Multiple Framework Contract FWC FPI PSF 2015
Lot 4 "Market Access and Trade & Investment Agreement Negotiation & Implementation"

Mapping of applicable technical regulations, conformity assessment procedures and supporting standards in support of EU-Brazil business development

DELIVERABLE 2

CHEMICAL SECTOR - PHARMACEUTICAL SECTOR

Eurosupport Consortium for:
PARTNERSHIP INSTRUMENT – POLICY SUPPORT FACILITY

AESA

A project implemented by
Eurosupport Consortium - AESA

Delegation of the European Union to Brazil

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May 2018

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This is a working document, and hence it represents research in progress. The opinions expressed in this paper are those of the research team and coordinator. They are not intended to represent the positions or opinions of the European Union or its members and are without prejudice to members' rights and obligations under the European Union. Any errors are attributable to the research team and coordinator.

LIST OF ABBREVIATIONS

ABIQUIM Brazilian Association of Chemical Industry
ABIFINA Brazilian Association of Fine Chemical Industry
ABNT Brazilian Association of Technical Standards
ACE Economic Complementation Agreement
AFFEE Authorization of Manufacture for Exclusive Purpose of Export
ALADI Latin American Integration Association
ANVISA National Health Surveillance Agency
ANTT National Land Transport Agency
ASTM American Society for Testing and Materials
BNDES Brazilian National Bank of Economic and Social Development
CAMEX Foreign Trade Chamber
CBPF Good Manufacturing Practices Certificate
CMC Common Market Council
CMED Regulatory Chamber of Medicines Market
CNI Brazil National Confederation of Industy
CORPROSAL Commission on Health Products
CSM Mercosul Sectorial Committees
DECEX Department of Foreign Trade Operations
DFPC Controlled Products Oversight Board
EFTA European Free Trade Association
EU European Union
FDI Foreign Direct Investment
FIESP Federation of Industries of the State of São Paulo
FNDCT National Fund of Scientific and Technological Development
GMC Common Market Group
GGMED General Management of Medicines and Biological Products
HS Harmonized System
IAF International Accreditation Forum
ILAC International Laboratory Accreditation Cooperation
ILO International Labor Organization
INMETRO Brazilian National Institute of Metrology, Quality and Technology
IPI Manufactured Products Tax
ISO International Standardization Organization
MAPA Ministry of Agriculture, Livestock and Supplies
MCR Adjusts the General Norms
MDIC Ministry of Industry, Foreign Trade and Services
MERCOSUL Common Market of the South
MMA Ministry of Environment
MRA Mutual Recognition Agreement
NAFTA North American Free Trade Agreement
NIP National Implementation Plan
NM Mercosul Standard
NR Regulatory Standard
POP Persistent Organic Pollutants
PROFARMA Programme for Supporting the Development of the Pharmaceutical Productive Chain
PRONAF National Program to Strengthen Family Agriculture
RDC Resolution of the Board of Directors
SDCI Secretariat of Industrial Development and Competitiveness
SGT Mercosul´s Working Group
SIEMA National Environmental Emergency System
SUS Unified Health System
TBT Technical Barriers to Trade
WTO World Trade Organization

Project Brazil – EU:
Mapping of applicable technical regulations, conformity assessment procedures and supporting standards in support of EU-Brazil business development

Deliverable 2

CHEMICAL SECTOR - PHARMACEUTICAL SECTOR

1. OVERVIEW

The pharmaceutical sector is an important sector for Brazil. The exports and imports of pharmaceutical products have contributed to strengthen the Brazilian economy and to foster international trade. In the last three years, the values of trade in pharmaceutical products oscillated between US$ 7,5 and US$ 9 billion and went down from 2014 until 2016 (MDIC, 2017). For Brazil, EU is an important origin of such products. Brazil imported more than US$ 3 billion in 2016 (MDIC, 2017). In 2016, ANVISA conceded 882 registers against 773 in 2015 and 366 in 2014. It reveals a more than double increase. The variants of registered medicines are encompassed by biologics, energized, specific, phytotherapeutic medicine, generic, active pharmaceutical ingredient, new medicines, radiopharmacology or similar.

A significant increase can be highlighted in the generic sub-sector. It increased from 146 in 2014 to 343 in 2015 and 404 in 2016. Similar medicines are also in a high level, 299 in 2015 and 317 in 2016. It can be inferred that the pharmaceutical industry has shown significant progress in the last years. From 2007 to 2011, the retail drug sales increased 82.2 per cent, from R$ 23.6 billion to R$ 43 billion and the prospection is that from 2016 to 2026, three main submarkets will grow: (i) Patented therapies - original brands of prescription drugs; (ii) Generic pharmaceuticals (generics) and (iii) OTC medicines - over-the-counter treatments.

2. MAIN REGULATIONS AND AUTHORITIES

The main authorities regulating the sector are: the Ministry of Health, ANVISA and IMETRO.

The main regulations of this sector are the following:

i) Constitution: The Brazilian Constitution, enacted in 1988, guarantees the right to universal, equal access to actions of promotion, protection and recovery of health (Article 196). It is competence of the Union, the States and the Federal District to legislate concurrently on health (Article 24, XII) and according to Article 30, I and VII, it is competence of the Municipal government to legislate about issues of local interest (including health) and health actions and public health services.

(ii) Main regulations: There are several basic laws enacted that cover health, and are related to pharmaceutical products. Federal Law n. 5,991/1973 provides the sanitary control of drugs, medicines, pharmaceutical and correlated inputs. According to Federal Law n. 6,360/1976 (amended several times, with the last amendment by Federal Law n. 13,411/2016), the following products will be subjects to the Health Surveillance (*Vigilância Sanitária*): medicines, drugs, pharmaceutical inputs and correlated (Federal Law n. 5,991/1973, law of sanitary control), as well as other hygienic products and cosmetics, among others. The Ministry of Health authorizes the entities and the establishments that can extract, produce, manufacture, process, synthesize, purify, fractionate, pack, repack, import, export, store or ship these products. These entities and establishments must also be authorized w by the sanitary organisms

from the Federative Units. The Ministry of Health has exclusive competence to register and authorize the use of medicines and the modification of its components.

Federal Law n. 8,080/1990, enacted to regulate Article 196 of Brazilian Constitution, creates the Unified Health System (SUS), which is financed by the Federal, State and Municipal Governments and the Federal District, among other sources. The objectives of the Unified Health System - SUS are: i) identification and disclosure of the factors that determine health; ii) the formulation of health policy to economically and socially promote: the assistance to people through actions to promote, protect and recover health, with the integrated realization of care actions and preventive activities.

(iii) Regulatory authority: Within the Health Surveillance, the regulatory initiatives are several, all promoted by ANVISA, an autarchy with special regime under to the Ministry of Health. The law that creates ANVISA is Federal Law n. 9,782/1999. Its institutional purpose is to promote the protection of the health of the population through the sanitary control of the production and consumption of products and services subject to health surveillance, including the environments, processes, inputs and related technologies, as well as to control ports, airports, borders and bonded sites.

Federal Law n. 10,742/2003 encompasses the regulation to the pharmaceutical sector and creates the Regulatory Chamber of Medicines Market (*Câmara de Regulação do Mercado de Medicamentos* - CMED). The producers of medicines must observe, for the adjustment and determination of their prices, the rules defined in this Law. Drug pricing will be based on a ceiling price model calculated on the basis of an index, a factor of productivity, and an intra-sector and cross-sector relative price adjustment factor.

(v) Transport of pharmaceutical products: The transport of medicines is regulated by private and public rules. Pursuant to Ordinance 1.052/MS/SVS/99 must authorize the companies that transport medicines and pharmaceutical products. Resolution n. 433/2005 from the National Council of Pharmacy provides that it is the responsibility of the pharmaceutical professional in a medicine transport company to monitor the compliance with sanitary regulations, to allow only the transport of registered medicines by authorized companies, to install a good practices manual for the transport of medicines, pharmaceutical products and products for health, to train the human resources involved, to elaborate cleaning procedures to register and control the temperature of the vehicles, to clean the vehicles and deposit terminals and to inspect the loading and unloading activities, among others.

(vi) Exports and imports:

RDC n. 81/2008[1] is relevant for the regulation on pharmaceuticals. It provides a *Technical Regulation on Imported Goods and Products for Sanitary Surveillance*, mainly for pharmaceutical products and food, adopting definitions, categories of imports, registration of the import license, among others.

According to the Technical Regulation on Imported Goods and Products for Sanitary Surveillance, imported products subject to sanitary surveillance intended for trade, industry or direct consumption, shall have ANVISA's consent for importation. To that end, they must be regularized by the sanitary authority regarding the mandatory registration, notification, or any other form of control determined by ANVISA (Chapter II of the Technical Regulation). In the

[1] RDC n. 81/2008 was modified by RDC n. 208/2018, RDC n. 172/2017, RDC n. 74/2016, RDC n. 48/2012, RDC n. 28/2011. They are available at <http://portal.anvisa.gov.br/legislacao#/>.

case of some controlled products, the importer must obtain a shipping authorization issued by ANVISA, according to Ordinance/ SVS N. 344/1998[2]

Products classified as medicines, which are in the intermediary stages of their production or manufacturing process, shall be submitted to the technical department of the importing company, installed in the national territory, for laboratory tests necessary to prove their nature, identity and quality in these stages of production or manufacture. The importing process of these products will be compulsory through SISCOMEX - Import Module (see RDC n. 74/2016).

Only the companies authorized by ANVISA for this activity (import) can import the goods and products subject to sanitary surveillance[3]. If a company does not have an Authorization to Operate or Special Authorization to Operate issued by ANVISA, it cannot import any raw material and pharmaceutical inputs for the manufacture of medicines (see item 2.1 of chapter IV of the Technical Regulation).

The importer and/or holder of product regularization shall be responsible for guaranteeing compliance with regulatory and legal rules, measures, formalities and requirements for the administrative import process, in all phases, from shipment abroad to sanitary release in the Brazilian territory. The importer will also be responsible for the proper customs classification of the product (Chapter III, Section I, Sub-section II), in accordance with the Administrative Treatment Table and the instructions of ANVISA.

In Brazilian territory, goods and products under sanitary surveillance shall have some characteristics: a) compliance with the Standards of Identity and Quality (PIQ) required by the relevant sanitary legislation; b) within the expiration date; (c) primary and secondary packaging identified in accordance with Good Manufacturing Practices (GMP)[4], established in relevant legislation; d) with external packaging identified for transportation, handling and storage (chapter V of the Technical Regulation).

