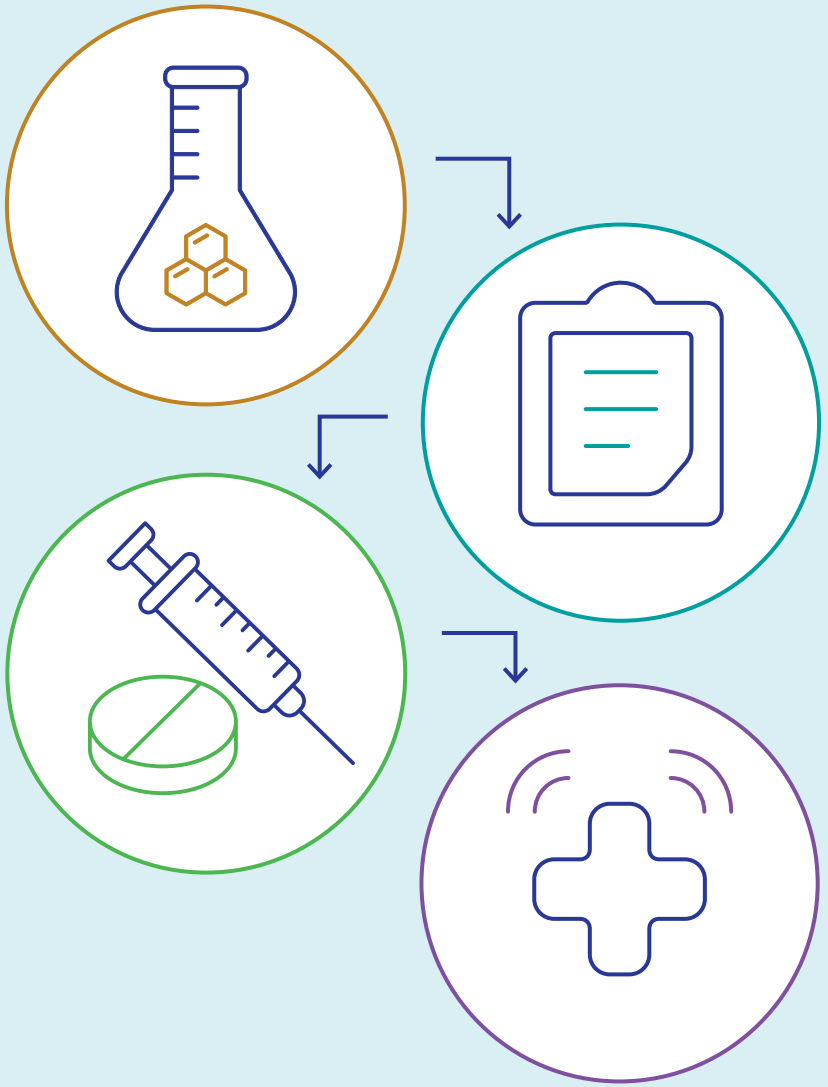
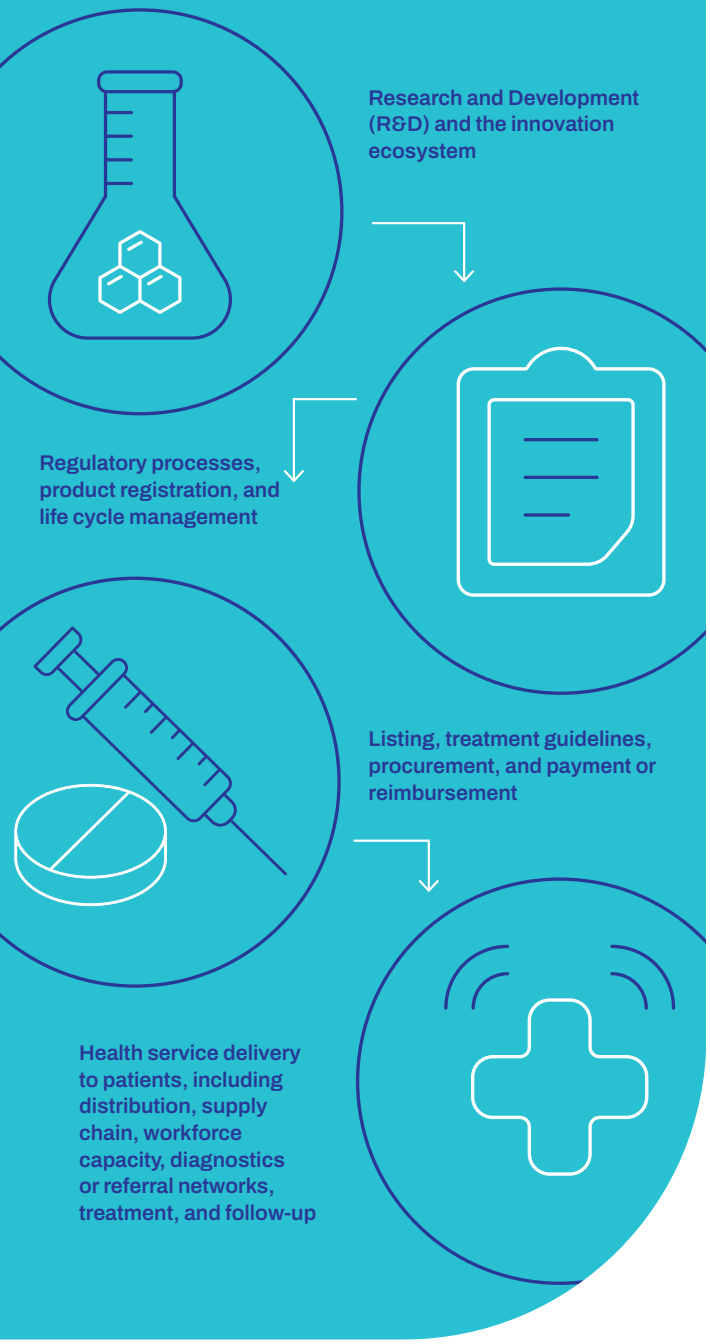
IFPMA

