

# Anti-Corruption Risks & Enforcement in LATAM Markets

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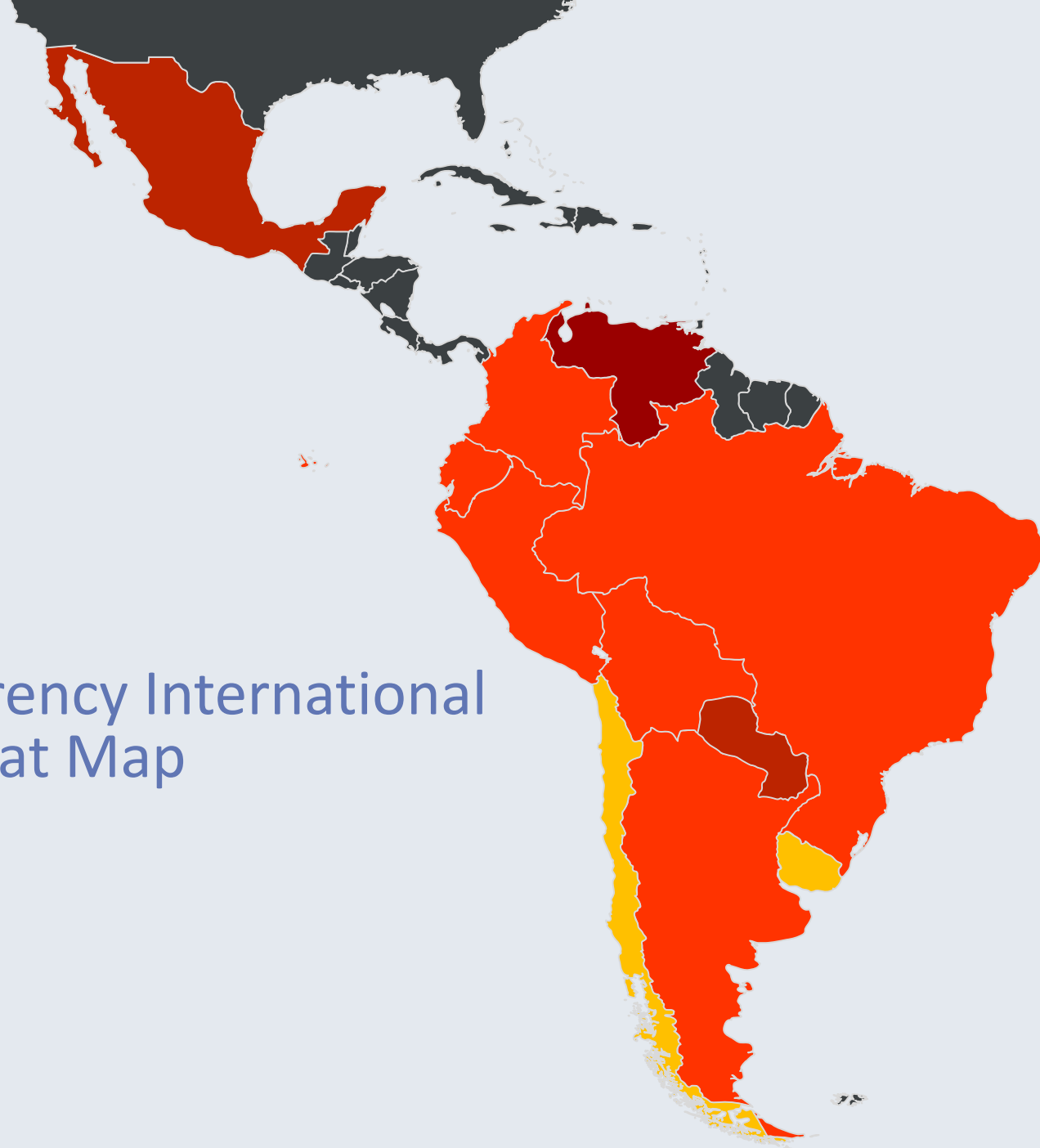
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# Transparency International 2017 Heat Map



Fund for Peace  
Fragile States Index  
“State Legitimacy Scores”



