

TRADE  
INTELLIGENCE  
INSIGHTS  
HEALTH

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SIDERA CONSULT  
— MARKET ACCESS & EXPANSION —

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## THE PURPOSE OF TI<sup>2</sup> HEALTH SECTOR – Brazil

Sidera's *Trade Intelligence Insights* – TI<sup>2</sup> – is a comprehensive instrument available for the market that monitors and advises on measures impacting global players accessing Brazil, and from Brazil abroad. We are not journalists. **We are Trade Experts** who analyze thousands of pieces of information at the WTO, WHO, Brazilian Ministries and their bodies and agencies, Congress and Senate, and most relevant jurisprudence every day. TI<sup>2</sup> provides an early-stage warning on measures, legislation, and industry movements that may distort or enhance the natural flow of trade. **Our readers benefit from an essential analytical tool to react in the face of uncertainty, the one stop shop for trade news.** The goal is to disseminate healthy, fair and free trade practices for the development and improvement of international trade and, thus, assist in global prosperity.

### Proposed Tax Exemption on Human Medication\*\*\*

The Constitutional Amendment (2/2015) proposes an overall tax exemption for medication intended for human use. The Amendment, which is awaiting to be voted by the Commission on Constitution, Justice and Citizenship (CCJC), foresees a gradual tax-rate reduction for human medication starting with a 20% discount in 2018, and reaching complete exemption by 2022. So far, this is not extended to medical device; nevertheless, there would be grounds for an extension.

### EU-Mercosur Window Provides Market Opportunity for Medical Device\*\*\*

There is unique window of opportunity (from May to June 2017). The European Union and Mercosur will conclude soon, a Free Trade Agreement (“FTA”) after 22 years of negotiations. There are still a few rounds of negotiation exchanges and requests which will take place until early 2018. As per a recent and informal approach with the EC trade negotiators, it is still possible to include European products in the liberalization list. Products listed will be granted permanent reduced duties. Priority will be given to products without regional production, or with insufficient regional production. The inclusion may be done through the submission of a market study, together with a 2-page fact sheet, to the EC Delegation, and it should be done as soon as possible, preferably until the end of June. This presents an unique business structuring opportunity to medical device multinationals.

### Anvisa to Hold Internal Meeting

The Board of Directors (DICOL) of the National Health Surveillance Agency (Anvisa) will hold an internal meeting, not open to the public, on May 16, 2017, to discuss the deliberation of several themes, among them:

- (i) presentation and discussion of Project P3, proposing the reformulation of work models and processes in ports, airports, borders and Customs, and goal 4.1, implementing the National Program for Verification of Medical Quality - PROMOVE, both included in Anvisa’s strategic planning 2016-2019;
- (ii) revision of actions and services that the National Unified Health System (SUS) offers to the population, as defined by Ordinance 841, of May 2, 2012;
- (iii) Anvisa’s manifestation regarding Bill of Law 120/2015, which aims to add a paragraph to the Consumer Defense and Protection Code (CDC) Law 8,078, obliging the indication of the number of doses remaining on the packaging of medicinal inhalers.
- (iv) Anvisa’s manifestation regarding Bill of Law 541/2015, which seeks to amend Law 6,360/76, reducing the time of analysis of registration concession by ANVISA and mandating the publication of registration renewal in the Brazilian Federal Register;
- (v) Anvisa’s manifestation regarding Bill of Law 299/2016, which aims to amend Law 6,437/77, prohibiting the reuse of health products that are not reprocessable.

### Withdrawal of Tax Incentives to Technology Companies

A number of Interministerial Ordinances (from 2,358 to 2,388) stipulated the cancellation of tax incentives previously granted to 24 tech companies. The previous exemption was granted via Decree 5,906, and was introduced with the objective of stimulating competition on tech and automated products by reducing or exempting from the Tax Over Industrialized Products (IPI). The incentives have been cancelled due to non-compliance of Art. 33 of the Decree. The Article mandates that companies must submit compliance reports, including information on R&D activities.

### Deadline for TV Label Compliance Extended

The National Institute of Metrology, Quality and Technology (Inmetro) has issued Ordinance 89, extending the deadline for television and monitor manufacturers to comply with the Conformity Assessment Requirements for Televisions (Ordinance 563). The extension has been granted given the difficulties faced by manufacturers to comply with the deadline initially set out in Ordinance 563, and already extended by Ordinance 286. The new deadline is 1 Oct 2017. Medical devices using monitors and screens must also comply with the new standards.

### Proposal Would Force Government to Provide Cancer Treatment

The Committee on Women's Rights Defense (CMULHER) recently approved Bill of Law 3,169/15, obliging the National Unified Health System (SUS) to provide treatment for metastatic breast cancer. The proposal aims to make the medication for the treatment part of the list of mandatory SUS' medical supply. The proposal will increase the demand for medical device within the public health system.

### Brazil-Chile Investment Facilitation Agreement Approved

The Senate approved Legislative Decree Bill 36/2017, ratifying the Agreement for Cooperation and Facilitation of Investments (ACFI) signed between Brazil and Chile in 2015. The Agreement aims at facilitating mutual investments by spreading information on business opportunities, exchanging information regarding regulatory issues, and providing a set of guarantees to investors. It also foresees the creation of a Joint Committee in charge of managing the ACFI, and strengthening the dialog between the countries.

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