The identification of the external packaging of each unit of imported products subject to sanitary surveillance shall contain: a) commercial name, when it is a final product or in bulk, when applicable; b) name of the basic active principle of the formulation, in the case of exclusive importation of medicine; (c) the common name or technical, chemical or biological name of the product in the case of raw material or input for the production of medicinal products; d) the number or code of the batch or production line of the packaged products; e) name of the manufacturer, city and country; f) special care for storage, including those related to the maintenance of the identity and quality of the goods or products, such as temperature, humidity, luminosity, among others.

Imported products cannot be commercialized in Brazil with identification or labeling in other language than Brazilian Portuguese, with exceptions to non-commercial imports covered by

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[2] It is available at <http://www.anvisa.gov.br/hotsite/talidomida/legis/Portaria_344_98.pdf>. The importer shall obtain ANVISA's prior consent and authorization to ship to Brazil any of the products enlisted in annexes "A1", "A2", "A3", "B1", "B2" and "D1" (raw material, semi-finished product or finished product), in addition to regular registration of Import Licensing and inspection by the sanitary authority before its customs clearance.

[3] The importation of medicines by consumers has other characteristics and is not executed through SISCOMEX. More details in http://portal.anvisa.gov.br/importacao.

[4] ANVISA issues certification of Good Manufacturing Practices for international manufacturers. It depends on inspection, as set forth in RDC N. 39/2013. More information in http://portal.anvisa.gov.br/registros-e-autorizacoes/empresas/cbpf/inspecao-para-certificacao

Chapters IX, X, XII, XIX, XX and XXI of RDC n. 81/2008[5]. However, it is possible to provide the labeling in Brazilian Portuguese within the Brazilian territory, as long as they are in conformity with Chapter XV and RDC n. 208/ 2018.

The importation of product presenting a label in Brazilian Portuguese that is not in conformity with the provisions of the sanitary legislation may still be approved on SISCOMEX portal but with reservations, which means basically that the importer shall sign a Term of Guard and Responsibility in order to transport the goods from the authorized area into the Brazilian market (Chapter XV and RDC n. 208/ 2018).

In the exercise of its administrative police power, ANVISA may withhold or seize products (see chapter XXXVI of the Technical Regulation, regarding penalties and restrictions). The retention of a product by ANVISA occurs when there is suspicion of sanitary irregularity or when the product presents some pending sanitary (requirement or awaiting result of laboratory analysis). Retention may be accompanied by an interdiction term. In such cases, the merchandise may be held in customs or delegated to the guard of the importer, if this is allowed by the responsible sanitary authority (upon presentation of Guard Term and Liability). Seizure of samples occurs when there is a need for laboratory analysis (section II of Chapter XXXVI of the Technical Regulation).

(vii) Good practices: There is also the requirement of a certificate of good practices, provided in the RDC n. 39/2013, RDC n. 15/2014, RDC n. 56/2014 and Ordinance n. 4/2008, attesting that a particular establishment complies with Good Distribution and Storage Practices. The RDC n. 39/2013 includes administrative procedures to the concession of Good Practices of Manufacturing Medicines, Health Products and Pharmaceutical Inputs.

(viii) Labeling: The Ordinance n. 510/1999 of the Ministry of Health, the RDC n. 92/2000, RDC n. 168/2002, RDC n. 137/2003, RDC n. 47/2009, RDC n. 60/2012, RDC n. 71/2009, RDC n. 61/2012, Ordinance n. 572/2002 and n. 230/2004 of the Ministry of Health provides regulation concerning the labeling of medicines and the content of the package inserts.

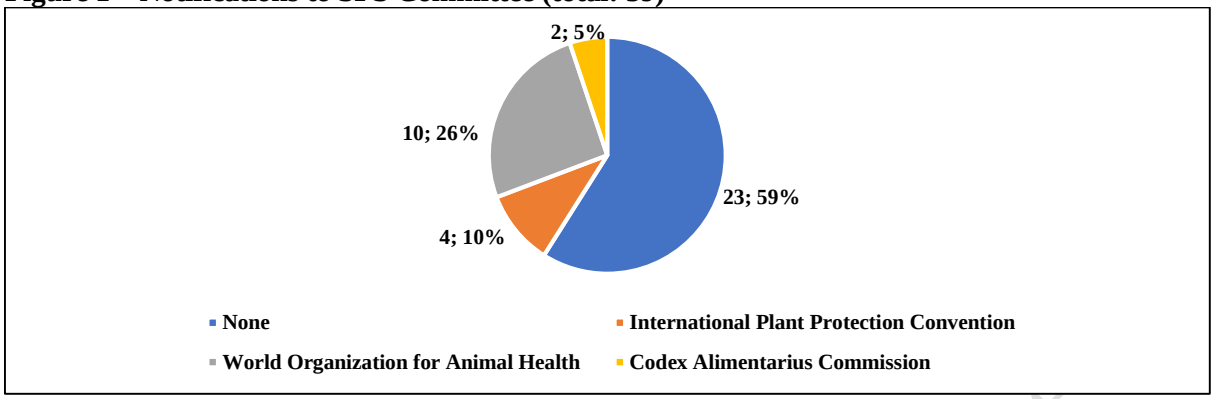
2.1. NOTIFICATIONS TO WTO

The interaction of such bodies with the WTO system, regarding the notifications made to SPS and TBT Committees, offer a good instrument to analyze the interaction of Brazilian Law and international instruments.

The following figure shows picture general framework of the international standards adopted by the Brazilian technical regulation on chemical sector. To the SPS Committee, Brazil notified 39 times; to the TBT Committee, another 43 times diverse regulations on chemical sector.

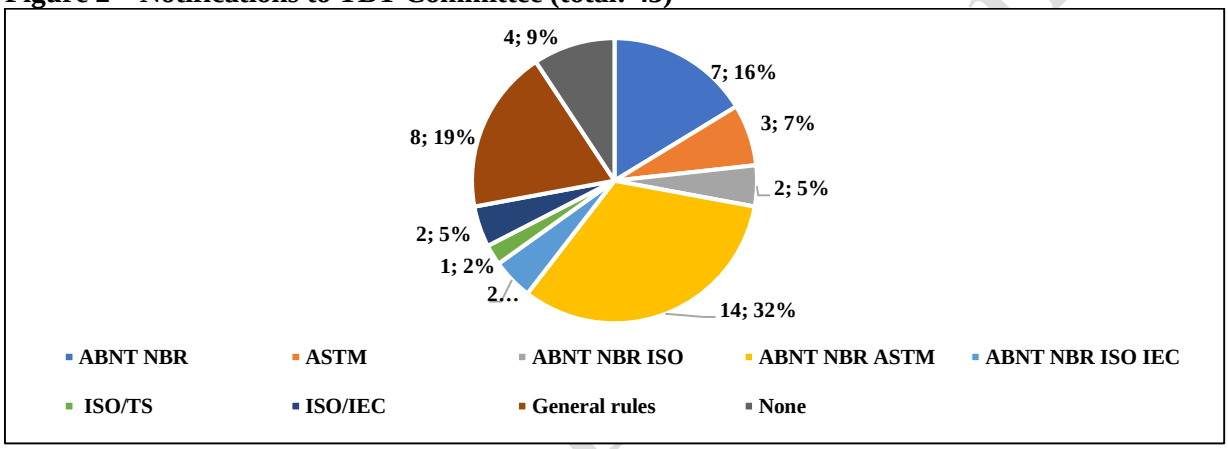
[5] In such cases, the sanitary authority can require a translation for essential information chapter XV of Technical Regulation and RDC n. 208/ 2018.

Figure 1 – Notifications to SPS Committee (total: 39)



Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

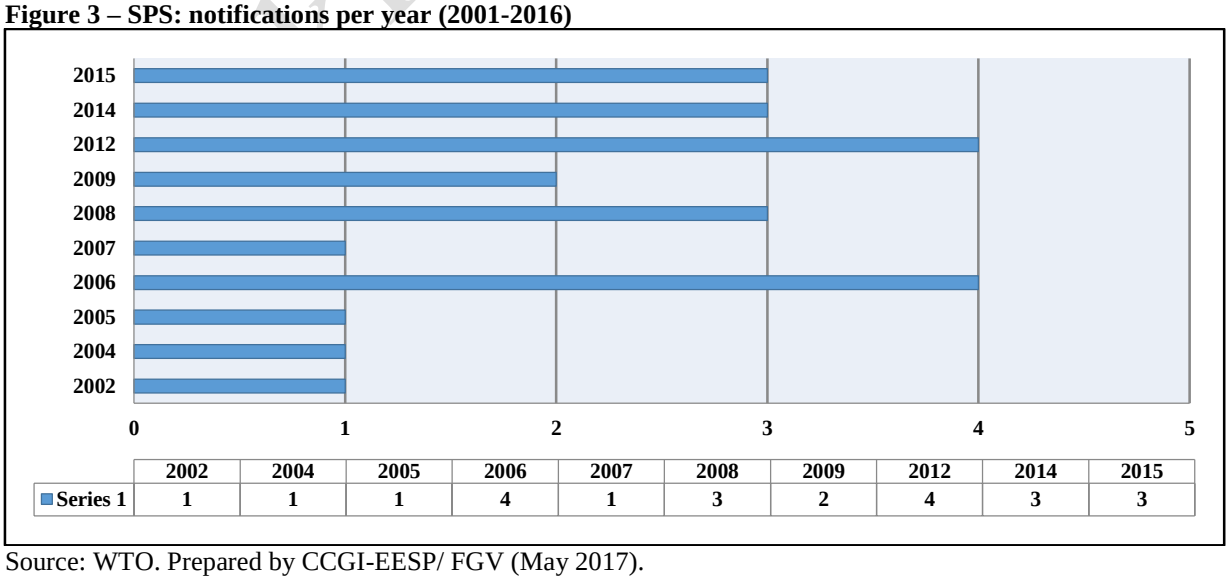
Figure 2 – Notifications to TBT Committee (total: 43)



Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

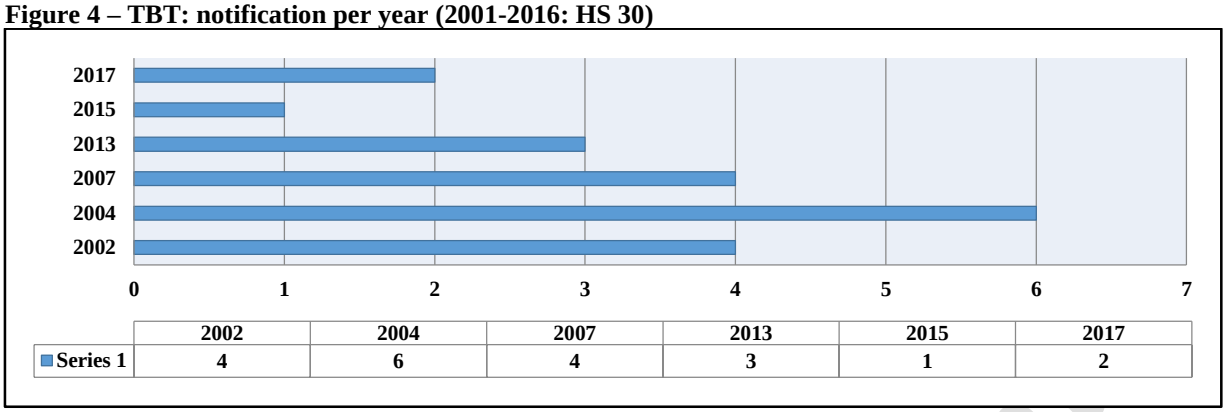
Brazilian agencies usually notify to the WTO TBT and SPS Committees regularly; however, in a few years from 2001-2016, no notifications were submitted to one or either of these WTO Committees as Figures 3 and 4 show.

