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## **ANALYSIS OF TECHNOLOGY ACQUISITION IMPACT IN CURRENT AND FUTURE SITUATION OF VACCINE INDUSTRY IN LATECOMER COUNTRIES**

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### **ABSTRACT**

Many ongoing changes influence vaccine industry over decades in Iran. Vaccine industry with high strategic importance has developed increasingly. The aim of this study is to explore the improvement pattern of technology acquisition in Iranian Vaccine Industry, Also identifying the pattern of vaccine technology acquisition in latecomer countries base on statistical trend analysis. This industry has experienced a quick growth in the last decades supported and protected by public policies and markets. Obviously, technology policy is the main characteristic of such development.

**Keywords:** *Technology Acquisition, Technological Capability, Innovation, Policy Making*

### **INTRODUCTION**

Iran as one of the most populated countries in the region is facing with the fast growing youth populace and definitely needs a health care system that could be able to provide excessive demands of various public health infrastructures and services throughout the country. The total healthcare expenditure is expected to rise from \$24.3 billion in 2008, to \$50 billion in 2015. The public-governmental structures as well as private sector and non-governmental organization (NGOs) altogether are playing major roles in order to dealing with the public problems. The public-governmental structures have facilitated public health preventive services through the establishment a widespread Primary Health Care Network. This network is conducting immunization program as one of the most cost effective public health interventions (WHO 2002a; Plotkin 2004; Blume *et al.*, 2005). At the moment, immunization of children is accessible to most in all urban and rural areas. Such initiative could be possibly done by providing vaccines.

Vaccines have significantly decreased maternal mortality rates and increased life expectancy at birth. The industry providing vaccines to the world market is exclusively conquered by a few oligopolistic firms belonging to some of the largest pharmaceutical companies. Those companies own the executive capabilities and can afford the high funds to invest in this dynamic trade .The main markets in terms of value are located in developed countries such as US, Canada, Europe and Japan. They have been characterized by their highly skilled technicians, high investments in research and development (R&D) and strong capabilities to perform the first stages of vaccine development process. The most successful matters have been acquired or formed by alliances with “Big Pharma”.

Local manufacturers in developing countries have recently been re-emerging in the vaccine industry and have performed an important role by providing low cost products by using old technologies usually required by their own public programs that are no longer produced by “Big Pharma” firms. However, they have struggled with acquiring the necessary capabilities for fulfilling the process of technical change and develop the vaccines for the neglected diseases of developing and poorer countries. Such needs in technological dimension of the industry go beyond the simple building of production capacity.

In Iran also national interest has been concentrated toward a successful and indigenous immunization program and almost all related industries sum up in Razi Vaccine & Serum Institute. As a result of governmental unidirectional policy in Iran, just like mentioned issue for other developing countries, innovation in the technological frontier has dealt with huge challenges for Iranian Vaccine Industry. In fact, achieving foreign technology is very crucial as an important source of knowledge and it should be part of strategic plan in order to supply the rising demands of public market for more advanced vaccines in suitable time. Therefore, the main firms have developed important capabilities rapidly and under very

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specific circumstances within the country. Although they have reversed the government's high dependence on importing vaccines but they have been unable to finish the technological transition to date. They have just been able to imitate and improve some existing non-patented technologies. So, being a fast-follower maybe a natural alternative strategy in a business which is dominated by few oligopolistic firms. Because of that, the major aim of these companies for being technological frontier in the country is seeking self-sufficiency in such a sector where the new required technologies are well protected by governmental regulations through National Immunization Program and innovation seems to be a result of high investments in R&D field.

### **Theoretical Context**

#### *Dynamics of Innovation in the Vaccine Sector*

Innovation is playing an important role in terms of developing every firm, industry and even each nation. Despite of innovation what really matters for the development is vital capability to generate innovation in the long run (Dahlman *et al.*, 1987; Rush *et al.*, 2007). Therefore, for better understanding of how innovation has been created, many academics have used the technological capability framework in last thirty years. Literature on technological accumulation in latecomer contexts shows that catching-up process of firms and industries develops through a common linear pattern if we consider attainment of foreign technologies and development of local innovative capabilities as two sources of knowledge (e.g. Dahlman & Fonseca, 1987; Bell & Pavitt, 1993, 1995; Hobday, 1995; Kim, 1997).

