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Agreement

on Mutual Recognition Between the United Kingdom of Great Britain and Northern Ireland and the United States of America

Washington, 14 February 2019

[The Agreement is not in force]

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by the Secretary of State for Foreign and Commonwealth Affairs
by Command of Her Majesty
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AGREEMENT ON MUTUAL RECOGNITION BETWEEN THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND AND THE UNITED STATES OF AMERICA

The United Kingdom of Great Britain and Northern Ireland ("the United Kingdom") and the United States of America ("the United States"), hereafter referred to as "the Parties",

CONSIDERING the traditional links of friendship that exist between the United States and the United Kingdom;

DESIRING to facilitate bilateral trade between them;

RECOGNIZING that mutual recognition of conformity assessment activities can be an important means of enhancing market access between the United States and the United Kingdom;

RECOGNIZING that an agreement providing for mutual recognition of conformity assessment activities is of particular interest to small and medium-sized businesses in the United States and the United Kingdom;

RECOGNIZING that any such mutual recognition also requires confidence in the continued reliability of the conformity assessments of the United States and the United Kingdom;

RECOGNIZING the importance of maintaining the high levels of health, safety, environmental, and consumer protection in the United States and the United Kingdom;

RECOGNIZING that mutual recognition agreements can positively contribute to the facilitation of bilateral trade;

NOTING that this Agreement is not intended to displace private sector bilateral and multilateral arrangements among conformity assessment bodies or to affect regulatory regimes allowing for manufacturers' self-assessments and declarations of conformity;

BEARING IN MIND that the Agreement on Technical Barriers to Trade, an agreement annexed to the Agreement Establishing the World Trade Organization (WTO), encourages WTO Members to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment procedures;

RECOGNIZING that any such mutual recognition needs to offer an assurance of conformity with applicable technical regulations or standards equivalent to the assurance offered by the Party's own procedures;

RECOGNIZING the need to conclude an Agreement on Mutual Recognition (MRA) in the field of conformity assessment with sectoral annexes; and

BEARING IN MIND the respective commitments of the Parties under bilateral, regional, and multilateral environment, health, safety, and consumer protection agreements,

HAVE AGREED AS FOLLOWS:

ARTICLE 1

Definitions

1. The following terms and definitions shall apply to this Agreement only:

   - **Designating Authority** means a body with power to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies as specified under this Agreement.

   - **Designation** means the identification by a Designating Authority of a conformity assessment body to perform conformity assessment procedures under this Agreement.

   - **Party** means the United States or the United Kingdom, as the case may be.

   - **Regulatory Authority** means a government agency or entity that exercises a legal right to control the use or sale of products within a Party's jurisdiction, and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

2. Other terms concerning conformity assessment used in this Agreement shall have the meaning given elsewhere in this Agreement or in the definitions contained in International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) ISO/IEC 17000:2004 and ISO/IEC Guide 2:2004. In the event of an inconsistency between ISO/IEC 17000:2004**,** ISO/IEC Guide 2:2004, and definitions in this Agreement, the definitions in this Agreement shall prevail.

ARTICLE 2

Purpose of the Agreement

This Agreement specifies the conditions by which each Party shall accept or recognize results of conformity assessment procedures, produced by the conformity assessment bodies or authorities of the other Party, in assessing conformity to an importing Party's requirements, as specified on a sector-specific basis in the Sectoral Annexes, and to provide for other related cooperative activities. The objective of such mutual recognition is to provide effective market access between the United States and the United Kingdom with regard to conformity assessment for all products covered under this Agreement. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the Party alleging its market access has been denied, may, within 90 days of such consultation, invoke its right to terminate this Agreement in its entirety, or any individual Sectoral Annex thereof**,** in accordance with Article 20.

ARTICLE 3

General Obligations

1. The United States shall, as specified in the Sectoral Annexes, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the United States, produced by designated conformity assessment bodies and/or authorities in the United Kingdom.

2. The United Kingdom shall, as specified in the Sectoral Annexes, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the United Kingdom, produced by designated conformity assessment bodies and/or authorities in the United States.

3. Where sectoral transition arrangements have been specified in Sectoral Annexes, the above obligations will apply following the successful completion of those sectoral transition arrangements, with the understanding that the conformity assessment procedures utilized assure conformity to the satisfaction of the importing Party with applicable legislative, regulatory, and administrative provisions of that Party, equivalent to the assurance offered by the importing Party's own procedures.

ARTICLE 4

General Coverage of the Agreement

1. This Agreement applies to conformity assessment procedures for products and/or processes and to other related cooperative activities as described in this Agreement.

2. Sectoral Annexes may include:

(a) a description of the relevant legislative, regulatory, and administrative provisions pertaining to the conformity assessment procedures and technical regulations;

(b) a statement on the product scope and coverage;

(c) a list of Designating Authorities;

(d) a list of agreed conformity assessment bodies or authorities or a source from which to obtain a list of such bodies or authorities and a statement of the scope of the conformity assessment procedures for which each has been agreed;

(e) the procedures and criteria for designating the conformity assessment bodies;

(f) a description of the mutual recognition obligations;

(g) a sectoral transition arrangement;

(h) the identity of a sectoral contact point in each Party's territory; and

(i) a statement regarding the establishment of a Joint Sectoral Committee.

3. This Agreement shall not be construed to entail mutual acceptance of standards or technical regulations of the Parties and, unless otherwise specified in a Sectoral Annex, shall not entail the mutual recognition of the equivalence of standards or technical regulations.

ARTICLE 5

Designating Authorities

Each Party shall ensure that the Designating Authorities specified in the Sectoral Annexes have the power and competence in their respective territories to carry out

decisions under this Agreement to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies.

ARTICLE 6

Designation and Listing Procedures

The following procedures shall apply with regard to the designation of conformity assessment bodies and the inclusion of such bodies in the list of conformity assessment bodies in a Sectoral Annex:

(a) The Designating Authority identified in a Sectoral Annex shall designate conformity assessment bodies in accordance with the procedures and criteria set forth in that Sectoral Annex;

(b) A Party proposing to add a conformity assessment body to the list of such bodies in a Sectoral Annex shall forward its proposal of one or more designated conformity assessment bodies in writing to the other Party with a view to a decision by the Joint Committee;

(c) Within 60 days following receipt of the proposal, the other Party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation through a decision by the Joint Committee**,** the inclusion in the Sectoral Annex of the proposed conformity assessment body or bodies shall take effect; and

(d) In the event that the other Party contests on the basis of documented evidence the technical competence or compliance of a proposed conformity assessment body, or indicates in writing that it requires an additional 30 days to more fully verify such evidence, such conformity assessment body shall not be included on the list of conformity assessment bodies in the applicable Sectoral Annex. In this instance, the Joint Committee may decide that the body concerned be verified. After the completion of such verification, the proposal to list the conformity assessment body in the Sectoral Annex may be resubmitted to the other Party.