Figure 3 – SPS: notifications per year (2001-2016)



Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

Figure 4 – TBT: notification per year (2001-2016: HS 30)

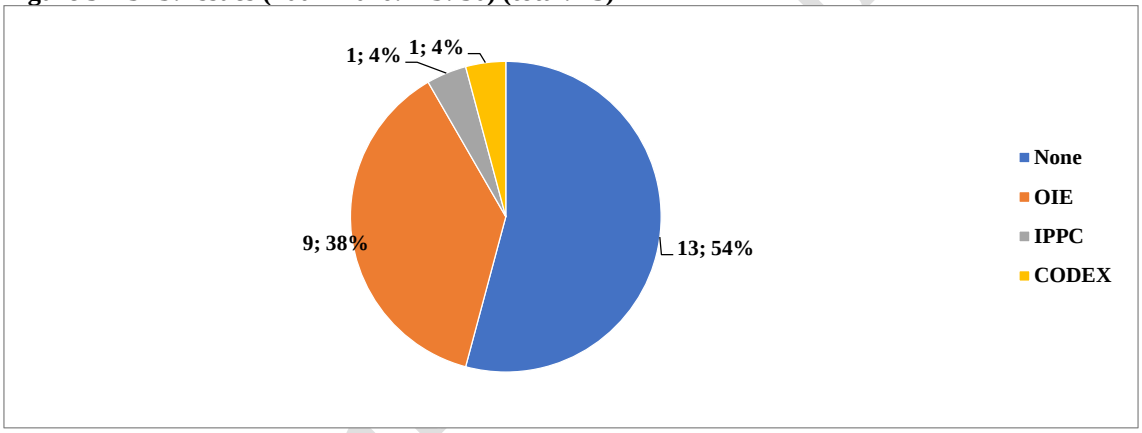


	2002	2004	2007	2013	2015	2017
Series 1	4	6	4	3	1	2

Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

The three international organizations mentioned in the SPS Agreement are mentioned in the notifications to the SPS Committee. However, there are many notifications regarding pharmaceutical sector that do not mention any of the three organizations.

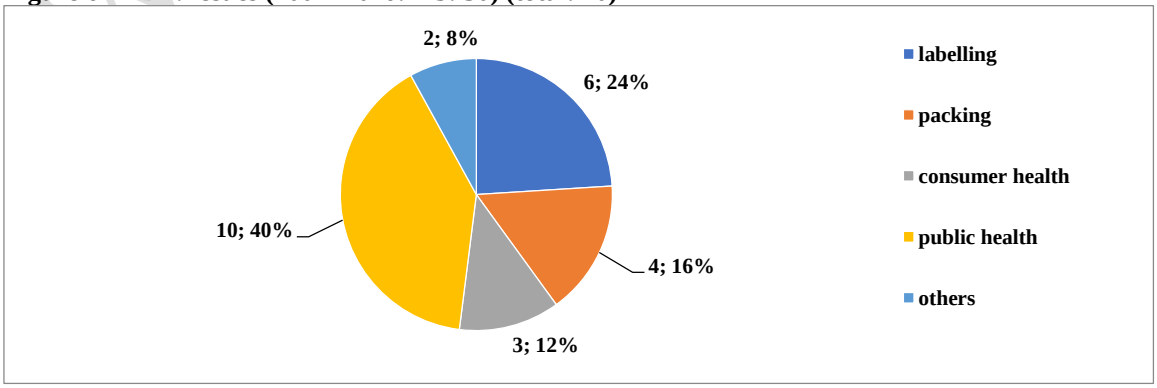
Figure 5 – SPS: Issues (2001- 2016: HS: 30) (total: 23)



Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

The most frequent issue in the notifications to the TBT Committee is the protection of the environment. Other important topics are consumer protection, labels with nutritional information and human health. No international standardization organization is explicitly mentioned in the notifications.

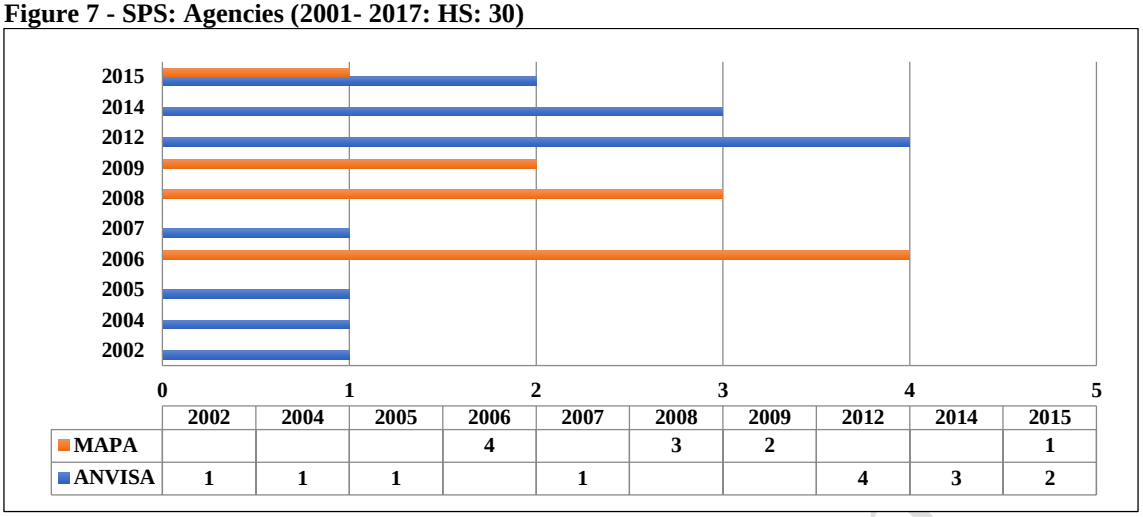
Figure 6 - TBT: Issues (2001- 2016: HS: 30) (total: 20)



Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

ANVISA is the Brazilian government agency that most notifies the SPS Committee. MAPA also made notifications.

Figure 7 - SPS: Agencies (2001- 2017: HS: 30)

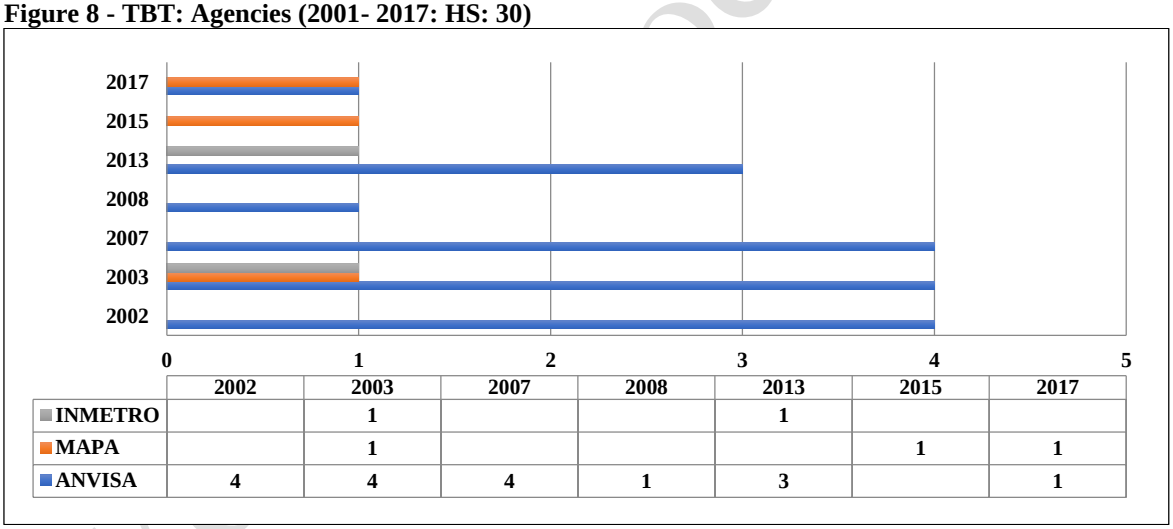


	2002	2004	2005	2006	2007	2008	2009	2012	2014	2015
MAPA				4		3	2			1
ANVISA	1	1	1		1			4	3	2

Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

ANVISA is the Brazilian government agency that most notifies the TBT Committee. INMETRO and MAPA also made notifications.

Figure 8 - TBT: Agencies (2001- 2017: HS: 30)



	2002	2003	2007	2008	2013	2015	2017
INMETRO		1			1		
MAPA		1				1	1
ANVISA	4	4	4	1	3		1

Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

3. STANDARDS AND SUPPORTING STANDARDS

Brazil adopts some standards concerning pharmaceutical products. ABNT is liable for the creation of Brazilian Standards. Prepared by its Committees, there are only 4 standards related to medicines or pharmaceutical products at ABNT. The standards can be found in the waste from health services committee, medical-hospital committee and safety in articles for babies and children committee. The following table shows the ABNT standards.