Innovation Development and Access pathway (IDAP):

A holistic approach to accelerating access to innovative medicines and vaccines





Introduction

Innovative medicines and vaccines have transformed healthcare around the world, extending life expectancy and improving quality of life. These achievements are the result of sustained investment in scientific research, pharmaceutical innovation, and close collaboration between public and private stakeholders across the entire value chain – from product development to implementation planning and patient access.

Yet, too often, innovative medicines and vaccines do not reach the people who need them in a timely way and in appropriate volumes, facing barriers and impediments at critical stages of drug development and health system delivery. This challenge is particularly acute in lower-resource settings. To address this, it is important to establish a shared understanding of the end-to-end pathway for health products – from the laboratory to a person in need at the point of care – with particular focus on identifying the barriers that hinder access, and to propose a way forward.

The innovative pharmaceutical industry is committed to improving access to innovative medicines and vaccines[1], and substantial efforts have been made over the years to identify challenges and address them – progress that is widely recognized by stakeholders.[2] However, manufacturers represent only one part of a broader ecosystem responsible for ensuring access along the entire access pathway. Many of the systems and processes that determine whether medicines and vaccines reach patients – including regulatory approvals, procurement mechanisms, and health workforce capacity – depend on the actions of other stakeholders. Among these, governments play a critical role, as they are uniquely positioned to prioritize health for their own populations through policies and budget planning that enables timely and equitable access to innovation.

In this paper, we seek to share the perspective of the innovative pharmaceutical industry on key elements of the innovation and access ecosystem in which we operate, in order to build a common understanding and identify opportunities for collaboration. Specifically, we outline the key stages that any medicine or vaccine must navigate from the laboratory to people at the point of care globally.

