Global Market Access Trends

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life ACCESS ACADEMY science

How are healthcare systems organised and funded?

Common models for healthcare systems in market economies

Model	Characteristics	Examples
Bismarck (aka social health insurance)	• Funded by premiums from employers and employees: may be a challenge as societies age • 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 comes 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.
- The administration of healthcare services is often delegated to regional administrations within a country, leading to pronounced geographic inequalities in access to care.

Inflation Reduction Act—a watershed in US pharmaceutical policy

Timeline for key health-related reforms in the Inflation Reduction Act

2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033

Pharma

Rebates for above-inflation price increases

Federal government price negotiation for some high-cost medicines: cumulative number of drugs

10 | 25 | 40 | 60 | 80 | 100 | 120 | 140

Repeal of Trump administration's drug rebate rule

Patients

End to cost sharing for Part D adult vaccines

End to 5% coinsurance for Part D catastrophic coverage

$2,000 annual out-of-pocket payment cap in Part D

$35 monthly cap on cost sharing for insulin

Expanded eligibility for Part D low-income subsidies

Tougher measures mooted in President Biden's recent budget proposals:

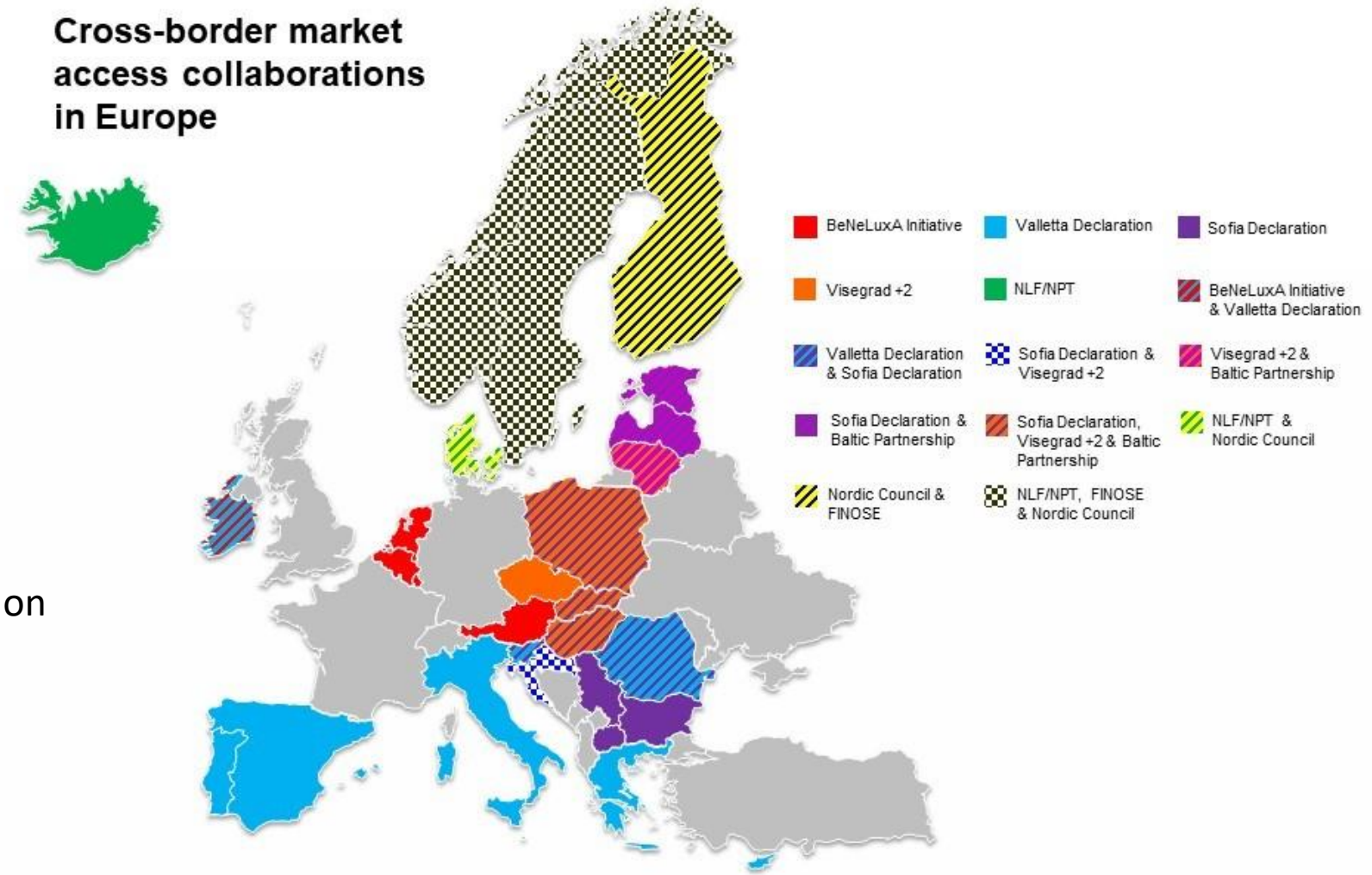
- Number of "high-spend" drugs to face Medicare price negotiation would increase to 300 by 2033
- Exemption period would be cut to a uniform five years for all drugs
- Penalties for above-inflation price increases would be extended to commercial insurance sector

