Previously Raised Concerns

2.2.2.1.6 Brazil - Health Products Good Manufacturing Practices (GMP) Requirements for Health Products (G/TBT/N/BRA/328) (IMS ID 233)

2.99. The representative of the United States recalled previously raised concerns on this issue in 2010, 2011, and 2012. She noted the National Health Surveillance Agency's (ANVISA) work with other regulatory agencies such as the US FDA (Food and Drug Administration) to develop a singleauditing programme to help address the backlog through work-sharing and developing criteria foraccreditation of third parties that would be implemented in 2014. As the inspection backlog continued to grow, her delegation had requested that ANVISA work with trading partners to develop interim steps. Recently, the US had noted that ANVISA had developed and published a strategy for 2013-2016 expanding its focus from health, safety, and cost effectiveness to also considering domestic market and industry impact for suppliers for medical products. She requested further information on this proposed change and voiced concerns about the potential impact on trade.

2.100. The representative of the European Union asked Brazil to provide an update on the situation as regards the Good Manufacturing Practices (GMP) inspections for medical devices and noted that a number of measures had been taken to accelerate inspection capacity. The EU asked if those measures were reflected in a concrete reduction of the backlog and if ANVISA was now in a position to guarantee that inspections were carried out within three months after the request had been filed. In case reasonable inspection deadlines could not be complied with, the EU invited ANVISA anew to rely on and take into account quality management system audits conducted by accredited auditing bodies such as EU Notified Bodies, and to consider accepting products authorised in the EU or in other major markets, pending the completion of ANVISA inspections. She invited ANVISA to consider subcontracting overseas inspections to accredited auditing bodies such as EU Notified Bodies, which would inspect EU facilities on behalf of ANVISA and allow for a reduction of the current backlog. The EU enquired if Brazil was considering these suggestions.

2.101. The representative of Brazil said that several measures had been adopted to improve the inspection capacity of ANVISA, such as the augmentation in the number of GMP inspectors. Measures included the relocation of experts from other areas of the agency, the enabling of experts from state and/or municipal level to act as international inspectors, and the publication of draft resolution No. 2 of 8 January 2013, still under public consultation, which aimed at, inter alia, optimising conditions for the concession of GMP certificates. To his knowledge, there had been no case of interruption of trade caused by the processing of GMP certification. He recalled that Brazil had joined the International Medical Device Regulators Forum (IMDRF). Brazil had taken note of the suggestions made by the EU with a view to finding a temporary solution – but these did not seem feasible in the context of the legal framework of Brazil, which required GMP certificates to be issued by ANVISA. In this sense, the representative of Brazil invited

the EU and other Members to consider an alternative previously suggested by Brazil: the confidentiality agreements between health agencies in Brazil and other Members to exchange inspection reports.

2.2.2.1.22 Brazil – Draft ANVISA Resolution on Used, Refurbished, Rented and Lent Medical Devices (G/TBT/N/BRA/440) (IMS ID 362)

2.191. The representative of the European Union reiterated concerns regarding the ANVISA draft resolution on used, refurbished, rented and lent medical devices (G/TBT/BRA/440). The draft resolution prohibited the importation of medical equipment reconditioned overseas and whose last place of installation, before reconditioning, was not Brazil. At the latest TBT Committee meeting, Brazil had informed the Committee that a final draft was not yet available and that a public hearing would be organised. The EU wished to have an update on the situation. The EU was of the opinion that any reconditioned equipment, independent of its place of first installation, should be allowed for importation in Brazil as long as it complied with the health and safety performance requirements established in the Resolution. She also reiterated that several developed countries such as the EU, US and Japan, which also had high health and safety standards, accepted and used refurbished medical devices. The EU invited Brazil to reconsider its Resolution and find other less trade restrictive means to fulfil its legitimate objectives.

2.192. The representative of Brazil stated that the subject had already been discussed; he recalled that in July 2011, Brazil had notified the public consultation 34/ANVISA of the Brazilian Health Surveillance Agency. A sixty day period had been opened for interested parties to provide their comments on the draft measure. During that period a significant number of comments had been received and they were still being examined and consolidated. He said that one of the main objectives of the draft measure was to avoid the use of medical equipment being exported to Brazil as a means of final disposal of those products. He underlined that another important objective was obliging producers of medical equipment to be responsible for the appropriate disposal of medical equipment. He stated that a public hearing on this issue would be organized so that stakeholders would be able to participate in an open and transparent exchange of views with the Brazilian regulators on this proposed measure which had not yet been implemented.