1. "Innovative medicines and vaccines" includes both recently introduced (usually on-patent) products as well as older products, many of which now have generic or biosimilar competition following patent expiry.
2. 2024 Index finds industry performs well on policy, but lags in practice | Access to Medicine, "14 of 20 companies having systematic policies to plan for access for all pipeline candidates from Phase II onwards"- 70% of companies in the recent Access to Medicines Foundation analysis have systemic access plans for all products in clinical development.

The Innovation Development and Access Pathway (IDAP)

We describe this process as the "Innovation Development and Access Pathway" (IDAP). We recognize that specific steps and relevant stakeholders will vary between countries and product or market archetypes. However, most medicines and vaccines follow four common phases:

1) Research and Development (R&D and the innovation ecosystem

3) Listing, treatment guidelines, procurement, and payment or reimbursement

2) Regulatory processes, product registration, and life cycle management

4) Health service delivery to patients, including distribution, supply chain, workforce capacity, diagnostics or referral networks, treatment, and follow-up

To build a common "baseline" view of the bottlenecks and barriers that hinder access to medicines and vaccines, particularly in lower-resource settings, IFPMA commissioned IQVIA to undertake a quantitative, data-driven project.[3] Where appropriate, this paper draws certain data points from that project amongst others, to illustrate the nature of the challenges.

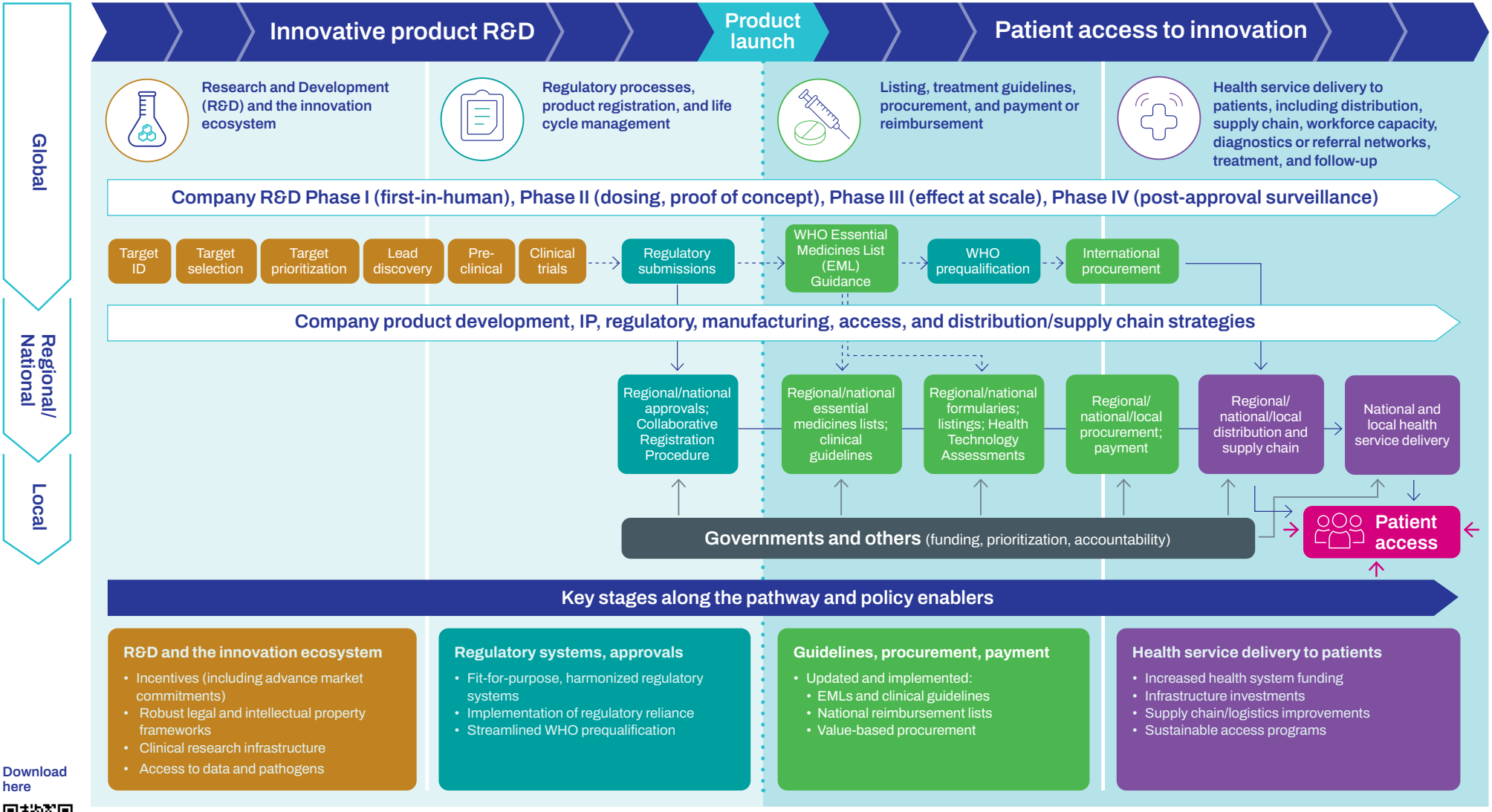
Focusing on the end-to-end pathway highlights critical bottlenecks and barriers that impede innovation and access to both recently launched and established medicines and vaccines. This approach helps illustrate where different stakeholders' accountabilities may lie along the development-to-delivery chain, recognizing that delays or bottlenecks at any point can prevent timely access for people, resulting in preventable mortality, poorer clinical outcomes, and increased costs to healthcare systems and society.

