P08
Licenses Needed

E356 Pharmaceutical and Bio-Chem Supply Chain

Diploma in Supply Chain Management

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 (anti-counterfeit technologies)
- Drug Recall
- Disposal of Bio-chem Products in Hospital Logistics

Regulating Pharma / Bio-chem Products

Many pharmaceutical products and bio-chemicals, are classified as dangerous goods and are highly regulated in Singapore.

- Pharmaceutical products, commonly known as medicinal products, chemical or biologic drugs, are now regulated as “Therapeutic Products” under the Health Products Act (HPA) which took effect in 1 Nov 2016. **HSA** administers the national regulatory frameworks for pharmaceuticals, complementary medicines, medical devices and other health products in Singapore.
- Bio-chemicals and other chemicals are often used in laboratories for medical testing or for manufacturing of pharmaceuticals. They can be hazardous and can be detrimental to environment or health if not stored or handled appropriately. They are regulated by different agencies (**NEA, SPF and SCDF**) in Singapore depending on the type of hazard.

To import these products, importers will need to apply to these agencies as well as identify the HS code for customs clearance.

HSA Health Sciences Authority

National Environment Agency
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SCDF
The Life Saving Force

Singapore Police Force
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SINGAPORE CUSTOMS

Health Products under HSA

HSA – Regulations on Health Products

Specific health products licensed by HSA include

1. **Therapeutic Products (TP)** - any substance which is to be used for administration to human beings and animals for the diagnosis, prevention or treatment of ailments including preparations intended for the promotion of health, for anaesthesia or for contraception.

2. Chinese Proprietary Medicines (CPM) – CPM are medicines with absence of western drugs, and test results of toxic heavy metals and microbial contents.

3. Poison - Poisons are **potent** medicinal substances, which are defined as any substances specified in the Schedule of the Poisons Act, Chapter 234.

4. Controlled Drugs – also known as narcotic drugs e.g. opium, morphine, heroin. These substances are specified in the First Schedule to the Misuse of Drugs Act

5. Restricted / Psychotropic Substances - **Restricted Substances** are substances which require additional Approval to import/export Therapeutic Products Containing Psychotropic Substances. A **psychoactive drug** or **psychotropic substance** is a chemical substance that acts primarily upon the central nervous system where it alters brain function, resulting in temporary changes in perception, mood, consciousness and behavior. E.g. pain killer, stimulants.

Licenses for Health Product

1. Manufacturer's License for Therapeutic Products/CPM. Under the Health Products Act and Medicines Act, all local manufacturing facilities engaged manufacture or assembly of therapeutic products and Chinese Proprietary Medicines (CPM) must be licensed with HSA.
2. Import License (IL) for Therapeutic Products/CPM.
3. Wholesale's license(WL) for Therapeutic Products/CPM

   Under the Health Products Act, the activity-based licensing framework requires companies to hold the Import license if they are involved in the import and/or wholesale of TP/CPM in Singapore. Companies will be subject to GDP compliance before they can be granted these licences. However, if the company outsources the import and wholesale activity including invoicing, IL, WL as well as GDP compliance are not required.

   Wholesale dealing is defined under the Medicines Act as selling (a product) to a person who buys it for the purpose of selling or supplying it in the course of a business carried on by that person except that it does not include any such sale by the person who manufactured it.

Note:

