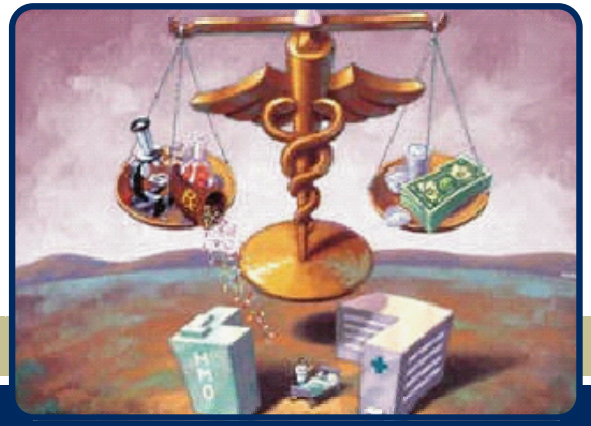
NJE-192515.016-20050310-sugnHR1

Update on International Medical Affairs



Alexander Petersen, McKinsey

Stan Bukofzer, Abbott Laboratories

March 30, 2005, 4:45-5:30 p.m.

AGENDA

4:45	**A map of international medical affairs**	**Alexander Petersen,** McKinsey & Company
5:00	**Managing the complexity – One perspective**	**Stan Bukofzer,** Abbott Laboratories
5:15	**Questions from the audience**	

INTRODUCTION

- **Medical affairs is a complex area to manage internationally**
- **Local-level officials, doctors, and industry figures have their own views of compliance and proper medical affairs conduct, resulting in a tremendous diversity of regulations, guidance, and norms across different national contexts**
- **At the same time, there are regional forces that are increasingly influential on local-level opinion and policy**
- **Managing medical affairs without taking into account local and regional variation can create compliance and business risk**
- **Five specific areas—communications with physicians, meetings and conventions, clinical trials, medical education, and direct-to-consumer information—provide a vivid demonstration of the diversity of international affairs**

Source: McKinsey & Company

WHAT INDUSTRY IS SAYING – EXAMPLES

When the government implemented the CTD in Belgium, they went too far. For several months, academic trials were halted.

– Belgian Medical Director

I was hired as the head of medical affairs; now, I spend most of my time being the head of risk management

– Italian Medical Director

With countries constantly changing their rules, it is getting harder and harder for headquarters to set meaningful global standards

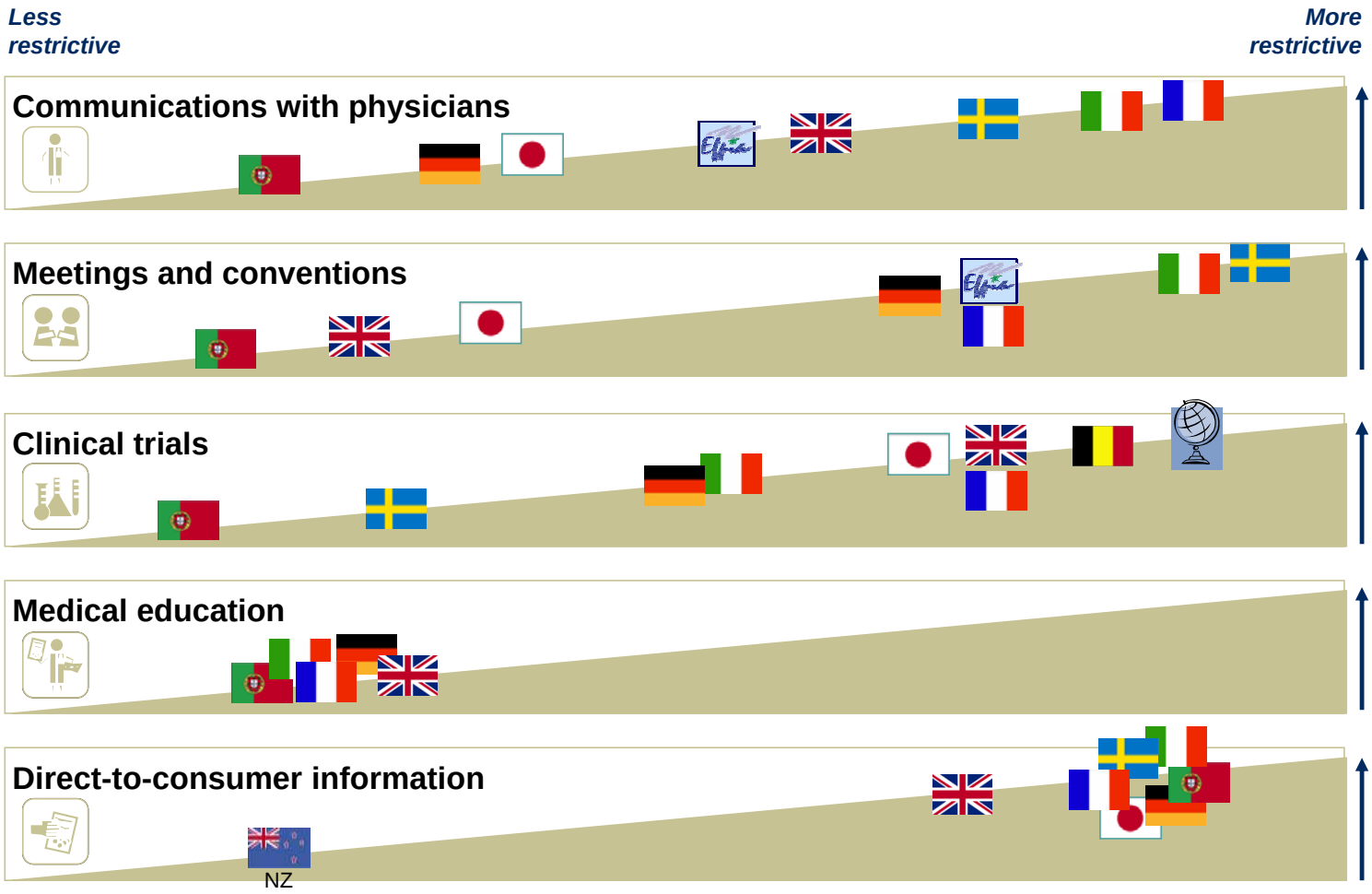
- Head of medical affairs, global pharmaceutical company

The Medical Visits Charter would have been much worse if the industry had not proposed its own reforms

