Increasing Access to Vaccines Through Technology Transfer and Local Production

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Increasing Access to Vaccines Through Technology Transfer and Local Production

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All reports associated with this project are available for free download from the following website: http://www.who.int/phi/en/

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Abbreviations

DCVMN	Developing Countries Vaccine Manufacturers Network
DTP3	three-dose diphtheria, tetanus and pertussis vaccine
EPI	Expanded Programme on Immunization
GAVI	Global Alliance for Vaccines and Immunisation
GPO	[Thai] Government Pharmaceutical Organization
GSK	GlaxoSmithKline
HBV	hepatitis B virus
Hib	*Haemophilus influenzae* B
HPV	human papilloma virus
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IVI	International Vaccine Institute
JPRI	Japanese Poliomyelitis Research Institute
LMIC	low- or middle-income country
MVP	Meningitis Vaccine Project
NGO	nongovernmental organization
NIH	National Institutes of Health
NVI	Netherlands Vaccine Institute
PATH	Program for Appropriate Technology in Health
PCV	pneumococcal conjugate vaccine
R&D	research and development
SII	Serum Institute of India Ltd.
WHO	World Health Organization

Executive summary

This report presents an overview of technology transfer and local production of vaccines in developing countries, and analyses emerging trends in this area and how technology transfer affects access to vaccines in developing countries.

Immunization is considered to be one of the greatest health interventions to prevent infectious diseases. According to World Health Organization (WHO)/ United Nations Children's Fund (UNICEF) estimates, global immunization coverage of children is at least 80% for the six Expanded Programme on Immunization (EPI) vaccines, against diphtheria, pertussis, tetanus, polio, measles and tuberculosis. However, there are huge inequalities in access to newer vaccines, such as Haemophilus influenzae B (Hib), rotavirus, pneumonia and human papilloma virus (HPV), between developed and developing countries. In addition, there are many poverty-related diseases for which vaccines do not exist, due to a lack of research and development (R&D) by industry. Technology transfer and local production can be an effective and sustainable strategy to address some of these issues, but they must be undertaken with planning and caution to ensure sustainability and success.

This report examines past and current trends and models of technology transfer and local production for vaccines; identifies barriers, challenges and opportunities; and presents some points to take into consideration for the future.

To provide evidence of the barriers and drivers of technology transfer for vaccines, and the benefits that arise from this, WHO commissioned a survey of technology transfers that have taken place over the past two decades. This survey identified and analysed over 100 technology transfers and was supplemented by a workshop with stakeholders in late 2010 where case studies were presented and stakeholder views expressed. The following main conclusions were identified:

- Technology transfer to developing countries has contributed significantly to increasing vaccine supply, and increased access to many vaccines has been documented. In several cases this technology transfer has also resulted in lower prices of vaccines, but this is not always so. For several basic (EPI) vaccines there is a risk that supply may soon outstrip demand, and establishment of new manufacturers for these vaccines could be counterproductive, potentially leading to some established manufacturers leaving the market.
- Establishing local vaccine manufacturing is not necessarily cost effective; however, vaccines should not be seen purely as commodities, and 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 is a changing dynamic in vaccine technology transfer, with joint ventures, acquisitions and establishment by multinational manufacturers of subsidiaries in developing countries becoming more frequent. The

establishment of research-based entities developing and providing new vaccines may also squeeze existing generic manufacturers out of the market. The latter will need to invest in R&D to remain competitive.

- The biggest barrier to vaccine technology transfer, perceived by both technology recipients and donors, is lack of R&D capacity in developing countries. Failure by manufacturers to invest in R&D, and failure by governments to create an enabling local environment of research infrastructure, make technology transfer less likely to succeed.
- For technology transfer to be attractive and successful, a win–win condition is required, which is facilitated by a commitment from the government to support the technology transfer or a large local or regional market.

As the public sector seeks to promote technology transfer for vaccines, the above points need to be considered.

1. Background and context

Vaccines are among the most cost-effective health interventions of all time. Despite this, the World Health Organization (WHO) estimates that 1.7 million annual deaths among children under 5 years of age are due to diseases that could have been prevented by routine vaccination (WHO, 2010).

For example, although it is estimated that Expanded Programme on Immunization (EPI) vaccines reach about 80% of children globally, the number of unimmunized children under 1 year of age who did not receive the three-dose diphtheria, tetanus and pertussis vaccine (DTP3) was 23.2 million in 2009 (WHO, 2010). Seventy per cent of these children live in ten countries: Chad, China, the Democratic Republic of the Congo, Ethiopia, India, Indonesia, Kenya, Nigeria, Pakistan and Uganda (WHO, 2010). There are many factors that prevent children from being immunized, including political instability in a country, the strength of the immunization programme (e.g. number of health-care workers, facilities, cold chain), geographical location, and communication/perceptions about the safety of vaccines. These barriers have been addressed in other documents (WHO, 2009a). The focus of this report is on increasing vaccine access though increased production.

In addition to the children who miss out on basic vaccines, there are huge inequalities in access to new vaccines between children in developed countries and children in developing countries. Furthermore, there are many poverty-related diseases for which vaccines do not exist, due to a lack of research and development (R&D) by industry. In the light of this, WHO has promoted activities to improve access to vaccines in developing countries, and to encourage the development of vaccines against poverty-related diseases for which there has previously been little incentive.

1.1 The vaccines market

The development and production of a new vaccine can take decades. Vaccine development poses huge scientific challenges and requires a large investment of funding and time. If the development of a vaccine is successful and a licensed product marketed, then these costs are usually recovered through vaccine sales. However, the burden of some diseases is greatest in the developing world, which makes developed country vaccine manufacturers hesitant to develop vaccines against these poverty-related diseases due to a belief that costs will not be recovered. In addition, although the original six EPI vaccines are generally affordable, the costs of many new vaccines are not affordable to developing countries.

Although countries with a gross national income below US$ 1500 are eligible for support from the Global Alliance for Vaccines and Immunisation (GAVI) to introduce these new vaccines, low- or middle-income countries (LMICs) are not eligible and current prices of new vaccines are not affordable in these countries. Although tiered pricing is an option that has been offered by industry, these tiered prices are believed to be higher than those that could be

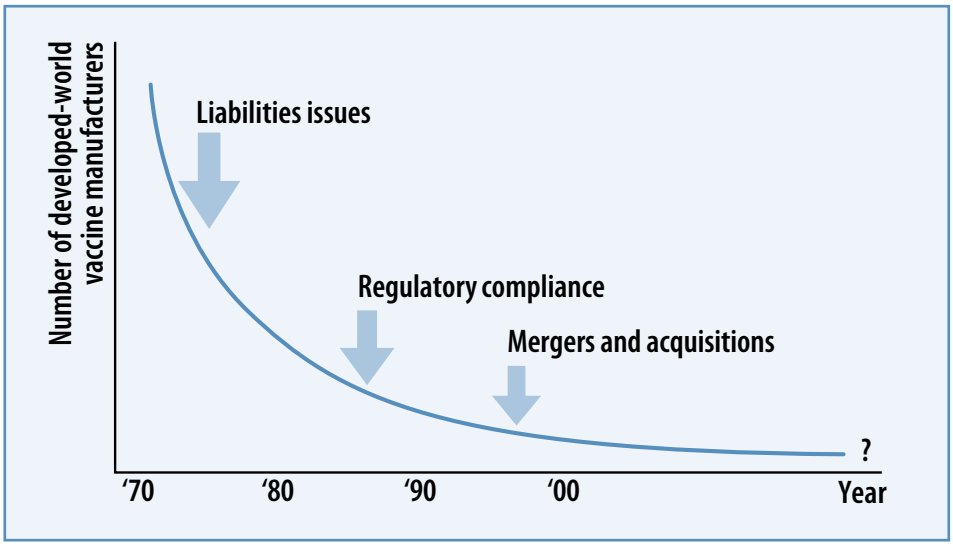
achieved through competitive pricing. With the entry of new manufacturers into the market for these new vaccine products, it is expected that vaccine prices would decrease through increased competition.

A number of mechanisms exist to promote R&D for new vaccines against poverty-related diseases, including pull funding, such as advanced market commitments; push funding, such as public-sector funding of R&D (e.g. see Section 1.3.3); and technology transfer (discussed further in this document).

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 growth rate, of 16% annually, is over double the growth rate of therapeutic drugs (WHO, 2009b). Most of this growth can be explained though the sales of new vaccines, such as pneumococcal conjugate vaccine (PCV) and human papilloma virus (HPV) vaccine, and new-generation vaccines, such as for rotavirus. Although many developing country manufacturers have recently entered the market (from which 53% of vaccines purchased by GAVI are procured (GAVI, 2010)), these newer, more expensive vaccines remain produced by only a few multinational companies.

