

Brazil's New Code and Collaborative Relationship with Other National Associations

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Interfarma

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COMPLIANCE BOOM

- ◆ Brazil
- ◆ Interfarma – Compliance Committee

DEVELOPMENT OF INTERFARMA'S CODE

- ◆ How it started
- ◆ Reasons for the Code
- ◆ Process of development and approval
- ◆ Obligation to act in accordance with the Code

TIMELINE

- ◆ 2005 – First drafts
- ◆ 2007 – Published the first version
- ◆ 2008 – Published the first revision
- ◆ 2012 – Published the second revision
 - ◆ In force since July 1st, 2012

2012 REVISION



2012 REVISION

- ◆ Incorporated the terms of the important agreement INTERFARMA signed with CFM, SBC, AMB – In defense of best practices in the relationship between physicians and pharmaceutical industry, contemplating the following topics:
 - ◆ Transparency
 - ◆ Medical Congresses – Schedule
 - ◆ Sponsorship of Physicians – Invitations to Attend Scientific Events
 - ◆ Relationship Actions During Satellite Symposia
 - ◆ Gifts
 - ◆ Rules for Visitation

PREVIOUS SITUATION WITH CFM...

- ◆ CFM (Federal Council of Medicine), which regulates the activities of 340,000 physicians, decided to impose rules to prohibit the interaction between the industry and the physicians

2012 REVISION

- ◆ Inspired in international codes
- ◆ Considered the necessary updates in Brazilian Legislation (ANVISA's promotion and sample regulations, among others)
- ◆ The 2012 Revision (as the 2008) is more strict than the Brazilian Legislation in several articles

2012 REVISION – KEY CHANGES

- ◆ Relationship with Public Officials and Government Authorities (included)
- ◆ Interactions and Relationship with Patient Associations (included)
- ◆ Participation of Healthcare Professionals in Scientific Events Invite by the Industry (CFM)
- ◆ Offer of Gifts (CFM)
- ◆ Composition of the Ethics Committee

2012 REVISION – SENSITIVE MATTERS – GIFTS

- ◆ Shall be items related to medical practice and/or strictly educational
- ◆ Shall be items of minor value (not higher than 1/3 of the Minimum National Wage), and may or may not have the Company logo
- ◆ The offer is limited to 3 times a years per ‘Healthcare Professional’ (according to the Code Definitions)
- ◆ Items used in the administrative routine, including, but not limited to pens, pencil holders, and notepads will not be considered as related to medical practice and, therefore, shall not be distributed.
- ◆ Pens and notepads can be offered as support material only during Scientific Events
- ◆ Offers of gifts, advantages or any other items that do not meet such criteria and the legislation in force shall not be made under any circumstance

2012 REVISION – SENSITIVE MATTERS – SCIENTIFIC EVENTS

- ◆ The payment or reimburse of expenses must be related to the event itself and refer exclusively to transport, meals, accommodation, and entry fees charged by the organizing entity (solely to the invited professional), and may be extended to the days immediately before and immediately after the official agenda, in case logistics and transport issues justify such extension
- ◆ Fees that refer to the issuance of a passport and/or request for travel visas are not considered transportation expenses and must not be paid or reimbursed
- ◆ Cruise ships are not considered appropriate venue to hold scientific events
- ◆ Payment or reimbursement of any expense related to leisure activities, such as tickets to shows, theatre, presentations, sports events etc. is expressly forbidden, regardless of being or not linked to the organization of the scientific event

2012 REVISION – ETHICS COMMITTEE

- ◆ The new Ethics Committee is composed of representatives appointed by companies and senior experts, not linked to any industry, but with proven experience, unblemished reputation and outstanding knowledge of the pharmaceutical industry practices (selected randomly)
- ◆ In the 2008 Revision, the Ethics Committee was composed only by the representatives appointed by the Companies
- ◆ The Ethics Committee is fully independent in regards to its prerogative to ensure strict compliance with the Code

ENFORCEMENT OF THE CODE

- ◆ The 2008 Revision (maintained in the 2012 Revision), brought the penalties that the companies are subject in case of violation of the Code of Conduct
 - ◆ 180 days suspension of its social rights at INTERFARMA (with no right to suspend contribution)
 - ◆ Exclusion of the Associated Company from INTERFARMA
 - ◆ Fine, defined according to the violation seriousness:
 - ◆ Minor Violations – R\$ 5,000 to 82,500
 - ◆ Serious Violations – R\$ 82,500 to 220,000
 - ◆ Very Serious Violations – R\$ 220,000 to 1,650,000

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Thank you

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