

Pharmaceutical distribution (and wholesaling)



JAMASOFT2014-2015

Pharmaceutical wholesalers

contribute an essential link

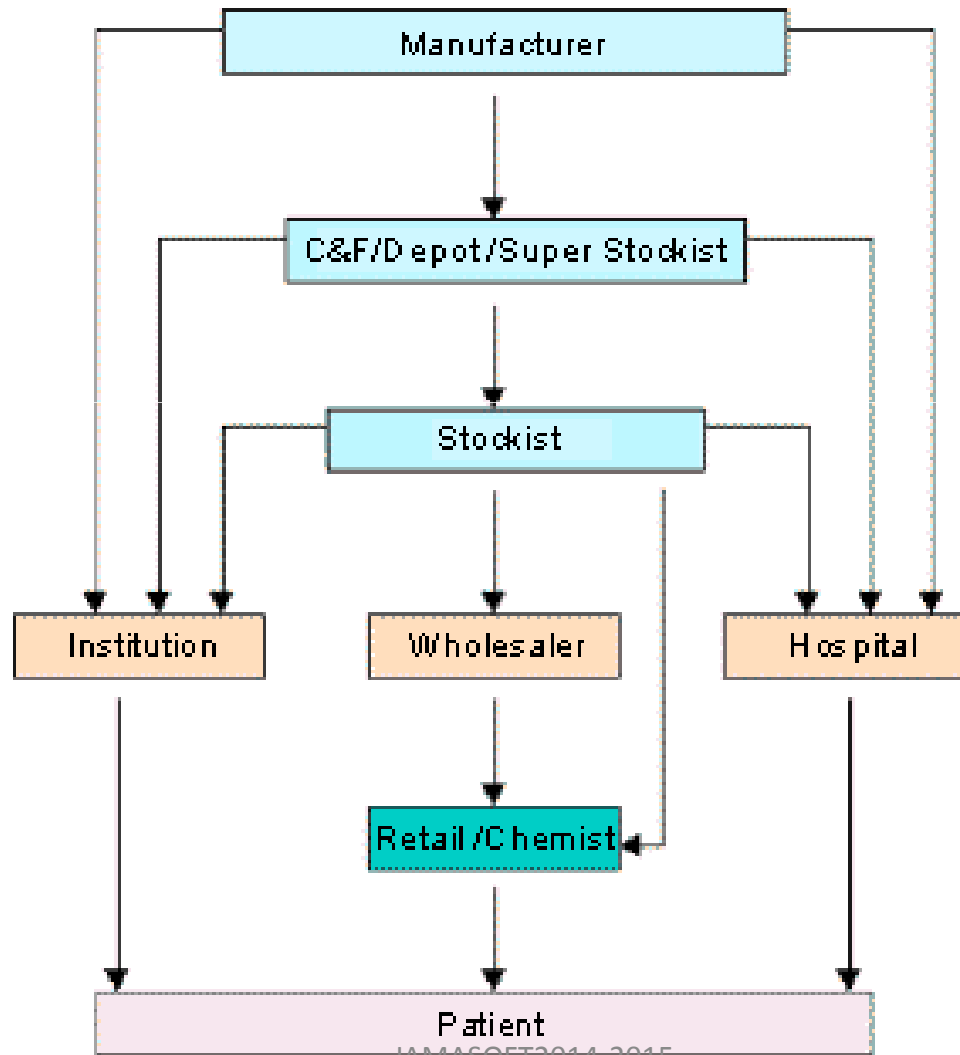
between

the pharmaceutical

industry and

pharmacies.

General view on Pharmaceutical distribution



„Pharmaceutical supply chain“

Pharmaceutical distribution

is an important activity
in the integrated
supply-chain management
of pharmaceutical products.

Various people and entities

are

generally responsible for

the **handling,**

storage

and **distribution**

of pharmaceutical

products.

Today, distributors do much more than simply optimise their inventory levels.

Activities in the areas of **supply chain integrity**, **assurance of stock availability**, **planning for and catering to individual store needs** and **ensuring contract compliance** are reviewed and adjusted real-time.

