

Transforming India's vaccine market

Saving lives, creating value





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Foreword

The last decade has marked an era of growth in India's healthcare sector and the next promises exciting times for it. There is no other health intervention as simple, powerful, and cost-effective as a 'vaccine'. Vaccines currently prevent more than 3 million deaths per year, and the positive economic impact is in excess of a billion dollars per year. During the 20th century, the average human life span has increased by approximately 30 years, a significant portion of which has been attributed directly to vaccination. Though vaccines have transformed public health throughout the world, for children in particular, the burden of vaccine-preventable diseases in India is still substantial and hence the usage of this powerful tool is still not optimal in our country.

In terms of value, India's vaccines market in 2012 remains small and under-penetrated with access much lower than in other parts of the world. But this could change. Over the next decade the Indian vaccines market has the potential to substantially increase lives saved by improving access to the types of vaccines available and the depth of coverage of those vaccines across the country.

So for individual players in the vaccines space, this decade of Indian healthcare presents new vistas of growth, provided challenges in terms of continuing policy barriers, lack of awareness and affordability issues are successfully tackled.

India vaccines landscape is getting rejuvenated with the National Immunisation Program (NIP) of the country with the emergence of domestic vaccines players and introduction of novel vaccines by the global players. But, there are unique critical issues and challenges in the use of vaccines, due to complex functioning of this Industry. These issues need to be addressed comprehensively through carefully identified initiatives, in an integrated manner for the transformation of the vaccines industry.

To answer this question, a variety of issues need to be considered:

- First, what is the current state of the Indian vaccines market in terms of access to life-saving vaccines?
- Second, what are the structural barriers to the growth of this market across stakeholders: the government, medical practitioners and patients among others?
- Third, what are the potential evolutionary paths for the vaccines market in India under different scenarios? What are the key assumptions for each of these scenarios in terms of determining access and realising value?
- Finally, what actions are needed to realise the potential by each of the stakeholders in the country?

OPPI believes that all stakeholders need to play a significant role in protecting the lives of children, adolescents and adults, through vaccination. Encompassing the challenges and complexities of vaccines segment in India, OPPI in partnership with McKinsey & Company has developed this publication with a roadmap on the expected deliverables from each stakeholder for accelerating the growth of the vaccines industry in India.

We would like to thank the McKinsey team particularly Meghana Narayan & Arjun Gobinath for investing their time and resources in building and driving the knowledge agenda for this effort. We would also like to thank the members of the Vaccines Committee and all stakeholders who helped us in preparation of this publication, which we hope will help in shaping the right environment for the vaccines industry in India.

Tapan Ray
Director General
OPPI

Masood Alam
Chairman
OPPI Vaccines Committee

Preface

In 2012, close to 2 million Indians, mainly children, died from diseases that could have been prevented by vaccines. This is reflected in the size of India's vaccine market which is small and under-penetrated.

Given this context, this effort has three objectives:

1. Develop an assessment of market potential of vaccines in India in a few scenarios in 2020 with the key assumptions for growth based on patients who access vaccines in through both public and private markets.
2. Develop a detailed understanding of key barriers that stakeholders need to overcome to drive growth in vaccines. We aimed to identify the main market drivers and barriers (exogenous and industry-driven) and assessment of impact of each driver on market potential. We also explored the likely evolution of drivers based on benchmarks from other countries and expert interviews.
3. Identify top few initiatives that will turbo charge the growth by each stakeholder. Specifically, what role can government play in driving the industry growth and how? What are the likely collaborations/partnerships between all stakeholders to help fast track the implementation?

During this effort, over 35 interviews were conducted to understand the barriers to growth of the market and the perspectives of multiple stakeholders. These included interviews with OPPI vaccines committee members (more than 10), other Indian & multinational pharmaceutical companies (over 6), key opinion leaders, specialty doctors and general practitioners (more than 15) and government and industry bodies (over 5) including IAP and WHO.

We are grateful to the Organisation of Pharmaceutical Producers of India (OPPI) for giving us the opportunity to be the knowledge partner for this effort. We would like to acknowledge the wholehearted support received from the OPPI Vaccines committee. The committee's thought leadership provided us with significant insights, differing perspectives, and valuable qualitative inputs that helped inform our approach.

The overall research effort was led by Arjun Gobinath and Meghana Narayan, Engagement Managers based in our Chennai and New Delhi offices. The core team comprised Nikhil Lohchab and Prakash Deep Maheshwari, consultants based in our Delhi and Mumbai offices. The team also included Sachin Nichal from the McKinsey Knowledge Centre.

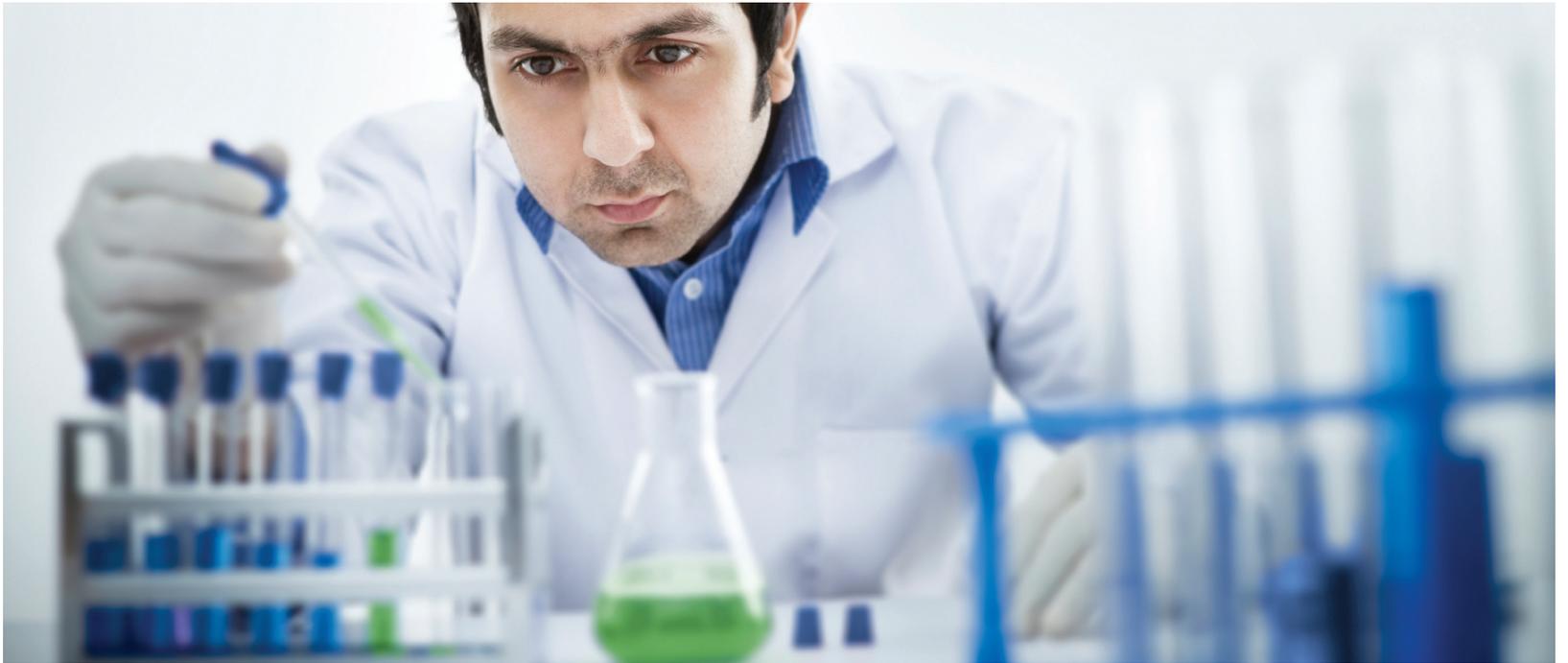
We would like to acknowledge the contributions of our colleagues Aravind Krishnan, Udyan Mittal, Kshitij Vijayvargiya and Ravi Yadav. Our research benefited from the support and expertise of several partners and senior consultants in McKinsey's Healthcare practice. We owe particular thanks to Kaustubh Chakraborty for his counsel and guidance. Additionally, several leaders of McKinsey's Healthcare practice across the world contributed to the report, provided practical inputs and continuously challenged the team to push for deeper insights—they include Alex de Jonquières, Brendan Manquin and Adam Sabow.

Finally, we would also like to acknowledge the efforts of our External Communications team, Jeanne Subramanian, Kulsum Merchant and Fatema Nulwala; our Visual Aid specialist Nipun Gosain and the New Media team in our Sydney office for their design support.

We fully expect the Indian vaccines market to evolve over the next decade. Our goal in this research is to provide industry leaders and policy makers with a view into this market evolution and what it would take to realise this opportunity. This work is independent and has not been commissioned or sponsored in any way by any business, government or other institution.

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1. Introduction

India's vaccine market, at around USD 500 million in value in 2012, remains small and underpenetrated. This situation needs to be remedied since it takes a heavy toll on India's citizens. In India, close to 2 million lives or 40 million life years are lost every year due to vaccine-preventable deaths, triple those in the United States, Germany, China and Brazil (Exhibit 1.1). India also lags behind its global peers in vaccine coverage (Exhibit 1.2). This is not surprising considering that India accounts for less than 2 percent of the global market for vaccines; per capita vaccine spend are extremely low, at USD 0.01, compared to USD 0.5 in China and USD 34.4 in the United States (Exhibit 1.3).