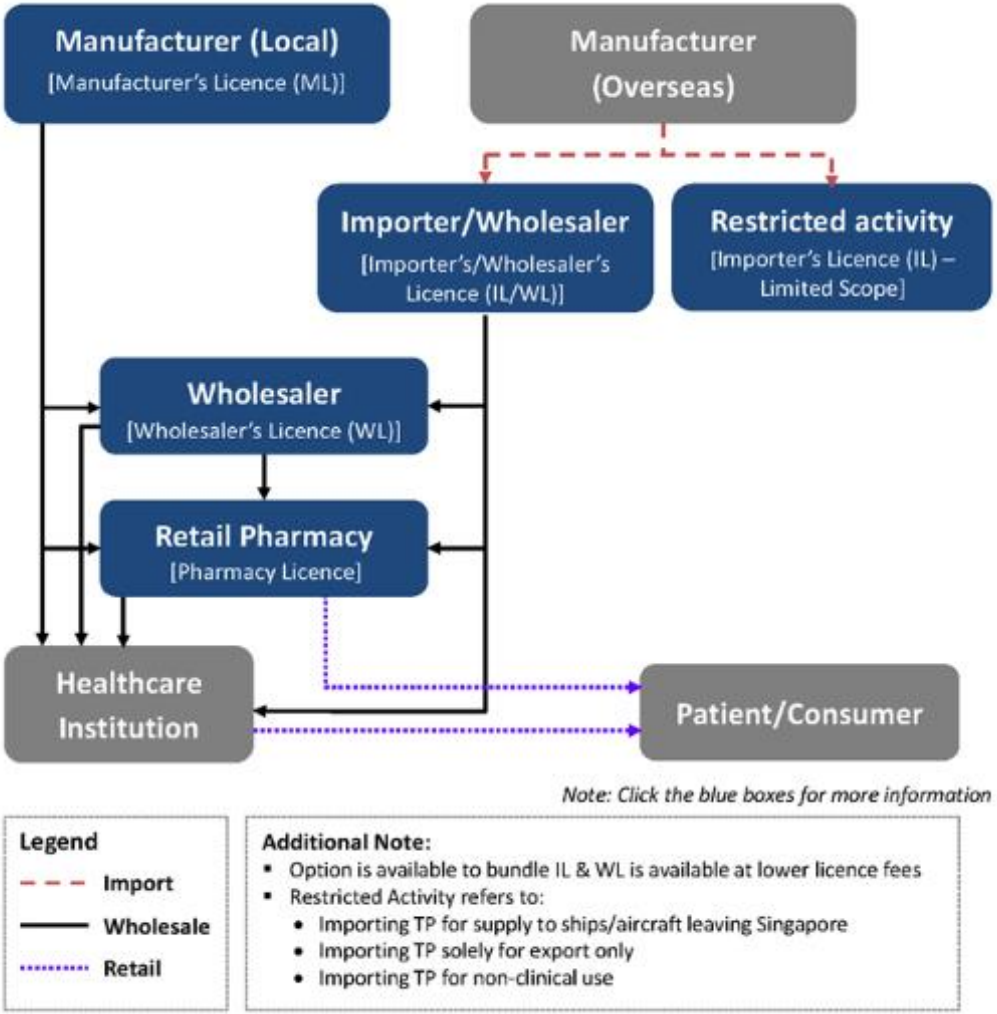
a) A holder of a Manufacturer's License for Therapeutic Products may import any health product without holding an Importer's License, if the health product is required for the purpose of carrying out the manufacture of a therapeutic product in accordance with the conditions of the Manufacturer's License.

b) The holder of a Manufacturer's License may also supply by wholesale any therapeutic product manufactured by the holder under the Manufacturer's License without holding a Wholesaler's License.

Licenses for Health Product

4. Form A Poisons License (FAPL). Any company, unless exempted under the Poisons Act, would need a license for the purpose of import, possess for sale, sell or offer for sale any poisons.
5. **Approval to Import / Export Therapeutic Products containing psychotropic substances.** Companies importing or exporting psychotropic substances should also hold a valid Form A Poisons Licence, Therapeutic Product Importer Licence or Therapeutic Products Wholesaler's Licence as appropriate. **Import or export any consignment of Psychotropic Substance or Restricted Substance in or out of Singapore for legitimate and authorized use of these substances, is regulated under Misuse of Drug Act .**
6. License to manufacture controlled drugs, License to import/export Controlled Drugs and License to sell Controlled Drugs by wholesale under Misuse of Drug Act.
7. Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) to ensure the reliability and quality of pharmaceutical materials and products during the manufacturing and distribution process.

