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Navigating Brazil's Regulatory Landscape: Trademarks issues and the naming of Pharmaceutical Products.

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DANIEL

INDEX

BRAZILIAN
HEALTH SYSTEM

BRAZILIAN HEALTH SYSTEM

10% of GDP comes from the healthcare industry, with pharmaceuticals accounting for **3%**.

2,2
TRILLION GDP

213
MILLION

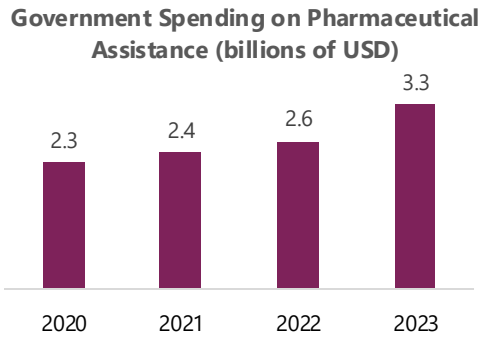
8,5
MILLION KM²

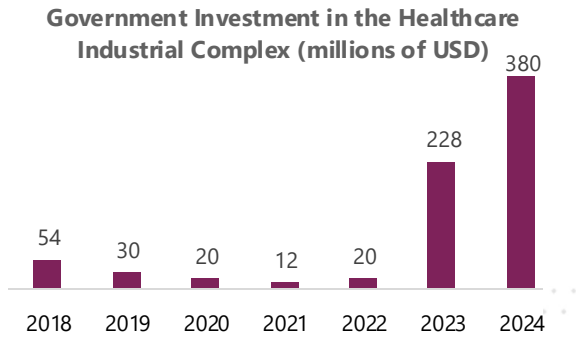
Publicly Funded Medication Access

- In 2024, the 'People's Pharmacy' program benefited 24 million people by providing 41 basic medicines and medical supplies free of charge.
- In addition to basic medicines, the government provides pharmaceuticals from a list of 519 substances, including those for medium- and high-complexity care.
- Free vaccine administration at public health clinics (over 100 million doses administered each year)

Dual Healthcare System

- Largest universal public healthcare system in the world, including primary, medium-complexity and high-complexity care.
- Private healthcare provided through around 1000 health insurers to over 52 million people.





Sources: Brazilian Ministry of Health, Brazilian National Treasury, IBGE, DATASUS, ANS, ANVISA - SCMED

ANVISA AND THE BPTO SCOPE
IN THE NAMING OF MEDICINES

ANVISA AND THE BPTO SCOPE IN THE NAMING OF MEDICINES

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The BPTO (Trademark Office) and ANVISA (Brazilian Health Regulatory Agency) perform independent analysis with different purposes and set of rules regarding the registrability of trademarks and medicine names:

- **ANVISA:** The regulations regarding the naming of medicines are ruled by **ANVISA's Resolution 59/2014**. These provisions aim to prevent potential health risks to the population.
- **BPTO:** Analysis of the registrability of marks based solely on the provisions of the **Brazilian Industrial Property Law (Law 9.279/1996 – BIPL)**.
- The regulatory registration of a medicine name is **mandatory** for the placement of a medicine on the market while the trademark registration is highly **advisable** (but not mandatory)

Medicines compliant with ANVISA regulations may feature unregistered —or even unregistrable— trademarks with the BPTO.

BRAZILIAN PATENT AND TRADEMARK OFFICE (BPTO)

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Requirements for registrability (BIPL – Law 9,279/96):

- Distinctiveness;
- Lawfulness;
- Availability;
- Compliance with legal prohibitions.

Analysis limited to the BPTO's database and considering both **absolute and relative grounds** for refusal.

Main purpose is to **prevent consumer confusion** and **protect the economic investment** made in the creation and promotion of the mark.

Average timeframes for publication and substantive decision (on application without obstacles) on Madrid or national filings **18 months;** Average time may increase to two to three years in case of a opposition or rejection decision

BRAZILIAN HEALTH REGULATORY AGENCY (ANVISA)

The mark should ***preferably*** follow this criteria (Article 7, Resolution 59/2014):

- One single word;
- Pronunciation in Portuguese related to its spelling;
- **Distinctiveness in relation to INN and other registered medicines**.

