



Advertising & Promotion of Drugs and Medical Devices

September 25, 2018, São Paulo

Seton Hall | Law
Latin America Healthcare Compliance Program



Advertising & Promotion of Drugs and Medical Devices

Part I - Opening Presentations: Adrián del Paso (15min)

September 25, 2018, São Paulo

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LBARRA
DEL PASO Y GALLEGOS

Off-label Promotion in Mexico

Adrián del Paso

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Latin America Healthcare Compliance Program

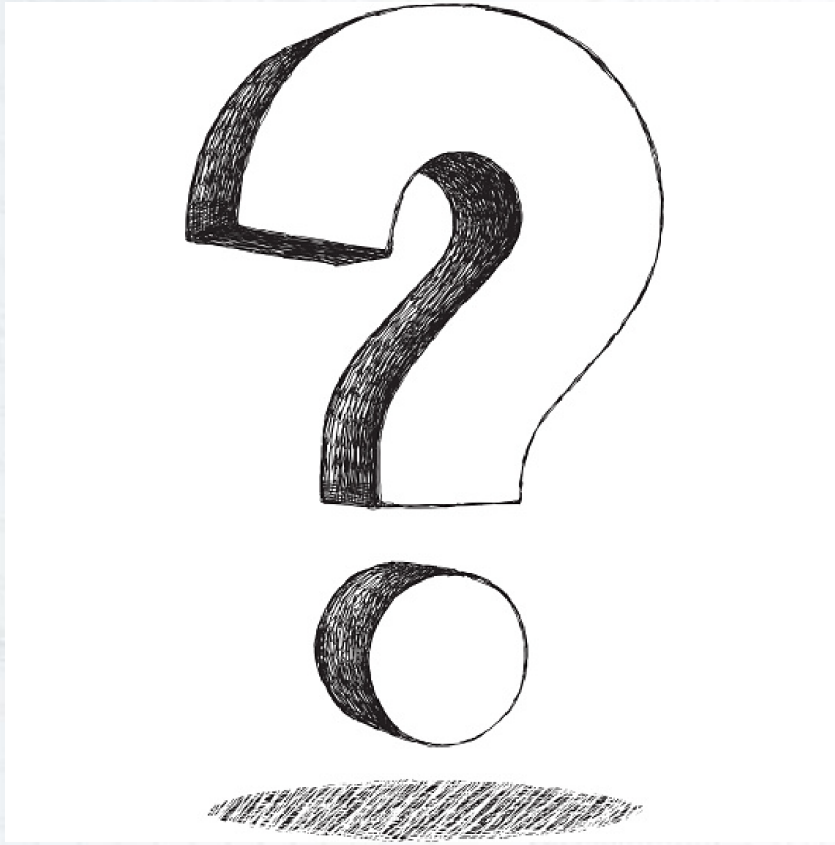
September 25, 2018, São Paulo

Road map

1. Off-label activities – Reminder
2. International facts regarding off-label prescription activities (and influence from companies)
3. Main rules applicable to OLP
4. Promotion of drug and devices – Web and social media/web based platforms
5. Gray areas and risks of OLP
6. Tips to differentiate scientific discussions from OLP
7. OLP – Do's and Don'ts from a compliance perspective
8. Conclusions and recommendations



