CLARIFICATIONS No:1 to TENDER DOSSIER

Contract Title: Supply of Vaccines and Antiserums
Publication Reference: SIHHAT/2021/SUP/INT/05

Doc: Document
Art: Article
TS: Annex II + III: Technical Specifications + Technical Offer / c4f_annexiitechspeciiitechoffer_en
TG: Tender Guarantee Form *(c4n_tenderguarantee_en)*
AICN: Additional Information to the Contract Notice
ITT: Instructions to Tenderers
App: Appendix

Further to the requests received from the tenderers, the following clarifications are provided.

#	Doc.	Art./ Item / Lot	CLAUSE	QUESTION / REQUEST	ANSWER
1	AICN	Art.15 Additional Information	a. Financial data to be provided by the tenderer in the standard tender form must be expressed in EUR. If applicable, where a candidate refers to amounts originally expressed in a different currency, the conversion to EUR shall be made in accordance with the InforEuro exchange rate of **March 2022**, which can be found at the following address: http://ec.europa.eu/budget/graphs/inforeuro.html.	Regarding Financial data (turnover, assets, liabilities etc.), currency converting is generally done with the currency (published on tcmb.gov.tr) on last day of related year. Acccording to our understanding, at this clause it is requested to convert all data with the rate of March 2022. Hovever for instance, it can be caused huge difference and failure to convert 2020 financial data with March 2022 currency. Therefore we kindly request further explanation and/or adaptation for currency converting.	This is a template sentence and does not subject to any modifiations. As stated in the article 15 of the AICN, in all financial calculations should be made in accordance with the InfoEuro exchance rate.
2	AICN	Art.16 Selection Criteria/ Part 3	**Technical capacity** (based on items 5 and 6 of the tender form for supply contracts). The reference period which will be taken into account will be the **last 5 (five) years** from submission deadline. References must be contracts implemented by the legal entity (or legal entities) submitting the tender form *(c4l_tenderform_en)* (with the exception of documented cases of company buyout or universal succession).	According to this clause, it is understood that period of 5 years is considered from the date of contract signed with related authority for related supplies in order to prove technical capacity. Your kind confirmation is needed if it is implemented in that way. Can previous vaccine/antiserum experience with your authority under SIHHAT Project be submitted for technical capacity?	As it stated in the related Article of the AICN, for all experiences to the reference period includes to last 5 (five) years from submission deadline. All experiences which are in accordance with the selection criteria within the specified

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<tr><td></td><td></td><td></td><td></td><td></td><td>period, will be evaluated.</td></tr>
<tr><td>3</td><td>ITT</td><td>2.Timetable</td><td><table><tr><th></th><th>DATE</th><th>TIME</th></tr><tr><td>Deadline for requesting clarifications from the contracting authority</td><td>17.05.2022</td><td>-</td></tr></table></td><td>Deadline for requesting clarifications from the contracting authority is stated to be “17.05.2022”. This date seems to be conflicting with the last date on which clarifications are issued by the contracting authority. Could you please clarify the date for requesting clarifications? This also means we can submit any change requests (addendums) to technical specifications until this deadline, is that correct?</td><td>Please see Changes to the Tender Dossier No.1</td></tr>
<tr><td>4</td><td>ITT</td><td>2.Timetable</td><td><table><tr><th></th><th>DATE</th><th>TIME</th></tr><tr><td>Last date on which clarifications are issued by the contracting authority</td><td>09.05.2022</td><td>-</td></tr></table></td><td>Deadline for requesting clarifications from the contracting authority is stated to be “09.05.2022”, Could you please clarify the date for clarifications issued by the authority?</td><td>It will remain same as the ITT. Please see Changes to the Tender Dossier No.1</td></tr>
<tr><td>5</td><td>ITT</td><td>11/Part 3</td><td>f. Tenderer that does not manufacture or produce the Goods (vaccines or antiserums) it offers to supply shall submit the Distributor or Manufacturer’s Authorization Certificate (as duly signed statement for offered products - Appendix III).
h. Duly authorised signature: an official document (statutes, power of attorney, notary statement, etc.) proving that the person who signs on behalf of the company, joint venture or consortium is duly authorised to do so.</td><td>Referring to item h), I will submit a document authorizing our company for the product in question.
In this case, is it obligatory to submit the Annex III document in Article f?</td><td>As stated in Part 3 of Article 11 of ITT; if the tenderer does not manufacture or produce the vaccines, should be summit an Authorization Certificate from distiributor or Manufacturer. Please see ITT and Administrative Compliance Grid for the requested documents.</td></tr>
<tr><td>6</td><td>ITT</td><td>11/Part 3</td><td>l. The tenderer shall provide current and valid certificate for the Quality Management System. (e.g. ISO 9001:2015 or etc.)</td><td>“The tenderer shall provide current and valid certificate for the Quality Management System. (e.g. ISO 9001:2015 or etc.)” GMPs will already be provided, is there any additional documentation required with this article?</td><td>As stated in Part 3 of Article 11 of ITT; the tenderer (legal person, consortium or joint-venture) should have a valid certificate for the Quality Management System.</td></tr>
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<tr><td>7</td><td>ITT</td><td>11/Part 3</td><td>o. Tenderers are requested to include the electronic versions (readable colour scanned) of the offer and the supporting documents (all signed tender dossier).</td><td>According to subject clause; should all tender dossier documents (general conditions, special conditions, instruction to tenderers, draft docs etc.) be signed separetly and added into the file?</td><td>Please see Art. 11 of the ITT.</td></tr>
<tr><td>8</td><td>ITT</td><td>11/Part 3</td><td>i. All experience documents and their certified copies (contract(s), invoice(s), list of insured services, annex(es), etc.) issued by the authorities have to an authenticity stamp (i.e. the apostille) excluding the work completion/work status certificates which registered by the Public Procurement Authority of the Turkish Republic.</td><td>Are only work completeion/work status certificates issued by the contracting authority enough as an experience document?

