CORRIGENDUM TO THE TENDER DOSSIER NO.1

Supply of Vaccines

Publication Reference: SIHHAT/2018/SUP/INT/11

The following alterations and/or corrections are made to the **Tender Dossier:**

INSTRUCTIONS TO TENDERERS

The former text:

Article 12 : Taxes and other charges

The applicable tax and customs arrangements are the following:

The European Commission and Republic of Turkey have agreed in IPA Framework Agreement on 11.02.2015 (this FWA adopted as law (no: 6647) by Turkish Parliament on 04 April 2015, which has been put into force by the government decree, no 2015/7708 that was published in Official Gazette no: 29393, dated 21 June 2015.) to fully exonerate the following taxes: Value Added Tax (VAT), Special Consumption Tax (SCT), Motor Vehicle Tax, Special Communication Tax, and/or taxes of equivalent effect, stamp or registration duties or any other charge having equivalent effect. Please refer to the articles 27&28 of the Framework Agreement.

Please also refer to the articles 25&26 of the Framework Agreement and the Communiqués issued by:

- The Ministry of Finance (MoF) thereto for further information, especially for exemption scope and implementation procedure, which are available at the MoF's website at: http://www.gib.gov.tr/uluslararasi_mevzuat.
- The Ministry of Customs and Trade (MoCT) thereto for further information, especially for facilities extended for customs clearance, which is available at the MoCT's website at: http://mevzuat.basbakanlik.gov.tr/Metin.Aspx?MevzuatKod=9.5.14369&Mevzuatiliski=0&sourceXmlSearch=Türkiye-AB Katılım Öncesi Yardım Aracı, published in the Official Gazette of Turkey, No:27730, on 15.10.2010.

Shall read as new text:

Article 12 : Taxes and other charges

The applicable tax and customs arrangements are the following:

The European Commission and Republic of Turkey have agreed in IPA Framework Agreement on 11.02.2015 (this FWA adopted as law (no: 6647) by Turkish Parliament on 04 April 2015, which has been put into force by the government decree, no 2015/7708 that was published in Official Gazette no: 29393, dated 21 June 2015.) to fully exonerate the following taxes: Value Added Tax (VAT), Special Consumption Tax (SCT), Motor Vehicle Tax, Special Communication Tax, and/or taxes of equivalent effect, stamp or registration duties or any other charge having equivalent effect. Please refer to the articles 27&28 of the Framework Agreement.

Please also refer to the articles 25&26 of the Framework Agreement and the Communiqués issued by:

- The Ministry of Finance (MoF) thereto for further information, especially for exemption scope and implementation procedure, which is available at the MoF's website at: http://www.gib.gov.tr/uluslararasi_mevzuat.
- The Ministry of Customs and Trade (MoCT) thereto for further information, especially for facilities extended for customs clearance, which is available at: http://www.resmigazete.gov.tr/eskiler/2010/10/20101015-5.htm Türkiye-AB Katılım Öncesi Yardım Aracı, published in the Official Gazette of Turkey, No:27730, on 15.10.2010.

ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER

Regarding to Lot 1: Hepatitis B Vaccine (Hep B)

The former text:

1.5	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.

Shall read as new text:

1.5	The vaccine shall preserve its stability at **between (+)2°C and (+)8°C** from the date of the last successful potency test of the manufacturer company till the date of expiry.

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The former text:

4.3.4	Unless specified in the specification, the product packages shall be in conformity with the Regulation of Package Details of Human Medical Products, Package Insert and Track dated 25th April 2017 and numbered 30048, furthermore "Brief Product Information" (KÜB) or prescribing information in Turkish or "Package Insert for the Patient" (HKT) prepared as minimum one shall be available in each of them. Furthermore, the following text shall be added at the top of KÜB or prescribing information in Turkish or HKT remarkably with bold and colored font. **"Aşı ve Serum uygulamalarında, Genişletilmiş Bağışıklama 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."**

Shall read as new text:

4.3.4	Unless specified in the specification, the product packages shall be in conformity with the Regulation of Package Details of Human Medical Products, Package Insert and Track dated 25th April 2017 and numbered 30048, furthermore "Brief Product Information" (KÜB) or prescribing information in Turkish or "**Patient Instruction Manual**" (HKT) prepared as minimum one shall be available in each of them. Furthermore, the following text shall be added at the top of KÜB or prescribing information in Turkish or HKT remarkably with bold and colored font. **"Aşı ve Serum uygulamalarında, Genişletilmiş Bağışıklama 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."**

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The former text:

4.3.6	The package boxes shall be put in styrofoams. Later the styrofoams shall be put in parcels. The dimensions of the parcels 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 but cooled. 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.

