CLARIFICATION No:1 to the
TENDER DOSSIER
Supply of Vaccines
Publication Reference: SIHHAT/2018/SUP/INT/11
Location –Europe (non EU/Turkey)

The following clarifiction is made to the tender dossier

GENERAL	
Question 1:	We could not find the application form/document that must be stamped and signed by hand and submit as original. Could you please let us know which document should be submitted as an application form.
Answer 1:	Please see Part 3: Documentation in Article 11 of Instructions to Tenderers
Question 2:	Should we submit exclusion criteria documents (Tax debts doc, social security doc, not banning from Professional activity etc.) with the tender file? If yes, as related docs can not be issued with the date of 25.03.2019 before tender date; should they be issued with any date in March 19? Or should we submit them not in tender file but before agreement step?
Answer 2:	Please see Answer 1
Question 3:	**Regarding to Lot 1;** The vaccine we plan to participate is manufactured and registered in Korea. Our product complies with the condition of being registered in Korea and the condition of being included in WHO prequalified vaccines list which is the first item of the technical specification and all other technical requirements. We understand that, since Korea is also listed in the document namded "a2a_ecprogrammes_eligibility2014_2020_en" which is the second attachment of the tender booklet, we can participate in the tender with a Korean product. Do we understand right? Please see Aricle 4 of Instruction to Tenderers and further information in section 3: for IPA II (CIR- Article 10) in the document namded "a2a_ecprogrammes_eligibility2014_2020_en".
Answer 3:	Please refer to the point 4 "Origin" of the Instructions to the Tenderers for further details. Please see also detailed information in section 3 of "a2a_ecprogrammes_eligibility2014_2020_en" document.

INSTRUCTION TO TENDERERS	
Question 4:	On Instructions To Tenderers document, 11. Clause, it is saying that the electronic version of technical offer and financial offer should be submitted. What must we understand with electronic version? Should they be signed with e-signature? **Part 1: Technical offer:** • a detailed description of the supplies tendered in conformity with the technical specifications, including any documentation required, including if applicable: o An electronic version of the technical offer The technical offer should be presented as per template (Annex II+III*, Contractor's technical offer) adding separate sheets for details if necessary. **Part 2: Financial offer:** • A financial offer calculated on a DDP[1] basis for the supplies tendered. This financial offer should be presented as per template (Annex IV*, Budget breakdown), adding separate sheets for details if necessary. o An electronic version of the financial offer
Answer 4:	Meaning of the electroning version is soft copies (scanned version) of the offers.

ANNEX II – III TECHNICAL SPECIFICATIONS & TECHNICAL OFFER

Question 5:

How should we fill the attached and below Annex II-III tech specifications + technical offer? Should we write the related supplied doc number & date, establishment etc to the coloumn of **''3. Specification Offered''** ?

Should we fill also topic of **3. Delivery of Vaccines, 4. Docs to be Requested At The Stage of Examination**, **5. Docs and Materials Neccesary For Laboratory**? If yes, which information should we fill to the coloumn of 3. Specificaiton Offered and 4. Notes for these topics?

Lot 4: Varicella Vaccine				
1. Item Number	**2. Specifications Required**	**3. Specifications Offered**	**4. Notes, remarks, ref to document ation**	**5. Evaluation Committee's Notes**
Brand/Model Name:				
Expiry date:				
Origin:				
1.	**TECHNICAL SPECIFICATIONS OF THE VACCINE**			
1.1	The product shall conform to the properties and conditions specified in the World Health Organization Technical Report Series 848 Annex II, of European Pharmacopeia 9.0 01/2011:0648 monograph.			

3.	**DELIVERY OF THE VACCINES**			
3.1	If the product is imported, the representative of the tenderer shall be present as well while the products are received from the customs and shall provide that the commodity shall be received in conformity with the properties sought and there will be no problem with the delivery of the same to the place deemed appropriate by the Office.			

Answer 5:

Columns 3-4 should be completed by the tenderer as clarified in Annex II-III, Please see first page of Annex II – III Technical Specifications & Technical Offer.

Question 6:

Regarding to Lot 1;

If the filling or production is performed in our country, product shall have licence included approval of filling or production facility/company in Turkey issued by Turkish Medicines and Medical Devices Agency of the Ministry of Health of Republic of Turkey or issued by The Health Authority located in manufacturer country or the product should be in the current pre-qualification list included filling or manufacturing facility/company in Turkey published by the World Health Organization (WHO)

Additional specification offer.

If the filling or manufacturing facility changed product shall have been licence approved this changing by related authority (Turkish MOH or abroad manufacturer authority or WHO)

Answer 6:

Additional specification offer was not approved, no changes or additions have been made.

Question 7:

Regarding to Lot 1;

Additional specification offer.

The product's characteristic in the documents submitted for examination to the Tender Commission shall be exactly the same as the characteristic of the product to be delivered (formulation, primary packaging type, manufacturers etc.).

Answer 7:

Additional specification offer was not approved, no changes or additions have been made.