# Laws Prohibiting Domestic Bribery



## Laws Prohibiting Foreign Bribery



# Potential Corporate Liability



# Value of Compliance Program



An In Depth Look  
at Argentina's New  
Anti-Corruption Law

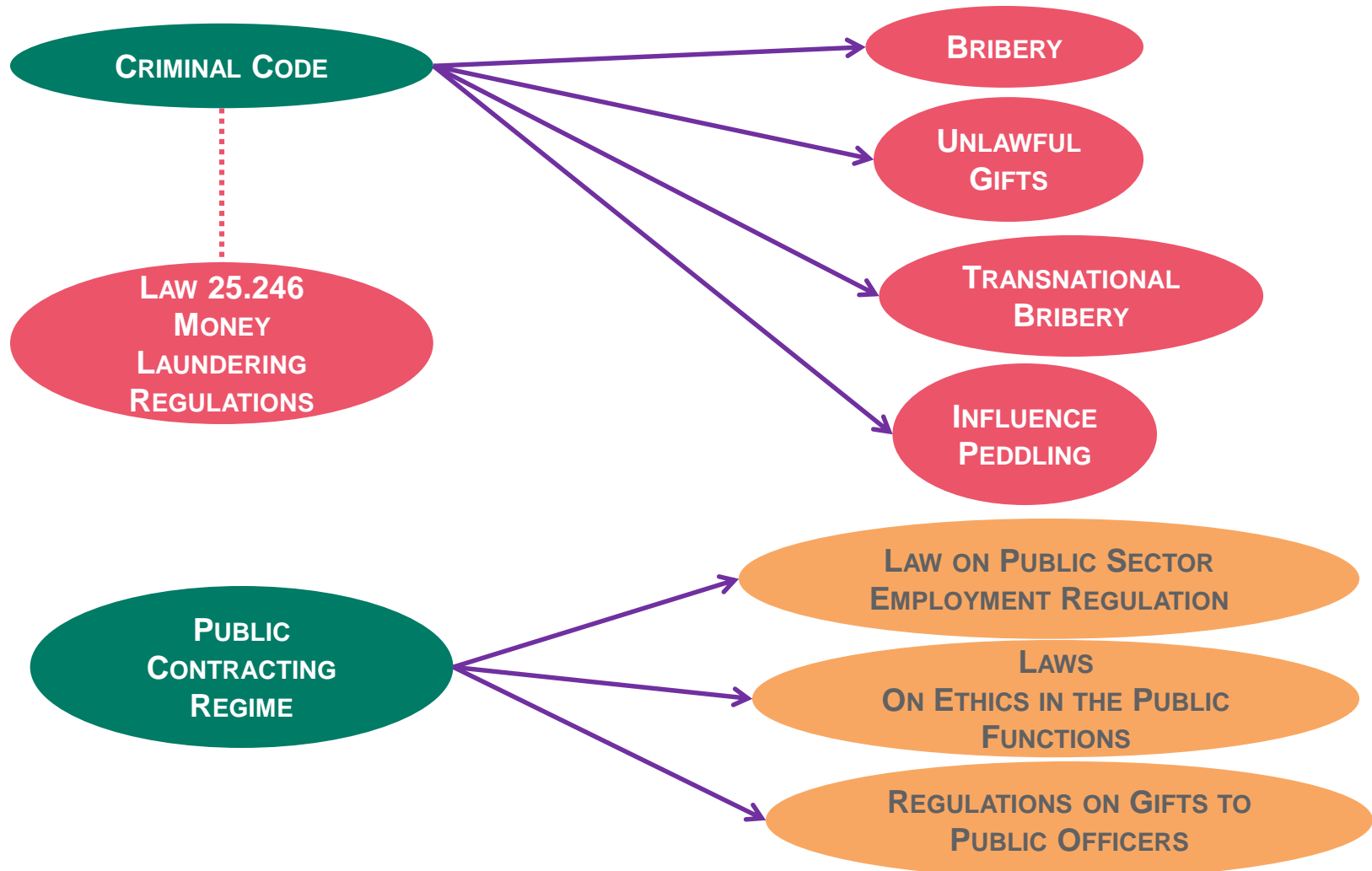




# Anti-Corruption Framework Argentina

## Applicable Regulations Before March 2018

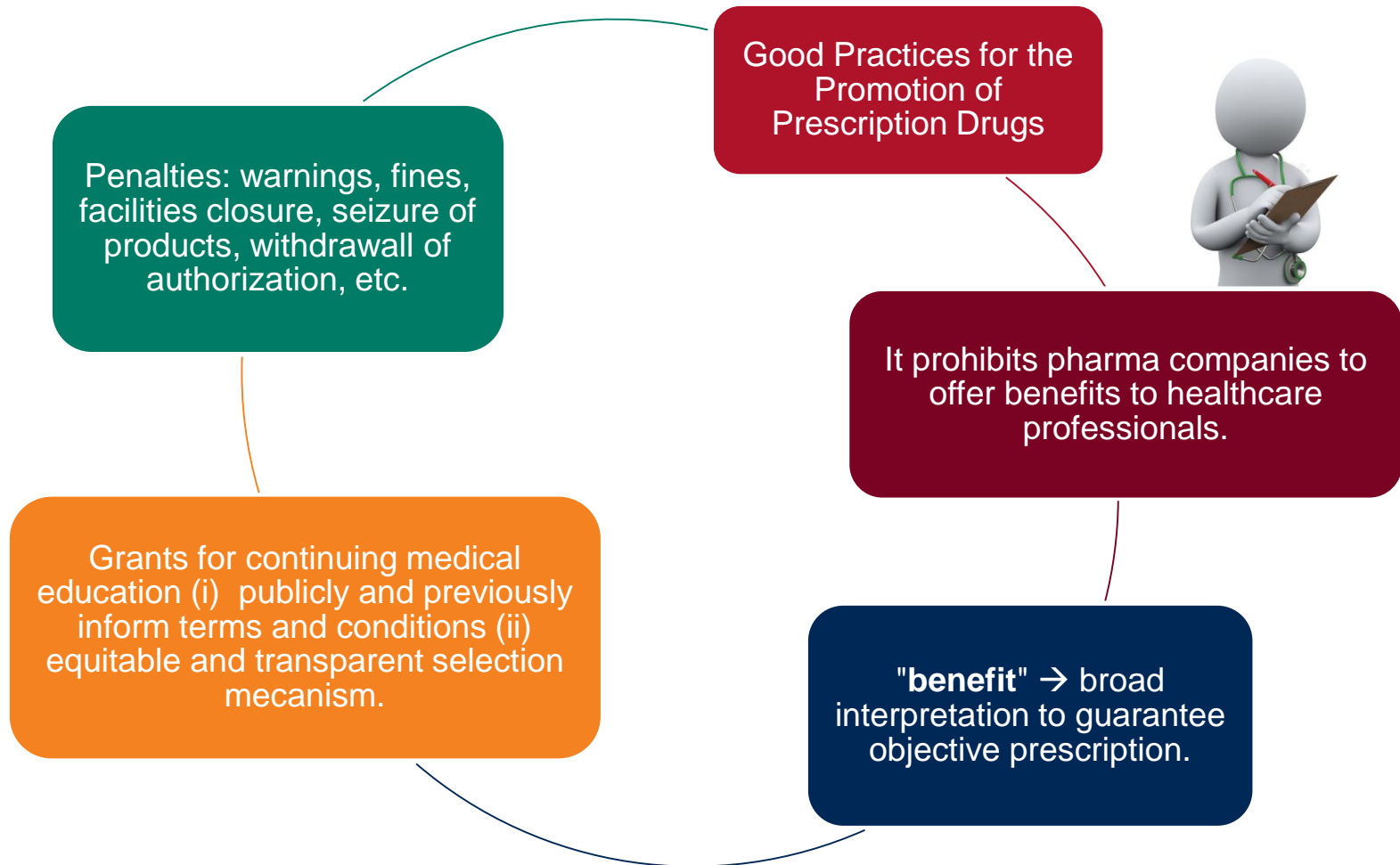
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# Anti-Corruption Framework Argentina

## Ministry of Health Resolution No. 627/2007

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# New Law. Corporate Liability for acts of Corruption

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## Criminal offenses



**Bribery**

**Influence Peddling**



**Conflicts of Interest**

**Illegal Enrichment**



**False Books and Records**



# Criminal Liability of Legal Entities

Direct

Indirect



## Liability

Legal entities will be criminally responsible for the offenses detailed above, when such offenses were committed with their intervention, or in their name, interest or benefit.

Companies are also liable for a third party's criminal offense even when the third party acting on their behalf did not have sufficient powers to represent them, if the legal entity confirms such third party's actions, expressly or implicitly.

## Successor Liability

The Law establishes the responsibility of the companies originated from mergers, acquisitions, or any other reorganization process.

