



### NOTIFICATION

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

<b>1. Notifying Member:</b> <u>Brazil</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Brazilian Health Regulatory Agency (ANVISA) <b>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:</b>  National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2145.3817 Email: <a href="mailto:barreirastecnicas@inmetro.gov.br">barreirastecnicas@inmetro.gov.br</a> Web-site: <a href="http://www.inmetro.gov.br/barreirastecnicas">www.inmetro.gov.br/barreirastecnicas</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b>  HS Code(s): 3003; 3004; 3005; 2941 (pharmaceutical products).
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Normative Instruction no. 819, 01 June 2020. <b>Language(s):</b> Portuguese. <b>Number of pages:</b> 46.
<b>6. Description of content:</b> This draft normative instruction proposes the revision of Resolution – RDC no. 107, 5 September 2016, which approves, the “List of Low-risk medicinal products subject to simplified notification”.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health.  RDC 199/2006 regulates the notification of low-risk drugs. The notification process aims to simplify the regularization of these drugs, which do not undergo analysis prior to their commercialization, thus optimizing the regulatory process and facilitating access. Only those well-established drugs, with low probability of causing harm to humans and exempt from medical prescription are subject to notification. Considering the need to rationalize the work processes related to the regularization of medicines, it is also necessary to update the list of low-risk drugs that can be communicated, which is the subject of RDC 107
<b>8. Relevant documents:</b> (1) Draft Normative Instruction no. 819, 01 June 2020, published in the Brazilian Official Gazette (Diário Oficial da União) no. 105, of 03 June 2020, section 1, page 502; (2) Resolution – RDC no. 107, 05 September 2016, published in the Brazilian Official Gazette no. 172, of 06 September 2016, Section 1, page 31; (3) Resolution – RDC no. 199, 26 October 2016, published in the Brazilian Official Gazette no. 208, of 30 October 2016, Section 1, page 167, full text available at <a href="http://www.in.gov.br/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/23527924/do1-">http://www.in.gov.br/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/23527924/do1-</a>

[2016-09-06-resolucao-rdc-n-107-de-5-de-setembro-de-2016-23527827](http://portal.anvisa.gov.br/documents/10181/2971718/%282%29RDC_107_2016_COMP.pdf/eee4a7f2-edc3-4018-ab69-754bff7b95f4)

[http://portal.anvisa.gov.br/documents/10181/2971718/%282%29RDC\\_107\\_2016\\_COMP.pdf/eee4a7f2-edc3-4018-ab69-754bff7b95f4](http://portal.anvisa.gov.br/documents/10181/2971718/%282%29RDC_107_2016_COMP.pdf/eee4a7f2-edc3-4018-ab69-754bff7b95f4)

Resolution - RDC no. 199, 26 October 2006.  
([http://portal.anvisa.gov.br/documents/10181/2718376/RDC\\_199\\_2006\\_COMP.pdf/6d77eb24-b247-4497-ab7e-c668795ef8cf](http://portal.anvisa.gov.br/documents/10181/2718376/RDC_199_2006_COMP.pdf/6d77eb24-b247-4497-ab7e-c668795ef8cf))

**9. Proposed date of adoption:** To be determined after the end of the consultation period.  
**Proposed date of entry into force:** To be determined after the end of the consultation period.

**10. Final date for comments:** 7 September 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:**

Draft:

<http://portal.anvisa.gov.br/documents/10181/5904481/CONSULTA+P%C3%9ABLICA+N+819+GGMED.pdf/7ebfa646-bb7c-4a03-bdde-00a3f0db9a7d>

Comment form: : [http://formsus.datasus.gov.br/site/formulario.php?id\\_aplicacao=56966](http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=56966)

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