

DECISION No. 1/2023

of the Joint Committee on Mutual Recognition established under the Protocol on Mutual Recognition of the Agreement between the United Kingdom of Great Britain and Northern Ireland and Japan for a Comprehensive Economic Partnership of 20 October 2023

THE JOINT COMMITTEE ON MUTUAL RECOGNITION,

Having regard to the Protocol on Mutual Recognition ('the Protocol') of the Agreement between the United Kingdom of Great Britain and Northern Ireland and Japan for a Comprehensive Economic Partnership and in particular paragraph 2 of Article 8, paragraph 9 of Article 8 and paragraph 3 of Article 9 of the Protocol,

HAS DECIDED AS FOLLOWS:

1. The Rules of Procedure for the Joint Committee on Mutual Recognition, as specified in the ANNEX 1 to this decision, are hereby adopted, according to paragraph 2 of Article 8 of the Protocol.
2. The following documents that were produced by Japan and the European Community and its successors with regard to the EC-Japan MRA are accepted, *mutatis mutandis*, according to paragraph 9 of Article 8 of the Protocol, and the Rules of Procedure for a subcommittee for the Sectoral Annex on Good Manufacturing Practice (GMP) for Medicinal Products attached to the Decision Nr.2/2002 is revised as set out in the ANNEX 2 to this decision.
 - (1) Joint declaration on international guides or recommendations concerning the technical competence of conformity assessment bodies (CABs)
 - (2) Joint declaration on facilitating market access
 - (3) Exchange of Letters concerning the completeness of the Sectoral Annexes
 - (4) Exchange of Letters on the use of languages
 - (5) Decision Nr.2/2002 of the Joint Committee set up under the Agreement on Mutual Recognition between the European Community and Japan on establishing a subcommittee for the Sectoral Annex on Good Manufacturing Practice (GMP) for Medicinal Products

- (6) Decision Nr.3/2002 of the Joint Committee set up under the Agreement on Mutual Recognition between the European Community and Japan on the publication of lists of confirmed facilities under the Sectoral Annex on Good Laboratory Practice (GLP) for Chemicals and the Sectoral Annex on Good Manufacturing Practice (GMP) for Medicinal Products
 - (7) Decision Nr.4/2004 of the Joint Committee set up under the Agreement on Mutual Recognition between Japan and the European Community on the definition of the emergency and the modalities of visits referred to in Article 10(2)(a) of the Agreement for the purposes of the Sectoral Annex on GMP for medicinal products
 - (8) Decision No2/JP/2018 of the Joint Committee established under the Agreement on Mutual Recognition between the European Community and Japan
3. The following conformity assessment bodies (CABs) of the Parties are registered as the conformity assessment bodies under the Protocol, according to paragraph 3 of Article 9 of the Protocol.
- (1) The UK CABs
 - Element Materials Technology Warwick Ltd (AB number: 0891; UKCA listing here: <https://www.gov.uk/uk-market-conformity-assessment-bodies/element-materials-technology-warwick-ltd>)
 - TUV SUD BABT (AB number: 0168; UKCA listing here: <https://www.gov.uk/uk-market-conformity-assessment-bodies/tuv-sud-babt>)
 - (2) Japan CABs
None
4. This Decision, in duplicate, will be signed by the co-chairs.

Tokyo, 20 October 2023

London, 20 October 2023

On behalf of Japan

On behalf of the United Kingdom of Great Britain and Northern Ireland

RULES OF PROCEDURE of the Joint Committee on Mutual Recognition

The Joint Committee on Mutual Recognition, hereinafter referred to as “The Joint Committee”) established under the Protocol on Mutual Recognition of the Agreement between the United Kingdom of Great Britain and Northern Ireland (hereinafter referred to as “the UK”) and Japan (hereinafter referred to collectively as “the Parties”) for a Comprehensive Economic Partnership (hereinafter referred to as “the UK-Japan CEPA”) (hereinafter referred to as “the Protocol”) has decided the Rules of Procedure of the Joint Committee as follows.

Paragraph 1

Chairmanship

1. The Joint Committee will be chaired jointly by a representative of the UK and a representative of Japan.
2. The co-chairs will be responsible for communications between the Parties in respect of the procedures set out in these Rules of Procedure and the Protocol.