Table 1 - Standards on the ABNT

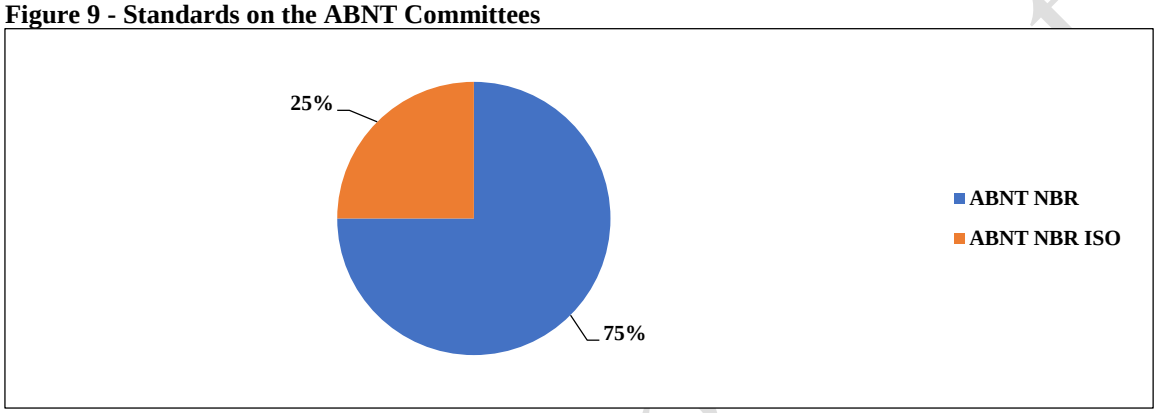
Norms	Status	Committee
ABNT NBR 16457:2016 Reverse logistics of overdue and / or disused human medicines - Procedure	In force	Committee ABNT/CE-129 Waste from Health Services

ABNT NBR ISO 14708-4:2016 Implants for surgery - Implantable active health products Part 4: Implantable infusion pumps	In force	Medical-Hospital Committee
ABNT NBR 15720-4:2009 Orthopedic Implants - Ceramic Materials Part 4: Specifications for glass and ceramic glass biomaterials	In force	Medical-Hospital Committee
ABNT NBR 10334:2003 Safety of pacifiers[6]	In force	ABNT / CB-210 Safety in articles for babies and children

Source: ABNT. Prepared by CCGI-EESP/FGV.

The only ABNT standard which follows ISO is the ABNT NBR ISO 14708-4:2016, located in the Medical-Hospital Committee representing 25 per cent of all the standards found in the present analysis. The other 75 per cent of the standards follows the ABNT NBR, manufactured by the own ABNT. The following graphic illustrates the percentage of each type of standard.

Figure 9 - Standards on the ABNT Committees



Source: ABNT. Prepared by CCGI-EESP/FGV.

4. CONFORMITY ASSESSMENT PROCEDURES AND CERTIFICATION

The RDC 60/2014 provides the criteria for grant renewal of registration of drugs with active principles, synthetic and semi-synthetic, classified as new, generic and similar, and gives other measures[7]. The company registration is the first stage to have access to ANVISA services. In this context, companies that provide products or services that may be regulated, supervised or sanitary inspected by ANVISA and/or by the State and Municipal Visas must register with ANVISA. In addition to allowing the registration of the company, the System of Registration of Companies also requests the registration of users linked to the company, who will be responsible for access to other ANVISA systems. These users can be registered in the following profiles: legal responsible, technical responsible, legal representative and security manager.

The Authorization of Operation of the Company (*Autorização de Funcionamento da Empresa* - AFE) is an act of competence of ANVISA that allows the operation of companies or establishments, by complying with the technical and administrative requirements contained in the RDC n. 16/2014. The AFE is required from companies that carry out activities of storage, distribution, packaging, shipping, export, extraction, manufacture, fractionation, import, production, purification, repackaging, synthesis, transformation and transportation of medicines and pharmaceutical products for human use, products for health, cosmetics, personal hygiene

[6] This Standard sets out the requirements for the manufacture of pacifiers, including packaging forms and safety recommendations, with the exception of pacifiers for therapeutic use, such as thermometers, which are intended to apply medicines and others.

[7] *BRASIL. Ministério da Saúde Agência Nacional de Vigilância Sanitária Diretoria Colegiada Resolução-RDC nº 60, de 10 de outubro de 2014.* Available at: http://www.poderesaude.com.br/novosite/images/publicacoes_13.10.2014-III.pdf>. Accessed on: May 15th, 2017.

products, perfumes, sanitizers and filling of medicinal gases. The interested company through the Petitioning System must make the AFE request. For this it is required the Certificate of Good Manufacturing Practices (*Certificado de Boas Práticas de Fabricação* - CBPF), issued by ANVISA, certifying that the establishment complies with Good Manufacturing Practices. CBPF is issued per plant, covering the production lines, pharmaceutical forms and special classes of drug products for which the company has been inspected. The authorization is granted exclusively by the health department of the state or local government to authorize establishments carrying out any business activities subject to sanitary surveillance to operate. It must be issued to each establishment separately (an independent, specific authorization). If the establishment aims to manufacture, industrialize or import products subject to sanitary laws, it must operate under the assistance and responsibility of a technician.

After the establishment is authorized, the drug must be registered. The registration is the act by means of which ANVISA authorizes the commercialization of the product, through evaluation of the legal-administrative and technical-scientific compliance related to the efficacy, safety and quality of the products. The registration, or market approval, issued by ANVISA is the effective authorization for the manufacturing and marketing of a drug in Brazil. The application for drug registration must be individualized by pharmaceutical form. If the drug is imported and labeled in Brazil, both CBPFs issued by the manufacturer and the local labeling site must be submitted.

The activity of drug registration is a responsibility of the Board of Authorization and Registration Sanitary (*Diretoria de Autorização e Registro Sanitários* - Diare) of ANVISA. Moreover, within Diare, it is the responsibility of the General Management of Medicines and Biological Products (*Gerência-Geral de Medicamentos e Produtos Biológicos* - GGMED) to coordinate activities and propose the granting or rejection of registration, renewal and post-registration of medicines, among other matters. The interested company through the ANVISA Petitioning System, following the stages below, must make the registration process: i) Company Registration; ii) Request; iii) Follow-up. The deadlines for the final decision in drug registration processes are for the priority category (120 days) and for the ordinary category (365 days). The table below summarizes the registration process.

Table 2 - Registration Process according to Law 6.360/1976 and amended by Law n°13.411/2016

Steps	Registration Process
1st	**COMPANY REGISTRATION:** Registration of the company is the first step to gain access to ANVISA's Petitioning System. Then the company must indicate the Company's Port, which will determine the amount of the fees to be paid by the interested party.
2nd	**REQUEST:** During the process, the interested party will be guided to the type of petition of the chosen Subject Code, being: manual petition with manual protocol; electronic petition with manual protocol; or electronic petition with electronic protocol. At the end of the petition process, the Union Recruitment Guide (*Guia de Recolhimento da União* - GRU) will be generated for the payment of the Health Surveillance Inspection Fee (Taxa de *Fiscalização de Vigilância Sanitária* - TFVS), a tax established by Law No. 9.782/1999. After payment of the GRU, the interested party must gather all the documentation requested in the checklist of the Subject Code, the completed forms and the proof of payment of the TFVS and protocol according to the type of petition of the selected Subject Code. After the Protocol Request, the registration will be grant in 90days (Law 63.60/1976, art.12, paragraph 3 (modified by Law n° 13.411/2016).
3rd	**FOLLOW-UP:** After filing the application, the interested party can follow the progress of their request, through the System of Consultation about Documents. On June 27, 2016, ANVISA published the RDC nº 86 that provides on the procedures for receiving documents in electronic format. The measure aims to facilitate the filing of documents in ANVISA.

Source: ANVISA. CCGI-EESP/FGV

ANVISA will define by its own act the mechanisms to publicize the registration, post-registration changes and renew of registration processes. The mandatory information is the following: i) the status analysis, ii) the deadline for the final decision and iii) its technical reasons of the decisions about the process. There is also the simplified notification, which is the procedure whereby the manufacture, importation and marketing of low-risk health products are

communicated to the federal health authority when all the characteristics of use and quality described in specific regulations are observed[8].

Medicines subject to notification shall be exempted from medical prescription. Low-risk medicines, traditional herbal products, energized medicinal products and medicinal gases are listed on specific lists for each of these categories. For medicines not registered in Brazil and with an exclusive purpose of export, free sample presentations and medicines only packaged in Brazil, the company must request the Authorization of Manufacture for Exclusive Purpose of Export (*Autorização de Fabricação para Fim Exclusivo de Exportação* - AFFEE) with ANVISA. ANVISA does not issue AFFEE for medicines that are registered in Brazil. In such situations, the company must request the certificate of registration. Drugs, medicines and pharmaceuticals coming from abroad must be registered in their country of origin in order to be register in Brazil. If a drug is not composed of effectively beneficial substances it cannot be registered in Brazil. Finally, imported products subject to sanitary surveillance intended for trade, industry or direct consumption must have ANVISA consent for its importation. Health products must be regularized before the sanitary authority regarding the obligatory, as applicable, of registration, notification, registration, model authorization, exemption from registration, or any other form of control regulated by ANVISA.

5. MERCOSUL REGULATION

In Mercosul, the pharmaceutical sector is target by some regulations. The executive decision-making body of Mercosul (*Grupo Mercado Comum* – GMC) is the responsible for setting work programs and negotiating agreements with third parties on behalf of Mercosul, including those related to pharmaceutical sector.

ANVISA is the responsible body in Brazil for the related execution. In Brazil, ANVISA has internalized some Mercosul regulation in RDCs. They are distributed in categories of inspection, authorization, control of information, quality control and importation, among others. It is possible to infer that the evolution of Mercosul Regulation concerning pharmaceutical products involves since the good practices of manufacturing and distribution until supervision on imports and exports. It was internalized by ANVISA since the beginning of the years 2000 through the RDCs and, until now, there are 17 RDCs in force. The following table contains the Mercosul normative internalized by ANVISA.

Table 3 - MERCOSUL Normative internalized by ANVISA

Resolution	Publication	Subject
RDC N° 108	September 8th, 2016	Minimum requirements for inspection in establishments which work with controlled products. Incorporates into the national legal order the GMC Resolution Mercosul n. 46/15.
RDC N° 67	March 23rd, 2016	Provides on the requests for authorization of habilitation, renewal of habilitation, modifications after habilitation, outsourcing of tests, suspensions and cancellations of Pharmaceutical Equivalence Centers and other measures.
RDC Nº 65	October 17th, 2014	Provides for prior notification of export of ephedrine, pseudoephedrine and special containing them. This Resolution incorporates the GMC Resolution Mercosul nº 30/12 into the national legal system.
RDC Nº 13	April 4th, 2011	Provides for the common criteria of the Mercosul for conversion factors for substances controlled nationally by the States Parties that are not objects of international control. This Resolution incorporates the Mercosul Resolution n°. 21/10 into the national legal system.
RDC Nº 12	April 4th, 2011	Provides on the Mercosul mechanism of periodicity of the updating of lists and exchange of information on narcotic, psychotropic, precursory and other substances under special control. This Resolution incorporates the MERCOSUL Resolution n° 20/10 into the national legal system.
RDC Nº 23	June 17th, 2010	It extends validity of Resolution of the Collegiate Board for purposes of adequacy of the productive sector to the requirements of the norm.

[8]The notification is processed through an electronic petition on the ANVISA website and does not exempt companies from the obligation to comply with Good Manufacturing Practices and other health regulations.