EU Pharmaceutical Strategy: increased transparency and changes to RDP and OME

- Orphan Regulation and Paediatric Regulation will be merged into one master regulation.
- EMA will allow for rolling review of drugs that offer potentially exceptional therapeutic advancement.
- A new regulatory sandbox will allow highly innovative technologies to be approved on a temporary basis.
- Companies will be required to list public funding or public support for conducting trials relevant to the MA.
- Manufacturers will be required to notify a member state if they plan to withdraw a drug from the market. In the case of a permanent withdrawal, they will first have to offer the drug to a third party.
- EMA will maintain contact with national agencies (including HTA) throughout a drug's lifecycle to share information on drug development, evaluation and access.
- RDP will be reduced to a baseline 6 years, with the possibility of extensions to a maximum of 8 years; repurposed drugs will gain four years of RDP (only once).
- Prevalence threshold for ODs will remain at 5/10,000, but there will be a tougher definition of significant benefit.
- Orphan market exclusivity (OME) period will be 9 years, with an extra year for addressing high unmet medical need.
- OME can be extended by one year on up to two occasions for approval for new orphan indications.
- Reforms will generally apply 18 months after they come into force.

Cross-border market access collaborations go trans-continental

- Around ten cross-border market access collaborations.
- Beneluxa Initiative is the best-known partnership.
- International Horizon Scanning Initiative currently has eight members.
- Valletta Declaration Group encompasses ten countries with a population of 160 million.
- Nordic Pharmaceutical Forum is working on procurement of ATMPs and hospital medicines.
- Beneluxa Initiative and Nordic Pharmaceutical Forum are working together.



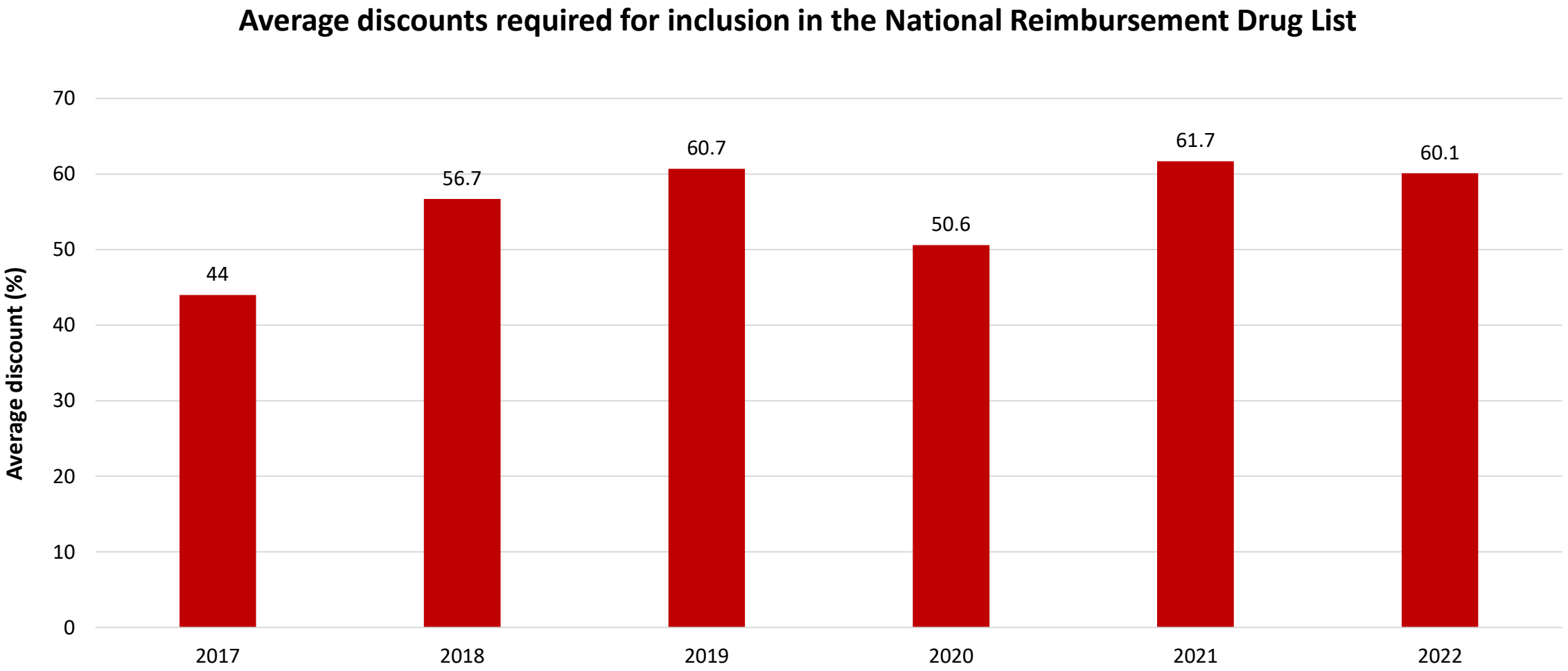
- AUS-CAN-UK Collaboration Arrangement and a recent co-operation between Canada and eight European countries are the first trans-continental access alliances.