In addition,

pharmaceutical distributors
are extending their retail services
to help their pharmacies

**remain relevant and patient-
focused.**

The storage, sale and distribution of
pharmaceutical products

are often

**carried out by various
companies, institutions and
individuals.**

Pharmaceutical distribution offers:

- a range of services that support the needs of our pharmaceutical distributors —national, regional and specialty — in areas such as:
- Performance measurement and management
- Program design, monitoring and measurement/ROI
- Advanced customer segmentation and targeting
- Utilization metrics
- Forecasting
- Category management
- Generic utilization tracking
- Customer contract compliance
- Commercial effectiveness services such as sales force alignment and incentive compensation.

WHO is the creator

of the

Guideline

**„Good distribution practices
for pharmaceutical products“
(2012).**

The objective of this Guideline is

to assist in ensuring the quality and identity of pharmaceutical products during all aspects of the distribution process.

These aspects include, but are not limited to, **procurement**, **purchasing**, **storage**, **distribution**, **transportation**, **repackaging**, **relabelling**, **documentation** and **record-keeping**.

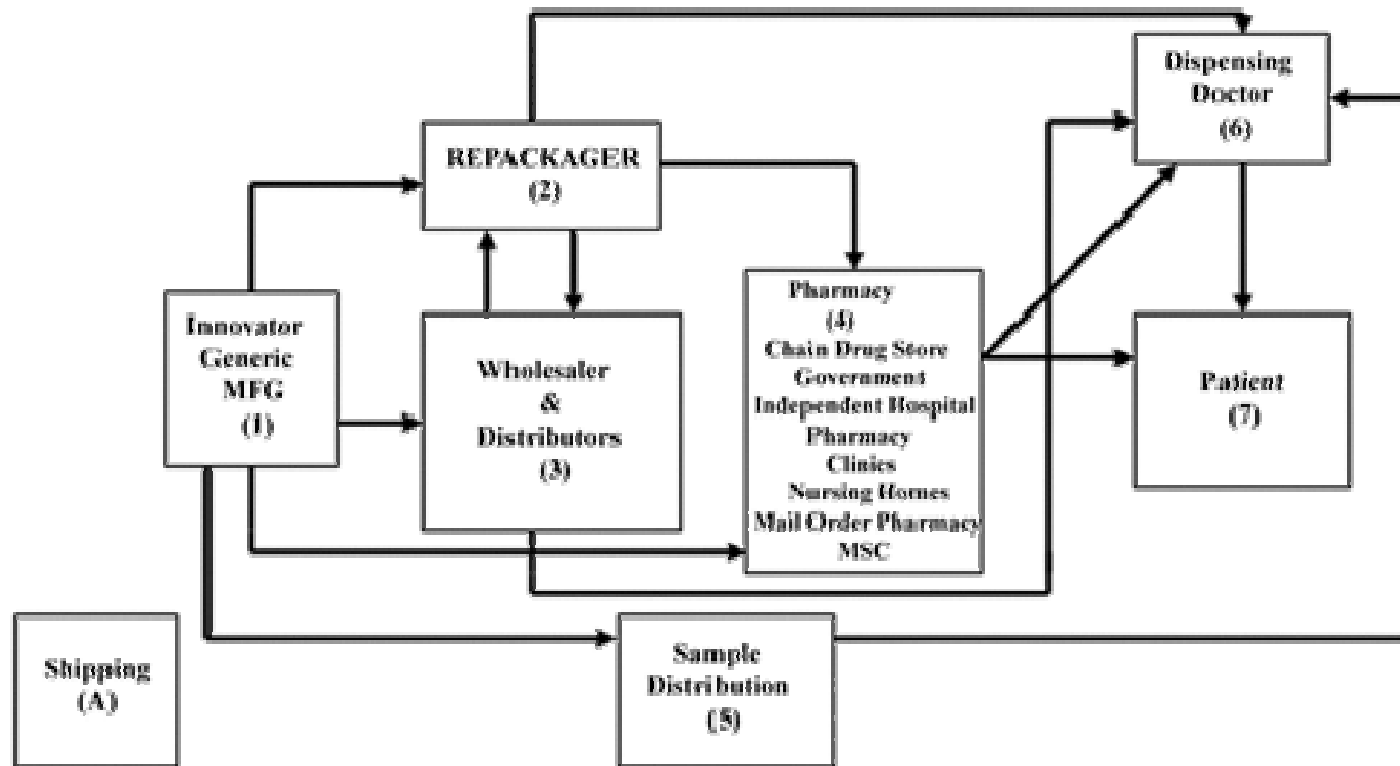
This Guideline sets out

appropriate steps to assist in fulfilling the responsibilities involved in the different aspects of the distribution process within the **supply chain**