Exhibit 1.1

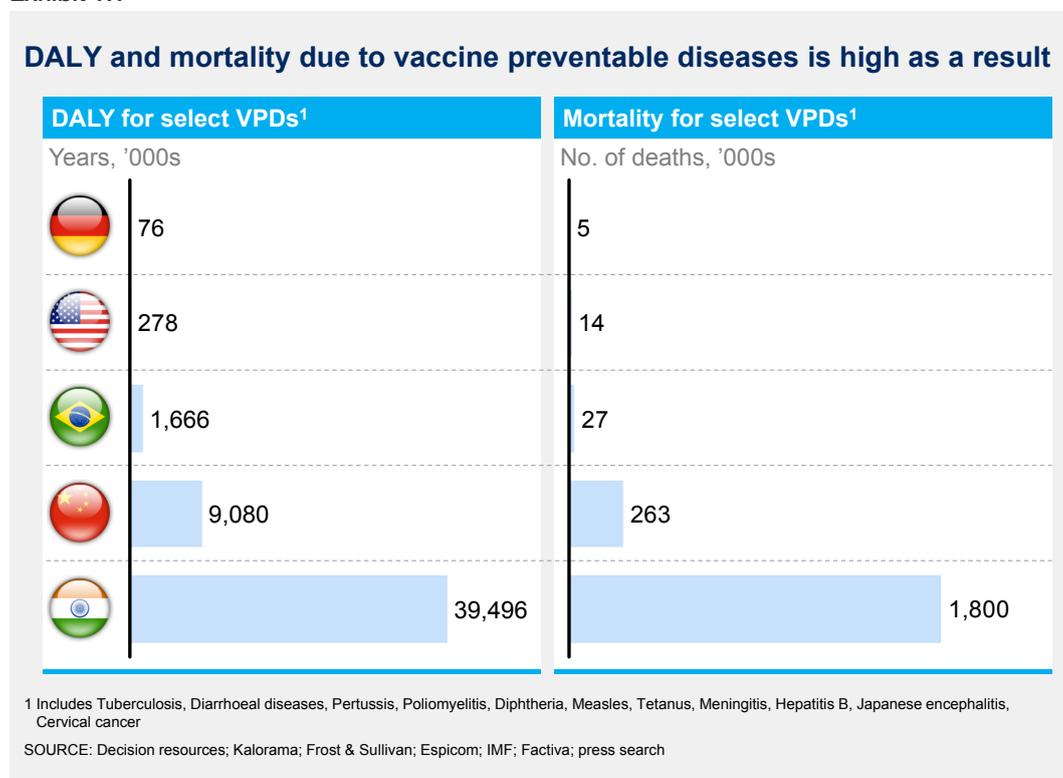


Exhibit 1.2

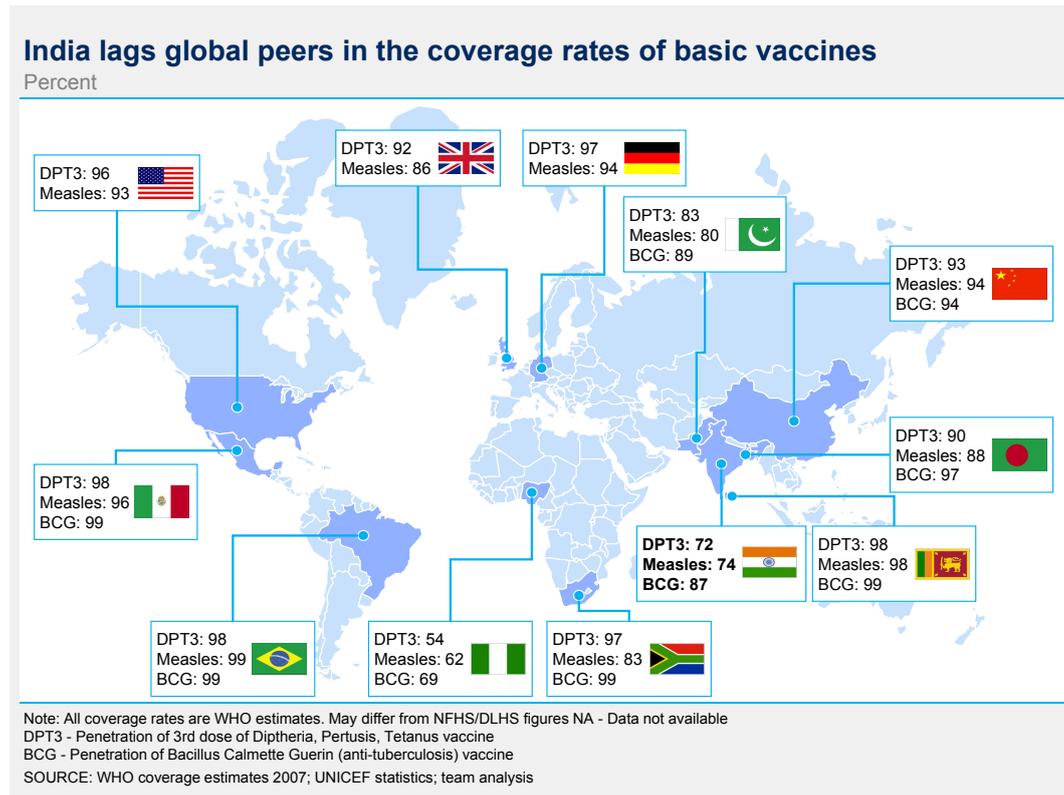
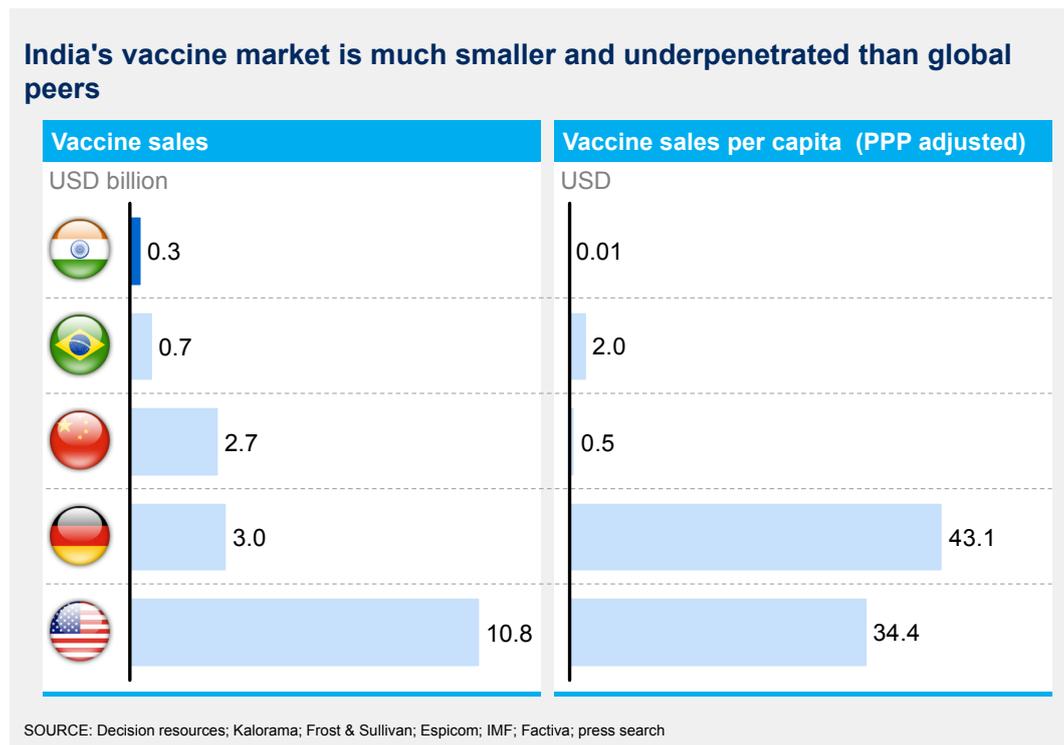


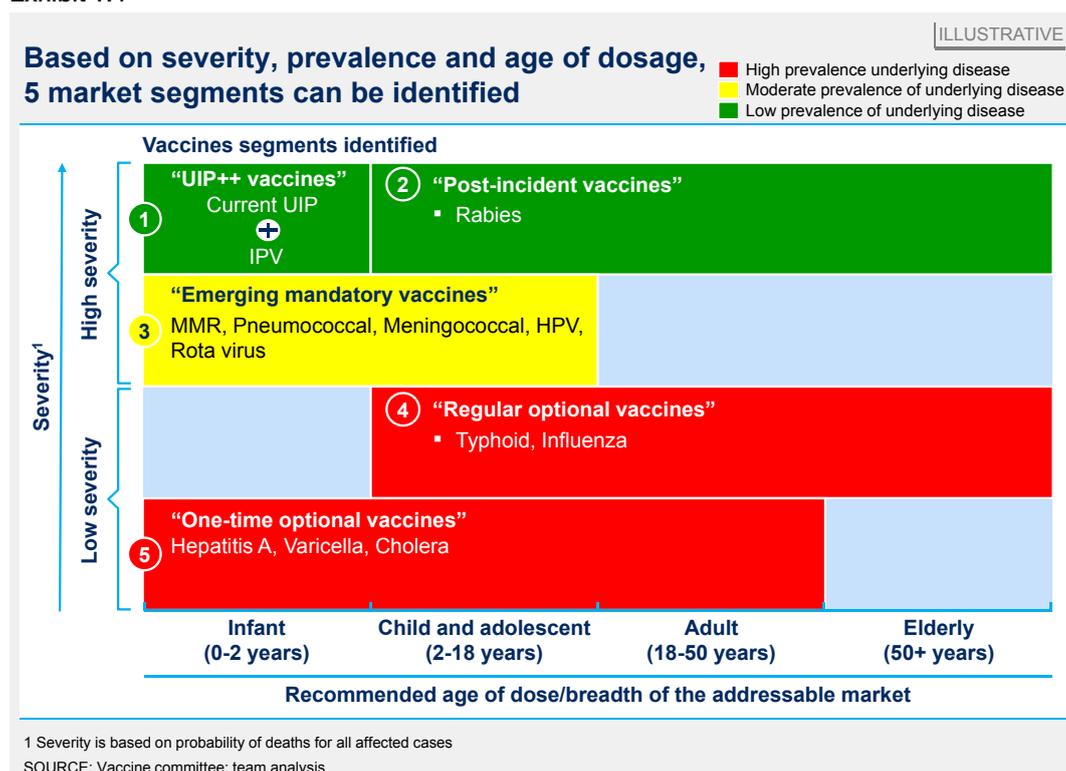
Exhibit 1.3



To understand India's vaccine market, we developed a segmentation model based on severity¹ and prevalence of diseases, and age at dosage. This revealed five main segments including Universal Immunisation Program ++ (UIP++) vaccines, post incident vaccines, emerging mandatory vaccines, regular optional vaccines and one-time optional vaccines (Exhibit 1.4). The segmentation is based on the following rationale:

- Vaccines for diseases with high life-threatening potential and recommended for infants are mostly part of the Universal Immunisation Program (UIP). These vaccines include Bacillus Calmette Guerin (BCG), Diphtheria Pertusis & Tetanus (DPT) vaccine, Measles Containing Vaccine (MCV), Polio, Tetanus Toxoid (TT) and Pentavalent vaccines, and are categorised in the segment called UIP++.
- Rabies has extremely high life-threatening potential, usage across age groups, and has a different usage pattern compared to other vaccines, since it is used only post an incident that leaves the patient at high risk of rabies. The anti-rabies vaccine is classified within the Post incident vaccine category.
- Several vaccines exist for diseases with moderate life-threatening potential. These vaccines are expected to be included in the UIP at some point of time, and usage is becoming mandatory e.g., Pneumococcal, Meningococcal, Measles Mumps Rubella (MMR), Human Papilloma Virus (HPV) and Rotavirus vaccines. These are classified as emerging mandatory vaccines.
- Vaccines for diseases with low life-threatening potential (primarily adult vaccines) are classified into two categories—regular optional vaccines e.g., typhoid, influenza and one-time optional vaccines e.g., Hepatitis A, Varicella and cholera.

Exhibit 1.4



¹ Based on the probability of death for all affected cases.