The end-to-end pathway, as seen from the perspective of the pharmaceutical industry, is illustrated in the figure to the right.[4]

3. In July 2025, IQVIA published a report entitled "Key Access Pathways and Bottlenecks for Medicines in LMICs" which examined key factors influencing medicine availability and accessibility, such as whether these products are registered locally, included on national essential medicines lists, reimbursed by healthcare systems, or sold in-country. The report revealed that many barriers in the 18 countries studied are systemic and limit access to both newly-launched and older, more established products. These findings aim to provide key data to support discussion around barriers and inform strategies to improve access to medicines and vaccines.
4. Other global health stakeholders are advocating for similar holistic approaches to improving innovation and access. For example, the WHO, in its 2025 report "Access to safe, effective and quality-assured health products and technologies: Roadmap for WHO action 2025-2030" describes the various health product and technology ecosystem components for improving innovation and access, which WHO has included within the scope of its roadmap for 2025-2030. Similarly, WHO's 2024 report "Improving access to medicines for neurological disorders" describes the magnitude of challenges affecting access to medicines.

Innovation development and access pathway for medicines and vaccines

Building a common understanding of the end-to-end pathway to identify collaborative approaches to accelerating access



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KEY ⟶ Defined path ⇢ Possible path

Activities or sequence of activities will vary by type of product or health system

Common phases of IDAP

We describe each key stage of the current pathway to patients and provide a brief overview of the main barriers to innovation and access at each step.

INNOVATIVE PRODUCT R&D

The R&D and innovation ecosystem for medicines and vaccines encompasses the discovery stage through clinical trials to regulatory approval and post-market monitoring. This complex, multi-stage process aims to deliver safe and effective products that meet important quality and regulatory requirements.

Stage 1
Research and Development (R&D) and the innovation ecosystem

It takes 10-15 years on average to develop one new medicine or vaccine from initial discovery through regulatory approval, at an average cost of USD 2.6 billion, considering the cost of failures.[5] This is a high risk set of activities, as on average one or two out of every 10,000 compounds (0.01% or 0.02%) synthesized in laboratories successfully pass all development stages required to bring a product to market.

