Chapter 14

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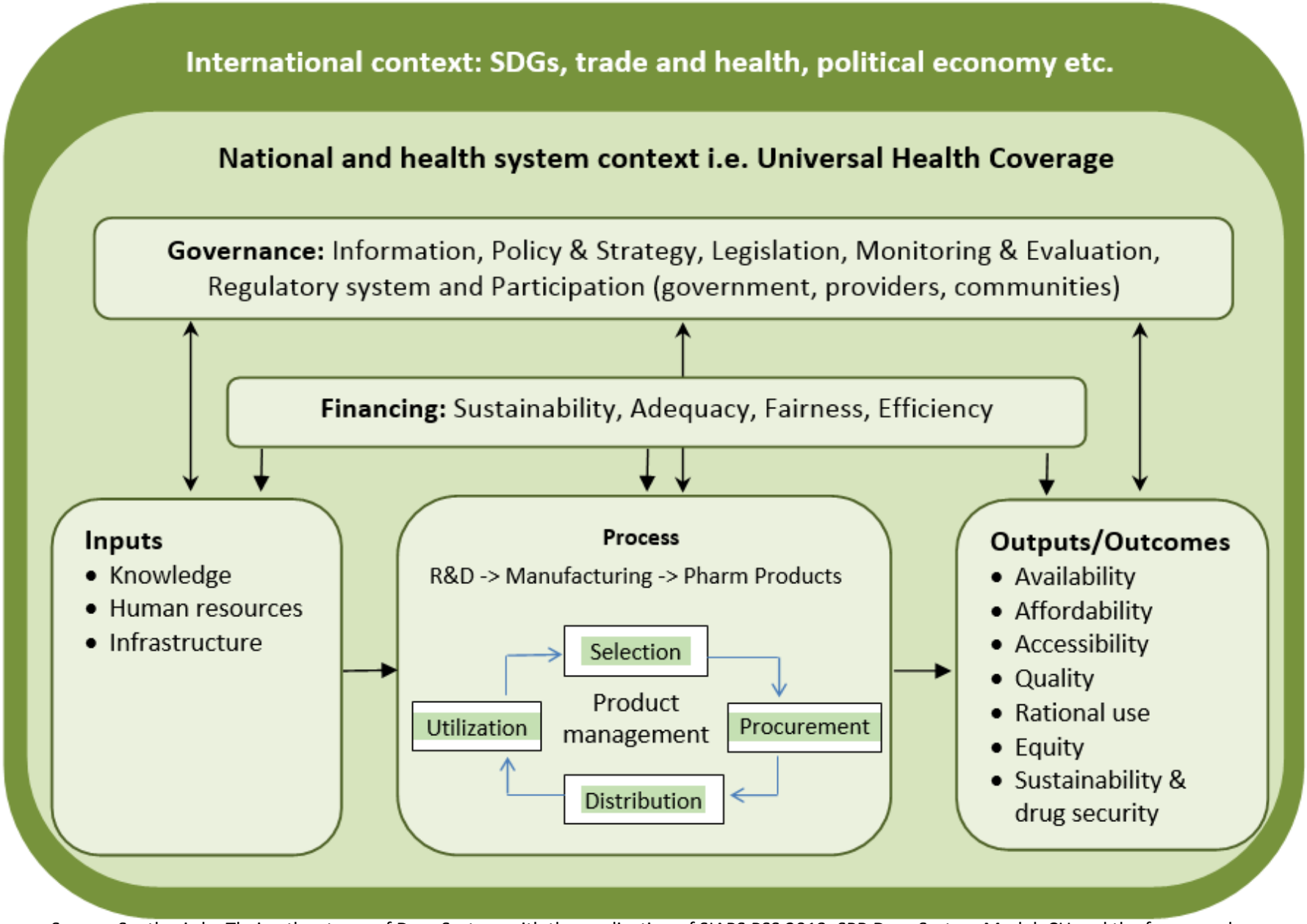
1. Summary against framework



Source: Synthesis by Thai author team of Drug System with the application of SIAPS PSS 2013, SPR Drug System Model, CU and the framework proposed by the Chair in the meeting at HSRI on 11 Feb 2019 (revised version as of 11 April 2019)

International context: SDGs, trade and health, political economy etc.

