SPECIFIC TRADE CONCERNS (*Retirado do documento G/TBT/M/51*)

New Concerns

UE, EUA, Suíça X Brasil - Health Products (G/TBT/N/BRA/328)

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The representative of the United States welcomed the step taken by Brazil to ensure that trade in safe, high quality medical devices was not disrupted since the 22 May 2010 implementation date for Resolution 25 and to provide additional details to industry on the inspection process. He noted that the US industry had informed the US government that Brazil had not prevented any of its products from being marketed in Brazil due to a failure to have a facility inspection in connection with re-registration of those products already on the market. However, during the ANVISA-industry meeting earlier in June 2010, Brazilian regulators had told companies that they should have applied for inspections six months in advance of the 22 May 2010 implementation date. He emphasized that ANVISA had not yet issued its clarifying guidance and answered the follow-up questions in sufficient time for the medical device industry to submit its applications by this deadline. Further, since industry had not been aware that they should have applied for inspection six months in advance, some companies had not done so for certain products and were concerned that Brazil might prevent the marketing of those products in Brazil. Given the initial lack of clarity on the requirements and time frames, the United States requested that Brazil clarify whether approved devices could continue to remain on the market pending a GMP inspection.

The representative of the European Union joined the United States in raising concerns with regard to Brazil's requirements for registration of medical devices. The European Union had just received Brazil's latest reply to the EU comments on notification G/TBT/N/BRA/328, focusing in particular on Brazil's non-acceptance of ISO 13485 certification. She announced that the European Union would analyze Brazil's reply in detail and would get back to Brazil bilaterally with further queries. In the meantime, and notwithstanding EU's request on acceptance of ISO certificates, the European Union asked Brazil to provide an update on the ongoing implementation of the good manufacturing practices (GMP) requirements. In particular, the European Union asked for information on the number of facilities for which ANVISA had completed audits and issued GMP certificates as well as those for which audits had been requested, but not yet completed. According to information available to the European Union, it appeared that not all manufacturing sites for which an audit request had been submitted had been audited by ANVISA by the 22 May deadline. In order to prevent possible market access disruptions and confusion of economic operators, the European Union asked Brazil to provide assurances that medical devices for which an audit request had been submitted to ANVISA continued to be placed on the Brazilian market pending the relevant GMP audits, even though their registration had expired.

The representative of Switzerland echoed the concerns raised by the European Union. Switzerland remained concerned about the change in Brazil's legislation regarding market access for medical devices classified in Brazil under risk 3 and 4. As had been mentioned, for these medical devices, Brazil no longer recognized quality inspection results based on the international standard ISO 13485. He recalled that this ISO standard was the main international standard for quality management systems for medical devices. Quality inspection results based on this ISO standard were accepted in Switzerland and were accepted in Brazil in the past. Switzerland was surprised that Brazil no longer accepted this ISO certification. This was even more surprising as in the context of the NAMA NTB negotiations, Brazil was a cosponsor of a framework understanding on non-tariff barriers (TN/MA/W/136). In this document ISO was recognized as a relevant international standard setting body. Switzerland asked Brazil to explain why ISO 13485 was considered

inappropriate to assure risk control and quality of medical devices classified in Brazil under risk 3 and 4.

The representative of Brazil recalled that ANVISA resolution no. 25/09 aimed at guaranteeing the quality of medical devices sold in Brazil and, consequently, protecting human health. This was a legitimate objective explicitly recognized by the TBT Agreement. He emphasized that Brazil had no intention of disrupting the entry of imported medical devices in Brazil due to the essential nature of those goods and due to the international obligations of the country. He informed the TBT Committee that the sanitary authorities of Brazil had not received any complaint of troubles related to the importation or commercialization of medical devices in Brazil. The representative further stressed that ANVISA resolution no. 25/09 had done nothing more than establish deadlines for companies to comply with requirements already laid down in ANVISA resolution no. 59, published in 2000. These requirements were already mandatory for domestic manufacturers, so there was no room for allegations of discrimination or surprise with the content of resolution no. 25/09.
He reported that the inspections necessary for the granting of certificates of good manufacturing practices were being carried out in a timely and orderly manner by ANVISA employees, thus allowing the regular flow of medical devices to Brazil. ANVISA had conducted 144 inspections so far, and 77 were already scheduled. There were 180 requests waiting to be scheduled, depending mostly on the definition of dates convenient both the ANVISA and companies.

