AGREEMENT

in the form of an Exchange of Diplomatic Notes with Japan in accordance with Article 15(3)(b) of the Agreement on Mutual Recognition (MRA) in order to amend Part B of the Sectoral Annex on Good Manufacturing Practice (GMP) for medicinal products

LETTER FROM JAPAN

Brussels, April 22, 2016

Sir,

I have the honour to propose, on behalf of the Government of Japan, that Sections I and II of Part B of the Sectoral Annex on Good Manufacturing Practice (GMP) for Medicinal Products of the Agreement on Mutual Recognition between Japan and the European Community, done at Brussels on April 4, 2001 (hereinafter referred to as the 'Agreement') be replaced by the Sections I and II of Part B attached to this Note, in accordance with subparagraph 3(b) of Article 15 of the Agreement.

I have further the honour to propose that, if the above proposal is acceptable to the European Union, it is suggested that this Note and your reply to that effect shall be regarded as constituting an agreement between the Government of Japan and the European Union on this matter which shall enter into force on the date of your reply.

I avail myself of this opportunity to extend to you the assurance of my high consideration.

Keiichi KATAKAMI

Ambassador Extraordinary and Plenipotentiary of Japan to the European Union

Mr Jean-Luc DEMARTY

Director-General

Directorate-General for Trade European Commission

LETTER FROM THE EUROPEAN UNION

Brussels, April 22, 2016

Excellency,

I have the honour to acknowledge the receipt of Your Excellency's Note of today's date, which reads as follows.

'I have the honour to propose, on behalf of the Government of Japan, that Sections I and II of Part B of the Sectoral Annex on Good Manufacturing Practice (GMP) for Medicinal Products of the Agreement on Mutual Recognition between Japan and the European Community, done at Brussels on April 4, 2001 (hereinafter referred to as the "Agreement") be replaced by the Sections I and II of Part B attached to this Note, in accordance with subparagraph 3(b) of Article 15 of the Agreement.

I have further the honour to propose that, if the above proposal is acceptable to the European Union, it is suggested that this Note and your reply to that effect shall be regarded as constituting an agreement between the Government of Japan and the European Union on this matter which shall enter into force on the date of your reply.'

I have the honour to inform Your Excellency, on behalf of the European Union, that the European Union accepts the above proposal of the Government of Japan and to confirm that Your Excellency's Note and this reply shall be regarded as constituting an agreement between the European Union and the Government of Japan on this matter which shall enter into force on the date of this reply.

I avail myself of this opportunity to extend to Your Excellency the assurance of my highest consideration.

Jean-Luc DEMARTY

Director-General

Directorate-General for Trade European Commission

His Excellency

Mr Keiichi KATAKAMI

Ambassador Extraordinary and Plenipotentiary of Japan to the European Union

ANNEX

PART B

Section I

The applicable laws, regulations and administrative provisions stipulating medicinal products, GMP requirements for medicinal products, verification and confirmation

European Union	Japan
1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67) and amendments thereto	1. The Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Law No 145, 1960) and amendments thereto
2. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34) and amendments thereto	2. Cabinet Order of the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Cabinet Order No 11, 1961) and amendments thereto
3. Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13) and amendments thereto	3. Ordinance of the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Ordinance of the Ministry of Health and Welfare No 1, 1961) and amendments thereto
4. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1) and amendments thereto	4. Pharmaceuticals Designated by the Minister for Health, Labour and Welfare under the provisions of subparagraphs 6 and 7 of Article 20-1 of the Cabinet Order of the Law on 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 Ordinance of the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Notice of Ministry of Health, Labour and Welfare No 431, 2004) and amendments thereto
5. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22) and amendments thereto	5. Ordinance for Facilities and Equipments for Pharmacies etc. (Ordinance of the Ministry of Health and Welfare No 2, 1961) and amendments thereto
6. Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use (OJ L 337, 25.11.2014, p. 1) and amendments thereto	6. Ministerial Ordinance for the Standard of Manufacturing Control and Quality Control for Drugs and Quasi Drugs (Ordinance of the Ministry of Health, Labour and Welfare No 179, 2004) and amendments thereto
7. Current versions of the Guide to good manufacturing practices contained in volume IV of Rules governing medicinal products in the European Union and Compilation of the European Union Procedures on Inspections and exchange of Information	

Section II

Competent authorities

European Union	Japan
Competent Authorities of the European Union are the following authorities of the Member States of the European Union or authorities succeeding them: Austria Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH Belgium Federaal Agentschap voor geneesmiddelen en gezondheidsproducten/Agence fédérale des médicaments et produits de santé Bulgaria Изпълнителна агенция по лекарствата Croatia Agencija za lijekove i medicinske proizvode (HALMED) Cyprus Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας Czech Republic Státní ústav pro kontrolu léčiv (SÚKL) Denmark Lægemiddelstyrelsen Estonia Ravimiamet Finland Lääkealan turvallisuus- ja kehittämiskeskus France Agence nationale de sécurité du médicament et des produits de santé (ANSM) Germany Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Paul-Ehrlich-Institut (PEI) Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel (biologicals only) Greece Ethnikos Organismos Farmakon (EOF) (ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ) Hungary Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (OGYÉI) Ireland Health Products Regulatory Authority (HPRA)	Ministry of Health, Labour and Welfare or an authority succeeding this ministry

European Union	Japan
Italy Agenzia Italiana del Farmaco Latvia Zāļu valsts aģentūra Lithuania Valstybinė vaistų kontrolės tarnyba Luxembourg Ministère de la Santé, Division de la Pharmacie et des Médicaments Malta Medicines Authority Netherlands Inspectie voor de Gezondheidszorg (IGZ) Poland Główny Inspektorat Farmaceutyczny (GIF) Portugal INFARMED — Autoridade Nacional do Medicamento e Produtos de Saúde, I.P Romania Agenția Națională a Medicamentului și a Dispozitivelor Medicale Slovakia Štátny ústav pre kontrolu liečiv (SUKL) Slovenia Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP) Spain Agencia Española de Medicamentos y Productos Sanitários Sweden Läkemedelsverket United Kingdom Medicines and Healthcare Products Regulatory Agency European Union European Medicines Agency	