

Assessment of the vaccine supply chain for fee-based immunization in Hanoi Capital and Ho Chi Minh City

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OPTIMIZE

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Acronyms

CIF	Cost, insurance, and freight
EPI	Expanded Programme on Immunization
GDP	Good Distributor Practice
GSK	GlaxoSmithKline
GSP	Good Storage Practice
HN	Hanoi Capital
HCM	Ho Chi Minh City
MOH	Ministry of health
NEPI	Vietnam National Expanded Programme on Immunization
NIHE	Vietnam National Institute for Health and Epidemiology
PMC	Preventive Medicine Center
SOP	Standard operating procedures

Section I: Introduction

Background

The Expanded Programme on Immunization (EPI) in Vietnam started in some provinces in 1981 and expanded nationwide by 1985. From 1993 to present, the full vaccination coverage rate of children under one year of age for tuberculosis, measles, polio, diphtheria, pertussis, and tetanus is above 90 percent. The present rate of hepatitis B vaccination is also above 90 percent. Vaccines used in the EPI are provided by local vaccine manufacturers, and some are imported through the United Nations Children's Fund or local importers. The EPI established a vaccine supply chain—including storage, transport, and distribution—that operates from the national, regional, provincial, and district level to the commune health center level where immunization sessions are implemented.

EPI's fee-based immunization services in Vietnam are quickly developing in scope and quantity, especially in urban areas. They are offered by both public- and private-sector providers. They are also fee-based and paid for directly by the consumer. Previously, the fee-based immunization service was implemented by the public sector only; however, in 2008, decree number 23/2008/QĐ-BYT issued by the Ministry of Health (MOH) granted access to the private-sector. Since then, relevant private entities may provide immunization services if they meet the specific requirements therein. To administer vaccines, all fee-based immunization facilities must purchase vaccines from vaccine distributors.

In Vietnam, a vaccine supply chain exists and is managed by private-sector importers and distribution companies, but not much was heretofore known about its scope, structure, and quality. Project Optimize, a collaboration between the World Health Organization and PATH, is working directly with the Vietnam National Institute for Health and Epidemiology–Vietnam National Expanded Programme on Immunization to help identify innovative approaches to creating a vaccine supply chain that is flexible and robust enough to handle increasing volumes of more costly new vaccines. One of the project's key activities in Vietnam in 2009 and 2010 was to assess fee-based immunization in the areas of immunization practices, vaccine supply chain, and relevant policies and to provide recommendations for improving supervision and monitoring of fee-based services by government offices. As part of the fee-based immunization service assessment, this report describes in detail the vaccine supply chain for fee-based immunization service in Hanoi Capital (HN) and Ho Chi Minh City (HCM).

Objective

The objective of the assessment was to understand the structure, scope, and quality of the vaccine supply chain for fee-based immunization services and to provide recommendations for strengthening management and monitoring the quality of the vaccine supply chain for fee-based immunization.

Location, time, and method

Location

Three of the companies visited were located in HN and four in HCM. A breakdown of the company types is as follows:

- One importer.
- Two importers/distributors.
- One importer/distributor/manufacturer.
- One distributor.
- Two sub-distributors.

Time

- January 2010.

Method

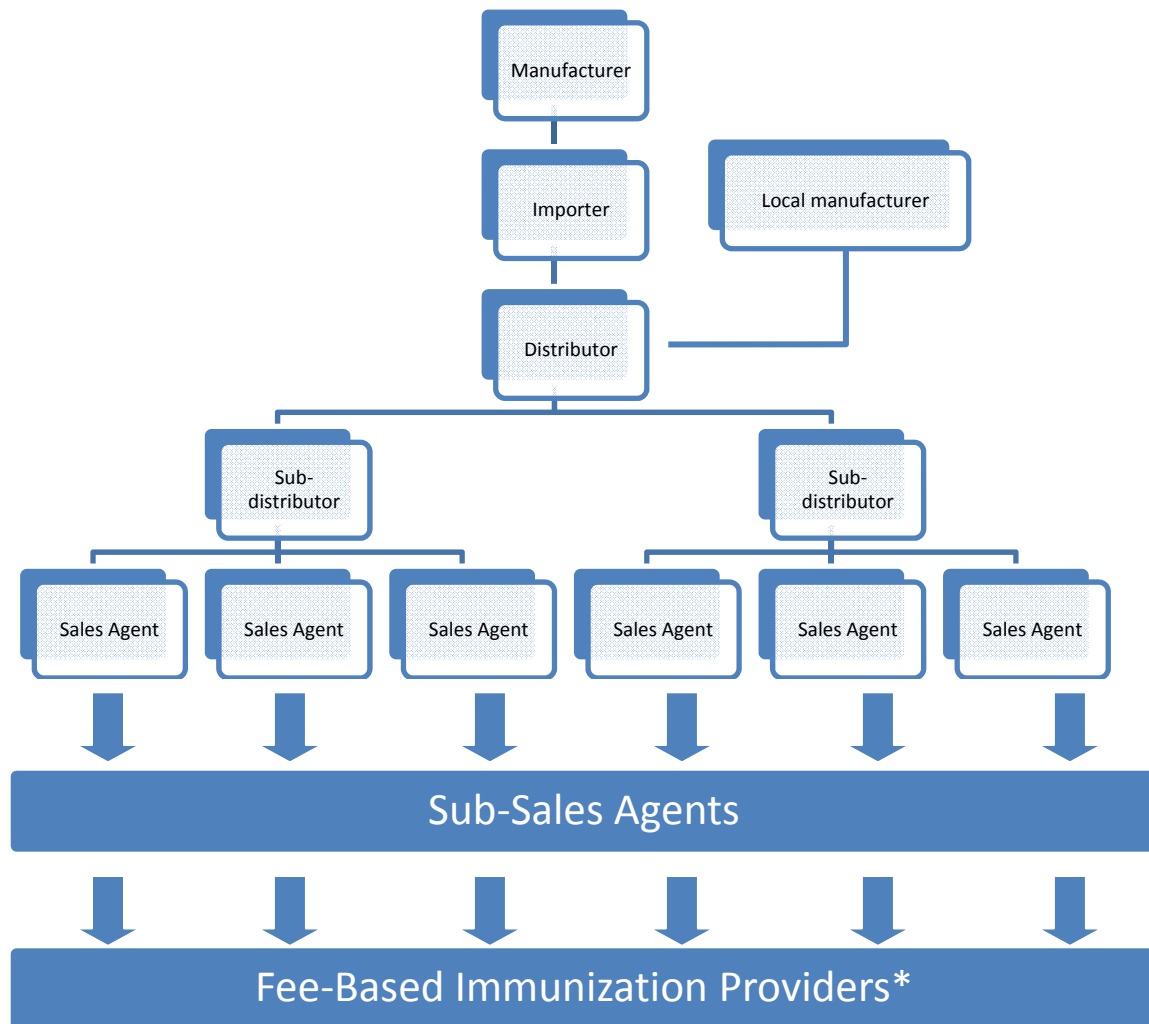
- In-depth interview of key subjects using a semi-structured questionnaire.
- Observe materials, facilities, and equipment at some companies.