Off-label activities – Reminder



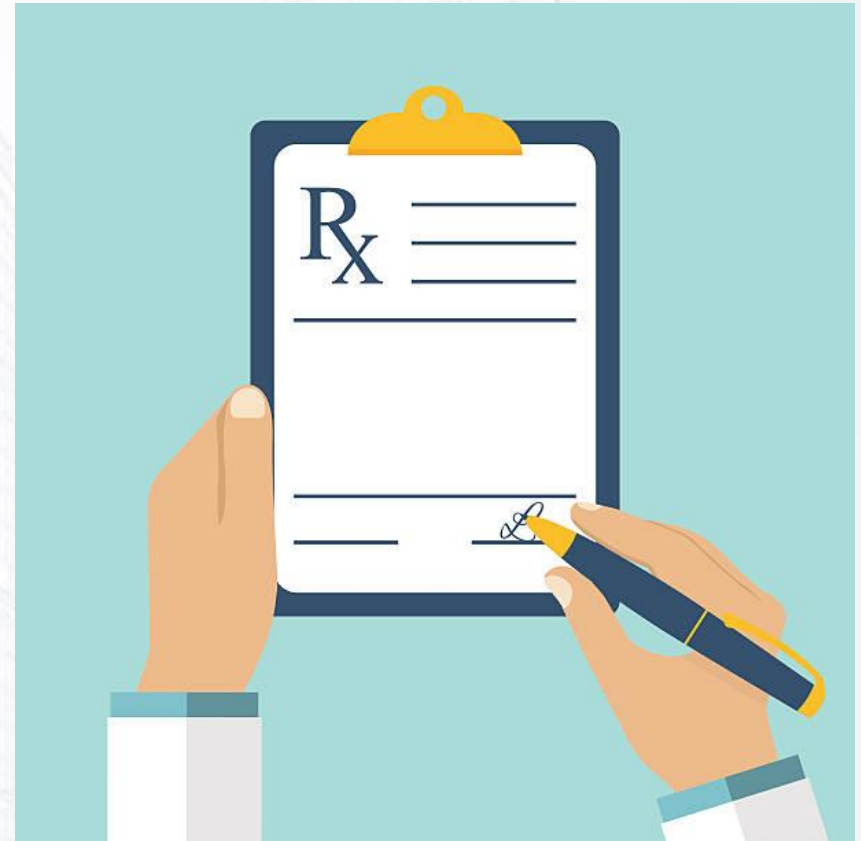
- Off-label prescription/Off-label use (**OLU**)-
Prescribing/using drugs for **non-approved**
indications or dosages

e.g., Pediatrics and oncology

- Off-label promotion (**OLP**) - **Any activity** that may
comprehend the creation, planning, execution and
diffusion of **promotional materials** in the media,
including oral communications or other forms for
fostering the above

Off-label activities (and influence from companies) – International facts

- **One** in **five** prescriptions written today in the US are for **off-label use** (Agency for Healthcare Research and Quality, Unit of the United States Department of Health and Human Services)
- A 2012 survey of 1,038 medical students across eight German university hospitals found that 24.6% of respondents believed **gifts** would **influence** their future **prescribing behavior**, while 45.1% thought gifts would influence their classmates' future prescribing behavior



Main rules applicable to OLP

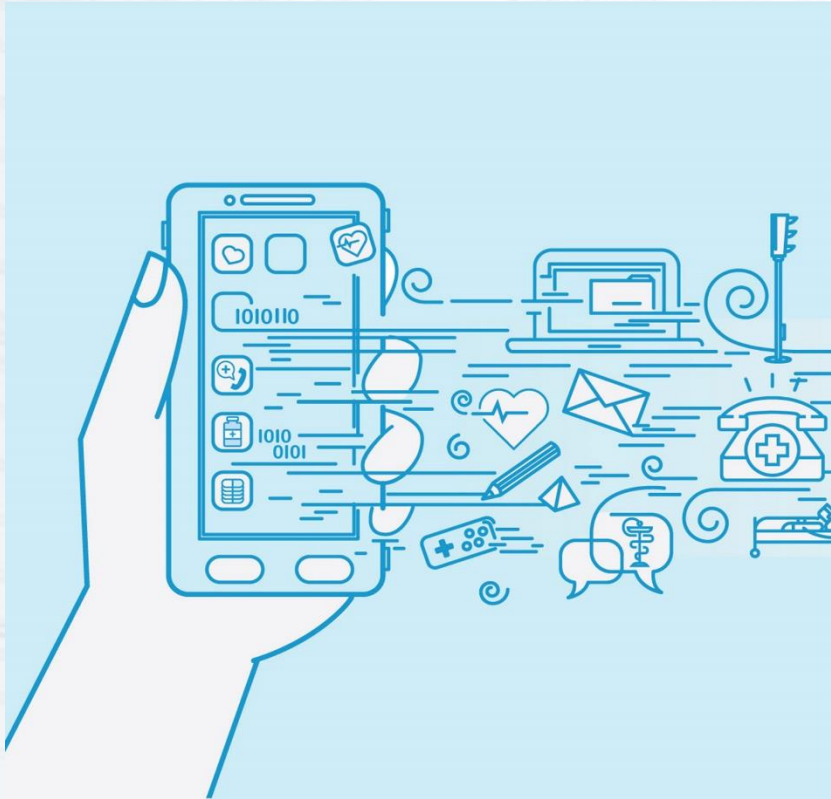
General requirement to avoid OLP

- **On Label** - To comply with the therapeutic indications/uses authorized in the relevant Sanitary Registry issued by COFEPRIS (for **OTC, Rx and medical devices, regardless of** what may be authorized for the same product in **other countries, including uses and target groups**) and to obtain relevant promotion permits when applicable