RDC Nº 21	June 17th , 2010	Provides the updating of Annex I, Lists of Narcotic Substances, Psychotropic, Precursors and Other under Control Special Issue of Ordinance SVS/MS nº 344 from May 12th, 1998 and makes other provisions.
RDC Nº 12	March 19th, 2009	Revoke Art. 1° of RDC nº. 239 from August 28th , 2002.
RDC Nº 63	September 10th, 2008	Revoke the provisions applicable to List "C4", to antiretroviral substances and medicinal enacted by RDC N° 103 from August 31st, 2016. New text to art. 34 of the Ordinance SVS/MS N° 344 of May 12th, 1998 providing that the purchase and sale on the internal and external market of the list in this Technical Regulation and its updates. It considers GMC Resolution n° 46/99, which provides for the use of a reimbursement system for the purchase / sale of narcotic drugs and psychotropic substances
RDC Nº 58	September 10th, 2008	Provides for the improvement of the control and monitoring of substances psychotropic and other measures.
RDC Nº 25	September 6th ,2007	Provides the outsourcing of production steps, analysis of quality control and storage of medicines.
RDC Nº 233	August 17th, 2005	Approves the technical regulation of production and quality control for registration, post-registration alteration and revalidation of allergenic extracts and allergenic products.
RDC Nº 217	August 1st, 2005	To approve the Extension of Use of the Additive Sulfur Dioxide and its Salts of Calcium, Sodium and Potassium.
RDC Nº 323	November 12th, 2003	Approve the technical regulation of registration, modification and revalidation of registration of probiotic medicines, according to the Technical Regulation attached.
RDC Nº 332	December 3rd, 2002	It is based on the technical criteria established and applicable to the inspections of drug-producing establishments located in countries outside MERCOSUL, according to Resolution - RDC nº 25, of December 9, 1999. Prohibits the importation and sale through the national territory, of the drug registered as a similar drug based on CICLOSPORINA of *Laboratório Químico Farmacêutico Bêrgamo* Ltda., under the name Pharmosporin.
RDC Nº 172	June 14th, 2002	It is based on the technical criteria established and applicable to the inspections of drug-producing establishments located in countries outside MERCOSUL, according to Resolution - RDC nº 25, of December 9, 1999. Prohibits the importation and sale, throughout the national territory, of medicines registered as medicines Similar products based on MICOFENOLATO MOFETIL.
RDC Nº 33	March 12th, 2001	It is established considering the importance of making national legislation compatible, Harmonized instruments in the Mercosul related to food additives (GMC Resolution 16/00). It creates the "Technical Regulation that approves the use of Food Additives, establishing their functions and their maximum limits for Food Category 12: Soups and Broths.

Source: ANVISA[9]. CCGI-EESP/FGV

6. MAIN GOVERNMENTAL AND PRIVATE ACTORS IN THE SECTOR

The main actors from the government side are: (1) Ministry of Health; (2) MDIC, more specifically SECEX (Trade) and SDCI (Sector Policies), (3) ANVISA; and (4) INMETRO.

From the private sector: (1) ABNT, (2) CNI, (3) FIESP, (4) ABIQUIM; and (5) ABIFINA.

[9] BRASIL. ANVISA. Available at: < http://portal.anvisa.gov.br/legislacao#/>. Accessed on: May 22nd, 2017.

ANNEX: TECHNICAL REGULATIONS NOTIFIED TO WTO

Table 4 - List of technical regulations notified to WTO – SPS

Doc.	Year	Products covered	Agency responsible	Notified document title	Situation	Description of content	Objective and rationale	Technical Provisions/Standards
G/SPS/N/BRA/45	1999	Animal drugs	MS	Title and number of pages of the notified document: Technical regulation applying to maximum residue limits and acceptable daily intake (ADI) for animal drugs (7 pages)	Description of content: The present regulation aims to set the maximum residue limits and acceptable daily intake for several animal drugs. Objective and rationale: Protection of health	Protection of health	None	
G/SPS/N/BRA/71	2002	Products containing raw material from animal (bovine, ovine, caprine and wild ruminants species) tissues or fluids used to produce drugs, cosmetics and health products. Human tissues, such as blood and its products, pituitary hormones, corneas, bones for grafts and grafts in general	ANVISA	Resolution RDC n.º 214, dated 30 July 2002 (5 pages), published in the Federal Official Journal (Diário Oficial da União) on 20 August 2002 (Available in Portuguese at http://www.anvisa.gov.br/legis/resol/2002/214_02rdc.htm)	This measure aims to establish rules, in order to comply with Resolution RDC n.º 213, previously notified as /SPS/N/BRA/56/Rev.1. It establishes that, besides the requirements already settled by Brazilian legislation, the importer must present the information listed in Resolution's annexes and fill in the forms contained in it.	protect humans from animal/plant pest or disease	None	
G/SPS/N/BRA/92	2004	Drugs, cosmetics, medical devices and food for human consumption containing tissues or fluids from bovine, ovine, caprine and wild ruminants species Pulmonary surfactants, by-products of milk and live animal wool are excluded from the restrictions provisioned for in the notified Resolution.	ANVISA	Draft Resolution Nº 10, published in the Federal Official Journal (Diário Oficial da União) on 2 March 2004.	This resolution defines the requirements for countries exporting the above-mentioned products to Brazil, according to their geographical risk and to the tissue infectivity level of the exported product. It also bans the import of high risk products. This Resolution does not apply for In Vitro Diagnostic Products. For these products, the Resolution RDC Nº 305 determines that they should advertise about the risks inherent to the products made of ruminant's tissues/fluids. This measure also defines the importing procedures of the products containing tissues derived from ruminants. This rule reinforces the prohibition, throughout	food safety protect humans from animal/plant pest or disease	World Organization for Animal Health (OIE)	

					the Brazilian territory, of the entrance, trade and display of the above-mentioned products that come from countries of certain regions, according the classification specified in the notified Resolution. When entering into force, this measure will revoke Resolution RDC Nº 305 (notified as G/SPS/N/BRA/305) and Resolution RDC Nº 68.		
G/SPS/ N/BRA/ 128	2005	Vaccine against Canine Visceral Leishmaniasis	MAPA	Title, language and number of pages of the notified document: Normative Instruction Nº 28, issued on 26 September 2005, published in the "Diário Oficial da União" Nº 193 (Federal Official Journal) from 6 October 2005, section 1, page 13 (Available only in Portuguese, a single page). The text may be downloaded from the following Internet site: http://oc4j.agricultura.gov.br/agrolegis/do/consultaLei?op=viewTextual&codigo=13473	Description of content: Draft normative instruction that approves the "Technical regulation for research, development, production, evaluation, registration and permit renewal, trade and use of vaccine against canine visceral leishmaniasis.	animal health	World Organization for Animal Health (OIE)
G/SPS/ N/BRA/ 165	2006	Poultry vaccines and diluents.	MAPA	Title, language and number of pages of the notified document: Normative Instruction Nº 7, issued on 10 March 2006, published in the "Diário Oficial da União" Nº 54 (Federal Official Journal) from 20 March 2006, section 1, pages 4, 5 and 6 (Available only in Portuguese, three pages). The text may be downloaded from the following Internet site: http://www.agricultura.gov.br/pls/portal/docs/PAGE/MAPA/LEGISLACAO/PUBLICACOES_DOU/PUBLICACOES_DOU_2006/PUBLICACOES_DOU_MARCO_2006/DO1_2006_03_20-MAPA_MAPA.PDF	Description of content: The notified regulation approves the "Technical regulation for production, evaluation, control and use of poultry vaccines and diluents".	protect humans from animal/plant pest or disease; animal health	World Organization for Animal Health (OIE)

G/SPS/N/BRA/225	2006	Veterinary products for the diagnosis of animal diseases	MAPA	Title, language and number of pages of the notified document: Portaria (Regulation) No. 270 of 2 October 2006, published in Official Journal No. 191 of 4 October 2006, pages 28 and 29 (available only in Portuguese). The text can be downloaded at: http://www.agricultura.gov.br/pls/portal/docs/PAGE/MAPA/LEGISLACAO/PUBLICACOES_DOU/PUBLICACOES_DOU_2006/PUBLICACOES_DOU_OUTUBRO_2006/DO1_2006_10_04-MAPA.PDF	Description of content: The notified text submits for public consultation the draft Instrução Normativa (Normative Instruction) approving the Regulamento Técnico para Produção, Controle, Comercialização e Modo de Usar de Produto de Uso Veterinário destinado ao Diagnóstico de Doenças dos Animais (Technical regulation on the production, control, marketing and directions for use of veterinary products for the diagnosis of animal diseases).	animal health, plant protection	World Organization for Animal Health (OIE)
G/SPS/N/BRA/152	2006	Veterinarian products	MAPA	Title, language and number of pages of the notified document: Normative Instruction Nº 4, issued on 7 February 2006, published in the "Diário Oficial da União" Nº 28 (Federal Official Journal) from 8 February 2006, section 1, page 7 (Available in Portuguese, 7 pages). The text may be downloaded from the following Internet site: http://www.agricultura.gov.br/pls/portal/docs/PAGE/MAPA/LEGISLACAO/PUBLICACOES_DOU/PUBLICACOES_DOU_2006/PUBLICACOES_DOU_FEVEREIRO_2006/DO1_2006_02_08-MAPA_MAPA.PDF	animal health	animal health	None
G/SPS/N/BRA/226	2006	Non-agglutinating antibody vaccine against bovine Brucellosis	MAPA	Title, language and number of pages of the notified document: "Portaria" Nº 263, issued on 27 September 2006, published in the "Diário Oficial da União" Nº 189 (Federal Official Journal) from 2 October 2006, section 1, pages 4 and 5 (available only in Portuguese, two pages). The text may be downloaded from the following Internet site: The text may be downloaded from the following Internet site: http://www.agricultura.gov.br/pls/portal/docs/PAGE/MAPA/LEGISLACAO/PUBLICACOES_DOU/PUBLICACOES_DOU_2006/PUBLICACOES_DOU_OUTUBRO_2006/DO1_2006_	Description of content: The notified regulation opens a period for public comments on the draft Normative Instruction that lays down criteria for the use of non-agglutinating antibody vaccines against bovine Brucellosis.	protect humans from animal/plant pest or disease; animal health	International Plant Protection Convention

