

# Pharmacists in the supply chain

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The role of the medicines expert in ensuring quality and availability

2018



## Colophon

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# Foreword

By the Chair of the People That Deliver Initiative and Programme Director, Pharmaceutical Systems Africa

This report could not have come at a more opportune time. Rapidly increasing health assistance from multilateral and bilateral donors has resulted in huge increases in the quantity and value of health supplies flowing through the health supply chains of middle- and low-income countries. This increase in commodities moving through supply chains has, unfortunately, not been accompanied by a commensurate increase in human resources or capacity to manage such resources. From a developed country supply chain perspective, manufacturing activities have been increasingly becoming more global. A number of large manufacturing companies and wholesalers have globalised their manufacturing and distribution services by acquiring local entities. In addition, they have invested in vertical integration by developing pharmacy chains, financing pharmacies, and introducing generic manufacturers in certain markets. This heightens pressures (e.g. increasing competition) on health supply chains that struggle even with existing requirements, putting both health supplies and health outcomes at risk.

Effective and efficient supply chains are vital in ensuring that communities receive the medicines, vaccines and the health supplies they need. Health supply chains are also complex and require skilled personnel to manage them. While the focus of international donors has been on the procurement of medicines, there remains a lack of recognition of the essential strategic role of the health supply chain workforce within health systems and of the technical and managerial competence required to run a supply chain successfully.

This report, with its excellent and practical case studies, highlights specifically the optimal role and use of pharmacists in the pharmaceutical supply chain. Too often, in the context of scarce human resources, pharmacists are being shifted out of the roles for which they have been trained in order to plug other gaps in the supply chain or health system. The report also documents the practice in many countries where, due to a lack of pharmacists, other health personnel are taking on the responsibility of pharmaceutical management, including the issuing of medicines to clients at service delivery points. This should be avoided where possible. Medicines are specialised commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance.

As this report rightly points out, pharmacists are the fulcrum of medicines management and should be involved in some of the components of the supply chain. However, some of these supply chain functions, such as procurement, distribution and storage of commodities, are rarely taught in pharmacy schools. The pharmacy profession should remedy this by including specialised supply chain components in the curriculum or by encouraging pharmacists interested in these components to undergo extra training in addition to their pharmacy degrees.

Using the People that Deliver (PtD) Initiative's Supply Chain Competency Framework, the report demonstrates that perceptions of the role of pharmacists vary substantially both within countries (between pharmacists and more logistics-focused personnel) and across countries (based on different health systems and legislative frameworks). At its core, however, the evidence from across the case studies stresses the desirability of pharmacists being involved in supply chain management and the feasibility of producing good outcomes if the supply of pharmacists is allocated efficiently and is sufficiently capacitated in these areas.

I applaud the International Pharmaceutical Federation (FIP) for producing this timely report that echoes PtD's own agenda. PtD advocates for a holistic approach to developing workforce excellence in supply chain management. The evidence presented in this report strengthens our call for international and national level interventions that improve the demand and supply of qualified supply chain professionals in low- and middle-income countries. Ultimately, it is people who are the heart of an efficient health supply chain, and it is pharmacists who are often the heart of an effective pharmaceutical supply chain.

FIP is right to put its focus on this important issue, and I as chair of PtD and as a pharmacist myself, look forward to working with the federation to put the recommendations of this report into action.

*Dr Lloyd Matowe, PhD, MSc, BPharm*

## Acknowledgements

This report was compiled by FIP's Board of Pharmaceutical Practice Working Group on Pharmacists in the Supply Chain, co-chaired by Ulf Janzon (BPP Executive Committee, Sweden) and Andrew Brown (FIP Education, Australia, until May 2017), with the input and support of the following working group members (in alphabetical order): Michael Anisfeld (nominated by FIP's Industrial Pharmacy Section, USA), Diogo Gouveia (European Healthcare Distribution Association, Portugal), Luna El Bizri (nominated by FIP's Community Pharmacy Section, Lebanon), Patricia Kienle (nominated by FIP's Hospital Pharmacy Section, USA), Lindsay McClure (nominated by the FIP Health and Medicines Information Section, UK), Erik Naeser (nominated by FIP's Industrial Pharmacy Section, Switzerland), Vaiyapuri, Subramaniam (nominated by the FIP Social and Administrative Pharmacy Section, USA), and Wendy Walker (nominated by FIP's Military and Emergency Pharmacy Section, Australia). The working group was coordinated by Zuzana Kusynová (FIP policy advisor and project manager, Netherlands).

The working group acknowledges the work of Jennifer Chen (FIP intern, USA), who made significant contributions to the survey development, literature review and report compilation, as well as Nuno Cardoso (Associação de Distribuidores Farmacêuticos, Portugal), Linda Hakes (FIP vice president, United Kingdom), Andy Gray (FIP vice president, South Africa) and Parisa Aslani (president, FIP Pharmacy Information Section, Australia) for their contributions to the report review.

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## Executive summary

As we enter the era of the Sustainable Development Goals and Universal Health Coverage, it is unfortunately a fact that a substantial proportion of the world's population is still without access to basic life-saving medicines. This is primarily a result of lack of financial resources but also of inefficient pharmaceutical (health) supply chains. An effort to increase the quality and efficacy of supply chains is consequently an important contribution to achieve the Sustainable Development Goals and Universal Health Coverage. This report discusses the optimal role and use of the pharmacist in the pharmaceutical supply chain in different environments.

The pharmacist's role can be analysed using both a top-down and a bottom-up approach. This report aims to do both in order to provide an overview of where broad competence is needed, as well as where detailed tasks are related to specialty competencies. Furthermore, in the global context of a lack of human resources for health, the common need to maximise the use of scarce resources has prompted a closer look at the actual role of pharmacists in pharmaceutical (health) supply chains.

The pharmaceutical (health) supply chain has been defined as: "The management of product supply from raw material sourcing to active ingredient manufacturing through formulation, packaging and distribution to the patient. It encompasses all related activities across the product lifecycle, including clinical supply, scale-up and transfer as well as outsourcing and product discontinuation. A key requirement is the safe and reliable supply of quality medicines through a supply chain which is responsive to true demand and understands the voice of the customer."<sup>1</sup>

Pharmacists are medicines experts with an essential role to play in the full range of activities of the supply chain, from the production of medicines (both industry scale and extemporaneous) to their administration to patients, and after. Starting with the production and supply of active pharmaceutical ingredients (APIs) and the production of medicines, through distribution of medicines to wholesalers, storage and repackaging of medicines and distribution to pharmacies, hospital pharmacies, etc., supply chain activities go on to include medicines selection and administration, and end with medicines use by patients, including individual counselling, follow up and pharmacovigilance.

This report aims to provide a global picture of the role of the pharmacist in supply chains. In doing so, it takes the scarcity of pharmacists in many settings into consideration, and identifies where the competencies of pharmacists are best used and most needed. Since the maturity of supply chains varies across the globe, particular attention is given to differences that may exist between low- and middle-income country contexts compared with high-income, more developed supply chain environments.

For the latter, the focus is mainly on the component of the supply chain of pharmaceutical products from manufacturer to dispensing points responsible for delivering medicines to patients, such as hospital and community pharmacies. This link is often undertaken by wholesalers, which occupy a central position in the supply chain and are responsible for bundling products from manufacturers and delivering them to the dispensing points, as well as for the backwards logistics, where applicable. The pharmaceutical supply chain aims to ensure the availability of the right medicine, at the right time, to the right patient.

Literature, survey data and detailed case studies have been used to present a global overview of the role of pharmacists in supply chains, identifying that pharmacists are medicines experts with clear expertise in medicines compounding, quality, procurement, storage and use, and pharmacovigilance. They are critical to supply chain integrity. At the same time, it acknowledges that pharmacists' roles in larger regional or national pharmaceutical supply chains should be strengthened by investments in further training and education, or by utilising other competencies where needed, or both.

This report presents:

- A definition of the pharmaceutical (health) supply chain, outlining the variety of stages that link the supply chain from manufacture to patient use;
- The range of competencies that need to be demonstrated by pharmacists for quality, well-functioning supply chains;
- The understanding that in some countries, pharmacists require specific professional training and/or academic education to take on specific roles in the supply chain;

- An acknowledgement that in many countries, due to a lack of pharmacists, especially in low-income countries and in rural and remote areas, a range of health personnel have taken on roles in pharmaceutical storage and distribution at the service delivery point level;
- The recognition that there are many countries where medicines are currently treated as simple commodities. Such practices devalue medicines and disregard their special characteristics that justify their supply partly or entirely through the regulated pharmaceutical supply chain.

## Glossary of terms

| Term   | Meaning   |
|--|---|
| <b>Behavioural competencies</b>  | Are expressions of what an individual does and is observed doing when effective performers apply motives, traits and skills to a relevant task. For example, for the domain of “Procurement”, and the competency area of “Manage tendering processes and supplier agreements”, such behavioural competencies may include: “Develop bidding documents”, “Use WHO prequalification system to confirm quality suppliers”, “Manage a tender process using country systems”, “Formalise contracts with successful companies” etc. <sup>2</sup>   |
| <b>Competency framework</b>  | Is a collection of competency areas with associated behavioural competencies that defines the expected requirements of particular personnel. For example, a competency framework may be developed for a warehouse manager, while a separate competency framework would be required for a hospital pharmacist. The composition of country-based, personnel-specific competency frameworks will also depend on the structure of the supply chain and at which levels various competencies are allocated. <sup>2</sup>   |
| <b>Domains</b>   | Are the high level groups, or clusters, of competency areas within a given competency framework. Traditionally domains do not exceed six. The six domains used in the People that Deliver supply chain competency framework are: Professional/personal, Resource management, Selection and quantification, Procurement, Storage and distribution, and Use. <sup>2</sup>   |
| <b>Good distribution practice (GDP)</b>  | Refers to the practices required to comply with the legislation and recommended guidelines in order to ensure control of the distribution chain and maintain the quality and integrity of pharmaceutical products. These guidelines are applicable both to products moving forward in the supply chain and to products which are moving backwards in the chain (for instance, a recall). GDP encompasses requirements for quality management, personnel, equipment, documentation, operations, complaints, returns, suspected falsified medicines and product recalls, outsourced activities, self-inspections, transportation and specific provisions for brokers. |
| <b>Pharmaceutical services</b>   | Refers to the range of activities required to deliver pharmaceutical products to patients to optimise effective, safe and quality use of medicines. These services vary according to each practice environment.   |
| <b>Prequalification programme</b>  | Is where an organisation (e.g. World Health Organisation) carries out a comprehensive, scientific evaluation of a medicinal product made by a specific manufacturer with consideration to quality. The evaluation is based on information submitted by the manufacturer and on an inspection of the corresponding manufacturing facilities and clinical sites.  |
| <b>Pharmaceutical supply chain or supply chain (several definitions are available)</b> | Is defined as the “management of product supply from raw material sourcing to active ingredient manufacturing through formulation, packaging and distribution to the patient. It encompasses all related activities across the product lifecycle including clinical supply, scale-up and transfer as well as outsourcing and product discontinuation. A key requirement is the safe and reliable supply of quality medicines through a supply chain which is responsive to true demand and understands the voice of the customer.” <sup>1</sup>   |
| <b>Substandard and falsified medical products</b>                                      | <i>Substandard</i> : Also called “out of specification”, these are authorised medicinal products that fail to meet either their quality standards or specifications, or both. Conditions are under national or regional regulation and legislation.<br><i>Falsified</i> : Medicinal products that deliberately misrepresent or fraudulently present their identity, composition or source. <sup>3</sup>   |



# 1 Introduction

## 1.1 Specific aims of this technical report

This report aims to provide a global picture of the role of the pharmacist in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies, clearly identifying the need for efficiency in task allocation in settings with a scarcity of pharmacists. Since the maturity of supply chains varies across the globe, particular attention is given to differences that exist between low- and middle-income country contexts compared with high-income, more developed supply chain environments.

This aim is met by:

- Describing the importance of ensuring an effective supply chain for medicines and other health products;
- Defining the stages of the supply chain for health products from manufacturing to delivery to the point of dispensing and, where applicable, to the patient;
- Presenting the competencies needed to oversee the different stages of the supply chain, and identifying where the competences of a pharmacist are best used;
- Discussing the important role of being responsive to any incidents occurring within the supply chain and capable of defining priorities when needed;
- Presenting where specialised training for pharmacists' supply chain competencies is required;
- Noting guidance for contexts where pharmacists are not available for critical competencies, making recommendations on safe, workable solutions using other personnel.

In this report, we will consider the supply chain from where medicines are approved and in principle available from the manufacturer, to where they are delivered to the point of dispensing, while acknowledging that in some cases direct delivery to the patient exists.

## 1.2 Overview of report methodology and structure

Three main inputs were used for the development of this report: literature review; primary survey data; and case studies. For the detailed case studies, see Appendix 1.

### 1.2.1 Literature review

A methodical literature scan was conducted using the Medline, Ebscohost and Embase bibliographic databases. A keyword search string was used that aimed to retrieve citations investigating aspects of the supply chain, medicines access, medicines availability and the role of the pharmacist and other pharmacy personnel. Approximately 50 citations were reviewed by Jennifer Chan and Andrew Brown using a title and abstract review. Selected articles representing the variety of work published in this field are embedded in the report. A systematic literature review was not conducted, as this was not possible within the resources of the working group. Besides the references used in the document, the report offers additional literature resources (Appendix 2).

Grey literature, specific legislation pertaining to supply chains, or associated regulations were not included in the search. However, case studies included in Appendix 1 aim to describe national and/or regional systems in place, thus providing examples of implemented policies.

### 1.2.2 Primary survey data.

The aim of the survey was to address the objectives outlined in the Terms of Reference (Appendix 3) with the focus on identifying "pharmacy-only competency areas" within the context of supply chain management. The survey tool was developed by Jennifer Chen and Andrew Brown in conjunction with the working group and reviewed by the FIP head office. The survey used the SurveyMonkey® tool and was circulated to FIP member

organisations through the FIP head office between April and May 2015 and via a variety of global list services, where pharmaceutical services delivery is discussed (e.g., E-DRUG, IAPHL, RHSC-SSWG, FIP CoP). The data were analysed by Andrew Brown and Michael Anisfeld. The data presented in this report capture the views of “all respondents” rather than country-specific details or regional variations. A copy of the survey tool can be found in Appendix 4.

### 1.2.3 Case studies

There is a global diversity concerning supply chain maturity and the role of pharmacists within supply chains in different practice contexts. The working group established an agreed set of comprehensive case studies that were developed by partners to reflect this diversity.

The content of this report has been reviewed by members of both the FIP Pharmacist in Supply Chain Working Group and the BPP Executive Committee.

## 2 Describing the supply chain

### 2.1 The global supply chain: From manufacture to use

The basic goals of national medicine policies and public sector pharmaceutical supply systems are to provide access to needed medicines and supplies, promote the responsible use of medicines, and ensure the quality, safety and efficacy of medicines. Various strategies exist to achieve these goals through different combinations of public and private involvement in the pharmaceutical management cycle. National systems vary with respect to public and private roles in financing, distribution, and dispensing of pharmaceuticals, ranging from fully public to fully private systems.

At least five alternatives have traditionally existed for supplying medicines:<sup>4</sup>

- Central medical stores (CMS): Traditional public sector pharmaceutical supply system, in which medicines are procured and distributed by a centralised government unit;
- Autonomous supply agency: An alternative to the CMS system, managed by an autonomous or semi-autonomous pharmaceutical supply agency;
- Direct delivery system: A decentralised, non-CMS approach in which medicines are delivered directly by suppliers to districts and major facilities. The government pharmaceutical procurement office selects the supplier and establishes the price for each item, but the government does not store or distribute medicines;
- Primary distributor (or prime vendor) system: Another non-CMS system in which the government pharmaceutical procurement office establishes a contract with one or more primary distributors as well as separate contracts with pharmaceutical suppliers. The contracted primary distributor receives the medicines from the suppliers and then stores and distributes them to districts and major facilities;
- Primarily private supply: A system that allows private pharmacies to provide medicines for public-sector patients. With such an approach, measures are required to ensure equity of access to the poor, medically needy and other target populations.

The systems vary considerably with respect to the role of the government, the role of the private sector and incentives for efficiency. Mixed systems with different categories of pharmaceuticals supplied through different mechanisms are frequently seen.<sup>4</sup>

It is possible to identify some advantages and disadvantages for each of the above systems and to make some theoretical comparisons, but true comparisons of cost-effectiveness have not been made. In part, this is because other issues have made such comparisons complex.<sup>5</sup> The introduction of policies on user charges, decentralisation, contracting-out and privatisation all have an impact on the pharmaceutical supply system. Each country has unique political, economic and geographical factors. It will probably never be possible to state that one system is “the best”. However, some basic factors will point in the direction of certain systems, for example, the existence of an effective private sector is necessary for either direct delivery or prime distributor systems to function.<sup>6</sup>

This report does not aim to identify a single “gold-standard” system that should be applied in all settings or countries, but rather to point out that all systems in place should ensure the integrity and efficiency of the distribution of medicines and other health products, in a way that contributes to and promotes their responsible use.

In this context, the efficiency of the supply chain can also be defined from the point of view of the different players in the supply chain.

In fact, the broad definitions of the supply chain (previously termed “logistics” in the 1980s–90s, with both terms currently used interchangeably) can mean different things to different people:

- For the pharmaceutical manufacturer, it relates to the sourcing and on-time availability of suitable approved quality raw materials such that the manufacturer can use them to meet its commitments to patients and customers, in other words to ensure that medicine shortages in the marketplace are avoided/ or minimised. On the other hand, it is also related to backwards logistics, in collaboration with other stakeholders, taking into account the need for repackaging or relabelling operations, as well as batch recalls or product withdrawals, which should be efficient in order to ensure patient safety;
- To wholesalers and distribution centres and to hospital and community pharmacies and clinics, it means the on-time availability of medicines for which product integrity is assured (absence of substandard and falsified medicinal products, maintenance of cold chain, no tampering with the product, no theft, and proper documentation of the handling of the finished product from shipment by the manufacturer to receipt). It also means a reliable backward supply chain, where in situations of repackaging, batch recall, product withdrawal, or expired medicines, safe transportation of these products to their final destination, which may be the manufacturer or waste facilities, is ensured;
- For patients, it means that quality medicines will be available where and when they need them, in the correct strength and dosage form, and in sufficient quantity as prescribed, together with advice on their use. It increasingly also means that can return expired or unused medicines (medicines waste management);
- For the environment, it means that unused medicines are collected and destroyed in an environmentally acceptable way.

The supply chain model by GIRP, the European Healthcare Distribution Association, depicts the supply chain stakeholders and their relationships in the supply chain (see Figure 1). This model highlights that the supply chain aims to promote the continuous availability of the right medicine, at the right time, to the right patient. To that end, supply chain integrity and efficiency is ensured by several stakeholders throughout the distribution pathway. In a simplistic manner, it can be described as beginning with the manufacturer, followed by wholesalers, which occupy a central position in the chain, responsible for delivering pharmaceutical products in an efficient, timely, safe and reliable manner. Wholesalers procure medicines from all manufacturers and deliver them to dispensing points, such as pharmacies and clinics, which are in turn responsible for dispensing medicines to patients. Some manufacturers outsource their stock storage to pre-wholesalers, placed between manufacturers and wholesalers in the supply chain.



Figure 1. The supply chain as defined by GIRP, the European Healthcare Distribution Association

These stakeholders often hold obligations in reverse logistics, ensuring a safe medicines waste management and, if necessary, recall and withdrawal operations.

Another specific example to assist in further defining the main elements of the supply chain is the global supply chain for vaccines as viewed by Gavi, The Vaccine Alliance. Figure 2 depicts Gavi’s model with the cycle of the supply chain from planning through to delivery of the vaccine to patients, and associated waste management.

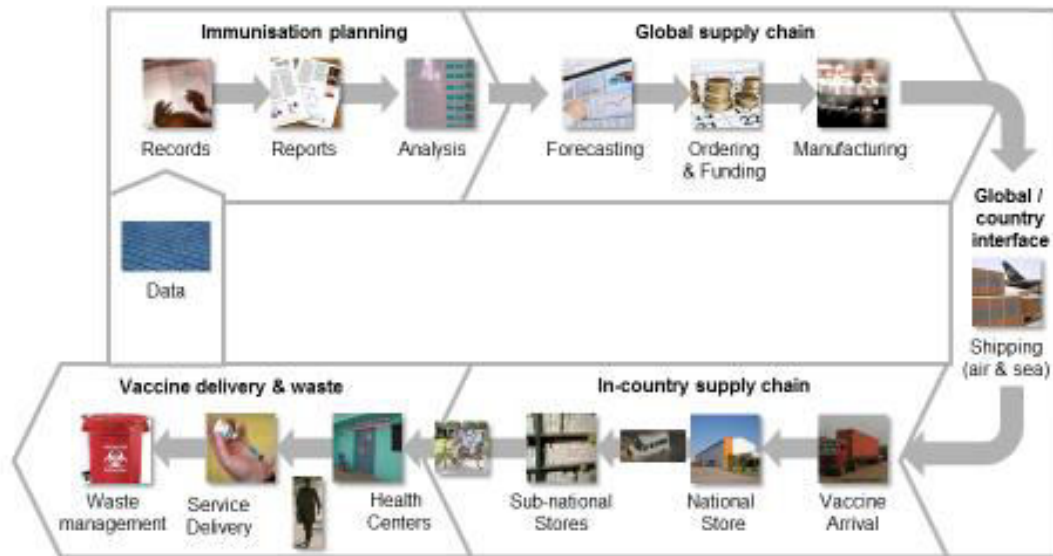


Figure 2. The immunisation supply chain as viewed by Gavi, The Vaccine Alliance

Table 1 expands on the terms used within the Gavi model:

Table 1. The supply chain terms and their definition as used in the Gavi immunisation supply chain model

| Term                            | Brief explanation  |
|---------------------------------|--|
| <b>Immunisation planning</b>    | <b>Planning undertaken to determine the vaccine needs of the country.</b>  |
| Records                         | Records indicating use of vaccines, wastage and population statistics.   |
| Reports                         | Summaries of records or health reports indicating burden of disease, or changing population trends.              |
| Analysis                        | Data from records and reports are reviewed to estimate the total needs of the country over a defined period.     |
| <b>Global supply chain</b>      | <b>Most medicines are manufactured in a different country from where they are used.</b>                          |
| Forecasting                     | Predicting the amount of product required for a specific population over a given period.                         |
| Ordering and funding            | The process of calling for tenders, awarding contracts, securing and dispersing the funding required for orders. |
| Manufacturing                   | The manufacture of medicines by specific companies.  |
| <b>Global/country interface</b> | <b>The international country border (customs and imports).</b>   |
| Shipping (air and sea)          | The modes of transport most used for the shipment of pharmaceuticals globally.                                   |
| <b>In-country supply chain</b>  | <b>The supply chain from when medicines enter the country to when they are administered to patients.</b>         |

|                                   |   |
|-----------------------------------|---|
| Vaccine arrival                   | For vaccines, there is specific attention to cold chain integrity.  |
| National store                    | Many low- and middle-income countries rely on national stores for medicines supply. Middle- to high-income countries rely on a network of private sector wholesalers. |
| Sub-national store                | Regional stores which are part of a government owned supply system. In private sector wholesaling similar stores may exist in regional centres                        |
| <b>Vaccine delivery and waste</b> | <b>Medicines are administered to patients at a variety of service delivery points depending on the healthcare system of the country.</b>                              |
| Health centres                    | One type of service delivery point. Others include, hospitals and clinics etc.  |
| Service delivery                  | The administration of a vaccine or interaction with a patient by a health professional to administer health care.   |
| Waste management                  | The disposal of waste following the administration of a medicine/vaccine or provision of medical service.   |

Figure 2 and Table 1, however, have limitations, such as the absence of the manufacturing and regulatory aspects that precede delivery, and are specific to a situation where financing is global rather than local, which is not the norm for all medicines. They lack also the backward logistics process. In addition, pharmacovigilance, a key aspect of medicines delivery through which adverse effects of medicines are monitored after their administration to patients, is not mentioned.