Consistency, orientation and educational principles

- Qualities shall correspond to **function or use (as authorized)**
- Promotion shall refer to the **specifications, properties and real uses acknowledged by COFEPRIS**
- Promotion shall only proceed when adjusted to **prescribing information and specifications of the Sanitary Registry** (and vice versa)

Promotion of drugs and devices – Web and social media



Main rules as per applicable Regulations in Mexico

Promotion requires:

- A previously authorized product by COFEPRIS (Sanitary Registry)
- A specific promotion permit issued by COFEPRIS, which shall be consistent with the corresponding prescribing information and the Sanitary Registry
- Advertising media/marketing and advertising agencies shall only proceed when the aforementioned items are duly evidenced by the advertising party

Gray areas and risks of OLP



- **Non-written Promotion/Detailing - Involvement of MSRs with HCPs**
- **Areas of opportunity regarding acts and conducts influencing HCPs (gifts, events and others)**
- **Scarce provisions of web and social media promotion of drugs and devices**
- **Lack of comprehensive legal provisions on governmental enforcement (limited audit/control from authorities) and counterbalance measures taken by Mexican Pharma and Devices Associations and companies**
- **Voluntary adherence of pharma and devices companies to CETIFARMA's Codes and self regulation/control of pharma and devices companies - International vs local Companies**
- **Scientific presentations by speakers in medical events - review/approval by companies**

Tips to differentiate scientific discussions from OLP

- **Key to scientific exchange: Non-promotional**
- Only **Medical/Scientific Personnel** (members of the company's **Medical Department**) from relevant companies may discuss **off-label indications with HCPs** (reactive approach rather than proactive)
- Only unsolicited off-label scientific discussions. **No solicited OLP**
- Clearly **separate scientific input from promotional messaging**
- **Product claims** shall **not be stronger than** what **scientific evidence** can support (use of superlatives such as “the best”, “strongest”, “safest” or others)
- **Balanced and referenced promotional materials** (claims-risks)



OLP - Do's from a compliance perspective

Do's

- Information consistent with: *i*) applicable legal and regulatory standards; *ii*) specifications of Sanitary Registry (Marketing Authorization); and *iii*) prescribing information
- General Promotion – Only of registered and authorized products in the country where such activities will be developed
- Promotion of Rx products - Strictly when addressed to HCPs (particular focus on online promotion)
- Duly train, establish clear rules and supervise non-written or non-authorized promotion by Medical Sales Representatives (MSRs)/Medical Science Liaisons (MSLs) with HCPs
- Foster MSLs' discussions and involvement with HCPs (rather than MSRs) only in response or reaction to unsolicited queries or requests. Leave evidence in writing
- Establish complaint mechanisms and channels for HCPs to report deviations to Compliance Officers of relevant companies



OLP - Don'ts from a compliance perspective

Don'ts

- Foster non-approved scientific information or indications / unsolicited OLP with HCP's
- Foster promotion to HCPs whose specialty/subspecialty make them unlikely for on label prescription
- Link company benefits to MSRs depending on HCP's prescriptions



Conclusions and recommendations

- Importance of avoiding OLP – Place patient safety and health as key concern
- OLP and OLU of Drugs and Devices may jeopardize science and medical practice (having a direct impact on patient's health) when not undertaken under strict compliance and ethics standards
- Extend compliance and ethics standards not only to relevant companies' personnel, but also to related third parties
- In interactions with HCPs, foster increasing involvement of MSLs rather than MSRs
- Standardize internal compliance standards (using the most stringent), specially in jurisdictions where OLP and OLU may be weakly or not sufficiently regulated, thus avoiding gray areas and risks (FDA)





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DEL PASO Y GALLEGOS

Thank You

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Advertising & Promotion of Drugs and Medical Devices

Part I - Opening Presentations: Ignacio Gillmore (15min)

September 25, 2018, São Paulo

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COMPARATIVE ADVERTISING IN CHILE

IGNACIO GILLMORE



Chile – Road map

1. General rules and principles for advertising and promotion of drugs and medical devices.
2. Comparative advertising.
3. Case study.
4. Conclusions and recommendations.