Shall read as new text:

4.3.6	The package boxes shall be put in styrofoams. Later the styrofoams shall be put in parcels. The dimensions of the parcels shall be **40x60x40cm ± 2cm** (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 but cooled. 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.

Regarding to Lot 2: BCG Vaccine

The former text:

3.2.3	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.

Shall read as new text:

3.2.3	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 "**T.C. Sağlık Bakanlığı Malıdır, SATILAMAZ, kontrolü (analizi) yapılmıştır.**" shall appear on the package of the product.

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The former text:

3.2.6	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.

Shall read as new text:

3.2.6	There will be "Brief Product Information" and "**Patient Instruction Manual**" in Turkish prepared in conformity with the Regulation of Medical Products Packaging and Labeling dated **25.04.2017** and numbered **30048**, 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 "**Patient Instruction Manual**" or "Prescribing Information" with bold and colored font.

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The former text:

3.2.7	"Aşı ve Serum uygulamalarında, genişletilmiş bağişiklama programi genelgesi 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"

Shall read as new text:

3.2.7	**"Aşı ve Serum uygulamalarında, GENİŞLETİLMİŞ BAĞIŞIKLAMA PROGRAMI GENELGESİ 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."**

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The former text:

3.2.9	The package boxes shall be put in styrofoams. Later the styrofoams shall be put in parcels. 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 does in the parcel, parcel dimensions and weight shall be written on those parcels.

Shall read as new text:

3.2.9	The package boxes shall be put in styrofoams. Later the styrofoams shall be put in parcels. 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 does in the parcel, parcel dimensions and weight shall be written on those parcels. **The package boxes shall be put in styrofoams. Later the styrofoams shall be put in parcels. The dimensions of the parcels shall be 40x60x40cm ±2 cm (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 but cooled. 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.**

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The former text:

3.2.10	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.

Shall read as new text:

3.2.10	Later the parcels shall be placed in a pallet. The pallets shall be euro pallet **(120x80x20cm ± 5cm)**. 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.**

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The former text:

3.2.12	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.

Shall read as new text:

3.2.12	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.

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The former text:

3.2.13.1	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.

Shall read as new text:

3.2.13.1	If the product and its diluents are in the same package, one temperature monitoring card and freezing indicator shall be available in each parcel and an electronic digital monitor sensitive to temperature and freezing that could make long term recording shall be available in each pallet.

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The former text:

3.2.13.2	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.

Shall read as new text:

3.2.13.2	If the product and its diluents are packaged separately one temperature monitoring card shall be available in each parcel and an electronic digital monitor sensitive to temperature and freezing that could make long term recording shall be available in each pallet; one freezing indicator shall be available in each parcel and an electronic digital monitor sensitive to temperature and freezing that could make long term recording shall be available in each pallet.

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The former text:

3.2.13.3	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.

Shall read as new text:

3.2.13.3	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 cannot be Class B.**

The former text:

3.3.1	The lifetime of the product shall be 15 (fifteen) months from the moment of delivery.

Shall read as new text:

3.3.1	The lifetime of the product shall be **minimum** 15 (fifteen) months from the moment of delivery.

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The former text:

4.5	Depending on the strain used, it shall contain living gem within the limits expected in 1 ml of vaccine.

Shall read as new text:

4.5	Depending on the strain used, it shall contain living **germ** within the limits expected in 1 ml of vaccine.

Regarding to Lot 3: The Measles, Mumps and Rubella Vaccine (MMR)

The former text:

1.4.	In the last two years, there shall be a certificate of analysis for any lot number produced by the manufacturer. The analysis certificate shall comply with the latest technical reports of the World Health Organization and the features and conditions specified in the latest published European Pharmacopoeia. At each dose of vaccine, at least 10^3 CCID50 live attenuated measles, 10^3 CCID50 live attenuated rubella, 103.7 CCID50 live attenuated mumps virus shall be included. The vaccine shall be produced from "heat stable" strains, which shall be disclosed on offer. The vaccine`s mumps component shall be Jeryl Lynn originated.

Shall read as new text:

1.4.	In the last two years, there shall be a certificate of analysis for any lot number produced by the manufacturer. The analysis certificate shall comply with the latest technical reports of the World Health Organization and the features and conditions specified in the latest published European Pharmacopoeia. At each dose of vaccine, at least 10^3 CCID50 live attenuated measles, 10^3 CCID50 live attenuated rubella, $10^{3.7}$ CCID50 live attenuated mumps virus shall be included. The vaccine shall be produced from "heat stable" strains, which shall be disclosed on offer. The vaccine`s mumps component shall be Jeryl Lynn originated. **The pork gelatine will not be included in the vaccine.**

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The former text:

2.2.	Before 5 working days of the delivery date of the contractor, the shipment details shall be sent to the Department of Diseases Preventable by Vaccines of the General Directorate of Public Health.

