

CHANGES to the TENDER DOSSIER No:1

Contract Title: Supply of Vaccines and Syringes (Injectors)
Publication Reference: SIHHAT/2024/SUP/INT/07

Doc: Document

Art: Article

ITT: Instructions to Tenderers

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

#	Doc.	Art./ Item/ Lot	FORMER TEXT / DOCUMENT(S)	SHALL READ AS NEW TEXT / DOCUMENT(S)
01	ITT	10. Submission of Tenders / 10.4.	... The technical and financial offers must be placed together in a sealed envelope. The envelope should then be placed in another single sealed envelope/package, unless their volume requires a separate submission for each lot.	... The technical and financial offers must be placed in two sealed envelopes, seperately. The envelopes should then be placed in another single sealed envelope/package, unless their volume requires a separate submission for each lot.
02	TS	Lot 1/ 4.6.2.	... The product package shall bear the statement "Property of the Turkish Ministry of Health, NOT FOR SALE."	... The product package shall bear the statement " T.C. Sağlık Bakanlığı malıdır, SATILAMAZ. " in Turkish.
03	TS	Lot 1/ 4.6.3.	... Additionally, the following text shall be added to the beginning of the "'Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention. "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."	... Additionally, the following text shall be added to the beginning of the "'Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "Aşı ve Serum uygulamalarında, GENİŞLETİLMİŞ BAĞIŞIKLAMA PROGRAMI GENELGESİ dikkate alınmalıdır. Bu konuda karşılaşılabacak her türlü soru ve problemlerle ilgili olarak T.C. Sağlık Bakanlığı Halk Sağlığı Genel Müdürlüğü Aşı ile Önlenebilir Hastalıklar ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir." in Turkish.
04	TS	Lot 2/ 4.6.2.	... The product package shall bear the statement " Property of the Turkish Ministry of Health, NOT FOR SALE. "	... The product package shall bear the statement " T.C. Sağlık Bakanlığı malıdır, SATILAMAZ. " in Turkish.

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05	TS	Lot 2/ 4.6.3.	... Additionally, the following text shall be added to the beginning of the "Summary of Product Characteristics" (SPC) or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention. <i>"In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact the Tuberculosis Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."</i>	... Additionally, the following text shall be added to the beginning of the "Summary of Product Characteristics" (SPC) or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: <i>"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 ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir."</i> in Turkish.
06	TS	Lot 3/ 1.1.	Vaccine production, quality control parameters, methods, and specifications comply with World Health Organization (WHO) Technical Report Series No:980 annex 2, European Pharmacopoeia 10.0 and Monograph 10.0 01/2020 and 01/2020:20920.	Vaccine production, quality control parameters, methods, and specifications comply with World Health Organization (WHO) Technical Report Series No:980 annex 2, European Pharmacopoeia 10.0 and Monograph 10.0 01/2020:0215 and 01/2020:20920.
07	TS	Lot 3/ 4.6.2.	... The product package shall bear the statement "Property of the Turkish Ministry of Health, NOT FOR SALE."	... The product package shall bear the statement "T.C. Sağlık Bakanlığı malıdır, SATILAMAZ." in Turkish.
08	TS	Lot 3/ 4.6.3.	... Additionally, the following text shall be added to the beginning of the "Summary of Product Characteristics" (SPC) or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: <i>"In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."</i>	... Additionally, the following text shall be added to the beginning of the "Summary of Product Characteristics" (SPC) or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: <i>"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 ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir."</i> in Turkish.
09	TS	Lot 4/ 1.1.	The product shall comply with the specifications and requirements set out in World Health Organization (WHO) Technical Report Series No. 848 Annex I and monograph 10.0 01/2020:0648 of the European Pharmacopoeia.	The product shall comply with the specifications and requirements set out in World Health Organization (WHO) Technical Report Series No. 848 Annex I and monograph 11.0 01/2019:0648 of the European Pharmacopoeia.

