

Strategies for Managing and Mitigating Drug Shortage by Taiwan FDA

Mei-Chen, Huang
Senior Technical Specialist, Division of Medicinal Products,
Taiwan FDA



衛生福利部
食品藥物管理署
Taiwan Food and Drug Administration

<http://www.fda.gov.tw/>

Drug Supply Chain



Licensed pharmaceutical holder



Pharmaceutical Affairs
Act §27-2



Trace and track system
of medicinal products

Pharmaceutical wholesaler



Draft regulations to
control the supply of
drugs in shortage.



Drug Distribution
Monitoring System

Medical institutions



Drug Shortage
Management



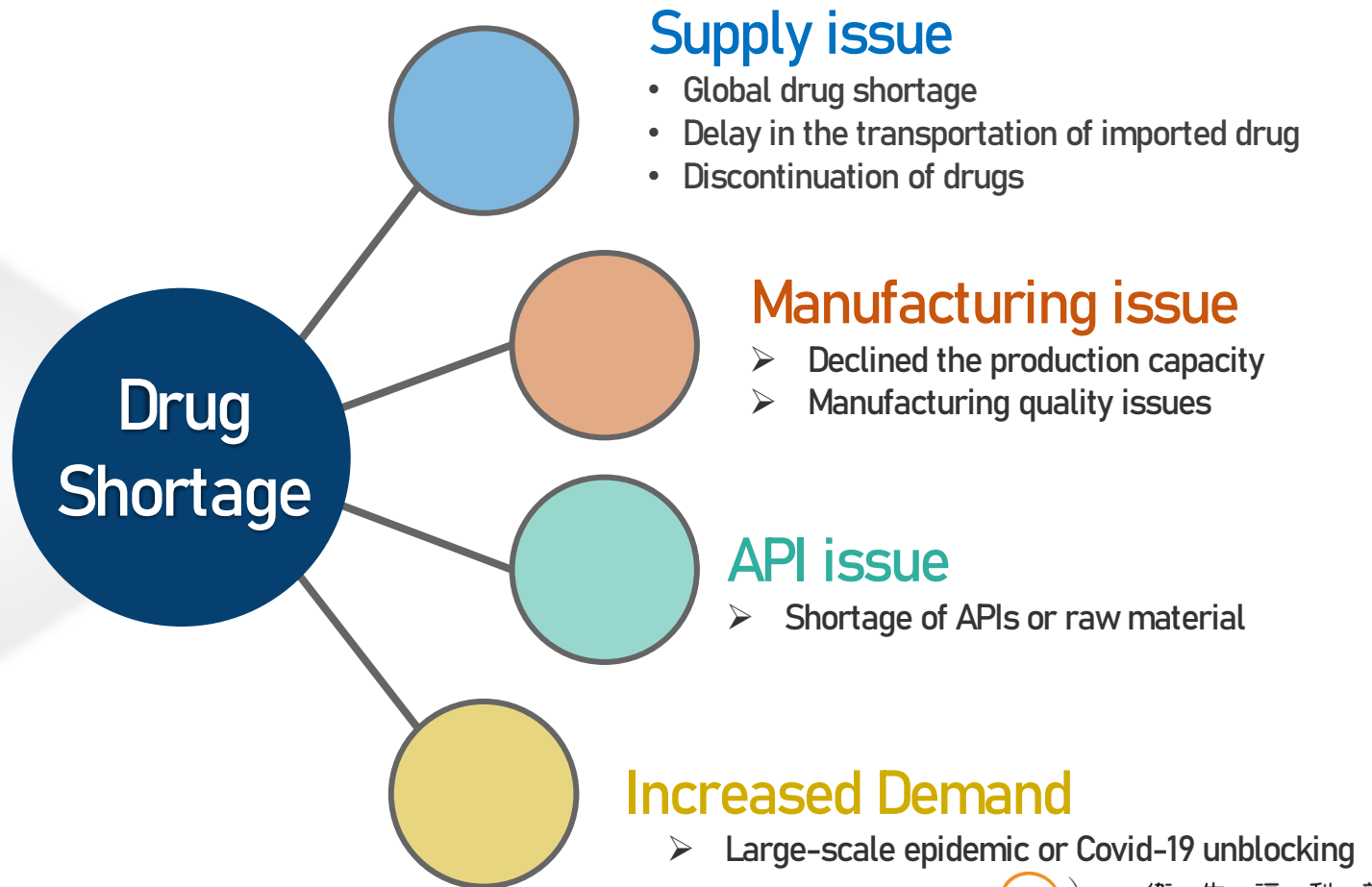
Drug Supply
Management System



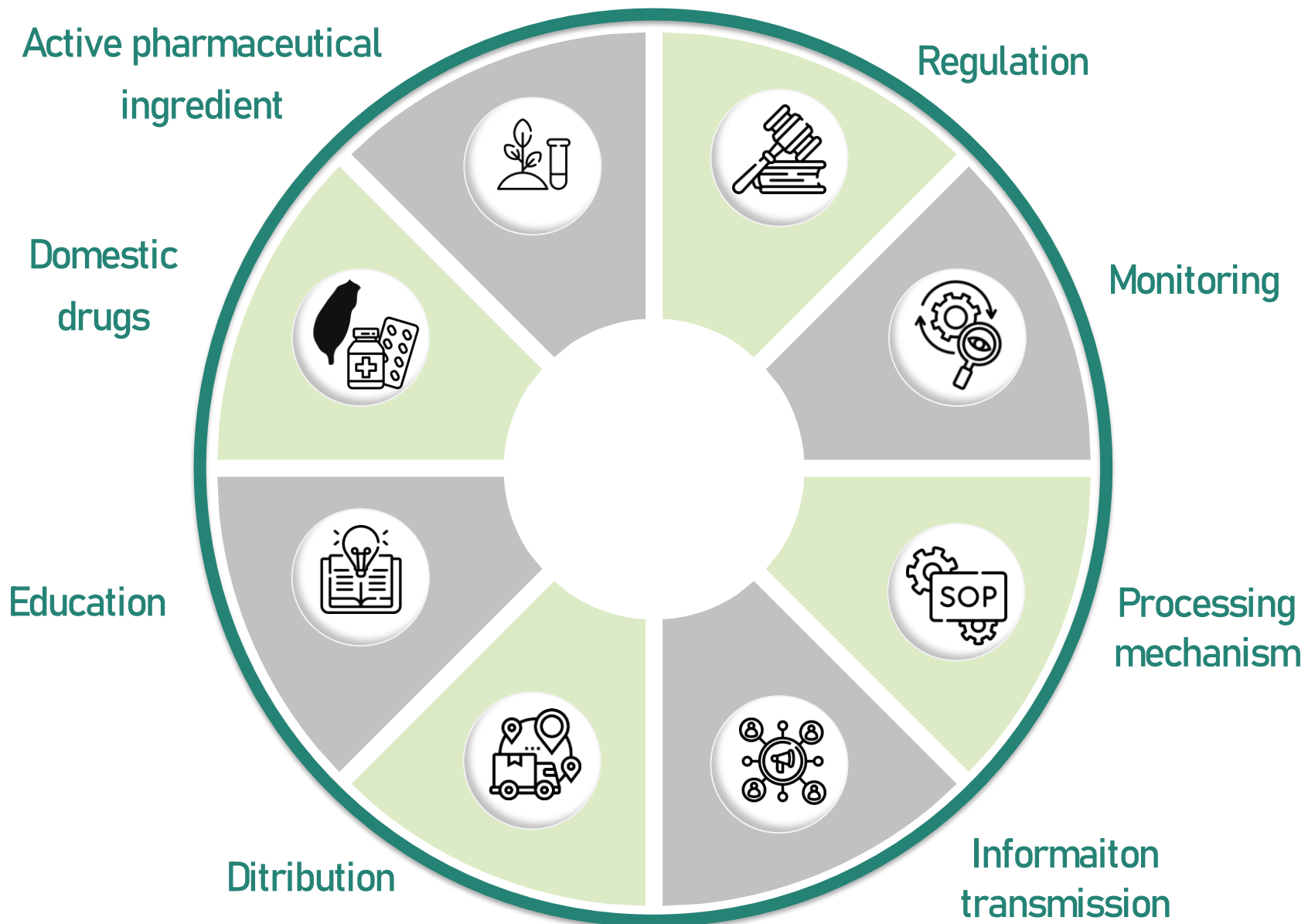
Taiwan's National
Health Insurance
Database

Drug Shortages

Due to factors such as epidemics, wars or inflation, how to avoid drug shortage is an important issue among countries.








Strategies to Prevent Drug Shortages



Essential Drugs List

Pharmaceutical Affairs Act § 27-2

Mainly refers to : (481 medicines in edition 2023)

-  World Health Organization (WHO) Essential Medicines List.
-  Recommendations from domestic medical associations.
-  Medications required for emergency patients in the List of Essential Medicines of the United States.
-  Reserved medicines according to the Mobilization of Reserve Medicines and Medical Devices Regulations.(mainly for trauma and emergency care)
-  Antimicrobial drugs and vaccines recommended by Taiwan CDC.