Shall read as new text:

2.1.	Before 5 working days of the delivery date of the contractor, the shipment details shall be sent to the Department of Diseases Preventable by Vaccines of the General Directorate of Public Health.

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The former text:

3.2.	There shall be a Batch Release Certificate issued by the WHO-approved National Regulatory Authority / Laboratory (NCL / NRA) for the batch number delivered. These documents should be in Turkish and English, and it should be the original or it shall be approved by notary as true copy of the original.

Shall read as new text:

3.1.	There shall be a Batch Release Certificate issued by the WHO-approved National Regulatory Authority / Laboratory (NCL / NRA) for the batch number delivered. These documents should be in Turkish and English, and it should be the original or it shall be approved by notary as true copy of the original.

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The former text:

4.2.	The product shall be a single dose and packaged in a vial or ampoule of up to ten vials or as a ready-to-use syringe. If the products are packed in ten packs, there shall be a separator such as foam, cardboard or plastic which prevents the vials or ampoule or the ready-to-use injectors from being broken by contact.

Shall read as new text:

4.1.	The product shall be a single dose and packaged in a vial or ampoule of up to ten vials or as a ready-to-use syringe. If the products are packed in ten packs, there shall be a separator such as foam, cardboard or plastic which prevents the vials or ampoule or the ready-to-use injectors from being broken by contact.

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The former text:

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 shall be written and be undeletable. On the package of the product, it shall say **"T.C Sağlık Bakanlığı Malıdır, SATILAMAZ."**

Shall read as new text:

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 shall be written **on inner package and package** and **they will be non-erasable**. On the package of the product, it shall say **"T.C. Sağlık Bakanlığı Malıdır, SATILAMAZ, kontrolü (analizi) yapılmıştır."**

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The former text:

4.4.	The amount of diluent to be delivered shall be 2% more than the number of product vials or ampoules.

Shall read as new text:

4.4.	The amount of diluent to be delivered shall be 2% more than the number of product vials or ampoules. **If the diluent and vaccine will be delivered together, shall be 0.2% more than the number of product vials or ampoules.**

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The former text:

4.5.	Turkish "Short Product Information" or "Patient Instruction Manual" prepared in accordance with the Regulation on Packaging and Labelling of Medicinal Products for Human Use, dated 12.08.2005 and numbered 25904, in the package of the individually packaged product, one in each, and one in each of the ten packages. In addition, the following text shall be inserted in bold and coloured text to Turkish "Short Product Information" or "Instruction of Use for Patient" or "prospectus". **"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."***

Shall read as new text:

4.5.	Turkish "Short Product Information" or "Patient Instruction Manual" prepared in accordance with the Regulation on Packaging and Labelling of Medicinal Products for Human Use, dated **25.04.2017** and numbered **30048**, in the package of the individually packaged product, one in each, and one in each of the ten packages. In addition, the following text shall be inserted in bold and coloured text to Turkish "Short Product Information" or "**Patient Instruction Manual** " or "prospectus". ***"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 Müdürliiği Aşı ile Önlenebilir Hastalıklar Daire Başkanlığı veya İl Sağlık Müdürlükleri ile temasa geçilmelidir."***

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The former text:

4.6.	The packages shall then be placed in the boxes. On these boxes, the name and address of the product manufacturer and representative company, the name of the product, the batch number, the storage grade, the expiry date and the dose amount in the box shall be written. If the products are packed singly, ten packages shall be placed in each box. If the products are packed in groups of ten, five packages shall be placed in each box.

Shall read as new text:

4.6.	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 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.

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The former text's item numbers:

4.12.	Temperature monitoring during transport;
4.12.2.	If the product and its diluent is in the same package, there shall be a temperature monitoring card and freezing indicator in each of the parcels stated in article 4.7. and a digital monitor sensitive to heat and freezing capable of recording for long periods in each pallet stated in article 4.8.

4.12.2.	If the product and its diluent are packed separately, there shall be a temperature monitor card in each of the vaccine parcels stated in article 4.7 and a digital monitor sensitive to heat and freezing capable of recording for long periods in each pallet stated in article 4.8., there shall be a freezing indicator in each of the diluent parcels stated in article 4.7. and a digital monitor sensitive to heat and freezing capable of recording for long periods in each pallet stated in article 4.8.
4.12.	Digital observers with electronic, heat and frost-sensitive long-term recording on the pallet shall be read during inspection; print-outs shall be signed with the firm and these devices shall be returned to the firm if requested by the firm. The products found not to be transported under appropriate conditions of heat monitors (World Health Organization WHO/IVB/05.23 for vaccines Annex I Class B packaging heat limits for diluents) shall be returned. The Contractor shall deliver the same amount of different batch products free of charge and in accordance with the specifications to the General Directorate of Public Health within 120 calendar days from the date of notification to the contractor.