ADVERTISING & PROMOTION OF PHARMACEUTICALS AND DEVICES

GENERAL REGULATORY ASPECTS

Chile – Pharmaceutical Products

ADVERTISING



General public /
Free media format

**PROMOTION or
INFORMATION
TO THE HCP**



Professionals legally entitled to
prescribe or dispense drugs

GENERAL RULES AND PRINCIPLES

1. OTC drugs only. →
2. Previously approved by the regulatory authority (“ISP”).
3. Within the sanitary registration scope (MA) - “on label”.
4. Truthfulness and susceptibility of scientific verification.
5. Not misleading.



Chile – **PROMOTION OR INFORMATION TO THE PROFESSIONAL**

GENERAL RULES AND PRINCIPLES

1. OTC + RX



2. Within the sanitary registration (MA) – exception for “off label” information.
3. Truthfulness and susceptibility of scientific verification.
4. Not misleading

MEDICAL DEVICES

- ✚ Lack of specialized regulation
- ✚ General rules and principles of pharmaceutical products and general legislation

COMPARATIVE ADVERTISING

COMPARATIVE ADVERTISING

Non-unified legislative scope

SANITARY REGULATION

(Supreme decree 03/2010 –
Sanitary Code)

**ETHICS
REGULATION**
(CONAR)

**UNFAIR
COMPETITION**
(Law 20,169)

**ANTITRUST
REGULATION**
(LD 211)

**CONSUMER
REGULATION**
(Law 19,496)

Chile – Comparative advertising

SANITARY REGULATION

1

- Sectorial regulation
- Not organically regulated / only some provisions in promotion for HCPs:
 - Comparison with other products having the same API shall be supported with relevant studies.
 - Common features or characteristics of pharmaceutical products cannot be claimed as exclusive for a single product.
- Must comply with the **general requirements** for advertising or promotion.

TRUTHFUL + SCIENTIFICALLY VERIFIABLE + NOT MISLEADING

Chile – Comparative advertising

CONAR ETHIC CODE REGULATION.

2

- Supplementary and self-regulatory provisions.
- Wide concept of advertising (advertising + promotion): *“all activity of communication directed to the public or a part thereof intending to influence their opinions and behavior through any means, including promotion, placement and other activities with promotional, commercial and/or competitive purposes”*.
- Comparative advertising →
 - **Compares** products implicitly or explicitly, to assert superiority or advantage.
 - **Identifies** the competition **or suggests the competition** (name, packaging, attribute or element of a competitor).

Chile – Comparative advertising

CONAR ETHIC CODE REGULATION.

2

- Comparative advertising: Acceptable but regulated.

Principles

Based in **objective background** that can be reliably verified

Cannot rely on exaggerations or other advertising licenses.

Exclusionary or “absolute” claims must be verifiable.

Guidelines

Compare products for the **same purpose** or aimed for the same needs.

Compare characteristics **objectively, truthfully and verifiably**.

Cannot lead to confusion between trademarks or advertiser w/ competitor

Cannot constitute **unfair competition or denigration or slander of the competitor**.

General claims (pharma)

Eg. “better”, “faster”, “safer” must be verifiable.

Chile – Comparative advertising

EXAMPLES - CONAR

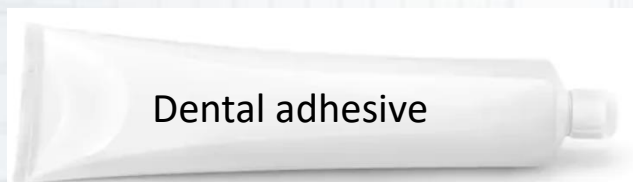
2



- **Pharma:** *“I am a drug”, “My active ingrediente helps to eliminate dandruff”*
- **Cosmetic:** *“I don’t, because I’m a cosmetic and...”*
- **Pharma:** *“Because you’re a cosmetic?, “If you want to eliminate the fungus of dandruff, look for me in the pharmacy”*

CONAR: “The superiority claims of the product regarding a cosmetic shampoo are justified and thus no infringement is configured”

CONAR:



“N°1 Brand” claim: So general it becomes ambiguous, the feature where the product is superior is not clear. **Not verified.**

Comparative advertising could be considered an ...