#### *National Systems of Innovation*

The first challenge in relation with interactions among institutions within the borders of a nation and their influence on economic growth is attributed to List in 1841 (Lundvall, 1992a; Freeman, 1995). This approach was first broadly used in order to investigate the relationship among national elements contributing to economic growth and innovative performance within the context of countries, and to stress similarities and differences across countries (e.g. Freeman, 1987; Dosi *et al.*, 1988; Lundvall, 1992b; Nelson, 1993). It does not mean that infuse the process of innovation are restricted or taken place only in a national dimension.

Another common view of these studies was related to the systemic nature of innovation. Likewise in this view R&D is not just as the only part of innovation process but known as a system where several elements interact and influence the whole process (Nelson and Rosenberg, 1993). In recent years several manufacturers are gradually developing their abilities for innovation.

#### *Relation between Innovation and Technological Capability Development*

Many researchers have studied the process of technological capability accumulation as a method of understanding whether innovation has been generated In last thirty years (e.g. Bell *et al.*, 1984; Fransman and King, 1984; Katz, 1987; Lall, 1992; Bell and Pavitt, 1992, 1993, 1995; Hobday, 1995; Ernst *et al.*, 1998a; Dutrénit, 2000, 2007; Figueiredo, 2001). Accumulation of the capabilities needed to generate continuous technical change is, consequently, essential for competitiveness (Bell and Pavitt, 1995). However, as stressed by Pavitt (1987), difficulty and nature of technology mean that development of technological competencies is essentially based on learning processes. Despite of differences across industrial sectors even for the technology borrowers, the accumulation of technological capabilities is not always an automatic process but requires substantial, frequent and explicit efforts in terms of undertaking different types of learning activities. According to the Bell learning refers to “acquisition of increased technological capacity – e.g. technical skills and knowledge – by individuals and organizations”. Fransman (1984) pointed out the high specificity of knowledge accumulation process.

#### *Innovation in the Knowledge Frontier*

There has been major breakthrough in the development of new vaccines in last decades (WHO, 2002b). Although R & D in vaccine industry is risky, costly and lengthy (WHO, 2002b), new technologies will guarantee its secure implication in current century (Plotkin and Plotkin, 2004). These new technologies are protected by patents, which impede the development in particular domains (Plotkin, 2005c). Catching up to this business becomes difficult for new entrants more and more. In turn, it makes them rely more often on technology transfers and licensing (Milstien *et al.*, 2007). Innovation and development of

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vaccines in the knowledge frontier is certainly one of the most complex issues influence the development of the Iranian vaccine industries. Consequently, Iranian vaccine industries have been unable to keep up with international developments.

### *Market*

All researchers agree that market is a basic motivation that may affects the development of technological capabilities by its competitive push. The huge Iranian public market for vaccine, along with governmental policies against internal competition and external players, has made a free field for Iranian vaccine industries growth. But the main issue has still remained. The thing is whether promoting long-term development of technological capabilities will be successful or not within current context of Iranian vaccine industries. In fact, according to Bell and Pavitt (1993) lack of competitive pressures and challenge served as non-incentives for the development of firms in centralized economies. Lessening technology transfer from “Big Pharma”, even non-mature one, regarding to Iranian government's strategies and policies does not seem to be beneficial for Iranian vaccine industries

### *Government Policies, Institutions and Regulation*

It has been widely agreed that national idiosyncrasies highly influence the system of innovation of the firms, and states have important roles in mediating the elements of this system (Lundvall, 1992b; Nelson, 1993). Freeman (1995) has pointed out that national policies remain decisive for catching-up strategies in developing countries. In fact, government has a major role. As well as policies for protecting and stimulating Iranian vaccine market, greater emphasis should be directed toward other aspects of the government initiatives which are directly encouraging or affecting vaccine industry. These include health and vaccination policies, S&T policies, R&D projects funding and effects of these policies on the interactions between Iranian vaccine industries and other domestic and foreign actors. The regulatory aspects also highly influence on pharmaceutical industry. The trend toward increasing regulation threatens vaccine development due to increasing costs and uncertain returns (Milstien and Candries, 2002).

### *International Context of Vaccine Industry, Market and Institutions in*

“Big Farma” companies are associated in the global pharmacological trade. They also have played key roles in vaccine business in recent last decades. These include Merck & Co. (Merck Sharp & Dohme), Sanofi-Aventis (Sanofi-Pasteur), Wyeth (Wyeth Pharmaceuticals), GlaxoSmithKline Biological and Novartis (Novartis Vaccines). Total sale of these four companies in 2000 was about 80% of the global market of vaccines (Gréco, 2002).