International Trade and Health

- Int trade agreement is unavoidable
- Impacts in various points of the systems
- Negative impacts e.g. higher drug expenditures, loss of opportunity for new innovation or generic medicines
- Thailand has knowledge and mechanisms to deal with these. However, still limited capacities and skills
- Position: delay process of TRIPS+
- Need more skills and knowledge (lessons learnt e.g. India / impact assessment)

Political Economy

Highlights of Thai performance

- WHO guideline on NLEM -> Thai NLEM -> Pharm benefit by insurance schemes
- Reference price - 1,490 items in 2019
- Patent / Compulsory licensing
- Enabling factors:
  - Triangle that moves the mountain
  - Knowledge generations
  - Critical mass of reformists
- Rooms for improvement: R&D, Pharm industrial sector

Policy

- Evolution: 1st NDP 2524 -> the draft of 4th NDP 2560-64
- **2551: the NDP cmt chaired by PM**
- Not MOPH Drug Policy
- 6 Sub-committees covering all important aspects
- Clear aims and objectives of the policy
- However, implementation is paved by roses – depend on FDA which has limited resources

Law and Regulations

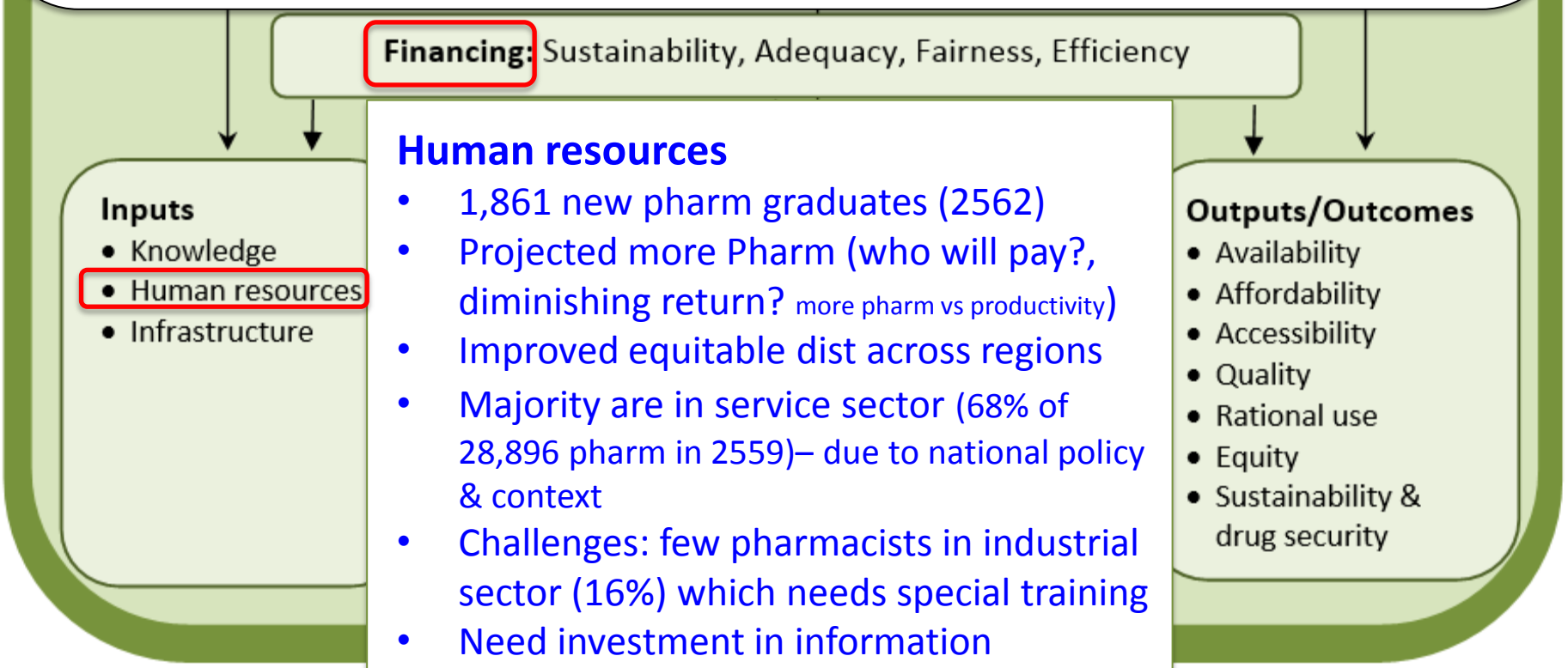
- Laws 33, PM-Regulations 1, Int Trade agreements 4

