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**Louise Heron**

# Practical Guidelines for Health Technology Assessments in Europe

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# Practical Guidelines for Health Technology Assessments in Europe

## Learn

- How the different functions within Pharma/Medtech companies need to collaborate for successful HTA submissions.
- How to prepare for HTA submissions in a step by step manner, at both global and local level.
- The critical success factors when preparing HTA.
- Lessons from real-world cases.
- How the HTA process and considerations differ for orphan drugs and biosimilars.
- What the impact of the move towards EU harmonization is on the HTA landscape.



## The Expert

Louise Heron

- Louise Heron is Senior Director and Deputy MD at Adelphi Values, part of the Adelphi Group, a group of specialist companies that uniquely embraces all the disciplines that integrate into Market Access.
- Louise is a health economist and leads PROVE (Payer-Reimbursement-Outcomes-Value-Evidence) projects to optimize market access for new products and treatments.

## Dates & Locations

27 November 2019, Brussels

Visit [www.celforpharma.com](http://www.celforpharma.com) for registration fees and updates.

## Additional Benefits

- This is a great opportunity to review real world examples of HTA submissions and outcomes, and explore how they have impacted market access.

## Why You Should Attend

This programme nicely complements Prof. Dr. Lieven Annemans' *The Health Technology Assessment Course* in that it focuses on the practical implications of HTA in Europe's complex market environment with its many HTA bodies. The expert will share and discuss concrete examples of HTA processes and demonstrate best working practices to ensure that HTA is incorporated effectively into market access strategy and commercial brand plans to maximise chances of success.

# Agenda

## 10:00 Welcome & Audience Expectations

## 10:15 HTA Within Pharma's Organisational Context

- Why it is important and how it fits into the drug development process
- Global vs. local role: While the Affiliate focusses on the individual country HTA, Global's strategic role is to ensure sequencing and outcome is beneficial to other markets and access as a whole, with a focus on major HTAs only.
- How does HTA fit into the market access plan as a whole and how does it align with the bigger picture within Pharma?
- Parallel activities: Value proposition development
  - Advocacy plans – Evidence development
  - Landscape analyses

## 10:45 Critical Success Factors for Pharma When Preparing HTA

- When does it start?
- HTA horizon scanning and developing the global value dossier to inform local HTA dossiers
- How to engage stakeholders: Gaining HTA advice
  - Ongoing dialogues – Payer research to inform likely opinion – etc.
- Evidence requirements and gap analysis – How do we know what is needed? – Payer research activities to inform HTA dossiers – etc.
- Key activities that are needed to facilitate HTA dossier development

## 11:45 Coffee Break

## 12:00 HTA Outcomes: What Happens Next?

- Examples of different outcome possibilities in key HTAs, e.g. what does ASMR 3 vs ASMR 4 mean, and what is the implication?
- Different roles of HTA and the implications in terms of reimbursement, pricing & access
- Timelines to reimbursement and next steps beyond HTA submissions

## 13:00 Lunch

## 13:45 Learning from HTA Decision Case Studies

- Deep dive review of two case study products which have received differential outcomes from HTA bodies across Europe, what reasons were given and what the implications were

## 15:15 Coffee Break

## 15:30 HTA in Germany

Besides being the biggest market in Europe with a favourable environment towards innovative treatments, Germany is exemplary because the HTA process there is complex, with very strict timings and evidence requirements. Other countries often look to Germany as a first step.

- IQWiG & GBA: a closer look at the process
- Step-by-step walk through for preparing the HTA submission from a Global and Local level

## 16:30 Evolving HTA Landscape: Global Developments

- Procedural differences and challenges with Orphan drugs as compared to Biosimilars
- Emerging HTAs & move toward EU harmonisation

## 17:30 Wrap-up & Close

# Registration Form

Complete the below form and email to [inge@celforpharma.com](mailto:inge@celforpharma.com) or fax to +32 2 721 13 82 or go to [www.celforpharma.com](http://www.celforpharma.com) and complete the online registration form.



Questions?

Inge Cornelis  
+32 2 709 01 43  
[inge@celforpharma.com](mailto:inge@celforpharma.com)

## Course(s)

Course Title .....

Course Date(s) .....

## Registration Fee

Visit our website [www.celforpharma.com](http://www.celforpharma.com) for information about the early-bird fee and full fee, group discounts, etc.

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Job Title .....

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City/Province .....

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Payment Method  Bank Transfer  Credit Card (+3%)

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