ANNEX II – III TECHNICAL SPECIFICATIONS & TECHNICAL OFFER	
Question 8:	**Regarding to Lot 1, Item 1.5;** Original clause: The vaccine shall preserve its stability at (+)2 ±C-(+) 8°C from the date of the last successful potency test of the manufacturer company till the date of expiry. Requested clause: The vaccine shall preserve its stability at (+)2 °C-(+) 8°C from the date of the last successful potency test of the manufacturer company till the date of expiry. ± will be 2°
Answer 8:	Please see Corrigendum No:1 to Tender Dossier.
Question 9:	**Regarding to Lot 1, Item 2.3;** Original clause: It shall have a Batch Release Certificate issued by 'National Regulatory Authority' (NRA) or National Control Laboratory (NCL) in WHO list if it belongs to any batch number manufactured within the last two years. If the product is manufactured in Turkey, it shall have batch release certificate or pharmaceutical product certificate issued by Turkish Medicines and Medical Devices Agency of the Ministry of Health of Republic of Turkey. Requested clause: It shall have a Batch Release Certificate issued by 'National Regulatory Authority' (NRA) or National Control Laboratory (NCL) in WHO list if it belongs to any batch number manufactured within the last two years. If the product is **filled or** manufactured in Turkey, it shall have batch release certificate or pharmaceutical product certificate issued by Turkish Medicines and Medical Devices Agency of the Ministry of Health of Republic of Turkey **manufactured in Turkey to any batch number within the last two years.** If the product is **filled or** manufactured in Turkey, batch release certificate must be prepared by Turkish MOH.
Answer 9:	Requested additions was not approved, no changes or additions have been made.
Question 10:	**Regarding to Lot 1, Item 2.6;** Original clause: Certificate of analysis of any batch manufactured within the last two years should be available. Requested clause: Certificate of analysis of any batch manufactured within the last two years should be available. **If the product is filled or manufactured in Turkey, it shall have certificate of analysis issued by filling or manufacturing company in Turkey within the last two years should be available.** If the product is filled or manufactured in Turkey, who is abroad manufacturer certificate of analysis should not be placed.
Answer 10:	Requested additions was not approved, no changes or additions have been made.
Question 11:	**Regarding to Lot 2;** Additional specification offer is "The list of the works which the subcontractor shall be made perform shall be available".
Answer 11:	Additional specification offer was not approved, no changes or additions have been made.
Question 12:	**Regarding to Lot 2;** If the filling or production is performed in our country, product shall have licence included approval of filling or production facility/company in Turkey issued by Turkish Medicines and Medical Devices Agency of the Ministry of Health of Republic of Turkey or issued by The Health Authority located in manufacturer country or the product should be in the current pre-qualification list included filling or manufacturing facility/company in Turkey published by the World Health Organization (WHO). Additional specification offer. If the filling or manufacturing facility changed product shall have been licence approved this changing by related authority (Turkish MOH or abroad manufacturer authority or WHO).
Answer 12:	Additional specification offer was not approved, no changes or additions have been made.

ANNEX II – III TECHNICAL SPECIFICATIONS & TECHNICAL OFFER	
Question 13:	**Regarding to Lot 2, Item 1.5;** Original clause: There will be a certificate of analysis of any batch number manufactured by the manufacturer within the last two years. The certificate of analysis shall contain the properties of the product specified in article 4. Requested clause: There will be a certificate of analysis of any batch number manufactured by the manufacturer within the last two years. If the product is filled or manufactured in Turkey, it shall have certificate of analysis issued by filling or manufacturing company in Turkey within the last two years should be available. The certificate of analysis shall contain the properties of the product specified in article 4. If the product is filled or manufactured in Turkey, who is abroad manufacturer certificate of analysis should not be placed.
Answer 13:	Requested additions was not approved, no changes or additions have been made.
Question 14:	**Regarding to Lot 2, Item 3.2.3;** Original clause: The name of the manufacturer and the product, its dose, batch number, date of expiry, quantity of ingredients per dose (in ml. or CFU), method of application (IM/IV/SC/ID etc.) and storage temperature shall be written. and they will be non-erasable. The expression of "Sağlık Bakanlığı Malıdır, SATILAMAZ" shall appear on the package of the product. Requested clause: The name of the manufacturer and the product, its dose, batch number, date of expiry, quantity of ingredients per dose (in ml. or CFU), method of application (IM/IV/SC/ID etc.) and storage temperature shall be written **on inner package and package** and they will be non-erasable. The expression of **"Sağlık Bakanlığı Malıdır, SATILAMAZ, kontrolü (analizi) yapılmıştır."** shall appear on the package of the product. This information must be on inner package and package. There is no information "kontrolü (analizi) yapılmıştır."
Answer 14:	Please see Corrigendum No:1 to Tender Dossier.
Question 15:	**Regarding to Lot 2, Item 3.2.4;** Original clause: If the diluents are not in the same package with the product, the packages of the diluents shall be in packages of minimum ten vials or bulbs as well as convenient with the vaccines and there will be separators such as foam, cardboard which prevent the vials or bulbs to be broken because of contact. The expression of "diluents of BCG vaccine" (in Turkish or in English), name and ingredients of the product, serial number, dose and date of expiry shall have been written on the vials/bulbs of the diluents. If the diluents are in the same package with the product it is sufficient to write the name of the manufacturer, ingredients, serial number, dose and date of expiry the vials/bulbs of the diluents. Requested clause: If the diluents are not in the same package with the product, the packages of the diluents shall be in packages of minimum ten vials or bulbs as well as convenient with the vaccines and there will be separators such as foam, cardboard which prevent the vials or bulbs to be broken because of contact. **Name, content, batch number, dose, amount, expiry date shall have been written on the diluent package**. The expression of "diluents of BCG vaccine" (in Turkish or in English), **manufacturer** name and ingredients of the product, serial number, dose and date of expiry shall have been written on the vials/bulbs of the diluents. If the diluents are in the same package with the product it is sufficient to write the name of the manufacturer, ingredients, serial number, dose and date of expiry the vials/bulbs of the diluents. The information on the diluent package should be added. Manufacturer name should be on the vials/bulbs of the diluent.
Answer 15:	Requested revision was not approved, no changes or additions have been made.

