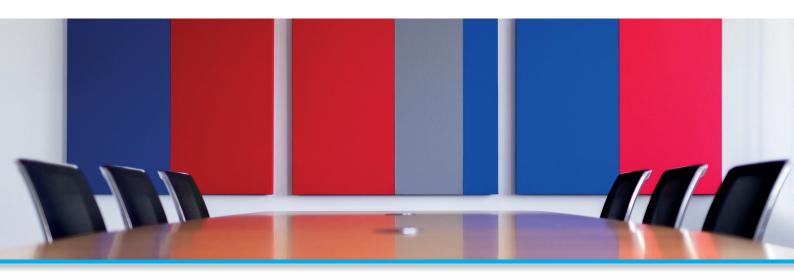


Your Gateway to Europe: Market Access for Biotech and Pharmaceutical Companies



# Local Market Access and EU HTA

**Our Services** 

# **Local Market Access**



Market Access is local. We offer a one-stop shop for Europe: Together with our partner companies we cover all key EU markets with local HTA submissions and Pricing and Reimbursement procedures. Currently we support submissions in Germany (G-BA), France (HAS), Italy (AIFA), Spain (AEMPS), Austria (Dachverband), UK (NICE, SMC, AWMSG), Switzerland (BAG), Poland (AHTAPol), Netherlands (ZIN, CieBAG), and further countries in the CEE region. To be Your Gateway to Europe.

#### **National Strategy Development**

- · Identification of route of reimbursement
- PICO simulation
- · Gap analysis
- · Price simulation
- · Market Access strategy development
- National Scientific Consultation
- · Early Access Program
- · Strategy update
- · Stakeholder management
- Monitoring

#### **National Assessment**

- Assessment Strategy
- · Dossier defense
- · Review of Resolution
- · Stakeholder management
- Monitoring

#### National Dossier Development

- · Statistical feasibility
- · Dossier outline
- · Statistical analysis
- · Dossier preparation
- · Alignment dossier
- · Quality check
- · Dossier submission
- Stakeholder management
- · Monitoring

#### **National Price Negotiation**

- · Negotiation strategy
- · Negotiation preparation
- · Actual negotiation
- · Conflict resolution
- · Price notification
- · Lessons learned
- · Regional negotiation
- Stakeholder management
- Monitoring



## **EU HTA**



National and EU HTA

Health Technology Assessment is increasingly European. Together with our partner companies we offer full-scale support for EU HTA, following one common methodology.

## **EU HTA Strategy Development**

- · Analysis EU HTA obligation
- · Simulation of consolidated PICOs
- · Gap analysis based on consolidated PICOs
- · Consolidated price simulation
- · EU HTA strategy
- · Scientific consultation
- · Strategy update
- · Stakeholder management
- Monitoring

#### **EU HTA Assessment**

- · Factual Accuracy Check
- · Review JCA Report
- · Lessons learned
- · Stakeholder management
- Monitoring

# **EU HTA Dossier Development**

- · Definition of assumed PICOs
- · Statistical feasibility
- · EU HTA dossier outline
- Alignment dossier outline (EU national)
- · Statistical analysis
- · Dossier draft
- · Communication of final PICOs
- · Adaptation of dossier to final PICOs
- · Quality check
- · Dossier submission
- · Stakeholder management
- · Monitoring

## Organizational Readiness

- Training
- · Organizational review
- · HTA pipeline management
- · Mock-up

need to be closely aligned. **Strategy Development Dossier Development** Assessment Simulation of nsolidated PICO Identification of Alignment Dossier Outline (EU – Nat.) **EU HTA** actual Accuracy Check Adaptation of Dossier Review JCA Report Gap Analysis nsultation Feasibility **Analysis** Quality Assurance EU Strategy Update Dossier Outline Dossier Draft Dossier Submission level der Managem Stakeholder Management Monitoring eg / [ evelopme **Price Negotiation** Stra Dossier evelopment essment Market Access Strategy Statistical Feasibility Negotiation Preparation Price Notification **National Review Resolution** level



Accessus Health offers Market Access services for all European markets. 250 local Market Access experts from our network of partner companies follow one common methodology.

#ToBeYourGatewayToEurope

#### Your contacts:

Janine Leismann CEO j.leismann@accessus-health.eu Phone: +49 40 4133081-26 www.accessus-health.eu Dr. Florentin Köhnemann CEO f.koehnemann@accessus-health.eu Phone: +49 40 4133081-48 www.accessus-health.eu