Limitation of assessment

This assessment was conducted in HN and HCM only and with a sampling of importers and distributors; thus, the results of the assessment only reflect a part of the current vaccine supply chain in the assessed facilities. Moreover, the assessment was conducted in a short period of time and included a relatively small number of companies. It is not a systematic observation or thorough exploration of all activities relating to receiving, transporting, and distributing vaccine in Vietnam. In particular it is known that there are many sub-distributors in Vietnam that follow different practices and adhere to varying degrees of quality. The report does not therefore intend to extrapolate the results to other provinces or to Vietnam as a whole.

Structure of the vaccine supply chain for fee-based immunization

Figure 1. Example of one structure of the vaccine supply chain for fee-based immunization in Vietnam



*Providers include public health hospitals and health centers, preventive medical centers (PMCs), and private facilities.

Note: Figure 1 is only a representation of the vaccine supply chain for fee-based immunization. Individual supply chains may contain any number of manufacturers, distributors, sub-distributors, sales agents, sub-sales agents, and immunization providers.

During the assessment we learned that there are at least two additional levels below the sub-distributor level which include sales agents and sub-sales agents. We did not visit any companies at this level although recommend that somebody does so in the future to better understand the entire supply chain for fee-based vaccines. Although some vaccines move from the importer/distributor directly to the immunization provider, there are other instances where the vaccines may travel through all layers of the system. According to one interviewee, principal distributors tend to distribute across the entire country,

sub-distributors are responsible for a region, and sales agents are typically responsible for a province. Flow charts depicting the supply chain of companies visited during the assessment can be found in Annex 1.

Section II: Overview of key findings

The following is a brief description of the key findings of the assessment. For more information see sections IV to XIII.

In-country supply chain

The in-country vaccine supply chain for fee-based immunization is not consistent in infrastructure or in the type and quality of cold chain and delivery equipment. Each supply chain model is diverse and is only likely to broaden in its diversity as more vaccine distributors emerge. Vaccine distribution is a profitable business in Vietnam. Most existing companies are growing in size and new companies join the market each year. The private sector has evolved into its own entity, and although government regulations exist, they do not appear to be rigorously enforced. Also, the quality of the cold chain does not appear to be standardized.

Time considerations from point of order to distribution

Distributors and importers in HN and HCM reported that procedures at countries of origin typically take four months from the time of manufacture to the time of actual shipment, sometimes longer. Based on interviews the main reason procedures take this long is the country-of-origin processes such as verification and the issuance of certificates of analysis. The long duration of time was reported as sometimes causing issues with short shelf-life vaccines as Vietnam regulations stipulate that vaccines must have a remaining shelf life of at least two-thirds of their total shelf life at the time of importation. However the government is hoping to move toward the requirement that vaccines have a remaining shelf life of at least one-half of their total shelf life at the time of importation. In the special case that a vaccine has a short shelf life, an exception can be proposed to the MOH for consideration. Manufacturer lead time was reported as typically being four months thus making the average duration from the placement of a purchase order to importation eight months or longer.

Once vaccines have been cleared by customs they are delivered to the importer's warehouse where they are quarantined until they have passed testing protocols. Sample batches are sent to the National Institute for Expertise of Vaccines and Medical Biologics in HN for safety testing. According to the MOH's Circular 8, testing time should take seven working days. However, importers and distributors reported that the procedure frequently takes up to 21 working days, especially if no mice and/or rabbits are available for safety testing.

Quality of cold chain equipment

Although the distributors visited during the assessment appeared to maintain adequate to good quality cold chain equipment within their warehouses, it is not clear what quality controls exist at lower-level facilities (i.e., sub-distributors) where only refrigerators may be available.