## 2.2 Globalisation and supply chains

Supply chains are global, with India often referred to as the “pharmacy of the developing world”, and China being an increasingly important source of active pharmaceutical ingredient (APIs). This globalisation of supply chains adds a degree of complexity (legal, transactional and transport), and necessitates management competencies to ensure that supply chains provide appropriate quantities of quality medicines in the appropriate time frame for specific countries and markets. International organisations such as Gavi, the Global Fund, UNICEF and the World Health Organization play a significant role in influencing global markets in areas of global health, particularly in HIV/AIDS, malaria and tuberculosis, and in maternal, child and reproductive health. The major pharmaceutical companies have concentrated their production of any specific product to one, or more often two, manufacturing sites which puts high demands on their supply chains, and in addition many wholesalers are increasingly international, some covering a large number of countries.<sup>7-9</sup>

Globalisation is also occurring in the developed world, with local private wholesalers becoming global. For example, in the USA, wholesale companies have grown by acquiring local competitors and expanding internationally. In addition, they have invested in vertical integration by developing pharmacy chains, funding pharmacies where chains are prohibited, and introducing generics manufacturers in certain markets. The global health care wholesale and distribution market is projected to grow an average of 6.82 percent annually in 2014–19, with revenues increasing from \$752 billion to \$1.04 trillion during this period. Key growth drivers include the rapid expansion of the pharmaceutical industry, technological advances, increased use of temperature-sensitive medicines, and growing demand for pharmacotherapy in emerging markets. In 2014, the Americas region dominated the pharmaceutical wholesale and distribution market, followed by the Asia Pacific region.<sup>7</sup>

## 2.3 Varied maturity of supply chains globally

The maturity of supply chains varies between countries and often reflects the economic status of the country. Differences exist also in public and private supply chain sectors and in the special cases when medicines are provided as part of a humanitarian action. The following model presents four phases that describe the evolutionary progression of supply chain management capacity in the public health context of low- and middle-income countries.<sup>10</sup>

**Ad hoc (phase 1)** At this stage, public sector supply chain practices and processes are unstructured and ill-defined with few, if any, metrics in place for performance measurement. Beyond the work of an individual or the scope of an isolated logistics function there is little to no visibility of demand and supply, and personnel define and perform their responsibilities based on their perception of what is needed and appropriate. Dependency of performance on individuals' abilities means that personnel turnover is disruptive.<sup>10</sup>

Stock-outs, shortages and product expiries are routine, and targets, if defined, are often missed. If existing, the private sector often works without adequate regulations and only serves a small proportion of the populations that can afford to pay the full cost of the medicines. Little collaboration exists among the various actors either within the Ministry of Health (MOH) administration or between the MOH and external counterparts.<sup>10</sup>

**Organised (phase 2)** At this stage, public sector processes have been defined for individual logistics functions (forecasting, procurement, storage, inventory control and distribution) and relevant personnel have been identified. Based on established standard operating procedures, supply and demand information can be used for operational decisions such as how much of each product a facility should receive in a given ordering cycle. Basic performance metrics may exist, but their use and quality depend highly on the strength of the logistics management information system. The private sector often works without many of the regulations and inspections existing in more developed systems and only serves a limited proportion of the populations that can afford to pay the full cost of the medicines.<sup>10</sup>

**Integrated (phase 3)** At this stage, the MOH has raised the profile of public sector supply chain management as a strategic approach to improving customer service and achieving its health improvement objectives. Individuals and separate institutions in the MOH not only understand their respective roles but also see them as part of the larger supply chain process. The MOH deliberately and strategically manages health commodities and supplies across partners, logistics functions and health system levels, meaning that it sets goals and monitors overall system performance and its individual functions. Typically, for non-pharmaceutical logistics, a logistics management unit serves as the focal point for strategic supply chain decision-making and coordinated management of multiple programmes' logistics functions on its own or in cooperation with contracted organisations. Medicines, however, are usually included in a stand-alone system, because of the highly regulated nature of the system, including the need for professional oversight. The private sector must follow a comprehensive set of regulations and inspection of services is developing. The private sector serves an increasing proportion of the population that can afford to pay the full cost of the medicines and private insurance is emerging.<sup>10</sup>

**Extended (phase 4)** At this stage, public supply chain management has expanded to cover institutionalised coordination between public and private sector distribution systems and the suppliers that serve these markets. This stage represents a challenge even for private sector supply chains in developed countries because it requires significant amounts of operating trust among separate organisations. At this stage, alignment of incentives and demand visibility across supply chain entities — including multiple distributors, suppliers, and manufacturers — leads to optimal performance throughout the network. Efforts to improve data visibility through systems such as electronic data interchanges give supplier partners a better picture of downstream demand and support the public and private sectors of the broader health system in achieving supply chain objectives.

As the supply chain of a country matures from “ad hoc” through to “extended” the roles of various personnel become more well defined with various professional groups taking on specific roles based on their scope of practice and competency and in line with the requirements of the supply chain. Pharmacists are better able to take on their role as medicine experts with the increased maturity of the supply chain.

In Europe, manufacturers mainly rely on full-line wholesalers as their partners to deliver all their products in a timely and secure manner, and pharmacists trust wholesalers for the continuous availability of all pharmaceutical products and efficient supply processes. For instance, almost three-quarters of all medicines are distributed through pharmaceutical full-line wholesalers (which carry the full range of medicines and typically take the risk of stock ownership), and most of those medicines are sold to community pharmacies (93.3%), followed by hospital pharmacies (5.5%). In the USA, pharmaceutical wholesalers supply approximately 94% of all pharmaceutical sales volume.<sup>11, 12</sup>

As wholesalers store and supply the complete range of medicinal products, in compliance with Good Distribution Practices, and ensure a quantity-based buffer function, stocking them in sufficient quantities in order to supply pharmacies even in peak demand times, they perform a vital link in the supply chain. When pharmacists order medicinal products, wholesalers bundle products from different manufacturers, reducing the time spent in ordering and processing invoices.

An Institute for Pharmacoconomics Research 2017 study conducted in six European countries (France, Germany, Italy, the Netherlands, Spain and the UK) found that the supply of medicines between manufacturers, wholesalers and pharmacies involves more than 795.6 million transactions per year. However, without wholesalers (direct supply from manufacturers to pharmacies), the study estimates this number would increase to 99.4 billion transactions.<sup>11, 13</sup>

In many European countries, medicines' supply is recognised as a public service obligation, ensuring that even an isolated patient can receive all essential medicines. To achieve this, wholesalers supply pharmacies daily throughout the territory, guaranteeing their capability to fulfil this duty.



## 3 The importance and integrity of the supply chain to global health

### 3.1 Universal Health Coverage and the Sustainable Development Goals

In 2015, the world transitioned from a focus on the Millennium Development Goals (MDGs) to a renewed focus on international equity through the application of 17 cross-cutting Sustainable Development Goals (SDGs).<sup>14</sup> The lack of medicines and underdeveloped supply chains, with insufficient human resources to run and sustain them, significantly contribute to the inability to meet these goals.<sup>16, 17</sup> This is in contrast to middle-income environments where medicines usually are readily available but access issues regarding the availability of medicines for rare diseases and substantial out-of-pocket expenses are the result of market realities or the level of a country's economy. The increasing complexity of pharmaceutical care in high-income countries requires the increasing engagement of pharmacists to ensure that availability and access results in responsible use. Understanding and using the role of pharmacists as medicine experts in the supply chain helps developing health systems to achieve universal health coverage as it is defined in different country contexts.

### 3.2 Medicines availability, access and people-centred health systems

The WHO published The World Medicines Situation report in 2011. Alarming, it noted that one-third of the world's population does not have access to regular life-saving medicines.<sup>18</sup> An analysis by The Lancet Commission on Essential Medicines Policies found that the cost of providing a basket of 201 essential medicines to all people in low- and middle-income countries could be as little as \$1 to \$2 per person per month, or \$13 to \$25 per person annually. Yet one in five countries worldwide spends less on each person each year, resulting in "massive inequities".<sup>18</sup> Also, when taking into account the fact that medicines are only part of the solution, together with health care resources, laboratory capacity, sanitation, nutrition, etc., millions of people are at risk of death and significant morbidities from preventable or treatable diseases (such as pneumonia, malaria, HIV/AIDS and tuberculosis), malnutrition and dehydration from diarrhoea. In high-income countries, ageing populations, polypharmacy (prescribing of multiple medicines for one patient), use of more complex medicines and rising costs of health care are placing pressure on health systems with many countries exploring how to better utilise pharmacists for their clinical skills. FIP acknowledges that there is a need to increase medicines access to patients while also ensuring the optimal use of the pharmacist in a variety of clinical settings, including supply chains.<sup>19, 20</sup>

Responsible use of medicines implies that health system stakeholders' activities and capabilities are aligned to ensure that patients receive the right medicines at the right time, use them appropriately, and benefit from them.<sup>21</sup> Therefore, there are several levers of opportunity that all countries can apply to ensure the responsible use of medicines, such as timely medicines use, which prevents costlier events later on, saving health system funds and improving health outcomes. An IQVIA (formerly, QuintilesIMS Institute for Healthcare Informatics) study found that untimely medicines use contributes to 13% of the world's total avoidable cost due to suboptimal medicines use, representing a total of 1.1% of global total expenditure. When patients do not obtain medicines at the right time it leads to an avoidable increase in disease burden and sometimes expensive complications.<sup>22</sup>

Ensuring timely medicines use requires the engagement of all supply chain stakeholders (involved in manufacturing, wholesaling, and dispensing), as well government decisionmakers (noting that medicines availability also depends on reimbursement, as in the case of innovative, but high-priced medicines).

## 3.3 Medicines shortages

Medicines shortages occur when demand exceeds supply at any point in the supply chain and may ultimately create a “stock out” at the point of delivery to the patient.<sup>23</sup> Medicines shortages are a complex and growing issue worldwide. The characteristics of medicines shortages vary greatly from country to country, and the vulnerabilities of low- and middle-income countries and high-income countries also differ in terms of policy, regulation, manufacturing, supply, etc., all of which can lead to shortages.<sup>24</sup>

There are multifactorial causes for medicines shortages, which often include issues in manufacturing as well as problems within the supply chain, but also additional factors that destabilise the market and increase their likelihood. Usually, causes and contributing factors can be classified in two groups, from the demand and supply sides.

In terms of demand, forecasting is a challenge for all stakeholders in the supply chain due to the difficulty in predicting market variance — affected by price, tenders, epidemics, composition and emergencies, On the supply side, several reasons can result in medicines shortages, such as a reduced or ceased production related to quality assurance decisions, availability of raw materials, or a batch recall.

All the above-mentioned reasons can result in an inability to supply medicines where and when they are needed. Some of them are independent or stand alone, while some may affect one another and exacerbate the issue.

Shortages can result in delayed or unavailable treatment and, therefore, in a worsening of a patient’s condition, which may require admission to hospital or even cause death. This has an impact on human lives, finances and indirect costs. Changing to an alternative medicine, often less appropriate, can have safety implications, including the potential for reduced efficacy, increased side effects, and adverse patient outcomes as a result. There may also be adverse impacts on the healthcare system where the cost of alternative medicines could be higher because the purchasing is usually made off-contract.

In 2013, FIP held a Summit on Medicines Shortages, which aimed to identify solutions to this issue at a global level. It emphasised the importance of the global community (governments, healthcare professionals, patients and supply chain stakeholders) working in collaboration to achieve transparency and an understanding of the contributing factors. Because of the summit, a set of recommendations to prevent or mitigate shortages has been presented, such as increased communication between the stakeholders, development of a global list of critical and vulnerable products, evidence-based risk mitigation strategies, and the improvement of the procurement processes to assure the continuity of supply of quality medicines.

In this regard, the benefit of the pharmacist’s intervention in prevention and management of shortages should be emphasised, namely promoting efficient and effective management throughout the supply chain. Pharmacists can play multiple roles in this prevention, such as through their knowledge of health and disease trends, for instance related to epidemics and seasonality and thus their ability to anticipate needs. In addition, in the manufacturing and supply area, their knowledge of good manufacturing practices can help to reduce failures related to quality in production, and in qualifying alternative suppliers of raw material.

It is of interest to note that in the USA, the Food and Drug Administration requires pharmaceutical manufacturers to notify it as soon as possible of projected shortages of medicines availability. Such shortages can be caused by lack of raw materials due to strikes by workers, or due to other causes (e.g., in 2017 due to Hurricane Maria devastated Puerto Rico, a major centre for the pharmaceutical industry). FIP published a report with an overview of different reporting systems for medicines shortages.<sup>25</sup> The same situation exists in the European Union.

A multidisciplinary response to shortages is recommended. In this respect, pharmacists should be able to manage shortages through identification of therapeutic alternatives, where they exist, supported by the latest evidence and scientific literature, in order to safely provide patients with desired clinical outcomes.

## 3.4 Product storage and medicines integrity (including the cold chain)

Many medicines, especially blood, sera, vaccines and other biological products, are temperature-sensitive and need special storage conditions if the medicine is to maintain its quality during its stated shelf life. A vaccine that has not been subject to storage and transportation as part of a cold chain is rendered useless to the patient and is of no therapeutic value. In some cases, it might even become dangerous. The same applies to medicines that require transportation under other specific conditions, such as non-freezing temperatures, dry conditions, etc.<sup>26</sup>

A cold chain is defined as the system used to protect heat-labile preparations (e.g., sera, vaccines) from deterioration. This is a concern in all countries, but particularly in countries with a tropical climate, and is a vital feature of immunisation programmes in tropical climate regions. The United States Pharmacopoeia (USP) defines “cold” as “any temperature not exceeding 8°C (46°F)” but this includes freezing, which may not be appropriate for many medicines. However, given that different terms and definitions are used in different pharmacopoeias and WHO guidance, terms like “ambient”, “room temperature” and “cold chain” should be avoided. Storage conditions are always better explicitly specified in terms of a defined temperature range (e.g., -15°C to 25°C or +2°C to +8°C).<sup>27</sup>

The need to maintain a cold chain is required from the moment a medicine leaves the manufacturer until it is received by the patient; and the cold chain must be maintained during all phases of transportation, storage and distribution. A refrigerator is the most common storage unit and it is defined as a cold place in which the temperature is maintained thermostatically between +2°C and +8°C (36°F and 46°F).

Some medicinal products (e.g., Ebola vaccine) need to be stored in a frozen condition, and the USP defines frozen as “a place in which the temperature is maintained thermostatically between -25°C and -10°C (-13°F and +14°F)”.<sup>28</sup>

Much less thought is given to the situation where the reverse of the cold chain requirements may be needed, for some liquid (oral), semi-solid (oral and topical) medicines and many vaccines. This is particularly important in Arctic climates. Exposure to cold and freezing conditions may result in crystallisation of active pharmaceutical ingredients or preservatives from some medicines, and they do not necessarily return to their original state when the medicine is warmed. Additionally, some semi-solid medicinal products (e.g., creams and lotions) can have their formulation disrupted by freezing or heating, resulting in separation into oil and water phases (technically termed “cracking”), which do not reconstitute to the original formulation on return to ambient temperatures.<sup>29</sup>

It is essential that products subject to cold chain requirements (and to a lesser extent to non-cold chain requirements) are constantly temperature-monitored. The use of data loggers, temperature dots and other methods are routine, but these must be used throughout the entirety of the supply chain, and supply chain staff must be trained to review the data from these devices before accepting the medicines on to the next step in the supply chain.<sup>28</sup>

Consideration should also be given to patients’ ability to store their medicines in an adequate way to maintain quality throughout the treatment regimen.

## 3.5 Substandard and falsified medicines and supply chain security

A further driver for considering the pharmaceutical supply chain in more detail is the rising prevalence of substandard and falsified medicines in the global marketplace. There is currently no universally agreed definition among WHO member states of what used to be widely known as “counterfeit medicine”. The WHO uses the term “substandard and falsified medical product” with a new definition agreed in November 2016. The previously used terminology, “substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medicines recognised that while spurious, falsely labelled, falsified or counterfeit medicines are by their very

nature substandard, it is not necessarily the case that all substandard medicines are spurious, falsely labelled, falsified or counterfeit. Such medicines include accidental manufacturing errors or where a medical product has degraded due to poor storage.

According to new research from the WHO released in November 2017, an estimated 1 in 10 medical products circulating in low- and middle-income countries is either substandard or falsified.<sup>30</sup> Since 2013, the WHO has received more than 1,500 reports of cases of substandard or falsified products. Of these, antimalarials and antibiotics are the most commonly reported. Most of the reports (42%) come from the WHO African Region, 21% from the WHO Region of the Americas and 21% from the WHO European Region. The WHO provides examples from around the world where substandard and falsified medicines have entered the supply chain, endangering the health of patients. “Fight the Fakes” (<http://fightthefakes.org/>) and “Rx 360” (<http://rx-360.org/en-us/>) are two global projects focusing on these issues.

Every year, substantial quantities of medicines are purchased by or through international procurement agencies — such as UNICEF, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and UNITAID — for distribution in resource-limited countries. WHO prequalification of medicines is a service provided by the WHO to assess the quality, safety and efficacy of medicinal products. It also prequalifies active pharmaceutical ingredients and quality control laboratories.

To address the concerns about increasing falsified medicines, the European Union amended its Directive 2001/83/EC, implementing measures to prevent the entry into the legal supply chain of falsified medicines through requiring a unique identifier and an anti-tampering device on the package of medicines for human use (prescription medicines and some non-prescription medicines). This system is guaranteed by an end-to-end verification of those medicines, supplemented by wholesalers’ verification of some medicines recognised as products at higher risk of falsification.

An end-to-end verification means that those safety features placed on the packs at the beginning of the supply chain (by manufacturers) should be verified at the time of their supply to the public. The authenticity verification is made by comparing that unique identifier with the information in a repository system (which stores the legitimate unique identifier data). After the verification of the unique identifier (for instance when dispensing a medicine in a pharmacy or distributing to outside the European Union), the package will be decommissioned in the repository system, so that any other pack with the same identifier would not be successfully verified. If a medicine in the supply chain has a unique identifier already decommissioned, the stakeholder should notify the competent authority in order to initiate an investigation of the incident or suspicion of falsification.

The European Medicines Verification System, where the information on the safety features is contained (also known as the European Hub), is managed by the European Medicines Verification Organisation (EMVO). EMVO is a Belgian non-profit organisation representing stakeholders united in securing the legal supply chain from falsified medicines (founded by the European Federation of Pharmaceutical Industries Associations, Medicines for Europe, the Pharmaceutical Group of the European Union, GIRP and the European Association of Euro-Pharmaceutical Companies). Furthermore, each European country is required to establish a National Medicines Verification System (NMVS), set up and managed by a National Medicines Verification Organisation, which acts as a platform to check the authenticity of a product (each NMVS must be connected to the European Hub). The implementation of these systems must be completed by February 2019.

## 4 Competencies involved in managing the supply chain

An end-to-end view of a supply chain in a country or organisational context incorporates a variety of activities, which need to be undertaken for supply chains to be effective, adaptable and sustainable. Figure 3 depicts the range of high-level activities that occur within a supply chain.

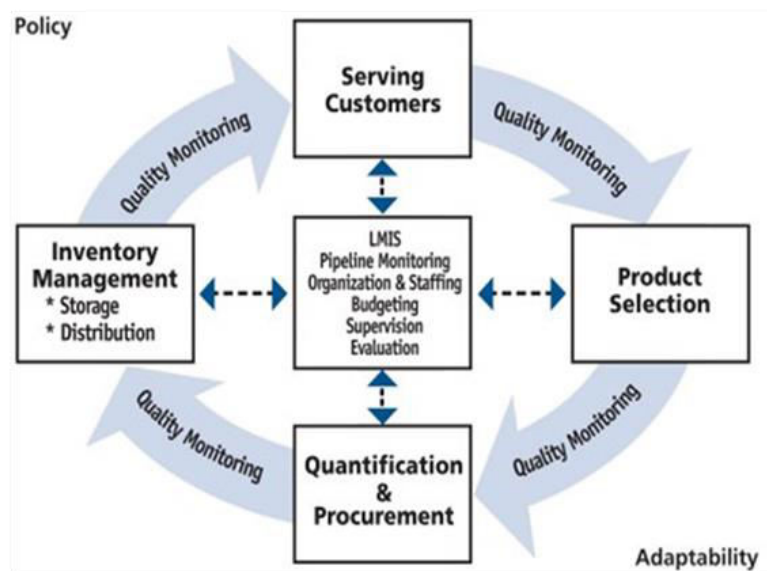


Figure 3. A pictorial representation of the logistic-related activities for finished pharmaceutical products that are undertaken in the supply chain (USAID | DELIVER)

Improving supply chains has been on the international development agenda in recent decades with an increased interest in the professionalisation of the human resources responsible for managing supply chains. In 2011, The People that Deliver (PtD) initiative ([www.peoplethatdeliver.org](http://www.peoplethatdeliver.org)) was formed with FIP as one of the board members. PtD is a global partnership whose mission is to build global and national capacity to implement evidence-based approaches to plan, finance, develop, support and retain the national workforces needed for the effective, efficient and sustainable management of supply chains.

