

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

November 10, 2008

LIFE SCIENCES ADVISORY SERVICES

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# Today's Agenda

- **Welcome and Introductory Comments**
- **Legal and Enforcement Issues: An Overview of International Enforcement**
- **Regional Codes of Conduct: A Comparison of Eucomed and AdvaMed and a Review of Country-Level Codes**
- **Perspectives from the Industry**
- **Compendium Case Study: Using the 2008 Huron Compendium as a Guide**
- **Faculty Roundtable on Top Ten Take-Aways**

# Self-Regulatory Codes of Conduct

# Self-Regulatory Codes of Conduct

## Major Areas of Similarity

- MTAA/MTANZ
- Eucomed/EDMA
- AdvaMed/MEDEC

# Eucomed vs. AdvaMed

Provision	AdvaMed	Eucomed
<b>General Compliance</b>	None	<p><i>“Code of Business Practice”</i></p> <ul style="list-style-type: none"> <li>• Quality/Regulatory</li> <li>• Interactions with HCPs</li> <li>• Advertising/Promo</li> <li>• Unlawful Payments</li> <li>• Competition*</li> <li>• Export Controls</li> <li>• Environmental Laws</li> <li>• Data Privacy</li> </ul>
<b>Interactions with HCPs</b>	Same as Eucomed - Eucomed just added FAQs similar to AdvaMed Code	<p><i>“Guidelines on Interactions with Healthcare Professionals”</i></p> <ul style="list-style-type: none"> <li>• Goal and Scope</li> <li>• Training &amp; Education</li> <li>• Educational Programs</li> <li>• Sales/Promo Mtgs</li> <li>• Consultants</li> <li>• Gifts</li> <li>• Reimbursement Info</li> <li>• Grants/Donations</li> </ul>
<b>Competition</b>	None	<p><i>“Guidelines on Competition Law”</i></p> <ul style="list-style-type: none"> <li>• Anticompetitive agreements</li> <li>• EUCOMED activities</li> <li>• Prohibition on use of dominant position</li> <li>• Potential breaches</li> <li>• Do’s and Don’ts</li> </ul>
<b>Industry-HCP Guidelines</b>	None	<p><i>“Joint Declaration of CPME-Eucomed on Physician Cooperation with Industry”</i></p> <ul style="list-style-type: none"> <li>• Education and training</li> <li>• Sales/promo</li> <li>• Clinical trials</li> <li>• Consultants</li> </ul>

# Eucomed vs. AdvaMed

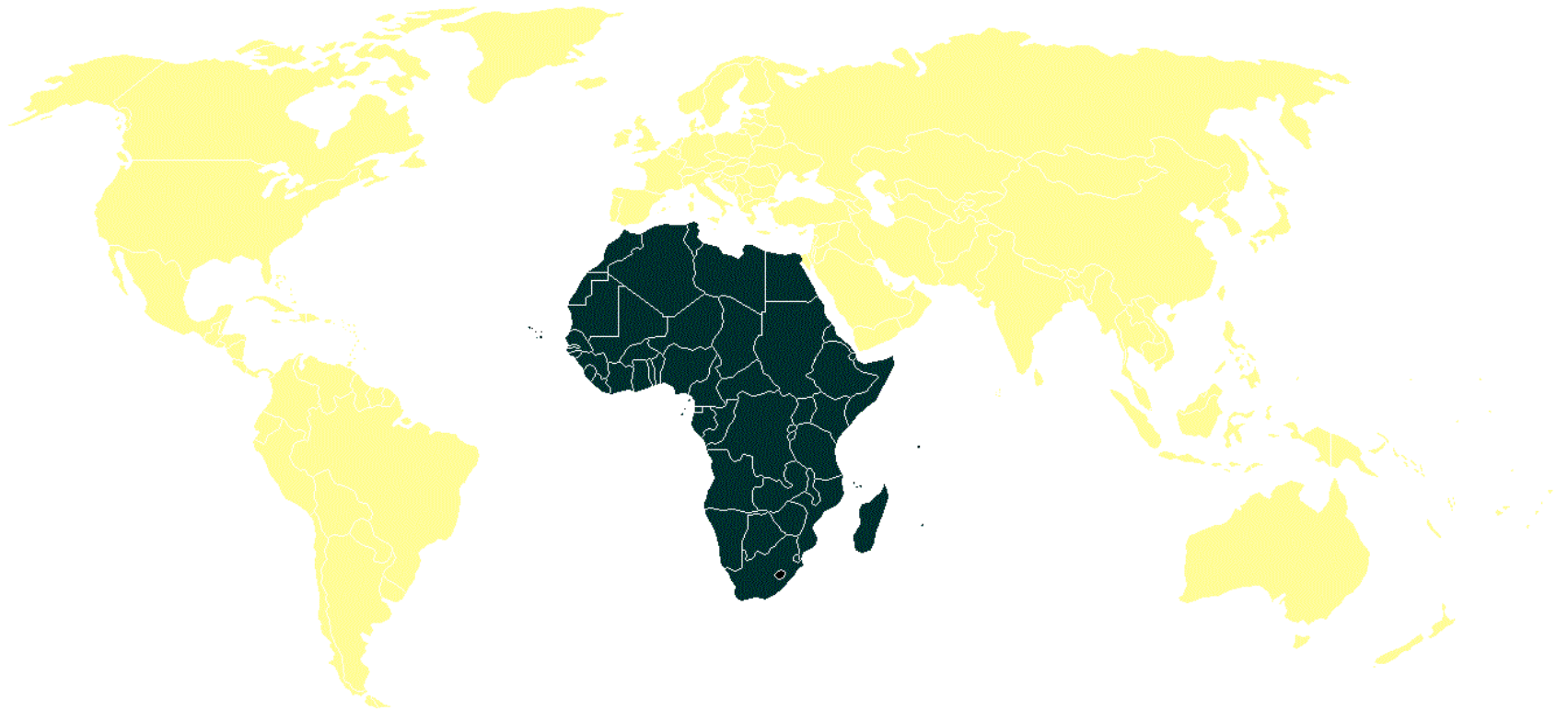
Provision	AdvaMed	Eucomed
<b>Member-Sponsored Training and Education</b>	Hospitality only in the form of modest meals and receptions	Hospitality, travel and lodging must be consistent with laws where HCP is licensed
	Inappropriate to pay for meals, hospitality or travel for spouses	Hospitality should be reasonable in value. No exclusion of spouses/guests.
<b>Support for Third-Party Educational Conferences</b>	Cannot pay travel and meal costs for non-faculty.	Support must be consistent with laws where HCP is licensed. If allowed in that HCP's country, can pay for travel and meal costs.
	Members may advertise via displays and booths, no requirement for stating support	Support must be clearly stated in advance of, at the meeting, and in the proceedings
<b>Consultants</b>	Payment must reflect FMV of services provided	Consultant arrangements must be consistent with laws where HCP is licensed (new guideline indicating FMV)
	Payment must be bona fide services identified in advance	Payment must be based on services actually provided
	Selection of consultants should not be based on volume or value of business generated	New provision now included

