Introduction to Global Market Access

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life ACCESS ACADEMY science

What is market access and how does it differ from marketing authorisation?

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	Marketing Authorisation	Market Access
Level of decision making	National and/or pan-European	National, regional, local
Number of decision-making bodies	Hundreds (just a few major bodies)	Tens of thousands
International collaboration	Well established	Relatively immature and politically contentious
Duration of process	6-18 months	0-36+ months (but may need to be revisited)
Scope of evaluation	Focused on one drug in isolation	Evaluates drug in context of market and medical practice
Evidence requirements	Safety, efficacy, quality	Relative clinical benefit, budget impact, cost-effectiveness, HRQoL, PROs
Nature of decision-making process	Clinical	Clinical, political, ethical, societal, financial
Impacts of decision making	Public health	Public health, political, societal, financial
Visibility of decisions	Generally low	Moderate to high (in the case of negative decisions)
Political sensitivity	Generally low	Moderate to high (in the case of negative decisions)
Government intervention	Minimal	Substantial
Post-approval burden	Moderate	Substantial

Marketing authorisation is about getting your medicine on the market, whereas market access is about getting your medicine in the hands of as many patients as possible.

How are healthcare systems organised and funded?

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Common models for healthcare systems in market economies

Model	Characteristics	Examples
Bismarck (aka social health insurance)	• Funded by premiums from employers and employees • Administered by private, non-profit health insurance funds • Physicians are typically reimbursed on a fee-for-service basis • More decentralised management may allow greater clinical flexibility	Germany, France, Netherlands, Belgium, Austria, Japan, employer-sponsored insurance in the US, urban employee insurance in China
Beveridge (aka known as National Health Service)	• Funded by tax deductions by the national government • Typically operate tight cost controls • Administered largely by publicly owned hospitals and clinics • Physicians are generally employees of the healthcare system • Large systems may be unwieldy and prone to political interference	UK, Italy, Spain, Scandinavia, Poland, military programmes in the US, urban and rural insurance in China
Douglas (aka National Health Insurance)	• Funding from a universal government-sponsored insurance programme • Services are administered by private-sector providers	Canada, South Korea, Taiwan, Medicare and Medicaid in the US
Out-of-pocket	• Citizens largely fund healthcare services themselves	Many developing nations, uninsured in the US

- Some countries combine elements of these approaches to funding.
- Decentralisation can lead to pronounced geographic inequalities in access to care.

Healthcare systems have not moved with the times—but change is now happening

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"Healthcare systems in Europe look like they are designed for the 1950s. They are oriented around acute care. Medical education is oriented around hospitals. Payment systems are oriented around particular interventions. Biomedical research is still based on the assumption that people have single diseases at a time, but already the biggest challenge is multiple morbidities. These require a more longitudinal approach and payment systems that can cope with care provided in more than one setting. Success will mean finding some way to move on from the acute care model."

Mark Pearson, Head of the Health Division, Organization for Economic Cooperation and Development

What are the main challenges of HTA?

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Challenge	Possible response
Misalignment of regulatory and HTA priorities	Use joint scientific advice and address both regulatory and key HTA demands in trial design
Variations in HTA approaches and evidence requirements	Understand key agencies and use early dialogue
Advice given in early dialogue could become obsolete	Monitor changes in clinical practice and competitive landscape; maintain dialogue with HTA agencies
Lack of understanding at global HQ level of national HTA nuances	Disseminate awareness of how the key agencies work
Uncertainty related to growing numbers of drugs	Prepare for more frequent post-marketing research; propose managed entry agreements
Methodological inflexibility of HTA agencies	Analyse outcomes for similar drugs; use early dialogue
Influence of one agency on others	Be aware of likely sequence of HTA evaluations and pay particular attention to most influential agencies
Long delays associated with HTA process	Rigorously quality check the dossier and prepare thoroughly for meetings

Will health technology assessment evolve into health technology *management*?

What are the common approaches to pricing medicines?

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- Payers generally control the prices of drugs they cover (they are effectively monopsony purchasers).