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10	TS	Lot 4/ 1.5.	Each dose of the vaccine shall contain at least 1350 PFU antigen or 2.13 log PFU of live Varicella-Herpes Zoster virus.	Each dose of the vaccine shall contain at least 1350 PFU antigen or 3,13 log PFU of live Varicella-Herpes Zoster virus.
11	TS	Lot 4/ 4.6.2.	... The product package shall bear the statement " Property of the Turkish Ministry of Health, NOT FOR SALE. "	... The product package shall bear the statement " T.C. Sağlık Bakanlığı mahdır, SATILAMAZ. " in Turkish.
12	TS	Lot 4/ 4.6.3.	... Additionally, the following text shall be added at the beginning of the SIP, Turkish package insert, or PUI in bold and coloured font to draw attention: "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact the Tuberculosis Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."	... Additionally, the following text shall be added at the beginning of the SIP, Turkish package insert, or PUI in bold and coloured font to draw attention: "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 ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir." in Turkish.
13	TS	Lot 4/ 5.6.	The vaccine shall comply with the characteristics and conditions specified in World Health Organization Technical Report Series 980 Annex 4, Annex 5, Annex 6, and European Pharmacopoeia 11.0 01/2020:20920 monograph in terms of physical appearance and laboratory analyses.	The vaccine shall comply with the characteristics and conditions specified in World Health Organization Technical Report Series No. 848 Annex I and monograph 11.0 01/2019:0648 of the European Pharmacopoeia in terms of physical appearance and laboratory analyses.
14	TS	Lot 5/ 1.1.	The product shall comply with vaccine production, quality control parameters, methods, and specifications in World Health Organization (WHO) Technical Report Series (TRS) No:978 Annex 4 and European Pharmacopoeia 11.0 01/2019:1056 and 01/2020:2920 Monograph.	The product shall comply with vaccine production, quality control parameters, methods, and specifications in World Health Organization (WHO) Technical Report Series (TRS) No:978 Annex 4 and European Pharmacopoeia 11.0 01/2019:1056 and 01/2020: 20920 Monograph.
15	TS	Lot 5/ 4.6.2.	... The product package shall bear the statement " Property of the Turkish Ministry of Health, NOT FOR SALE. "	... The product package shall bear the statement " T.C. Sağlık Bakanlığı mahdır, SATILAMAZ. " in Turkish.
16	TS	Lot 5/ 4.6.3.	... Additionally, the following text shall be added to the beginning of the "Summary of Product Characteristics" (SPC) or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention:	... Additionally, the following text shall be added at the beginning of the SIP, Turkish package insert, or PUI in bold and coloured font to draw attention: "Aşı ve Serum uygulamalarında, GENİŞLETİLMİŞ

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			<i>"In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration.</i> <i>For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."</i>	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 ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir." in Turkish.
17	TS	Lot 5/ 5.6.	The vaccine shall comply with the characteristics and conditions specified in World Health Organization (WHO) Technical Report Series 980 Annex 4 and European Pharmacopoeia 11.0 01/2019:1056 and 01 /2020:2920 monograph in terms of physical appearance and laboratory analyses.	The vaccine shall comply with the characteristics and conditions specified in World Health Organization (WHO) Technical Report Series 978 Annex 4 and European Pharmacopoeia 11.0 01/2019:1056 and 01 /2020:20920 monograph in terms of physical appearance and laboratory analyses.
18	TS	Lot 6/ 4.6.2.	... The product package shall bear the statement "Property of the Turkish Ministry of Health, NOT FOR SALE."	... The product package shall bear the statement "T.C. Sağlık Bakanlığı malıdır, SATILAMAZ." in Turkish.
19	TS	Lot 6/ 4.6.3.	... Additionally, the following text shall be added to the beginning of the ""Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: <i>"In vaccine and serum applications, the EXPANDED PROGRAM ON IMMUNIZATION (EPI) CIRCULAR shall be taken into consideration.</i> <i>For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."</i>	... Additionally, the following text shall be added to the beginning of the ""Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "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 ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir." in Turkish.
20	TS	Lot 7/ 4.6.2.	... The product package shall bear the statement "Property of the Turkish Ministry of Health, NOT FOR SALE."	... The product package shall bear the statement "T.C. Sağlık Bakanlığı malıdır, SATILAMAZ." in Turkish.
21	TS	Lot 7/ 4.6.3.	... Additionally, the following text shall be added to the beginning of the ""Summary of Product Characteristics" (SPC)" or Turkish	... Additionally, the following text shall be added to the beginning of the ""Summary of Product Characteristics" (SPC)" or Turkish

