

A new tool for spurring industry engagement

Access to Vaccines Index

Methodology 2015



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A new catalyst for action: The first evaluation of how vaccine companies address access to vaccines



“The Access to Vaccines Index is a new tool for catalysing positive change in the vaccine industry. It will chart how vaccine companies are responding to the mechanisms put in place by many stakeholders to improve access to vaccines. By uncovering what is working, where and why, we can help to build inclusive vaccine markets that also reach the poorest and most remote communities. To develop this tool, our team has followed the Foundation’s tried-and-tested model for spurring change: first we build consensus on where vaccine companies can make a difference; then we trigger companies to join a “race to do well” by publicly recognising the good performers; lastly, we share their best practices with peers and stakeholders, to inspire and stimulate greater progress. On behalf of my team at the Foundation, thank you to everyone who has contributed to the emergence of this tool for action.”

Jayasree K. Iyer, PhD
Executive Director, Access to Medicine Foundation

Since the first vaccine was discovered in 1796, no other health commodity has had such a profound effect on childhood mortality.¹ By protecting children from the threat of disease, vaccines give them the opportunity to realize their full potential. Many communities, particularly in low- and middle-income countries, have yet to gain access to full immunisation. However, we see a global will to ensure every child receives the vaccinations they need.

Through the Global Vaccine Action Plan (GVAP) and the Sustainable Development Goals (SDGs), the most important actors in the vaccine landscape have endorsed clear targets for driving up global immunisation rates. This includes the WHO, national governments, the major vaccine procurement agencies, other multi-lateral agencies and vaccine manufacturers and suppliers.

Achieving such targets, and access to vaccines more broadly, depends on a multi-stakeholder framework, with clear expectations on the role for each participant being translated into firm commitment and concrete action. Success also depends on tracking progress toward each goal: data-driven performance management is essential for identifying what is working and why, and for aligning outcomes with agendas.

The first Access to Vaccines Index

To date, there has been no publicly available tool for mapping the efforts of vaccine developers and manufacturers to make their vaccines more available, accessible and affordable. Here at the Access to Medicine Foundation, we have stepped into this gap. We have applied our established multi-stakeholder process to crystallise society’s expectations of vaccine developers and manufacturers in this space. We have established the first set of metrics for tracking how vaccine companies are fulfilling these expectations, and for identifying where greater insight into their behaviour can lead to new solutions. These metrics form the core of the methodology for the first Access to Vaccines Index.

A first baseline of companies’ access efforts

The Access to Vaccines Index will provide an initial baseline of industry activity regarding access to vaccines, a critical first step for stimulating change and increasing accountability. It will publicly recognise the good performers, triggering vaccine companies to join a “race to do well” on access-to-vaccine targets. By examining where and how companies are already taking action, the Index will bring good practices to the attention of other companies and stakeholders, and encourage greater information-sharing. Stakeholders will be able to use this information to inform priorities and strategies, and to clarify where new incentives or stronger mechanisms would spur companies towards greater engagement in access issues.

The founding principles of the Access to Vaccines Index

We have developed the methodology for the Access to Vaccines Index by drawing on our ten years' experience of tracking and benchmarking the efforts of pharmaceutical companies to improve access to medicine in low- and middle-income countries. Our aim was to ensure that the Access to Vaccines Index complements the work of other organisations working in this space, and that all stakeholders can use our data and insights to inform future interventions.

The methodology rests on a set of four founding principles:

1. **The role for vaccine companies** in improving access to vaccines rests primarily in the areas of Research & Development, Affordability and Manufacturing & Supply.
2. **In Research & Development**, companies are expected to continually address high-priority gaps for new and improved vaccines and delivery technologies.
3. **In Affordability**, companies are expected to actively address the affordability of their vaccines for governments with limited resources.
4. **In Manufacturing & Supply**, companies are expected to have strong policies and processes in place to ensure sufficient supplies of high-quality vaccines are reliably available.

Metrics to stimulate change

We believe that the Access to Vaccines Index will stimulate change within companies and inform other actors of new opportunities for working with companies to break down access barriers. It will increase industry accountability and act as a review mechanism for international immunisation agendas and priorities, including those set out in the GVAP and the SDGs. It will do this by:

- Spurring dialogue on what the barriers to access to vaccines are and how they can be broken down;
- Analysing the landscape in which vaccine manufacturers operate;
- Reporting, tracking and comparing companies' contributions to access to vaccines;
- Identifying access gaps where companies and others can play a greater role;
- Providing a clear overview of vaccines in the pipeline and vaccines on the market;
- Highlighting best practices for increasing access to vaccines; and
- Highlighting opportunities for collaborative and individual action.

Parameters for measuring performance

The Access to Vaccines Index measures the efforts of a core group companies with regard to certain product types, for a set of high-need diseases and countries:

2 product types: Preventive vaccines and, in Research & Development and Manufacturing & Supply, vaccine and packaging technologies.

69 diseases: 44 diseases where no vaccines yet exist on the market, and 25 diseases where vaccines do exist but where issues surround their accessibility.

107 countries: all low income countries (LICs) and lower-middle income countries (LMICs) (World Bank-defined), supplemented by countries with the lowest levels of human development and the highest inequalities.

9 companies: eight large research-based pharmaceutical companies with significant vaccine units, and one large vaccine manufacturer based in an emerging market. The companies are: AstraZeneca, Daiichi Sankyo, GSK, Johnson & Johnson, Merck & Co., Pfizer Inc., Sanofi, Serum Institute of India and Takeda Pharmaceutical Co.

Introduction

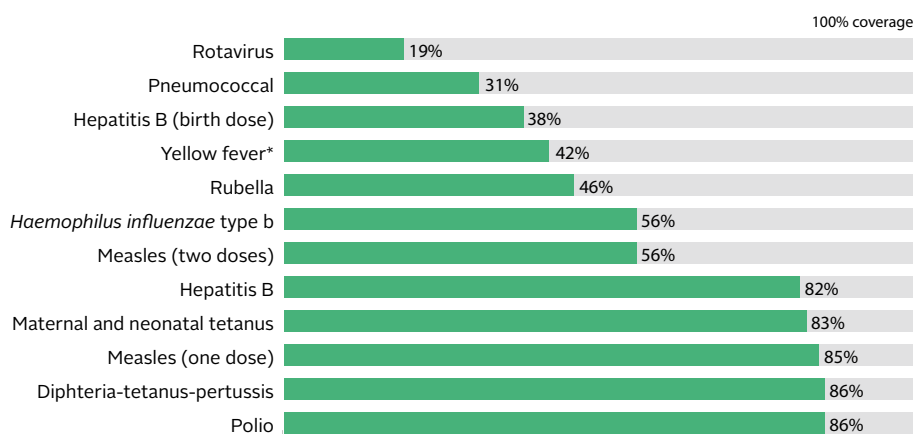
Alongside water sanitation, antibiotics and antivirals, the discovery of vaccines has played a central role in the most significant achievements in global public health. Vaccination protects children from the threat of disease, giving them the opportunity to thrive and realise their full potential.^{2,3} No other single health commodity has had such a major effect on the reduction of childhood mortality.¹

Immunisation has led to the global eradication of smallpox,³ and a 99% drop in the global incidence of polio.³ Between 2000 and 2010, the global childhood mortality rate was cut by more than 50% through mass immunisation against just five diseases: pertussis, tetanus, diphtheria, measles and polio.³ The WHO has set targets for eliminating measles and rubella by 2020.²⁻⁴ With sufficient funding and a strong political will, vaccines against pneumococcal and rotavirus vaccines could avert a further one million deaths.⁵

Vaccines save lives, but access is unequal

Many communities, however, cannot access full immunisation. While coverage of older vaccines can go beyond 80% (see Figure 1), coverage of newer vaccines remains relatively low.⁶ Some children receive no vaccines at all, or only some of the doses they need to be fully protected. Vaccination rates are often lower in poorer countries or where socio-economic inequality is higher.^{2,3}

Figure 1 Coverage of older vaccines can go beyond 80% – for newer vaccines coverage remains relatively low



Source: UNICEF; WHO. Global Immunization Data - July 2015⁶

Understanding the access barriers

Achieving access to vaccines depends, first, on bringing vaccines to the market that are safe, effective, good-quality and suitable for use by the communities that need them. The next priorities are to ensure immunisation programmes reach a high proportion of people, that local people are willing to be vaccinated and to allow their children to be vaccinated, and that they can complete the full vaccination schedule needed to achieve immunity. Immunisation programmes also need to be monitored to check whether adequate protection is achieved.

