P01: Our Health Products

E356 Pharmaceutical and Bio-Chem Supply Chain

Diploma in Supply Chain Management (DSCM)

E356 Topic Tree

Pharmaceutical and Bio-chem Supply Chain

- Introduction to Pharma and Bio-chem
- Classification of Dangerous Goods
- Best Practices (GMP/GDP)
- Clinical Supply Chain
- Cold Chain Management

Import, Packaging and Distribution

- Import and Distribution of Medical Devices
- Import of Pharmaceutical and Bio-Chem Products
- Local Transportation of Pharmaceutical and Bio-Chem Products
- Packaging of Pharmaceutical DG for Air Transport
- Declaration of Pharmaceutical DG for Air Transport

Product Tracing, Recall and Disposal

- Product Tracing
- Drug Recall
- Disposal of Bio-chem Products in Hospital Logistics

Health products and HSA

Health care is the maintaining and restoration of health by the treatment and prevention of disease especially by trained and licensed professionals

In Singapore, health products are regulated under various Acts that are governed by Health Science Authority (HSA). The regulated items include drugs, innovative therapeutics, medical devices and health-related products.

HSA
Health Sciences Authority

Health Sciences Authority

Biochemical Substances

Biochemicals: Chemical substances characterized by, produced by, or involving chemical reactions in living organisms.

Biochemicals are chemicals produced from organic sources known as biomass. Biomass is any living matter that can be naturally and regularly replenished, including agricultural food and feed crop residues, aquatic plants, animal wastes and other waste materials.

Biochemical Substances

Biochemicals include commodity chemicals, fine chemicals and chemical intermediates.

- Solvents
- Fuel Additives
- Lubricants
- Adhesives
- Inks

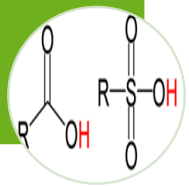
Commodity Chemicals

- Pharmaceuticals
- Nutraceuticals
- Enzymes

Fine Chemicals

- Sugars
- Organic Acids

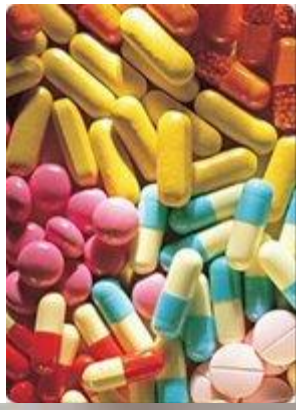
Chemical Intermediates



For biochemicals, this module will focus on the fine chemicals.

Pharmaceuticals

Pharmaceuticals: Substances used in the diagnosis, treatment, or prevention of disease and for restoring, correcting, or modifying organic functions.



Pharmaceuticals are also commonly known as medicine or drugs, they also include vaccines and pharmaceutical wastes.

The active ingredients in pharmaceuticals exert a biochemical effect on the body.

Pharmaceuticals
- Obtaining Pharmaceutical Products

Countries use different terms to categorise medicines with varying levels of access to the public. For example,

In Singapore, therapeutic products are classified as follows::

1) General Sales List (GSL), (e.g. Panadol): a therapeutic product that can be freely obtained from any retailer.

2) Pharmacy Only Medicines (P). (e.g. Piriton): a therapeutic product that can be obtained from a pharmacist at a retail pharmacy

3) Prescription Only Medicines (POM). (e.g. Antibiotics): a therapeutic product that can only be obtained from a doctor or a dentist, or from a pharmacist with a prescription from a doctor or a dentist

Note: Controlled drugs (e.g. Morphine) are POMs, Distribution is tightly controlled because of its abuse potential. Most controlled drugs are only for use by doctors and not available to consumers.

Resource:
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Western_Medicines/Reclassified_Medicines.html

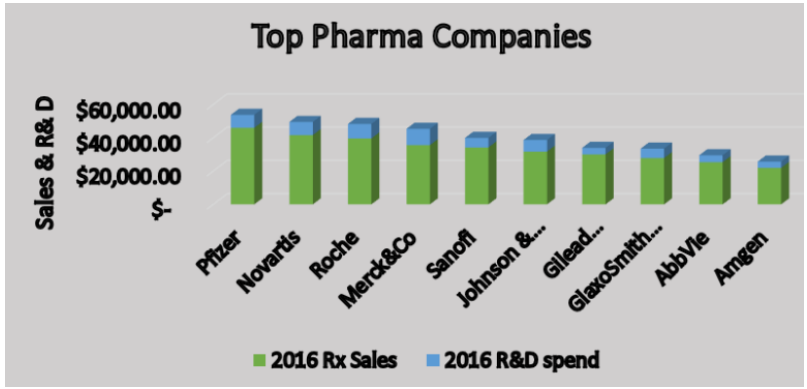
In US, there are two categories:

1) Over the Counter (OTC) medicines, which would be similar to 'GSL'
2) Prescription Only Medicines (POM).