ANNEX II – III TECHNICAL SPECIFICATIONS & TECHNICAL OFFER	
Question 16:	**Regarding to Lot 2, Item 3.2.6;** Original clause: There will be "Brief Product Information" and "Package Insert for the Patient" in Turkish prepared in conformity with the Regulation of Medical Products Packaging and Labeling dated 12.08.2005 and numbered 25904, one in each package of the products packaged singly and minimum one for ten products in multi-packaged packages. Furthermore the following text (in item 3.2.7) in Turkish shall be inserted at the top of the "Brief Product Information" or "Package Insertfor the Patient" or "Prescribing Information" with bold and colored font. Requested clause: There will be "Brief Product Information" and "Package Insert for the Patient" in Turkish prepared in conformity with the Regulation of Medical Products Packaging and Labeling dated 12.08.2005 and numbered 25904, one in each package of the products packaged singly and minimum one for ten products in multi-packaged packages. Furthermore the following text (in item 3.2.7) in Turkish shall be inserted at the top of the "Brief Product Information" or "Package Insertfor the Patient" or "Prescribing Information" with bold and colored font. If the diluents and the product are packaged separately it should be in only vaccine package. This document is placed only in vaccine package.
Answer 16:	Requested addition was not approved. Please see Corrigendum No:1 to Tender Dossier.
Question 17:	**Regarding to Lot 2, Item 3.2.10;** Original clause: Later the parcels shall be placed in a pallet. The pallets shall be euro pallet (120±80x20cm±5%). After the parcels are placed in the pallet, the total height including that of the pallet shall not exceed 2 (two) meters. The parcels may overflow from the pallet maximum ±2 cm. Requested clause: Later the parcels shall be placed in a pallet. The pallets shall be euro pallet (120±80x20cm±5%). After the parcels are placed in the pallet, the total height including that of the pallet shall not exceed 2 (two) meters. The parcels may overflow from the pallet maximum ±2 cm. **There will be maximum 16 (sixteen) parcels in the pallet.** Rule of 16 parcel will be add.
Answer 17:	Please see Corrigendum No:1 to Tender Dossier.
Question 18:	**Regarding to Lot 2, Item 3.2.12;** Original clause: If the diluents and the product are packaged separately, articles 3.2.7-3.2.8 and 3.2.10 shall apply to the diluents as well. Requested clause: If the diluents and the product are packaged separately, articles 3.2.8-3.2.9, 3.2.10 and **3.2.11** shall apply to the diluents as well. Article 3.2.7. will be remove, article 3.2.11. will be add (3.2.11 for 2D barcode)
Answer 18:	Please see Corrigendum No:1 to Tender Dossier.
Question 19:	**Regarding to Lot 2, Item 3.2.13.1;** Original clause: If the product and its diluents are in the same package, one temperature monitoring card and freezing indicator shall be available in each parcel specified in article 3.2.8 and an electronic digital monitor sensitive to temperature and freezing that could make long term recording shall be available in each pallet specified in article 3.2.9. Requested clause: If the product and its diluents are in the same package, one temperature monitoring card and freezing indicator shall be available in each parcel specified in article **3.2.9** and an electronic digital monitor sensitive to temperature and freezing that could make long term recording shall be available in each pallet specified in article **3.2.10**. Related articles numbers are wrong.
Answer 19:	Please see Corrigendum No:1 to Tender Dossier.