Need for strong policies, systems and procedures

At the national level, successful immunisation programmes depend on effective immunisation strategies and on having strong, up-to-date policies and procedures in place,⁷ supported

by financing and comprehensive, transparent multi-year planning.⁸ Effective procurement systems ensure that countries receive high-quality products at affordable prices and in a timely manner.⁹ Integrating national vaccination campaigns with other healthcare delivery programmes brings crucial efficiency and coverage benefits.¹⁰

Need for robust supply chains

National immunisation programmes face several challenges along the supply chain, starting with matching demand to supply. Due to the biological nature of vaccines, production is a complex and lengthy process. It can take up to three years to produce a market-ready vaccine, leading to long waits of up to one year before individual orders can be filled.^{11–13} Vaccine shortages can be caused by many factors, including inaccurate demand forecasting, manufacturing interruptions, bureaucratic delays, or a lack of funds for purchasing vaccines to match demand.

Many vaccines require strictly controlled refrigeration, which adds tremendous complexity to transportation and storage systems. As a result, distribution systems are not always capable of ensuring effective vaccines reach remote areas, or that booster shots are available when needed.¹³ Tracking systems are needed to ensure that children receive all vaccine doses and gain full immunity to the disease in question. When vaccines reach the end of the supply chain, an adequate number of trained health workers are needed to correctly administer them.³

Need for new or improved vaccines

Although many effective vaccines have already been developed, persistent product gaps remain. The WHO has singled out vaccines for malaria, dengue and HIV as high priority.¹⁴ There is also a high need for certain vaccines to be adapted for use in resource-limited settings – including versions of measles and rotavirus vaccines that can be stored at room temperature, and a universal influenza vaccine.³ Other adaptations, for example to reduce the number of doses needed to reach full protection or to simplify delivery systems, are also needed, as well as vaccines targeting specific, localized disease strains.¹⁵ However, R&D for vaccines is risky and costly: a lack of a strong market incentives may be discouraging the pharmaceutical industry from investing in R&D for diseases that primarily affect the developing world.²

Need for greater affordability

Immunisation spending is expected to more than double in the coming decade.³ New and more complex vaccines will put pressure on healthcare budgets and governments will be confronted with competing health priorities such as demand for new, high-cost essential medicines, and managing outbreaks of infectious diseases. The introduction of new vaccines into national immunisation programmes has already raised the cost of immunising a child: Médecins Sans Frontières (MSF) estimates that costs have risen from less than a dollar in 2001 to USD45.59 in 2014, through the addition of six new vaccines to the WHO Expanded Programme on Immunization.¹⁵

For developing countries, vaccines are commonly purchased through pooled-procurement systems, which enable groups of countries to purchase vaccines in bulk against lower prices. There are three main multilateral organizations managing these systems: UNICEF, the Pan American Health Organization (PAHO), and Gavi the Vaccine Alliance. UNICEF is the world's largest supplier of vaccines to children and works with many stakeholders to increase demand for vaccines, including through pooled procurement. PAHO is a UN public-sector procurement agency that has established a global fund that enables member states to access lower vaccine prices. Gavi brings together many key organizations in a single decision-making body regarding access to vaccines, and works to accelerate the introduction of new and underused vaccines in over 70 of the poorest countries. Despite the success of these organisations in negotiating lower vaccine prices for developing countries, affordability remains an issue, particularly for newer vaccines.

Vaccines: a consolidated growth market

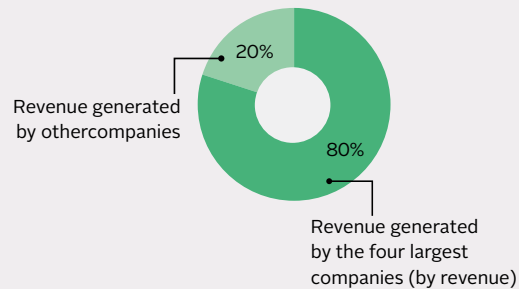
The vaccine market has grown substantially over the past ten years, partly due to the introduction of new vaccines.³ The global market was worth USD25 billion in 2013 and is expected to grow to USD41 billion in 2020,¹⁷ a higher growth rate than for the pharmaceutical sector as a whole.¹⁶

The vaccine market is also highly consolidated, both on the demand and supply sides.¹⁷ Greater consolidation means less competition (and, potentially, higher prices), as well as a greater chance that vaccine shortages will occur. On the demand side, high-income markets are the largest group of purchasers by revenue. Pooled procurement mechanisms, such as those operated by UNICEF, PAHO and Gavi, comprise the second major group of purchasers by revenue.¹⁸ Together, low- and middle-income countries account for approximately 18% of the value of global vaccine sales. This translates into approximately 80% of the total volume of vaccines sold annually.¹⁸

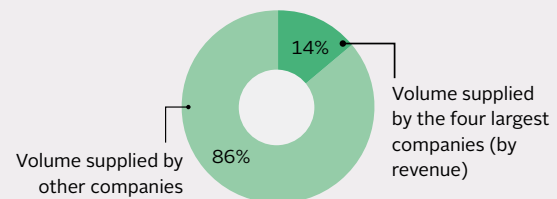
On the supply side, 80% of global vaccine revenue is generated by four large pharmaceutical companies (GSK, Merck & Co., Pfizer and Sanofi).¹⁶ This follows a series of recent alliances, mergers and acquisitions. However, only 14% of the vaccines produced by these four companies (by volume) goes to low- and middle-income countries.¹⁹ The bulk of the vaccine volume currently sold to these countries is manufactured by vaccine manufacturers based in those countries, often referred to as Developing Country Vaccine Manufacturers (DCVMs).^{1,19} DCVMs are considerably smaller than the large pharmaceutical companies, yet these players are rapidly changing the vaccine market: the number of quality-assured DCVMs has increased in recent years, as has the number of high-quality vaccines they produce.^{1,19}

Figure 2 Global vaccine market: revenues and volume

Vaccine revenues, global



Vaccine volume for developing countries (approximate)



The bulk of vaccine revenues are generated by the four largest companies in mature markets.¹⁶ Their vaccine revenue is generally derived from first-to-market vaccines. The majority of global vaccine volume goes to low- and middle-income countries,¹⁸ and is supplied by smaller companies.¹⁹ These other companies are generally focused on supplying traditional vaccines.

Countries with higher national income levels typically fall outside of pooled-procurement systems for vaccines. Consequently, they often have to pay much higher prices for their vaccines, especially for newer ones, such as the human papillomavirus (HPV), rotavirus and pneumococcal vaccines. Typically, this affects those countries moving from low income country (LIC) status to lower-middle income country (LMIC) status, as defined by the World Bank, at which point they enter a transition phase and can no longer access pooled procurement systems.

