

# EVIDENCE BASED DECISION MAKING FOR PRICING AND REIMBURSEMENT: FROM THEORY TO PRACTICE

*Base course, Vienna, 15–18 November 2018*

This module is designed for professionals working in the pharmaceutical and medical device industry, in the public health sector and those who are involved in negotiations and decision making for pricing and reimbursement. Those who have a need to understand how evidence based decision making is being used to direct reimbursement and market access decisions will also benefit from this course.

## DAY 1

THURSDAY, 15 NOVEMBER 2018

09:00–09:15	[15 min]	<b>OPENING &amp; GENERAL INTRODUCTION TO THE COURSE</b>	Heinrich Klech (AT)
09:15–10:15	[60 min]	<b>1. LECTURE   BASICS OF HEALTH ECONOMICS</b> Principles of health economics, overview of health economic topics	Lieven Annemans (BE)
10:15–10:30	[15 min]	Coffee break	
10:30–12:00	[90 min]	<b>2. LECTURE   HEALTH ECONOMIC EVALUATIONS: CONCEPTS AND PRINCIPLES</b> ICER, QALY, ICER thresholds, role of budget impact and medical need	Lieven Annemans (BE)
12:00–12:20	[20 min]	<b>3. KNOWLEDGE TEST</b>	Lieven Annemans (BE)
12:20–13:20	[60 min]	Lunch Break	
13:20–14:10	[60 min]	<b>4. LECTURE   HTA vs. ECONOMIC EVALUATION</b> Focus on difference between HTA and health economic evaluation	Lieven Annemans (BE)
14:30–16:00	[90 min]	<b>5. GROUP EXERCISE   ROLE PLAY</b> (to pay or not to pay in the view of different stake holders, i.e. government, payers, industry)	Lieven Annemans (BE)
16:00–16:30	[30 min]	Coffee break	
16:30–17:30	[60 min]	<b>6. LECTURE   COST ANALYSIS</b> Perspective, discounting	Lieven Annemans (BE)
17:30–18:00	[30 min]	<b>7. KNOWLEDGE TEST</b>	Lieven Annemans (BE)

## DAY 2

FRIDAY, 16 NOVEMBER 2018

09:00–11:00	[120 min]	<b>8. LECTURE   HEALTH ECONOMICS MODELS: CONCEPTS AND PRINCIPLES</b> Decision trees; Markov Models	Lieven Annemans (BE)
11:00–11:15	[15 min]	Coffee break	
11:15–12:45	[90 min]	<b>9. GROUP EXERCISE   DESIGN A MODEL</b>	Lieven Annemans (BE)
12:45–13:15	[30 min]	<b>10. KNOWLEDGE TEST</b>	Lieven Annemans (BE)
13:15–14:15	[60 min]	Lunch break	
14:15–16:15	[120 min]	<b>11. LECTURE   GUIDELINES FOR HEALTH ECONOMIC EVALUATIONS</b>	Lieven Annemans (BE)
16:15–16:30	[15 min]	Coffee break	
16:30–18:00	[90 min]	<b>12. GROUP EXERCISE   ASSESS A HEALTH ECONOMIC PAPER</b> (published paper following the guidelines)	Lieven Annemans (BE)
18:00–18:30	[30 min]	<b>13. KNOWLEDGE TEST</b>	Lieven Annemans (BE)

## DAY 3

SATURDAY, 17 NOVEMBER 2018

09:00–09:20	[20 min]	<b>OPENING &amp; INTRODUCTION TO DAYS 3 AND 4  </b> learning objectives, warm-up, ice breaker	Keith Tolley (UK)/Heinrich Klech (AT)
09:20–10:40	[80 min]	<b>14. LECTURE   APPLICATION OF HEALTH TECHNOLOGY ASSESSMENT</b> <ul style="list-style-type: none"> <li>☞ Why understanding the value and value for money of innovative pharmaceuticals and other health technologies is important! The payer perspective</li> <li>☞ Why healthcare systems engage in HTA</li> <li>☞ Assessment versus appraisal for market access</li> <li>☞ Key stakeholders: EUNetHTA, ICER (US), NICE, EMA, other</li> <li>☞ ISPOR top 10 HEOR trends</li> <li>☞ Value for money vs affordability challenge in practice. Why budget impact is important to payers</li> <li>☞ Overview of country differences in the application of HTA</li> <li>☞ HTA for decision/policy making: pricing and reimbursement of pharmaceuticals and devices</li> <li>☞ Special cases: ultra- orphan drugs and regenerative medicines</li> <li>☞ HTA and the patient perspective</li> <li>☞ The challenge of BREXIT</li> </ul>	Keith Tolley (UK)/Maximilian Lebmeier (UK)