Specific and different rules for:

- over the counter drugs,
- families of medicines,
- Suffixes: must distinguish one medicine from the another registered by the same company within the same product line,
- vitamins, minerals, amino acids,
- phytotherapeutics.

Like the BPTO, ANVISA's analysis aims to prevent **consumer confusion**, but with the focus on preserving **individual health and well-being**.

ANVISA AND THE BPTO PROSECUTION AND TIMING

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In Brazil, the approval process for the trade name of a drug by ANVISA is integrated into the general drug registration procedure.

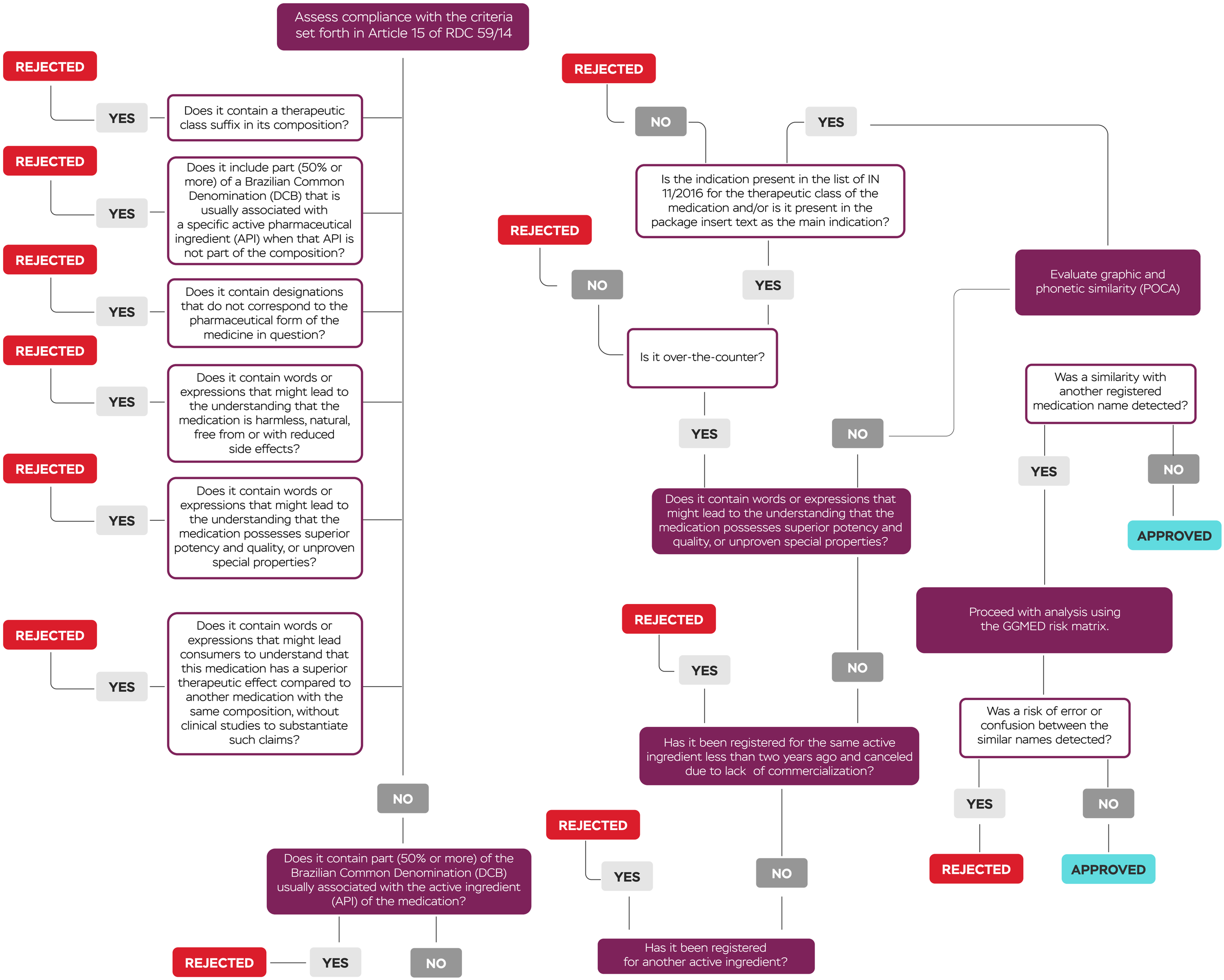
The evaluation of a drug name is made by ANVISA's **General Management of Medicines (GGMED)** using a Risk Matrix and the approval of the trade name is an **essential requirement** for ANVISA to grant the drug registration.