# Eucomed vs. AdvaMed

Provision	AdvaMed	Eucomed
<b>Gifts</b>	Gifts should not be provided with FMV greater than \$100	Does not specify a maximum FMV for gifts – must be “modest” in value and in accordance with local laws.
<b>Reimbursement Information</b>	No significant differences	No significant differences
<b>Grants/Donations</b>	One section with focus on: <ul style="list-style-type: none"> <li>• Advancement of Med Ed</li> <li>• Support of Research with Scientific Merit</li> <li>• Public Education</li> </ul>	Two separate sections: <ol style="list-style-type: none"> <li>1. Charitable and philanthropic</li> <li>2. New section on educational grants:               <ul style="list-style-type: none"> <li>• Scholarships</li> <li>• Advancement of HC education</li> <li>• Research</li> <li>• Public Education</li> </ul> </li> </ol>

# Self-Regulatory Codes of Conduct

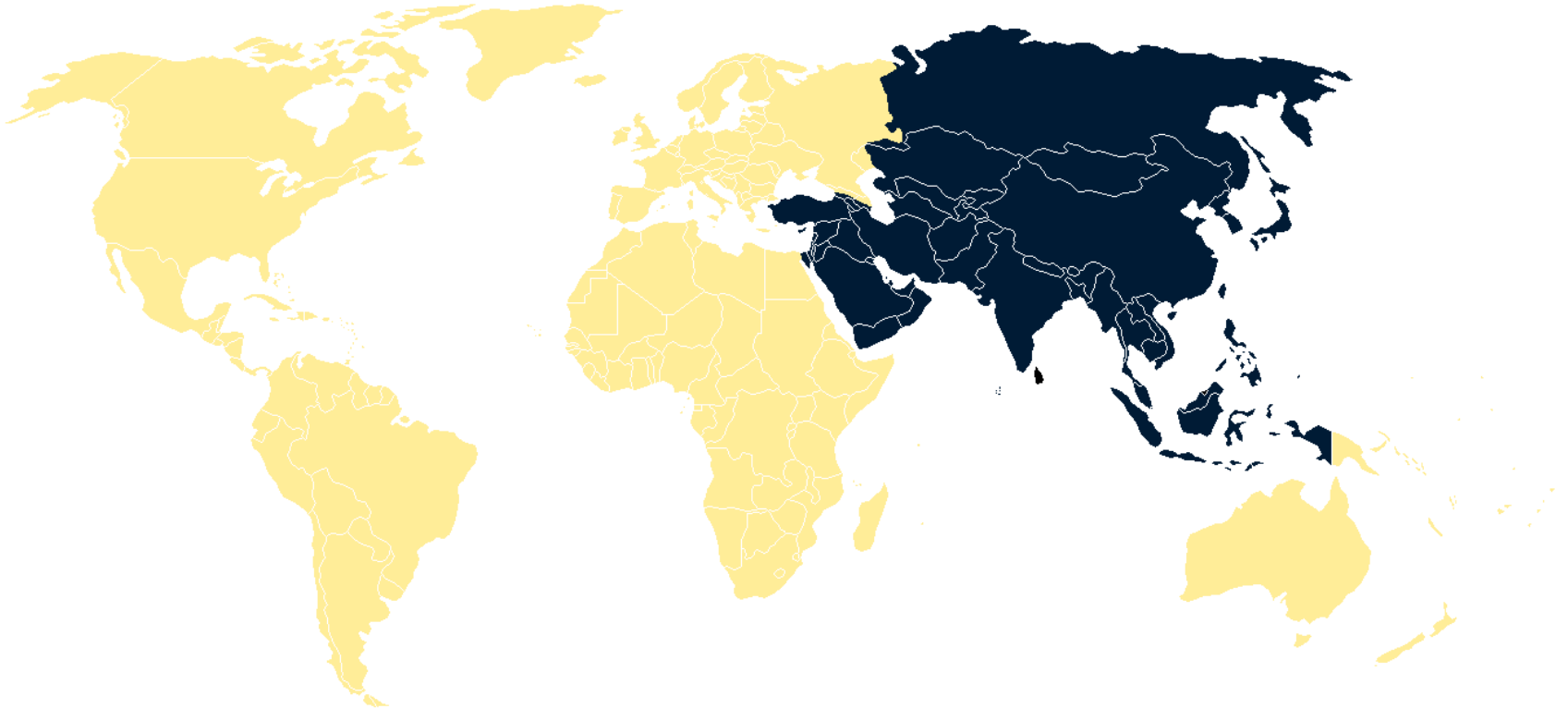