In many areas of unmet medical need, the intellectual property (IP) framework and market dynamics provide incentives and attract investments into R&D, resulting in a robust and deep R&D pipeline. Today, there are over 12,700 medicinal products in development globally. However, for some products with a high public health need, the economics are not sufficient to attract investment, including those sold mainly in lower-income countries (such as malaria, tuberculosis, neglected tropical diseases) and those where the future demand is unpredictable (such as products to address antimicrobial resistance (AMR) or preparedness against future pandemics). This dynamic can lead to limited private investment from companies, investors and venture capitalists, including the substantial investments required for late-stage clinical trials, regulatory approvals, and manufacturing capacity. To address these gaps, approaches such as product development partnerships, advance market commitments, and other funding mechanisms are essential to de-risk and incentivize investment in products for unmet needs. Yet, even with the existence of such tools, not all product development efforts successfully cross the finish line to reach the patients who need them most.

A country ecosystem that enables and supports clinical research – through appropriate infrastructure and a clear link to access pathways – fosters inclusivity in clinical trials, advances health equity, and accelerates the adoption of therapies that better reflect the needs of the populations they serve, ultimately improving health outcomes and strengthening healthcare systems.

5. IFPMA, Always Innovating: Pharmaceutical Industry Facts & Figures.

Stage 2
Regulatory processes, product registration, and life cycle management

Effective and efficient regulatory systems are essential to approve quality, safe, and effective medicines and vaccines and oversee their performance up to and after registration. At the same time, it is important that resources needed for appropriate regulatory requirements are proportionate and avoid creating unnecessary delays that limit patient access. Balancing these objectives is challenging.

Regulatory barriers can often play a part in delaying or limiting access to medicinal products. In some countries, approval timelines are prolonged due to resource constraints or overly complex processes, resulting in significant delays. The IQVIA report showed significant variability in the number of both recently-launched and more established products approved in the countries studied.

Additional requirements, such as submitting large numbers of product samples, add further delays and costs. A survey conducted by IFPMA found that, in 17 African countries, companies must submit between 2 and 50 samples of the finished product for approval, and in some cases also provide raw ingredients and laboratory materials.[6]

Even after a product is approved, updating information or implementing manufacturing improvements can be challenging if local rules are not aligned with international standards. This leads to delays, backlogs, and additional workload for both regulators and companies, ultimately slowing patient access and discouraging companies from registering or maintaining medicines in certain markets. When companies make post-approval changes, they are often required to submit new samples for testing, which can disrupt supply chains. This can create further delays, regulatory backlogs, and even disrupt supply. An IFPMA study comparing regulatory frameworks worldwide found significant differences in procedures, timelines, and requirements for these post-approval changes.[7] These variations make it challenging for companies to maintain a consistent supply of medicines globally.

Another example of regulatory barriers is the requirement imposed by a few countries to register each manufacturing site (for the same product) separately. This reduces flexibility to shift production when there are changes in demand or when disruptions in the supply chain may occur.

IFPMA recommends adopting a system where multiple sites can be registered under a single license, in line with WHO guidance, to strengthen supply resilience and ensure patients get faster, more reliable access to medicines.

Efforts are underway around the world to improve and strengthen regulatory systems, many of which remain constrained by institutional capacity, fragmented processes, divergent national requirements, and lengthy timelines – ultimately delaying timely access for patients. Global efforts led by the World Health Organization (WHO), together with various regional regulatory authorities, and other organizations are crucial to addressing these challenges. Strengthening national regulatory systems and promoting regulatory reliance – where countries leverage assessments and approvals from trusted authorities – are key strategies to reduce approval timelines, eliminate duplicative or country-specific requirements, and improve predictability in regulatory processes.[8]

6. IFPMA infographic: Streamlining samples management to strengthen health outcomes in Africa, 2025.
7. IFPMA study: Global regulatory approaches to post-approval changes in biotherapeutic products, 2024.
8. Note that increasingly many stakeholders are calling for increased post-approval evidence generation to continuously monitor the safety of the medicinal products. The value of such studies should be weighed against potential delays caused in patient access while such evidence is generated, along with the opportunity cost (i.e. funding for such studies comes at the expense of other potentially more beneficial healthcare investment).

The access side of the IDAP pathway focuses on the various steps required to ensure access for people at the point of care.