Interviewees reported that vaccines travel with electronic temperature data loggers part of the time and without the data loggers the other part time of the time. It is the opinion of

the assessors that, especially if vaccines are traveling through multiple levels of the supply chain, it would be difficult for a vaccine provider to know whether or not the temperature range of the vaccine has jeopardized the vaccine. We were informed that regulations (the Decision no. 23/2008/QD-BYT on promulgation of the regulation on using vaccine, medical biological in prevention and treatment) are clear, consistent, and strict but that enforcement might not be adequate.

Gel packs were seen at most of the cold chain facilities visited. At one warehouse a frozen gel pack was taken straight from the freezer into the box with the vaccine shipment. This is a cause for concern as the vaccines could be subjected to freezing during transit. We did not receive information about what type of gel or chemical is used in the gel packs.

Various methods of transport are used from company to company including trucks, motor bikes, planes, customer vehicles, and outsourcing to third parties. It is unknown at this time what type and level of quality controls and measures are required for third parties or customers picking up orders.

During a courtesy visit to a PMC, the PMC staff member recommended that a vaccine vial monitor should be included with the vaccine from the time it leaves the manufacturer until the time it reaches the end-user. Placing thermometers in each box was not recommended as thermometers are not easy to check during transport.

Forecasting

All of the companies visited reported that forecasting data is not made available from the hospitals, clinics, and PMCs. Orders and deliveries were reported as coming at random without advance notice.

The majority of the companies visited reported that advertising for a vaccine in newspapers and on television can increase customer demand. An example provided by one interviewee was the advertisement of hepatitis A vaccine. The distributor of the vaccine was not made aware of the advertisement before it hit the public, thus making it difficult to meet the sudden increase in public demand for the vaccine. The demand can then disappear after a few weeks or months making it difficult for the distributors to forecast.

Standard operating procedures

All of the companies visited had standard operating procedures (SOPs) for cold chain management, and according to the companies, having SOPs is a government requirement. However, no standards or models on the format or level of content are provided by the government, so it is left to the individual company to write SOPs as they see appropriate. It is likely that the subject of SOPs is regulated but not the quality of the contents. Most SOPs reviewed were written instructions although at least one company's SOPs were diagrams. It is also not clear how often a company's SOPs are utilized or adhered to by their staff.

Section III: Regulations and government requirements

For a more complete description of government regulations and requirements for importing and distributing vaccines see, “Review of government policy, regulations, guidelines, and licensing pertaining to fee-based health services, especially immunization services in Vietnam,” that was produced by Bui Thi Thanh Mai, MD, MSc. under project Optimize. Another relevant document describing policy and regulation for vaccines in Vietnam is Circular 08/2006/TT-BYT, “Guiding the import of vaccines, medical biologicals; chemicals, insecticidal or germicidal preparations for domestic and medical use; and medical equipment.”

Any company distributing vaccines in Vietnam must adhere to good distribution practices and hold a Good Distributor Practice (GDP) certificate which is regulated by the MOH and issued by the Provincial Health Service. Cold chain systems within these companies however can range from a modern, fully equipped cold room to a simple refrigerator. The provincial health service also issues the Certificate on Adequate Condition for Pharmaceutical Business to distributors of vaccines.

Companies that store vaccine, such as importers, must adhere to and hold a Good Storage Practice (GSP) certificate. This is issued and regulated by the MOH. Importers are also required to obtain a certificate for online customs clearances. The GSP, GDP, and conditional certificate must all be renewed every two years after being inspected by the MOH or health department. Any companies not meeting the appropriate requirements will lose their certifications. Other key certificates required for importing and distributing vaccines include the Certificate for Registration on Export and Import, the Certificate for the Business, and the Tax Registration.

Section IV: Import timelines and requirements

Several companies reported that the average amount of time it takes for a vaccine to go from being manufactured to being shipped is three to four months, although it can take as long as six months. Companies also reported that a National Certificate of Manufacturer must be obtained in the country of origin for each flight prior to any vaccines being exported. It is unclear as to whether this is a country of origin requirement or a requirement in Vietnam. Other key documents required before export include certificates of analysis. Vietnam regulation requires that vaccines must have a minimum of two-thirds of their total shelf life remaining at the time of importation, so lengthy country of origin procedures can cause importation issues. Importers reported that final import clearance procedures take no more than 24 hours in Vietnam.

Once vaccines have been cleared by customs the importer must ensure that they are batch tested before they can be distributed. Vaccine testing time takes approximately 7 working days although it has been reported as sometimes taking up to 21 working days especially if mice or rabbits are not available for testing. The national regulatory agency is the National Institute for Control of Vaccines and Biological in HN. As of January 2010, the National Institute for Control of Vaccines and Biological has not been certified according to good laboratory practices.

Prior to distribution the manufacturer and importer information as well as the vaccine instructions must be written in Vietnamese on all first-level packaging and secondary level if applicable. Instructions and importer labels may be added by the manufacturer although it was reported this is primarily done in Vietnam by the importer due to lower costs. Distributor labels are optional and are not enforced. The drug administration is responsible for issuing vaccine import licenses and issuing a visa number (valid for five years) for each type of vaccine being imported.

Section V: Pricing and customer payments

Fee-based vaccines need to comply with current government regulations on pricing. The cost of imported vaccines is determined by the importer/distributor. Although according to law and regulation on drug pricing the price must be declared before circulation into the market. If the price is found unreasonable, the drug administration will require an explanation. The cost, insurance, and freight (CIF) for importing the vaccines is provided to the MOH along with the selling price. One company confirmed that their selling price is determined by the CIF plus eight percent and adjustments for the rate of exchange. All companies reported setting their prices at the CIF plus distributor fees including transportation, management fees, and staffing. The majority of the companies visited also set the prices for any sub-distributors and sales agents that work further down the supply chain although one company reported that each level of the supply chain justifies their own costs to the MOH.

