AKDENİZ İHRACATÇI BİRLİKLERİ
GENEL SEKRETERLİĞİ

Sayı: 17812098-TİM.AKİB.GSK.SAN.2021/219-2635 Mersin, 12/05/2021
Konu: Türkiye-Birleşik Krallık STA-Teknik Düzenlemeler

Sayın Üyemiz,

Ticaret Bakanlığı İhracat Genel Müdürlüğü'nden alınan yazıda; Ülkemiz ile BK arasında tesis edilen Serbest Ticaret Anlaşması'nın (STA) "Ticarette Teknik Engeller (TTE)" Faslının mezkur STA'nın yürürlüğe girişinden itibaren 3 ay içerisinde gözden geçirilmesine ilişkin mevcut taahhüt bağlamında Bakanlıkları içerisinde bu Fasıl özelinde oluşturulan Çalışma Grubu dahilinde ülkemiz pozisyonunun oluşturulması amacıyla sektör istişare toplantılarının gerçekleştirildiği belirtilmektedir.

Bu kapsamda, BK ile ülkemiz arasındaki STA'nın TTE bölümünün gözden geçirilmesi sürecinde atılabilecek sektörel adımlar göz önünde bulundurularak; makine, elektrikli cihaz ve kablo alanında AB ve BK arasında tesis edilen UKCA uygulamalarının yanı sıra TTE metnin üçüncü sektörel ekini oluşturan ve bir örneği ekte sunulan (Ek-2) "Annex TBT-3: Kimyasallar" ve (Ek-3) "Annex TBT-2: Beşeri Tıbbi İlaçlar" ile Türkiye'nin AB'nin ilgili teknik mevzuatına uyum süreci de gözetilerek BK ile tesis edilebilecek işbirliği alanları hakkındaki sektör çatı kuruluşlarının görüşlerinin alınması önem arz etmektedir.

Yukarıda ifade edilen hususlar çerçevesinde, ülkemiz ile BK arasında başlatılması öngörülen "Ticarette Teknik Engeller" (TTE) Faslının gözden geçirilmesi, ülkemiz pozisyonuna ilişkin istişarelerde bulunulması amacıyla Ürün Güvenliği ve Denetimi Genel Müdürü Sayın Veysel Parlak başkanlığında, **makine, elektrikli cihaz ve kablo sektörünün** ele alınacağı çevrimiçi toplantı **17 Mayıs 2021 tarihinde** saat 14.30'da; **tıbbi ilaç sektörünün** ele alınacağı toplantı ise **18 Mayıs 2021 -tarihinde** saat 14.30'da; **kimyasallar sektörünün** ele alınacağı toplantı ise **21 Mayıs 2021 tarihinde** saat 14:30'da gerçekleştirileceği ifade edilmekte olup, söz konusu toplantılara katılım sağlaması öngörülen sektör temsilcilerinin isim ve irtibat bilgilerinin **12 Mayıs 2021 Çarşamba günü 13:00'e kadar** ve sanayi@akib.org.tr adresine bildirilmesi gerekmektedir.

Bilgileri ve gereğini rica ederim.

Mehmet Ali ERKAN
Genel Sekreter

Ekler;
1- AB-BK Anlaşması TTE Faslı
2- Annex TBT-3: Kimyasallar
3- Annex TBT-2: Beşeri Tıbbi İlaçlar

Akdeniz İhracatçı Birlikleri Genel Sekreterliği
Limonluk Mah. Vali Hüseyin Aksoy Caddesi No:4
Yenişehir/MERSİN
Telefon: (0324) 325 37 37 Fax.: (0324) 325 41 42
E-posta: info@akib.org.tr Elektronik Ağ: www.akib.org.tr

Ayrıntılı bilgi için: Feyzanur Şimşek - Şef

[AB-BK Ticaret ve İşbirliği Anlaşması Metnine https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2020.444.01.0014.01.ENG adresinden erişim sağlanabilmektedir.]

Chapter 4: Technical barriers to trade

Article TBT.1: Objective

The objective of this Chapter is to facilitate trade in goods between the Parties by preventing, identifying and eliminating unnecessary technical barriers to trade.

Article TBT.2: Scope

1. This Chapter applies to the preparation, adoption and application of all standards, technical regulations and conformity assessment procedures, which may affect trade in goods between the Parties.

2. This Chapter does not apply to:

(a) purchasing specifications prepared by governmental bodies for production or consumption requirements of such bodies; or

(b) SPS measures that fall within scope of Chapter 3 [Sanitary and phytosanitary measures].

3. The Annexes to this Chapter apply, in respect of products within their scope, in addition to this Chapter. Any provision in an Annex to this Chapter that an international standard or body or organisation is to be considered or recognised as relevant, does not prevent a standard developed by any other body or organisation from being considered to be a relevant international standard pursuant to Article TBT.4 (4) and (5).

Article TBT.3: Relationship with the TBT Agreement

1. Articles 2 to 9 of and Annexes 1 and 3 to the TBT Agreement are incorporated into and made part of this Agreement *mutatis mutandis*.

2. Terms referred to in this Chapter and in the Annexes to this Chapter shall have the same meaning as they have in the TBT Agreement.

Article TBT.4: Technical regulations

1. Each Party shall carry out impact assessments of planned technical regulations in accordance with its respective rules and procedures. The rules and procedures referred to in this paragraph and in paragraph 8 may provide for exceptions.

2. Each Party shall assess the available regulatory and non-regulatory alternatives to the proposed technical regulation that may fulfil the Party's legitimate objectives, in accordance with Article 2.2 of the TBT Agreement.

3. Each Party shall use relevant international standards as a basis for its technical regulations except when it can demonstrate that such international standards would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.

4. International standards developed by the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), International Telecommunication Union (ITU) and Codex Alimentarius Commission (Codex) shall be the relevant international standards within the meaning of Article 2, Article 5 and Annex 3 of the TBT Agreement.

5. A standard developed by other international organisations, could also be considered a relevant international standard within the meaning of Article 2, Article 5 and Annex 3 of the TBT Agreement, provided that:

(a) it has been developed by a standardising body which seeks to establish consensus either:

(i) among national delegations of the participating WTO Members representing all the national standardising bodies in their territory that have adopted, or expect to adopt, standards for the subject matter to which the international standardisation activity relates, or,

(ii) among governmental bodies of participating WTO Members, and,

(b) it has been developed in accordance with the Decision of the WTO Committee on Technical Barriers to Trade on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5, and Annex 3 of the TBT Agreement[1].

6. Where a Party does not use international standards as a basis for a technical regulation, on request of the other Party, it shall identify any substantial deviation from the relevant international standard, explain the reasons why such standards were judged inappropriate or ineffective for the objective pursued, and provide the scientific or technical evidence on which that assessment was based.

7. Each Party shall review its technical regulations to increase the convergence of those technical regulations with relevant international standards, taking into account, *inter alia*, any new developments in the relevant international standards or any changes in the circumstances that have given rise to divergence from any relevant international standards.

8. In accordance with its respective rules and procedures and without prejudice to Title X [Good Regulatory Practices and Regulatory Cooperation], when developing a major technical regulation which may have a significant effect on trade, each Party shall ensure that procedures exist that allow persons to express their opinion in a public consultation, except where urgent problems of safety, health, environment or national security arise or threaten to arise. Each Party shall allow persons of the other Party to participate in such consultations on terms that are no less favourable than those accorded to its own nationals, and shall make the results of those consultations public.