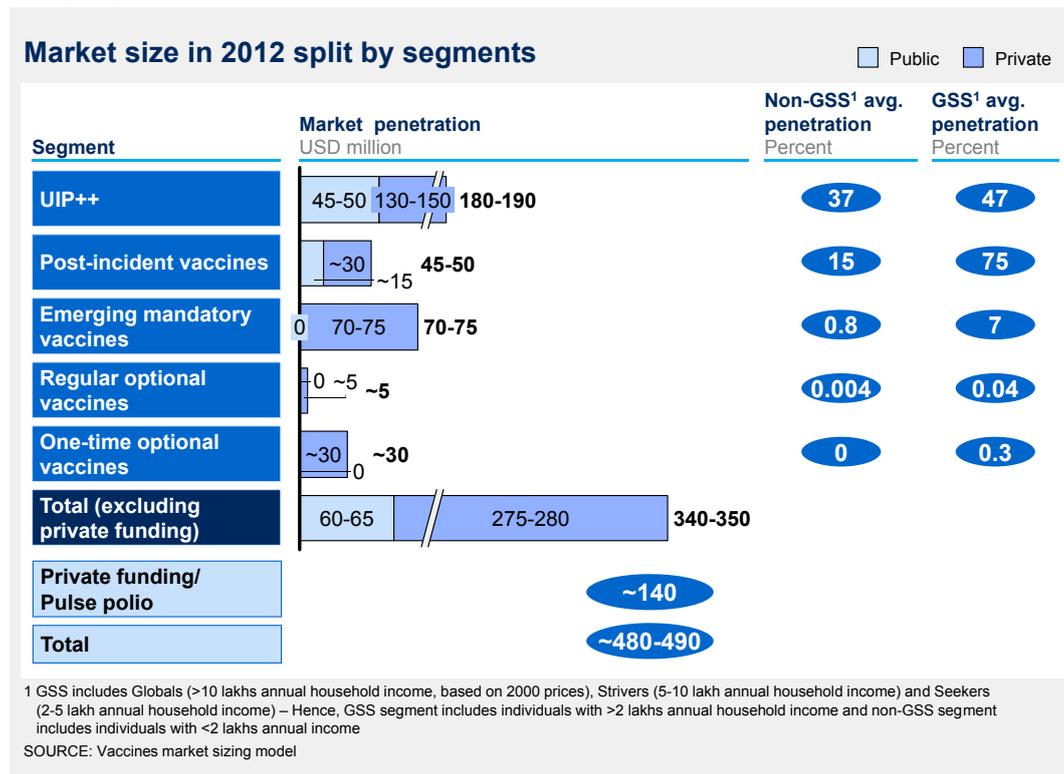
Exhibit 1.5 lays out the current market size of each of these segments.

The market, across several of these segments, remains under-penetrated for several reasons. The root causes can be understood through a detailed customer funnel by vaccine based on:

- Awareness of the vaccine
- Consideration (to purchase the vaccine)
- Access (ability to purchase the vaccine, based on affordability or availability)

A customer funnel was created for each vaccine in the market and then triangulated with publicly available penetration figures and validated with market size obtained from industry interviews. Several structural barriers hinder growth and penetration across vaccine and segment, resulting in drop offs across the customer funnel, as described in the next chapter.

Exhibit 1.5





2. Obstacles to the growth of India's vaccines market

A number of factors have subdued the growth and penetration of vaccines in India, both in the public and private markets. They include difficulties in introducing new vaccines into the country's massive universal immunisation programme (UIP), a lack of awareness and understanding of vaccines among the health community, limitations in affordability / access and constraints to manufacturing and supply (Exhibit 2.1).

Exhibit 2.1

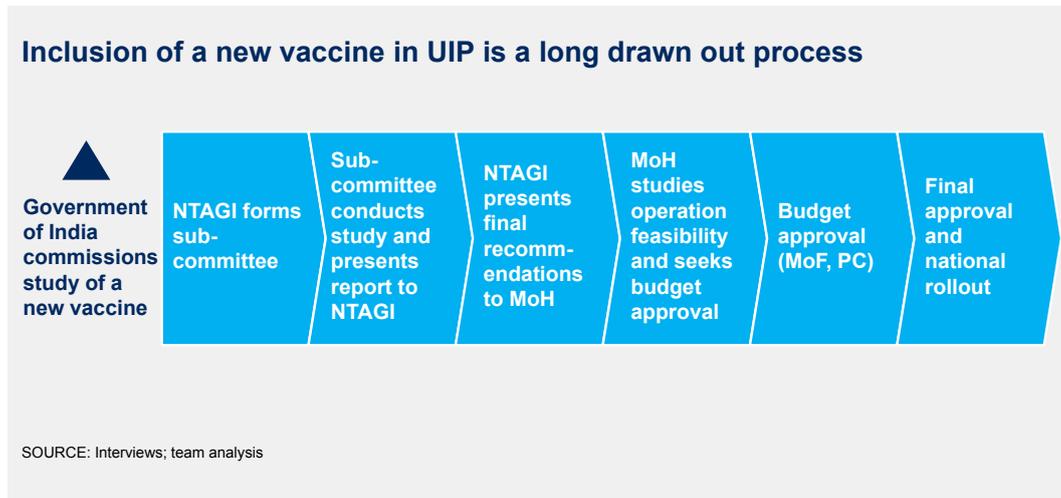
Several structural barriers affect Indian vaccine market		
	Themes	Evidence/Rationale
UIP introduction	1 Process to include vaccines in UIP is unclear and is bounded by constraints, e.g., funding	<ul style="list-style-type: none"> Other than Pentavalent vaccine, no UIP vaccine introduction at scale in a decade Criteria for introduction unclear (e.g., whether vaccines for non-life threatening diseases would be added to UIP)
Awareness	2 Limited knowledge of spectrum of vaccines among doctors, and consequently among patients	<ul style="list-style-type: none"> Current vaccine sales teams do not cover GPs and several other specialists and hence have limited information about vaccine introductions, dosage, and efficacy – consequently, patient trust is also low Patient awareness low as time spent by doctors in explaining importance of vaccines is limited beyond handing over vaccination schedule
	3 Lack of clarity on disease burden and consequent economic impact	<ul style="list-style-type: none"> Lack of quality data on disease burden, and limited epidemiological studies hindering assessment of vaccine importance and impact
	4 Awareness building initiatives highly skewed towards the Polio vaccine	<ul style="list-style-type: none"> Mass media and other campaigns primarily focused on Pulse Polio program Vaccines are not endorsed in government health programmes unless they are part of the UIP; unlike in several developed countries
Consideration	5 Perceived lack of clarity on vaccine efficacy	<ul style="list-style-type: none"> Several vaccines e.g., HPV and Influenza are considered to be unproven by stakeholders such as doctors, who say they are not convinced of efficacy due to perceived lack of scientific studies / literature
	6 Vaccine uptake highly skewed towards high mortality diseases	<ul style="list-style-type: none"> Strong patient preference to treat (rather than prevent) Vaccine Preventable Diseases (VPDs) that are not very severe e.g., Influenza, Diarrhoea Several vaccines considered only for high risk situations e.g., Typhoid, Hepatitis A
	7 Physicians do not prescribe optional vaccines due to liability risks	<ul style="list-style-type: none"> Physicians say they would avoid prescribing optional vaccines to reduce their risk/liability in case of side effects/complications
	8 Concept of adult vaccine not established in India	<ul style="list-style-type: none"> Preferences to use high dose of antibiotics/other treatment in adults rather than use vaccines Adult vaccine efficacy not established among Health Care Professionals (HCPs); overall view that most adult vaccines are 15-20 years away from wide acceptance
Action	9 Medical insurance does not cover vaccines in India	<ul style="list-style-type: none"> Most medical insurance policies (including corporate insurance) do not cover vaccination, unlike in China/developed countries
	10 Limitations in cold chain & last mile distribution	<ul style="list-style-type: none"> Difficulties in maintaining stock (e.g., need to have 2-8 deg C temperatures, regular electricity blackouts, stock updation issues) at a doctor's clinic Except for Peds, HCPs not maintaining regular stock due to logistical difficulties/access to market Vaccine coverage in Tier 3-4 regions much less than pharmaceuticals products due to cold chain storage and distribution restrictions
	11 High vaccine prices limiting UIP introduction and affordability in private market	<ul style="list-style-type: none"> Takes time for vaccines to become affordable beyond top income segments (usually when an Indian manufacturer starts producing it) Government usually includes vaccine in UIP when it is priced at a certain target price (usually less than a few USD per dose) but this takes time
	12 Limitations in public health delivery systems (such as inaccurate data) leading to drop-outs, delay in UIP introduction, and funding gap	<ul style="list-style-type: none"> Penetration levels of UIP vaccines limited to 70-75% due to limited health delivery systems (across coverage, bandwidth, tracking, accountability); also leading to drop offs after first dose States with better health systems and tracking methods, e.g., TN, Kerala, enjoy accelerated UIP rollout e.g., Pentavalent vaccine is now part of state supply only in these two states Lower propensity for external funding when delivery systems are poor, e.g., GAVI has funded the Pentavalent introduction in more developed states
	13 Limited supply capacity of MNCs	<ul style="list-style-type: none"> Most MNCs are supply constrained – and prioritize supply to higher return bulk channels, which excludes Indian private and public market supply

SOURCE: Stakeholder interviews; team analysis

Unclear process in introducing new vaccines

In India, the government is a large buyer of vaccines, which it provides to the public through the UIP. But the process for including new vaccines into the UIP is unclear, in many cases slow, and dogged by supply and funding constraints. Approval for inclusion in the UIP can take many years. For instance, Pentavalent¹ vaccine was included in the UIP after over a decade of deliberations. The process for inclusion requires the government's agreement to study a new vaccine for inclusion, study by a subcommittee, recommendations to the health ministry, a feasibility study, budget approval, final approval and national roll-out (Exhibit 2.2).

Exhibit 2.2



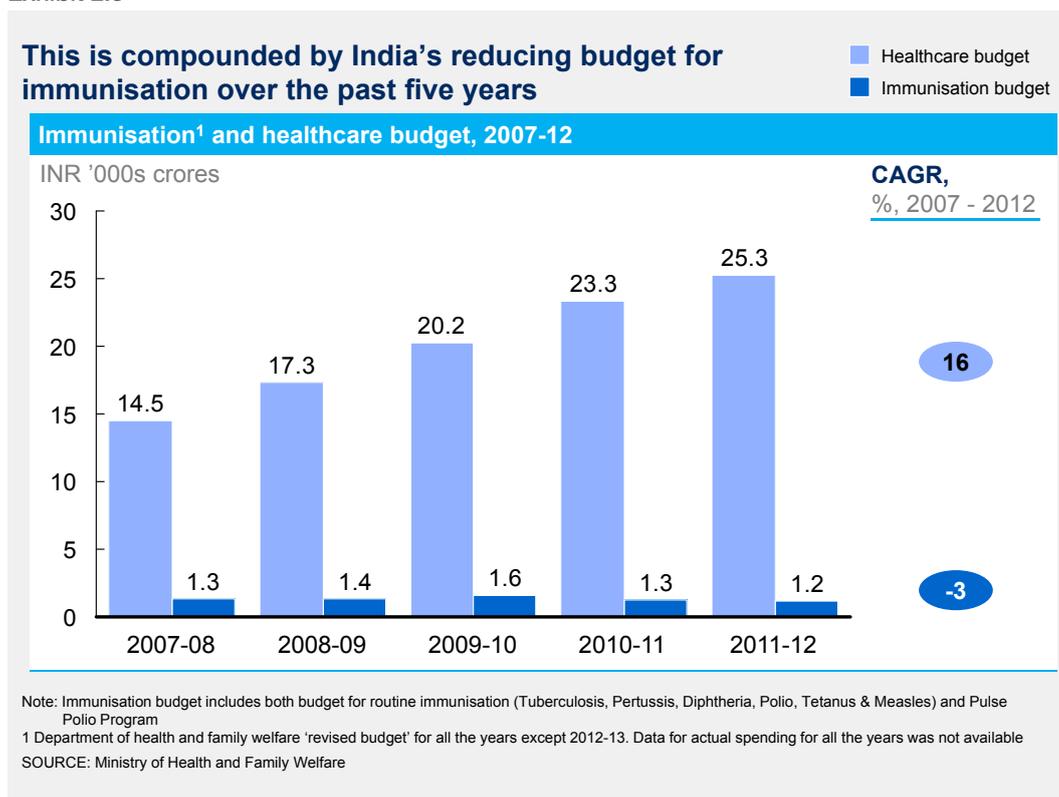
Currently, the UIP program's main focus is to increase coverage of existing vaccines in poor-performing states, leaving little room for consideration of new vaccines. Further, the minimal budget for new vaccines does not help matters; the immunisation budget as a whole has declined from a little over 9 percent of the total healthcare budget in 2007-08 to around 5 percent in 2011-12 (Exhibit 2.3). Over the past decade, the focus on polio eradication has also reduced the chances of consideration of other vaccines.

