Business Engagement Strategy

Expanding and accelerating access to tuberculosis diagnostics and laboratory services

2nd meeting of the Global Laboratory Initiative (GLI)

World Health organization and Fondation Mérieux

15 - 16 October 2009

Stop TB Partnership Private Sector Constituency
Jean-François de Lavison, Mérieux Alliance, Corporate Sector Representative,
Member of the Stop TB Executive Committee, EDMA President
PSC Role in the Partnership

Structure:

• First independent evaluation in 2003-2004, recommended including NGOs and private sector on Coordinating Board.

• Constituency of >110 companies registered (health and non-health).

• PSC on Coordinating Board since October 2004 and member of the Execo since 2008.

• Active across Partnership board committees, working groups, committees, task forces.

• Participating in major Partnership activities and events.
PSC Role in the Partnership

Objectives:

- Leverage core business skills and capabilities, facilitate corporate sector participation, stimulate participation of the private sector in TB control.

- Bring business perspectives, input, expertise, and multi-faceted resources to the Partnership.
EDMA Members
38 Corporate Associated Members (CAMs)

From 14 to 38
2006-2008
Amorfix
Arkray
Biosystems
BMD
Cellestis
Cepheid
Chiron
FIND Diagnostics
Focus Diagnostics
Genzyme
Innogenetics
Luminex
Mallinkrodt
MLT
Orion
Phadia
Philips
Randox
Sebia
Siemens
STAGO
TECAN
ThermoFisher
Tosoh

All major players present
EDMA Members
23 National Association Members (NAMs)

Through its affiliated National Associations, EDMA represents in total more than 500 companies (or over 700 legal entities) across Europe.

Working to develop new IVD associations

From 20 to 23

2007
Turkey
Denmark

2009
Slovakia
Advocating the value of IVDs
IVDs: Expense or Investment?
Health expenditures

Macro-economic datas and Total Healthcare Expenditures show that:

The amount spent on IVDs out of the Total Healthcare Expenditure is less than 2% (i.e. around €20 per capita and per annum in EU15 and €6.2 in new members states) - Its information influences about 64% of the medical decision (JD. Kruse-Jarrest, Lab. Med. 18:213/1994)

In Europe, less than 10% of GDP is spent on healthcare in most countries (more than 15% for USA)

⇒⇒ EDMA is campaigning to present laboratory testing as a valuable asset that is a cost-effective component of health maintenance and disease management. The overall aim is to ensure that healthcare resources are properly allocated and appropriately used. Laboratory testing has an important role to play in achieving this aim.
Defining & Voicing the IVD industry’s consensus positions

Development of Key Messages & Fact Sheets

9 TOPICS: HIV, Cardiovascular Diseases, Diabetes, Nosocomial Infections, Tuberculosis, Cervical Cancer / HPV, Colorectal cancer, Prostate cancer, Theranostics

EDMA HIV-AIDS Team

Key Messages

- Early diagnosis + early treatment = reduced impact of HIV/AIDS
- A relative lack of progress in preventing and treating HIV/AIDS, through heterosexual contact exists and this still affects people worldwide.
- More than half (56%) were acquired during heterosexual intercourse in 2005. About three quarters of heterosexual HIV infections were among immigrants and refugees.
- Among 8916 individuals who were diagnosed with HIV in Europe in 2002, 55% discovered their seropositivity or less before developing AIDS.
- About one third of persons with HIV in the EU they have been infected in the EU the proportion of newly infected is estimated to be as high as 30%.
- Prevention strategy based on universal resources and effective, e.g., in systematic blood donation screening and paediatric screening, and should be extended.
- As treatment becomes more widespread, transmission of resistant, so antiretroviral drugs might increase.

Tuberculosis Key Messages

European Diagnostic Manufacturers Association

In Vitro Diagnostics

Making a real difference in health & life quality

HAI Facts

- Every year, an estimated 2 million people are affected by hospital-acquired infections (HAIs), not only in Europe but in many other countries, making it a major concern for both hospitals and patients.
- In the EU, a deep bacterial infection can result in a patient being readmitted to hospital, possibly leading to a delay in recovery.
- More than 60% of HAIs are related to the use of medical devices, e.g., catheters, blood products.
- In the USA, hospital-acquired infections are estimated to account for $18 billion in additional health care costs.
- Prevalence of HAIs varies significantly among countries, with higher rates observed in intensive care units.
- Prevention strategies include increased use of evidence-based practices, improved communication, and the adoption of new technologies.