1. Control of products, 2. Control of professional & service provision, 3. Consumers, 4. Trade, 5. Third party

- Focus on "CONTROL"
- Challenges:
  - In response to online pharm, bio-pharm
  - Support/strengthen R&D, innovation, Pharm Industry
  - Role of GPO – PPP
  - Cost structure
- Recommendations on FDA Reform

Financing

- Current health expenditure about 4% of GDP (2558)
- Expenditure on drug as % of current health expenditure increased from 21% (2543) to 44% (2558) due to both price and quantity
- The chapter focuses on health insurance schemes but does not cover others and out-of-pocket
- The chapter shows sustainability, adequacy (compared to other countries), equity (?), efficiency (pool procurement), accessibility, quality



Human resources

- 1,861 new pharm graduates (2562)
- Projected more Pharm (who will pay?, diminishing return? more pharm vs productivity)
- Improved equitable dist across regions
- Majority are in service sector (68% of 28,896 pharm in 2559)– due to national policy & context
- Challenges: few pharmacists in industrial sector (16%) which needs special training
- Need investment in information

Selection

- Thailand -> NLEM -> Schemes -> health facilities -> community -> users???
- Evolution of selection by FDA (to Thailand and NELM-Aj Vichai's highlight)
- Key success: political will, law & regulations, process, social support, HR, accountability and transparency
- Challenges: orphan drug or medicines for rare diseases

Procurement and distribution

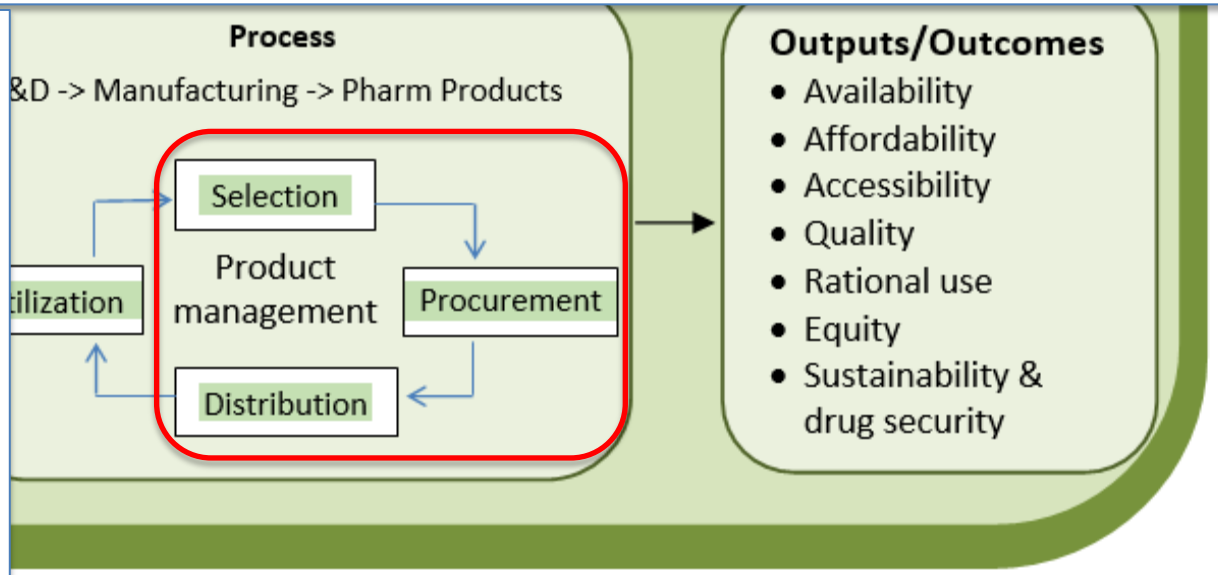
- Evolution of procurement: before UHC era (2001), UHC era (2002-now)
- Before 2001: h facility base, pool negotiation & procurement of few area/item
- UHC era: <u>A. UC Scheme level</u>: pool negotiation & procurement and improved distribution of high cost medicines, PD solution???