Paragraph 2

Meetings

1. The Joint Committee will meet when necessary upon request by either Party at a mutually agreeable time. Teleconferencing or videoconferencing may be used with mutual consent of the Parties.
2. Meetings of the Joint Committee will be convened by the co-chairs.
3. The co-chairs will decide a date for the meeting in sufficient time to ensure adequate preparation, where possible this should be no later than six weeks prior to the meeting.
4. The Party hosting a meeting will arrange logistical matters. Meetings convened by videoconferencing or teleconferencing will be arranged by the co-chair requesting the meeting.

Paragraph 3

Delegations

At least one week prior to a meeting, the Parties will notify, to the extent possible, each other of the intended composition of their delegations.

Paragraph 4

Agenda for the meetings

1. A provisional agenda for each meeting will be drawn up by the co-chairs, no later than 15 calendar days before the date of the meeting, unless otherwise decided by the Parties.
2. Either Party may propose items for the provisional agenda no later than 21 calendar days before the date of the meeting, unless otherwise decided by the Parties. Requests to add items to the provisional agenda will be sent in writing where possible.
3. The final agenda will be adopted by the Joint Committee at the beginning of each meeting. An item other than those appearing on the provisional agenda may be placed on the agenda if the Parties decide and will be accommodated to the extent possible.

Paragraph 5

Records of the meetings

1. A draft of the record will be prepared as soon as possible by the co-chair hosting the meeting.
2. The record will, as a general rule, indicate in respect of each item on the agenda:
 - (a) the documentation submitted to the Joint Committee;
 - (b) statements which a Party has requested to be entered; and
 - (c) decisions taken and the conclusions adopted on a specific item.
3. The record will also indicate the participants in the meeting.
4. The record will be approved by the Joint Committee and signed by the co-chairs.

Paragraph 6

Joint Committee decisions

1. The Joint Committee will take decisions by consensus.

2. The Joint Committee may adopt a decision by written procedure other than formal Joint Committee meetings, if the Parties decide.

3. All Decisions of the Joint Committee will be entitled "Decisions" followed by a serial number, and by a description of their subject. The date the decision comes into operation will also be indicated. Decisions will be signed by the co-chairs. Decisions will be drawn up in duplicate, each version being equally authentic. A model Joint Committee decision is attached in Appendix I.

4. Decisions related to the registration of a conformity assessment body will, as a general rule, be adopted by a written procedure. For this purpose, pursuant to Article 9 of the Protocol, the following procedures will apply.

(a) A Party will forward its proposal, in the form of a draft Joint Committee decision to register a conformity assessment body (a model of which is attached as Appendix II), to the other Party in writing. The proposal will be accompanied by a proposal format and the necessary supporting documentation, the formats of which are to be decided by the Parties. The receiving Party will acknowledge in writing the date of its receipt of the proposal. The Party receiving the proposal will indicate in writing its consent or opposition within 90 days from its receipt.

(b) If the Party receiving the proposal requires additional information, it will indicate in writing the information requested and the reasons for this. A request for additional information suspends the 90-day period which starts running again once the additional information has been received.

(c) The Parties may consult with each other, where necessary, on matters related to the proposed registration.

(d) Upon consent to the proposal, the receiving Party will sign and date the Joint Committee decision and forward it to the proposing Party. The registration of the proposed conformity assessment body is effective from the date indicated in the Joint Committee decision.

(e) If the Party receiving a proposal for registration fails to indicate its consent or opposition within the 90-day time limit, the matter will be referred to the Joint Committee.

(f) If the Joint Committee cannot take a decision to register a proposed conformity assessment body then Article 9(1)(c) of the Protocol will apply.

Notification and proposal procedures

1. The notification of the suspension or lifting of the suspension of the designation of a registered conformity assessment body pursuant to Article 6 of the Protocol, and the proposal for terminating the registration of a conformity assessment body pursuant Article 9(5) of the Protocol, will be made in writing.
2. The Party receiving such notification or proposal will immediately, and within seven working days for the receiving Party at the latest, acknowledge its receipt in writing and indicate the date of receipt. The suspension, lifting of suspension or termination of registration of the conformity assessment body will apply from the date of receipt of the notification or the proposal by the co-chair of the receiving Party, unless pursuant to Article 9(5) of the Protocol, otherwise determined by the Joint Committee.

Paragraph 8

Subcommittees

In accordance with Article 8.2 of the Protocol, the Joint Committee may establish subcommittees and delegate specific tasks to the subcommittees. Any subcommittee established by the Joint Committee will keep the Joint Committee informed and provide reports in relation to implementation of the Sectoral Annexes.