ARTICLE 7

Suspension of Listed Conformity Assessment Bodies

The following procedures shall apply with regard to the suspension of a conformity assessment body listed in a Sectoral Annex:

(a) A Party shall notify the other Party of its contestation of the technical competence or compliance of a conformity assessment body listed in a Sectoral Annex and its intent to suspend such conformity assessment body. Such contestation shall be exercised when justified in an objective and reasoned manner in writing to the other Party;

(b) The conformity assessment body shall be given prompt notice by the other Party and an opportunity to present information in order to refute the contestation or to correct the deficiencies which form the basis of the contestation;

(c) The Parties shall discuss any such contestation in the relevant Joint Sectoral Committee. If there is no Joint Sectoral Committee, the contesting Party shall refer the matter directly to the Joint Committee. If agreement to suspend is reached by the Joint Sectoral Committee or, if there is no Joint Sectoral Committee, by the Joint Committee, the conformity assessment body shall be suspended;

(d) Where the Joint Sectoral Committee or Joint Committee decides that verification of technical competence or compliance is required, it shall normally be carried out in a timely manner by the Party in whose territory the body in question is located, but may be carried out jointly by the Parties in justified cases;

(e) If the matter has not been resolved by the Joint Sectoral Committee within 10 days of the notice of contestation, the matter shall be referred to the Joint Committee for a decision. If there is no Joint Sectoral Committee, the matter shall be referred directly to the Joint Committee. If no decision is reached by the Joint Committee within 10 days of the referral to it, the conformity assessment body shall be suspended upon the request of the contesting Party;

(f) Upon the suspension of a conformity assessment body listed in a Sectoral Annex, the contesting Party is no longer obligated to accept or recognize the results of conformity assessment procedures performed by that conformity assessment body subsequent to suspension. The contesting Party shall continue to accept the results of conformity assessment procedures performed by that conformity assessment body prior to suspension, unless a Regulatory Authority of that Party decides otherwise based on health, safety, or environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex; and

(g) The suspension shall remain in effect until agreement has been reached by the Joint Committee with respect to the future status of that conformity assessment body.

ARTICLE 8

Withdrawal of Listed Conformity Assessment Bodies

The following procedures shall apply with regard to the withdrawal from a Sectoral Annex of a conformity assessment body:

(a) A Party proposing to withdraw a conformity assessment body listed in a Sectoral Annex shall forward its proposal in writing to the other Party;

(b) Such conformity assessment body shall be promptly notified by the other Party and shall be provided a period of at least 30 days from receipt to provide information in order to refute or to correct the deficiencies which form the basis of the proposed withdrawal;

(c) Within 60 days following receipt of the proposal, the other Party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation through a decision by the Joint Committee, the withdrawal from the list in the Sectoral Annex of the conformity assessment body shall take effect;

(d) In the event that the other Party opposes the proposal to withdraw by supporting the technical competence and compliance of its conformity assessment body, the conformity assessment body shall not at that time be withdrawn from the list of conformity assessment bodies in the applicable Sectoral Annex. In this instance, the Joint Sectoral Committee or the Joint Committee may decide to carry out a joint verification of the body concerned. After the completion of such verification, the proposal for withdrawal of the conformity assessment body may be resubmitted to the other Party; and

(e) Subsequent to the withdrawal of a conformity assessment body listed in a Sectoral Annex, the contesting Party shall continue to accept the results of conformity assessment procedures performed by that conformity assessment body prior to withdrawal, unless a Regulatory Authority of that Party decides otherwise based on health, safety, and environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex.

ARTICLE 9

Monitoring of Conformity Assessment Bodies

The following shall apply with regard to the monitoring of conformity assessment bodies listed in a Sectoral Annex:

(a) Designating Authorities shall assure that their conformity assessment bodies listed in a Sectoral Annex are capable and remain capable of properly assessing conformity of products or processes, as applicable, and as covered in the applicable Sectoral Annex. In this regard, Designating Authorities shall maintain, or cause to maintain, ongoing surveillance over their conformity assessment bodies by means of regular audit or assessment;

(b) The Parties undertake to compare methods used to verify that the conformity assessment bodies listed in the Sectoral Annexes comply with the relevant requirements of the Sectoral Annexes. Existing systems for the evaluation of conformity assessment bodies may be used as part of such comparison procedures;

(c) A Designating Authority shall consult as necessary with its counterpart(s), to ensure the maintenance of confidence in conformity assessment procedures. With the consent of each Party concerned, this consultation may include joint participation in audits/inspections related to conformity assessment activities or other assessments of conformity assessment bodies listed in a Sectoral Annex; and

(d) Designating Authorities shall consult, as necessary, with the relevant Regulatory Authorities of the other Party to ensure that all technical requirements are identified and are satisfactorily addressed.

ARTICLE 10

Conformity Assessment Bodies

The United States and the United Kingdom recognize that the conformity assessment bodies listed in the Sectoral Annexes fulfill the conditions of eligibility to assess conformity in relation to their respective requirements as specified in the Sectoral Annexes, and they shall specify the scope of the conformity assessment procedures for which such bodies are listed.

ARTICLE 11

Exchange of Information

1. The Parties shall exchange information concerning the implementation of the legislative, regulatory, and administrative provisions identified in the Sectoral Annexes.

2. Each Party shall notify the other of legislative, regulatory, and administrative changes related to the subject matter of this Agreement at least 60 days before their entry into force. Where considerations of safety, health, or environmental

protection require more urgent action, a Party shall notify the other Party as soon as practicable.

3. Each Party shall promptly notify the other of any changes to its Designating Authorities and/or conformity assessment bodies.

4. The Parties shall exchange information concerning the procedures used to ensure that the listed conformity assessment bodies under their responsibility comply with the legislative, regulatory, and administrative provisions outlined in the Sectoral Annexes.

5. Regulatory Authorities identified in the Sectoral Annexes shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures and to ensure that all technical requirements are identified and are satisfactorily addressed.

ARTICLE 12

Sectoral Contact Points

Each Party shall appoint and confirm in writing contact points to be responsible for activities under each Sectoral Annex.

ARTICLE 13

Joint Committee of the Parties

1. The Parties hereby establish a Joint Committee consisting of representatives of each Party. The Joint Committee shall be responsible for the effective functioning of this Agreement.

2. The Joint Committee may establish Joint Sectoral Committees comprised of appropriate Regulatory Authorities and others deemed necessary.

3. Each Party shall each have one vote in the Joint Committee. The Joint Committee shall make its decisions by unanimous consent. The Joint Committee shall determine its own rules and procedures.

4. The Joint Committee may consider any matter relating to the effective functioning of this Agreement. In particular it shall be responsible for:

(a) listing, suspension, withdrawal, and verification of conformity assessment bodies in accordance with this Agreement;

(b) amending transitional arrangements in Sectoral Annexes;

(c) resolving any questions relating to the application of this Agreement and its Sectoral Annexes not otherwise resolved in the respective Joint Sectoral Committees;

(d) providing a forum for discussion of issues that may arise concerning the implementation of this Agreement;

(e) considering ways to enhance the operation of this Agreement;

(f) coordinating the negotiation of additional Sectoral Annexes; and

(g) considering whether to amend this Agreement or its Sectoral Annexes in accordance with Article 20(2).

5. Following the entry into force of this Agreement, the Joint Committee shall consider decisions of the Joint Committee established under Article 14 of the *Agreement on mutual recognition between the European Community and the United States of America* in respect of the matters listed in paragraph 4.

6. When a Party introduces new or additional conformity assessment procedures affecting a Sectoral Annex, the Parties shall discuss the matter in the Joint Committee with a view to bringing such new or additional procedures within the scope of this Agreement and the relevant Sectoral Annex.

ARTICLE 14

Preservation of Regulatory Authority

1. Nothing in this Agreement shall be construed to limit the authority of a Party to determine, through its legislative, regulatory, and administrative measures, the level of protection it considers appropriate for safety; for protection of human, animal, or plant life or health; for the environment; for consumers; and otherwise with regard to risks within the scope of the applicable Sectoral Annex.

2. Nothing in this Agreement shall be construed to limit the authority of a Regulatory Authority to take all appropriate and immediate measures whenever it ascertains that a product may: (a) compromise the health or safety of persons in its territory; (b) not meet the legislative, regulatory, or administrative provisions within the scope of the applicable Sectoral Annex; or (c) otherwise fail to satisfy a requirement within the scope of the applicable Sectoral Annex. Such measures may include withdrawing the products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, and preventing the recurrence of such problems, including through a prohibition on imports. If the Regulatory Authority takes such action, it shall inform its counterpart authority(ies) and the other Party within 15 days of taking such action, providing its reasons.

