



### 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> The 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 2563.2918 Telefax: +(55) 21 2563.5637 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: 3822  (reference medicine)
<b>5. Title, number of pages and language(s) of the notified document:</b> Resolution - RDC 290, 4 June 2019. (3 pages, Portuguese).
<b>6. Description of content:</b> This Resolution - RDC amends the articles 8 and 9 of the Resolution - RDC number 35, 15 June 2012, establishing exceptions for the purchase of reference medicine from another country other than Brazil.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of Human Health
<b>8. Relevant documents:</b> RDC number 35, June 15th, 2012.
<b>9. Proposed date of adoption:</b> June 5th, 2019 <b>Proposed date of entry into force:</b> June 5th, 2019
<b>10. Final date for comments:</b> Not applied
<b>11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b>  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](http://www.anvisa.gov.br)

[http://portal.anvisa.gov.br/documents/10181/3231220/RDC\\_290\\_2019\\_.pdf/c729b150-cdf0-4dab-827b-8ccb0f1bb3b3](http://portal.anvisa.gov.br/documents/10181/3231220/RDC_290_2019_.pdf/c729b150-cdf0-4dab-827b-8ccb0f1bb3b3)