藥事法第二十七條之二必要藥品清單 V2.0

編號	藥品名稱及成分	劑型
1	麻醉劑(Anaesthetics)	
1.1	全身麻醉劑及吸入氣體(General anaesthetics and medical gases)	
1	desflurane	吸入劑型
2	etomidate	吸入劑型
3	nitrous oxide	吸入劑型
4	ephedrine	吸入劑型
1.2	術前用藥及鎮靜劑(Preoperative medication and sedation for short-term procedures)	
5	midazolam	口服劑型
2	抗過敏及治療過敏反應藥品(Antiallergics and medicines used in anaphylaxis)	
6	mizolastine	口服劑型
3	解毒劑(Antidotes and other substances used in poisonings)	
7	naloxone	注射劑型
8	penicillamine	注射劑型
9	desferrioxamine(deferoxamine)	注射劑型
10	edetate calcium disodium	注射劑型
11	antivenin of B. multicinctus and N. naja atra	注射劑型
12	antivenin of D. acutus	注射劑型
13	antivenin of Tr. Mucrosquamatus and Tr. Gramineus	注射劑型
14	calcium folinate (leucovorin)	口服劑型
15	deferasirox	注射劑型
16	flumazenil	注射劑型
17	glucagon	注射劑型
18	pralidoxime	注射劑型
19	protamine sulfate (protamine sulphate)	注射劑型
4	抗癲癇/海癲藥品(Anticonvulsants/antiepileptics)	
20	diazepam	口服劑型 (速效用液劑)
21	lorazepam	注射劑型
22	phenobarbital	注射劑型
23	phenytoin	注射劑型
24	valproic acid and derivatives (eg. sodium valproate)	注射劑型
25	vigabatrin	口服劑型
26	clobazam	口服劑型
5	抗感染藥品(Anti-infective medicines)	
5.1	驅蟲藥品-抗腸蠕蟲、抗血吸蟲、抗吸蟲(Anthelmintic-cs-intestinal antihelminthics, Antifilarials, Antischistosomes and other antitrematode medicines)	
27	levamisole	口服劑型
28	praziquantel	口服劑型
29	quinine	口服劑型
5.2	抗細菌藥品(Antibacterials)	
5.2.1	β-內酰胺類(Beta-lactam medicines)	

Reporting Responsibility of Industry

Pharmaceutical Affairs Act

§ 27-2 The time at which essential drugs license holders shall report their incapability to continue drug supply.

- In general situations : **6 months** ahead of time.
- In irresistible situations : within **30 days** of the incident's occurrence.

TFDA may post information about alternative drugs on a public website and may grant special permission to manufacture or import the drug.

§ 96-1 Penal Provisions

- TFDA may public announcement of the base information of the firm, and the violation detail.
- In the case of a serious violation or continued violation, may be imposed with a fine of not less than NT\$60,000 but not more than NT\$300,000.



Special Permission to Manufacture/Import

According to Regulation for Drug Shortage Management (Announced Date: 2016-07-11)



1

Assessment

The drug is incapable of continuing supply and there is no alternative drug available.



2

Solicitation

Public solicitation of alternative drug at "Drug Shortage Management System (DSMS)"



3

Approval

Approval of the project application form pharmaceutical company.



4

Publication

Announce the approval information on the DSMS website.



Reporting System

- Established Drug Supply Management System (website) in 2016.
- Online reporting and information sharing.
- Unified reporting format, including Shortage Report and Supply Investigation Report.



西藥供應資訊平台

請輸入藥品關鍵字



搜尋

登入

首頁 設置宗旨 公告資訊 專案輸入/製造專區 建議使用替代藥品品項 無替代藥品品項 已恢復供應品項 下載及相關連結 案件查詢 FAQ 操作手冊



通報系統
我要通報

社區藥局通報
評估結果專區

專案輸入/製造
專區

建議使用替代
藥品品項

無替代藥品
品項

已恢復供應
品項

案件辦理情形

相關連結

FAQ

最新消息

- 2023/03/23 因「Melphalan 注射劑型」短缺，公告已徵得有意願供應之廠商及相關資訊
- 2023/03/23 因「Epinephrine 注射筆劑型」短缺，徵求有意願供應之廠商
- 2023/03/22 因「Ixabepilone 注射劑型」短缺，徵求有意願供應之廠商
- 2023/03/22 因「Cisatracurium 注射劑型」短缺，公告已徵得有意願供應之廠商及相關資訊
- 2023/03/22 因「Magnesium oxide 口服劑型」短缺，公告已徵得有意願供應之廠商及相關資訊
- 2023/03/21 因「Verteporfin 注射劑型」短缺，公告已徵得有意願供應之廠商及相關資訊
- 2023/03/17 因「Tocilizumab 靜脈點滴注射劑型」短缺，公告已徵得有意願供應之廠商及相關資訊
- 2023/03/15 因「Hydralazine 口服劑型 (以25毫克或50毫克優先)」短缺，徵求有意願供應之廠商
- 2023/03/15 因「Moxifloxacin 注射劑型」短缺，公告已徵得有意願供應之

西藥供應資訊平台短缺通報案件供應狀態調查表 (本單狀態：待審核)

一、通報短缺品項資訊

案件編號	1120001
藥品許可證字號	衛署藥字第021860號
廠名	"永信" 宏亞和信藥業有限公司
學名(成分)	AMOXICILIN CAPSULES 500MG "YUNG SHEN"
劑型	AMOXICILIN, AMOXICILIN
包裝規格	500mg/100g

二、藥品供應狀態

供應狀態	備註(可複選，請於備註欄填寫3至5字)
1.1 供應正常	
1.2 投資中	
1.3 停產	
1.4 停產	
1.5 短期短缺或預期會短缺	
1.6 即將停產	