In 2014, PtD conducted a global project resulting in the publication of the “PtD supply chain competency framework for managers and leaders”. PtD introduced a validated, comprehensive framework, documenting the domains, competencies and behaviours required to be in place for effective supply chain management.<sup>31</sup> By its nature the PtD competency framework is a services-based competency framework and does not specify which personnel are required in any specific context, but rather allows for the wide country variation that exists globally. Similar service-based competency frameworks have been published for pharmaceutical service delivery in Pacific island countries where a range of personnel are involved in pharmaceutical services delivery.<sup>32-34</sup>

The globally validated PtD supply chain competency framework has six domains: four technical (selection and quantification; procurement; storage and distribution and use) and two managerial (resource management; and professional and personal), with 33 competency areas (Tables 2 and 3). The framework defines the skills, competencies and associated behaviours that are required for effective supply chain management from selection through to use. It can be used to map existing competencies with desired competencies at all levels of the system and inform a capacity development plan to address the gaps. It can help define what is needed for sustainable health supply chain management (SCM). Figure 4 is a variation on the better-known MSH cycle, popularised in Managing Drug Supply.<sup>35</sup>

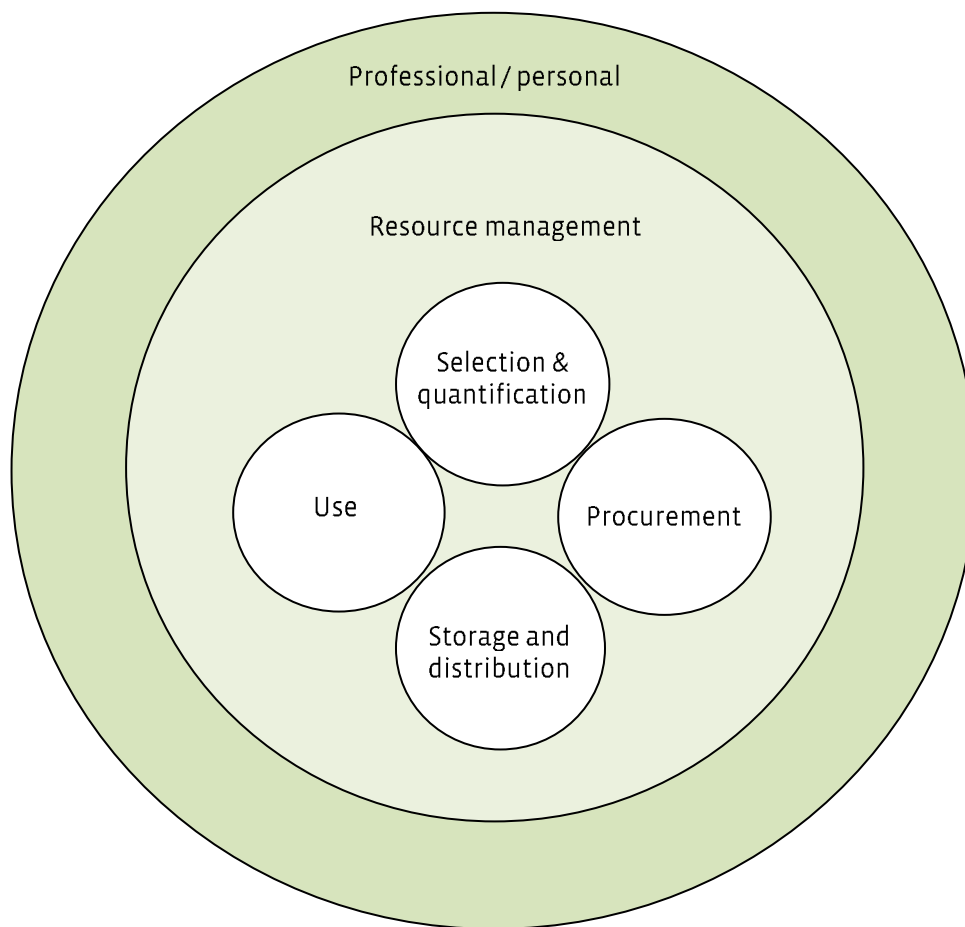


Figure 4. The relationship of the six domains within the PtD public supply chain competency compendium

Table 2. PtD competency framework domain descriptions

|                   | Domain                          | Domain plain language description   |
|-------------------|---------------------------------|---|
| <b>Technical</b>  | 1. Selection and quantification | The competencies that are required by a worker to be able to select and quantify the correct supplies for their work situation (e.g., their country, the needs and capacity of their facility).   |
|                   | 2. Procurement                  | The competencies that are required by a worker to be able to procure the supplies needed for their work situation.  |
|                   | 3. Storage and distribution     | The competencies that are required by a worker to be able to store and distribute the supplies needed for their work situation. This includes moving supplies to their facility and sending them to other facilities. It also includes the competencies required to manage the outsourcing of these activities, and partnerships related to these activities. |
|                   | 4. Use                          | The competencies that are required by a worker to be able to ensure the best possible outcomes from the use of the supplies in their work situation where patients are treated.   |
| <b>Management</b> | 5. Resource management          | The competencies that are required by a worker to be able to manage money/people etc., to ensure the system works effectively.  |

|  |                              |  |
|--|------------------------------|--|
|  | 6. Professional and personal | The competencies that are required by a worker to be able to manage his/her day-to-day responsibilities and create a path for future career development. This includes competencies such as communication, stress management and time management skills. |
|--|------------------------------|--|

Table 3. Summary of competency areas within the PtD supply chain competency framework

|   | Domain   | Competency   |
|---|--|--|
| <b>Technical</b>                                      | 1. Selection and quantification  | 1.1 Select the appropriate product<br>Demonstrate a complex prioritisation effort to select the molecule and dosage form, before seeking an appropriate example on the market. Selection is usually a multi-disciplinary effort that demands clinical and epidemiological, as well as health economics competencies. Seeking the input of other health professions. (This paragraph is adapted by FIP) |
|   |  | 1.2 Define the specifications and quality of the product   |
|   |  | 1.3 Take into account any special considerations for the product   |
|   |  | 1.4 Forecast and quantify product needs (less relevant to mixed systems)   |
|   | 2. Procurement   | 2.1 Manage procurement costs and budget  |
|   |  | 2.2 Build and maintain supplier relationships  |
|   |  | 2.3 Manage tendering processes and supplier agreements   |
|   |  | 2.4 Undertake contract management and risk and quality management  |
|   |  | 2.5 Assure quality of products   |
|   |  | 2.6 Manage import and export of products   |
|   |  | 2.7 Manage donations of products   |
|   |  | 2.8 Prepare for product supply during disasters and emergencies  |
|   |  | 2.9 Undertake or manage manufacturing or compounding of products, <i>when applicable</i>   |
|   |  | 2.10 Undertake or manage re-packing of products  |
|   | 3. Storage and distribution  | 3.1 Undertake storage, warehousing and inventory management  |
|   |  | 3.2 Supply commodities to facilities   |
| 3.3 Manage transport for commodities                  |  |  |
| 3.4 Manage disposal of products                       |  |  |
| 3.5 Dispense or provide commodities to patients/users |  |  |
| 4. Use  | 4.1 Understand use of medical products including medicines and equipment |  |
| <b>Management</b>                                     | 5. Resource management   | 5.1 Manage, plan and implement projects  |
|   |  | 5.2 Manage resources and financial activities  |
|   |  | 5.3 Oversee human resources (e.g., recruitment, training, team management/supervision)   |
|   |  | 5.4 Implement quality assurance and risk management activities   |
|   |  | 5.5 Recognise and understand the complementary requirements of a sustainable supply chain management (SCM) system  |
|   |  | 5.6 Oversee and/or support operation of a logistics management information system  |
|   |  | 5.7 Manage outsourcing SCM functions   |

|  |                              |   |
|--|------------------------------|---|
|  | 6. Professional and personal | 6.1 Demonstrate basic generic skills (e.g., literacy, numeracy, technology) |
|  |                              | 6.2 Demonstrate strong communication skills                                 |
|  |                              | 6.3 Utilise problem solving skills  |
|  |                              | 6.4. Exhibit professional and ethical values                                |
|  |                              | 6.5 Prove leadership abilities  |
|  |                              | 6.6 Abide by rules/laws/legislation   |



# 5 Pharmacists' unique competencies in the supply chain

## 5.1 Overview of survey methodology

Table 4. The subset of behaviours from the PtD supply chain competency framework where the technical working group noted that the pharmacist may play a significant role.

| Behaviours   |
|--|
| Describe the broad concepts of National Medication Policy, Essential Medicines Lists, Essential Equipment Lists, Standard Treatment Guidelines and Dangerous Drug (DDA) or narcotics policy  |
| Use the processes required to add and subtract items from the Essential Medicines List and the Essential Equipment List  |
| Follow the processes required to alter standard treatment guidelines, dangerous drugs and narcotics policy, and national medicines policy  |
| Confirm the type of medical supplies that are required to be kept  |
| Advise on product specifications (e.g., active ingredient, form, pharmacopeia standard) for the procurement of medicines   |
| Describe the principles and processes of category management for medicines (i.e., medicines categorised by similar use or storage needs, such as cold chain, antiretroviral medicines, controlled substances such as narcotics and psychotropics), including market segmentation principles for common needs and interests |
| Demonstrate the required knowledge for the quantification (determining the quantities required to order) of health programme-specific medicines (e.g., antiretroviral, family planning commodities, vaccines, etc.)  |
| Maintain a working knowledge of the handling requirements for medicines  |
| Identify the factors that affect usage patterns for medication (e.g., disease outbreaks, seasonal variation, expanding clinical need), and identify how this affects ordering  |
| Maintain a working knowledge of the critical requirements for effective forecasting of medicines (i.e., predicting future needs)   |
| Establish policies and procedures for forecasting control for medicines (i.e., predicting control for medicines)   |
| Use and monitor the process for pre-qualification of suppliers from which medicines are purchased (i.e., selecting appropriate quality approved suppliers.)  |
| Ensure that medicines are not counterfeit <sup>a</sup> , and meet quality standards  |
| Implement, conduct, and maintain a reporting system of pharmacovigilance (e.g., adverse drug reactions and medicine incident reporting)  |
| Describe the procurement and logistic requirements for the emergency supply of medicines in a disaster   |
| Undertake the assessment of local capacity before the supply of medicines in an emergency or disaster  |
| Compound (make a pharmaceutical from base components) under the code of good manufacturing practice (GMP) for the production of medicines  |
| Describe and demonstrate the recall procedures to be used in response to a medicine product recall notice  |
| Dispose of expired medicines according to national policy  |
| List which medicines are allowed to be prescribed by different prescribers, and monitor this   |
| Identify medicines by their generic name, and have a general understanding of what medicines are used for  |
| Implement key security systems and appropriate levels of access for the workplace where medicines are stored (e.g., including, narcotics, other controlled substances and investigational medicines etc.   |

<sup>a</sup> This refers to substandard and falsified medicines, and not only those with possible breaches of trademark or other intellectual property

In order to gather global, comparable data, a survey was developed to determine which of the competency areas described in the PtD supply chain competency framework (if any) would be considered to be most suitably completed by a pharmacist, and to seek feedback from respondents regarding what should be done where pharmacists are not available for these competency areas.

Table 4 summarises the 22 behaviours that were selected to be included in the survey, based on the expertise of the working group. With more than 200 behavioural competencies within the technical domains of the PtD supply chain competency framework, the working group noted that the vast majority of competencies required to run a pharmaceutical supply chain were not within the general role of a pharmacist. Participants were then asked to consider if the pharmacist was the most suitable professional to undertake this behavioural competency.

There is no doubt that pharmacists play a key and essential role at both ends of the supply chain: first, in selecting medicines that need to be available for the benefit of a population (selection of medicines for inclusion in a formulary, or in a national Essential Medicines List); and, secondly, at the point of dispensing where the pharmacist can advise the patient on the optimal use of the medicine they are receiving. In addition, pharmacists play an important role in many countries and organisations in having oversight of the supply system, and being able to make corrections should anything deviate from normal procedures.

## 5.2 Demographics of respondents

Survey returns were received from 379 respondents, from 178 countries/territories and of these (as defined by the World Bank)<sup>36</sup>:

- 111 responses (29%) came from low-income countries;
- 140 responses (37%) came from middle-income countries;
- 128 responses (34%) came from high-income countries.

Of the 379 respondents:

- 282 (74%) were pharmacists;
- 97 (26%) were other professionals involved with healthcare settings, government, purchasing, agencies, or with the supply chain;
- 112 (30%) worked in a government position;
- 36 (10%) worked in the private sector;
- 74 (20%) worked in a non-governmental or technical organisation.

## 5.3 Themes from the data

For each of the 22 behaviours listed in Table 4, respondents were asked: Is a pharmacist the most appropriate professional to demonstrate this behaviour?

Table 5 summarises the results for each of these behaviours based on professional grouping and according to country income status. Where 95% or more of respondents agreed in that subgroup, this is highlighted in the Table. The data were analysed by Andrew Brown and Michael Anisfeld. The design of the survey instrument and the fact that most respondents were pharmacists indicates an inherent bias in the results. Having said that, it is clear that although not statistically significant (due to survey numbers), the following trends are noted:

- Pharmacists are more likely to agree that they are the most suitable profession for the competencies identified (nine behaviours scored 95% or more);
- Non-pharmacist logisticians are less likely to agree that pharmacists are the most suitable profession (two behaviours scored 95% or more);
- Respondents from lower middle- to upper middle-income countries are more likely to agree than high-income countries (two behaviours scored 95% or more for high-income countries compared with nine for lower middle- and upper middle-income countries);

- Agreement that pharmacists are the most suitable profession for these specific supply chain behavioural areas is not universal among any subgroups in the survey but acknowledgment of pharmacists as the medicines expert is clear;
- Competency areas that are linked with clinical behaviours (the pharmacist as a medicines expert) were rated higher than supply chain technical areas (logistics expert), as noted in Table 5.

The richness in the data from the respondents was in the open comments made under each of the behaviour areas.

The bulk of comments made in response to the question was that the pharmacist needs to work as part of a team to best serve the patient (the population)

Table 5. The top 10 behaviours where participants noted pharmacists as the most suitable profession for that competency (note that columns represent subsets of the data by the category noted and percentages represent the percentage that agreed)

|  | All data<br>(n=384) | Pharmacist<br>(n=284) | Supply<br>chain<br>profession<br>als (n=24) | Low-income<br>countries<br>(n=89) | Low middle-<br>income<br>countries<br>(n=90) | Upper<br>middle-<br>income<br>countries<br>(n=68) | High-income<br>countries<br>(n=128) |
|--|---------------------|-----------------------|---|-----------------------------------|--|---|-------------------------------------|
| Advise on product specifications (e.g., active ingredient, form, pharmacopeia standard) for the procurement of medicines   | 99%                 | 100%                  | 96%   | 100%                              | 100%   | 100%  | 98%                                 |
| Identify medicines by their generic name, and have a general understanding of what medicines are used for  | 96%                 | 97%                   | 81%   | 94%                               | 97%  | 97%   | 95%                                 |
| Describe the principles and processes of category management for medicines (i.e., medicines categorised by similar use or storage needs, such as cold chain, antiretroviral medicines, controlled substances such as narcotics and psychotropics), including market segmentation principles for common needs and interests | 95%                 | 97%                   | 70%   | 96%                               | 99%  | 97%   | 89%                                 |
| Compound (make a pharmaceutical from base components) under the code of good manufacturing practice (GMP) for the production of medicines  | 95%                 | 97%                   | 95%   | 95%                               | 97%  | 100%  | 92%                                 |
| Describe the broad concepts of National Medication Policy, Essential Medicines Lists, Essential Equipment Lists, Standard Treatment Guidelines and dangerous drugs or narcotics policy   | 94%                 | 97%                   | 84%   | 93%                               | 99%  | 97%   | 88%                                 |
| Maintain a working knowledge of the handling requirements for medicines  | 94%                 | 96%                   | 75%   | 95%                               | 96%  | 90%   | 92%                                 |
| Ensure that medicines are not counterfeit <sup>2</sup> , and meet quality standards  | 93%                 | 94%                   | 75%   | 97%                               | 97%  | 95%   | 85%                                 |
| Implement, conduct and maintain a reporting system of pharmacovigilance (e.g., adverse drug reactions and incident reporting)  | 92%                 | 95%                   | 91%   | 92%                               | 96%  | 97%   | 88%                                 |
| Describe and demonstrate the recall procedures to be used in response to a medicine product recall notice  | 93%                 | 97%                   | 67%   | 93%                               | 93%  | 98%   | 89%                                 |
| Implement key security systems and appropriate levels of access for the workplace where medicines are stored (e.g., including narcotics, other controlled substances and investigational medicines etc.  | 91%                 | 95%                   | 70%   | 93%                               | 94%  | 93%   | 86%                                 |

<sup>2</sup> This refers to substandard and falsified medicines, and not only those with possible breaches of trademark or other intellectual property

## 6 Pharmacists as medicine experts and part of the supply chain team

### 6.1 Global human resources for health crises and the role of pharmacists

In 2006 the WHO brought to the world's attention the vast shortage of human resources required for minimum health service delivery.<sup>37</sup> In 2016, it estimated that the needs-based shortage of health care workers globally would be about 17.4 million, with the largest needs-based shortages being in South East Asian and African regions. If current trends continue, the global needs-based shortage of health care workers is projected still to be over 14 million in 2030.<sup>38</sup> About 85% of WHO member states report to have less than one pharmaceutical personnel per 1,000 population. Realistically, the scale-up required to address existing shortfalls and the expected turnover is greater than existing estimates, and implies the need to train and deploy up to 40–50 million new health and social services workers globally in the coming decades, based on increasing longevity and the current ways of working. The FIP 2012 Workforce Report and recent Workforce Trends Report also highlight these shortages.<sup>39, 40</sup> Pharmacists have a unique role to play as medicine experts within the health systems of countries. It is important that the roles of pharmacists are optimised to ensure the best use of their skills, especially in environments where pharmacists are scarce.

### 6.2 Pharmacists' roles

The 2012, [“Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services”](#) notes ‘six components’ to this mission of pharmacy practice:

- Being readily available to patients with or without an appointment;
- Identifying and managing or triaging health-related problems;
- Undertaking health promotion activities;
- Assuring effectiveness of medicines;
- Preventing harm from medicines;
- Making responsible use of limited health care resources.

These elements describe the usual hospital or community pharmacy environment for pharmacists.

The clinical roles of pharmacy practice are the emphasis of this document. “Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products” clearly suggests that the medicines supply function is central to pharmacy practice. This is particularly so in hospitals, community pharmacies and other health care institutions where pharmacists are present. Pharmacists also play a key role in medicines regulatory authorities, including approval of medicines, inspection of production facilities, pharmacies, wholesalers, clinical trials, etc. Furthermore, in many countries pharmacists are required for the role of Qualified Person, the person who oversees quality adherence within pharmaceutical production, pharmaceutical distribution (wholesaling), pharmaceutical companies, etc. The Qualified Person is not only the designated person responsible for the overall quality of operations but also has a personal responsibility for the quality of operations, and consequently their decisions cannot be challenged by the management of the operation. In countries where national distributions systems exist, a range of other personnel, including logistics experts, are involved, with pharmacists taking on some specific roles as medicines experts within these systems.

Our literature review and survey results have noted that the expertise of pharmacists as medicines experts is needed as part of a team approach to supply chains, and Table 6 summarises those behaviours where pharmacists are most needed, according to participants' views. This is further supported by the detailed country case studies in Appendix 1, although it can also be concluded that there is great variation between different regions.

In fact, from the case studies presented in Appendix 1, it is clear that the contribution of pharmacists to the supply chain varies considerably from country to country and also between different organisations. In some countries, such as France, the role of the pharmacist is ensured through legislation, whereas in others, such as Namibia, factors such as a lack of pharmacists or poor understanding of the special requirements of pharmaceuticals mean that supply chains have limited input from pharmacists. Nevertheless, the countries presented in the case studies all seem to recognise that the involvement of pharmacists in the supply chain is desirable, even if there are hurdles to the practical implementation.

The case studies also show that the economic or developmental state of a country is not necessarily an indicator of the level of involvement of pharmacists. Countries such as France and Portugal have strong legislation that guarantees input from pharmacists at all stages, whereas in the USA distribution centres for medicines seldom employ pharmacists. Similarly, in Cameroon, legislation requires pharmacists to be involved wherever drugs are procured, stored or dispensed whereas in Ethiopia and Namibia, although the input of pharmacists is desired, a severe shortage of personnel means that this is seldom the case.

Most countries claim that the pharmacy training enables pharmacists to work in the supply chain but some countries such as UK and USA are moving to a more clinically focused training which means that although pharmacists of the future may be well placed to contribute to formulary development and decisions relating to appropriate drugs for procurement, they may be less well equipped to manage the quality and storage aspects of supply chain management such as understanding the impact of temperature on stability and quality of medicines.

Interestingly, organisations involved in emergency and humanitarian supply efforts (such as demonstrated in the case studies from Lebanon and Canada) value the input of pharmacists. The Canadian case study reports that significant problems occurred when the supply chain for medicines was merged with that for other materials required by the military. Lack of understanding of how medicines are used and their requirements during shipment were at the root of these problems. A return to using a supply chain managed by pharmacists resulted in much more successful delivery of the appropriate service levels. In Lebanon, where large numbers of Syrian refugees are being cared for, pharmacists are in short supply but are employed at the head offices of the various agencies that are responding to the humanitarian emergency.

Given that the pharmaceutical supply chain is often long and complex, requiring the expertise of various disciplines with different skill levels, it is not surprising that the role of pharmacists varies around the world. The case studies show that although the model may vary, good quality service can be provided if appropriate consideration is given to how best to use the skills of the individuals available. For example, in the Solomon Islands, a geographically challenging area encompassing 800 small islands, it would not be feasible to have pharmacists at every point in the supply chain. However, by employing them in management roles where they can supervise the various activities, their influence has maximal impact.

Regardless of the role of pharmacists in the supply chain, all countries report challenges and potential changes. In some cases, this relates to the training that pharmacists receive, in others changes in the type of medicines supplied will require an increase in the level of control in the supply chain. Ensuring quality and excluding falsified medicines from the supply chain is a challenge everywhere and it is noteworthy that France considers the close involvement of pharmacists to have been a key factor in preventing such products from reaching the legitimate supply chain in that country to date. Pharmacists and all those involved in the planning, procurement, manufacture, storage and distribution of medicines must consider how most effectively to use the skills of the staff and personnel available, provide training where needed and keep their systems and role descriptions under review to adapt to changing circumstances.

## 6.3 Supply chain education

Supply chains globally are staffed by a variety of personnel, typically “pharmacists”, “logisticians and supply chain specialists”, and “other health professionals”. The education for each of these personnel groups is significantly different and their exposure to specific supply chain competencies is also varied.

### 6.3.1 Pharmacists

#### Academic qualifications

An undergraduate programme sets out to deliver a competent generalist pharmacist, meeting all minimum competencies required, appropriate to local needs. Pharmacists typically undergo a four- to six-year undergraduate training degree, and in addition often a six-months to one-year internship. In France and some French-speaking countries, such as Belgium and Morocco, students in their final year can choose to specialise in logistics and/or supply chain.

#### Professional short courses

Pharmacists wishing to deepen their knowledge of the supply chain — particularly pharmacists in high-income countries who engage in supply chain work — can undertake an additional professional qualification. Further, in low- and middle-income countries there is a large international development focus on developing supply chain and logistics competencies, with large investments from the UK Department for International Development, Gavi The Vaccine Alliance, the Global Fund, the United National Population Fund, UNICEF, USAID and others. More recently, there has been an increase in online professional education for supply chain competencies open to all personnel involved in supply chain delivery.

[LAPTOP](#) is an online search tool created by the Reproductive Health Supplies Coalition that lists an extensive range of both academic and professional short course education opportunities. It is an open access site.

#### General observations regarding supply chain management training for pharmacists

A typical first professional qualification — a BPharm, MPharm or PharmD, for instance — makes the pharmacist the first obvious candidate to be a central focus (together with other health science disciplines such as medical practitioners and nurses) in undertaking medicines-related activities.

It is essential that pharmacists, if they are to engage in supply chain management as a central competency, undertake professional certification and/or academic education and training consistent with the supply chain functions they wish to undertake, particularly if such training is not already included in their university training. Such training can cover the range of logistics and supply chain competencies typically required for overall logistics and supply chain functions (e.g., procurement, warehousing, distribution etc.).

In environments where pharmacists are scarce, the exact areas of pharmacy engagement will depend on the country context of the supply chain in question, and the legal environment.

### 6.3.2 Logisticians and supply chain specialists

Typically, logisticians and supply chain specialists obtain competence through professional or academic qualifications.

#### Professional qualifications

A number of organisations provide certification examinations that are accepted across the logistics and supply chain industry. These include the Association for Operations Management, the Chartered Institute of Logistics and Transport, the Chartered Institute of Procurement and Supply, the Council of Supply Chain Management Professionals, the International Institute for Procurement and Market Research and the International Supply Chain Education Alliance.

#### Academic qualifications

Typically supply chain management Bachelor, Master and PhD qualifications are available in developed countries worldwide, from within the business or finance schools of universities.

From an FIP perspective, pharmacists as medicines experts have a role in the quality, availability and use of medicines — key competencies required for effective medicines supply.

### 6.3.3 Other health professionals

In many environments, especially low- and middle-income countries or rural and remote environments in high-income countries, some aspects of supply chain management are undertaken by other health professionals (e.g., medical practitioners, nurses, midwives and a range of health assistants). There are many local contextual reasons for these choices.

In general terms, the undergraduate curricula for non-pharmacist health personnel has little content addressing supply chain management competencies. In low- and middle-income countries there has been a drive by the development community to produce a model supply chain management curriculum and have this inserted into the curricula of various health care workers who are likely to be engaged in supply chain management.<sup>41</sup>

Similarly to the situation for pharmacists, short-course, professional training opportunities have been made available by many providers in low- and middle-income countries in an attempt to address the existing competency gap.

## 6.4 FIP guidelines and standards that consider aspects of pharmacists in supply chains

The following statements underpin the role of pharmacists in health care delivery:

- [FIP statement of policy on improving access to medicines in developing countries](#)
- [FIP statement on ensuring quality and safety of medicinal products to protect the patient](#)
- [FIP statement of policy on the role of the pharmacist in pharmacovigilance](#)
- [FIP Good Pharmacy Practice in developing countries – recommendations for stepwise implementation](#)
- [Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services](#)
- [FIP statement of policy on counterfeit medicines](#)

Building on the understanding of pharmacists as medicines experts and their clinical role in pharmaceutical services delivery, it is also important to consider the technical and managerial aspects of supply chains in detail. Depending on the role the pharmacist plays in the supply chain in individual countries and organisations, it may be necessary also to look at which aspects of their education support them in these functions and consider potential improvements. It follows that optimal use of pharmacists will vary between country contexts, influenced by available personnel, history, finance and the regulatory environment.



