

NOTIFICATION

The following notification is issued in accordance with Article 10.6.

1.	Notifying Member: <u>COLOMBIA</u> If applicable, name of the local government concerned (Articles 3.2 and 7.2):
2.	Agency responsible: Ministry of Health and Social Protection Name and address (including telephone and fax numbers, e-mail addresses and websites, if available) of the agency or authority designated to handle comments regarding the notification, in the case of a Body or authority: Ministry of Commerce, Industry and Tourism
3.	Notified under Article 2.9.2 [] 2.10.1 [X] 5.6.2 [] 5.7.1 [], Or under:
Four.	Products covered (HS heading or NCCA where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Antivenenos
5.	Title, number of pages and language (s) of the notified document: Decree 821 of 2017 <i>"Whereby emergency technical regulations for obtaining sanitary registration of antivenom is established and the Guide to Good Manufacturing Practices for manufacturing is adopted"</i> (25 page (s), in Spanish)
6	Description of the content: It establishes the sanitary requirements that must be met by those interested in importing or manufacturing within the national territory antivenoms that are used in the treatment of accidents caused by venomous animals and adopting the Guide to Good Manufacturing Practices for the manufacture of Antivenenos. Purpose, Field of Application, Definitions, Procedure for the application of Sanitary Records of Antivenenos, Pharmacological Evaluation for the Obtention of the Sanitary Record of Antivenenos, Pharmaceutical Evaluation of Antivenenos for the Obtention of the Sanitary Record of Antivenenos, Legal Evaluation for the Obtention of the Sanitary Registry Of Antivenenos, Renewal of Sanitary Registration, Modifications of Sanitary Registry, Exhaustion of Stock of Products and Packages in the Market, Certificate of Good Manufacturing Practices and Release of Antivenenos Lots, Certificate of Good Manufacturing Practices, Release of Antivenenos Batches, Pharmacovigilance, Inspection, Surveillance, and Control and Provision of Antivenoms and Final Provisions.
7.	Objective and rationale, including, where applicable, the nature of urgent problems: Protecting human life and health (For public health reasons, and given the threat of sanitation due to the persistence of increased notifications of accidents caused by poisonous animals, it is necessary to determine specific emergency health regulations, aimed at establishing the requirements Of local manufacture and import of antivenoms used in the country, through an emergency technical regulation that provides sanitary requirements without prejudice to their quality, safety and efficacy.
8.	Relevant documents: Decree 677 of 1995
9.	Proposed date of adoption: Date signed Proposed date of entry into force: 16 May 2017
10.	Final date for comments: Does not apply
eleven.	Texts available from: National inquiry point [X] or address, telephone and fax numbers and e-mail addresses and Web site addresses , if available of the other body:

Point of Contact:

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And it's also available here:

https://members.wto.org/crnattach/members/2017/TBT/COL/17_2517_00_s.pdf