Independent scientific opinion for CE mark or early dialogue for HTA: A unique expert panel for both?

Medical device industry perspective

Andrea Rappagliosi

VP Public Affairs EMEA, Canada, LATAM - Edwards Lifesciences

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Conformity assessment and HTA: complementary…

Conformity assessment for CE mark	Health technology assessment

Questions addressed

- Does the device achieve the **intended medical purpose**?
- Do the **estimated clinical benefits** for the patient outweigh the residual risks (i.e. is the device “safe” when used as intended?)
- Does the technology **meet the performance, quality, and safety requirements** of the EU MDR?

- **PICO* framework** to identify relevant evidence needs
- Is the **technology needed** (unmet need)?
- Does it meet its claim in a routine practice?
- **How do the benefits (and risks) compare relative to the current standard of care/comparator?**
- **Does it result in better clinical/patient outcomes?**
- **Is it cost-effective** versus the comparator?
- Is it worth it?
- **Can we afford it**?

…and serve different purposes

* PICO - Patient, Intervention, Comparator, Outcome

Conformity assessment and HTA: complementary…

CE Conformity assessment for CE mark	HTA eunethta Health technology assessment
Involvement of experts	
Panel of experts might provide, **before certification, an independent opinion to Notified Bodies on** the clinical data provided by the manufacturer (certain new and high-risk devices).	Committees include multiple **experts from several different disciplines** (medical experts from different specialties, nurses, pharmacists, statisticians/methodologists, health economists, patients, social sciences….).

…and require different expertise and perspectives

What is the added value of having a unique expert panel?

- Would it simplify or accelerate the **Innovation Value Assessment and Adoption**?
- Would the assessment **methods** be improved ?
- Is the expertise of both panels **interchangeable**? What **Governance** we may consider?
- Will the HTA outcome lead to **better adoption and funding of safe and effective innovations** for the patients, the healthcare systems and the Innovators?

HTA should involve early and active scientific dialogue between all relevant stakeholders, including regulators, manufacturers, patients, and clinicians.
However, more visibility is still needed on the HTA regulation implementation.

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life is now