

Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Preconference IV: Is Brazil the Next Hot Spot?

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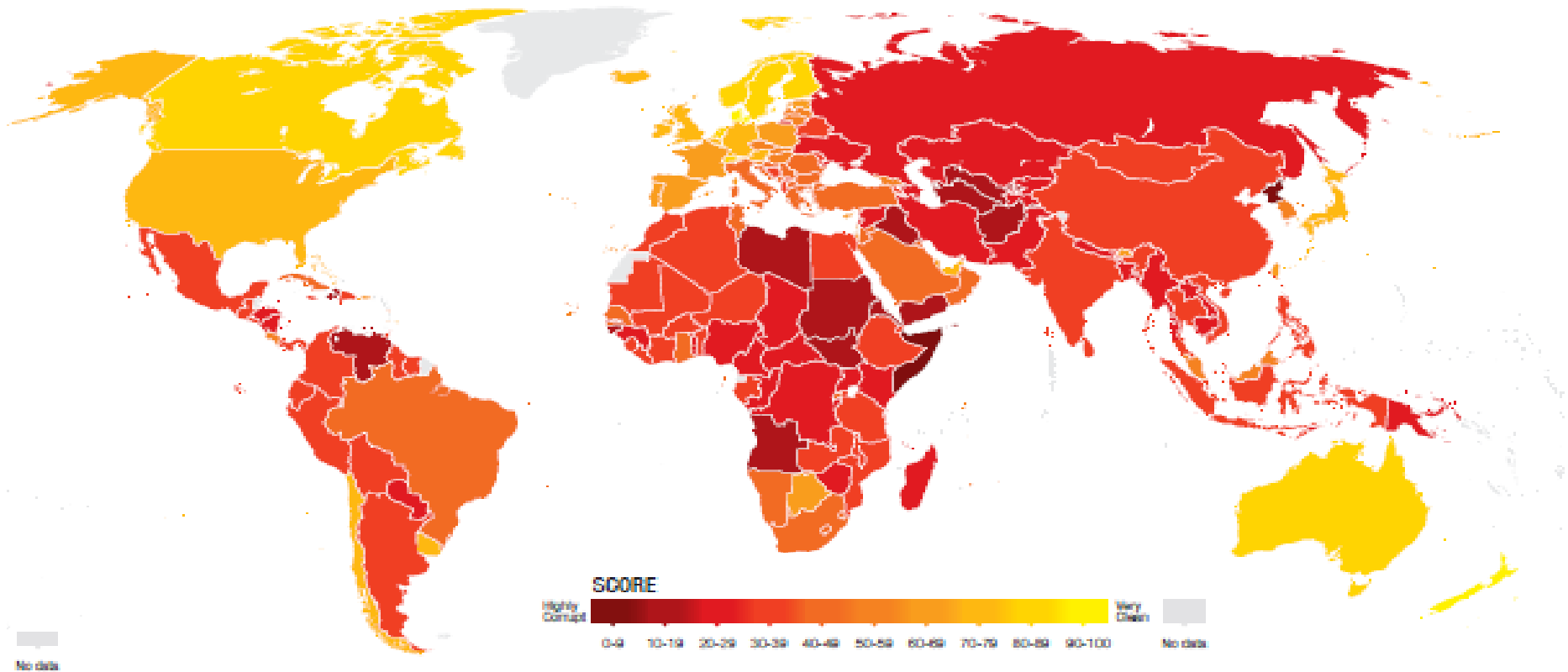
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Brazilian Anti-Corruption Enforcement

Corruption Perception



Context: Fight Against Corruption in Brazil

- Increasing number of arrests for crimes against the Public Administration between **2008** and **2012** – **133%**
- In **2014**, the Brazilian Federal Police conducted **336** special operations; **2,353** individuals were arrested
- **Significant increase** in cooperation with foreign authorities
- Approval of **new anti-corruption laws**, including: Money Laundering Law (2012); Clean Companies Act (2013), and Conflict of Interest Law (2013)



