

Tokyo, 20 September 2019

The Rt Hon Elizabeth Truss MP
Secretary of State for International Trade and President of the Board of
Trade
The United Kingdom of Great Britain and Northern Ireland

Dear Secretary of State,

The Government of Japan, taking into account the necessity of ensuring transparency, predictability and legal stability in case the obligation contained in the Agreement on Mutual Recognition between Japan and the European Community (Japan-EC MRA) ceases to apply to the United Kingdom of Great Britain and Northern Ireland (UK), confirms that the Government of Japan will take the measures listed in the following 1 to 4 points, in accordance with the existing laws and regulations, in the case that the Japan-EC MRA ceases to apply to the UK, from that date until a new agreement on mutual recognition between Japan and the UK enters into force, as long as the reciprocity is secured by the UK and the UK will communicate to Japan in an equivalent undertaking in an exchange of letters.

1. Telecommunications Terminal Equipment and Radio Equipment

With respect to telecommunications terminal equipment and radio equipment, the Government of Japan will, where third-party conformity assessment procedures are required, accept the results of conformity assessment procedures conducted by conformity assessment bodies (CABs) in the UK, which apply to and subsequently are recognised by the Government of Japan in accordance with Article 104 of Telecommunications Business Act of Japan and paragraph 31 of Article 38 of Radio Act of Japan.

2. Electrical Products

With respect to electrical products, the Government of Japan will, where third-party conformity assessment procedures are required, accept the results of conformity assessment procedures conducted by the CABs in the UK, which apply to and subsequently are registered by the Government of Japan in accordance with Article 29 of Electrical Appliances and Materials Safety Act of Japan. The conformity assessment scheme operated by the International Electrotechnical Commission (IECEE CB Scheme) is commonly used to demonstrate conformity of electrical products with technical standards in Japan.

3. Good Laboratory Practice (GLP) for Chemicals

In accordance with the Decision of the Council of the OECD concerning the Mutual Acceptance of Data in the Assessment of Chemicals, which stipulates that “data generated in the testing of chemicals in an OECD Member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment” (paragraph 1. of Part I), the Government of Japan will continue to accept (i) the confirmation on conformity with GLP of test facilities in the UK conducted by the competent authority of the UK based upon the results of verification and in accordance with the criteria for confirmation and (ii) the data generated by test facilities in the UK whose conformity with GLP has been confirmed by the competent authority of the UK.

4. Good Manufacturing Practice (GMP) for Medicinal Products

The Government of Japan will continue to recognise the equivalence of GMP requirements for medicinal products and their implementation of the two countries as long as the GMP requirements for those products and their implementation have been confirmed as equivalent under the Japan-EC MRA, by adopting relevant standards set out in guidelines regarding GMP standards and quality systems of inspectorates developed by the Pharmaceutical Inspection Co-operation Scheme (PIC/S), as well as in guidelines regarding quality adopted in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human

Use (ICH). The Government of Japan will accept the confirmation on conformity with GMP of manufacturing facilities in the UK conducted by the competent authority of the UK, will accept the certificate issued by the manufacturing facilities in the UK whose conformity with GMP has been confirmed by the competent authority of the UK, of the conformity of each batch to marketing authorisation or product specifications, and will exempt the importers from the testing of each batch in Japan.

If any problem arises with respect to this exchange of letters, the Government of Japan will seek an amicable solution through the contact points.

When the Government of Japan discovers particular circumstances which may cause imminent and serious danger to the public, it will immediately communicate its findings to the Government of the UK.

The Government of Japan will appoint contact points to serve as liaisons for communication on each respective sector and inform the Government of the UK of such contact points.

Sincerely,

MOTEGI Toshimitsu
Minister for Foreign Affairs of Japan

Tokyo, 20 September 2019

Mr. MOTEGI Toshimitsu
Minister for Foreign Affairs of Japan

Dear Minister,

The Government of the United Kingdom of Great Britain and Northern Ireland (UK), taking into account the necessity of ensuring transparency, predictability and legal stability in case the obligation contained in the Agreement on Mutual Recognition between Japan and the European Community (Japan-EC MRA) ceases to apply to the UK, confirms that the Government of the UK will take the measures listed in the following 1 to 4 points, in accordance with the existing laws and regulations, in the case that the Japan-EC MRA ceases to apply to the UK, from that date until a new agreement on mutual recognition between Japan and the UK enters into force, as long as the reciprocity is secured by Japan and Japan will communicate to the UK in an equivalent undertaking in an exchange of letters.

1. Telecommunications Terminal Equipment and Radio Equipment

With respect to telecommunications terminal equipment and radio equipment, the Government of the UK will, where third-party conformity assessment procedures are required, continue to accept the results of conformity assessment procedures conducted by conformity assessment bodies (CABs) in Japan, which have been recognised pursuant to the Japan-EC MRA, in accordance with the Conformity Assessment (Mutual Recognition Agreements) Regulations 2019 together with the Radio Equipment Regulations 2017 and the Electromagnetic Compatibility Regulations 2016 both as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

2. Electrical Products

With respect to electrical products, the conformity assessment scheme operated by the International Electrotechnical Commission (IECEE CB Scheme) is commonly used to demonstrate conformity of electrical products with technical standards in the UK.

3. Good Laboratory Practice (GLP) for Chemicals

In accordance with the Decision of the Council of the OECD concerning the Mutual Acceptance of Data in the Assessment of Chemicals, which stipulates that “data generated in the testing of chemicals in an OECD Member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment” (paragraph 1. of Part I), the Government of the UK will continue to accept (i) the confirmation on conformity with GLP of test facilities in Japan conducted by the competent authorities of Japan based upon the results of verification and in accordance with the criteria for confirmation and (ii) the data generated by test facilities in Japan whose conformity with GLP has been confirmed by the competent authorities of Japan.

4. Good Manufacturing Practice (GMP) for Medicinal Products

The Government of the UK will continue to recognise the equivalence of GMP requirements for medicinal products and their implementation of the two countries as long as the GMP requirements for those products and their implementation have been confirmed as equivalent under the Japan-EC MRA, by adopting relevant standards set out in guidelines regarding GMP standards and quality systems of inspectorates developed by the Pharmaceutical Inspection Co-operation Scheme (PIC/S), as well as in guidelines regarding quality adopted in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The Government of the UK will accept the confirmation on conformity with GMP of manufacturing facilities in Japan conducted by the competent authority of Japan, will accept the certificate issued by the manufacturing facilities in Japan whose conformity with GMP has been confirmed by the competent authority of Japan, of the conformity of each batch to marketing authorisation or product specifications, and will exempt

the importers from the testing of each batch in the UK.

If any problem arises with respect to this exchange of letters, the Government of the UK will seek an amicable solution through the contact points.

When the Government of the UK discovers particular circumstances which may cause imminent and serious danger to the public, it will immediately communicate its findings to the Government of Japan.

The Government of the UK will appoint contact points to serve as liaisons for communication on each respective sector and inform the Government of Japan of such contact points.

Please accept the assurance of my highest consideration.

The Rt Hon Elizabeth Truss MP
Secretary of State for International Trade and President of the Board
of Trade
For the Government of the United Kingdom of Great Britain and Northern
Ireland