The average total time for granting drug registrations is:

188 DAYS for generics and similar drugs,
276 DAYS for new drugs, and
356 DAYS for innovative drugs.

CLICK TO READ MORE

SCRIPT FOR THE ANALYSIS OF MEDICINE NAMES – GGMED/ANVISA



SOURCE:
https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/medicamentos/bulas-rotulos-e-nome-comercial/arquivos/fluxograma-nomes-de-medicamentos.pdf

BRAZILIAN HEALTH REGULATORY AGENCY (ANVISA) – RDC 59/2014

OTC – may evoke approved main therapeutic indication

BRAZILIAN HEALTH REGULATORY AGENCY (ANVISA) – RDC 59/2014

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Family of medicines – products from the same company must have the same API to be grouped under a common name and only differentiated by complements

Tylenol® DC

Tylenol® Sinus

Tylenol® Criança

Old rules:

Dorflex® Duo


VICK
Qualidade Vick ®
VapoRub®
levomentol 28,2mg, cânfora 52,6mg, óleo de eucalipto 13,3mg
VAPORIZANTE DESCONGESTIONANTE
USO TÓPICO E INALANTE
UNGUENTO
USO ADULTO E PEDIÁTRICO ACIMA DE 2 ANOS
12 g


VICK
Qualidade VICK
Xarope 44E
guaifenesina 13,33 mg/mL
bromidrato de dextrometorfano monoidratado 1,33 mg/mL
EXPECTORANTE E ANTITUSSÍGENO
Para o alívio da tosse que acompanha gripes e resfriados.
Alivia a tosse seca e com catarro.
120 mL
Uso Oral
USO ADULTO E PEDIÁTRICO ACIMA DE 6 ANOS.


VICK
Pyrena
paracetamol 500mg/5g
ANALGÉSICO E ANTITÉRMICO
SABOR MEL E LIMÃO
Para dor de cabeça,
Febre e dores no corpo próprias da gripe
5 g
Uso Oral
USO ADULTO E PEDIÁTRICO ACIMA DE 12 ANOS.
Atenção: Este produto é um medicamento


Vapo Spray
cloreto de sódio 0,9%
DESCONGESTIONANTE EM JATO CONTÍNUO
SPRAY MULTIDIRECIONAL
360°
Qualidade VICK
Para nariz entupido
Sem conservantes
Limpa profundamente
Ajuda a respirar melhor
USO ADULTO E PEDIÁTRICO
100 mL
Vapo Spray
Qualidade VICK
100 mL

RDC 59/2014 – MARK SUFFIXES (“NAME COMPLEMENTS”)

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DISTINGUISH ONE MEDICINE FROM THE ANOTHER REGISTERED BY THE SAME COMPANY WITHIN THE SAME PRODUCT LINE

- ANVISA will not consider the exclusivity of using suffixes for registration purposes.
- The use of the same suffixes with distinct meanings is prohibited.
- **Optional** - suffixes **may** be used to distinguish the route of administration, pharmaceutical form, target population, absorption, or other situations, with a reasoned justification from the company.
- **Mandatory** - medicines with distinct release kinetics, pharmaceutical form, or route of administration within the same **family of medicines must** adopt suffixes.