– French Medical Director

Source: McKinsey & Company

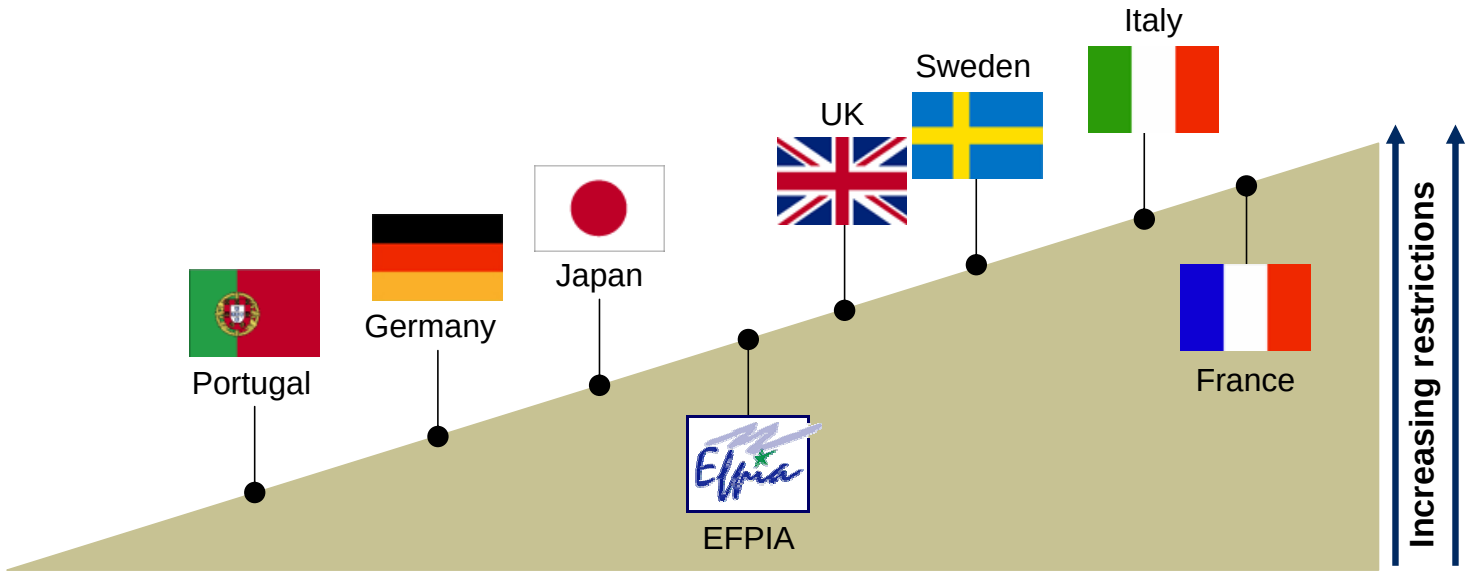
SUMMARY OF COUNTRY DATA



Source: McKinsey & Company

COMMUNICATIONS WITH PHYSICIANS

- Frequency of office visits
- Other channels of communication (phone, fax, email)
- Limitations on leaving samples



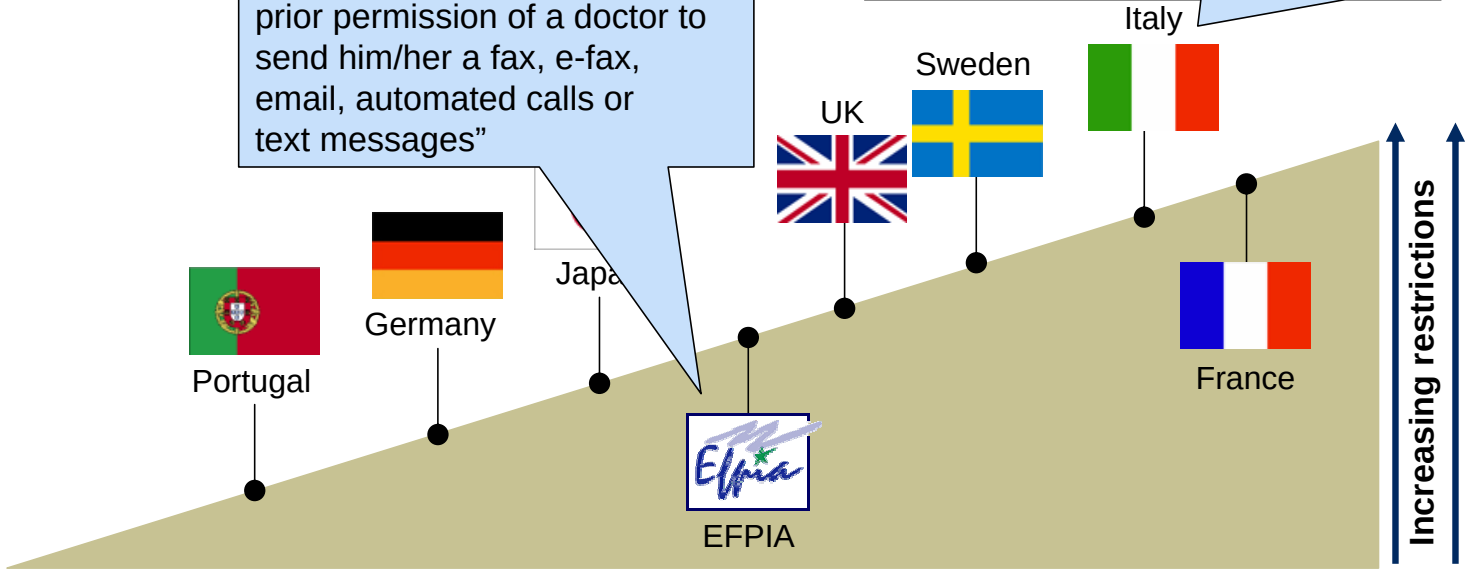
Source: McKinsey & Company

COMMUNICATIONS WITH PHYSICIANS

- Frequency of office visits
- Other channels of communication (phone, fax, email)
- Limitations on leaving samples

"It is even illegal to track doctor prescribing information"
"The rules aren't quite clear, but it would be risky to make more than 5 visits/year to a doctor"

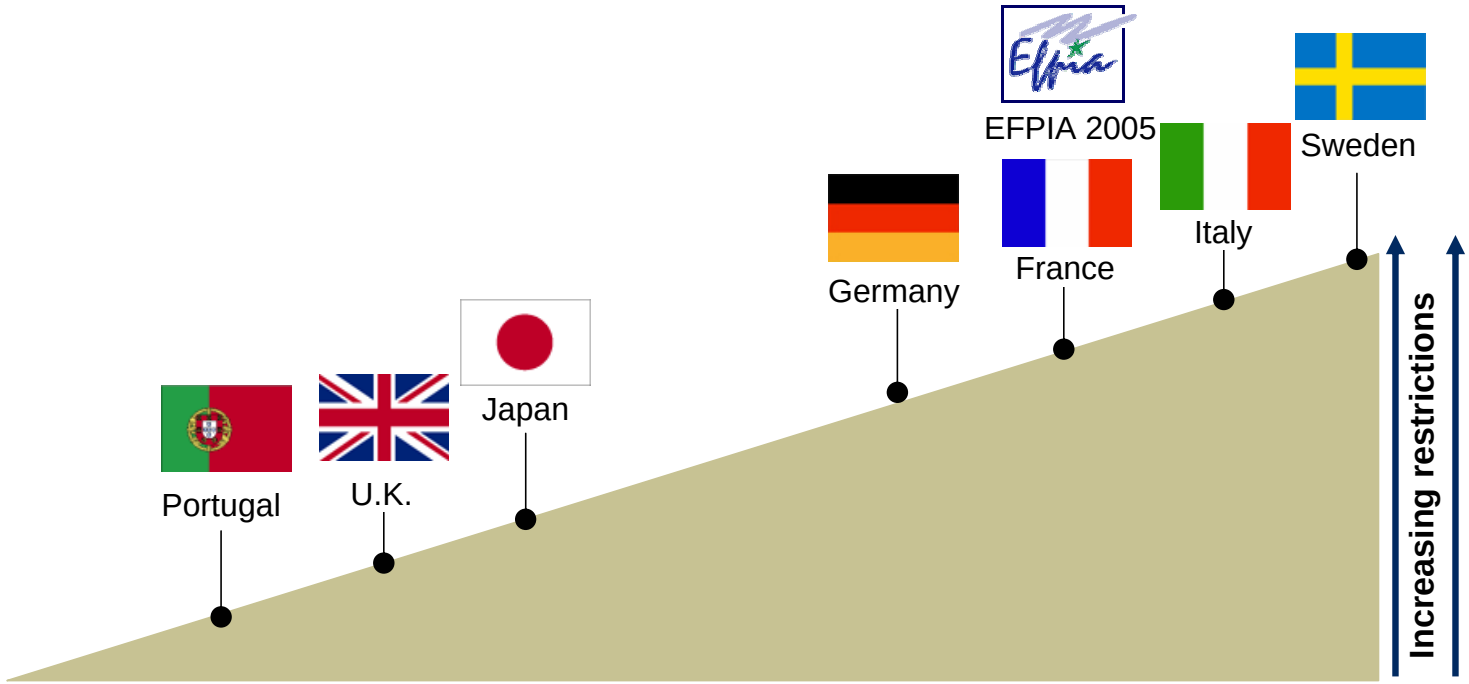
"EFPIA expects us to ask for prior permission of a doctor to send him/her a fax, e-fax, email, automated calls or text messages"