Since the early 1970s, the vaccine market has changed dramatically, with a significant reduction in global vaccine suppliers (see Figure 1), leading to a reduction in excess capacity production, which in turn led to a vaccine supply crisis in the late 1990s. This supply crisis was addressed by the United Nations Children's Fund (UNICEF) through the Vaccine Security Strategy to ensure the uninterrupted and sustainable supply of vaccines that are both affordable and of assured quality (WHO, 2009b). However, vaccine supply continues to remain reliant on a limited number of manufacturers.

***Figure 1** Number of developed country vaccine manufacturers*



Source: Watson (2010).

1.2 Vaccines versus drugs

Vaccines are very different from drugs (Table 1). These differences affect the drivers and barriers to technology transfer, and the impact that technology transfer can have on access.

First, for vaccines there is no true generic version. Unlike drugs, where a generic can be made and licensed on chemical equivalence, a vaccine made in a new facility is treated as a new vaccine and has to undergo rigorous preclinical and clinical studies to be approved for use. The reason for this is that vaccines are complex biological entities, and simple bioequivalence is not adequate proof that a vaccine will be safe and efficacious. This need for a complete preclinical and clinical development path, usually coupled with a dedicated manufacturing facility that makes only that specific vaccine, means that establishing new manufacturing sites and approving a copy of an existing vaccine is both costly and time-consuming.

Second, for vaccines, know-how rather than intellectual property has been the main barrier to local production. Making vaccines requires a skilled workforce with experience in a broad range of specialty areas, which may be specific to a particular vaccine. These skills are generally learnt in vaccine manufacturing facilities or through technology transfer and are not readily available in most countries. For the majority of vaccines that have been approved, any intellectual property has been on specific processes, where alternative manufacturing methods can provide a work-around but require R&D infrastructure. For more recent vaccines such as HPV vaccine, and possibly for future vaccines, intellectual property on the vaccines may be an additional barrier.

Third, the market forces and parameters for vaccines are different from those for drugs. Vaccines are for the most part purchased and distributed by the public sector – through procurement agencies or governments – and there are only a limited number of vaccine suppliers (fewer than 40, and with over 90% of vaccines produced by 15 of those companies).

Finally, vaccines are almost always cost effective in terms of public health outcomes. For many drugs, cost effectiveness and public health outcomes are not always as clearly linked.

***Table 1** Differences between the drugs and vaccines markets*

	Drugs	Vaccines
Technical nature	Various; chemical synthesis may be easy to establish	Complicated
Intellectual property	Significant barrier for newer drugs	Patents not major barrier in past, but know-how critical
Market force	Dominated by private sector	Highly regulated by national policy; global procurement
Market dynamics	Various; good competition for generics	Limited number of manufacturers: >90% produced by 15 companies; IFPMA and DCVMN; fewer transfers of technology
Public health impact	Not all drugs have significant impact	Vaccines generally cost effective

DCVMN, Developing Countries Vaccine Manufacturers Network; IFPMA, International Federation of Pharmaceutical Manufacturers and Associations.

1.3 Effect of technology transfer on access to vaccines

When discussing technology transfer of pharmaceutical products, it is often difficult to provide hard evidence that the technology transfer has an impact on local access to the product. In the case of vaccines, this is much easier to demonstrate. There are numerous examples of technology transfer to developing countries resulting in improved access to vaccines, with a consequent improvement in population health. In the early to mid-twentieth century, technology for many basic vaccines was transferred to numerous developing countries to serve national supply (Barton, 2006). As a result of this technology transfer, currently 64% of all basic EPI vaccines purchased by United Nations purchasing agencies are now made by developing country manufacturers.

However, there are also numerous, more recent examples where technology transfer for modern vaccines has demonstrated improved access. Several situations can be considered:

- The disease is of global significance, but there are only a small number of industrialized country manufacturers, with limited capacity, producing the vaccine. Increased capacity through production in developing countries results in a vaccine becoming available at a lower price. Examples of this include the Hib vaccine and the hepatitis B virus (HBV) vaccine. Currently 42% of all UNICEF Hib and HBV vaccine purchases are made through developing country vaccine manufacturers.
- The disease is not of significant importance in industrialized countries, high-volume, low-price production by industrialized country manufacturers is not taking place, and there is no interest from industrialized manufacturers to produce the vaccine specifically for developing-country populations

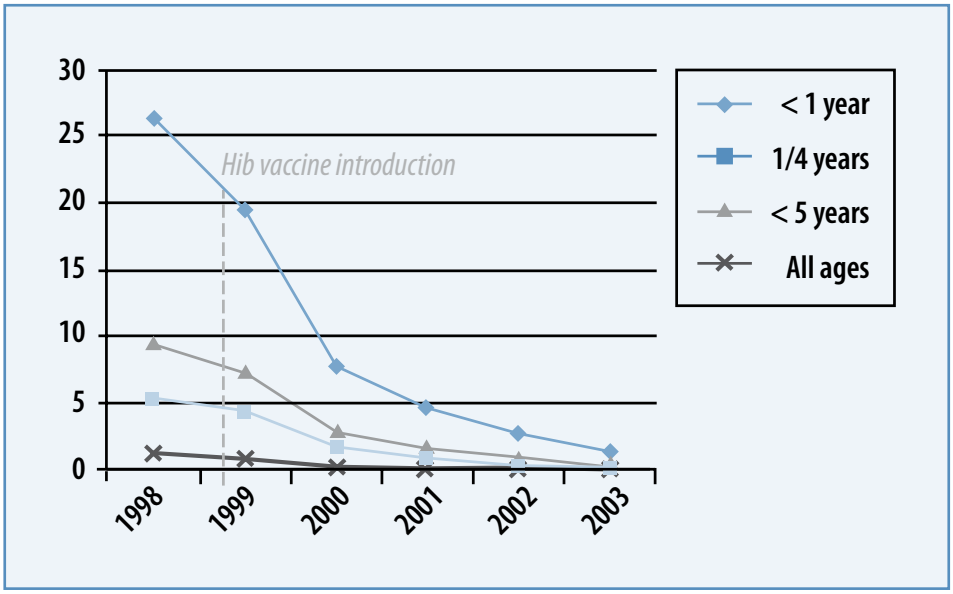
at a price that is affordable for this population. An example of this is the meningitis A vaccine technology transfer.

- The disease is of global significance but the global capacity is severely limited. Technology transfer to developing countries increases the global capacity and ensures access for the local population to the vaccines. An example of this is the pandemic influenza vaccine.

1.3.1 Example 1: Hib vaccine

The conjugate Hib vaccine was first licensed in 1987, but until 1998 this vaccine was not widely used in developing countries. The vaccine was expensive compared with other EPI vaccines; there were no developing country manufacturers; and in many regions the disease burden was not known, and so there was little justification for introducing a vaccine. Between 1998 and 2001 several Hib technology transfer activities were undertaken, including from the Netherlands Vaccine Institute (NVI) (the Netherlands) to three manufacturers in India, and in 1998 from GlaxoSmithKline (GSK; Belgium) to one manufacturer in Brazil, which immediately implemented the vaccine in the national immunization programme, resulting in an immediate reduction in disease incidence (Figure 2).

***Figure 2** Incidence of* **Haemophilus influenzae** *type b meningitis before and after implementation of Hib vaccine in the Brazilian National Immunization Programme*



Source: MS/SVS/COVER

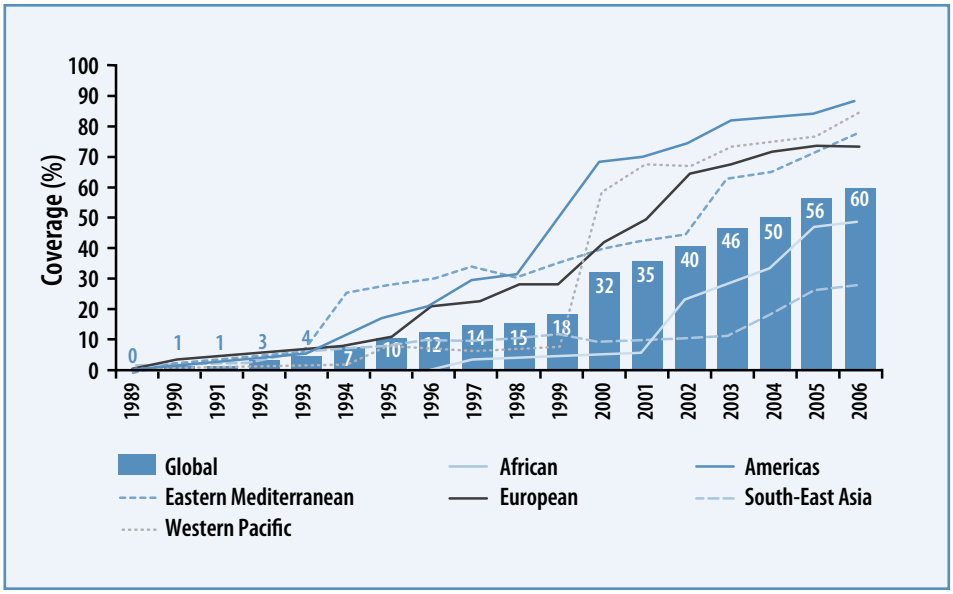
As a result of these technology transfer activities, there was an increase in vaccine capacity and a marked decrease in price. There are now eight prequalified (UN agency) manufacturers providing Hib-containing vaccines. This increased capacity, supplemented by epidemiological studies by WHO to demonstrate that the disease was prevalent in many countries, and with financial assistance from GAVI to enable the poorest countries to purchase

the vaccine, has enabled the vaccine to be introduced into many national immunization programmes.