ARTICLE 15

Suspension of Recognition Obligations

Either Party may suspend its obligations under a particular Sectoral Annex, in whole or in part, if:

(a) it suffers a loss of market access for its products within the scope of the Sectoral Annex as a result of the failure of the other Party to fulfill its obligations under this Agreement;

(b) the adoption of new or additional conformity assessment procedures, as referenced in Article 13(6), by the other Party results in a loss of market access for its products within the scope of the Sectoral Annex because conformity assessment bodies designated by it in order to meet such requirements have not been recognized by the other Party; or

(c) the other Party fails to maintain legal and regulatory authorities capable of implementing the provisions of this Agreement.

ARTICLE 16

Confidentiality

1. Each Party shall maintain, to the extent allowed under its laws, the confidentiality of information exchanged under this Agreement.

2. In particular, no Party shall disclose to the public, nor permit a conformity assessment body to disclose to the public, information exchanged under this Agreement that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation.

3. A Party or a conformity assessment body may, upon exchanging information with the other Party or with a conformity assessment body of the other Party, designate the portions of the information that it considers to be exempt from disclosure.

4. Each Party shall take all precautions reasonably necessary to protect information exchanged under this Agreement from unauthorized disclosure.

ARTICLE 17

Fees

Each Party shall endeavor to ensure that fees imposed for services under this Agreement shall be commensurate with the services provided. Each Party shall ensure that, for the sectors and conformity assessment procedures covered under this Agreement, it shall charge no fees with respect to conformity assessment services provided by the other Party.

ARTICLE 18

Agreements with Other Countries

Except where there is written agreement between the Parties, obligations contained in mutual recognition agreements concluded by a Party with a party not a signatory to this Agreement (a third party) shall have no force and effect with regard to the other Party in terms of acceptance of the results of conformity assessment procedures in the third party.

ARTICLE 19

Territorial Application

This Agreement shall apply, on the one hand, to the territory of the United States, and, on the other hand, to the territory of the United Kingdom and the territories of the Isle of Man and the Channel Islands.

ARTICLE 20

Entry into Force, Amendment, Withdrawal, and Termination

1. This Agreement, including its Sectoral Annexes on Telecommunications Equipment, Electromagnetic Compatibility, and Pharmaceutical Good Manufacturing Practices, shall enter into force on the date of the later notification in an exchange of written notifications between the Parties certifying that they have completed their respective internal requirements and procedures. In submitting a notification, the United Kingdom shall take account of its obligations arising in

respect of any agreement between the European Union and the United Kingdom pursuant to Article 50 of the Treaty on European Union.

2. The Parties may amend this Agreement, including the Sectoral Annexes, through written agreement. The Parties may add a Sectoral Annex to this Agreement by an exchange of letters. Any such Sectoral Annex shall enter into force on the first day of the second month following the date on which the Parties have exchanged notes confirming the completion of their respective procedures for the entry into force of such Sectoral Annex. The Joint Committee may also amend Sectoral Annexes in accordance with Article 13.

3. Either Party may terminate this Agreement in its entirety or any individual Sectoral Annex thereof by giving the other Party six months' notice in writing. In the case of termination of one or more Sectoral Annexes, the Parties will seek to amend this Agreement, with a view to preserving the remaining Sectoral Annexes in accordance with the procedures in this Article. If the Parties cannot agree on an amendment to this Agreement or a Sectoral Annex, this Agreement or the relevant Sectoral Annex shall terminate at the end of six months from the date of notice.

4. Following termination of this Agreement in its entirety or any individual Sectoral Annex thereof, a Party shall continue to accept the results of conformity assessment procedures performed by conformity assessment bodies under this Agreement prior to termination, unless a Regulatory Authority of that Party decides otherwise based on health, safety, and environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex.

ARTICLE 21

Final Provisions

1. The Sectoral Annexes referred to in Article 20(1), as well as any new Sectoral Annexes added pursuant to Article 20(2), shall form an integral part of this Agreement.

2. For a given product or sector, the provisions contained in the relevant Sectoral Annexes shall apply in the first place, and the provisions of this Agreement in addition to those provisions. In the case of any inconsistency between the provisions of a Sectoral Annex and this text, the Sectoral Annex shall prevail, to the extent of that inconsistency.

3. This Agreement shall not affect the rights and obligations of the Parties under any other international agreement.

IN WITNESS WHEREOF, the undersigned, being duly authorized by their respective Governments, have signed this Agreement.

DONE at Washington, in duplicate, this fourteenth day of February 2019.

For the United Kingdom of Great Britain and Northern Ireland	For the United States of America
KIM DARROCH	**CJ MAHONEY**

UK – U.S MRA

SECTORAL ANNEX

FOR

TELECOMMUNICATIONS EQUIPMENT

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition Between the United States of America and the United Kingdom of Great Britain and Northern Ireland.

SECTION I

LEGISLATIVE, REGULATORY, AND ADMINISTRATIVE PROVISIONS

United Kingdom	United States
Radio Equipment Regulations 2017 (SI 2017/1206); For pure wired telecommunications terminal equipment without a radio component, see Electromagnetic Compatibility Regulations (SI 2016/1091).	Communication Act of 1934, as amended by the Telecommunication Act of 1996 (Title 47 of the United States Code); The U.S. regulatory and administrative provisions in respect of telecommunications equipment, including 47 CFR Part 68, and FCC interpretation thereof; The U.S. regulatory and administrative provisions in respect of all radio transmitters subject to an equipment authorization requirement. A non-exclusive list of FCC regulations are contained in Section II; For electromagnetic compatibility aspects, see Electromagnetic Compatibility (EMC) Sectoral Annex to the Agreement.

SECTION II

SCOPE AND COVERAGE

1. This Sectoral Annex shall apply to equipment, interfaces, and services subject to Section I. In general terms the provisions of this Sectoral Annex shall apply to the following types of telecommunications terminal equipment, satellite terminal equipment, radio transmitters, and information technology equipment:

(a) equipment intended for connection to the public telecommunications network in order to send, process or receive information, whether the

equipment is to be connected directly to the "termination" of the network or to inter-work with such a network, being connected directly or indirectly to the termination point. The system of connection may be wire, radio, optical or other electro-magnetic means;

(b) equipment capable of being connected to a public telecommunications network even if it is not its intended purpose, including information technology equipment having a communication port; and

(c) all radio transmitters subject to an equipment authorization procedure by each Party.

2. The following is a non-exclusive list of the equipment, interfaces, and services included within the scope of this Sectoral Annex:

United Kingdom	United States
U.S. access to the UK market: The following equipment categories are included: Pure wired telecommunications terminal equipment without a radio component covered by the EMC Regulation (SI 2016/1091), including: ISDN Basic Rate Access ISDN Primary Rate Access ISDN Telephony X21/V.24/V.35 Access X25 Access PSTN Non-Voice PSTN Voice Band (Analog) ONP Leased Line Terminal types: -64 kbits/sec -2048 kbits/s unstructured -2048 kbits/s structured -34 Mbits/s access -140 Mbits/s access -2 wire analogue -4 wire analogue Radio equipment covered by the Radio Equipment Regulation (SI 2017/1206)	UK access to the U.S. market: The following equipment categories are included: Telephone Terminal Equipment that are contained in the following: (1) 47 CFR Part 68 and; (2) Documents published by the Administrative Council for Terminal Attachment (ACTA), established in the FCC CC Docket 99-216. Radio transmitters subject to an equipment authorization requirement, including: Equipment Authorization Requirements (Part 2) Radio Frequency Devices (Part 15) Commercial Mobile Services (Part 20) Public Mobile Services (Part 22) Personal Communication Service (Part 24) Satellite Communications (Part 25) Miscellaneous Wireless Communication

that is subject to equipment authorization, including: Short range devices, including low power devices such as cordless telephones/ microphones; Land mobile, including: - Private Mobile Radio (PMR/PAMR) - Mobile telecom - Paging systems Terrestrial fixed Satellite mobile Satellite fixed Broadcast Radio determination	Services (Part 27) Upper Microwave Flexible Use Service (Part 30) Broadcast (Part 73) Auxiliary Broadcast (Part 74) Cable Television Radio (Part 78) Maritime Services (Part 80) Aviation Services (Part 87) Private Land Mobile (Part 90) Personal Radio Services (Part 95) Citizens Broadband Radio Service (Part 96) Amateur Radio (Part 97) Fixed Microwave Services (Part 101)

Note: A list of acronyms and a glossary is contained in Appendix 1 to this Sectoral Annex.