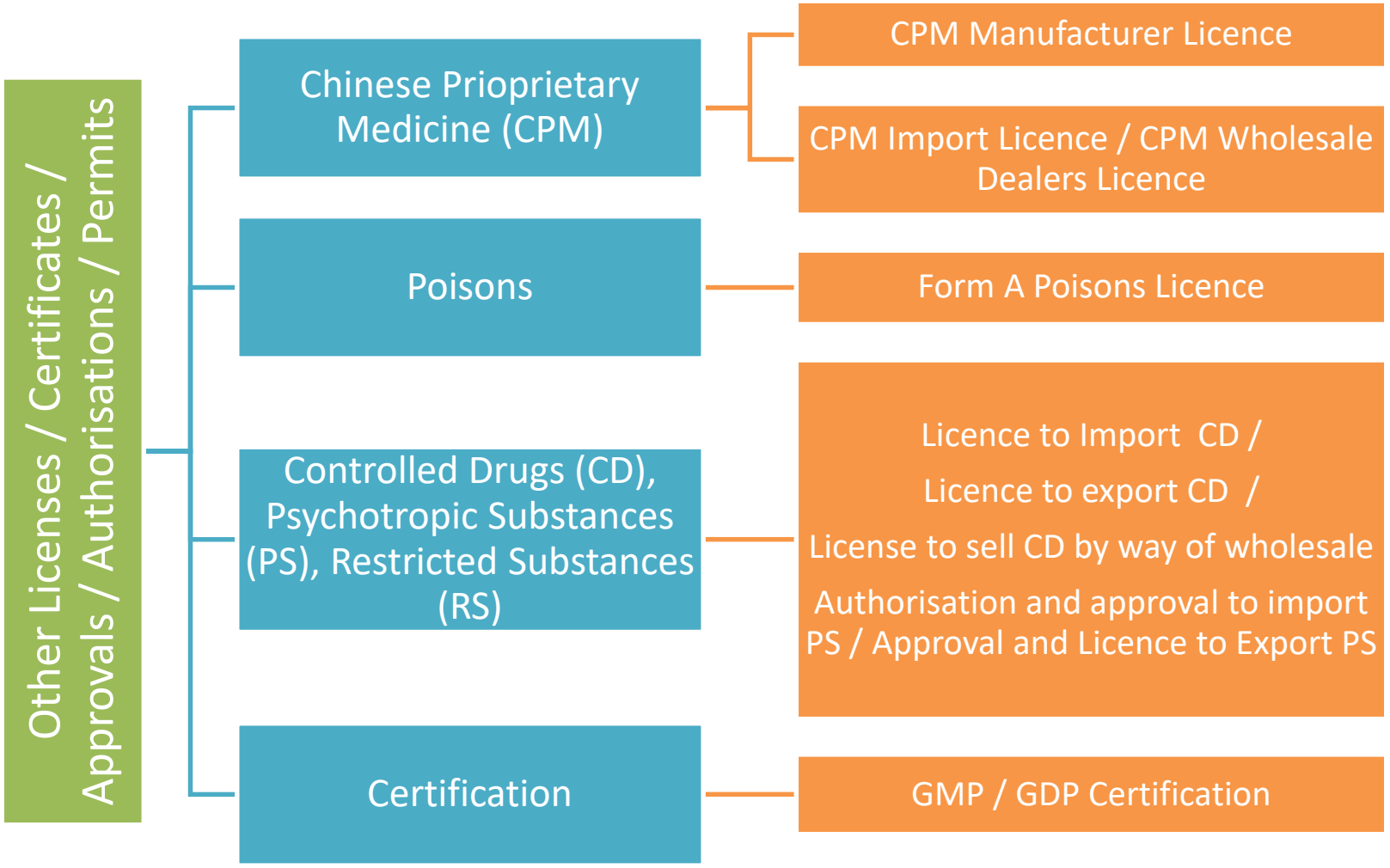
Supply Chain of Therapeutic Products and the Licensing Requirements



Local importers, wholesale dealers and exporters are required to hold the relevant licenses as listed on the left, for the importation and wholesale dealing of products regulated under these three Acts. Importers and wholesale dealers are expected to comply with the relevant legislative and regulatory requirements as well as the HSA's Good Distribution Practice standard.

Resource:
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview.html

Supply Chain of Therapeutic Products and the Licensing Requirements



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Hazardous Substances under NEA

National Environment Agency

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NEA - Regulations on Hazardous Substances (HS)

- **The National Environment Agency (NEA) plays an important role in regulating Hazardous Substances (HS) in Singapore.**
- **Hazardous substances controlled by NEA are generally those that**
  - Pose a mass-disaster potential
  - Are highly toxic and polluting
  - Generates waste which cannot safely and adequately disposed of
- **Pollution Control Department (PCD) of NEA controls toxic and environmentally hazardous chemicals under The Environmental Protection and Management Act (EPMA) and The Environmental Protection and Management (Hazardous Substances) Regulations.**

NEA - Regulations on Hazardous Substances (HS)

- **Many of the chemicals used in the study of Biochemistry are listed as dangerous goods (DG / Hazmat) e.g. Hydrocyanic acid used in reagent kits for medical purposes, Sodium hydroxide for biochemical tests.**