<u>B. National level</u>

B1. Vaccine management – pool procurement and improved distribution with VMI

B2. Antidote & antivenom by Rama

- Online Pharmacy?
- Distribution in com?
- ? in this chapter or not



Herbal medicines

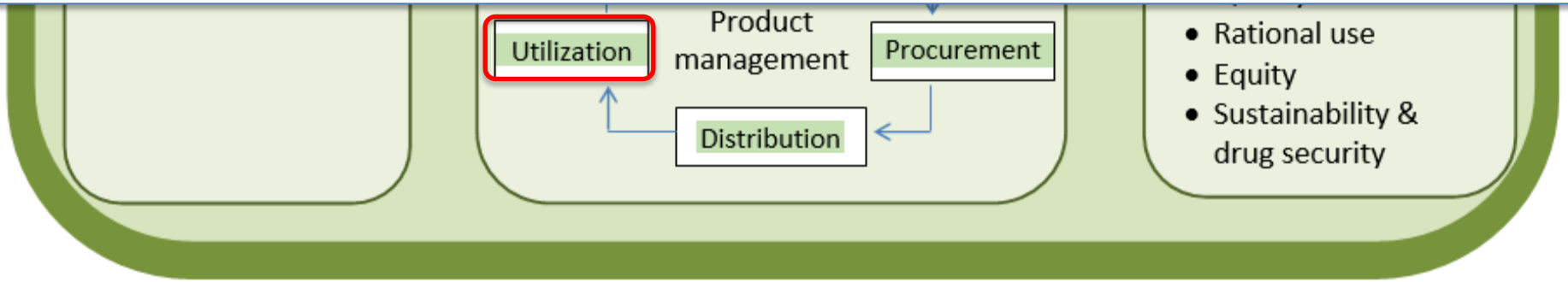
- Thai NLEM has 746 items, including 34 items of E2
    - Herbal medicines 74 items (traditional 50 + modern 24) or 10%
- ***Act on herbal medicines 2562***
- Factors on herbal medicines: PESTEL
- Politics (Thailand 4.0), Economy (ASEAN), Social (aging), Technology (GMP, innovation), Environment (green, climate change), Legal (Act)
- Raw material -> สมุนไพรแปรรูป -> Herb products
- Challenges: the same criteria of modern medicines (e.g. safety, efficacy) might be difficult. So some flexibilities (mentioned by Aj Vichai)

Biologics ชีววัตถุ

- Growth from 11% (2002) to 19-20% (2017) of total sales
- Concepts (biologics vs micro-molecule), definition of biosimilars and biobetters
- Categories: a. inactivated/subunit/DNA vaccine, b. therapeutic protein and c. advanced therapy medicinal products (ATMP)
- Situation in Thailand: พรบ เซลล์บำบัด, R&D, productions, regulations, selection to NLEM, UHC schemes, procurement, cold chain storage, distribution, use, M&E
- Lessons learnt from BioScience,
- Tech transfer, risk management, security, prevention of bio- terrorism

Utilization

- Country level: medicines = 40% of current health expenditure per capita (consistency across chapters)
- Scheme and facility level: ED รพ สป 80%, CSMBS non ED, RDU, DUE E2, non ED, wasted 2 billion baht (1% of drug expenditures 200,000 mln baht), GPP in ขย1 และ 2
- Community level:
  - Limited health literacy of medicines (antibiotics) in population
  - Drug management in community (in school, grocery)
  - RDU: irrational use of antibiotics in pet, food animals/aqua, citrus
- สภาองค์กรผู้บริโภค will be newly established. Which role in health?
- Challenges: regulations of fake information, online medicines, link with selection (e.g. Serratiopeptase)
- Problems in drug use: which problem and how to deal with