			10_02-MAPA.PDF			
G/SPS/N/BRA/285	2007	Antimicrobial products for veterinary use	MAPA	Title, language and number of pages of the notified document: Draft Ministerial Act number 29 (Portaria Nº 29), issued on 29 January 2007, published in the "Diário Oficial da União" Nº 22 (Federal Official Journal) from 31 January 2007, section 1, pages 18 and 19 (Available only in Portuguese, two pages). The text may be downloaded from the following Internet site: http://extranet.agricultura.gov.br/sislegis-consulta/consultarLegislacao.do?operacao=visualizar&id=17601	Description of content: Draft Technical Regulation which disciplines the requirements and the criteria for authorization of antimicrobial products for veterinary use.	protect humans from animal/plant pest or disease; animal health	Codex Alimentarius Commission
G/SPS/N/BRA/446	2008	Veterinary products with controlled substances	MAPA	Title, language and number of pages of the notified document: "Portaria" N° 91, 6 June 2008 (available only in Portuguese, 12 pages) http://members.wto.org/crnattachments/2008/sps/BRA/08_1875_00_x.pdf	Description of content: The notified document is a draft released for a 60-day public consultation period that regulates trading of controlled substances and products with controlled substances of veterinary usage under mandatory prescription of veterinarian.	animal health	World Organization for Animal Health (OIE)

G/SPS/N/BRA/481	2008	Blood plasma/serum	MAPA	Title, language and number of pages of the notified document: Sanitary Requirements for importation of bovine blood plasma/serum (available only in Portuguese, 1 page) http://members.wto.org/crnattachments/2008/sps/BRA/08_3163_00_x.pdf	Description of content: Draft regulation that establishes the sanitary requirements for importation of bovine blood plasma/serum.	animal health	World Organization for Animal Health (OIE)
G/SPS/N/BRA/480	2008	Bovine fetal serum	MAPA	Title, language and number of pages of the notified document: Sanitary Requirements for importation of bovine fetal serum (available only in Portuguese, 2 pages) http://members.wto.org/crnattachments/2008/sps/BRA/08_3162_00_x.pdf	Description of content: Draft regulation that establishes the sanitary requirements for importation of bovine fetal serum.	animal health	World Organization for Animal Health (OIE)
G/SPS/N/BRA/567	2009	Veterinarian antimicrobial drugs	MAPA	Title of the notified document: Normative Instruction number 26, issued on 9 July 2009, published in the "Diário Oficial da União" number 130 (Federal Official Journal) from 10 July 2009, section 1, pages 14 to 16 Language: Portuguese Number of pages: 3	Description of content: The notified document approves the technical regulation regarding the manufacturing, quality control, trading and the usage of antimicrobial drugs in animals.	animal health	World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number) Terrestrial Animal Health Code – Chapter 6.7

G/SPS/N/BRA/546	2009	Microorganisms and material of animal origin	MAPA	Title of the notified document: "Portaria" Nº 110, issued on 28 May 2009, published in the "Diário Oficial da União" Nº 101 (Federal Official Journal) from 29 May 2009, section 1, pages 28 to 31 Language: Portuguese Number of pages: 4	Description of content: The notified regulation opens a 90-day period for public comments on the draft Normative Instruction that lays down general criteria for the import of microorganisms, material of animal origin, with insignificant or non-insignificant risk, for scientific purposes, diagnostic or use as input.	animal health, protect humans from animal/plant pest or disease, protect territory from other damage from pests.	World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number)
G/SPS/N/BRA/796	2012	Gibberellic acid	ANVISA	Draft Resolution on Gibberellic acid	This draft sanitary regulation modifies Resolution RE nº165, 29 August 2003, by changing in it the use of gibberellic acid in the cultures of banana (Brushing or immersion, MRL and safety period not determined due type of application).	food safety	None
G/SPS/N/BRA/797	2012	Copper hydroxide	ANVISA	Draft Regulation on Compounds of Copper Hydroxide Resulted in RDC N° 11, DE 16 DE FEVEREIRO DE 2012	This draft sanitary regulation modifies Resolution RE nº165, 29 August 2003, by including in it the use of copper hydroxide in the culture of soy (Leaf application).	food safety	None

G/SPS/ N/BRA/ 790	2012	Enteral nutrition	ANVISA	Title of the notified document: Draft Resolution on Enteral Nutrition Language(s): Portuguese Number of pages: 6	Description of content: This draft technical resolution establishes nutrient compounds and substances for enteral nutrition. This draft resolution aims to establish nutrient compounds and other substances that can be used in formulas for enteral nutrition. It is not included in this draft resolution the modified formulas for enteral nutrition for children under three-years old, which nutrients and other substances are specified in specific technical regulation. It will be granted a period of 18 (eighteen) months, from the date of adoption of this Resolution, for the establishments to make the necessary adjustments to attend this technical regulation.	food safety	None
G/SPS/ N/BRA/ 791	2012	Enteral nutrition	ANVISA	Title of the notified document: Draft Resolution on Enteral Nutrition Language(s): Portuguese Number of pages: 11	6. Description of content: This draft technical resolution establishes the formulas for enteral nutrition. This draft Resolution applies to formulas of enteral nutrition that aims the feeding of patients under enteral nutrition therapy. It revokes resolution ANVS no 449, 9 September 1999.	food safety	None

G/SPS/N/BRA/927	2014	Insecticides: sale to the general public: liquids and aerosols (maximum allowed concentration: 0.6% p/p); liquid repellent (maximum allowed concentration: 0.88% p/p); repellent tablets and strips (maximum allowed concentration: 15mg/each); spirals (maximum allowed concentration: 0.06% p/p); anti moth paper (maximum allowed concentration: 1.0% g/m2); gel repellents (maximum allowed concentration: 39.5% p/p); long lasting repellents, tablets and discs (maximum allowed concentration: 330 mg/each). (*) Label or package leaflet must contain the following wording: Do not use in poorly ventilated environment, especially in the presence of children. This product cannot be used by asthmatic persons, with respiratory problems or allergic to pyrethroids.	ANVISA	Draft resolution regarding the active ingredient TRANSFLUTRINA of the monograph list of active ingredients for pesticides, household cleaning products and wood preservers, published by Resolution - RE n° 165 of 29 August 2003, Brazilian Official Gazette (DOU Diário Oficial da União) of 2 September 2003.	Draft resolution regarding the active ingredient TRANSFLUTRINA of the monograph list of active ingredients of pesticides, household cleaning products and wood preservers. This resolution proposes to increase the maximum allowed concentration from 280 to 330 mg/each for use in household cleaning products: Sale to the general public: liquids and aerosols (maximum allowed concentration: 0.6% p/p); liquid repellent (maximum allowed concentration: 0.88% p/p); repellent tablets and strips (maximum allowed concentration: 15mg/each); spirals (maximum allowed concentration: 0.06% p/p); anti moth paper (maximum allowed concentration: 1.0% g/m2); gel repellents (maximum allowed concentration: 39.5% p/p); long lasting repellents, tablets and discs (maximum allowed concentration: 330 mg/each).	protect humans from animal/plant pest or disease	None
G/SPS/N/BRA/940	2014	Pharmacopoeial monographs on the heparin sodium from bovine and porcine in the Brazilian Pharmacopoeia	ANVISA	Title of the notified document: Draft resolution of the pharmacopoeial monographs on the heparin sodium from bovine and porcine in the Brazilian Pharmacopoeia Language(s): Portuguese Number of pages: 13 http://portal.anvisa.gov.br/wps/wcm/connect/66e64a804451d511a4fcac7f5a7b924e/Consulta+P%C3%BAblica+n+38+COFAR.pdf?MOD=AJPERES	Description of content: Draft resolution of the pharmacopoeial monographs on the heparin sodium from bovine and porcine in the Brazilian Pharmacopoeia. The heparin sodium from bovine is extracted from the bovine intestine and contains a mix of polysaccharide chains with different molecular weight. It is composed of units of α D glucosamine and acid α iduronic 2 sulfated. The units of α D glucosamine present a more heterogeneous pattern of sulphatation in comparison with the heparin from porcine. In	protect humans from animal/plant pest or disease	None

special we observe higher proportion of units of α D glucosamine non-sulphated in the position 6. It has anticoagulant activity by the inhibition of many factors of the coagulation system, prolonging the time of coagulation in blood. This occurs mainly through potentiation of the Xa factor inactivation and of the thrombin through the antithrombin. It contains, at least, 160 units of anti-factor lla activity for mg of heparin, respectively, in relation to desiccated substance. The reason of the anti-factor Xa activity for the anti-factor lla activity must be of 1.0 ± 0.1. The animals from which the heparin is extracted must fulfil the sanitary requirements of the species and the manufacturing process must ensure the elimination or the inactivation of infectious agents.

The heparin sodium from porcine is extracted from the intestine of the porcine and contains a mix of polysaccharide chains with different molecular weight. It is composed, preponderantly, for alternated units of α D glucosamine N- and 6-disulfated and acid α iduronic 2-sulfated. It has anticoagulant activity due to the inhibition of many factors of the coagulation system, prolonging the time of coagulation in blood. This occurs mainly through potentiation of the Xa factor inactivation and of the thrombin through the antithrombin. It contains, at least, 180 units of anti-factor lla activity for mg of heparin, in relation to desiccated substance. The reason of the anti-factor Xa activity for the anti-factor lla activity must be 1.0 ± 0.1. The animals from which the heparin is extracted must fulfil the sanitary requirements of the species in question and the manufacturing process must ensure the elimination or the inactivation of infectious agents.

					These monograph proposals set standards for the identity, dosage (according to methods Anti-factor Xa activity and Anti-factor IIa activity / ion-exchange high-performance liquid chromatography technique for detection and separation of possible contaminants of the heparin), characteristics, purity assays, biological safety tests, packaging, storing and labeling of the heparin sodium from bovine and porcine in the Brazilian Pharmacopoeia.		
G/SPS/ N/BRA/ 939	2014	I. Cereals containing gluten, namely wheat, rye, barley, oats and their hybridised strains; II. Crustaceans; III. Eggs; IV. Fish; V. Peanut; VI. Soy; VII. Milk; VIII. Almond (Prunus dulcis); IX. Hazelnut (Corylus spp.); X. Cashew nut (Anacardium occidentale); XI. Brazil nuts (Bertholletia excelsa); XII. Macadamia (Macadamia spp.); XIII. Nut (Juglans spp.); XIV. Pecan (Carya illinoensis); XV. Pistachio (Pistacia vera L.); and XVI. Sulphites (sulphur dioxide and its salts) in concentration equal to or greater than 10 (ten) parts per million (ppm), expressed in sulphur dioxide.	ANVISA	Draft resolution that adopts provisions on the mandatory declaration in the label of packaged food, of recognized sources of food allergies or food intolerances in sensitive persons	Draft resolution that adopts provisions on the mandatory declaration in the label of packaged food, of recognized sources of food allergies or food intolerances in sensitive persons. This resolution applies to food, ingredients, food additives, technological coadjuvants and raw material which are packaged in the absence of consumers, including those intended to be used exclusively for industrial processing and at food establishments. This resolution is complementary to the Resolution number 259, of 20 September 2002, which approves the technical regulation for labelling packaged food, and to the Law 10.674, of 16 May 2003, which establishes mandatory providing information on the presence of gluten in marketed food products. The following are recognized sources of food allergies or food intolerances in sensitive persons: I. Cereals containing gluten, namely wheat, rye, barley, oats and their hybridised strains; II. Crustaceans; III. Eggs; IV. Fish; V. Peanut; VI. Soy; VII. Milk; VIII. Almond (Prunus dulcis); IX. Hazelnut (Corylus spp.); X. Cashew nut (Anacardium occidentale); XI. Brazil nuts (Bertholletia excelsa); XII. Macadamia (Macadamia spp.); XIII. Nut (Juglans spp.); XIV. Pecan (Carya illinoensis); XV. Pistachio	Food safety, Protect humans from animal/plant pest or disease	None