1.3.2 Example 2: Hepatitis B vaccine

Recombinant hepatitis B vaccines were introduced in industrialized countries by GSK and Merck in 1983. For over a decade the cost was in the region of US$ 100 per dose, and there was no significant use of the vaccine by developing countries. In the late 1990s technology transfer to the Republic of Korea, India and Brazil resulted in a price drop initially to US$ 5–7 per dose. This increase in supply, the entry of purchasing agencies and financial assistance from GAVI drove demand up and price down to less than US$ 0.3 per dose. As a result the vaccine is now in most national immunization programmes, and hepatitis B vaccine coverage is increasing continually (Figure 3).

Figure 3 *Global immunization 1989–2006: third dose of hepatitis B coverage in infants – global coverage 60% in 2006*



Source: Zanetti et al (2008).

1.3.3 Example 3: Meningitis A vaccine

A vaccine against meningitis C was developed in Europe and introduced in some European countries in the late 1990s. Industrialized country vaccine manufacturers then focused on the development of vaccines against a number of meningitis strains including A and C, and A, C, W and Y, intended for industrialized country markets. These vaccines were unaffordable for deployment in sub-Saharan Africa, where meningitis A is epidemic; industrialized country manufacturers were unwilling to develop a vaccine for this population at a price that the governments would be able to afford (at that time, identified at less than US$ 0.5 per dose).

WHO, in collaboration with the Program for Appropriate Technology in Health (PATH), facilitated the transfer of technology for the production of a meningitis

A vaccine to the Serum Institute of India, which developed the vaccine – now being provided at a price below US$ 0.5 per dose. This vaccine is now prequalified and is used in numerous sub-Saharan African countries. Without such technology transfer, the vaccine would not be available at this affordable price, and there would be no widespread use of the vaccine.

2. Landscape of vaccine technology transfer

These few examples demonstrate that technology transfer of vaccines can have an enormous impact on access to vaccines and subsequent improvements in health. There has, however, been little rigorous evaluation of how many technology transfers have taken place, who the donors were, who the recipients were, and most importantly what the drivers and barriers were. Identification of these could contribute to improved identification of future technology donors and recipients, and how to promote successful technology transfer leading to improved local or regional access.

In response to this, WHO has undertaken a project to identify the main challenges and obstacles to technology transfer and local production in developing countries, and to provide points for consideration on the feasibility and sustainability of such production. This project has been carried out in partnership with the United Nations Conference on Trade and Development and the International Centre for Trade and Sustainable Development, and with funding from the European Union.

The overall project reviews separately the cases of pharmaceuticals, diagnostics and vaccines. For the field of vaccines, where previously know-how rather than intellectual property has been the main barrier to local production, the project has been implemented through three research activities: (i) landscape analysis of technology transfer initiatives and trends, (ii) case study analysis and (iii) workshop and stakeholder analysis.

Technology transfer is the sharing of knowledge from those who own the know-how to those who do not. It is shaped by many factors, including the capacity of recipient countries to absorb the knowledge and translate the know-how into the manufacture of vaccines. In many areas a simple licence to a proprietary technology is termed "technology transfer". For the purposes of this report, we have not considered such licences to count as technology transfer, unless they are also associated with training of the recipient in the use of the technology and technical support to the recipient. For this report, therefore, the term "technology transfer" is limited to activities that involve a capacity-building component at the recipient site intended to enable the recipient to produce a vaccine.

2.1 Project objectives

1. Conduct a survey of technology transfer and local production of vaccines for developing countries.

2. Analyse the global trend of technology transfer and local production for vaccines in the context of improved access to vaccines for infectious diseases, with specific country examples.
3. Conduct stakeholder interviews and a workshop on technology transfer of vaccine production technologies to developing countries.
4. Collate and synthesize all data into a summary technical report with points for consideration on the way forward.

2.2 Project activities

1. Survey of technology transfer and local production of vaccines in developing countries.
2. Assessment of opportunities and barriers to technology transfer and local production of vaccines.
3. Stakeholder consultation/workshop with regard to technology transfer for local manufacturing capacity of vaccines.
4. Compilation of evidence and stakeholder opinion on technology transfer and local production.
5. Generation of points for consideration for improved access to vaccines through technology transfer for local innovation and production.

2.3 Methodology

From June to August 2010 evidence was gathered and collated through a combination of literature and Internet research, interviews with suppliers and recipients of technologies, and a web-based survey of manufacturers to develop a landscape of technology transfer for vaccines. The purpose of the analysis was to describe drivers, barriers and trends, with the goal to provide an evidence-based reference for decision-making in future technology transfers of vaccines. Three different questionnaires were developed, one each for technology suppliers, technology recipients, and others with an interest in the process. Questions included manufacturer's information; nature of technology and transfer; intellectual property and licensing aspects; achievements; and perceived challenges, including external factors.

A broad review of cases was undertaken and included both north–south and south–south technology transfer conducted in the past two decades. A total of 101 cases of technology transfer were identified and analysed; this is thought to represent a comprehensive analysis of all the technology transfers that have taken place over the past two decades.

In addition to the web survey and interviews, on 30 November–1 December 2010, WHO organized the Workshop on Technology Transfer for Local Manufacturing Capacity of Vaccines. The aim of this workshop was to bring together the main players in vaccine technology transfer, including industrialized country vaccine manufacturers, developing country vaccine manufacturers, public-sector vaccine developers, nongovernmental

organizations (NGOs), and public health agencies and funding agencies. Findings from the landscape analysis background paper and case studies of technology transfer from manufacturers (from both developed and developing countries) were presented. During the workshop manufacturers and public-sector agencies were invited to present their experiences with, and views on, technology transfer of vaccines. Presentations included those from members of the Developing Countries Vaccine Manufacturing Network (DCVMN) and the International Federation of Pharmaceutical Manufactures and Associations (IFPMA) and from public-sector agencies such as the International Vaccine Institute (IVI), NVI and PATH.

3. Results

3.1 Landscape analysis of technology transfer initiatives and trends

From the information gathered, 101 cases of technology transfer over the past two decades were identified, which were classified as completed, abandoned or ongoing. Of these 101 cases, 92 were validated (confirmed through multiple sources) and used in the subsequent analysis. Findings showed that the drivers and barriers of technology transfer for vaccines varied among regions and sectors. Semiquantitative studies were undertaken to analyse the main players, models of technology transfer and trends.

3.1.1 Trends in recipient countries

Figure 4 shows the distribution of technology recipients by country, demonstrating that although 13 countries have received vaccine technology transfer, the vast majority of these transfers have been to China, India, Brazil and Indonesia. When this is broken down over time (Figure 5), although the rate of technology transfers has increased exponentially over the past two decades, across all of the time periods it is India, China and Brazil that stand out as being the main recipient countries.