## Safe Harbor

If the individual acted in his/her exclusive benefit with no profit/advantage for the company, the legal entity shall not be prosecuted and/or convicted.



# Statute of Limitations

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**6 years**



# Penalties

**FINED**

## Fines

2 to 5 times  
the actual or  
potential  
benefit



## Suspension

to participate in  
public tenders or  
contracts

(maximum of 10  
years)

**Liquidation /  
winding up**  
(mandatory)

**Suspension  
of activities**  
(total or  
partial)

**Publishing  
of Court's  
decision in  
newspapers**

**Loss or  
suspension  
of  
governmental  
benefits (tax,  
etc.)**

**PENALTY  
NOTICE**

# Judge will consider for sentencing

- Compliance with internal procedures – SOPs
- Number and seniority of officers/employees
- Lack of monitoring/surveillance
- Extent of damages caused
- Amount of money involved in the offense





# Judge will consider for sentencing

**Company size and value**

**Self disclosure**

**Subsequent behavior**

**Willingness to repair damage**

**Recidivism (3 years)**



## Additional rules for sentencing and penalty determination



**Essential continuation of activity or company → no liquidation or suspension of activity**

**Payment of fines in installments (up to five annual) → if risk to bankrupt company**

**No penalty if the company**

- self discloses
- has previously implemented internal controls; and
- returns the benefits obtained from the offense



**Confiscation ( ≠ fine/penalty)**

# Cooperation Agreements with D.A.

## Minimum Conditions

50% (of minimum fine)