Global momentum to eliminate diseases

We see a global will to address the major barriers to access to vaccines, spurred by the WHO's endorsement of the Global Vaccine Action Plan (GVAP) in 2012, and the launch of the Sustainable Development Goals (SDGs) in 2015. Ensuring universal access to vaccines will be indispensable for achieving many of the health-related targets set out in SDG 3. Specifically, target 3.8 calls for access to safe, effective, quality and affordable vaccines for all; and target 3.b calls for support for research and development into vaccines for diseases that primarily affect developing countries.²⁰ The GVAP itself includes a comprehensive set of immunisation targets, including for global and regional coverage and disease elimination, for the reduction of child mortality, and for the development and introduction of new and improved vaccines.³

Cooperation, commitment, action

Success depends on a multi-stakeholder framework, with each participant playing a crucial role and committing to its fulfilment. The GVAP outlines the roles of the different players in the vaccine landscape, including governments, the developers and manufacturers of vaccines, global agencies, non-governmental organisations (NGOs) and civil society. Each group has its own unique responsibilities for addressing vaccine access challenges.³

A functional immunisation system is widely seen as being the primary responsibility of national governments.³ Many are actively addressing key access challenges in procurement, supply and demand for vaccines. Civil society and NGOs, such as Médecins Sans Frontières (MSF), are implementing immunisation programmes on the ground and routinely challenging access barriers. Philanthropic organisations such as the Bill & Melinda Gates Foundation and the Clinton Health Access Initiative (CHAI) play an important role in priority-setting, market-shaping and the support of global agencies such as Gavi.²¹

The role for vaccine companies

The developers and manufacturers of vaccines also have a key role to play improving access to vaccines, due to their technical expertise, know-how and production capacities. They are positioned at the start of the innovation value chain and supply chains, and are integral to development and deployment of vaccines in the market.

Action guided by data

We believe that success also depends on continually tracking progress toward specific goals; data-driven performance management is essential for determining what is working and why, and for aligning outcomes with agendas. It requires a high level of disclosure, with quality data and objective insights about each actor's progress being shared between stakeholders.

Since the endorsement of the GVAP in 2012, many stakeholders, including governments, companies and NGOs, have ramped up efforts to improve access to vaccines. However, progress toward the GVAP goals is slower than planned. The use of data has been singled out for criticism.²

This emphasises the need for continual information-sharing between stakeholders. Greater transparency will, for example, help to improve the functioning of vaccine markets by reducing information asymmetries between buyers and sellers – markets need solid information to operate efficiently. Crucially, good data is the foundation of good performance management. Appropriately analysed and interpreted, quality data can be used to show where performance is strong and where progress may be stagnating. Using data to track progress towards set goals is essential for understanding what is working and why, and for responding with effective policies and strategies.

The efforts of all major players in the vaccine ecosystem and the effectiveness of their programmes can potentially be measured. There are already some tools available that monitor the activities and progress of different vaccine stakeholders. National governments for example report to the WHO and UNICEF on their immunisation policies and the performance of national immunisation programmes. In turn, the WHO and UNICEF are held accountable by their member states. Gavi publicly self-reports on the effectiveness and efficiency of their interventions using goal-level indicators. Progress towards the goals set in the GVAP are independently assessed by the SAGE Decade of Vaccines Working Group.

A tool to track manufacturers

To date, there has been no publicly available tool or set of indicators for mapping the efforts of vaccine developers and manufacturers with regard to improving access to vaccines. We know that companies now routinely report on their corporate responsibility efforts in their annual reports. However, these are not independently assessed. Civil society organisations^{15,22} have called for increased transparency regarding companies' practices. A tool that tracks company progress would increase industry accountability and act as a review mechanism for international immunisation agendas and priorities, including those set out in the GVAP and the SDGs.

The first Access to Vaccines Index

The Access to Medicine Foundation has stepped in to fill this gap by developing the first set of metrics for mapping the current efforts of vaccine developers and manufacturers to make high-need vaccines more available, accessible and affordable for the global poor.

To develop these metrics, we drew on our ten years' experience of tracking the efforts of pharmaceutical companies to improve access to medicine and vaccines. We mined our extensive data on pharmaceutical company policies and practice, gathered while compiling four successive iterations of the Access to Medicine Index. We established a multi-stakeholder process to challenge our proposals, testing them against global agendas and trends with the major stakeholders already working to improve access to vaccines. Through this process, we were able to crystallise society's expectations of vaccine developers and manufacturers, and identify where greater insight into their behaviour can lead to greater change across the industry. The result is the methodology for the first Access to Vaccines Index.

A first baseline of companies' access efforts

The Access to Vaccines Index will provide an initial baseline of industry activity regarding access to vaccines, a critical first step for increasing accountability and tracking progress in the future. It will provide a fair comparison of how individual companies are performing in specific areas of access to vaccines, namely Research & Development, Affordability and Manufacturing & Supply. By publicly recognising the good performers, the Index will trigger vaccine companies to join a "race to do well" on access-to-vaccine targets.

Best practices and opportunities

The Index will examine where and how companies are already taking action, bringing practices to wider public attention and trigger greater information-sharing between the actors at the interface between the demand and supply sides of the vaccine market. The Index will highlight where further incentives are needed to spur companies to engage in less lucrative or viable markets. Importantly, it will reveal opportunities for more effective mechanisms that enable companies and other stakeholders to break down access barriers and implement new solutions to the most urgent access challenges.

Building the methodology

The Access to Medicine Foundation has developed the first metrics for mapping how vaccine developers and manufacturers are working to improve access to vaccines. These metrics form the methodology for the first Access to Vaccines Index, and reflect stakeholders' views on how vaccine companies can contribute to global immunisation targets.

Defining the founding principles

The Index team established the broad parameters of the Access to Vaccines Index through an initial feasibility exercise, landscaping study and literature review. These studies used the priorities defined in the Global Vaccine Action Plan (GVAP) as a background framework, and drew on the Foundation's ten years' experience in engaging with stakeholders and tracking company behaviour to stimulate change. Based on their conclusions, the Index team developed the founding principles of the Access to Vaccines Index:

1. **The role for vaccine companies** in improving access to vaccines rests primarily in the areas of Research & Development, Affordability and Manufacturing & Supply.
2. **In Research & Development**, companies are expected to continually address high-priority gaps for new and improved vaccines and delivery technologies.
3. **In Affordability**, companies are expected to actively address the affordability of their vaccines for governments with limited resources.
4. **In Manufacturing & Supply**, companies are expected to have strong policies and processes in place to ensure sufficient high-quality vaccines are available.

To support these principles, the team defined the potential range of diseases and companies that the Access to Vaccines Index could focus on. They also proposed metrics for benchmarking vaccine company behaviour. These proposals were based on the team's knowledge of measuring pharmaceutical companies' efforts to improve access to medicine, including vaccines. They were tested using the Foundation's extensive data on pharmaceutical company policies and practices.

Challenging the founding principles

The Index team challenged these founding principles through consultations with the major players working to improve access to immunisation. Stakeholders also interrogated the parameters of the proposed methodology to see if other areas of company behaviour, such as managing intellectual property or donations, should also be included. The aim was to ensure that the Access to Vaccines Index complements the work of other organisations active in this space, and that all stakeholders can use the Index's data and insights to inform future interventions. We spoke with many different experts and market shapers, asking which metrics would help them most in their efforts to stimulate change.

The Index team gathered in-depth feedback from experts working in industry, governments, NGOs, procurers, philanthropic organisations and research organisations. The IFPMA provided consolidated feedback from companies with vaccine units, and the Index team held individual discussions with large research-based pharmaceutical companies as well as the largest manufacturers based in emerging markets. Further critical feedback was provided by a group of Expert Advisors, from CHAI, Gavi the Vaccine Alliance, UNICEF and the IFPMA.

Finalising the methodology

Stakeholder consultations confirmed that a comprehensive vaccine-specific Index would indeed complement the work being carried out by other organisations: by increasing information disclosure, sharing valuable new data and providing objective insights that look across industry, disease areas and geographical regions.