Shall read as text's new item numbers:

Incorrect numbering for Lot 3, has been corrected as follows;

4.11.	Temperature monitoring during transport;
4.11.1.	If the product and its diluent is in the same package, there shall be a temperature monitoring card and freezing indicator in each of the parcels stated in article 4.7. and a digital monitor sensitive to heat and freezing capable of recording for long periods in each pallet stated in article 4.8.
4.11.2.	If the product and its diluent are packed separately, there shall be a temperature monitor card in each of the vaccine parcels stated in article 4.7 and a digital monitor sensitive to heat and freezing capable of recording for long periods in each pallet stated in article 4.8., there shall be a freezing indicator in each of the diluent parcels stated in article 4.7. and a digital monitor sensitive to heat and freezing capable of recording for long periods in each pallet stated in article 4.8.
4.12.	Digital observers with electronic, heat and frost-sensitive long-term recording on the pallet shall be read during inspection; print-outs shall be signed with the firm and these devices shall be returned to the firm if requested by the firm. The products found not to be transported under appropriate conditions of heat monitors (World Health Organization WHO/IVB/05.23 for vaccines Annex I Class B packaging heat limits for diluents) shall be returned. The Contractor shall deliver the same amount of different batch products free of charge and in accordance with the specifications to the General Directorate of Public Health within 120 calendar days from the date of notification to the contractor.

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The former text:

4.13.	The lifetime of the product shall be 15 (fifteen) months from the moment of delivery.

Shall read as new text:

4.13.	The lifetime of the product shall be **minimum** 15 (fifteen) months from the moment of delivery.

Regarding to Lot 4: Varicella Vaccine

The former text:

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.

Shall read as new text:

1.1	The product shall conform to the properties and conditions specified in the World Health Organization Technical Report Series 848 **Annex I**, of European Pharmacopeia 9.0 01/2011:0648 monograph.

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The former text:

1.3	The vaccine shall be attenuated, purified and lyophilized.

Shall read as new text:

1.3	The vaccine shall be attenuated, purified and lyophilized. **The pork gelatine will not be included in the vaccine.**

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The former text:

3.2	The contractor shall have served the shipment details to the Office 5 working days before the date of delivery of the product.

Shall read as new text:

3.2	The contractor shall have served the shipment details to the Office **(DGoPH, Directorate of Vaccine Preventable Diseases)** 2 **calendar days** before the date of delivery of the product.

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The former text:

3.4	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 DGOPH are imported products, they will be brought to the Vaccine Warehouse of DGOPH within 48 hours (except for the products filled in Turkey). The modifications necessary to be performed after the first examination (packaging, 2-D barcode etc.) shall be performed in the Vaccine Warehouse of DGOPH. Those products not delivered to the Vaccine Warehouse of DGOPH within 48 hours from the moment of clearance from the customs shall not be accepted. The products filled in Turkey will be brought to the Vaccine Warehouse of DGOPH within 24 hours from their exit from the filling facility. If they will not be delivered to the Vaccine Warehouse of DGOPH within 24 hours but will be kept in any other warehouse, it is mandatory that the institution where interim storage shall be made is licensed by the Ministry of Health of Republic of Turkey; the temperature records from the place of production to the warehouse as well as inside of warehouse should be stored and the copies of the same approved by the product quality representative should be delivered to the Office in product delivery. Those stages should be available for examination and assessment if deemed necessary by the Office. The Office should be informed in the case interim storage is required. If the conditions specified are not met, the products shall not be accepted.

Shall read as new text:

3.4	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 DGOPH are imported products, they will be brought to the Vaccine Warehouse of DGOPH within 48 hours (except for the products filled in Turkey). The modifications necessary to be performed after the first examination (packaging, 2-D barcode etc.) shall be performed in the Vaccine Warehouse of DGOPH. Those products not delivered to the Vaccine Warehouse of DGOPH within 48 hours from the moment of clearance from the customs shall not be accepted. The products filled in Turkey will be brought to the Vaccine Warehouse of DGOPH within 24 hours from their exit from the filling facility. If they will not be delivered to the Vaccine Warehouse of DGOPH within 24 hours but will be kept in any other warehouse, it is mandatory that the institution where interim storage shall be made is licensed by the Ministry of Health of Republic of Turkey; the temperature records from the place of production to the warehouse as well as inside of warehouse should be stored and the copies of the same approved by the product quality representative should be delivered to the Office in product delivery. Those stages should be available for examination and assessment if deemed necessary by the Office. **If the product required interim storage after the Import, Filling or Production; interim storage can be made on the condition that information is given to the DGoPH, Directorate of Vaccine Preventable Diseases (which storage and storage period) and its approval is obtained.** If the conditions specified are not met, the products shall not be accepted.

