



**PPI** Healthcare  
Consulting

**International Market Access:**  
**Overview from**  
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**PPI HC: Adding global value through local expertise and insight**

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# (Market Access) Market Needs

- Market entry strategies for Europe must consider Regional and National regulations; both regulatory & reimbursement
- Pricing & reimbursement (P&R) processes are at country level but now an EU component with new 2025 HTA (Health Technology Assessment) rules
- For new products, achieving optimal P&R requires data on unmet need and comparative value vs standard of care
  - This is usually clinical and economic
- Securing formal & informal scientific & payer advice provides essential guidance on development plans
- Optimising market access has many components (see next slides)

# PPi Market Access Services (1)

(What do we at PPi mean by Market Access?)

1. In-licensing due diligence & go/no go decisions
2. Early HTA (Health Technology Assessment) and evaluation of commercial issues/opportunities
3. 'Joint Scientific Consultation' & 'Joint Clinical Assessments'
4. Integrated Regulatory plan
5. Pricing
  - Initial & subsequent price assessments
  - Country & regional revenue optimisation
  - Repricing (of marketed products)
6. Clinical & economic study design to meet Market Access requirements

# PPi Market Access Services (2)

(What do we at PPi mean by Market Access?)

7. Client structural/representational guidance
8. Landscape, stakeholder and comparator assessment
9. Indication sequencing & launch sequencing
10. Early access schemes – strategy & implementation
11. P&R (Pricing & Reimbursement)/HTA submissions support (dossiers, models & agency liaison)
12. 'Managed Access schemes' (risk sharing)
13. Contribute to policy debate (lead AND follow)
14. Innovation/investment Grant sourcing

# International Market Research Scoping Questions for Medical Technology

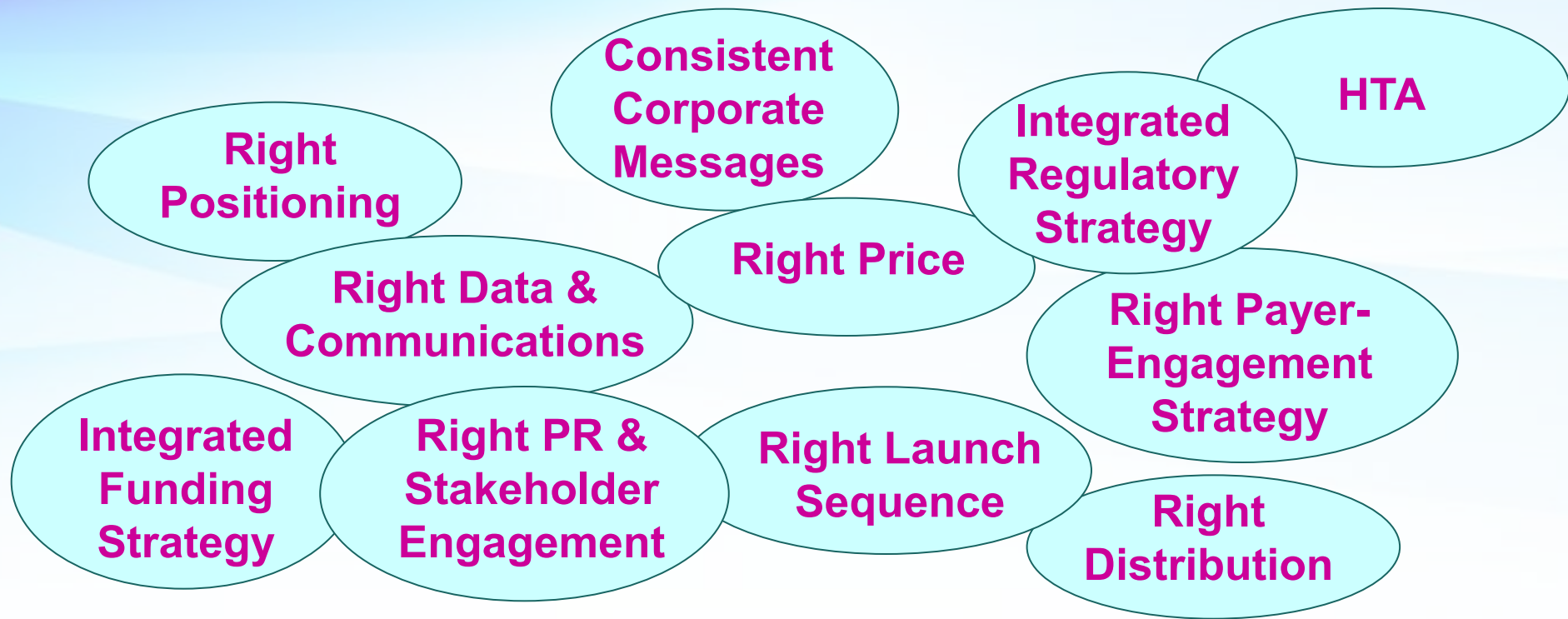
## General Market Information

- Which countries of interest?
- What types of medical device products of interest?
- When does company plan to commercialise?
- Is company looking to use distributors already operational in target markets or looking to establish own selling entities + staff?
- What information is wanted?
  - Enlistment process to support coverage (reimbursement) including stakeholder information (= who does what)?
  - Pricing process including stakeholder information (= who does what)?
  - How tenders and procurement work?
  - Data requirements to support market entry? (e.g. what general economic or comparator evidence/data would be needed)

## Or for specific product(s)

- Which countries of interest?
- When does company plan to commercialise?
- For how many specific products is guidance sought?
- Is company looking to use distributors already operational in target markets or looking to establish own selling entities + staff?
- What information is wanted?
  - Achievable prices?
  - How tenders and procurement will work?
  - Market opportunity assessment?
  - Market access strategic guidance?
  - Product positioning strategy?
  - Market intelligence on standard of care and unmet need?
  - Data requirements to support market entry? (e.g. what specific economic or comparator evidence/data would be needed)

# Integrated approach needed to ensure optimal international Market Access



✦ **Achieving successful market access involves a series of pre- and peri-launch strategies which need to be co-ordinated**



# Pricing needs to be considered across Europe, and beyond

- International Reference Pricing (IRP) sees prices in 1 Eur country effected by prices in others - example low Romania prices
- IRP to Europe also effects countries' drug prices outside Europe – example Canada
- Domestic Reference Pricing (DRP) caps prices in one country to prices of local comparators – example Germany
- Parallel Trade (PI) can damage revenues if differentiated prices - example Portugal



**Very important to develop a pan-global pricing strategy and a launch sequence strategy to protect and optimize revenues, especially across Europe**

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### **Some PPI publications:**

**Orphan drugs: pricing, reimbursement and patient access**

IJPHM, Volume 5, Number 4. 2011

Adam Barak & Jyoti Shankar Nandi

**The PPRS – new UK medicines pricing system reviewed**

Pharmaphorum. May 13, 2014

Adam Barak

**These and others at:**

<https://ppi.consulting/publications/>