[1] G/TBT/9, 13 November 2000, Annex 4.

Article TBT.5: Standards

1. Each Party shall encourage the standardising bodies established within its territory, as well as the regional standardising bodies of which a Party or the standardising bodies established in its territory are members:

(a) to participate, within the limits of their resources, in the preparation of international standards by relevant international standardising bodies;

(b) to use relevant international standards as a basis for the standards they develop, except where such international standards would be ineffective or inappropriate, for example because of an insufficient level of protection, fundamental climatic or geographical factors or fundamental technological problems;

(c) to avoid duplications of, or overlaps with, the work of international standardising bodies;

(d) to review national and regional standards that are not based on relevant international standards at regular intervals, with a view to increasing the convergence of those standards with relevant international standards;

(e) to cooperate with the relevant standardising bodies of the other Party in international standardisation activities, including through cooperation in the international standardising bodies or at regional level;

(f) to foster bilateral cooperation with the standardising bodies of the other Party; and

(g) to exchange information between standardising bodies.

2. The Parties shall exchange information on:

(a) their respective use of standards in support of technical regulations; and

(b) their respective standardisation processes, and the extent to which they use international, regional or sub-regional standards as a basis for their national standards.

3. Where standards are rendered mandatory in a draft technical regulation or conformity assessment procedure, through incorporation or reference, the transparency obligations set out in Article TBT.7 [Transparency] and in Articles 2 or 5 of the TBT Agreement shall apply.

Article TBT.6: Conformity assessment

1. Article TBT.4 [Technical regulations] concerning the preparation, adoption and application of technical regulations shall also apply to conformity assessment procedures, *mutatis mutandis*.

2. Where a Party requires conformity assessment as a positive assurance that a product conforms with a technical regulation, it shall:

(a) select conformity assessment procedures that are proportionate to the risks involved, as determined on the basis of a risk-assessment;

(b) consider as proof of compliance with technical regulations the use of a supplier's declaration of conformity, i.e. a declaration of conformity issued by the manufacturer on the sole responsibility of the manufacturer without a mandatory third-party assessment, as assurance of conformity among the options for showing compliance with technical regulations;

(c) where requested by the other Party, provide information on the criteria used to select the conformity assessment procedures for specific products.

3. Where a Party requires third party conformity assessment as a positive assurance that a product conforms with a technical regulation and it has not reserved this task to a government authority as specified in paragraph 4, it shall:

(a) use accreditation, as appropriate, as a means to demonstrate technical competence to qualify conformity assessment bodies. Without prejudice to its right to establish requirements for conformity assessment bodies, each Party recognises the valuable role that accreditation

operated with authority derived from government and on a non-commercial basis can play in the qualification of conformity assessment bodies;

(b) use relevant international standards for accreditation and conformity assessment;

(c) encourage accreditation bodies and conformity assessment bodies located within its territory to join any relevant functioning international agreements or arrangements for harmonisation or facilitation of acceptance of conformity assessment results;

(d) if two or more conformity assessment bodies are authorised by a Party to carry out conformity assessment procedures required for placing a product on the market, ensure that economic operators have a choice amongst the conformity assessment bodies designated by the authorities of a Party for a particular product or set of products;

(e) ensure that conformity assessment bodies are independent of manufacturers, importers and economic operators in general and that there are no conflicts of interest between accreditation bodies and conformity assessment bodies;

(f) allow conformity assessment bodies to use subcontractors to perform testing or inspections in relation to the conformity assessment, including subcontractors located in the territory of the other Party, and may require subcontractors to meet the same requirements the conformity assessment body must meet to perform such testing or inspections itself; and

(g) publish on a single website a list of the bodies that it has designated to perform such conformity assessment and the relevant information on the scope of designation of each such body.

4. Nothing in this Article shall preclude a Party from requiring that conformity assessment in relation to specific products is performed by its specified government authorities. If a Party requires that conformity assessment is performed by its specified government authorities, that Party shall:

(a) limit the conformity assessment fees to the approximate cost of the services rendered and, at the request of an applicant for conformity assessment, explain how any fees it imposes for that conformity assessment are limited to the approximate cost of services rendered; and

(b) make publicly available the conformity assessment fees.

5. Notwithstanding paragraphs 2 to 4, each Party shall accept a supplier's declaration of conformity as proof of compliance with its technical regulations in those product areas where it does so on the date of entry into force of this Agreement.

6. Each Party shall publish and maintain a list of the product areas referred to in paragraph 5 for information purposes, together with the references to the applicable technical regulations.

7. Notwithstanding paragraph 5, either Party may introduce requirements for the mandatory third party testing or certification of the product areas referred to in that paragraph, provided that such requirements are justified on grounds of legitimate objectives and are proportionate to the purpose of giving the importing Party adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks that non-conformity would create.

8. A Party proposing to introduce the conformity assessment procedures referred to in paragraph 7 shall notify the other Party at an early stage and shall take the comments of the other Party into account in devising any such conformity assessment procedures.

Article TBT.7: Transparency

1. Except where urgent problems of safety, health, environmental protection or national security arise or threaten to arise, each Party shall allow the other Party to provide written comments on notified proposed technical regulations and conformity assessment procedures within a period of at least 60 days from the date of the transmission of the notification of such regulations or procedures to the WTO Central Registry of Notifications. A Party shall give positive consideration to a reasonable request to extend that comment period.

2. Each Party shall provide the electronic version of the full notified text together with the notification. In the event that the notified text is not in one of the official WTO languages, the notifying Party shall provide a detailed and comprehensive description of the content of the measure in the WTO notification format.

3. If a Party receives written comments on its proposed technical regulation or conformity assessment procedure from the other Party, it shall:

(a) if requested by the other Party, discuss the written comments with the participation of its competent regulatory authority, at a time when they can be taken into account; and

(b) reply in writing to the comments no later than the date of publication of the technical regulation or conformity assessment procedure.

4. Each Party shall endeavour to publish on a website its responses to the comments it receives following the notification referred to in paragraph 1 no later than on the date of publication of the adopted technical regulation or conformity assessment procedure.

5. Each Party shall, where requested by the other Party, provide information regarding the objectives of, legal basis for and rationale for, any technical regulation or conformity assessment procedure that the Party has adopted or is proposing to adopt.

6. Each Party shall ensure that the technical regulations and conformity assessment procedures it has adopted are published on a website that is accessible free of charge.

7. Each Party shall provide information on the adoption and the entry into force of technical regulations or conformity assessment procedures and the adopted final texts through an addendum to the original notification to the WTO.

8. Each Party shall allow a reasonable interval between the publication of technical regulations and their entry into force, in order to allow time for the economic operators of the other Party to adapt. 'Reasonable interval' means a period of at least six months, unless this would be ineffective in fulfilling the legitimate objectives pursued.

9. A Party shall give positive consideration to a reasonable request from the other Party received prior to the end of the comment period set out in paragraph 1 to extend the period of time between the adoption of the technical regulation and its entry into force, except where the delay would be ineffective in fulfilling the legitimate objectives pursued.

