



# The Corporate Representative's Presentation

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## Agenda

- 1. News from the Corporate Members**
2. Revision of MedTech Europe's Code of Ethical Business Practice
3. Challenges and opportunities for the IVD industry
4. IFCC Strategy Workshop

## News from the Corporate Members

- **46** members in total (effective March 2016).
- Annual fees of **> CHF 300.000** (>17% of IFCC's total annual income) in 2015.
- In addition, Corporate Members' organizations continued sponsoring of IFCC **conferences, workgroups, scientific awards, e-learning programs and travel scholarships**.
- 7 members decided to discontinue their membership: Care, Dako, Drew Scientific, Labquality Scipac, Wiener Lab, and, early in 2016, Biocrates Life Sciences and Merck Millipore.
- **Helena Biosciences Europe, UK, and Ningbo Medical System Biotechnology**, China, joined IFCC as Corporate Members in 2015.

## New Corporate Members

- **Helena Biosciences Europe (UK)**  
Helena Biosciences is a medical diagnostic company comprising two business divisions that specialize in Clinical Electrophoresis and Haemostasis systems. (Source: corporate website)
- **Ningbo MedicalSystem Biotechnology (China)**  
Ningbo Medicalsystem Biotechnology Co., Ltd. develops, produces, and sells diagnostic products for the medical and health institutions in the in vitro diagnostic industry in China. (Source: Bloomberg)

## IFCC Corporate Members (46)

- |   |   |
|---|---|
| Abbott (USA)  | Ningbo MedicalSystem Biotechnology (China)                |
| ADx Neurosciences (Belgium)   | Nova Biomedical Corporation (USA)                         |
| Agappe Diagnostics Ltd (India)                                      | Oneworld Accuracy Collaboration (Canada)                  |
| Analisis R&D Diag (Belgium)   | Ortho-Clinical Diagnostics, Inc. (UK)                     |
| Asahi Kasei Pharma Corporation (Japan)                              | Philips (The Netherlands)                                 |
| Axis Shield Point of Care Division (Norway)                         | PPD Inc. (USA)  |
| BD Diagnostics (UK)   | Radiometer Medical ApS (Denmark)                          |
| Beckman Coulter, Inc. (France)                                      | Randox Laboratories Ltd. (UK)                             |
| The Binding Site Group, Ltd. (UK)                                   | Response Biomedical Corporation (Canada)                  |
| Bio-Rad Laboratories (France)                                       | Roche Diagnostics GmbH (Switzerland)                      |
| C.P.M. Diagnostic Research SAS (Italy)                              | Sebia S.A. (France)                                       |
| Diasys (Germany)  | Sekisui Diagnostics (UK) Ltd. (UK)                        |
| Diatron (Hungary)   | Sentinel CH SpA (Italy)                                   |
| ELGA LabWater (UK)  | Shanghai Zhicheng Biological Technology Co., Ltd. (China) |
| Fujirebio Europe (Belgium)  | Sichuan Maker Biotechnology Co., Ltd. (China)             |
| Gentian AS (Norway)   | Siemens Healthcare Diagnostics (USA)                      |
| Guangzhou Wondfo Biotech Co. Ltd. (China)                           | Snibe Co., Ltd (China)                                    |
| Helena Biosciences Europe (UK)                                      | Sonic Healthcare Europe (Germany)                         |
| HyTest Ltd. (Finland)   | Sysmex Europe GmbH (Germany)                              |
| Instrumentation Laboratory (USA)                                    | Thermo Fisher Scientific (Finland)                        |
| A. Menarini Diagnostics (Italy)                                     | Unilabs (Switzerland)                                     |
| Mindray – Shenzhen Mindray Bio-Medical Electronics Co. Ltd. (China) | Wako Pure Chemical Industries, Ltd. / Wako (Japan)        |
| Mitsubishi Chemical Europe GmbH (Germany)                           | Wisplighoff Laboratoriumsmedizin Köln (Germany)           |

## Major ways how Corporate Members seek to benefit from IFCC membership

- **Increasing awareness for the importance of lab testing** in general and providing education with focus on countries with limited resources. ✓
- Together with clinical societies, **supporting medical claims leading to reimbursement.** !
- Emphasizing the **importance of quality and use of IFCC's unique expertise in standardization.** ✓
- **Co-operating intensely** with others (CLSI, FDA, clinical societies, etc.) to get **alignment of guidelines and recommendations.** !
- Providing **opportunities for exhibitions, industry symposia and networking** with lab professionals during high-level academic conferences. ✓

## Members of IFCC executive committees

The following corporate representatives are members of the executive committees of IFCC's operational units:

- **Scientific Division:**  
James Pierson-Perry (Siemens)  
(1<sup>st</sup> term 2015-2017)
- **Education & Management Division:**  
Christoph Ebert (Roche)  
(2<sup>nd</sup> term 2016-2018)
- **Communications & Publications Division:**  
Bruce Jordan (Roche)  
(2<sup>nd</sup> term 2014-2016)
- **Congresses & Conferences Committee:**  
Peng Yin (Abbott)  
(2<sup>nd</sup> term 2015-2017)

## Members of the Congress Organizing Committee

The following persons were / are corporate members of the Congress Organizing Committee (COC):

- **IFCC / EuroMedLab 2015, Paris, France:**  
Christine Flandre (Sebia) and Ulrich Schwörer (Roche)
- **IFCC / EuroMedLab 2017, Athens, Greece:**  
Angelos Evangelopoulos (Roche) and Thomas Brinkmann (Sonic Healthcare).
- **IFCC / WorldLab 2017, Durban, South Africa:**  
Beth Slavic (Ortho Clinical Diagnostics)



## Upcoming conferences

- Two conferences in one year (2017): companies will focus their resources
- Companies show strong interest in Greece (85% of exhibition space sold)
- So far only two companies confirmed for South Africa

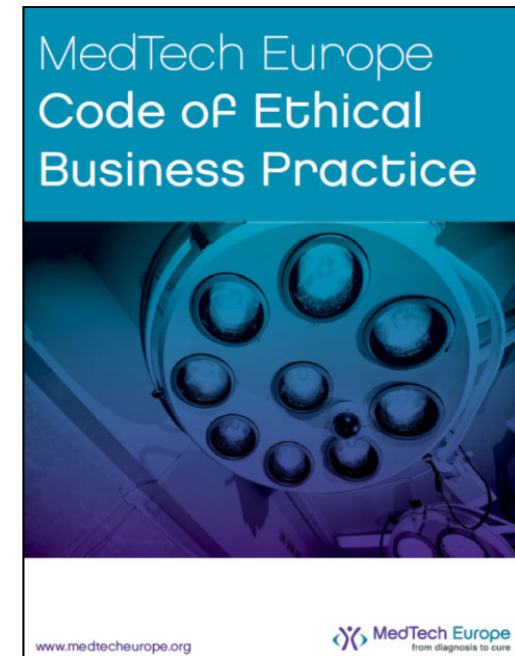


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- 2. Revision of MedTech Europe's Code of Ethical Business Practice**
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## Industry's behavior must respect high ethical standards and values

- **MedTech Europe** has developed a new **Code of Ethical Business Practice**, setting mandatory rules for the interaction between industry and healthcare professionals / healthcare organizations.
- **MedTech Europe** comprises the members of
  - **Eucomed** (Medical Devices),
  - **EDMA** (In-vitro Diagnostics).
- The code was passed by Eucomed's and EDMA's members in December 2015 and will become effective in January 2017.
- The part describing sponsorship of conferences will become effective in January 2018.



➔ **The new code will impact all medical conferences substantially !**

# MedTech Europe Code of Ethical Business Practice

What the phase out of direct sponsorship will mean in practice:

- **Third-party organized conferences** (main program):  
Companies may not directly support an HCP, neither as a delegate, nor as a speaker.
- **Company-organized events in the framework of third-party organized conferences** (e.g. satellite symposia):  
Companies may directly support speakers (i.e. their consultants) but not delegates.
- **Third-party organized procedure / hands-on trainings:**  
Companies may support delegates but not speakers, the latter being independent.
- **Company-organized product / procedure trainings:**  
Companies may directly support an HCP either as a delegate and/or as a speaker.

# MedTech Europe Code of Ethical Business Practice

How the rules for educational grants will change:

- Grants will be **publicly disclosed**, ensuring **increased transparency** of the funds allocated to medical education.
- Grants can only **be provided to legal entities but never individuals** and will require a **written contract** & other related documentation.
- Companies will be able to define the **type of recipients** which should be eligible for the grant **but not individual recipients**.
- Companies must have an **internal & independent process** based on objective criteria to assess the grant requests.
- Conferences will still need to **comply with specific requirements** and with the **Conference Vetting System**.