Figure 4 Technology recipient countries

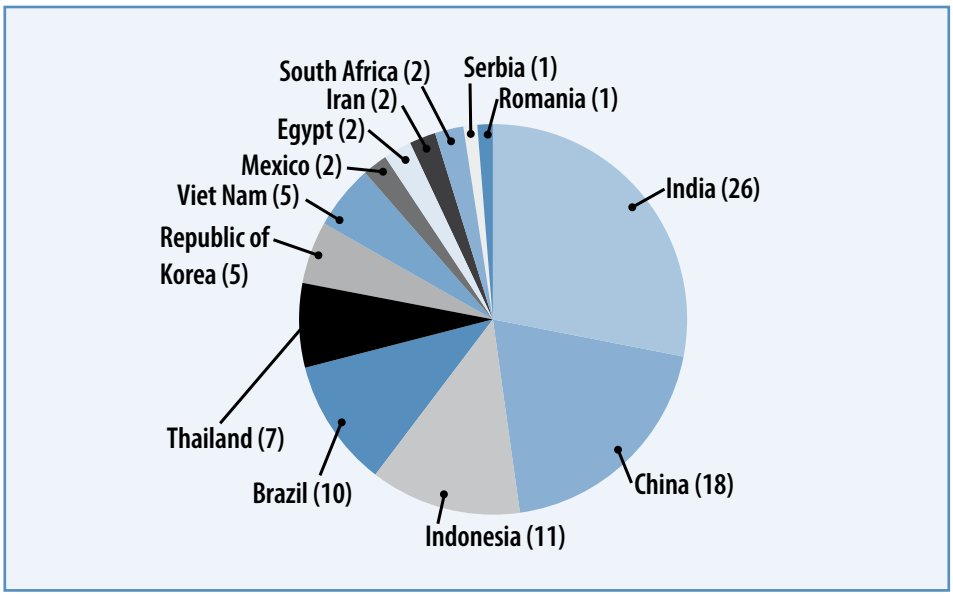
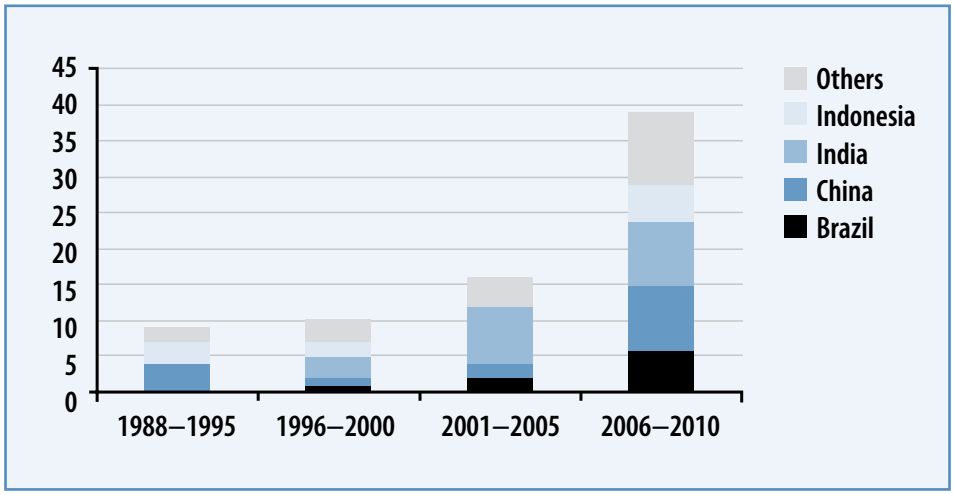


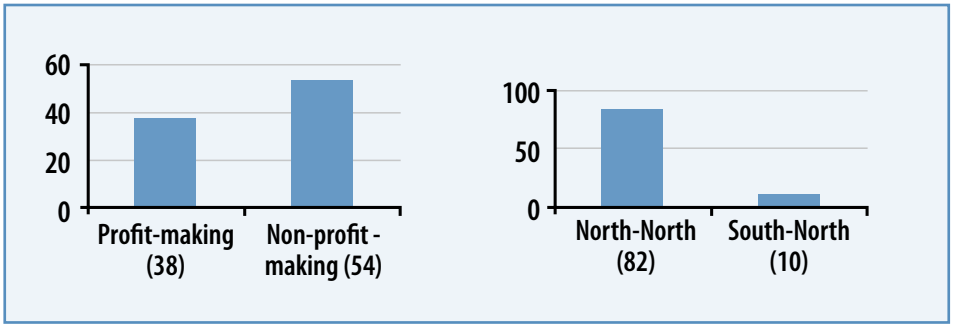
Figure 5 Technology recipient countries over time



3.1.2 Mode and purpose of technology transfer trends

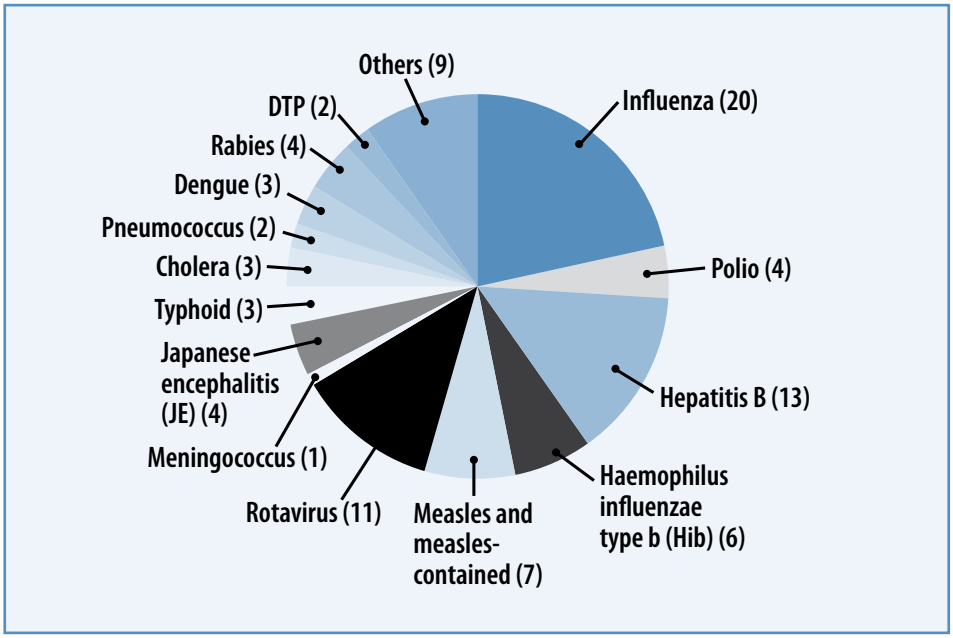
An analysis of suppliers of technology transfer was also undertaken to identify trends in the types of transfer (south–south versus north–south, and non-profit-making versus profit-making). The results summarized in Figure 6 show that non-profit-making organizations and institutes have contributed the majority of technology transfers, and although some technology transfer from developing countries to developing countries (south–south) has taken place, the vast majority is from developed countries to developing countries.

***Figure 6** Technology suppliers*



Analyses were also undertaken on which vaccines had undergone technology transfer (Figure 7), demonstrating that these have nearly all been for licensed vaccines, but with a large number for influenza, hepatitis B, rotavirus and Hib.

***Figure 7** Disease targets (vaccines)*



For many of the technology transfers analysed, the technology transfer is still ongoing, in that the recipient has not yet achieved production and market authorization. This is especially true for the rotavirus and influenza vaccine technology transfers, for which the majority have been initiated only in the past 5 years. The analysis also showed that technology transfer of vaccines is done with technologies at different levels of maturity of the donor, ranging from R&D-stage experimental technologies, through pilot processes, to turnkey transfer of large-scale production processes. In addition, different mechanisms of transfer are used, ranging from one-off transfer of the production scale process, including all associated technologies, through a stepwise process over several years beginning with quality control and distribution of imported vials, through fill-finish and distribution, to full local production. These are

shown schematically in Figure 8. As discussed later in this report, the research-based vaccine industries tend to favour the stepwise approach, since it gives them confidence in the recipient and builds a relationship of trust between the donor and recipient over time. In contrast, public-sector-originated technology transfers are for the most part at the R&D stage or pilot plant, requiring the recipient to invest know-how and capital in the scale-up, which can be risky and take longer than initially expected. In some cases, technology transfer is not on the manufacturing process but on improved quality control/quality assurance processes to improve the quality of the processes existing at the recipient site. The relative frequencies and examples of the various stages of technology transfer are given in Table 2, which shows that pilot-stage transfer is the most common, followed by transfer of full-scale production processes.

***Figure 8** Maturity of technology being transferred*

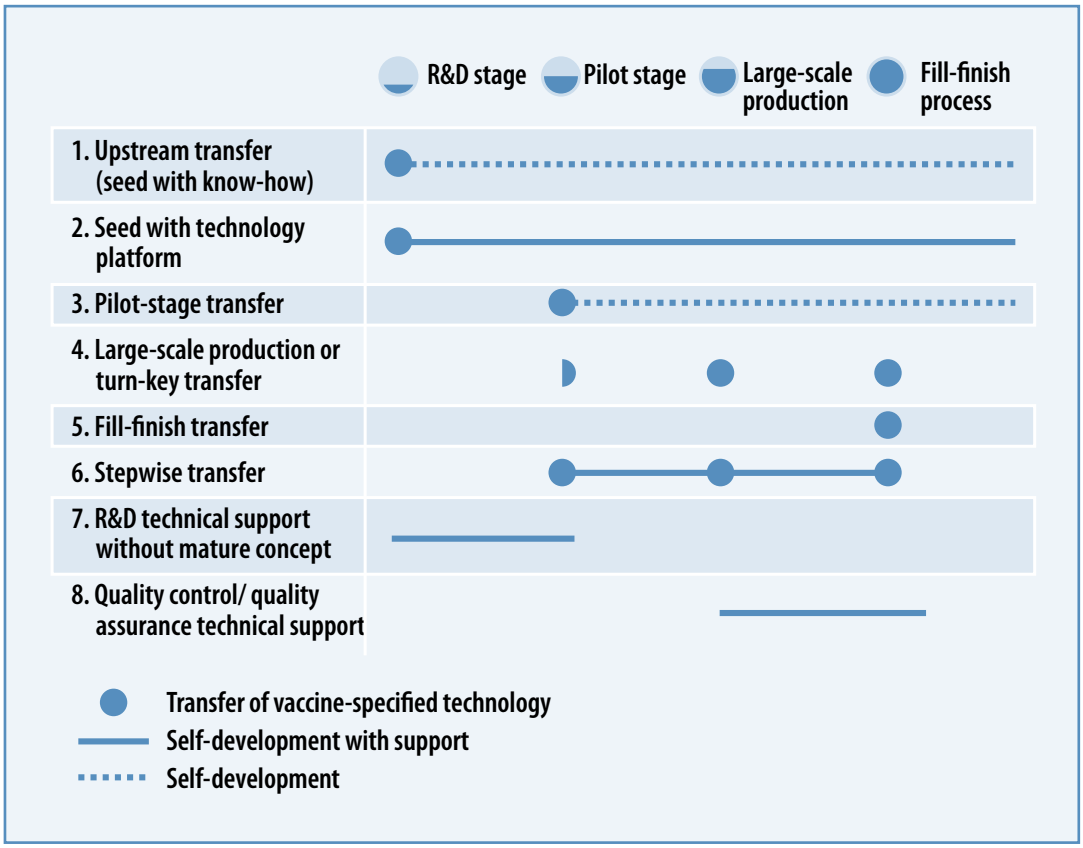


***Table 2** Analysis of maturity of technology transfers*

	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.

