Vaccine market in India
Opportunities for Dutch Vaccine industry
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Introduction

Global scenario
Asia is emerging as the vaccine hub of the world and India is on the go to play a key role in the vaccine market. The global vaccine market is expected to reach USD50 billion by the end of year 2017. A sharp increase in sales is expected in areas of influenza and hepatitis vaccines. Through the paediatric vaccines have been dominating the vaccine market in the past; a change in this trend is expected in the coming years due to a high demand forecasted for adult vaccines.

![Global Vaccine Market Growth 2000-2014](image)

**Fig 1**: The growth of vaccine market between 2000 and 2014. Between 2000 and 2014, the global vaccine market grew at a CAGR of 20.54%

Indian Vaccine Market
In India, close to 2 million lives are lost every year due to vaccine-preventable deaths, triple to those in US, Germany, China and Brazil. India also lags behind its global peers in vaccine coverage. Globally, it can be observed that there is a much larger proliferation of vaccines in Higher Income Countries (HIC) than there is in Middle Income Countries (MIC) and Lower Income Countries (LIC). More than half the global vaccine market is accounted for in Higher Income Countries. India accounts for less than 2% of the global market for vaccines. In India, the per capita spending on vaccines is extremely low, at USD 0.01, compared to USD 0.5 in China and USD 34.4 in the United States.
The Indian vaccine industry began as a network of state-owned manufacturers supplying basic paediatric vaccines to the national immunization program. In recent decades, the number of private owned firms active in the sector has grown rapidly. Their success in bringing low cost vaccine solutions to the public vaccine markets is an important driver behind the emergence of the sector. As the industry is becoming more sophisticated, there is an increasing focus on innovation. Across the industry, a dozen or so new vaccines are in clinical development. Diseases and viruses against which vaccines are being developed include, amongst others – Rotavirus, Japanese Encephalitis, Typhoid and Malaria. Many more projects are at early stages, including efforts to combat Dengue, Zika and Chikungunya.

The Indian government supports these initiatives through growing investment in R&D. Relevant government funding agencies like the Department of Biotechnology (DBT), The Indian Council of Medical Research (ICMR) and Indian Council of Agricultural Research (ICAR) have been scaling up their investment in vaccine related R&D.

The Indian vaccine industry has been instrumental in facilitating cost effective vaccination in India and also export of vaccines to majority of the developing and underdeveloped world.

### Export trends

The Global Alliance for Vaccines and Immunization (GAVI), The United Nations Children Emergency Fund (UNICEF) and other international agencies have doubled their procurement of Vaccines from India during the year 2010-2014. UNICEF’s procurement of vaccines from India has grown at a CAGR of 25.3% between 2003 and 2014. Procurement of vaccines by other global agencies from India has shown a similar increase over comparable time period.
Fig 3: UNICEF vaccine procurements from India between 2003 and 2014. During the period, the UNICEF vaccine procurement from India grew by a CAGR of 25.3%.

Key drivers for the vaccine market in India:

a) Relatively low cost of manufacturing;
b) Reasonable Research & Development expenditure;
c) Low cost of clinical trials;
d) Availability of skilled manpower and scientists;
e) A large, local consumer base;
f) Assistance from the relevant Government bodies;
g) Export oriented production.

Main market players:

A large number of vaccine manufacturers have set up their operations in and around Hyderabad and Pune regions. Hyderabad in Telangana is considered the epicentre for the Pharma and Vaccine industry in India owing to the presence of large pharmaceutical and vaccine producers.

The key market makers in the Indian vaccine market (human and animals) are as follows:

a) Serum Institute of India Limited
b) Panacea Biotech Limited
c) Venkateshwara Hatcheries Limited
d) Indian Immunologicals Limited
e) GlaxoSmithKline Pharma Limited
f) Aventis Pharma Limited
g) Shantha Biotechnics
h) Eli Lilly India  
i) Haffkine Bio Pharma Corporation Limited (HBCL)  
j) Intervet India  
k) Lupin  
l) Avesthagen  
m) Wyeth  
n) Merck  
o) Bharat Biotech Limited  
p) Biological E Limited  
q) CPL Biologicals Limited  
r) USV Biopharmaceuticals Limited

Challenges and Opportunities
Currently, the vaccine industry in India faces the following challenges, which in turn could open up opportunities for the Dutch entrepreneurs.

   a) Lack of sufficient cold chain infrastructure;
   b) Minimal resource allocation for Research and Development (R&D) of complex vaccines;
   c) Access to state-of-the-art technologies and equipment;
   d) Evolving Intellectual Property (IP) regime;
   e) Regulatory hurdles;
   f) Commercialisation of technology;
   g) Process optimisation challenges.

Lack of sufficient cold chain infrastructure
The supply chain of the vaccines has to be strictly monitored for temperatures as the vaccines tend to be very sensitive to temperature variations. India being a large country, logistical challenges exist in distributing the vaccines to various parts of the country, especially to small villages. Storing the vaccines in temperature controlled boxes proves to be challenging in India, because of problems with electricity supply, which in many places in India tends to get interrupted frequently.