Africa – No Codes





# Self-Regulatory Codes of Conduct

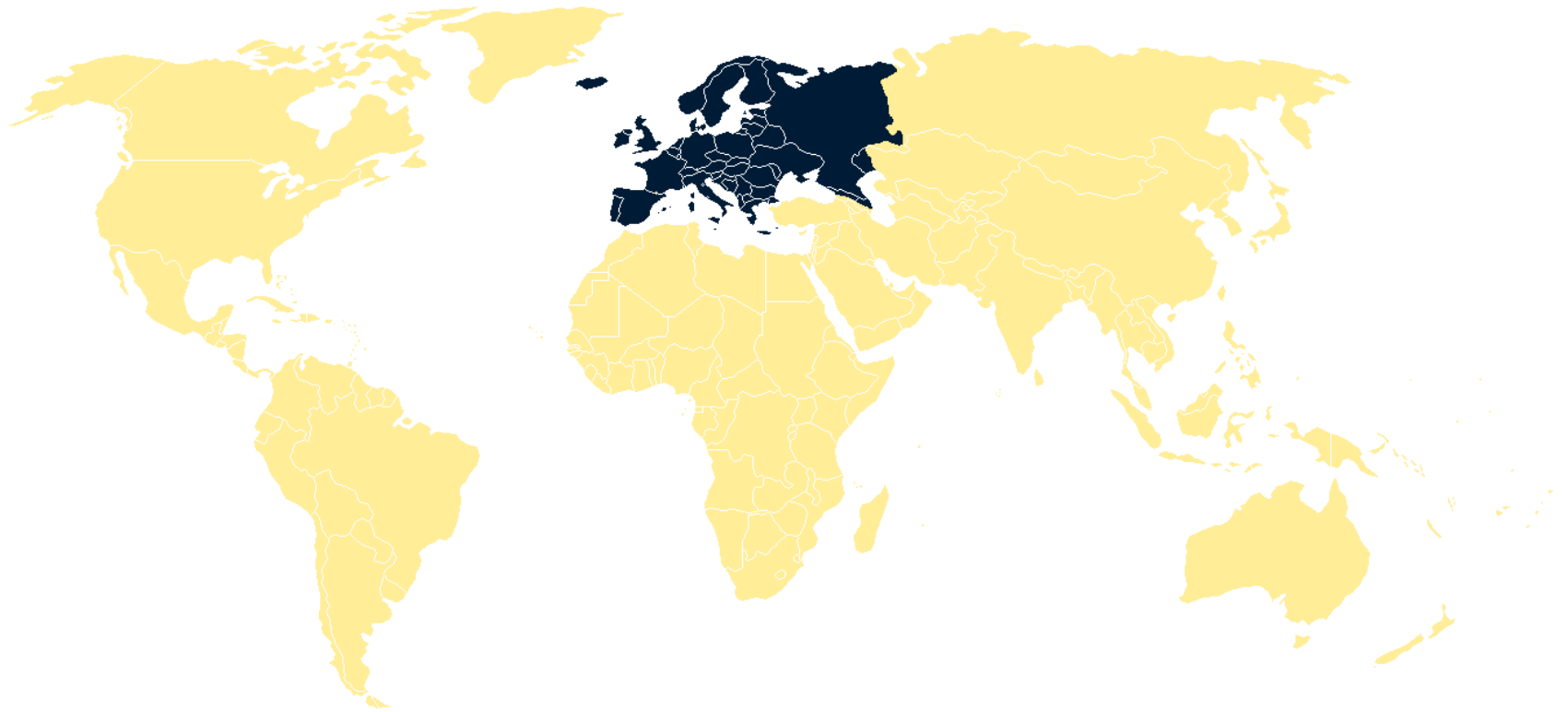
## Asia



- **China:** HKAPI
- **Japan:** JFMDA

# Self-Regulatory Codes of Conduct

## Europe



# Self-Regulatory Codes of Conduct

## Europe

- **Austria** – EDMA, Eucomed, AUSTROMED, ODGH
- **Belgium** – EDMA, Eucomed, UNAMEC, pharma.be diagnostics
- **Bulgaria** – EDMA, BTMA
- **Czech Republic** – EDMA, Eucomed, CZECHMED, CZEDMA
- **Denmark** – Eucomed, Medicoindustrien
- **Finland** – EDMA, Eucomed, SAI-LAB
- **France** – EDMA, Eucomed, APPAMED, SNITEM, SFRL
- **Germany** – EDMA, Eucomed, BVMED, VDPGH
- **Greece** – EDMA, Eucomed, HELLASMES
- **Hungary** – EDMA, Eucomed, AMDM
- **Ireland** – EDMA, Eucomed, IMDA
- **Italy** – EDMA, Eucomed, Assobiomedica
- **Netherlands** – EDMA, Eucomed, Nefemed
- **Norway** – EDMA, Eucomed, LFH