The survey also identified numerous models of conducting technology transfer, including bilateral agreements between a technology donor and technology recipient (the most common, accounting for 41 of the documented cases); joint ventures or acquisitions where a technology donor (typically an industrialized research-based manufacturer) acquires an existing facility in developing countries or jointly funds with a local manufacturer the establishment of a manufacturing facility but retains significant rights over the use of the technology and the product; de novo manufacturing, where a manufacturer in an industrialized country (in the examples identified) establishes from scratch a wholly owned facility in a developing country, providing technology transfer but retaining all the rights to the product; facilitated transfer, where there is technology transfer from one or more donors to a single recipient but facilitated by a public agency such as WHO or PATH, which provides funding, technical support and so on; shared technology platforms, similar to facilitated transfer but where there are numerous recipients and the facilitating agency provides a set of tools for each of the recipients; and technology transfer hubs, where a central hub is established by the public sector to provide technology (in the examples either at pilot-plant stage or R&D stage) to numerous recipients, including national drug regulatory authorities.

The various models used, and their relative frequencies, are shown in Table 3. The perceived value of the hub or shared-platform models is discussed in more detail below.

***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

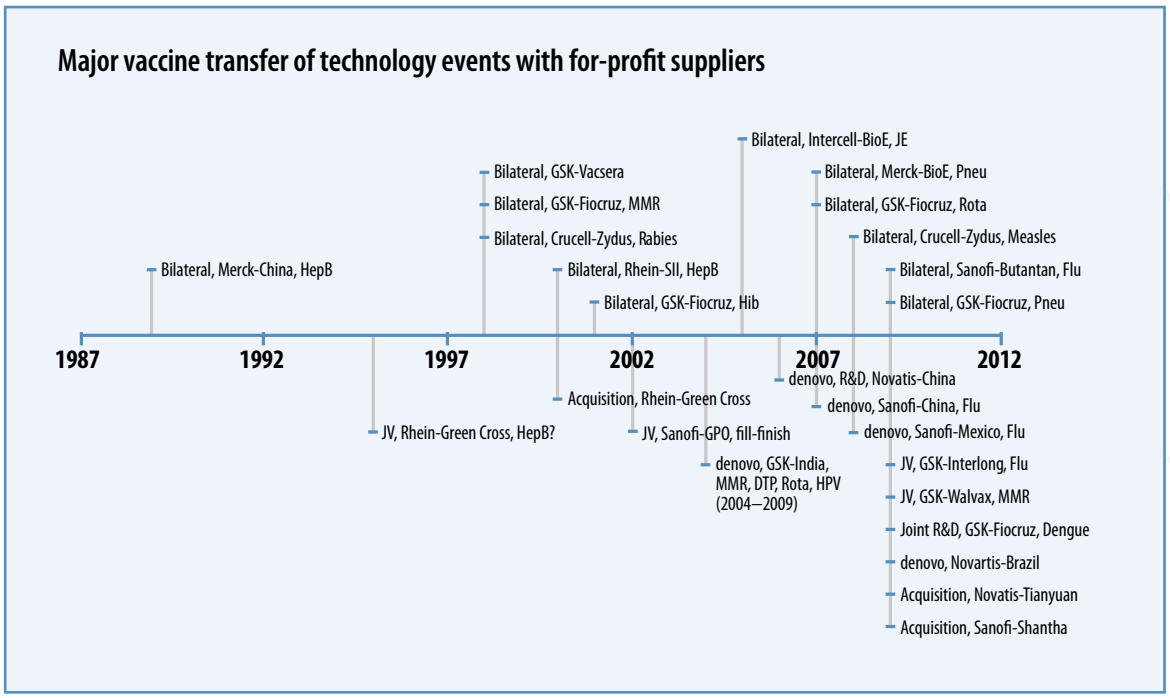
MVP, Meningitis Vaccine Project.

3.1.3 Technology transfer trends over time

The identification of the different models of technology transfer highlighted two emerging trends, which we discuss below. These are (i) the trend for technology transfer from industrialized countries to emerging and developing countries to be in the form of joint ventures, acquisitions or establishment of wholly owned subsidiaries; and (ii) the trend for technology transfer facilitated by the public sector to use centralized technology transfer hubs or platforms where a technology is established and multiple recipients can receive training.

An analysis of the major technology transfers of the past two decades was mapped by bilateral transfers versus acquisitions, mergers and establishing, which showed that over time the number of technology transfers undertaken (with profit-making suppliers) has continued to increase dramatically since the late 1990s, especially for acquisitions, mergers and establishing de novo manufacturing facilities. This is shown in Figure 9, which maps technology transfers from the research-based multinationals to developing country vaccine manufacturers with bilateral transfers above the timeline, and joint ventures, acquisitions and de novo establishment below the timeline. It is striking how the shift in recent years has been to joint ventures, acquisitions and de novo establishment, particularly in India, China and, to a lesser extent, Brazil. As discussed later, this is probably driven by the growth in these economies and the interest from the research-based multinationals in capturing these emerging markets. This trend was highlighted at the stakeholder workshop, where different views on the trend were voiced: Although these activities certainly meet the needs of the developing countries and contribute to local supply and capacity building, over time some of the local generic manufacturers may be squeezed out of the market, which could result in vaccine prices increasing. Stakeholders agreed that in order to compete, the local manufacturers need to invest in R&D capacity to be able to adapt to changing markets, which means they should ensure that the sale price of their products includes a fraction for reinvestment in R&D.

Figure 9 *Bilateral transfer versus acquisition, merging and establishing*

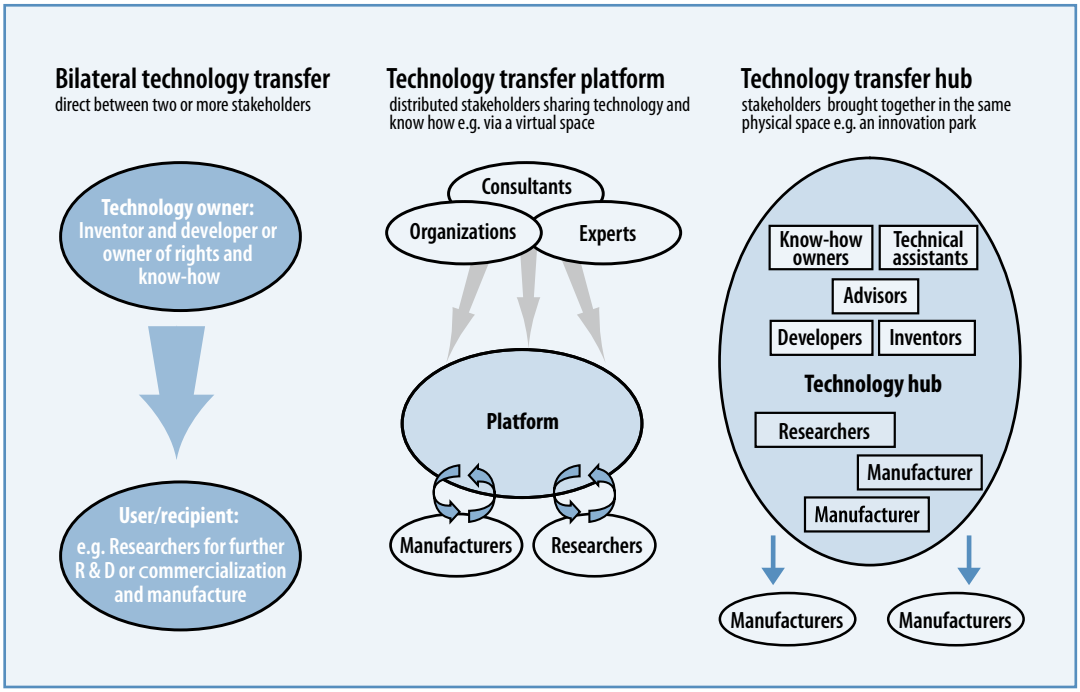


The second trend identified was the emergence of the hub or shared technology platform, particularly as public entities such as PATH, WHO and IVI strive to transfer vaccine technology to the greatest number of recipients. The hub concept, exemplified by the influenza vaccine technology transfer centre created by WHO at NVI in the Netherlands, functions to provide a working pilot-plant process with all standard operating procedures, documentation and training on all aspects of the production process to numerous manufacturers, and also to train the national drug regulatory authorities from those countries in order to facilitate the registration process. This model works well when the technology can be established in a central hub, by bringing together experts in various components of the process, and where numerous recipients are interested in receiving a standard process. This is more resource-effective than having each expert travel to each recipient and reinvent the procedures, standard operating procedures and so on in each place. In the case of the NVI influenza hub, over 15 vaccine researcher/manufacturer recipients have received training on the process, several of which have since established approved influenza vaccine manufacturing in their countries. A similar hub has been established at the University of Lausanne in Switzerland, where technology for the production of oil-in-water emulsion adjuvant for addition to pandemic influenza vaccines is provided.

