EUROPEAN UNION

DELEGATION TO THE REPUBLIC OF SERBIA

Belgrade,

CONTRACTING AUTHORITY'S CLARIFICATIONS No. 1

Supplies for combating classical swine fever

Publication ref.: EuropeAid/133909/DH/SUP/RS

No	Question	Answer
1	Instructions to tenderers 1.1 Article 2 "Notification of award to the successful tenderer : June 2014 (provisional date)" It is important to know in which extend the time line will be the one mentioned. For an industrial company operating in EU territory, the quantity is quite big and unusual. Whereas GMP production cycle for vaccines is a much longer process than 90 days (first delivery after signature). Date of notification is therefore Key to launch the production. Is it reasonable to consider a date of notification before June the 20th? Considering that tender committee will have compliant offer in his hand, Please comment and inform us about a more precise time schedule for notification. 1.2 Article 21.4 *"... the total value of the supplies may not, as a result of the variation of the quantities, rise or fall by more than 25% of the tender price..."* An additional quantity of vaccines up to 25% (over the 6Mds planned) is quite an important parameter for industrial purposes. - In which extend the time frame will be adapted taking into account this parameter? - What is the probability known today about final	Due to the nature of the tender process, no further information in this relation than that specified as provisional date in the instructions to tenderers can be provided at this stage. As per the terms and conditions of the tender dossier, and subject to the success of the tender procedure, the notification of award is only one of the steps prior to Contract signature with the successful tenderer. Please note that the implementation period starts to run only from the date of Contract signature (provisional date is July 2014, as per item 2 "Timetable" of the Instructions to Tenderers). The foreseen quantities are indicated in the tender dossier (technical specifications). At present there are no plans to vary this quantity. However, as a general provision for any supply tender, the possibility for variation of the quantity is foreseen in the tender dossier, and the Contracting Authority reserves the right to refer to those provisions if and where relevant.

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No	Question	Answer
	quantities: o More than 6 million doses (with a max of 7.5million doses) o Exactly 6 million doses o Less than 6 million doses (with a min of 4.5million doses)?	
2	Draft Contract 2.1 For the successful tenderer, will it be possible to adapt, in the same time frame, the quantity per shipment in a different way keeping a total volume equal to 6 millions doses. For example, more than 2 million doses for the 3rd shipment and less than 2 millions for phase 1 or phase 2. 2.2 See table article 1 "Phase 2 or 3: vaccines … with delivery within 150 or 210 days from the date of the contract" Our interpretation is that the successful tenderer, depending of its capability, may deliver much earlier than the time limit? (for example at 91 days after the contract signature for the phase 2 and 151 days for the phase 3". Please comment about this flexibility.	Please refer to the terms and conditions of the tender dossier, which define the maximum delivery periods ("*within...days*") for specific phases. Earlier deliveries for certain phases could be possible subject to close coordination with the Beneficiary and their approval.
3	Annex II+III Technical Specifications + technical offer (§1.1) "… 4,000,000 million doses of vaccines will be furnished in 10 doses bottle and 2,000,000 doses in 20 or 25 or 50 doses bottles." For the successful tenderer, will it be possible to open discussion and get a modification of the ratio for the smaller pack sizes (quantity requested in 10 doses vials is 2/3 of the total). This parameter has important impact on Industrial aspects and on availability of finished products. Can a ratio of 50% in small pack size (10 doses) be accepted? Please comment possible flexibility on that parameter.	Please note that the requirements of the technical specifications are not subject to negotiations before or after the award of the contract. Any contract modification is subject to the conditions set out in the relevant paragraphs of the contract's Special and General Conditions and of the applicable Practical Guide. The offers should meet the requirements of the technical specifications.

