ORT_37 - Normal human immunoglobulin - post product analysis market

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Introduction: Normal Human Immunoglobulin (Ig) is a sterile solution or lyophilisate that contains several antibodies, mainly of the IgG class, present in the blood of normal individuals. In response to the need for human Ig products, mainly intended for patients with severe COVID-19, ANVISA promulgated Resolution RDC Nº. 563/21, which provides, in an extraordinary and temporary manner, the requirements for the import and use of human Ig , due to the international public health emergency related to SARS-CoV-2, making imported products available on the national market without registration with ANVISA. According to art. 9th, batches of imported human Ig may only be intended for use, after technical release of the Import License, by INCQS, under the terms of Resolution RDC no 58, of 12/17/2010.

Objectives: This work aimed to present the results of monitoring batches of normal human Ig sent for analysis at INCQS from 01/01/2022 to 12/31/2022.

Methodology: The information registered in the INCQS sample management system, Harpya, version 2.5.015, during the evaluated period was used, as well as a notebook of blood products and process unarchiving and an Excel® spreadsheet was created for data analysis.

Results: The 800 lots of human Ig analyzed were distributed as follows: 696 (87%), lots were unregistered and were acquired on an exceptional basis and 104 (13%), were registered and are routinely sold in the country. The exceptionally imported products were manufactured in 6 different countries: China; Argentina; South Korea; India; Sweden and Ukraine. Regarding those requesting analysis: 488 (61%), batches of products were purchased by the Ministry of Health; 312 lots (39%), by private importers. A total of 786 (98%) batches obtained SATISFACTORY results and 14 (2.0%) batches were considered UNSATISFACTORY, due to the absence of essential documents for product approval or safety testing, and were not distributed to patients.

Conclusion: Continuous monitoring of the quality of normal human Ig distributed for consumption, with the purpose of evaluating compliance regarding guarantee, efficacy and safety, is an instrument for exercising Health Surveillance action, which aims to eliminate, reduce or prevent risks to population health. The unsatisfactory batches were not distributed in the health network, and consequently were not used, thus avoiding the occurrence of risks or health problems.

Keywords: Normal Human Immunoglobulin; Exceptionality; Quality control