

**Our Vision** To earn trust, every day.



...Compliance along the way

Leading with Integrity 



# Comparing, Contrasting and Complying with the Global Codes of Conduct

Pre-conference Cession II

Gabor DANIELFY



**1. Code of Conduct, Codes of Conducts ?**

**2. The Jungle of Codes, how to cope ?**

**3. Complexity Challenges**



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# Global Standards as the cornerstone for SP's Corporate Training Curriculum & Policies

*SP's Global Standards of Business Practices as a cornerstone...*

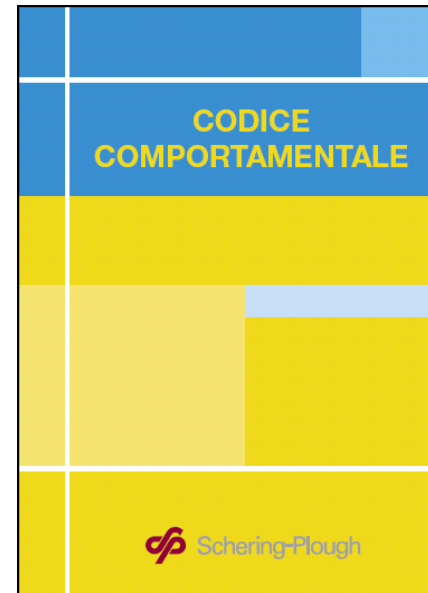




- Value Driven, High Level
- Serves as a base for both Corporate Policies and Corporate Compliance Training curriculum
- Some implementation challenges :
  - Standards need to be accessible :
    - Translation, Booklets, Intranet, web
  - In Compliance with Local Laws :
    - Thorough review process
    - Overcoming local hurdles (France, Italy)



- Italy :
  - Global Conduct code seen by authorities and courts as too general and disconnected from local needs/local laws
  - Need for a specific local code : at SP Italy implementation of a Codice Comportamentale
  - 1 per legal entity
  - Includes all violations with criminal law implications with precise reference to the italian law (bribery, antitrust, fight against terrorism...)





- France :

- The French labor law only recognizes the “work rule book” as the only legal document applicable to colleagues in France. There is no recognition of a Code of Conduct as such
- First step 3 years ago : SP France distributed the “Standards” traduced in french to all colleagues, collecting acknowledgements only on a "for information" basis, no enforcement/no sanctions possible on the basis of the Standards
- In 2007, the ambition was to incorporate the Standards within the rule book. This implied :
  - Rulebook has to be submitted to the "Hygiene, Security and working conditions committee" as well as to the Works Council“
  - Slight but mandatory adaptations to comply with local laws like :
    - Remove rules that are illegal in France (i.e. color, religion, race, ...)
    - Recall French law requirements when the standards were too “high level” (ex: anti-gift law “DMOS”)
    - Adjust wording if seen pejorative in a labor context (ex : rendement/performance).
  - Privacy law impact on Integrity Action Lines : calls cannot be Anonymous but must remain Confidential (anonymity being authorized for financial matters having a serious impact on the company as a whole)





- **France (II) :**
  - **This work has been performed in coordination with HR, Law and Compliance**
  - **After slight changes were agreed upon with the works council, it still needed to be submitted to the ‘Labor Inspector’ for approval. A month after this submission, the Standards became fully part of the French SP work rulebook**
  - **7 months after its implementation (ie NOW), SP France has received comments and change requests from the Labor Inspector, focusing on the several aspects**
  - **A discussion will follow between the French affiliate and the Labor Inspector on each of those aspects**



