Previously Raised Concerns

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

112. 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. A GMP certificate was issued only after ANVISA had inspected the manufacturing premises. The EU was aware that Brazil was taking some steps to accelerate GMP inspections. However, there was still 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. The EU asked for an update on the current situation.

113. The EU stressed that ANVISA needed to carry out inspections to foreign manufactures within 3 months after the request had been filed. In case reasonable inspection deadlines could not be met, 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 consider accepting, on the Brazilian market, 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 the EU Notified Bodies that would inspect EU facilities on behalf of ANVISA. This procedure would allow for a reduction of the current backlog.

114. The representative of Brazil recalled a bilateral meeting with the EU on this issue and that Brazilian authorities were aware of the current situation. ANVISA continued to work to improve the efficiency of the GMP inspections. His delegation had provided considerable detail at the last meeting about the measures adopted or are under consideration by ANVISA; he invited Members to refer to the minutes of that meeting. He highlighted some of the main actions envisaged by ANVISA to better organize the international GMP inspections: ANVISA was considering new criteria to prioritize inspections taking into account, for example, the proximity between companies in the same region or the risk of lack of supply of certain products in the Brazilian market; ANVISA had sought to make the best use of its human resources to avoid capacity deficiencies in inspection teams; and Brazil was considering changes in its legislation so

that experts from other federal or local bodies could be incorporated in the inspection teams. He informed the Committee that up to May 2012, ANVISA conducted 104 inspections which pointed to an increase in the pace of inspections. Brazil reiterated its interest in pursuing bilateral arrangements with Members like the EU in health surveillance, and that some arrangements such as confidentiality agreements, for example, could speed up the process of GMP certification since they would allow information exchange between the authorities of both parties. Finally, Brazil joined the International Medical Device Regulators Forum (IMDRF) and was committed to the objectives of regulatory convergence in this area.

xiv) Brazil – Draft Resolution No. 112, 29 Nov 2010; maximum levels of tar, nicotine and carbon monoxide permitted on tobacco products and prohibition of additives (G/TBT/N/BRA/407)

129. The representative of Mexico said that, despite answers provided by Brazil, her delegation remained concerned that some aspects of the draft resolution could be inconsistent with Articles 2.2 and 2.8 of the TBT Agreement, and requested further information on the resolution's implementation. 130. The representative of Guatemala reiterated her delegation's concern that this draft resolution could have negative impacts on the marketing of cigarette products of American tobacco mixture because it prohibited the use of certain types of additives necessary for its preparation. She requested Brazil to clarify how each of the ingredients of the American mix would be covered by Article 7 of the draft resolution, and whether the American mix could be marketed in Brazil.

131. The representative of the Dominican Republic supported Mexico and Guatemala. He asked that Brazil take proper account of these observations and provide information on this measure.

132. The representative of Colombia recalled previous concerns expressed regarding this measure, and noted that no response had yet been provided by Brazil to their comments and questions.

133. The representative of Chile, while appreciative of the recent notification of the addendum, restated her delegation's concerns and requested more information on the measure's implementation.

134. The representative of Turkey expressed regret that the draft resolution entered into force on 15 March 2012 without taking Turkey's and other countries' comments into consideration. Banning additives in tobacco products should be based on scientific evidence that proved that the additives posed increased risk to human health. A ban on all additives constituted, in Turkey's view, a disproportionate measure. As a result of comments, however, Brazil had removed sugar from the list of banned additives. However, this modification was insufficient to address their concerns.

135. He reiterated that some of the prohibited additives were essential components of blended cigarettes, in which both Oriental and Burley tobaccos were used. Since blended and non-blended tobacco products were "like products", a measure resulting in a prohibition of blended tobacco products would be discriminatory. Further, these additives did not give characterizing flavor to tobacco products. Thus, Brazil failed to consider the effects of such ingredients on final products, and Turkey expected it to reconsider adoption of this resolution and to amend it to avoid discrimination.

136. The representative of Australia welcomed Brazil's decision to implement tobacco control policies and preventative measures aimed at reducing the attractiveness, in particular to children and youth, of certain tobacco products. Each Member had the right to implement measures necessary to protect public health, while complying with relevant international treaty obligations. Australia remained prepared to continue to defend this right.

137. The representative of Brazil recalled bilateral discussions with Mexico where some concerns were addressed. He informed Members that the definitive regulation on the control of additives in tobacco products was published as Resolution RDC14 2012 from ANVISA in March 2012; and notified to the TBT Committee in April 2012. Brazil had also prepared a compilation of the answers to comments submitted during the consultation period; they were willing to transmit them to interested Members. In relation to the concern regarding the American blend of tobacco products in Brazil, the production of tobacco products known as "American blend" was not affected by this regulation, since the use of sugar - a key ingredient for this product - as an additive in tobacco products was permitted under the Brazilian measure.

138. He invited Members to consult the minutes of the previous meeting, where they could find extensive answers and explanations on some of the points raised. He recalled

that two hundred thousand people died every year in Brazil due to tobacco consumption-related diseases. This measure was intended to protect public health by reducing the attractiveness of tobacco products, especially among children and young people. He assured Members that this resolution would not discriminate between domestic and foreign producers. Finally, Brazilian authorities had circulated a compilation of the international and scientific references used as the basis for this measure.