WORLD TRADE ORGANIZATION

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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):** Medicines (HS – 3003-3004)
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution No. 1050, 31 May 2021. **Language(s):** Portuguese. **Number of pages:** 4. Draft: http://antigo.anvisa.gov.br/documents/10181/6279847/CONSULTA+P%C3%9ABLICA+N+1050+GIMED.pdf/5c0906c0-7b02-475e-826e-2a90aefce168 Comment form: https://pesquisa.anvisa.gov.br/index.php/551215?lang=pt-BR
6.	**Description of content:** Draft resolution of risk assessment and control of potentially carcinogenic nitrosamines in medicines for human use.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health In 2018, the world's regulatory agencies became aware of the presence of nitrosamines above the levels allowed in drugs, after manufacturers of active pharmaceutical inputs in the group of medicines commonly called sartanas issued alerts of their possible presence in this class of drugs. Since then, these agencies have promoted actions to protect patients' health from exposure to nitrosamines in drugs above acceptable levels. Anvisa's initial actions involved inspections in 30 drug manufacturers, with 31 health actions carried out.

	In this sense and so that medicines in the Brazilian market do not contain levels of harmful impurities, it is proposed the publication of the Guide on nitrosamine control in medicines.
8.	**Relevant documents:** 01) Brazilian Official Gazette 103 on 02 June 2021, section 1, page 120 02) Regulatory Impact Analysis (RIA) dispensation motivations https://www.in.gov.br/web/dou/-/consulta-publica-n-1.050-de-31-de-maio-de-2021-323567102 http://antigo.anvisa.gov.br/documents/10181/6279847/Parecer+com+as+motiva%C3%A7%C3%B5es+de+dispensa+de+AIR.pdf/6574a23e-7418-4dfb-bd74-c9cae143c653
9.	**Proposed date of adoption:** To be defined **Proposed date of entry into force:** To be defined
10.	**Final date for comments:** 08/07/2021
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://antigo.anvisa.gov.br/documents/10181/6279847/CONSULTA+P%C3%9ABLICA+N+1050+GIMED.pdf/5c0906c0-7b02-475e-826e-2a90aefce168 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