PROTOCOL ON MUTUAL RECOGNITION

THE PARTIES HAVE AGREED AS FOLLOWS:

ARTICLE 1

1. For the purposes of this Protocol:

(a) "conformity assessment procedure" means any procedure to determine, directly or indirectly, whether products or processes fulfil relevant technical requirements set out in the applicable laws, regulations and administrative provisions of a Party;

(b) "conformity assessment body" means a body which conducts conformity assessment procedure, and "registered conformity assessment body" means the conformity assessment body registered pursuant to Article 9 of this Protocol;

(c) "designation" means the designation of conformity assessment bodies by a Designating Authority of a Party pursuant to the applicable laws, regulations and administrative provisions of that Party;

(d) "Designating Authority" means an authority of a Party with the power to designate, monitor, withdraw the designation of, suspend the designation of, and withdraw the suspension of the designation of the conformity assessment bodies in its territory that conduct conformity assessment procedures based upon requirements set out in the applicable laws, regulations and administrative provisions of the other Party;

(e) "criteria for designation" means the criteria which conformity assessment bodies of a Party are required to fulfil in order to be designated by the Designating Authority of that Party, and other relevant conditions which designated conformity assessment bodies are required to continuously fulfil after the designation, as set out in the applicable laws, regulations and administrative provisions of the other Party specified in the relevant Sectoral Annex;

(f) "confirmation" means the confirmation of the compliance of manufacturing facilities or test facilities (hereinafter referred to as "facilities") with the criteria for confirmation by a Competent Authority of a Party pursuant to the applicable laws, regulations and administrative provisions of that Party;

(g) "Competent Authority" means an authority of a Party with the power to conduct inspection or study audits on facilities in its territory to confirm their compliance with the criteria for confirmation set out in the applicable laws, regulations and administrative provisions of that Party;

(h) "criteria for confirmation" means the criteria which a facility of a Party is required to continuously fulfil in order to be confirmed by the Competent Authority of the Party, as set out in the applicable laws, regulations and administrative provisions of that Party specified in the relevant Sectoral Annex;

(i) "verification" means an action to verify in the territory of a Party, by such means as audits or inspections, compliance with the criteria for designation or the criteria for confirmation by a conformity assessment body or a facility respectively; and

(j) "EC-Japan MRA" means the Agreement on Mutual Recognition between the European Community and Japan, done at Brussels on 4 April 2001 and all amendments thereto which entered into force when that agreement was in force for the United Kingdom.

2. Any term used in this Protocol, unless otherwise defined herein, has the meaning assigned to it in ISO/IEC 17000:2020, "Conformity assessment – Vocabulary and general principles" and the ISO/IEC Guide 2:2004, "Standardization and related activities – General vocabulary".

ARTICLE 2

1. Each Party shall accept, in accordance with the provisions of this Protocol, the results of conformity assessment procedures required by the applicable laws, regulations and administrative provisions of that Party specified in the relevant Sectoral Annex, including certificates and marks of conformity, that are conducted by the registered conformity assessment bodies of the other Party.

2. Each Party shall accept, in accordance with the provisions of this Protocol:

(a) the confirmation of facilities conducted by the Competent Authorities of the other Party based upon the results of verification and in accordance with the criteria for confirmation stipulated in the laws, regulations and administrative provisions of that other Party as specified in the relevant Sectoral Annex; and

(b) the data generated by confirmed facilities of the other Party.

ARTICLE 3

1. This Protocol applies to designation of conformity assessment bodies and conformity assessment procedures for products or processes, and to confirmation of facilities and data generated by them, covered by its Sectoral Annexes. Sectoral Annexes may consist of Parts A and B.

2. Part A of Sectoral Annexes shall include, *inter alia*, provisions on scope and coverage.

3. Part B of Sectoral Annexes shall set out the following matters:

(a) the applicable laws, regulations and administrative provisions of each Party concerning the scope and coverage;

(b) the applicable laws, regulations and administrative provisions of each Party stipulating the requirements covered by this Protocol, all the conformity assessment procedures covered by this Protocol to satisfy such requirements and the criteria for designation of conformity assessment bodies, or the applicable laws, regulations and administrative provisions of each Party stipulating the criteria for confirmation of the facilities covered by this Protocol; and

(c) the list of Designating Authorities or Competent Authorities.

ARTICLE 4

1. Each Party shall ensure that Designating Authorities have the necessary power to designate, monitor (including verification), withdraw the designation of, suspend the designation of and withdraw the suspension of the designation of the conformity assessment bodies that conduct conformity assessment procedures based upon the requirements set out in the applicable laws, regulations and administrative provisions of the other Party specified in the relevant Sectoral Annex.

2. Each Party shall ensure that Competent Authorities have the necessary power to conduct, in accordance with its applicable laws, regulations and administrative provisions, verification of facilities to confirm their compliance with the criteria for confirmation set out in the applicable laws, regulations and administrative provisions of that Party specified in the relevant Sectoral Annex.

ARTICLE 5

1. Each Party shall ensure, through appropriate means such as audits, inspections or monitoring, that the registered conformity assessment bodies fulfil the criteria for designation set out in the applicable laws, regulations and administrative provisions of the other Party specified in the relevant Sectoral Annex. When applying the criteria for designation of the conformity assessment bodies, Designating Authorities of a Party should take into account the bodies' understanding of and experience relevant to the requirements set out in the applicable laws, regulations and administrative provisions of the other Party.

2. Each Party shall, in accordance with its applicable laws, regulations and administrative provisions and through appropriate means such as study audits, inspections or monitoring, ensure that the confirmed facilities fulfil the criteria for confirmation set out in the applicable laws, regulations and administrative provisions of that Party specified in the relevant Sectoral Annex.

3. Each Party may request the other Party, by indicating in writing a reasoned doubt on whether a registered conformity assessment body or a confirmed facility complies with the criteria for designation or the criteria for confirmation set out in the applicable laws, regulations and administrative provisions specified in the relevant Sectoral Annex, respectively, to conduct verification of the conformity assessment body or the facility in accordance with the laws, regulations and administrative provisions of that other Party.

4. Each Party may, on request, participate as an observer in the verification of conformity assessment bodies conducted by the Designating Authorities or the verification of facilities conducted by the Competent Authorities of the other Party, with the prior consent of such conformity assessment bodies or such facilities respectively, in order to maintain a continuing understanding of that other Party's procedures for verification.