10. Each Party shall ensure that the enquiry point established in accordance with Article 10 of the TBT Agreement provides information and answers in one of the official WTO languages to reasonable enquiries from the other Party or from interested persons of the other Party regarding adopted technical regulations and conformity assessment procedures.

Article TBT.8: Marking and labelling

1. The technical regulations of a Party may include or exclusively address mandatory marking or labelling requirements. In such cases, the principles of Article 2.2 of the TBT Agreement apply to these technical regulations.

2. Where a Party requires mandatory marking or labelling of products, all of the following conditions shall apply:

(a) it shall only require information which is relevant for consumers or users of the product or information that indicates that the product conforms to the mandatory technical requirements;

(b) it shall not require any prior approval, registration or certification of the labels or markings of products, nor any fee disbursement, as a precondition for placing on its market products that otherwise comply with its mandatory technical requirements unless it is necessary in view of legitimate objectives;

(c) where the Party requires the use of a unique identification number by economic operators, it shall issue such a number to the economic operators of the other Party without undue delay and on a non-discriminatory basis;

(d) unless the information listed in points (i), (ii) or (iii) would be misleading, contradictory or confusing in relation to the information that the importing Party requires with respect to the goods, the importing Party shall permit:

(i) information in other languages in addition to the language required in the importing Party of the goods;

(ii) internationally-accepted nomenclatures, pictograms, symbols or graphics; and

(iii) additional information to that required in the importing Party of the goods;

(e) it shall accept that labelling, including supplementary labelling or corrections to labelling, take place in customs warehouses or other designated areas in the country of import as an alternative to labelling in the country of origin, unless such labelling is required to be carried out by approved persons for reasons of public health or safety; and

(f) unless it considers that legitimate objectives may be undermined, it shall endeavour to accept the use of non-permanent or detachable labels, or marking or labelling in the accompanying documentation, rather than requiring labels or marking to be physically attached to the product.

Article TBT.9: Cooperation on market surveillance and non-food product safety and compliance

1. The Parties recognise the importance of cooperation on market surveillance, compliance and the safety of non-food products for the facilitation of trade and for the protection of consumers and other users, and the importance of building mutual trust based on shared information.

2. To guarantee the independent and impartial functioning of market surveillance, the Parties shall ensure:

(a) the separation of market surveillance functions from conformity assessment functions; and

(b) the absence of any interests that would affect the impartiality of market surveillance authorities in the performance of their control or supervision of economic operators.

3. The Parties shall cooperate and exchange information in the area of non-food product safety and compliance, which may include in particular the following:

(a) market surveillance and enforcement activities and measures;

(b) risk assessment methods and product testing;

(c) coordinated product recalls or other similar actions;

(d) scientific, technical and regulatory matters in order to improve non-food product safety and compliance;

(e) emerging issues of significant health and safety relevance;

(f) standardisation-related activities;

(g) exchanges of officials.

4. The Partnership Council shall use its best endeavours to establish in Annex TBT-XX, as soon as possible and preferably within six months of entry into force of this Agreement, an arrangement for the regular exchange of information between the Rapid Alert System for non-food products (RAPEX), or its successor, and the database relating to market surveillance and product safety established under the General Product Safety Regulations 2005, or its successor, in relation to the safety of non-food products and related preventive, restrictive and corrective measures.

The arrangement shall set out the modalities under which:

(a) the Union is to provide the United Kingdom with selected information from its RAPEX alert system, or its successor, as referred to in Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety or its successor;

(b) the United Kingdom is to provide the Union with selected information from its database relating to market surveillance and product safety established under the General Product Safety Regulations 2005, or its successor; and

(c) the Parties are to inform each other of any follow-up actions and measures taken in response to the information exchanged.

5. The Partnership Council may establish in Annex TBT-ZZ an arrangement on the regular exchange of information, including the exchange of information by electronic means, regarding measures taken on non-compliant non-food products, other than those covered by paragraph 4.

6. Each Party shall use the information obtained pursuant to paragraphs 3, 4 and 5 for the sole purpose of protecting consumers, health, safety or the environment.

7. Each Party shall treat the information obtained pursuant to paragraphs 3, 4 and 5 as confidential.

8. The arrangements referred to in paragraphs 4 and 5 shall specify the type of information to be exchanged, the modalities for the exchange and the application of confidentiality and personal data protection rules. The Partnership Council shall have the power to adopt decisions in order to determine or amend the arrangements set out in Annexes TBT-XX and TBT-ZZ.

9. For the purposes of this Article, 'market surveillance' means activities conducted and measures taken by market surveillance and enforcement authorities, including activities conducted and measures taken in cooperation with economic operators, on the basis of procedures of a Party to enable that Party to monitor or address safety of products and their compliance with the requirements set out in its laws and regulations.

10. Each Party shall ensure that any measure taken by its market surveillance or enforcement authorities to withdraw or recall from its market or to prohibit or restrict the making available on its market of a product imported from the territory of the other Party, for reasons related to non-compliance with the applicable legislation, is proportionate, states the exact grounds on which the measure is based and is communicated without delay to the relevant economic operator.

Article TBT.10: Technical discussions

1. If a Party considers that a draft or proposed technical regulation or conformity assessment procedure of the other Party might have a significant effect on trade between the Parties, it may request technical discussions on the matter. The request shall be made in writing to the other Party and shall identify:

(a) the measure at issue;

(b) the provisions of this Chapter or of an Annex to this Chapter to which the concerns relate; and

(c) the reasons for the request, including a description of the requesting Party's concerns regarding the measure.

2. A Party shall deliver its request to the contact point of the other Party designated pursuant to Article TBT.12 [Contact points].

3. At the request of either Party, the Parties shall meet to discuss the concerns raised in the request, in person or via videoconference or teleconference, within 60 days of the date of the request and shall endeavour to resolve the matter as expeditiously as possible. If a requesting Party believes that the matter is urgent, it may request that any meeting take place within a shorter time frame. In such cases, the responding Party shall give positive consideration to such a request.

Article TBT.11: Cooperation

1. The Parties shall cooperate in the field of technical regulations, standards and conformity assessment procedures, where it is in their mutual interest, and without prejudice to the autonomy of their own respective decision-making and legal orders. The Trade Specialised Committee on Technical Barriers to Trade may exchange views with respect to the cooperation activities carried out under this Article or the Annexes to this Chapter.

2. For the purposes of paragraph 1, the Parties shall seek to identify, develop and promote cooperation activities of mutual interest. These activities may in particular relate to:

(a) the exchange of information, experience and data related to technical regulations, standards and conformity assessment procedures;

(b) ensuring efficient interaction and cooperation of their respective regulatory authorities at international, regional or national level;

(c) exchanging information, to the extent possible, about international agreements and arrangements regarding technical barriers to trade to which one or both Parties are party; and

(d) establishment of or participation in trade facilitating initiatives.

3. For the purposes of this Article and the provisions on cooperation under the Annexes to this Chapter, the European Commission shall act on behalf of the European Union.

Article TBT.12: Contact Points

1. Upon the entry into force of this Agreement, each Party shall designate a contact point for the implementation of this Chapter and shall notify the other Party of the contact details for the contact point, including information regarding the relevant officials. The Parties shall promptly notify each other of any change of those contact details.