Pharmaceutical Markets and Opportunities

Global market

- The global market for pharmaceuticals is expected to grow at an annual rate of 4.9% to $1.3 trillion by 2020.
- The U.S pharma market is expected to grow to $320 billion by 2020.
- The Japan market, the third largest pharmaceutical market, has a forecasted growth of 3% while the U.S has an expected growth rate of 5.6%.



- Refer to: https://investmentbank.com/pharma-industry-overview/

Pharmaceutical Markets and Opportunities

Singapore market

- In Singapore, between 2011 and 2015, the Singapore government committed S$3.7 billion in funding to R&D in the biomedical science industry, attracting companies globally to set up operations here – from HQs to manufacturing facilities.

At a Glance

3x

of the pharmaceutical sector's manufacturing output produced today since 2000. In 2016, the sector produced more than S$16 billion worth of products for global markets[1].

>6,000

people in the skilled workforce employed in the biopharmaceutical sector[2], more than double since the early 2000s.

8

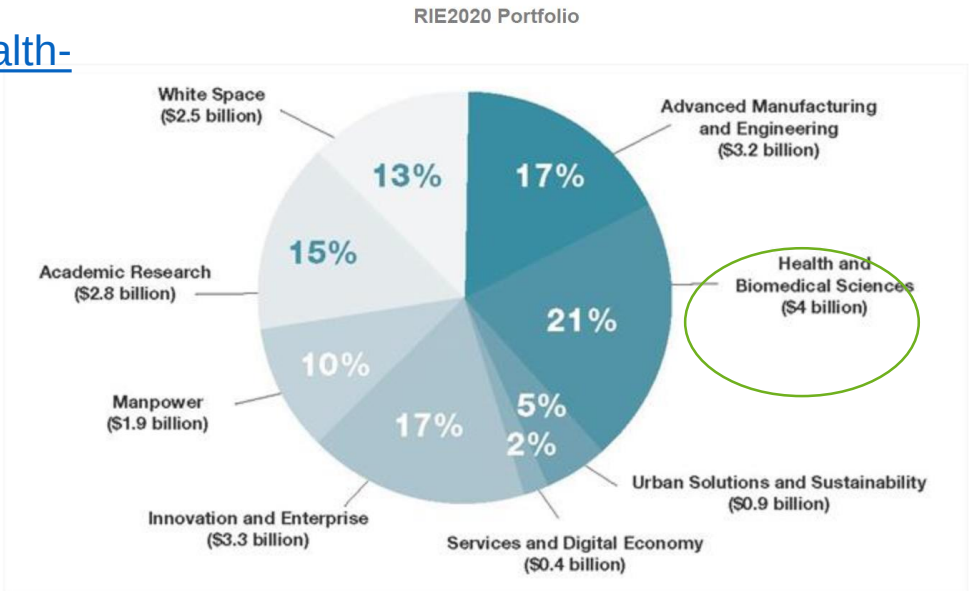
of the top 10 pharmaceutical companies have facilities in Singapore, manufacturing 4 of the top 10 drugs by global revenue.

Refer to: https://www.edb.gov.sg/en/our-industries/pharmaceuticals-and-biotechnology.html

Pharmaceutical Research and Opportunities

In RIE2020 (Research, Innovation and Enterprise 2020), public research agencies plan to develop an ecosystem that better enables translation of research to improving health outcomes, including greater emphasis on Health Services Research to contain healthcare costs, and transform and enhance the efficiency of health services delivery. The ecosystem will be supported by building a strong core and pipeline of Singapore researchers, clinician-scientis
investors.