- ✚ **Unfair competition act** → Untruthful & non verifiable information
“*all comparison of products [...] based upon non verifiable or truthful information*”
- ✚ **Act against free competition** → Untruthful & non verifiable information
+
Purpose of **reaching, maintaining or increase a dominant market position.**

Chile – Comparative advertising ANTITRUST & FAIR COMPETITION REGULATION.

3

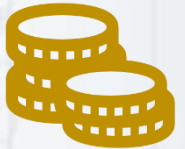
📌 Unfair competition act

Sanctions:

Cease or prohibition of the act + economic compensation

Remission to specialized court → up to approx. \$70.000 USD

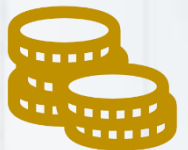
CIVIL COURT



📌 Act against free competition

Sanctions: Cease of the act, fines up to approx. \$18 million USD.

ANTITRUST
COURT



Chile – Comparative advertising

CONSUMER REGULATION

4

- Supplementary regulation

**SAME PRINCIPLES IN
CONSUMER
REGULATION**



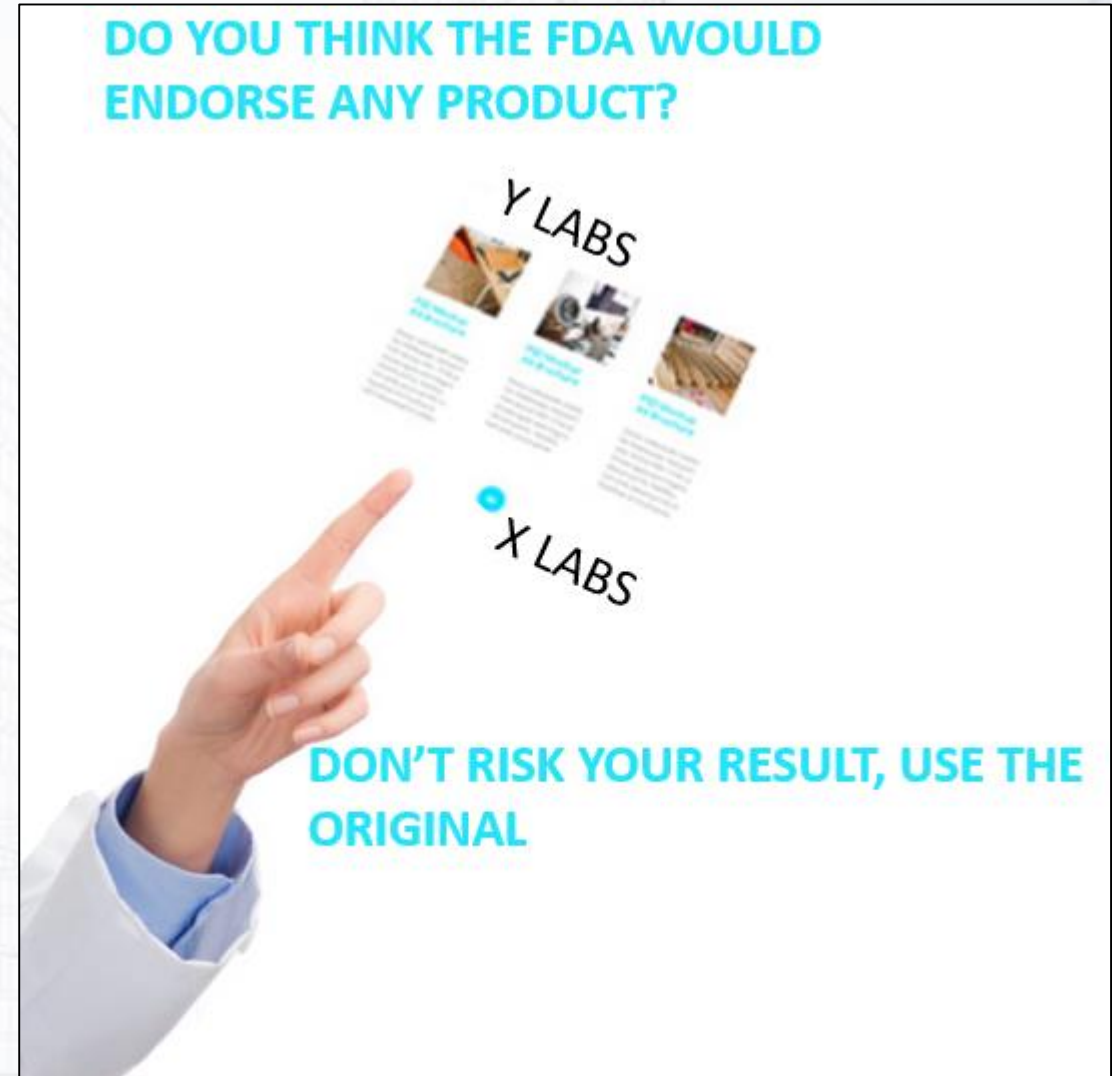
TRUTHFUL + VERIFIABLE + NOT MISLEADING

- Comparative advertising which is not supported may be considered false or misleading advertising subject to fines.

Chile – Comparative advertising CASE STUDY

JURISPRUDENTIAL CRITERIA

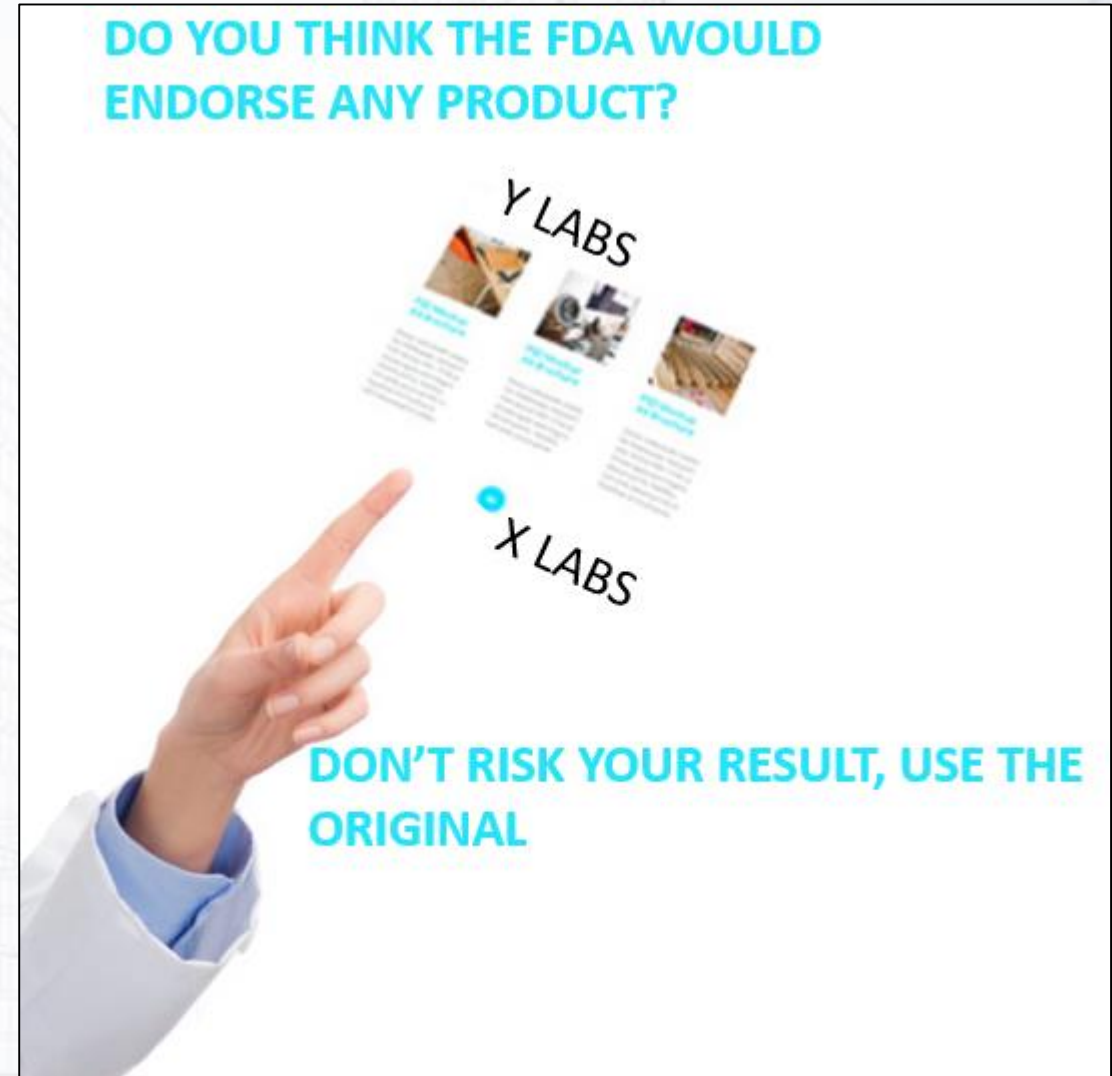
¿Lawful or unlawful
comparative advertisement?