Interviews with experts also suggest that lack of data on burden of disease and vaccine efficacy are obstacles to UIP expansion. Further, inclusion in the UIP also requires local manufacturing capacity of the vaccine, which has its own constraints. Vaccine manufacturing entails high fixed cost, amounting to 60 percent of total cost and the need for scale trumps any labour cost advantages in emerging markets.

Finally, the criteria for introducing a vaccine into the UIP can be further clarified, as several stakeholders bring differing perspectives. For example, it is not clear whether the government would add vaccines for non-life threatening diseases such as Varicella, Hepatitis A and Influenza vaccines, all of which are part of the public vaccination program in the US.

¹ Pentavalent protects children from five life-threatening diseases: diphtheria, pertussis, tetanus, hepatitis b and hib (haemophilus influenzae type b).

Exhibit 2.3

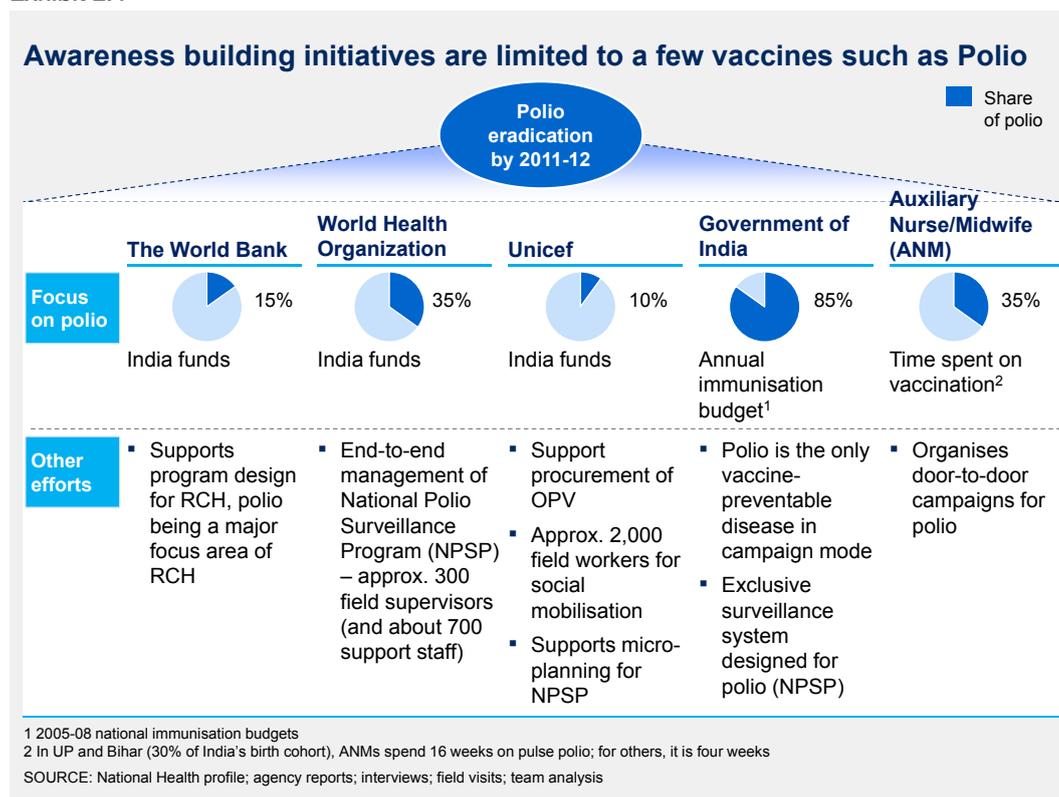


Lack of awareness

Awareness of the importance and availability of vaccines is low for several reasons. First, doctors and hence patients have limited knowledge of vaccines. Current vaccine sales teams do not cover general practitioners (GPs) and so doctors are not sufficiently aware of vaccine introductions, dosage and efficacy. Second, patients know very little about vaccines because doctors usually do not spend time explaining their importance, usually just handing over the vaccination schedule. Third, due to a perceived lack of knowledge on the part of GPs and non-paediatric specialists, parents do not trust their advice when it comes to vaccinations for their children.

Finally, most government and public health awareness building initiatives, apart from the successful polio vaccination program, appear to receive comparatively less notice from the mass media (Exhibit 2.4).

Exhibit 2.4



Physician and patient preferences

Physicians tend not to prescribe optional vaccines to avoid liability in case of side effects or complications. Patients on their part tend to prefer treating rather than preventing diseases that are not severe, such as influenza and diarrhoea. Vaccines are considered mainly for high-risk diseases such as tuberculosis, diphtheria or rabies.

In addition, the concept of adult vaccines is not well-established in India, even among health care practitioners. Experts believe that most adult vaccines are typically 15 to 20 years away from wide adoption.

Affordability issues

Vaccines are provided free under the UIP but only for a few highly communicable and life-threatening diseases. Obtaining vaccines through the private system can be expensive. Hence some newer vaccines, for e.g., Pneumococcal vaccine, can be afforded only by GSS², when the cost is lowered by local manufacturing. A compounding factor is that in India, most medical insurance policies (including corporate insurance) do not cover vaccination, unlike in China and developed countries. The Indian government usually includes a vaccine in the UIP only when it is priced usually at less than a few US dollars per dose.

² Globals, Strivers and Seekers defined as those with an annual household income of greater than Rs. 2 lakh based on 2000 prices.

Lack of data

A lack of quality data on disease burdens and vaccine efficacy is cited as the biggest obstacle to new vaccine adoption in India as disease burden is the main factor in setting priorities for vaccine inclusion in immunisation programmes. Data on vaccine efficacy is perceived to be another critical gap. Decision makers in India need evidence of the safety and effectiveness of vaccines in the local population.

Limitations in distribution and supply

Difficulties in distribution, limitations of the public health delivery system and supply constraints all hinder the growth and penetration of vaccines in India.

Distribution is hampered by an inadequate cold chain and constraints to last-mile distribution, which has limited penetration of basic vaccines to 60–70 percent. Difficulties are faced even in maintaining stocks at clinics. Many vaccines need to be kept at very low temperatures of 2–8 degrees centigrade. Frequent electricity blackouts in India make this problematic. As a result, except for paediatricians, most physicians do not keep a regular stock of vaccines.

Additionally, there are limitations in coverage, bandwidth of health workers and the accountability of the public health delivery system. One of the consequences of this is “drop out” after the first dose of the vaccine (Exhibit 2.5), while over-reporting is also quite common (Exhibit 2.6). States with better health systems and tracking methods such as Tamil Nadu and Kerala have enjoyed an accelerated UIP rollout, given sufficient infrastructure exists to handle the extra load of a new UIP vaccine.

Exhibit 2.5

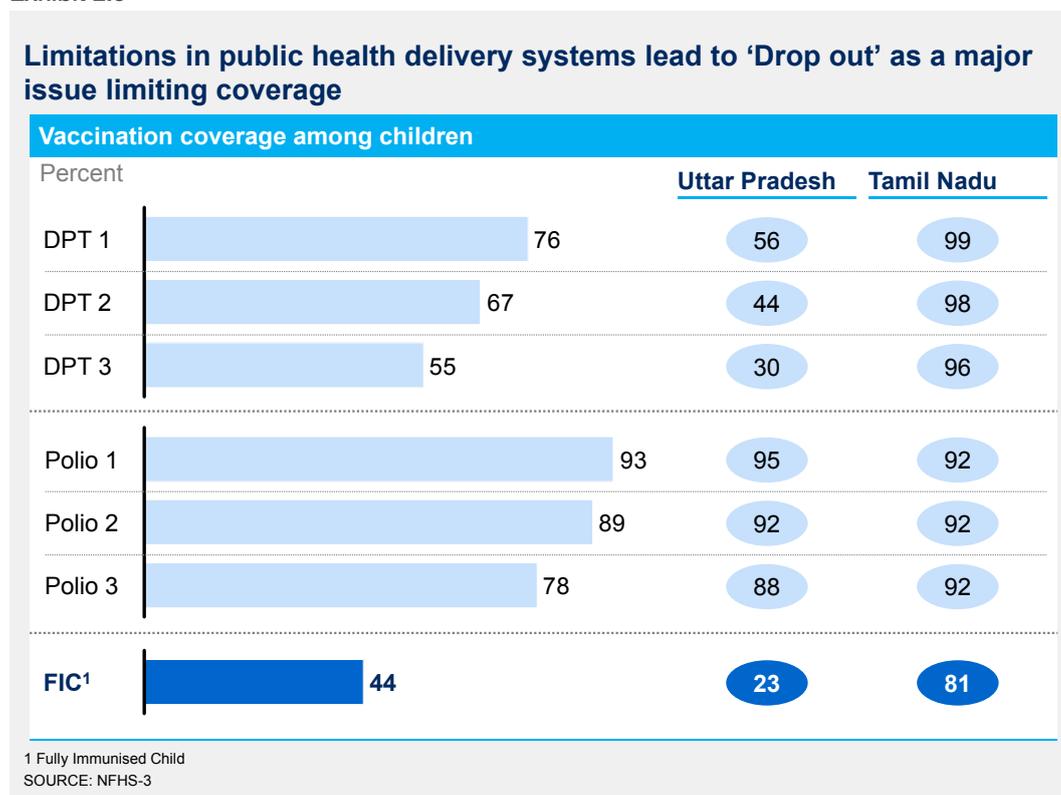
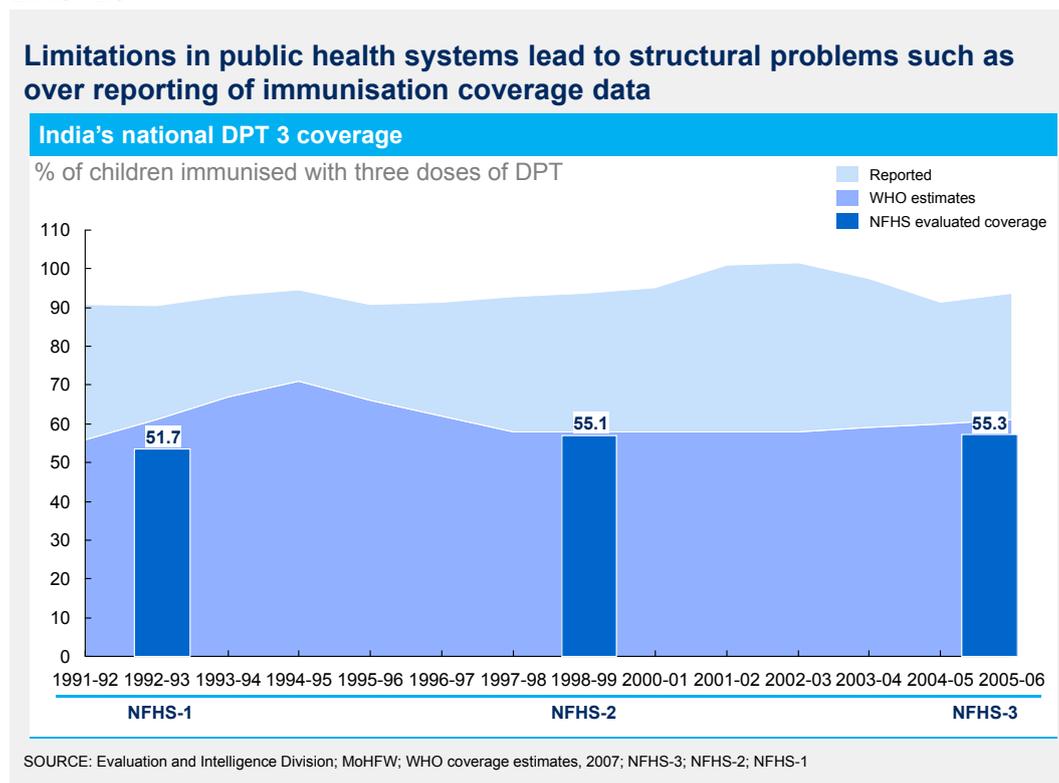