Buyer payments are made via a variety of methods including cash, wire transfers, and credit. At least two companies reported that government health facilities are on a credit system and make payments via bank transfers. There were also reports that payments from government health facilities are on average about two months late.

Section VI: Quality of purchase and quality during transit

Most companies reported that they rely on the country of origin's batch release certificate and Vietnam's testing procedures to guarantee the quality of an imported vaccine. A few distributors purchasing vaccines stated that they require World Health Organization prequalification where it exists.

All companies reported that vaccines are imported with some form of temperature monitor. One company mentioned that they use data loggers that measure the temperature every 15 minutes along with a freeze-tag device. Many companies use single-use temperature tags. Temperature monitors, however, appear to be randomly used when vaccines move through the in-country supply chain. One company in HN reported using their own thermometer to monitor temperatures when delivering vaccines to remote PMCs but not doing so when delivering locally. Yet another company reported putting a thermometer in every cold box distributed and providing thermometers to clinics because there is no standardization in the country.

At least two companies reported using foam boxes with ice for delivery. Other companies reported using gel packs and at least one company was witnessed taking a frozen gel pack straight from the freezer into the box with the vaccine shipment. This is a cause for concern as the vaccines could be subjected to freezing during transit.

Section VII: Ordering/forecasting

One of the biggest challenges reported by companies is the ability to forecast. PMCs and government health facilities do not quantify or provide the supplier with information regarding their estimated needs. Most companies reported being too nervous to order too much vaccine because they may not only lose the product but also may have to pay for its destruction. Companies reported having a tendency to under order what they estimate the needs might be, and one company reported purchasing 70 percent of their estimates. One company reported basing their forecast on the previous year's performance although for 2010 they took the 2009 quantities purchased and doubled the amount. Another company reported ordering the same amount of vaccine as purchased the previous year.

One company reported that their five regional sales people (one in each region) quantify based on market demands but also on how much they want to sell. Their decision is based on the number of staff, salary, administration costs, and how much profit they want to make. The sales people send their requests to the distributor where adjustments are made and final estimates decided. These numbers are reviewed every six months and increases/decreases are made as necessary.

All companies visited reported that their customers (including health facilities, sub-distributors, and agents) order randomly including those that have sales agents and who sign an annual plan. This is especially prevalent during outbreaks. Companies reported providing vaccines immediately upon order except during a stock-out situation. Most customers apparently will wait for an order to arrive, but if the situation is urgent will go to another supplier.

One of the sub-distributors reported not needing to forecast as they were informed each year of what they would receive and sell. GlaxoSmithKline (GSK) has local representatives who handle the forecast, and the distributor simply distributes. This sub-distributor also reported that provincial-level customers can place orders with the distributors or sub-distributors but only the sub-distributor can sell.

Section VIII: Inventory/stock-outs

Every company visited reported some level of stock-outs. Their reports ranged from “very frequently” to “rarely.” The most common reasons for stock-outs were reported as follows:

- High demand in country.
- The time it takes for vaccines to be imported (from the time of order).
- Forecasting is difficult and is lacking.
- Manufacturer capacity (that is during 2009 some manufacturers focused on influenza and did not produce enough of the other vaccines).
- Testing time during importation can be longer than anticipated.
- Outbreaks.
- Do not want to over order as it is too costly to waste the vaccine and then pay to destroy it.

Every company reported shipping partial orders when they are unable to meet the needs of every customer in order to share what is available among everybody. The majority of companies reported shipping partial orders on a frequent basis. One company reported informing their customers when vaccines requiring second and/or third doses were low and notifying them to only treat recurrent patients and not new ones during the shortage period.

Different companies reported maintaining different levels of vaccine inventory. The larger importers/distributors reported trying to maintain between three to six months of inventory whereas smaller companies, such as sub-distributors, reported maintaining three days to two weeks of inventory.

The types of vaccines suffering stock-outs seemed to be across the board, and reports of stock-outs included measles, mumps, and rubella (GSK Priorix); rotavirus (GSK Rotarix); hepatitis A and B bivalent (GSK Twinrix); and hepatitis B (GSK Engerix B). *Haemophilus influenzae* type b (GSK Hiberix); diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, and *Haemophilus influenzae* type b (GSK Infanrix Hexa); and hepatitis B (GSK Engerix B) were reported as vaccines that tend to stock-out more frequently than the others. Reported stock-out durations were typically one to two weeks to three months.

Section IX: Warehouses/equipment and SOPs

The cold chain facilities seen during the assessment appeared to all have good systems within the warehouses. Vaccines are isolated in the importer warehouse while waiting for test results. The majority of warehouses viewed had separate isolation rooms, although at least one company used the same room but different shelves. Some companies had SOPs on the labeling room walls, and the temperature in these rooms was also recorded daily. Others did not appear to have either.

Some companies keep their cold room temperature monitor between 2° to 8°C. Other companies keep their cold room temperature monitor between 3° to 7°C. For instance, one company opened their cold room's door to let us see the vaccines and the alarm went off at 8.1°C.

