



**PPi Healthcare
Consulting**

International Market Access:
Overview from
Adam Barak, PPi Healthcare Consulting Ltd

PPi HC: Adding global value through local expertise and insight

T +44 (0)7811 363098 E info@ppi.consulting W www.ppi.consulting

5 The Chambers, Vineyard, Abingdon-on-Thames, Oxfordshire OX14 3PX, UK

(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

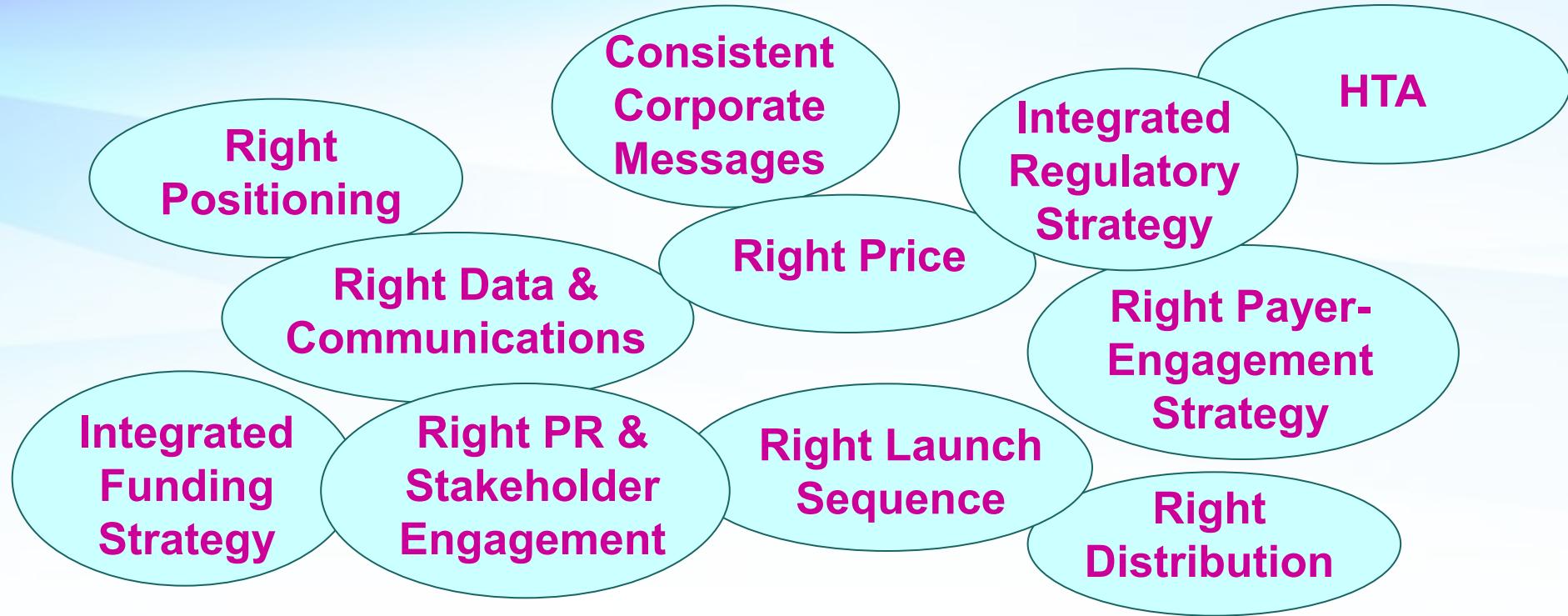
General Market Information

- 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)

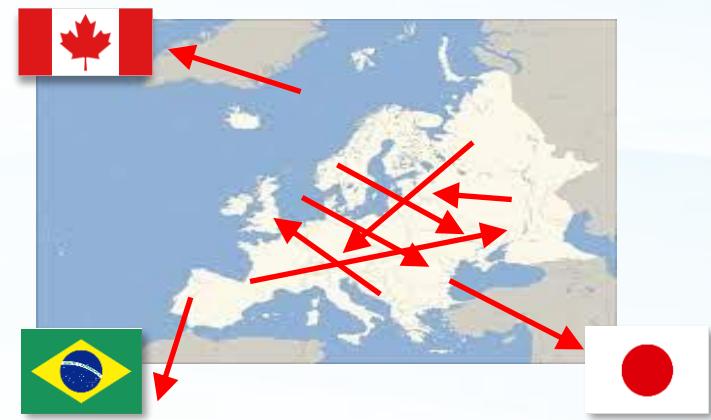
Integrated approach needed to ensure optimal international Market Access



- ⊕ 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

Email: info@ppi.consulting

Web: www.ppi.consulting

Tel (UK): **+44 (0)7811 363098**

Registered office (UK): **5 The Chambers, Vineyard, Abingdon on Thames, Oxfordshire, OX14 3PX, UK**

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/>