OVERVIEW

Adjusting the route to the market is vital to support innovation and timely approvals for products that could cover unmet or high medical needs. However, what remains unclear is how to shape regulatory strategy to overcome the barriers and whether the evidence gathered for authorisation marries up with the health technology assessment (HTA) strategy. Also the bottlenecks in bringing products onto the market and legislative frameworks at national level are of particular interest.

The workshop aims to look into both the regulatory hurdles as well as discuss improvements in market access based on evidence from recent years and the situation in European countries. Insights from experts from both regulatory as well as market access side are brought to the table, connecting all stakeholders. The outcomes will be compiled into white paper.

OBJECTIVES

› Screen the actual situation of regulatory pathways on conditionally approved drugs – successes or failures?
› Identify gaps or barriers in adaptive licensing system in order to allow full use of it
› Get the complete picture of the whole system from regulatory approval to pricing and reimbursement
› Discuss the best ways forward to give recommendations to different stakeholders
› Identify the challenges brought forward by additional evidence generation
› Recognise barriers in global registration programmes

WHO WILL ATTEND

› Regulatory professionals from industry and consultants
› Market Access professionals from industry and consultants
› HTA responsibilities from government bodies
› Regulators
› Health Professionals
› Reimbursement bodies
› Patients
09:20 Registration and Welcome Coffee
10:20 Welcome Remarks
10:30 Session 1
Introduction – setting the historical scene and the current perspective
Session 1 aims to define adaptive pathways, introduce the concept from both regulatory and market access point of views and discuss the differences between the systems in Europe and the US. The EMA Pilot Project, its outcomes and learnings will be presented to provide a comprehensive view, which will serve as a basis for the whole workshop.
12:00 Lunch
13:00 Session 2
Current developments – where we are today
Session 2 focuses on learnings from the system in place both from the industry perspective and HTA assessment body point of view. Results from a survey conducted by the Working Party will be presented, followed by an analysis of the products that have been approved through adaptive licensing looking into the outcomes of HTA assessment at Member State level.
14:30 Refreshment Break
14:50 Session 3
Issues raised by the survey and other learnings - where are the gaps and what can we do about them?
Participants will be divided into smaller groups to discuss questions which have arisen from the analysis and discussions in sessions 1 and 2. The intention is to bring market access and regulatory professionals to the same table for cross functional discussion and sharing of best practice and company/agency initiatives.
16:00 Session 4
Recommendations for the future
The EMA is planning to broaden the scope of adaptive licensing to adaptive pathways to take a more holistic approach. What is the message that should be sent to them? The session aims to give recommendations and suggest points of improvements to different stakeholders involved in developing the system. Points raised throughout the day will be considered and feedback from the small groups debated.
17:10 Closing Remarks
17:15 End of Workshop

Venue
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A special room rate is available for attendees at EUR 147.50 per single room (inc. breakfast, VAT and city tax). To book a bedroom at The Pullman please email Angelique on H7431-SB@accor.com. The room rate is available until 29th of May or until the group block is sold-out, whichever comes first.

Registration
Participation fees (inc. VAT):

Industry GBP 665.50
Government GBP 332.75
Academic GBP 332.75
Student GBP 114.95

Registration will be handled through TOPRA website
https://www.topra.org/AdaptivePathways15

This conference is currently in development. Please visit www.diahome.org or www.topra.org/AdaptivePathways15 for regular programme updates or contact inka.heikkinen@diaeurope.org
DIA is a global volunteer and member community representing thousands of life science professionals working together to bring innovative, safe and effective medical products to patients. An association of more than 30,000 key stakeholders, DIA builds productive relationships by bringing together regulators, life sciences professionals, academics and researchers, patient advocates and other influencers to exchange knowledge and collaborate in a neutral setting.

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TOPRA

The Organisation for Professionals in Regulatory Affairs
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