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			prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "In vaccine and serum applications, the EXPANDED PROGRAM ON IMMUNIZATION (EPI) CIRCULAR shall be taken into consideration. <i>For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."</i>	prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "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 ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir." in Turkish.
22	TS	Lot 8/ 1.1.	The product shall comply with the conditions and characteristics specified in DST/WHO TRS 980 Annex 4, Annex 5, Annex 6 WHO/IVB/11.11, /WHO/VSQ/97.04, and 11.0 07/2022:2764 monograph of European Pharmacopoeia in terms of physical appearance and laboratory analyses.	The product shall comply with the conditions and characteristics specified in DST/WHO TRS 980 Annex 4, Annex 5, Annex 6 WHO/IVB/11.11, /WHO/VSQ/97.04, and 11.0 07/2022: 0647 monograph of European Pharmacopoeia in terms of physical appearance and laboratory analyses.
23	TS	Lot 8/ 4.3.	The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a <u>manufacturer-approved</u> commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of <u>manufacturer approval</u> .	Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed.
24	TS	Lot 8/ 4.6.2.	... The product package shall bear the statement " Property of the Turkish Ministry of Health, NOT FOR SALE. "	... The product package shall bear the statement " T.C. Sağlık Bakanlığı malıdır, SATILAMAZ. " in Turkish.

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25	TS	Lot 8/ 4.6.3.	... Additionally, the following text shall be added to the beginning of the "Summary of Product Characteristics" (SPC) or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "In vaccine and serum applications, the EXPANDED PROGRAM ON IMMUNIZATION (EPI) CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."	... Additionally, the following text shall be added to the beginning of the "Summary of Product Characteristics" (SPC) or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "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 ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir." in Turkish.
26	TS	Lot 9/ 1.1.	The product shall comply with the conditions and characteristics specified in World Health Organisation WHO TRS 980 Annex 4, Annex 5, Annex 6 and European Pharmacopoeia 11.0 07/2022:2764 monograph in terms of physical appearance and laboratory analyses.	The product shall comply with the conditions and characteristics specified in World Health Organisation WHO TRS 980 Annex 4, Annex 5, Annex 6, World Health Organisation WHO TRS 979 Annex 4 and European Pharmacopoeia 11.0 07/2022:2764 monograph in terms of physical appearance and laboratory analyses.
27	TS	Lot 9/ 4.6.2.	... The product package shall bear the statement "Property of the Turkish Ministry of Health, NOT FOR SALE."	... The product package shall bear the statement "T.C. Sağlık Bakanlığı mahdır, SATILAMAZ." in Turkish.
28	TS	Lot 9/ 4.6.3.	... Additionally, the following text shall be added to the beginning of the "Summary of Product Characteristics" (SPC) or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "In vaccine and serum applications, the EXPANDED PROGRAM ON IMMUNIZATION (EPI) CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."	... Additionally, the following text shall be added to the beginning of the "Summary of Product Characteristics" (SPC) or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "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 ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir." in Turkish.

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29	TS	Lot 10/ 4.6.2.	... The product package shall bear the statement " Property of the Turkish Ministry of Health, NOT FOR SALE. "	... The product package shall bear the statement " T.C. Sağlık Bakanlığı malıdır, SATILAMAZ. " in Turkish.
30	TS	Lot 10/ 4.6.3.	... Additionally, the following text shall be added to the beginning of the ""Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "In vaccine and serum applications, the EXPANDED PROGRAM ON IMMUNIZATION (EPI) CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."	... Additionally, the following text shall be added to the beginning of the ""Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "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 ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir." in Turkish.
31	TS	Lot 10/ 5.6.	The vaccine shall comply with the characteristics and conditions specified in World Health Organization (WHO) Technical Report Series 979 Annex IV, Technical Report Series 980 Annex IV, Technical Report Series 993 Annex III, Technical Report Series 1024 Annex III and European Pharmacopoeia 11.0 07/2022: 1934 and 01/2020:2.9.20 monographs in terms of physical appearance and laboratory analyses.	The vaccine shall comply with the characteristics and conditions specified in World Health Organization (WHO) Technical Report Series 979 Annex IV, Technical Report Series 980 Annex IV, V Technical Report Series 993 Annex III, Technical Report Series 1024 Annex III and European Pharmacopoeia 11.0 07/2022: 1934 and 01/2020:2.9.20 monographs in terms of physical appearance and laboratory analyses.
32	TS	Lot 11/ 4.5.2.	... The product package shall bear the statement " Property of the Turkish Ministry of Health, NOT FOR SALE. "	... The product package shall bear the statement " T.C. Sağlık Bakanlığı malıdır, SATILAMAZ. " in Turkish.
33	TS	Lot 11/ 4.5.3.	... Additionally, the following text shall be added to the beginning of the ""Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: " When administering tetanus immunoglobulin, the regulations concerning tetanus prophylaxis prepared by the Turkish Ministry of Health and currently in force should be taken into consideration.	... Additionally, the following text shall be added to the beginning of the ""Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "Tetanos immünglobulinin uygulanmasında, T.C. Sağlık Bakanlığı tarafından hazırlanan ve halen yürürlükte bulunan tetanos profilaksisine yönelik düzenlemeler dikkate alınmalıdır. Bu konuda karşılaşılabilecek her türlü soru ve problemlerle ilgili