and to avoid the introduction of counterfeits into the marketplace via the distribution chain.

The central role of Pharmaceutical distribution

Drug Product Distribution



Different models

for the distribution of pharmaceutical products

are used in different countries and sometimes
within the same country,

for example, in the public and the private sector.

Drug Distribution Models

1. **Manufacturer** → **Retailer**

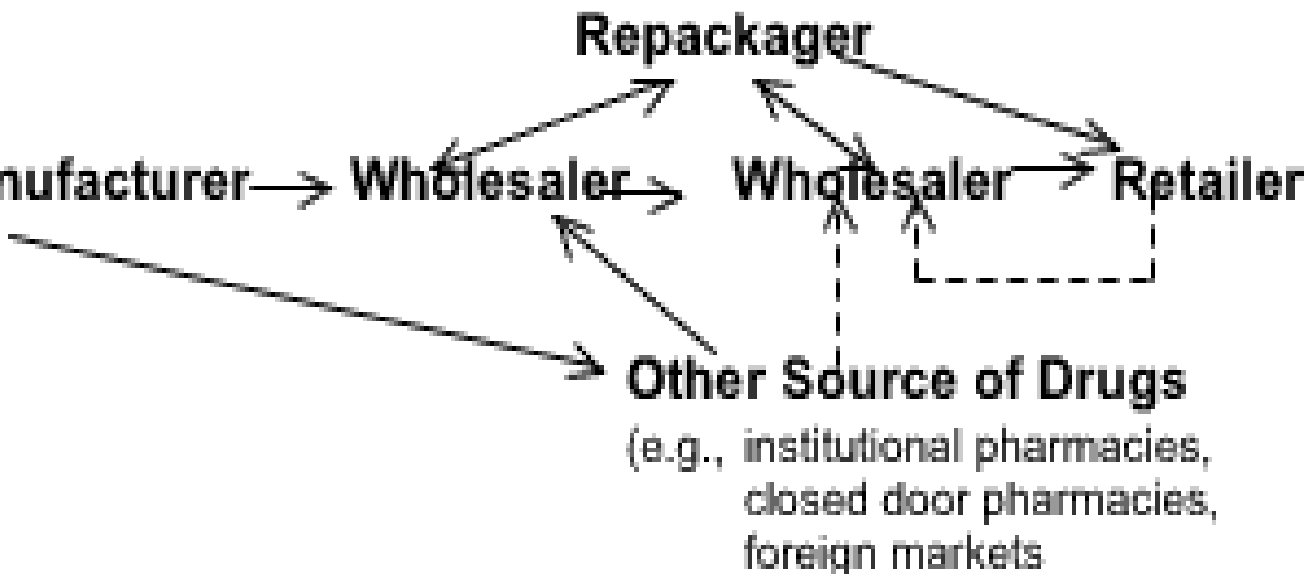
2. **Manufacturer** → **Wholesaler** → **Retailer**

Repackager



3. **Manufacturer** → **Wholesaler** → **Wholesaler** → **Retailer**

Repackager



Other Source of Drugs
(e.g., institutional pharmacies,
closed door pharmacies,
foreign markets)

The structure of Pharmaceutical Distribution in Europe.

The dominant form of drug distribution had long followed a pattern where the pharmacist acted primarily as a retailer and health service provider, sourcing products from wholesalers who purchased medicines from manufacturers, and stocked them in anticipation of demand.