Common Pricing Methods

Pricing Method	Key Features
Free pricing	Notional freedom to set prices at launch, but discounts or other concessions may be needed to secure/maintain favourable reimbursement terms
Value-based pricing	Comparing a new drug with established therapies: evidence of clinical superiority does not guarantee higher prices
Cost-effective pricing	A drug's price must meet cost-effectiveness requirements (not always explicit)
Cost-plus pricing	Covering the costs of key elements in drug development, manufacture, and marketing, plus an acceptable profit margin
Internal reference pricing	Setting a maximum reimbursement price for a molecule, drug class or therapeutic category, with patients often required to pay any excess out of pocket
External reference pricing	Benchmarking the proposed price for a new drug against prices in other markets

- Payers often criticise the pharmaceutical industry for a lack of transparency, but the problem cuts both ways.
- Increasingly, payers will require manufacturers to renegotiate prices several years after launch.

Three main objectives of managed entry

Objective	Managed entry approach	Level of activity
Control budget impact	Financially-based agreements	Population/patient
Tackle uncertainty	Coverage with evidence development	Population
Manage variable drug response rates	Outcomes-based agreements	Patient

Innovative access arrangements

Innovative pricing approach	Potential application
Instalment/annuity payments	One-time potentially curative therapies (e.g., gene therapies)
Warranties	High-cost drugs with variable response rates (e.g., cell and gene therapies, oncology drugs)
Subscription (“Netflix”) model	Drugs with high price and potentially large patient population (e.g., direct-acting antivirals for hepatitis C)
Portfolio pricing	Portfolio of drugs for a single indication (e.g., cystic fibrosis)
Delinked payment	Drugs that will not be routinely prescribed (e.g., reserve antibiotics)
Indication-specific pricing	Drugs used for multiple indications (e.g., oncology drugs, auto-immune therapies)
Population health management	Drugs used to prevent/manage common chronic diseases (e.g., treatments for cardiometabolic disorders)

How do cost-containment pressures evolve over a drug's life cycle?

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At launch	• Payers control prices, may (temporarily) limit prescribing to specialists and may restrict reimbursement terms.
Post-launch	• Payers may impose price cuts if a drug's sales grow strongly and/or levy clawbacks if sales exceed specified limits.
Product maturity	• Pricing and/or reimbursement terms may be reviewed as competitive landscape evolves—internal reference pricing is a common response.
Loss of exclusivity	• Price cuts to originator drugs or competitive tendering; policies that favour the use of generics/biosimilars.

Crucial to monitor—and anticipate—the changing competitive landscape.

Outlook: evolution of launch environments

Future launch environments will be characterised by more complex patient journeys, higher evidence requirements, greater uncertainty and shifts in care settings

	2010-2013	2014-2019	Future (without pandemic)	Post-pandemic future
Stakeholder environment	Simple: payers then prescribers	Complex: web of stakeholders—payer-led	Personalised and patient journey based	Increased patient journey complexity
Payer priorities	Price	Value-based, HTA	Outcomes, RWE, new funding approaches	Tighter budgets, higher evidence bar
Launch positioning	First line, mass market	Later line, segmentation	Companion diagnostic, biomarker, genotype	Complex, uncertain environment
Launch type	Small molecules and biologics increasingly specialty	High-cost specialty, orphan drugs, ATMPs	Further diversification, digital therapeutics, diagnostics	Self-/home-administered drugs have new advantage

Source: Adapted from *IQVIA Launch Excellence VII*

What do you need to do to prepare for the future?

- Be aware of the growing divergence between regulatory and access requirements.
- Monitor changes in healthcare systems, including health insurance coverage/pharmacy benefits.
- Explore opportunities to work in partnership with healthcare systems.
- Keep up with changes in HTA processes.
- Be prepared for increasing pressure for transparency (with IRP repercussions) and cost-plus pricing.
- Recognise the potential—and limitations—of managed entry and innovative contracting.
- Plan ahead for changes in cost containment across the life cycle.
- Understand how governments will seek to boost local drug development and production: carrots or sticks?
- Anticipate how the relative attractiveness of different markets may change significantly.
- Understand how health policy, economic policy, industrial policy and geopolitics will shape global pharma market—and disseminate that knowledge in your organisation.