## 7 Where there are no pharmacists

As noted in the introduction to this report, in 2006 the WHO brought to the world's attention the vast shortage of human resources required for minimum health service delivery.<sup>37</sup> At that time an estimated global shortage of 4.3 (currently 7.2) million health workers was noted, with critical shortages in 57 of the poorest countries in the world. It is clear that globally there are insufficient pharmacists to serve the population — for example, in Sub-Saharan Africa there is less than one pharmacist per 10,000 population.<sup>39</sup> Small island states including many Pacific island countries, also have few pharmacists.<sup>42, 43</sup> In these countries and in the rural and remote regions of many developed nations, consideration needs to be given to how to ensure distribution of medicines using available personnel. In many cases, this will not be a pharmacist.

Every country is governed by its own regulations concerning pharmaceutical distribution and the scope of practice of various personnel. In many developing countries, legislation has fallen behind practice, and weak enforcement of legislation has a bearing on practice. Every effort should be made to ensure that national governments have appropriate legislation and the structures required to enforce the legislation, and thus to ensure safe distribution and use of medicines.

As stewards of the health system, governments have the responsibility to ensure that personnel involved in pharmaceutical distribution and dispensing have the competencies required to fulfil these functions. In Section 3, the global variation in supply chain maturity is noted. Consistent with this model is the understanding that less mature systems are often run by personnel with less professional expertise, compared with mature supply chain systems and this is often in lower income countries. There is a wide variety of both online and face-to-face short courses available to equip the core personnel with basic competencies required for the distribution and use of medicines. This approach is often required in low- and middle-income country contexts. Typically, these courses cover procurement, storage, distribution and use with an emphasis on medicines safety.

Many service delivery points in low- and middle-income countries are typically staffed by nurses, nurse assistants or other mid-level health care workers, while in some countries untrained sellers distribute and sell medicines as simple commodities in an unregulated environment. Even when health care workers fill these roles, they are required to order, store, distribute and dispense medicines, often without being taught these competencies in their pre-service education.<sup>32, 44</sup>

As part of the international survey conducted for this paper, participants were asked “what should be done in circumstances where there are no pharmacists?”. The most frequent answers are noted below. The numbers in brackets with the # prefix indicate how many times that theme appeared, and indicative quotes are provided:

### Delegate tasks (#88)

“Delegate tasks” was the most common suggestion from respondents. Pharmacy assistants, technicians and other healthcare personnel were suggested in incidences where clinical aspects are concerned, while logistics personnel were recommended for technical tasks. Delegation, supported by remote supervision and mentoring, with telephone or other communication support was suggested. Any personnel taking on medicine supply tasks should be appropriately trained.

- *Use of pharmacy technicians or assistants is acceptable where pharmacist is unavailable. Ideally these technicians will have been trained and will have mentoring/supervision/regular oversight by a pharmacist even if off site. — Survey quote*
- *Healthcare supply chains are complex but not rocket science. Hence a proper team composition, a well-managed and well-trained team go a long way in achieving a good supply chain. A pharmacist should take a role in this team and has some specific responsibilities; many of those responsibilities can be delegated and performed by others with the appropriate checks and balances. — Survey quote*

### Training and education (#67)

Under “training and education”, the importance of appropriate competency based training is emphasised, ensuring that all staff playing a role in supply chains should be prepared for the task and supervised to ensure quality service provision. Training should follow the establishment of clear standard operating procedures for various activities. A variety of training methods was proposed.

- *Through on job training after standardising the business process. — Survey quote*
- *Through provision of pre- and in-service training and implementing and effective monitoring system like regular supervision. — Survey quote*

### Pre-approved protocols (#23)

The predominant subtheme under “pre-approved protocols” was that initial standard operating procedures should be prepared in consultation with pharmacists.

- *There should be an SOP at any level of work, and at least it should be expected that other health professionals should be competent enough to deal with such situations in the absence of a pharmacist, especially in cases where technical aspect or laws are not mandatory. — Survey quote*

### Outreach and communication (#18)

The theme of “outreach and communication” emphasised the importance of non-pharmacists having clear communication pathways and accessibility to pharmacists, albeit remotely, where personnel were working with medicines.

- *Make best use of available skills which will depend on circumstances. Pharmacist oversight can be provided remotely: it doesn't necessarily have to be available locally on the ground for all tasks all the time. — Survey quote*
- *There should be a designate available that will feedback the information to the pharmacist and also to the team(s). — Survey quote*

### Always pharmacist (#3)

Some respondents could not imagine a situation where pharmacists would not be present.

- *There must be always a pharmacist to fulfil its competencies; I can't imagine a situation when a pharmacist is not available. — Survey quote*

## 8 Concluding remarks

As we enter the era of Sustainable Development Goals and Universal Health Coverage, it is noted that one-third of the global population is still without access to basic life-saving medicines. In the global context of challenges such as substandard and falsified medicines, as well as a lack of human resources for health (including those involved in the supply chain), the need to ensure effective and safe supply chains has prompted a closer look at the actual role of pharmacists in pharmaceutical (health) supply chains.

In this report, literature, survey data and detailed case studies have been used to present a global overview of the role of pharmacists in pharmaceutical (health) supply chains. Given that the pharmaceutical supply chain is often long and complex, requiring the expertise of various disciplines with different skill levels, it is not surprising that the role of pharmacists varies around the world. Although the model may vary, good quality service can be provided if appropriate consideration is given to how best to use the skills of the individuals available.

Pharmacists and all those involved in the planning, procurement, manufacture, storage and distribution of medicines must consider how to most effectively use the skills of the staff and personnel available, provide and seek training where needed, and keep their systems and role descriptions under review in order to adapt to changing circumstances.

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## Appendix 1 – Detailed country case studies

The following detailed case studies have been chosen to represent a range of locations, health supply chain systems and health supply chain maturity from a cross section of countries. Each case study provides a deeper look at the health supply chain of the country, the role of pharmacists and other personnel in that supply chain, the legislation that governs how systems operate and the education undertaken for those personnel that work within that system. These case studies were written by country-based contacts, with the final version of the case study reviewed by the relevant FIP member organisation where available.

### Cameroon

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#### Overview

The health supply chain in Cameroon is organised in two sectors: the public and private sectors. The public sector consists of Government health institutions and para-public hospitals, while the private sector consists of the private hospitals and mission (church base) hospitals. These health structures are classified into 4 categories: (1) reference hospitals, central hospitals and university teaching hospitals; (2) regional hospitals; (3) district and subdistrict hospitals; and (4) integrated health centres. The health system is coordinated by a referral system from the fourth to the first category, i.e., patients consulted at the health centre level are referred to a district hospital, then to a regional hospital from where they are referred to a reference hospital, where they can get specialist consultation.

Pharmacists are responsible for the procurement and dispensing of drugs at all the different levels of the health system. Pharmacists also play a major role in manufacturing facilities, where they are in charge of production and quality assurance of the products and manage the staff of the facility. At the level of wholesale procurement, pharmacists are responsible for the importation, storage, quality control and distribution of drugs to the appropriate facilities. In community pharmacies, pharmacists are responsible for the drugs in the pharmacy and ensure the quality and storage conditions. They advise patients on public health issues and are the first point of contact with patients in the community. Most patients seek advice from a pharmacist before going to a hospital for formal consultation. The pharmacist dispenses medicines to the population after consultation. Pharmacists are also responsible for drugs regulation, control and inspections. The quality of drugs is controlled at the National Quality Control Laboratory during registration of the products and their importation is controlled at the CENAME (National Central Store for Pharmaceuticals Supplies), by pharmacists. There are pharmacists in the reference hospitals, central hospitals and university teaching hospitals and some regional hospitals. But in the district and subdistrict hospitals and health centres, there are no pharmacists and drugs are dispensed by other hospital staff.

#### Current legislation that guides the role of the pharmacist

The Pharmacy Law of 10 August 1990, Article No. 90-035, states that all health facilities in which drugs are procured, stored and dispensed to patients must employ a pharmacist who should be responsible for this activity.<sup>1</sup>

The law also states that only a pharmacist can open and operate a pharmacy after having obtained an authorisation from the National Pharmaceutical Society.

There is a need for continuous education as most pharmacists do not have opportunities for further training. It is difficult for pharmacists in a community pharmacy to leave their practice for further studies for one reason or another.

#### Organisation of the pharmaceutical sector

Drugs procurement is regulated in Cameroon. It is carried out through authorised structures of the official circuit (SYNAME) which is divided into two sub sectors — public and private. According to the legislation in force, only drugs having obtained marketing authorisations from the Ministry of Public Health can be sold or distributed free of charge in Cameroon.

**Procurement in the public sector**

Public sector procurement is organised at three levels: CENAME at the central level imports and ensures the supply of essential drugs to CAPRs (Centre d'Approvisionnement en Médicaments Essentiels et Consommables Médicaux de Région; the equivalent of regional medical stores), and hospitals in the first and second categories, i.e., the reference and central Hospitals. The CAPRs in turn ensure the supply of drugs to regional and district hospitals and health centres. The delivery of drugs to patients is done within pharmacies of hospitals and health centres.

**Procurement in the private sub-sector**

Local wholesale distributors purchase drugs from local foreign manufacturers, CENAME and national manufacturers in order to supply private (community) pharmacies (having obtained authorisation from the National Pharmaceutical Society) and internal pharmacies in clinics and polyclinics. Exceptions are sometimes granted to pharmacies for direct imports when needed; moreover some associations and NGOs benefit from it. Some first and second category hospitals sometimes turn to private wholesalers for specific drugs.

Private non-profit making hospitals and health centres (faith-based) are supplied by their own wholesale purchasing centres (Catholic, Baptist and AD LUCEM) which have the ability to import or order drugs from private wholesale distributors or CENAME.

**Challenges and future trends**

Despite this organisation, several dysfunctions remain in the drugs supply chain, compromising particularly the complementarities of the public and private subsectors in the health supply chain:

- Pharmacists are dependent on the decision-making process since they cannot procure the required medicines for the hospital without a formal authorisation.
- Proceeds from sales are not managed by pharmacists but by directors of health facilities.
- Absence of pharmacists at all the levels of the health supply chain.
- Non-compliance with the legislation with regards to procurement for clinics and polyclinics.
- Delivery of drugs to anyone in hospital and health centre pharmacies in violation of the law on recovery of cost on drugs.
- Limited availability of emergency and hospital drugs as well as some specialised medical devices in pharmacies of health facilities.
- Non-compliance with good storage and distribution practices (cramped space, poor quality of the cold chain etc.).
- Shortages of drugs in the public sector because products are not available at CENAME and CAPRs where all public health facilities are supposed to procure their drugs from.
- Some health facilities procure from the illicit market meaning that quality cannot be guaranteed.
- In most health facilities the cold chain cannot be guaranteed since a constant 24-hour supply of electricity is not guaranteed and temperatures are not noted daily.
- Although the health map provides all health districts with pharmacy sites, these are not always exploited because of their non-attractiveness and remoteness.

Finally, large stocks of drugs circulate in the country without any control of their quality, since quality control at port of entry is not systematic and the supervision and control of importation and distribution channels is not easy. Despite the existence of guidelines, donations constitute a significant proportion of non-controlled drugs.

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# Ethiopia

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## Overview of the health supply chain in Ethiopia

Ethiopia is the second most populous (96.9 million) and the 10th largest country in Africa. Over the past 10 years (2004–15), the country has shown impressive economic growth with real GDP of 10.9%.<sup>1</sup> In terms of per capita income, it is still among the lowest in the world.<sup>2</sup> According to the World Bank, the 2015 gross domestic product (GDP) of the country was estimated to be \$55 billion. Of this, it spent 5.06% on health.<sup>3</sup> The pharmaceutical market has an estimated compounded annual average growth of 14.3%.<sup>4</sup> With this forecast, the current value of the pharmaceutical market for 2016 is \$682 million (i.e., 24.5% of the healthcare budget)

In 1993, Ethiopia prepared a national medicine policy, which guides the pharmaceutical sector of the country. One of the major objectives of this policy is to systematise the pharmaceutical supply and distribution and ensure accessibility of essential medicines. The policy also identified establishing new pharmaceutical manufacturing plants, creating favourable conditions and incentives for private investors (importers and distributors), and establishing government-owned enterprise that supplies pharmaceuticals, as strategies to meet policy objectives.<sup>5</sup>

The pharmaceutical supply chain is the means through which medicines are delivered to patients. It is heavily regulated and hugely complex as it involves many stakeholders. Some of these actors in Ethiopia are Federal Ministry of Health (FMOH), particularly the Pharmaceutical Logistics Management Unit, the regulatory authority, developmental partners, importers (private and public), wholesalers, retailers, regulatory authority, customs authority, bank and insurance, Ethiopian shipping lines, Ethiopian airlines, and freight forwarders.

Ethiopia is heavily dependent on the import (80%) of pharmaceuticals.<sup>6</sup> As part of the medicine policy implementation process, the country has prepared a comprehensive Pharmaceutical Logistics Master Plan in 2006 with the support of stakeholders. The aim of this plan was to integrate all 'vertical programmes' health commodities management into one supply chain.<sup>7</sup> Following this, the Pharmaceutical Fund and Supply Agency (PFSA) was established by proclamation (Proclamation No. 553/2007) with a view to ensure constant and uninterrupted supply of vital and essential health commodities for all public health facilities. It also supplies essential health commodities to private and non-governmental health institutions in accordance with directives of the board of the agency.

Currently, the PFSA is responsible for the whole supply chain management (forecast, procurement, storage and distribution of health commodities). It covers almost 70% of the country's need. In addition, it distributes contraceptives, test kits and vaccines that are procured by developmental partners to various health facilities. Besides this, the agency is tasked to revolve funds to procure health commodities for other programmes and support the capacity of local pharmaceutical and medical equipment manufacturers. Accordingly, the PFSA provides them up to 25% of price protection when they compete in an international bid and rewards 30% of advance payments for tender winners. For instance, in 2013/14, it awarded local manufacturers contracts to manufacture pharmaceuticals and medical supplies worth ETB 614.4 million.<sup>8</sup>

Private pharmaceutical importers (224 medical equipment/supplies importers and 187 wholesalers) cover 30% of the total import needs.<sup>9</sup> They import medicines that are registered and permitted by the regulatory authority in the country and have an attractive market. As the country follows a free market economy, there is no pricing policy for medicines. They follow a cost-led pricing system, i.e., account for all their expenses and add a margin ranging from 40% to the highest possible.<sup>10</sup> Wholesalers and retailers also set selling prices by adding margins from 7 to 14% and 18 to 25%, respectively, on each product. Foreign currency shortage and credit based sales are some of the major challenges of the private importers.

Both private and public importers are estimated to serve more than 311 hospitals, 3,547 health centres, 16,440 health posts and 4,000 private clinics.<sup>11</sup> There are more than 780 community pharmacies, 3,266 drug stores and

<sup>3</sup> Various health programmes such as HIV/AIDS, Malaria, TB and Leprosy, EPI, MCH, Family planning that are funded, managed, delivered and monitored vertically by different parties. These include forecasting, procurement, storage and distribution and the overall management of pharmaceuticals for these programmes.

1,090 rural drug vendors in the country.<sup>12</sup> However, it should be noted that these health facilities and medicine retail outlets are not evenly distributed across the country. For instance, 48.5% of community pharmacies, and 8.3% of drug stores are concentrated in the capital city, Addis Ababa.

Local pharmaceutical manufacturers cover 20% of the total demand of the country.<sup>13</sup> Although the first manufacturing of medicines was started in 1964, the development of the industry has not been completely satisfactory. Today, there are 15 pharmaceutical manufacturers, of which only nine produce medicines. While four of them comply with basic GMP standards, two have acquired Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Certification. The rest operate under the Ethiopian regulatory authority's manufacturing licence.<sup>14</sup>

In the coming years, the pharmaceutical market is expected to grow. The main drivers for this are booming population growth; an increasing burden of communicable and non-communicable diseases; life-style changes such as diet and sedentary living; expanding health coverage; improved awareness about modern medicines; introduction of health insurance; and steady economic growth. In contrast, limited business experience and talent among staff, low disposable income, tight regulation in the pharmaceutical industry, poor labour skills and slow adoption of new technologies, a limited number of trained professionals within the medical field, credit issues, issues of quality of operation among local distributors, and shortage of foreign currency could be restraints.<sup>14-16</sup>

## Current legislation that guides the role of personnel

Like many other developing countries, the health supply chain system in Ethiopia is mainly managed by health professionals, especially pharmacists. A census conducted in 2010 indicated that most pharmacists practise in hospital (33.6%), sales and marketing (18.8%) and community pharmacy (18.5%)<sup>17</sup> where managing the pharmaceutical supply chain is their core activity.<sup>18,19</sup>

Code of ethics, reform guidelines and minimum standards are some of the main guiding documents that detail the role and responsibilities of pharmacists and pharmacy technicians in relation to the health supply chain. For instance, as per the code of ethics and standards of practice for pharmacists practising in Ethiopia,<sup>20</sup> Article 2.3.1 to 2.3.11 obliges pharmacists to carry out selection, quantification, procurement, physical inspection, storage and distribution of pharmaceuticals and other health commodities relevant for service provision, providing the principles that the pharmacist should apply. The code of ethics also requires the recording of relevant information on consumption and stock-keeping records.

Another legal document prepared by FMOH to guide the role of personnel working in health supply chain is a hospital reform implementation guideline. Under the "Pharmacy Services" chapter, it is clearly stated that the selection of medicines should be made by a hospital's drug and therapeutic committee (DTC). Nothing explicitly states who should do the quantification except mentioning the methodology and the steps to be followed. However, it mentions there should be a designated pharmacist, preferably a drug supply management officer, who is responsible for the purchase, storage and distribution of all pharmaceuticals.<sup>21</sup>

The Ethiopian Standards Agency has also prepared minimum standards for hospitals, health centres, health posts, clinics and specialty centres with the view to protect the public from sub-standard medical services and ensure high professional standards of practice among professionals. Here also the DTC is mandated to do the selection of medicines. Regarding the procurement, stock management, warehousing, distribution and disposal of medicines, a designated pharmacist/pharmacy technician (as appropriate) is responsible. The pharmacist is empowered to ensure that the supplier and the source of any medicine purchased are reputable and licensed by the appropriate organisation.<sup>22-25</sup>

Ethiopia is one of those countries with a severe shortage (i.e., 2.38 pharmacists per 100,000 population) and uneven distribution of pharmacists.<sup>17</sup> In areas where pharmacists are in shortage, the country has many years of experience using mid-level trained professionals such as pharmacy technicians and health extension workers (HEWs) to provide basic pharmacy services, including health supply chain management. For instance, currently, HEWs are tasked with the overall management of 59 items including antibiotics, antimalarials, analgesics, vaccines, contraceptives, supplementary foods, gloves and syringes in health posts.<sup>26</sup>

Although the above documents recognise managing pharmaceutical and other health commodities as primary roles and responsibilities of pharmacists and pharmacy technicians, they also advocate health supply chain activities to be done in collaboration and coordination with all relevant stakeholders and professionals. In line

with this, currently the country is training and involving physicians to take part in a national quantification exercise, which was not been practised before. Such initiatives need to be strengthened.

### Specific reference to the role pharmacists play

In 2014, People that Deliver (PtD) prepared a Competency Compendium for Health Supply Chain Management (HSCM) professionals. The main domains of this document are selection and quantification, procurement, storage and distribution, and use. As per this compendium, the school of pharmacy at Addis Ababa University assessed the competency of pharmacy professionals. Accordingly, most pharmacists indicated that they were comfortable with the afore-mentioned domains of HSCM. However, they felt that they had little awareness, knowledge and experience on how to execute and manage contract, import and export products, tender processes, manage procurement costs and budget, or build and maintain relationship with suppliers.<sup>27</sup> These activities might not be as frequent at public health facilities level given the existing health supply chain system. But the risk associated with this should be mitigated by using the appropriate expertise like logistics and supply chain management graduates. The provision of specialise training supply chain management for pharmacists and other health professionals might also be alternative solutions.

### Education approaches used to equip pharmacists and other personnel

The first successful training in pharmacy (at the certificate level) began in 1943 at the Menelik II Hospital. Then, Bachelor of Pharmacy (B. Pharm) and Master's programmes in pharmaceuticals were launched at Addis Ababa University (AAU) in 1961 and 1998, respectively. Currently, there are 11 public universities, one publicly owned health college and eight private colleges that train pharmacists at bachelor level in the regular, evening, summer and weekend programmes. More than 4,000 pharmacists graduate annually from these completing their four years of intensive courses and one year of practical attachment.<sup>28</sup> Four universities, namely AAU, Jimma University (JU), Mekelle University and Gondar University, also train at master's level. In addition, AAU trains at PhD level.

To make students fit for the work they are required to do, schools of pharmacy in Ethiopia regularly revise their curricula. Health supply management recently had more time allocated to it. Courses addressing this topic, such as drug supply management, inclusion of practical attachment session for final-year students (though it is elective for students who are interested in the supply chain) and visits to the PFSA and other stakeholders are some of the interventions. Such hands-on practice and site visits are expected to solidify their knowledge and skills and connect learning with performance. However, given the responsibility they will assume upon graduation and the value of the commodities they handle, it is still not enough. This could also be the reason that the government and other stakeholders are forced to arrange short-term, in-service training, which is costly and unsustainable.

Unlike in other countries, the clinical and industrial aspect of pharmacy practice is not as well developed in Ethiopia. This means pharmacists still retain supply chain management as one of their main jobs. So, further and advanced training is needed to develop their competence and bring more efficiency in pharmaceutical supply chain management, and JU school of pharmacy has launched a master's degree in pharmaceutical supply chain management, which is first of its kind in the country.<sup>29</sup>

Similarly, the school of pharmacy with the school of commerce at AAU, in collaboration with UNFPA, USAID|DELIVER, PtD and other development partners identified supply chain management gaps in pre-service, in-service and postgraduate training of pharmacy professionals through a workshop and needs assessment survey. Based on these, a competency-based curriculum was developed and was approved at different levels of the university. Such an endeavour will resolve the shortage of trained personnel in the area and also support the system by undertaking research on major gaps of the sector.

### Current challenges and trends

HSCM in Ethiopia has numerous challenges that need to be addressed strategically. Some of these are medicines and other health commodities being out of stock, especially in tertiary hospitals; wastage of pharmaceuticals due to expiry, theft or damage; lack of transparent, accountable pharmaceutical transactions and services; poor performance of suppliers; long procurement lead times for some pharmaceuticals and medical equipment; poor record keeping and data quality; delayed installation and maintenance of medical equipment; shortage of vehicles to distribute pharmaceuticals from health centres to health posts; inadequate follow-up and support; lack of performance monitoring and evaluation systems; training gaps; and high staff turnover. Inadequate coverage of supply chain courses in the undergraduate training of pharmacists and a lack of hands-on experience have also been noted.<sup>30, 31</sup>

These challenges could further be compounded by the introduction of social and community based health insurance in the country, which is expected to increase the total number of patients who visit health facilities and their expectations.<sup>16</sup> The rapidly expanding number of health facilities in the country and training of medical professionals, demographics, epidemiologic transitions, and government commitment to improve quality of the service also create huge demands and these could be major sources of customer dissatisfaction unless the required changes and preparation are made in advance to meet these expectations.<sup>13</sup> Cognisant of this, the FMOH has prepared a health sector transformation plan for the coming five years, identifying supply chain and logistics management of health commodities as one of its strategic objectives.<sup>32</sup>

In conclusion, there is an established health supply chain system in Ethiopia, which has been improving over the past two decades. To sustain these changes and to satisfy the ever-growing demands of customers, it is essential to develop and retain skilled human resources with the right mix of professionals for HSCM. In addition, strengthening the coordination and collaboration of all supply chain partners and continued system improvement is needed to help build a health supply chain system that is ready to react to sudden changes in demand or supply, able to adapt to environmental changes and also match the interests of all members of the network through optimisation. Finally, using the health sector transformation plan as an opportunity to improve the health supply chain, and thereby the service, is crucial, since this encourages more initiatives and improvements to emerge in the health supply chain system.