Recent estimations demonstrate that this image remains unchanged. An clarifying portrait of the dynamics of acquisitions, mergers and alliances of the vaccine industry pushed by the current “Big Pharma” has shown in Figure 1.

The medicine market in Iran is heavily in favor of generic medicines, which contributed US \$1.23billion in 2009. In 2006, fifty five pharmaceutical companies in Iran produce more than 96 percent of medicines over the market. The market share of local production has declined from 85.2% to 63.4% from last eight years till now (2009). At the same time value of importation has jumped from 14.8% to 36.6%. Although government imposed 90% tariff on importing but 1.8 million units of pharmaceutical products were imported into the country in 2009. Meanwhile, Iran has produced a wide range of medicines for cancer, diabetes, infection and depression treatments.

### *Pharmaceutical Companies*

#### *Developing Countries Vaccine Manufacturers Network (DCVMN)*

DCVMN has been considered by some as the main representative of emerging manufacturers in the international scenario (Jadhav *et al.*, 2008). The need for mechanisms to strengthen the capabilities for production and development as well as easy access to new technologies is already addressed by the main emerging manufacturers. In 2001 most of them formed Developing Countries Vaccine Manufacturers Network (DCVMN) which is an international non-profit and public health organization. Some of the members have WHO pre-qualification, which means they comply with WHO required standards for producing vaccines and are able to sell their products to international organizations (e.g. UNICEF, GAVI,

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PAHO). According to Milstien (2005), obtaining WHO pre-qualification is indicative of their viability. Other members are still pursuing this status. The list of members is shown in Table 1.

Milstien *et al.*, (1997) studied thirty one manufacturers from 13 countries. Seven critical elements for viability were assessed. These elements were proposed based on the characteristics of successful producers and only five manufacturers were considered viable whilst fifteen fell into the second group and eleven into the low viability group. Amongst the main findings, three of need to be mentioned: 1) fundamental importance of governmental commitment to the viability of the manufacturers, 2) size of the national population as important but not critical for the success of local manufacturers, 3) The rationalization of facilities within countries as means of increasing the viability of production. Moreover, the authors added that the current technological standard of vaccine and vaccine production require a new and expensive quality system where quality assurance capabilities are having more importance. Producing a new vaccine can take decades. Vaccine development poses huge scientific challenges and requires large amounts of funding and time consuming. If developing a new vaccine was successful and a licensed product was marketed properly then those costs are usually recovered. In one hand burden of some diseases is greater in developing countries, in another hand make developed country vaccine manufacturers hesitant to develop vaccines against these poverty-related diseases due to a belief that costs will not be recovered. Although original six vaccines in Expanded Program on Immunization (EPI) are generally inexpensive, costs of many new vaccines are not affordable for developing countries. Whenever new manufacturers are allowed to come into the market, vaccine prices would decrease through increased competition. From 2000 to 2008 the global vaccine market almost tripled, reaching over US\$ 17 billion in global revenue by mid-2008 (Milstien *et al.*, 2006). This 16% annually growth is over double the growth rate of therapeutic drugs (WHO, 2009b) and most of that can be gained through new vaccines sales. Although many developing country manufacturers have recently entered to the market but still more expensive vaccines are producing by only a few multinational companies. Vaccine market has changed dramatically since early 1970s, with a significant reduction in global vaccine suppliers. So vaccine supply has remained dependent on a limited number of manufacturers as always.

#### ***Pharmaceutical Companies in Iran***

There are ninety two active pharmaceutical companies in Iran. Social Security Investment Company (SSIC) which is affiliated to Ministry of Welfare, presently owns and controls 22 pharmaceutical manufacturing companies and possesses a 40% share of total pharmaceutical production in Iran. Darou Pakhsh is a leading pharmaceuticals company which has majority-owned by Social Security Organization. There are over 100 Iranian companies representing the international suppliers in this market. Major international companies are present in Iranian market such as 3M, Boston Medical Group, Aesculap, Cordis, Ohmeda.

#### ***Consequence of Technology Transfer on Access to Vaccines***

Although proving impact of transferred technology on regional access is difficult but in vaccines field, this is much easier. There are numerous examples of technology transfer to developing countries result better access to vaccines, with a consequent improvement in population health. Previously, technology was transferred to numerous developing for many basic vaccines countries in order to serving national supply (Barton, 2006). Consequently, 64% of all basic EPI vaccines purchased by United Nations related agencies are now made by developing country manufacturers currently. Also there are many more recent examples where technology transfer has demonstrated improved access for new vaccines.