No	Question	Answer
4	1.3. Technical specifications, Item Number 1.1 "Vaccines for vaccinations of domestic pigs against classical swine fever. Lyophilized C strain virus vaccine. Supply of live virus produced in cell cultures (different from swine) or in rabbits for the vaccination of pigs against classical swine fever." Question No. 1: Is it possible to produce this vaccine on the PK15 (porcine kidney) cell line?	Please observe the requirements of the technical specifications and also refer to the answer to question no. 7 below. Please further note that in line with section 4.3.4 of the Practical Guide, "the Contracting Authority cannot give a prior opinion on the assessment of the tender".
5	1.3. Technical specifications. Item Number 1.1 "The vaccine must comply with monograph no. 0065 *"Classical Swine-fever vaccine (live, prepared in rabbit or in cell cultures, not from porcine origin)"* of the European Pharmacopoeia and must be registered by either the European Medicines Agency (EMA), or competent authority of any European Member State at least in one member of the EU, or competent authority in the Republic of Serbia." Question No. 2: The vaccination of classical swine fever is not permitted in the European Union at the moment. Therefore there is no need to have vaccines against swine fever registered. However, our company is authorized holder of the marketing authorisation for this vaccine in other countries of the World. Would it be sufficient to submit registration certificates from at least other non EU countries?	Please observe the requirements of the Tender Dossier, in particular those of Annex II+III: Technical Specifications + Technical Offer.
6	Letter of Invitation to Tender and Special conditions - EuropeAid/133909/DH/SUP/RS "Supplies for combating classical swine fever" vs. EuropeAid/133909/C/SUP/RS "Vaccines for vaccinations of domestic pigs against classical swine fever" The published documents contain different codes - DH and C and different contract titles. Consequently some parts of the published documentation, in particular the Special Conditions, contain information that is obviously not related to the subject in question (f.e. "electrical	The difference in the publication reference ("DH" vs. "C") comes from the recent change in the coding of the management modes and the publication of the related tender procedures ("C" is now coded as "DH"). However, "C" and the "DH" refer to the same management mode and the two publication references (EuropeAid/133909/DH/SUP/RS and EuropeAid/133909/C/SUP/RS) refer to the same project/procedure, as indicated by the unique number "133909". Therefore, please read "DH" instead of "C" whenever mentioned in the publication reference and consider EuropeAid/133909/DH/SUP/RS as the correct reference.

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<tr><th>No</th><th>Question</th><th>Answer</th></tr>
<tr><td></td><td>works" in Special Conditions (DH)).

<u>Question:</u>

Please clarify what the correct publication reference and contract title is.

Please revise in particular the content of the Special conditions (DH).</td><td>The contract title in Annex II + III: Technical Specifications + Technical Offer is wrongly typed and should read "Supplies for combating classical swine fever".

Please note that the content of the Special Conditions remains unchanged.</td></tr>
<tr><td>7</td><td><u>Technical Specification:</u>

1.1 Vaccines for vaccinations of domestic pigs against classical swine fever.

Lyophilized C strain virus vaccine. Supply of live virus produced in cell cultures (different from swine) or in rabbits for the vaccination of pigs against classical swine fever.

Article 1.1 of Technical Specification determines that the live virus should be propagated in cell cultures different from swine.

<u>Question:</u>

Would you please provide explanation and clarification why live virus propagated in cell culture from swine should be excluded?

There are several vaccines available propagated on permanent cell line from swine that are intensively tested for safety and efficacy. We do not understand the rational to exclude those.</td><td>The quoted requirement was based on the World Organisation for Animal Health (OIE) requirements. However, the formulation of the requirement may indeed be the consequence of an editing omission.

This requirement should therefore be read as follows:

"Vaccines against CSF are based on live virus that has been attenuated by passage through cell cultures or through a suitable host species that is not of the family Suidae."

Consequently, the following requirement "The label states that the vaccine has been prepared in cell cultures (different of swine) or in rabbits as appropriate" shall read as follows:

"The label states that the vaccines against CSF are based on live virus that has been attenuated by passage through cell cultures or through a suitable host species that is not of the family Suidae, as appropriate."

In this relation, please note that every batch of the vaccine must pass all the quality control tests, according to the European Pharmacopeia. The quality control certificate must be accompanying each batch delivered.</td></tr>
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