Paragraph 9

Exchange of information

Without prejudice to Paragraph 1(2), the Parties will establish and communicate to each other a contact point, or contact points as necessary, for the exchange of information foreseen by the Protocol. The contact points will be responsible for transmitting and receiving information exchanged under the Protocol and in particular Article 5(5) and Article 8(8) of the Protocol.

Paragraph 10

Publication

When publishing the lists of registered conformity assessment bodies and confirmed facilities in accordance with the Protocol and relevant Joint Committee decisions, it will be done

according to the Parties' respective domestic requirements. The Parties will make available on their respective Internet sites such updated lists, in a timely and regular manner.

Paragraph 11

Consultation of experts

The Committee may consult experts on particular issues if the Parties decide.

Paragraph 12

Expenses

1. Each Party will be responsible for the expenses they incur by reason of their participation in the meetings of the Joint Committee, including staff, travel and subsistence, expenditure and postal or telecommunications expenditure.
2. Other expenses arising from the organisation of the meetings will generally be covered by the Party hosting the meeting.

Paragraph 13

Administrative Procedures

1. Unless otherwise decided, the meetings of the Joint Committee will not be open to the public.
2. Records and other documents of the Joint Committee will be considered information exchanged under Article 12 of the Protocol for purposes of confidentiality.
3. Participants other than officials of the Parties may be invited by mutual consent of both co-chairs and will be subject to the same confidentiality requirements in accordance with Article 12 of the Protocol.
4. The Parties may organise public briefings or otherwise inform interested members of the public of the results of the Joint Committee meetings, upon consultation with each other at the end of each meeting on the results to be communicated.

Paragraph 14

Languages

1. Written communication between the co-chairs, in particular as it relates to Articles 4, 5, 6 and 7 of the Protocol, will be in English.
2. The Party hosting a meeting of the Joint Committee will provide interpretation between Japanese and English and bear the costs for this.
3. Decisions of the Joint Committee will be drawn up in English. The Parties undertake to translate, as necessary, such decisions into their own respective official language or languages.

Appendix I to the Rules of Procedure of the Joint Committee

Model Joint Committee decision

Decision No x/ of the Joint Committee set up under the Protocol on Mutual Recognition between the United Kingdom of Great Britain and Northern Ireland and Japan

THE JOINT COMMITTEE,

Having regard to the Protocol on Mutual Recognition between the United Kingdom of Great Britain and Northern Ireland (“the United Kingdom”) and Japan, and in particular Article 8(3)(a) and 9(1)(b) thereof;

HAS DECIDED AS FOLLOWS:

- 1.
2. This Decision, in duplicate, will be signed by the co-chairs. The decision will be valid from the date of the later of these signatures.

On behalf of Japan

On behalf of the United Kingdom of
Great Britain and Northern Ireland

Appendix II to the Rules of Procedure of the Joint Committee

Model Joint Committee decision for the registration of a Conformity Assessment Body

Decision No x/ of the Joint Committee set up under the Protocol on Mutual Recognition between the United Kingdom of Great Britain and Northern Ireland and Japan related to the registration of a Conformity Assessment Body under the Sectoral Annex on [Telecommunications Terminal Equipment and Radio Equipment][Electrical Products]

THE JOINT COMMITTEE,

Having regard to the Protocol on Mutual Recognition (“the Protocol”) between the United Kingdom of Great Britain and Northern Ireland (“the United Kingdom”) and Japan and in particular Article 8(3)(a) and 9(1)(b) thereof;

HAS DECIDED AS FOLLOWS:

1. The Conformity Assessment Body indicated below is registered under the Sectoral Annex on [Telecommunications Terminal Equipment and Radio Equipment] [Electrical Products] of the Protocol, for the products and conformity assessment procedures as indicated below.

name, acronym and contact details of the Conformity Assessment Body:

scope of registration in terms of products and conformity assessment procedures:

2. This Decision, in duplicate, will be signed by the co-chairs. The decision will be valid from the date of the later of these signatures.