The three main models of distribution—in order to access the right services for the right cost:

- **1. Wholesaler Model:** This cost-effective distribution alternative for the majority of pharmaceutical products allows wholesalers to provide logistical efficiencies across manufacturers and focus on demand fulfillment and provide a high level of service to end customers.
- **2. Limited Distribution Model:** By limiting wholesaler relationships, manufacturers hope to improve inventory management, reduce costs, and mitigate concerns about product and supply chain integrity.
- **3. Direct Distribution Model:** Direct distribution by manufacturers has emerged as a viable distribution model, particularly for high-priced biologics with a limited provider base and direct-bulk shipments to customers with their own central distribution warehouse.

To maintain the original quality
of pharmaceutical products, every party
active in the distribution chain

has to comply with the applicable legislation
and regulations.

Although an effort has been made

to use standard definitions
as far as possible, they may have different
meanings in other contexts and
documents.

GLOSSARY

- **Distribution**

The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of pharmaceutical products, with the exception of the dispensing or providing pharmaceutical products directly to a patient or his or her agent.

GLOSSARY

- *supplier*

A person or entity engaged in the activity of providing products and/or services.

GLOSSARY

- **Batch**

A defined quantity of pharmaceutical products processed in a single process or series of processes so that it is expected to be homogeneous.

GLOSSARY

- **batch number**

A distinctive combination of numbers and/or letters which uniquely identifies a batch, for example, on the labels, its batch records and corresponding certificates of analysis.

GLOSSARY

- **consignment**

The quantity of pharmaceutical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include pharmaceutical products belonging to more than one batch.

GLOSSARY

- **container**

The material employed in the packaging of a pharmaceutical product.

Containers include primary, secondary and transportation containers.

Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product.

GLOSSARY

- **counterfeit pharmaceutical product**

A pharmaceutical product which is deliberately and fraudulently mislabelled with respect to identity and/or source.

Counterfeiting can apply to both branded and generic products, and counterfeit pharmaceutical products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an incorrect quantity of active ingredient or with fake packaging.

GLOSSARY

- **expiry date**

The date given on the individual container (usually on the label) of a pharmaceutical product up to and including the date on which the product is expected to remain within specifications, if stored correctly.

It is established for each batch by adding the shelf-life to the date of manufacture.

GLOSSARY

- **first expiry/first out (FEFO)**

A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used.

GLOSSARY

- **labelling**

Process of identifying a pharmaceutical product including the following information, as appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier.

GLOSSARY

- marketing authorisation

A legal document issued by the competent medicines regulatory authority

for the purpose of marketing or free distribution of a product after evaluation

for safety, efficacy and quality

Marketing authorisation

must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics.

It specifies the information on which authorization is based (e.g. “The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence”).

Marketing authorisation

also contains

the product information

approved for health professionals and the public, the sales

category, the name and address of the holder of the authorization, and the period of validity of the authorisation.

Marketing authorisation.

Once a product has been given marketing authorization, it is included on a list of authorized products — the register — and is often said to be “registered” or to “have registration”.

Market authorization may occasionally also be referred to as a “licence” or “product licence”.

Dispatch and receipt

Pharmaceutical products should only be sold and/or distributed to persons or entities that are authorized to acquire such products in accordance with the applicable **national**, **regional** and **international** legislation.

Written proof of such authority must be obtained prior to the distribution of products to such persons or entities.

Regulation of the distribution of pharmaceutical products.

National legislation should be in place to regulate the activities of persons or entities involved in the distribution of pharmaceutical products.

Regulation of the distribution of pharmaceutical products.

The distributor or the organization to which the distributor belongs should be an entity that is appropriately authorized in terms of applicable legislation to perform the function(s) that it intends to perform.

The distributor or the organisation to which it belongs should be held accountable for the activities that it performs which relate to the distribution of pharmaceutical products.







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Pharmaceutical distribution

provide high core service levels to pharmacists
in terms of:

- frequency of delivery,
- product availability,
- delivery accuracy,
- timeliness and reliability at competitive prices.

Pharmaceutical distribution

Provides services to pharmaceutical manufacturers who are increasingly seeking to gain greater control over their product distribution while at the same time outsourcing non-core activities.

These services include pre-wholesale and contract logistics, direct deliveries to pharmacies, and specialised medicine delivery, including related home healthcare.