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The former text:

4.1	The lifetime of the product shall be 15 (fifteen) months from the moment of delivery.

Shall read as new text:

4.1	The lifetime of the product shall be **minimum** 15 (fifteen) months from the moment of delivery.

.....

The former text:

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.

Shall read as new text:

4.2.6	The documents requested in 4.2 **(except that 4.2.5)** 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. **Also, electronic version (soft copies) of these documents will be provided in the CD/DVD/Flash disk.**

.....

The former text:

4.3.2	The name of the manufacturer and the product, its dose, batch number, date of expiry, quantity of ingredients per dose (in ml. or U), 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 vaccines or if any blister and package. It should be written on the package rather than blister.

Shall read as new text:

4.3.2	The name of the manufacturer and the product, its dose, batch number, date of expiry, quantity of ingredients per dose (in ml. or U), 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 "**T.C. Sağlık Bakanlığı Malıdır, SATILAMAZ, kontrolü (analizi) yapılmıştır.**" shall appear on the vaccines or if any blister and package. It should be written on the package rather than blister.

.....

The former text:

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."

Shall read as new text:

4.3.3	Each vaccine package shall contain minimum one "Brief Product Information" (KÜB) or prescribing information in Turkish or "**Patient Instruction Manual**" (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 BAGIŞIKLAMA PROGRAMI GENELGESİ 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 Sağlık Müdürlükleri ile temasa geçilmelidir."***

.....

The former text:

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.

Shall read as new text:

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 **or fifty** shall be put in each box. If the products are packaged in ten, five shall be put in each box.

.....

The former text:

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.

Shall read as new text:

4.3.5	The package boxes shall be put in styrofoams. Then the styrofoams shall be put in parcels. The parcel dimensions shall be **40x60x40cm ± 20cm** (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. **Each parcels' gross weight maximum shall be 40 kg.**

.....

The former text:

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.

Shall read as new text:

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. **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.

APPENDIX 1 OF ANNEX II – III TECHNICAL SPECIFICATIONS & TECHNICAL OFFER

The former text:

Lot No	Lot Name	Delivery Period and Delivery Place	
		2019	
1	Hepatitis B Vaccine (Hep B)	675.000 doses in 2019 July	Saracalar Mahallesi Turgut Özal Bulvarı General Özkan Özgün Sk. No.349 Akyurt-ANKARA
2	BCG Vaccine	1.050.000 doses in 2019 July	Saracalar Mahallesi Turgut Özal Bulvarı General Özkan Özgün Sk. No.349 Akyurt-ANKARA
3	The Measles, Mumps and Rubella Vaccine (MMR)	450.000 doses in 2019 July	Saracalar Mahallesi Turgut Özal Bulvarı General Özkan Özgün Sk. No.349 Akyurt-ANKARA
4	Varicella Vaccine	225.000 doses in 2019 July	Saracalar Mahallesi Turgut Özal Bulvarı General Özkan Özgün Sk. No.349 Akyurt-ANKARA

Shall read as new text:

Lot No	Lot Name	Delivery Period and Delivery Place	
		Doses/2019	**Delivery Place**
1	Hepatitis B Vaccine (Hep B)	675.000 doses in 2019 July	Saracalar Mahallesi Turgut Özal Bulvarı General Özkan Özgün Sk. No.349 Akyurt-ANKARA
2	BCG Vaccine	1.050.000 doses in 2019 July	Saracalar Mahallesi Turgut Özal Bulvarı General Özkan Özgün Sk. No.349 Akyurt-ANKARA
3	The Measles, Mumps and Rubella Vaccine (MMR)	450.000 doses in 2019 **September**	Saracalar Mahallesi Turgut Özal Bulvarı General Özkan Özgün Sk. No.349 Akyurt-ANKARA
4	Varicella Vaccine	225.000 doses in 2019 **September**	Saracalar Mahallesi Turgut Özal Bulvarı General Özkan Özgün Sk. No.349 Akyurt-ANKARA

TENDER DOSSIER

Following attachments have been added to Tender Dossier and Annex V-ii- Taxes and Customs Arrangements (*c4m_taxcustomsarrangements_en_IPA-II*) **has been revised:**

- **Administrative Compliance Grid** *(c4j_admingrid_en)*
- **Evaluation Grid** *(c4k_evalgrid_en)*
- **Annex V-ıı: Taxes and Customs Arrangements** *(c4m_taxcustomsarrangements_en_IPA-II)*

