



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>BRAZIL</u> 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 2563.2918 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas The comments to this Draft Regulation shall be sent to http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=33294
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): medicines
5. Title, number of pages and language(s) of the notified document: Draft Resolution Nº 551, 3 September 2018 (14 page(s), in Portuguese)
6. Description of content: This Draft Resolution 551/2018 establishes the Good Pharmacovigilance Practices to be watched by all the registration holder of medicine for human use. The medicine registration holder: <ul style="list-style-type: none">- is responsible for the actions of Pharmacovigilance related to their products and must preset the information requested by the health surveillance authority concerning Pharmacovigilance in the deadline established;- must assign 1 (one) Responsible Person for the Pharmacovigilance and offer the proper means for the development of the pharmacovigilance activities, including material and human resources, communications tools and access to all the necessary sources of information;- must implement mechanisms to inform the Responsible Person about all emergencies related to medicine safety under his responsibility and any information related to the evaluation of the risk-benefit relation;- must have a contingency plan for unforeseen events that includes software or hardware fails on the databases, to ensure the continuity of the Pharmacovigilance activities;

- can transfer to a third part the execution of any Pharmacovigilance activity regulated by this Resolution;
- must implement a Pharmacovigilance System appropriated for its needs that allows, when necessary, the adoption of measures related to the products the registration holder is responsible for and have documentation containing the detailed description of the Pharmacovigilance System, including information on structure, interfaces, work process, responsibilities and risk management activities;

The Pharmacovigilance System:

- must be situated in Brazil, nevertheless System elements and process can be developed in other countries as long as it does not compromise the operative capacity of monitoring and the problem identification of the products on national territory;
- must be developed in compliance with all safety requirements related to the medicines including manufacturing aspects of quality assurance and quality control.

The medicine registration holder must have a self-inspection program on pharmacovigilance and conduct at least one self-inspection per year.

The Good Pharmacovigilance Practices established in this Draft Resolution 551/2018 also addresses adverse event notification to Anvisa; relation benefit-risk evaluation and risk management plan.

The Brazilian Health Regulatory System (SNVS) can conduct a pharmacovigilance inspection at the medicine registration holder at any time, announced or not.

This Draft Resolution 551/2018 revokes:

- Collegiate Board Resolution - RDC nº 4, from 10 February 2009;
- Normative Instruction - IN nº 14, from 27 October 2009;
- item V of Art. 18 of the Collegiate Board Resolution - RDC nº 31, from 29 May 2014;
- item III of Art. 47 of the Collegiate Board Resolution - RDC nº 200, from 26 December 2014;
- item II of Art. 119 of the Collegiate Board Resolution - RDC nº 49, from 20 September 2011;
- item IV and paragraph 3 of Art. 35 of the Collegiate Board Resolution - RDC nº 26, from 13 May 2014;
- paragraph 2 of Art. 48 of the Collegiate Board Resolution - RDC nº 24, from 14 June 2011;
- item IX of Art. 37 of the Collegiate Board Resolution - RDC nº 64, from 18 December 2009;

7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety

8. Relevant documents: (1) Brazilian Official Journal (Diário Oficial da União) 172, 05 September 2018, section 1, pages 91/92; (2) Not applicable (3) Brazilian Official Journal; (4) Not stated.

9. Proposed date of adoption: On the date of its publication

Proposed date of entry into force: 90 days after the date of its publication

10. Final date for comments: 12 November 2018

11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:

Agency Responsible

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