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# France

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## Role of the pharmacist in the pharmaceutical chain in France

In France, pharmacists are present all along the pharmaceutical chain: from manufacturing to wholesaling companies, community pharmacies, hospital pharmacies and clinical laboratories, they play a key role.

For safety/security reasons, authorities granted a monopoly to pharmacists not only on dispensing medicines, (both prescription-only and non-prescription medicines) but also on manufacturing and wholesale distribution. Therefore, manufacturing, importing/exporting, wholesale and retail distribution can only be performed by pharmaceutical companies (legal status), which are regulated and authorised by health authorities. At each step of this chain, pharmacists are responsible for ensuring that quality and security requirements are met. Besides, manufacturers are only allowed to sell medicines to authorised pharmaceutical establishments (wholesalers or pre-wholesalers) or community pharmacies.

In this system, there are no uncontrolled intermediaries such as "brokers". Wholesale distribution establishments can only have an activity provided they have obtained an authorisation, which is granted by the Medicines Agency based on an inspection. During this visit, inspectors check that the establishment complies with wholesale distribution good practices, which set rules on supply conditions and require wholesalers to purchase only from authorised pharmaceutical establishments.

At an individual level, every pharmacist, including wholesale distribution pharmacists, must be registered at the French Chamber of Pharmacists to practise as a pharmacist in a pharmaceutical establishment. The Chamber ensures that pharmacists are competent (checks qualifications and other legal requirements at registration, controls pharmacists' compliance with their continuing professional development obligations, etc.) and their proper behaviour (submitting the ethics code to the government and holding disciplinary meetings). If a pharmacist ever introduces counterfeit medicines in the legal distribution chain, he knows his diploma will be revoked and he can no longer practise.

This system probably contributed to the fact that no counterfeit products have been seized in the legal pharmaceutical chain in France.

## Wholesale distribution in France: regulatory framework

Wholesale distribution of drugs for human use and other products pertaining to the pharmaceutical monopoly can only be performed by pharmaceutical establishments, which are mainly either full-line wholesalers or pre-wholesalers:

- **Full-line wholesalers** devote themselves to the purchase and storage of drugs other than those intended for human trials, with a view to their distribution wholesale and in the same condition, with approximately 200 agencies in the French territories. Using a fleet of vehicles, they supply the entire dispensing pharmacy network. Full-line wholesalers own their stock and receive deliveries from the pharmaceutical companies or their pre-wholesalers. They are bound by public service obligations: the holding of 90% of the existing drug references, a stock of at least two weeks of sales, delivery within 24 hours to any pharmacy in its sector, and service to all dispensing pharmacies who request it within their stated territory of activity. They also have an on-call duty: on weekends, there is always a wholesaler that can be contacted by health authorities to provide medicines in case of an urgent health problem.
- **Pre-wholesalers** are providers of services that devote themselves to the storage of these drugs, products, objects or articles, which they do not own, with a view to their distribution wholesale and in the same condition.

Similarly to the location of premises for the practice of pharmacy, the wholesale distribution establishment must be installed in specific premises that are suitable for the activities carried out there and appropriately equipped and maintained. These obligations are determined by best practices.

In France, any company having at least one pharmaceutical distribution establishment must be owned by a company whose management or executive board includes a pharmacist ([article R 5124-34 of the public health code](#)<sup>1</sup>). These pharmacists, as chief pharmacist officers, are personally responsible for compliance with the provisions governing their activity (their missions are described in [article R 5124-36 of the public health code](#)<sup>2</sup>). They organise and monitor all the pharmaceutical activities of the company, and ensure that the transport conditions ensure good storage, integrity and security of the medicines.

They are assisted by designated pharmacists who provide the same degree of responsibility for each of the establishments.

## Training and key competences of pharmacists in the distribution chain

In France, pharmacists' studies last six years and conclude with the conferment of the state degree of doctor of pharmacy.

Pharmacists practising in the wholesale distribution sector usually follow the industry section within these pharmacy studies, and obtain in addition a complementary diploma, which is a master's degree in pharmaceutical distribution or quality management.

This training allows pharmacists practising in the wholesale distribution sector to benefit from a rigorous scientific pharmaceutical background/general education, which is key because it is essential for wholesalers to have a precise knowledge of how medicines work in order to fully understand their storage and transport requirements, and to be able to adopt appropriate and proportionate measures in case of a problem. They know, for instance, that if a vaccine is not stored under the right temperature conditions, it will not work and it will therefore be useless to the patient. In the future, there will be more thermolabile medicines with complex storage and transport requirements (i.e., biologic medicines), so this knowledge of medicines is crucial.

It is also essential for wholesalers to understand the pharmaceutical chain as a whole — its legal and technical specificities and constraints. It is beneficial that all pharmacists along the chain share this same culture of understanding each other, in order to meet challenges such as the implementation of serialisation, to ensure full traceability along the chain.

Compared with non-pharmaceutical distributors, pharmaceutical wholesalers have a public health role and responsibility: they must check their sales, and notify, for instance, health authorities if they notice an unusual volume of sales on a product that can be misused. This public health role relies also on ensuring an equal access to medicines in any part of France: pharmaceutical wholesalers do not choose the patients/pharmacies they supply and they do not choose the medicines they supply.

On top of their basic common training, pharmacists acquire, during their masters' degree, additional competencies on quality management and logistics.

Quality management is also a key competency today, because patients expect from the pharmaceutical chain a no default/risk approach, and a continuous improvement of the practices and procedures based on lessons learnt from past problems. Pharmacists are trained to do that and take preventive measures to ensure this high level of quality, applying pharmaceutical distribution best practices.

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# Lebanon: Medicines supply to Syrian refugees

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Lebanese order of Pharmacists

## Introduction

After the Syrian crisis, thousands of Syrians fled into neighbouring countries. In Lebanon, there is an estimated 1,048,275 persons registered as Syrian refugees, representing 253,302 households; 52% of them are female and the majority are children. There are tremendous gaps in support for the refugee population, particularly in the health sector. Many refugees are unable to receive health care from Lebanese hospitals and clinics. Children and women (especially women of child-bearing age) suffer the most. Within the overall coordinated approach to the Syrian refugee response in Lebanon, the health sector brings together different UN agencies, national and international NGOs, donors and government actors (particularly the Ministry of Public Health (MOH) and the Ministry of Social Affairs), which are all working to support the continued provision of essential health services to Syrian refugees.

## Medicine sources

There are two main sources of medicines for Syrian refugees: donating countries and Lebanese suppliers. Donating countries can directly ship medicines from their sources or they can donate cash and supply medicines from the local Lebanese market.

### Directly donating medicines

All health programmes coordinate closely with MOH. The medicine shipments arrive either at Lebanese airports or ports. They will remain in storage until MOH inspectors approve their release to the NGOs or local Lebanese associations involved in Syrian medical health support. One of the major problems encountered is the delay of inspection over several days (due to legal administrative procedures approval). In this situation, medicines will remain in hangars that lack the minimal storage conditions in relation to humidity and temperature control. Sometimes it is necessary to discard medicines because of the damage that occurs during this storage, even if the medicines have long expiry dates. Some associations are aware of this problem and so they ship the medicines in specific cold storage containers that can stay cool for a longer period.

### Medicines from local suppliers

When cash is provided, medicines are sourced from the local market. These medicines can be directly purchased from suppliers representing international or national manufacturers. They are reliable with regard to their safety, efficacy and storage conditions. In this case, all purchased medicines must by law be labelled “free of charge, donations”.

In addition some local suppliers choose to donate medicines free of charge but unfortunately these medicines often have short expiry dates and may have expired by the time they reach patients.

## Medicines on the premises, warehousing and storage

Many local associations work closely with the MOH and international NGOs. They are approved by the MOH as providers of health services to the population affected by the Syrian crisis. Usually these associations have primary healthcare centres located across Lebanon.

Once medicines arrive at the airport or port and approval is obtained from MOH inspectors, the local association’s pharmacist will be in the hangars to receive the medicines. Usually the medicines are then directly transported to the main store, which is well equipped to receive either cold chain products or other medicines with normal humidity and temperature control. The main store is air-conditioned equipped and cold chain medicines are stored in refrigerators with temperature control (readings are done in the morning and pm before closing). These storage centres are also under MOH inspection to assure that they meet all guidelines for good storage and distribution practices for pharmaceutical products.

## Transferring medicines to Syrian refugee areas?

There are two ways in which medicines are transferred to the areas where Syrian camps are concentrated. Either Syrians will go out to primary healthcare centres (PHCs) located outside their camps, or they remain in the camp and a medical mobile unit (MMU) will come to them.



### Primary healthcare centres

PHCs involved with the Syrian refugees must be accredited by the MOH. This is because a number of NGOs may have a “humanitarian face” but in fact could be illegal, fraudulent or laundering money. PHCs usually give medicines to patients free of charge. Only in the main office (usually located in the capital Beirut), is a registered pharmacist available. The main duties of this pharmacist include:

- Managing medicines and medical supply requests, consumption data and donation coordination for all supported PHCs and MMUs;
- Conducting regular visits to the supported clinics to ensure delivered pharmaceuticals and medical supplies are available, properly dispensed, and managed;
- Supervising and training pharmacy assistants in the supported clinic and MMUs in all topics related to medicines, pharmacy management, stock control, generating stock lists and the proper handling of medicines;
- Conducting inventory checks every three to six months;
- Ensuring quality standards are applied with regards to ordering, expiration dates and proper storage (cleanliness, security, access, etc.);
- Ensuring that a one-month buffer stock is available to avoid shortages;
- Following-up on expired drugs.

On the other hand, in all PHCs pharmacist assistants hold either a biology, biochemistry or chemistry degree. In many PHCs, only nurses are responsible for distributing medicines. These nurses will undergo training about medicines, especially chronic medicines, medicines for pregnant women and vaccinations. The transfer of medicines from the main store to PHCs is carried out by vans. Usually in hot weather, the transfer is done early in the morning before the temperature rises. Only cold chain products are refrigerated. Once medicines arrive in the PHC, stock quantities and expiry dates are recorded. A special software program allows the movement of medicines to be checked.

### Medical mobile units

MMUs are buses converted into consultation and treatment rooms. They can travel to the largest villages. Their staff is composed of at least one doctor and a nurse. In some MMUs, there are two doctors, a nurse and a social worker (health educator or counsellor).

Many Syrian refugees are unable to get treatment for chronic diseases such as diabetes, asthma, hypertension and cardiovascular diseases, either because it is too expensive or because it is not available. Some 25% of patients were suffering from a chronic disease requiring treatment, yet nearly one in five patients were not receiving the treatment they needed. Four out of 10 said they were unable to access a hospital in Lebanon, due either to prohibitive costs or to insecurity. Beyond medical visits and medicines delivery, patients in need can be transferred to the nearest PHC or to a local hospital. Each MMU team develops monthly schedules and shares these with the field Inter-Agency Health Working Group to enhance coordination. MMUs should have a close link with a PHC facility, where staff can collect vaccines, medicines and medical consumables.

There are usually no pharmacists in MMUs or PHCs outside Beirut. Nurses usually deliver medicines upon receipt of a physician’s prescription. These nurses will undergo intensive training in medicines delivery as well as other essential training (e.g., sexually transmitted diseases, psychological health, chronic diseases). In some cases, physicians will also undergo this training.

### What is the case inside the Syrian refugee camps?

Most of the Syrian Refugees camps lack medical clinics or pharmacies. Inside the camp’s responsible office, they will have a small medicines cabinet. Unfortunately, the person responsible for this cabinet usually has no medicines training but can sometimes deliver medicines in urgent cases. The responsible person usually holds a bachelor’s degree or has a technical diploma.

### Conclusion

Medicines delivery to Syrian refugee camps has evolved positively with regards to storage conditions. The “non-pharmacists” involved in medicines delivery direct to patients are trained in the PHCs and MMUs. However, inside the camps, medicines supply conditions need improvement. The work of the pharmacist is rather managerial and consists of controlling the flow of medicines to patients.

# Namibia

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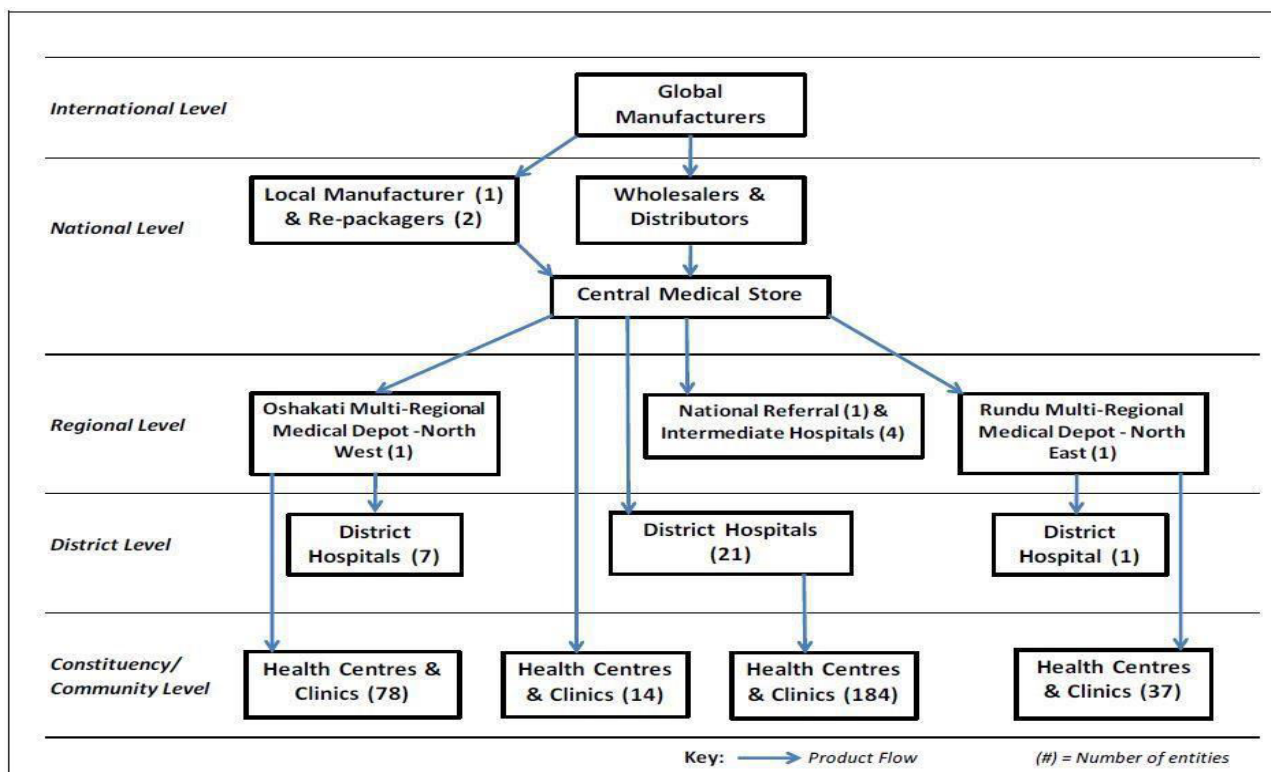
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## Background

Namibia is a vast country with a surface area of approximately 824,116km<sup>2</sup> and a population estimated at 2.1 million.<sup>1</sup> The country has the second lowest population density in the world (2.6 inhabitants per square kilometre). The vastness of the country and the sparse population distribution pose logistical challenges in ensuring increased access to healthcare services. The Namibian public health system serves about 85% of the total population. In the private sector, community pharmacies provide services to about 15% of the population covered by some form of health insurance. In 2009, 78 licensed community pharmacies employed about 109 pharmacists, accounting for most registered pharmacists in Namibia. About 50% of community pharmacies are in the Khomas region (which encompasses the capital, Windhoek) and with the rest mainly found in the urban and tourist centres of Oshana and Erongo regions.

## Brief overview of the health supply chain

The Ministry of Health and Social Services (MOHSS) manages a supply chain that serves approximately 350 public health facilities, including 29 hospitals, four intermediate or referral hospitals, one national tertiary hospital, as well as 313 primary health care facilities (see Figure 5).<sup>2</sup>



Source: Onger 2015

Figure 5. Namibia’s public health sector supply chain map

The country has limited pharmaceutical manufacturing capacity with only one GMP-approved local manufacturer, which mainly produces oral liquids, creams and ointments. Namibia imports most originator

and generic pharmaceuticals from South Africa or from generic manufacturers in India. A government-owned central medical store procures and distributes pharmaceuticals to all public health facilities.

In addition, two regional medical depots (RMDs) act as intermediate stock holding points: the Oshakati RMD located 700km to the northwest of Windhoek, and the Rundu RMD, located 700km to the northeast. These two RMDs provide last-mile distribution to health facilities in northern Namibia—serving five of the country's 13 regions—where the vast majority of the population resides.

## An overview of the current legislation

Under South African law, all pharmaceutical wholesalers and distributors must be managed by a pharmacist. However, pharmacy practice, a key part of the last mile of the supply chain, is under the purview of Namibian law. Pharmacy practice in Namibia is regulated through the Pharmacy Act (Act No.9 of 2004),<sup>3</sup> which targets the profession, and the Medicines and Related Substances Control Act (Act No. 13 of 2003),<sup>4</sup> which targets the product (medicines):

- The Pharmacy Act, which is administered by the Pharmacy Council of Namibia under the umbrella of the Health Professions Council of Namibia, prescribes the minimum requirements for registration of persons to practise as pharmacists or as allied to the pharmacy profession, identified as pharmaceutical technicians and pharmacist assistants. The Act also specifies the education, training and qualifications of persons practising such professions;
- The Medicines and Related Substances Act restricts the manufacturing, packaging and selling of medicines only to persons who have been duly licensed. By this law, only pharmacists may handle Schedule 3 and 4 medicines (narcotics and psychotropic substances) and all tasks associated with them.

## Specific reference to the role pharmacists play in the supply chain

Although neither the Pharmacy Act or the Medicines and Related Substances Control Act explicitly mention the role of pharmacists in the supply chain, the role exists in the fabric of the public health supply chain in Namibia. However, the number of pharmacists available to fill these positions is limited as Namibia faces the one of the most severe health workforce shortages in the world. While the number of pharmacists per capita (1.4 per 10,000 population) in Namibia is above the African region average of about 0.5 per 10,000 population,<sup>5</sup> there is marked disparity between the public and private sectors and between urban and rural areas. For example, as of 2012, out of the 312 registered pharmacists in Namibia, only 35 (11%) were employed in the public sector, of which 24 (68%) were foreign nationals employed on two- to three-year contracts.<sup>6</sup>

Pharmacists and pharmacist assistants occupy a variety of roles within the supply chain that vary depending on the level and location. In addition, in 2015 the University of Namibia began training new personnel, pharmaceutical technicians, who will serve primarily at the district level in support roles to pharmacists and will have supply chain responsibilities. Table 6 lists a sample of job titles by level of the supply chain.

Table 6. Pharmacist and pharmacist assistant positions within the public health supply chain

|                           | National level   | Regional level   | District level   | Community level                                 |
|---------------------------|--|--|--|---|
| Pharmacist                | <ul style="list-style-type: none"> <li>• Deputy director pharmaceutical services</li> <li>• Chief pharmacist (central medical store)</li> <li>• Distribution pharmacist (CMS)</li> <li>• Procurement pharmacist (CMS)</li> </ul> | <ul style="list-style-type: none"> <li>• Regional pharmacist</li> <li>• Distribution pharmacist</li> </ul> | <ul style="list-style-type: none"> <li>• Hospital pharmacist</li> <li>• Pharmaceutical technician (in future)</li> </ul> | No pharmacy personnel at health centres/clinics |
| Pharmacist assistant (PA) | <ul style="list-style-type: none"> <li>• Senior PA</li> <li>• PA</li> </ul>  | <ul style="list-style-type: none"> <li>• Senior PA</li> <li>• PA</li> </ul>                                | <ul style="list-style-type: none"> <li>• Senior PA</li> <li>• PA</li> </ul>  | PA in urban area health centres                 |

Pharmacists duties related to the supply chain usually include some combination of the following depending on the level and specific job site — supply management and planning and budgeting responsibilities that require the individual to: ensure availability of pharmaceutical supplies; regularly control inventory; supervise adherence to appropriate stock management techniques, appropriate storage conditions and monitoring of ward supplies; determine pharmaceutical requirements; prepare budgets; monitor expenditure; and compile statistics regarding medicines utilisation in different departments.<sup>7</sup>

Pharmacist assistants' general supply chain responsibilities (again dependent on level and job site) usually include receipt, issuing, record-keeping and general stock management.

## Education approaches used to equip pharmacists and other personnel

The MOHSS worked with development partners and Namibian educational institutions to introduce a four-year full-time Bachelor of Pharmacy programme at the University of Namibia (UNAM), which was accredited in 2011. As of 2014, 107 students were enrolled, and the first 14 pharmacy students graduated in April 2015.<sup>8</sup> Currently, 140 students are enrolled.<sup>9</sup> In terms of supply chain training, the programme includes a four-week supply chain management course (developed with US government support through the Systems for Improving Access to Pharmaceutical Services) and taught in the third year. The programme also requires a one-year internship during which students apply supply chain concepts learned in the classroom. In terms of learning post-education, pharmacists are required to complete 30 continuing education units, which allows pharmacists to renew their licences.<sup>10</sup> However, additionally, pharmacists learn on the job either through in-service training opportunities or through mentoring via supportive supervision. In reality, in-service training opportunities in the supply chain are limited and are usually supported by donor partners. Mentoring in supply chain topics by regional pharmacists is highly dependent on the relationship between the supervisor and supervisee and time available to focus on those topics. Additionally, no standard curriculum exists for such mentored learning in the supply chain.

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# Portugal

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## Overview of the health supply chain

Over the past few years, Portugal has been through a period of serious economic and financial instability. The implementation of numerous governmental measures resulted in several challenges to the pharmaceutical sector. These measures, which were particularly intense from 2008 onwards, affected the pharmaceutical distribution sector severely, due to successive administrative reductions of medicines' prices and trade margins.

Striking evidence can be found, therefore, of the devaluation of the wholesale medicines distribution market as compared with 14 years ago. This value suffered a reduction of 27.3% between 2008 and 2015 (around EUR 770 million, based on IQVIA's (formerly QuintilesIMS Institute for Healthcare Informatics) data, while wholesaler margins decreased 22% between 2005 and 2014.

By December 2015, 1,656 pharmacies (representing over 50% of the total number of pharmacies in Portugal) had suspended supplies from at least one wholesaler, bringing the global debt arguable between pharmacies and wholesale medicines distributors to a total of EUR 265 million.

Although the state implemented measures to counteract the crisis, while reacting to the arising challenges, pharmaceutical wholesalers have been undergoing an internal adjustment process. This process aimed at optimising operational costs, through infrastructure centralisation and distribution systems efficiency improvement. Following this premise, restructuring plans were implemented, along with rationalisation of existing resources. In order to achieve this, distribution platform numbers were decreased, the number of employees (both undifferentiated and specialised staff) was reduced, service levels (number of deliveries) were kept to a minimum and credit limit levels were substantially lowered.

## Current legislation

In Portuguese legislation, wholesale distribution of medicinal products is defined as all activities consisting of procuring, holding, supplying and providing medicinal products destined for transportation, resale or use in medical services, health units, hospitals and pharmacies, specifically excluding any direct-to-patient supply.

Operating a wholesale medicines distribution business in Portugal is dependent on prior appraisal and licensing by the National Authority of Medicines and Health Products (INFARMED), — with an exception for manufacturing authorisation holders, in respect of the medicines they manufacture.

Obtaining a wholesale medicines distribution authorisation is a complex procedure, requiring compliance with various requirements. These include presenting all information related to the company organisation, as well as the facility's blueprint (detailing areas for reception, storage, order preparation, shipping, returns, recalls and rejects). These should be compliant with the regulation on good distribution practice of medicinal products for human use and with the legal requirements for fire prevention. The company must also submit the quality handbook (which describes the quality management system) as well as information on the technical director responsible for the distribution activity.