5. The Parties shall, in accordance with the procedures to be determined by the Joint Committee on Mutual Recognition to be established pursuant to Article 8 of this Protocol, exchange information on methods, including accreditation systems, used to designate the conformity assessment bodies and to ensure that the registered conformity assessment bodies fulfil the criteria for designation and on methods to ensure that the confirmed facilities fulfil the criteria for confirmation.

6. Each Party should encourage its registered conformity assessment bodies to cooperate with the conformity assessment bodies of the other Party.

ARTICLE 6

1. In case of suspension of the designation of a registered conformity assessment body, the Party whose Designating Authority has suspended the designation shall immediately notify the other Party and the Joint Committee on Mutual Recognition to that effect. The registration of that conformity assessment body shall be suspended from the date of receipt of the notification by the co-chair of that other Party on the Joint Committee on Mutual Recognition. The other Party shall accept the results of the conformity assessment procedures conducted by that conformity assessment body prior to the suspension of the designation.

2. In case of lifting of the suspension of the designation of a registered conformity assessment body, the Party whose Designating Authority has lifted the suspension of the designation shall immediately notify the other Party and the Joint Committee on Mutual Recognition to that effect. The suspension of the registration of that conformity assessment body shall be lifted from the date of receipt of the notification by the co-chair of that other Party on the Joint Committee on Mutual Recognition. The other Party shall accept the results of the conformity assessment procedures conducted by that conformity assessment body from the date of lifting of the suspension of the registration.

ARTICLE 7

1. Each Party may contest the compliance with the criteria for designation or the criteria for confirmation set out in the applicable laws, regulations and administrative provisions specified in the relevant Sectoral Annex by a registered conformity assessment body or a confirmed facility of the other Party, respectively. Such contestation shall be notified to the Joint Committee on Mutual Recognition and to that other Party in writing with an objective explanation of the reason for the contestation. The Joint Committee on Mutual Recognition shall discuss such contestation within 20 days after the date on which such notification is made.

2. Where the Joint Committee on Mutual Recognition decides to conduct a joint verification, it will be conducted in a timely manner by the Parties with the participation of the Designating Authority that designated the contested conformity assessment body and with the prior consent of the conformity assessment body. The result of such joint verification shall be discussed in the Joint Committee on Mutual Recognition with a view to resolving the issue as soon as possible.

3. The registration of the contested conformity assessment body shall be suspended 15 days after the date on which the notification is made or on the date on which the Joint Committee on Mutual Recognition decides to suspend the registration, whichever is the sooner. The registration of the contested conformity assessment body shall remain suspended until the Joint Committee on Mutual Recognition decides to lift the suspension of the registration of the conformity assessment body. In the event of such suspension, the contesting Party shall accept the results of conformity assessment procedures conducted by that conformity assessment body prior to the date of suspension.

4. The Joint Committee on Mutual Recognition will decide on the actions to be taken by a Party or the Parties with a view to resolving issues concerning the contestation of facilities as soon as possible.

5. The contesting Party shall not be obliged to accept the confirmation of, and the data generated by, the contested facility from the date on which the co-chair of the other Party on the Joint Committee on Mutual Recognition receives the notification referred to in paragraph 1 until the date on which the Joint Committee on Mutual Recognition decides otherwise.

ARTICLE 8

1. A Joint Committee on Mutual Recognition made up of representatives of the Parties shall be established on the date of application of this Protocol, as a body responsible for the effective functioning of this Protocol.

2. The Joint Committee on Mutual Recognition shall take decisions and adopt recommendations by consensus. It shall meet at the request of either Party under the co-chairs of the Parties. The Joint Committee on Mutual Recognition may establish sub-committees and delegate specific tasks to such sub-committees. The Joint Committee on Mutual Recognition shall adopt its rules of procedure.

3. The Joint Committee on Mutual Recognition may consider any matter related to the operation of this Protocol. In particular, it shall be responsible for and/or decide on:

(a) registration of a conformity assessment body, suspension of registration of a conformity assessment body, lifting of suspension of registration of a conformity assessment body, and termination of registration of a conformity assessment body;

(b) establishment and, unless otherwise decided, publication on a Sector by Sector basis of lists of the registered conformity assessment bodies and the confirmed facilities;

(c) establishment of appropriate modalities of information exchange referred to in this Protocol; and

(d) appointment of experts from each Party for the joint verification referred to in paragraph 2 of Article 7 of this Protocol and subparagraph 1(c) of Article 9 of this Protocol.

4. If any problem arises to the interpretation or application of this Protocol, the Parties shall seek an amicable solution through the Joint Committee on Mutual Recognition.

5. The Joint Committee on Mutual Recognition is responsible for coordinating and facilitating the negotiation of additional Sectoral Annexes.

6. Each Party shall provide the other Party and the Joint Committee on Mutual Recognition, at least annually, with a list of the confirmed facilities.

7. Any decision made by the Joint Committee on Mutual Recognition will be notified promptly in writing to each Party.

8. The Parties shall, through the Joint Committee on Mutual Recognition:

(a) specify and communicate to each other the applicable articles or annexes contained in the laws, regulations and administrative provisions set out in the Sectoral Annexes;

(b) exchange information concerning the implementation of the applicable laws, regulations and administrative provisions specified in the Sectoral Annexes;

(c) notify each other of any scheduled changes in the laws, regulations and administrative provisions related to this Protocol prior to their entry into force; and

(d) notify each other of any scheduled changes concerning their Designating Authorities, Competent Authorities, the registered conformity assessment bodies and the confirmed facilities.

9. Without prejudice to the provisions of preceding paragraphs of this Article, the Joint Committee on Mutual Recognition shall, on the date of application of this Protocol, decide to accept, *mutatis mutandis*, documents that were produced by Japan and the European Community and its successors with regard to the EC-Japan MRA, including joint declarations, exchange of letters and decisions of the Joint Committee established pursuant to the EC-Japan MRA, and that are considered appropriate by the Parties.

