



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: The 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
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: 30049099; 3006; 5302.(cannabis based medicine, its derivatives and synthetic analogues)
5. Title, number of pages and language(s) of the notified document: Draft resolution (Consulta Publica) number 654, June 13rd, 2019. 7 pages, Portuguese. Published on D.O.U, June 14th, 2019, page 82. Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=48031
6. Description of content: This draft resolution establishes the procedure for the marketing authorization and monitoring of Cannabis spp. based medicines, its derivatives and synthetic analogues.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
8. Relevant documents: 1) Brazilian Official Journal (Diário Oficial da União), number 114, June, 14 th 2019; Section 1, page 82; 2) Law 6.437, August 20 th 1977; Decree 54.216, August 27 th 1964; 3) Brazilian Official Journal; 4) Not stated.
9. Proposed date of adoption: In the date of its publication Proposed date of entry into force: In the date of its publication
10. Final date for comments: 20/08/2019
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

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<http://portal.anvisa.gov.br/documents/10181/5533192/CONSULTA+PU%C2%B4BLICA+N+654+GGMED.pdf/4116aee5-5a0b-4673-a554-f12b131f2741>