Source: https://www.nrf.gov.sg/rie2020/health-and-biomedical-sciences



Pharmaceuticals
- Common Pharmaceutical Forms

Drugs that are consumed orally

Gel Capsule

Capsule

Orally disintegrating tablets e.g. lozenges

Tablet

Syrup

Powder

Pharmaceuticals
- Common Pharmaceutical Forms

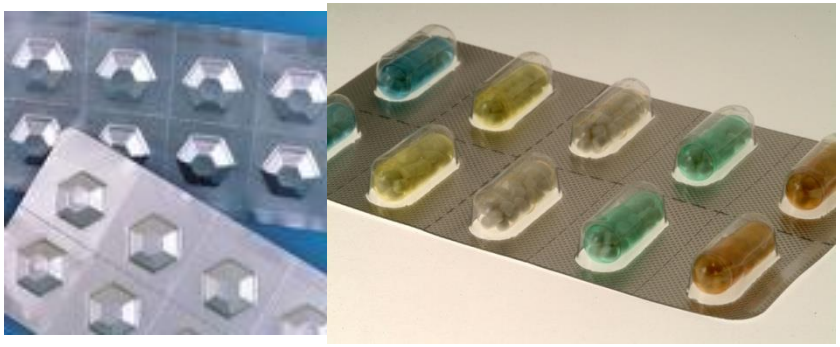
Inhalation

Topical – cream, gel,
eye drop, spray

Injection / Intravenous

Suppository

Pharmaceuticals - Common Consumer Pharmaceutical Packaging



Blister

Bottle

Tube

Sachet

Vial

Pharmaceuticals - Raw Form Bulk Pharmaceutical Packaging

Drums

IBC (Intermediate Bulk Container)

Paper

Paper IBC

Pails

Super Sacks

Newer Green Packaging System

Paper IBC is used for non-hazardous products e.g. Food, palm oil and adhesives

Example: https://www.youtube.com/watch?v=L9zcjCM0OUg

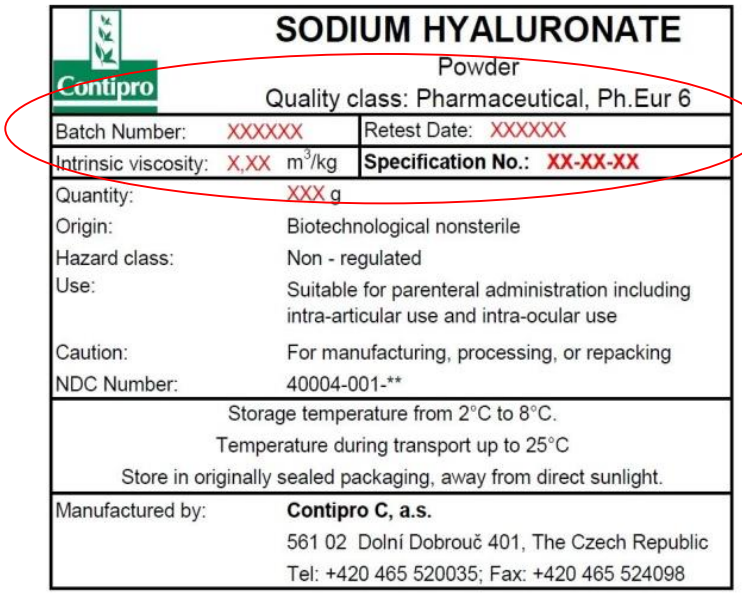
Advantages:

- Lower cost compared to PE/ Steel containers
- Significant Space Saving as PaperIBCs are collapsible before use
- Optimization of container loading, thus unit delivery cost is lowered. 20 PaperIBCs versus 18 normal plastic IBCs can be loaded into one 20 ft container