ARTICLE 9

1. The following procedure shall apply to the registration of a conformity assessment body:

(a) Each Party shall make a proposal that a conformity assessment body of that Party designated by its Designating Authority be registered under this Protocol, by presenting its proposal in writing, supported by necessary documents, to the other Party and the Joint Committee on Mutual Recognition;

(b) The other Party shall consider whether the proposed conformity assessment body complies with the criteria for designation set out in the applicable laws, regulations and administrative provisions of that other Party specified in the relevant Sectoral Annex and indicate its position regarding the registration of that conformity assessment body within 90 days from the receipt of the proposal referred to in subparagraph (a). In such consideration, such other Party should assume that the proposed conformity assessment body complies with the aforementioned criteria. The Joint Committee on Mutual Recognition shall take a decision whether to register the proposed conformity assessment body within 90 days from the receipt of the proposal;

(c) In the event that the Joint Committee on Mutual Recognition cannot decide to register the proposed conformity assessment body, the Joint Committee on Mutual Recognition may decide to conduct a joint verification or to request the proposing Party to conduct a verification of the proposed body with the prior consent of such body. After the completion of such verification, the Joint Committee on Mutual Recognition may reconsider the proposal.

2. The proposing Party shall provide the following information in its proposal for registration of a conformity assessment body and keep such information up to date:

(a) the name and address of the conformity assessment body;

(b) the products or processes the conformity assessment body is authorised to assess;

(c) the conformity assessment procedures the conformity assessment body is authorised to conduct; and

(d) the designation procedure and necessary information used to determine the compliance of the conformity assessment body with the criteria for designation.

3. Notwithstanding paragraphs 1 and 2, the Joint Committee on Mutual Recognition shall, on the date of application of this Protocol, decide to register the conformity assessment bodies of the Parties that have been registered as the conformity assessment bodies under the EC-Japan MRA and that are considered appropriate by the Parties.

4. Each Party shall ensure that its Designating Authority withdraws the designation of a registered conformity assessment body when the Designating Authority considers that the conformity assessment body no longer complies with the criteria for designation set out in the applicable laws, regulations and administrative provisions of the other Party specified in the relevant Sectoral Annex.

5. Each Party shall propose the termination of the registration of its conformity assessment body when that Party considers that the conformity assessment body no longer complies with the criteria for designation set out in the applicable laws, regulations and administrative provisions of the other Party specified in the relevant Sectoral Annex, or the Designating Authority of that Party withdraws the designation of a conformity assessment body. Proposals for terminating the registration of that conformity assessment body shall be made to the Joint Committee on Mutual Recognition and the other Party. The registration of that conformity assessment body shall be terminated upon receipt of the proposal by the co-chair of that other Party on the Joint Committee on Mutual Recognition, unless otherwise determined by the Joint Committee on Mutual Recognition.

6. In the case of a registration of a new conformity assessment body, the other Party shall accept the results of conformity assessment procedures conducted by that conformity assessment body from the date of the registration. In the event that the registration of a conformity assessment body is terminated, the other Party shall accept the results of the conformity assessment procedures conducted by that conformity assessment body prior to the termination, without prejudice to paragraph 1 of Article 6 of this Protocol and paragraph 3 of Article 7 of this Protocol.

ARTICLE 10

1. Nothing in this Protocol shall be construed to limit the authority of a Party to take measures it considers appropriate, for protecting health, safety or the environment or prevention of deceptive practices.

2. (a) The Competent Authority of a Party may visit manufacturing facilities of the other Party on the condition that such other Party and the manufacturing facilities concerned consent to such visit and, if such other Party so requests, officials of the Competent Authority of such other Party join the visit, for the purpose of deciding whether to continue to accept the confirmation of the manufacturing facilities concerned and the data generated by them pursuant to paragraph 2 of Article 2 of this Protocol, where an emergency as defined in subparagraph (b) takes place. Such visit shall be carried out in a manner not inconsistent with the laws and regulations of that other Party and in accordance with the modalities to be decided pursuant to subparagraph (b). The Party shall use the information obtained by its Competent Authority in connection with such visit only for the purpose specified in this subparagraph.

(b) The definition of the emergency and the modalities of such visit referred to in subparagraph (a) will be decided by the Joint Committee on Mutual Recognition as part of the preparatory work to be done in accordance with the provisions of the relevant Sectoral Annex.

ARTICLE 11

1. Without prejudice to paragraph 2 of Article 2 of this Protocol, nothing in this Protocol shall entail mutual acceptance of the standards or technical regulations of the Parties.

2. Nothing in this Protocol shall be construed to entail an obligation upon a Party to accept the result of the conformity assessment procedures of any third country.

3. Nothing in this Protocol shall be construed so as to affect the rights and obligations that either Party has as a Member to the WTO Agreement, including the TBT Agreement and the TRIPS Agreement.

ARTICLE 12

A Party shall not disclose any information obtained under this Protocol as confidential, unless otherwise required under its laws or regulations.

ARTICLE 13

1. This Protocol shall not be subject to the following provisions of this Agreement:

(a) Article 1.5 and Article 1.6 ;

(b) Chapter 17;

(c) Article 20.3;

(d) Chapter 22;

(e) Chapter 23;

(f) Article 24.2; and

(g) paragraph 1 of Article 18 of Annex 2-C.

2. In the event of any inconsistency between the provisions of this Protocol and the other provisions of this Agreement, the provisions of this Protocol shall prevail to the extent of the inconsistency.

ARTICLE 14

1. The Sectoral Annexes to this Protocol are an integral part of this Protocol.

2. In case of conflict between the provisions of Part A of a Sectoral Annex and Articles 1 to 13 of this Protocol, the provisions of Part A of the Sectoral Annex shall prevail.

3. (a) The provisions concerning the scope and coverage of paragraph 1 of Part A of each Sectoral Annex shall not be changed unless the Parties amend this Protocol in accordance with the first sentence of subparagraph (b).

(b) This Protocol may be amended by agreement between the Parties. However, if the amendments relate only to changes of laws, regulations and administrative provisions, Designating Authorities or Competent Authorities specified in Part B of the Sectoral Annexes, the amendments may be made by exchange of diplomatic notes between the Governments of the Parties, in conformity with their applicable domestic procedures.

4. If a Party introduces new or additional conformity assessment procedures within the same product coverage to satisfy the requirements set out in the applicable laws, regulations and administrative provisions specified in the relevant Sectoral Annex, Part B of the Sectoral Annex shall be amended to set out the applicable laws, regulations and administrative provisions stipulating such new or additional conformity assessment procedures, in accordance with the procedures set out in the second sentence of subparagraph 3(b).