- **The full list of hazardous substances listed in the 2nd schedule of the EPMA can be found in TABLE 1 - LIST OF CONTROLLED HAZARDOUS SUBSTANCES**
  (*please refer to resource file for the full list ,or download from* https://www.nea.gov.sg/docs/default-source/default-document-library/hs--table-1.pdf)

NEA - Regulations on Hazardous Substances (HS)

- **The first two substances in TABLE 1 is shown below. Note that some items might have exclusions.**
- **Based on the TABLE 1**
  https://www.nea.gov.sg/docs/default-source/default-document-library/hs--table-1.pdf

1. 1,2-dibromoethane (EDB) does not have any exclusion, hence the HS license has to be obtained under all circumstances.
2. For acetic acid, as long as it does not contain more than 80% weight in weight, or if it is for photographic use, it is not necessary to obtain the HS license.

	Substance	Exclusion
1)	1,2-dibromoethane (EDB)	
2)	Acetic acid	Substances containing not more than 80%, weight in weight, of acetic acid; Preparations and solutions for photographic use.

HS License

- **Any person who wishes to import, sell or export, any Hazardous Substance controlled under EPMA must obtain a Hazardous Substances License.**
- **A license will be issued to a person if:**
  - he could show proof that the Hazardous Substances will be stored safely in an approved location and in compliance with the storage requirements
  - the use of the Hazardous Substances at his factory has been approved
  - he has sat and passed the Management of Hazardous Substances Course conducted by Singapore Environment Institute (SEI), and
  - his academic qualification must be at least a technical diploma

HS Permit

- **Any person who wishes to purchase, store and/or use any hazardous substance controlled under the Environmental Protection and Management (Hazardous Substances) Regulations must obtain a Hazardous Substance Permit.**
- **A Permit will be issued to a person if:**
  - he could show proof that the Hazardous Substances will be stored safely in an approved location and in compliance with the storage requirements;
  - the use of the Hazardous Substances at his factory has been approved
  - he has declared that he has read and understood the Environmental Protection and Management Act (EPMA) and its Regulations.

Explosive Precursors under SPF

SPF – Regulations on Explosive Precursors (EP)

- An **explosives precursor** is a chemical substance which can be made into an explosive with relative ease e.g. by mixing or blending with other substances, or by simple chemical processing.
- The focus of the Arms & Explosives Act under SPF is to monitor and regulate the use and movement of explosive precursors within Singapore.
- The **15 explosive precursors** that have been identified are widely used for research, industrial and agricultural purposes.
- They were assessed based on their chemical properties and their widespread use in Singapore and also on their potential for use by terrorist in improvised explosive devices.

Many household items are explosive precursors

SPF – Regulations on Explosive Precursors (EP)

The table below is extracted from the list of explosive precursors, together with the exclusion criteria.

https://www.police.gov.sg/e-services/apply/licenses-and-permits/~/media/spf/files/e-services/list_of_15_eps.pdf

LIST OF 15 EXPLOSIVE PRECURSORS

		Exclusions
1.	Ammonium Nitrate	a. aqueous solutions containing less than 60% weight in weight of ammonium nitrate b. any material in solid form comprising a mixture of components, one of which is ammonium nitrate, where the nitrogen content derived from ammonium nitrate is less than 28% by weight of the said mixture.
2.	Ammonium Perchlorate	-

SPF – Regulations on Explosive Precursors (EP)

Main licenses for Explosive Precursors:

Long Term Licences

(a) Licence to possess explosive precursors
(b) Licence to deal in explosive precursors
(c) Licence to manufacture explosive precursors
(d) Licence to store explosive precursors

Short Term Licences

(a) Licence to import explosives precursors
(b) Licence to export explosive precursors

SPF – Regulations on Explosive Precursors (EP)

Criteria on application for licenses to deal in, manufacture, possess and/or store explosive precursors include

- The applicant, directors/ partners and staff who will be directly involved in the handling explosive precursors must fulfil the following criteria:
  a) be a fit and proper person e.g. free from criminal record; and
  b) have the relevant experience and knowledge in the handling of explosive precursors.
- Storage Facilities
  - There must be proper and secured facilities for storing of the explosive precursors.