Return illegally obtained profits and assets

## Possible Additional Conditions

Repair damages

Community service

Sanction individuals

Implement/enhance compliance program



# Compliance Program

## MUST PROVIDE:

- Code of ethics and/or politics (SOPs),
- Policies to prevent offenses when executing contracts with any public officer
- Training periodically

## MAY PROVIDE:

- Periodic risk review
- Tone from top clear
- Hotlines
- Whistleblower protection
- Penalties in case of violation
- Third party diligence
- Compliance officer(s)



# Compliance Program

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**Companies that do significant business with the government**

**must have a compliance program to be able to close contracts with the government**



# Draft of guidelines to create an adequate Compliance Program

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- Draft by the AntiCorruption Office: Secretary of Public Ethics, Transparency and AntiCorruption, lead by Laura Alonso.
- Possibility of making observations, contributions and/or comments to the content of the Guidelines.
- Suggestion of questions to include in the "questionnaires for corroboration of adequate implementation".
- Suggestion of content for text boxes (intended for emphasizing or highlighting certain items of the Guidelines). Suggestion of additional guidelines to adapt the content to mediam/small companies.

# Los Cuadernos

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"Fernández, Cristina & others in re. illicit association", Federal Judge Bonadio. Initiated in 2018 following photocopies of alleged drafts by Oscar Centeno (former driver of a public official) containing information of bribe collection and transportation, were delivered to the Federal Courthouse.

Actually, 52 defendants. Approx. 18 are providing information of the corruption schemes to obtain a reduction of their penalties.

# Los Cuadernos

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Several detentions, dawn raids, subpoenas and self defense hearings of former public officials and private business owners, as State contractors.

According to the Judge, there was an illicit association formed by public officials and conducted mainly by the Heads of the Executive Branch (Néstor Kirchner and Cristina Fernández) and the Ministry of Public Investment and Services (Julio De Vido).



# Finadiet

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Federal Judge Sebastián Ramos indicted 5 individuals, who issued checks to 3 physicians, who were also indicted.

These payments were made in exchange for prescriptions of pharmaceuticals.

In addition to the indictments, embargos were ordered over the assets of the individuals and physicians.

# Areas of Concern

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Public  
Procurement

Hospitality



Contracts  
with  
physicians

Market  
Access

# Opportunity

- For many international companies, compliance with anti-corruption laws has become a competitive advantage
- Many companies also recognize the importance of strong alignment between partners in the supply and sales chain



# Main Compliance Concerns

40%

*Third Party Misconduct*



Regulatory  
Complexity

Employee  
Misconduct

Resources

JVs

Other



# Key Areas of Concern

- Prohibited payments
- Excessive discounts/commissions
- Product regulation/registration
- Tender management
- Emerging “path to market” strategies



# Key Relationships of Concern

- HCPs
- Customs/customs brokers
- Tender officials
- Distributors and their third parties
- Product regulators
- “Facilitators”



# Compliance Environment in Brazil

After the “car wash” operation and the enactment of the BCCA, the level of awareness in connection with compliance issues have raised significantly.

- There is a new standard brought by these scandals: Inversion of the principle of innocence presumption – companies have to proof its innocence, it is no longer an attribution of the law enforcement authorities to proof guilt.
- Attention to grey areas is key!



# Compliance Environment in Brazil

The healthcare industry is on the spot of authorities: (i) it is a very appealing sector, given the tight connection with public health; (ii) there are several actors involved, HCP, HCOs, patient associations, distributors, etc; (iii) the government is a relevant player in the market and (iv) it is an extremely regulated area.

- Recent scandals, such as the “Operação Fatura Exposta”, “Operação Ressonância” and the “prosthesis mafia” are examples.



## Practical View of the Main Risk of the Industry

# Distribution

Essential for the supply chain of medicines and healthcare products, distributors can create considerable risks for the register holders:

- Exclusivity issues.
- Differentiated discounts issues;
- Improper relationships;
- Non-application of CAP;
- Collusion;
- Assistance on the achievement of results.



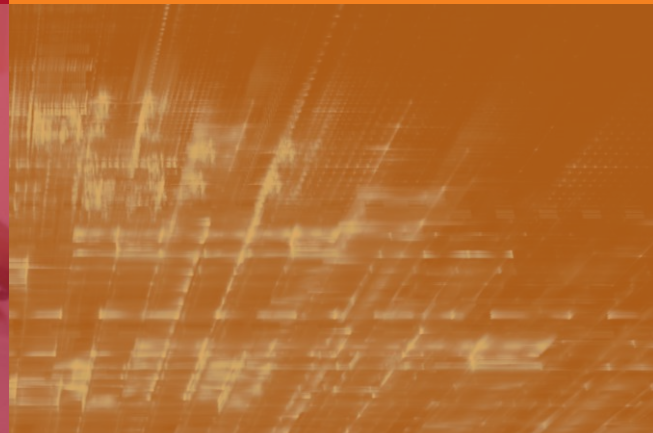
Practical View of the Main Risk  
of the Industry

## Public Procurement Unfeasibility

Problem on  
defining the  
exclusivity of  
some products –  
“Biosimilars” and  
interchangeability

Healthcare  
products: division  
of the public  
procurements in  
lots of specific  
brands;

Centralized  
purchases and  
incorporation of  
technologies.



