IVD industry perspective on HTA

DG SANTE meeting with MTE members

Brussels, Sept. 22, 2016
Thank you for being here with us!

How valuable and diverse IVDs are and how innovative and supportive of European economy the IVD industry is

That 99% of IVDs don’t have HTA in their access pathways to patients and that works well to ensure timely patient access

That when Assessments are done on IVDs they are rarely informing access decisions at national level. Examples show that patient have more difficulties to gain access to novel IVDs when HTA is present.

That Experience is lacking on how a European HTA model focusing on IVDs can support patient access, sustainable health systems or industry

We have proposals we would like to share and continue to think together
Getting to know IVDs

IVDs are non-invasive tests done on samples

Provide information of key value for patients, society, economy, and health systems

Influence 70% of healthcare decisions

**Diagnosis:**
- Diabetes
- Infectious diseases
- Cholesterol
- Heart Disease
- Pregnancy
- Allergy
- Immunology
- Renal disease

**Screening-Prevention-early detection:**
- Cancer
- Infectious diseases
- HAI-AMR
- Diabetes
- Genetic conditions
- Rare diseases

**Prognosis**
- Cancer
- HIV
- Heart disease
- Immunology
- Sepsis

**Prediction**
Select patients likely to respond to treatment:
- CDx for Cancer
- AMR
- Cystic Fibrosis
- HIV
- Growth failure

**Monitor**
Treatment performance:
- diabetes
- anticoagulation
- Antibiotics
- Viral load

**Production information**
- Know and change to healthier habits and more effective treatments
- Make plans: Genetic conditions counseling, allocation of patients in hospitals
- Keep people healthy, active, out of hospitals
- Guide the use of other techs, and avoid waste of resources

EDMA represents the in vitro diagnostic companies, ranging from innovative small and medium-sized enterprises to worldwide leading manufacturers, as well as national IVD associations from across Europe.

MedTech Europe is an Alliance of European medical technology industry associations. The Alliance was founded in October 2012 and currently has two members: EDMA and Eucomed.

1. In vitro diagnostics Fact Sheet
2. EDMA calc. based on survey to manufact. 2016
With less than 1% of total healthcare expenditure in IVDs, they are key to sustainable healthcare systems.

Total healthcare expenditure in Europe¹, breakdown:

- 75% Inpatient & outpatient care
- 7.5% Medical technology
- 6.7% Medical Devices (ind. imaging)
- 0.8% In vitro diagnostics
- 17% Pharmaceuticals & other medical non-durables

IVDs expenditure is less than 1% of total EU HC expenditure.

- Sexually Transmitted Diseases: £11.7 million/a can be saved² (ATB + in patient care)
- Infections resistant to antibiotics (AMR): US 20 billion direct med cost & US 35 billion prod. Loss could be saved³
- Cervical cancer screening: 230 mill. y. of life free of disability or US$1 trillion could be saved globally⁴

How do IVDs reach patients in Europe?

The majority of IVDs (incremental innovation) are purchased by hospitals and/or labs in a decentralized way and that is working well to ensure timely access to valuable IVDs.

Authorities in different countries, regions, hospitals, in -patient and out -patient sectors can decide differently according to their context and priorities.

HTA is done for less than 1% of IVDs, very differently across countries, with low impact on reimbursement or adoption.

Current HTA processes are designed to inform centralized decisions and not decentralized like IVDs’.

The access pathways are different for IVDs than for medical devices and medicines; the role of HTA is also different for IVDs.
What happens when HTA is applied to novel IVDs in two of the larger IVD markets?

**Situation in France when HTA is positive**

- BRAF V600 E test
- KRAS test
- EGFR tissue test
- NAAT- PCR rapid test
- Gonorrheae test

**Pending decision/action to reimburse when HTA positive (years)**

**Situation in Germany when HTA is positive**

- Preeclampsia test
- Strep. B Screening
- Procalcitonin test
- HPV screening test

**Pending decision/action to reimburse when HTA is positive (years)**

**Patients face difficulties to access valuable innovative IVD tests (and subsequent treatment and care) when they need them if HTA is done**

- **CDx test to aid in selecting melanoma patients who may respond to specific treatment**
- **CDx test to identify patients with advanced lung or colon cancer who will not respond to specific therapy**
- **CDx test to identify patients with advanced lung cancer who may respond to specific treatment**
- **Rapid near patient test to confirm viral infection and reduce unnecessary antibiotic therapy and AMR**
- **Rapid diagnostic test for Sexually Transmitted Disease allows fast treatment and preventts complications - spread of disease**
- **Test to rule out and predict course of life-threatening condition in pregnant women (preeclampsia)**
- **Screening test to diagnose Infection in pregnant women to prevent neonatal infection**
- **Test to evaluate the risk that a seriously ill person develops a generalised bacterial infection (sepsis)**
- **Screening test for HPV infection to identify women at risk of cervical cancer**
What challenges do we see ahead on HTA and EU HTA?

Is HTA informing access decisions at national level?

Is the High Cost of Evidence generation a limiting factor for manufacturers?

What decisions can EU HTA inform on IVDs at the national level?

Could manufacturers sustain the economic impact of a mandatory EU HTA system?

It will be important to **assess the effects that a mandatory EU HTA system would have on IVD industry** such as:

- Increased demand of EU HTAs and data generation while no ROI expected as HTA not informing decisions at national level.
- Increased time to patient access.
- Decrease external funding for SMEs if highly regulated environment.
- Rate of innovation in Europe.
- Possible market concentration, impact on prices and adoption of novel IVDs.