ARTICLE 15

Without prejudice to Article 24.3, the Governments of the Parties, at any time prior to the entry into force of this Agreement, may decide by an exchange of diplomatic notes not to apply this Protocol until the date to be agreed upon by the Governments of the Parties. Such date shall be identified in an exchange of diplomatic notes between the Governments of the Parties.

ARTICLE 16

Either Party may notify in writing the other Party of its intention to cease to apply this Protocol. This Protocol shall cease to apply six months after the date of receipt by that other Party of the notification, unless the Parties otherwise agree.

SECTORAL ANNEX ON TELECOMMUNICATIONS TERMINAL EQUIPMENT AND RADIO EQUIPMENT

PART A

SCOPE AND COVERAGE

1. This Sectoral Annex applies to conformity assessment procedures for all telecommunications terminal equipment and radio equipment, which in the United Kingdom and Japan respectively are subject to conformity assessment procedures conducted by the conformity assessment body, as set out in the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex.

2. It is understood that the term "amendment" referred to in Part B of this Sectoral Annex includes the following cases:

(a) a Party entirely or partially changes its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex, whether or not those names are changed;

(b) a Party repeals its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and/or administrative provisions substituting for the previous laws, regulations and/or administrative provisions, whether or not the previous names are changed; and

(c) a Party incorporates the whole or a relevant part of its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and/or administrative provisions.

PART B

SECTION I: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING TELECOMMUNICATIONS TERMINAL EQUIPMENT AND RADIO EQUIPMENT

THE UNITED KINGDOM	JAPAN
1. Radio Equipment Regulations 2017 (SI 2017/1206) and amendments thereto 2. For pure wired telecommunications terminal equipment: Electromagnetic Compatibility Regulations 2016 (SI 2016/1091) and amendments thereto	1. Telecommunications Business Law (Law No. 86 of 1984) and amendments thereto 2. Ordinance concerning Technical Standards Conformity Approval, Etc. for Terminal Equipment (Ministerial Ordinance of Ministry of Internal Affairs and Communications No. 15 of 2004) and amendments thereto 3. Radio Law (Law No. 131 of 1950) and amendments thereto 4. Ordinance concerning Technical Regulations Conformity Certification Etc. of Specified Radio Equipment (Ministerial Ordinance of Ministry of Posts and Telecommunications No. 37 of 1981) and amendments thereto

SECTION II: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE REQUIREMENTS AND THE CONFORMITY ASSESSMENT PROCEDURES

THE UNITED KINGDOM	JAPAN
1. Radio Equipment Regulations 2017 (SI 2017/1206) and amendments thereto 2. Electromagnetic Compatibility Regulations 2016 (SI 2016/1091) and amendments thereto	1. Telecommunications Business Law (Law No. 86 of 1984) and amendments thereto 2. Ordinance concerning Terminal Facilities Etc. (Ministerial Ordinance of Ministry of Posts and Telecommunications No. 31 of 1985) and amendments thereto 3. Ordinance concerning Technical Standards Conformity Approval, Etc. for Terminal Equipment (Ministerial Ordinance of Ministry of Internal Affairs and Communications No. 15 of 2004) and amendments thereto 4. Radio Law (Law No. 131 of 1950) and amendments thereto 5. Ordinance concerning Radio Equipment (Radio Regulatory Commission Regulations No. 18 of 1950) and amendments thereto

THE UNITED KINGDOM	JAPAN
	6. Ordinance concerning Technical Regulations Conformity Certification Etc. of Specified Radio Equipment (Ministerial Ordinance of Ministry of Posts and Telecommunications No. 37 of 1981) and amendments thereto

SECTION III: DESIGNATING AUTHORITIES

THE UNITED KINGDOM	JAPAN
Department for Business, Energy and Industrial Strategy or an authority succeeding it	For Radio Equipment Regulations 2017 (SI 2017/1206) and amendments thereto: Ministry of Internal Affairs and Communications or an authority succeeding it For Electromagnetic Compatibility Regulations 2016 (SI 2016/1091) and amendments thereto: Ministry of Internal Affairs and Communications or an authority succeeding it Ministry of Economy, Trade and Industry or an authority succeeding it

SECTION IV: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE CRITERIA FOR DESIGNATION

THE CRITERIA TO BE APPLIED BY JAPAN IN DESIGNATING CONFORMITY ASSESSMENT BODIES TO ASSESS PRODUCTS AGAINST THE UNITED KINGDOM'S REQUIREMENTS	THE CRITERIA TO BE APPLIED BY THE UNITED KINGDOM IN DESIGNATING CONFORMITY ASSESSMENT BODIES TO ASSESS PRODUCTS AGAINST JAPAN'S REQUIREMENTS
1. Radio Equipment Regulations 2017 (SI 2017/1206) and amendments thereto 2. Electromagnetic Compatibility Regulations 2016 (SI 2016/1091) and amendments thereto	1. Telecommunications Business Law (Law No. 86 of 1984) and amendments thereto 2. Ordinance concerning Technical Standards Conformity Approval, Etc. for Terminal Equipment (Ministerial Ordinance of Ministry of Internal Affairs and Communications No. 15 of 2004) and amendments thereto 3. Radio Law (Law No. 131 of 1950) and amendments thereto 4. Ordinance concerning Technical Regulations Conformity Certification Etc. of Specified Radio Equipment (Ministerial Ordinance of Ministry of Posts and Telecommunications No. 37 of 1981) and amendments thereto

SECTORAL ANNEX ON
ELECTRICAL PRODUCTS

PART A

SCOPE AND COVERAGE

1. This Sectoral Annex applies to conformity assessment procedures for all electrical products, which in the United Kingdom and Japan respectively are subject to conformity assessment procedures conducted by the conformity assessment body, as set out in the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex.

2. It is understood that the term "amendment" referred to in Part B of this Sectoral Annex includes the following cases:

(a) a Party entirely or partially changes its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex, whether or not those names are changed;

(b) a Party repeals its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and/or administrative provisions substituting for the previous laws, regulations and/or administrative provisions, whether or not the previous names are changed; and

(c) a Party incorporates the whole or a relevant part of its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and/or administrative provisions.