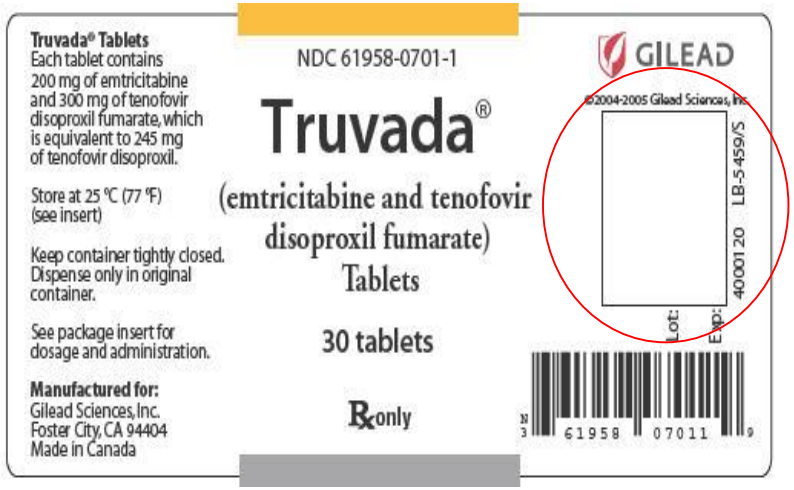
Challenges

- Need customer and industry buy in for the integrity and reliability of the new package
- Covered Storage is required – not able to withstand rain and shine

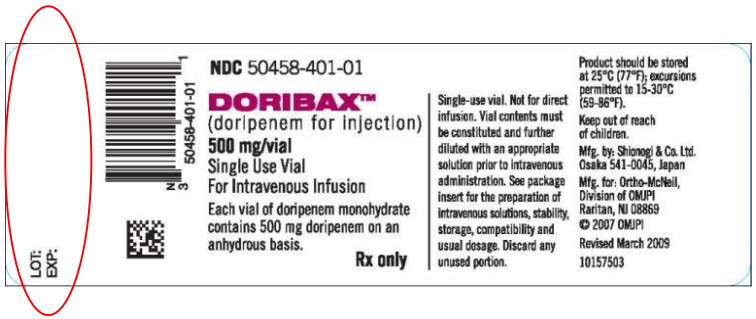
Pharmaceuticals
- Information on Package Label



Bulk label



Blister label



Vial label

Sachet label

Pharmaceuticals - Special storage conditions

Some drugs can denatured if exposed to undesirable environmental conditions, these drugs may be sensitive to

- Temperature
- Light
- Humidity

These drugs may require special packaging / storage conditions

Light sensitive drugs are contained in brown bottles

Nutraceuticals

Nutraceuticals **are complementary medicines of natural origin. Usually obtained from a food source, they are sold as isolated, purified components in pharmacological doses for specific ailments.**

Nutraceuticals include

- **Traditional Chinese Medicine**
- **Ayurveda (Traditional medicine originated from India)**
- **Health supplements e.g. Vitamins**
- **Probiotic drinks like yoghurt**

Enzymes

Enzymes are any of numerous complex proteins that are produced by living cells and catalyze specific biochemical reactions at body temperatures. Used to manipulate DNA in genetic engineering, important in pharmacology and medicine.

Enzymes include

- Reagents used for medical testing
- Yeast for sugar fermentation in making bread
- Barley enzymes for fermentation in beer production

Medical Devices

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of

(*a*) diagnosis, prevention, monitoring, treatment or alleviation of any disease;
(*b*) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(*c*) investigation, replacement, modification, or support of the anatomy or of a physiological process;
(*d*) supporting or sustaining life;
(*e*) control of conception;
(*f*) disinfection of medical devices;
(*g*) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body

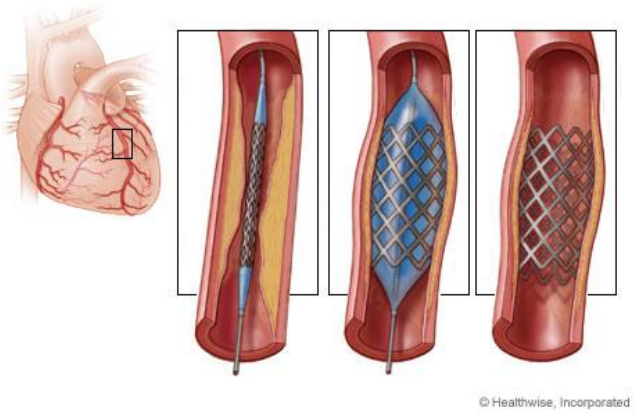
and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

(as defined in Health Product Act 2007)

Medical Devices

Medical devices can include:

- Instruments
- Appliances
- Implants
- Machines
- Software
- Materials
- Calibrators
- Apparatuses
- In vitro reagents
- Related articles