All of the companies visited had at least one cold room and some also had refrigerators for small stocks. All of the refrigerators had electronic temperature monitors on them. A freezer for ice or gel packs was at every warehouse visited. Temperature sensors with alarms were viewed in cold rooms as well as manual thermometers. The sensors were linked to the computers in some companies and in others temperature records were being keyed into the computers manually. Temperature logs were manual and were checked three times a day on average.

All suppliers visited had a generator, and the majority of the alarm systems assessed had both light and sound warnings. The suppliers visited were large companies with good-sized warehouses. The assessment, however, did not reveal whether lower-level suppliers (sales agents and sub-sales agents) had generators to back up smaller storage areas such as refrigerators.

Most of the companies visited handled their own cold chain maintenance, although one company reported outsourcing the work. The government has regulations that require that cold chain equipment be calibrated yearly and that a certificate of proof be obtained.

According to Circular 8, the customers' cold chain equipment has to be in good working order, and the distributing company has to have maintained the vaccine in the proper environment. However, one of the companies interviewed reported that, "once an order is handed over the vaccines are the responsibility of the customer."

SOPs are required by the government in order to obtain a GDP certificate. However, some of the SOPs assessed were very general, and one company had their SOPs in a diagram form rather than in a written form. No standards or recommended models for SOPs are provided by the government. Every company had between 25 to 40 SOPs. It is not known how many of the SOPs are required under government regulations or how many are the in-house decisions of the companies. The majority of distributors and sub-distributors reported having to follow manufacturer regulations.

Section X: Records/stock management

Each company uses its own software and/or reporting systems although the government stipulates that all companies have to maintain certain information that can be inspected at any time. An Excel form we reviewed contained the following information: date in or out, invoice number, lot number, date of manufacture, expiry date, quantity in, quantity out, balance (vials), and notes/comments (which contained information on where the vaccines were purchased and who the goods were sold to). There are no set government required forms although most forms viewed contain similar information.

The three groups that can inspect records are the health authorities, market control, and economic police. The MOH (Drug Authority) requires an annual report of the number of vaccines remaining on hand by type.

The majority of documents that companies showed us were in and out minutes of stock. These were either written as minutes or were in a warehouse log book. Most companies maintain manual and computerized records. The in minutes confirm that a vaccine meets all requirements including a physical inspection (a physical inspection that ice is present, that a vaccine vial monitor or temperature monitor shows the correct reading, quantities, lot number, expiration date, receipt number, and packaging integrity).

We also reviewed documents such as, “The Diary of Monitoring Hygiene in the Cold Room,” that included information on daily tasks such as cleaning and, the “Temperature Monitoring Log Book,” that recorded daily temperature and humidity logged at 8:00 am and 8:00 pm. Both documents contained information required by the government to be maintained, although the form of record keeping is at the discretion of the company.

Section XI: Training

All companies reported that they provide some form of training to their customers although we were not able to review any of the training materials or gain a clear picture as to exactly what the training entailed. The consensus is that the majority of training provided by a distributor is on new vaccine information. Two companies reported that they perform safe injection training. From a different assessment it was found that injection providers, both in the public and private sectors, reported receiving 100 percent of their vaccine stock management training from the government.

Section XII: Basic company information—supply chain

The following is a list of the companies that were visited with a brief description of each company. Diagrams of the supply chain that each company operates within can be found in Annex 1. The purpose of this section is to provide information about scope and operation of the assessed companies. At the request of the companies their names are left out of the report.

Company A in HN (50 employees)

Company A is the sole importer and distributor for Sanofi Pasteur in North Vietnam, importing approximately 15 different types of fee-based vaccines. Imports occur on a monthly basis. Their main customers are government hospitals and provincial PMCs in the north of the country that Company A sells to directly. No sub-distributors or sales agents are utilized. Company A uses their own refrigerated vehicles for local deliveries in HN whereas PMCs pick up orders.

Company B in HN (200 employees)

Company B is an importer/distributor/manufacturer. They import from four manufacturers and sell to two sub-distributors; one in the south and the other in the north of the country. The sub-distributors sell primarily to the provincial PMCs (63) and approximately 10 hospitals which is a small amount of the business. Company B imports approximately five different types of vaccines with importations occurring on average every three to four months.

Company B does not own refrigerated vehicles, and the sub-distributors pick up vaccines once a month although orders are placed twice yearly. The sub-distributors are allowed to pick up emergency orders on an as needed basis. PMCs order randomly from the sub-distributors.

Company C in HN (250 employees [120 for vaccines])

Company C is a distributor. In the past they were also an importer but currently do not have a GSP certificate. Company C is in the process of building a new warehouse and will reapply for their GSP certificate allowing them to import again once the new warehouse is complete.

Company C purchases vaccines directly from international manufacturers and then distributes to five sub-distributors who in turn distribute to sales agents, sub-sales agents, provincial and district PMCs, health centers, hospitals, and clinics. Until the new warehouse is finalized and the GSP certificate is obtained, Company C hires an importer to handle customs clearance processes, testing procedures, and labeling requirements. Two sub-distributors are based in North Vietnam (Red River Delta and the northwest); one is in the high-central region and two are in the south. Company C also distributes approximately 25 percent of their vaccine business to hospitals and clinics in HN who have a GSP. They distribute approximately 13 different vaccines.

Company C owns and operates one refrigerated vehicle which is used for deliveries to the north of the country and is 5 to 6 cubic meters. They plan to purchase another refrigerated vehicle in 2010 at around 15 to 16 cubic meters for deliveries to the south which will be more cost-effective than the current practice of shipping via air. Orders for the central region are also currently being shipped via air. Company C also owns and operates five general vehicles across the entire country.