SECTION III

CONFORMITY ASSESSMENT PROCEDURES FOR TELECOMMUNICATIONS EQUIPMENT

1. Description of Mutual Recognition Obligations

In accordance with the provisions of the Agreement, the results of the conformity assessment procedures produced by a Party's conformity assessment bodies listed in Section V shall be recognized by the Regulatory Authorities of the other Party without any further conformity assessment of the products, pursuant to Section I.

2. Conformity Assessment Procedures

Taking into account the legislative, regulatory, and administrative provisions as identified in Section I, each Party recognizes that the conformity assessment bodies of the other Party, listed in Section V, are authorized to perform the following procedures with regard to an importing Party's technical requirements for equipment identified in Section II:

(a) testing and issuing of test reports;

(b) issuing certificates of conformity to the requirements of the laws and regulations applicable in the territories of the Parties for products covered under this Sectoral Annex;

(c) performing procedures related to quality assurance approval pursuant to Radio Equipment Regulations 2017 (SI 2017/1206); and

(d) performing procedures related to type examination pursuant to Radio Equipment Regulations 2017 (SI 2017/1206) and Electromagnetic Compatibility Regulations SI 2016/1091.

SECTION IV

AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

United Kingdom	United States
Department for Business, Energy and Industrial Strategy (BEIS)	National Institute of Standards and Technology (NIST)

AUTHORITIES RESPONSIBLE FOR APPROVING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

United Kingdom	United States
Department for Business, Energy and Industrial Strategy (BEIS)	Federal Communications Commission (FCC)

SECTION V

CONFORMITY ASSESSMENT BODIES

UK access to U.S. market	U.S. access to UK market
Conformity assessment bodies located in the United Kingdom shall be designated by the UK Authorities identified in Section IV following the procedures set out in Section VI of this Annex. The United States confirms that the conformity assessment bodies located in the territory of the United Kingdom that were recognized by the United States the day preceding the entry into force of this Agreement shall continue to be recognized by the United States upon entry into force of this Agreement. After entry into force of this Agreement, the United States shall maintain an up-to-date list online of the conformity assessment bodies located in the territory of the United Kingdom that have been recognized by U.S. Authorities.	Conformity assessment bodies located in the United States shall be designated by the U.S. Authorities identified in Section IV following the procedures set out in Section VI of this Annex. The United Kingdom confirms that the conformity assessment bodies located in the territory of the United States that were recognized by the United Kingdom the day preceding the entry into force of this Agreement shall continue to be recognized by the United Kingdom upon entry into force of this Agreement. After entry into force of this Agreement, the United Kingdom shall maintain an up-to-date list online of the conformity assessment bodies located in the territory of the United States that have been recognized by UK Authorities.

SECTION VI

DESIGNATING, LISTING, SUSPENDING, WITHDRAWING, AND MONITORING CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

UK access to U.S. market	U.S. access to UK market
UK Authorities identified in Section IV	U.S. Authorities identified in Section IV

shall designate conformity assessment bodies located in the United Kingdom in accordance with the legislative, regulatory, and administrative provisions of the United States identified in Section I that govern designation of conformity assessment bodies, based on compliance with the appropriate standards in the ISO/IEC 17000 series (e.g., 17000, 17011, 17020, 17025, and 17065). Procedures for designating, listing, suspending, withdrawing, and monitoring a conformity assessment body listed in Section V shall be undertaken pursuant to Articles 6, 7, 8, and 9 of the Agreement.	shall designate conformity assessment bodies located in the United States in accordance with the legislative, regulatory, and administrative provisions of the United Kingdom identified in Section I that govern designation of conformity assessment bodies, based on compliance with the appropriate standards in the ISO/IEC 17000 series (e.g., 17000, 17011, 17020, 17025, and 17065). Procedures for designating, listing, suspending, withdrawing, and monitoring a conformity assessment body listed in Section V shall be undertaken pursuant to Articles 6, 7, 8, and 9 of the Agreement.

SECTION VII

ADDITIONAL PROVISIONS

1. SUB-CONTRACTING

1.1 Any sub-contracting by conformity assessment bodies of one Party shall be in accordance with the sub-contracting requirements of the other Party. Notwithstanding the use of sub-contracting, the final results of conformity assessment remain the full responsibility of the listed conformity assessment body.

1.2 The conformity assessment bodies shall record and retain details of their investigation of the competence and compliance of their subcontractors and maintain a register of all sub-contracting. These details will be made available to the other Party on request.

2. POST-MARKET SURVEILLANCE, BORDER MEASURES, AND INTERNAL MOVEMENT

2.1 For the purpose of post-market surveillance, the Parties may maintain any existing labeling and numbering requirements. The assignment of the numbers may take place in the territory of the exporting Party. The numbers will be allocated by the importing Party. Numbering and labeling systems shall not introduce additional requirements within the meaning of this Sectoral Annex.

2.2 Nothing in this Sectoral Annex shall prevent the Parties from removing products from the market that do not in fact conform to the requirements for approval.

2.3 Border inspections and checks of products which have been certified, labeled or marked as conforming with the importing Party's requirements specified in Section I shall be completed as expeditiously as possible. With regard to any inspections related to internal movement within their respective territories, these shall be completed in no less a favorable manner than for like-domestic goods.

3. JOINT SECTORAL COMMITTEE

3.1 A combined Joint Sectoral Committee for this Sectoral Annex and the EMC Sectoral Annex is hereby established (the JSC). The JSC shall meet as appropriate to discuss technical, conformity assessment, and technology issues relating to this Sectoral Annex and the EMC Sectoral Annex. The JSC shall determine its own rules of procedure.

3.2 The JSC consists of representatives of the United States and the United Kingdom for telecommunications and EMC. JSC representatives may each invite manufacturers and other entities as deemed necessary. The representatives for the United States shall have one vote in the JSC. The representatives of the United Kingdom shall have one vote in the JSC. Decisions of the JSC shall be made by unanimous consent. In the event of disagreement, either representatives of the United States or the United Kingdom may raise the matter in the Joint Committee.

3.3 The JSC may address any matter related to the effective functioning of this Sectoral Annex, including:

(a) providing a forum for discussion of issues and resolving problems that may arise concerning the implementation of this Sectoral Annex;

(b) developing a mechanism for ensuring consistency of interpretations of legislation, regulations, standards, and conformity assessment procedures;

(c) advising the Parties on matters relating to this Sectoral Annex; and

(d) providing guidance.

4. CONTACT POINT

Each Party shall establish a contact point to provide answers to all reasonable inquiries from the other Party regarding procedures, regulations, and complaints under this Sectoral Annex.

UK Contact Point	U.S. Contact Point
Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom	Federal Communications Commission (FCC) 7435 Oakland Mills Road Columbia, MD 21046 Tel: 301-362-3000 Fax: 301-362-3290 www.fcc.gov

5. REGULATORY CHANGES AND UPDATING THE SECTORAL ANNEX

In the event that there are changes to the legislative, regulatory, and administrative provisions referenced in Section I or the introduction of new legislative, regulatory, and administrative provisions affecting a Party's conformity assessment procedures under the Agreement, such changes shall take effect for the purpose of this Sectoral Annex at the same time they take effect domestically within the territory of that Party. The Parties shall update this Sectoral Annex to reflect the changes.