#### ***Technology Transfer Initiatives and Trends***

Technology transfer is about sharing the knowledge from those who know-how to those who do not. It contains factors such as knowledge absorbing capacity of recipient countries. In many areas a simple license of proprietary technology is termed “technology transfer”. In this study such licenses did not take to account as technology transfer unless they have got associated with training and technical support for recipient. Therefore, the term “technology transfer” is limited to activities that involve a capacity-building component at the recipient site to enable it for producing vaccines. Transferring vaccine technology may have a huge impact on access to vaccines and health improvement later on. However few evaluations

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have taken place about number of technology transfers, exact donors and recipients, and most importantly about drivers and barriers. All these aspects could contribute better recognition of future technologies, donors and recipients, and how to promote successful transferring method which can lead local or regional access improvements. Our findings showed that drivers and barriers of technology transfer for vaccines varied among regions and sectors. Semi quantitative studies were undertaken to analyze the main players, models of technology transfer and trends.

#### **Trends in Recipient Countries**

Figure 2 shows the distribution of technology recipients by country. It reveals that the vast majority of transfers have taken place toward China, India, Brazil and Indonesia. Rate of technology transfers have increased exponentially towards India, China and Brazil over past two decades (Figure 3).

#### **Mode and Purpose of Technology Transfer Trends**

Suppliers was analyzed in order to their trends in different types of transfers (south–south versus north–south, and non-profit-making versus profit-making).

Type of vaccines were also assessed (Figure 4). Assessments demonstrated that these have nearly all been for licensed vaccines, but mostly for influenza, hepatitis B, rotavirus and Hib.

In some cases recipients have not yet achieved production and market authorization. Cases are particularly related to rotavirus and influenza vaccines which have initiated only in past 5 years. Findings also showed that technology transfers of vaccines are done with technologies at donor's different level of maturity, ranging from R&D-stage experimental technologies and pilot processes to turnkey transfer of large-scale production processes.

In addition, different mechanisms of transfer have been used ranging from all associated technologies, through a stepwise process over several years beginning with quality control and distribution to full local production (Figure 5).

As discussed later, research-based vaccine industries tend to be in stage function in order to confide recipients and build up trustworthy relationships among them and donors over time. In some cases, technology transfer is not on the manufacturing process but will be taken place for improving quality control and quality assurance processes at the recipient side.

The relative frequencies and examples of the various stages of technology transfer are given in Table 2. It shows that pilot-stage transfer is the most common transfer method which is following by full-scale production processes.

This survey also revealed various models of conducting technology transfers, including bilateral agreements between a technology donor and technology recipient. These models used, and their relative frequencies, are shown in Table 3.