ADMINISTRATIVE COMPLIANCE GRID

Contract title :	**Supply of Vaccines**	**Publication reference :**	SIHHAT/2018/SUP/INT/11

Tender envelope number	Name of tenderer	Is tenderer (consortium) nationality[1] eligible? (Y/N)	Is documentation complete? (Y/N)	Is language as required? (Y/N)	Is tender submission form complete? (Y/N)	Is tenderer's declaration signed (by all consortium members if a consortium)? (Yes/No/ Not Applicable)	Other administrative requirements of the tender dossier? (Yes/No/Not applicable)	Overall decision? (Accept / Reject)
1								
2								
3								
4								
5								
6								

Chairperson's name	
Chairperson's signature	
Date	

ıationalities of **all** the consortium members must be eligible.

EVALUATION GRID

Contract title :	**Supply of Vaccines**	**Publication reference :**	**SIHHAT/2018/SUP/INT/11**

Tender envelope No	Name of tenderer	Rules of origin respected? (Y/N)	Economic & financial capacity? (OK/a/b/…)	Professional capacity? (OK/a/b/…)	Technical capacity? (OK/a/b/…)	Compliance with [1]technical specifications? (OK/a/b/…)	Ancillary services as required? (OK/a/b/…/NA)	Subcontracting statement in accordance with art. 6 of the general conditions? (Y/N)	Other technical requirements in tender dossier? (Yes/No/Not applicable)	Technically compliant? Y/N)	Justification/ notes:
1											
2											
3											
4											

Evaluator's name & signature	
Evaluator's name & signature	
Evaluator's name & signature	
Date	

[1] The selection criteria, in the previous section of this form, have to be met before the technical requirements are assessed.

ANNEX V- TAXES AND CUSTOMS ARRANGEMENTS

Article 27 and 28 from the Framework Agreement[1], signed on 11th of February 2015

The contract is, as a rule, exempt from all taxes and duties, including value added tax (VAT) and Special Consumption Tax (SCT), Motor vehicle tax, Special communication tax, and/or taxes of equivalent effect, stamp or registration duties, special charges or any other charge having equivalent effect, pursuant to the provisions of Articles set out in the Framework Agreement signed between the Republic of Turkey (hereinafter will be referred "Turkey") and the EU in 2015, extract of Article 27 & 28 of which are provided below.
The Contractor shall accordingly complete the necessary formalities with the relevant authorities to ensure that the goods and/or services and/or works and/or grant activities required for performance of the Contract are exempt from taxes, customs, import duties, levies and/or taxes of equivalent effect, and stamp or registration duties or special charges or any other charge having equivalent effect in accordance with the rules that are set out below. Any matter not covered by the below provisions on tax and customs arrangements shall remain subject to the national legislation of Turkey.
The relevant provisions of the Framework Agreement (the FWA) are as follows:

Granting of facilities for the implementation of programmes and execution of contracts

(1) In order to ensure the effective implementation of programmes under IPA II, Turkey shall take all necessary measures to ensure:

(a) that, in case of service, supplies or works tender procedures as well as grant awards and twinnings, natural or legal persons eligible to participate in award procedures pursuant to Article 19 shall be entitled to temporary installation and residence where the importance or the duration of the contract so warrants. This right shall be acquired only after the procedure has been launched and shall be enjoyed by the managerial and technical staff including RTAs, needed to carry out studies and other preparatory measures to the drawing up of bids/applications/proposals. This right shall expire one month after the decision of contract award;

(b) that tenderers and applicants can submit their bids/applications/proposals without encountering any obstacle such as additional legal, administrative or customs related requirements that impair equal treatment among tenderers or applicants unless such requirements are enshrined in an underlying programme document adopted by the Commission;

(c) that personnel taking part in the implementation of IPA II assistance and members of their immediate family are accorded no less favourable benefits, privileges and exemptions than those usually granted to other international or expatriate staff employed in the Republic of Turkey, under any other bilateral or multilateral agreement or arrangements for assistance and technical co-operation;

(d) that personnel taking part in the implementation of IPA II assistance and members of their immediate family are allowed to enter the Republic of Turkey, to establish themselves in the

[1] This is an extract of Article 27 and 28 of the IPA Framework Agreement signed between Turkey and the European Union Commission on 11.02.2015, and adopted as law by Turkish Parliament (no: 6647) on 04 April 2015 and which was published in the Turkish Official Gazette on 28 April 2015, no: 29340. It has been put into force by the government decree, no 2015/7708 that was published in Official Gazette no: 29393, dated 21 June 2015.