According to contracts/agreement with the authority, contracts are signed with verified electronic signature by the authority an it can be verified from www.turkiye.gov.tr adress. Invoices are sent via system as an electronic invoice. In that way, are they needed an authenticity stamp (apostile)?</td><td>Please see “i”bullet of Art.11 of the ITT.</td></tr>
<tr><td>9</td><td>App-I(A)</td><td>Lot 1</td><td><table><tr><th>Lot Name</th><th>Total Quantity</th><th>1st Delivery Period</th><th>2nd Delivery Period</th></tr><tr><td>DaBT-IPA-Hib Vaccine</td><td>991.200</td><td>500.000 doses in 2022 September</td><td>491.200 doses in October 2022</td></tr></table></td><td>Requested ammendment:<table><tr><th>Lot Name</th><th>Total Quantity</th><th>1st Delivery Period</th><th>2nd Delivery Period</th></tr><tr><td>DaBT-IPA-Hib Vaccine</td><td>991.200</td><td>500.000 doses in 2022 November</td><td>491.200 doses in December 2022</td></tr></table></td><td>Please see Changes to the Tender Dossier No.2</td></tr>
<tr><td>10</td><td>App-I(A)</td><td>Lot 2</td><td><table><tr><th>Lot Name</th><th>Total Quantity</th><th>Delivery Period</th></tr><tr><td>DaBT-IPA Vaccine</td><td>247.800</td><td>247.800 doses in August 2022</td></tr></table></td><td>Requested ammendment:<table><tr><th>Lot Name</th><th>Total Quantity</th><th>Delivery Period</th></tr><tr><td>DaBT-IPA Vaccine</td><td>247.800</td><td>247.800 doses in September 2022</td></tr></table></td><td>Please see Changes to the Tender Dossier No.2</td></tr>
<tr><td>11</td><td>App-I(A)</td><td>Lot 4</td><td><table><tr><th>Lot Name</th><th>Total Quantity</th><th>Delivery Period</th></tr><tr><td>Hepatit A (Pediatrics) Vaccine</td><td>495.600</td><td>495.600 doses in September 2022</td></tr></table></td><td>Requested ammendment:<table><tr><th>Lot Name</th><th>Total Quantity</th><th>1st Delivery Period</th><th>2nd Delivery Period</th></tr><tr><td>Hepatit A (Pediatrics) Vaccine</td><td>495.600</td><td>200.000 doses in November 2022</td><td>295.600 doses in March 2023</td></tr></table></td><td>Please see Changes to the Tender Dossier No.2</td></tr>
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<tr><td>14</td><td>App-I(A)</td><td>Lot 6</td><td><table><tr><th>Lot Name</th><th>Total Quantity</th><th>Delivery Period</th></tr><tr><td>MMR Vaccine</td><td>743.400</td><td>743.400 doses in September 2022</td></tr></table></td><td>Requested ammendment:<table><tr><th>Lot Name</th><th>Total Quantity</th><th>1st Delivery Period</th><th>2nd Delivery Period</th></tr><tr><td>MMR Vaccine</td><td>743.400</td><td>500.000 doses in December 2022</td><td>243.400 doses in March 2023</td></tr></table></td><td>Please see Changes to the Tender Dossier No.2</td></tr>
<tr><td>15</td><td>TS</td><td>General Requirements Part 1.2. Visibility</td><td>….</td><td>Where will the application of the logo be? Pallet or parcel or box of 50?</td><td>This issue will be evaluated following the signature of the contract with Contracting Authority and Administration.</td></tr>
<tr><td>16</td><td>TS</td><td>Lot 1 / 1.4.1.</td><td>Expiration date must be at least 18 (eighteen months) after the products are delivered to the storage of the Ministry.</td><td>Requested ammendment:
Expiration date must be at least 12 (twelve months) after the products are delivered to the storage of the Ministry.</td><td>Please see Changes to the Tender Dossier No.2</td></tr>
<tr><td>17</td><td>TS</td><td>Lot 1 / 1.4.5.2.</td><td>Name of the manufacturer and product, dose, batch no, expiration date, content amount of the dose (in ml or U/µg), manner of administration (IM/IV/SC/ID etc.), storage temperature must be available on inner and outer package ensuring that the said information do not fade</td><td>Due to the small dimensions of the inner packaging of our vaccine, one of the information that must contain on the package which is "storage temperature" cannot be induded. For this reason, it is necessary to revise the relevant article</td><td>Please see Changes to the Tender Dossier No.2</td></tr>
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			away. Outer packaging must bear the following statement: "Sağlık Bakanlığı Malıdır, SATILAMAZ".	by enabling the concerned information to appear either on the inner packaging or on the unit box as follows: *Name of the manufacturer and product, dose, batch no, expiration date, content amount of the dose (in ml or U/µg), manner of administration (IM/IV/SC/ID etc.), storage temperature must be available on inner* ***and/or*** *outer package ensuring that the said information do not fade away. Outer packaging must bear the following statement: "Sağlık Bakanlığı Malıdır, SATILAMAZ".* We kindly request your approval and ammendment in the technical specifications.	
18	TS	Lot 4/ 4.4.2.4	**An analysis certificate** (component, analysis result, date of production/expiration) which pertains to any series produced by the manufacturer within the past two years must be available.	Technical spesifications require submission of certificate of analysis for the series to be delivered during delivery. Can you please clarify.	In line with the TS; During the tendering stage from any series from the last 2 years, At the acceptance stage, the analysis certificate of the delivered lot is required.
19	TS	Lot 4/ 4.2.6	Originals or notary certified copies of the documents requested must be submitted to the Tender Evaluation Commission; original documents must be submitted during inspection stage.	Are apostilled copies of documents also acceptable? Can the copy of the original documents without apostilled/notarized be also acceptable during initial application with the commitment of providing the original notarized/apostilled version at the next stage?	Originals, apostilled or notary certified copies of the requested documents should be submitted.
20	TS	Lot 4/ 4.4.1.	Expiration date must be at least 18 (eighteen months) after the products are delivered to the storage of the Ministry.	Could expiration date be changed to 15 months?	It will remain as it is. No changes will be made.
21	TS	Lot 4 / 4.4.5.2	Name of the manufacturer and product, dose, batch no, expiration date, content amount of the dose (in ml or U/µg), manner of administration (IM/IV/SC/ID etc.), storage temperature must be available on inner and outer package ensuring that the said information do not fade	Due to the small dimensions ofthe inner packaging ofour vaccine, one ofthe information that must contain on the package which is "storage temperature" cannot be induded. For this reason, it is necessary to revise the relevant article	Please see Changes to the Tender Dossier No.2