2. The contact point shall provide any information or explanation requested by the contact point of the other Party in relation to the implementation of this Chapter within a reasonable period of time and, if possible, within 60 days of the date of receipt of the request.

Article TBT.13: Trade Specialised Committee on Technical Barriers to Trade

The Trade Specialised Committee on Technical Barriers to Trade shall supervise the implementation and operation of this Chapter and the Annexes to it and shall promptly clarify and address, where possible, any issue raised by a Party relating to the development, adoption or application of technical regulations, standards and conformity assessment procedures under this Chapter or the TBT Agreement.

ANNEXES:

- ANNEX TBT-1: MOTOR VEHICLES AND EQUIPMENT AND PARTS THEREOF
- ANNEX TBT-2: MEDICINAL PRODUCTS
- ANNEX TBT-3: CHEMICALS
- ANNEX TBT-4: ORGANIC PRODUCTS
- ANNEX-TBT-5: TRADE IN WINE
- ANNEX TBT-XX – ARRANGEMENT REFERRED TO IN ARTICLE TBT.9(4) FOR THE REGULAR EXCHANGE OF INFORMATION IN RELATION TO THE SAFETY OF NON-FOOD PRODUCTS AND RELATED PREVENTIVE, RESTRICTIVE AND CORRECTIVE MEASURES
- ANNEX TBT-ZZ – ARRANGEMENT REFERRED TO IN ARTICLE TBT.9(5) FOR THE REGULAR EXCHANGE OF INFORMATION REGARDING MEASURES TAKEN ON NON-COMPLIANT NON-FOOD PRODUCTS, OTHER THAN THOSE COVERED BY ARTICLE TBT.9(4)

[AB-BK Ticaret ve İşbirliği Anlaşması Metnine https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2020.444.01.0014.01.ENG adresinden erişim sağlanabilmektedir.]

Chapter 4: Technical barriers to trade

Article TBT.1: Objective

The objective of this Chapter is to facilitate trade in goods between the Parties by preventing, identifying and eliminating unnecessary technical barriers to trade.

Article TBT.2: Scope

1. This Chapter applies to the preparation, adoption and application of all standards, technical regulations and conformity assessment procedures, which may affect trade in goods between the Parties.

2. This Chapter does not apply to:

(a) purchasing specifications prepared by governmental bodies for production or consumption requirements of such bodies; or

(b) SPS measures that fall within scope of Chapter 3 [Sanitary and phytosanitary measures].

3. The Annexes to this Chapter apply, in respect of products within their scope, in addition to this Chapter. Any provision in an Annex to this Chapter that an international standard or body or organisation is to be considered or recognised as relevant, does not prevent a standard developed by any other body or organisation from being considered to be a relevant international standard pursuant to Article TBT.4 (4) and (5).

Article TBT.3: Relationship with the TBT Agreement

1. Articles 2 to 9 of and Annexes 1 and 3 to the TBT Agreement are incorporated into and made part of this Agreement *mutatis mutandis*.

2. Terms referred to in this Chapter and in the Annexes to this Chapter shall have the same meaning as they have in the TBT Agreement.

Article TBT.4: Technical regulations

1. Each Party shall carry out impact assessments of planned technical regulations in accordance with its respective rules and procedures. The rules and procedures referred to in this paragraph and in paragraph 8 may provide for exceptions.

2. Each Party shall assess the available regulatory and non-regulatory alternatives to the proposed technical regulation that may fulfil the Party's legitimate objectives, in accordance with Article 2.2 of the TBT Agreement.

3. Each Party shall use relevant international standards as a basis for its technical regulations except when it can demonstrate that such international standards would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.

4. International standards developed by the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), International Telecommunication Union (ITU) and Codex Alimentarius Commission (Codex) shall be the relevant international standards within the meaning of Article 2, Article 5 and Annex 3 of the TBT Agreement.

5. A standard developed by other international organisations, could also be considered a relevant international standard within the meaning of Article 2, Article 5 and Annex 3 of the TBT Agreement, provided that:

(a) it has been developed by a standardising body which seeks to establish consensus either:

(i) among national delegations of the participating WTO Members representing all the national standardising bodies in their territory that have adopted, or expect to adopt, standards for the subject matter to which the international standardisation activity relates, or,

(ii) among governmental bodies of participating WTO Members, and,

(b) it has been developed in accordance with the Decision of the WTO Committee on Technical Barriers to Trade on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5, and Annex 3 of the TBT Agreement[1].

6. Where a Party does not use international standards as a basis for a technical regulation, on request of the other Party, it shall identify any substantial deviation from the relevant international standard, explain the reasons why such standards were judged inappropriate or ineffective for the objective pursued, and provide the scientific or technical evidence on which that assessment was based.

7. Each Party shall review its technical regulations to increase the convergence of those technical regulations with relevant international standards, taking into account, *inter alia*, any new developments in the relevant international standards or any changes in the circumstances that have given rise to divergence from any relevant international standards.

8. In accordance with its respective rules and procedures and without prejudice to Title X [Good Regulatory Practices and Regulatory Cooperation], when developing a major technical regulation which may have a significant effect on trade, each Party shall ensure that procedures exist that allow persons to express their opinion in a public consultation, except where urgent problems of safety, health, environment or national security arise or threaten to arise. Each Party shall allow persons of the other Party to participate in such consultations on terms that are no less favourable than those accorded to its own nationals, and shall make the results of those consultations public.

[1] G/TBT/9, 13 November 2000, Annex 4.

Article TBT.5: Standards

1. Each Party shall encourage the standardising bodies established within its territory, as well as the regional standardising bodies of which a Party or the standardising bodies established in its territory are members:

(a) to participate, within the limits of their resources, in the preparation of international standards by relevant international standardising bodies;

(b) to use relevant international standards as a basis for the standards they develop, except where such international standards would be ineffective or inappropriate, for example because of an insufficient level of protection, fundamental climatic or geographical factors or fundamental technological problems;

(c) to avoid duplications of, or overlaps with, the work of international standardising bodies;

(d) to review national and regional standards that are not based on relevant international standards at regular intervals, with a view to increasing the convergence of those standards with relevant international standards;

(e) to cooperate with the relevant standardising bodies of the other Party in international standardisation activities, including through cooperation in the international standardising bodies or at regional level;

(f) to foster bilateral cooperation with the standardising bodies of the other Party; and

(g) to exchange information between standardising bodies.

2. The Parties shall exchange information on:

(a) their respective use of standards in support of technical regulations; and

(b) their respective standardisation processes, and the extent to which they use international, regional or sub-regional standards as a basis for their national standards.

3. Where standards are rendered mandatory in a draft technical regulation or conformity assessment procedure, through incorporation or reference, the transparency obligations set out in Article TBT.7 [Transparency] and in Articles 2 or 5 of the TBT Agreement shall apply.

Article TBT.6: Conformity assessment

1. Article TBT.4 [Technical regulations] concerning the preparation, adoption and application of technical regulations shall also apply to conformity assessment procedures, *mutatis mutandis*.