Pharmaceutical distribution

also offers its customers
innovative added-value
services which help
pharmacists develop their
own businesses.

Governments

are implementing measures to encourage greater usage of lower cost generic medicines.

Scale and international sourcing capabilities are important to secure lower prices and better cash margins on generics in a way which legislation typically does not permit for branded products.

An increasing number of branded pharmaceutical manufacturers

are seeking further efficiencies and control by switching from selling via multiple pharmaceutical wholesalers to either selling direct to pharmacies (using relatively few distributors to deliver, invoice customers and collect payments), or selling via a select, reduced number of national wholesalers.

Counterfeit pharmaceutical products

are a real threat to public health and safety.

Consequently, it is essential to protect the pharmaceutical supply chain against the penetration of such products.

Counterfeit pharmaceutical products

Weak points in the distribution processes of pharmaceutical products provide an avenue for counterfeit as well as illegally imported, stolen and substandard medicines to enter the supply chain.

Counterfeit pharmaceutical products

This is a concern in both developed and developing countries.

The methods by which such products enter the supply chain have become increasingly complex and have resulted in the development of thriving secondary and grey markets throughout the world.

Modern technologies in Pharmaceutical distribution:

- Pallet Handling
- Sortation Systems
- Bar Code and RFID Systems
- Automated Bridge Cranes
- Power and Free Systems
- Automated Transfer Cars
- WMS Integration (warehouse management system, or WMS, is a key part of the [supply chain](#) and primarily aims to control the movement and storage of pharmaceuticals).

Pharmaceutical distribution

places a heavy burden on the operational and logistics resources of any company.

Industry-specific regulations and institutional requirements, forecasting, procurement, customer service, picking, dispatch and special treatment of physical inventory can all place a burden on logistical decisions. Add to that low margins, high customer service expectations, a constant fight against counterfeit medicines and global competitive pressures, and the margin for error is negligible.

Six trends that will change the fundamentals of pharmaceutical distribution.

They will fundamentally change the way pharmaceutical companies make and distribute products:

Six trends that will change the fundamentals of pharmaceutical distribution.

1. Health reform shifts emphasis from product features to patient outcomes.

The government's emphasis on health outcomes as a basis for payments will require pharmaceutical companies to not only manage the manufacturing and distribution of medicines and companion diagnostics, but also to combine product offerings with data and supplemental services that add value through improved outcomes and efficiencies.

Six trends that will change the fundamentals of pharmaceutical distribution.

2. New products types.

The growth of biologics, bioengineered vaccines and advancements such as stem cell research and nanotechnology are diversifying pharma's portfolio with products that have a shorter shelf life and require more complex manufacturing and distribution processes than shelf-stable pills and conventional medicines.

Six trends that will change the fundamentals of pharmaceutical distribution.

3. Incremental product launch alters the sales curve.

Both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have shown interest in limited label approvals, granting “live licenses” contingent on ongoing testing versus the all-or-nothing phase I through IV approach.

Current processes support revenue projections for “big bang” product launches, with peak sales upfront. Pharmaceutical companies will need more adaptable cost structures that preserve gross margins at each stage of the product lifecycle.

Six trends that will change the fundamentals of pharmaceutical distribution.

4. New modes of healthcare delivery.

Greater use of electronic health records,
e-prescribing, mobile health applications, and remote monitoring

are moving healthcare delivery, including medication management, beyond hospitals and physicians offices into homes, communities, and *direct to patients*.

Pharmaceutical companies will need real-time information to manage wider distribution networks and demand-driven manufacturing and distribution processes.

Six trends that will change the fundamentals of pharmaceutical distribution.

5. Growing importance of emerging markets.

The growing importance of the emerging markets will require pharmaceutical companies to understand patient needs and preferences in the developing world, and modify cost and design of product offerings and services accordingly.

Six trends that will change the fundamentals of pharmaceutical distribution.

6. Greater public scrutiny.

Globalization, the foreign sourcing and manufacture of regulated products, and an increase in the volume and complexity of imported products have increased the need for supply chain control to identify the risk of contamination and fake medicines.

**Thanks for your
attention.**