HTA & Medical Devices
Same Same But Different
Tanya Watson
• **Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article—**

• (a) intended by the manufacturer to be used, alone or in combination, for human beings for—
  – (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
  – (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
  – (iii) investigation, replacement, modification or support of the anatomy or of a physiological process;
  – (iv) supporting or sustaining life;
  – (v) control of conception;
  – (vi) disinfection of medical devices; or
  – (vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

• (b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

• **IVD’ (in vitro diagnostic medical device) means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.**
**MEDICAL DEVICES VS. PHARMA**

**THE DIFFERENCES**

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<th>Devices</th>
<th>Pharma</th>
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<td>• Efficacy determined by Device capabilities structure and programmes and by the surgeons abilities. Outcomes often depend on surgical skill.</td>
<td>• Efficacy purely on molecule characteristics (pharmakinetics) → No learning (Water and swallow).</td>
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<td>• Short life cycle due to demand from Surgeons to improve i.e., if a difficulty is shown with a catheter this is given to the manufacturer. You launch new one in 2 years.</td>
<td>• Long product life cycles → If its twice daily, molecules aren’t just waiting to manipulated.</td>
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<td>• R&amp;D cost are never complete as constant innovation is mandatory.</td>
<td>• R&amp;D is protected by patency.</td>
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<td>• HTA for medical devices recently started using Pharma standards as a baseline even with the above differences.</td>
<td>• HTA processes for drugs long-established.</td>
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<td>• Good quality scientific data often not available – regulatory environment</td>
<td>• Good quality scientific data usually available due to different regulatory requirements.</td>
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Same Same but Different
HTA Perspectives

A process of evaluating medical technologies and their use through the synthesis, or the systematic review, of scientific evidence

...includes drugs, devices, medical and surgical procedures, the knowledge associated with these, in the prevention, diagnosis and treatment of disease, as well as in rehabilitation, including the organisational and supportive systems within which care is provided.

World Health Organisation (WHO)

“any process of examining and reporting properties of a medical technology used in healthcare, such as safety, efficacy, feasibility and indications for use, cost, and cost-effectiveness, as well as social, economic and ethical consequences, whether intended or unintended”

(IOM)

“Health Technology Assessment (HTA) is the collective name given to a number of activities applying systematic methods of scientific inquiry to the evaluation and use of new or existing health care technologies...evaluation can focus on all impact of a particular healthcare technology, including its clinical, ethical, social, legal and economic implications”

(Eucomed)
Local Perspective

“This refers to a comprehensive, systematic evaluation of the assumptions for, and consequences of the application (initial and continued) of health technology.”

- **Macro HTA**
  - Impact on patient, organisation, economy, society etc
  - Multidisciplinary approach

- **Micro HTA**
  - Assesses scientific soundness of technology on the basis of safety, efficacy, effectiveness and cost effectiveness
  - Specialists and professionals charged with the assessment task.

DoH
HTA – SAME SAME but DIFFERENT
WHY DIFFERENT FOR MEDICAL DEVICE

1. They are often diagnostics (e.g. diagnostic/predictive genetic tests and impact onto “personalised medicine”): challenge to measure health outcomes

2. Experimental studies (e.g. RCTs) are more challenging (e.g. unethical, difficult, impossible): no general consensus on robust alternatives yet (e.g. registries, cohort studies), yet:

3. No general consensus on which experimental studies to be considered in HTA (e.g. comparator(s), head-to-head vs. placebo, direct vs. indirect comparisons): HTA bodies seldom agree

4. Medical devices’ performance highly depends on end-users: learning curve

5. Timing of assessment (Buxton Law’s “It is always too early until, unfortunately, it’s suddenly too late”): challenge to assess long-term benefits and/or spillovers vs. upfront costs

6. Medical devices have wider economic implications (e.g. organisational impact): rarely assessed*

7. Pricing strategies also depend upon country-based procurement policies: instability of ICERs vs. threshold values

Conclusion

The Industry supports a **transparent** and **collaborative partnership** on development of HTA processes and methodologies for medical technologies. Where there is a **gap** between sufficient and available evidence, the **value** of additional information should be carefully considered, in particular elements related to technological improvements or a movement on the learning curve.

It is recognised that the level of uncertainty in evaluating medical devices may be greater than with other health technologies and that more emphasis may be placed on value judgements. *Our goal is to ensure rapid access to innovative medical technologies of value to patients and society.*

References