2. Where a Party requires conformity assessment as a positive assurance that a product conforms with a technical regulation, it shall:

(a) select conformity assessment procedures that are proportionate to the risks involved, as determined on the basis of a risk-assessment;

(b) consider as proof of compliance with technical regulations the use of a supplier's declaration of conformity, i.e. a declaration of conformity issued by the manufacturer on the sole responsibility of the manufacturer without a mandatory third-party assessment, as assurance of conformity among the options for showing compliance with technical regulations;

(c) where requested by the other Party, provide information on the criteria used to select the conformity assessment procedures for specific products.

3. Where a Party requires third party conformity assessment as a positive assurance that a product conforms with a technical regulation and it has not reserved this task to a government authority as specified in paragraph 4, it shall:

(a) use accreditation, as appropriate, as a means to demonstrate technical competence to qualify conformity assessment bodies. Without prejudice to its right to establish requirements for conformity assessment bodies, each Party recognises the valuable role that accreditation

operated with authority derived from government and on a non-commercial basis can play in the qualification of conformity assessment bodies;

(b) use relevant international standards for accreditation and conformity assessment;

(c) encourage accreditation bodies and conformity assessment bodies located within its territory to join any relevant functioning international agreements or arrangements for harmonisation or facilitation of acceptance of conformity assessment results;

(d) if two or more conformity assessment bodies are authorised by a Party to carry out conformity assessment procedures required for placing a product on the market, ensure that economic operators have a choice amongst the conformity assessment bodies designated by the authorities of a Party for a particular product or set of products;

(e) ensure that conformity assessment bodies are independent of manufacturers, importers and economic operators in general and that there are no conflicts of interest between accreditation bodies and conformity assessment bodies;

(f) allow conformity assessment bodies to use subcontractors to perform testing or inspections in relation to the conformity assessment, including subcontractors located in the territory of the other Party, and may require subcontractors to meet the same requirements the conformity assessment body must meet to perform such testing or inspections itself; and

(g) publish on a single website a list of the bodies that it has designated to perform such conformity assessment and the relevant information on the scope of designation of each such body.

4. Nothing in this Article shall preclude a Party from requiring that conformity assessment in relation to specific products is performed by its specified government authorities. If a Party requires that conformity assessment is performed by its specified government authorities, that Party shall:

(a) limit the conformity assessment fees to the approximate cost of the services rendered and, at the request of an applicant for conformity assessment, explain how any fees it imposes for that conformity assessment are limited to the approximate cost of services rendered; and

(b) make publicly available the conformity assessment fees.

5. Notwithstanding paragraphs 2 to 4, each Party shall accept a supplier's declaration of conformity as proof of compliance with its technical regulations in those product areas where it does so on the date of entry into force of this Agreement.

6. Each Party shall publish and maintain a list of the product areas referred to in paragraph 5 for information purposes, together with the references to the applicable technical regulations.

7. Notwithstanding paragraph 5, either Party may introduce requirements for the mandatory third party testing or certification of the product areas referred to in that paragraph, provided that such requirements are justified on grounds of legitimate objectives and are proportionate to the purpose of giving the importing Party adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks that non-conformity would create.

8. A Party proposing to introduce the conformity assessment procedures referred to in paragraph 7 shall notify the other Party at an early stage and shall take the comments of the other Party into account in devising any such conformity assessment procedures.

Article TBT.7: Transparency

1. Except where urgent problems of safety, health, environmental protection or national security arise or threaten to arise, each Party shall allow the other Party to provide written comments on notified proposed technical regulations and conformity assessment procedures within a period of at least 60 days from the date of the transmission of the notification of such regulations or procedures to the WTO Central Registry of Notifications. A Party shall give positive consideration to a reasonable request to extend that comment period.

2. Each Party shall provide the electronic version of the full notified text together with the notification. In the event that the notified text is not in one of the official WTO languages, the notifying Party shall provide a detailed and comprehensive description of the content of the measure in the WTO notification format.

3. If a Party receives written comments on its proposed technical regulation or conformity assessment procedure from the other Party, it shall:

(a) if requested by the other Party, discuss the written comments with the participation of its competent regulatory authority, at a time when they can be taken into account; and

(b) reply in writing to the comments no later than the date of publication of the technical regulation or conformity assessment procedure.

4. Each Party shall endeavour to publish on a website its responses to the comments it receives following the notification referred to in paragraph 1 no later than on the date of publication of the adopted technical regulation or conformity assessment procedure.

5. Each Party shall, where requested by the other Party, provide information regarding the objectives of, legal basis for and rationale for, any technical regulation or conformity assessment procedure that the Party has adopted or is proposing to adopt.

6. Each Party shall ensure that the technical regulations and conformity assessment procedures it has adopted are published on a website that is accessible free of charge.

7. Each Party shall provide information on the adoption and the entry into force of technical regulations or conformity assessment procedures and the adopted final texts through an addendum to the original notification to the WTO.

8. Each Party shall allow a reasonable interval between the publication of technical regulations and their entry into force, in order to allow time for the economic operators of the other Party to adapt. 'Reasonable interval' means a period of at least six months, unless this would be ineffective in fulfilling the legitimate objectives pursued.

9. A Party shall give positive consideration to a reasonable request from the other Party received prior to the end of the comment period set out in paragraph 1 to extend the period of time between the adoption of the technical regulation and its entry into force, except where the delay would be ineffective in fulfilling the legitimate objectives pursued.

10. Each Party shall ensure that the enquiry point established in accordance with Article 10 of the TBT Agreement provides information and answers in one of the official WTO languages to reasonable enquiries from the other Party or from interested persons of the other Party regarding adopted technical regulations and conformity assessment procedures.

Article TBT.8: Marking and labelling

1. The technical regulations of a Party may include or exclusively address mandatory marking or labelling requirements. In such cases, the principles of Article 2.2 of the TBT Agreement apply to these technical regulations.

2. Where a Party requires mandatory marking or labelling of products, all of the following conditions shall apply:

(a) it shall only require information which is relevant for consumers or users of the product or information that indicates that the product conforms to the mandatory technical requirements;

(b) it shall not require any prior approval, registration or certification of the labels or markings of products, nor any fee disbursement, as a precondition for placing on its market products that otherwise comply with its mandatory technical requirements unless it is necessary in view of legitimate objectives;

(c) where the Party requires the use of a unique identification number by economic operators, it shall issue such a number to the economic operators of the other Party without undue delay and on a non-discriminatory basis;

(d) unless the information listed in points (i), (ii) or (iii) would be misleading, contradictory or confusing in relation to the information that the importing Party requires with respect to the goods, the importing Party shall permit:

(i) information in other languages in addition to the language required in the importing Party of the goods;

(ii) internationally-accepted nomenclatures, pictograms, symbols or graphics; and

(iii) additional information to that required in the importing Party of the goods;

(e) it shall accept that labelling, including supplementary labelling or corrections to labelling, take place in customs warehouses or other designated areas in the country of import as an alternative to labelling in the country of origin, unless such labelling is required to be carried out by approved persons for reasons of public health or safety; and

(f) unless it considers that legitimate objectives may be undermined, it shall endeavour to accept the use of non-permanent or detachable labels, or marking or labelling in the accompanying documentation, rather than requiring labels or marking to be physically attached to the product.

Article TBT.9: Cooperation on market surveillance and non-food product safety and compliance

1. The Parties recognise the importance of cooperation on market surveillance, compliance and the safety of non-food products for the facilitation of trade and for the protection of consumers and other users, and the importance of building mutual trust based on shared information.