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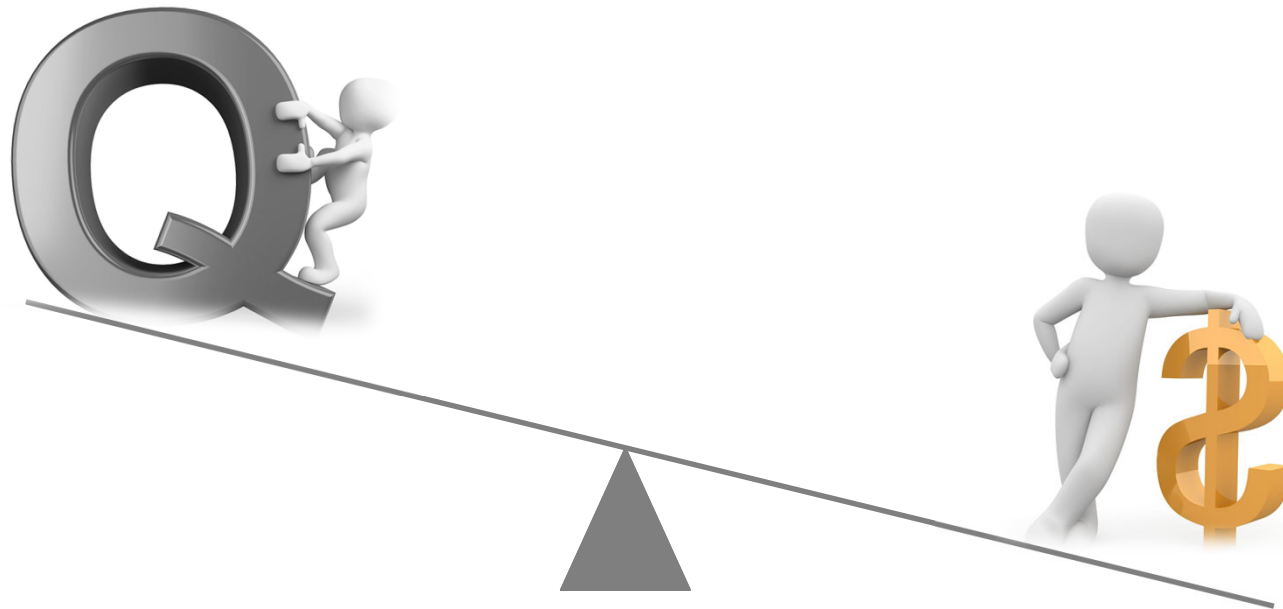
## Challenges and opportunities for the IVD industry

- Making the medical value associated with new tests / products available to patients and HCPs at adequate reimbursement in reasonable time even after successful HTA assessments.



## Challenges and opportunities for the IVD industry

- Decision making is shifted from lab professionals to financial controllers  
→ price often 'eats' quality.





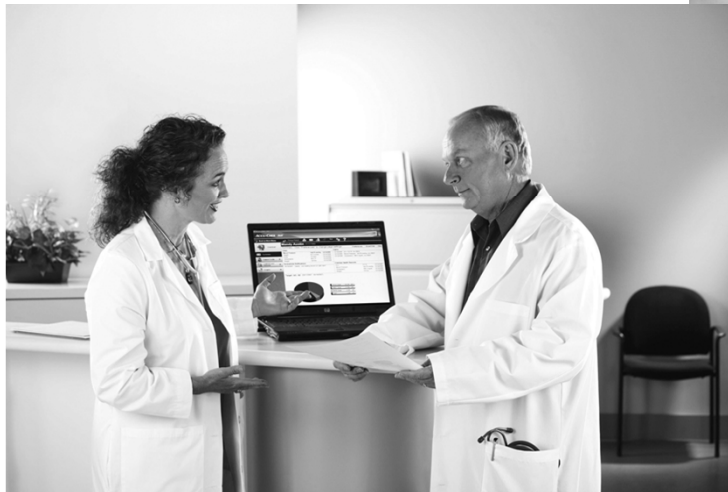
## Challenges and opportunities for the IVD industry

- Regulatory submissions are becoming more complex; local regulatory requirements are increasing.



## Challenges and opportunities for the IVD industry

- The recognition of lab professionals being in charge of lab testing, quality assurance and result interpretation is sometimes challenged.  
→ The belief becomes prevalent that 'everyone' can test and interpret the data, including new tests or combinations of tests.



## Challenges and opportunities for the IVD industry

- More people get access to healthcare.
- Economic growth often goes along with better access to healthcare for a large proportion of the population.
- 'Middle-class' people are becoming more health-conscious.



## Challenges and opportunities for the IVD industry

- 'Big Data' companies are providing solutions that are partially complementary to IVD products, enhancing their usefulness, and partially competitive.



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# IFCC SWOT analysis

In January IFCC conducted an analysis of its strengths, weaknesses, of opportunities and threats (SWOT).

The major topics from a corporate point of view:

- **How to re-define & enhance the value of IFCC for Corporate Members to increase corporate membership and avoid membership termination to guarantee the important financial contribution of the IVD industry?**
- **How to better (1) enable and (2) monitor the efficacy and effectiveness (= output) of committees, working groups and task forces?**
- **How to better link IFCC to clinical societies?**



## IFCC's new vision



**Corporate Members fully support IFCC's new vision:**

**We advance excellence  
in laboratory medicine  
for better healthcare worldwide.**