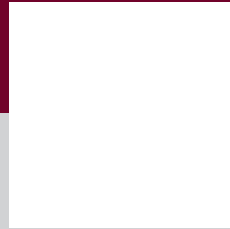


PINHEIRO NETO
ADVOGADOS



Lessons from the Trenches – Brazil

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Summary

- The Brazilian Health System
- Entities involved
- Regulations applicable
- Relevant issues on clinical trials
- Relevant issues on safety and efficacy of drugs
- Aspects to be considered
- Judicial Review

Brazilian Health System

- Administrative entities
- Difficulties on interaction between several agencies
- Similar powers of federal and state agencies
- Extensive and non-codified regulation
- Limited number of precedents and case-by-case review
- Protective approach to patients/consumers

Entities Involved

- National Agency for Sanitary Surveillance - ANVISA
- Local/State Entities
- Differences in the interpretation of statutes and regulations
- Powers of ANVISA
- Powers of Local Entities
- Involvement/Power of the Ministry of Health
- Interaction with foreign entities

Regulations Applicable

- Extensive and non-codified regulations
- Broad language to allow room for interpretation
- Limited use of precedents: lack of reliable database
- General interpretation is as strict and protective as possible
- International standards

Regulations Applicable

- Main aspects to be considered:
 - Civil
 - Criminal
 - Consumer
 - Constitutional
 - ANVISA's Regulations

Relevant Issues on Clinical Trials

- Protective approach
- Political issues
- Ethical Committees
- Involvement of Ministry of Health
- Need of review and development

Relevant Issues on Safety and Efficacy of Drugs

- Reference Drugs, Non-Branded Generics and Branded Generics
- Issues involving Branded Generics
- Transition period and issues on safety and efficacy
- Legal definition and tests required
- Price issues
- Political pressure

Aspects to Be Considered

- Limited number of precedents
- Decisions are not made public
- Case-by-case interpretation: uncertainty
- Political pressure
- Domestic and Foreign Pharma Companies
- Need to increase judicial review

Judicial Review

- Limited number of cases submitted to court review
- Complexity of issues to the courts
- Courts hesitance to analyze issues (limitations on the legality of the acts)
- Concerns of political pressure

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