Company D in HCM

Company D is the importer for Zuellig and Sanofi Pasteur in HCM. They import approximately nine different vaccines. Company D delivers to the distributors using their own cold boxes and refrigerated truck. The distributors, however, can also collect their vaccines from the Company D warehouse.

Company E in HCM (186 employees)

Company E is the sub-distributor for Zuellig in HCM, who is one of two storage service/logistic providers for GSK in South Vietnam. Company E distributes mainly to provisional PMCs although they also deal with district PMCs and government hospitals in two of the southern regions (East and Mekong) and to a small number of district PMCs. Another sub-distributor mainly distributes to the third southern region. All of Company E's business is with the public sector.

Deliveries to the regions would ideally be one trip with one truck per region per month but is usually two trips per region per month. If more trips are required within a month, Company E outsources the delivery. For hospitals within 40 km of HCM, Company E delivers on a random "as-needed" basis, or customers can pick up the vaccines.

According to Company E, there are three types of distributors in Vietnam. Some are better known as traders who can buy and sell vaccines at their required price, others are distributors who have their own markets and sales that are agreed to with the principal distributor, and the third type is the physical distributor who simply distributes and enjoys the commission. Company E fits into this final category.

Company F in HCM (18 employees)

Company F is the second sub-distributor for Zuellig vaccines in South Vietnam. Zuellig provides storage and logistics services to Merck & Co., Inc. as well as GSK. Company F also distributes for two domestic manufacturers, IVAC and Vabiotech, although 90 percent of their business is imported vaccines. Company F distributes approximately 14 different types of vaccines with about 70 percent of their business being with the public sector. They own one refrigerated vehicle and no regular vehicles.

Company G in HCM (120 employees)

Company G is the sole importer/distributor for Sanofi Pasteur in South Vietnam. They do not work with sub-distributors or sales agents. Their main customers are provincial and district PMCs as well as district and provincial health centers. They also distribute to private clinics that have permission to provide vaccines. We were not provided with a list of vaccines that Company G imports but during a tour noted that there are at least six.

Deliveries are random, and we were informed that set plans cannot be implemented “because they are not real.” Company G owns refrigerated vehicles although they also have a contract with an outsourced delivery company. The outsourced company is able to pick up vaccines within 24 hours. Within the city, motor bikes are more commonly utilized.

Section XIII: Recommendations

Based on the above, we recommend that the government consider conducting an assessment of the quality of the cold chain throughout the in-country supply chain with any trends analyzed to determine what quality issues exist, if any. Such a study can uncover anomalies and unexpected issues about the cold chain.

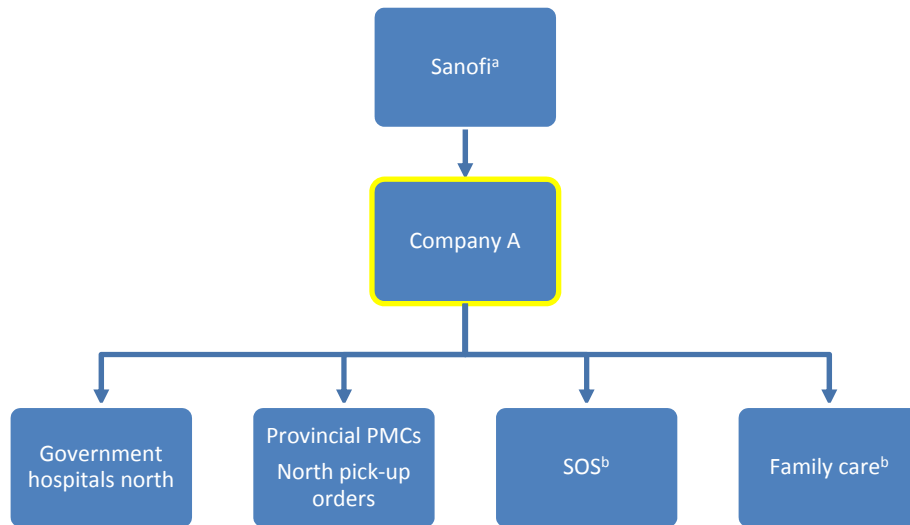
As a result of the overall quality assessment, we would also hope to achieve the following:

- Understand what cold chain regulations the government is actually enforcing and where there are gaps.
- Recommend to the government how any regulatory gaps could be closed (for example audits, quality systems, technical agreements, and stricter licensing).
- Provide or recommend training to those within the supply chain including injection providers on how to analyze vaccine excursions and make decisions on whether vaccines should be used. Training should occur in all aspects of packing and transport as witnessed during this assessment when frozen gel packs were seen being put into vaccine shipments. Also a PMC employee informed us that during a recent study, vaccines were found in refrigerators without the proper temperature.
- Discuss and determine with stakeholders a clarification of private-sector and public-sector roles within the private-sector supply chain.
- Recommend that standardization monitors be established such as report systems and SOPs.

All of the companies visited during the assessment confirmed that stock-outs are one of the largest challenges for fee-based vaccines. From another assessment, it was found that stock-outs are also occurring at the health facilities and that the main reason was that suppliers were out of stock. We recommend that the PMCs and government work closely together to provide data to the private sector that can in turn provide more efficient forecasts to the manufacturers. There appears to be no “point person” in country who captures information on need versus the number of imported vaccines or the amount of stock-outs and wastage.