Regarding questions about the imposition of requirements going beyond ISO 13485, he clarified that the international standard and the requirements of RDC no. 59/00 had different scopes, although they were not conflicting. ISO 13485 focused on the characteristics of the manufacturing company quality system, whereas RDC no. 59/00 dealt directly with production processes and methods and its main focus was the risk of the medical devices classified under high risk classifications (Risks 3 and 4).

With regard to the question from Switzerland on the compatibility of the Brazilian regulation with the proposal made by Brazil on the NTB negotiating group (NAMA), he stated that although the proposal sought to recognize some international standard setting bodies as relevant, the proposal did not derogate from what the TBT Agreement had established, i.e. that a country might deviate from an international standard to protect legitimate public policy objectives, which was the satiation in this case.

He further pointed out that the imposition of the certification requirements additional to ISO 13485 was common international practice. In fact, the requirements set by RDC 59/00 were based on the requirements imposed by the United States in Part 820 of the Quality System Regulation contained in the Code of Federal Regulation - Food and Drugs. As for the European Union, Directive 93/42 established combinatory models of conformity assessment procedures which combined ISO 13485 with other methods, such as clinical trials, project evaluation and type approval.

He emphasized that, so far, Brazil was not aware of any concrete case of problems with this resolution. It was very important that companies that wanted to register a new medical device classified under Risks 3 and 4 or whose existing registration was about to expire applied for the certification within a reasonable time in advance. He recommended a period of six months in advance and clarified that that in case the existence of GMP expired, it would remain valid until the inspection necessary for the renewal if it was requested by the company at least 120 days before the expiry date of certification and that was according to resolution 66 of ANVISA of October 2007.

The representative of the United States clarified that the US Food and Drug Administration did not require re-registration for approved products to remain on the US market.

EUA e UE x Brazil – Alcoholic Beverages (G/TBT/N/BRA/348 and Suppl.1)

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The representative of the European Union reiterated concerns with regard to Brazil's Ministerial Act No. 327 of 17 September 2009 and its possible negative impact on European Union economic operators. The European Union had submitted comments on this notification in December 2009 and had raised its concern in the March 2010 Committee meeting; and now requested from Brazil an update on its legislative process as well as a reply to the written comments by the European Union.

The representative of the United States informed the Committee that in bilateral discussions with Brazil regarding this measure the United States had expressed its concerns about the potential impact of the measure on US exports of beer, wine and spirits. The United States had submitted comments to Brazil seeking clarification on several aspects of the proposed measure including the proposal to prohibit the use of certain abbreviations, illustrations and expressions commonly used in the labelling of alcoholic beverages. The United States also expressed concerns regarding the need for certain mandatory formatting and advisory statements. Furthermore, the transition period granted for labelling requirements may be insufficient due to the total redesign of the label that could be required for compliance. The United States hoped to continue to discuss these issues bilaterally, and requested an update on the status of the measure from Brazil.

The representative of Brazil informed the Committee that Brazilian authorities were still in the process of examining the comments received on the draft regulation on beverage labelling and assured delegations that those comments would be taken into account before the publication of the final measure. He noted that although the deadline for submitting comments on the draft regulation had expired, Brazilian authorities remained available to questions concerning the content of the draft regulation. Since the draft was still being discussed internally by regulators, Brazilian authorities were not yet in a position to provide definitive answers on how several provisions of the draft would be implemented. He reminded delegations that the objective of the new regulation was to guarantee an adequate level of information and protection for consumers and that the requirements laid down in the draft regulation applied equally to domestic and imported alcoholic beverages.

The representative of Brazil recalled that at the last meeting, the European Union had asked about the registration mark that imported beverages would have to have. The representative of Brazil stated that the requirement of introducing this registration number related to the very fact that the beverage was imported. Domestic producers would face a similar requirement to insert a registration number of their product in their labels. Brazil believed that these requirements were necessary in order to accord a sufficient level of protection for consumers, as registration numbers allowed interested parties to identify the person legally responsible for introducing the beverage in the market. The Brazilian authorities were of the view that allowing registration numbers to be affixed by separate stickers would not offer the same level of protection.