Exhibit 2.6



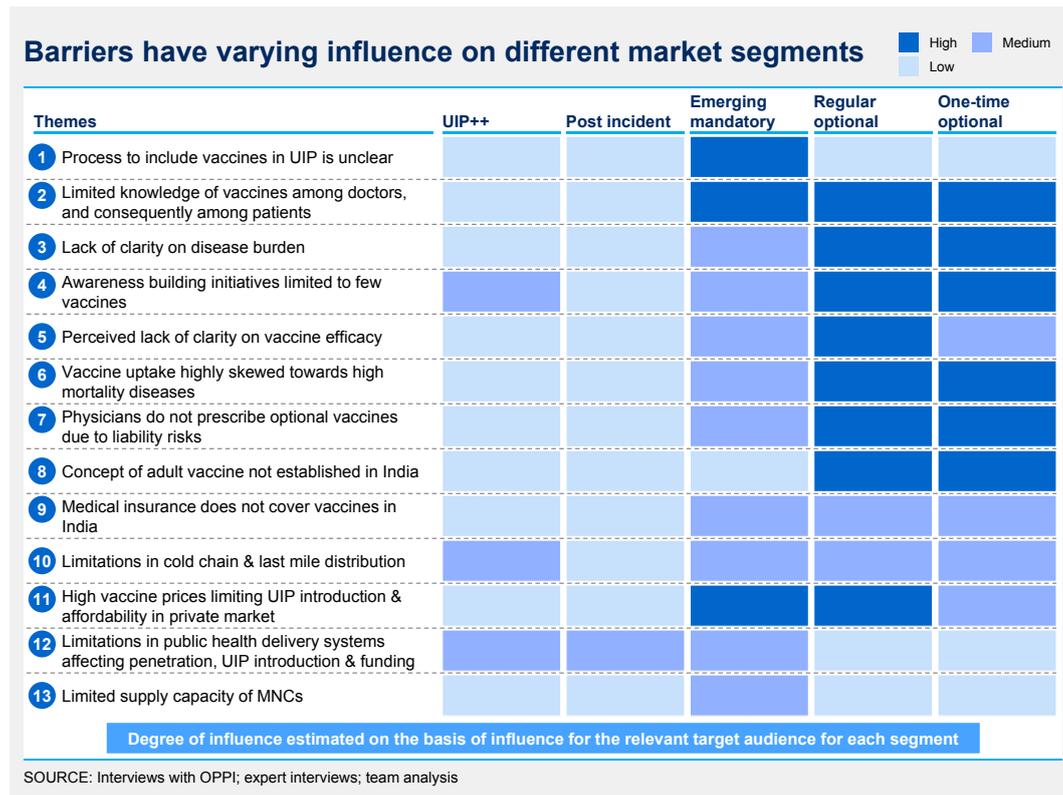
The quality of data maintained in the public system also hinders uptake of vaccines. A review of the UIP in 2004, through field visits and other sources of information, reveal several issues at various levels across the health system. Healthcare workers such as auxiliary nurse/midwives (ANM) and *anganwadi*² workers in healthcare (AWW) who administer vaccines under the UIP usually do not record data on the number of vaccination sessions actually held. There is also duplication of data between ANMs and AWWs. ANM targets are based on data available at district level and not actual children in the district. Finally, analysis of individual vaccine availability is not possible, as often, supply information on vaccinations combine two or more vaccines, leading to misinterpretation.

At the Primary Healthcare Centre (PHC) level, inaccurate data is used to determine achievement against targets. Vaccine consumption and wastage is not recorded or monitored. Further, reporting of Vaccine Preventable Diseases (VPDs) and any adverse events following immunisation is limited.

Each of these barriers has a varying influence on different market segments, as illustrated in Exhibit 2.7. The further expansion of vaccines in India hinges on the extent to which these barriers are overcome. One of three scenarios is possible, as described in the next chapter.

² *Anganwadi* means courtyard shelter; set up by the government in 1975, *anganwadi* centres provide pre-school education and also basic health care in Indian villages as part of the a programme to combat child hunger and malnutrition.

Exhibit 2.7





3. India's vaccine market in 2020 – Three scenarios

Interventions by the government and a concerted effort by both public and private players are essential to expand the growth of vaccines in India. Depending on the extent of actions taken, India's vaccines market could develop into one of three possible scenarios, each with differing implications on market size and characteristics, and on various health metrics.

THREE POSSIBLE SCENARIOS

Our analysis shows that one of the three scenarios described below will emerge by 2020.

Pessimistic scenario

This scenario is likely if the market continues at its current momentum and trajectory, which would mean that no major growth or transformative initiatives are taken by the government or private players. In this scenario, growth will have come partly from an increase in the number of people to be vaccinated, in line with population growth, and from a marginal increase in penetration in line with the historical trajectory. Also, no new additions will have been made to the list of UIP vaccines.

We expect the market to reach about USD 550 million to USD 570 million in value by 2020, growing at about 5–7 percent a year, in line with current vaccine market growth and overall economic growth.

Expected scenario

This is the most likely end state for the Indian vaccines market in 2020, assuming that several public market interventions as well as supporting initiatives are made by the government and private players. Many of these interventions are already in various stages of implementation. This scenario assumes the following interventions would have been made:

- Five new vaccines would have been added by the government to the UIP between 2012 and 2020, namely, anti-diarrheal rotavirus vaccine, anti-pneumonia pneumococcal vaccine; anti-cervical cancer Human Papilloma Virus vaccine (HPV); the measles, mumps and rubella vaccine (MMR); and the meningococcal vaccine (protecting against meningitis and septicaemia among other diseases). We expect introduction of the rotavirus and MMR vaccines before 2015 and the subsequent introduction of the rest.
- The penetration of most UIP vaccines has exceeded 60–70 percent in line with 'traditional' UIP penetration, e.g., of the anti-tuberculosis BCG vaccine and the DPT (anti diphtheria, tetanus and pertussis) vaccine.
- A moderate increase (10–20 percent) in the penetration of other optional vaccines has been achieved through private sector interventions.

In this scenario, we expect the market to have reached about USD 1.60 billion to USD 1.65 billion in value in 2020, growing at 20 percent year-on-year from 2012 onwards. The expected scenario would have a higher penetration of vaccines among lower income groups (non-GSS)¹, compared to today, driven by the introduction of new vaccines in the UIP. Also, non-GSS would be as large as 50 percent of the overall market by value, up from 32 percent at present. The public market for vaccines would account for more than 25 percent of the total market. Five vaccines in the UIP will have crossed USD 100 million in size, constituting 60 percent of the market (Exhibit 3.1).

¹ Less than Rs. 2 lakh household income in 2000 prices, commonly referred to as Aspirers and Deprived income classes, also called non-GSS.

Exhibit 3.1

Mega vaccines emerging in Indian vaccines market	
USD million, 2020	
Expected scenario – Mega vaccines Market size: >100 million	Optimistic scenario – Mega vaccines Market size: >250 million
HPV	170 – 180
MMR	110 – 120
Pneumococcal	400 – 420
Rotavirus	150 – 160
Pentavalent acellular	130 – 140
Influenza	280 – 300
Typhoid	450 – 470
HPV	470 – 480
Pneumococcal	470 – 480
Hepatitis A	280 – 290

SOURCE: Vaccines market sizing model

Optimistic scenario

In this scenario, the vaccine market achieves distinctive performance and penetration on the back of strong innovation in regulation, manufacturing, supply chain, and sales and marketing. Achieving this scenario will not be easy, calling for several initiatives both by the government and private companies. This scenario assumes the following interventions have been made:

- The five new vaccines listed in the expected scenario have been added to the UIP
- High levels of penetration (beyond 70-80 percent) of most UIP vaccines has been achieved through private-and public sector-driven improvements
- A substantial growth in the penetration of optional / adult vaccines has occurred (both one-time vaccines such as the hepatitis A vaccine and regular vaccines, e.g., against influenza and typhoid).