Stage 3
Listing, treatment guidelines, procurement, and payment or reimbursement

Access to medicines and vaccines depends on effective market approval and subsequent processes: listing [9], treatment guidelines, procurement, and payment or reimbursement. These mechanisms vary widely across global, regional, and national levels, and across product types. While there is no "one-size-fits-all" solution, gaps in these processes often lead to confusion, delays, and reduced access.

Listing may be managed by multilateral and regional organizations, national public healthcare authorities, private healthcare authorities, hospitals or pharmacies. Its purpose is to help countries prioritize products that meet population needs within their health system structure. The WHO Essential Medicines List (EML) has long served as a reference point for countries with limited resources, but inclusion on the WHO EML does not guarantee access at the point of care in countries. National Essential Medicines Lists (nEMLs) can play a greater role in countries but must be regularly updated to reflect evolving health needs, scientific advances, and disease burden of each population, along with national clinical guidelines. They must also be founded on evidence-based criteria to offer adequate therapeutic options across disease areas. IQVIA analysis shows that none of the nEMLs reviewed included more than 21 of the recently launched products, and more than half of the lists were updated before 2019. This illustrates that regular revision and updating of nEMLs is a challenge for many countries.[3]

National formularies or reimbursement lists determine which products and health services are paid for or reimbursed by health systems, ensuring patients can access medicines without paying out of pocket (OOP).[10] Public funding and reimbursement as part of Universal Health Coverage (UHC) is an ambition pursued by many countries, but remains limited in many low-and middle-income countries (LMICs). IQVIA data shows only one-third of recently launched products are included in public reimbursement systems in any of the LMICs studied, and only 13% of them are reimbursed in more than one country.[3] The data also shows that a greater proportion of the more established products are reimbursed, with two countries covering about 50% of them. Ultimately, patients should have access to the best available treatments through reimbursement systems - but current data shows there is still significant progress to be made. Sustainable payment models are critical to ensure access to health products, in the context of finite public and private resources.

A sustainable funding and reimbursement ecosystem should reflect national health priorities and be linked to effective and efficient procurement systems.

In addition, most high-income countries and a growing number of middle-income countries incorporate in their reimbursement and/or procurement decision-making process clinical and economic assessments, often in the format of Health Technology Assessments (HTAs). All of these processes, where they exist, need to be regularly updated based on transparent, data-driven decisions and systemically connected to inform the prioritization of the right products for local access. HTA agencies, including public agencies, national and regional agencies as well as networks of academic centers, that are incorporated in the formal decision-making process should be well resourced. They should foster transparency in multistakeholder engagement and have a holistic approach in the assessment of alternative medical interventions. HTA processes must not only consider price, but also clinical outcomes, quality of life, and broader economic impact. This ensures decisions reflect both patient needs and health system sustainability.

Clinical guidelines provide healthcare professionals with evidence-based recommendations on which

9. This term includes listing on WHO or national essential medicines lists, national formularies, and national reimbursement lists, as may be relevant for a particular country.
10. The absence of reimbursement for innovative products is a key contributing factor to the fact that up to 80% of the population in LMICs purchase medicines through OOP payments, pushing ~100 million people into extreme poverty each year.

products to use, for which patients, and under what specific circumstances. They play a critical role in ensuring access to quality care, but must be widely adopted and regularly updated.

Procurement is vitally important for medicines and vaccines. Effective procurement requires robust planning, accurate demand forecasting, sustainable financing models, and criteria that quality, reliability of supply, and service. When these elements are weak or absent, the consequences can include product stockouts, delayed access to products, higher costs over time, and circulation of substandard and falsified products in the supply chain – with ramifications for procurers, suppliers, health systems, healthcare professionals, and patients.

Pooled procurement can be an effective solution in smaller or less resourced health systems in low- and lower-middle-income countries, allowing them to leverage pooled demand, collective financing, and bargaining power of a larger group (e.g. an international organization or group of countries) to meet common unmet healthcare needs that national systems alone cannot fulfil. Yet, there remain critical gaps for the pooled procurement of health products in regions where this could unlock access to innovative products, such as in oncology care for low-income countries. Pooled procurement mechanisms are not a universal solution for access. A one-size-fits-all approach to procurement often falls short in addressing the distinct needs of individual countries, especially when participating countries are at different stages of economic development. Furthermore, any pooled procurement mechanism should follow well-established economic country tiers – for example, following the World Bank classification.