2. To guarantee the independent and impartial functioning of market surveillance, the Parties shall ensure:

(a) the separation of market surveillance functions from conformity assessment functions; and

(b) the absence of any interests that would affect the impartiality of market surveillance authorities in the performance of their control or supervision of economic operators.

3. The Parties shall cooperate and exchange information in the area of non-food product safety and compliance, which may include in particular the following:

(a) market surveillance and enforcement activities and measures;

(b) risk assessment methods and product testing;

(c) coordinated product recalls or other similar actions;

(d) scientific, technical and regulatory matters in order to improve non-food product safety and compliance;

(e) emerging issues of significant health and safety relevance;

(f) standardisation-related activities;

(g) exchanges of officials.

4. The Partnership Council shall use its best endeavours to establish in Annex TBT-XX, as soon as possible and preferably within six months of entry into force of this Agreement, an arrangement for the regular exchange of information between the Rapid Alert System for non-food products (RAPEX), or its successor, and the database relating to market surveillance and product safety established under the General Product Safety Regulations 2005, or its successor, in relation to the safety of non-food products and related preventive, restrictive and corrective measures.

The arrangement shall set out the modalities under which:

(a) the Union is to provide the United Kingdom with selected information from its RAPEX alert system, or its successor, as referred to in Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety or its successor;

(b) the United Kingdom is to provide the Union with selected information from its database relating to market surveillance and product safety established under the General Product Safety Regulations 2005, or its successor; and

(c) the Parties are to inform each other of any follow-up actions and measures taken in response to the information exchanged.

5. The Partnership Council may establish in Annex TBT-ZZ an arrangement on the regular exchange of information, including the exchange of information by electronic means, regarding measures taken on non-compliant non-food products, other than those covered by paragraph 4.

6. Each Party shall use the information obtained pursuant to paragraphs 3, 4 and 5 for the sole purpose of protecting consumers, health, safety or the environment.

7. Each Party shall treat the information obtained pursuant to paragraphs 3, 4 and 5 as confidential.

8. The arrangements referred to in paragraphs 4 and 5 shall specify the type of information to be exchanged, the modalities for the exchange and the application of confidentiality and personal data protection rules. The Partnership Council shall have the power to adopt decisions in order to determine or amend the arrangements set out in Annexes TBT-XX and TBT-ZZ.

9. For the purposes of this Article, 'market surveillance' means activities conducted and measures taken by market surveillance and enforcement authorities, including activities conducted and measures taken in cooperation with economic operators, on the basis of procedures of a Party to enable that Party to monitor or address safety of products and their compliance with the requirements set out in its laws and regulations.

10. Each Party shall ensure that any measure taken by its market surveillance or enforcement authorities to withdraw or recall from its market or to prohibit or restrict the making available on its market of a product imported from the territory of the other Party, for reasons related to non-compliance with the applicable legislation, is proportionate, states the exact grounds on which the measure is based and is communicated without delay to the relevant economic operator.

Article TBT.10: Technical discussions

1. If a Party considers that a draft or proposed technical regulation or conformity assessment procedure of the other Party might have a significant effect on trade between the Parties, it may request technical discussions on the matter. The request shall be made in writing to the other Party and shall identify:

(a) the measure at issue;

(b) the provisions of this Chapter or of an Annex to this Chapter to which the concerns relate; and

(c) the reasons for the request, including a description of the requesting Party's concerns regarding the measure.

2. A Party shall deliver its request to the contact point of the other Party designated pursuant to Article TBT.12 [Contact points].

3. At the request of either Party, the Parties shall meet to discuss the concerns raised in the request, in person or via videoconference or teleconference, within 60 days of the date of the request and shall endeavour to resolve the matter as expeditiously as possible. If a requesting Party believes that the matter is urgent, it may request that any meeting take place within a shorter time frame. In such cases, the responding Party shall give positive consideration to such a request.

Article TBT.11: Cooperation

1. The Parties shall cooperate in the field of technical regulations, standards and conformity assessment procedures, where it is in their mutual interest, and without prejudice to the autonomy of their own respective decision-making and legal orders. The Trade Specialised Committee on Technical Barriers to Trade may exchange views with respect to the cooperation activities carried out under this Article or the Annexes to this Chapter.

2. For the purposes of paragraph 1, the Parties shall seek to identify, develop and promote cooperation activities of mutual interest. These activities may in particular relate to:

(a) the exchange of information, experience and data related to technical regulations, standards and conformity assessment procedures;

(b) ensuring efficient interaction and cooperation of their respective regulatory authorities at international, regional or national level;

(c) exchanging information, to the extent possible, about international agreements and arrangements regarding technical barriers to trade to which one or both Parties are party; and

(d) establishment of or participation in trade facilitating initiatives.

3. For the purposes of this Article and the provisions on cooperation under the Annexes to this Chapter, the European Commission shall act on behalf of the European Union.

Article TBT.12: Contact Points

1. Upon the entry into force of this Agreement, each Party shall designate a contact point for the implementation of this Chapter and shall notify the other Party of the contact details for the contact point, including information regarding the relevant officials. The Parties shall promptly notify each other of any change of those contact details.

2. The contact point shall provide any information or explanation requested by the contact point of the other Party in relation to the implementation of this Chapter within a reasonable period of time and, if possible, within 60 days of the date of receipt of the request.

Article TBT.13: Trade Specialised Committee on Technical Barriers to Trade

The Trade Specialised Committee on Technical Barriers to Trade shall supervise the implementation and operation of this Chapter and the Annexes to it and shall promptly clarify and address, where possible, any issue raised by a Party relating to the development, adoption or application of technical regulations, standards and conformity assessment procedures under this Chapter or the TBT Agreement.

ANNEXES:

- ANNEX TBT-1: MOTOR VEHICLES AND EQUIPMENT AND PARTS THEREOF
- ANNEX TBT-2: MEDICINAL PRODUCTS
- ANNEX TBT-3: CHEMICALS
- ANNEX TBT-4: ORGANIC PRODUCTS
- ANNEX-TBT-5: TRADE IN WINE
- ANNEX TBT-XX – ARRANGEMENT REFERRED TO IN ARTICLE TBT.9(4) FOR THE REGULAR EXCHANGE OF INFORMATION IN RELATION TO THE SAFETY OF NON-FOOD PRODUCTS AND RELATED PREVENTIVE, RESTRICTIVE AND CORRECTIVE MEASURES
- ANNEX TBT-ZZ – ARRANGEMENT REFERRED TO IN ARTICLE TBT.9(5) FOR THE REGULAR EXCHANGE OF INFORMATION REGARDING MEASURES TAKEN ON NON-COMPLIANT NON-FOOD PRODUCTS, OTHER THAN THOSE COVERED BY ARTICLE TBT.9(4)

ANNEX TBT-2: MEDICINAL PRODUCTS

Article 1: Definitions

1. For the purposes of this Annex:

(a) “authority” means an authority of a Party as listed in Appendix A;

(b) “Good Manufacturing Practice" or "GMP” means that part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use and as required by the applicable marketing authorisation or product specifications, as listed in Appendix B;

(c) "inspection" means an evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with Good Manufacturing Practice and/or commitments made as part of the approval to market a product, which is conducted in accordance with the laws, regulations and administrative provisions of the relevant Party, and includes pre-marketing and post-marketing inspection;

(d) “official GMP document” means a document issued by an authority of a Party following the inspection of a manufacturing facility, including, for example, inspection reports, certificates attesting the compliance of a manufacturing facility with GMP, or a GMP non-compliance statement.