三、目前尚未分配方式

分配方式	備註
2.1 合約醫院	
2.2 非合約醫院	
2.3 醫用藥物供應	
2.4 社區藥局	
2.5 診所藥局	

四、供應資訊

供應資訊	備註
3.1 3.2 3.3 3.4 3.5 3.6 3.7 3.8 3.9 4.0 4.1 4.2 4.3 4.4 4.5 4.6 4.7 4.8 4.9 5.0 5.1 5.2 5.3 5.4 5.5 5.6 5.7 5.8 5.9 6.0 6.1 6.2 6.3 6.4 6.5 6.6 6.7 6.8 6.9 7.0 7.1 7.2 7.3 7.4 7.5 7.6 7.7 7.8 7.9 8.0 8.1 8.2 8.3 8.4 8.5 8.6 8.7 8.8 8.9 9.0 9.1 9.2 9.3 9.4 9.5 9.6 9.7 9.8 9.9 10.0	

藥品短缺通報表

電話: (02) 28712121#4045
傳真: (02) 2875-7706
公務電子郵件信箱: shortage@fda.gov.tw

1. 通報者基本資訊

填表日期 2023/05/19
*通報者姓名
*聯絡電話
*單位類別
*機構名稱
*電子郵件

*快捷資訊來源 ○藥廠/藥商 ○食藥署 ○醫院 ○媒體 ○其他

下一步

- <https://dsms.fda.gov.tw>



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Active Monitoring



Global drug shortage events

- Drug shortage news and websites, such as US ASHP, TGA, Health Canada



Domestic clinical drug demand and supply situation

- Domestic infectious disease development trends, such as COVID-19, influenza, enterovirus



GMP warning letters

- Finished products and APIs
- US FDA, EDQM, PIC/S

Drug Distribution Monitoring System

Pharmaceutical wholesaler
stock data



Medical institutions

Place an order for medicine
with available wholesalers.



TFDA and TFPA

Monitor pharmaceutical
wholesalers' inventory
levels in real-time and
predict the risk of drug
shortages.



TFPA: Federation of Taiwan Pharmacists Associations

Cooperation



- Investigating the supply status of reported shortage drugs
- Assessing alternative drugs.
- Monitoring the recovery of the supply of reported shortage drugs.

- Coordinating with the drug license holders of shortage drugs to expedite the restoration of supply.
- Collaborating with pharmaceutical companies of alternative drugs to increase production or imports.
- Publishing information on drug shortages and their alternative drugs.
- Initiating solicitations for importing or manufacturing alternative drugs when necessary.

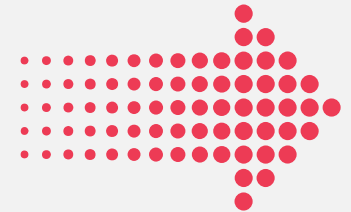
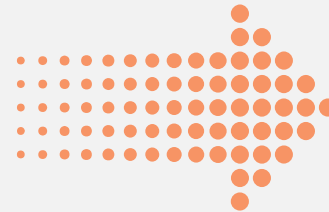
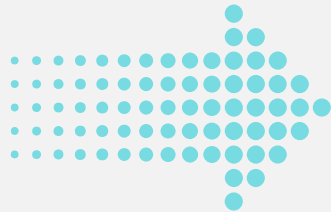
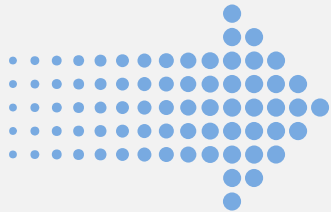
Standard Procedure

- Clinical impact and alternatives of drug shortage

Evaluate

- Publish on the website
- Inform relevant associations

Announce



Investigate

- The supply situation of drugs

Take action

- Encourage the supply of alternatives
- Grant special permission to manufacture or import if necessary

Follow up

- Resupply date
- Supply situation of alternatives.

Information transmission

Information of drug shortages

- Drug information
- Reason of shortage
- Supply situation and shortage period
- Alternative drugs



Drug Supply Management System (website)



Inform relevant associations



Open data files



Proper Pharmaceutical Distribution

Strengthening Drug Supply Monitoring.

Enhancing Distribution drugs to pharmacies.

- To **establish a distribution and allocation mechanism** for medications between pharmacies.
- **Monitoring** the supply of drugs at mid- and downstream vendors.
- **Reserve a certain percentage of drugs for clinics and pharmacies.**



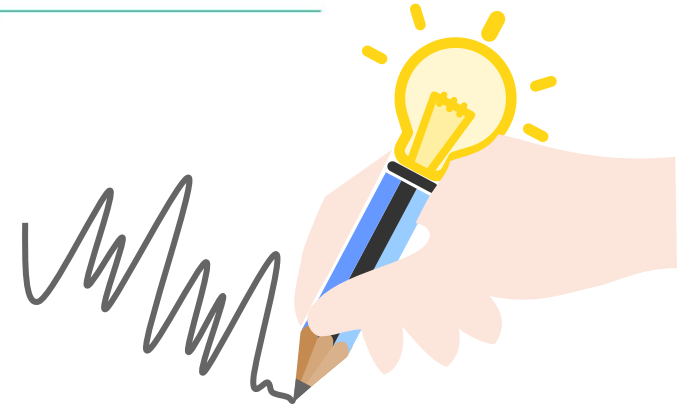
Healthcare Professional Education



- 1 How to report a drug shortage ?
- 2 How to check for medicine shortages ?
- 3 How to find alternative medicines ?
- 4 How to communicate with patients ?