APPENDIX 1

LISTS OF ACRONYMS AND GLOSSARY

CFR	U.S. Code of Federal Regulations, Title 47 CFR
FCC	Federal Communications Commission
IEC	International Electrotechnical Commission
ISDN	Integrated Services Digital Network
ISO	International Organization for Standardization
ITU	International Telecommunications Union
MRA	Mutual Recognition Agreement
NIST	National Institute of Standards and Technology
ONP	Open Network Provision
PSTN	Public Switched Telephone Network
X21	ITU-T Recommendation X21
X25	ITU-T Recommendation X25

UK – U.S MRA

SECTORAL ANNEX

FOR

ELECTROMAGNETIC COMPATIBILITY (EMC)

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition Between the United States of America and the United Kingdom of Great Britain and Northern Ireland.

SECTION I

LEGISLATIVE, REGULATORY, AND ADMINISTRATIVE PROVISIONS

United Kingdom	United States
Electromagnetic Compatibility Regulations 2016 (SI 2016/1091) For telecommunications equipment, terminal equipment, and radio transmitters, see also Telecommunications Equipment Sectoral Annex to the Agreement.	Communications Act of 1934, as amended by the Telecommunication Act of 1996 (Title 47 of the United States Code); The U.S. regulatory and administrative provisions in respect of equipment subject to electromagnetic requirements including 47 CFR Parts 11, 15, and 18, and FCC interpretation thereof; For telecommunications equipment and radio transmitters, see also Telecommunications Equipment Sectoral Annex to the Agreement.

Note: A list of acronyms and a glossary appears at Appendix 1 to the Telecommunications Equipment Sectoral Annex.

SECTION II

SCOPE AND COVERAGE

United Kingdom	United States
U.S. access to the UK market: Any product falling under the scope of Electromagnetic Compatibility	UK access to the U.S. market: Any products falling under the scope of 47 CFR Parts 11, 15, and 18.

Regulations 2016 (SI 2016/1091), except for pure wired telecommunications terminal equipment covered by the sectoral annex for telecommunications equipment to this Agreement.	

SECTION III

CONFORMITY ASSESSMENT PROCEDURES FOR EQUIPMENT IDENTIFIED IN SECTION II

1. Description of Mutual Recognition Obligations

In accordance with the provisions of the Agreement, the results of the conformity assessment procedures produced by a Party's conformity assessment bodies listed in Section V shall be recognized by the Regulatory Authorities of the other Party without any further conformity assessment of the products, pursuant to Section I.

2. Conformity Assessment Procedures

Taking into account the legislative, regulatory, and administrative provisions as identified in Section I, each Party recognizes that the conformity assessment bodies of the other Party, listed in Section V, are authorized to perform the following procedures with regard to an importing Party's technical requirements for equipment identified in Section II:

(a) testing and issuing of test reports;

(b) issuing certificates of conformity to the requirements of the laws and regulations applicable in the territory of the importing Party for products covered under this Sectoral Annex;

(c) performing procedures related to type examination pursuant to Electromagnetic Compatibility Regulations 2016 (SI 2016/1091).

SECTION IV

AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

United Kingdom	United States
Department for Business, Energy and Industrial Strategy (BEIS)	National Institute of Standards and Technology (NIST)

AUTHORITIES RESPONSIBLE FOR APPROVING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

United Kingdom	United States
Department for Business, Energy and Industrial Strategy (BEIS)	Federal Communications Commission (FCC)

SECTION V

CONFORMITY ASSESSMENT BODIES

UK access to the U.S. market	U.S. access to UK market
Conformity assessment bodies located in the United Kingdom shall be designated by the UK Authorities identified in Section IV following the procedures set out in Section VI of this Annex. The United States confirms that the conformity assessment bodies located in the territory of the United Kingdom that were recognized by the United States the day proceeding the entry into force of this Agreement shall continue to be recognized by the United States upon entry into force of this Agreement. After entry into force of this Agreement, the United States shall maintain an up-to-date list online of the conformity assessment bodies located in the territory of the United Kingdom that have been recognized by U.S. Authorities.	Conformity assessment bodies located in the United States shall be designated by the U.S. Authorities identified in Section IV following the procedures set out in Section VI of this Annex. The United Kingdom confirms that the conformity assessment bodies located in the territory of the United States that were recognized by the United Kingdom the day preceding the entry into force of this Agreement shall continue to be recognized by the United Kingdom upon entry into force of this Agreement. After entry into force of this Agreement, the United Kingdom shall maintain an up-to-date list online of the conformity assessment bodies located in the territory of the United States that have been recognized by UK Authorities.

SECTION VI

DESIGNATING, LISTING, SUSPENDING, WITHDRAWING, AND MONITORING CONFORMITY ASSESSMENT BODIES LISTED IN SECTION V

UK access to the U.S. market	U.S. access to UK market
UK Authorities identified in Section IV shall designate conformity assessment bodes located in the United Kingdom in accordance with the legislative, regulatory, and administrative provisions of the United States identified in Section I that govern designation of conformity assessment bodies, based upon compliance with the appropriate standards in the ISO/IEC 17000 series (e.g., 17000, 17011, 17020, 17025. and 17065). Procedures for designating, listing, suspending, withdrawing, and monitoring a conformity assessment body listed in Section V shall be undertaken pursuant to Articles 6, 7, 8, and 9 of the Agreement.	U.S. Authorities identified in Section IV shall designate conformity assessment bodies located in the United States in accordance with the legislative, regulatory, and administrative provisions of the United Kingdom identified in Section I that govern designation of conformity assessment bodies, based on compliance with the appropriate standards in the ISO/IEC 17000 series (e.g., 17000, 17011, 17020, 17025, and 17065). Procedures for designating, listing, suspending, withdrawing, and monitoring a conformity assessment body listed in Section V shall be undertaken pursuant to Articles 6, 7, 8, and 9 of the Agreement.

SECTION VII

ADDITIONAL PROVISIONS

1. SUB-CONTRACTING

1.1 Any sub-contracting by conformity assessment bodies of one Party shall be in accordance with the sub-contracting requirements of the other Party. Notwithstanding the use of sub-contracting, the final results of conformity assessment remain the full responsibility of the listed conformity assessment body.

1.2 The conformity assessment bodies shall record and retain details of their investigations of the competence and compliance of their subcontractors and maintain a register of all sub-contracting. These details will be made available to the other Party on request.

2. POST-MARKET SURVEILLANCE, BORDER MEASURES AND INTERNAL MOVEMENT

2.1 For the purpose of post-market surveillance, the Parties may maintain any existing labeling and numbering requirements. The assignment of the numbers may take place in the territory of the exporting Party. The

numbers will be allocated by the importing Party. Numbering and labeling systems shall not introduce additional requirements within the meaning of this Sectoral Annex.

2.2 Nothing in this Sectoral Annex shall prevent the Parties from removing products from the market that do not in fact conform to the requirements for approval.

2.3 Border inspections and checks of products which have been certified, labeled or marked as conforming with the importing Party's requirements specified in Section I shall be completed as expeditiously as possible. With regard to any inspections related to internal movement within their respective territories, these shall be completed in no less a favorable manner than for like-domestic goods.

3. JOINT SECTORAL COMMITTEE

3.1 A combined Joint Sectoral Committee for this Sectoral Annex and the Telecommunications Equipment Sectoral Annex is hereby established (the JSC). The JSC shall meet as appropriate to discuss technical, conformity assessment, and technology issues relating to this Sectoral Annex and the Telecommunications Equipment Sectoral Annex. The JSC shall determine its own rules of procedure.

