ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 2/JP/2018

of 17 July 2018

of the Joint Committee established under the Agreement on Mutual Recognition between the European Community and Japan [2018/1104]

Having regard to the Agreement on Mutual Recognition between the European Community and Japan (hereinafter 'Agreement') and in particular paragraph 3 of Article 8 thereof;

Whereas the Joint Committee is to confirm the operational product scope of the Sectoral Annex on Good Manufacturing Practice for Medicinal Products (hereinafter 'Sectoral Annex'), established by the Sub-committee under the Sectoral Annex in its 6th Meeting;

HAS DECIDED AS FOLLOWS:

1. The new operational scope of the categories of medicinal products subject to the Sectoral Annex of this Agreement, done at Brussels on April 4, 2001 now includes the following categories:

   (1) Chemical pharmaceuticals;

   (2) Homeopathic medicinal products (as long as treated as medicinal products and subject to the GMP requirements in Japan);

   (3) Vitamins, minerals and herbal medicines (if considered as medicinal products in both Parties);

   (4) Biological pharmaceuticals ([1]), including immunologicals and vaccines, belonging to the following categories;

   (4.1) Medicinal products produced by cell culture utilising natural microorganisms or established cell lines;

   (4.2) Medicinal products produced by cell culture utilising recombinant microorganisms or established cell lines; and

   (4.3) Medicinal products derived from non-transgenic plants and non-transgenic animals;

   (5) Active pharmaceutical ingredients (APIs) for any of the above categories; and

   (6) Sterile products belonging to any of the above categories.

2. This Decision, done in duplicate, shall be signed by the co-chairs. The Decision shall be effective from the date of the later of these signatures.

Signed in Tokyo, 17 July 2018.
On behalf of Japan
Daisuke OKABE

Signed in Brussels, 28 June 2018.
On behalf of the European Community
Ignacio IRUARRIZAGA

([1]) For the purpose of the Sectoral Annex on GMP, biological pharmaceuticals include products which are not necessarily designated by the Ministry of Health, Labour and Welfare as 'biological products' in accordance with laws and regulations of Japan but which would be considered as biological products in the EU.