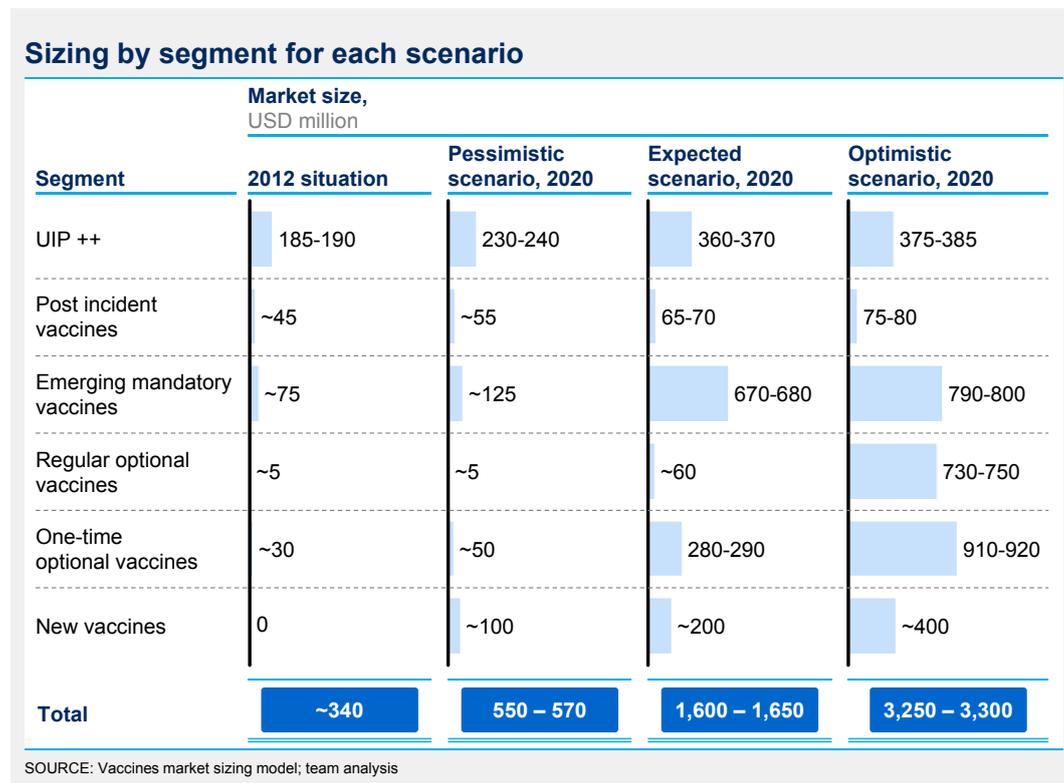
We expect that the market will have reached about USD 3.2 billion to USD 3.3 billion in value in 2020, growing at 30-35 percent year-on-year from 2012 onwards. The private market will have returned to prominence, accounting for over 85 percent of the market, unlike the 75 percent estimated in the expected scenario. In all likelihood, there will be five 'mega' vaccines of over USD 250 million each in size, constituting 60 percent of the market, namely the anti-influenza, anti-typhoid, HPV, pneumococcal and hepatitis A vaccines.

IMPACT ON VACCINE MARKET SEGMENTS

Each scenario will reflect the differential impact of actions taken in the public and private sectors. In the pessimistic scenario the relative sizes of the five vaccine market segments will be quite close to 2012 estimates. In the expected scenario, emerging mandatory vaccines e.g., Pneumococcal, HPV will outstrip the growth of others, contributing the most to the vaccine market, i.e., USD 650 million to USD 700 million of the USD 1.60 billion to USD 1.65 billion market. In the optimistic scenario, three of

the five segments—emerging mandatory vaccines, regular optional vaccines, and one-time optional vaccines—will be substantial, accounting for over USD 750 million each in value (Exhibit 3.2).

Exhibit 3.2



Several vaccines are poised to enter the Indian market before 2020, of which the anti-dengue and anti-malaria vaccines, currently in Phase 3 trials, have the highest potential to become very successful in the Indian market. In the optimistic scenario, these vaccines could account for up to USD 400 million in sales (Exhibit 3.3).

Exhibit 3.3

Several new vaccines can be potential blockbusters in 2020

Stage	Underlying disease/ vaccine	Blockbuster potential in India
Registration	▪ H5N1 Influenza (Aflunov, KD 334, Others)	▪ Medium
	▪ Hepatitis E (Hecolin)	▪ Low
Phase 3	▪ Dengue	▪ High
	▪ Pseudonomas	▪ Low
	▪ Malaria	▪ High
	▪ Enterovirus 71	▪ Low
Phase 2	▪ Hepatitis C	▪ Low
Phase 1	▪ Difficile	▪ Medium
Pre-clinical	▪ Chikungunya	▪ High

SOURCE: TrialTrove; Press search

IMPACT ON HEALTH METRICS

The expected and optimistic scenarios will show a significant improvement in key health metrics in India due to the containment of vaccine preventable diseases (VPD). Mortality could reduce by 50 percent and loss of life years by 30–40 percent by 2020, in these scenarios.

In contrast, there is barely any decrease in mortality or loss of life years in the pessimistic scenario since the penetration of vaccines would have remained at the current level. There will be a steep drop in mortality and life years lost in the expected scenario primarily due to induction of new vaccines in UIP. A further reduction of about 10 percent in mortality and life years lost is seen between the expected and optimistic scenario. In addition, there will be a significant drop in VPD prevalence in the optimistic scenario, compared to the expected scenario (Exhibit 3.4).

Exhibit 3.4

APPROXIMATE

The 3 scenarios have different implications on fundamental health metrics

	Estimated mortality ¹ Million	Estimated DALYs ¹ Million	Estimated prevalence ¹ Million
2012 situation	1.05	27.1	5.6
Pessimistic scenario, 2020	0.98	27.9	4.7
Expected scenario, 2020	0.63	19.8	1.9
Optimistic scenario, 2020	0.57	18.7	1.3

¹ Computed for currently available vaccines only (no new vaccines taken into account). Does not take into account disease variants not currently impacted by available vaccines e.g. Non-rotavirus diarrhoeal mortality and DALYs

SOURCE: Vaccines market sizing model; team analysis

For the expected and optimistic scenarios to emerge, several interventions will be needed, by all stakeholders in India's vaccine sector, the subject of the next chapter.



4. *Actions needed to realise the potential of India's vaccine market*

The government and pharmaceutical companies can stimulate the expansion of vaccines in India through a number of actions, notably reducing complexity in the UIP process, increasing the prescriber base, improving sales and marketing and investing in delivery and supply.

INTERVENTIONS NEEDED TO REACH THE EXPECTED SCENARIO

For the expected scenario, given the thrust on the public market, and the need to introduce new vaccines to the UIP, the focus needs to be on making the case for introducing new vaccines into the UIP, ensuring adequate supply of these vaccines and increasing public market penetration (Exhibit 4.1).

A. Making the case for introducing new vaccines into the UIP. To overcome barriers to growth, stakeholders need to work together to streamline the UIP inclusion process. Additionally, pharmaceutical companies need to expand existing knowledge about disease burdens and the socioeconomic impact of vaccines through public-private partnerships (PPP) and engage stakeholders to build a long-term agenda for UIP inclusion.

B. Ensuring adequate supply of new UIP vaccines at the right price. Technology transfer to local players will be essential to ensure supply of UIP vaccines at the scale and price required. On its part, the government could provide incentives to manufacturers by committing to larger volumes and providing tax and duty concessions to manufacturers outside India. Pharmaceutical players will also need to pursue design-to-cost of vaccines. New donors will also be needed to fund R&D and delivery of new UIP vaccines.

C. Increasing penetration. To increase the coverage and penetration of vaccines, private players and donors could help ease the burden on the health system by investing in public infrastructure and in the introduction of alternative delivery mechanisms and routes of administration. To further increase penetration, the government could conduct mass media awareness campaigns and leverage existing networks of more than 8.5 lakh health workers to build awareness.

Exhibit 4.1

Interventions for switching from pessimistic to expected scenario		
Themes	Stakeholders	Interventions
Clarify the case for new UIP introductions	Pharmacos	1 Set up PPP for data collection, analysis and dissemination of data on disease burden and socio-economic impact of vaccines; Explore joint studies for vaccine efficacy and complications
		2 Engage various stakeholders e.g., NTAGI consistently on a long-term agenda to increase number and coverage of vaccines
	Government	3 Streamlining UIP introduction process e.g., evaluate priorities to include vaccines with significant impact on lives saved
Ensure scale supply of new UIP vaccines at right price	Pharmacos	4 Engage in technology transfer to local players in lieu of committed volumes, especially in states with higher disease burden
		5 Design to cost of vaccines added to UIP through a combination of manufacturing and packaging innovations
	Government	6 Provide incentives to manufacturers through larger committed volumes and tax/duty breaks (for MNC manufacturers etc.)
	Others	7 New donor funding (similar to GAVI co-financing model) for new UIP vaccines (both R&D and delivery)
Reach the last mile to improve penetration	Pharmacos	8 Support in increasing coverage/penetration of UIP vaccines by investing in public infrastructure (e.g., partnerships) and introducing alternative delivery mechanisms and routes of administration
	Government	9 Create a dissemination campaign for creating wider awareness on the adult immunisation schedule
		10 Improve awareness for new UIP vaccines through mass media campaigns (similar to Polio) as well as leveraging NRHM/ICDS network of FLWs
	Others	11 Donor funding for strengthening public health delivery systems to increase coverage of vaccines

SOURCE: Team analysis

INTERVENTIONS NEEDED TO REACH THE OPTIMISTIC SCENARIO

Achieving the optimistic scenario would also require a three-pronged effort: increase vaccine prescriber base, enhance vaccine delivery channels, and penetrate lower income segments (Exhibit 4.2).

D. Increase the vaccine prescriber base across health care practitioners: To deepen coverage of paediatricians and to cover more physicians and paramedics, pharmaceutical firms need to scale up their sales forces. To build trust with patients, GPs could be supported through an accreditation programme that trains and certifies them (and their clinics) in vaccine knowledge and administration.

E. Enhance vaccine delivery channels to drive penetration of private-sector vaccines. A major government intervention would be the introduction of private (non-covered) vaccines in public dissemination channels (government hospitals, PHCs) to increase distribution points for non-UIP vaccines. Further, companies need to focus on (a) pursuing institutional sales (b) bundling vaccines with health check-ups for adults and (c) partnering with providers to serve high income segment customers to ease access.

F. Penetrate lower income groups. Since high price is a major deterrent to vaccine adoption among lower income groups, ways to manage funding are important. One option is engaging with insurers to include vaccines in insurance coverage, at least in specific high-risk situations. Pharmaceutical companies could consider introducing lower priced second brands to reach lower income groups.

Exhibit 4.2

Interventions for switching from expected to optimistic scenario		
Themes	Stakeholders	Interventions
Increase vaccine prescriber base across HCPs	Pharmacos	12 Scale up sales force to cover GPs/CPs (and paramedics) in the top 100-200 cities and increase coverage of Peds
		13 Create an immunisation accreditation program for GPs/paramedics to train and certify vaccine knowledge/administration capability
		14 Support HCPs in setting up immunisation certified clinics (with accredited HCPs, cold storage) through innovative service offerings (e.g., low cost financing for infrastructure)
		15 Engage with KOLs and specialty doctor associations to endorse and recommend relevant vaccines e.g., Chest society endorsement of Pneumo vaccine
Enhance dissemination channels to drive private penetration	Pharmacos	16 Set up an institutional sales channel (for catch up cohort and regular vaccines) by engaging employers, educational institutions and corporates
		17 Work with providers to include vaccinations, especially adult vaccines in regular health check-up packages
		18 Partner with providers (nursing homes, hospitals) to include service component for high end consumers (e.g., home delivery and administration, enrolment on 'helpline', online education)
Government	19 Introduce private (non-covered) vaccines in public market (government hospitals, PHCs) to enhance distribution points for non-UIP vaccines	
Penetrate deeper into the income pyramid	Pharmacos	20 Create second brands of adult vaccines to expand reach to low income sections of the pyramid through differential pricing
	Government	21 Explore innovating funding options – Engage with insurers through IRDA interventions, to include vaccines in insurance coverage, at least for high risk and co-morbidity situations

SOURCE: Team analysis

DETAILED INTERVENTIONS TO REACH EXPECTED SCENARIO

The interventions described above can be achieved through 11 main actions led by different stakeholder groups, as described below.