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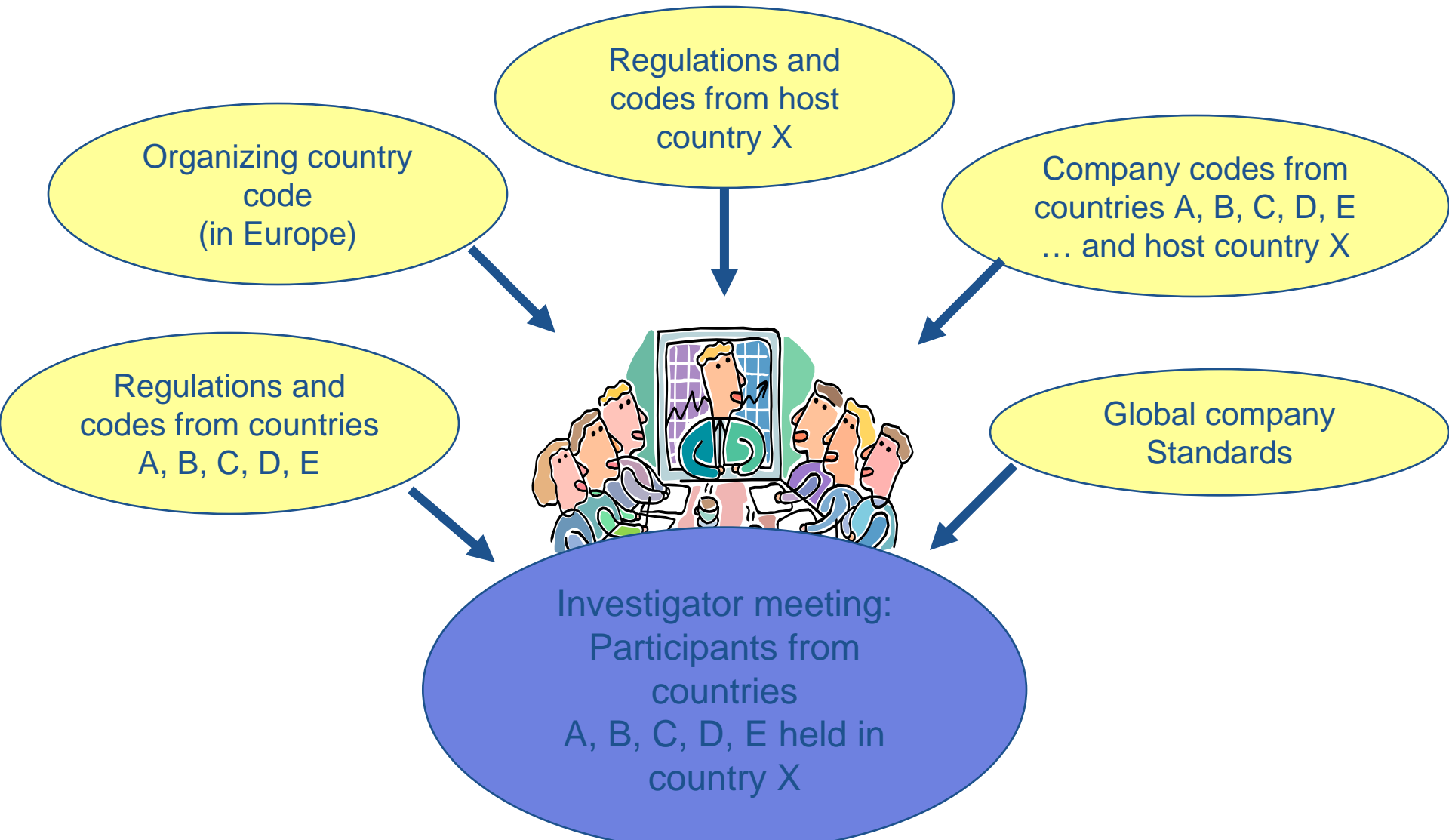
3. Complexity Challenges



- Multiple rules in addition to IFPMA and national codes
  - Regulatory bodies, court actions, health professional codes, HCP employers rules, etc. etc.
- International Meetings involve multiple codes and laws
- Impossible to have one stand alone global training programme and materials

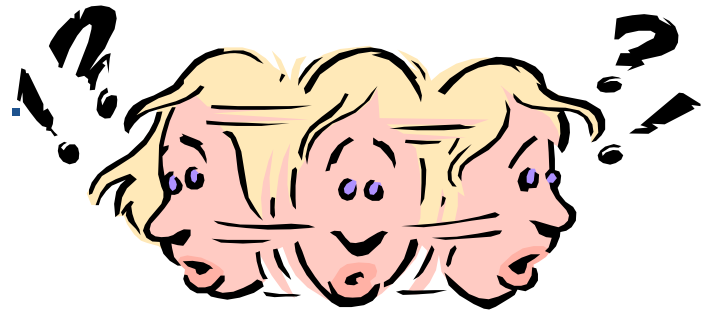


# Multi-country events: What limits apply to hotel accommodation?





- Question: Can I ...
- Answer: Well, It all depends .....
  - Which codes apply?
  - Which regulations apply?
  - Any guidance issued? Company specific Policy ?
  - Any relevant case reports or precedents?
  - The details of this particular case are unique
  - What will the company's local promotion signatories think?
  - What might an adjudication body (code panel, regulatory body, court) think?
    - ... And the appeal body?