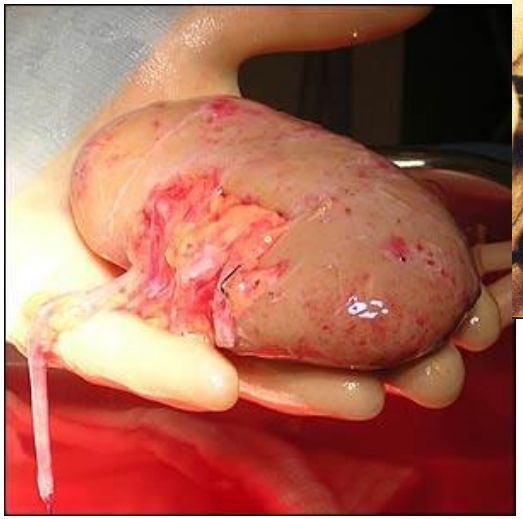


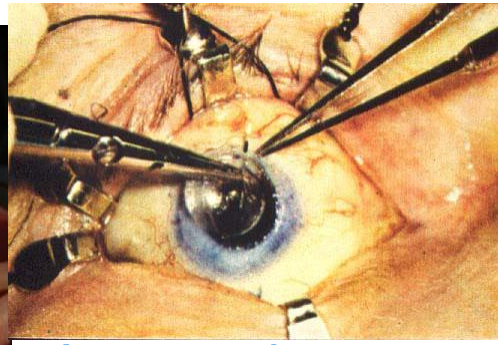
Some medical devices may be combined with pharmaceuticals.
E.g. Plasters with antiseptic cream applied on it.

Samples from Human / Plants / Animals

Blood sample
for lab test

Blood Plasma





Tissues / Organs
for transplant

Blood bags for
banking / transfusion

Pharma and Biochemical Logistics Requirements

- May be dangerous in nature (e.g. Blood sample infected with H1N1) and may require special packaging, handling and storage
- Maybe time critical, e.g. organs for transplant, samples for clinical trials
- Need proper / special disposal
- 24x7 logistics support- transport and storage accessibility
- May need to conform to special regulatory control, and documentation. e.g. controlled drugs.
- Usually have limited shelf life, manufactured date and expiry dates are printed.
- Tracking of pharmaceuticals are necessary, batch / lot numbers are printed on packaging.

Drug Patent vs Generic Drugs

- A patent is a monopoly right given by the Government to the owner of an invention to enable him to prevent others from copying the invention without his consent.
- A patent takes effect and continues to be in force until the end of the 20-year period beginning from the *date of filing* the application for the patent. E.g. Paracetamol was patented and branded as Panadol by Frederick Stearns & Co.
- During the patent period, the company sets the price of the drug at the level, which maximizes profitability.
- When patent expires, any pharmaceutical company can manufacture and sell the drug. A drug, which is produced and distributed without patent protection is called a generic drug. E.g. Paracetamol is the generic drug name.

Drug Patent vs Generic Drugs

- A generic drug must have the same active ingredients as the branded drug. It has to be in an identical strength and dosage form (tablet, liquid, etc.), and be administered in the same manner (oral, injection, etc.), as the branded product. The generic drug must also supply the same amount of the active ingredient to the human body, at the same absorption rate as the branded drug.
- The primary reason for the relatively low price of generic medicines is that competition increases among producers when drugs are no longer protected by patents.
- Generic manufacturers do not incur the cost of drug discovery, and instead are able to reverse-engineer known drug compounds to allow them to manufacture bio-equivalent versions.

Today's Problem

- Retail pharmacies sell pharmaceutical items as well as many other types of health care products including medical devices and Chinese Proprietary Medicine.
- As pharmaceuticals can be abused, different levels of access are used to regulate them.
- Pharmaceuticals come in various forms and packaging and depending on its usage and sensitivity to the environment.
- Normally, the price of generic medicines is lower than the that of branded ones.
- Batch / Lot number and expiry dates are important information printed on all pharmaceutical items.

Learning Objectives

- Define pharmaceutical products and explain the different levels of access to pharmaceutical products.
- Define and classify bio-chem products.
- Identify medical devices and other healthcare products that may have unique supply chain requirements.
- Recognize the common forms of pharmaceutical products and equipment (packaging/labels) used in pharmaceutical and bio-chemical supply chain.
- Interpret the needs for different storage and handling requirements of pharmaceutical products from packaging labels.
- Identify the difference between patent and generic drugs.