WORLD TRADE ORGANIZATION

G/TBT/W/556

9 July 2018

(18-4299)

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Committee on Technical Barriers to Trade

Original: English

CHINA — REGULATIONS FOR THE SUPERVISION AND ADMINISTRATION OF MEDICAL DEVICES (ORDER NO. 650 OF THE STATE COUNCIL)

STATEMENT BY THE EUROPEAN UNION TO THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE 20 AND 21 JUNE 2018

The following communication, dated 9 July 2018, is being circulated at the request of the delegation of the European Union.

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1. The European Union would like to reiterate its concerns on the Chinese regulations regarding medical devices notified under CHN/1022 to 1026 and 1029 sent to the Chinese authorities on 23 June 2014 and subsequently raised in recent TBT Committees.

2. The EU would like to refer to its concerns raised during the last meetings of the Committee in relation to the issue of the clinical trials required for the registration in China for Class II or Class III medical devices, the delays in this registration procedure, and the requirement to register the medical devices in the country of origin.

3. The EU maintains its concerns with regard to the unnecessary duplicative clinical trials to be conducted in China.

4. So far, the Chinese FDA has published four catalogues with medical devices exempted from clinical trials – the first list with 567 devices in August 2014, the second one with an additional 359 devices in September 2016, the third one - covering only 28 devices – was published for public consultation in May 2017, and on 31.10.2017. a fourth list of 164 medical devices exempted from clinical trials has been released. This is still a very small number compared with other markets. In addition to these catalogues, Article 17 of the Order No. 650 stipulates that "substantially equivalent" medical devices may be exempted from clinical trials. However, in practice, exemption from clinical trials based on Article 17 has only been granted for only a few medical devices and a very small number of in-vitro medical devices (around 131 out of the total 1118 devices are in-vitro medical devices).

5. The EU would like to ask again for a clarification whether the clinical trials would have to be performed for class II and III in-vitro diagnostic medical devices on Chinese populations living in a Chinese mainland environment, and whether results of testing on Chinese populations living abroad or on non-Chinese population would not be accepted. As China was not in the position to fully answer these questions during the last Committee meeting, the EU asks China again for further clarification on this issue; in particular whether data from clinical trials abroad are sufficient.

6. The EU also reiterated the request for China to continue accepting electromagnetic compatibility (EMC) testing carried out in internationally accredited laboratories and remove the requirement for in-country testing. The EU once more asks China to grant a transitional period of three years and to issue guidelines detailing the relevant processes.

7. In relation to the implementation of Order No. 650 the EU has noticed that China's Ministry of Finance and National Development and Reform Commission recently cancelled administrative fees

in an effort to reduce cost and complexity to manufacturers but that this has had a negative effect on resources for medical device registration testing.

8. The goal of the government in issuing the Notice to alleviate the cost burden placed on enterprises from fees associated with administrative approvals is an important one and well worth pursuing. However, the implementation of this policy has resulted in an immediate and negative impact on availability of testing services critical to the registration process.

9. Many labs have indicated they will no longer guarantee timelines for completion of testing nor will they accept product testing responsibilities that involve domestic or overseas travel for on-site testing in the manufacturer's home city or country. This will lead to significant increase of costs and delays in the registration process for new products.

10. At the meeting of the DG GROW-CFDA working group on medical devices on 20 November 2018 CFDA informed about its intention to issue new regulation allowing for acceptance of in-house testing reports as well as 3rd party testing reports, as a response to the backlog caused by the the cancellation of testing fees. However, no specific timetable for adoption of this regulation could be revealed at the meeting. The EU would appreciate information from the Chinese government about the development and publishing of this regulation, as well as other related implementation measures or guidelines.

11. The EU appreciates the intentions of the Chinese government to reduce expenses and complexity within the regulatory system. The EU would like to bring the unexpected negative consequences to China's attention in the hope that a solution can be found to the benefit of regulators, manufacturers, and patients who depend on advanced medical technology.