Program for day 3 continues on next page >

**DAY 3 (CONTINUED)**
**SATURDAY, 17 NOVEMBER 2018**

10:40–11:00	(20 min)	Coffee break	
11:00–12:00	(60 min)	<b>14. LECTURE CONTINUED   APPLICATION OF HEALTH TECHNOLOGY ASSESSMENT</b> (continued)	Keith Tolley (UK)/ Maximilian Lebmeier (UK)
12:00–12:45	(45 min)	<b>15. GROUP EXERCISE   BREAK OUT SESSION ON HTA APPLICATIONS FOR DECISION MAKING</b>	Keith Tolley (UK)/ Maximilian Lebmeier (UK)
12:45–13:00	(15 min)	<b>16. KNOWLEDGE TEST</b>	Keith Tolley (UK)
13:00–14:00	(60 min)	Lunch break	
14:00–14:45	(45 min)	<b>17. SPECIAL LECTURE  </b>  <b>HOW TO DEFINE INNOVATION?</b> How much are we willing or capable to pay for innovation? Opportunities and Hurdles to access to innovation – a global perspective  <b>RESPONSE FROM INDUSTRY AND LESSONS LEARNED</b>	Suerie Moon (CH)/Jürgen Raths (CH)  Suerie Moon (CH)  Jürgen Raths (CH)
14:45–15:25	(40 min)	<b>18. PANEL DISCUSSION   VALUE AND PRICE OF INNOVATION IN PHARMACEUTICALS AND DEVICES WITH LOCAL PERSON FROM AUSTRIA. INDUSTRY PERSPECTIVE OF AUSTRIA, HTA/PAYER REPRESENTATIVES</b> Invited participants: Jan Oliver Huber (AT), Anna Bucsics (AT), Claudia Wild (AT) and other stakeholders from industry and government, etc.	Keith Tolley (UK)
15:25–15:40	(15 min)	Coffee break	
15:40–16:00	(20 min)	<b>19. LECTURE   EUNetHTA AND ITS ROLE</b> The purpose of joint EMA-HTA scientific advice	Claudia Wild (AT)
16:00–16:20	(20 min)	<b>20. LECTURE   WHAT MIGHT BREXIT MEAN FOR VALUE ASSESSMENT KEITH TOLLEY (UK) ACROSS EUROPE</b>	Keith Tolley (UK)
16:20–17:00	(40 min)	<b>21. LECTURE   EUROPEAN PRICING CHALLENGES FOR VALUE ASSESSMENT</b>	Bert Verbakel (BE)
17:00–17:40	(40 min)	<b>22. LECTURE   ASSESSING AND INTERPRETING THE VALUE OF ORPHAN DRUGS?</b>	Anna Bucsics (AT)
17:40–18:00	(20 min)	<b>23. KNOWLEDGE TEST</b>	Keith Tolley (UK)

**DAY 4**
**SUNDAY, 18 NOVEMBER 2018**

08:30–10:00	(90 min)	<b>24. LECTURE   HTA, PRICING AND REIMBURSEMENT: CHALLENGES OF VALUE ASSESSMENT FRAMEWORKS ACROSS MARKETS</b>  Panel of speakers comparing and contrasting the following:	Keith Tolley (UK)
		<ul style="list-style-type: none"> <li>✎ The established HTA/cost-effectiveness approach: e.g. UK+, Scandinavia, Benelux, Australia</li> <li>✎ Performing HTA model with limited resources: e.g. CEE and Russia</li> <li>✎ Traditional therapeutic value model: e.g. Germany</li> <li>✎ The budget impact focussed model: Italy and Spain</li> <li>✎ Asia-Pacific HTA models</li> <li>✎ Austria: the local model</li> </ul>	Keith Tolley (UK)  David Danko (HU)  Friedhelm Leverkus (DE)  Maximilian Lebmeier (UK) Keith Tolley (UK) Anna Bucsics (AT)
10:00–10:20	(20 min)	Coffee break	
10:20–11:00	(40 min)	<b>25. GROUP EXERCISE   BREAK OUT SESSION ON HTA/P &amp; R CHALLENGES ACROSS KEY MARKETS</b>	Keith Tolley (UK)
11:00–12:00	(60 min)	<b>26. LECTURE   CRITERIA FOR SUCCESS AND FOR PITFALLS FOR HTA SUBMISSIONS – A CASE STUDY</b>	Jürgen Rath (CH)
12:00–12:15	(15 min)	<b>27. KNOWLEDGE TEST</b>	Keith Tolley (UK)
12:15–13:15	(60 min)	Lunch break	
13:15–15:00	(105 min)	<b>28. WORKSHOP   HOW TO MAKE A GOOD SUBMISSION FOR HTA : ASSESSING THE EVIDENCE, REAL CASE STUDIES, WHAT MIGHT INFLUENCE DECISION MAKERS.</b>	Keith Tolley (UK)/ Maximilian Lebmeier (UK)
15:00–15:15	(15 min)	<b>CLOSING REMARKS, PLUS EVALUATION OF STUDENTS ASSESSMENTS AND HANDOVER OF CERTIFICATES AND AWARDS</b>	Keith Tolley (UK)/Heinrich Klech (AT)