As a data-driven tool for tracking company activity, the Index is expected to stimulate a race to do well in key areas, by objectively comparing companies' performances, and helping to unpick some of the major barriers to access to vaccines.

Three Research Areas

Stakeholder discussions also confirmed the main areas of company activity that the Index should focus on: A) Research & Development; B) Affordability; and C) Manufacturing & Supply. These are the areas where vaccine companies have the largest role to play, and where a benchmark of company behaviour could have the most impact. Companies can also take action in other areas, such as in licensing or to strengthen local capacities, yet their efforts here are currently seen as less likely to improve access to vaccines.

13 metrics for measuring company behaviour

Together with stakeholders, the Index team assessed various potential metrics for capturing company activity. The outcome is a set of 13 metrics: four in Research & Development; three in Affordability; and six in Manufacturing & Supply. They are designed to reveal what companies can and are doing to improve access to vaccines; bring best practices to wider attention; and highlight where individual or collaborative engagement can occur.

Parameters for measuring performance

Products: Preventive and therapeutic vaccines were both considered for inclusion. However, as therapeutic vaccines are used to treat, rather than prevent, disease, the access barriers to these two groups of vaccines are very different. As a result, it was decided to exclude therapeutic vaccines from the Index. In the Research & Development Research Area, the Index will capture efforts to develop relevant technologies, such as needle-free delivery devices.

Diseases: Stakeholders identified that the Index should measure vaccines with the highest priority for improving public health. As a result, the Index will look at vaccines for 69 diseases: 44 diseases where no vaccines yet exist on the market; and 25 diseases where vaccines do exist, but with issues surrounding their accessibility.

Countries: Countries with the highest barriers to access to vaccines were agreed to include all low- and lower-middle income countries, supplemented by countries with the lowest levels of human development and the highest inequalities. As a result, the Access to Vaccines Index will explore company activities in 107 countries.

Companies: Stakeholders confirmed that the Index should focus on the largest global players developing and manufacturing vaccines. This led to a scope of eight large research-based pharmaceutical companies with significant vaccine units, as well as the largest vaccine company based in an emerging market.

How we measure: access to preventive vaccines

The Access to Vaccines Index will evaluate how major vaccine companies are improving access to preventive vaccines for a specific group of priority diseases in high-need countries. The scopes of analysis were created following an in-depth landscaping review, with guidance from external experts in access to vaccines and the vaccine market and industry.

The Access to Vaccines Index focuses on preventive vaccines, which protect healthy children against future disease and are generally administered via mass immunisation programmes. Therapeutic vaccines, on the other hand, are used on a patient-by-patient basis to treat chronic diseases. As many stakeholders agreed, this makes them much more comparable to medicines and other therapies, particularly when it comes to access barriers. As a result, they have been excluded from the scope of the first Access to Vaccines Index.

In addition to the vaccines themselves, the Index will also cover vaccine technologies. Specifically, it will look at whether companies are developing and implementing platform technologies that can be used for different vaccines and vaccine types, and that make vaccines more suitable for use in resource-limited settings. Company efforts to improve access to vaccine platform technologies will be examined under the Research & Development and Manufacturing & Supply Research Areas.

Disease scope: 69 diseases

The disease scope of the Access to Vaccines Index consists of 69 diseases that are vaccine preventable, and have the highest priority when it comes to improving access to immunisation.

Priority depends on a combination of factors that is unique to the disease in question, to the needs of the population at risk of infection, and to the nature of the market for an effective vaccine. For example, priority depends on whether effective treatment is already available, or whether vaccination would be the leading tool against a specific disease (i.e., for certain pathogens, new strains are constantly emerging, resulting in a continual need for research and development into new vaccines).

Defining the scope

The disease scope covers: 1) all diseases recommended by the WHO for routine immunisation²³ where a cost-effective vaccine is already available; 2) all diseases identified by the WHO as having a high need for further vaccine R&D¹⁴; and 3) five groups of diseases included on the basis of stakeholder recommendations.

- Diseases suitable for prevention via maternal immunisation;
- Emerging infectious diseases, such as Ebola;
- Diarrhoeal diseases;
- Lower respiratory infections; and
- Neglected tropical diseases (NTDs).

Figure 3 Diseases with existing vaccines included in the 2017 Access to Vaccines Index - 25 diseases.

Disease	Included based on WHO position			Included based on stakeholder recommendation				
	Need for routine immunisation	Need for R&D	Need for infection	Lower respiratory	Diarrhoeal disease	Neglected tropical disease	Maternal immunisation	Emerging infectious disease
Cholera	■				■			
Diphtheria	■							
<i>Haemophilus influenzae</i> type B (Hib)	■			■				
Human papillomavirus (HPV)	■							
Japanese encephalitis	■							
Malaria*		■						
Measles	■							
Meningococcal disease	■	■					■	
Mumps	■							
Pandemic influenza		■		■			■	■
Pertussis	■						■	
Plague (<i>Yersinia pestis</i>)								■
Pneumococcal disease	■			■				
Polio	■							
Rabies	■					■		
Rotavirus	■				■			
Rubella	■							
Seasonal influenza	■	■		■			■	■
Tetanus	■						■	
Tick-borne encephalitis	■							
Tuberculosis	■	■						
Typhoid	■				■			
Varicella	■							
Viral hepatitis (A, B, C, E)**	■						■	■
Yellow fever	■							

*A malaria vaccine received a positive scientific opinion in 2015 from the European Medicines Agency (EMA), but is currently not registered for use in countries relevant to the Index.
 **Vaccines exist against hepatitis viruses type A and B. No vaccines exist against types C or E.

Figure 4 Diseases without existing vaccines included in the 2017 Access to Vaccines Index - 44 diseases

Disease	Included based on WHO position			Included based on stakeholder recommendation						
	Need for routine immunisation	Need for R&D		Lower respiratory infection	Diarrhoeal disease	Neglected tropical disease	Maternal immunisation	Emerging infectious disease		
Adenovirus				■						
Amoebiasis					■					
Balantidiasis					■					
Buruli Ulcer						■				
Campylobacter enteritis					■					
Chagas disease						■				
Chikungunya						■				
<i>Clostridium difficile</i>					■					
Cryptosporidiosis					■					
Cytomegalovirus (CMV)							■			
Dengue		■				■				
Dracunculiasis						■				
Ebolavirus								■		
Echinococcosis						■				
Enterovirus 71								■		
<i>Escherichia coli</i> infections					■			■		
Food-borne trematodiasis						■				
Giardiasis					■					
Group B streptococcus							■			
Hantavirus pneumonia								■		
Human African trypanosomiasis						■				
Human Immunodeficiency virus (HIV)		■								
Human metapneumovirus				■						
Human monkeypox								■		
Isosporiasis					■					
<i>Klebsiella pneumoniae</i>				■						
Lassa fever								■		
Leishmaniasis						■				
Leprosy						■				
Lymphatic filariasis						■				
Marburg (haemorrhagic) virus								■		
Onchocerciasis						■				
Parainfluenza				■						
<i>Pneumocystis jiroveci</i>				■						
Respiratory Syncytial Virus (RSV)				■			■			
Schistosomiasis						■				
Severe Acute Respiratory Syndr. (SARS)								■		
Shigellosis					■					
Soil-transmitted helminthiasis						■				
<i>Staphylococcus aureus</i> *				■				■		
Taeniasis/cysticercosis						■				
Trachoma						■				
Yaws						■				
<i>Yersinia enterocolitica</i>					■					

■ Included ■ Included

*This includes methicillin-resistant *S. aureus* (MRSA).