➤ ***PRACTICAL BUSINESS CASE :***  
***What model could be used for the process of Hiring International HCP's ?***

– **Option A : ‘Do Nothing’**

- The company has not identified the Jungle of Code risks
- There is no infrastructure to implement the needed process
- The Business will be at risk (Code violation, unfair competition, FCPA, etc...)

➤ **Not recommended..**

- . *Risks for the company and for the HCP*
- . *Aggregate spending aspect*



## **– Option B : ‘The Shareware’**

- Every subsidiary shares its standard/template agreements (with own applicable legislation) in a database to be used by the inviting country affiliate**
- Financial conditions offered based on the company’s pre-defined Fair Market value**
- Central Approval (?)**
- Central database of approved and executed agreements**

## **– Option C : ‘Own your risk’**

- Hiring of HCP only through the owning local country affiliate (that ‘owns’ the HCP and that will contract, pay and abide by local laws/tax regulations etc.**
- Internal rebilling process**



## **– Option D : ‘Track’n track’**

- Central database tracking and documenting all steps**
- Project initiator makes sure activity/venues etc are compliant with place of activity applicable laws/codes**
- Project is submitted through hiring requests to country of residence of the HCP to make sure agreement abides by local laws (approval by country reviewer)**
- Cross-check and fine-tuning phase**
- Post-service reconciliation, documented proof of performance etc...**

## **– Option E : ...**





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- Codes coverage is increasing : interactions with HCP's, Patients, Patient Organizations dealing with a wide range of aspects like hospitality, FMV, Records management, content review...
- Conflicts between applicable codes become separate sections of codes...
- Everyone wants to have their own-code : Physicians, Pharmacists, Nurses, (EU commission reference to the joint EFPIA/UEMS declaration...)

*All this ends up asking marketers to be lawyers as well...*



- In the EU for the same pathology, a wide range of remedies are used on rules and sanctions...Aren't we shooting in our own foot ? Why not going for best practices ?
- The US seems to start following the same route (one state-one rule)



State	Date Passed	Prohibit reps from providing gifts, payments, or travel*	Require all reps to be licensed	Require disclosure of payments made by drug companies**	Consider advertising costs or samples as gifts	Prohibit use of MDs' Rx information for commercial use***
CA	3/5/03			X	X	
DC	3/24/04			X	X	
FL	7/1/06				X	
ME	1/1/04			X	X	X (6/07)
MA	6/1/06	X	X			
MN	1/6/05	\$50 limit		X	X	
NH	6/20/06					X
VT	1/1/04			X	X	X (6/07)
WV	2/26/04			X	X	

\* Legislation attempted in: IA, ME, NJ, NY and WV

\*\* Legislation attempted in: AL, CO, CT, HI, IL, MA, MS, NH, OH, PA and RI

\*\*\* Legislation attempted in: AR and WV

General physical-marketing legislation proposed in: AR, IA, MD, OK, SC, SD, TN and WI





Like micro-management,  
is this reasonable/efficient in a Global market ?

Self-regulation can on the contrary offer a  
platform for convergence but does not always  
comply with this goal



- Growing Gap between Members and Non-Members (or even between large vs small/mid-size companies): is self-regulation enough ?
- Time race in India/China : those countries are about to generate significant Global players in Pharma. Are we making all the steps to win 'hearts and minds' over there so that self-regulation keeps momentum ?



- Leveraging the Compliance effort :
  - Complexity also means confusion, loss of efficiency and misuse of the by definition limited resources for Compliance
  - It's good most players converged to self-regulation, now there is a NEED FOR CONVERGENCE WITHIN SELF-REGULATION
  - Convergence requires discipline and goodwill from all stakeholders under the leadership of PhRMA and EFPIA, with IFPMA, while reinforcing Asia, MEA and Latin America's representation/involvement
- Winning Initiatives : Belgium / Mdeon, South African Code