This technical director must be a pharmacist, who may not simultaneously fulfil any technical direction at any other health unit. During the authorisation process, the pharmacist is required to present an updated copy of the professional card (or a declaration that attests to his or her status in terms of payment of membership fees, good standing and fitness to practise issued by the Portuguese Pharmaceutical Society, the national competent authority for pharmacists) which confirms all academic and professional qualifications required to undertake the role of technical director. The pharmacist is also required to present a signed consent form undertaking the technical responsibility; an original document of police clearance (showing the absence of a criminal record); and a copy of the contract signed between the pharmacist and the wholesale distribution company.

The wholesale medicines distribution authorisation holder is obliged to comply with good distribution practices. It should only procure and supply medicines through entities that are licensed to distribute. At all times, it should own medicines in sufficient quantity and variety to ensure the correct, adequate and continuous supply of the relevant geographic market, thus ensuring that patients' needs are met. The distribution authorisation or licence is to be issued concomitantly with a certificate of good distribution practices, which will be included in the European Union database (EudraGMDP).

The wholesale medicines distribution of products containing narcotics or psychotropic substances is subject to the instruction of a different and separate process, which also happens in the case of medicines for veterinary use (in that case, the authorisation is granted by the Portuguese National Authority for Animal Health).

## Good distribution practices

The current legislation lays out that wholesale medicines distribution authorisation holders should, along with other obligations, comply with the good distribution practices (GDP) regulated by INFARMED, taking into consideration the relevant European Commission Directives, Regulations and Guidelines.

Through Resolution no. 47/CD/2015, INFARMED has regulated GDP, covering the following main aspects of wholesale distribution activity: quality management; personnel; premises and equipment; documentation; operations; complaints, returns, suspected falsified medicinal products and medicinal product recalls; outsourced activities; self-inspections; transportation; and specific provisions for brokers.

Regarding quality management, wholesale distributors must maintain a quality system (accountable to the organisation's top management) setting out responsibilities, processes and risk management principles related to their activities. The quality system should ensure that medicinal products are procured, held, supplied or exported in a way that is compliant with the GDP requirements, and that products are delivered to the right recipients within a satisfactory time frame. This quality system should ensure that established procedures are kept, using real-time records, allowing for deviations to be documented and investigated, and the appropriate corrective and preventive actions taken, in line with risk management principles. All distribution activities should be clearly defined and systematically reviewed.

Regarding personnel, the responsibilities of the technical director should be well defined and described in detail. Records, medicine recalls, personnel training and hygienic care should be in line with the quality system. The organisational structure of the wholesale distributor should be set out in an organisational chart. The roles, responsibilities and interrelationships of all personnel should be clearly indicated. All personnel involved in wholesale distribution activities are to be trained on GDP requirements.

Wholesale distributors must have suitable and adequate premises, installations and adapted equipment to ensure the proper storage and distribution of medicinal products. The premises should be clean, dry and maintained within acceptable temperature limits.

In the latest version of the Good Distribution Practices (2015) the following chapters were added:

- **Outsourced activities** Any activity covered by the GDP guidelines that is outsourced should be properly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product. There must be a written contract between the contractor and contractee which clearly establishes the duties of each party.
- **Transportation** It is the responsibility of the supplying wholesale distributor to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature and humidity conditions are maintained within acceptable limits during transport. Regardless of the mode of transport, it should be possible to demonstrate that the medicines have not been exposed to conditions that may compromise their quality and integrity.
- **Specific provisions for brokers** This chapter considers the entities involved in activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person.

GDP certificates are valid for 5 years, and INFARMED is responsible for routine inspections.

## Specific reference to the role pharmacists play

Technical director responsibilities must be performed by pharmacists registered by the Portuguese Pharmaceutical Society (PPS), and are subject to the duties in the PPS statutes, namely: to comply with the law and regulations that apply to their practice; to collaborate effectively in all initiatives that value the PPS; to follow and uphold PPS deliberations and legitimate resolutions; to pay membership fees and any regulatory charges; and partake in continuous professional development training. Pharmacists should also collaborate in preparing technical and scientific content and advise their fellow colleagues, providing up-to-date information and contributing to science development. The ethical duties to which pharmacists are bound through the PPS should be stressed. This allows for independence in decision-making and necessary actions, maintaining a high level of responsibility, guaranteeing medicines quality in the health supply chain, without undue economic, political or cultural pressure.

Responsible pharmacists (or technical directors) should not only meet the qualification requirements but also have relevant competence and experience, as well as knowledge and training in GDP. These pharmacists are obliged to fulfil their personal responsibilities and should be continuously available, being able to delegate tasks but never their responsibilities.

When a wholesale medicines distribution authorisation is requested for a place located in the same building where there are already other premises included in a previous authorisation, the technical director can accrue those functions from the new authorisation, up to a maximum of five places.

The responsibilities of the technical director include:

- Ensuring that a quality management system is implemented and maintained;
- Focusing on and prioritising the management of authorised activities and the accuracy and quality of records;
- Ensuring that initial and continuous training programmes are implemented and maintained;
- Coordinating and promptly performing any recall operations for medicinal products;
- Ensuring that relevant customer complaints are dealt with efficiently;
- Ensuring that suppliers and customers are approved by the competent authorities;
- Approving any subcontracted activities which may impact on GDP;
- Ensuring that self-inspections are performed at appropriate regular intervals, following a prearranged programme and necessary corrective measures are put in place;
- Keeping appropriate records of any delegated duties;
- Deciding on the final disposition of returned, rejected, recalled or falsified products;
- Approving any returns to saleable stock and supervising the process;
- Ensuring that any additional requirements imposed on certain special products by national law are complied with, namely immunological products, radiopharmaceutical products, products derived from human blood or plasma, or medicines containing controlled substances.

Pharmacists' academic training in Portugal allows for knowledge acquisition on managing medicines-related processes. In this way both safety and preservation of medicines' original characteristics can comply with regulatory requirements.

This knowledge has also proven to be valuable in the risk management of a medicine's legal cycle. Pharmacists play an essential role in ensuring that procured and acquired medicines are of known origin, verifying traceability, and compliant with the security devices on the packaging, according to the European Commission's established requirements, further informing and reporting both INFARMED and the marketing authorisation holder in case any falsified medicines are detected.

Pharmacists' contribution is key in terms of pharmacovigilance. This contributes to and protects public health, specifically in the definition of emergency plans that allow the immediate and effective recall of medicines when requested by INFARMED or in collaboration with the manufacturer or the market authorisation holder. Pharmacists are also of the utmost importance in priority setting within emergency plans, considering the pharmacotherapeutic characteristics of the relevant medicines.

With respect to the distribution of medical devices, good practice standards define only that the technical director shall be properly qualified and have adequate training in management. These guidelines also lay out that the responsible person should have enough knowledge of the laws and regulations applied to medical

devices, show appropriate competence and experience to carry out the task, and have previous knowledge and training in GDP. It is not mandatory, though, that the responsible person is a pharmacist, or even a graduate. However, it is desirable and highly recommended that pharmacists perform this technical responsibility. Having pharmacists performing the technical director role guarantees quality assurance of the developed activities, monitoring and implementing good storage practices.

The pharmacist's role has been essential in building partnerships between the different stakeholders in the supply chain, mostly through relationships with pharmacist peers and other healthcare professionals, in the pharmaceutical industry, in hospital and community pharmacies and in different health units.

It is important to highlight the project VALORMED, which is one example of such collaboration. This project is responsible for managing the collection system of empty medicines packaging, expired, unused and unwanted medicines. This has been a joint venture of the pharmaceutical industry, wholesalers and community pharmacies. Unused medicines and empty medicines packaging are considered a special type of waste, therefore, it ought to be selectively collected, under pharmacist control, to be processed later in operational stations. Through the installation of specific containers in all pharmacies, VALORMED provides citizens with a safe and convenient way to get rid of unused medicines and empty medicines packaging. After being filled in the pharmacies, these containers are sealed and delivered to wholesalers, which then transport them to their facilities and keep them in special airtight containers. These containers are then transferred to a sorting facility by a waste management operator, where it is sorted and classified to be delivered to the right certified waste managing companies, responsible for the correct disposal of these products, either by recycling or safe incineration with energy recovery.

It should also be highlighted that wholesalers also contribute by offering their logistics services, collaborating with other projects of high social value, such as influenza vaccination, methadone substitution therapy and dispensing hospital medicines (e.g., antiretroviral therapy) in community pharmacies.

Recently, the "Medicines Green Line Project" was established, managed by INFARMED, aimed at reducing shortages of medicines essential to public health. With this project, the goal is to ensure that medicines supply chain operators maintain a minimum stock of critical medicines, safeguarding their availability to the population within no more than 12 hours after ordering. This is achieved with the manufacturers' provision of stock (particularly when the stock is on consignment, and still belongs to the manufacturers) residing within the wholesalers' premises and its swift release to the pharmacies, upon patient needs.

### Educational approaches used to equip pharmacists

In Portugal, the use of the professional title of pharmacist and professional practice are dependent on registration as a full member of the Portuguese Pharmaceutical Society (PPS). This registration requires a diploma awarded on completion of a certain level of education and training in pharmaceutical sciences, granted by a higher education institution of university level, which corresponds today to the integrated master's in pharmaceutical sciences (IMPS).

The syllabus of the IMPS programme includes a minimum duration of 10 semesters and six months' curricular internship. It provides the education and training of professionals able to take up responsibilities in the medicines supply chain, such as distribution facilities, pharmacies and hospitals. Moreover, these healthcare professionals can inform and educate the population on the responsible use of these products. At the full-line wholesalers' level, pharmacists are fully able to plan, manage, control and perform several activities, such as storage and correct distribution of medicines.

Pharmacists' academic training in Portugal allows them to excel in wholesale distribution as they can exceed the efforts of any other professional carrying out the same tasks. Unique assets of pharmacists in wholesale distribution include the knowledge of the pharmacological characteristics of the active pharmaceutical ingredients, pharmaceutical dosage forms, medical devices, as well as each medicine's innate characteristics. Their knowledge also includes prescription requirements, storage needs (e.g., temperature, humidity and light), regulatory requirements and the medicine's pharmacotherapeutic classification.

Notwithstanding pharmacists' existing multidisciplinary education, the need to reinforce the pedagogic core-content related to pharmaceutical distribution is acknowledged. This is supported by the constant evolution and development of logistics, supply chains and respective challenges, such as process risk management and process validation.



At post-graduate level, the PPS organises continuing professional education training sessions or short courses on the topic of quality assurance and GDP. The PPS has provided this training, as there are limited training offers that are publicly available or these are insufficiently differentiated for the pharmaceutical sector. The PPS meets the need for regular investment in the development and optimisation of the competence of those professionals who work in pharmaceutical distribution, which is essential to guarantee the integrity and quality of medicines.

In this regard, it is important to highlight the internship programme developed by the PPS, together with the associations of wholesalers, young pharmacists and pharmaceutical students, which aims at providing extracurricular internship opportunities for students in the final years of the IMPS, and professional internships targeting young pharmacists in wholesale medicines distribution companies operating in Portugal. This programme aims to enhance both students' and young professionals' interaction with national pharmaceutical distribution companies. Ultimately, these initiatives also contribute to a better professional qualification, through direct contact with the pharmaceutical profession, and integration in the labour market.

## Current challenges and trends

The following challenges and trends have been identified:

- Strengthening undergraduate pharmaceutical training in areas such as pharmaceutical distribution;
- Providing a greater choice of post-graduate training opportunities which are regular and differentiated, allowing pharmacists' specialisation in pharmaceutical distribution;
- Regulation and definition of pharmacists' minimum experience requirements to undertake technical director roles and the respective responsibilities;
- Technical director role exclusivity for pharmacists in medical devices distribution;
- Promotion of a greater stability and predictability of medicines-related policy and national health system (NHS) financing, allowing a sustainable development of the pharmaceutical distribution sector, with consolidation of personnel, namely pharmacists;
- Development of logistics synergies between the NHS and the network of private sector operators;
- Highly expensive hospital-only medicines to be dispensed in community pharmacies, such as the Antiretroviral Therapy Pilot Project (others to follow, such as oncology medicines);
- Fee for supporting state-run public health programmes, such as the Needle Exchange Pilot Project;
- Hospital logistics intervention by wholesalers;
- Regular updates on the export list of medicines that requires previous notification to authorities (INFARMED), assuring continuity of medicines supply on the national market, without compromising patient access.

## Solomon Islands

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### Introduction

The Solomon Islands is an archipelago of around 800 small islands. There are nine provinces in total with a population of 523,000 in 2009 with one of the highest birth rates in the world at 2.6%.<sup>1</sup> The annual gross domestic product (GDP) growth rate is -2.20%. The GDP per capita was \$1,257.23 (at the 2016 exchange rate).<sup>2</sup> Of the total Solomon Islands population, 39% is under 15 years of age and 5% is over 60 years of age. The urban population currently stands at 18% of the total population. The fertility rate in the Solomon Islands is 3.8 births per woman.<sup>3</sup>

The Pharmacy Division in the Solomon Islands has a total of 87 personnel comprised of 16 pharmacists, 54 pharmacy officers and 14 stores assistants. About 80% of the total pharmacy workforce of 87 is stationed at the national level in the capital city of Honiara while the other 20% are spread throughout the island's nine provinces.

## Health supply chain overview

Three tiers comprise the distribution and provision of health services in the country: second level medical stores, area health centres and rural health clinics.<sup>4</sup>

The national medical stores (NMS) play a central role in the oversight of the entire health supply chain in the Solomon Islands. The NMS is set up like many other central medical stores with customer services, and warehouse operations that include picking, packing, receiving of medical supplies into the stores, distribution, procurement shipping and customs clearance. The NMS has a procurement plan that commences from the end of the first quarter of each calendar year. The process begins with the quantification process to the receipt of medical supplies. The procurement process takes three to four months to complete.

The award system used for the supply of medical supplies contracts is a line-by-line selection of all items based on the product certification, past performance and price. Medical supplies collected from the entry points are brought to the warehouse, checked by the quality assurance unit and then placed into allocated locations using Msupply, a newly introduced inventory system. Msupply is a dynamic inventory system that allows for real time reporting on stock status, as such, monitoring of stock is made easy. However, there are downsides to such technology as well, especially in a country where internet and computer support is lagging behind. The other significant aspect is the “garbage in, garbage out” theory, and this entirely depends on the quality of data entered into the system.

All drugs (pharmaceutical products) and medical supplies are distributed through a network of second level medical stores (SLMS) that are located in strategic locations throughout the nine provinces. Each SLMS orders its supplies through the NMS and then distributes them to clinics and health centres in its catchment area. A catchment area is a zone that provincial administrations have mapped out as strategic locations for economic activities and where other essential services are provided closer to the rural communities. SMLS are located in these strategic locations according to transport routes, population and where existing area health centres are located. Therefore, varying populations in these catchment areas determine the level of supply and distribution activities.

SLMS are manned by pharmacy officers who also provide medicines information to the public and other health professionals. Strengthening this system directly impacts on the availability and use of medical supplies at the point of care for most patients in the primary healthcare facilities.<sup>5</sup>

## Pharmaceutical legislation

Regulation within the Solomon Islands is nationally managed by the Pharmacy Division through its regulatory affairs unit. The Pharmacy Practitioners Act 1997 (PPA 1997) regulates the practice of pharmacy in the Solomon Islands. This piece of legislation was developed to define the introduction of pharmacy assistants into the system.

The Pharmacy and Poisons Act is the overarching legislation that takes into account conduct of pharmacy personnel, registration of pharmacy businesses, sale and supply of medicines and the schedules under which different categories of medicines and chemicals fall. Unfortunately, this piece of legislation is old and does not address the current trends.

There are two main personnel types within pharmacy that are defined by the PPA 1997, namely, technical personnel and professional personnel. Professional personnel comprise mainly pharmacists with a degree in pharmacy as minimum requirement. Technical personnel consist of the pharmacy officers who have undergone and have passed the in-house pharmacy officer certificate course. Both personnel are mandated to be formally registered with the Pharmacy and Poisons Board. It is mandatory that both personnel meet the core competencies designed as a guide to the minimum required level.<sup>6</sup>

Both of these personnel types overlap in carrying out most of the duties designed to achieve the performance indicators. This is due to the shortage of qualified personnel and the challenge of retaining pharmacists in remote health facilities.

Standards have also been developed to improve the key outcomes of pharmacy services within the country. They are designed to standardise the work being conducted by pharmacy staff and to ensure that work meets the minimum criteria necessary to achieve best practice.<sup>7</sup>

## The role of pharmacists and pharmacy assistants in the supply chain

Pharmacists have been engaged in dispensing services, in medicines information, very little in compounding, and significantly in supply chain management. This is very much seen in the peripheral health facilities when pharmacists are posted at these remote provinces where 80% of the population reside. The dominant indicator for the Pharmacy Division under the Ministry of Health Key Result Area (KRA) is to ensure a 90% availability of safe, accessible essential medicines in all health facilities.<sup>8</sup> Therefore, the fundamental role designates that all

pharmacists would be mostly engaged in supply chain management. This has shifted the establishment of the Pharmacy Division structure to employ most pharmacists into managerial posts in the two lower tiers, i.e., area health centres and rural health clinics.

Recent reforms have seen a wider scope of responsibility added to the duties of technical personnel to address the human resources gaps that are currently faced by the pharmacy sector. The impact has been evident in an increase in availability of essential medicines generally throughout the country's health facilities and more confidence in the pharmacy officers and their roles.

## Human resources training and development roadmap

The pharmacy officer certificate course (POCC) began in the 1990s when the Ministry of Health produced nurses to be sent out to the provinces. The need for inpatient and outpatient services, and ward supplies in medicines and pharmaceuticals became crucial in the provinces. The POCC originated in 1993 following the need for formal training for pharmacy officers to assist pharmacists working at the national and provincial level. To date it is the only formalised pharmacy assistant training in the Solomon Islands.<sup>7</sup> The training was largely conducted as an on-the-job training programme and has been running for almost 22 years.

The need for further review of the programme emerged in the late 1990s and again in 2007. A major review of the training programme is being undertaken with an expected outcome of proper accreditation from a local or regional institution and the upgrade of knowledge with supply chain management as a core competency. The upgraded course structure should enable pharmacy assistants or officers to be better equipped to manage supply chain at the periphery more effectively. A wider recognition by the employing ministry and reviewed remuneration are also expected when the upgrade is complete.

## Current challenges and trends

There are many challenges to the Solomon Islands supply chain system. The islands have little road infrastructure, thereby limiting connectivity between health facilities and the distribution centres. Boats are more often used inter-island as the only means of transportation to and from the capital city, Honiara. Second level medical stores (SMLS) were built in an attempt to get essential medicine supplies closer to the rural community. One of the obvious challenges faced is the delivery of medical supplies and pharmaceuticals from the SMLS to the service delivery points or rural health clinics. There needs to be a clearly defined responsibility between the provincial health distribution and the National Medical Stores. The overlap between responsibilities has affected negatively on the availability of medical supplies at service delivery points.

Training focused on supply chain management is crucial to achieving the availability targets. Pharmacy officers and assistants who are posted to remote locations wear a number of hats, working as cold chain managers and collaborating with vertical programmes in distribution. Most of the time the pharmacy officers would be seen managing other programmes in order to try to meet the funding agency's indicators, causing a diversion in focusing on the core functions of pharmacy supply and distribution plans. There needs to be a holistic approach to training with an emphasis on supply chain management and the integration of vertical programmes in the distribution of supplies. Pharmacy services cross cuts all vertical programmes, as such resources should be shared with clear guidelines on the responsibilities of each programme.

The current legislation is out of date with ambiguous laws in regulation of pharmaceuticals and medical devices. Recent surveys have shown that post-marketing surveillance, pharmacovigilance and adverse drug event reporting are absent in the services provided by pharmacy. There is also a lack of a drug registration system, causing the private sector market to be difficult to monitor.<sup>9</sup> Quality of pharmaceuticals is a shared responsibility between preferred suppliers, which are also mandated to provide certificates of analysis, assays and other supporting information about a particular medicine. The quality assurance unit of the National Medical Stores merely does visual checks on received medicines while during awards of contracts the suppliers are assessed on their past performance and price. However, this checking process is insufficient because of the lack of laboratory support services in country.

Health is free for all as a national policy by the Solomon Islands government. This raises many public health challenges. Peoples' behaviour in looking after their health has deteriorated over the years because of the notion that medicines are free for all. Plans have been in place to implement user fees policies or subsidised medication schemes, but the pressure the system will put on most rural dwellers who live on subsistence farming is one of limited accessibility to services. Health promotion, on both communicable and non-communicable diseases, and the rational use of medicines are priorities to ensure behavioural change among the population with regards to medicines use.

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## United Kingdom

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### Brief overview of the health supply chain

The health supply chain within the United Kingdom follows a traditional model adopted by many countries globally. This is typically the sourcing of products from manufacturer to pharmacy (hospital and community) via wholesaler or direct. New models of delivery are being piloted and evaluated to improve supply chain efficiency and effectiveness (see Challenges, section 10.8.5.).

Figure 6 summarises the health supply chain stakeholder influence within England. The type of influence is denoted by line type and depth by the contact point of arrow, e.g., the General Pharmaceutical Council has a regulatory influence over three tiers of the supply chain, whereas the Royal Pharmaceutical Society has advisory influence over the inner two tiers of the supply chain. National variations can be found in Scotland, Wales and Northern Ireland but these are customisation of regional and local associations as opposed to regulatory governance.