Please, also refer to the Framework Agreement, and the Communiqués issued by:

- ***the Ministry of Trade (the MoT) thereto for further information, especially for exemption scope and implementation procedure, which are available at the MoF's website at: http://www.gib.gov.tr//sites/default/files/fileadmin/mevzuatek/uluslararasi_mevzuat/1_SIRA_NOLU_IPA_GENEL_TEBLIGI.pdf***
- ***The Ministry Trade (MoT) thereto for further information, especially for faclities extented for customs clearance, which is available at: http://www.resmigazete.gov.tr/eskiler/2010/10/20101015-5.htm , Türkiye - AB Katılım Öncesi Yardım Aracı, published in the Offcial Gazzette of Turkey, No: 27730, on 15.10.2010.***

Republic of Turkey, to work there and to leave the Republic of Turkey, as the nature of the underlying contract so justifies;

(e) the granting of all permits necessary for the importation of goods, in particular professional equipment, required for the execution of the underlying contract, subject to existing laws, rules and regulations of Turkey*;*

(f) that imports carried out under IPA II will be exempted from all charges;

(g) the granting of all permits necessary for the re-export of the above goods, once the underlying contract has been fully executed;

(h) the granting of authorisations for the import or acquisition of the foreign currency necessary for the implementation of the underlying contract and the application of national exchange control regulations in a non-discriminatory manner to contractors, regardless of their nationality or place of establishment;

(i) the granting of all permits necessary to repatriate funds received in respect of the action financed under IPA II, in accordance with the foreign exchange control regulations in force in the Republic of Turkey;

(j) that transactions necessary for carrying out contracts financed under IPA II will be exempted from procedures requiring the transfer of the payment for goods and/or services to their contractors abroad through banks or financial institutions operating in the Republic of Turkey.

(2) Turkey shall ensure full co-operation of all relevant authorities. It will also ensure access to state-owned companies and other governmental institutions, which are involved or are necessary in the implementation of a programme or in the execution of the contract.

(3) After the entry into force of this Agreement Turkey shall adopt or amend the legislation and/or enabling acts necessary to enforce the requirements of the procedures laid down in this article while keeping these procedures as simple, reasonable and time efficient as possible.

Rules on taxes, customs duties and Other Fiscal Charges

(1) Except where otherwise provided for in a Sectoral Agreement or a Financing Agreement, taxes, customs and import duties and levies and/or charges having equivalent effect are not eligible under IPA II. The tax exemptions under the scope of the above-mentioned rule shall also apply to co-financing provided by Turkey and natural and/or legal persons that receive IPA II assistance.

(2) The following provisions shall apply:

(a) All imports by Union contractors shall be allowed to enter the Republic of Turkey without being subject to customs or import duties, Value Added Tax (VAT), excise duties and other special consumption taxes or to any other similar tax, duties or charges having equivalent effect. Such exemption shall only be applied to imports in connection with the goods supplied and/or services rendered and/or works executed by the Union contractors under a Union contract. The Republic of Turkey shall ensure that the imports concerned will be released from the point of entry for delivery to the Union contractors as required by the provisions of the contract and for immediate use as required for the normal implementation of the contract, without any delays or disputes over the settlement of the above mentioned duties, taxes or charges;

(b) Union contractors shall be exempted from VAT for any service rendered and/or goods supplied and/or works executed under the Union contract. Goods supplied or services rendered or works executed by a contractor to the Union contractor shall also be exempted from VAT in so far that they are connected with the objectives and activities under the Union contract;

(c) The exemption provided for in paragraph (b) shall in principle be put into effect through ex-ante exemption. Where this is not technically and/or practically feasible, it shall be put into effect through refund/offsetting.

Where ex-ante exemption applies, the Union contractor or the contractor supplying goods and/or rendering services and/or executing works for a Union contractor, shall issue an invoice exclusive of VAT for which Turkey shall ensure that an effective mechanism and procedures for VAT ex-ante exemption has been put in place beforehand.

Where the refund procedure applies, Union contractors and contractors to the Union contractors shall be able to obtain a VAT refund directly from the tax administration upon submission of a written request to the tax administration accompanied by the necessary documentation required under the Republic of Turkey law for the refund of VAT.

The Union contractor and contractors to the Union contractors shall be entitled to offset or deduct any input VAT in connection with the goods supplied and/or services rendered and/or works executed under IPA II assistance which are exempted from VAT, as provided in this Agreement, against any VAT collected by them for any of their ordinary business transactions outside IPA II.