PART B

SECTION I: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING ELECTRICAL PRODUCTS

THE UNITED KINGDOM	JAPAN
Electromagnetic Compatibility Regulations 2016 (SI 2016/1091) and amendments thereto	1. Electrical Appliances and Materials Safety Law (Law No. 234 of 1961) and amendments thereto 2. Cabinet Order for Enforcement of the Electrical Appliances and Materials Safety Law (Cabinet Order No. 324 of 1962) and amendments thereto

SECTION II: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE REQUIREMENTS AND THE CONFORMITY ASSESSMENT PROCEDURES

THE UNITED KINGDOM	JAPAN
Electromagnetic Compatibility Regulations 2016 (SI 2016/1091) and amendments thereto	1. Electrical Appliances and Materials Safety Law (Law No. 234 of 1961) and amendments thereto 2. Regulation for Enforcement of the Electrical Appliances and Materials Safety Law (Ministerial Ordinance of Ministry of International Trade and Industry No. 84 of 1962) and amendments thereto 3. Ministerial Ordinance on Technical Standards for Electrical Appliances and Materials (Ministerial Ordinance of Ministry of Economy, Trade and Industry No. 34 of 2013) and amendments thereto 4. The Notification of the Interpretation of the Ministerial Ordinance on Technical Standards for Electrical Appliances and Materials (Notification of Ministry of Economy, Trade and Industry, 20130605 Shokyoku No. 3) and amendments thereto

SECTION III: DESIGNATING AUTHORITIES

THE UNITED KINGDOM	JAPAN
Department for Business, Energy and Industrial Strategy or an authority succeeding it	Ministry of Economy, Trade and Industry or an authority succeeding it

SECTION IV: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE CRITERIA FOR DESIGNATION

THE CRITERIA TO BE APPLIED BY JAPAN IN DESIGNATING CONFORMITY ASSESSMENT BODIES TO ASSESS PRODUCTS AGAINST THE UNITED KINGDOM'S REQUIREMENTS	THE CRITERIA TO BE APPLIED BY THE UNITED KINGDOM IN DESIGNATING CONFORMITY ASSESSMENT BODIES TO ASSESS PRODUCTS AGAINST JAPAN'S REQUIREMENTS
Electromagnetic Compatibility Regulations 2016 (SI 2016/1091) and amendments thereto	1. Electrical Appliances and Materials Safety Law (Law No. 234 of 1961) and amendments thereto 2. Cabinet Order for Enforcement of the Electrical Appliances and Materials Safety Law (Cabinet Order No. 324 of 1962) and amendments thereto 3. Regulation for Enforcement of the Electrical Appliances and Materials Safety Law (Ministerial Ordinance of Ministry of International Trade and Industry No. 84 of 1962) and amendments thereto

SECTORAL ANNEX ON
GOOD LABORATORY PRACTICE (GLP) FOR CHEMICALS

PART A

1. This Sectoral Annex applies to:

(a) the confirmation of the compliance of test facilities with the principles of GLP for the testing of chemicals, being either substances or preparations, as set out in the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex; and

(b) the acceptance of the data generated by confirmed test facilities.

2. (a) For the purposes of this Sectoral Annex:

(i) "criteria for confirmation" means the principles of GLP as stipulated in the laws, regulations and administrative provisions of each Party specified in Section III of Part B of this Sectoral Annex and that are consistent with Annex II of the OECD Council Decision of 12 May 1981 [C(81)30(Final)] as amended by the OECD Council Decision of 26 November 1997 [C(97)186(Final)]; and

(ii) "verification" means the monitoring of the compliance of a test facility with the principles of GLP by procedures such as study audits and inspections that are set out in the laws, regulations and administrative provisions of each Party specified in Section III of Part B of this Sectoral Annex and that are consistent with the OECD Council Decision – Recommendation of 2 October 1989 [C(89)87(Final)], and in particular its Annexes I and II, as amended by the OECD Council Decision of 9 March 1995 [C(95)8(Final)].

(b) For the purpose of this Sectoral Annex, any term, unless otherwise defined in this Protocol, has the meaning assigned to it in the "OECD Principles of Good Laboratory Practice" as contained in Annex II of the OECD Council Decision of 12 May 1981 [C(81)30(Final)], the "Guides for Compliance Monitoring Procedures for Good Laboratory Practice" as contained in Annex I of the OECD Council Decision – Recommendation of 2 October 1989 [C(89)87(Final)], the GLP Consensus Document "The Application of the GLP Principles to Field Studies" (OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 6), and all amendments made thereto.

(c) It is understood that the term "amendment" referred to in Part B of this Sectoral Annex includes the following cases:

(i) a Party entirely or partially changes its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex, whether or not those names are changed;

(ii) a Party repeals its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and/or administrative provisions substituting for the previous laws, regulations and/or administrative provisions, whether or not the previous names are changed; and

(iii) a Party incorporates the whole or a relevant part of its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and/or administrative provisions.

3. In making amendments to the laws, regulations and administrative provisions specified in Section III of Part B of this Sectoral Annex, the Parties should take account of the need to maintain consistency with the relevant decisions and recommendations of the OECD.

4. With respect to paragraph 2 of Article 2 of this Protocol, each Party shall, as a result of the acceptance of the confirmation of test facilities by the Competent Authorities of the other Party, accept the data for a test item generated by the confirmed test facilities as equivalent to the data generated by its own test facilities which are confirmed to be compliant with the principles of GLP, taking into account the equivalence of GLP compliance monitoring programme of both Parties, which are consistent with the OECD Council Decision-Recommendation of 2 October 1989 [C(89)87(Final)] as amended by the OECD Council Decision of 9 March 1995 [C(95)8(Final)], provided that:

(a) a certificate or an alternative document on the GLP compliance status of the test facility issued by the Competent Authority of that other Party, in accordance with the applicable laws, regulations and administrative provisions of that other Party specified in Section III of Part B of this Sectoral Annex, is attached to the data; and

(b) the testing for which the data is generated is covered by the principles of GLP in both Parties pursuant to the applicable laws, regulations and administrative provisions of each Party.

5.(a) The list of the confirmed facilities referred to in paragraphs 3 and 6 of Article 8 of this Protocol shall be provided in an appropriate agreed format and include the following information:

(i) the name and address of the test facility;

(ii) the dates of verification or confirmation;

(iii) the GLP compliance status; and

(iv) the areas of expertise as listed in point 4 of the Appendix to Annex III of the OECD Council Decision-Recommendation of 2 October 1989 [C(89)87(Final)].