Article 2: Scope

The provisions of this Annex apply to medicinal products as listed in Appendix C.

Article 3: Objectives

With regard to the products covered the objectives of this Annex are:

(a) to facilitate the availability of medicines in each Party’s territory;

(b) to set out the conditions for the recognition of inspections and for the exchange and acceptance of official GMP documents between the Parties;

(c) to promote public health by safeguarding patient safety and animal health and welfare, as well as to protect high levels of consumer and environmental protection, where relevant, by promoting regulatory approaches in line with the relevant international standards.

Article 4: International standards

The relevant standards for the products covered by this Annex shall ensure a high level of protection of public health in line with standards, practices and guidelines developed by the World Health Organization (WHO), the Organization for Economic Cooperation and Development (OECD), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

Article 5: Recognition of inspections and acceptance of official GMP documents

1. A Party shall recognise inspections carried out by the other Party and shall accept official GMP documents issued by the other Party in accordance with the laws, regulations and technical guidelines listed in Appendix B.

2. An authority of a Party may in specific circumstances opt not to accept an official GMP document issued by an authority of the other Party for manufacturing facilities located in the territory of the issuing authority. Examples of such circumstances include the indication of material inconsistencies or inadequacies in an inspection report, quality defects identified in post-market surveillance or other specific evidence of serious concern in relation to product quality or patient safety. Each Party shall ensure that where an authority of a Party opts not to accept an official GMP document issued by an authority of the other Party, that authority notifies the relevant authority of the other Party of the reasons for not accepting the document and may request clarification from the authority of the other Party. The relevant Party shall ensure that its authority endeavours to respond to the request for clarification in a timely manner.

3. A Party may accept official GMP documents issued by an authority of the other Party for manufacturing facilities located outside the territory of the issuing authority.

4. Each Party may determine the terms and conditions under which it accepts official GMP documents issued under paragraph 3.

Article 6: Exchange of official GMP documents

1. Each Party shall ensure that if an authority of a Party requests an official GMP document from the authority of the other Party, the authority of the other Party shall endeavour to transmit the document within 30 calendar days of the date of the request.

2. Each Party shall treat the information in a document obtained pursuant to paragraph 1 as confidential.

Article 7: Safeguards

1. Each Party has the right to conduct its own inspection of manufacturing facilities that have been certified as compliant by the other Party.

2. Each Party shall ensure that, prior to conducting an inspection under paragraph 1, the authority of the Party that intends to conduct the inspection notifies the relevant authority of the other Party of the inspection in writing, stating the reasons for conducting its own inspection. The authority of the Party that intends to conduct the inspection shall endeavour to notify the authority of the other Party in writing at least 30 days before a proposed inspection, but may provide a shorter notice in urgent situations. The authority of the other Party may join the inspection.

Article 8 – Changes to applicable laws and regulations

1. Each Party shall notify the other Party at least 60 days before adopting any new measures or changes relating to Good Manufacturing Practice concerning any of the relevant laws, regulations and technical guidelines listed in Appendix B.

2. The Parties shall exchange all the necessary information, including changes to their respective laws, regulations, technical guidelines or inspection procedures relating to Good Manufacturing Practice so that each Party can consider whether the conditions for the recognition of inspections and acceptance of official GMP documents pursuant to Article 5(1) continue to exist.

3. If as a result of any of the new measures or changes referred to in paragraph 1 of this Article, a Party considers that it can no longer recognise inspections or accept official GMP documents issued by the other Party, it shall notify the other Party of its intention to apply Article 9 and the Parties shall enter into consultations within the Working Group on Medicinal Products.

4. Any notification under this Article shall be done via the designated contact points in the Working Group on Medicinal Products.

Article 9: Suspension

1. Without prejudice to Article 5(2), each Party has the right to suspend totally or partially the recognition of inspections and acceptance of official GMP documents of the other Party pursuant to Article 5(1) for all or some of the products listed in Appendix C. That right shall be exercised in an objective and reasoned manner. The Party exercising such right shall notify the other Party and provide a written justification. A Party shall continue to accept official GMP documents of the other Party issued prior to such suspension, unless the Party decides otherwise on the basis of health or safety considerations.

2. Where, following consultations referred to in Article 8(3), a Party nevertheless suspends the recognition of inspections and acceptance of official GMP documents pursuant to Article 5(1), it may do so in accordance with paragraph 1 of this Article not earlier than 60 days after the commencement of the consultations. During that 60-day period, both Parties shall continue to recognise inspections and accept official GMP documents issued by an authority of the other Party.

3. Where recognition of inspections and acceptance of official GMP documents pursuant to Article 5(1) is suspended, at the request of a Party, the Parties shall discuss the matter within the Working Group on Medicinal Products and they shall make every effort to consider possible measures that would enable the recognition of inspections and acceptance of official GMP documents to be restored.

Article 10: Regulatory cooperation

1. The Parties shall endeavour to consult one another, as permitted by their respective law, on proposals to introduce significant changes to technical regulations or inspection procedures, including those that affect how documents from the other Party are recognised in accordance with Article 5 and, where appropriate, to provide the opportunity to comment on such proposals, without prejudice to Article 8.

2. The Parties shall endeavour to cooperate with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines including, where feasible, through the presentation of joint initiatives, proposals and approaches in the relevant international organisations and bodies referred to in Article 4.

Article 11: Amendments to appendices

The Partnership Council shall have the power to amend Appendix A in order to update the list of authorities, Appendix B in order to update list of applicable laws and regulations and technical guidelines, and Appendix C in order to update the list of covered products.

Article 12: Working Group on Medicinal Products

1. The Working Group on Medicinal Products shall assist the Trade Specialised Committee on Technical Barriers to Trade in monitoring and reviewing the implementation and ensuring the proper functioning of this Annex.

2. The functions of this Working Group shall be the following:

(a) discussing any matter arising under this Annex at the request of a Party;

(b) facilitating cooperation and exchanges of information for the purposes of Articles 8and 10;

(c) functioning as the forum for consultations and discussions for the purposes of Articles 8 (3) and 9(3)

(d) carrying out technical discussions in accordance with Article TBT.10 [Technical discussions] of this Agreement on matters falling within the scope of this Annex; and

(e) maintaining a list of contact points responsible for matters arising under this Annex.

Article 13 : Non-application of dispute settlement

Title I [Dispute settlement] of Part Six of this Agreement does not apply in respect of disputes regarding the interpretation and application of this Annex.

