

# **Latin America Healthcare Compliance Certification Program**

**Industry Interactions  
With Patient Organizations**

# PATIENT ORGANIZATIONS

- Where they come from.
- What they are.
- Snapshot.
- Relationship with Pharmaceutical Industry: **(IFPMA, EFPIA, PhARMA, INTERFARMA, CAEME)**
- Interaction in a “nutshell”.

- Patient Organizations appeared, in the beginning of the 20<sup>th</sup> century, as a result of the shortage of resources for public health and the increase of the “number” of chronic diseases.
- After World War II, communities started taking increased interest in the health sector.
- Real growth in their number came from the perception of patients of some diseases that they were being isolated and stigmatized.
- In the area of genetic diseases Patient Organizations direct a lot of effort to pressure governments and health plans to supply drugs, as these types of drugs are, as a general rule very expensive.

# PATIENT ORGANIZATIONS SNAPSHOT

- More than 100 organizations in Brazil.
- Over 50 related to Rare Diseases.
- A considerable number has been started and are managed by family members of people affected by a rare disease. (emotional involvement)
- Although some “collective” effort exists this is rare.
- Funding is always a difficult task, especially in times of crisis.
- Brazilian Constitution has somewhat fostered the creation of a few “specific purpose organizations”.

# PATIENT ORGANIZATIONS SNAPSHOT

- Low degree of professionalism. Lack of management structure.
- Lack of compliance practices and codes of conduct.
- Very little knowledge of public policies and lobby practices.
- Although some “collective national” efforts exists this is rare.
- Judicialization is a very sensitive theme and requires caution.
- A few exceptions are found in organizations related to HIV, Hepatitis, and Cancer (especially breast cancer).

# Relationship Basic Frame

- There needs to be clear independence between the associations and the industry;
- Industry vision of the organizations must keep “healthy” distance from commercial and marketing efforts;
- Donations must be preceded by formal presentation of projects and must not include any consideration in return for them.

# **INDUSTRY ASSOCIATIONS'** **REGULATIONS**

## IFPMA

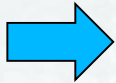
- The industry has common interests with patient organizations.
- Interactions must be **ethical** and respect the **independence** of the organizations.
- **The nature of that involvement must be clear from the outset.**
- **Financial support must be documented** and inform the nature of support
- Support if **primary purpose of the meeting is professional, educational, and scientific** in nature, or otherwise supports the mission of the patient organization



# PhRMA

- Same basic rules as IFPMA

Companies may provide financial support for patient organization activities, including fundraising events and other events where the primary **purpose of the meeting is professional, educational, or scientific in nature**, or otherwise supports the mission of the patient organization

It would be **acceptable** under these PhRMA principles for a company **to be the only** company **providing funding** as long as that company does not make its support conditional on the company being the sole funder. 

## EFPIA

- Local codes provisions should not be less rigorous than EFPIA code
- There should be **no promotion of prescription drugs**.
- All financial **support** must be **reflected in written agreements**.
- Companies may not influence development of information material prepared by organizations.
- Companies must have publicly available list of organizations supported and nature and value of support.
- Companies cannot require to be the sole founder or contributor to any program

# INTERFARMA (Brazil)

- Interaction must be related to disease awareness, and supplying of “proper” information on treatment, prevention and diagnosis.
- Approval of projects **cannot include marketing** and sales personnel.
- Companies may **not influence development of information material developed by organizations.**
- Companies cannot be responsible for payment of administrative expenses, except in few cases (new organizations for 3 year max)
- Companies **must maintain appropriate record of donations / sponsorships.** (not to exceed 15% of any project)

## CAEME (Argentina)

- Interaction must be clear and must not induce prescription or promotion.
- Companies **must respect the autonomy** principle.
- Interaction must comply with the legislation, especially related to data privacy and direct to consumer advertising.
- Companies **cannot require to be the sole founder or contributor to any program.**
- Companies **cannot require any consideration for donations or sponsorships.**

# **PATIENT ORGANIZATIONS INVOLVED IN POLICE INVESTIGATIONS IN BRAZIL**

- **Associação Nacional de Doenças Raras e Crônicas - ANDORA.**  
Hypercholesterolemia – Interaction with Aegerion;
- **Associação dos Familiares e Amigos de Portadores de Doenças Graves - AFAG.**  
Paroxysmal nocturnal hemoglobinuria – Interaction with Alexion;
- **Associação do Portadores de Vitiligo e Psoríases no Estado de São Paulo - APVPESP.**  
Psoriasis – Interaction with Merck-Serono/Wyeth/Mantecorp;

# INTERACTION IN A NUTSHELL

- Nature of interaction must be absolutely clear;
- Components of interaction should be documented. If financial or economic, MUST be documented;
- Independence of parties must be respected.
- Essentially scientific and/or educational;
- No product promotion and no “quid-pro-quo”;
- No sole sponsoring of entity;
- In Europe disclosure of organizations and nature/value of support.
- **Perception is Reality or: “Caesar’s Wife”**

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**President – Associação Vidas Raras**



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# A. LOPES MUNIZ

## Advogados Associados

DESDE 1975

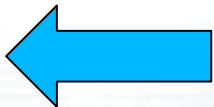
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## BACK-UP

- The fact that some patient organizations have been sponsored/supported by only one company, has been used by the Prosecutors' Offices and by State and Federal Governments as a hard indication that these sponsors would surely have powers to interfere in the management of the patient organizations, including in relation to the filing of lawsuits requesting the importation of drugs by the government.
- Disregarding the fact that the number of companies working with products for rare diseases is very small and so is the number of specific patient organizations.



## PATIENT ORGANIZATIONS



There are more than 100 patient organizations in Brazil

Around 50 related to Rare Diseases – About 30 that are very active