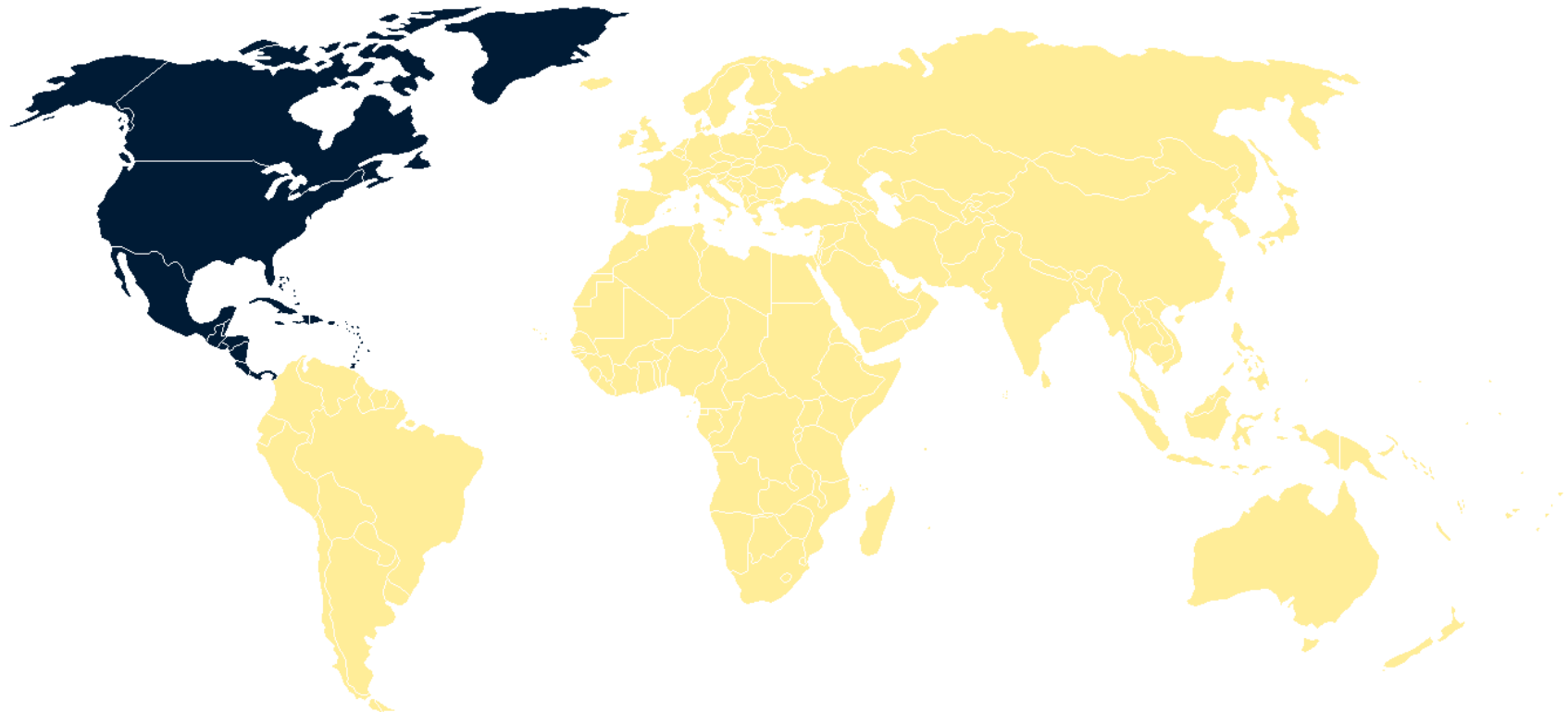
# Self-Regulatory Codes of Conduct

## Europe - Continued

- **Poland** – EDMA, Eucomed, POLMED
- **Portugal** – EDMA, Eucomed, APORMED, APIFARMA
- **Romania** – EDMA, Eucomed, AFPM **Russia** – IMEDA
- **Slovakia** – Eucomed, SK-MED
- **Slovenia** – Eucomed, Gospordarska Zbornica Slovenije
- **Spain** – EDMA, Eucomed, FENIN
- **Sweden** – EDMA, Eucomed, Swedish Medtech
- **Switzerland** – EDMA, Eucomed, FASMED
- **Turkey** – AIRMDTM, TUMDEF
- **United Kingdom** – EDMA, Eucomed, ABHI, BIVDA