Some Recent Enforcement Actions

- Operation Zelotes (2015)
- Fifa-related cases (2015)
- Operation Car Wash (2015)*
 - 716 proceedings initiated
 - 28 plea agreements
 - 105 arrests
 - 356 search and seizures
 - charges brought against 143 individuals
 - 53 international cooperation requests



Brazilian Anti-Corruption Laws

Corruption on Brazilian Legislation

- Corruption under the Criminal Code (articles 317 and 333):
 - offer or the promise to offer to public officials
 - any benefit
 - that relates to an express or implied request or suggestion that the public employee performs or refrains from performing, or even delays any act within the scope of his duties.
- Any individual who contributes to any act of corruption may be subject to penalties of up to **12 years of imprisonment**.
- Possible penalties imposed by Public Procurement Law and Administrative Improbability Law
- Facilitation or “Grease” Payments are completely forbidden under Brazilian laws and are considered corruption acts

New Anti-Corruption Law

- Effective: January 29, 2014
- Liability does not depend on proving intent or fault (strict liability)
- Liability for illegal acts committed either by employees or by third parties.
- Liability of the company does not depend on and does not exclude the liability of officers
- Illegal acts covered by the law
 - Include **not only acts of corruption, but other illicit conducts** (e.g.: fraud on public tender)
 - **Broad definition of corruption** (e.g.: concept of public official; undue advantage)
 - Include acts committed against the **domestic or foreign Public Administration**
- Possibility of leniency or cooperation agreements as mitigating factors

Sanctions

Administrative	Judicial
<ul style="list-style-type: none">➤ fine of 0,1% to 20% of the gross revenue of the previous year<ul style="list-style-type: none">✓ R\$ 6,000 to R\$ 60,000,000 (if not possible to use gross revenue criteria)➤ publication of the condemnatory decision	<ul style="list-style-type: none">➤ Prohibition to receive incentives and public financing from 1 to 5 years➤ Seizure and confiscation of assets and gains➤ Partial suspension or interdiction of its activities➤ Compulsory dissolution of the legal entity

- The fine amount is calculated in accordance to a pre-defined matrix
- The existence of a compliance program may be relevant for the fine reduction.

Decree 8.420/2015 – Elements of a Compliance Program

- 1) commitment of high management and board members to the program;
- 2) policies and procedures applicable to everyone at the company;
- 3) policies and procedures applicable to third parties (suppliers, service providers, intermediaries, etc.);
- 4) periodic training;
- 5) periodic risk assessment;
- 6) accurate and complete books and records;
- 7) internal controls to assure the reliability of financial statements;
- 8) specific procedures related to public procurement and interaction with government officials;

Decree 8.420/2015 – Elements of a Compliance Program (cont'd)

- 9) independence, structure and authority of the compliance function;
- 10) channels to report irregularities openly and broadly disseminated among employees and third parties, and mechanisms to protect good-faith whistleblowers;
- 11) application of disciplinary measures in case of wrongdoing;
- 12) procedures to immediately stop irregularities detected and to take measures to remediate damages caused;
- 13) due diligence on third parties;
- 14) due diligence in corporate and M&A transactions;
- 15) continuous monitoring of the program; and,
- 16) transparency in political contributions.

Ordinance 909/2015: Evaluation of Compliance Programs

Profile Report	Compliance Report
indicate the sectors and countries in which it has business	inform the structure of the compliance program, indicating which and how the parameters set forth in Decree 8.420/2015 have been implemented
present its organizational structure	demonstrate how the compliance program's operations are integrated into the activities of the legal entity
provide the number of employees	demonstrate how the compliance program worked in the prevention, detection and remediation of the violation under investigation
specify and contextualize the interactions with public and foreign administration	
describe its corporate structure	
inform if it is a small size company.	

Brazilian Pharmaceutical Sector Next Spot?

