

CLARIFICATIONS No:1 to TENDER DOSSIER

Contract Title: Supply of Vaccines, Antiserums and Injectors

Publication Reference: SIHHAT/2022/SUP/INT/08

Doc: Document

Art: Article

AICN: Additional information about the Contract Notice (a5f_additional_information_contract_notice_en)

TS: Annex II + III: Technical Specifications + Technical Offer / c4f_annexiitechspeciitechoffer_en

PG: Model Performance Guarantee (c4h_perfguarantee_en)

SC: Special Conditions (c4d_specialconditions_en)

ITT: Instructions to Tenderers

Ann: Annex


App: Appendix

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

#	Doc.	Art. / Lot / Item	CLAUSE	QUESTION / REQUEST	ANSWER
1	SC	Art.10	All goods purchased must originate in an eligible source country as defined in a Member State of the European Union or a country covered by the IPA II programme. For these purposes, ‘origin’ means the place where the goods are mined, grown, produced or manufactured. The origin of the goods must be determined according to the EU Customs Code or to the relevant international agreement applicable.	We kindly request a clarification for suitable origin countries that can participate the tender.	Please see Article 4 of AICN and ITT. It is referred to Annex 2 of practical guide.
2	TS	Lot 1 / 1.4.1.	Expiration date must be at least 18 (eighteen months) after the products are delivered to the storage of the Ministry. For the products that come in with diluents, 0.2% of the total number of diluents shall be delivered under the same conditions.	We kindly request to change this clause as follows; Expiration date must be at least 12 (twelve months) after the products are delivered to the storage of the Ministry.	Please see Changes to the Tender Dossier No.1
3	TS	Lot 3 / 3.4.1.	Expiration date must be at least 18 (eighteen months) after the products are delivered to the storage of the Ministry.	“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.1

#	Doc.	Art. / Lot / Item	CLAUSE	QUESTION / REQUEST	ANSWER
4	TS	Lot 3 / 3.4.5.3.	<p>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:</p> <p>"Aşı ve Serum uygulamalarında, GENİŞLETİLMİŞ BAĞIŞIKLAMA PROGRAMI GENELGESİ dikkate alınmalıdır. Bu konuda karşılaşılabilecek 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."</p>	<p>"Aşı ve Serum uygulamalarında, GENİŞLETİLMİŞ BAĞIŞIKLAMA PROGRAMI GENELGESİ dikkate alınmalıdır Bu konuda karşılaşılabilecek 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?</p>	<p>Please see Changes to the Tender Dossier No.1</p>
5	TS	Lot 3 / 3.4.5.8.	<p>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.</p>	<p>"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."</p> <p>What should be the remaining shelf life of the new stock in case replacement is needed?</p>	<p>The changed products should be complied with the Annex II: Technical Specifications.</p>
6	TS	Lot 4 / 4.2.7.	<p>If the product is used outside the country in which it is manufactured, the list of counties where it is used, the number of doses covering the past two years, and its import permit or a document covering license numbers must be available. The number of doses used in the said countries in the last five years should not be fewer than the number of doses to be procured through this tender.</p>	<p>Please amend the following article as shown below as it is not possible to provide "confidential commercial data of our company" due to the global procedures.</p> <p><u>To be corrected as:</u></p> <p>If the product is used outside the country in which it is manufactured, the list of counties where it is used, the number of doses covering the past two years, and its import permit or a document covering license numbers must be available.</p>	<p>Please see Changes to the Tender Dossier No.1</p>

#	Doc.	Art. / Lot / Item	CLAUSE	QUESTION / REQUEST	ANSWER
7	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.	Expiration date must be at least 14 (fourteen months) after the products are delivered to the storage of the Ministry.	Please see Changes to the Tender Dossier No.1
8	TS	Lot 6 / 6.1.7.	It must maintain stability between (+2°C) - (+8°C) until the date of expiration as of the date of the last potency control testing the manufacturer has successfully passed.	Our rabies antiserum product is lyophilized. Therefore, since the storage temperature of our rabies antiserum product is below 25°C at room temperature. Stability studies are followed at 25°C for the long term, 30°C for the interim period and 40°C for the accelerated period. We request that this expression in the technical specification be evaluated as "monitoring the stability in accordance with the storage conditions until the expiration date"	This item will remain as it was stated in TS.
9	TS	Lot 6 / 6.4.3.5.	Packaging boxes shall be placed in Styrofoam which later shall be placed in parcels sized <u>40cmX60cmX40cm ±20cm</u> (width, length, height). A sufficient number of cool packs or gels which must be cooled, not frozen shall be available inside the parcels. These parcels shall bear the name and address of the manufacturer and representative firms, name of the product, batch no, expiration date, amount of the dose, storage temperature, and measurement & weight of the parcels.	Since the storage temperature of our rabies antiserum product is below 25°C at room temperature, by protecting it from light, cool-packs or gels will not be used. We request that the no addition of gel and cool packs for non-cold chain products to the technical specification should be evaluated.	This item will remain as it was stated in TS.
10	TS	Lot 7 / 7.2.6.	An analysis certificate which pertains to any series produced by the manufacturer within the past two years must be available.	The new serial snake antiserum, whose license process has just been completed, has been included in our production plan. Would it be appropriate to attach a certificate of analysis of a batch that was last produced but older than 2 years? Please your evaluation.	Please see Changes to the Tender Dossier No.1
11	TS	Lot 7 / 7.4.3.6.	Packaging boxes shall be placed in Styrofoam which later shall be placed in parcels sized 40x60x40cm ±20cm (width, length, height). Sufficient number of cool-packs or gels which must be cooled, not frozen shall be available inside the parcels. These parcels shall bear the name and address of the manufacturer and representative firms, name of the product, batch no, expiration date, amount of the dose, storage temperature and measurement & weight of the parcels.	Our snake antiserum product is lyophilized. Therefore, since the storage temperature of our snake antiserum product is below 25°C at room temperature, by protecting it from light, cool-packs or gels will not be used. We request that the no addition of gel and cool packs for non-cold chain products to the technical specification should be evaluated.	This item will remain as it was stated in TS.

