



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 CCCN 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 552, 3 September 2018 (8 page(s), in Portuguese)
6. Description of content: This Draft Resolution 552/2018 establishes the content of the Periodic Report of Evaluation of Risk-Benefit provided by the medicine registration holder. The Periodic Report of Evaluation of Risk-Benefit: <ul style="list-style-type: none">- applies to all the registered medicines in national territory (Brazil);- is a technical document prepared by the medicine registration holder and must be presented to Anvisa on specific periods according to the active principal;- consists of the update of the national and international safety information and the analysis of the risk/benefit relation;- must provide information about indications, pharmaceutical formulation and posology by active principle;- shall be used by the holders to conduct systematical analysis in order to previously identify problems and propose interventions; The product registration holder is responsible for the Report elaboration and submission to Anvisa.

<p>The medicine registration holder must have its own Reference Document on Medicine Security containing the consolidated information about medicine safety to provide a practical, efficient and consistent approach of the risk/benefit evaluation.</p> <p>The compulsory utilization of the Medical Dictionary for Regulatory Activities (MedDRA) is established.</p> <p>The Reports submitted to Anvisa must follow the format and content established on the updated version of the E2C Guide of the International Conference on Harmonization (ICH).</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety</p>
<p>8. Relevant documents: (1) Brazilian Official Journal (Diário Oficial da União) 172, 05 September 2018, section 1, pages 92; (2) Not applicable (3) Brazilian Official Journal; (4) Not stated.</p>
<p>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</p>
<p>10. Final date for comments: 12 November 2018</p>
<p>11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>Agency Responsible Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: http://portal.anvisa.gov.br/english</p> <p>http://portal.anvisa.gov.br/documents/10181/4858873/CONSULTA+P%C3%9ABLICA+N%C2%BA+552+GFARM.pdf/3d89cd99-243f-4afc-b13b-f6659ff4ee06</p>