provide inspiration for the most effective preparation of the contract ensuring a commercially attractive contract with balanced terms.

SSI is dependent on further information from potential suppliers in order to establish a complete set of terms and conditions for the procurement procedure and the agreement in accordance with what the market operators are able to meet.

The market dialogue will be based on the present invitation to dialogue. The expected qualification requirements are described in section 3 below, but all interested parties and any industry associations are welcome to participate in the market consultation. Participants in the market consultation are invited to consider the questions posed but are also welcome to send input related to themes that are not mentioned in this material. Written comments or questions to SSI should be sent by e-mail to Ole Jensen, olj@ssi.dk or Grith Skovgaard Ølykke, grol@kammeradvokaten.dk, no later than 14 May 2021.

Potential tenderers or relevant industry associations are also encouraged to request a confidential virtual meeting with the SSI, where questions posed in this invitation can be discussed. Virtual meetings can take place on 19-21 May 2021. The available slots are:

Slot 1 – 19 May 2021: 13-15
Slot 2 – 19 May 2021: 16-18
Slot 3 – 20 May 2021: 8-10
Slot 4 – 20 May 2021: 11-13
Slot 5 – 20 May 2021: 13-15
Slot 6 – 20 May 2021: 15-17
Slot 7 – 21 May 2021: 12.30- 14.30

Meetings should be requested by e-mail to Ole Jensen, olj@ssi.dk or Grith Skovgaard Ølykke, grol@kammeradvokaten.dk, no later than 12 May 2021 at 12 pm. Requests for meetings should indicate your availability regarding the slots on the list above, include a draft agenda, which SSI can supplement with further items before final adoption of the agenda, as well as email-addresses, names and positions for all participants. As a starting point, these meetings are offered with a length of max. 2 hours. However, SSI reserves the right to adapt the length of meetings. SSI will send out a link to a video conference in due time before the meeting. The language of the meeting will be English.

If a participant in its response to the consultation provides confidential information, it is requested to expressly state so.[3]

3. QUALIFICATION

In order to ensure that only serious and relevant providers are invited to submit tenders, a number of minimum requirements regarding the financial and technical capacities of the applicants apply. In order to meet the minimum requirements regarding financial and technical capacities, the applicant may, where appropriate, rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. If an applicant, which relies on the technical and professional capacities of another entity, wins the tender, the supporting entity must carry out the relevant tasks and must in general not be replaced in this function by other entities including the applicant itself. Therefore, the applicant may only rely on the technical and professional capacities of other entities where those will perform the relevant activities for which these capacities are required. Further, the applicant shall prove to the SSI that it will have at its disposal the resources necessary, by documenting a commitment by those entities to that effect.

SSI considers posing the following minimum requirements for participation:

- Economic/financial capabilities.
- Prior experience with production of biological medicinal products and aseptic filling.

[3] Bekendtgørelse af lov om offentlighed i forvaltningen (the Access to Public Administration Files Act), lbk nr. 145 af 24. februar 2020 applies. SSI is obliged to grant access to documents to the extent provided by law but is entitled to exempt documents or information from disclosure to the extent provided by law, including for the purpose of protecting information about the business affairs of others. The act is available in Danish at: https://www.retsinformation.dk/eli/lta/2020/145.

- Current manufacturing and importation authorisation for manufacture of active substance using biological processes and manufacture of sterile active substances (aseptically prepared).[4]

4. CONSULTATION THEMES AND QUESTIONS

4.1 Quality and safety

SSI wants to procure a COVID vaccine that is effective and is approved for the widest possible range of the population.

Questions

a. *Which technology is your vaccine based on?*
   i. *Is it your own technology or is it fully or partially in-licensed?*
   ii. *If you rely on in-licensed technology, how will you ensure that licensee's changes, improvements etc. to the vaccine are implemented fully and without delays?*

b. *Does your vaccine hold a Marketing Authorisation (MA) granted by the European Commission (EC)?*
   i. *If no, when do you expect this to be the case?*
   ii. *Is/will the EC MA be your own MA or will you produce under another company's EC MA (identity of the MA holder)?*

c. *What is the (expected) efficiency of your vaccine?*

d. *Which part of the population has/will your vaccine been/be approved for (are children, elderly etc. eligible for the vaccine)?*
   i. *What are your expectations for approval of your vaccines for children (under 16 years)?*

e. *What is the (expected) side effect profile for the vaccine?*

f. *How many doses are required for a vaccination regimen?*

[4] Cf. § 39 in bekendtgørelse af lov om lægemidler, lbk nr. 99 af 16. januar 2018, available in Danish at: https://www.retsinformation.dk/eli/lta/2018/99. The provision implements Articles 40 in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ 2001 L 311/67, as amended.

g. *How many doses are required to revaccinate per person?*

h. *How long does the protective effect of the vaccine last?*

i. *How is the vaccine packaged, e.g. vials with/without syringes and diluents or pre-filled syringes?*

j. *How must the vaccine be stored?*

k. *How long is the "shelf life" of the vaccine?*

l. *How will you ensure that the vaccine is continuously developed to ensure coverage for new mutations of the virus?*

m. *How will you ensure compliance with the updated version of EU GMP Annex 1 on aseptic production which applies from end of 2021?*

4.2 Number of doses (vaccine regimens) covered by the contract

SSI needs to ensure vaccines for the Danish population in the duration of the contract (see below on duration). Depending on how many people in the Danish population who has been vaccinated at the time of commencement of the contract, the contract will be for revaccination of the Danish population irrespective of the number of doses required per year. The Danish population is 5-6 million, and SSI's demand will depend on which part of the population the vaccine is approved for.