Pharmaceutical Industry Education

TFDA advocate for pharmaceutical companies to:



Importing drugs:



1. Track the production and supply of drugs from foreign.
2. Increasing domestic safety stock levels.



Domestic drugs:

Stockpile APIs for at least 6 months.



Regularly review domestic medication demands.



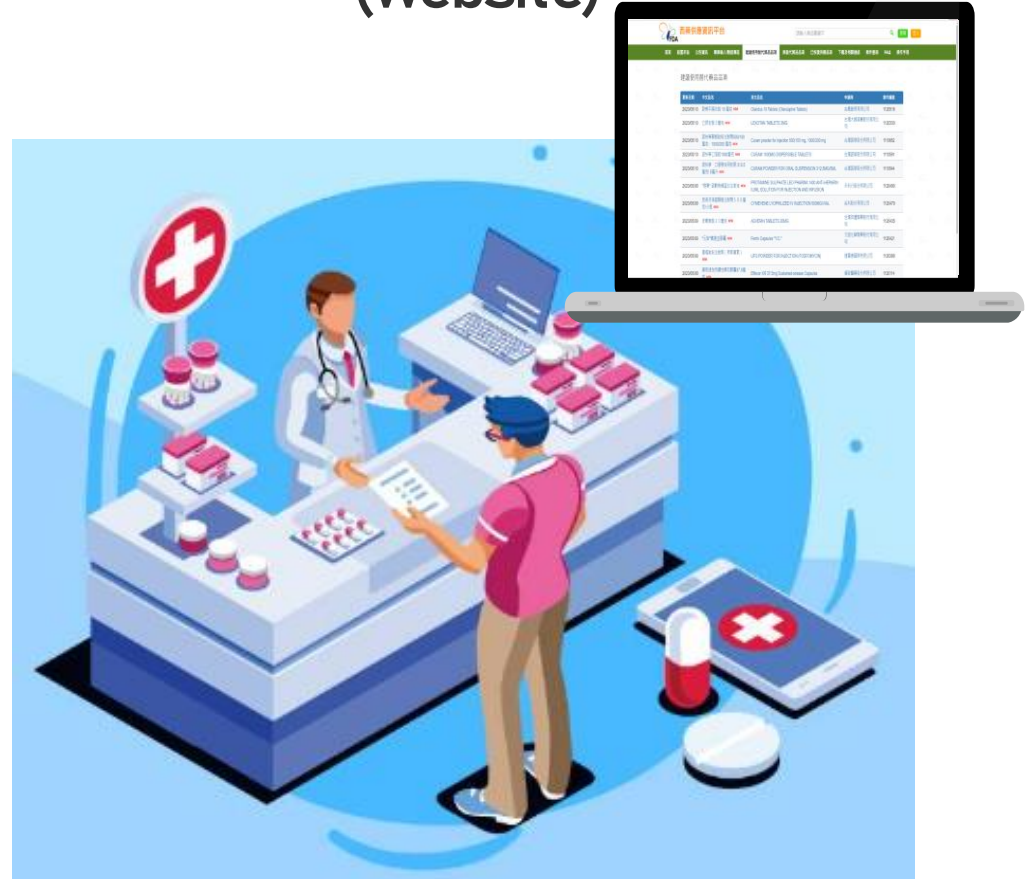
To strengthen internal information sharing and establish a dedicated drug shortage reporting window.

