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Product Certification Body versus Demand of Electro-medical Devices: the Brazilian scenario, limitations, disparity and opportunities

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Background, Motivation and Objective. The monitoring of real-time physiological signals using Electro-medical devices (EMD) can assist the diagnosis and ongoing treatment of many diseases. In Brazil, EMD are regulated by the Brazilian Agency for Health Regulation (Anvisa), which aims to ensure their safety and effectiveness. Within the requirements for accreditation, it is necessary to obtain the EMD Certificate of Conformity, issued by a Safety Certification Body (SCB), which guarantees that the EMD follows pre-established requirements in standards and technical regulations (NBR IEC 60601 family of standards). Although existing goods manufacturing practices and well-structured legislation contributes to assure EMD performance and safety, the certification process is highly bureaucratic, which potentially limits the national market growth. This is especially true for smaller sized companies, where specialized knowledge on EMD regulation and resources are limited. This study aims to analyze the national EMD industry and SCB scenario to detect disparities that could affect Brazil market competition and identify possible opportunities.

Methods. First, the ranking of Brazil at the EMD international scenario was investigated, followed by calculation of the trend between EMD import and export rates (trade balance) according to Annual Reports from National EMD Entities (ABIMO/SINAEMO). Subsequently, a panoramic view of the national manufacturing companies of EMD was made, classifying them according to the geographical location and the size of their financial income. To identify the national demand of conformity certification for EMD, the number of accredited SCBs by INMETRO was identified and clustered following their geographical location at the national territory as well. A revision on the general Brazilian technical standards was used as base for the EMD certification of conformity tests. The analysis was followed by an exploratory investigation of the average cost and required time for an EMD conformity certification, and finally, the ABNT ISO/IEC Guia 17065:2013 and the NIT-DICOR 001 (INMETRO) were studied, enabling an analysis of the process and the identification of the investment needed for the creation of new SCBs.

Results. The global EMD market represents approximately US$ 325 billion a year. In 2013, the EMD market reached US$ 5.6 billion in Brazil, registering a growth of 14.6% over a five-year period, 2008 to 2013. Brazil has become the fourth most attractive EMD market in the Americas in recent years, outlining more than US$ 713.82 million in imports against US$ 67.45 million in exports during 2017. Moreover, EMD exports increased 43% between 2010 and 2017. On the other hand, imports decreased 1.79% during the same period. Although exports have increased significantly, the trade balance deficit still presents a great disparity. Imports are concentrated in innovative products with high added value, such as diagnostic imaging devices, while exports are diversified on EMD types, such as incubators for newly-born babies, respirators, equipment for

anesthesia and other basic equipment for a developing country with low technological dynamism. Currently, it is estimated that there are about 4,290 health products companies in Brazil, and only 450 are EMD manufacture companies. According to their geographical location, 76.8% of the EMD companies locates in the state of São Paulo, while the southeast region of Brazil totals 87.3%. The remaining 12.7% is distributed as follows: 11.1% (South), 0.60% (Northeast), 0.60% (Midwest) and 0.40% (North). Most companies are medium-sized (58.6%), followed by medium-large/large companies (23.4%), and micro and small companies (18%). Currently, the EMD conformity certifications of these companies are produced by 16 SCBs, all of which are in the state of São Paulo, with 7 in São Paulo capital, 5 in São Paulo metropolitan area, 3 in Campinas and 1 in Itu. In an interview conducted with an SCB, it was identified that the time required to obtain a certification varies between 10 working days and three months, with an estimated cost of around R$ 45K, depending on the type of EMD. The creation of new SCBs seems to be justified by the current national demand of conformity certification for EMDs. The process of accreditation of new SCBs also includes a series of documents cited in the NIT-DICOR -017. The initial cost for INMETRO accreditation of a new SCB is around R$ 12K with an average time of 12 months.

Discussion and Conclusions. The state of São Paulo plays an important role in the EMD sector. The number of EMD companies and regulation entities are centralized, almost in their entirety, in the capital São Paulo, highlighting the regional difference in the development of EMDs, which then need certification, which are produced in the state of São Paulo. Incentives for EMD companies and new SCBs for strategic regions would contribute to the growth of the national sector. In addition, increasing exports and developing EMDs with high added value could also change the Brazilian deficit in this area. Although medium-sized companies have the largest share in the national EMD sector, micro and small companies occupy a quarter of the sector and represent a great opportunity for development. When comparing the relationship between the number of EMD companies and the number of SCB available, some may claim the need of new SCBs. The action of national entities focused on smaller companies, such as the formation of consortiums guided by EMD regulatory consulting, could also help reduce the costs and time required for accreditation, boosting the Brazilian market. In addition, improvements on the streamlining bureaucracy of the certification process could also directly affect positively the EMD national market.

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