					(Pistacia vera L.); and XVI. Sulphites (sulphur dioxide and its salts) in concentration equal to or greater than 10 (ten) parts per million (ppm), expressed in sulphur dioxide. Alterations in the list provided here within can be made upon updates on Codex Alimentarius guidelines or scientific evidences showing the cause-effect of the food consumption and adverse events, its epidemiological magnitude and its severity. The food, ingredients, additives, technological coadjuvants and raw materials which are packaged in absence of consumers, including those intended to be used for manufacturing and for food establishments must contain the declaration: Contains Gluten or Gluten Free, as appropriate. Food that are, derives from or have been intentionally added of ingredients, food additives, technological coadjuvants or raw materials from recognized sources of food allergies or food intolerances described in sections II to XVI of article 4, in any quantity, must bring the declaration: Allergic: Contains (source names), or Allergic:		
G/SPS/ N/BRA/ 1053	2015	Draft Resolution regarding a technical regulation to the active ingredient Prochloraz due to its toxicological re-evaluation	ANVISA	Draft resolution regarding the active ingredient PROCHLORAZ of the monograph list of active ingredients for pesticides, household cleaning products and wood preservers, published by Resolution - RE n°165 of 29 August 2003, Brazilian Official Gazette (DOU *Diário Oficial da União*) of 2 September 2003	Draft Resolution regarding a technical regulation to the active ingredient Prochloraz due to its toxicological re-evaluation.	food safety	None

G/SPS/N/BRA/1077	2015	Monetary update on registration and GMP certification fees related to health products	ANVISA	Title of the notified document: Interministerial Ordinance nº 701, 31 August 2015, regarding a monetary update on registration and GMP certification fees related to health products in Brazil Language(s): Portuguese Number of pages: 4 http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=02/09/2015&jornal=1&pagina=26&totalArquivos=104	Description of content: Interministerial Ordinance nº 701, 31 August 2015, regarding a monetary update on registration and GMP certification fees related to health products in Brazil. This Ordinance promoted a monetary update on registration and GMP certification fees related to health products in Brazil. It was necessary once the values of ANVISA's fees were obsolete since its creation in 1999, with accumulated losses of 193.5% according to Brazilian official inflation rate. So it is considered not to be a tribute increase, but a currency value reconstitution.	food safety	None
G/SPS/N/BRA/1072	2015	Antiparasitic veterinary products - HS Code: 300490	MAPA	Title of the notified document: "Portaria" SDA/MAPA Nº. 88 from 6 November 2015 Language(s): Portuguese Number of pages: 1 http://members.wto.org/crnattachments/2015/SPS/BRA/15_4552_00_x.pdf	Description of content: The notified text submits to public consultation the draft of Normative Instruction that approves the technical regulation on antiparasitic products for veterinary use and the criteria and procedures for registration.	Food safety, animal,	None

Table 5 - List of technical regulations notified to WTO - TBT

Doc.	Year	Products covered	Agency responsible	Notified document title	Situation	Description of content	Objective and rationale	Technical Provisions/Standards
G/TBT/N/BRA/00000054	2002	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution number 61, August 12th, 2002 (Consulta Pública no. 61 de 12 de agosto de 2002) issued by the Brazilian Sanitary Surveillance Agency on registration procedures for phytotherapic drugs. (2 pages, in Portuguese).	Draft not found	Description of content: Draft Resolution establishing registration procedures for phytotherapic drugs. It lays down the technical and legal registration requirements for new drugs, exemption cases and prior- and post-registration measures for four drug categories: new phytotherapic drugs, similar phytotherapic drugs, traditional phytotherapic drugs and exempt phytotherapic drugs. It also lays down marking, packaging and labelling requirements for the above mentioned products.	Marking, packaging and labelling requirements and public health	
G/TBT/N/BRA/00000056	2002	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution number 60, August 12th, 2002 (Consulta Pública no. 60 de 12 de agosto de 2002) issued by the Brazilian Sanitary Surveillance Agency on registration procedures for new and innovative drugs, with synthetic or semi-synthetic active principles. (2 pages, in Portuguese).	Draft not found	Description of content: Draft Resolution proposing registration procedures for new and innovative drugs, with synthetic or semi-synthetic active principles. It lays down the technical and legal requirements to register new drugs as well as prior- and post-registration measures. It also lays down the marking, labelling and packaging requirements for the above-mentioned products.	Marking, packaging and labelling requirements and public health.	

G/TBT/N/BRA/00000057	2002	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution number 59, August 12th, 2002 (Consulta Pública no. 59 de 12 de agosto de 2002) issued by the Brazilian Sanitary Surveillance Agency on reporting procedures for drugs exempt from registration. (2 pages, in Portuguese).	Draft not found	Description of content: Draft Resolution proposing the establishment of reporting procedures for drugs exempt from registration. It also lists those drugs that are exempt from registration at the Brazilian Sanitary Surveillance Agency, as well as the marking and labelling requirements for the above-mentioned products.	Marking and labelling requirements and consumer's health.
G/TBT/N/BRA/00000058	2002	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution number 63, August 12th, 2002 (Consulta Pública no. 63 de 12 de agosto de 2002) issued by the Brazilian Sanitary Surveillance Agency on technical procedures which apply to similar, exempt, phytotherapic and new drugs. (6 pages, in Portuguese).	Draft not found	Description of content: Draft Resolution proposing the establishment of a list of guidelines that may be used to describe technical procedures related to products subject to sanitary surveillance, namely similar, exempt, phytotherapic and new drugs. It also lays down marking, packaging and labelling requirements for the above mentioned products. Similar drugs, as defined by the present draft resolution, are those drugs which contain the same active principles, at the same concentration and pharmaceutical form, administration route, posology and therapeutic indication, being thus equivalent to the drug registered at the federal organism responsible for the sanitary surveillance, differing only on what concerns those characteristics relative to the size and shape of the product, expiry date, packaging, labelling, excipient and vehicle, requiring identification either by a trade name or mark.	Marking, packaging and labelling requirements and public health.

G/TBT/N/BRA/00000111	2003	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution number 11, April 09th, 2003 (Consulta Pública no. 11 de 9 de abril de 2003) issued by the Brazilian Sanitary Surveillance Agency on Technical Regulation on drugs labeling (23 pages, in Portuguese) The draft technical regulation notified under G/TBT/N/BRA/111, on mandatory technical requirements for phytotherapic drugs, has entered into force through Resolution RDC number 48, dated 16 March 2004, issued by the Brazilian Sanitary Surveillance Agency - Anvisa.	Revoked	Description of content: This draft technical regulation establishes labeling and packaging requirements applied to drugs in general and specifically to generic drugs, drugs exempt from registration, phytoterapic drugs, drugs under special control, homeopathic drugs, small volume parenteral solutions and polyelectrolitic concentrate for hemodialysis.	Labeling requirements and public health.
G/TBT/N/BRA/00000075	2003	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Resolution number 298, 6 November 2002 (Resolução RDC no. 298, de 6 de novembro de 2002) issued by the Brazilian Sanitary Surveillance Agency on ganglioside-based drugs. (4 pages, in Portuguese).	Draft not found	Description of content: This technical regulation establishes that requirements concerning raw material importation, ganglioside-based drugs manufacturing, distribution, trading and prescription as well as drug usage will be subject to the control of the Brazilian Sanitary Surveillance Agency. It also includes ganglioside-based drugs in the list C1 - Substances Subject to Special Control, found in Annex I of Ministerial Act number 344, 12 May 1998 (Portaria SVS/MS no. 344 de 12 de maio de 1998). In addition, the directions of the above mentioned drugs must contain the following warnings in Portuguese: - Medicamento a base de tecido nervoso que pode desencadear a Síndrome de Guillan Barre (SGB).("Nervous tissue based drugs which can arouse Guillain-Barré Syndrome (SGB)" and - Medicamento a base de tecido nervoso bovino. Os tecidos bovinos estão associados à aparição da Encefalite Espongiforme	Consumer's health and safety and directions requirements

						Bovina, variável humana. (“Bovine nervous tissue based drugs. The nervous tissues are associated with the appearance of bovine spongiform encephalopathy, human variant”) It also revokes the following Resolutions: 1. Resolution number 527, 17 April 2001 (Resolução RE no. 527 de 17 de abril de 2001) 2. Resolution number 2, 5 March 2002 (Resolução RE no. 2 de 5 de março de 2002) 3. Resolution number 198, 12 July 2002 (Resolução RDC no. 198 de 12 de julho de 2002) 4. Resolution number 278, 24 October 2002 (Resolução RDC no. 278 de 24 de outubro de 2002) Obs: Also notified under SPS Agreement	
G/TBT/N/BRA/00000100	2003	3003-Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale., 3004-Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution number 99, December 16th, 2002 (Consulta Pública no. 99 de 16 de dezembro de 2002) issued by the Brazilian Sanitary Surveillance Agency on registration, amendments, post registration inclusion and validation of allergenic products. (20 pages, in Portuguese). This addendum aims at informing that the Draft Technical Regulation, issued by Brazilian Sanitary Surveillance Agency and notified under G/TBT/N/BRA/100, which proposed mandatory technical requirements for the registration of allergenic products (HS: 3003; 3004), has been changed through Draft Resolution number 47, 7 June 2005 (Consulta Pública Nº 47, de 7 de Junho de 2005).	Draft not found	Description of content: This draft technical regulation aims at regulating registration and post registration procedures of allergenic products. It also establishes the text to be included in the directions and labelling as well as external packaging requirements. Observation: Also notified under SPS Agreement	Labelling requirements and public health