Source: McKinsey & Company

MEETINGS AND CONVENTIONS

- Social activities/hospitality a pharmaco can pay for at a meeting
- Reimbursement for travel and expenses
- Limitations of international conferences

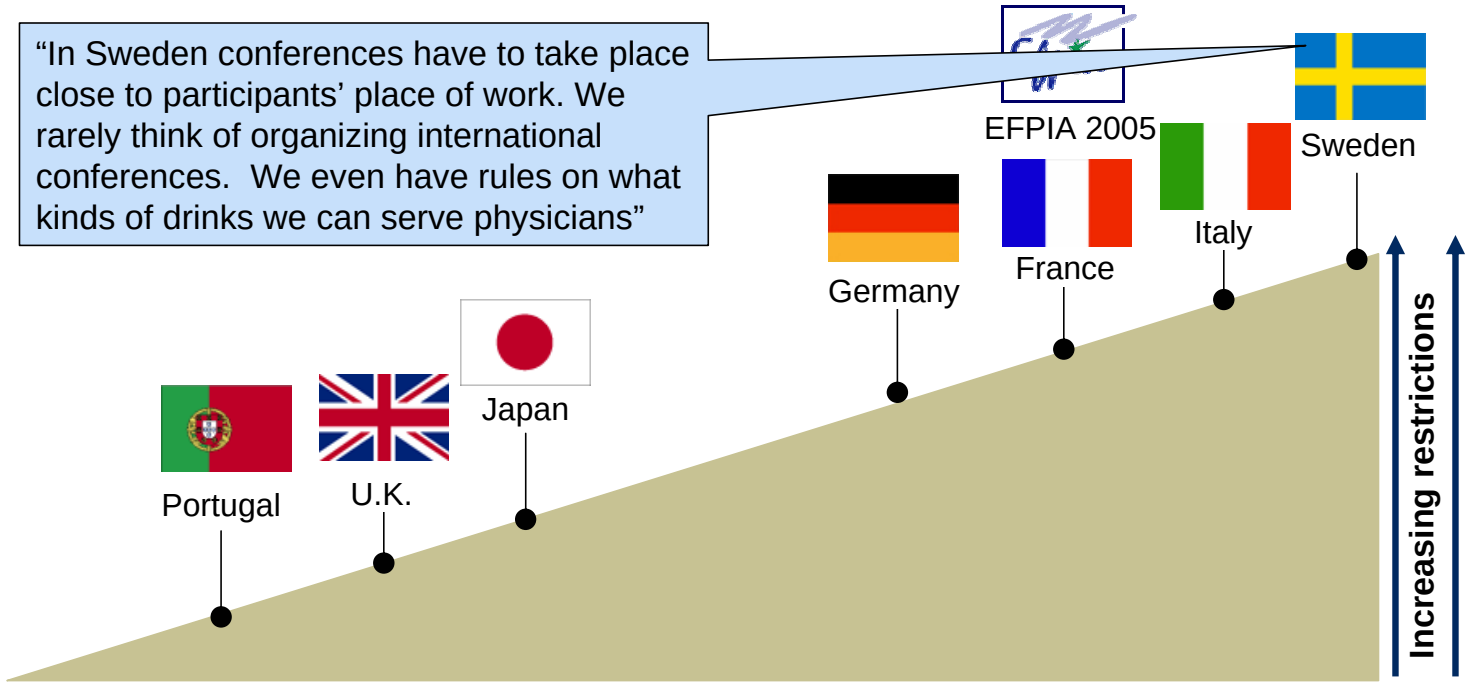


Source: McKinsey & Company

MEETINGS AND CONVENTIONS

- Social activities/hospitality a pharmaco can pay for at a meeting
- Reimbursement for travel and expenses
- Limitations of international conferences

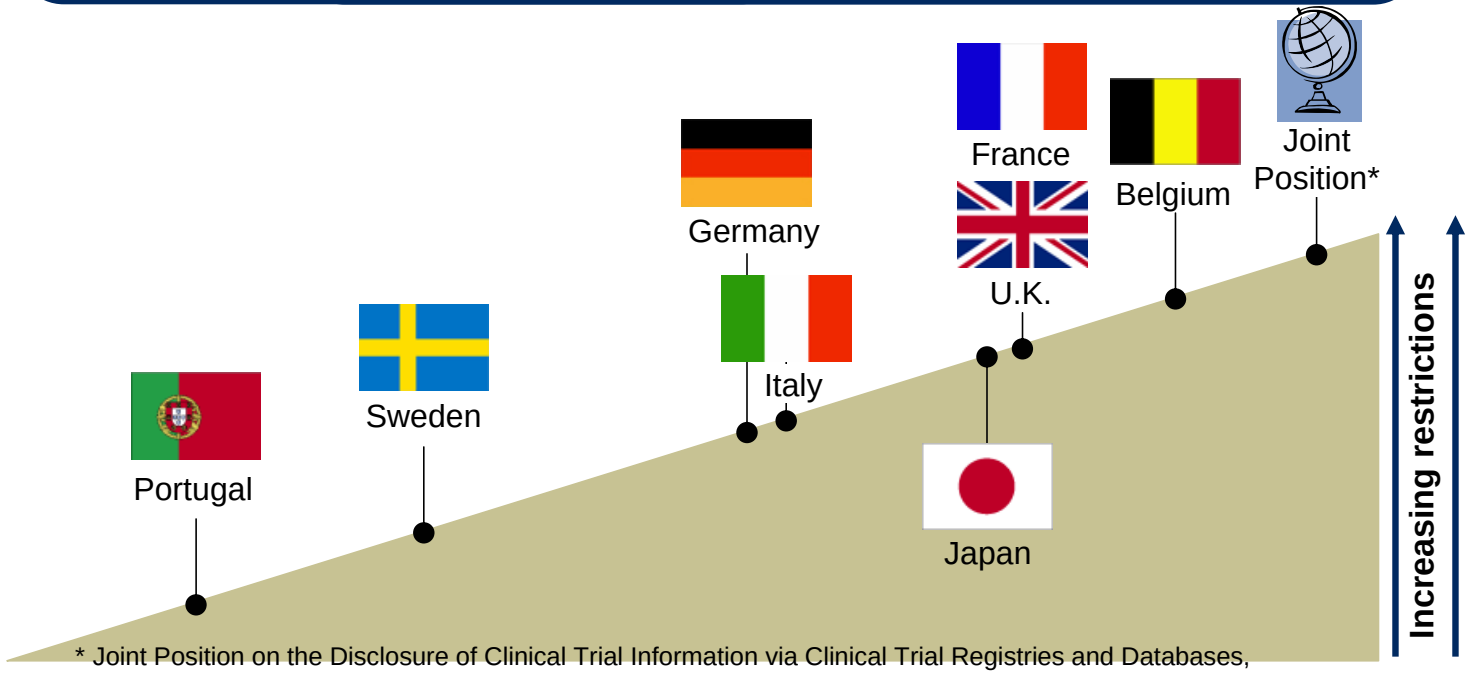
"In Sweden conferences have to take place close to participants' place of work. We rarely think of organizing international conferences. We even have rules on what kinds of drinks we can serve physicians"



Source: McKinsey & Company

CLINICAL TRIALS

- Mandatory reporting of trial outcomes and adverse events
- Insurance requirements
- Number of enrollees