3.2 The JSC consists of representatives of the United States and the United Kingdom for telecommunications and EMC. JSC representatives may each invite manufacturers and other entities as deemed necessary. The representatives for the United States shall have one vote in the JSC. The representatives of the United Kingdom shall have one vote in the JSC. Decisions of the JSC shall be made by unanimous consent. In the event of disagreement, either representatives of the United States or the United Kingdom may raise the matter in the Joint Committee.

3.3 The JSC may address any matter related to the effective functioning of this Sectoral Annex, including:

(a) providing a forum for discussion of issues and resolving problems that may arise concerning the implementation of this Sectoral Annex;

(b) developing a mechanism for ensuring consistency of interpretations of legislation, regulations, standards, and conformity assessment procedures;

(c) advising the Parties on matters relating to this Sectoral Annex; and

(d) providing guidance.

4. CONTACT POINTS

Each Party shall establish a contact point to provide answers to all reasonable inquiries from the other Party regarding procedures, regulations, and complaints under this Sectoral Annex.

UK Contact Point	U.S. Contact Point
Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom	Federal Communications Commission (FCC) 7435 Oakland Mills Road Columbia, MD 21046 Tel: 301-362-3000 Fax: 301-362-3290 www.fcc.gov

5. REGULATORY CHANGES AND UPDATING THE SECTORAL ANNEX

In the event that there are changes to the legislative, regulatory, and administrative provisions referenced in Section I or the introduction of new legislative, regulatory, and administrative provisions affecting a Party's conformity assessment procedures under the Agreement, such changes shall take effect for the purpose of this Sectoral Annex at the same time they take effect domestically within the territory of that Party. The Parties shall update this Sectoral Annex to reflect the changes.

UK – U.S MRA

SECTORAL ANNEX

FOR

PHARMACEUTICAL GOOD MANUFACTURING PRACTICES (GMPs)

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition Between the United States of America and the United Kingdom of Great Britain and Northern Ireland.

ARTICLE 1

Definitions

For purposes of this Annex:

1. "Assessment pursuant to this Sectoral Annex" means:

for the United Kingdom, an equivalence assessment; and

for the United States, a capability assessment.

An assessment pursuant to this Sectoral Annex includes a reassessment.

2. "Recognized authority" means:

for the United Kingdom, an equivalent authority; and

for the United States, a capable authority.

3. "Capable authority" means an authority that the U.S. Food and Drug Administration (FDA) has determined is capable according to the criteria and procedures specified in Appendix 4 and referred to in the U.S. laws, regulations, and administrative provisions listed in Appendix 1. For greater certainty, a finding that a regulatory authority is "capable" does not require that the authority maintain procedures for conducting inspections and overseeing manufacturing facilities that are identical to FDA's procedures.

4. "Equivalent authority" means an authority in respect of which the United Kingdom has made a positive equivalence determination according to the criteria and procedures specified in Appendix 4 and as referred to in the UK laws, regulations, and administrative provisions listed in Appendix 1.

5. "Equivalence" means that the regulatory system under which an authority operates is sufficiently comparable to assure that the process of inspection and the ensuing official GMPs documents will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. For greater certainty, "equivalence" does not require that the respective regulatory systems have identical procedures.

6. "Enforcement" means an action taken by an authority to protect the public from products of suspect quality, safety, and efficacy or to assure that products

are manufactured in compliance with appropriate laws, regulations, standards, and commitments made as part of the approval to market a product.

7. "Good Manufacturing Practices" (GMPs) means systems that assure proper design, monitoring, and control of manufacturing processes and facilities, the adherence to which assures the identity, strength, quality, and purity of pharmaceuticals. GMPs include strong quality management systems, obtaining appropriate quality raw materials (including starting materials) and packaging materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories.

8. "Inspection" means an on-site evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMPs and/or commitments made as part of the approval to market a product.

9. "Inspection Report" means a report written by an investigator or inspector of an authority listed in Appendix 2 concerning an inspection of a manufacturing facility that the investigator or inspector conducted that describes the purpose and scope of an inspection and includes written observations and findings bearing on the manufacturing facilities conformance to applicable GMPs requirements set out in the laws, regulations, and administrative procedures listed in Appendix 1 and any commitments made as part of the approval to market a product.

10. "Official GMPs document" means a document issued by an authority listed in Appendix 2 following an inspection of a manufacturing facility. Examples of official GMPs documents include inspection reports, certificates issued by an authority attesting the compliance of a manufacturing facility with GMPs, GMPs non-compliance statement issued by a UK authority, and notices of observation, untitled letters, warning letters, and import alerts issued by the FDA.

11. "Pharmaceuticals" includes drugs and medicinal products as defined in the laws and regulations listed in Appendix 1.

12. "Post-approval inspections" means application specific inspections following a recent authorization carried out in the territory of a Party.

13. "GMP surveillance inspections" means inspections of pharmaceuticals manufacturing facilities conducted in the territory of a Party during the marketing of products.

14. "Pre-approval inspections" means pharmaceutical inspections of manufacturing facilities carried out in the territory of a Party as part of the review of an application before marketing approval is granted.

15. "Regulatory System" means the body of legal requirements for GMPs, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

ARTICLE 2

Purpose

This Sectoral Annex facilitates the exchange of official GMPs documents between the Parties and reliance on the factual findings in such documents. This Sectoral Annex seeks to facilitate trade and benefit public health by allowing each Party to leverage and to reallocate its inspection resources, including by avoiding duplication of inspections, so as to improve oversight of manufacturing facilities and better address quality risk and prevent adverse health consequences.

ARTICLE 3

Scope

1. The provisions of this Sectoral Annex apply to GMP surveillance inspections and, to the extent provided for in Article 9 of this Sectoral Annex, pre- and post-approval inspections, as well as, to the extent provided for in Article 6.3 of this Sectoral Annex, to pharmaceutical inspections of manufacturing facilities carried out outside the territory of either Party.

2. Appendix 1 names the laws, regulations, and administrative provisions governing these inspections and the GMPs requirements.

3. Appendix 2 lists all the authorities responsible for the oversight of facilities that manufacture products within the product coverage of this Sectoral Annex.

4. Articles 5, 6, 7, 8, 9, 10, and 11 of the Agreement do not apply to this Sectoral Annex.

ARTICLE 4

Product Coverage

1. The provisions of this Sectoral Annex apply to marketed finished pharmaceuticals for human or animal use, intermediates (for the United Kingdom as defined in UK legislation) and in-process materials (for the United States as defined under U.S. law), certain marketed biological products for human use, and active pharmaceutical ingredients, only to the extent they are regulated by the authorities of both Parties as listed in Appendix 2 and subject to Article 17 of this Sectoral Annex.

2. Human blood, human plasma, human tissues and organs, and veterinary immunologicals are excluded from the scope of this Sectoral Annex.

3. Appendix 3 contains the list of products covered by this Sectoral Annex.

ARTICLE 5

Recognition of Authorities

1. For purposes of this Sectoral Annex, the United States confirms that it recognizes the Medicines and Healthcare product Regulatory Agency (MHRA) as a capable authority according to the criteria and procedure specified in Appendix 4.

2. For purposes of this Sectoral Annex, the United Kingdom confirms that it recognizes the FDA as an equivalent authority according to the criteria and procedure specified in Appendix 4.

ARTICLE 6

Recognition of Inspections

1. A Party shall recognize pharmaceutical inspections and accept official GMPs documents issued by a recognized authority of the other Party for manufacturing facilities located in the territory of the issuing authority, except as provided in paragraph 2.

2. A Party may in specific circumstances opt not to accept an official GMPs document issued by a recognized 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 the post-market surveillance, or other specific evidence of serious concern in relation to product quality or consumer safety. A Party opting not to accept an official GMPs document issued by a recognized authority of the other Party shall notify the other Party and the relevant authority of the reasons for not accepting the document and may request clarification from that authority. The authority shall endeavour to respond to the request for clarification in a timely manner and shall normally provide the clarification based on input from one or more members of the inspection team.

