New Concerns

2.2.1.4 Brazil – Draft ANVISA Resolution on used, refurbished, rented and lent medical devices (G/TBT/N/BRA/440)

2.30. The representative of the European Union stated that this draft resolution prohibited the importation of medical equipment reconditioned overseas and whose last place of installation, before reconditioning, was not Brazil. The EU was of the opinion that any reconditioned equipment, independent of its place of first installation, should be allowed to be imported into Brazil as long as it complied with the health and safety performance requirements established in the Resolution. It was important to distinguish refurbished products that had been reprocessed and subjected to good refurbishment practices - and could thus be considered as safe and efficient as new equipment - from products that fell into the waste category. The EU also noted that several developed countries - such as the EU, the US and Japan - which also had high health and safety standards, accepted and used refurbished medical devices. Further, on the implicit suggestion to carry out the refurbishment in Brazilian territory, the EU noted that there was not enough good quality used equipment in Brazil that could be sourced and be refurbished locally. The draft measure therefore unnecessarily restricted trade in this area. The EU invited Brazil to reconsider its measure and find other less trade restrictive means to fulfil its legitimate objectives. For instance, Brazil could require that refurbished medical equipment be subject to good refurbishment practices and that the equipment imported still had a sufficiently long life cycle.

2.31. The representative of Brazil informed the Committee that the Brazilian and the EU delegations had held bilateral meetings on the margins of the Committee meeting. He also recalled that in July 2011, Brazil had notified public consultation 34 by ANVISA, its health agency, about used and refurbished medical devices. A 50-day period for comment had been given for interested parties so that they could provide their comments on the draft measure. During that period, a significant number of comments had been received and were still being examined and consolidated. ANVISA intended to organize in the near future a public hearing on this issue so that stakeholders could have an open and transparent exchange of views with Brazilian regulators on this proposed measure, which had not yet been implemented. He also explained that one of the main objectives of the draft measure was to avoid used medical equipment being exported to Brazil as a means of final disposal of those products. Another important objective was to oblige producers of medical equipment to be responsible for the appropriate disposal of medical equipment at the end of their life cycle. Indeed, this was an objective also pursued by EU regulations, in particular EU directive 2002/96/EC, also known as WEEE (Waste in Electrical and Electronic Equipment).

Previously Raised Concern

2.2.2.17 Brazil - Health Products (G/TBT/BRA/328)

2.122. The representative of the European Union reiterated concerns about the timelines for the registration of medical devices in Brazil. As of May 2010, a Good Manufacturing Practices (GMP) certificate had to be presented with the application for registration of health products in Brazil.Moreover, a GMP certificate would be issued only after the National Health Surveillance Agency (ANVISA) had inspected the manufacturing premises. Currently, there were a number of manufacturing sites for which an inspection request had been submitted but no inspection had taken place, and 20 months appeared to be the average waiting time. In this sense, the EU sought an update from Brazil. He stressed the need for ANVISA to carry out inspections of foreign manufactures within a period of 3 months after the request had been filed. In case reasonable inspection deadlines could not be complied with, the EU invited ANVISA to rely on and take into account quality management system audits conducted by accredited auditing bodies such as EU Notified Bodies, which guaranteed that the products were safe, and to consider accepting products authorized in the EU or in other major markets, pending the completion of ANVISA inspections. As an alternative, ANVISA was invited to consider subcontracting overseas inspections to accredited auditing bodies such as EU Notified Bodies that would inspect EU facilities on behalf of ANVISA.

2.123. The representative of the United States was also concerned about Brazil's capacity to provide timely inspections for US medical device facilities. According to the US industry sources, Brazil's ANVISA had roughly a three year backlog at the rate of current inspections on US facilities.Nevertheless, she expressed appreciation for the recent efforts by ANVISA in conjunction with its regulatory counterparts in the US, Canada and Australia to develop a single audit program for medical devices which could help address the matter. However, since the joint program was not expected to commence in the short term, the US requested Brazil to renew its efforts to address the backlog, and to work with the US industry and other international partners to develop a way forward that would enable timely inspections and authorizations for the sale of medical device products.

2.124. The representative of Singapore shared the concerns expressed by other delegations. She said that Singapore's concern was whether Brazil had the resources to audit all manufacturing facilities to ensure that the importation was done in a timely manner so as to avoid disruption to trade. She asked if it would be possible for Brazil to consider trade facilitative alternatives which would achieve Brazil's objectives, such as relying on ISO 13485 certification issued by the exporting countries.

2.125. The representative of Brazil said had his delegation did not have much to add to what had already been stated at previous meetings – he referred to the minutes of those meetings. He reasserted that authorities in Brazil were aware of the situation and that several measures had been adopted to address it, particularly the augmentation of the

number of GMP inspectors. To his knowledge there had been no case of interruption of trade caused by the processing of GMP certification. Moreover, Brazil had taken note of the suggestions made by the EU in order to find a temporary solution – but those suggestions 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 agents in Brazil and other Members to exchange inspection reports and issue GMP certificates based exclusively on these reports.