Annex 1

Figure 1. Importer/distributor (sole distributor for Sanofi in North Vietnam)

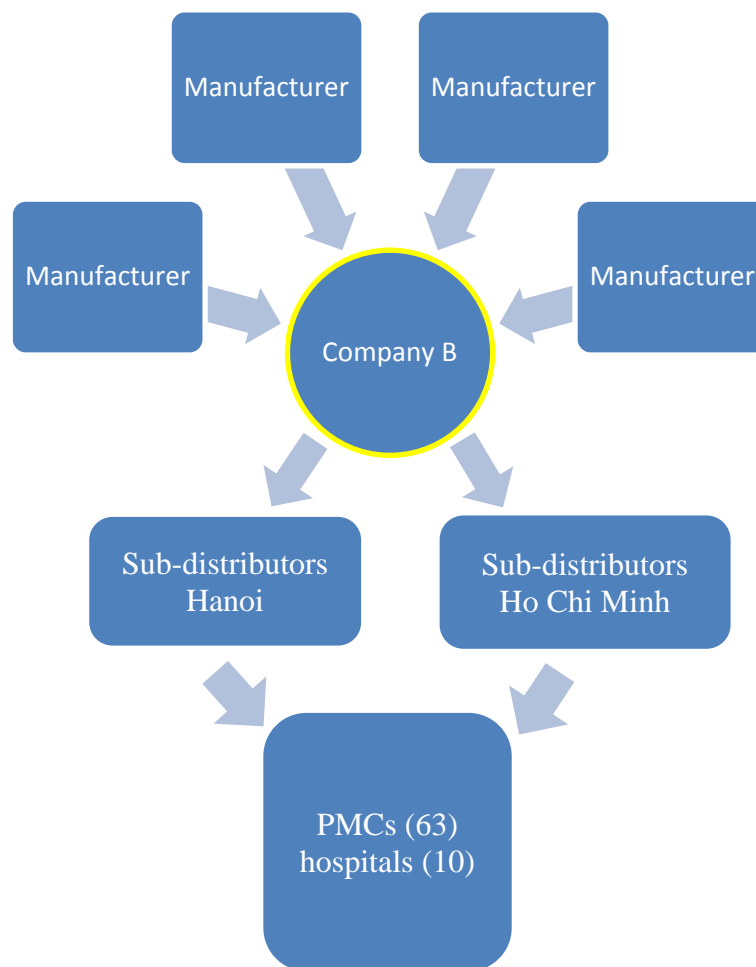


Note: a= manufacturer; b= private facility

Company A:

- Fifteen of its vaccines are imported.
- Has spent 17 years in the vaccine industry.
- Has 50 employees.
- Ninety-eight percent of its customers are in the public sector.
- It imports monthly.

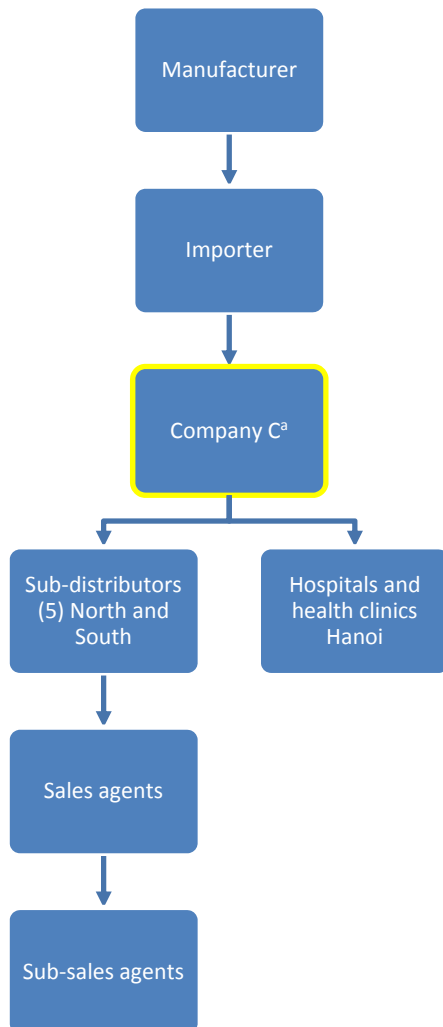
Figure 2. Importer/distributor/manufacture



Company B:

- Five of its vaccines are imported.
- Has spent 10 years in the vaccine industry.
- Has 200 employees.
- Ninety percent of its customers are in the public sector.
- It imports every three to four months.

Figure 3. Distributor lost GSP

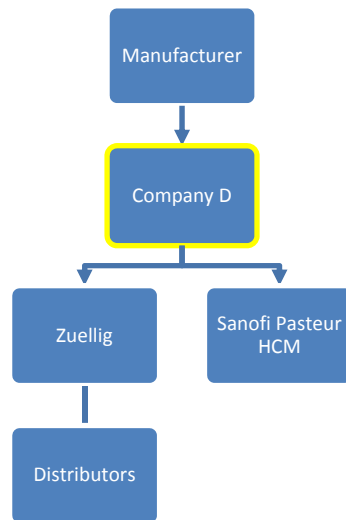


Note: a= distributor

Company C:

- Thirteen of its vaccines are imported.
- Has spent 8 years in the vaccine industry.
- Has 250 employees (120 for vaccines).
- Seventy-five percent of its customers are in the private sector.

