



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 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: 98041000 (products of advanced therapies)
5. Title, number of pages and language(s) of the notified document: Draft resolution number 706, August 26 th , 2019. Number of pages: 17; Language(s): Portuguese. Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=49682
6. Description of content: This Draft Resolution defines the market authorization for products of advanced therapies of human origin and gives other measures.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health.
8. Relevant documents: Not applied
9. Proposed date of adoption: To be determined after the end of the consultation period. Proposed date of entry into force: 30 days after the date of its publication.
10. Final date for comments: October 18 th , 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 CEP: 71.205-050 Phone.: +(55) 61 3462.5402

Website: www.anvisa.gov.br

<http://portal.anvisa.gov.br/documents/10181/3086545/SEI+-+CP+706-2019.pdf/bf8206a0-dff5-4175-997c-f832cf4021e6>