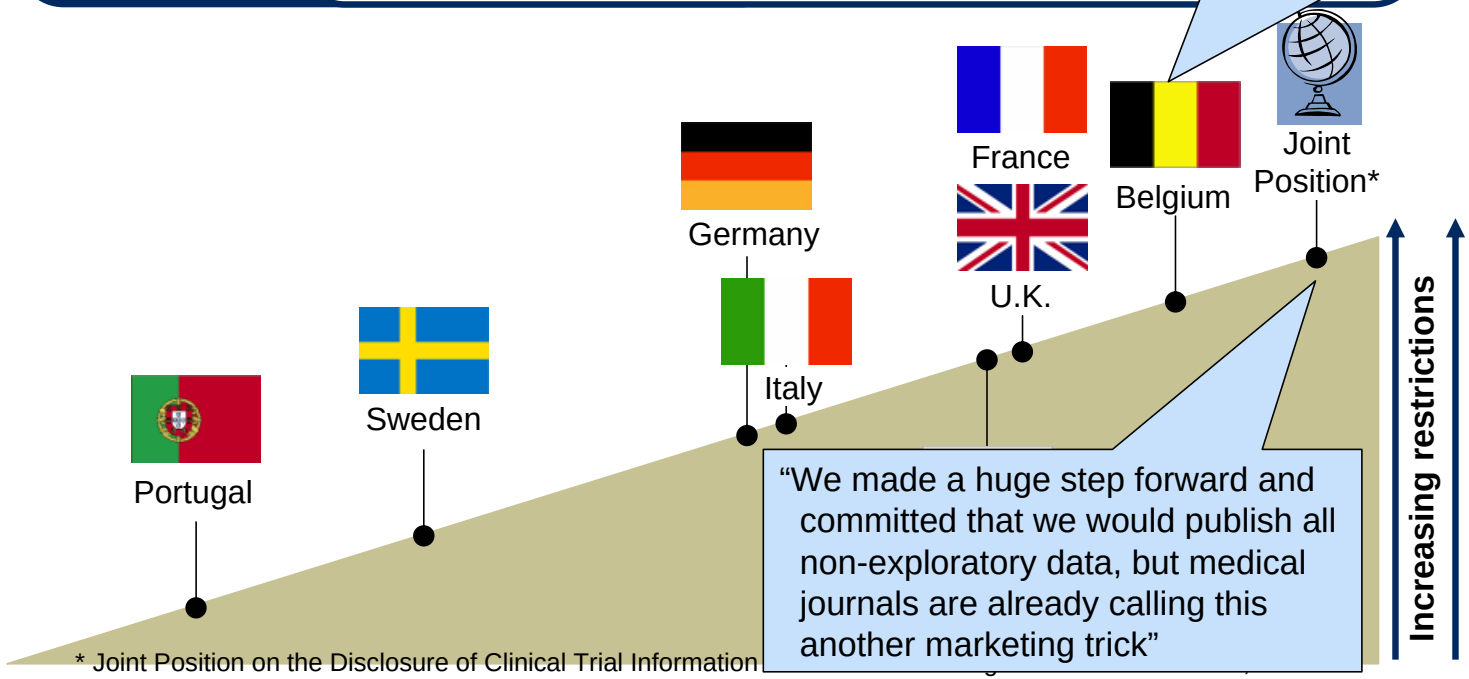
* Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases, January 6, 2005, signed by EFPIA, IFPMA, JPMA, and PhRMA

Source: McKinsey & Company

CLINICAL TRIALS

- Mandatory reporting of trial ou events
- Insurance requirements
- Number of enrollees

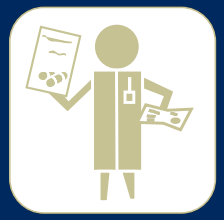
"We virtually had to halt academic studies as no one could afford insurance. If a pharmacist hurt his back while lifting a box, that was considered part of the trial!"



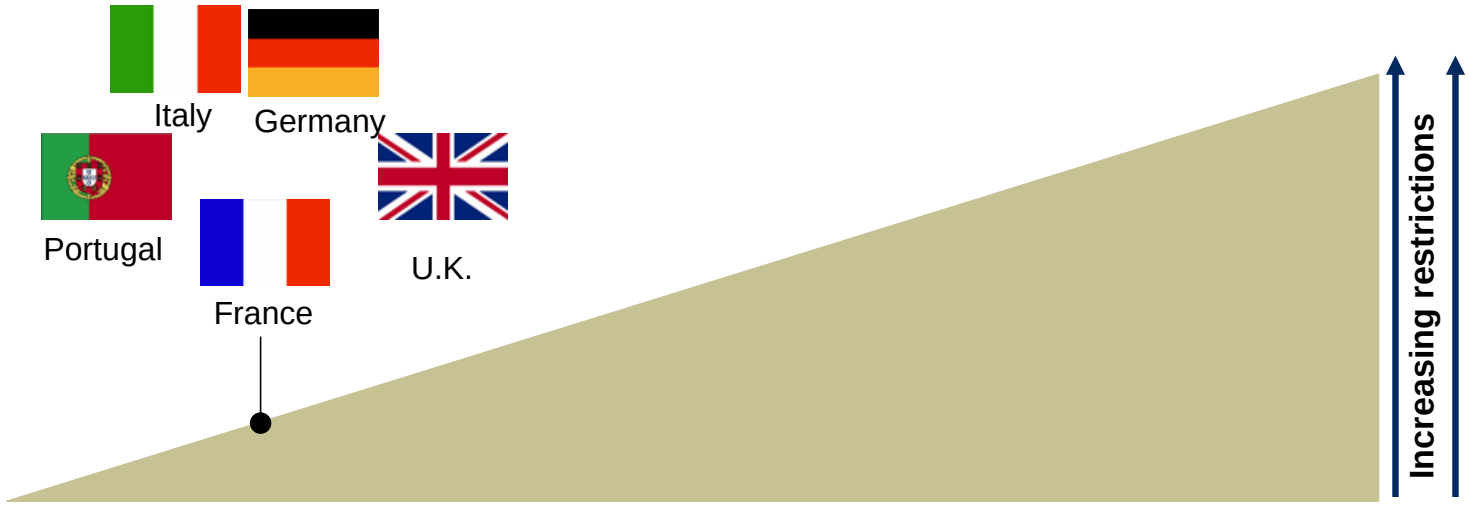
* Joint Position on the Disclosure of Clinical Trial Information … January 6, 2005, signed by EFPIA, IFPMA, JPMA, and PhRMA

Source: McKinsey & Company

MEDICAL EDUCATION



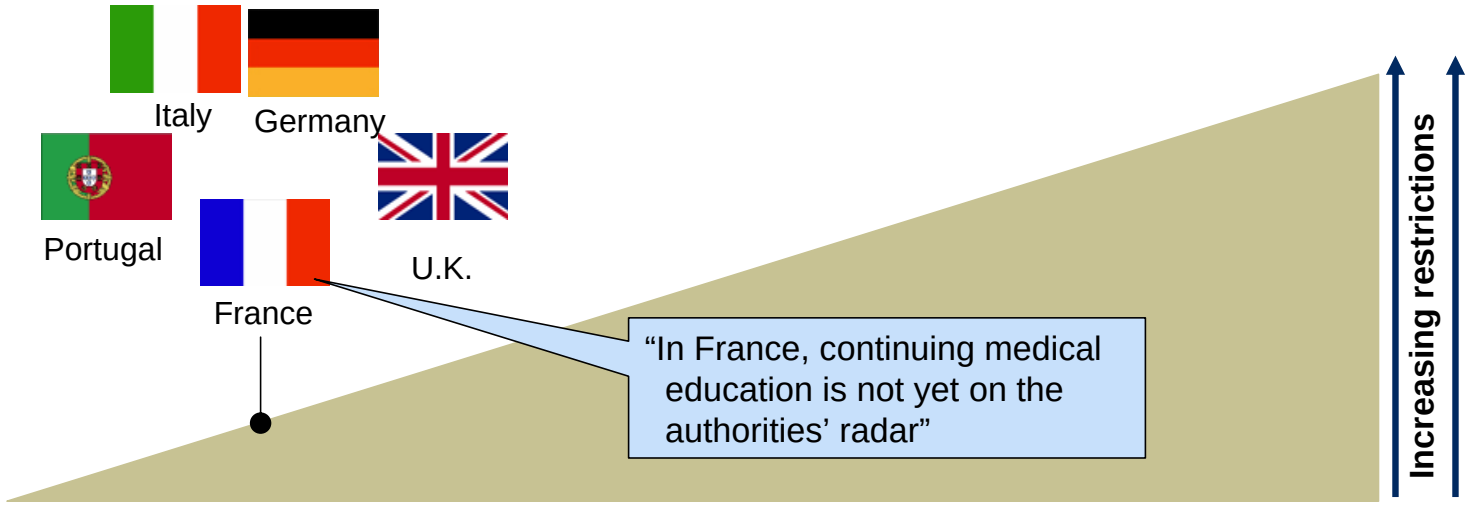
- Limits on content
- Financial limits of sponsorship
- Independence of pharmaco from those who receive funds (speakers, CME)



