The IVD Industry

Innovation in a challenging environment

Serving Patients, Physicians and Payers
Key Figures

• The total IVD market is worth 57Bn$ in 2015; stable in value due to important currency variations (€/$/Y)
• Glucose self-monitoring accounts for >8bn; POC for 6bn
• Emerging markets continue to grow faster than the rest of the World
• High revenue countries are rather trying to keep healthcare budgets under control, (price pressure)
The IVD WW Market

**WW IVD Market, by segment**
- Diabetes: 15%
- POC/POL: 11%
- Laboratory: 74%

**WW IVD Market, by Region**
- N. America: 43%
- EMEA: 34%
- AP: 12%
- Japan: 6%
- LA: 5%

Source: Enterprise Analysis Corporation (EAC) April 2015
Opportunities for IVD

• Ageing population: monitoring chronic diseases
• Personalised medicine: cancer, cardiac
• Infectious diseases
  • HAI
  • Control of antibiotic resistencies
  • Addressing emerging diseases alerts: SARS, Dengue, Chick, Ebola, Zika…..
• And also …
  • Prevention: need for more predictive assays
• Healthcare becomes part of a more global concept: well-being
A new vision for health

Monitor and /or cure
Diagnose
Prevent
Predict

Well-being
A more regulated environment

• Many national regulatory systems in place, with no mutual recognition
  • Increased costs for access to market
  • Slowing down innovation

• In Europe
  • A new directive is under preparation for CE-IVD products
  • New constraints under discussion: HTA

• Reinforced rules for Ethics and compliance (FCPA, Loi Bertrand, …)
  • Relationships with third parties (customers, consultants, distributors) are more formalised and restricted to comply with the rules
78% of the IVD products will have to be reviewed by Notified Bodies.

The costs to comply with the new regulation are estimated at 2Bn€ by the Industry.
Impact on the IVD Industry

• Market access is going to be more difficult:
  • Development time
  • Cost
  • Post market surveillance costs
  • Regulatory harmonization and/or mutual recognition could help

• Innovation is not paid at the right price
  • In most cases, no fast track for reimbursement
  • Adjacent cost savings are barely considered by Health authorities to provide the right level of price and reimbursement
Our Customers evolve

- Pressure on reimbursement
- Improved quality requirements: Accreditation
- Rationalization of hospital structure
- Private labs Concentration ➔ Full automation
- Data management and data transfer ➔ traceability, cybersecurity
- Boarding new technologies and new markers

The IVD industry is affected by each point
Labs concentration in France

Nombre de laboratoires privés inscrits au CNQ

Source: ANSM
The economic environment

• Growing needs in a context of budget restrictions
• The IVD industry productivity is balanced by higher services provided at lower costs:
  • Reagent rentals
  • Hardware and software interface
  • Hot line support, remote maintenance
  • Service, metrology
Trends

• Customers are looking for less complexity
  • Total automation and IT interface
  • Improve cash flow management (inventory management)

• From local to « global » agreements
  • Global suppliers
  • Global supply agreements for international groups

• From a « product supply » pattern to « providing a service »
  • Cost per reportable result / cost per patient
Consequences for the IVD industry

• The market growth rate does not favour major investments for costs improvements and innovation (R&D investments >10% in average)

• The need to reach a more critical mass requires more concentration (M&A) ➔ less competition
The Industry in 2015

• The top 5 groups(*): 60% M.S.

• The top 10 : 75%

• The top 20: 84%

(*) Taking into account the recent M&A announcement
New growth areas in IVD

• Labs concentration and chronic diseases monitoring create new needs for low volume remote testing and/or unitary tests:
  • Emergencies
  • POC /POL /NPT
  • Self testing

• Companion diagnostics required for expensive treatments

• Self testing can open a path to cost savings for Governments (not reimbursed)
New Trends in the landscape

- Decentralization is boosted by the emergence of « e-health » and « connected health » concepts
- For lab testing as for remote testing, data safety and transmission are key. New operators are coming (GAFA)
- The IOT is coming with this revolution. This new segment raises interest, as it is not financed by the Healthcare systems
- This fits with the new decisions models shared with patients
- Connectivity providers may come with different economic models
What we shall do

• Continue to support our customers in all market segments and adapt our offer to their new environment

• Sustain our investments in science and new technologies to bring cost effective solutions addressing the new needs in healthcare

• Pursue our lobbying to facilitate market access
  • Fast track procedure for innovation / Accurate reimbursement level
  • More harmonization in regulatory requirements and mutual recognition?

• Collaborate with the new players
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THANK YOU