Applicant must technically justify its request, highlighting how it helps to distinguish the medicines within the same family or from other medicines with similar designations

RDC 59/2014 – MARK SUFFIXES (“NAME COMPLEMENTS”)

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DISTINGUISH ONE MEDICINE FROM THE ANOTHER REGISTERED BY THE SAME COMPANY WITHIN THE SAME PRODUCT LINE

RDC 59/2014 PROHIBITS

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ARTICLE 15

I - suffixes of the common denomination recommended for each therapeutic class of pharmaceutical substances, even if in a position different from the usual one, within the same chemical class or not;

II - part of the common denomination of the drug, not referred to in item I, usually associated with a certain active principle, when this is not part of the medicine composition;

III - abbreviations, isolated letters, random sequences of letters, Arabic or Roman numerals, including in full, without evident meaning to the consumer or having no relationship to the product's characteristics in the case of distinguishing complements;

Source: https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/medicamentos/bulas-rotulos-e-nome-comercial/arquivos/fluxograma-nomes-de-medicamentos.pdf

RDC 59/2014 PROHIBITS

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ARTICLE 15

IV - designations that do not correspond to the pharmaceutical form of the medicine in question;
V - words or expressions that could suggest that the medicine is harmless, natural, free of or with reduced side effects, or has superior potency and quality, or unproven special properties; or
VI - words or expressions that exaggerate a therapeutic action, without clinical studies proving it, and could lead the consumer to believe that such a medicine would have a therapeutic effect superior to another medicine of the same composition;
VII - the name of a medicine that was denied for effectiveness and safety reasons, except when of the same therapeutic indication.
Sole paragraph. ANVISA, in evaluating other situations not foreseen in this article, may refuse the requested name for the medicine due to consumer risk.

Source: https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/medicamentos/bulas-rotulos-e-nome-comercial/arquivos/fluxograma-nomes-de-medicamentos.pdf

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CASES
FOR ANALYSIS

CASES FOR ANALYSIS

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(Case n. 0963482-83.2023.8.19.0001)

FARMOQUÍMICA S.A (FQM) AND DIVCOM S.A V. SUPERA FARMA LABORATORIES

PLAINTIFF´S CLAIMS: Violation of FQM's trademark rights and unfair competition. *Unauthorized use* of the **K TRIZ®** trademark by Supera Farma.

FACTS: The plaintiffs hold the registration for the nominative trademarks **K TRIZ®** and **KATRIZE®**. Defendant was manufacturing products identified with the registered **KTRIZ** trademark.

Plaintiff's Registrations

K TRIZ
KATRIZE

Defendant's use

KTRIZ
KTRIZ GINO
KTRIZ UNO

CASES FOR ANALYSIS

DANIEL

(Case n. 0963482-83.2023.8.19.0001)

FARMOQUÍMICA S.A (FQM) AND DIVCOM S.A V. SUPERA FARMA LABORATORIES

RELEVANT DECISION **The court granted the preliminary injunction.**

In the decision, the judge emphasized that "*The granting of the* ***trademark registration*** *by BPTO demonstrates that the* ***plaintiffs hold exclusive rights to its use***" and recognized the harmful conduct towards the plaintiffs' rights, with the risk of damage that could be, if not irreparable, difficult to remedy.

STATUS

The case has not yet been ruled. **The injunction remains in force.**

CASES 2023/2024 – BPTO DECISION. JUDICIAL APPEAL

Hypera vs. BPTO and Laboratil

FIRST –TO-FILE RULE AND BAD FAITH

- Despite the oppositions, the Brazilian PTO (INPI) granted the trademark registration for BUSCOVERAN, which uses the prefix and suffix of two prior trademark registrations on behalf of the same company (Hypera).
- In spite of the dilution of the prefix BUSCO at the BPTO, the Federal Trial Court annulled BUSCOVERAN registration and ordered the cessation of the trademark use.
- The Federal Court usually takes into consideration bad faith and unfair competition issues. These issues or grounds are not usually considered by the BPTO.

BUSCOPAN

+

ATROVERAN = BUSCOVERAN

CASES FOR ANALYSIS

DANIEL

Case n. 5014526-14.2020.4.02.5101

BLAU PHARMACEUTICAL S.A. V. APSEN PHARMACEUTICAL S.A

ISSUE: **annulment of the BPTO's rejection** of application for **DNAREN** based on the prior registration for **DONAREN**.

PLAINTIFF'S CLAIMS: Lack of confusion because

(i) DNAREN is a drug for exclusive use in **hospitals**, whereas DONAREN is an antidepressant sold in **pharmacies**;

(ii) **ANVISA approved** DNAREN, deeming there to be no risk of confusion with other trademarks;

(iii) the **forms of presentation**, as well as the target **consumer base**, are completely different.