Diseases suitable for maternal immunisation and emerging infectious diseases were selected using the data provided by *Rappuoli et al.*²⁴ Diarrhoeal diseases were included based on the 2016 Access to Medicine Index disease scope.²⁵ The most prevalent causes of lower respiratory infections among children were selected using data from *Rudan et al.*²⁶ All diseases classified by the WHO as neglected tropical diseases (NTDs) are included in scope.²⁷

Geographic scope: 107 countries

The geographic scope of the Access to Vaccines Index consists of 107 countries with the highest perceived need for greater access to vaccines.

While access to vaccines is needed equally in all countries in the world, the challenge of achieving sufficient coverage and access is disproportionately high in developing countries.¹ The scope is defined using three criteria: (1) countries' levels of income (gross national income [GNI] per capita); (2) their levels of development; and (3) the scope and scale of inequality in each country. These assessments are based on data from the World Bank, the United Nations Development Programme (UNDP), and the United Nations Economic and Social Council (ECOSOC).

Figure 5 List of countries included in the 2017 Access to Vaccines Index - 107 countries

Defining the scope

Step 1: All countries defined by the World Bank as low income or lower-middle income³⁰ are included. For the 2017 Index, this step accounts for the lion's share of the geographic scope, bringing 82 countries into scope.

Step 2: All countries defined by the UNDP as either low or medium human development³¹ are included. This ensures that several central measures of human development (life expectancy, education and standard of living) are taken into account. This resulted in a further 11 inclusions.

Step 3: All countries that receive a score of less than 0.6 on the UN Inequality-Adjusted Human Development Index³¹ are included. This measure takes account of how health, education and income are distributed within each country. This resulted in 13 inclusions.

Step 4: The final step is to include all least developed countries (LDCs), as defined by the Committee for Development Policy of the UN Economic and Social Council (ECOSOC).³² This brings Tuvalu into scope. Although Tuvalu is classed by the World Bank as being an upper-middle income country, it is also an LDC.



Out of the 107 countries in scope, 71 are currently receiving support from Gavi, the Vaccine Alliance for financing and implementing their national immunisation programmes. This includes 21 countries that are currently transitioning from the Gavi system.²⁸ The transition period lasts five years, after which countries can no longer access Gavi support, putting the future sustainability of their immunisation programmes at risk.¹⁵ Of the countries in scope, 18 are members of the Pan-American Health Organization (PAHO), five of which are also members of Gavi.²⁹ Through the PAHO revolving fund, these countries have access to pooled procurement of vaccines and thus potentially lower prices.

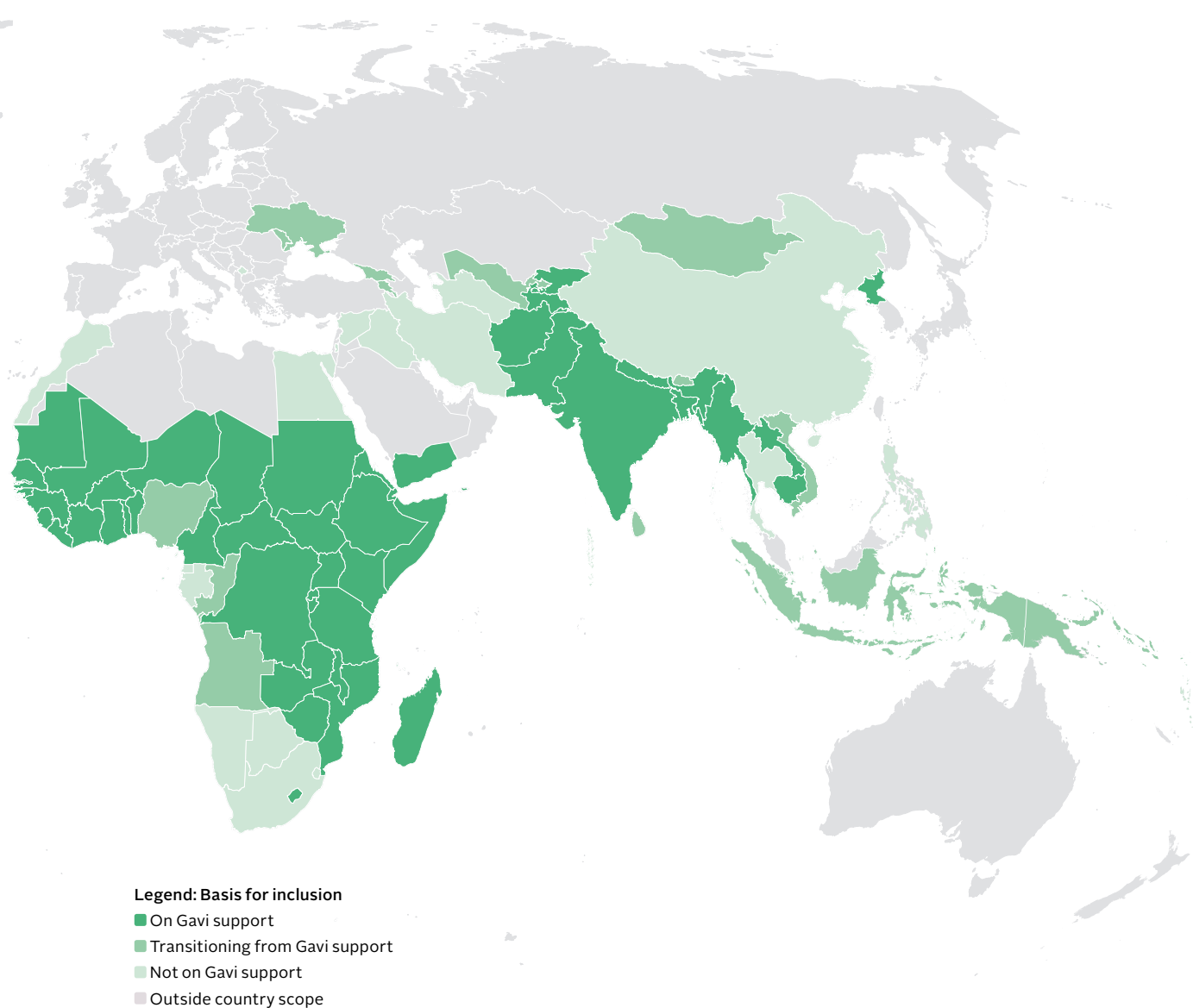


Table 1 List of countries included in the 2017 Access to Vaccines Index - 107 countries