Source: McKinsey & Company

MEDICAL EDUCATION

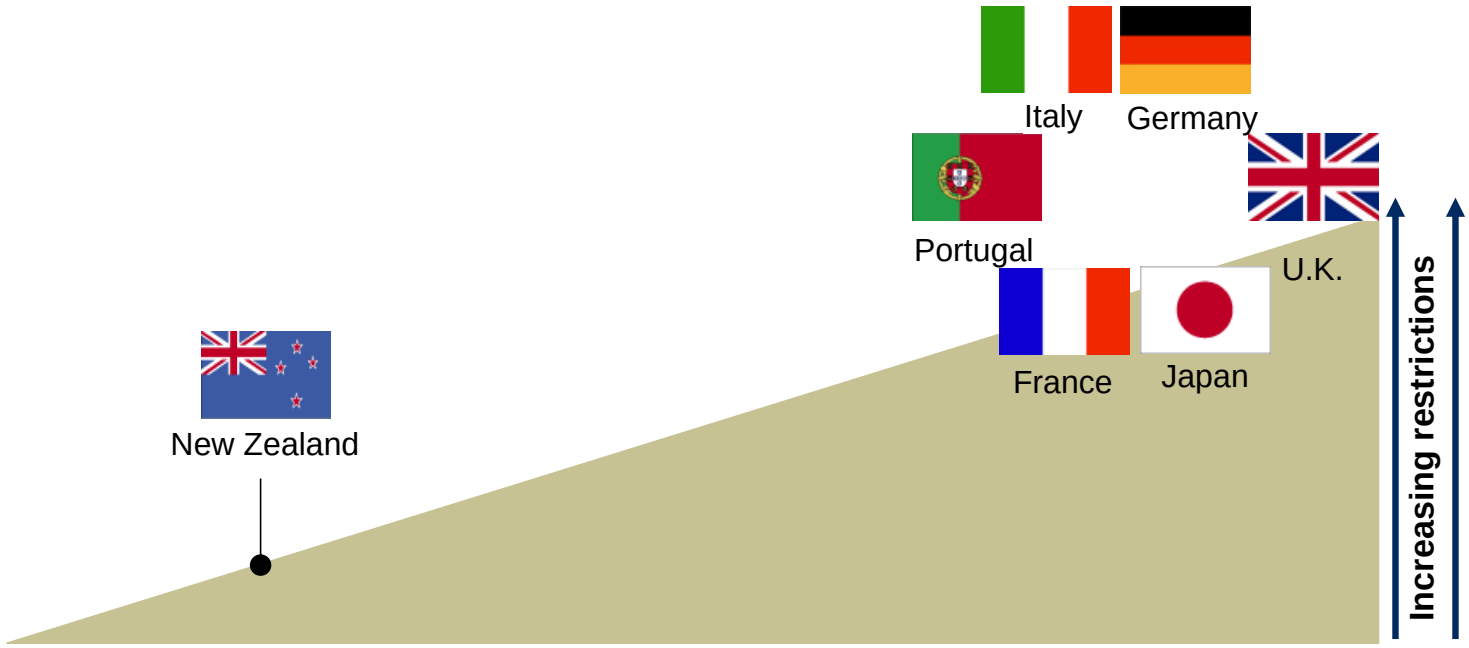
- Limits on content
- Financial limits of sponsorship
- Independence of pharmaco from those who receive funds (speakers, CME)



Source: McKinsey & Company

DIRECT-TO-CONSUMER COMMUNICATIONS

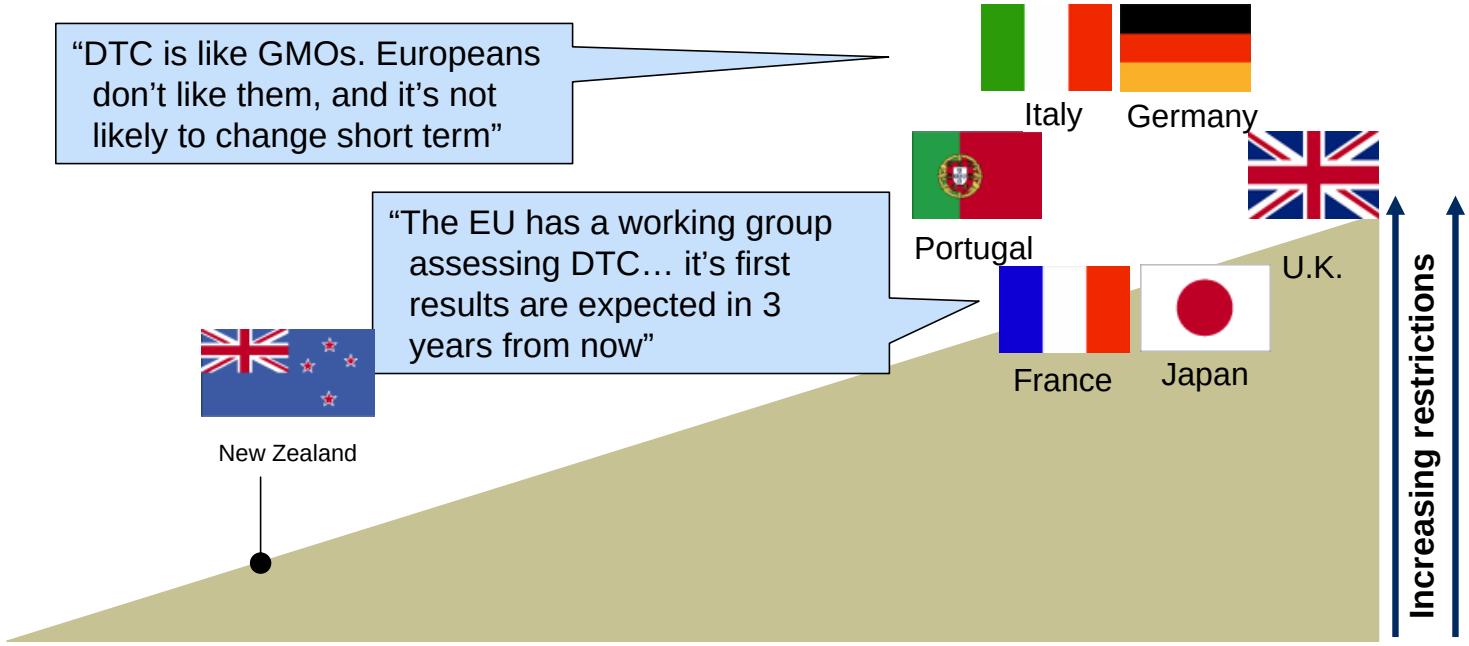
- Restrictions on direct-to consumer communication
  - –Television
  - –Print ads