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Question 20:	**Regarding to Lot 2, Item 3.2.13.2;** Original clause: If the product and its diluents are packaged separately one temperature monitoring card shall be available in each parcel specified in article 3.2.8 and an electronic digital monitor sensitive to temperature and freezing that could make long term recording shall be available in each pallet specified in article 3.2.9 one freezing indicator shall be available in each parcel specified in article 3.2.8 and an electronic digital monitor sensitive to temperature and freezing that could make long term recording shall be available in each pallet specified in article 3.2.9. Requested clause: If the product and its diluents are packaged separately one temperature monitoring card shall be available in each parcel specified in article **3.2.9** and an electronic digital monitor sensitive to temperature and freezing that could make long term recording shall be available in each pallet specified in article **3.2.10** one freezing indicator shall be available in each parcel specified in article **3.2.9** and an electronic digital monitor sensitive to temperature and freezing that could make long term recording shall be available in each pallet specified in article **3.2.10**. Related articles numbers are wrong.
Answer 20:	Please see Corrigendum No:1 to Tender Dossier.
Question 21:	**Regarding to Lot 2, Item 3.2.13.3;** Original clause: The electronic digital monitors sensitive to temperature and freezing that could make long term recording placed in the pallet shall be read at the stage of examination, the outputs shall be recorded in a minute and undersigned together with the company and upon request of the company those devices shall be returned to the company. The products detected not to have been transferred under convenient conditions (Annex 1 Class B packaging temperature limits for vaccines numbered WHO/IVB/05.23 published by the World Health Organization) under the control of those temperature monitors. The contractor shall deliver the products with the same quantity from a different lot free of charge and in conformity with the specification to Turkish General Directorate of Public Health within 120 calendar days from the date of notification to the contractor. Requested clause: The electronic digital monitors sensitive to temperature and freezing that could make long term recording placed in the pallet shall be read at the stage of examination, the outputs shall be recorded in a minute and undersigned together with the company and upon request of the company those devices shall be returned to the company. The products detected not to have been transferred under convenient conditions (Annex 1 Class B packaging temperature limits for vaccines numbered WHO/IVB/05.23 published by the World Health Organization) under the control of those temperature monitors. **If the product and diluent are packed separately**, **vaccines will be evaluated as Class B, diluents will be evaluated as Class C.** The contractor shall deliver the products with the same quantity from a different lot free of charge and in conformity with the specification to Turkish General Directorate of Public Health within 120 calendar days from the date of notification to the contractor. If the diluent is packed separately diluent can not be Class B.
Answer 21:	Please see Corrigendum No:1 to Tender Dossier.
Question 22:	**Regarding to Lot 2, Item 4.5;** Original clause: Depending on the strain used, it shall contain living gem within the limits expected in 1 ml of vaccine. Requested clause: Depending on the strain used, it shall contain living **germ** within the limits expected in 1 ml of vaccine. Gem will be germ.
Answer 22:	Please see Corrigendum No:1 to Tender Dossier.

ANNEX II – III TECHNICAL SPECIFICATIONS & TECHNICAL OFFER	
Question 23:	**Regarding to Lot 3, Item 1.4;** The Ministry of Health of Republic of Turkey procured the MMR vaccine on 02.07.2018with the tender registration number of 2018/249234. MMR vaccines are administered to the 1.3 million babies with a 99,2% Muslim percentage born every year in Turkey. For this reason, the technical specifications of the tender received; It included the following statement "**The pork gelatin will not be included in tlıe vaccine**" in section 1.4 in the above tender specifications. Considering the same religious sensitivities in the population to be vaccinated, we kindly request to add same statement (c4f_annexiitechspeciiitechoffer_en) as "**The pork gelatin will not be included in the vaccine**" in this tender as well.
Answer 23:	Please see Corrigendum No:1 to Tender Dossier.
Question 24:	**Regarding to Lot 3, Item 4.2;** In c4f 4.2, in the product's internal packaging and over the packages, the manufacturer's and product's name, number, batch number, expiry date, amount of content (in mI or CFU), application type (IM/IV /SC/ID etc.), storage temperature are written and undeletable. On the package of the product, it says "T.C Sağlık Bakanlığı Malıdır, SATILAMAZ.", it is not possible to add/write any statement on blister from a technical perspective, it is possible to add only on carton and vaccine. Confirmation about blister artwork is required.
Answer 24:	Please see Corrigendum No:1 to Tender Dossier.
Question 25:	**Regarding to Lot 3, Item 4.4;** It is mentioned in the Technical Specification (c4f_annexiitechspeciiitechoffer_en) that the additional 2% of the total delivered desired diluents of the vaccines requested in section 4.4; ***however there is a posibility that the vaccines and diluent may include in the same package that will be delivered so we would like to request to change the defination to "diluent and vaccine together".*** In all and previoıs MMR teıders, 0.2% additional diluents reqıested in the Technical Specification. We woıld like to ask yoı to amend the percentage of additional doses to 0.2% from 2%.
Answer 25:	Please see Corrigendum No:1 to Tender Dossier.
Question 26:	**Regarding to Lot 3, Item 4.5;** The definitionin 4.5 section of in technical specifications (c4f_annexiitechspeciiitechoffer_en) which is: In Vaccine and Serum administrations, ***"Aşı ve Serum uygulamalarında, GENİŞLETİLMİŞ BAGIŞIKLAMA PROGRAMI GENELGESİ dikkate alınmalıdır. Bu konuda karşılaşılacak her tiirlii soru ve problemlerle ilgili olarak, Halk Sağlığı Genel Müdürlüğü Aşı ile Önlenebilir Hastalıklar Daire Başkanlığı veya İl Sağlık Müdürlükleri iletemasa geçilmelidir."*** To define as ***"Aşı ve Serum uygulamalarında, GENİŞLETİLMİŞ BAGIŞIKLAMA PROGRAMI GENELGESİ dikkate alınmalıdır.Bu konuda karşılaşılacak her türlü soru ve problemlerle ilgili olarak, T.C. Sağlık Bakanlığı Halk Sağlığı Genel Miidürliiği Aşı ile Önlenebilir Hastalıklar Daire Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir."***
Answer 26:	Please see Corrigendum No:1 to Tender Dossier.
Question 27:	**Regarding to Lot 3, Item 4.6;** The definition in 4.6 section of in technical specifications which is: Packages will then be placed in boxes. These boxes should include the name and address of the, manufacturer and representative, the name of the product, batch number, storage class, expiry date and the quantity of dose in the box. When the products are packed individually, ten boxes are placed in each box. If the products are packaged in groups of ten people, five boxes are placed in each box. To be rephrase as; **Packages will then be placed in boxes. These boxes shoıld include the name and address of the manufacturer and representative, the name of the product, batch number, storage class, expiry**