G/TBT/N/BRA/00000142	2003	30-PHARMACEUTICAL PRODUCTS, 33-ESSENTIAL OILS AND RESINOIDS; PERFUMERY, COSMETIC OR TOILET PREPARATIONS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Ministerial Act number 93, 4 November 2003 (Consulta Pública número 93 de 4 de novembro de 2003) issued by the Brazilian Sanitary Surveillance Agency on cosmetics, perfumes and personal hygienic products (15 pages, in Portuguese).	Draft not found	Description of content: This Draft Technical Regulation defines those cosmetics, perfumes and personal hygienic products that can be fractionated and directly sold to consumers, as well as their minimum labelling requirements. It also lays down good fractionating practices for companies, stores and/or shops that fraction out cosmetics, perfumes and personal hygienic products directly sold to consumers	Human health and safety protection. Labelling requirements	
G/TBT/N/BRA/00000097	2003	3005-Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes.	INMETRO	Title, number of pages and language(s) of the notified document: Ministerial Act number 001, January 8th 2003 (Portaria no. 001 de 8 de janeiro de 2003), issued by Inmetro, on the labelling requirements for crepe bandages, orthopaedic bandages, gauze compresses and pre-washed surgery filed compresses. (2 pages, in Portuguese). Since the draft technical regulation notified under G/TBT/N/BRA/97, issued by Inmetro, has not stated a date for entry into force of its requirements on crepe bandages, orthopaedic bandages, gauze compresses and pre-washed surgery filed compresses, it fell to Ministerial Act number 106, 18 June 2003, to establish that those will enter into force in 23 December 2003, without changes in their content.	In force	Description of content: This Draft Technical Regulation lays down the labelling requirements concerning metrological information for crepe bandages, orthopaedic bandages, gauze compresses and pre-washed surgery filed compresses.	Labelling requirements, consumer's safety and prevention of deceptive practices	General rules
G/TBT/N/BRA/00000131	2003	300230-- Vaccines for veterinary medicine	MAPA	Title, number of pages and language(s) of the notified document: Public Consultation number 162, August 22nd, 2003 and annex draft technical regulation (Consulta Pública no. 162 de 22 de agosto de 2003) issued by the Ministry of Agriculture on brucellosis vaccine (8 pages, in Portuguese).	Draft not found	Description of content: Public consultation and annex draft technical regulation which proposes technical requirements for the quality control of brucellosis vaccine, including packaging requirements.	Protection of human and animal health	

G/TBT/N/BRA/00000255	2007	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution nº 81, 29 August 2007 – Technical Regulation on Terminology for Drug Packaging (5 pages, in Portuguese).	Draft not found	Description of content: This draft technical regulation establishes the standardized terminology of names and abbreviations to be used on package inserts and register process of drugs.	Protection of consumer health and prevention of deceptive practices
G/TBT/N/BRA/00000261	2007	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution nº 94, 19 October 2007 – Technical regulation on Good Manufacturing Practices of radiopharmaceutical products (6 pages, Portuguese). Resulted in RDC 82/2007	RDC not found	Description of content: This draft technical regulation establishes the Good Manufacturing Practices of radiopharmaceutical products.	Protection of consumer health
G/TBT/N/BRA/00000262	2007	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution nº 96, 19 October 2007 – Technical regulation on Good Manufacturing Practices of medicinal gases (10 pages, Portuguese). Resulted in RDC 84/2007	RDC not found	Description of content: This draft technical regulation establishes the Good Manufacturing Practices of medicinal gases.	Protection of consumer health

G/TBT/N/BRA/00000263	2007	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution nº 97, 19 October 2007 – Technical regulation on Registration of Medicinal Gases (9 pages, Portuguese). Resulted in RDC 85/2007	RDC not found	Description of content: This draft technical regulation establishes a list of medicinal gases which must be registered at Brazilian Health Surveillance Agency - ANVISA. It also establishes requirements to the registration of medicinal gases.	Protection of consumer health
G/TBT/N/BRA/00000275	2008	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution nº 8, 4 March 2008 – Technical regulation on the Drugs Traceability and Authenticity Mechanisms (4 pages, in Portuguese).	Draft not found	Description of content: This draft technical regulation opens for public consultation to determine minimum requirements of drugs traceability and authenticity mechanisms in the whole chain of pharmaceutical products. This chain includes production, distribution, transportation, storage and dispensation to the final consumer.	None

G/TBT/N/BRA/00000531	2013	3004-Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.	ANVISA	Title, number of pages and language(s) of the notified document: Draft Ordinance No. 14, 14 May 2013 - Draft Normative Instruction that determines the publication of the List of herbal medicines that requires simplified registration and the List of herbal medicines of traditional use that requires simplified registration at Anvisa (13 pages, in Portuguese). Resulted in IN nº 10/2014	In force	This draft Normative Instruction determines the publication of the list of herbal medicines that requires simplified registration at Anvisa and the list of herbal medicines of traditional use that requires simplified registration at Anvisa to be commercialized in Brazil. This Normative Instruction will enter into force on the date of its adoption. It will revoke Normative Instruction n. 5, 11 December 2008.	Protection of Human Health	None
G/TBT/N/BRA/00000532	2013	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Ordinance No. 15, 14 May 2013 - Draft Technical Regulation that establishes requirements to commercialize traditional Chinese medicine products in Brazil (3 pages, in Portuguese)	In force	Description of content: This draft Technical Regulation has the objective to establish requirements to commercialize traditional Chinese medicine products in Brazil. It establishes a period of three years from the date of publication of this Resolution for the monitoring of the use of traditional Chinese medicine products in the country. For the purposes of this Resolution traditional Chinese medicine products are formulations obtained from vegetable and mineral raw materials in accordance with traditional Chinese medicine techniques and part of the Chinese Pharmacopoeia. It is forbidden for the use of animal origin raw material in the formulations to be commercialized in Brazil.	Protection of Human Health	General rules

G/TBT/N/BRA/00000526	2013	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution No. 10, 2 April 2013 - Anvisa proposal for the implementation of the Brazilian System of Medicines Control Mechanisms and Procedures for Traceability of Production, Commercialization, Dispensation and Prescription of Medicines (6 pages, in Portuguese) Resulted in RDC 54/2013 revoked by RDC 157/2017	In force	This draft Technical Regulation establishes the implementation of the Brazilian System of Medicines control mechanisms and procedures for traceability of production, commercialization, dispensation and prescription of medicines. It is established, within the Brazilian System of Medicines Control, mechanisms and procedures for traceability of drugs though capture technology, electronic storage and transmission of data through all the chain that involves production, commercialization, import, dispensation and prescription and other types of movement provided by health controls. The provisions contained in this draft Technical Regulation applies to all medicines that must be registered at Anvisa to be commercialized in Brazil. This draft Technical Regulation revokes Resolution RDC 59, 24 November 2009. According to article 23, it will be granted periods of 180 and 360 days from the date of entry into force of this Resolution for companies to promote the necessary adjustments to comply with this Technical Regulation.	Protection of Human Health	ISO/IEC 16022:2006

G/TBT/N/BRA/00000654	2015	30-PHARMACEUTICAL PRODUCTS	MAPA	Title, number of pages and language(s) of the notified document: Draft Ordinance Nº 88, 6 November 2015 (28 pages, in Portuguese)	In force	Description of content: Draft technical regulation establishing rules and procedures for antiparasitic products registration for veterinary use, including labelling requirements according to the rules set by Decree Nº 5053, 22 April 2004 and additional normative acts, set in Ordinance Nº 88, 6 November 2015, Annex III, to ensure an adequate level of protection for animals, public health and environment. It revokes Ordinance MAPA Nº 301, 19 April 1996, and the MAPA/SDA Ordinance Nº 48 12 May 1997.	Protection of human health or safety	General rules
G/TBT/N/BRA/00000707	2017	30-PHARMACEUTICAL PRODUCTS	ANVISA	Title, number of pages and language(s) of the notified document: Draft Resolution No. 311, 15 February 2017 (7 pages, in Portuguese). Resulted in RDC nº 157 de 11/05/2017	In force	Description of content: This Draft Resolution proposes the implantation of the National Medicine Control System (NMCS) and the mechanisms and procedures for medicine track and tracing, besides other measures. These mechanisms and procedures for medicine track and tracing is applicable throughout the national territory. The provisions of this proposal apply to all medicines registered at the Brazilian Health Regulatory Agency (ANVISA). It is not applicable to serum and vaccines that are part of the National Immunization Program; radiopharmaceuticals; non-prescription medicaments; medicines included on the Programs of medicines for free distribution and individualized delivery control of the Ministry of Health; specific medicines and phytomedicines; free samples. Medicine track and tracing system establishes mechanisms and procedures that allow to recovery the medicine history, identify its current location and the last known destination. The bidimensional bar code is the	Protection of human health	ISO/IEC 16022:2006

			technology used to capture, store and comunicate events related to medicine track and tracing on the NMCS and the DATAMIX is the adopted standard as established on ISO/IEC 16022:2006. The owner of the medicine marketing authorization is responsible for the generation and inclusion of the Datamix on the comercial package, including data of the Unique Medicine Identificiation (UMI) and other provisions established at RDC Nº 71 from 22 December 2009 (available at http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2009/res0071_22_12_2009.html) and modified by the RDC Nº 26 from 16 June 2011 (available at http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2011/rdc0026_16_06_2011.pdf). Every transport package, from expedition at the marketing authorization owner, should have a unique identification code that allows identify the UMI inside it. Imported medicines may have the Datamix and serial code printed by the manufacture on the country of origin or by the owner of the authorization in Brazil. The option adopted should be informed to Anvisa at the process for the Import Licence. Each member at the medicine supply chain should store and transmit electronically the data regarding the events of the medicine under its responsibility. The technological specifications related to the NMCS procedures will be published as Normative Instruction before the end of the fourth month after the date of publishing of this technical regulation. This proposal revokes the Resolution RDC Nº 54 from 10 December 2013 (available at http://bvsms.saude.gov.br/bvs/saudelegis/anv

						isa/2013/rdc0054_10_12_2013.pdf) and the RDC Nº 114 from 29 September 2016 (available at http://portal.anvisa.gov.br/documents/10181/2718376/RDC_114_2016.pdf/823dbdb9-c11f-45fa-b313-220426e75fb0)	
G/TBT/N/BRA/0000070 4	2017	30-PHARMACEUTICAL PRODUCTS	MAPA	Title, number of pages and language(s) of the notified document: Ordinance N° 23, 22 December 2016 (Instrução Normativa MAPA/SDA N° 23, de 22 de Dezembro de 2016). (2 pages, in Portuguese). Description of content: This Ordinance set the guidelines on performance of the Ministry of Agriculture, Livestock and Supply (MAPA), as federal registering agency responsible establishing the necessary criteria and procedures for changes in registration for veterinary pharmaceutical and biological products.	Draft not found	This Ordinance set the guidelines on performance of the Ministry of Agriculture, Livestock and Supply (MAPA), as federal registering agency responsible establishing the necessary criteria and procedures for changes in registration for veterinary pharmaceutical and biological products.	Quality requirements; Protection of Human health or Safety