Stage 4
Health service delivery to patients

Distribution and supply chain deficiencies for medicines and vaccines remain major barriers to access in low-income and lower-middle income countries. While private supply chains can be efficient, they often add a significant cost, usually paid by patients. Fragmented public sector supply chains can also increase product costs and lead to product stockouts, especially in remote areas. Centralized procurement mechanisms can suffer from financing uncertainties, complex decision-making with a lack of accountability, long resupply intervals, and a lack of supply chain planning data, capacity, and incentives to improve performance. These challenges, including supply chain markups on medicinal products, can have a significant impact on affordability.[11]

Health service delivery capacity and capability limitations, one of the six key health system building blocks defined by WHO, is another critical barrier. Underinvestment in infrastructure, workforce, diagnostics, and essential medicines directly impacts timely access to care. Common gaps include a lack of essential medical equipment, low availability of an adequate, appropriately qualified or remunerated health workforce, lack of diagnostic facilities, lack of essential medicines and unreliable infrastructure such as water, electricity, and telecoms.

Adequate health system financing is essential to overcome limitations in service delivery. Insufficient levels of government spending on health leads to weak health system capacities. In 2022, according to the WHO, more than 140 countries invested less than 5% of GDP and less than 15% of their national budgets into health. These are two broad benchmarks for achieving a minimum standard of care. This underinvestment affects potentially over 80% of the world's population.[12] In many low-income and lower-middle-income countries, official development assistance (ODA) for health has supported global health objectives particularly in resource-constrained settings. However, recent reductions in ODA for health risk undermining critical programs and place additional pressure on LMIC governments to accelerate domestic resource mobilization and adopt innovative financing models. These efforts are vital to sustain progress toward universal health coverage (UHC) and ensure equitable access to medicines and vaccines.

11. PATH's "Journey of the Pill" project in Kenya (2020) assessed national supply chains for diabetes and other non-communicable disease (NCD)-related products and showed that price markups and supply chain deficiencies significantly impact the price of NCD care to patients. Markups for some medicines reached 288% in the public sector and 176% in the private sector - hugely impacting affordability for patients at the point of care. The impact of supply chain markups on prices was also highlighted in a European Journey of Health Economics study of 35 countries which determined that distribution markups plus taxes can add up to 187% of ex-factory prices. In Latin America, markups added $20 billion and taxes added $10.5 billion of cost across eight major markets, leading to a 63% increase above ex-factory prices. Aligning these markups and taxes with international benchmarks could yield up to $19 billion in savings for patients and payers.
12. WHO Global Health Expenditure Database reported in New Data Exposes Global Healthcare Funding Inequalities | Human Rights Watch.

Driving access through collaboration: Key enablers for discussion

Access to innovative medicines and vaccines transforms how we prevent, treat, and cure disease, and can support people everywhere to lead healthier, longer, and more productive lives. Investing in medicines and vaccines supports medical professionals, giving them the right tools to better treat people, creating more efficient, stronger healthcare systems.

The innovative pharmaceutical industry is committed to work in collaboration with governments, multilateral organizations, funders, regulators, procurement agencies, and other key partners to strengthen each stage of the Innovation Development and Access Pathway (IDAP) and support a shared ambition to support access.

Progress will require coordinated actions to address system-level bottlenecks at each stage of the pathway. This begins with building on a common understanding of the current barriers, and, over time, developing improved ways to measure progress – such as setting quantifiable targets and ensuring clear accountability for all stakeholders involved.

The IDAP also outlines **key enablers across the pathway**, to support constructive discussions and identify where greater alignment, investment, and policy coherence are needed to translate scientific progress into the next generation of medicines and vaccines - delivering a healthier future for people everywhere.