Country	Classification			
East Asia & Pacific		Middle East & North Africa		Nigeria
Cambodia	LIC	Djibouti	LMIC	LMIC
China	HiHDI	Egypt, Arab Rep.	LMIC	Rwanda
Indonesia	LMIC	Iran, Islamic Rep.	HiHDI	LMIC
Kiribati	LMIC	Iraq	MHDC	São Tomé and Príncipe
Korea, Dem.Rep.	LIC	Morocco	LMIC	LMIC
Lao PDR	LMIC	Palestine, State of	LMIC	Senegal
Micronesia, Fed. Sts.	LMIC	Syrian Arab Rep.	LMIC	LMIC
Mongolia	MHDC	Yemen, Rep.	LMIC	Sierra Leone
Myanmar	LMIC	South Asia		LIC
Papua New Guinea	LMIC	Afghanistan	LIC	Somalia
Philippines	LMIC	Bangladesh	LMIC	LMIC
Samoa	LMIC	Bhutan	LMIC	South Africa
Solomon Islands	LMIC	India	LMIC	MHDC
Thailand	HiHDI	Maldives	MHDC	South Sudan
Timor-Leste	LMIC	Nepal	LIC	LIC
Tuvalu	LDC	Pakistan	LMIC	Sudan
Vanuatu	LMIC	Sri Lanka	LMIC	LMIC
Vietnam	LMIC	Sub-Saharan Africa		Swaziland
Europe & Central Asia		Angola	LMIC	LMIC
Armenia	LMIC	Benin	LIC	Tanzania, United Rep.
Georgia	LMIC	Botswana	MHDC	LIC
Kosovo	LMIC	Burkina Faso	LIC	LIC
Kyrgyz Rep.	LMIC	Burundi	LIC	LIC
Moldova	LMIC	Cameroon	LMIC	Uganda
Tajikistan	LMIC	Cape Verde	LMIC	LIC
Turkmenistan	MHDC	Central African Rep.	LIC	Zambia
Ukraine	LMIC	Chad	LIC	LMIC
Uzbekistan	LMIC	Comoros	LIC	LIC
Latin America & Caribbean		Congo, Dem. Rep.	LIC	Zimbabwe
Belize	HiHDI	Congo, Rep.	LMIC	LIC
Bolivia	LMIC	Côte d'Ivoire	LMIC	
Brazil	HiHDI	Equatorial Guinea	MHDC	
Colombia	HiHDI	Eritrea	LIC	
Dominican Rep.	HiHDI	Ethiopia	LIC	
Ecuador	HiHDI	Gabon	MHDC	
El Salvador	LMIC	Gambia, The	LIC	
Guatemala	LMIC	Ghana	LMIC	
Guyana	LMIC	Guinea	LIC	
Haiti	LIC	Guinea-Bissau	LIC	
Honduras	LMIC	Kenya	LMIC	
Jamaica	HiHDI	Lesotho	LMIC	
Mexico	HiHDI	Liberia	LIC	
Nicaragua	LMIC	Madagascar	LIC	
Panama	HiHDI	Malawi	LIC	
Paraguay	MHDC	Mali	LIC	
Peru	HiHDI	Mauritania	LMIC	
Suriname	HiHDI	Mozambique	LIC	
		Namibia	MHDC	
		Niger	LIC	

Table legend

LIC	Low-income country
	<i>World Bank income classifications</i>
LMIC	Lower-middle-income Country
	<i>World Bank income classifications</i>
LDC	Least Developed Country
	<i>UN Human Development Index</i>
LHDC	Low Human Development Country
	<i>UN Human Development Index</i>
MHDC	Medium Human Development Country
	<i>UN Human Development Index</i>
HiHDI	High Human Development Country
	with high inequality
	<i>UN Inequality-Adjusted Human Development Index</i>
■	On Gavi support
■	Transitioning from Gavi support
■	Not on Gavi support

Company scope: 9 companies

The Access to Vaccines Index will measure 9 vaccine companies: eight large research-based pharmaceutical companies based in mature markets and one vaccine manufacturer based in an emerging market. These companies have been identified by the Index team and through stakeholder discussions as having the potential for improving access to existing and future vaccines. Stakeholders confirmed that the Index should focus on the largest global players in the vaccine market. When the Index is published, these companies will be compared where they have relevant vaccine activities.

The vaccine market is highly consolidated, with a small group of companies generating the majority of global revenues.^{1,16,17,19} In recent years, this consolidation has increased further, driven by large mergers, acquisitions and strategic alliances. Notably, AstraZeneca acquired MedImmune in 2007¹⁹; Sanofi acquired Indian vaccine maker Shantha Biotechnics in 2009¹⁹; Johnson & Johnson moved into the vaccine space with the acquisition of Crucell in 2011¹⁹; Serum Institute of India, India's largest vaccine company, acquired Bilthoven Biologicals of Netherlands in 2012¹⁹; Novartis transferred the majority of its vaccines business to GSK, with CSL picking up its influenza vaccines, in 2014^{33,34}; Pfizer acquired Baxter's marketed vaccines in 2014³⁵, as well as Redvax in 2015³⁶, and two of GSK's meningitis vaccines.³⁷

Defining the scope

The Index team first examined the pipelines and portfolios of 20 of the world's largest research-based pharmaceutical companies to identify: 1) those with a large vaccine business or subsidiary; and 2) those with relevant, high-need vaccines on the market or in their pipelines. This brought AstraZeneca, Daiichi Sankyo, GSK, Johnson & Johnson, Merck & Co., Pfizer, Sanofi and Takeda into scope.

The Index team then sought advice from experts on other major players in the vaccine market, who suggested several further additions to the company scope. The Index team assessed whether these companies would be: a) suitable for measurement, looking for publicly-listed or privately-owned companies with relevant products on the market or in the pipeline and a presence in countries included in the geographic scope of the Index; and b) companies that are able and willing, at the time of writing, to participate in the Access to Vaccines Index. So far, this has resulted in the inclusion of Serum Institute of India to the company scope.

Table 2 List of companies included in the 2017 Access to Vaccines Index – 9 companies

Ticker	Company	Country	Total revenue 2014 (bn USD)*	Vaccine revenue 2014 (bn USD)
AZN	AstraZeneca plc	GBR	26.1	0.295***
4568	Daiichi Sankyo Co. Ltd.	JPN	7.6	n/a
GSK	GlaxoSmithKline plc	GBR	37.9	5.26**
JNJ	Johnson & Johnson	USA	74.3	n/a
MRK	Merck & Co. Inc.	USA	42.2	6.25**
PFZE	Pfizer Inc.	USA	49.6	4.48**
SAN	Sanofi	FRA	43.1	5.85**
n/a	Serum Institute of India Ltd.	IND	n/a	n/a
4502	Takeda Pharmaceutical Co. Ltd.	JPN	14.8	0.315***

* Data from Bloomberg Business [Accessed 9th October 2015]

** Data from EvaluatePharma [Accessed 9th October 2015]

*** Data from statista.com [Accessed 9th October 2015]

A Research & Development

The Access to Vaccines Index will map how companies are responding to vaccine R&D priorities. The aim is to enable companies and other organisations working in the field to identify persistent product gaps and stimulate further R&D where it is most needed.

To improve access to immunisation, there is a strong role for R&D into new and improved vaccines. For certain diseases, such as HIV/AIDS and NTDs, the first vaccines are yet to reach the market. For other diseases, existing vaccines need to be adapted, for example, for use by specific age groups, or to target specific strains of the disease. Or they may need to be made easier to transport and administer in low-resource settings. R&D into vaccines is complex, costly and lengthy, and the challenges vary widely depending on the disease in question. Vaccine development is scientifically challenging, and vaccine candidates have to go through increasingly rigorous and complex clinical trials. Only a few candidates make it through the pipeline to reach the market.²

Developing the metrics in Research & Development

The Index team tested its proposed Research & Development metrics in discussion with the leading organisations working in the field (a list of contributors can be found on page 2).

Mapping vaccine pipelines

There was widespread agreement among experts with proposals to map companies' vaccine pipelines, spanning from early-stage discovery through to product registration. Stakeholders emphasised the need to recognise companies that engage in R&D for high-need product gaps, dedicate sufficient resources and are successful at pushing projects along the pipeline. This includes tracking where companies are putting measures in place during the R&D process (access provisions) to ensure vaccines are rapidly available, accessible and affordable upon reaching the market. This overview will cover the 69 diseases included in the Index scope, providing the most comprehensive review to date of the industry's vaccine pipeline.

Priorities in adaptive R&D

Stakeholders particularly emphasised the need to track company efforts in adaptive R&D: to make vaccines more suitable for use in resource-limited settings or for use by certain populations. Particular emphasis was given to uncovering whether companies are researching the heat-sensitivity of existing vaccines and developing heat-stable formulations. Other priority adaptations were also identified: the development of new combination vaccines or to target specific strains; simpler immunisation schedules with fewer doses; improved packaging; simpler delivery technologies; and adapted vaccines that can be used in new delivery technologies (e.g., needle-free technologies).

Assessing R&D Investments

Most stakeholders confirmed that the Index should seek to capture and compare companies' investments in vaccine R&D, as this can reflect a company's commitment to bringing new vaccines to the market. Various options for assessing R&D investments were discussed, while acknowledging the difficulty of gathering comparable, detailed data on R&D investments.