APPENDIX A – AUTHORITIES of the Parties

1) European Union:

Country	For medicinal products for human use	For medicinal products for veterinary use
Belgium	Federal agency for medicines and health products / Federaal Agentschap voor geneesmiddelen en gezondheidsproducten/ Agence fédérale des médicaments et produits de santé	See authority for medicinal products for human use
Bulgaria	Bulgarian Drug Agency / ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА	Bulgarian Food Safety Agency/ Българска агенция по безопасност на храните
Czechia	State Institute for Drug Control/ Státní ústav pro kontrolu léčiv (SÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments / Ústav pro státní kontrolu veterinárních biopreparátů a léčiv (ÚSKVBL)
Denmark	Danish Medicines Agency/ Laegemiddelstyrelsen	See authority for medicinal products for human use

Germany	Federal Institute for Drugs and Medical Devices / Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Paul-Ehrlich-Institute (PEI), Federal Institute for Vaccines and Biomedicines / Paul-Ehrlich-Institut (PEI) Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel Federal Ministry of Health / Bundesministerium für Gesundheit (BMG)/ Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG) [97]	Federal Office for Consumer Protection and Food Safety / Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) Federal Ministry of Food and Agriculture, Bundesministerium für Ernährung und Landwirtschaft
Estonia	State Agency of Medicines / Ravimiamet	See authority for medicinal products for human use
Ireland	Health Products Regulatory Authority (HPRA)	See authority for medicinal products for human use
Greece	National Organisation for Medicines / Ethnikos Organismos Farmakon (EOF) - (ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ))	See authority for medicinal products for human use
Spain	Spanish Agency of Medicines and Medical Devices / Agencia Española de Medicamentos y Productos Sanitarios [98]	See authority for medicinal products for human use

[97] For the purpose of this Annex, and without prejudice to the internal division of competence in Germany on matters falling within the scope of this Annex, ZLG shall be understood as covering all the competent Länder authorities issuing GMP documents and conducting pharmaceutical inspections.

[98] For the purpose of this Annex, and without prejudice to the internal division of competence in Spain on matters falling within the scope of this Annex, Agencia Española de Medicamentos y Productos Sanitarios shall be understood as covering all the competent regional authorities issuing official GMP documents and conducting pharmaceutical inspections.

France	French National Agency for Medicines and Health Products Safety Agence nationale de sécurité du médicament et des produits de santé (ANSM)	French agency for food, environmental and occupational health safety- *National Agency for Veterinary Medicinal Products/* Agence Nationale de Sécurité Sanitaire de l'alimentation, de l'environnement et du travail- Agence Nationale du Médicament Vétérinaire (Anses-ANMV)
Croatia	Agency for Medicinal Products and Medical Devices / Agencija za lijekove i medicinske proizvode (HALMED)	Ministry of Agriculture, Veterinary and Food Safety Directorate / Ministarstvo Poljoprivrede, Uprava za veterinarstvo i sigurnost hrane
Italy	*Italian Medicines Agency /* Agenzia Italiana del Farmaco	*Direction General for Animal Health and Veterinary Medicinal Products* Ministero della Salute, Direzione Generale della Sanità Animale e dei Farmaci Veterinari
Cyprus	Ministry of Health - Pharmaceutical Services / Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας	Ministry of Agriculture, Rural Development and Environment- Veterinary Services / Κτηνιατρικές Υπηρεσίες- Υπουργείο Γεωργίας, Αγροτικής Ανάπτυξης και Περιβάλλοντος
Latvia	State Agency of Medicines / Zāļu valsts aģentūra	Assessment and Registration Department of the Food and Veterinary Service/Pārtikas un veterinārā dienesta Novērtēšanas un reģistrācijas departaments
Lithuania	State Medicines Control Agency / Valstybinė vaistų kontrolės tarnyba	State Food and Veterinary Service / Valstybinės maisto ir veterinarijos tarnyba
Luxembourg	Minìstere de la Santé, Division de la	See authority for medicinal products

		for human use
Pharmacie et Médicaments	des	
Hungary	Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet / National Institute of Pharmacy and Nutrition	National Food Chain Safety Office, Directorate of Veterinary Medicinal Products / Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állatgyógyászati Termékek Igazgatósága (ÁTI)
Malta	Medicines Regulatory Authority	Veterinary Medicines Section of the National Veterinary Laboratory (NVL) within The Animal Health and Welfare Department (AHWD)
Netherlands	Healthcare and Youth Inspectorate / Inspectie Gezondheidszorg en Youth (IGJ)	Medicines Evaluation Board / Bureau Diergeneesmiddelen, College ter Beoordeling van Geneesmiddelen (CBG)
Austria	Austrian Agency for Health and Food Safety / Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH	See authority for medicinal products for human use
Poland	The Main Pharmaceutical Inspectorate / Główny Inspektorat Farmaceutyczny (GIF) /	See authority medicinal products for human use
Portugal	National Authority of Medicines and Health Products / INFARMED, I.P Autoridade Nacional do Medicamento e Produtos de Saúde, I.P	General Directorate of Food and Veterinary / DGAV - Direção Geral de Alimentação e Veterinária (PT)
Romania	National Agency for Medicines and Medical Devices /	National Sanitary Veterinary and Food Safety Authority / Autoritatea Naţională Sanitară Veterinară şi

	Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale	pentru Siguranţa Alimentelor
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia / Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)	See authority for medicinal products for human use
Slovakia	State Institute for Drug Control / Štátny ústav pre kontrolu liečiv (ŠÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments / Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (USKVBL)
Finland	Finnish Medicines Agency /	See authority for medicinal products for human use
Sweden	Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA) Medical Products Agency / Läkemedelsverket	See authority for medicinal products for human use

2) United Kingdom

Medicines and Healthcare Products Regulatory Agency

Veterinary Medicines Directorate

APPENDIX B – List of applicable laws, regulations and technical guidelines relating to Good Manufacturing Practice

(1) For the European Union:

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;[99]

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products;[100]

Directive 2001/20/EC of European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;[101]

Regulation (EU) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC;[102]

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;[103]

Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004;[104]

Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use;[105]

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products;[106]

Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use;[107]

Commission Delegated Regulation (EU) 1252/2014 of 28 May 2014 of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use;[108]

99 OJ L 311, 28.11.2001, p. 67.
100 OJ L 311, 28.11.2001, p. 1.
101 OJ L 121, 1.5.2001, p. 34.
102 OJ L 158, 27.5.2014, p. 1.
103 OJ L 136, 30.4.2004, p. 1
104 OJ L 324, 10.12.2007, p. 121.
105 OJ L 262, 14.10.2003, p. 22.
106 OJ L 228, 17.8.1991, p. 70.
107 OJ L 238, 16.9.2017, p. 44.

Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections;[109]

Current version of the Guide to good manufacturing practice contained in volume IV of Rules governing medicinal products in the European Union and compilation of the community procedures on inspections and exchange of information.

(2) For the United Kingdom:

The Human Medicines Regulations 2012 (SI 2012/1916)

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031

The Veterinary Medicines Regulations 2013 (SI 2013/2033)

Regulations on good manufacturing practice made under regulation B17, and guidelines on good manufacturing practice published pursuant to regulation C17, of the Human Medicines Regulations 2012

The principles and guidelines on good manufacturing practice applicable for the purposes of Schedule 2 to the Veterinary Medicines Regulations 2013

108 OJ L 337, 25.11.2014, p. 1.
109 OJ L 238, 16.9.2017, p. 12.

APPENDIX C – COVERED PRODUCTS

Medicinal products for human use and veterinary use:

- marketed medicinal products for human or veterinary use, including marketed biological and immunological products for human and veterinary use,
- advanced therapy medicinal products,
- active pharmaceutical ingredients for human or veterinary use,
- investigational medicinal products.