Committee on Technical Barriers to Trade Original:

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	**Notifying Member:** Brazil **If applicable, name of local government involved (Articles 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):** HS Code(s): 2941; 3003; 3004; 3005; 3006 (pharmaceutical products).
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution number 932, 13 October 2020. **Language(s)**: Portuguese. **Number of pages:** 17. Draft: http://antigo.anvisa.gov.br/documents/10181/5457402/CONSULTA+P%C3%9ABLICA+N+932+COINC.pdf/290358b1-135e-47d3-b05d-fc2feb58cecc Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=60162
6.	**Description of content:** This draft resolution establishes criteria for the concession of market authorization for medicines with synthetic and semisynthetic active principles for human use categorized as new, innovative, generic, and similar.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health. RDC No. 60, of October 10, 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.
8.	**Relevant documents:** 1) Brazilian Official Gazette 204 on 23 October 2020, section 1, page 481 2) Report of Impact Assessment 3) RDC No. 200, 26 December 2017 https://www.in.gov.br/web/dou/-/consulta-publica-n-932-de-13-de-outubro-de-2020-284700540 http://antigo.anvisa.gov.br/documents/10181/5457402/REMAI+-+CP+932-2020.pdf/464c17d3-e7e5-4cbf-a086-94a56fb45781 http://antigo.anvisa.gov.br/documents/10181/3836387/%283%29RDC_200_2017_COMP.pdf/6316bee6-095d-426b-9398-6b1f659078b5
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 [X] 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+932+COINC.pdf/290358b1-135e-47d3-b05d-fc2feb58cecc