Chile – Comparative advertising CASE STUDY

*“It is evidently **inductive to error** since, indirectly, imputes to the competitor flaws in the production of the product, and **tries to discredit the same, not having verified the information**, presumably, with the purpose of increasing its participation in the market at the expense of its closest competitor, which configures a typical act of **unfair competition**”.*

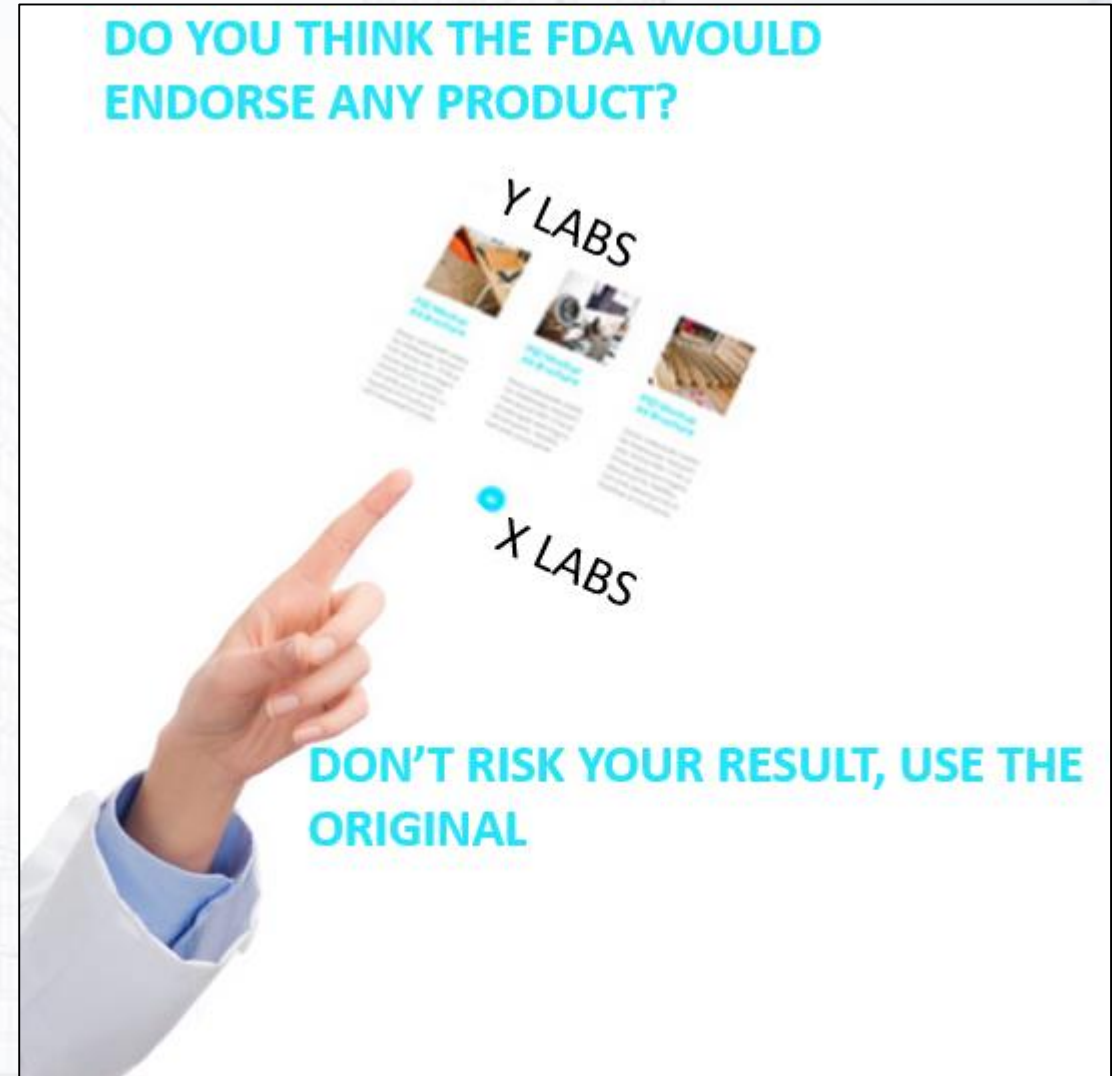
Opinion N° 08/2004, Antitrust Court, September 22th, 2004.