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			<i>For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."</i>	<i>olarak T.C. Sağlık Bakanlığı Halk Sağlığı Genel Müdürlüğü Aşı ile Önlenebilir Hastalıklar ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir."</i> in Turkish.
34	TS	Lot 12/ 4.6.2.	... The product package shall bear the statement " Property of the Turkish Ministry of Health, NOT FOR SALE. "	... The product package shall bear the statement " T.C. Sağlık Bakanlığı malıdır, SATILAMAZ. " in Turkish.
35	TS	Lot 12/ 4.6.3.	... Additionally, the following text shall be added to the beginning of the "'Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: <i>"The regulations concerning rabies prophylaxis prepared by the Turkish Ministry of Health and currently in force shall be considered when administering the rabies vaccine and immunoglobulin</i> <i>For any questions or problems encountered in this regard, contact Department of Zoonotic and Vectoral Diseases of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."</i>	... Additionally, the following text shall be added to the beginning of the "'Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: <i>"Kuduz aşısının ve immünglobulinin uygulanmasında, T.C. Sağlık Bakanlığı tarafından hazırlanan ve halen yürürlükte bulunan ilgili Genelge ve ekinde yer alan rehberle yönelik düzenlemeler dikkate alınmalıdır. Bu konuda karşılaşılabilecek her türlü soru ve problemlerle ilgili olarak T.C. Sağlık Bakanlığı Halk Sağlığı Genel Müdürlüğü Zootonik ve Vektörel Hastalıklar Dairesi veya İl Sağlık Müdürlükleri ile temasa geçilmelidir."</i> in Turkish.
36	TS	Lot 13/ 4.6.2.	... The product package shall bear the statement " Property of the Turkish Ministry of Health, NOT FOR SALE. "	... The product package shall bear the statement " T.C. Sağlık Bakanlığı malıdır, SATILAMAZ. " in Turkish.
37	TS	Lot 13/ 4.6.3.	... Additionally, the following text shall be added to the beginning of the "'Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: <i>"In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration.</i> <i>For any questions or problems encountered in this regard,</i>	... Additionally, the following text shall be added to the beginning of the "'Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: <i>"Kuduz aşısının ve immünglobulinin uygulanmasında, T.C. Sağlık Bakanlığı tarafından hazırlanan ve halen yürürlükte bulunan ilgili Genelge ve ekinde yer alan rehberle yönelik düzenlemeler dikkate alınmalıdır. Bu konuda karşılaşılabilecek her türlü soru ve problemlerle ilgili olarak T.C. Sağlık Bakanlığı</i>

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			<i>contact and Department of Zoonotic and Vectoral Diseases and the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."</i>	<i>Halk Sağlığı Genel Müdürlüğü Zootonik ve Vektörel Hastalıklar Dairesi veya İl Sağlık Müdürlükleri ile temasa geçilmelidir."</i> in Turkish.
38	TS	Lot 14/ 4.7.2.	... The product package shall bear the statement "Property of the Turkish Ministry of Health, NOT FOR SALE."	... The product package shall bear the statement " T.C. Sağlık Bakanlığı mahdır, SATILAMAZ. " in Turkish.
39	TS	Lot 14/ 4.7.3.	... Additionally, the following text shall be added to the beginning of the "'Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention. "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates."	... Additionally, the following text shall be added to the beginning of the "'Summary of Product Characteristics" (SPC)" or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "Aşı ve Serum uygulamalarında, GENİŞLETİLMİŞ BAĞIŞIKLAMA PROGRAMI GENELGESİ dikkate alınmalıdır. Bu konuda karşılaşılabacak her türlü soru ve problemlerle ilgili olarak T.C. Sağlık Bakanlığı Halk Sağlığı Genel Müdürlüğü Aşı ile Önlenebilir Hastalıklar ve Bağışıklama Dairesi Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir." in Turkish.

In addition, Appendix II: Manufacturer's or Distributor's Authorization document was submitted to the Tender Dossier.

All other terms and conditions of the contract notice and tender dossier remain unchanged. The above alterations and /or corrections are integral part of the tender dossier.