WORLD TRADE ORGANIZATION

G/TBT/N/BRA/1094

29 October 2020

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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 2145.3817 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):** Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic uses, not in measured doses or put up for retail sale (excl. goods of heading 3002, 3005 or 3006) (HS 3003); Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses "incl. those for transdermal administration" or in forms or packings for retail sale (excl. goods of heading 3002, 3005 or 3006) (HS 3004); Wadding, gauze, bandages and the like, e.g. dressings, adhesive plasters, poultices, impregnated or covered with pharmaceutical substances or put up for retail sale for medical, surgical, dental or veterinary purposes (HS 3005); Pharmaceutical preparations and products of subheadings 3006.10.10 to 3006.60.90 (HS 3006)
5.	**Title, number of pages and language(s) of the notified document:** Draft Normative Instruction number 931, 13 October 2020 (4 page(s), in Portuguese) Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=60163
6.	**Description of content:** This draft normative instruction establishes new codes for the administrative request of market authorization for new and innovative synthetic and semisynthetic medicines.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** RDC No. 60, of 10 October 2014, had the criteria for granting and renewing the registration of drugs with synthetic and semisynthetic active ingredients, classified as new, generic and similar. The resolution brought greater regulatory robustness in understanding what is expected as proof of quality and safety and efficacy in the registration of synthetic and semisynthetic drugs in relation to previous regulations. However, the possible categories of registration by RDC 60/2014 were New Drug, New Association, New Fixed Dose Association, New Pharmaceutical Form, New Concentration, New Route of Administration, Drug with Same(s) IFA(s) Of New Drug Already Registered,

	Generic and Similar. For this categorization, RDC No. 60/2014 made it impossible to frame some drugs that brought an innovation that did not fall into any of the categories defined in the resolution, creating an administrative-regulatory – and non-technical – obstacle to the entry of innovative drugs into the national market. This situation was a constant demand of the regulated sector and brought internal discussion about the need for a broad revision of the standard.; Protection of human health or safety
8.	**Relevant documents:** 1) Brazilian Official Gazette 204 on 23 October 2020, section 1, page 480; 2) Report of Impact Assessment https://www.in.gov.br/web/dou/-/consulta-publica-n-931-de-13-de-outubro-de-2020-284700465 http://antigo.anvisa.gov.br/documents/10181/5457402/Relat%C3%B3rio+de+Mapeamento+de+Impactos+-+REMAI+-+CP+931-2020.pdf/5d99a3f0-3230-453e-be85-5e509842290c
9.	**Proposed date of adoption:** To be defined **Proposed date of entry into force:** To be defined
10.	**Final date for comments:** 28 December 2020
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: www.anvisa.gov.br http://antigo.anvisa.gov.br/documents/10181/5457402/CONSULTA+P%C3%9ABLICA+N+931+COINC.pdf/3166ca86-fa37-4581-af7a-7c06ea8ebd78