The IVD industry is willing to collaborate with the European Commission on the assessment of these effects.
How do we see the way forward?

Evolution to value based assessment needed

• Fit-for-purpose methods and tailored outcomes to unfold the wide value of IVD information
• IVDs assessed at the ‘right time’ in the technology lifecycle
• HTA responding to the needs of patients and decision makers
• Increasing predictability of evidence requirements within and across agencies

Voluntary application of HTA to transformative IVDs

• This is true only if the demand comes from multiple MS or is initiated by manufacturers AND health systems commit to adopt the valuable IVD innovation picked up by fit-for-purpose joint/collaborative HTA

Appropriate methods, capacity and structure IVD focused at national and EU level

Stakeholder dialogue will enable this evolution of HTA

1. It may vary for different IVD types but it’s not at market launch, it’s predictable and agreed with manufacturers.
2. They can solve high clinical, social and health systems unmet needs and for that require structural, organizational, health services or business changes.
3. Upfront adoption plan (e.g. innovation fund) in place from EU countries before the Joint assessment is initiated. EU could help MS transition through innovation funds, or becoming an evidence incubator (e.g. supporting evidence generation that should be accepted at MS level, facilitating development of conditional access schemes at nat. level, real world evidence (RWE) data collection systems, among others)
99 % of IVDs don’t have HTA in their access pathways to patients
The majority are purchased by hospitals and/or labs in a decentralized way and that is working well to ensure timely access to valuable IVDs

Assessments of IVDs are rarely associated with appraisals
Improved uptake of a joint EU assessment by a national HTA agency would not necessarily relate to efficiencies or predictability for manufacturers, as the national HTA agency rarely informs reimbursement, funding or adoption of IVDs

Experience is lacking on how a European HTA model focusing on IVDs should look like to support patient access and sustainable health systems
We believe it should be voluntary, at the ‘right time’ in the technology lifecycle, with tailored methods, specifically focused capacity and organizational structures, and responding to the needs of patients and decision makers

European HTA needs to focus on detecting and supporting the adoption of transformative IVDs that can solve high unmet clinical, social or health system’s needs across Europe
We believe EU HTA topics should be driven by common MS needs and EU HTA initiatives supporting evidence generation for IVDs and the set-up of national adoption plans for novel IVDs would be needed.
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Back-up information on IVDs
How do IVDs reach patients in Europe?

The majority of IVDs (incremental innovation) are purchased by hospitals and/or labs in a decentralized way and that is working well to ensure timely access to valuable IVDs.

Authorities in different countries, regions, hospitals, in-patient and out-patient sectors can decide differently according to their context and priorities.
What are the specificities of IVDs that relate to HTA?

- **Direct Clinical Effect**: Contact with human body
- **Clinical Effectiveness**: Added therapeutic benefit
- **Clinical utility context dependent**: (learning curve, use of information)
- **Clinical utility affected**: by healthcare pathway, availability and effectiveness of downstream treatment/care, sequence of testing, prevalence and stage of disease
- **Wide range of outcomes beyond clinical ones**: Novel specific methods needed to unfold full value incl. socio-econ value and value of diagnostic information
- **High methodological complexity of assessment**: Resource intensive

Direct effect is to produce information
Change management and value of knowing
Clinical effect/utility linked to subsequent treatment or care
One test can influence multiple treatments / multiple conditions
What national decisions could EU HTA for IVDs inform?

Very few countries are performing HTA for IVDs
Very few countries are asking the same question on IVDs at the same time
What could be the benefit of assessing jointly?

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<tr>
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<th>2014</th>
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<tbody>
<tr>
<td>Total HTA reports MedTech</td>
<td>372</td>
<td>372</td>
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<tr>
<td>Total HTA reports IVDs</td>
<td>28</td>
<td>16</td>
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<tr>
<td>80% of all IVD reports published in</td>
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<td>3 countries: UK, Spain, Norway</td>
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<tr>
<td>43 % of all report published in</td>
<td></td>
<td>1 country: UK</td>
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- **Common topics assessed in 2014**
  - Breast cancer recurrence prognostic test
  - Diabetes monitoring test
  - Self monitoring coagulation test

- **No common topics assessed in 2015**

Statistic based on Synergus database (link)
* EU28 + Switzerland + Norway
What experience EU HTA and manufacturers have developed on Joint Assessments for IVDs?

- No REAs have been conducted on IVDs (no experience from EU HTA or manufacturers)
- 2 Full HTAs have been conducted on IVDs
  - 1 in JA-1 without participation of manufacturers
  - 1 in JA-2 without direct participation of manufacturers, with feedback from EDMA.
- 6 countries used the JA-2 Full HTA report as input for their national report (Au, Ro, Esl, Est, Sp, Sw).
- Only 1 (Spain) used it to inform decision making.
What challenges do we see ahead on HTA and EU HTA?

- Enough expertise/capacity specific units/programmes at national level: Yes
- Are tailored methods to account for the full tech. value ready: No
- Enough experience at EU HTA level (pilots): Yes
- EU REA /Full HTA face challenges to be transferable and inform the national level as is context dependent.: Yes
- Are countries asking the same question at the same time so an EU HTA can bring efficiencies at national level: Yes
- Are MS doing HTA differently (dif. methods, results they consider important, dif. evidence requirements, processes): Yes
- Are reimbursement systems rewarding evidence of value: No

It’s difficult to understand what decisions can EU HTA inform for IVDs at the national level.