CHANGES to the TENDER DOSSIER No:1

Contract Title: Supply of Vaccines, Antiserums and Injectors
Publication Reference: SIHHAT/2022/SUP/INT/08

Doc: Document
Art: Article
TS: Annex II + III: Technical Specifications + Technical Offer / c4f_annexiitechspeciiitechoffer_en
PG: Model Performance Guarantee *(c4h_perfguarantee_en)*
AICN: Additional Information to the Contract Notice
SC: Special Conditions *(c4d_specialconditions_en)*
ITT: Instructions to Tenderers
Ann: Annex
App: Appendix

#	Doc.	Art./ Item/ Lot	FORMER TEXT / DOCUMENT(S)	SHALL READ AS NEW TEXT / DOCUMENT(S)
1	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.	Expiration date must be at least **12 (twelve 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. In the event that the products cannot be used before the end of the date of expiration, these shall be replaced, within 120 days at the latest, with products equal to the number of doses that are returned and have an expiration date of **at least 12 months**, upon the request of the Administration.
2	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 **15 (fifteen months)** after the products are delivered to the storage of the Ministry. In the event that the products cannot be used before the end of the date of expiration, these shall be replaced, within 120 days at the latest, with products equal to the number of doses that are returned and have an expiration date of **at least 15 months**, upon the request of the Administration.
3	TS	Lot 3 / 3.4.5.3.	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:	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

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<tr><td></td><td></td><td></td><td>"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.”</td><td>PROGRAMI GENELGESI dikkate alınmalıdır
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<tr><td>4</td><td>TS</td><td>Lot 4 / 4.2.7.</td><td>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.</td><td>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. Or the certificate of pharmaceutical product should be provided in the offer.</td></tr>
<tr><td>5</td><td>TS</td><td>Lot 4 / 4.4.1.</td><td>Expiration date must be at least 18 (eighteen months) after the products are delivered to the storage of the Ministry.</td><td>Expiration date must be at least 12 (twelve months) after the products are delivered to the storage of the Ministry.
In the event that the products cannot be used before the end of the date of expiration, these shall be replaced, within 120 days at the latest, with products equal to the number of doses that are returned and have an expiration date of at least 12 months, upon the request of the Administration.</td></tr>
<tr><td>6</td><td>TS</td><td>Lot 7 / 7.2.6.</td><td>An analysis certificate which pertains to any series produced by the manufacturer within the past two years must be available.</td><td>An analysis certificate which pertains to any series produced by the manufacturer within the past four (4) years must be available.</td></tr>
<tr><td>7</td><td>TS</td><td>Lot 8 / 8.1.2.</td><td>It must feature a body of 2 ml.</td><td>The product must range between 1ml(cc) and 2,5 ml(cc) in volume.</td></tr>
<tr><td>8</td><td>TS</td><td>Lot 8 / 8.2.1.</td><td>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.</td><td>Injectors must be packaged individually to be packed in boxes of 100, 200, 250, 300 or 350. The boxes must then be placed in parcels that are safe for driving and delivery. Each parcel shall contain between 1000 and 4000 injectors.</td></tr>
<tr><td>9</td><td>App. A</td><td>Lot 1</td><td><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></td><td><table><tr><th>Lot No</th><th>Quantity</th><th>Delivery Period</th></tr><tr><td>1</td><td>208.500 doses</td><td>Within 150 calendar days as of the following day after the contract is signed.</td></tr></table></td></tr>
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<tr><td>11</td><td>App. A</td><td>Lot 6</td><td><table><tr><th>Lot No</th><th>Quantity</th><th>Delivery Period</th></tr><tr><td>6</td><td>10.500</td><td>In June 2023</td></tr></table></td><td><table><tr><th>Lot No</th><th>Quantity</th><th>Delivery Period</th></tr><tr><td>6</td><td>10.500 vials</td><td>Until the end of the July 2023</td></tr></table></td></tr>
<tr><td>12</td><td>App. A</td><td>Lot 7</td><td><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></td><td><table><tr><th>Lot No</th><th>Quantity</th><th>Delivery Period</th></tr><tr><td>7</td><td>370 vials</td><td>Until the end of the July 2023</td></tr></table></td></tr>
<tr><td>13</td><td>Ann. 5</td><td>PG</td><td>… 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. …</td><td>This paragraph removed.</td></tr>
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All other terms and conditions of the tender dossier remain unchanged. The above alterations and /or corrections are integral part of the tender dossier.