Chile – Comparative advertising CASE STUDY

*“Comparative advertising shall be **truthful, sufficient, objective and grounded**, this is, orientated to catch the consumer preferences through persuasive strategies, based in objective and relevant elements associated to the behavior and needs of the consumer”.*

Opinion N° 08/2004, Antitrust Court, September 22th, 2004.



Chile – COMPLIANCE RECOMMENDATIONS

NEVER



MISLEAD



DISCREDIT

WHETHER IT
IS THROUGH

**Advertising
campaigns**

**Information or any
kind of relationship
w/ healthcare
specialists.**

Chile – COMPLIANCE RECOMMENDATIONS

ALWAYS



**HAVE SCIENTIFIC
BACK UP**



OBJECTIVE

ACCURATE

VERIFIABLE



**REVIEW THE
WORDING PRIOR TO
LAUNCH**



**BE EMPATHIC /
COMPETITOR
INTELLIGENCE**



CHECK WITH LEGAL

/Carey
ABOGADOS

THANK YOU





Advertising & Promotion of Drugs and Medical Devices

Part I - Opening Presentations: Angela Kung (15min)

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Promotion and Advertising in Brazil

Angela Kung

Seton Hall | Law
Latin America Healthcare Compliance Program
September 25, 2018, São Paulo

Brazil

1. Principles for Promotion and Advertising
2. Marketing Strategy x Scientific Discussion
3. Points of concern

Brazil - Promotion and Advertising of Medicines

Principle: complete, correct and clear information

- Must observe the Advertising law, Consumer Protection Code and ANVISA's rules
- INTERFARMA Code of Ethics applicable to the associates and as self regulation standard

Brazil - Promotion and Advertising of Medicines

➤ Advertising of medicines shall not:

- be misleading
- be abusive
- be indirect
- encourage and/or induce indiscriminate use of medicines
- suggest or encourage diagnoses
- display images of persons making use of the medicine
- include any certification seals
- be present in any part of the medical prescription pad

Brazil - Promotion and Advertising of Medicines

➤ Free samples are advertising tool:

- prohibited for biologicals
- require special packaging
- contain at least 50% of the quantity of the commercial
- contraceptive must have the same content of commercial presentation
- can only be dispensed through the physician

➤ OTC can be advertised to the public in general

➤ **Rx can only be advertised to health professionals qualified to prescribe or dispense said product**

Brazil - Marketing Strategy x Scientific Discussion

- Promotion at hospitals and clinics
- Advisory Boards
- Speaker Programs
- Mini Meetings
- Consultancy Agreement

Brazil - Points of Concern

- Promotional x Scientific intent
 - Commercial area x medical area
 - If commercial, all rules for advertising shall be observed
- Audience
 - Prescribers x non-prescribers
- Interactions with KOL (governmental officials)
 - Majority of the KOLs are GO (professor of Federal Universities)
- Conflict of Interest
 - Technical Advisory Committee
 - Decision maker (purchases)

Brazil - Points of Concern

➤ Promotion at hospitals and clinics

- Only institutional gifts
- Free samples
- Reactive off label discussion
- MSL's role
- Audience - interactions with HCPs (nurses and pharmacists)

Brazil - Points of Concern

➤ Advisory Boards

- KOLs screening
- Scientific content
- Conflict of Interest

➤ Speaker Program

- KOLs screening
- Scientific content
- Conflict of Interest
- Audience

Brazil - Points of Concern

➤ Mini Meetings

- KOL screening
- Reactive off label discussion
- Commercial x Scientific discussion (Sales Rep and MSL's role)
- Rules of the public institution
- Audience - interactions with HCPs (nurses and pharmacists)

➤ Consultancy Agreements

- KOL screening
- FMV
- Conflict of Interest

PINHEIRONETO

ADVOGADOS

Thank you!

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Advertising & Promotion of Drugs and Medical Devices

Part II - Mediator & Audience Q&A (until 12h50m)

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