WORLD TRADE ORGANIZATION

G/TBT/N/TPKM/295

27 November 2017

(17-6477)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION臺灣　通知-細胞及基因治療產品

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU 臺灣 **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Food and Drug Administration (FDA) Ministry of Health and Welfare No.161-2 Kunyang St., Nangang Dist. Taipei City 115, Taiwan Tel: 886-2-27878246 Fax: 886-2-27877498 E-Mail: wan411@fda.gov.tw **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicinal products (biologic) 細胞及基因治療產品
5.	**Title, number of pages and language(s) of the notified document:** Draft of Cell and Gene Therapy Medicinal Product Management Act (10 page(s), in English; 8 page(s), in Chinese)
6.	**Description of content:** With cell and gene therapy medicinal products being commonly used to cure diseases all over the world, in order to safeguard the rights of patients and public health, the Food and Drug Administration (FDA), Ministry of Health and Welfare, proposes to enact "Cell and Gene Therapy Medicinal Product Management Act" to ensure the quality, safety and efficacy of cell and gene therapy medicinal products.隨著細胞及基因治療產品廣泛運用在世界各地治療疾病，為了維護患者的權利和公眾衛生，衛生福利部食品藥物管理署提案制定「細胞及基因治療產品管理法」以確保細胞及基因治療產品的品質、安全和功效。 Measures for implementing the Act will be drafted by FDA after the adoption of this Act.執行辦法在本法通過採行後由食藥署草擬。
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Consumer information, labelling; Protection of human health or safety
8.	**Relevant documents:** 1. U.S. FDA: Public Health Service Act, 21 Code of Federal Registration Part 1271 2. EMA: Directive 2001/83/EC; Directive 2001/83/EC; Directive 2003/63/EC;

	Regulation 1394/2007 3. Japan: the Pharmaceuticals and Medical Devices (PMD) Act and the Act on the Safety of Regenerative Medicine (ASRM)
9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** To be determined
10.	**Final date for comments:** 60 days from notification
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** WTO/TBT Enquiry Point The Bureau of Standards, Metrology and Inspection Ministry of Economic Affairs 4, Jinan Road, Section 1 Taipei City 100, Taiwan Tel.: (886-2) 2343-1916 Fax: (886-2) 2343-1804 E-mail: tbteng@bsmi.gov.tw https://members.wto.org/crnattachments/2017/TBT/TPKM/17_5278_00_e.pdf https://members.wto.org/crnattachments/2017/TBT/TPKM/17_5278_00_x.pdf