Public Education

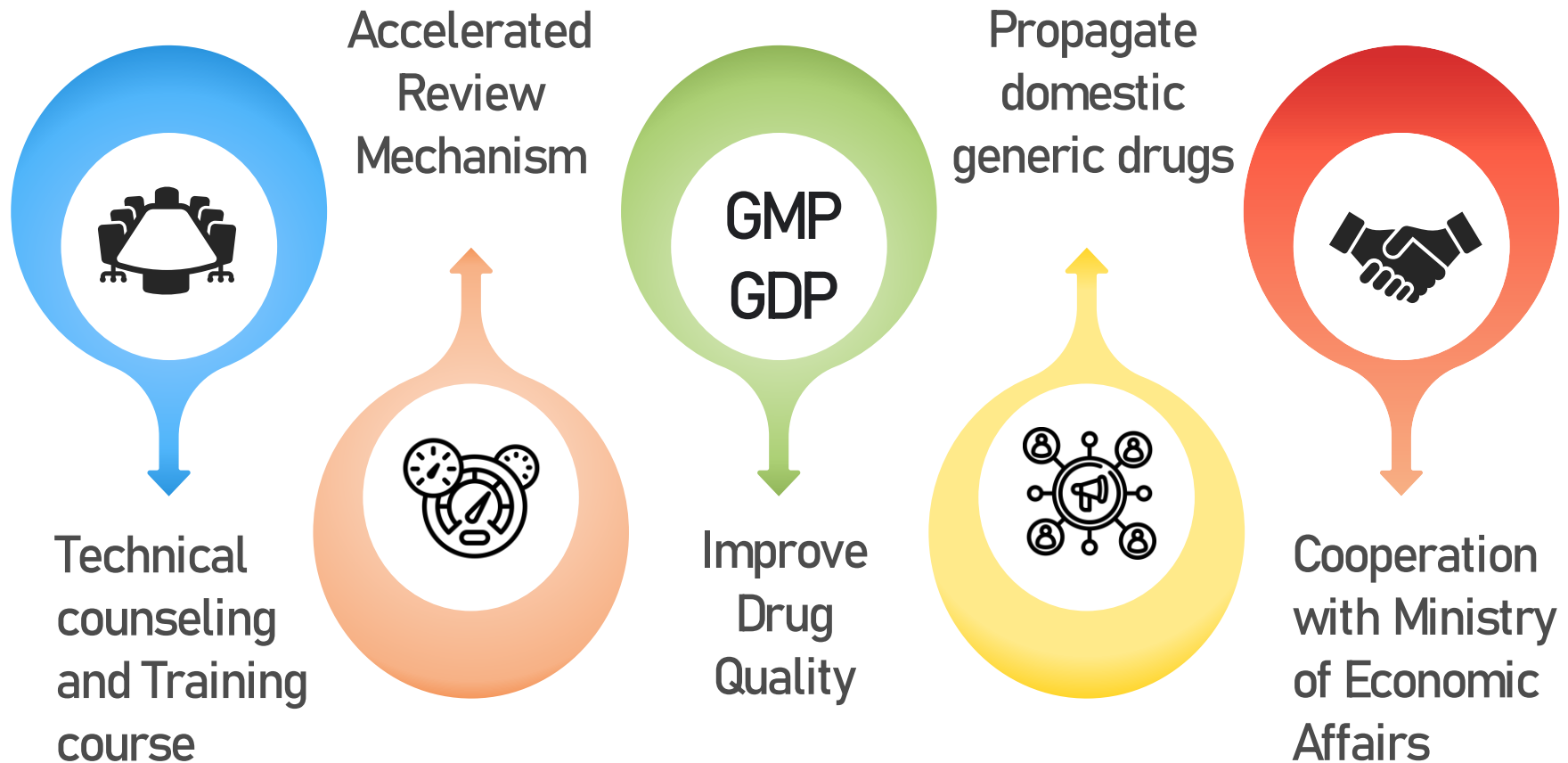
Promotional leaflets



Drug Supply Management System (website)

