# Building Health Technology Assessment into Your Regulatory Strategy

**9-10 November 2017**  
TOPRA 6th Floor, 3 Harbour Exchange, London, E14 9GE  

**Day 1**  
Chair: Kate Betteridge, Pfizer

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tr>
<td>09:30</td>
<td>Registration</td>
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<tr>
<td>09:45</td>
<td>Tea and Coffee</td>
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<tr>
<td>10:00</td>
<td>Welcome from TOPRA</td>
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<td>10:10</td>
<td><strong>Session 1: Introduction to HTA</strong></td>
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<td>Mike Chambers - <em>MC Healthcare Evaluation, UK</em></td>
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<td></td>
<td>• Understand the developing role and purpose of HTA in health care systems</td>
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<td>• Be able to define HTA and understand how it has emerged and spread in recent years</td>
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<td>• Highlight some differences between regulatory and reimbursement/HTA approaches</td>
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<td>10:35</td>
<td><strong>Evolving interface between HTA and regulators: What is of critical importance to the regulatory affairs professional?</strong></td>
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<td>Kate Betteridge - <em>Pfizer</em></td>
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<td>• Outline the areas of overlap between the two functions.</td>
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<td>• What are advantages of greater understanding and collaboration between the two disciplines.</td>
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<td>• Consider barriers and solutions</td>
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<td>11:00</td>
<td><strong>Session 2: Health Technology Assessment: Concepts, Methods and Process</strong></td>
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<td>Eli Gajraj - <em>National Institute for Health and Care Excellence (NICE), UK</em></td>
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<td>Mike Chambers - <em>MC Healthcare Evaluation, UK</em></td>
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<td><strong>Evidence requirements for HTA</strong></td>
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<td>• Understand the building blocks of HTA, from value proposition to evidence requirements to decision-making</td>
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<td>• Understand the importance of measuring relative effectiveness, and how to derive health outcomes such as QALYs</td>
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<td>• Understand how to measure resource use and costs for HTA</td>
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<td>• Be able to calculate and interpret incremental cost-effectiveness ratios (ICERs)</td>
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<td>• Understand how health outcomes and costs are combined in economic evaluations for HTA</td>
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<td>• Understand the strengths and limitations of RCTs for HTA</td>
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<td>12:00</td>
<td><strong>Practical: Scoping an HTA appraisal</strong></td>
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<td>• Understand the importance of specifying the decision problem and scoping topics for HTA appraisal at NICE</td>
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<td>Use a PICO table to structure the scope of a technology appraisal</td>
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**Practical 1: Scoping HTA appraisals**

11:45

- Understand the importance of understanding the decision problem and scoping topics for HTA appraisal at NICE
- Group exercise: Use the PICO table to structure the scope of a technology appraisal

**HTA in decision-making**

12.25

- Understand how HTA outputs are used in decision-making
- Understand how to assess uncertainty and the role decision thresholds

12:45

**Lunch**

**Session 3: Health Technology Assessment organisations in Europe**

- Consider the different remits of a different European HTA bodies in Europe, and how they are linked to the regulatory pathway
- Understand the breadth of each HTA organisation, with an overview of their processes, key assessment criteria, outputs and current hot topics
- Understand how and when pharmaceutical (and other) companies can engage with each HTA organisation

13:45

1. Scotland
   * Scottish Medicines Consortium

14:15

2. Germany
   * Regina Skavron G-BA

14:45

3. Sweden
   * Niklas Hedberg TLV

15:15

4. NICE
   * Eli Gajraj, NICE

15:45

**Tea coffee break**

**Session 4: View from the coalface**

Prof. David Barnett, University of Leicester, formerly chairman of the UK NICE Technology Appraisal Committee

16:00

- Learn how HTA-driven decision-making (for reimbursement of pharmaceuticals) works in practice, drawing from the first hand experience of a committee chair
- Hear about issues that have arisen in the HTA of different interventions at UK NICE

**Panel discussion with all of todays speakers**

16.45

- Your chance to ask the panel about key issues for HTA in each country or across Europe

17:30

**Close**
### Introduction to Day 2

- Why and when SA is needed
- What advice is available

### Session 5: Seeking early scientific advice

*National advice, European network for Health Technology Assessment (EUnetHTA) and parallel advice with regulators. These talks will outline the processes involved, what is offered by agencies and the benefits to industry. The talks will explore experience to date and possible future developments.*

#### EMA HTA Parallel Scientific Advice

*Speaker TBC*

- Why seek EMA HTA parallel advice?
  - Practicalities and observations of EMA HTA parallel advice
  - Learn about recent updates to the parallel advice process and what next?

#### HTA perspective

*Speaker TBC*

- Why seek national HTA advice?
  - A national perspective on the national and parallel EMA EUnetHA advice processes
  - Constraints/ considerations on receiving advice

#### Industry perspective

*Speaker TBC*

- Why seek national, EMA HTA parallel advice or multi-HTA advice?
  - Practicalities and observations of advice processes
  - Constraints/ considerations on receiving advice – what can regulatory professional apply?

### Tea Coffee break

10:45

### Session 6: Emerging topics in HTA

- Why the recent focus on “Real World data”? How are Pharma companies addressing this?
- What are adaptive pathways and when might they be implemented? What are the implications for RA professionals?
### Eu co-operation on HTA
Intro to EUnetHTA and JA3 – Speaker TBC
- An introduction to EUnetHTA and previous work packages
- Joint Action 3 – objectives, deliverables, timings and practicalities

**11:00**

HTA perspective - G-BA – Regina Skavron
- G-BA role in HTA nationally and as part of EUnetHA
- Perspectives on future trends for HTA in Germany and across EU

### Adaptive pathways
Adaptive pathways and pricing - Francois Maignen, OHE
- Comparison of traditional and adaptive regulatory and pricing pathways
- Challenges and opportunities for industry, regulators and HTA bodies in utilising adaptive pathways

**12:00**

**12:30** Lunch

### Use of Real World data and Involvement of regulatory affairs professionals in Industry
Speaker TBC
- Integrated Evidence Generation Planning
- Drivers of Evidence needs
- RWD to RWE
- How can regulatory affairs professionals help extract the most value from RWD?

**13:30**

### Early Scientific HTA advice – collaboration with Regulatory Affairs – a practical discussion
David Weinstein
- What are the data/information needs of HTA and Payers and how can they be assessed when seeking early advice – during early clinical development
- How are these data/information similar and different from Regulatory Needs
- How can Regulatory Affairs and Market Access collaborate in ensuring getting the best label

**14:30**

**15:00** Panel Q&A

**15:45** Conclusion and key take homes for regulatory affairs

**16:00** Close