Upon submission of the necessary documentation, the tax administration shall complete any request for exemption, tax refund, and offsetting within a maximum of 30 calendar days without any cost other than minimum and reasonable administrative fees;

(d) Profit or income arising from Union contracts shall be taxable in the Republic of Turkey in accordance with the national/local tax system. However, natural and legal persons, including expatriate staff and RTAs, resident or established in the Member States of the European Union or other countries eligible under IPA II other than Turkey, executing Union contracts shall be exempted from profit or income tax in the Republic of Turkey, including withholding and provisional or temporary taxes except in cases where the natural and/or legal person making such profit and/or income has its residence or a permanent establishment to which such income is attributable in the Republic of Turkey according to the provisions of the applicable double taxation agreements.

A Union grant to a grant beneficiary shall not be construed as a profit or income to that grant beneficiary. Where a profit is generated from a grant contract, the Commission shall be entitled to recover the percentage of the profit in accordance with the terms of the underlying contract. The remaining profit may be taxable according to the national/local tax system. "Profit" in the context of this paragraph means a surplus of the receipts over the eligible costs approved by the Contracting Authority when the request for payment of a balance is made;

(e) Expenditures of the Union contractors shall be relieved from special consumption taxes or excise duties or from any other taxes or charges having equivalent effect for the expenditure in connection with the goods supplied and/or services rendered and/or works executed by that Union contractor under the Union contract;

(f) Those benefiting from actions and/or contracts and/or activities carried out under IPA II shall be exempted from “Inheritance and Transfer Tax” or any other taxes or charges having equivalent effect resulting from goods and/or rights and/or constructed facilities and/or funds transferred to them without consideration in any way under IPA II;

(g) Personal and household effects imported for personal use by natural persons (and members of their immediate families), other than those recruited locally, carrying out tasks defined in service and/or works and/or grant contracts and/or twinning contracts or covenants, shall be exempted from customs duties, import duties, taxes and levies and/or taxes having equivalent effect and/or deterrent excessive collateral requirements, the said personal and household effects being re-exported or disposed of in the state, in accordance with the regulations in force in the Republic of Turkey after termination of the contract;

(h) Union contracts, contracts signed by Union contractors as well as partners in a consortium or joint venture or co-beneficiaries and affiliated entities (as defined in Article 122 of the Financial Regulation) in grants shall not be subject to stamp or registration duties, or to any other charge having equivalent effect in the Republic of Turkey. This exemption shall also

apply to transactions (including assignment of rights) and documents related to payments made to the Union contractor, including contracts concluded between grant beneficiaries (including their partners, affiliated entities or sub-grant beneficiaries) and their contractors (including their staff or contracted experts), and contracts concluded for incidental and provisional expenditure under service contracts and works contracts respectively where such payments are directly related to the Union contract;

(i) For the purposes of this Agreement, the term "*Union contractor*" shall be construed as natural and legal persons, rendering services and/or supplying goods and/or executing works under a Union contract. The term "Union contractor" shall also refer to grant beneficiaries (including partners, affiliated entities as identified in a Union contract and sub-grant beneficiaries as well as twinning contractors), partners in a consortium or joint venture, contractors and RTAs under twinning contracts as well as contractors under the Technical assistance and Information exchange instrument (TAIEX);

(j) The term "*Union contract*" means any contract or grant contract, including sub-grant contracts and delegation agreements under indirect management, through which an activity is financed under IPA II, including the co-financing by Turkey or natural and/or legal persons of IPA II assistance and which is signed by the European Commission or Turkey or a grant beneficiary when related to Union contracts. The term "Union contract" shall also cover provisions of assistance under TAIEX and participation in Union programmes including grants received under Union programmes and co-financing of such grants;

(k) The following charges shall also be exempted for Union contractors implementing a Union contract:

(i) special communication tax;

(ii) motor vehicle taxes;

(iii) special charges applied under:

The law as to Revenues of Municipalities re.no 2464 (Belediye Gelirleri Kanunu, in particular Additional Article 1 -Charges for Construction of Buildings, 79-Registration and Copies of Document, 80- Charges to Land Development)

The law on the Conservation of Cultural Heritages and Natural Property, ref.no 2863 (Kültür ve Tabiat Varlıklarını Koruması Kanunu)".

(3) Whenever necessary, Turkey shall adopt or amend the secondary legislation and/or enabling acts necessary to enforce the tax provisions in this Agreement immediately upon its entering into force.

(4) The rules and procedures referred to in this Article shall also apply to any similar tax, duty, levy or charges having equivalent effect which are in force or which may be instituted after the date of entry into force of this Agreement in addition to, or in replacement of existing ones.

(5) In case of conflict between the provisions in this Article and the national legislation of Turkey, the provisions of this Agreement shall prevail. In the event of accession to the Union, Turkey will continue to apply the provisions in articles 27 and 28 except where these are incompatible with its obligations under the relevant Union acquis.