<table>
<tr><th colspan="2">ANNEX II – III TECHNICAL SPECIFICATIONS & TECHNICAL OFFER</th></tr>
<tr><td></td><td>date and the quantity of dose in the box. If the size of the presentation is not appropriate for the maximum by using a styrofoam volume from inside, packages can be placed into styrofoam without boxes or different box combinations can be used to use the maximum volume.</td></tr>
<tr><td>Answer 27:</td><td>Please see Corrigendum No:1 to Tender Dossier.</td></tr>
<tr><td>Question 28:</td><td>Regarding to Lot 3, Item 4;

In the order of the tender file c4f_annexiitechspeciiitechoffer_en, there is a transition from 4.10 to 4.12 in the order of the document. There is no 4.11 section. We kindly require the detials of of section 4.11</td></tr>
<tr><td>Answer 28:</td><td>Please see Corrigendum No:1 to Tender Dossier.</td></tr>
<tr><td>Question 29:</td><td>Regarding to Lot 4, Item 1.1;

Our Clarification requests are as follows;
Annex II-Technical Specifications
LOT-4 ; Item 1.1. TECHNICAL SPECIFICATION OF VACCINE ;
“The product shall conform to the properties and conditions specified in the World Health Organization Technical Report Series 848 Annex II, of European Pharmacopeia 9.0 01/2011:0648 monograph.."
Please consider to change the above specification as below:
“This shall be Annex I which is related to Varicella Vaccine.

It is a misspelling. In all the previous technical specifications, it is ‘Annex I’</td></tr>
<tr><td>Answer 29:</td><td>Please see Corrigendum No:1 to Tender Dossier.</td></tr>
<tr><td>Question 30:</td><td>Regarding to Lot 4, Item 2.1;

LOT-4 ; Item 2.1. DOCUMENTS TO BE INCLUDED IN THE FILE TO BE EXAMINED BY THE TENDER COMMISSION
" The product in question;
• should have the license or permission of use granted by the Ministry of Health of Republic of Turkey or,
• should be in the pre-qualification list published by the World Health Organization (WHO) the most recently or,
• should have the license of EMA (European Medicines Agency) or,
• should have the license of FDA (Food and Drug Administration) or,
• should have the license of Japanese Pharmaceuticals and Medical Devices Agency or,
• should have the license of South Korea Food and Drug Administration or,
• should have the license of Canada’s Food and Drug Administration or,
• should have the license of Australian Department of Health Therapeutic Goods Administration.
The product should have been used in minimum half of the annual cohort in the country where it is produced and for more than two years. "
Please consider to change the above specification as below:
" " The product in question;
• should have the license or permission of use granted by the Ministry of Health of Republic of Turkey or,
• should be in the pre-qualification list published by the World Health Organization (WHO) the most recently or,
• should have the license of EMA (European Medicines Agency) or,
• should have the license of FDA (Food and Drug Administration) or,
• should have the license of Japanese Pharmaceuticals and Medical Devices Agency or,
• should have the license of South Korea Food and Drug Administration or,
• should have the license of Canada’s Food and Drug Administration or,
• should have the license of Australian Department of Health Therapeutic Goods Administration.
<s>The product should have been used in minimum half of the annual cohort in the country where it is</s></td></tr>
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	~~***produced and for more than two years.***~~ *"* The product should have been used in minimum half of the annual cohort in the country where it is produced and for more than two years.' This shall be deleted. Such a request has never been done by Turkish MoH for any vaccine purchased up to now. Any vaccine which has been registered in any of these countries where regulatory requirements are very strict, means that it has been approved for its technical and clinical aspects. Further, varicella vaccine is a well established vaccine which has been in use for more than 10 years. Further even for any product registered in Turkey, it goes into public usage without any restrictions. Further such a limitation also blocks the competition where even there is such a low number of canditates are available. MoH was not able to get any offers for the first tender and this is why tender is opened to other possible suppliers out of EU.
Answer 30:	Requested revision was not approved, no changes or additions have been made.
Question 31	**Regarding to Lot 4, Item 2.4;** *"Brief Product Information" (KÜB) or prescribing information or "User Instruction for the Patient" (HKT) for the products as well as Turkish translations thereof should be available.* **Revised as follows:** Removal of the Turkish translation requirement as the language of the tender is English and the "Brief Product Information" is available in English.
Answer 31	Requested revision was not approved, no changes or additions have been made.
Question 32	**Regarding to Lot 4, Item 3.2;** *The contractor shall have served the shipment details to the Office 5 working days before the date of delivery of the product.* **Due to limited no of trucks from İstanbul to Ankara (with GMP compliant transporter company) we kindly ask this condition to be Revised as follows:** The contractor shall have served the shipment details to the Office minimum 2 working days before the date of delivery of the product.
Answer 32	Please see Corrigendum No:1 to Tender Dossier.
Question 33	**Regarding to Lot 4, Item 3.4;** *After the products are imported, the handling procedures are carried out by our contracted subcontractor residing in Istanbul. The ability to carry out the handling of the product in HSGM warehouses will result in additional costs by our subcontractor organizing the dispatch of technical equipment and personnel to work in Ankara. For this reason, after the first inspections are made under the supervision of the personnel of the institution, revision of the related article in order to enable the relevant handling operations in the intermediate warehouse licensed by TITCK and to enable the delivery of the heat records without being subject to a time limitation provided that the heat records are submitted.* **Revised as follows:** - In order the products purchased by DGOPH to be cleared from the customs, the contractor company shall enter the product details via Single Window Portal System (https://uygulama.gtb.gov.tr/Tek Pencere). If the products purchased by HSGM are imported, they will be brought to HSGM vaccine store within 48 hours after withdrawal. Necessary changes after the first examination (packaging, 2D Barcode etc) can be made in HSGM vaccine warehouse. - If the package change is to be made in a different place, this situation should be notified to the HSGM, the interim storage place must be licensed by MoH, the package of the customs cleared product should be opened under the supervision of the personnel of the institution and the shipment and interim storage heat records must be submitted during the inspection phase. HSGM can control all this process at any time and day after customs operations. If the HSGM allows the contractor company to use the interim storage must be licensed by MoH. Heat records should be kept from the production site to the warehouse and inside of