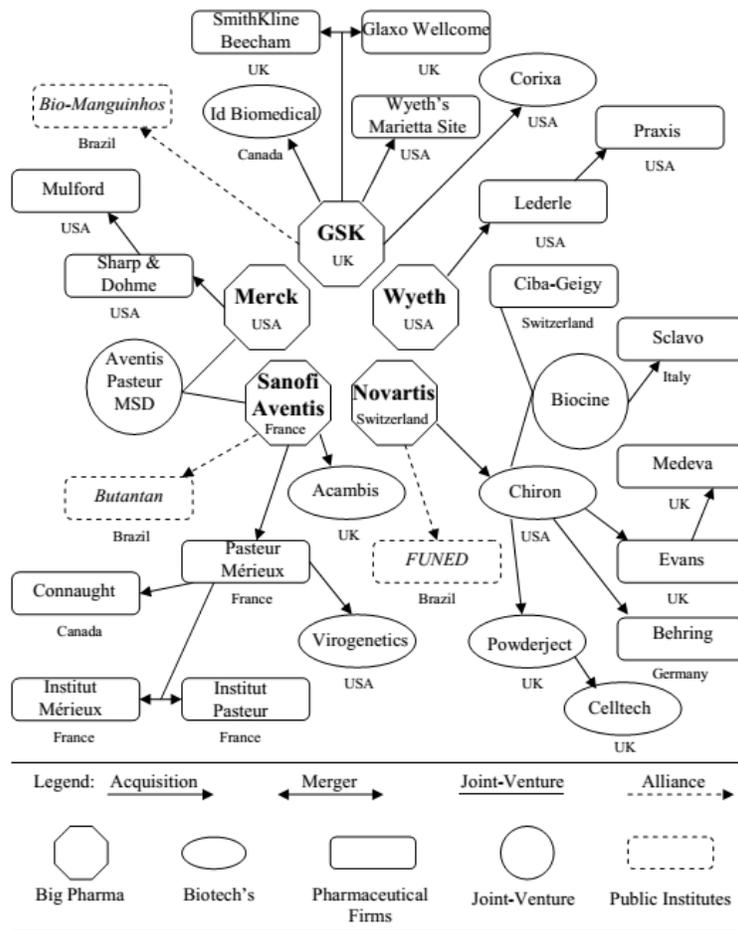
## **RESULTS AND DISCUSSION**

### **Discussion**

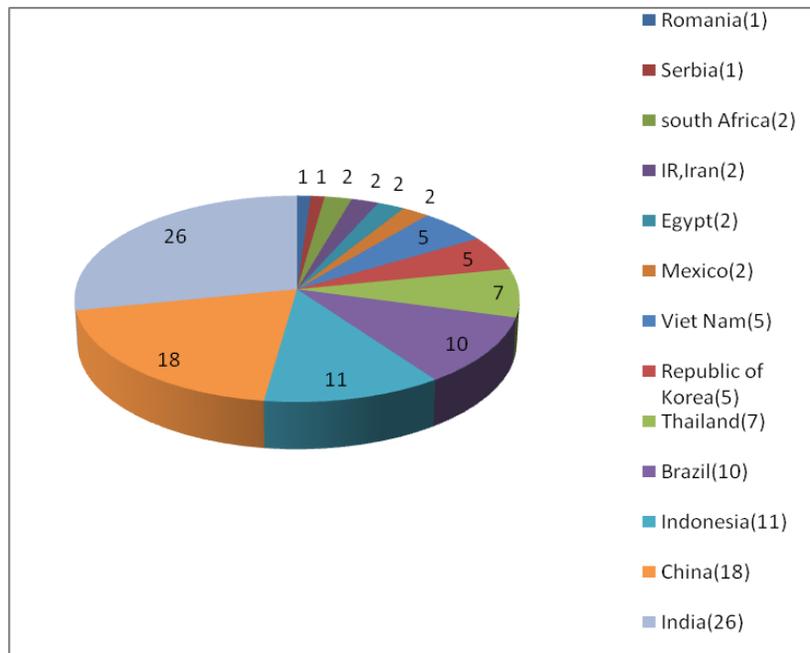
This study has set up in order to evaluate these main questions as below:

- 1- Which condition is important for successful technology acquisition process and how vaccines technology transfers impact on national manufacturer?
- 2- What is the role of vaccine technology transfer in the future?

Regarding first question- through interviews with professionals and researchers- it revealed that successful technology acquisition process vary by nature of public–private relation, profit and donor-driven objectives.

