The Corporate Representative's Presentation

IFCC General Conference, Madrid, 2016-03-19

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

- **Scientific Division:**
  James Pierson-Perry (Siemens)
  (1\textsuperscript{st} term 2015-2017)

- **Education & Management Division:**
  Christoph Ebert (Roche)
  (2\textsuperscript{nd} term 2016-2018)

- **Communications & Publications Division:**
  Bruce Jordan (Roche)
  (2\textsuperscript{nd} term 2014-2016)

- **Conferences & Conferences Committee:**
  Peng Yin (Abbott)
  (2\textsuperscript{nd} term 2015-2017)
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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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!
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.

Source: MedTech Europe
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**.

Source: MedTech Europe
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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.
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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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?
Corporate Members fully support IFCC's new vision:

We advance excellence in laboratory medicine for better healthcare worldwide.