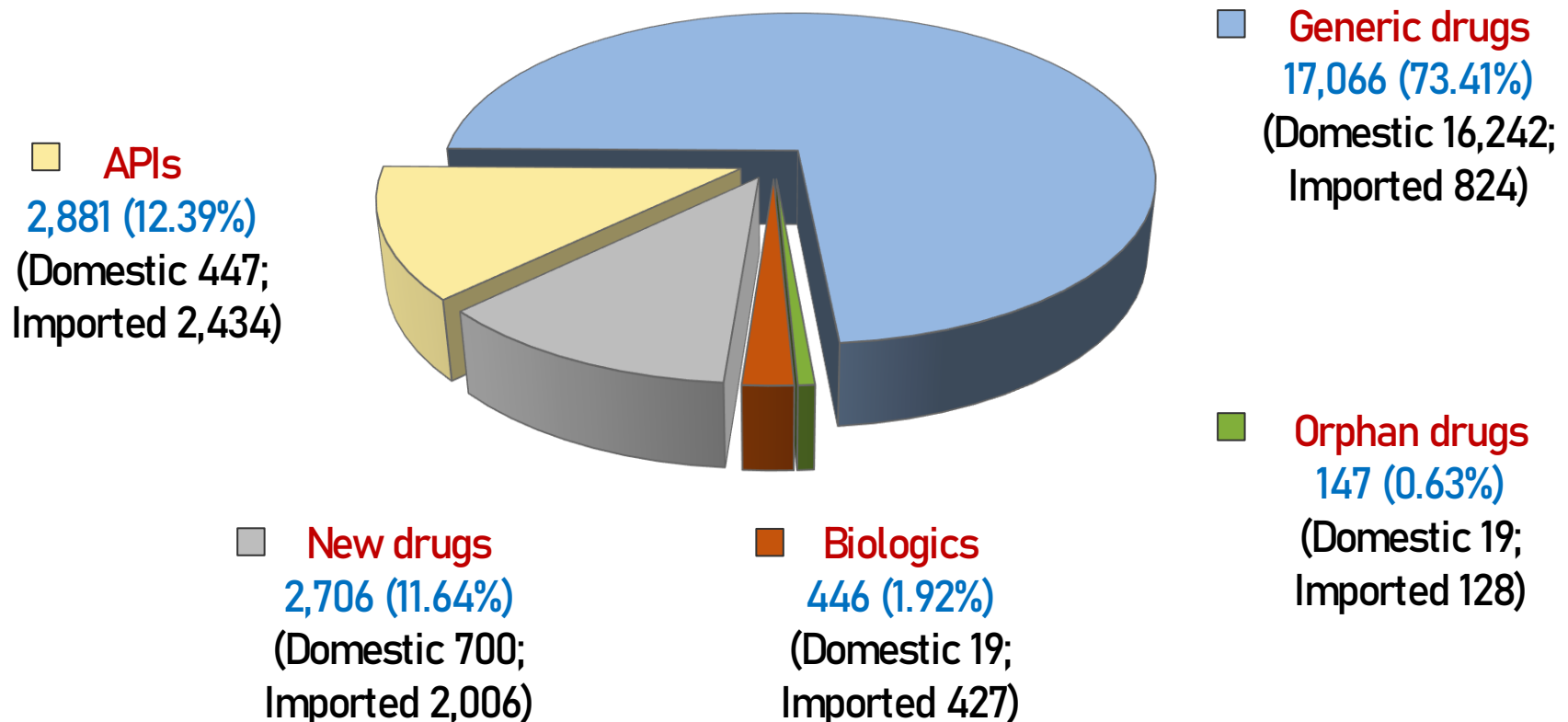


Encourage the Development



Domestic Drugs and Manufacturers in Taiwan

- **286** Manufacturers of drug products
- **15055** Domestic drug products
- **32** APIs manufacturers
- **447** Domestic APIs