Practical View of the Main Risk  
of the Industry

## Interaction with Health Services

Financial discounts:  
practice in which  
the company bills  
the product at full  
price and grants  
discounts only at  
the time of actual  
payment;

Specifications of  
RFPs and  
effective  
competition;

Requirements  
regarding  
sponsorships on  
public events and  
the public  
procurements;

“Legit”  
relationships with  
decision-makers.





Practical View of the Main Risk of the Industry

# Patient Programs


- The problem of judicialization;
- Donation of materials to public hospitals;
- Donation of medicines to patients waiting for the free supply (*bridge supply*);
- Access support.




# Fatura Exposta



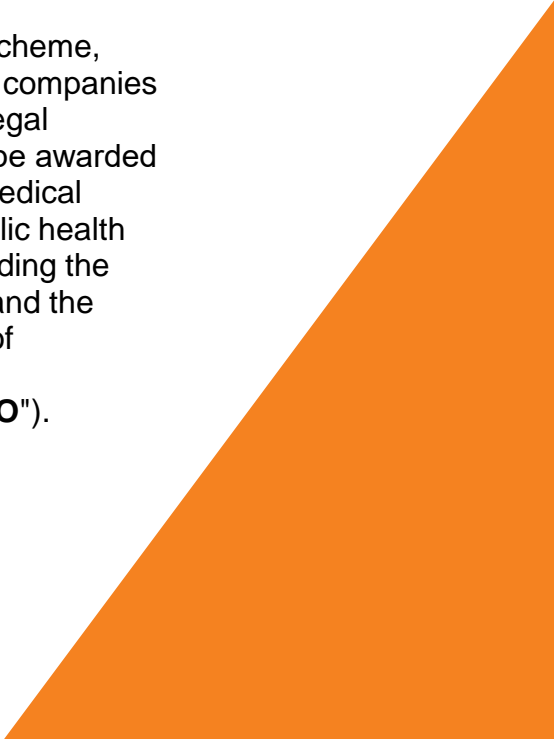
In April, 2017, Brazilian Federal Police carried out a series of 41 dawn raids and 3 detentions, including of former Rio de Janeiro State's Health Secretary, Sérgio Côrtes.




A *spin-off* Car Wash Operation, focused on the State of Rio de Janeiro involving important public officials of the State (up to its former governor, Sérgio Cabral) and several Brazilian and multinational companies in the healthcare sector.




Under the illegal scheme, private healthcare companies paid bribes and illegal “commissions” to be awarded contracts to sell medical devices to the public health care system, including the State Secretariat and the National Institute of Traumatology and Orthopedics (“**INTO**”).




# Fatura Exposta




In July, 2018, Brazilian Federal police launched a new phase of the Fatura Exposta Operation, the Resonance Operation, extending the investigation to 37 companies, in which it has carried out 21 arrest warrants and 44 search warrants.



In September, 2018, a new indictment was presented, against 8 agents involved in the fraudulent contracts involving INTO.