The shared technology platform exemplified by PATH's rotavirus technology transfer is similar to the hub model but differs in that the vaccine technologies are well established and each licence recipient can access the processes in the platform.

The hub and shared platform are shown schematically and compared with classical bilateral transfers in Figure 10.

***Figure 10** Schematic diagram of technology transfer platform and hub, compared with bilateral transfer*



3.1.4 Key issues identified through the web-based survey and interviews

The web-based survey and the interviews with technology donors and technology recipients asked the players to identify the key issues and challenges to technology transfer. These were analysed from the perspective of the recipients' views and donors' views.

From the recipients' perspective, the main challenges, in order of priority, included:

- R&D capacity to support technology transfer: over 70% of developing country vaccine manufacturers expressed this as the most important barrier to technology transfer, and rated their capacity less than 3 on a scale of 5;
- weaknesses in human resources for R&D and lack of experience of staff in R&D;
- prioritization of resources in company level;
- licence negotiation skills and training;
- evaluation and assessment for quality of technologies.

From the technology donors' perspective, the main challenges, in order of priority, included:

- R&D ability for supporting technology transfer;
- R&D budget to support technology transfer;
- business case/sustainability;
- clinical trial expertise;
- quality control facility and human resources;
- national drug regulatory authority capacity weakness (reported in some countries).

The concordance between the views of the technology recipients and technology donors is striking and highlights areas where focused training and capacity building will help promote successful technology transfer: R&D expertise and staffing, and business development expertise (licence negotiation, business case development, and determining when technology transfer is likely to be sustainable).

4. Workshop and stakeholder analysis

On 30 November–1 December 2010, WHO organized the Workshop on Technology Transfer for Local Manufacturing Capacity of Vaccines. The results of the survey and interviews were presented, and the participants were invited to present their views on technology transfer and the results obtained from the survey. The aim of the workshop was to bring together the main players in vaccine technology transfer, including industrialized country vaccine manufacturers, developing country vaccine manufacturers, public-sector vaccine developers, NGOs, and public health agencies and funding agencies.

A total of 46 participants attended the workshop, including 19 vaccine manufacturers from both developed and developing countries, public-sector and nongovernmental vaccine development groups such as PATH, NVI and IVI, and umbrella organizations representing IFPMA and DCVMN.

Several manufacturers and public-sector agencies were invited to present case studies and their experiences with technology transfer of vaccines. Presentations included those from members of DCVMN and IFPMA and from public-sector agencies such as IVI, NVI and PATH.

4.1 Perspective from umbrella organizations

4.1.2 International Federation of Pharmaceutical Manufacturers and Associations

The history of vaccine technology transfer shows that before 1990 technology transfer was driven by national public health institutes, not private industry. The period between 1950 and 1980 saw the development of a host of new vaccines, technologies and regulations. From a peak in the 1970s, when much of the vaccine manufacturing was done by publicly owned national vaccine

manufacturers, the number of vaccine manufacturers has declined significantly, globally but most significantly in industrialized countries. This decline was due to liability issues in the late 1970s, regulatory compliance in the mid-1980s and mergers and acquisitions in the late 1990s. The 1990s also saw significant pressure on vaccine prices, which led to several of the manufacturers leaving the market. This resulted in a transient shortage of some essential vaccines, associated with a spike in the vaccine price. When considering technology transfer, one has to bear in mind that if price pressure due to excess production capacity becomes too great, then such a phenomenon may occur with some manufacturers (of low-price vaccines) leaving the market to pursue more profitable products.

Several case studies of IFPMA technology transfers to emerging manufacturers were presented, including Hib vaccine technology from Wyeth (United States of America) to Bharat Biotech (India), polio and measles from Biken (Japan) to Bio Farma (Indonesia), and DTP-Hib from Novartis to Panacea Biotech (India).

From the perspective of IFPMA, transfer of a biological process is very complex, and success depends on the location, the product and the people involved. It was emphasized that technology transfer should be reserved for mature products – that is, already licensed and manufactured in the country of technology origin. IFPMA members favour a stepwise approach – that is, starting by transfer of packaging and distribution, and then fill-finish, and moving to local production of the vaccine only once confidence in the market distribution, quality control and approval processes have been established.

IFPMA also considers that there are other ways to ensure lower-cost vaccines are made available to low-income countries, such as tiered pricing and advanced market commitment. Before technology transfer is decided upon, long-term factors need to be considered, such as market, innovation, sustainability and long-term commitment by all partners. Finally, maintaining a free and healthy market is key to ensuring the sustainability of innovation and affordability of vaccines.

4.1.3 Developing Countries Vaccine Manufacturers Network

DCVMN is a voluntary public-health-driven alliance of vaccine manufacturers from developing countries that aims to make a consistent supply of good-quality vaccines that are accessible to developing countries. DCVMN members have been the recipients of the vast majority of technology transfers over the past two decades. As a result of these technology transfers, members of the network now provide the bulk of basic (EPI) vaccines purchased by the international procurement agencies. This technology transfer has also resulted in increased R&D capacity in several of the members' countries, which are now able to receive technology for more recent vaccines (e.g. PCV, candidate dengue vaccines) and able to undertake independent R&D of novel vaccines.

Although there are numerous examples of technology transfer to DCVMN members, DCVMN summarized the importance of technology transfer for developing country manufacturers through six examples of successful

technology transfers to the Serum Institute of India Ltd. in Pune, India. The six examples included measles, mumps and rubella vaccine from the Institute of Immunology, Zagreb; Hib vaccine from NVI; meningitis A vaccine with PATH–WHO; influenza vaccine through WHO; rabies monoclonal antibody though Massachusetts Biologic Laboratories (MBL); and hepatitis B vaccine though Rhein Biotech. The various methods used for each of these cases were presented, generating an overall list of prerequisites for successful technology transfer, including the need for good staff with appropriate technical experience (i.e. functional quality assurance, regulatory affairs, analytical clinical research) and the need for a project leader with appropriate experience to steer and drive the project. Critical factors affecting the success of technology transfer include the need to consider costs (royalty payments, milestone payments), regulatory issues, timelines and scale-up activities. It was emphasized that the technology recipient and technology donor need to have complete understanding of the entire project and need to have the same goals, ideas and drive to ensure success. Most importantly, before conducting transfer of technology it is important to look beyond 5–10 years to see what the long-term value of the product is. This is especially true for vaccines, where even with transfer of a mature technology it may take up to 5–7 years for the locally produced product to be tested and licensed, by which time the market may have changed.

4.2 Perspective from the public sector

For case studies from the public sector, see Annex I.

5. Discussion and consensus

Following the presentations[1] and case studies, extensive discussion took place to try and reach consensus on the main challenges and enabling factors for successful technology transfer, and the role of technology transfer in the future. This discussion was set around four questions:

5.1 What preconditions are required for successful technology transfer from the point of view of technology donors and recipients?

The consensus was that this will vary by nature: public–private, profit-driven, donor-driven. The main points to consider include:

- value-proposition: it is essential that the objectives, aims, benefits and sustainability plan are clearly established with a demonstrated local relevance;
- human resources: success is dependent on the pool of human resources at the recipient site, and staff experience across all stages of vaccine production, including R&D, scale-up and production capacity, analytical methods, quality assurance, regulatory affairs and clinical development. In addition, an experienced business development manager to negotiate

[1] See http://www.who.int/phi/news/workshop_tt_vaccines2010/en/.

licences and establish the business model, and a project leader with experience, are required;
- adequate funding to realize the project;
- government commitment to the project, in terms of commitment to purchase the locally produced vaccine, or market with an agreed access and market price;
- a functional national drug regulatory authority;
- common values, trust and commitment from all parties.