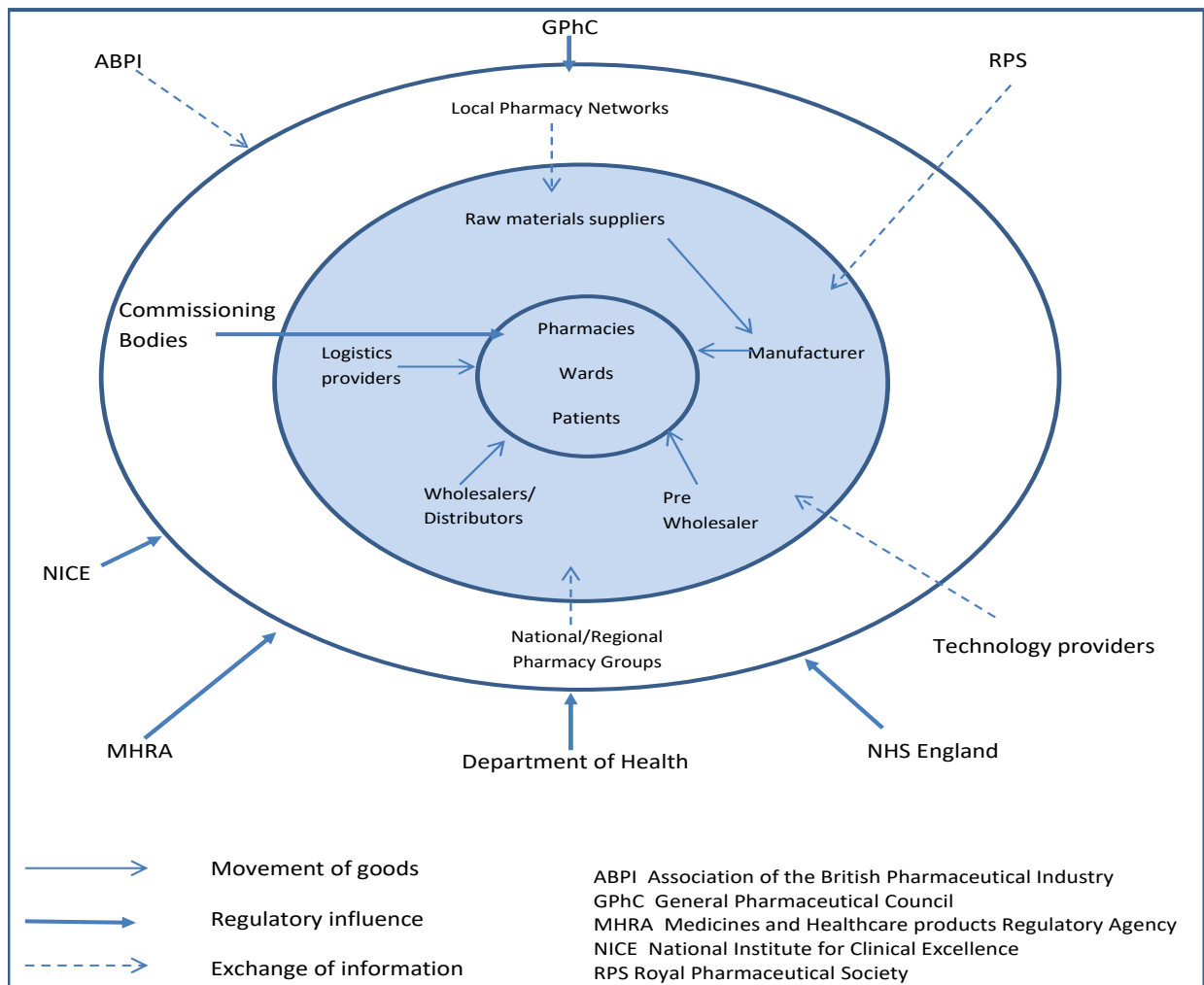


Figure 6. Stakeholder analysis of the health supply chain (England)

A large proportion of activity within the healthcare supply chain is undertaken by pharmaceutical wholesalers. According to the Healthcare Distribution Association, changes within this supply chain have encouraged these suppliers to develop into “integrated health care service providers”. The distribution industry has to change, with wholesalers taking more of a role in central dispensing, informatics and big data, as well as reacting to continued consolidation, online pharmacies and new picking and delivery mechanisms).<sup>2</sup> Currently, the main wholesalers in this supply chain are AAH Pharmaceuticals, Alliance Healthcare, Lexon UK Ltd, Sangers Ltd, Mawdsleys, United Drug Sangers, and Phoenix Healthcare Distribution Ltd.<sup>1</sup> Wholesaler operations can have bespoke sub-operations for both community and hospital operations, e.g., AAH Pharmaceuticals distributes to community (Enterprise) and hospital (AAH Hospital Service). AAH is the largest pharmaceutical wholesaler in the UK, with 3,800 employees and 20 locations across the country.<sup>2</sup> Key activities of a typical UK wholesaler are selection, licensing, procurement, importation and repackaging of pharmaceutical preparations as well as the provision of competitively priced generics.<sup>3</sup>

### Current legislation that guides the role of personnel

The supply of medicines within the UK is underpinned by extensive legislation and associated statutory instruments. The Human Medicines Regulation Act 2012<sup>4</sup> and Misuse of Drugs Act 1971 provide the legal framework for the manufacture, licensing, prescribing, supply and administration of medicines plus the regulation of controlled drugs (CDs) to prevent misuse.<sup>5,6</sup> The healthcare professionals who may legally possess and supply CDs are identified within this legislation and the controls around prescribing, administration, safe custody, dispensing, record keeping and destruction or disposal are established. More recently, publication of the Human Medicines Regulations 2012 has brought previous legislation in line with

EU legislation and provides a range of exemptions to the restrictions on the sale, supply and administration of medicines.<sup>7</sup>

The mechanisms through which a medicine can be supplied may vary based on its legal classification and the practitioner who is supplying or administering it. Various regulators and authorities oversee health care within the UK. Most relevant to the supply chain are the [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#) and the [National Institute for Health and Care Excellence \(NICE\)](#). Before a medicine can be widely used in the UK, it must be granted a licence (or marketing authorisation). This is sanctioned by the MHRA, a government agency which ensures that medicines and medical devices work and are acceptably safe, and which ensures wholesaler/distribution site compliance.<sup>8</sup>

To ensure fair practice by the pharmaceutical industry, the Prescription Medicines Code of Practice Authority (PMCPA) was established. It is responsible for administering the Association of the British Pharmaceutical Industry Code of Practice for the pharmaceutical industry. The code regulates the advertising of prescription medicines to health professionals and administrative staff. It also covers information about prescription only medicines made available to the public.<sup>9</sup>

### What role do pharmacists play in the health supply chain?

The role of pharmacists within the UK health supply chain varies throughout the profession. Pharmacists dispense and supply medicines to patients but also fulfil many other critical roles such as advising on medicines procurement and primary and secondary care formularies contribute to advisory groups/consultations for key issues, e.g., critical shortages.<sup>10</sup> They also attend specialist interest groups, e.g., Guild of Healthcare Pharmacists, Procurement and Distribution Interest Group, and work in national and regional operational groups or purchasing hubs to inform the shape and direction of the pharmaceutical supply chain within the UK (see Challenges, section V). Pharmacists and pharmacy technicians can also have senior supply chain roles within national advisory or regulatory bodies, e.g., ABPI, MHRA, and NICE. Community pharmacy teams are directly impacted upon and can influence the supply chain due to their management of direct pharmacy inbound logistics. This requires a comprehensive operational/management skill set to complement their clinical skills to run what is effectively a Small to Medium Size Enterprise (SME).<sup>11</sup> The role of pharmacy technicians (working with pharmacists) in secondary care has developed significantly over the past few years. They have become involved in activities such as anticoagulation clinics, medicines information, discharge planning teams and specialised prescribing roles.<sup>12</sup> Within community pharmacies, pharmacy technicians play a significant part in the technical part of dispensing, the assembly process (picking and labelling).

### Education within the profession

To practise in Great Britain, pharmacists and pharmacy technicians must be registered with and have met the educational requirements of the GPhC.<sup>13</sup> Pharmacists and pharmacy technicians must renew their registration every year, which involves completing a declaration stating that they meet all our professional, fitness to practise and ethical standards. “Standards for initial education and training for pharmacists” sets out the criteria against which schools of pharmacy must deliver their undergraduate education and training for student pharmacists and preregistration trainee pharmacists (see Figure 7).<sup>14</sup>

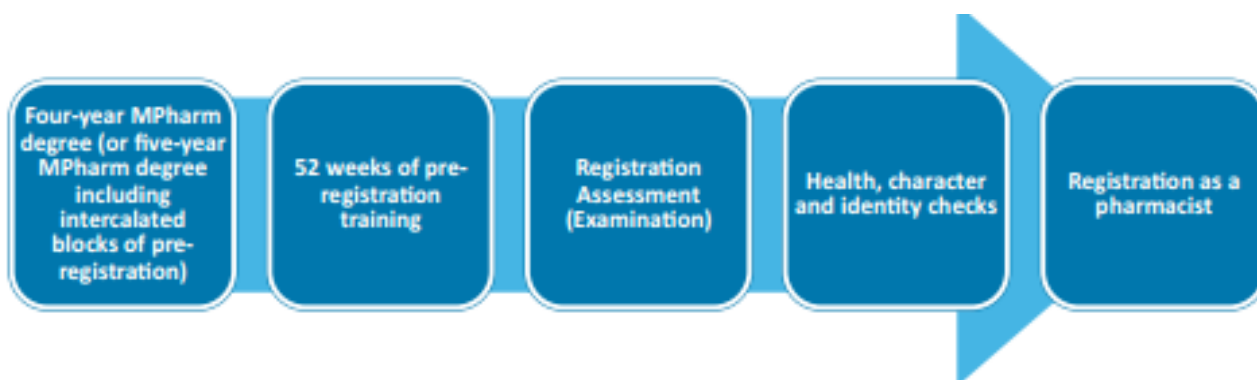


Figure 7. Education and registration process for pharmacists<sup>14</sup>

Pharmacy technicians must have completed both a competency qualification and a knowledge-based qualification and meet the qualifying period of work experience before being eligible for registration. This is a Level 3 NVQ (QCF) qualification. A medicines counter assistant who is involved in the sale of over-the-counter medicine is trained to offer advice on common ailments and works under the supervision of a pharmacist. The GPhC requires that a medicines counter assistant has completed their training in a maximum of three years.<sup>15</sup> Dispensing assistants (pharmacy assistants) who are involved in the dispensing process must complete relevant modules of the Level 2 NVQ (QCF) Certificate in Pharmacy Service Skills or Level 2 NVQ (QCF) Certificate in Pharmaceutical Science (or equivalent in Scotland) whether they work in community or hospital practice.<sup>15</sup>

There are currently no formal standard training programmes for pharmacy staff employed as delivery drivers, pharmacy porters or pharmacy stores workers (e.g., picking orders, providing top up of ward stock). As described in Figure 7, in order for pharmacists to practise in Great Britain they must obtain a master of pharmacy degree (MPharm). In Great Britain, the four-year MPharm degree is separate from the 52-week pre-registration training with one exception: a five-year MPharm degree with two intercalated periods of pre-registration training. The GPhC is in discussions with higher education institutes and other stakeholders pursuing the design of an integrated degree combining academic study and pre-registration training (see Challenges, section 10.8.5).

### Current challenges and trends evident within the health supply chain

The pharmacy profession is in a state of transition from new clinical opportunities for the pharmacy team (see below) to significant changes in remuneration that pharmacy contractors will receive. The government has announced over £170 million in cuts to the community pharmacy contract, which could lead to the closure of up to 3,000 pharmacies.<sup>16</sup>

The Department of Health and the MHRA in 2016 consulted with pharmacists on changes to legislation which will allow all community pharmacies to adopt centralised dispensing “hub and spoke” systems — which will assemble, dispense and label medicines and distribute to pharmacies for patient collection. This legislation change has been put on hold following feedback of possible unintended consequences.

Pharmacy education and training is at a crossroads. The GPhC has asked for stakeholders’ opinions on the education and training of “tomorrow’s pharmacy team”,<sup>17</sup> the aim being to design a more professionally integrated and comprehensive curriculum for future pharmacist skills development (clinical and managerial).

Summary Care Records in primary care provide healthcare professionals such as pharmacists with faster access to key clinical information to treat patients (to be completed by 2017).<sup>18</sup>

The roles of the pharmacist within primary care in the UK are changing rapidly. Pharmacists can be a critical addition to a general practice team, using their medicines expertise to better address pharmaceutical care, reduce medicines waste and support GP clinical activity.

Both the primary and secondary care sectors have been profoundly affected by regular medicines shortages within the medicines supply chain, negatively affecting patient care.<sup>10</sup>

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## United States of America

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### Introduction

The combination of no regulatory oversight or restrictions on the prices charged for pharmaceuticals and the large numbers of prescriptions makes the United States the world's largest market for pharmaceuticals. The sales of pharmaceuticals in the US were \$424.8 billion (2016 IQVIA; former QuintilesIMS Institute for Healthcare Informatics) and the market has been growing at an average rate of 8–9%. In addition to being the largest market for sales, the US is also the leading location for pharmaceutical research. Seven of the top 15 global pharmaceutical and biotechnology firms are headquartered in the US, and all of the top 20 firms have research laboratories in the country. Pharmaceutical firms provide employment for more than 700,000 workers along with approximately 2.5 million jobs in supporting industries (2010 data).

Before delving into the details of the pharmaceutical markets in the US, it is useful to understand the structure of health financing and service delivery in the US. In contrast to either state-run or coordinated social



insurance systems found in other OECD (Organisation for Economic Co-operation and Development) countries, the US is mostly a private insurance market with selected programmes such as Medicare, Medicaid and the Veteran's Administration receiving public financing. The delivery of care is mostly through privately operated (a combination of for-profit and non-profit) hospitals and physicians working independently or in small groups. Coverage has expanded incrementally in the recent years due to the Affordable Care Act of 2010.<sup>1</sup>

## Regulation and standards

The federal Food and Drug Administration (FDA) regulates marketing authorisation to ensure the safety and efficacy of medicines and regulates pharmaceutical manufacturing and interstate commerce in pharmaceuticals. However, states are the primary regulator of pharmacies, pharmaceutical wholesaling and the practice of pharmacy. Every state (primarily through its State Board of Pharmacy) has laws and regulations guiding pharmacy standards and requirements, addressing issues such as required licences for each wholesale and retail facility and for the credentialing pharmacists and other employees who work in such facilities. In various respects, state licensing systems have moved to update their standards to match those provided by the National Association of the State Board of Pharmacy (NABP) model laws but differences remain in some aspects. For example, the FDA has guidelines for state licensing of wholesalers but differences have been noted in the stringency of this from state to state.

In addition to regulatory standards, there are multiple voluntary standards. For example, the Center for Pharmacy Practice Accreditation runs a voluntary accreditation programme for community and hospital pharmacies. Similarly, the NABP runs a Verified-Accredited Wholesale Distributors® programme, which accredits wholesale distributors after they achieve compliance with a number of criteria. A similar programme is also run for internet pharmacies.

Pharmacists are assisted by pharmacy technicians in simple administrative tasks such as verifying insurance and other patient information, receiving electronic prescription requests from doctor's offices and entering them into the system, preparing prescription labels, and preparing pharmacy inventories together with the pharmacist. In some cases, they also pour, weigh, measure and count medicines.

Pharmacy technicians in the US typically require a high school diploma or equivalent and must have passed the Pharmacy Technician Certification Examination (PTCE). The Pharmacy Technician Certification Board develops, maintains, promotes, and administers an accredited certification programme for pharmacy technicians. It administers the PTCE.

## Flows in the pharmaceutical supply chain

Products from manufacturing sites are transferred to wholesale distributors for distribution to retail, mail order, and in-hospital pharmacies. In some cases, manufacturers distribute the product directly to specialty pharmacies, hospital chains, and some health plans. Some government purchasers, such as the Veterans Administration and Vaccines for Children (VFC) receive supplies directly from manufacturers through their logistics service providers.

A vast majority (80-90%) of pharmaceuticals are distributed through wholesale distributors.

Table 7 shows the total monetary value of sales through each channel from 2011 to 2015. A growing fraction of this (\$150 billion) in 2015 is for specialty pharmaceuticals, i.e., biologics and specialised drugs for oncology, hepatitis C and other conditions. Table 8 shows total monetary value of prescriptions dispensed through each channel from 2011 to 2015.

Table 7. Total \$ value of sales through each channel from 2011-2015

| SALES BY CHANNEL, 2011-2015          |              |              |              |              |              | % change    |
|--------------------------------------|--------------|--------------|--------------|--------------|--------------|-------------|
| Billion \$,<br>ex-manufacturer sales | 2011         | 2012         | 2013         | 2014         | 2015         | 2014-15     |
| <b>Total US market</b>               | <b>328.3</b> | <b>317.8</b> | <b>331.5</b> | <b>378.6</b> | <b>424.8</b> | <b>12.2</b> |
| <b>Retail and Mail</b>               | <b>235.9</b> | <b>227.4</b> | <b>237.6</b> | <b>272.7</b> | <b>305.9</b> | <b>12.2</b> |
| Chain stores                         | 109.8        | 106.3        | 109.8        | 121.8        | 130.7        | 7.3         |
| Mail service                         | 63.9         | 60.9         | 65.3         | 82.3         | 97.4         | 18.3        |
| Independent                          | 38.3         | 36.5         | 36.7         | 42.2         | 48.0         | 13.7        |
| Food stores                          | 23.8         | 23.6         | 25.7         | 26.4         | 29.7         | 12.5        |
| <b>Non-retail</b>                    | <b>92.4</b>  | <b>90.4</b>  | <b>93.9</b>  | <b>105.9</b> | <b>118.9</b> | <b>12.3</b> |
| Clinics                              | 38.6         | 39.5         | 42.3         | 48.4         | 56.2         | 16.1        |
| Non-federal hospitals                | 28.1         | 28.1         | 28.4         | 30.2         | 33.4         | 10.6        |
| Long-term care                       | 15.2         | 13.9         | 14.0         | 16.2         | 16.7         | 3.0         |
| HMO                                  | 2.6          | 2.8          | 3.0          | 3.9          | 4.9          | 25.6        |
| Home healthcare                      | 2.7          | 2.7          | 2.8          | 3.4          | 3.9          | 14.7        |
| Federal facilities                   | 4.2          | 2.5          | 2.4          | 2.7          | 2.7          | 0.0         |
| Miscellaneous                        | 1.9          | 0.9          | 0.9          | 1.0          | 1.1          | 10.0        |

Source: *Pharmaceutical Commerce*, IMS Health, National Sales Perspectives, Jan 2016

Table 8. Total number of prescriptions in 2015 was over 5 million (Source: Pharmaceutical Commerce)

| PRESCRIPTIONS DISPENSED BY CHANNEL, 2011-2015 |              |              |              |              |              | % change    |
|---|--------------|--------------|--------------|--------------|--------------|-------------|
| thousands*                                    | 2011         | 2012         | 2013         | 2014         | 2015         | 2014-15     |
| <b>Total US Market</b>                        | 4,988        | 5,265        | 5,382        | 5,506        | 5,603        | 1.8         |
| <b>Retail and mail</b>                        | <b>4,654</b> | <b>4,931</b> | <b>5,012</b> | <b>5,117</b> | <b>5,220</b> | <b>2.0</b>  |
| Chain stores                                  | 2,547        | 2,753        | 2,903        | 3,053        | 3,151        | 3.2         |
| Independent                                   | 825          | 833          | 843          | 855          | 865          | 1.2         |
| Food stores                                   | 573          | 630          | 632          | 636          | 649          | 2.0         |
| Mail service                                  | 709          | 715          | 634          | 573          | 555          | -3.2        |
| <b>Non-Retail</b>                             | <b>333</b>   | <b>335</b>   | <b>370</b>   | <b>389</b>   | <b>383</b>   | <b>-1.6</b> |
| Long-term care                                | 333          | 335          | 370          | 389          | 383          | -1.6        |

\*counts are normalized for varying prescription lengths

Figure 8 shows the flows from the manufacturer to different types of pharmacies and providers. In some cases, chain pharmacies receive deliveries from distributors to their own distribution centres and warehouses, from where they distribute to their stores.

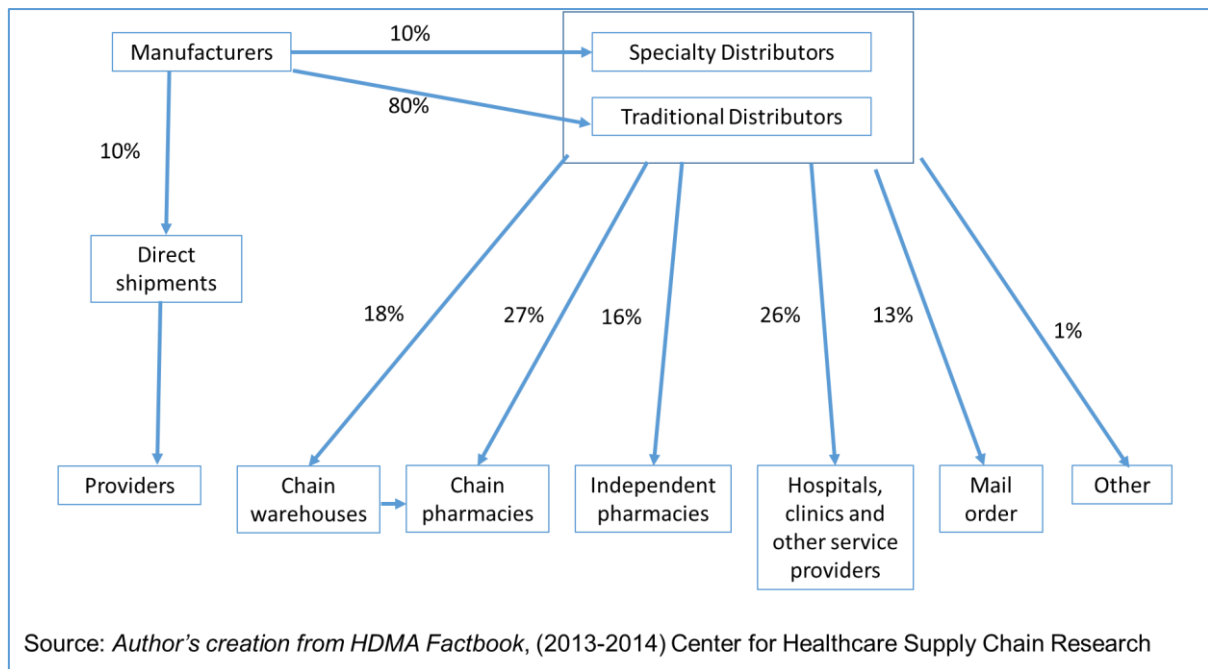


Figure 8. Flows in the US pharmaceutical supply chain (Source: Author)

There are over 88,000 retail pharmacies in the US and over 70% of them are chain stores. Some 230,000 community pharmacists work in retail pharmacies around the country.

Pharmacies place orders for products to their wholesaler distributor every day using electronic data interchange, online ordering and occasionally telephone or fax. The distributor receives the order, picks and packs it at the closest distribution centre and ships it to the pharmacy, in some cases as early as the same day of placing the order. There are approximately 150 pharmaceutical distribution centres in the US and all of them deliver to pharmacies, hospitals and other locations five days per week. A typical US distribution centre ships to 1,042 customer locations, including pharmacies, clinics, hospitals and chain warehouses. Distribution centres are run by a highly trained supply chain workforce skilled in forecasting, planning, inventory management and other such functions. The centres rarely employ pharmacists and, unlike in Europe, there are no regulations requiring them to do so.

In addition to manufacturers, wholesaler and retail or hospital pharmacies, the US pharmaceutical supply chain also has pharmaceutical benefit managers (PBMs) which work with third party payers (health insurance companies) to offer price negotiation, formulary management, drug utilisation analytics and basic administrative functions such as claims processing, record keeping, and reporting. PBMs employ pharmacists, data and analytics experts, pharmacoeconomics and health economics experts and administrative staff. PBMs do not manage drug supplies per se, but determine which drugs are maintained in formulary and the level of reimbursement that patients are paid by their insurance company. Several of the larger PBMs are owned by, or have a heavy investment from, pharmaceutical manufacturers.

### Professional associations, organisations and groups

The American Pharmacists Association, the National Association of Boards of Pharmacy, and the American Society of Health-System Pharmacists are three active professional associations that have a strong influence and impact on the practice of pharmacy in the US. For wholesaling and distribution, the Healthcare Distribution Alliance is the national organisation representing pharmaceutical distributors. The National Association of Chain Drug Stores represents chain drug stores, supermarkets, and mass merchants with pharmacies. The Accreditation Council for Pharmacy Education is the national agency for the accreditation of

professional degree programmes in pharmacy and providers of continuing pharmacy education and the American Association of Colleges of Pharmacy is an organisation representing colleges of pharmacy.

## Pharmacist, workforce and future outlook

Full-time pharmacists in 2014 devoted 49% of their time to patient care services associated with medicines dispensing, 21% to patient care services not associated with medicines dispensing, 13% to business/organisation management, 7% to education, 4% to research, and 6% to other activities (2014 national pharmacist workforce survey — American Association of Colleges of Pharmacy).

As described earlier, pharmaceutical distribution centres are run by highly trained supply chain workforce skilled in forecasting, planning, inventory management and other such functions. They work closely with hospital and community pharmacists who manage the technical aspects of filling the orders and ensure compliance to federal and state pharmaceutical regulations and standards. There are over 195 institutions offering university or four-year college courses in supply chain management in the US (Council of Supply Chain Management Professionals). Pharmaceutical distribution centres increasingly employ graduates of such programmes to work as fulfilment and distribution centre managers and planners.

The expansion of health care through the Affordable Care Act, an increased need for services for an ageing population with more complex medication needs, and new complex biologic and other drugs that require dose adjustments will further increase the need for pharmacists in the US in the future. However, technology will continue to allow community pharmacists to focus more on patient advice, drug use safety, dose adjustments, providing immunisations, and to expand into providing basic care and diagnosis. Functions such as replenishment planning, forecasting and order fulfilment will be carried out by analytics algorithms run by supply chain experts.