Minimal resource allocation for Research and Development (R&D) of complex vaccines
The Indian vaccine industry has been gradually building its R&D capacity for at least a decade. Spurred by the prospect of sales to the Global Alliance for Vaccines and Immunizations (GAVI), firms have strengthened their capabilities in biotechnology, built collaborations with international partners, and moved from basic vaccines to more sophisticated technologies. However, resource allocation for R&D in complex vaccines has been, at best, dismal. The Indian vaccine industry has for years focused on improving generic vaccines, rather than develop vaccines for newer diseases such as Zika. This provides a very good opportunity for Dutch companies to work in Indian vaccine industry as the lower cost base and availability of cheaper
human resources would allow them to channel ground breaking research into complex vaccines in India.

**Access to state-of-the-art technologies and equipment**

Indian vaccine industry has for years lagged behind the western world owing to lack of access to state-of-the-art technologies and equipment. The FDI rules are still evolving, slowing giving the industry the much needed access to latest technologies and equipment. The changing landscape offers Dutch companies a very good opportunity to enter the market of supplying technology and equipment.

**Evolving Intellectual Property (IP) regime**

The Intellectual Property Regime in India vis-à-vis pharmaceutical sector has been viewed in bad light for a long time, owing to the support the successive Governments have shown towards generic market. However, the evolving IP regime has increasingly become reassuring to IP holders from worldwide who are looking at the Indian market. The Patents Act, 1970, which was amended after the turn of the century to bring it in line with global standards in Intellectual Property Rights, has strong enforcement provisions in place, to protect the Intellectual Properties of companies seeking to enter the Indian market. Dutch vaccines companies which enter this market can be assured of their intellectual properties being protected.

**Regulatory hurdles**

Regulatory pathway for vaccines is currently laden with delays and redundancies. All vaccines are classified as new drugs even if they are follow-on products to currently approved vaccines. There are multiple agencies involved in the regulatory process and the overall timeline for product approval is much stretched. Globally, most advanced regulatory frameworks have specified time stipulations that obligate regulators to respond within a defined period and provide alternatives for industry. India, however, has not yet reached that level and therefore, there exists still various regulatory hurdles in bringing new vaccines to market in India.

**Commercialisation of technology**

Although the Indian vaccine industry has come a long way in the past few decades, one area that the sector still lags behind is commercialisation of technologies. The Indian vaccine industry has made significant advancements in the R&D of vaccines, especially of the generic variety, but the methodologies of commercializing the same are still foreign to the industry. Dutch vaccine industry, with its acumen and expertise in commercialising new technologies in the sector, could contribute significantly to the growth of the vaccine industry in India.

**Process optimisation challenges**

Indian vaccine companies are moving from basic vaccines to more sophisticated technologies and companies are facing challenges in process optimisation. The productivity of the Indian vaccine industry could be optimised, by using better techniques with higher quality standards and by the use of superior equipment. The Dutch industry, with its ever strong focus on optimisation gains has the opportunity to work with the Indian vaccine industry, thereby help turning it into a well-oiled machine.
All of the above challenges offer infinite opportunities to Dutch entrepreneurs. The Netherlands is already a longstanding partner of the vaccine industry in India and has been providing equipment and technology for the whole value chain. With the ever growing demand for vaccines and India positioning itself as the key manufacturer/exporter of vaccines, there exist a lot of unexplored potential for the Dutch vaccine industry in the Indian market.

**Relevant trade fairs**

A few conferences / fairs are organized in India in the field of Vaccines each year. In connection with these exhibitions, Netherlands Embassy and Netherlands Business Support Offices (NBSO) organize events, such as Holland pavilion and/or networking events, so as to provide the participating Dutch companies with a wholesome experience of the industry.

The upcoming events in the sector are:

a) **8th Annual Vaccine World Summit**
   Hyderabad, India
   20 – 21 February, 2018

b) **BioAsia 2018**
   Hyderabad – India
   6-8 February, 2018
   [http://bioasia.in/](http://bioasia.in/)

World Vaccine Summit is an annual event in India. Since 2014 more than 4 Dutch companies have participated in World Vaccine Summit and have bagged good business deals.

**What we can offer**

Dutch Trade Network in India (TNI) has very good contacts with main market participants in the vaccine market and also various regulatory authorities in India vis-à-vis vaccine industry. TNI offers active support to Dutch companies interested in doing business in India in finding potential clients / JV partners / participating in the trade fairs etc.

**Contact**

You can always contact us for more information at:

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Netherlands Business Support Office, Bangalore, Email: Bangalore@nbso.info.
Image Gallery

**Image 1:** Applikon Biotechnology participated in the World Vaccine Summit 2016, held at Hyderabad, India. In the picture is the Applikon team at World Vaccine Summit, 2016 with the representative of NBSO Hyderabad.

**Image 2:** Viroclinics Biosciences B.V. participated in the World Vaccine Summit 2016, held at Hyderabad, India. In the picture is the Viroclinics representative at World Vaccine Summit, 2016 with the representative of NBSO Hyderabad.
Colofon

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