What particular challenges do healthcare systems in emerging markets present?

Characteristic	Challenge for pharmaceutical companies
Volatile economies	Uncertainty regarding long-term price stability and payment of debts
Underdeveloped healthcare infrastructures and shortages of qualified healthcare professionals	Difficulty in diagnosing some conditions and in administering state-of-the art therapies; geographic disparities in access to care, with rural areas often at a considerable disadvantage compared with cities
Difficulty in maintaining a supply chain	May be impractical to supply drugs that require a carefully controlled supply chain (e.g., cold storage)
Limited access to health insurance	Coverage may be particularly poor for the elderly (typically the heaviest consumers of prescription drugs)
Poor drug benefits and dominance of cash markets	Patients may struggle to afford out-of-pocket costs for many drugs, severely limiting market size
Relatively weak intellectual property protection	Companies may be reluctant to launch in markets that do not safeguard their intellectual property or demand knowledge transfer; use of copy products (as distinct from generics) may be widespread
Government favouritism towards domestic companies	Multinationals may be disadvantaged in terms of drug registration, pricing, admission to reimbursement
Lack of robust health technology assessment systems	Pricing and reimbursement decisions may be arbitrary rather than evidence-based
Generally low prices	May be economically unattractive, or even unsustainable, to do business in some markets
Restrictive and infrequently updated reimbursement lists	Risk of very long access delays, prescribing restrictions or permanent refusal of reimbursement

As affluence grows, emerging markets increasingly resemble mature markets—with increased investment in healthcare, improved infrastructure, broader and more generous health insurance coverage (including drug benefits), stronger intellectual property protection, and faster and more generous reimbursement of innovative medicines. China is the prime example of this transition.

China has improved access but still presents formidable challenges



In 2022, China's seventh round of centralised drug procurement yielded price cuts averaging 48% on 327 off-patent products covering 60 molecules. Some prices were cut by more than 90%.

Pharma forges new alliances to improve access in low- and middle-income countries (LMICs)

Since 2008, the Access to Medicine Index has monitored the activity of the world's largest pharmaceutical companies in LMICs to measure how they are doing in making their drugs available globally.

- The Access to Oncology Medicines (ATOM) Coalition brings together eight leading pharmaceutical companies—AstraZeneca, BeiGene, BMS, Gilead, Novartis, Roche, Sanofi and Teva—with 18 other organisations to improve access to cancer treatments in LMICs. It will seek to improve the availability and affordability of cancer drugs, and to increase the capacity to use these medicines appropriately.

- An innovative partnership will expedite access to a novel reserve antibiotic—Shionogi's cefiderocol—in 135 LMICs. The deal involves GlaxoSmithKline, the Global Antibiotic Research and Development Partnership (GARDP), the Clinton Health Access Initiative (CHAI) and the Ping An Insurance (Group) Company of China. Shionogi and GARDP will publish their licensing agreement to provide a model for other public-private partnerships to improve access to antibiotics. GSK worked with Shionogi on the development of cefiderocol and has agreed to forgo its royalties in LMICs.

- Pfizer has pledged to make its full portfolio of 500 patented and off-patent drugs available at production cost to 45 LMICs with a combined population of 1.2 billion. In addition, all new drugs and vaccines launched by the company will be included in the Accord. The company will also offer expertise to support diagnosis, healthcare professional education and training, along with supply chain management and other infrastructure enhancements. It will additionally work with governments to streamline regulatory pathways and procurement processes.

What are the main challenges of HTA?