Some Recent Enforcement Actions in the Industry

- **Vampire Operation (2004)**
 - Fraud in public tenders for hemoderivates
 - Damages estimated in USD 40 million
- **Operation Garra Rufa (2008-2010)**
 - Collaboration between pharmaceutical companies and patient organizations to stimulate the purchase of drugs by the Public Health System
- **Prosthesis Mafia (2015)**
 - Medical devices companies formed a cartel to coordinate sales to the public sector
 - Doctors received commission per implanted unit and also bribes to influence the technical specification in public tenders.

Brazil – main rules

- In addition to the general compliance rules applicable to public practice HCPs, compliance in pharmaceutical sector is mostly regulated by industry codes:
 - Interfarma's and ABIMED's Codes of Conduct;
- ANVISA Resolution RDC No. 96/2008 contains some rules regarding HCPs and industry interactions;
- Some rules are also found in HCPs codes of ethics (medical, pharmaceutical etc.);
- No similar legislation to the Sunshine Act (only a bill of law).

Interfarma's Code of Conduct

- Self-regulation in effect since 2012;
- Applicable to the affiliated pharmaceutical companies (“ACs”);
- Reimbursements to the HCP must be exceptional and ACs shall certify that they are backed by fiscal documents and that they do not include any expense/payment made in benefit of third parties;
- ACs shall keep a file with all receipts, records and documents related to the expenses made in name of the invited professional (fiscal year);
- The AC that violates the rules is subjected to penalties such as suspension of the AC's social rights, exclusion of the AC and fine.
- Note: similar provisions in ABIMED's Code of Conduct (medical devices companies).

ANVISA Resolution RDC No. 96/2008

- Rules the advertisement and other practices aiming at the promotion and marketing of drugs, including provisions about gifts and sponsorships;
- Any support or sponsorship in favor of HCPs for attending sponsored conferences and scientific events shall not be conditioned to the prescription, distribution and/or advertising of any kind of drug;
- In scientific events, disclose that the HCP hired as a speaker has a relationship with the company / inform about potential conflicts of interest;
- Except for institutional gifts and scientific and educational items (such as models), companies must not grant, offer, promise or distribute gifts, benefits and advantages to HCPs.

Best Practices

Recommendations – Best Practices

- Transparency in the relationship shall always be pursued - flaws in the documentation can give raise to suspicions of fraud and the commitment of unlawful act.
 - This becomes more relevant when the healthcare professional is also a public servant or when the medical institution is government owned.
 - File all receipts, records and documents related to the expenses made in name of the HCP;
- Limit of the value for gifts/presents to R\$ 100.00 per year;
 - Gifts are objects related to medical practice and/or strictly educational, such as, publications, stand-alone issues of scientific periodicals, and anatomic models;
 - Gifts do not have the Companys' logo.
- Any services relationship, support or sponsorship in favor of HCPs shall not be conditioned to prescription, distribution and/or advertising of any kind of drug (never practice the quid pro quo);

Recommendations – Contracts

- Especially when hiring public HCPs as consultants, (i) require prior disclosure to or written consent from the HCP's employer and (ii) document the relationship and abide by fair market practices and prices.
 - Detail the services to be performed, the consideration to be paid and include compliance and anti-corruption clauses;
 - Keep evidences of the respective performance;
 - Important clause: reciprocal obligation of the company and the healthcare professional (or medical institution) to disclose the relationship whenever a potential conflict of interest arises.

Recommendations – Events

- Relationship actions shall be modest and secondary to the scientific event;
- Do not pay for/reimburse any expense related to leisure activities
- Do not pay for/reimburse any expense related to third parties;
- In scientific events, disclose that the HCP hired as a speaker has a relationship with the company. Such topic should be included in the respective sponsorship agreement.
- Do not pay for/reimburse fees that refer to the issuance of HCP's passport and/or visa;

South America - Scenario

- In general, companies are prohibited from giving any kind of gifts or benefits to HCPs;
- HCPs are bound to their codes of ethics;
- Companies are bound to industry codes;
- There are no similar laws to the Sunshine Act - in some countries, enacting such type of legislation is not even considered (e.g. Argentina and Venezuela);
- Still low level of law enforcement.

Thank you!

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