BPTO's Position **Dismissal of the plaintiff's claim.**

Impossibility of coexistence between the marks:

- Same market segment;
- Similarities between the expressions **DNAREN** and **DONAREN**.

CASES FOR ANALYSIS

DANIEL

BLAU PHARMACEUTICAL S.A. V. APSEN PHARMACEUTICAL S.A

RULING

Annulment request was **denied**.

Plaintiff's first sanitary registration for **DNAREN** dated back to the early 2000s.

Since then, the regulation of pharmaceuticals in Brazil has undergone significant changes, and **there is now a requirement for drug names to have sufficient graphic and phonetic distinction from other registered drugs** (Article 7 of RDC 59/2014).

Therefore, the decision to refuse the trademark registration by the **BPTO** was *fully aligned* with the current regulatory framework.

ADVERTISING REGULATIONS

In Brazil, advertising of medicines are very restricted by **ANVISA**.

In addition, for ANVISA restrictions all advertising must comply with regulations from **CONAR (National Council for Advertising Self-Regulation)**.

If an advertisement violates any of the CONAR's Code, it can be reported and face administrative penalty.

ADVERTISING OF MEDICINES: GENERAL ASPECTS

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ANVISA's Resolution 96/2008

Rules for the **promotion** and **commercial advertising** of medicines in Brazil.

- The advertising **can only be conducted for OTC (over-the-counter) medicines.**

Key Restrictions Set by Resolution 96/2008

- Prohibition on promoting the **indiscriminate use** of medications.
- Prohibition on featuring **images of individuals using the medication.**
- Prohibition on **language imperatives** that directly encourage medication consumption.

ADVERTISING OF MEDICINES: GENERAL ASPECTS

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CONAR's Rules/Principles

MAIN PRINCIPLE
Truth/Veracity and Honesty

Main reasons for challenges

- **Transparency**
- **Prohibition of Deception or Misleading**
- **Loyal and fair Comparative Advertisings**
- **Non violation of IP rights**
- **Advertising indication**

CASES FOR ANALYSIS

CONAR V. CELLERA PHARMACEUTICAL

SUMMARY

Cellera Farmacêutica's advertisement via a local influencer on TikTok **violated CONAR's regulations** because it involved the promotion of a **prescription drug** in a mass media platform.

In its defense, **Cellera denied any involvement in the advertisement**, claiming they neither authorized nor contracted the promotion.

DECISION

The rapporteur **accepted Cellera's defense and proposed that the case be closed**, which was unanimously accepted.

Following the decision, CONAR **approved a motion to notify TikTok**, **relevant authorities (especially ANVISA), and professional associations** (e.g., the Federal Pharmacy Council and Brazilian Pharmacy Networks Association) about the case, emphasizing concerns over the marketing of prescription drugs through social media.

CASES FOR ANALYSIS

DANIEL

CONAR V. SANOFI MEDLEY PHARMACEUTICAL

SUMMARY

A laxative ad, posted on social media (X/Twitter), was considered to promote **irresponsible behavior by linking the product to compensation for overeating**.

The ad depicted a character surrounded by food, joyfully stating, "*Indulging is delightful!*" and reinforcing the message with other phrases about food overconsumption.

Sanofi Medley defended the ad, stating they used humor to communicate the product's properties, emphasizing that the laxative doesn't require a prescription and **denying it would lead to any misuse of the medication**.

The rapporteur concluded that the ad implied excessive consumption of food, contradicting CONAR's Code principles.

DECISION

As a result, the rapporteur recommended **suspending the ad** and issuing a warning to Sanofi Medley. This decision was unanimously accepted.

Brazilian Advertising Self Regulation – CONAR HANDLES IP MATTERS

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Hypera vs. HALEON

TRADEMARK INFRINGEMENT

- **Neosa** and **Neosaldina** are registered Brazilian Trademarks on behalf of Hypera.
- Conar considered the use of the Hypera' registered trademark as unnecessary and the campaign as non-objective.
- Decision: Suspension of campaign.

- I have a headache
- Call Neosa
Neosa is the name of the lady who suggests an Advil
- Even Neosa knows it.

https://www.youtube.com/watch?v=_RW3xYwSCTQ

Thank you!

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