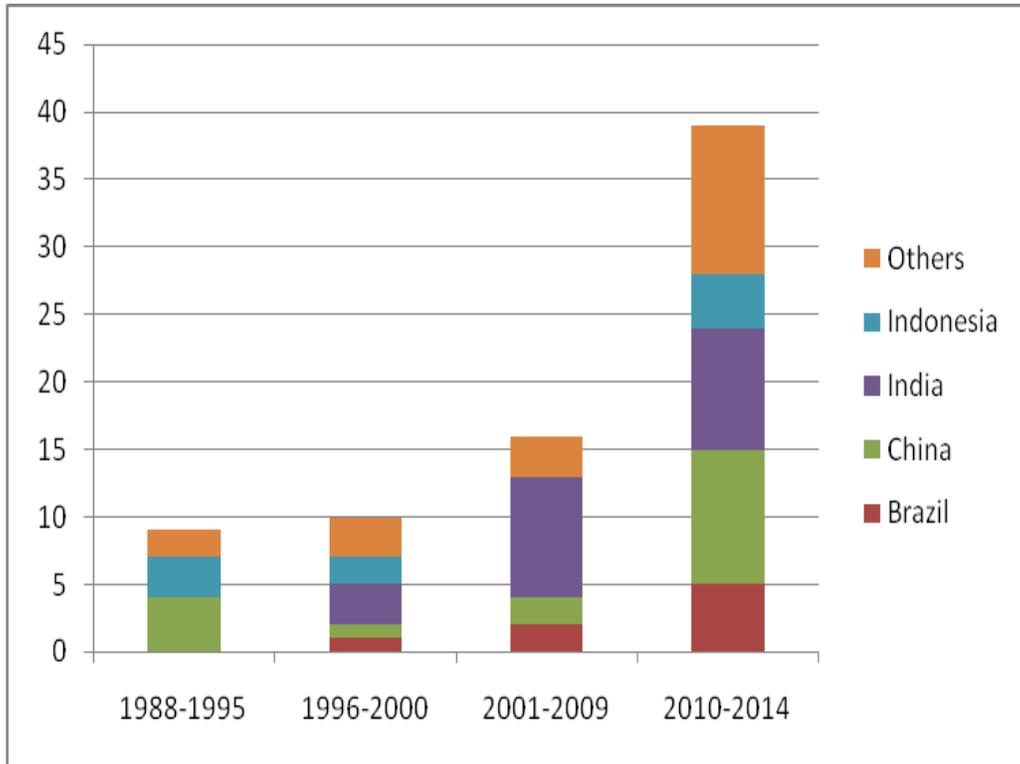


**Figure 1: Mergers, Acquisitions and Alliances in the Vaccine Industry**

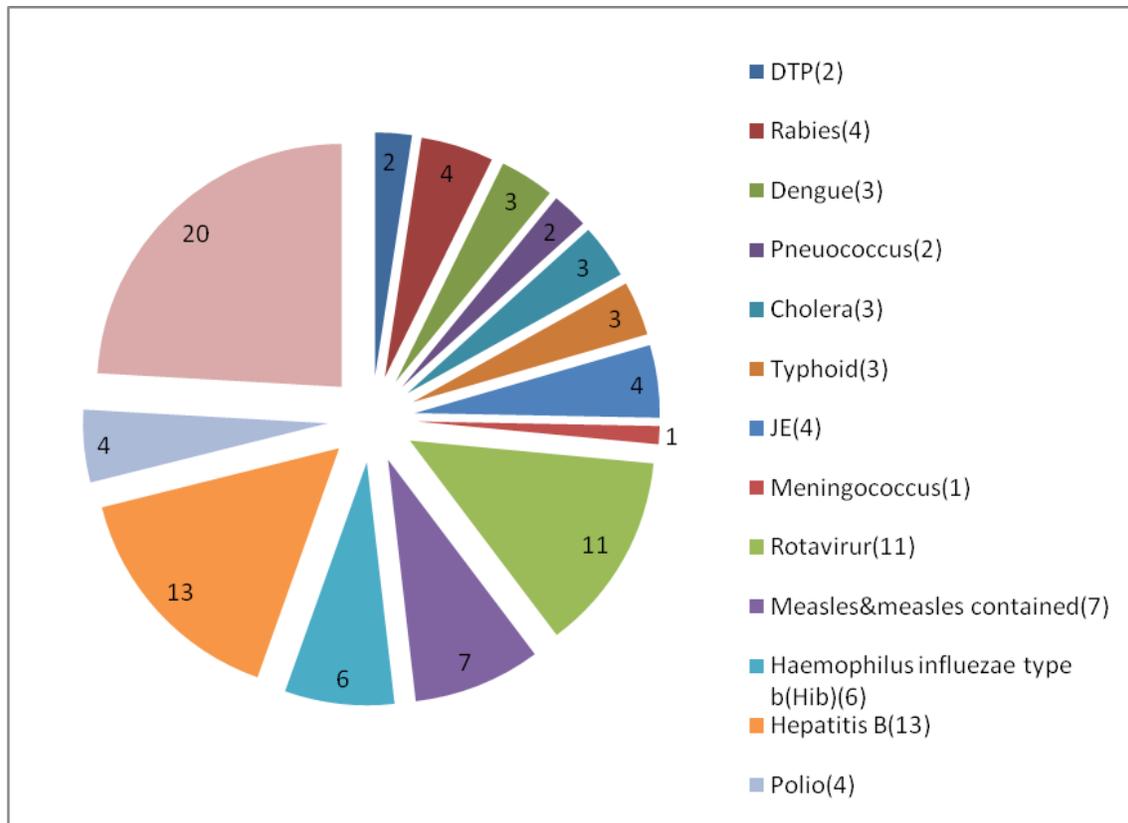


**Figure 2: Technology recipient countries**

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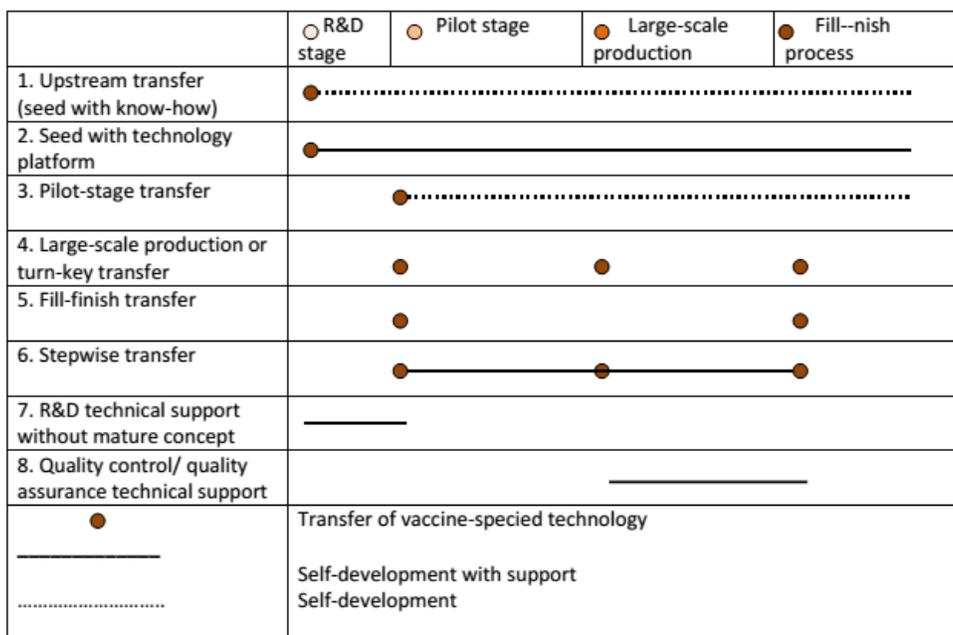


**Figure 3: Technology recipient countries over time**



**Figure 4: Disease targets (vaccines)**

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**Figure 5: Maturity of technology being transferred**

**Table 1: Developing Countries Vaccine Manufacturers Network – DCVMN**

Vaccine Manufacturer/member	Country	Category1
Bio Farma	Indonesia	FM
Bio-Manguinhos/Fiocruz	Brazil	FM
Bionet-Asia Co., Ltd	Thailand	FM
Finlay Instituto Cuba FM	Cuba	FM
LG Life Sciences	Korea	FM
Panacea Biotec	India	FM
Serum Institute of India	India	FM
Bharat Biotech	India	PFM
Biological E Ltd	India	PFM
Indian Immunobiologicals Ltd	India	PFM
Instituto Butantan	Brazil	PFM
JGAD	China	PFM
The Biovac Institute	South Africa	PFM
Zydus	India	PFM
CNBG	China	AM
INNOVAX	China	AM
IVAC	Vietnam	AM
Queen Saovabha Memorial Institute	Thailand	AM
Razi Vaccine & Serum Research Institute	Iran	AM
TIANYUAN Bio-Pharma	China	AM
VABIOTECH	Vietnam	AM
VACSERA	Egypt	AM
Birmex	Mexico	PFM

1 FM – Full Member (manufacturers with WHO pre-qualification and with a fully functional National Regulatory Authority – NRA); PFM – Prospective Full Member (manufacturers of countries with fully functional NRA and working towards attaining status of WHO pre-qualification); AM – Associate Member (manufacturers committed to become viable but from countries with no fully functional NRA).

Source: DCVMN (web page, accessed in 10/2009).

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**Table 2: Maturity of technology transfers**

	Quantity	Example
Upstream transfer (seed with know-how)	5	NIH–Bharat, typhoid Vi-DT
Seed with technology platform	11	NIH–Sinopharm, with PATH, rotavirus vaccine
Pilot-stage transfer	25	NVI–SII, Hib vaccine
Large-scale production or turnkey transfer	17	JPRI–BioFarma, oral polio vaccine
Fill-finish transfer	6	Sanofi–GPO Mèrieux, mumps, measles and rubella (MMR) vaccine
Stepwise transfer	7	Sanofi–Butantan, seasonal flu
R&D technical support or joint development	9	GSK–Fiocruz, dengue
Quality control/quality assurance technical support	5	GSK–Vacsera, general technical support