A Research & Development

Indicators and rationales

Metrics in this area focus on mapping companies' vaccine pipelines, including new, adapted and improved vaccines, as well as vaccine technologies.

A.1 R&D investments

Proportion of financial R&D investments dedicated to vaccine development for diseases relevant to the Index out of the company's total R&D expenditures.

Rationale

This metric will examine how companies allocate resources to vaccines R&D. With sufficient resources, companies can help ensure that vaccine candidates travel successfully through the pipeline. The Index will view the amounts companies allocate as a proxy for their commitment to bringing new vaccines to the market.

A.2 R&D projects - vaccines

Number of investigational vaccines that the company is developing for vaccine-preventable diseases in scope of the Index, including innovative and adaptive vaccines (developed in-house or through collaborative R&D).

This metric will lead to the most comprehensive review to date of the industry's vaccine pipeline, comprising an overview of high-level project profiles, including which partners are involved. This will reveal where needs and priorities are already being addressed, by whom, and where gaps and opportunities remain for companies and other research organisations to address.

A.3 R&D projects - technologies

Number of projects the company is engaged in to develop technologies for vaccine packaging and delivery in order to overcome barriers* to vaccines in countries relevant to the Index (developed in-house or through collaborative R&D).

This metric will reveal where companies are improving or developing vaccine packaging and delivery technologies, for example to reduce unit sizes and improve supply chains, or to introduce needle-free technologies that are easier to administer and better tolerated. Such information will provide governments and global technical agencies with valuable insights into where new adaptations are emerging, and provide companies with feedback on where to focus attention and investments.

A.4 Facilitating access

Number of late-stage** vaccine R&D projects for which the company provided evidence of having access provisions in place, with the aim of ensuring future availability, affordability, and/or accessibility in Index Countries (for both in-house and collaborative R&D).

This metric will map whether companies are taking steps (called access provisions), during the R&D process, to ensure successful vaccine candidates are rapidly made available, accessible and affordable. By putting access provisions in place while vaccines are under development, companies can significantly accelerate the speed at which they become available at an affordable price and at sufficient volumes. Access provisions can include pricing commitments, supply commitments or licensing agreements.

*Barriers include stock-outs, imperfect supply chains, controlled temperature chains, high manufacturing costs resulting in high prices and lack of trained healthcare professionals.

**Late-stage R&D includes projects in phase II and III of clinical development.

B Affordability

The Access to Vaccines Index will benchmark how companies consider affordability when pricing their vaccines. The aim is to understand companies' strategic thinking and to stimulate more open discussions on what sustainable vaccine pricing looks like.

When a new vaccine reaches the market, its affordability comes under close scrutiny. For many governments, financing for vaccine procurement remains a challenge, whether or not vaccines are purchased directly from suppliers or through pooled procurement agencies. New vaccines are generally more expensive than traditional vaccines, putting additional pressure on healthcare budgets. Indeed, some new vaccines are reportedly already viewed by governments as being too costly to include in national immunisation schedules.¹⁵ Vaccine manufacturers have a responsibility to work with other stakeholders to ensure both older and newer vaccines are affordable for low- and middle-income countries, where the need for better access to vaccines is greatest. This is particularly important for high-priority vaccines that need to be made universally accessible.

Developing the metrics in Affordability

The Index team tested its proposed Affordability metrics in discussion with the leading organisations working in the field (a list of contributors can be found on page 2).

Examining efforts to ensure affordability

Stakeholders welcomed proposals for a comprehensive examination of the pricing strategies employed by all companies for all priority vaccines. This includes an investigation into the demand- and supply-side factors that vaccine companies consider when setting pricing strategies, and how they take affordability into account. Through this analysis, the Index will encourage robust pricing strategies that aim for affordability, and enable governments and other procurers to understand the criteria for negotiating lower prices.

Vaccine pricing structures for certain low-income and middle-income countries are built around the architectures used by Gavi and PAHO. Stakeholders emphasised the value of companies thinking outside of these structures, to take other socio-economic factors into account, as well as income. This is especially valuable where countries experience income-level fluctuations that do not translate into higher purchasing power, or where they fall under a relatively high national income bracket but struggle with financing constraints.

Comparing price points

Many stakeholders debated whether the Index should capture and analyse individual vaccine price points: the affordability of vaccine can only be truly assessed if its price point is known. Numerous organizations are already collecting price data on vaccines (e.g., UNICEF, Gavi, PAHO, WHO).³⁸⁻⁴¹ The Index team felt that an additional attempt to investigate specific price points would not add value.

Multiple stakeholders commented on the need for greater transparency around prices and pricing policies in order to better understand the issues relating to vaccine affordability.⁴² The Index will assess whether companies prevent governments from disclosing information, for example through non-disclosure clauses in procurement contracts.

Registration as a gateway for access

Stakeholders agreed that the Index should assess whether companies file vaccines for registration in the markets that need them, regardless of whether or not there is a lucrative market there. Registering a vaccine for use in a particular market is seen as a first step in enabling access. With each additional needed vaccine that is registered in a country, the government and pooled procurement agents gain more choice when it comes to procurement.

B Affordability

Indicators and rationales

Metrics in this area focus on examining companies' pricing strategies and whether they are transparent about them, whether they propagate price transparency, and whether they file for registration in low- and middle- income countries.

B.1 Pricing strategy

The company has a pricing strategy that takes into account income and other socio-economic criteria* when selling products to governments and through pooled procurement.

Rationale

This metric will assess the various factors companies consider when constructing pricing strategies. It will look at whether companies consider demand- and supply-side and other socio-economic factors, in order to ensure vaccines are priced affordably.

B.2 Pricing policy transparency

The company publicly discloses its pricing policy for vaccines and provides evidence that it does not prevent governments from making publicly available manufacturer prices.

This metric will examine whether the factors companies consider in their pricing strategies are publicly available so that governments and other procurers can understand the criteria for negotiating lower prices. It will also assess whether companies limit vaccine-price transparency by influencing governments' ability to disclose prices.

B.3 Registration

The company makes efforts to ensure vaccines are available in low- and middle-income countries by filing for registration there.

This metric will examine whether companies register their vaccines for sale in the countries that need them most, rather than focusing solely on the most lucrative markets. Registration is widely seen as the gateway to greater access to vaccines.

*This includes how the company uses Gavi classifications (eligible, transitioning, non-eligible) when setting the public price of its products.

C Manufacturing & Supply

The Access to Vaccines Index will assess companies' policies and processes for providing reliable supplies of vaccines. The aim is to identify information gaps and opportunities for market actors to work together to align supply and demand.

Effective immunisation programmes depend on a reliable supply of suitable high-quality vaccines. Vaccine shortages, however, occur regularly: over 40% of low- and middle-income countries suffered a national-level stock-out of at least one vaccine in 2013.² Shortages can be caused by many reasons, including sudden disease outbreaks, production interruptions, insufficient stockpiling or a lack of adequate financing. Positioned at the start of vaccine supply chains, the companies that manufacture and supply vaccines clearly have a key role to play in overcoming such hurdles.

Developing the metrics in Manufacturing & Supply

The Index team tested its proposed Manufacturing & Supply metrics in discussion with the leading organisations working in the field (a list of contributors can be found on page 2).

Defining the role of companies

The majority of discussions focused on where and how vaccine manufacturers can be expected to influence vaccine supply: it is generally agreed that they cannot be held solely responsible. In order for companies to play their part, they need certain incentives to be in place: for example, sufficient demand, accurate forecasting, insight into procurers' long-term planning, and sustainable price points.