#	Doc.	Art. / Lot / Item	CLAUSE	QUESTION / REQUEST	ANSWER						
12	TS	Lot 7 / 7.5.4.5.	It must maintain stability between (+2°C) - (+8°C) until the date of expiration as of the date of the last potency control testing the manufacturer has successfully passed.	Since the storage temperature of our snake antiserum product is below 25°C at room temperature. Stability studies are followed at 25°C for the long term, 30°C for the interim period and 40°C for the accelerated period. We request that this expression in the technical specification be evaluated as "monitoring the stability in accordance with the storage conditions until the expiration date"	This item will remain as it was stated in TS.						
13	TS	Lot 8 / 8.1.2.	It must feature a body of 2 ml.	Can we offer 2 cc injector which has mark on the 2,5-cc level like the attached reference picture? 	Please see Changes to the Tender Dossier No.1						
14	TS	Lot 8 / 8.2.1.	Injectors must be packaged individually to be packed in boxes of 100, 200, or 250. The boxes must then be placed in parcels that are safe for driving and delivery. Each parcel shall contain 1000 or 2000 injectors.	Can we offer products packaged as 350 pieces in internal box and 3500 pieces in parcel?	Please see Changes to the Tender Dossier No.1						
15	TS	Lot 8 / 8.2.1.	Injectors must be packaged individually to be packed in boxes of 100, 200, or 250. The boxes must then be placed in parcels that are safe for driving and delivery. Each parcel shall contain 1000 or 2000 injectors.	Due to our current packaging system, we suggest it be replaced as follows. Injectors must be packaged individually to be packed in boxes of 100, 200, 250, or 300 . The boxes must then be placed in parcels that are safe for driving and delivery. Each parcel shall contain 1000 or 2400 injectors.	Please refer to the Answer No:14						
16	App. A	Lot 1	<table><tr><th>Lot No</th><th>Quantity</th><th>Delivery Period</th></tr><tr><td>1</td><td>208.500</td><td>In April 2023</td></tr></table>	Lot No	Quantity	Delivery Period	1	208.500	In April 2023	We kindly request to change delivery period as follows; Within 150 days after the date of agreement.	Please see Changes to the Tender Dossier No.1
Lot No	Quantity	Delivery Period									
1	208.500	In April 2023									
17	App. A	Lot 1	<table><tr><th>Lot No</th><th>Quantity</th><th>Delivery Period</th></tr><tr><td>1</td><td>208.500</td><td>In April 2023</td></tr></table>	Lot No	Quantity	Delivery Period	1	208.500	In April 2023	We kindly request a clarification for quantity. Is the quantity of 208.500 pediatric doses or vials?	The requested quantity of the product is 208.500 doses.
Lot No	Quantity	Delivery Period									
1	208.500	In April 2023									

#	Doc.	Art. / Lot / Item	CLAUSE			QUESTION / REQUEST	ANSWER						
18	App. A	Lot 3	<table><tr><th>Lot No</th><th>Quantity</th><th>Delivery Period</th></tr><tr><td>3</td><td>371.700</td><td>In June 2023</td></tr></table>	Lot No	Quantity	Delivery Period	3	371.700	In June 2023			Could the delivery of Lot 3 (Hepatitis B (Pediatrics) Vaccine) be changed to 371.700 doses in November 2023?	Please see Changes to the Tender Dossier No.1
Lot No	Quantity	Delivery Period											
3	371.700	In June 2023											
19	App. A	Lot 6	<table><tr><th>Lot Name</th><th>Quantity</th><th>Delivery Period</th></tr><tr><td>6</td><td>10.500</td><td>In June 2023</td></tr></table>	Lot Name	Quantity	Delivery Period	6	10.500	In June 2023			Due to the biological origin of antiserum products, we need an additional 1 month for the delivery of snake antiserum according to our production plans. We request that the delivery date be changed to July 2023.	Please see Changes to the Tender Dossier No.1
Lot Name	Quantity	Delivery Period											
6	10.500	In June 2023											
20	App. A	Lot 7	<table><tr><th>Lot No</th><th>Quantity</th><th>Delivery Period</th></tr><tr><td>7</td><td>370</td><td>In June 2023</td></tr></table>	Lot No	Quantity	Delivery Period	7	370	In June 2023			Due to the biological origin of antiserum products, we need an additional 1 month for the delivery of snake antiserum according to our production plans. We request that the delivery date be changed to July 2023.	Please see Changes to the Tender Dossier No.1
Lot No	Quantity	Delivery Period											
7	370	In June 2023											
21	Ann. 5	PG	... Any request to pay under the terms of the guarantee must be countersigned by the head of delegation of the European Union or his designated empowered deputy as per the applicable Commission rules. In case of a temporary substitution of the contracting authority by the Commission, any request to pay will only be signed by the representative of the Commission, namely whether the head of delegation, his designated empowered deputy or the authorised person at headquarters' level. ...			“Any request to pay under the terms of the guarantee must be countersigned by the head of delegation of the European Union or his designated empowered deputy as per the applicable Commission rules. In case of a temporary substitution of the contracting authority by the Commission, any request to pay will only be signed by the representative of the Commission, namely whether the head of delegation, his designated empowered deputy or the authorised person at headquarters' level.” This paragraph was removed in the previous tender (SIHHAT/2021/SUP/INT/05). Will this be removed again?	Please see Changes to the Tender Dossier No.1						