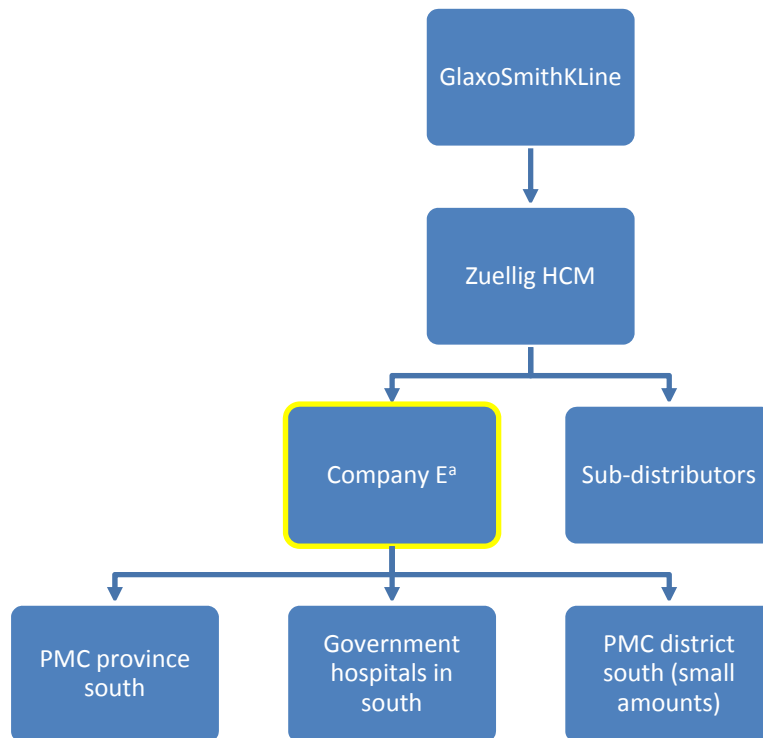
Figure 4. Importer



Company D:

- Nine of its vaccines are imported.

Figure 5. Vaccine sub-distributors

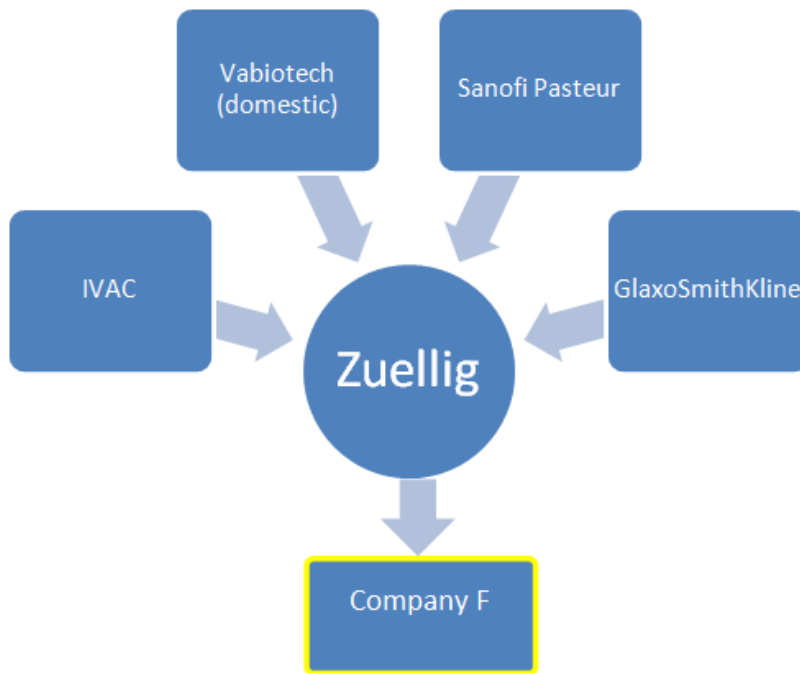


Note: a= importer

Company E:

- Nine of its vaccines are imported.
- Has spent 14 years in the vaccine industry.
- Has 186 employees.
- All of its customers are in the public sector.
- Consists of 20 hospitals, 19 provincial PMCs, and 100 district PMCs.

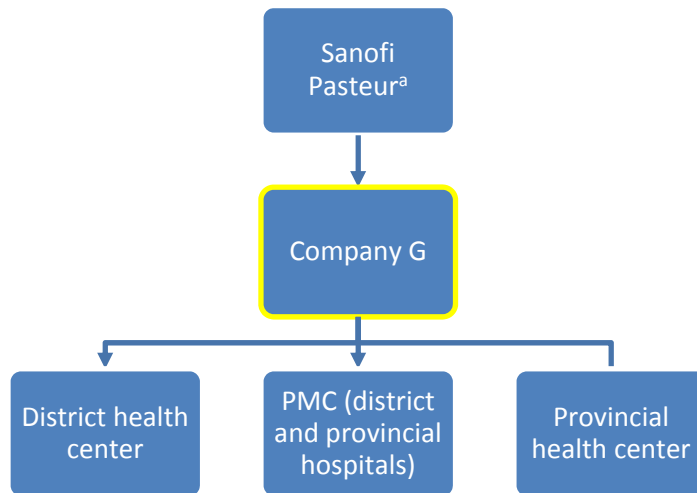
Figure 6. Vaccine distributors



Company F:

- Distributes 14 types of vaccines.
- Has spent 3 years in the vaccine industry.
- Has 18 employees.
- Seventy percent of its customers are in the public sector.
- Thirty percent of its customers are in the private sector.

Figure 7. Vaccine importers and distributors



Note: a= manufacturer

Company G:

- Has spent 7 years in the vaccine industry.
- Has 120 employees.