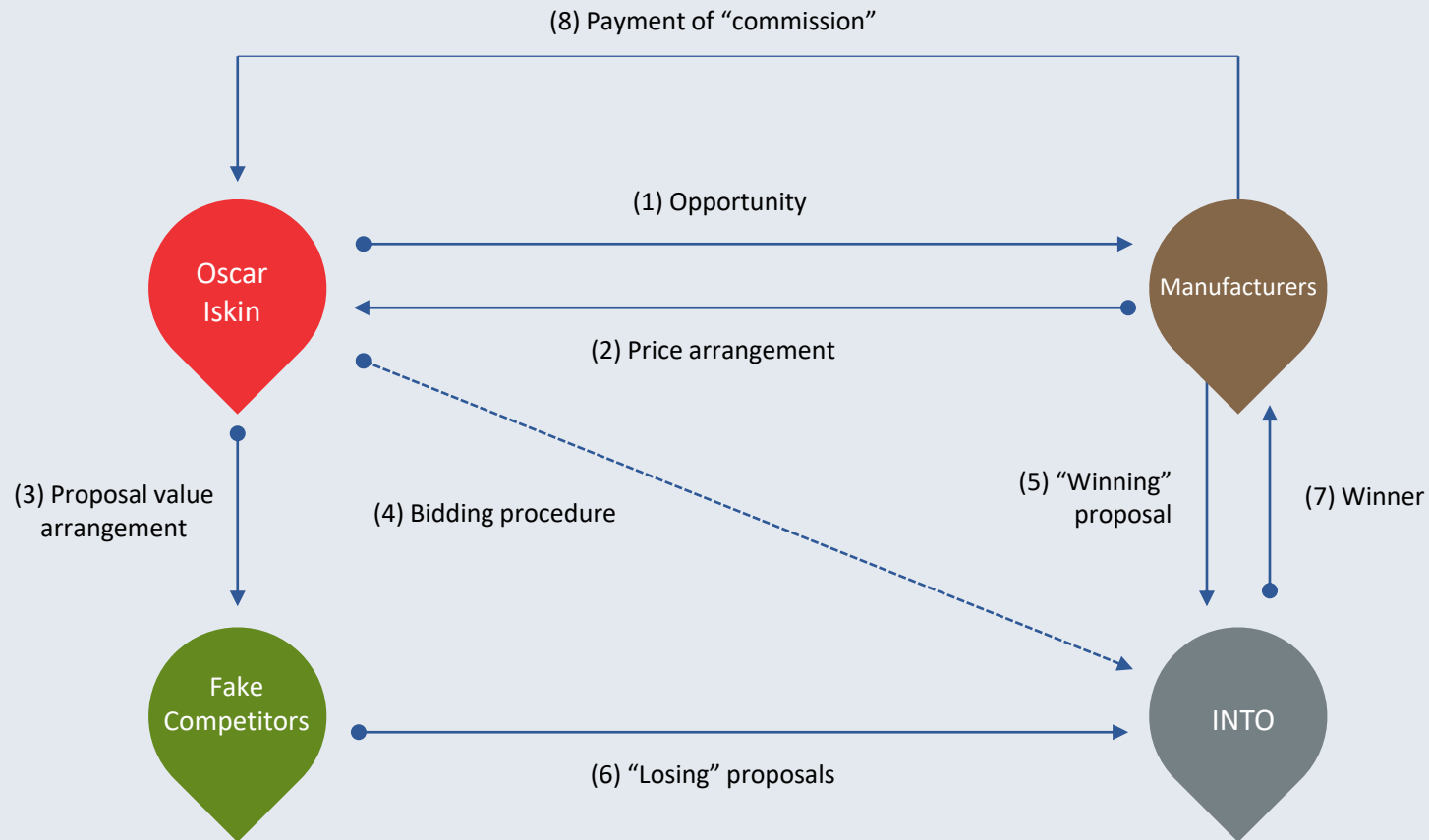
The scheme would involve the manipulation of public tender procedures (mainly in INTO, but also in other public entities), including technical requirements in the requests for proposals of the public tenders.



In August, 2018, the Federal Public Prosecutor's Office presented an indictment against 23 agents, including public servants, officers and former officers of Brazilian and multinational companies.