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			away. Outer packaging must bear the following statement: "Sağlık Bakanlığı Malıdır, SATILAMAZ".	by enabling the concerned information to appear either on the inner packaging or on the unit box as follows: *Ready-to-use injectors, ampoules or vials must bear the name of the manufacturer and product, dose, batch no, expiration date, content amount of the dose (in ml or U/µg), manner of administration (IM/IV/SC/ID etc.) and storage temperature must be available on inner package and/or box ensuring that the said information do not fade away. Outer packaging must bear the following statement: "Sağlık Bakanlığı Malıdır, SATILAMAZ".* We kindly request your approval and ammendment in the technical specifications.	
22	TS	Lot 4/ 4.4.5.3.	Each vaccine package must contain at least one Short Product Information prepared in accordance with Regulation dated 25.04.2017 and 30048 on Packaging Information of Medicinal Products for Human Use, User Instructions and Follow up, prospectus or "Instruction Book for Patients" in Turkish. Additionally, the following text must be placed in bold and red at the beginning of the SPI, Turkish prospectus or IBP: **"Aşı ve Serum uygulamalarında, Genişletilmiş Bağışıklama Programı Genelgesi dikkate alınmalıdır.** **Bu konuda karşılaşılacak her türlü soru ve problemlerle ilgili olarak, T.C. Sağlık Bakanlığı Halk Sağlığı Genel Müdürlüğü Aşı ile Önlenebilir Hastalıklar Daire Başkanlığı veya İl Sağlığı Müdürlükleri ile temasa geçilmelidir."**	For all other lots, the text above stated as "…Hastalıklar Daire Başkanlığı veya İl Sağlık Müdürlükleri…" however for this lot it is stated as "Sağlığı". Could you please clarify on that? Which statement should we use?	Please see Changes to the Tender Dossier No.2
23	TS	Lot 4 / 4.4.5.8.	If, at a later date, any faulty operations with the barcoding system are detected, the costs of changing the product packaging and –if necessary- pulling them from the market shall be covered by the contractor. If this process takes longer than a month, products with new expiration dates may be requested by the Department in order to avoid problems caused by expired products.	We should be the remaining shelf life of the new stock in case a replacement is needed?	All supplies should be compliant with the TS.