Challenge	Possible response
Enormous variations in payers' approaches to HTA and evidence requirements	Develop a thorough understanding of the key agencies and take advantage of opportunities for early dialogue
Lack of understanding at pharmaceutical companies' global HQ level of nuances of HTA in national markets	Disseminate awareness of how the key agencies work and what customisation of evidence may be required in some markets
Risk that advice given in early dialogue could be superseded by the time of evaluation	Monitor changes in clinical practice and competitive landscape; maintain dialogue with HTA agencies
Uncertainty related to growing numbers of drugs at launch	Prepare for more frequent requirements for post-marketing research, including real-world data collection; propose managed entry agreements
Methodological inflexibility of HTA agencies	Analyse outcomes for similar drugs to identify—and avoid—potential problems; use early dialogue to try to forestall difficulties
Influence of an unfavourable assessment from one agency on others	Be aware of the likely sequence in which HTA evaluations will be published and give particular attention to the most influential agencies
Long delays associated with HTA process	Rigorously quality check the dossier before submission and prepare thoroughly for meetings to avoid unnecessary delays to the HTA process

Managed entry and innovative pricing gather momentum

PhRMA reported 73 value-based contracts as of end of 2019, but there are many more not in the public domain

Pan-Canadian Pharmaceutical Alliance has negotiated >400 product listing agreements; OBAs are still rare

A leader in managed entry thanks to online registries and legal obligations; shifting to appropriate prescribing

Favours simple discounts but increasingly open to “smart deals” and confidential commercial arrangements

Historical resistance and reservations from government, but several recent OBAs for ATMPs negotiated by SHI funds and new requirements for price-volume agreements

Regional and local MEAs; new VALTERMED platform will support national OBAs

Extensive use of price-volume agreements; CEPS has not been enthusiastic about pay for performance but recent legislation promotes instalments and OBAs for ATMPs

Financial agreements dominate but a few OBAs have been negotiated

Managed entry is in its infancy but Pfizer negotiated an OBA for Ibrance with two private health insurers

South Korea, Taiwan, Brazil, Mexico, Russia, a dozen or more smaller CEE markets and several Middle Eastern and North African countries have all experimented with MEAs

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

At launch

- Payers control the price of a new drug, may (temporarily) limit prescribing to specialists and may restrict reimbursement terms (sometimes pending collection of real-world data).

Post-launch

- Payers may impose price cuts if a drug's sales grow strongly (possibly as a result of approval for additional indications) and/or levy clawbacks if sales exceed specified limits.

Product maturity

- Pricing and/or reimbursement terms may be reviewed as a consequence of an evolving competitive landscape (e.g., the launch of new drugs within the same class or of new drug classes for the same indication, or the approval of generic/biosimilar versions of competing drugs)—the imposition of internal reference pricing is a common response to such changes.

Loss of exclusivity

- You may be required to reduce the price or your originator drug or enter into competitive tendering; payers may adopt policies that favour the use of generic/biosimilar versions of the molecule.

It is crucial to monitor—and anticipate—the changing competitive landscape for your drugs to be prepared for potentially significant changes to cost-containment policy that could have a major impact on sales.

How will changing government attitudes towards the research-based pharmaceutical industry impact access?

The EU wants the European pharmaceutical industry to "innovate, flourish and continue to be a global leader."

President Macron acknowledged that French pricing policy has "damaged the industrial fabric" of the pharmaceutical sector. He wants to invest in drug development and production in France, reward and accelerate access to innovative medicines, and boost use of generics and biosimilars. His ambition is to "make France the leading European nation in health innovation and sovereignty" by 2030.

Italy is keen to use its strong drug manufacturing base to claim a sizeable share of the estimated €1 trillion pharma is expected to invest globally in coming years. The government sees the need to create an access environment more conducive to innovation.

The UK government's new Life Sciences Vision aims to "make the UK the best place in the world to discover, develop, test, trial, launch and adopt new treatments and technologies, by creating a forward-thinking commercial environment where the NHS can strike flagship deals and where proven, clinically and cost-effective innovations are rapidly adopted and spread across the country to bolster the health of the nation, deliver greater value for the taxpayer and stimulate economic growth."

The Spanish government sees pharma as a "key player" in economic reconstruction because of "its productive capacity" and "the traction it exerts on other sectors." A Strategic Plan for the Pharmaceutical Industry is due to be published soon.

The Canadian government plans to invest an extra C$2.2 billion in life sciences and is open to discussions about how to make the access environment more attractive; it recently abandoned some planned pricing reforms that had been criticised by the industry.

The Australian government wants to "ensure Australia is a global priority for launching new medicines and that delays in accessing innovative therapies for patients are reduced."

The Made in China 2025 programme identifies biopharmaceuticals as one of 10 growth industries. The government has streamlined the regulatory process, strengthened intellectual property protection and introduced annual updates to National Reimbursement Drug List. Sales of innovative drugs are forecast to treble in five years. Domestic drugs are gaining ground over global brands.

Such comments are encouraging signs that politicians recognise the value of the research-based pharmaceutical industry in their territories, but it remains to be seen if words will translate into action to create innovation-friendly access environments as financial pressures increase.