(b) Each Party shall, to the extent possible, provide the other Party with additional information on the confirmed facilities upon a reasoned request by that other Party.

(c) Each Party shall transmit to the other Party, without delay, information on any withdrawal of the certificate of a confirmed test facility if the facility has been found to be non-compliant with the principles of GLP.

6. (a) Each Party may request the other Party, by indicating in writing a reasoned doubt on whether a study was conducted in accordance with the principles of GLP, to conduct further inspections or study audits on a confirmed test facility, in accordance with the applicable laws, regulations and administrative provisions of that other Party.

(b) The requested Party shall inform the requesting Party of the results of the inspections or study audits, or provide an explanation of why such an inspection or study audit has not been carried out.

(c) The requesting Party shall not be obliged to accept the data generated by the test facility concerned from the date on which the request is made, until the results of the further inspection or study audit conducted by the Competent Authority of the requested Party have reconfirmed the compliance of the test facility with the principles of GLP.

(d) If, in exceptional cases, doubts persist, and the requesting Party can justify a specific concern, that Party may contest the compliance of the test facility concerned in accordance with Article 7 of this Protocol.

PART B

SECTION I: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE COVERAGE OF CHEMICALS SUBJECT TO TESTING IN ACCORDANCE WITH THE PRINCIPLES OF GLP

THE UNITED KINGDOM	JAPAN
1. Medical Products: The Human Medicines Regulations 2012 (SI 2012/1916) and amendments thereto 2. Veterinary Medicinal Products: The Veterinary Medicines Regulations 2013 (SI 2013/2033) and amendments thereto 3. Plant Protection Products: (a) Plant Protection Products Regulations 2011 and amendments thereto (b) Plant Protection Products Regulations (Northern Ireland) 2011 and amendments thereto 4. Biocides: Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (EU Exit) Regulations 2019 and amendments thereto	1. Pharmaceuticals: (a) Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Law No. 145 of 1960) and amendments thereto (b) Regulation for Enforcement of the Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Ministerial Ordinance of Ministry of Health and Welfare No. 1 of 1961) and amendments thereto 2. Veterinary Drugs: (a) Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Law No. 145 of 1960) and amendments thereto

THE UNITED KINGDOM	JAPAN
5. Feed Additives: Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, and United Kingdom law amendments thereto 6. New and Existing Chemicals: Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (EU Exit) Regulations 2019 and amendments thereto 7. Food Additives: Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, and United Kingdom law amendments thereto 8. Cosmetics: Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, and United Kingdom law amendments thereto	(b) Ordinance concerning Control of Veterinary Drugs Etc. (Ministerial Ordinance of Ministry of Agriculture, Forestry and Fisheries No. 107 of 2004) and amendments thereto 3. Agricultural Chemicals: (a) Agricultural Chemicals Regulation Law (Law No. 82 of 1948) and amendments thereto (b) Ministerial Ordinance concerning Good Laboratory Practice for Agricultural Chemicals (Ministerial Ordinance of Ministry of Agriculture, Forestry and Fisheries No. 76 of 2018) and amendments thereto 4. Feed Additives: (a) Law concerning Safety Assurance and Quality Improvement of Feed (Law No. 35 of 1953) and amendments thereto (b) Regarding Establishment of the Standards for Evaluation of Feed Additives (4 Chiku A No. 201 of 1992) and amendments thereto

THE UNITED KINGDOM	JAPAN
	5. Industrial Chemicals: Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, Etc. (Law No. 117 of 1973) and amendments thereto 6. Chemical Substances Controlled for the Protection of Health of Workers: (a) Industrial Safety and Health Law (Law No. 57 of 1972) and amendments thereto (b) Cabinet Order for Enforcement of the Industrial Safety and Health Law (Cabinet Order No. 318 of 1972) and amendments thereto (c) Ordinance on Industrial Safety and Health (Ministerial Ordinance of Ministry of Labour No. 32 of 1972) and amendments thereto

SECTION II: COMPETENT AUTHORITIES

THE UNITED KINGDOM	JAPAN
For all: Department of Health and Social Care (Medicines and Healthcare products Regulatory Agency) or an authority succeeding it	For Pharmaceuticals: Ministry of Health, Labour and Welfare or an authority succeeding it For Veterinary Drugs: Ministry of Agriculture, Forestry and Fisheries or an authority succeeding it For agricultural chemicals: Ministry of Agriculture, Forestry and Fisheries or an authority succeeding it For Feed Additives: Ministry of Agriculture, Forestry and Fisheries or an authority succeeding it For Industrial Chemicals: Ministry of Health, Labour and Welfare or an authority succeeding it Ministry of Economy, Trade and Industry or an authority succeeding it

THE UNITED KINGDOM	JAPAN
	Ministry of the Environment or an authority succeeding it For Chemical Substances Controlled for the Protection of Health of Workers: Ministry of Health, Labour and Welfare or an authority succeeding it

SECTION III: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE PRINCIPLES OF GLP, VERIFICATION AND CONFIRMATION

THE UNITED KINGDOM	JAPAN
The Good Laboratory Practice Regulations 1999 (SI 1999/3106) and amendments thereto	1. Pharmaceuticals: (a) Law concerning Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Law No. 145 of 1960) and amendments thereto (b) Ministerial Ordinance concerning Good Laboratory Practice for Non-clinical Laboratory Studies on Safety of Drugs (Ministerial Ordinance of Ministry of Health and Welfare No. 21 of 1997) and amendments thereto (c) Regarding Treatment of Materials concerning Non-clinical Laboratory Studies on Safety of Pharmaceuticals, Medical Devices and Regenerative Medicine Products Which Should Be Attached to the Application for the Products for Manufacturing and Marketing Approval Etc. (Yakushokushinsahatsu 1121 No. 9/Yakushokukisanhatsu 1121 No. 13 of 2014) and amendments thereto

THE UNITED KINGDOM	JAPAN
	(d) Regarding Guidelines for the Conduct of Pharmaceutical GLP On-site Inspection Conducted by Ministry of Health, Labour and Welfare (Yakushokushinsahatsu No. 0805003 of 2005) and amendments thereto 2. Veterinary Drugs: (a) Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Law No. 145 of 1960) and amendments thereto (b) Ministerial Ordinance concerning Good Laboratory Practice for Non-clinical Laboratory Studies on Safety of Veterinary Drugs (Ministerial Ordinance of Ministry of Agriculture, Forestry and Fisheries No. 74 of 1997) and amendments thereto (c) Regarding Management of the Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (12 Chiku A No. 729 of 2000) and amendments thereto