Key stages along the pathway and policy enablers

R&D and the innovation ecosystem

- Incentives (including advance market commitments)
- Robust legal and intellectual property frameworks
- Clinical research infrastructure
- Access to data and pathogens

Regulatory systems, approvals

- Fit-for-purpose, harmonized regulatory systems
- Implementation of regulatory reliance
- Streamlined WHO prequalification

Guidelines, procurement, payment

- Updated and implemented:
  - EMLs and clinical guidelines
  - National reimbursement lists
  - Value-based procurement

Health service delivery to patients

- Increased health system funding
- Infrastructure investments
- Supply chain/logistics improvements
- Sustainable access programs

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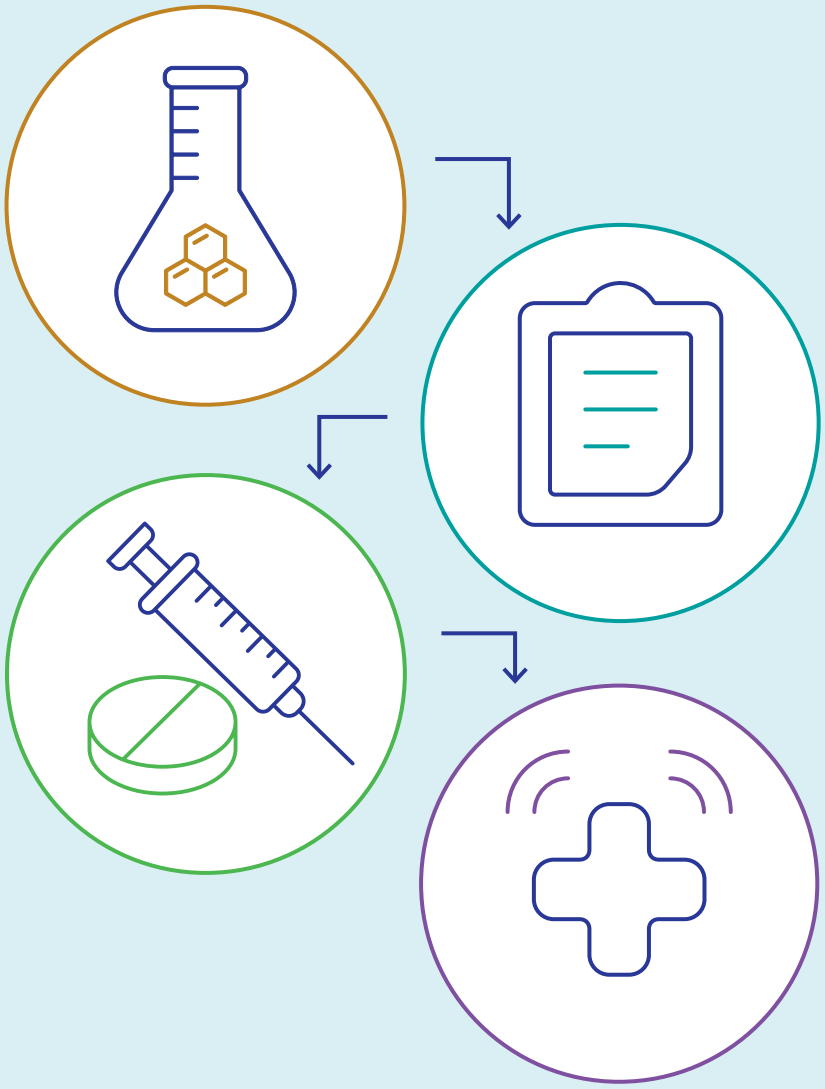

About IFPMA

IFPMA represents the innovative pharmaceutical industry at the international level, engaging in official relations with the United Nations and multilateral organizations. Our vision is to ensure that scientific progress translates into the next generation of medicines and vaccines that deliver a healthier future for people everywhere. To achieve this, we act as a trusted partner, bringing our members' expertise to champion pharmaceutical innovation, drive policy that supports the research, development, and delivery of health technologies, and create sustainable solutions that advance global health.

Visit the IDAP pathway on our website here

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