Industrial Pharmacy

- Ratio of import : local production = 65 : 35
- ประมาณ 75% ของรายได้ทั้งอุตสาหกรรมผลิตมาจากผู้ประกอบการประมาณ 30 ราย โดยองค์การเภสัชกรรมมีส่วนแบ่งการตลาดมากสุด (ประมาณ 9%)
- แม้จะมี พ.ร.บ.จัดซื้อฯใหม่ แต่การให้สิทธิพิเศษแก่องค์การเภสัชกรรมและการกำหนดราคากลางที่เหมาะสม ยังคงเป็นปัญหาหลักต่อการจัดซื้อภาครัฐ และความมั่นใจในการลงทุนพัฒนายาตัวใหม่ของภาคเอกชน
- Value chain: R &D, registration, manufacturing, logistics, marketing, export
- Currently, this chapter focuses at chemical medicines
- Challenges: Policy and government support on IP?, HR Pharmacy – service:IP:SAP 6:3:1, invest in R&D
- Further collaborative research -> global level

- Review roles and regulations on GPO
- Review NLEM
- CL by third party esp NGO
- Innovation
- Compared to other countries (every chapter)
- Vaccine Security Act ✓ vs Medicine Security Act? พรบ. ความมั่นคงทางยา

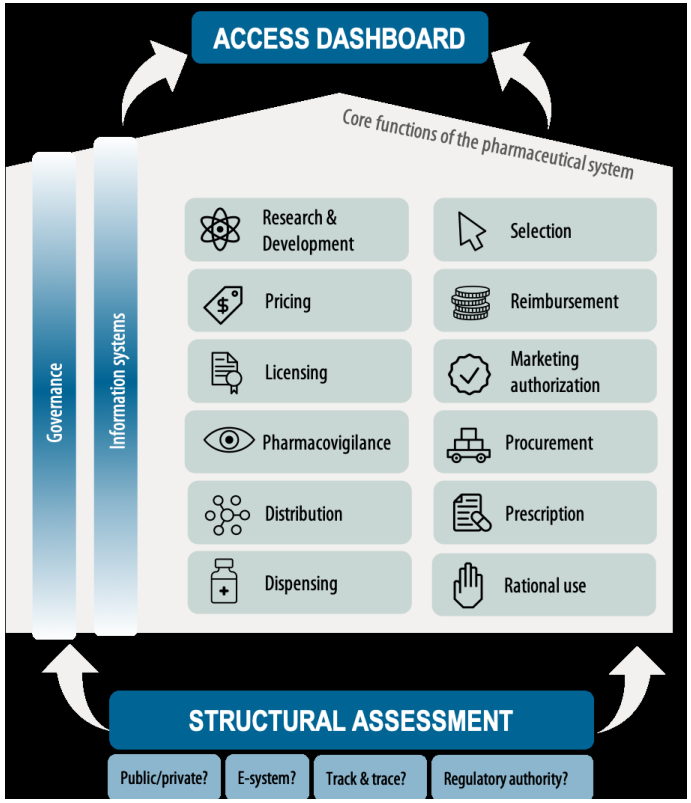
International context: SDGs, trade and health, political economy etc.

National and health system context i.e. Universal Health Coverage

Governance: Information Policy & Strategy, Legislation, Monitoring & Evaluation,

ระบบสารสนเทศด้านยา (reduce part of technology)

- Operation and analytic levels
- Generic vs personalize information
- Data, information and **systems**
- Focus on governance
- Focus on medicines, information, reduce T
- Usefulness of using information by consumers



eHealth components

Leadership and governance

Strategy and investment	**Services and applications**	**Legislation, policy and compliance**	**Workforce**
	Standards & interoperability		
	Infrastructure		

2. Highlights

From Aj Vichai

- Evolution of NLEM
- Reference price of medicines
- Compulsory licensing

3. Rooms for improvement

Drug systems

- Law and regulations to deal with new challenges such as e-commerce, online pharmacy, fake info, BioPharm
- Organizational/structure/function reforms: GPO, FDA
- Strengthening Research & Development
- Industrial pharmacy -> PPP
- Investment in information
  - Systems, Financing, HR Pharm and non-pharm
  - Big data: data collection, analysis and use of information

This book: Consistency across chapters, Duplication