5.2 Will existing public-sector manufacturers in developing countries, including emerging economies, survive as research-based manufacturers establish competing production in these countries?

The trend towards joint ventures and acquisitions of existing manufacturers in the emerging economy countries was recognized by the participants as having a likely impact in the medium to long term on existing local manufacturers currently producing low-cost basic vaccines.

There was general agreement that these generic manufacturers may be squeezed out unless a national vaccine policy on purchase and investment is established.

The survival of these manufacturers may also be assured through investment in R&D and being able to produce newer vaccine combinations and formats. Weakness in local R&D capacity is also a barrier to receiving technology transfer that could help them compete. There is therefore a critical need to invest in R&D and upgraded capacity and manufacturing facilities, both at the manufacturer level (which implies that the sale price of the vaccine should include some revenue for reinvestment in R&D) and at the national level for education, training, R&D and so on.

5.3 What forms of technology transfer are in the interests of public health in vaccines, and how can we best facilitate it, in terms of policy, market and non-market incentives, international activities and so on?

There was consensus that vaccines are not commodities like drugs, and cost-effective analyses alone cannot be used to justify whether to invest in local production. A coherent national policy on vaccine access and use (free market versus policy on local production) is required. Some countries have a vaccines policy (similar to an essential medicines policy), and broad development of such policies could provide the basis on which countries and vaccine manufacturers can determine when technology transfer and local production is appropriate. For this, guidelines on national vaccine policy need to be developed.

5.4 What is the role of transfer of technology in the vaccines field in the future? Is there a justification (price-based or otherwise) for production in newer countries and is there a need to expand towards producing newer products in developing countries that currently demonstrate production capacity?

There was consensus that for vaccines with unmet demand, national security and so on, this is a strategic imperative. However, the industry needs to ensure that supply does not exceed demand, otherwise price pressures will drive some players out of the market, potentially resulting in vaccine shortages.

There are more players ready to undertake technology transfer, and in particular some DCVMN members are interested in providing technology transfer to countries with fledging vaccine industries. This increased offer may also make the transaction costs for the recipient lower.

Costs in Brazil, the Russian Federation, India and China are increasing, which may make vaccine production in developing countries cheaper. However, since staffing is not a major component of vaccine costs, this is not certain.

For new vaccines, an increase in the number of suppliers would increase security, but there is intellectual property on many of these new vaccines, so new models of technology transfer may be needed.

5.5 Challenges identified

There are considerable obstacles to be overcome if access to vaccines in developing countries is to be improved. Barriers to access of vaccines are complex and are not due simply to supply or affordability issues. Although the traditional EPI vaccines are affordable and new vaccines are more expensive, compared with other health-care interventions these new vaccines are still relatively cost effective. Increasing local production through technology transfer can be risky and must be undertaken with caution to avoid failures, resulting in a huge loss of money and time. In addition, technology transfer for vaccines should be undertaken only when there is a real need or gap, such as to reduce the price of new vaccines to make them affordable to LMICs or developing a vaccine against a poverty-related disease with little interest from large multinational pharmaceutical companies such as the Meningitis Vaccine Project (MVP). As highlighted above, to ensure success a win–win situation must be in place for both the recipient and the technology donor, and both parties must have common values, trust and commitment. Sustainability must be ensured through clear objectives, aims, benefits, a sustainability plan and a significant local market or need. Expertise in leadership, vaccine production, R&D, analytical methods, good manufacturing practice, quality assurance, regulatory affairs, clinical development and licence negotiation is essential. Adequate funding is required and government commitment, political stability or market incentive must be in place. A country must have a functional national drug regulatory authority in place before embarking on vaccine development. Finally, profits made from vaccine sales must be reinvested in R&D to ensure

sustainability of new manufacturers and to drive the development of new and improved vaccines.

6. Conclusions

A list of key issues was identified during the workshop with stakeholders based upon the results of the landscape analysis, the case studies and presentations from the various players involved in technology transfer. As the public sector seeks to promote technology transfer for vaccines, these issues need to be taken into consideration to ensure the success of the transfer:

- Technology transfer to developing countries has contributed significantly in increasing vaccine supply and increased access to many vaccines. In several cases this technology transfer has also resulted in lower prices of vaccines, but this is not always the case. For several basic (EPI) vaccines there is a risk that supply may soon outstrip demand, and establishment of new manufacturers for these vaccines could be counterproductive, potentially leading to some established manufacturers leaving the market.
- Establishing local vaccine manufacturing 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 is a changing dynamic in vaccine technology transfer, with joint ventures, acquisitions and establishment by multinational manufacturers of subsidiaries in developing countries. The establishment of research-based entities developing and providing new vaccines may squeeze existing generic manufacturers out of the market. The latter will need to invest in R&D to remain competitive.
- The biggest barrier to vaccine technology transfer, perceived by both the technology recipients and donors, is lack of R&D capacity in developing countries. Failure by manufacturers to invest in R&D, and failure by governments to create an enabling local environment of research infrastructure, will make technology transfer less likely to succeed.
- For technology transfer to be attractive and successful a win–win condition is required, which is facilitated by a commitment from the government to support the technology transfer or a large local or regional market.

Annex I: Public-sector case studies

The case studies presented here have been selected as examples of successful public-sector technology transfer taken from the landscape analysis of technology transfers and from presentations given during the stakeholders' workshop.

Meningitis Vaccine Project

MVP presents an example of a product development partnership and public-sector technology transfer through a technology transfer platform.

MVP was formed in June 2001 through a grant from the Bill & Melinda Gates Foundation and a 10-year partnership between WHO and PATH. The goal of the project was to eliminate epidemic meningitis (caused mainly by group A strains of meningococcus) as a public health problem in sub-Saharan Africa through the development, testing, licensure and widespread use of affordable conjugate meningococcal vaccines. Because MVP could not reach agreement with major vaccine manufacturers, the project created a consortium to identify sources of raw materials (meningococcus A polysaccharide and tetanus toxoid); to identify a conjugation method; to find a vaccine manufacturer willing to accept technology transfer (fermentation and conjugation); and to make the vaccine available at a price less than US$ 0.50 per dose. Transfer of technology was provided to the Serum Institute of India Ltd. from three institutes: polysaccharide development from SynCo BioPartners (the Netherlands), conjugation method from Center for Biologics Evaluation & Research/United States Food and Drug Administration (United States), and lyophilization and stabilization from Aerial (France).

The vaccine (MenAfriVac) is now licensed, WHO prequalified and being rolled out in Burkina Faso, Mali and Niger. This case demonstrates a north–south transfer of a technology not currently available, a south–south transfer of a vaccine product at an affordable price, and capacity building for an Indian manufacturer and for Indian and African clinical investigators.

Netherlands Vaccine Institute influenza technology hub

The NVI influenza vaccine technology transfer, under the National Institute for Public Health and the Environment, is an example of technology transfer through the hub model.

Through a memorandum of understanding signed between NVI and WHO in 2007, a 5-year relationship was established for a collaboration in international technology transfer of influenza vaccine technologies. WHO has assigned NVI to the International Technology Platform on Influenza Vaccines Project, which strives to increase the production capacity for influenza vaccines in developing countries. NVI offers training courses and technical assistance for the development of inactivated whole virion influenza vaccines produced in embryonated chicken eggs.

NVI has since run several training courses on influenza vaccine production, with much participation from developing country manufacturers.

According to NVI, access to vaccine technology is determined by three factors: intellectual property, technical know-how and a viable market.

The lessons learnt from the WHO influenza technology hub project are (i) long-term investment and commitments are required on both sides of transfer or technology; (ii) the time to market is critical, as changing perceptions can jeopardize a technically feasible approach; (iii) competition is an important factor; (iv) generic capacity building can generate unexpected indirect beneficial effects; (v) sustainability in the supplier's side is important; and (vi) interested recipients should meet the viability criteria established previously by WHO in 1997.

NVI believes that current technology transfer recipients may become technology suppliers in future transfers of technology.

Advancing Rotavirus Vaccines Project: The enabling platform model

The enabling platform concept was proposed in 2007 as "a toolbox of technologies, training, methodologies, and material designed to meet common needs among emerging vaccine manufacturers and maximize global availability of rotavirus vaccines". The enabling platform of the Advancing Rotavirus Vaccines project comprises a pool of organizations, consultants and PATH experts with specific expertise to assist four manufacturers to develop rotavirus vaccines: Butantan (Brazil), Shantha Biotechnics (India), Serum Institute of India Ltd. (India)and Wuhan Institute of Biological Products (China). Activities at these organizations are ongoing, but this represents another hub model concept to increase the supply and reduce the cost of new vaccines.