9 Fact Sheets available

Cardiovascular Diseases (CVDs) Fact Sheet

In Vitro Diagnostics

Making a real difference in Health & Life Quality

Infections in Hospitalized Patients

HIV-AIDS Team

EDMA

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Lab Tests Online

HON-code certificate
Awarded in Germany
And in other countries?

Global access to all sites www.labtestsonline.info

Soon available in • French • Portuguese
Under discussion in • Netherlands • Turkey • Romania

Czech Republic: www.LabTestsOnline.cz
Poland: www.LabTestsOnline.pl
Hungary: www.LabTestsOnline.hu

Spain: www.LabTestsOnline.es
Germany: www.LabTestsOnline.de
Italy: www.LabTestsOnline.it
Greece: www.LabTestsOnline.gr

Choose your version:

PRIVATE SECTOR CONSTITUENCY
Representing the industry viewpoint

Regular participation in ongoing political and legislative processes:

**EU:**
- Late payments
- Information to patients
- Rare diseases
- DG SANCO Work Plan 09
- Health - Future challenges – etc.

**WHO:**
- Primary Technologies
- Nomenclature – etc.

**Development of guidance with EU Commission**

Position Papers

- Laboratory accreditation
- Revision new approach (EMIG)
- Unique Device Identifier (UDI)
- Unit-Price, Result-based contracts
- Texts Displayed on Screens (TBC)

Consultations

- Early consultation of relevant DGs and DG SANCO
- Consultation of relevant DGs and DG SANCO on new approaches
- Consultation of relevant DGs and DG SANCO on new approaches

**EDMA Achievement IFU**

**Consultations**

- Vigilance
- Supply of IFU by other means e.g. Internet allowed
- Classification/Borderline
- Report on new & emerging technologies

STOP TB Partnership
PRIVATE SECTOR CONSTITUENCY

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STOP TB Partnership
PRIVATE SECTOR CONSTITUENCY
International activities
Japan

- Presentation of JACRI activities at EDMA General Assembly in Brussels, Oct 07 & NAM meeting, Oct 08
- Presentation of EDMA activities at JACRI General Assembly in Tokyo, May 08 & March 09
China

- Sep 06: CT presentation of EU regulations & GHTF guidance to the Chinese Competent Authorities SFDA in Beijing
- Sep 07: Visit of an EDMA Execo delegation to SFDA and the European Commission in Beijing
- Oct 07: Visit of a delegation of the European Commission (with EDMA participation) to SFDA in Beijing
- Jun 08: Medical Devices Expert Roundtable (MDER) meeting in Brussels – involving the European Commission DG Enterprise, the Chinese Competent Authorities SFDA, the Chinese MD Industry association CAMDI, COCIR and EDMA
- Jan 09: Visit of a delegation of the European Commission (with EDMA participation) to SFDA in Beijing
- 09: Workshop with SFDA in Beijing to facilitate the process of accessing the Chinese market to CE marked devices.

International consultations
Comments on new legislations in: China, India, Singapore, Korea, Malaysia, Costa Rica, Colombia, Saudi Arabia etc

Cooperation with AdvaMed (US), MIAA (Australia), CBDL (Brazil) and JACRI (Japan)
IVDs Industry: Need to shape our future

- TB IVD Initiative:
  - Diagnostic Industry Leadership Forum (DILF) members agreed on the necessity of showing a global commitment of diagnostic industry on TB.
  - The EDMA *ad hoc* group’s main task will be identifying one or two concrete projects (Education – Advocacy) involving the IVD industry in general (and not promoting individual technology) in order to:
    1. Demonstrate that IVD testing contributes significantly to the diagnosis and treatment of TB by providing benefits to healthcare practitioners and patients.
    2. Demonstrate that extensive IVD testing will be cost-effective and will improve healthcare outcomes.
    3. Explain that IVDs offer an invaluable contribution to the prevention and treatment of TB.
    4. Strengthen the role of Public Private Partnership (PPP).
IVDs Industry : Need to shape our futur

- **Swiss representation : Geneva**

- We need to represent all the IVDs associations and be a strong interface between diagnostic industry and inter governmental organizations (WHO, Global Fund, UNICEF..). We need to secure an international policy environment and maximize access of IVDs to the global health initiatives in the world.

- We need to play a more constructive role in the Geneva based discussion around global health challenges. Today we are not present, it’s a lack (World Health Assembly..)

- **Proposals :**

- Create a global non profit NGO (like IFPMA) representing the IVDs and developing a world health partnership
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