THE UNITED KINGDOM	JAPAN
	3. Agricultural Chemicals: (a) Agricultural Chemicals Regulation Law (Law No. 82 of 1948) and amendments thereto (b) Ministerial Ordinance concerning Good Laboratory Practice for Agricultural Chemicals (Ministerial Ordinance of Ministry of Agriculture, Forestry and Fisheries No. 76 of 2018) and amendments thereto (c) Regarding Confirmation and Inspection on Compliance with the Requirements from Articles 5 to 19 of the Ministerial Ordinance concerning Good Laboratory Practice for Agricultural Chemicals (30 Shouan No. 4215 of 2018) and amendments thereto 4. Feed Additives: (a) Law concerning Safety Assurance and Quality Improvement of Feed (Law No. 35 of 1953) and amendments thereto

THE UNITED KINGDOM	JAPAN
	(b) Regarding Standards for the Conduct of Animal Studies on Feed Additives (63 Chiku A No. 3039 of 1988) and amendments thereto (c) Regarding the Establishment of the Guidelines for the Inspection Based on the Standards for the Conduct of Animal Studies on Feed Additives (1 Chiku A No. 3441 of 1990) and amendments thereto 5. Industrial Chemicals: (a) Law concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, Etc. (Law No. 117 of 1973) and amendments thereto (b) Ministerial Ordinance on Items Etc. of Test concerning New Chemical Substances and Study of Hazardous Properties of Chemical Substances Requiring Priority Assessment and Monitoring Chemical Substances (Ministerial Ordinance of Ministry of Health, Labour and Welfare, of Ministry of Economic Trade and Industry and of Ministry of the Environment No. 3 of 2010) and amendments thereto

THE UNITED KINGDOM	JAPAN
	(c) The Notice on Tests designated by Minister for Health, Labour and Welfare, Minister for Economy, Trade and Industry and Minister for the Environment based on Paragraph 2 of Article 1, Article 3 and Subparagraph 4 of Article 5 of the Ministerial Ordinance on Items Etc. of Test concerning New Chemical Substances and Study of Hazardous Properties of Chemical Substances Requiring Priority Assessment and Monitoring Chemical Substances (Notice of Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry and Ministry of the Environment, No. 5 of 2011) and amendments thereto (d) Regarding the Good Laboratory Practice for test facilities conducting tests of New Chemical Substances Etc. (Yakusyokuhatsu 0331 No. 8/Heisei 23.03.29 Seikyoku No. 6/Kanhokihatsu No. 110331010 of 2011) and amendments thereto

THE UNITED KINGDOM	JAPAN
	(e) Regarding the Rules and Requirements for Test Results for Evaluating New Chemical Substances Etc. (Yakusyokuhatsu 0331 No. 9/Heisei 23.03.29 Seikyoku No. 7/Kanhokihatsu No. 110331011 of 2011) and amendments thereto 6. Chemical Substances Controlled for the Protection of Health of Workers: (a) Industrial Safety and Health Law (Law No. 57 of 1972) and amendments thereto (b) Ordinance on Industrial Safety and Health (Ministerial Ordinance of Ministry of Labour No. 32 of 1972) and amendments thereto (c) The Notice on Standard to be Satisfied by the Test Facility Etc. under the Provisions of Paragraph 2 of Article 34-3 of the Ordinance on Industrial Safety and Health (Notice of Ministry of Labour No. 76 of 1988) and amendments thereto

THE UNITED KINGDOM	JAPAN
	(d) Regarding Implementation of the Ministerial Ordinance to Amend a Part of the Ordinance on Industrial Safety and Health, Ministerial Ordinance to Amend a Part of the Ordinance on Safety of Boiler and High Pressure Vessels and the Ministerial Ordinance to Amend a Part of the Ordinance on Preventing Organic Solvents Poisoning, Etc. (Kihatsu No. 602 of 1988) and amendments thereto (e) Regarding Establishment of the Guideline of Certification of Compliance of Test Facilities Etc. with GLP under the Industrial Safety and Health Law (Kihatsu No. 123 of 1989) and amendments thereto

SECTORAL ANNEX ON
GOOD MANUFACTURING PRACTICE (GMP) FOR MEDICINAL PRODUCTS

PART A

1. This Sectoral Annex applies to:

(a) the confirmation of the compliance with GMP requirements of manufacturing facilities for medicinal products to which the GMP requirements of both Parties are applied in accordance with the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex; and

(b) the acceptance of the data generated by confirmed manufacturing facilities (the certificate issued by confirmed manufacturing facilities in accordance with the provisions of Part A of this Sectoral Annex).

2.(a) For the purposes of this Sectoral Annex:

(i) "criteria for confirmation" means the GMP requirements;

(ii) "Good Manufacturing Practice (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;

(iii) "inspection" means an on-site evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMP requirements including the requirements of the applicable marketing authorisation or product specifications. Such inspection is conducted in accordance with the laws, regulations and administrative provisions specified in Section I of Part B of this Sectoral Annex carried out by a Competent Authority listed in Section II of Part B of this Sectoral Annex, and may include pre-marketing and post-marketing inspection; and

(iv) "medicinal products" means drugs which are industrially manufactured for human use as defined in the laws, regulations and administrative provisions of Japan specified in Section I of Part B of this Sectoral Annex, and medicinal products and intermediate products which are industrially manufactured for human use as defined in the laws, regulations and administrative provisions of the United Kingdom in Section I of Part B of this Sectoral Annex.

The definition of medicinal products above may include medicinal products intended for clinical trials, active ingredients, chemical and biological pharmaceuticals, immunologicals, radiopharmaceuticals, stable medicinal products derived from human blood or human plasma, and where appropriate, vitamins, minerals and herbal medicines.

(b) It is understood that the term "amendment" referred to in Part B of this Sectoral Annex includes the following cases:

(i) a Party entirely or partially changes its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex, whether or not those names are changed;

(ii) a Party repeals its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and/or administrative provisions substituting for the previous laws, regulations and/or administrative provisions, whether or not the previous names are changed; and

(iii) a Party incorporates the whole or a relevant part of its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and/or administrative provisions.