Technology transfer of Hib GSK to Bio-Manguinhos/Fiocruz, Brazil

This case study presents an example of north–south technology transfer, from a multinational pharmaceutical company to a Brazilian public-run manufacturer. Bio-Manguinhos/Fiocruz is a public entity, under the Brazilian Ministry of Health, with the vaccine market and price guaranteed by the Brazilian Government. The Brazilian Government provides vaccines to the public free of charge, and the public market for vaccines in Brazil is about 90%. The Brazilian Government must always consider local production (including through transfer of technology) before introducing a vaccine into the national immunization programme.

Hib vaccine technology transfer from GSK was a stepwise transfer that took 8 years. The first two steps of the transfer consisted of capacity building, including staff training and upgrading of facilities and equipment. The first step of the transfer, conducted between 1999 and 2003, involved the importation of bulk material and formulation, filling, freeze-drying and quality control. The second step, conducted between 2003 and 2006, involved the conjugation of

polysaccharides and tetanus toxoid using imported materials. From 2004 to 2006, production of polysaccharides and conjugation using locally produced tetanus toxoid was undertaken, followed by a non-inferiority study (using the polysaccharide and tetanus toxoid conjugated from imported materials as a control) in 2005–2007. Finally, the product was licensed in Brazil in 2007.

The features of Bio-Manguinhos/Fiocruz and GSK that made it possible for successful transfer of technology include specialized human resources, equipment and facilities and proper management. There was also a win–win situation in place.

Annex II: Workshop participants

Manufacturers

Khaled Alsaleh, Barakat Pharmaceutical Industries, Aleppo, Syria

Michel Baijot, GlaxoSmithKline Biologicals, Wavre, Belgium

Michael Begg, Biovac Institute, Pinelands, South Africa

Le Van Hiep, Institute of Vaccine & Medical Biologicals, Nha Trang, Viet Nam

Rajeev M Dhere, Vaccine Production, Serum Institute of India Ltd., Pune, India

Akira Homma, Director and President of Developing Countries Vaccine Manufacturers Network, Bio-Manguinhos/Fiocruz, Rio de Janeiro, Brazil

Sulaiman Krait, Ultra Medica Pharmaceutical Industries, Damascus, Syria

Hechmi Louzir, Director General, Institut Pasteur de Tunis, Tunis, Tunisia

Morena Makhoana, Biovac Institute, Pinelands, South Africa

Mario Ottiglio, International Federation of Pharmaceutical Manufacturers and Associations, Geneva, Switzerland

Sai D Prasad, Rotavirus Development Program, Bharat Biotech International Ltd., Turkapally, India

Li Ruan, Sinovac Biotech Ltd., Beijing, China

Mahendra Suhardono, Bio Farma, Bandung, Indonesia

Rajinder Kumar Suri, Panacea Biotec Ltd., New Delhi, India

Emilien Teyrouz, Aleppo Pharmaceutical Industries, LLC, Aleppo, Syria

Michael Watson, Chair of International Federation of Pharmaceutical Manufacturers and Associations Biologicals and Vaccines Committee, Sanofi Pasteur SA, Lyon, France

Wouter Verhoeven, Crucell Business Development, Leiden, the Netherlands

Hamdallah Zedan, Egyptian Organization for Biological Products and Vaccines (Vacsera), Cairo, Egypt

Haifa Zheng, Beijing Minhai Biotechnology Co., Ltd., Beijing, China

Public

Claire Boog, Netherlands Vaccine Institute, Bilthoven, the Netherlands

Rodney Carbis, International Vaccine Institute, Seoul, Republic of Korea

Nicolas Collin, Vaccine Formulation Laboratory, University of Lausanne, Lausanne, Switzerland

Wenfeng Gong, Duke Global Health Institute, Durham, NC, United States

Jan T Hendriks, Netherlands Vaccine Institute, Bilthoven, the Netherlands

Elodie Jambert, Médecins Sans Frontières Campaign for Access to Essential Medicines, Geneva, Switzerland

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Gerard Cunningham, Bill & Melinda Gates Foundation, Seattle, WA, United States

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Thea Emmerling, First Councellor, Health and Food Safety, Delegation of the European Union to the International Organisations in Geneva, Geneva, Switzerland

Jinna Lee, Delegation of the European Union to the International Organisations in Geneva, Geneva, Switzerland

WHO Secretariat

Peter Beyer, Innovation, Information, Evidence and Research (IER)/Public Health, Innovation and Intellectual Property (PHI)

Robinson Esialimba, IER/PHI

Martin Friede, IER

Padmashree Gehl Sampath, IER/PHI

Joachim Hombach, Family and Community Health, (FCH)/Immunization, Vaccines and Biologicals (IVB)/Initiative for Vaccine Research (IVR)

Miloud Kaddar, FCH/IVB/Expanded Programme on Immunization (EPI)

Anna-Lea Kahn, Health Security and Environment (HSE)/Polio Eradication Initiative (POL)

Alireza Khadem Broojerdi, FCH/IVB/Quality, Safety and Standards (QSS)

Zafar Mirza, IER/PHI

Sergio Nishioka, FCH/IVB/QSS

Erin Sparrow, IER

Roland Sutter, HSE/POL

Annex III: Workshop agenda

Background

In May 2008, the World Health Assembly adopted the global strategy and plan of action on public health, innovation and intellectual property. Two elements highlighted by the global strategy are the need to build and improve capacity in developing countries, and to facilitate the transfer of health-related technologies. In response to this, WHO is undertaking a project to identify the main challenges and obstacles to technology transfer and local production in developing countries, and to provide evidence-based recommendations on the feasibility and sustainability of such production. This project is being carried out in partnership with the United Nations Conference on Trade and Development and the International Centre for Trade and Sustainable Development and with funding by the European Union.

The project is reviewing separately the cases of pharmaceuticals, diagnostics and vaccines. For the field of vaccines, where in the past know-how rather than IP has been the main barrier to local production, the project is being implemented through three research activities: 1. A landscape analysis of technology transfer initiatives and trends; 2. Case study analysis; and 3. Workshop and stakeholder analysis (this meeting).

This workshop aims to bring together the main players in vaccine technology transfer including industrialized-country vaccine manufacturers, developing country vaccine manufacturers, public-sector vaccine developers, NGOs as well as public health agencies and funding agencies.

Objectives

The objectives of the meeting are to:

- Review the technology transfers that have taken place in the last decade, and identify emerging trends.
- Identify the conditions that need to be in place in the technology-recipient country and institute to favour successful technology transfer.
- Identify the benefits and drivers for technology transfer from both the technology donor and technology recipient points of view.
- Discuss through case studies models of technology transfer to identify how different models suit different objectives.

Agenda

Tuesday 30 November

Chair: Claire Boog

13:00–13:30 Introductions – Zafar Mirza (WHO/PHI)

13:30–14:00 Landscape of technology transfer in vaccines – W Gong (Duke University)

Case studies

14:00–14:25 Hib to Brazil – A Homma (Brazil)

14:25–14:50 Meningitis A to India – J-M Préaud (PATH)

14:50–15:15 Technology transfer and vaccines: The GSK experience – M Baijot (GSK)

15:15–15:35 Coffee

15:35–16:00 IVI programme: Cholera, typhoid vaccine to India and other IVI technology transfer initiatives – R Carbis (IVI)

16:00–16:25 Influenza technology hub – J Hendriks (NVI)

16:25–16:50 New trends in tech transfer methods: Rotavirus BRV project – the "enabling platform" model and Japanese encephalitis project – "capacity building" in China – J-M Préaud (PATH)

16:50–17:15 China: Technology transfer from the perspective of Sinovac – L Ruan (Sinovac)

17:15–18:00 Discussion: Lessons learnt from the case studies

18:00 Cocktail: WHO restaurant

Wednesday 1 December

Chair: Claire Boog

Perspectives and new approaches

9:00–9:30 Technology transfer from the perspective of IFPMA members – M Watson (IFPMA)

9:30–10:00 DCVMN view: role of technology transfer and local innovation in developing country – R Dhere (SII)

10:00–10:30 Adjuvant technology transfer hub – N Collin (UNIL)

10:30–11:00 Coffee

11:00–11:30 The role of NRA in technology transfer – A Khadem (WHO/QSS)

11:30–12:00 Intellectual property and licence management – M Friede (WHO/IER)

12:00–13:00 Lunch

13:00–15:00 Feedback from stakeholders on key issues:

1. What preconditions are required for successful transfer of technology from point of view of technology donor and recipient?
2. Will existing public sector manufacturers in developing countries, including emerging economies, survive as research-based manufacturers establish competing production in these countries?
3. What forms of transfer of technology are in the interests of public health in vaccines, and how can we best facilitate it (in terms of policy, market and non-market incentives, international activities, etc)?
4. What is the role of transfer of technology in the vaccines field in the future – that is, is there a justification (price-based or otherwise) for production in newer countries and equally importantly, is there a need to expand towards producing newer products in developing countries that currently demonstrate production capacity?

15:00–16:00 Panel discussion and conclusions

16:00 End of meeting

Annex IV: Workshop presentations

See http://www.who.int/phi/news/workshop_tt_vaccines2010/en/.

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