# Self-Regulatory Codes of Conduct

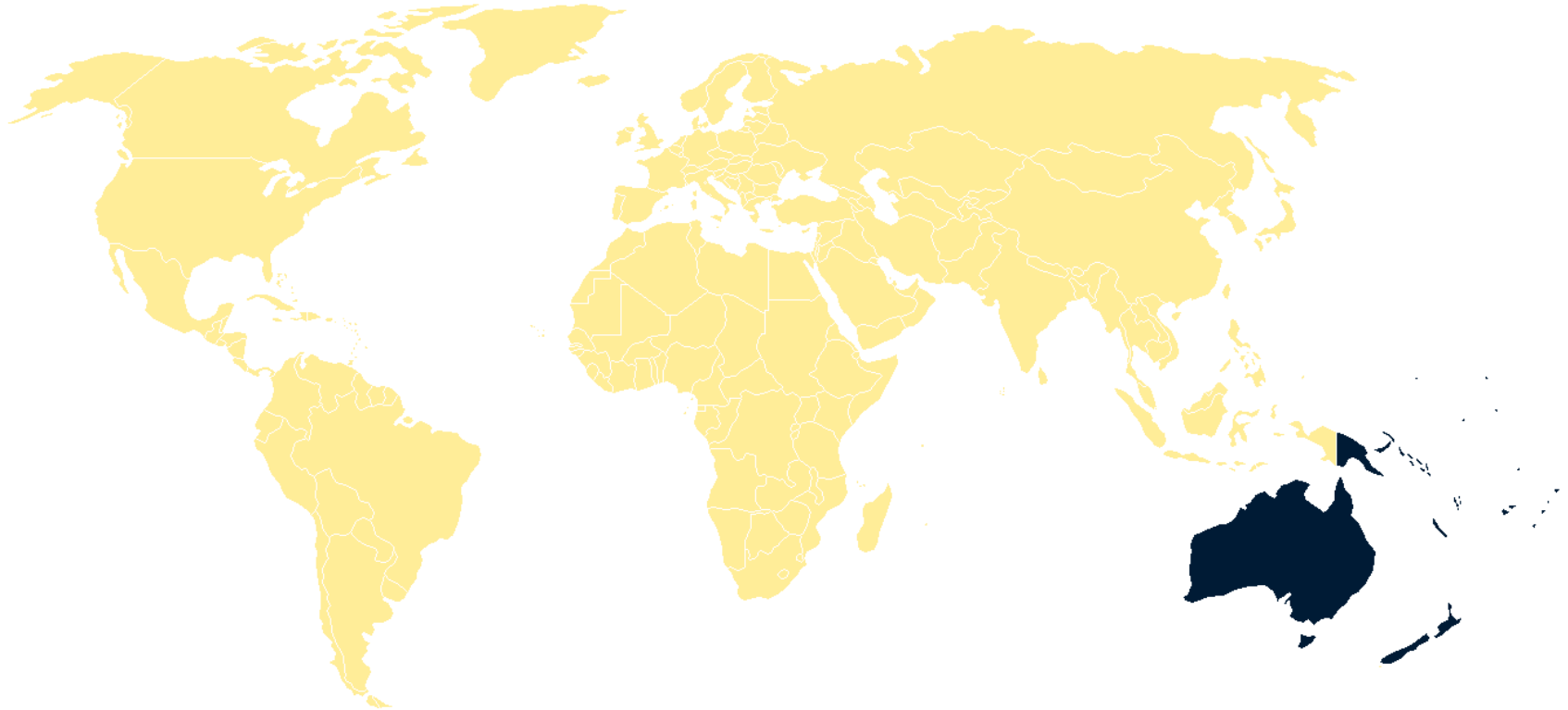
## North America



- **Canada** – MEDEC
- **United States** – Advamed, NEMA
- **Mexico** – AMID

# Self-Regulatory Codes of Conduct

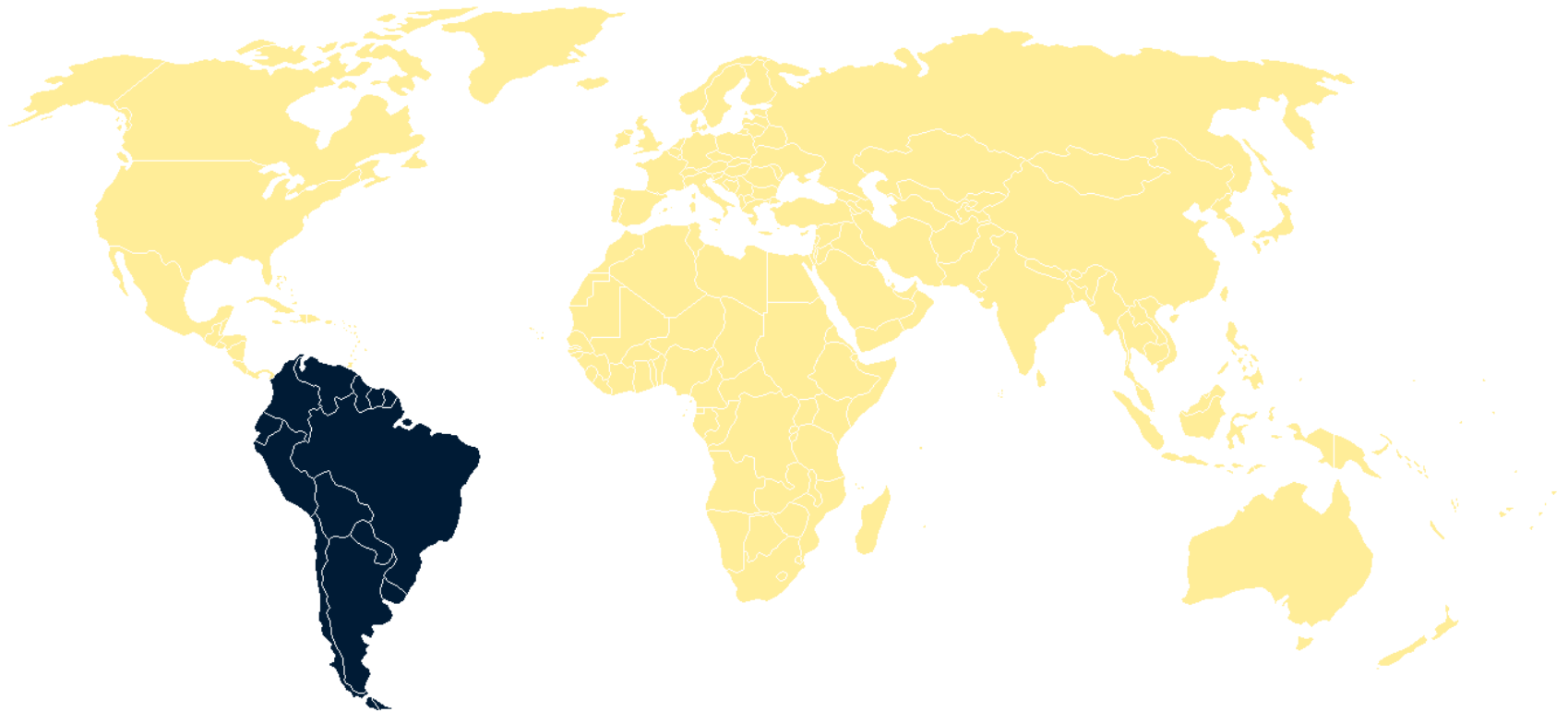
## Oceania



- **Australia** – ACCC, MTAA
- **New Zealand** – MTANZ

# Self-Regulatory Codes of Conduct

## South America



- **Brazil – ABIMED**

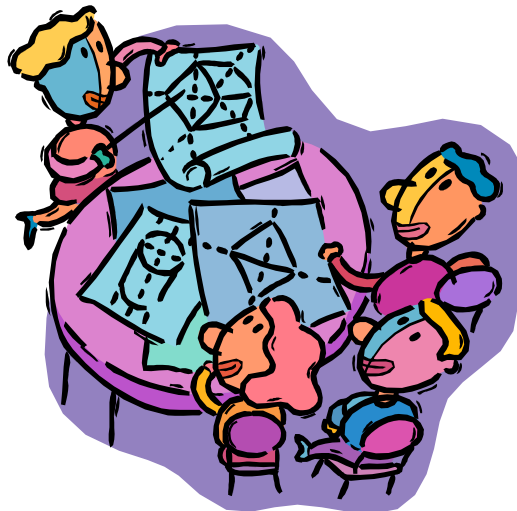
**Case Study:  
Finding the Answers to Common  
Questions**



# International Sales, Marketing, and Promotion Scenario

Medical Devices International, an international medical device manufacturing company headquartered in the U.S. has recently developed a new drug eluting stent. The company is holding a retreat in Nice, France for their European healthcare providers. At the meeting will be medical professionals from Belgium, France, Italy, Spain and the United Kingdom.

Where in the Compendium would I go to determine what considerations need to be taken when planning this meeting?



# Codes of Conduct

## Governing Interactions with Healthcare Professionals

What Codes Must Companies Be Aware Of Regarding This Particular Issue? Where Would I Find This Information In The Compendium?