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	the warehouse, and certified copies must be delivered at the time of product delivery by the quality representative. HSGM should be open to review and evaluation if necessary. There should be no time limit for storage period under this circumstance. - In our country, the products that are filled / produced will be brought to the HSGM storage within 24 hours after leaving the facility. If the product which leaves the facility will not ready to be delivered to the HSGM storage within 24 hours after leaving the facility, the interim storage must be licensed by MoH. Heat records should be kept from the production site to the warehouse and inside of the warehouse, and certified copies must be delivered at the time of product delivery by the quality representative. HSGM should be open to review and evaluation if necessary.
Answer 33	Please see Corrigendum No:1 to Tender Dossier.
Question 34	**Regarding to Lot 4, Item 4.2.5;** *The stability works and their results which evidence the true shelf life of the product in question if any shall be available. Those documents shall not be requested in the preliminary acceptance but shall be delivered to the Presidency of Office of Diseases Preventable when the stability works are completed if the product is manufactured or filled in our country.* **Revised as follows:** Article 4.2.5 The stability works and their results which evidence the true shelf life of the product in question if any shall be available. Those documents shall not be requested in the preliminary acceptance but shall be delivered to the Presidency of Office of Diseases Preventable when the stability works are completed if the product is manufactured or filled in our country or imported to our country.
Answer 34	Requested revision was not approved, no changes or additions have been made.
Question 35	**Regarding to Lot 4, Item 4.2.6;** *The documents requested in 4.2 shall be in Turkish and if the documents submitted are not the original copies, they will be certified by DGOPH or notary public to be the true copies of the original documents.* **Revised as follows:** **The documents requested in 4.2 shall be in English and if the documents submitted are not the original copies, they will be certified by DGOPH or notary public to be the true copies of the original documents.**
Answer 35	Please see Corrigendum No:1 to Tender Dossier.
Question 36	**Regarding to Lot 4, Item 4.3.3;** *Each vaccine package shall contain minimum one "Brief Product Information" (KÜB) or prescribing information in Turkish or "Package Insert for the Patient" (HKT) prepared in conformity with the Regulation of Package Details of Human Medical Products, Package Insert and Track dated 25th April 2017 and numbered 30048. Furthermore, the following text shall be added at the top of KÜB or prescribing information in Turkish or HKT remarkably with bold and coloured font.* *"Aşı ve Serum uygulamalarında, GENİŞLETİLMİŞ BAĞIŞIKLAMA PROGRAMI GENELGESİ dikkate alınmalıdır.* *Bu konuda karşılaşılacak her türlü soru ve problemlerle ilgili olarak, Halk Sağlığı Genel Müdürlüğü Aşı ile Önlenebilir Hastalıklar Daire Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir."* **Revision of the article by adding the following sentence:** **As the product we purpose is not licensed by TITCK it is not subject to this regulation (25th April 2017 and numbered 30048) For the products that are not licensed in Turkey, package insert for the patient will be direct translation from its original.**
Answer 36	Requested revision was not approved, no changes or additions have been made.