1. Set up PPP studies for analysis of disease burden, vaccine efficacy and complications.

Globally, PPPs have been successful in leveraging the capabilities of private and public stakeholders across surveillance, clinical evaluation and R&D. Such partnerships in India would address barriers to understanding the disease burden in the country (especially for emerging mandatory vaccines), the need for vaccine efficacy data (especially for HPV and influenza vaccines) and the limited availability of scientific studies on vaccine complications.

Already, a PPP between the central government's Department of Biotechnology, the Gates Foundation, Bharat Biotech and other knowledge partners such as AIIMS and Stanford University is developing a rotavirus vaccine at the price of USD 1. Government and donor support has already been provided for funding clinical trials, with Bharat Biotech leveraging its R&D capabilities.

Similarly, a partnership between GSK and Fiocruz (a public laboratory in Brazil) to study the cost effectiveness of the rotavirus and pneumococcal vaccines led to their subsequent inclusion in Brazil's national immunisation program.

2. Engage different stakeholders at various stages of the vaccine inclusion process to accelerate rollout and improve post-deployment penetration. To increase the number and coverage of vaccines, pharmaceutical firms also need to engage stakeholders consistently and on a long-term basis. Approaching a number of agencies including professional groups, e.g., IAP, IMA, state governments, the ministries of health and family welfare, NGOs (e.g., PATH), GAVI, research bodies (e.g., ICMR), and entrepreneurs can help establish the case for inclusion in the UIP and expedite approval (Exhibit 4.3).

Exhibit 4.3

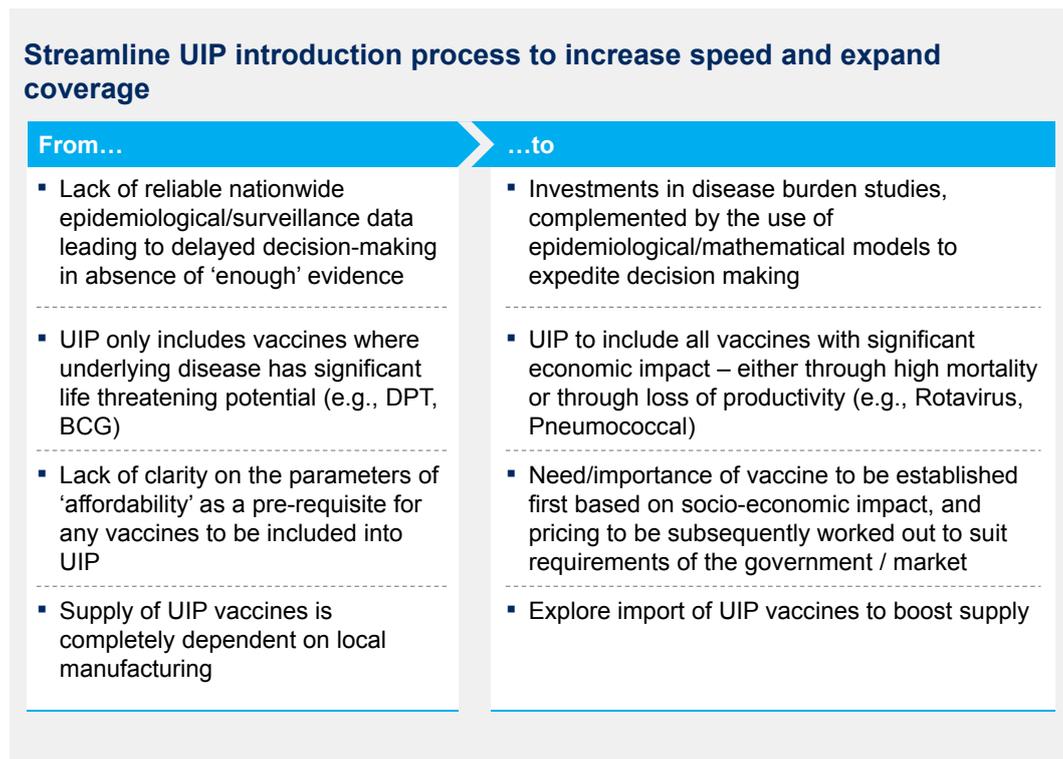
Engaging different stakeholders at various stages of the vaccine inclusion process can accelerate rollout and improve post deployment penetration

Process of inclusion	Key stakeholders	Desired support
Establish case for inclusion	<ul style="list-style-type: none"> Professional groups (IAP, IMA) State govt., MoH & FW NGOs (e.g., PATH), GAVI Research bodies (e.g., ICMR) 	<ul style="list-style-type: none"> Endorse pilot study Approve pilot rollout Provide funding support Collaborate to conduct study
Advocate for inclusion	<ul style="list-style-type: none"> NGOs (PATH), GAVI WHO, GAVI IAP Prof. groups (IAP, IMA) Policy entrepreneurs, Prof. groups (IAP, IMA) Media 	<ul style="list-style-type: none"> Support inclusion Recommend for inclusion in UIP Include in vaccination schedule Endorse inclusion to NTAGI Propagate case in technical journals, and workshops Propagate case to general public
Recommend inclusion	<ul style="list-style-type: none"> NTAGI 	<ul style="list-style-type: none"> Expedite process and recommend to MoH once adequate data available
Approve inclusion	<ul style="list-style-type: none"> MoH 	<ul style="list-style-type: none"> Expedite process and approve inclusion once adequate data available
Reward contract	<ul style="list-style-type: none"> UIP bureaucracy MoH 	<ul style="list-style-type: none"> Give supply contract for UIP

SOURCE: Expert interviews; secondary research

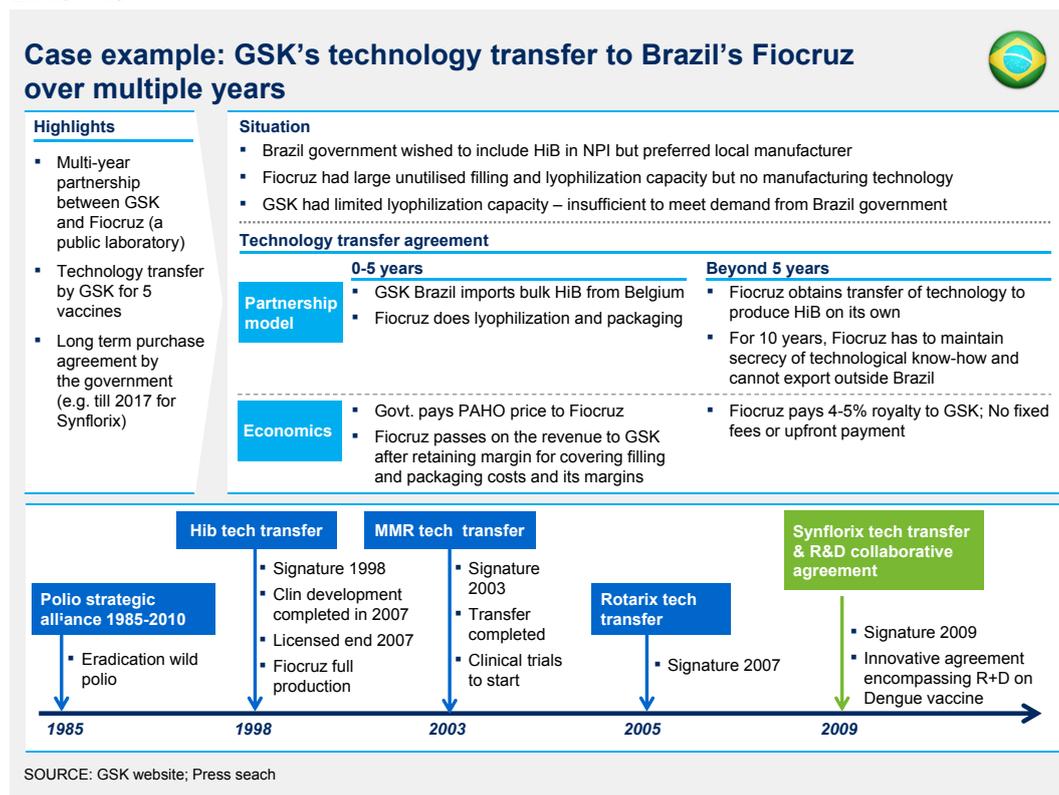
3. Streamline the UIP introduction process to increase speed and expand coverage. To facilitate the timely introduction of new drugs into the UIP, the speed of introduction should be improved and the decision making process rationalised. This would entail improving the quality of data on disease burdens and the efficacy of a vaccine, adding the socioeconomic impact of vaccines as a key criterion for vaccine inclusion in the UIP, and the potential inclusion of imported vaccines for public market usage (Exhibit 4.4).

Exhibit 4.4



4. Consider technology transfer to local players. With sufficient technology support, local players could significantly improve the immunisation record of a region. Multinational firms could engage in technology transfer to local players to provide that support, while the local government / player can offer committed uptake volumes or a royalty. GSK's partnership with Fiocruz in Brazil is one such case. A technology transfer partnership helped the Brazil government utilise Fiocruz's spare capacity and created market access for GSK (Exhibit 4.5).

Exhibit 4.5



5. Pursue design-to-cost of new UIP vaccines. The total cost of delivering a vaccine is a critical consideration for any new vaccine proposed for inclusion in the UIP programme. The cost is considerable given the scale and government funding involved. Designing these vaccines to increase cost-effectiveness will be an important means for reducing the total cost of delivery. Pharmaceutical companies could explore manufacturing and packaging innovations in this regard.

6. Provide incentives to manufacturers through larger committed volumes and tax / duty breaks.

To tackle the affordability issue, the government could encourage lower pricing through incentives to the manufacturers. For example, they could:

- Improve the economics for ramping up installed capacity through **longer duration purchase agreements** (e.g., three years instead of one year which is the current norm)
- Provide incentives to MNCs (manufacturing outside India) through tax and duty breaks on import of vaccines.

7. Secure donor funding for R&D and delivery of new UIP vaccines. Given the significant outlay involved on R&D and delivery systems for vaccines introduced into the UIP, additional funding will be needed. While existing donors such as GAVI will continue to play a role, new donors can also be sought, with a more significant role to play, e.g., BMGF and WHO. Options similar to GAVI's co-financing model could be explored.

8. Invest in public infrastructure and introduce alternative delivery mechanisms. The lack of infrastructure poses a significant challenge to successful delivery of vaccines. Pharmaceutical

companies can help improve infrastructure by investing in strengthening the cold chain and introducing alternative delivery channels such as a mass-market retail channel. An example in this regard is Farmacias de Similares's network of 3,400 pharmacies in Mexico and Latin America, with an adjacent medical clinic offering doctor consultations for around USD 2, serving more than 50 percent of the Mexican population.

Pharmaceutical firms can also innovate in vaccine delivery and administration methods to reduce the reliance on current infrastructure. This could take the form of oral or intradermal administration and patches. Firms could also help reduce wastage, e.g., by introducing multi dose vials with partitions/locks after every dose or create new delivery methods (e.g., improvements in temperature stability through heat-resistant vaccines/packaging or improvements in cold chain infrastructure through cooling systems, alternative energy refrigerators). Such innovations would help ease the pressure on last-mile infrastructure and reduce the burden on rural healthcare practitioners, hence increasing penetration.