Source: McKinsey & Company

DIRECT-TO-CONSUMER COMMUNICATIONS

- Direct-to consumer communication
  - –Television
  - –Print ads



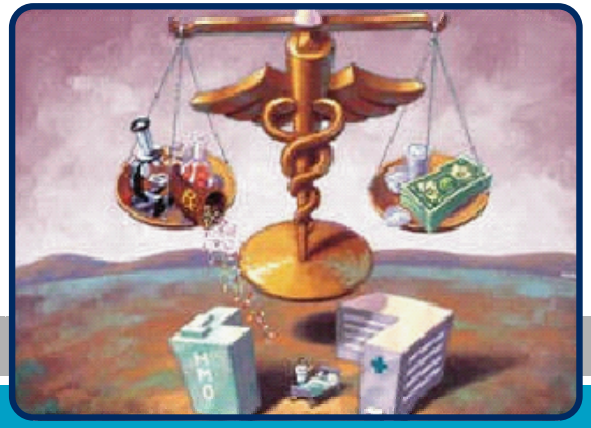
Source: McKinsey & Company

MANAGEMENT CHALLENGES DRIVEN BY LOCAL DIVERSITY

- **Do I need to rethink my model of communicating medical information to customers?**
- **How do I stay abreast of the new developments, especially in making sure country operations are always compliant?**
- **Should I attempt to have a single set of comprehensive corporate-wide guidelines around medical affairs?**
- **Without a corporate-wide standard, how do I explain my compliance posture to my customers?**
- **How do I coordinate trial strategy in a world of more transparency?**

Source: McKinsey & Company

Managing the Complexity – One Perspective

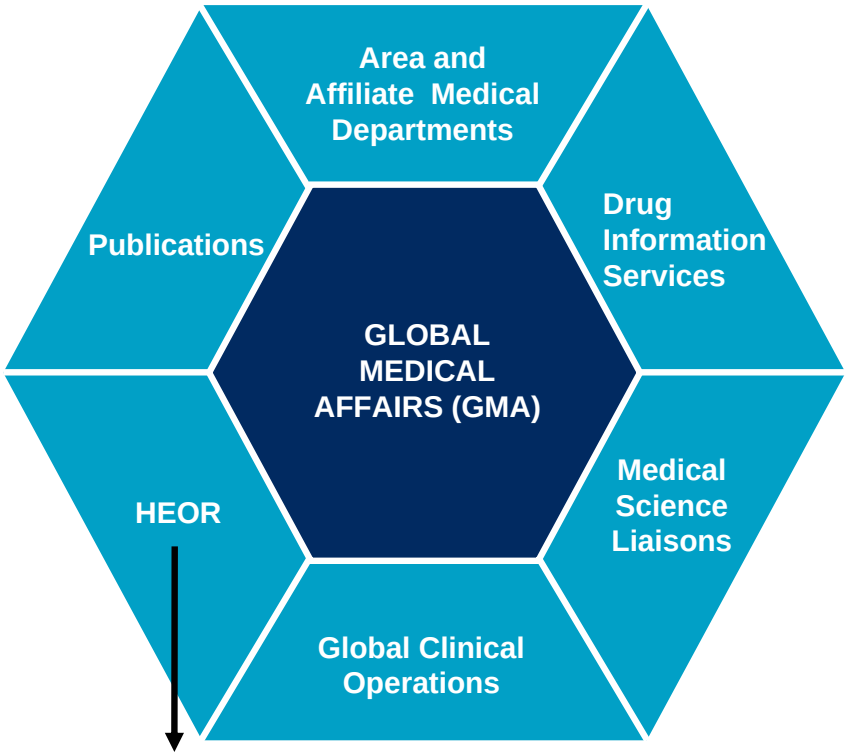


Stan Bukofzer

Divisional Vice President
and Head of Global Medical Affairs

Abbott Laboratories

DIVERSITY OF GLOBAL MEDICAL AFFAIRS (GMA) RESPONSIBILITIES CREATES MANAGEMENT CHALLENGES



Health Economics and Outcomes Research

Irrespective of the specific structure, key activities include

- Creating and disseminating science
- Ensuring legal, ethical and regulatory standards
- Function efficiently and in an integrated fashion

Management challenges include

- Diversity of responsibility
- Global scope
- Local and regional variation of the laws

ABBOTT'S GUIDING PRINCIPLES TO MANAGE GMA

- **1. Patient's well-being is the top priority**

- **2. Structural separation of GMA from commercial**
  - *GMA reporting to R&D*

- **3. Centralized decision making within GMA**
  - *Simple and clear processes*

- **4. Cross functional communication teams that include regional and local structures**
  - *Specific Communication Channels*

- **5. Application of global clinical SOPs**
  - *Clear Understanding of Legal and Regulatory Requirements as well as ethical and best practices*

- **6. Standardized clinical training world-wide**

2. INDUSTRY APPROACHES TO GMA REPORTING STRUCTURE VARIES – ABBOTT SEPARATES GMA FROM COMMERCIAL, BY GMA REPORTING TO R&D (MODEL 2)

Model 1

Majority of pharmacos have this structure

International Medical Affairs decentralized

AstraZeneca
Aventis
Johnson & Johnson
PHARMACIA
Schering-Plough

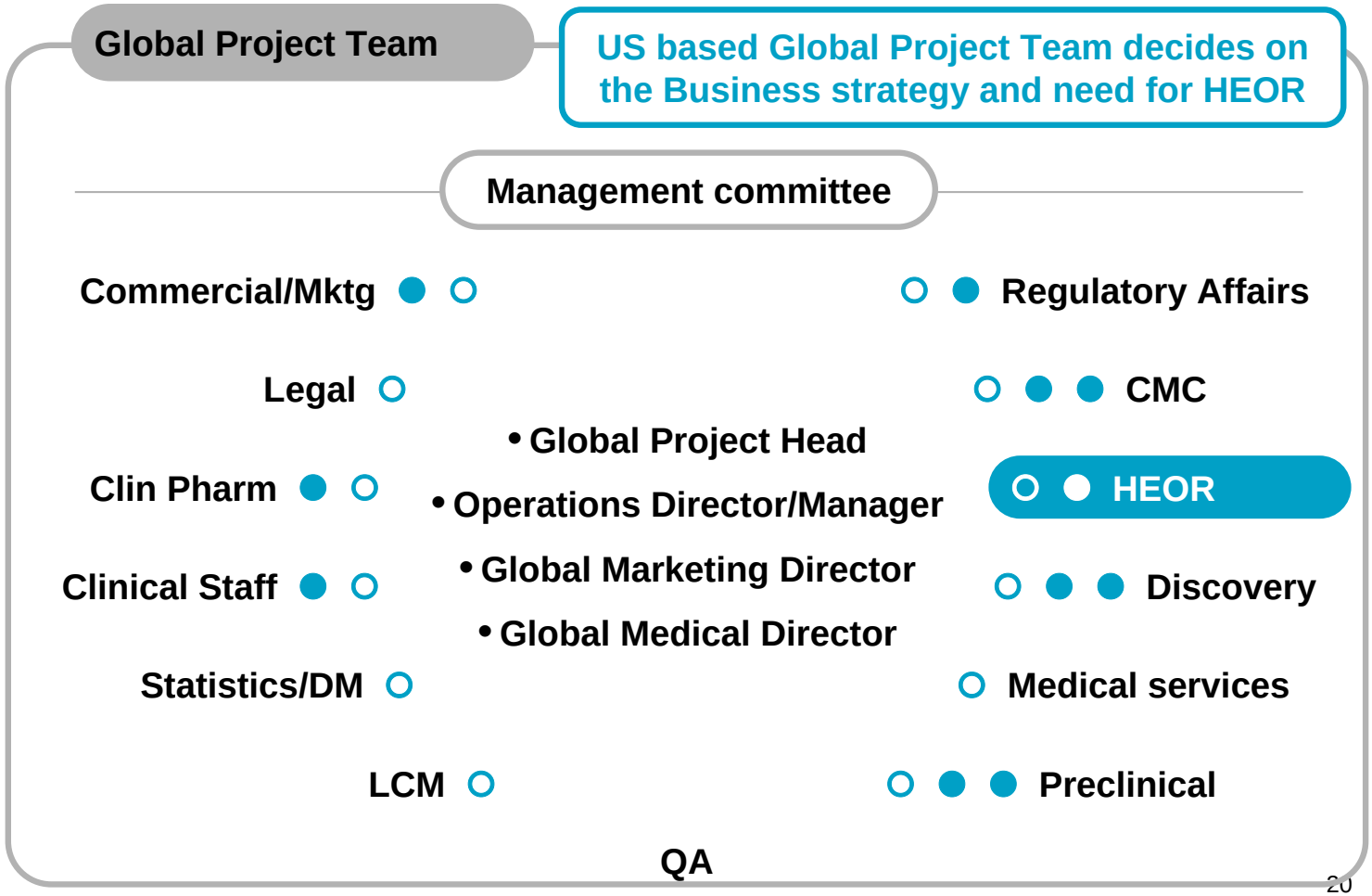
Model 2

Trend away from this model in recent years, **but some now reconsidering post OIG guidelines**