Country	Are They A Member of Eucomed?	Are They A Member of EDMA?	Medical Device Association and Code of Conduct
Belgium			
France			
Italy			
Spain			
UK			

What Types Of Issues Should I Review In Each of These Codes to Ensure I Understand My International Compliance Risks?

# Codes of Conduct

## Governing Interactions with Healthcare Professionals

What Codes Must Companies Be Aware Of Regarding This Particular Issue? Where Would I Find This Information In The Compendium?

Country	Are They A Member of Eucomed?	Are They A Member of EDMA?	Medical Device Association and Code of Conduct
Belgium (pgs. 30-31)	Yes	Yes	UNAMEC
France (pgs. 36-37)	Yes	Yes	APPAMED, SFRL, SNITEM
Italy (pgs. 42-43)	Yes	Yes	Assobiomedica
Spain (pgs. 50-51)	Yes	Yes	Fenin
UK (pgs. 54-55)	Yes	Yes	ABHI, BIVDA

# Codes of Conduct

## Issues to Review

- **Member-Sponsored Product Training and Education:**
  - EDMA/Eucomed requires that hospitality, travel and lodging provided must be “in compliance with the regulations of the country where the healthcare professional is licensed to practice”
  - EDMA/Eucomed allows spouses or guests of healthcare professionals to participate in group hospitality “provided that incremental costs to members are nominal”
  - FENIN (Spain) states that companies may only sponsor or fund the attendance of professionals to scientific events organized by reputable organizations certified as being of scientific interest and may not sponsor events, meetings, or congresses where the time allocated to entertainment is in excess of 30 percent. Also, they ideally want these to be located in Spain, away from recreational and tourist areas

# Codes of Conduct

## Issues to Review

- **Supporting Third-Party Educational Conferences:**
  - EDMA/Eucomed requires conference support must be (a) consistent with the regulations of the country where the healthcare professional is licensed to practice; and (b) clearly stated in advance of, at the meeting, and in the proceedings
  - The Medicines Act (Belgium) states that healthcare professionals may only be invited for a meal in the context of a meeting with an exclusive scientific character, provided the invitation can be justified by the duration and timing of the meeting. Inviting healthcare professionals to cultural or sporting events is not permitted.
  - In France, contributions to a doctor's attendance at scientific meetings or congresses and "hospitality" are authorized if they are reasonable and if the selection of a remote site is justified.
  - FENIN (Spain) states that companies may only sponsor or fund the attendance of professionals to scientific events organized by reputable organizations certified as being of scientific interest and may not sponsor events, meetings, or congresses where the time allocated to entertainment is in excess of 30 percent.

# Codes of Conduct

## Issues to Review

- **Sales and Promotional Meetings:**
  - FENIN (Spain) states that hospitality may at no time be subject, whether implicitly or explicitly, to an obligation to use or purchase any product or service.
- **Arrangements with Consultants:**
  - EDMA/Eucomed requires that consulting arrangements be consistent with the regulations if the country where the healthcare professional is licensed to practice.
  - EDMA/Eucomed does not mention “fair market value”, but states that compensation should be paid “based on services actually provided and in accordance with applicable tax and other legal requirements”.
  - FENIN (Spain) states that payments made to the healthcare professionals in return for studies, lectures, compilation of data, or any information available in medical institutions must be known to the said institution.

# Codes of Conduct

## Issues to Review

- **Gifts:**
  - The Medicines Act (Belgium) states that it's prohibited for healthcare professionals to directly or indirectly request or accept any benefits, advantages, invitations, or hospitality offered or granted by any other such professionals or third parties.
  - The French medical association dictates that a doctor should not accept gifts from pharmaceutical companies.
  - In Italy, there are restrictions on hospitality offered to healthcare professionals in connection with the promotion of medical devices.
  - FENIN (Spain) states that gifts provided to customers or to individuals who directly or indirectly participate in the acquisition of medical devices must be small.

# Practical Compliance Strategies

- Eucomed and AdvaMed standards on *Interactions with HCPs* are similar and can serve as basis for global business practice standards.
- Eucomed -- but not AdvaMed -- addresses other practices (e.g., advertising and promotion, privacy, quality, and regulatory). Eucomed generally is consistent with U.S. laws and regulations and can serve as standard for global compliance standards.
- National codes may be more restrictive in some areas, but differences are largely in degree, not in kind.
- Variations in international codes are not so significant as to justify inaction -- at a general level, variations should not be difficult to address by local country managers/compliance personnel.



