



# Drug Ads' Restrictions Limited by Brazil's Superior Court

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September 3, 2024

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In a groundbreaking decision, the First Chamber of the Superior Court of Justice of Brazil ("STJ") ruled that the National Health Surveillance Agency ("Anvisa") lacks the authority to impose restrictions on the advertising practices of pharmaceutical companies if those regulations conflict with the standards set by relevant legislation. This ruling came in response to a lawsuit filed by a pharmaceutical company against Anvisa, seeking to suspend sanctions imposed for violating Anvisa's Resolution-RDC No. 96/08.

Anvisa is a regulatory body linked to Brazil's Ministry of Health, responsible for overseeing and regulating drugs, foods, cosmetics, and health products. It establishes standards to ensure the safety and effectiveness of those products and plays a crucial role in protecting public health, including overseeing the advertising and promotion of health-related items.

Resolution-RDC No. 96/08, enacted in December 2008, sets guidelines for the advertising and commercial promotion of drugs. It aims to prevent inappropriate use and self-medication by imposing

restrictions such as bans on indirect advertising in films and shows and requiring warnings about side effects. While designed to safeguard public health, RDC No. 96/08 has faced controversy regarding its compliance with federal legislation, which has led to ongoing debates about the extent of Anvisa's regulatory authority in Brazil.

In the mentioned lawsuit<sup>[1]</sup>, the Plaintiff argued that Anvisa overstepped its authority by imposing restrictions not authorized by law. Both the lower court and the Federal Regional Court of the 1st Region accepted this argument, emphasizing that the regulation of drugs' advertising falls exclusively under federal legislation, as established by the 1988 Federal Constitution.

At the appellate level, Minister Regina Helena Costa, the rapporteur for the case at the STJ, emphasized that while the Federal Constitution permits restrictions on commercial advertising of certain products to protect public health, such limitations must comply with the law. In this context, the rapporteur noted that RDC No. 96/08 exceeded the boundaries established by Law No. 9.294/96, which regulates restrictions on the use and advertising of tobacco products, alcoholic beverages, drugs, therapies, and agricultural pesticides. Consequently, RDC No. 96/08 was found to impose obligations that were deemed illegal.

The STJ concluded by recognizing the need to update Brazil's legislation on mdrugs' advertising, particularly in light of new technologies and the increasing use of the internet. However, it emphasized that any modifications to advertising restrictions should be made through legislative amendments. In a gesture of institutional dialogue, the rapporteur recommended that the Judiciary inform the Ministry of Health and the National Congress about the decision to

evaluate the necessity of revising the current legislation.

[1] Special Appeal No. 2035645/DF (2022/0236370-0)