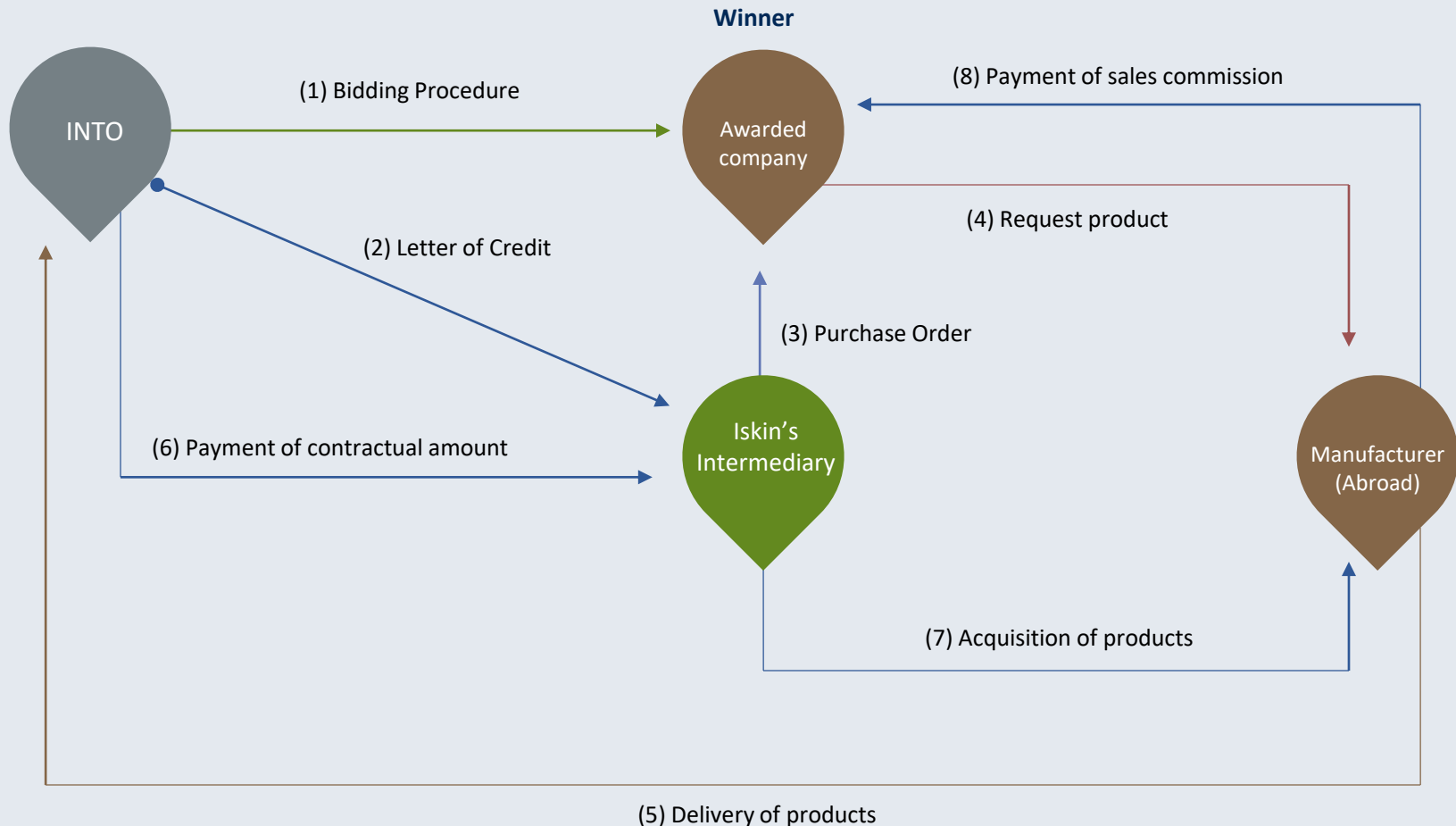
# Fatura Exposta – The Scheme

The scheme was mainly conducted by Miguel Iskin, one of INTO's main suppliers and CEO of Oscar Iskin, together with public agents and private companies.



# Fatura Exposta – The Scheme

In some cases, the scheme involved an intermediary company, that would substitute the awarded company in the execution of the contract.

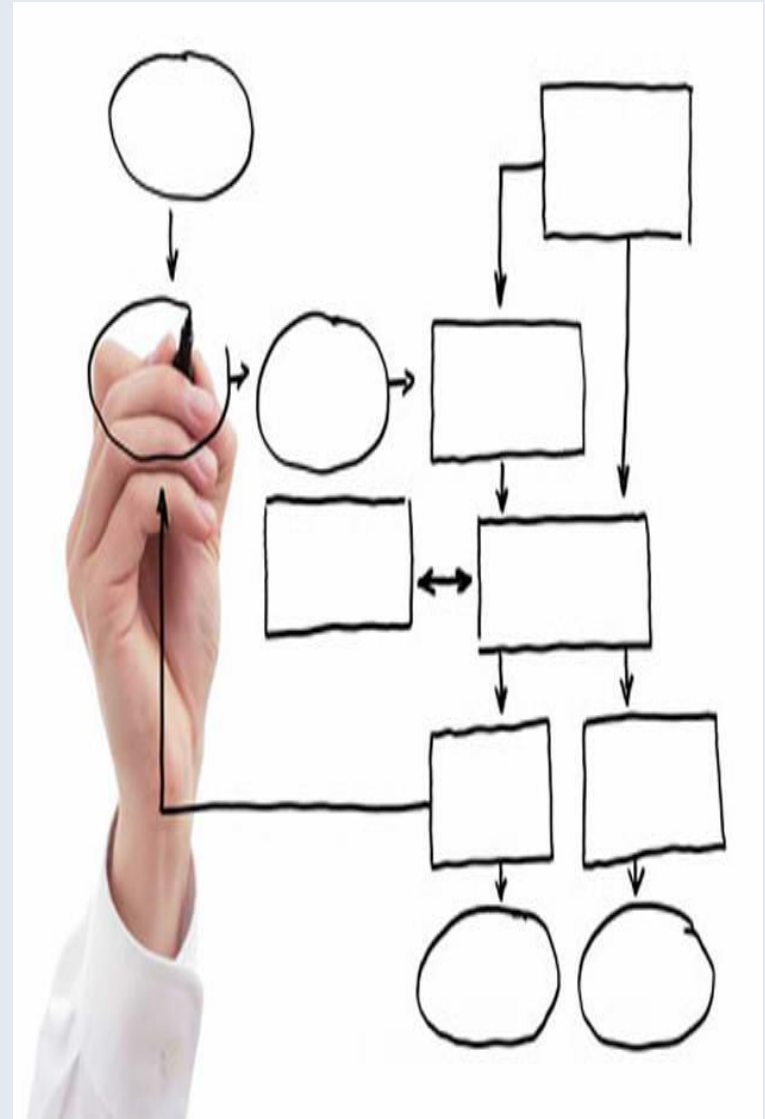




## What If...

There are still uncertainties regarding the extent of effects due to a leniency agreement:

- High number of law enforcement authorities, which not necessarily communicate among their selves.
- The company confesses the acts and presents evidence that can be used by other authorities.
- Confidentiality in general is guaranteed until the effectiveness of the agreement, or to ensure the effectiveness of the investigations: in any case, it usually contains a clause authorizing sharing with other authorities.