Abbott Laboratories
GlaxoSmithKline
MERCK
NOVARTIS
Pfizer

Source: McKinsey & Company

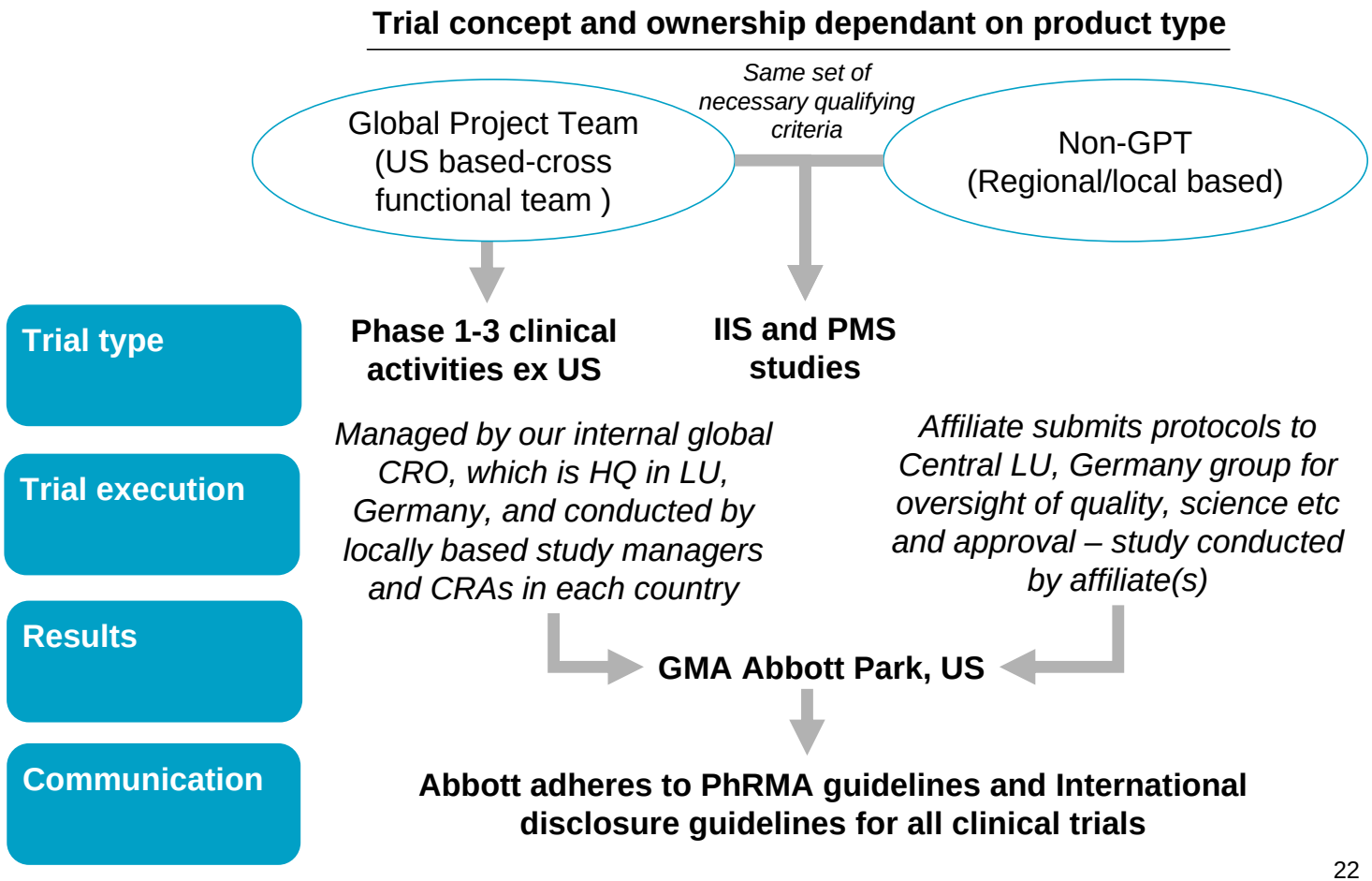
3. ABBOTT GMA USES CENTRALIZED DECISION MAKING PROCESS WITH REGIONAL TACTICAL CONTROL



3. ABBOTT GMA USES CENTRALIZED DECISION MAKING PROCESS WITH REGIONAL TACTICAL CONTROL

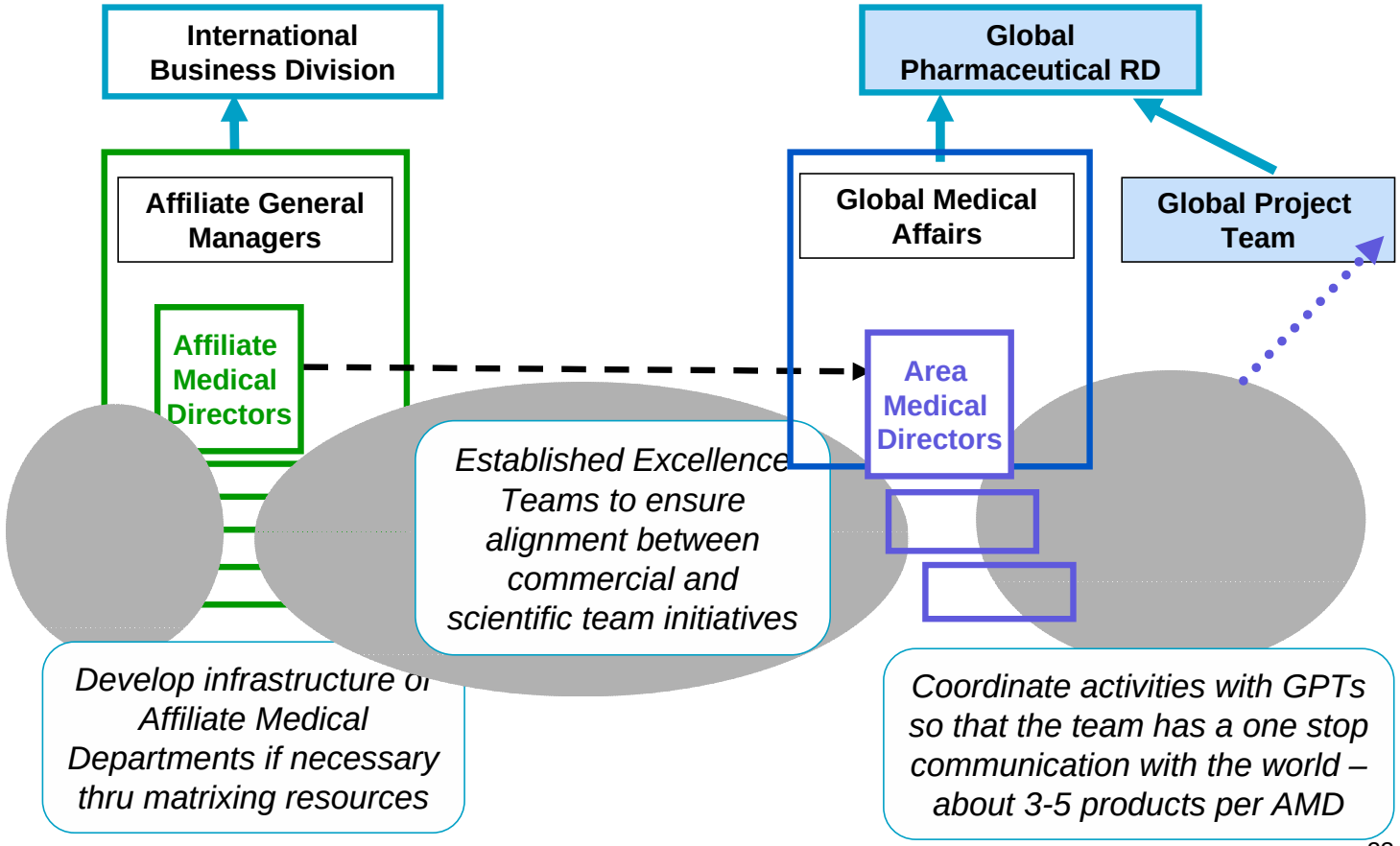
Global Project Team	US based Global project team decides on the Business strategy and need for HEOR
'Factory': Scientific info produced centrally	GMA HEOR team in US/ Ex US work on a strategy and decide on what projects are needed.g. QOL, economic model etc
Regional "packaging" into appropriate format	Core dossier sent to region/ country where GMA HEOR scientist adapts package for local market e.g. NICE submission
Local delivery by affiliate based scientist	Affiliate based field scientist presents info to appropriate payer etc