3. A Party may accept official GMPs documents issued by a recognized 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 GMPs documents issued under paragraph 3.

5. For purposes of this Sectoral Annex, to accept an official GMPs document means to rely on the factual findings in such document.

ARTICLE 7

Batch Testing

In the United Kingdom, as provided in The Veterinary Medicines Regulations 2013 (SI 2013/2033) and The Human Medicines Regulations 2012 (SI 2012/1916), the qualified person will be relieved of responsibility for carrying out the controls laid down in The Veterinary Medicines Regulations 2013 (SI 2013/2033) and The Human Medicines Regulations 2012 (SI 2012/1916) provided that these controls have been carried out in the United States, the product was manufactured in the United States, and that each batch/lot is accompanied by a batch certificate (in alignment with the WHO Certification Scheme on the quality of pharmaceutical products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

ARTICLE 8

Transmission of Official GMPs Documents

If an importing Party requests a recognized authority of the other Party for an official GMP surveillance inspection document, the recognized authority shall transmit the document to the importing Party within 30 calendar days of the date of the request. If, based on that document, the importing Party determines that a new inspection of the manufacturing facility is needed, the importing Party shall notify the relevant recognized authority of the other Party and request, in accordance with Article 9 of this Sectoral Annex, the recognized authority of the other Party to conduct a new inspection.

ARTICLE 9

Requests for Pre-approval, Post-approval, and GMP Surveillance Inspections

1. A Party or a recognized authority of a Party may request in writing that a recognized authority of the other Party conduct a pre-approval, post-approval, or GMP surveillance inspection of a manufacturing facility. The request shall include the reason for the request and identify the precise issues to be addressed in the inspection and the requested timeline for completing the inspection and transmitting the official GMPs documents.

2. In the United Kingdom, requests shall be sent directly to the relevant recognized authority.

3. Within 15 calendar days of receipt of the request, the recognized authority shall acknowledge receipt and confirm whether it will conduct the inspection in

accordance with the requested timelines. Where the authority receiving the request is of the opinion that official GMPs documents relevant to the request are already available or are pending, it should inform the requesting authority accordingly and share these documents upon request.

4. For greater certainty, if the recognized authority indicates that it will not conduct the inspection, the requesting authority has the right to conduct its own inspection of the manufacturing facility and the requested authority has the right to join the inspection.

ARTICLE 10

Maintenance

Each Party shall maintain ongoing activities to monitor whether recognized authorities in its territory are maintaining the criteria for recognition. For the purpose of such monitoring activities, each Party shall rely on established programmes that include regular audits or assessments of authorities based on the criteria specified in Appendix 4. The frequency and nature of such activities shall be consistent with international best practices. A Party may invite the other Party to participate in these monitoring activities at the other Party's expense. Each Party shall notify the other Party of any significant changes to its monitoring programmes.

ARTICLE 11

Suspension of a Recognized Authority

1. Each Party has the right to suspend recognition of a recognized authority of the other Party. This right shall be exercised in an objective and reasoned manner and communicated in writing to the other Party and the recognized authority.

2. A Party suspending recognition of a recognized authority of the other Party shall, upon request of the other Party or the authority whose recognition was suspended, promptly discuss in the Joint Sectoral Committee set up in accordance with Article 12 of this Sectoral Annex, the suspension, the reason for the suspension, and corrective actions that would need to be taken for the suspension to be lifted. Efforts shall be made by the Joint Sectoral Committee to discuss within three months of the suspension the appropriate timeframe and exact steps to be taken to lift the suspension or reassess the relevant authority according to the criteria specified in Appendix 4.

3. Upon the suspension of an authority listed as a recognized authority, a Party is no longer obligated to accept official GMPs documents of the suspended authority. A Party shall continue to accept official GMPs documents of that authority prior to suspension, unless the Party decides otherwise based on health or safety considerations. The suspension shall remain in effect until the Parties decide to lift the suspension or until a positive determination of recognition has been made pursuant to a reassessment in accordance with the criteria specified in Appendix 4.

4. A Party suspending recognition of a recognized authority of the other Party shall promptly notify the other Party of the reasons for the suspension and provide sufficient detail to allow the authority of the other Party to understand corrective measures that must be taken to lift the suspension or to attain a positive determination of recognition pursuant to a reassessment.

ARTICLE 12

Role and Composition of the Joint Sectoral Committee

1. A Joint Sectoral Committee is set up to monitor the activities performed under this Sectoral Annex.

2. The Joint Sectoral Committee shall be co-chaired by a representative from the FDA for the United States and a representative of the United Kingdom, who each shall have one vote in the Joint Sectoral Committee. The Joint Sectoral Committee shall make its decision by unanimous consent. The Joint Sectoral Committee shall determine its own rules and procedures.

3. The Joint Sectoral Committee's functions include in particular:

(a) developing and keeping up to date the list of recognized authorities, including any limitation in terms of inspection type or products and the list of authorities in Appendix 2, and communicating the lists to all authorities listed in Appendix 2 and the Joint Committee;

(b) providing a forum to discuss issues relating to this Sectoral Annex;

(c) in accordance with Article 17 and Appendix 3 of this Sectoral Annex, considering the status, and taking decisions on the inclusion, of the products referred to in Article 17 of this Sectoral Annex; and

(d) adopting, where necessary, appropriate complementary technical and administrative arrangements for the effective implementation of this Sectoral Annex.

4. The Joint Sectoral Committee shall meet at the request of either Party with respect to issues relating to disagreements as regards to determinations of

recognition or suspension and otherwise at such times as the Parties may agree. The Joint Sectoral Committee may meet in person or by other means.

ARTICLE 13

Regulatory Cooperation

The Parties shall inform and consult one another, as permitted by law, on proposals to introduce new controls or to change existing technical regulations or significant changes to pharmaceutical inspection procedures and to provide the opportunity to comment on such proposals.

ARTICLE 14

Exchange of Information

The Parties shall establish appropriate arrangements, including access to relevant databases, for the exchange of official GMPs documents and other appropriate information related to the inspection of a manufacturing facility and the exchange of information concerning any confirmed problem reports, corrective actions, recalls, rejected import consignments, and other regulatory and enforcement problems for products subject to this Sectoral Annex.

ARTICLE 15

Alert System

Each Party shall maintain an Alert System that permits authorities of the other Party when relevant to be made aware proactively and with the appropriate speed in case of quality defect, recalls, counterfeit or falsified products, or potential serious shortages and other problems concerning quality or non-compliance with GMPs, which could necessitate additional controls or suspension of the distribution of the affected products.

ARTICLE 16

Safeguard Clause

1. Each Party recognizes that the importing Party has a right to fulfil its legal responsibilities by taking actions necessary to ensure the protection of human and animal health at the level of protection it deems appropriate. An authority of a

Party has the right to conduct its own inspection of a manufacturing facility in the territory of the other Party.

2. An authority of a Party conducting its own inspection of a manufacturing facility in the territory of the other Party should be an exception from the normal practice of a Party as of the date on which this Sectoral Annex enters into force.

3. An authority of a Party, prior to conducting an inspection under paragraph 1, shall notify the other Party in writing, and the authority of the other Party has the right to join the inspection conducted by the Party.

ARTICLE 17

Transitory Provisions

1. No later than four months following the entry into force of this Agreement, the Joint Sectoral Committee shall consider whether to include veterinary products with the product coverage of this Sectoral Annex.

2. No later than 15 July 2022, the Joint Sectoral Committee shall consider whether to include vaccines for human use and plasma derived pharmaceuticals within the product coverage of this Sectoral Annex. Without prejudice to this consideration, as of the effective date of this Sectoral Annex, a Party shall notify the relevant authority of the other Party in advance of conducting a post-approval inspection of a manufacturing facility of such products located in the territory of the Party and give the authority the option of joining the inspection. In order to support the inclusion of vaccines for human use and plasma-derived pharmaceuticals within the product coverage of this Annex, the Joint Sectoral Committee shall take into account, in particular, the experience gained through such joint inspections.