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24	TS	Lot 6/ 6.2.6	Originals or notary certified copies of the documents requested must be submitted to the Tender Evaluation Commission; original documents must be submitted during inspection stage.	Are apostilled copies of documents also acceptable? Can the copy of the original documents without apostilled/notarized be also acceptable during initial application with the commitment of providing the original notarized/apostilled version at the next stage?	Originals, apostilled or notary certified copies of the documents shoul be evaluated.
25	TS	Lot 6/ 6.4.1	Expiration date must be at least 18 (eighteen months) after the products are delivered to the storage of the Ministry.	Could expiration date be changed to 15 months?	Please see Changes to the Tender Dossier No.2
26	TS	Lot 6/ 6.4.2.4	An analysis certificate (component, analysis result, date of production/expiration) which pertains to any series produced by the manufacturer within the past two years must be available.	Technical spesifications require submission of certificate of analysis for the series to be delivered during delivery. Can you please clarify.	In line with the TS; During the tendering stage from any series from the last 2 years, At the acceptance stage, the analysis certificate of the delivered lot is required.
27	TS	Lot 6/ 6.4.5.3.	Each vaccine package must contain at least one Short Product Information prepared in accordance with Regulation dated 25.04.2017 and 30048 on Packaging Information of Medicinal Products for Human Use, User Instructions and Follow up, prospectus or "Instruction Book for Patients" in Turkish. Additionally, the following text must be placed in bold and red at the beginning of the SPI, Turkish prospectus or IBP: **"Aşı ve Serum uygulamalarında, GENIŞLETILMIŞ BAĞIŞIKLAMA PROGRAMI GENELGESI dikkate alınmalıdır** **Bu konuda karşılaşılacak her türlü soru ve problemlerle ilgili olarak, T.C. Sağlık Bakanlığı Halk Sağlığı Genel Müdürlüğü Aşı ile Önlenebilir Hastalıklar Daire Başkanlığı veya İl Sağlığı Müdürlükleri ile temasa geçilmelidir."**	For all other lots, the text above stated as "…Hastalıklar Daire Başkanlığı veya İl Sağlık Müdürlükleri…" however for this lot it is stated as "Sağlığı". Could you please clarify on that? Which statement should we use?	Please see Changes to the Tender Dossier No.2
28	TS	Lot 6 / 6.4.5.8.	If, at a later date, any faulty operations with the barcoding system are detected, the costs of changing the product packaging and –if necessary- pulling them from	We should be the remaining shelf life of the new stock in case a replacement is needed?	All supplies should be compliant with the TS.

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			the market shall be covered by the contractor. If this process takes longer than a month, products with new expiration dates may be requested by the Department in order to avoid problems caused by expired products.		
29	TG	first paragraph	…..this amount representing the guarantee referred to in article 11 of the contract notice.	There is not article 11 on the documents of the contract notice and additional information to contract notice. We kindly request to clarify.	Please see Changes to the Tender Dossier No.2