3. CENTRALIZED DECISION MAKING WITH REGIONAL TACTICAL CONTROL



3. CENTRALIZED DECISION MAKING WITH REGIONAL TACTICAL CONTROL

Affiliate medical departments and area medical directors



4. GLOBAL MEDICAL AFFAIRS HAS DEVELOPED A STRONG SET OF GLOBAL SOPs BASED ON A CLEAR UNDERSTANDING OF LEGAL REGULATORY REQUIREMENTS

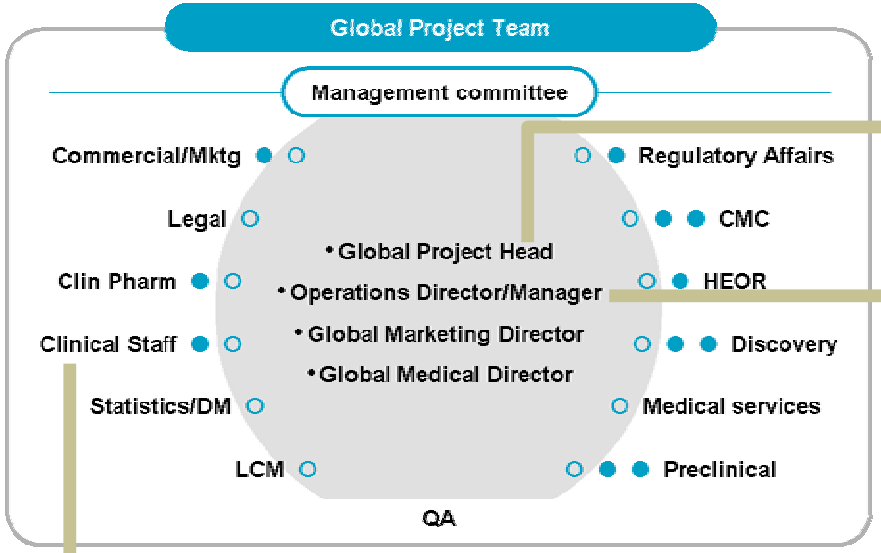
Try to keep abreast of rapidly changing environment

- Trends in legislation at state and federal/country level
- Address new requirements in their formative stages
- Participate in industry organizations
- Bench mark and apply Best Practices

Standard global SOPs generally use US/ EU laws and regulations as a base – where affiliate more stringent/ different local laws exist, an additional local SOP will be issued

Where applicable ICH practice guidance are reflected – many not yet actually adopted, but best practice dictates use

5. CROSS FUNCTIONAL TEAMS ARE UTILIZED TO ACQUIRE INPUT AND COMMUNICATE SPECIFIC INFORMATION (E.G., SOP CHANGES, NEW REGULATIONS ETC.)



Global Project Head Forum

Global Clinical Operations Director Forum

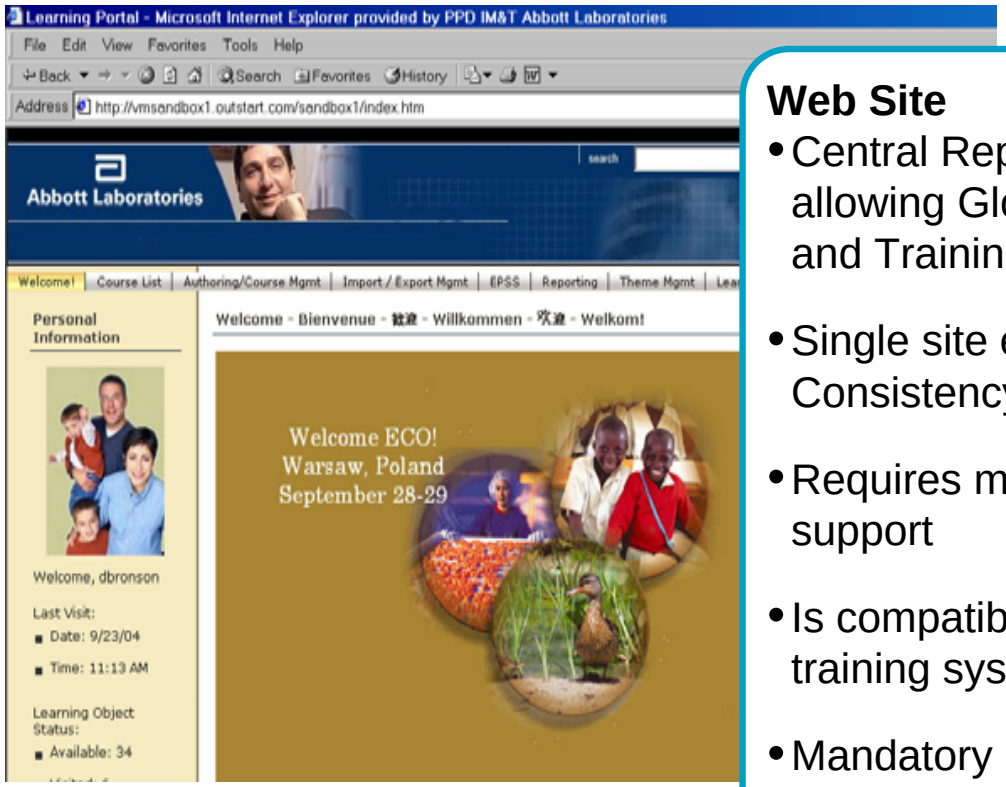
Assistant Clinical Directors Forum

Disseminate Development Staff Forum

AMD Meetings

Monthly highlights

6. STANDARDIZED TOOLS FOR CLINICAL TRAINING WORLD-WIDE (e.g. TRAINING MATERIALS AVAILABLE THROUGH WEB BASED PORTAL)



Web Site

- Central Repository for Training allowing Global Access to CBTs and Training links
- Single site ensures Consistency/Training
- Requires minimal internal IT support
- Is compatible with Abbott's other training systems
- Mandatory legal and ethical training of relevant roles

MANAGEMENT CHALLENGES DRIVEN BY LOCAL DIVERSITY

- **Do I need to rethink my model of communicating medical information to customers?**
- **How do I stay abreast of the new developments, especially in making sure country operations are always compliant?**
- **Should I attempt to have a single set of comprehensive corporate-wide guidelines around medical affairs?**
- **Without a corporate-wide standard, how do I explain my compliance posture to my customers?**
- **How do I coordinate trial strategy in a world of more transparency?**

E-mail contacts:
Stam Bukofzer: Stan.Bukofzer@abbott.com
Alexander Petersen: Alexander_Petersen@Mckinsey.com