9. Launch a dissemination campaign to create awareness on adult immunisation. India lags significantly behind developed vaccine markets in terms of penetration of adult vaccines such as those against typhoid and hepatitis A. One of the biggest barriers to growth of the adult vaccine market is poor awareness among adults about the existence of these vaccines, and the absence of an immunisation schedule for adults as is pursued for infants. The government could consider campaigns to create awareness about these vaccines and to create and disseminate an adult immunisation schedule (e.g., using posters, banners), through the public health delivery network.

10. Improve awareness of new UIP vaccines through mass media campaigns and the front-line-worker network. The Indian government has made significant investments in increasing awareness about the polio vaccine through the Pulse Polio program, using mass media channels as well as the network of front line workers (Accredited Social Health Activists or ASHAs, AWWs and ANMs) under the ICDS and NRHM programs. All India Radio can potentially cover more than 90 percent of the country's population, while the network of 8.5 lakh ASHAs visits about 35 lakh households every week. ASHA workers can be trained better to educate people on the health and economic implications of diseases and the importance and positive outcomes of these new vaccines. Also, a popular mass media campaign (e.g., the Amitabh Bachchan campaign for Pulse Polio) can help generate tremendous publicity and awareness for these vaccines.

11. Pursue donor funding for strengthening public health delivery systems. Existing as well as new donors can provide funding to strengthen public health delivery systems (e.g., setting up immunisation centres in PHCs). This is in line with several donors' priorities for strengthening public health infrastructure in India. A co-financing model as followed by GAVI is a potential option for ensuring engagement and ownership from the government, ensuring sustainability.

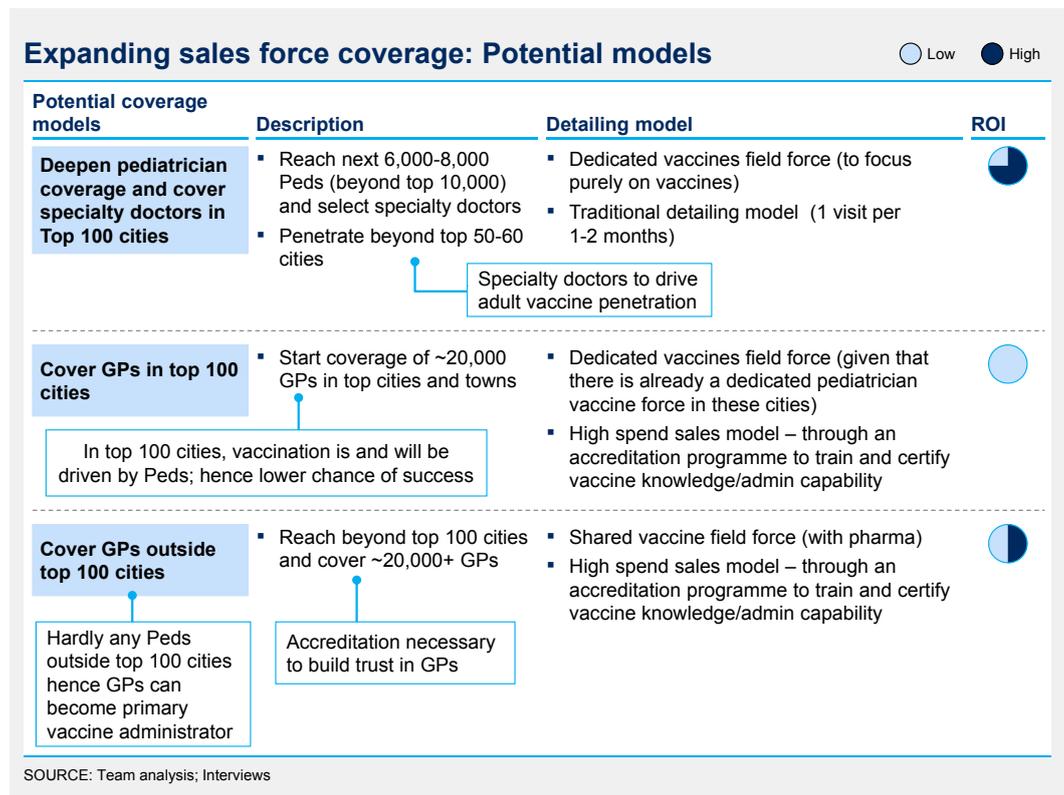
DETAILED INTERVENTIONS NEEDED TO REACH OPTIMISTIC SCENARIO

In addition to the above interventions, an additional set of ten actions would help achieve the optimistic scenario.

12. Scale up sales forces to cover GPs / CPs (and paramedics) and deepen coverage of paediatricians. Pharmaceutical manufacturers can increase coverage of vaccines to GPs, CPs, paediatricians and paramedics through a dedicated or shared vaccines sales force, in underpenetrated geographies. Deepening pediatrician coverage (beyond the top 6000-8000 pediatricians) and covering relevant specialty doctors in the top 100 cities with a dedicated vaccines sales force would be the first step. Pharma companies could then evaluate covering GPs / CPs outside the top 100 cities, where

vaccine penetration and paediatrician presence is relatively low. However, this sales force likely needs to be shared with a pharma force to make economic sense and retain high ROIs (Exhibit 4.6).

Exhibit 4.6



13. Introduce an immunisation accreditation programme for GPs / paramedics. To ensure quality control and create demand among customers and practitioners, pharmaceutical makers could introduce an accreditation program certifying the skill level and vaccine knowledge of a practitioner. This would help promote healthy competition among GPs and paramedics as well as ensure the standardisation of immunisation practices.

14. Support healthcare practitioners in setting up immunisation certified clinics through innovative service offerings. Pharmaceutical companies can support healthcare practitioners (HCPs) in establishing immunisation clinics or centres through service offerings within the new Medical Council of India guidelines such as enabling access to low-cost financing, facilitation of bulk purchases. Two recent examples demonstrate the success of this model. In the United States, GSK joined forces with the AI Borg chain of private pathology laboratories to deliver vaccine services, leveraging AI Borg's cold chain infrastructure to deliver the vaccines while providing training for 270 branch managers, physicians, technicians, receptionists and call agents. As a result, more than 160,000 people had received the vaccine at the centres till 2010. In the second example, Indian Immunologicals Ltd. (a government entity) provided cold storage infrastructure and vaccines directly to doctors (GPs and specialists), bypassing stockists and retailers, thus ensuring cost benefits. Services offered included setting up of cold storage facilities and delivery of vaccines through couriers, awareness campaigns through print and multimedia and value added services for patients such as antibody titre tests. At

present, there are more than 3,000 clinics using this option across the country covering 100 million to 120 million people.

15. Engage with key opinion leaders and specialty doctor associations to endorse and recommend relevant vaccines. For specific VPDs, specialty doctor associations (e.g., the Chest Society for the pneumococcal vaccine) and a set of key opinion leaders in some cases have demonstrated influence in the market. Their endorsement would be critical to ensuring broader community buy-in for the vaccine. Pharmaceutical companies can start a systematic process of engaging with these stakeholders.

16. Set up an institutional sales channel for one time optional and regular optional vaccines. Pharmaceutical companies should invest in building awareness about adult vaccines through joint immunisation awareness campaigns with corporates and educational institutions. They could also generate sales through immunisation camps at corporate / institution campuses (either institutionally sponsored or paid for by individuals).

17. Work with providers to include adult vaccinations in regular health check-up packages. Pharmaceutical companies should advocate bundling of adult vaccines as a component of annual / regular health check-ups through tie-ups with health care professionals (hospitals, clinics), insurers (for reimbursement) and corporates.

18. Partner with providers to include service component for high income segment. Pharmaceutical companies can help increase service revenue for providers and increase demand for vaccines from highest end of the income pyramid by providing additional services, at a cost, such as 'at home' administration of vaccines, enrolment for vaccine alerts, online updates and recommendations for upcoming vaccines.

19. Introduce private (non-covered) vaccines in the public market (government hospitals, PHCs) to increase distribution points. The public health delivery system comprising of district hospitals, community health centres or CHCs, PHCs, and other units, offers a massive distribution infrastructure, currently utilised primarily for distributing UIP vaccines. To increase access for non-UIP vaccines, the government could consider introducing distribution at a price for non-UIP vaccines.

20. Create second brands of adult vaccines to expand reach to low-income groups through differential pricing. The high prices of adult vaccines are a significant barrier to their widespread acceptance and consumption. Pharmaceutical companies can consider introducing low-priced second brands for some of these vaccines to make them affordable to a larger segment of the population. A successful example is Roche's launch of a low-priced version of the Hepatitis C vaccine (containing vial and syringe separately) to add to its higher priced variant (pre-filled syringe) (Exhibit 4.7).

Exhibit 4.7

Case example: Lower cost second brands to reach down the income pyramid

Roche launched a second brand of HCV treatment ...

- High prevalence of Hepatitis C virus (HCV) in Egypt. Egyptian government was unable to treat patients with Pegasys, Roche's treatment for HCV, due to budget constraints
- Sales potential had existed for Pegasys since its introduction in 2004 but were restricted to very limited income groups in the private sector, thus growth was relatively slow
- In 2006, Roche worked with the MoH to package Pegasys locally in a vial form. This move was in line with the MoH directive to encourage local manufacturing
- To differentiate the locally packaged Pegasys, it carries the trade name Pegferon and is packed in a vial form rather than the more convenient pre-filled syringe form sold in the private sector at lower price

Private market
Pegasys: pre-filled syringe



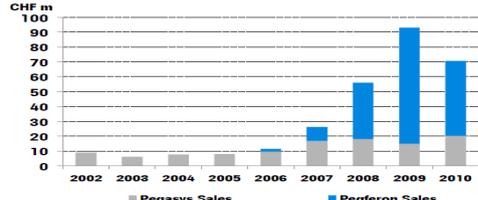
Second brand for Public market
Pegferon: vial + syringe



... which led to a 9-fold increase in sales

- Project resulted in more than 104,000 patients receiving access to treatment
- Sales of the vaccine dramatically increased 9-fold from 2005 to 2010; Egypt became a top 10 market for HCV for Roche
- Positioned Roche as the partner of the Ministry of Health, in both public and medical societies
- Avoided potential issues associated with parallel imports and reach into private market

Sales Performance - Before and after 2nd brand launch



Year	Pegasys Sales	Pegferon Sales	Total Sales
2002	10	0	10
2003	10	0	10
2004	10	0	10
2005	10	0	10
2006	10	0	10
2007	10	10	20
2008	10	40	50
2009	10	70	80
2010	10	60	70

SOURCE: Press search; team analysis

21. Engage with insurers to include vaccines in insurance coverage. The government could engage with insurers (possibly through IRDA interventions) to include vaccines as a part of medical insurance packages. There is a strong economic case for high-risk and co-morbidity situations, where the total cost to insurer for funding vaccines may be much lower in comparison to pay-outs.

The varying impact of the 21 interventions discussed above across the five vaccine segments is depicted in Exhibit 4.8.

Exhibit 4.8





India's vaccines market has the potential to transform over the next decade. Stakeholders such as government and industry need to play a crucial role in realising this transformation to counter the significant mortality associated with a small and under-penetrated vaccines market. Sustained, progressive and collaborative efforts by the industry and policy makers can make this potential a reality.

