



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 (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 989, 15 December 2020. Language(s): Portuguese. Number of pages: 3. Draft: http://antigo.anvisa.gov.br/documents/10181/6165008/CONSULTA+P%C3%9ABLICA+N+989+GGMED.pdf/15feb8f0-c7b9-4a5c-952f-b4e36aec7cea Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=60955
6. Description of content: This draft resolution changes the Resolution – RDC number 47, 8 September 2009, which establishes technical requirements for the development, harmonization, updating, publication, and provision of medicine leaflets to patients and healthcare professionals.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health. A study conducted in Montes Claros-MG showed the importance of consulting the leaflets of THE MIPs in view of their indiscriminate use. In this study, dipyrone, paracetamol and acetylsalicylic acid were the major causes of adverse and toxicological reactions, and 75.74% of the interviewed population had the habit of buying MIPs in primary packages. It can be concluded that the lack of information for the use of these medicines may result in administration errors. Another study showed that written information on medicines has been recognized as an important tool for health education. Of 28,427 individuals, 59.6% answered that they generally read the leaflets and 98.4% considered them necessary. In view of the importance of the package leaflet for the patient, the proposal aims to change article 26 of RDC No. 47/2009 in a timely manner to allow the package leaflet to be made available also through a digital mechanism printed on the primary and secondary packaging

	of medicines, which can be read through a mobile phone or free internet reading applications, allowing full access to the patient's and the most up-to-date health care leaflets contained in the Electronic Package Leaflet of Anvisa.
8.	Relevant documents: 1) Brazilian Official Gazette 245 on 23 December 2020, section 1, page 140 2) RDC number 47, 8 September 2009 3) Justification for resolution draft 4) Report of Impact Assessment https://www.in.gov.br/web/dou/-/consulta-publica-n-989-de-15-de-dezembro-de-2020-295784823 http://antigo.anvisa.gov.br/documents/10181/2718376/%281%29RDC+47+2009+COMP.pdf/cd434aae-fca0-448e-bd40-1b8e85e5570b http://antigo.anvisa.gov.br/documents/10181/6165008/Justificativa+++CP+989-2020.pdf/11f0c4c7-9adc-4256-9a51-86a180c53514 http://antigo.anvisa.gov.br/documents/10181/6165008/Relat%C3%B3rio+de+Mapeamento+de+Impactos+++CP+989-2020.pdf/9aff7d60-9456-4b6f-9124-7566e8055a6e
9.	Proposed date of adoption: To be defined Proposed date of entry into force: To be defined
10.	Final date for comments: 12 February 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: 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