WORLD TRADE ORGANIZATION

G/TBT/N/BRA/758

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** BRAZIL **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Brazilian Health Regulatory Agency (Anvisa) **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563 2840 Telefax: +(55) 21 2563 5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** HS 3002 - Blood
5.	**Title, number of pages and language(s) of the notified document:** Resolution – RDC n. 187, November 8th, 2017. (13 page(s), in Portuguese)
6.	**Description of content:** This Resolution establishes the minimum requirements for the registration of Hyperimmune Serum in order to guarantee the quality, safety and efficacy of these products. It applies to Hyperimmune Serum submitted for analysis for registration purposes. Due to the biological origin of its Active Principles and the diversity of the technological processes used to obtain these products, all requests for the registration of Hyperimmune Serum will be analyzed according to the requirements established in this Resolution. Only Hyperimmune Serum registered at the Brazilian Health Regulatory Agency - Anvisa, manufactured or imported by establishments authorized by the Federal Government and licensed at a state level, may be marketed and distributed in Brazil. The Hyperimmune Serum manufactured in other countries may only be Authorized (registered) by Anvisa if the product is registered and liberated for use in its country of manufacture. Hyperimmune Serum not registered in their country of manufacture, but registered in another country due to epidemiological necessity, may be registered with Anvisa, after evaluation of the documentation presented, provided that the epidemiological impact of its use in Brazil is proven. Only those Hyperimmune Serum with their validated manufacturing process will be registered and have at least one method of inactivation and / or viral removal validated in their manufacturing process will be registered. For products manufactured in other countries, the latest periodic pharmacovigilance report shall be submitted, if available.

	Failure to submit any data requested in this Resolution relating to quality, safety and efficacy of the product to be registered shall be technically and scientifically justified.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** (1) Brazilian Official Journal (Diário Oficial da União), Nº 215 9 December 2017; Section 1 page 57. (2) Law nº 9.782, de 26 January 1999; Law nº 13.097, de 19 January 2015 (3) Brazilian Official Journal; (4) Not stated.
9.	**Proposed date of adoption:** On the date of its publication **Proposed date of entry into force:** On the date of its publication
10.	**Final date for comments:** Not applicable
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** http://portal.anvisa.gov.br/documents/10181/3233294/RDC_187_2017_.pdf/af6f9ea2-ff17-42ad-a147-0f3f14523250