# The Top Ten Issues of Global Medical Device Compliance – Take Aways

1. Varying Compliance Expectations and Culture
2. Applying Codes of Conduct Across Regions/Countries/Global
3. Developing Standard Compliance Structures
4. Auditing and Monitoring Compliance on an International Level
5. The Constantly Changing Landscape
6. Communication
7. Combination Products and Device Definitions
8. Training and Education
9. Compliance Roles and Responsibilities
10. Distributor Issues and Structures

# Perspectives From The Industry

# Questions and Discussion

# Appendix



# Belgium

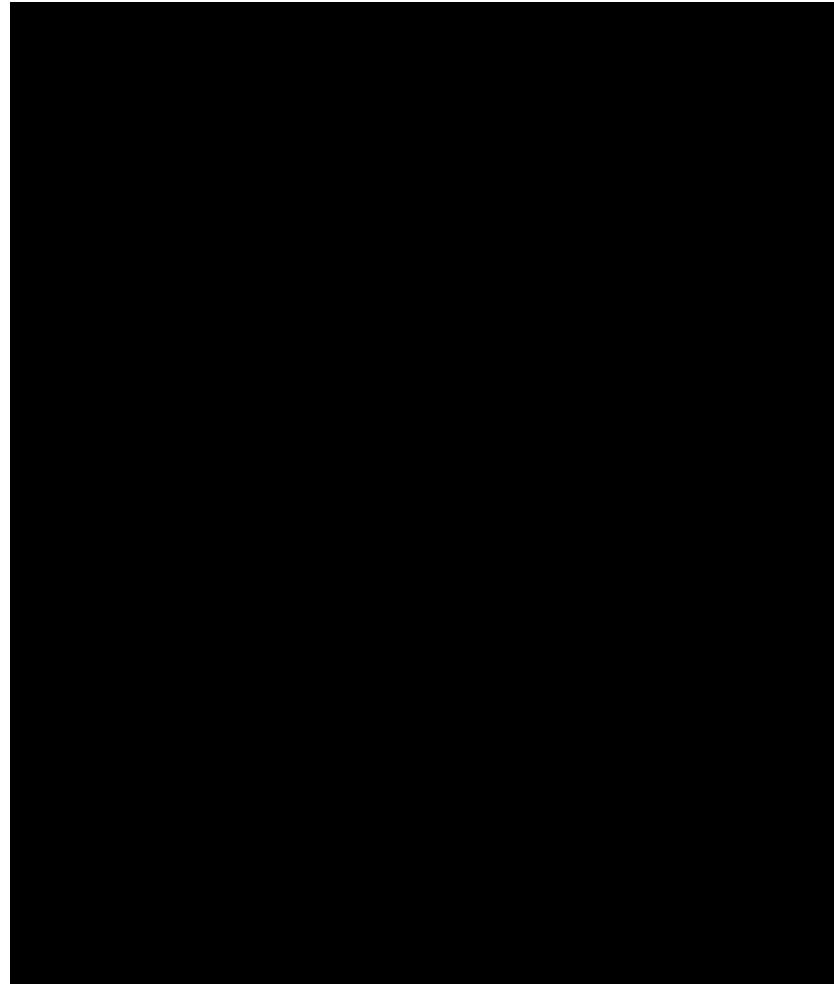
Pages 30-31





# France

Pages 36-37



# Italy

Pages 42-43

## Italy

### Organizations

#### Regional-Specific Guidance: [EDMA](#)

The European Diagnostic Manufacturers Association (EDMA) is a trade association for the *in vitro* diagnostic (IVD) industry in Europe. Its members include 20 national associations and 19 affiliated companies that are involved in R&D, manufacturing, and distribution of IVD products in Europe. EDMA works with other European and international trade associations as well as government entities to support regulation and product standards in the IVD industry.

#### Regional-Specific Guidance: [Eucomed](#)

Eucomed is a trade association for designers, manufacturers, and suppliers of medical technology in Europe. Membership spans national trade and European product associations, companies with at least one manufacturing facility in Europe, and start-up ventures. Eucomed partners with key European institutions and decision-makers to influence policy and regulation.

#### Country-Specific Guidance: [Assobiomedica](#)

Italy is a member of both EDMA and Eucomed which contain provisions on interactions with healthcare professionals. Italy has its own medical device association (Assobiomedica), which is a member of Eucomed and EDMA. Assobiomedica members follow Eucomed and EDMA guidelines. Currently, Italy has no country-specific code regarding medical device companies and their interactions with healthcare professionals. However, there are restrictions on payments or hospitality offered to healthcare professionals in connection with the promotion of medical devices.<sup>92</sup>



# Spain

Pages 50-51





# UK

## Pages 54-55

### United Kingdom

#### Organizations

##### Regional-Specific Guidance: [EDMA](#)

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##### Country-Specific Guidance: [ABHI](#) and [BIVDA](#)

The United Kingdom is a member of both EDMA and Eucomed which contain provisions on interactions with healthcare professionals. The United Kingdom has its own medical device association (ABHI), which is a member of Eucomed. ABHI members follow Eucomed guidelines. In addition, the United Kingdom also has a medical device association (BIVDA) that is a member of EDMA. BIVDA members follow EDMA guidelines. Currently, the United Kingdom has no country-specific laws or codes regarding medical device companies and their interactions with healthcare professionals.<sup>142</sup> Additionally, the United Kingdom has other regulations and laws on advertising medical devices directly to the consumer, which are regulated under The Control of Misleading Advertisements Regulations, 1988.<sup>143</sup> These regulations are aimed at protecting the interests of consumers and traders from misleading or unacceptable comparative advertising.

# Huron

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