ACQUIRE BUSINESS-CRITICAL MARKET ACCESS COMPETENCIES

LEARN from Pharma's international top experts

Paul Craddy & Graham Foxon

Strategic Market Access Planning for Orphan Drugs

LEARN from interacting with your industry peers

Excellent training course led by very knowledgeable trainers! Well worth the time and cost!"

Takeda
Mattias Klefbeck
New Product Planning Lead Nordics
Sweden (December 2022)

CELforPharma
NEVER STOP LEARNING

Strategic Market Access Planning for Orphan Drugs

Learn

- The opportunities and challenges of Orphan and Rare Diseases from a market access perspective.
- Guidelines for your Rare Disease access strategy: timelines, country customisation, value pricing…
- The perspective of payers and regulators, and which evidence you will need to secure patient access at the right time and the right price.
- Lessons from real-world cases about what works well and what doesn't in orphan drug pricing.
- How Managed Entry Agreements can facilitate patient access.
- The benefits and challenges of different types of early access programs.
- How to develop a convincing value proposition for your Rare Disease treatment.

The Experts

Paul Craddy
& Graham Foxon

- Founders of Remap Consulting, a specialist pharmaceutical pricing and market access consultancy.
- Paul and Graham have supported many pharma companies in developing and implementing pricing and market access strategies to enable patient access for rare diseases.
- Dr. Paul Craddy's experience includes European pricing and market access positions at Takeda/Nycomed and IMS/Cambridge Pharma.
- Dr. Graham Foxon's market access and pricing experience includes both consultancy at IMS and Adelphi Values, as well as senior positions at GSK, Ferring and a start-up biotech.

Dates

24 May 2023 *(Brussels)*
28 November 2023 *(Brussels)*

Visit **www.celforpharma.com** for registration fees and updates.

Additional Benefits

- To reinforce peer learning, the experts will use a small pre-course questionnaire (by email) and polling during the day to actively engage the whole audience throughout the course.
- Real-life case studies will be used to illustrate the theory and in small groups you will put the key learnings into practice on a real-world case study.

What Participants Say About This Course

Excellent training course led by very knowledgeable trainers! Well worth the time and cost!"

Takeda
Mattias Klefbeck
New Product Planning Lead Nordics
Sweden (December 2022)

The Optimising Access for Orphan and Rare Diseases course was an excellent overview of the market access challenges in the ever-evolving space of rare and orphan diseases. The presenters were very knowledgeable and shared a lot of their experiences in the disease area."

Clinigen Group
Janet Lac
Consulting Associate
United Kingdom (December 2022)

The most beautiful thing about this course is that you can definitely learn new things, no matter whether you already have experience in access or you don't."

SOBI
Marian Marocico
Patient Access and Launch Excellence Lead
Romania (December 2022)

Agenda

All courses are held in CET/Brussels Time. Please check the Dates & Locations section on our website for the exact start and end times, or send an email to kealeigh.steel@celforpharma.com.

Welcome & Audience Expectations (~30 min)

Opportunities and Challenges from an HTA & Pricing Perspective (~25 min)

- Orphan drug vs. rare disease - what is the difference?
- Why are pharmaceutical companies interested in orphan drugs/rare diseases?
- Pricing of orphan drugs, is it really as good as we think?
- Why are payers so uncertain about orphan drugs?

HTA for Orphan Diseases: Current Practices (~1 h)

- Similarities and differences in HTAs of traditional and orphan drugs
- HTA process for the evaluation of orphan drugs
- The need for country customisation across EU5 and US
- Health economic considerations for orphan drugs
- What are HTA agencies doing to support orphan drug development?

Framework for Assessing Value of Orphan Drugs (~1 h 20 min)

- A 6 step approach to developing your orphan drug access strategy
- Defining your patient population and their unmet needs
- The importance of understanding the current treatment options and patient management systems
- Comparator selection: what to do and what not to do!
- Determining appropriate outcomes, knowing the major hurdles and how to alleviate them
- Challenges of demonstrating economic value of orphan drugs
- Approaches for addressing the evidence gaps

Lunch Break

How to Price Rare/Orphan Disease Drugs (~ 30 min)

- Key drivers needed to secure a commercially viable price for an orphan drug
- Case study analysis of successful and unsuccessful orphan drug pricing
- How to justify orphan drug prices, from unmet need to evidence of medical benefit
- The impact of missing the mark on orphan drug pricing

Use of Managed Entry Agreements to Facilitate Patient Access (~30 min)

- Why implement a managed entry agreement?
- Types of managed entry agreements
- Use of performance-based agreements for orphan drugs
- Key trends and key considerations for companies launching orphan drugs

Securing Early Access for Rare Disease Treatments (~30 min)

- What is early access?
- Different processes available to companies to secure early patient access for orphan drugs
- The benefits and challenges of each early access program and the considerations companies should make when deciding whether to instigate early access

Group Exercise: Developing an Optimal Access Strategy For an Orphan Drug (~1 h)

In small groups, participants will develop an optimal access strategy for a real-life orphan drug case study, utilising learnings from the course.

Considerations to Build a Successful Access Strategy for Your Orphan Drug (~30 min)

- Key challenges in developing a value proposition for an orphan product
- Emphasising the evidence and acknowledging the gaps
- EU HTA considerations when developing an orphan drug access strategy
- Key considerations when developing value propositions for orphan products

Summary (~15 min)

Close

Registration Form

Complete the below form and email to aswaan@celforpharma.com or fax to +32 2 721 13 82 or go to www.celforpharma.com and complete the online registration form.

Questions?

Annelies Swaan
+32 2 709 01 42
aswaan@celforpharma.com

Course(s)

Course Title .....

Course Date(s) .....

Registration Fee

Visit our website www.celforpharma.com for information about the early bird fee and full fee, group discounts, etc.

Participant Details

Title .....

First Name .....

Last Name .....

Job Title .....

Email .....

Mobile Number .....

Country of Work .....

Company Details

Company Name .....

VAT Number .....

Invoicing Address

Street Address .....

City/Province .....

Postcode .....

Country .....

Payment

Payment Method ☐ Bank Transfer (+3%) ☐ Credit Card

PO Number (optional) .....

Confirm Registration

In order to complete the registration, please tick the following box(es):

☐ I, the participant(s), have read and accept CELforPharma's Transfer & Cancellation Policy (www.celforpharma.com/transfer-cancellation-policy) and Privacy Policy (www.celforpharma.com/we-value-your-privacy)

☐ I accept that CELforPharma regularly sends me information by email on topics discussed within their website (www.celforpharma.com) and relevant to my function, under the condition that I can unsubscribe at any time. I accept that relevant personal details are stored in a database for that purpose, as per CELforPharma's Privacy Policy (www.celforpharma.com/we-value-your-privacy), of which I accept the terms.