Questions

a. *What do you think would be a realistic annual delivery plan for the vaccines?*

b. *SSI wants to obtain as much flexibility as possible, but acknowledges that non-exclusivity may need to be combined with an obligation to buy a certain number of vaccine regimens– do you have any comments or suggestions in this regard?*

c. *What are the terms for resale and donation?*

4.3 Security of supply

The procurement is motivated by a need to ensure security of supply of high-quality vaccines to the Danish citizens. To reduce the risk of non-performance of the contract due to e.g., shortage or export restrictions, it

is required that the vaccine is produced in Denmark. This requirement may be fulfilled in several phases: for example, phase 1 could be the filling of the vaccine in Denmark, and phase 2 could be production and filling in Denmark.

4.3.1 Production in Denmark

Questions

a. *What timeline do you foresee for production in Denmark (for example phase 1 and 2, respectively)?*

b. *What would be the expected production capacity for a Danish production facility?*

c. *To what extend will the Danish production rely on export sales and how can you assure that the deliveries to SSI are not affected by other contractual obligations or commercial/economic issues including realisation of export sales?*

d. *Which main obstacles do you foresee in relation to establishing production facilities for COVID vaccine in Denmark?*

e. *Any other comments to the requirement of production in Denmark?*

4.3.2 Supply chain management

Questions

a. *Which excipients or other components used for the vaccine production are necessary to produce your vaccine?*

b. *Which excipients or other components used for the vaccine production are produced by you/or affiliated companies and which are produced by subcontractors?*

c. *Which excipients or other components used for the vaccine production are produced in Denmark, and where is the production of the remaining excipients and other components located, i.e. inside or outside the EU?*

d. *Which excipients or other components used for the vaccine production do you consider to be in most risk of international shortage in the shorter and longer term, respectively?*

e. *How do you intend to fulfil SSI's need for security of supply, in other words, how will you ensure that the vaccines are allocated to SSI?*

f. *Any other comments on supply chain management or security of supply in general?*

4.4 Duration of the contract

SSI is aware of the investment costs connected to the requirement of production in Denmark and is willing to discuss the duration of the contract to make it commercially attractive.

Questions

a. *What would be the optimal duration of the contract from your perspective, and what is the basis for this assessment?*

b. *What would be the shortest duration you would find commercially attractive, and what is the basis for this assessment?*

c. *Which benefits would SSI – in your opinion – obtain from tendering a contract of the duration you consider optimal?*

4.5 Payment

SSI acknowledges that it is difficult to fix a price for vaccines in a long-term contract and therefore seeks input to a possible structure of the payment. SSI expects that it will be possible to offer a fixed price per vaccine regiments for a certain period of time but that a mechanism is needed to adjust the price subsequently and in the light of necessary adaptions of the vaccine. Below, we encourage you to consider possible advantages and disadvantages of different pricing models, taking into account that it is necessary to ensure a transparent payment structure that will apply for the entire duration of the contract, as the possibility for amendments is very limited. Please note that the final price evaluation mechanism is not yet determined, and that it might be entirely different from the models mentioned below or may be a combination of the models mentioned below, depending among others on the input obtained in this consultation.

Questions

<u>Fixed price model</u>

a. *What level do you expect that the price will be per vaccine regiments if the price is fixed for the duration of the contract, for one year or for five years, respectively?*

b. *How long do you think the price should be fixed for, and why?*

c. *How do you suggest that adaptions of the vaccine should be priced?*

Alternative price models to consider

d. *The price may be based on a net cost model meaning that price competition will be for the expected net cost of fulfilling the contract, including a reasonable profit – any comments or suggestions regarding such a price structure?*

e. *The price may relate to a certain part of the capacity/production per year – any comments or suggestions regarding such a price structure?*

f. *The price may consist of a fixed price per vaccine regiments together with a price per adaption, implying that the update would not affect the fixed price – any comments or suggestions regarding such a pricing structure?*

g. *Part of the price may be paid upfront, and the price pr. vaccine regiments will then be relatively lower – any comments or suggestions regarding such a pricing structure?*

h. *The price may be tied to the "market price" of COVID vaccines.*
    i. *What would be a fair measure for the "market price" in your opinion?*
    ii. *How would a fixed price tied to the development in the market price affect the level of the fixed price you would offer?*

i. *What do you consider to be a fair pricing structure/mechanism, taking into account the need to adapt the vaccine?*

Other aspects related to the payment

j. *Which currency do you prefer the payment to be made in?*

k. *How should the risk of fluctuation in the exchange rate be divided between you and SSI?*

l. Any other comments or suggestions related to the payment structure?

4.6 Product liability

SSI finds that due to the COVID outbreak and the urgent need to develop and approve vaccines, it may be reasonable that a part of the product liability rests with the public authorities until the effects of the vaccines are further documents. However, at some point in time, the product liability should be transferred to the producers of vaccines.

Question

a. What do you consider is a fair division of liability between you and SSI?