ANNEX II – III TECHNICAL SPECIFICATIONS & TECHNICAL OFFER	
Question 37:	**Regarding to Lot 4, Item 4.3.3;** *"Each vaccine package shall contain minimum one "Brief Product Information" (KÜB) or prescribing information in Turkish or "Package Insert for the Patient" (HKT) prepared in conformity with the Regulation of Package Details of Human Medical Products, Package Insert and Track dated 25th April 2017 and numbered 30048. Furthermore, the following text shall be added at the top of KÜB or prescribing information in Turkish or HKT remarkably with bold and coloured font.* *"Aşı ve Serum uygulamalarında, GENİŞLETİLMİŞ BAĞIŞIKLAMA PROGRAMI GENELGESİ dikkate alınmalıdır.* *Bu konuda karşılaşılacak her türlü soru ve problemlerle ilgili olarak, Halk Sağlığı Genel Müdürlüğü Aşı ile Önlenebilir Hastalıklar Daire Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir."* **Please consider to change the above specification as below:** *"Each vaccine package shall contain minimum one "Brief Product Information" (KÜB) or prescribing information in Turkish or "Package Insert for the Patient" (HKT) prepared in conformity with the Regulation of Package Details of Human Medical Products, Package Insert and Track dated 25th April 2017 and numbered 30048. Furthermore, the following text shall be added at the top of KÜB or prescribing information in Turkish or HKT remarkably with bold and coloured font.* *"Aşı ve Serum uygulamalarında, GENİŞLETİLMİŞ BAĞIŞIKLAMA PROGRAMI GENELGESİ dikkate alınmalıdır.* *Bu konuda karşılaşılacak her türlü soru ve problemlerle ilgili olarak, Halk Sağlığı Genel Müdürlüğü Aşı ile Önlenebilir Hastalıklar Daire Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir."* ***In case of separately packaging of the diluent, it shall be available only in vaccine packages."*** **This specification should be changed according to the case of separately packaging of vaccines and diluents (Ref: Item number 4.3.9).**
Answer 37:	Requested revision was not approved, no changes or additions have been made.
Question 38	**Regarding to Lot 4, Item 4.3.4;** *Later, the packages shall be put into boxes. The names and addresses of the manufacturer and representative companies of the product, the name, batch number of the product, storage temperature, date of expiry, quantity of dose in the box shall be written on those boxes. If the products are packaged in one, ten shall be put in each box. If the products are packaged in ten, five shall be put in each box.* **Revised as follows:** **Later, the packages shall be put into boxes. The names and addresses of the manufacturer and representative companies of the product, the name, batch number of the product, storage temperature, date of expiry, quantity of dose in the box shall be written on those boxes. If the products are packaged in one, fifty shall be put in each box. If the products are packaged in ten, five shall be put in each box.**
Answer 38	Please see Corrigendum No:1 to Tender Dossier.
Question 39	**Regarding to Lot 4, Item 4.3.5;** *The package boxes shall be put in styrofoams. Then the styrofoams shall be put in parcels. The parcel dimensions shall be 40x60x40±2 (Width, Length, Height). Sufficient number of cool-packs or gel etc. shall be put in the parcels. The cool-packs or gel etc. put in the parcels shall be non-frozen. The names and addresses of the manufacturer and representative companies of the product, the name, batch number of the product, storage temperature, date of expiry, quantity of dose in the parcel, parcel dimensions and weight shall be written on those parcels.* **Revised as follows:** The package boxes shall be put in styrofoams. Then the styrofoams shall be put in parcels. The parcel dimensions shall be 40x60x40 **±20** (Width, Length, Height). Sufficient number of cool-packs or gel etc. shall be put in the parcels. The cool-packs or gel etc. put in the parcels shall be non-frozen. The names and addresses of the manufacturer and representative companies of the product, the name, batch number of the product, storage temperature, date of expiry, quantity of dose in the parcel, parcel dimensions and weight shall be written on those parcels.
Answer 39	Please see Corrigendum No:1 to Tender Dossier.