3. No later than four months following the entry into force of this Agreement, the Joint Sectoral Committee shall review experience gained in order to decide whether the provisions on pre- and post-approval inspections provided in Article 9 of this Sectoral Annex shall be reviewed. Each party may decide to postpone this review until nine months following the entry into force of this Agreement.

4. Products referred to in paragraphs 1 and 2 shall be included within the product coverage of this Sectoral Annex only once the Joint Sectoral Committee so decides pursuant to paragraphs 1 and 2.

APPENDIX 1

List of Applicable Laws. Regulations, and Administrative Provisions

For the United States:

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq. Of particular relevance: 21 U.S.C. 351(a)(2)(B) (drug adulterated if not manufactured in conformance with current good manufacturing practice); 21 U.S.C. 355(d)(3); 21 U.S.C. 355(j)(4)(A) (approval of human drug contingent on adequacy of methods, facilities, and controls for manufacturing, processing, and packing to preserve the identity, strength, quality, and purity of drug); 21 U.S.C. 360b(c)(2)(A)(i) and 360b(d)(l)(C) (approval of animal drug contingent on adequacy of methods, facilities, and controls for manufacturing, processing, and packing to preserve the identity, strength, quality, and purity of drug); 21 U.S.C. 374 (inspection authority); 21 U.S.C. 384(e) (recognition of foreign government inspections)

Public Health Service Act Section 351, 42 U.S.C. 262. Of particular relevance: 42 U.S.C. 262(a)(2)(C)(i)(II) (licensing of biologic contingent on demonstration that the facility in which it is manufactured, processed, packed, or held meets standards designed to assure that the product continues to be safe, pure, and potent); 42 U.S.C. 262(j) (Federal Food, Drug, and Cosmetic Act applies to biologic products)

21 CFR Part 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding Drugs; General)

21 CFR Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals)

21 CFR Part 600, Subpart B (Establishment Standards) and Subpart C (Establishment Inspection)

For the United Kingdom:

The Human Medicines Regulations 2012 (SI 2012/1916)

The Veterinary Medicines Regulations 2013 (SI 2013/2033)

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

Current version of the Guide to good manufacturing practices found at https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice
governing medicinal products in the United Kingdom and compilation of the community procedures on inspections and exchange of information.

APPENDIX 2

List of Authorities

United States:

Food and Drug Administration

United Kingdom:

Medicines and Healthcare products Regulatory Agency

Veterinary Medicines Directorate

APPENDIX 3

List of Products Covered by the Sectoral Annex

Recognizing that precise definition of medicinal products and drugs are to be found in the laws, regulations, and administrative provisions referred to in Appendix 1, an indicative list of products covered by the Sectoral Annex is given below. This applies to processing, packaging, testing, and sterilizing facilities, including contract facilities performing these functions.

1. Marketed finished pharmaceuticals for human use in various pharmaceutical dosage forms such as tablets, capsules, ointments, and injectables, including:

   (a) Medical gases;

   (b) Radiopharmaceuticals or radioactive biological products;

   (c) Herbal (botanical) products*; and

   (d) Homeopathic products.

2. Marketed biological products:

   (a) Vaccines for human use**;

   (b) Plasma derived pharmaceuticals**;

   (c) Therapeutic biotechnology-derived biological products; and

   (d) Allergenic products.

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* These are included to the extent that they are regulated as drugs by the FDA and medicinal products by the United Kingdom.

** These products are only included within the product coverage of this Sectoral Annex to the extent the Joint Sectoral Committee decides to include them pursuant to Article 17 of this Sectoral Annex.

3. In process materials (for the United States as defined under U.S. law) and intermediates (for the United Kingdom as defined in UK legislation);

4. Active pharmaceutical ingredients or bulk drug substance;

5. Investigational products (clinical trial material)[***]; and

6. Veterinary products[**]:

   (a) veterinary pharmaceuticals, including prescription and non-prescription drugs, with the exclusion of veterinary immunologicals; and

   (b) pre-mixes for the preparation of veterinary medicated feeds (UK), Type A medicated articles for the preparation of veterinary medicated feeds (U.S.).

APPENDIX 4

Criteria and Procedure for Assessments Under this Sectoral Annex

I. Criteria for Assessments under this Sectoral Annex

Each Party will apply the following criteria to determine whether to recognize an authority listed in Appendix 2:

(i) The authority has the legal and regulatory authority to conduct inspections against a standard for GMPs (as defined in Article 1 of this Sectoral Annex).

(ii) The authority manages conflict of interest in an ethical manner.

(iii) The authority has the ability to evaluate risks and mitigate them.

(iv) The authority maintains appropriate oversight of manufacturing facilities within its jurisdiction.

[***] The FDA does not routinely conduct GMP surveillance inspections for investigational medicinal products. Inspection information on these products will be provided to the extent that they are available and resources allow. These products are only included within the product coverage of this Sectoral Annex to the extent the Joint Sectoral Committee decides to include them.

(v) The authority has and uses sufficient resources.

(vi) The authority employs trained and qualified inspectors with the skills and knowledge identify manufacturing practices that may lead to patient harm.

(vii) The authority has the tools necessary to take action to protect the public from harm due to poor quality drugs or medicinal products.

II. Procedures for Assessment under this Sectoral Annex

A. Assessment of UK authorities by FDA

1. To receive a capability assessment for an authority listed in Appendix 2, the United Kingdom shall submit capability assessment packages containing the following materials before the FDA will initiate an assessment:

(i) a finalized PIC/S audit report of an audit, where the FDA has been given three months advance notice to be an ·observer, that includes the full report of the observed inspection, any associated corrective measures, and all documents cited by the auditors in the report for the indicators as identified by FDA in the audit checklist as essential for the assessment and for any indicators that required the authority to propose a corrective and preventative action;

(ii) a completed conflicts of interest questionnaire established by the FDA signed by a principal of the authority;

(iii) a total of four inspection reports including the report from the inspections observed during the PIC/S audit;

(iv) standard operating procedures or a description on how the authority finalizes inspection reports;

(v) standard operating procedures related to training and inspector qualification, including training files for all inspectors who conducted the inspections in the reports provided to the FDA (pursuant to subparagraph (iii)); and

(vi) its most recent inventory of manufacturing facilities within its territory and under the authority's jurisdiction, including type of manufacturing facility of products falling within the product coverage of this Sectoral Annex,

and upon request, completion of a table provided by the FDA detailing types of manufacturing facilities.

2. During a capability assessment, the FDA may require additional information or further clarification from a UK authority.

3. The FDA may waive the requirement to submit certain information listed under IIA. I and may request alternative information from a UK authority. The decision to waive any assessment materials will be made by the FDA on a case by case basis.

B. Assessment of FDA by the United Kingdom

The United Kingdom will carry out its assessment of FDA based on:

(i) The performance of an audit in the framework of the Pharmaceutical Inspection Convention/Scheme (PIC/S) and audits performed in the context of the Human Medicines Regulation 2012, in particular regulation 45O of those Regulations.

(ii) An assessment of the equivalence of legislative and regulatory GMPs requirements.

C. Reassessment of an authority

In the event an assessing Party issues a suspension or negative determination of an authority of the other Party, it may reassess the authority. The scope of the reassessment shall relate to the reasons for the negative determination or suspension.

III. Maintaining Recognition

To maintain recognition, it is required that the authority continue to meet the criteria set out in paragraph I.A and remain subject to the monitoring activities described in Article 10 of this Sectoral Annex, which for a UK authority the FDA requires monitoring through an audit program that includes an audit (that the FDA has the option to observe) of each recognized UK authority every five to six years. In case an authority has not been subject to an audit for a period of six years, the other Party shall have the right to audit such authority.

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