On behalf of Japan

On behalf of the United Kingdom of
Great Britain and Northern Ireland

RULES OF PROCEDURE

The sub-committee under the Sectoral Annex on Good Manufacturing Practice (GMP) for medicinal products

1. Introduction

The role of the sub-committee ('the SC') for the Sectoral Annex on GMP for medicinal products ('the Annex') to the Protocol on Mutual Recognition ('the Protocol') of the Agreement between the United Kingdom of Great Britain and Northern Ireland ('the United Kingdom') and Japan for a Comprehensive Economic Partnership ('the Agreement') is, according to paragraph 6 of the Annex, to monitor the progress of the preparatory work set out in paragraph 9 of the Annex and the operation of the Annex. In order to ensure the efficient operation of the SC, the description in the Annex is supplemented as follows to explain the SCs responsibilities, composition, and procedures in detail.

2. Responsibilities

The responsibilities of the SC are as follows:

- (a) to report to and communicate with the Joint Committee on Mutual Recognition established under the Protocol ('the Joint Committee');
- (b) to coordinate joint activities;
- (c) to monitor progress of the preparatory work set out in paragraph 9 of the Annex and the operation of the Annex;
- (d) to facilitate regulatory collaboration and communications between the Japanese and the UK competent authorities;
- (e) to establish a procedure for coordinating equivalence of GMP for specific products or classes of products;
- (f) to discuss and resolve where possible any major problems that occur and to present to the Joint Committee any issue which cannot be resolved;
- (g) to establish and maintain a list of contact points for each Party to the Agreement ('Party');
- (h) to ensure that documentation and other information set out in paragraph 7(a) of the Annex are communicated to the other Party;
- (i) to decide detailed alert procedures;
- (j) to reconfirm the equivalence of GMP requirements and their implementation as set out in paragraph 9(b) of the Annex;
- (k) to identify products and classes of products falling under the definition of medicinal products under the scope of the Annex;
- (l) to prepare, for adoption by the Joint Committee, the definition of emergency and modalities of visits to manufacturing facilities in such cases;
- (m) to develop procedures to exchange documents and information;
- (n) to prepare the detailed procedures for the implementation of the Annex, which are to be decided by the Joint Committee.

3. Composition of the SC

The SC will be composed as follows:

- (a) each Party will nominate a representative who will jointly chair meetings of the SC. Participation in the SC from each Party should be balanced in terms of the size of their respective delegations;
- (b) participants in the meetings of the SC will not include external parties such as representatives of industry, trade associations, or the press. All meeting attendees will be bound by the same confidentiality, conflict of interest and non-disclosure requirements as regulatory authority employees. The Party on whose behalf a person is attending will ensure the attendee is bound by the

relevant confidentiality, conflict of interest and non-disclosure requirements.

4. Procedures of meetings

- (a) Unless otherwise decided, the meetings of the SC will not be open to the public.
- (b) The SC will meet in person or by teleconference with the consent of both Parties, if meetings are required for the effective functioning of the Annex.
- (c) The date and exact venue of the prospective meetings will be decided by the co-chairs.
- (d) The draft agenda for each meeting will be prepared by the host co-chair and circulated to the participants in advance of the meeting along with the list of participants.
- (e) Co-chairs are to decide the draft agenda.
- (f) Each Party will endeavour to circulate the papers and reports to be tabled at each meeting at least two weeks beforehand.
- (g) The host will prepare and circulate a table of confirmed actions within two weeks from the end of each meeting and the draft summary record of each meeting within one month from the end of each meeting.
- (h) Draft summary record and table of confirmed actions should be finalised within a further four weeks and endorsed by the co-chairs.
- (i) The SC will hold meetings as requested by either party and as frequently as both Parties decide is necessary to fulfil the commitments of the Annex.
- (j) The Party hosting a meeting will arrange logistical matters. Meetings convened by teleconferencing will be arranged by the co-chair that requested the meeting.
- (k) The following will apply with regard to the use of languages:
 - written communication between the co-chairs will be in English,
 - the Party hosting a meeting of the SC will provide interpretation between Japanese and English and bear the costs for this.

5. Adoption of documents

The SC will:

- (a) adopt the agenda at each meeting.
- (b) review the table of confirmed actions from the previous meeting during each meeting.
- (c) adopt all documents to be submitted to the Joint Committee.
- (d) adopt documents by consensus. If the Parties have different positions on a topic, a document may describe each Party's views.

6. Reporting arrangements with the Joint Committee

The SC will transmit copies of the adopted agendas and summary records of its formal meetings to the Joint Committee.

7. Communications to external parties

- (a) Both Parties will confirm a common statement on the status and operation of the Annex, as

appropriate, at the end of each meeting.

(b) This external communication is to be issued as soon as possible after the meeting; each Party will distribute the common statement as it determines appropriate.