Petroleum and Flammable Material under SCDF

SCDF – Regulating Petroleum and Flammable Materials (P&FM)

- Petroleum and flammable materials can pose fire risks and endanger life and property in the event of fire. It is also important that such materials do not fall into the hands of terrorists or their collaborators and be used as weapons for mass destruction.
- SCDF controls licensing and step up the safety measures for the movement and distribution of P&FM in Singapore under the Fire Safety Act and Fire Safety (Petroleum & Flammable Materials) Regulations 2013 .
- Chemicals regulated under the Fire Safety (Petroleum & Flammable Materials) Regulations 2013 are divided into 3 groups
  - Petroleum
  - Flammable materials
  - Mixtures that contain petroleum and / or flammable materials.

SCDF – Regulating Petroleum and Flammable Materials (P&FM)

- Anyone who intends to import, transport or store flammable materials at any premise beyond the stipulated exemption quantities is required to obtain an import license or storage license from SCDF. Transport licensing will be covered in a later lesson.
- All storage of P&FM, regardless of quantity stored, have to comply with fire safety requirements for storage of flammable materials in premises. Storage license is not required if the quantity stored or kept is below the license exemption quantity The exemption quantities for the 366 classes of Flammable Materials can be found in the link below.

  https://www.scdf.gov.sg/home/fire-safety/petroleum-and-flammable-material-licences/general-information-pfm-licence

  https://www.scdf.gov.sg/docs/default-source/scdf-library/p-fm/complete-list-of-licensable-p-fm-2018.pdf

SCDF – Regulating Petroleum and Flammable Materials (P&FM)

The following product are exempted from P&F license application:

- Adhesives
- Cigarette lighters and portable gas lighters
- Cosmetic and beauty products including hair styling products
- Food and beverages including beer, wine and liquor
- Insecticides and pesticides
- Lacquer solvents
- Lubricants
- Medicine
- Paints
- Pharmaceutical products
- Varnishes

https://www.scdf.gov.sg/home/fire-safety/petroleum-and-flammable-material-licences/general-information-pfm-licence

Summary of regulations on regulating Pharmaceutical, Bio-chem and DG

HSA	• Manufacturer's License for Therapeutic Products / CPM • Import License / Wholesale License for Therapeutic Products / CPM • Authorisation and approval to import Psychotropic Substances (PS) and Approval and Licence to export PS • License to import / export Controlled Drugs and license to sell Controlled Drugs by wholesale. • Form A Poison License • GMP / GDP certification
NEA	• HS License to import, sell or export • HS Permit to purchase, store and/or use
SPF	• Licence to possess explosive precursors • Licence to deal in explosive precursors • Licence to manufacture explosive precursors • Licence to store explosive precursors • Licence to import explosives precursors • Licence to export explosive precursors
SCDF	• P&FM Import License • P&FM Storage License

Today's Problem

1. **Benzodiazepines** is considered as a **controlled drug** under HSA, to be able to import and deal **Benzodiazepines**, PharMax needs to apply to **HSA** for
   - License to import Controlled Drugs
   - License to sell Controlled Drugs by wholesale.

2. **Orapred** is classified as **Therapeutic Product** under **HSA.** To be able to bring in and deal **Orapred**, PharMax needs to apply to HSA for
   - Import License (IL) for Therapeutic Products.
   - Wholesale's license(WL) for Therapeutic Products

Today's Problem

3. Ammonia Reagent Set which contain Ammonia, 15% weight in weight, falls under the **Hazardous Substances** List under **NEA**. Ammonia is used as a lab reagent and is list under Annex I, PharMax has to apply for license / permits individually. (If it is a lab reagent but does not appear in Annex I, they can apply for Laboratory reagents Except Those in Annex I in their Hazardous Substances License or Permit.) Hence, import and store **Ammonia Reagent Set**, PharMax needs to apply to NEA for

- HS License to import
- HS Permit to store

Today's Problem

4. Ammonium Perchlorate is classified as one of the 15 **explosive precursors (EP)** by **Singapore Police Force (SPF)**. As a wholesaler, PharMax is involved in importing, distributing of **Ammonium Perchlorate**, hence, they will need to apply to SPF for

- license to import explosive precursors
- license to deal in explosive precursors.

5. Acetylene is a **Flammable Material (FM) under Singapore Civil Defence Force (SCDF).** To import and store **Acetylene (15 kg)**, PharMax needs to apply to SCDF for

- P&FM Import License
- P&FM Storage License (required as it is beyond the stipulated exemption quantities .i.e.10 kg)

Learning Outcomes

- Identify the regulatory authority regulating the import, storage and export of pharmaceutical bio-chem.
- Describe specific import requirement for pharmaceutical and bio-chem product including permits and licenses application.

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