The role for vaccine companies relates to four main areas: 1) information sharing, to align supply and demand; 2) contributing to the global security of vaccine supply; 3) working with others to improve global manufacturing capacities; and 4) adopting vaccine packaging and delivery technologies that help overcome local barriers to distribution (e.g., smaller doses that mean more can be shipped at once, or vaccine delivery technologies that are easier to use). Most experts also agreed that vaccine companies have a responsibility to limit the impact of strategic business decisions on global public health.

Securing global supply of vaccines

Experts suggested several actions companies can take to help ensure a consistent supply of high-quality vaccines for developing countries. These ranged from agreeing stockpiling agreements, to allocating more products to developing countries, to building flexible capacity into production processes. Yet, experts disagreed on the relative importance of such actions. It was seen as more important for companies to have sturdy processes in place for responding quickly to potential shortages, and to ensure their business strategies consider the needs of developing countries and the actors that purchase vaccines on their behalf. For example, do companies commit to staying in a particular market even where revenues are limited, in order to meet a public health need? Do they clearly communicate decisions that will have a significant impact on vaccine supply? In turn, companies can best plan ahead when they know where there is a demand for vaccines, supported by firm purchasing commitments.

Overcoming local barriers in distribution

Regarding distribution, the role for vaccine companies is limited: the main responsibility lies with distributors, custom officials and national governments. Companies can help overcome local barriers to access to vaccines by making their products easier to transport and administer, for example through packaging adaptation or the implementation of suitable delivery technologies. Companies can also provide clear instructions on how to administer the vaccine correctly.

C Manufacturing & Supply

Indicators and rationales

Metrics in this area focus on the strategies and processes companies put in place to ensure a reliable supply of vaccines. Additionally, this area will measure whether companies engage with local vaccine manufacturers, as this can increase local production capacities and ensure production of quality vaccines. Lastly, this measurement area will look at whether companies adapt brochures and/or packaging or other delivery technologies to overcome barriers to vaccines in developing countries.

C.1 Overcoming local barriers

The company is implementing vaccine packaging and delivery technologies* in order to overcome barriers to access to vaccines in Index countries (e.g., stock-outs, imperfect supply chains, manufacturing costs, lack of trained health care professionals) and ensure these vaccines are non-inferior to the standard vaccine in terms of quality.

Rationale

This metric will assess whether companies help to overcome local barriers to access to vaccines by either adapting vaccine packaging or implementing new delivery technologies.

C.2 Ensuring rational use

The company adapts package inserts/packaging to ensure rational use of the vaccine at the point of delivery, i.e., that the vaccine is administered appropriately.

This metric will look at whether companies provide clear instructions in the packaging materials on how to administer a vaccine, which minimise the risk of vaccines being given incorrectly.

C.3 Responding to shortages

The company has a strategy in place to help ensure sufficient or additional supplies of vaccines are made available** in case of global, regional or local shortages (both for vaccines that are part of routine immunisation as well as those needed in emergency situations, such as outbreaks, natural disasters, etc.).

This metric will reveal the strategies and procedures companies have in place to quickly avert potential vaccine shortages. The aim is to provide insight into the best actions companies can take to prevent shortages from developing, and into opportunities for other actors to trigger a timely response from companies.

C.4 Collaboration to align supply and demand

The company has a mechanism in place to engage with vaccine purchasers and partners on a regular basis to align supply and demand of its vaccines in order to identify, prevent or bridge periods of global, regional or local stock-outs, for example due to supply delays, due to the company exiting a specific vaccine market or in response to urgent, unplanned or accelerated demand.

This metric will assess the mechanisms companies have put in place to ensure they regularly engage with other stakeholders to align supply and demand (for example, with governments, UNICEF, Gavi and PAHO). The aim is to identify gaps in information sharing and highlight opportunities for closer collaboration.

* For example reduced volume, single, or multi-doses, adapted formulations for alternative routes of administration (e.g., intradermal/intranasal, oral), delivery technologies (e.g., disposable syringes,) and adaptations to packaging (e.g., vaccine vial monitors, reconstitution technologies).

**For example through spare production capacity, spare stocks, ability to re-allocate vaccines to emergency or stock-out situations, donations or affordability measures in place for emergency situations.

C Manufacturing & Supply

Indicators and rationales

C.5 Supporting vaccine security

The company has a strategy in place that takes into account global health needs for vaccines, including a commitment to continue vaccine production for its vaccines which have either few or no other suppliers AND a commitment to proactively and clearly communicate any intentions on altering supply plans, manufacturing capacity and/or exiting a specific vaccine market, and to work with stakeholders to bridge the period when supplies would diminish or cease.

Rationale

This metric aims to identify whether companies take public health into account when making strategic and business decisions. This analysis will help understand how companies balance business priorities with public health needs.

C.6 Increasing global manufacturing capacity

The company has engaged in partnerships, training and/or technology transfer that support the growth of manufacturing capabilities with the aim of increasing vaccine supply and innovation in manufacturing.

This metric will assess companies' efforts to increase global vaccine manufacturing capacity, e.g., through partnerships, training exercises or technology transfers with other manufacturers; or by sharing manufacturing innovations. The aim is to share practices that could be applied for different vaccines, and to identify where manufacturing capacity is potentially not being strengthened sufficiently.

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Definitions

Access provisions

Access measures put in place during product development to help ensure that public health needs are taken into consideration and to facilitate rapid access to affordable vaccines after market entry. Examples of access provisions include non-exclusivity in field/territories, price caps, pricing strategies, licensing strategies, supply guarantee, waiving patent rights, royalty-free provisions or registration targets.

Adaptive R&D

Adaptive R&D covers the adaptation of existing vaccines to make them more suitable for use in low- and middle-income countries, or to address a need relevant to those countries, including adaptations that address demographic segments (e.g., infants, children, pregnant women), environmental conditions (e.g., heat-stable formulations), new formulations (e.g., combination vaccines), programmatic suitability or existing vaccines in new delivery technologies (e.g. intradermal, oral, sublingual, intranasal, pulmonary delivery technologies).

Affordability

[Working definition, used for analysis]

A measure of governments' and other procurement agencies' ability to finance a vaccine. The Index takes this into account when assessing pharmaceutical companies' pricing strategies for vaccines. Pharmaceutical companies may use many different criteria to assess affordability.

Innovative R&D

Innovative R&D covers the development of new vaccines (or adjuvants) against diseases and serotypes for which no vaccine is yet available.

Vaccine packaging and delivery technologies

Technologies that allow for adaptations to vaccines packaging and/or administration and that will reduce barriers to vaccines in resource-limited settings. Packaging and delivery technologies are not specific to certain vaccines. Packaging technologies refer to technologies that address product presentations and primary and secondary containers, for example, reduced volume containers, single or multi-dose presentations, vaccine vial monitors and reconstitution technologies. Delivery technologies include alternative routes of administration and changes to delivery devices, for example, intradermal, intranasal, oral/sublingual, pulmonary delivery, microneedle patches and auto-disable syringes.

Disclaimer

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Acronyms/abbreviations

AIDS	Acquired immune deficiency syndrome
CHAI	Clinton Health Access Initiative
DCVM	Developing Country Vaccine Manufacturer
ECOSOC	United Nations Economic and Social Council
Gavi	Gavi, the Vaccine Alliance
GVAP	Global Vaccine Action Plan (WHO)
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
LDC	Least developed country (ECOSOC-defined)
LIC	Low-Income Country (World Bank-defined)
LMIC	Lower-Middle-Income Country (World Bank-defined)
MSF	Médecins Sans Frontières
NGO	Non-governmental organisation
NTD	Neglected tropical disease
PAHO	Pan American Health Organization
R&D	Research and development
SDGs	Sustainable Development Goals
UN	United Nations
UNDP	United Nations Development Programme
USD	United States Dollar
WHO	World Health Organization

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