### Reference

1 Affordable Care Act of 2010, available from: <https://www.hhs.gov/healthcare/about-the-law/read-the-law>

## Appendix 2 — Resources

### Professional networks for people working health logistics and the supply chain

- International Association of Public Health Logisticians (IAPHL) <http://iaphl.org/>, a professional discussion forum to share ideas, obtain development and network
- Humanitarian Logistics Association <https://www.humanitarianlogistics.org/>, a professional association focused on humanitarian logistics and supply chain issues
- E-Drug global Listserv for all things to do with pharmaceutical products in developing countries. To subscribe or unsubscribe visit <http://lists.healthnet.org/mailman/listinfo/e-drug>


### Tools for using in day-to-day health logistics and supply chain practice

- PSM Toolbox <http://www.psmtoolbox.org/en/>, a repository of health logistics and supply chain tools that can be searched and investigated for local application.

### Tools for assessing the maturity of your supply chain

- Supply Chain Compass, <https://scc.deliver.jsi.com/> provides a quick, high-level diagnosis of how mature your public health supply chain is across key managerial and functional areas.
- World Bank “Logistics performance index” <http://lpi.worldbank.org/>

### Online resources for service delivery point staff in low-income countries

- [Guidelines for the Storage of Essential Medicines and Other Health Commodities](#) (2003; 114 pages) [[Arabic](#)] [[Chinese](#)] [[French](#)] [[Hindi](#)] [[Russian](#)] [[Spanish](#)] 
- [Where There Are No Pharmacists: A Guide to Managing Medicines for All Health Workers](#)
- Sarah Andersson, Beverley Snell, 2010

### Education resources for health logistics and the supply chain

- LAPTOP <http://www.rhsupplies.org/activities-resources/tools/laptop/>, a web-based portal providing access to ongoing pre-service and in-service education for supply chain professionals
- People that Deliver (PtD) <http://www.peoplethatdeliver.org/>, to remain up to date on human resources for supply chain management
- SCM Dictionary <http://lscms.org/scm-dictionary/>,
- IAPHL repository of free e-learning modules <http://iaphl.org/resource-library/e-learning-resources/>
- PtD repository of tools and guidance for curriculum development <http://www.peoplethatdeliver.org/node/26631>
- Supply Chain Brain <http://www.supplychainbrain.com/content/about-us/> is a global private sector supply chain management information resource.

### Open access health supply chain text books

- Managing drug supply, 3rd addition, Management Sciences for Health <https://www.msh.org/news-events/press-room/managing-drug-supply-third-edition-now-available-online>, a text for all aspects of health logistics and supply chain from a health perspective
- The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities [http://deliver.jsi.com/dlvr\\_content/resources/allpubs/guidelines/LogiHand.pdf](http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/LogiHand.pdf)
- A text for all aspects of health logistics and supply chain from a health perspective

## Appendix 3 — Draft terms of reference for the FIP working group

### Introduction

Medicines are essential to the provision of universal health care services in all countries, cultures and societies. Medicines are an indispensable part of disease prevention programmes and treatment plans with the role of governments to ensure that the populations they serve have appropriate access to quality health products via sustainable, quality-driven health supply chains. In this context pharmacists play various roles in health supply chains, including assuring quality of medicines, their appropriate use and adequate pharmacovigilance supervision. With increased interest from many global parties regarding the optimal role of pharmacists in health supply chains, FIP is the appropriate international professional body to provide guidance in this regard.

The joint statement — “Ensuring quality and safety of medicinal products to protect the patient” — of FIP and the International Federation of Pharmaceutical Manufacturers Association (IFPMA) states: “FIP and IFPMA have a common goal to protect the well-being of patients in all parts of the world by ensuring that all medicinal products are of good quality and proven safety and efficacy.”

The FIP statement of policy — “The role of the pharmacist in pharmacovigilance” — provides the WHO definition of pharmacovigilance as being “the science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other possible drug-related problems”.

Technical advances in the development of new health products require appropriate supply chain control mechanisms to ensure these products are delivered in a viable state to enable provision of the required level of health care. Health commodities, which include pharmaceuticals and vaccines, require specialised management and knowledge to deliver them to the end user in an effective, efficient, and safe manner. Health commodities can be dynamic, photosensitive, thermolabile, toxic, carcinogenic, corrosive, dangerous, shelf-life limited, or easily counterfeited, and may be subject to recall. The health supply chain is governed by extensive and sometimes conflicting legislation between countries and even regions within the same country, and success or failure of the logistics continuum is measured by the outcome of health care interventions, and severe failures may even affect patient morbidity and mortality rates.

To that end, at a global level there is an increasing interest in involving the pharmacist in the supply chain of medicines.<sup>4</sup> The supply chain can be defined as being the activities involved with planning, sourcing, manufacturing and distributing products. Many militaries and some aid (Government and NGO) agencies require the presence of a pharmacist as part of the health supply chain team to ensure quality warehousing and distribution not only of medicines, but also of all medical products (consumables and equipment) and medical gases. This is not to say the pharmacist has to conduct every single aspect of the supply chain, rather play a significant professional role (often managerial), and be available to make alternative arrangements should there be an absence of critical medicines or the reporting of adverse events. Cold chain distribution is especially important and without appropriate knowledge of the medicines involved and exact cold chain requirements, many thousands of dollars’ worth of vaccines and other cold store pharmaceuticals can be wasted.

Global level concern regarding a lack of international focus regarding human resources in health supply chains saw the launch in 2011 of the People that Deliver (PtD) initiative. FIP joined the board of PtD in 2014. This global partnership of over 80 organisations has the joint vision of a world where national supply chain workforces are planned, financed, developed and supported in a way that ensures equitable and sustainable access to medicines and other commodities needed for optimal health outcomes. Pharmacists form part of this workforce but in many countries where there is a shortage of pharmacists there is concern to ensure that the few pharmacists that are present are used most effectively in the health system.<sup>5</sup> Where pharmacists are

<sup>4</sup> Email FIP General Secretary to Professional Secretary on the possibility of establishing a new WG on wholesalers/supply chain

<sup>5</sup> PtD Healthcare Supply Chains in Developing Countries SITUATIONAL ANALYSIS 2011; <http://www.peoplethatdeliver.org/sites/peoplethatdeliver.org/files/dominique/files/Healthcare%20Supply%20Chains%20-%20Situation%20Analysis%20EN.pdf>; Soucat, A. Scheffler, R. Ghebreyesus, T. The Labor Market for Health Workers in Africa: A new Look at

used in the health supply chain it is important that they have received the education and training required for the competencies they are to undertake.

In addition to PtD, other international work streams looking at the role and use of human resources in health supply chains include:

- The interagency Supply Chain Working Group (chaired by UNICEF and WHO with other members including: USAID, UNFPA, DFID, Global Fund, Gates Foundation and Gavi The Vaccine Alliance)
- World Bank research group engaging the Kühne Logistics University in Germany to investigate supply chain competency development
- Humanitarian Logistics Association working group on professionalism and career progression.

With international interest in human resources in health supply chains growing momentum, it is an ideal time for FIP to convene this working group to investigate the role of pharmacists in health supply chains, clearly identifying where the competencies of pharmacists are best used and most needed. With the maturity of health supply chains varied across the globe, particular attention needs to be given to any differences that exist between low- and middle-income country contexts compared with high-income, more developed supply chain environments.

### Objectives

The objectives of the WG are as follows:

- Define the stages of the supply chain for health commodities from manufacturing to delivery to the patient (manufacture to use).
- Determine the competencies needed in the different stages of the supply chain and where the competences of a pharmacist are best used.
- Determine if and when specialised training is required for each of the above-mentioned, both where the competencies of pharmacists are needed and where not.
- Where pharmacists are not available for stages where it is determined that they possess critical competencies, make recommendations on safe, workable solutions using other cadres.
- Provide a technical report on the findings for international distribution.

### Working group plan and methodology

To achieve the above-mentioned objectives, the WG will:

- Review currently available documentation from various international activity streams regarding competency requirements in health supply chains.
- Undertake a survey to determine the current involvement of pharmacists in the supply chain from different organisations in different country contexts. Include military, private sector, government run supply chains, in different geographical contexts.
- Research the health supply chain to define the variety of stages from manufacture to patient use.
- Through a process of engagement with the pharmacy profession and other health supply chain stake holders, determine the health supply chain competencies that are deemed as “pharmacist only”.

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the Crisis. Washington DC: World Bank; USAID DELIVER PROJECT, Task Order 4. 2013. Human Resource Capacity Development in Public Health Supply Chain Management: Assessment Guide and Tool. Arlington, Va.; [http://deliver.jsi.com/dlvr\\_content/resources/allpubs/guidelines/HumaResoCapaDeve\\_AsseGuid.pdf](http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/HumaResoCapaDeve_AsseGuid.pdf) [accessed July 2014]; Capacity Plus Technical Brief 12, 2013 Applying the HRH Action Framework to Develop Sustainable Excellence in the Health Supply Chain Workforce <http://www.capacityplus.org/files/resources/applying-hrh-action-framework-developsustainableexcellence-health-supply-chain-workforce.pdf> [accessed July 2014]

- Through a process of engagement with the pharmacy profession and other health supply chain stakeholders, determine what education and training approaches are required for pharmacists to gain the required “pharmacist only” health supply chain competencies.
- Through a process of engagement with the pharmacy profession and other health supply chain stakeholders, determine what approaches should be taken to ensure safe and workable solutions where pharmacists are not available for “pharmacy only” competencies.
- Map the currently available education, training and professional development offerings that meet the requirements to develop “pharmacy only” health supply chain competencies.
- Prepare a draft report for the Board of Pharmaceutical Practice (BPP).
- Finalise the technical report, after approval, for adoption by the BPP, FIP Bureau, the WHO. and the wider international health supply chain community.
- Prepare and publish an article in the *International Pharmacy Journal (IPJ)*, and make a reference document.

### Expected final outcome

It is expected that the WG will submit a report that details:

- The defined stages of the health supply chain from manufacture to patient use.
- A defined set of health supply chain competencies that are deemed as “pharmacist only”
- A set of guidelines to follow for the development of health supply chain “pharmacy only” competencies by pharmacists through appropriate education and training.
- A set of guidelines to follow to enable safe and workable solutions for “pharmacy only” competencies to be delivered by other cadres if there are no pharmacists.

The *IPJ* article and reference document will be produced from the report once endorsed at all levels.

### Working group team

The WG will consist of pharmacists who already have experience in the supply chain or logistics continuum. Co-chairs: Wendy Walker (Military and Emergency Pharmacists Section) and Ulf Janzon (Industrial Pharmacy Section)IPS

Secretariat: FIP

Members:

- Community Pharmacy Section representative
- Hospital Pharmacy Section representative
- Board of Pharmaceutical Science representative
- FIPeD representative
- Andrew Brown, executive manager of the People that Deliver initiative (self-funded)
- Executive director of the International Association of Public Health Logisticians (self-funded)
- An experienced health supply chain pharmacist from a low-income country

### Collaboration with external stakeholders

The following external stakeholders will be consulted during the research phase:

- FIP Military and Emergency Pharmacy section members
- Pharmacy Support Workforce Domain of FIPeD
- PtD, IAPHL and HLA members
- Interagency Supply Chain Working Group
- A variety of universities that engage in supply chain and logistics

### Publication of results

The final report will be printed and forwarded to all FIP member organisations with the pdf version being made available on the FIP website. The article summarising the results and recommendations will be made available to all FIP individual members via publication in the *IPJ*. To increase the audience, the article may also be published in other journals after *IPJ* publication and circulated through the international stakeholder networks described above.



## Expenses

A budget for this WG and its activities is yet to be established but it is noted that the majority of the work required for this group can be done virtually. (It should be noted that due to the international interest in this work a submission could be made to a relevant international donor to share reasonable costs associated with research and report preparation.)

## Proposed timeline

| Description                                  | Who                       | Deadline      |
|--|---------------------------|---------------|
| Preparation of the first draft of the TOR    | WG Chair elect            | August 2015   |
| Preparation of the draft Tor for submission  | WG Chair elect +1         | August 2015   |
| Adoption of the TOR                          | FIP BPP ExCO              | October 2015  |
| Adoption of the TOR                          | FIP BPP                   | October 2015  |
| Appoint the Chair(s) of the working group    | FIP BPP ExCO              | November 2015 |
| Appoint the members of the working group     | FIP BPP ExCO              | November 2015 |
| Begin work                                   | WG members                | December 2015 |
| Draft Outcome Report                         | WG members                |               |
| Submit the draft Outcome Report              | WG Chair                  |               |
| Review the draft Outcome Report              | BPP ExCO                  |               |
| Review the draft Outcome Report              | BPP                       |               |
| Consultation                                 | WG members                |               |
| Revision of draft Outcome Report             | WG members                |               |
| Prepare final version of the Outcome Report  | WG members                |               |
| Submit final version of Outcome Report       | WG Chair                  |               |
| Adoption of the final Outcome Report         | FIP BPP and FIP ExCO      |               |
| Preparation of the <i>IPJ</i> article        | WG members                |               |
| Validation of the article                    | FIP BPP ExCO and FIP ExCO |               |
| Submission of article to <i>IPJ</i>          | WG Chair                  |               |
| Submission of the article other publications | WH Chair                  |               |

# Appendix 4 — FIP 2016 Pharmacists' Role in Health Supply Chains

## FIP 2016 Pharmacists' Role in Health Supply Chains

Welcome to our Survey

Dear reader,

Thank you for participating in our survey. Your feedback is very important to us. This survey should take approximately 15-30 minutes.

Around the world a variety of professionals are involved in 'health supply chains' (*the supply chain responsible for moving medicines and medical equipment from manufacture to the patient*). In some countries these are professional logistics and supply chain personnel. In other countries, health personnel (*pharmacists, doctors, nurses*) and in many countries a combination of these.

A *pharmacist* is a scientifically-trained graduate healthcare professional who is an expert in all aspects of the supply and use of medicines. Pharmacists assure access to safe, cost-effective and quality medicines and their responsible use by individual patients and healthcare systems. ([http://www.fip.org/pharmacy\\_practice](http://www.fip.org/pharmacy_practice))

This survey aims to determine *pharmacist only* competencies and behaviors needed in the health supply chain. Understanding such competencies can maximize supply chain efficiency, and highlight gaps in personnel, education, and/or training. This evidence may also support the best utilization of existing pharmacists, where pharmacists are few.

We have included a list of 26 behavioral competencies from the *People that Deliver Health Supply Chain Framework for Managers and Leaders*. Please consider if you believe that the pharmacist is the most suitable professional to complete the competencies that are presented and why.

Technical competencies from the following five domains (competency areas) are considered:

1. Selection and Quantification of correct supplies in the right quantities
2. Procurement of supplies needed
3. Storage and Distribution of supplies needed
4. Use of the suppliers in their work situation where patients are treated
5. Resource Management of money/people to ensure the system works efficiently

Thank you.

FIP Pharmacists in Supply Chain Working Group

Please contact Dr. Andrew Brown, Working Group co-chair, [anbrown.hss@gmail.com](mailto:anbrown.hss@gmail.com) for further information

## FIP 2016 Pharmacists' Role in Health Supply Chains

### Demographics

This section looks at your location and role in the medicines supply chain.

\* 1. In what country do you work?

Other (please specify)

\* 2. What is your job role?

- Pharmacist
- Pharmacist assistant, technician, or other pharmacist workforce cadre (para-professional)
- Supply chain professional (non-pharmacist)
- Other Health Professional (e.g., doctor, nurse, midwife)
- Other (please specify)

\* 3. In what type of organization do you currently work?

Other (please specify)

4. Do you have any qualifications from any of the following supply chain certification programs? *Please check all that apply.*

- Supply Chain Management Association (SCMA, SCMP)
- International Institute for Procurement and Market Research (IIPMR)
- Certified Supply Chain Specialist (CSCS)
- Certified Procurement Professional (CPP)
- Institute for Supply Management (ISM)
- Certified Professional in Supply Management (CPSM)
- The Association for Operations Management (APICS)
- Certified Supply Chain Professional (CSCP)
- International Supply Chain Education Alliance (ISCEA)
- Certified Supply Chain Manager (CSCM)
- American Society of Transportation and Logistics (AST&L)
- Certification in Transportation and Logistics (CTL)
- Certified Production and Inventory Management (CPIM)
- Certified Supply Chain Analyst (CSCA)
- Institute of Supply Chain Management (IOSCM)
- Certified Purchasing Manager (CPM)
- Certified Demand Driven Planner (CDDP)
- Chartered Supply Chain Management Professional (CSCMP)
- Pharmacy Technician Certification (CPhT)

Other (please specify)

## FIP 2016 Pharmacists' Role in Health Supply Chains

### Pharmacist ONLY Competencies: (1) Selection and Quantification

#### Technical domain 1: Selection and Quantification

##### 1.1 Select the appropriate product (questions 5-8)

5. Do you agree that a pharmacist is the most suitable professional to 'describe the broad concepts of National Medication Policy, Essential Medicines Lists, Essential Equipment Lists, Standard Treatment Guidelines and "Dangerous Drug" (DDA) or narcotics policy?'

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

6. Do you agree that a pharmacist is the most suitable professional to 'use the processes required to add and subtract items from the Essential Medicines List and the Essential Equipment List?'

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree (pharmacist takes some responsibility), why?

7. Do you agree that a pharmacist is the most suitable professional to 'follow the processes required to alter standard treatment guidelines, dangerous drug policy (i.e. DDA, narcotics), and national medicine policy?'

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

8. Do you agree that a pharmacist is the most suitable professional to 'confirm the type of medical supplies that are required to be kept?'

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

## FIP 2016 Pharmacists' Role in Health Supply Chains

### Technical domain 1: Selection and Quantification

#### 1.2 Define the specifications and quality of the product (question 9)

9. Do you agree that a pharmacist is the most suitable professional to 'advise on product specifications (e.g. active ingredient, form, pharmacopeia standard) for the procurement of medicines?'

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

## FIP 2016 Pharmacists' Role in Health Supply Chains

### Technical domain 1: Selection and Quantification

#### 1.3 Take into account any special considerations for the product (e.g., temperature requirements, size, implications for infrastructure) (questions 10-12)

10. Do you agree that a pharmacist is the most suitable professional to 'describe the principles and processes of category management for medicines (i.e. medicines categorized by similar *use* or *storage* needs, such as cold chain, anti-retroviral medicines, controlled substances such as narcotics and psychotropics), including market segmentation principles for common needs and interests?'

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

11. Do you agree that a pharmacist is the most suitable professional to 'demonstrate the required knowledge for the quantification (determining the quantities required to order) of health program-specific medicines (e.g. antiretrovirals, family planning commodities, vaccines, etc)?'

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?



12. Do you agree that a pharmacist is the most suitable professional to have 'a working knowledge of the handling requirements for medicines?'

Agree (pharmacist is the most suitable professional)

Disagree

If partially agree/disagree, please explain why?

## FIP 2016 Pharmacists' Role in Health Supply Chains

### Technical domain 1: Selection and Quantification

#### 1.4 Forecast and quantify product needs (questions 13-15)

13. Do you agree that a pharmacist is the most suitable professional to 'identify the factors that affect usage patterns for medication (e.g. disease outbreaks, seasonal variation, expanding clinical need), and identify how this affects ordering'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

14. Do you agree that a pharmacist is the most suitable professional to have 'a working knowledge of the critical requirements for effective forecasting of medicines (i.e., predicting future needs)'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

15. Do you agree that a pharmacist is the most suitable professional to 'establish policies and procedures for forecasting control for medicines (i.e., predicting control for medicines)'?

Agree (pharmacist is the most suitable professional)

Disagree

If partially agree/disagree, please explain why?

## FIP 2016 Pharmacists' Role in Health Supply Chains

### Pharmacist ONLY competencies: (2) Procurement

#### Technical domain 2: Procurement

#### 2.5 Assure quality of products (questions 16-18)

16. Do you agree that a pharmacist is the most suitable professional to 'use and monitor the process for pre-qualification of suppliers who are used to purchase medicines from (i.e. selecting appropriate quality approved suppliers.)'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

17. Do you agree that a pharmacist is the most suitable professional to 'ensure that medicines are not counterfeit, and meet quality standards'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

18. Do you agree that a pharmacist is the most suitable professional to 'implement, conduct, and maintain a reporting system of pharmacovigilance (e.g. adverse drug reactions and medicine incident reporting)'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

## FIP 2016 Pharmacists' Role in Health Supply Chains

### Pharmacist ONLY competencies: (2) Procurement

#### Technical domain 2: Procurement

#### 2.8 Prepare for product supply during disasters and emergencies (questions 19-20)

19. Do you agree that a pharmacist is the most suitable professional to 'describe the procurement and logistic requirements for the emergency supply of medicines in a disaster'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

20. Do you agree that a pharmacist is the most suitable professional to 'undertake the assessment of local capacity before the supply of medicines in an emergency or disaster'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

**FIP 2016 Pharmacists' Role in Health Supply Chains****Pharmacist ONLY competencies: (2) Procurement****Technical domain 2: Procurement****2.9 Undertake or manage manufacturing or compounding products (question 21)**

21. Do you agree that a pharmacist is the most suitable professional to 'compound (make a pharmaceutical from base components) under the code of good manufacturing practice (GMP) for the production of medicines'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

## FIP 2016 Pharmacists' Role in Health Supply Chains

### Pharmacist ONLY competencies: (3) Storage and Distribution

#### Technical domain 3: Storage and Distribution

#### 3.4 Manage disposal of products (e.g., expired, damaged, redundant products) (questions 22-23)

22. Do you agree that a pharmacist is the most suitable professional to 'describe and demonstrate the recall procedures to be used in response to a medicine product recall notice'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

23. Do you agree that a pharmacist is the most suitable professional to 'dispose of expired medicines according to national policy'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?



## FIP 2016 Pharmacists' Role in Health Supply Chains

### Pharmacist ONLY competencies: (3) Storage and Distribution

The following question refer to the *Health Supply Chain Competency Framework for Managers and Leaders* created by People that Deliver. Please consider if you think that a 'pharmacist' is the most suitable professional to complete the following.

#### Technical domain 3: Storage and Distribution

#### 3.5 Dispense or provide commodities to patients/users (i.e., ensuring the product goes "the last meter" appropriately") (question 24)

24. Do you agree that a pharmacist is the most suitable professional to 'list which medicines are allowed to be prescribed by different prescribers, and monitor this'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

## FIP 2016 Pharmacists' Role in Health Supply Chains

### Pharmacist ONLY competencies: (4) Use

#### Technical domain 4: Use

#### 4.1 Understand use of medical products including medicines and equipment (e.g., safety, dispensing protocols, standard treatment/testing guidelines) (question 25)

25. Do you agree that a pharmacist is the most suitable professional to 'identify medicines by their generic name, and have a general understanding of what medicines are used for'?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

**FIP 2016 Pharmacists' Role in Health Supply Chains****Pharmacist ONLY competencies: (5) Resource Management****Technical domain 5: Resource Management****5.4 Implement quality assurance and risk management activities (question 26)**

26. Do you agree that a pharmacist is the most suitable professional to 'implement key security systems and appropriate levels of access for the workplace where medicines are stored (e.g. including, narcotics, other controlled substances and investigational medicines etc' ?

- Agree (pharmacist is the most suitable professional)
- Disagree

If partially agree/disagree, please explain why?

## FIP 2016 Pharmacists' Role in Health Supply Chains

### Additional pharmacist ONLY competencies

27. Please list any other competencies or behaviors in the health supply chain where you would consider that a pharmacist is the most suitable professional to complete those competencies or behaviors.

**FIP 2016 Pharmacists' Role in Health Supply Chains****Additional pharmacist ONLY competencies**

28. How should any competencies considered to be most appropriately dealt with by **apharmacist**, be addressed in circumstances where pharmacists are NOT available?

29. What other comments would you like to make regarding the work of pharmacists in health supply chains?

## FIP 2016 Pharmacists' Role in Health Supply Chains

### The End

**Thank you for participating in this survey. We appreciate your time and input very much.**

**For more questions or comments, please contact Dr. Andrew Brown, FIP Working Group Co-Chair, at [anbrown.hss@gmail.com](mailto:anbrown.hss@gmail.com).**

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