SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/42)

New Concerns

EUA e UE x Brasil - Registration requirements for medical devices

Brazil – Registration requirements for medical devices

The representative of the United States expressed concerns about Brazil's proposed registration requirements for medical devices, which would require manufacturers to submit detailed economic data with each product registration. Of particular concern were proposed revisions to Resolution 185, which would require companies seeking to register or re-register a medical device to submit information concerning manufacturers' pricing data, including tax and distribution margin information; anticipated sales volumes; intended retail price of the product in Brazil; estimated sales and marketing expenses; and a list of substitute products in the Brazilian market and their corresponding prices. He pointed out that much of the requested information could not be provided, because it either did not exist or was not publicly available. For example, it was the US understanding that there was no published database of prices for medical devices around the world. Furthermore, some of the requested data, such as information on prices, anticipated sales volumes and expected marketing costs were highly sensitive business-proprietary information and no assurance was provided that the information would be kept confidential.

It was the view of the United States that the proposed revision to Resolution 185 could have the effect that companies refrain from shipping such products to Brazil. The issue had been raised bilaterally by the United States, but no response had been received. Brazil needed to notify the measure to the WTO and indicate the status of the measure, and whether US comments had been taken into account.

The representative of the European Communities expressed his delegation's interest in obtaining an update on the status of the proposed amendment to the Resolution and states his intention to examine the proposal and raise possible concerns at a later date.

The representative of Brazil took note of the concerns raised.

Previously Raised Concerns

UE x Brasil - Mandatory certification of batteries

Brazil – Mandatory certification of batteries

The representative of the European Communities reiterated the concerns expressed at the previous meeting of the Committee about the Brazilian draft regulation by the regulatory agency for telecommunications "Anatel" for mandatory certification of batteries for electronic items, including mobile phones. He appreciated the information provided by Brazil in bilateral contacts, but, considering the Brazilian decision not to notify the measure under Article 2.9.2 of the TBT Agreement, was still concerned that mandatory third party certification of batteries – even if based on international standards as indicated by Brazil - would lead to more trade-restrictive obstacles than necessary. He invited the Brazilian delegation to reconsider the necessity of third party certification of mobile phone batteries and also to consider notifying the draft regulation to the TBT Committee.

The representative of Brazil explained that the aim of the resolution was to address reported incidents of battery explosion. The resolution included an exception to the general rule of third party certification by providing the possibility of first party tests where adequate laboratories did not exist in Brazil. With respect to the notification, he stressed that the resolution complied with the legitimate objectives set out in Article 2.2 of the TBT Agreement and was based on international standards IEC 61960, IEC 62133, IEC 6100042. Therefore, in accordance with Article 2.9 and 5.6 of the TBT Agreement which provided that a notification should be made in the absence of an international standard or if the measure was not based on an existing one, a notification was not necessary.

The representative of Brazil further explained that the resolution was still pending the approval of the National Council of Telecommunications. Once approved, a period of 150 days for all parties concerned to adjust to the new specifications would be provided. Furthermore, the resolution was based on an earlier measure by the same agency covering the same products, Resolution 242, which was still in force.

The representative of the European Communities sought clarification on whether manufacturers could provide self-declaration of conformity or whether laboratory tests outside Brazil needed be used.

The representative of Brazil confirmed that, in exceptional circumstances, a first party test could be used. He would transmit the questions to the experts and provide more detailed information in due time.