ANNEX II – III TECHNICAL SPECIFICATIONS & TECHNICAL OFFER	
Question 40:	**Regarding to Lot 4, Item 4.3.8;** *"Temperature monitoring during transfer; inside each parcel: one temperature monitor card and freezing indicator shall be available and there will be electronic digital monitor sensible to temperature and freezing that could make long term recording placed in each pallet. The digital monitors sensible to temperature and freezing that could make long term recording placed in each pallet shall be read at the stage of examination, the outputs shall be recorded in a minute and undersigned together with the company and upon request of the company those devices shall be returned to the company. The products detected not to have been transferred under convenient conditions (Annex 1 Class C packaging temperature limits for vaccines numbered WHO/IVB/05.23 published by the World Health Organization) under the control of those temperature monitors shall be returned. The contractor shall deliver the products with the same quantity from a different lot free of charge and in conformity with the specification to DGOPH within 120 calendar days from the date of notification to the contractor."* **Please consider to change the above specification as below:** " .Temperature monitoring during transfer; **If the vaccine and diluent are in the same package;** inside each parcel: one temperature monitor card and freezing indicator shall be available and there will be electronic digital monitor sensible to temperature and freezing that could make long term recording placed in each pallet. **If the vaccine and diluent are not in the same package: inside each vaccine parcel one temperature monitor card and inside each diluent parcel: one freezing indicator shall be available and there will be electronic digital monitor sensible to temperature and freezing that could make long term recording placed in each vaccine pallet** The digital monitors sensible to temperature and freezing that could make long term recording placed in each pallet shall be read at the stage of examination, the outputs shall be recorded in a minute and undersigned together with the company and upon request of the company those devices shall be returned to the company. The products detected not to have been transferred under convenient conditions (**If the vaccine and diluent are in the same package;** Annex 1 Class C packaging temperature limits for vaccines numbered WHO/IVB/05.23 published by the World Health Organization) under the control of those temperature monitors shall be returned. **In case of separate packaging of the diluent, vaccines will be considered Class B**. The contractor shall deliver the products with the same quantity from a different lot free of charge and in conformity with the specification to DGOPH within 120 calendar days from the date of notification to the contractor. **Products can be transferred by active temperature-controlled air cargo container without Styrofoam box. If it is transferred by active temperature-controlled air cargo; inside each vaccine parcel one temperature monitor card and inside each diluent parcel: one freezing indicator shall be available and there will be electronic digital monitor sensible to temperature and freezing that could make long term recording, placed in each vaccine pallet. If it is transferred by active temperature-controlled air cargo, products will be considered Class C."** This specification should be changed according to the case of separately packaging of vaccines and diluents (Ref: Item number 4.3.9). Ref. Document: WHO/IVB/05.23 Addition of transferred by active temperature-controlled air cargo container
Answer 40:	Please see Corrigendum No:1 to Tender Dossier.

APPENDIX 1 OF ANNEX II – III TECHNICAL SPECIFICATIONS & TECHNICAL OFFER	
Question 41:	2019 July delivery dated tender documents for Lot 3 The Measles, Mumps and Rubella Vaccine (MMR) 450.000 doses in Appendix-1 of TS_Delivery List and Period document to be rearrenged as November 2019 as production and logistic processes are effected due to the outbreak of measles in Europe.
Answer 41:	Please see Corrigendum No:1 to Tender Dossier
Question 42	About Lot 4 Varicella Vaccine Delivery schedule was planned as 225.000 doses to be delivered in July 2019. We started to work on supply schedule but unfortunately we will not be able to commit delivery in July as required. In order to get ready for any commitment we kindly ask from you to postpone the tender for

	at least 2 months. If it is postponed we will have the chance to work on a better delivery schedule and have an opportunity to participate the tender with a competitive price. Our proposal for this tender is: December 2019 75.000 ds February 2020 75.000 ds March 2020 75.000 ds
Answer 42	Please see Corrigendum No:1 to Tender Dossier

TENDER SUBMISSION FORM	
Question 43:	The c4l_tenderform_en document of the tender dossier is 9 pages in total. However, pages 8 and 9 are not visible in their order. We kindly request detailed information about the issue.
Answer 43:	The c4l_tenderform_en document is 9 pages as total, there is no missing pages. It has automatic page numbering error. when the related document is examined detaily, numbering as of 3rd page has returned to the top.
Question 44:	In the c4l_tenderform doc, there is a section as experiences. We are filling it with the vaccine and serum tenders that we supplied to Ministry of Health (MOH). The issues; - Which rate of currency should be applied for supply value (EUR) ? Most tenders were done in TL or USD. Should we use the currency of tender date to convert the supply value in EUR? - What does the origin of funding mean? For MOH's tender, the budget is reserved from MOH, Turkey. Therefore should the origin of funding be Turkey? - For ''Dates'' coloumn, which dates should we write? Should it be tender date or delivery term?
Answer 44:	For purposes of converting another currency to Euro, the Conversion rates, published in the Official Journal of European Communities shall be used, which can be found at: http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/index_en.cfm Please see Article 16 of Contract Notice

Ref # (maximum 15)	**Project title**		…					
Name of legal entity	**Country**	**Overall supply value (EUR)**	**Proportion supplied by legal entity (%)**	**No of staff provided**	**Name of client**	**Origin of funding**	**Dates**	**Name of members if any**
…	…	…	…	…	…	…	…	…
Detailed description of supply						**Related services provided**		
…						…		

TENDER GUARANTEE	
Question 45:	Must ''Tender Guarantee'' form be submitted in English draft form or can we submit the Turkish translation of it or both Turkish/English version in one letter? As our bank is only able to issue Turkish letter and not able to issue an English guarantee letter without receiver's (contracting authority) confirmation, we need to receive your instutation's feedback. Additionally our bank must pay the amount of tender guarantee in Turkish Liras for any need of recovery regarding international bank laws/rules. A related statement must be added on tender guarantee form as it is paid from the selling rate of exchange on the date of recovery. Please confirm if it is acceptable.
Answer 45:	The tender guarentee is one of the documents, which must be in the form of the template. Please refer to the point 11 "Content of tenders" of the Instructions to the Tenderers for further details.