## What If...

It may result in other procedures or actions involving the company: e.g. affected third parties, Federal Revenue Office (Receita Federal), agencies of other levels of the federation, etc.

Strategic decision that should be considered in its macro context and taking into account the conducts practiced.



# Managing Third Parties

- ☐ **Risk-Based and Integrated Processes** – How has the company's third-party management process corresponded to the nature and level of the enterprise risk identified by the company? How has this process been integrated into the relevant procurement and vendor management processes?
- ☐ **Appropriate Controls** – What was the business rationale for the use of the third parties in question? What mechanisms have existed to ensure that the contract terms specifically described the services to be performed, that the payment terms are appropriate, that the described contractual work is performed, and that compensation is commensurate with the services rendered?
- ☐ **Management of Relationships** – How has the company considered and analyzed the third party's incentive model against compliance risks? How has the company monitored the third parties in question? How has the company trained the relationship managers about what the compliance risks are and how to manage them? How has the company incentivized compliance and ethical behavior by third parties?





# Managing Third Parties

## KEY TAKE-AWAYS:

- Understand the role played by the third party
- Understand and monitor compensation
- Understand risks in the relationship
- Build controls to contain the risk
- Cultivate culture where concerns are elevated and addressed promptly
- Update agreements to reflect expectations
- Resolve “red flags” in responsible ways
- Impose appropriate sanctions where warranted-

# Out-of-Control Margins

## Orthofix (Brazil)

Orthofix Brazil provided a high discount ranging in certain instances of up to 70% to the distributors, who then used part of the profit generated by the discount to make improper payments to certain doctors at public hospitals.

# Managing Margins

## Orthofix (Brazil)

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profit

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public

## Third Party Management

**Management of Relationships** – How has the company considered and analyzed the third party's incentive model against compliance risks? How has the company monitored the third parties in question? How has the company trained the relationship managers about how to manage the compliance risks?

# The Slush Fund

## Orthofix (Brazil)

Orthofix Brazil made payments for services that were never rendered. These payments were inaccurately described in the company's books and records as "consulting for sales" payments, when, in fact, the payments to the distributors were made to facilitate improper payments to doctors.

# Payment Approval

## Orthofix (Brazil)

Orthofix Brazil made payments for services that were never rendered. These payments were

inaccurate

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to facilitate

## Operational Integration

**Approval/Certification Process** – How have those with approval authority or certification responsibilities known what to look for, and when and how to escalate concerns?



# No Distributor Controls

## Teva (Mexico)

Teva Mexico conducted no due diligence on Company, did not have a written distribution agreement, did not require Company to certify compliance with Teva's anti-corruption policies, and knew there was no legitimate purpose for an increased margin received on sales to Mexican government customers.

# Distributor Management

## Teva (Mexico)

Teva Mexico conducted **no due diligence** on

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compliance

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## Third Party Management

**Appropriate Controls** – What was the business rationale for the use of the third parties in question? What mechanisms have existed to ensure that the contract terms specifically described the services to be performed, that the payment terms are appropriate, and that the described contractual work is performed?

# No Room for Compliance

## Teva (Mexico)

In 2011, at a meeting of the Company's compliance team for Teva Mexico, the Regional Compliance Officer said that the compliance program “was not relevant for the Latin America region and was to be ignored.”

# Compliance as Business Partner

## Teva (Mexico)

In 2011, at a meeting of the Company's compliance team for Teva Mexico, the Regional Compliance

Officer s

relevant

ignored

## Autonomy and Resources

**Stature** – How has the compliance function compared with other strategic functions in the company in terms of stature? What role has compliance played in the company's strategic and operational decisions?

# Emerging Paths to the Market

- Turnkey Projects
  - Consortia led by non-health care companies build and equip hospitals
  - “Hospitals for Bolivia” plan
- Integrators
- Placement programs
- Combinations of insurers and clinical services
  - UnitedHealth (USA) acquired Banmedica, Chilean provider of health insurance and clinical services with operations in Chile, Colombia and Peru
  - Peru: 50% interest in Pacifico Insurance; San Felipe, San Borja and Sanchez Ferrer clinics; Rodec Laboratory and medical devices importer Procemedic



*Tacna Health facility in Peru, a US\$82M “turnkey” project*