3. This Protocol does not cover mutual recognition of batch release (Kentei) referred to in Article 43 of the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Law No. 145 of 1960) of Japan and batch release referred to in regulation 60A of the Human Medicines Regulation 2012 of the United Kingdom.

4. With respect to paragraph 2 of Article 2 of this Protocol, each Party shall, as a result of the acceptance of confirmation of manufacturing facilities carried out by the Competent Authorities of the other Party, accept, regarding the medicinal products for which its marketing authorisation has been issued or for which product specifications are applicable, the certificate issued by the confirmed manufacturing facilities of the conformity of each batch to the marketing authorisation or product specifications and exempt the importers from the testing of each batch, in accordance with the laws, regulations and administrative provisions of each Party specified in the Section I of Part B of this Sectoral Annex, taking into account the equivalence of GMP requirements of both Parties, provided that:

(a) such certificate is issued by the confirmed manufacturing facilities on the results of a full qualitative analysis, a quantitative analysis of all the active constituents and all the other tests or checks;

(b) the certificate contains a statement that the product has been manufactured in conformity with GMP requirements; and

(c) both Parties apply the equivalent GMP requirements to the products of which the certificate is issued.

5. In the certificate issued by the confirmed manufacturing facilities and related to each batch to be exported, as referred to in paragraph 4, it will be certified, through the testing which is required for the manufacturing of medicinal products in accordance with the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex, that each batch of medicinal products is manufactured as required by the applicable marketing authorisation or product specifications of the importing Party.

6. A sub-committee of the Joint Committee on Mutual Recognition will be established in particular to monitor the progress of the preparatory work set out in paragraph 9 of this Sectoral Annex and the operation of this Sectoral Annex. It will report to the Joint Committee on Mutual Recognition.

7. (a) The Parties will exchange information on, in particular:

(i) GMP for specific products or classes of products;

(ii) new technical guidance or inspection procedures;

(iii) quality defects, batch recalls, counterfeiting and other problems concerning quality; and

(iv) any suspension or withdrawal of a manufacturing authorisation.

(b) The Parties will agree detailed alert procedures through the sub-committee of the Joint Committee on Mutual Recognition to fulfil specific objectives of this Sectoral Annex.

(c) Equivalence of GMP for specific products or classes of products will be coordinated according to a procedure established by the sub-committee of the Joint Committee on Mutual Recognition.

(d) Notwithstanding paragraph 6 of Article 8 of this Protocol, each Party shall provide the other Party and the Joint Committee on Mutual Recognition with a list of the confirmed manufacturing facilities at the frequency to be decided by the Joint Committee on Mutual Recognition.

(e) Each Party will, upon reasoned request by the other Party, provide a copy of the most recent inspection report on a confirmed facility within 30 days from the date of the request. If the requested Party conducts an additional inspection, that Party will provide a copy of the report of such additional inspection to the requesting Party within 60 days from the date of the request. If after the exchange of inspection reports there remains serious cause for concern on whether a manufacturing facility in the other Party complies with GMP requirements, each Party may request the other Party to conduct further inspections on that facility.

(f) The Competent Authority of a Party will, upon request by an exporter, importer or the Competent Authority of the other Party, confirm that a manufacturing facility in its territory:

(i) is appropriately authorised to manufacture medicinal products in accordance with its laws, regulations and administrative provisions specified in Section I of Part B of this Sectoral Annex;

(ii) is regularly inspected by the Competent Authorities; and

(iii) complies with its GMP requirements that are recognised by both Parties as equivalent.

8. With regard to paragraph 2 of Article 5 of this Protocol, the exporting Party shall, in accordance with its applicable laws, regulations and administrative provisions, inspect periodically the manufacturing facilities in order to ensure that the facilities fulfil its GMP requirements set out in the laws, regulations and administrative provisions of that Party specified in Section I of Part B of this Sectoral Annex.

9.(a) With respect to medicinal products for which the equivalence of GMP requirements have not been confirmed, Articles 2, 4, 5, 7 and subparagraph 2(a) of Article 10 of this Protocol relating to this Sectoral Annex and the provisions of this Sectoral Annex other than paragraph 6, subparagraph 7(b) and this paragraph shall not be applied before the 30th day after the date of exchange of diplomatic notes confirming to each other that the preparatory work is completed.

(b) Through the preparatory work, the Parties shall reconfirm the equivalence of GMP requirements and their implementation through the Joint Committee on Mutual Recognition. The Joint Committee on Mutual Recognition will decide the detailed procedures for implementing this Sectoral Annex.

PART B

SECTION I: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING MEDICINAL PRODUCTS, GMP REQUIREMENTS FOR MEDICINAL PRODUCTS, VERIFICATION AND CONFIRMATION

THE UNITED KINGDOM	JAPAN
The Human Medicines Regulations 2012 (SI 2012/1916) and amendments thereto	1. Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Law No. 145 of 1960) and amendments thereto 2. Cabinet Order for Enforcement of the Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Cabinet Order No. 11 of 1961) and amendments thereto 3. Regulation for Enforcement of the Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Ministerial Ordinance of Ministry of Health and Welfare No. 1 of 1961) and amendments thereto

THE UNITED KINGDOM	JAPAN
	4. The Notice on Pharmaceuticals Designated by the Minister for Health, Labour and Welfare under the Provisions of Subparagraphs 6 and 7 of Paragraph 1 of Article 20 of the Cabinet Order for Enforcement of the Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, and under the Provisions of Subparagraphs 6 and 7 of Article 96 of the Regulation for Enforcement of the Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Notice of Ministry of Health, Labour and Welfare No. 431 of 2004) and amendments thereto 5. Ordinance concerning Facilities and Equipments for Pharmacies Etc. (Ministerial Ordinance of Ministry of Health and Welfare No. 2 of 1961) and amendments thereto

THE UNITED KINGDOM	JAPAN
	6. Ministerial Ordinance concerning the Standard of Manufacturing Control and Quality Control for Drugs and Quasi Drugs (Ministerial Ordinance of Ministry of Health, Labour and Welfare No. 179 of 2004) and amendments thereto

SECTION II: COMPETENT AUTHORITIES

THE UNITED KINGDOM	JAPAN
Medicines and Healthcare Products Regulatory Agency or an authority succeeding it	Ministry of Health, Labour and Welfare or an authority succeeding it

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