*GPO, [Thai] Government Pharmaceutical Organization; JPRI, Japanese Poliomyelitis Research Institute; NIH, National Institutes of Health; SII, Serum Institute of India Ltd; Vi-DT, typhoid Vi-polysaccharide–diphtheria toxoid conjugate vaccine*

**Table 3: Models of technology transfer and approach to transfer**

	Quantity	Example
Bilateral know-how transfer or joint development	41	Biken–GPO, Japanese encephalitis vaccine
Joint venture and acquisition	12	Sanofi–GPO Mèrieux
De novo manufacture	8	GSK–Singapore
Single recipient joint development with active input by facilitation entity	8	NIH–SII, with MVP, meningitis A vaccine
Shared technology platform	9	NIH–Shantha, with PATH, rotavirus vaccine
Technology transfer hub	2	NVI to several DCVM, with WHO, flu vaccine

*Source: MVP, Meningitis Vaccine Project.*

It is essential that the objectives, aims, benefits and sustainability plans are clearly defined within a well demonstrated local relevance context. Successful technology acquisition process is also dependent on human resources at the recipient side. Staff expertise in technical areas such as R&D, scaling-up and production capacity, analytical methods, quality assurance, regulatory affairs and clinical development will definitely play major roles across all stages of vaccine productions. In addition, an experienced business development manager is required to negotiate licenses and establish the business model as well as project leader who can allocate reasonable funding for the project. Meanwhile, governmental commitment is necessary to the project, in terms of purchasing the locally produced vaccines, or having a market plan with an agreed price. Participants all agreed that vaccine technology acquisition will be having impact on local manufacturers which are currently producing low-cost basic vaccines in long term period.

There was also general agreement that current generic manufacturers might be squeezed by entering new technologies. Participants emphasized that these national manufacturer can be rescued by an established national vaccine policy on purchasing and investment. Such survival plan may also be assured through investment in R&D and being able to produce newer vaccine combinations and formats. Receiving new

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technologies which can help manufacturer to compete could be restricted by weakness in local R&D capacity. Therefore, there is an urgent need to invest on R&D field in order to upgrading capacity and facilities, education, training, both at the manufacturer and national level. According to consensus among the professionals, vaccines are not commodities like other medicines and cost-effectiveness analyses alone cannot be used to justify whether to invest in local production or not. So a coherent national vaccine policy is absolutely required on its availability and usage. Some countries have vaccines policies similar to essential medicines policies which show vaccine manufacturers can determine appropriate time of technology transfers. So, guidelines on national vaccine policy need to be developed essentially. There was consensus amongst participations that strategically national security has a crucial importance particularly for unmet demand vaccines. However industry needs to ensure that supply does not exceed demand; otherwise price pressure will pull some players out of the market. It potentially leads to vaccine shortage. In accordance with second question professionals confirmed that there are more players ready to undertake technology transfer. In particular cases some DCVMN members are interested in providing technology transfer to those countries with novice vaccine industries. Such an offer may also facilitate lower cost transaction for recipient. Costs in Brazil, Russian Federation, India and China are increasing which might cause cheaper cost for vaccine production in developing countries. However, since staffing is not a major component of vaccine costs, this is just an uncertain matter. Larger number of suppliers would increase security for new vaccines but there are intellectual properties concerning many of them, so obviously new models for technology transfers will be required.

### **Conclusion**

Technology transfer to developing countries has contributed significantly to vaccines supplying and increases access to many of them. In some cases technology transfer has also resulted lower prices of vaccines. There is a risk for basic (EPI) vaccines that their supply may soon exceed demands and establishment of new manufacturers can be counterproductive and potentially a reason for some established manufacturers to leave the market. Establishing local vaccine manufacturer is not necessarily cost effective. Vaccines should not be seen purely as commodities. However factors such as national health security need to be considered. The establishment of a vaccine policy by countries may assist countries in identifying how and when to consider local production. There are changing dynamics in vaccine technology transfer with its related venture, acquisition as well as its establishment by multinational manufacturers of subsidiaries among developing countries. Establishment of research-based entities, developments and providing new vaccines may take existing generic manufacturers out of the market. They need to invest on R&D field to remain competitive latter on. The biggest barrier for vaccine technology transfer, perceived by both recipients and donors, is lack of R&D capacity in developing countries. Lack of investment on R&D field and government's failure to create an enabling national environment for research and infrastructure will cause technology transfer less successful. Win-win condition is required in terms of giving more attraction to technology transfer paradigm.

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