Ensure the Supply



Accelerate the review of new source of API

Encourage local production of APIs

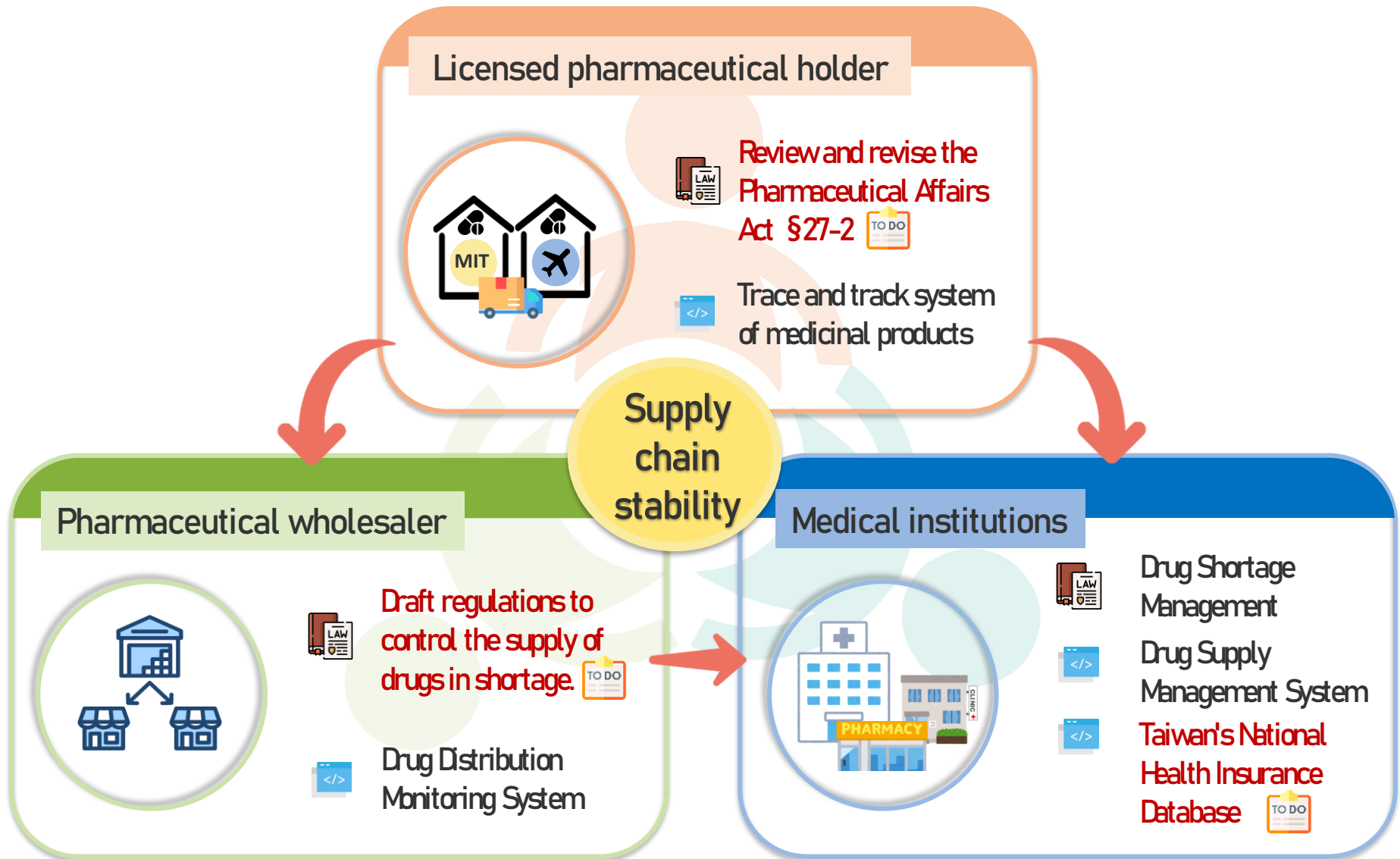
Encourage the Increase of APIs reserves

Encourage the Increase of sources of APIs

Provide incentives for using domestic APIs

*API: active pharmaceutical ingredient

Forecast





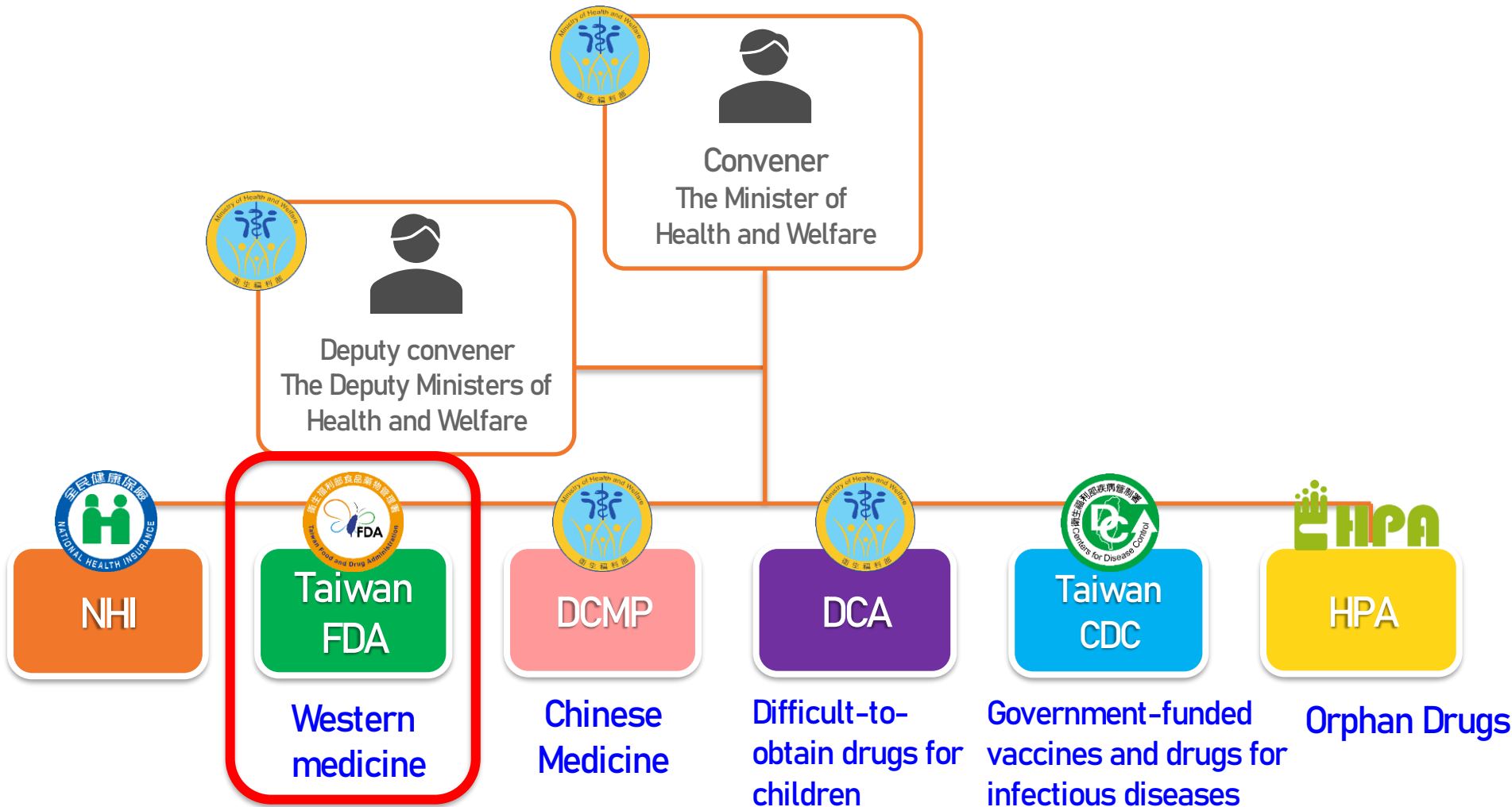
Thanks for your attention



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Drug Supply Management Center



- DCA: Department of Medical Affairs
- DCMP: Department of Chinese Medicine and Pharmacy

- NHI: National Health Insurance Administration
- HPA: Health Promotion Administration

Strategies to Prevent Drug Shortages



01 Develop domestic pharmaceutical industry



02 Enhance Drug Shortage Management



03 Ensure the supply of APIs