

## Regulating Antibiotic Distribution in Thailand: Entry Point for Addressing Inappropriate Use.

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### Background

Exposure of susceptible bacteria to low doses antibiotics can lead to the selection of resistance. Evidence shows strong association between antimicrobial resistance and inappropriate use of antibiotics (1, 2). Among others, the Global Action Plan on AMR, adopted by the World Health Assembly in 2015 will optimize the use of antibiotics in human and veterinary medicines.

### Objectives

To investigate Thailand's importation, manufacture, distribution and regulation of antibiotics.

### Methods

Mixed method was used including

- In-depth interviews with 43 key informants from farms, health facilities, pharmaceutical and animal feed industries, private pharmacies and regulators,
- A review of the relevant drug regulations including the 1987 drug Act and the 2015 Animal Feed Quality Control Act and
- Database searches.

## Findings

The large number of licensed individuals involved in the antibiotic supply and provision are categorized by type of license granted to them under the relevant Acts and regulations (Table 1).

**Table 1.** The types and numbers of individuals involved in the distribution of antibiotics and other medicines, Thailand, 2016–2017

Type	License held	No. of individuals
<b>Licensed providers</b>		
Medicine importers	Pharmaceutical import	793 <sup>a</sup>
Medicine manufacturers	Pharmaceutical manufacture	187 <sup>a</sup>
Medicine distributors	Pharmaceutical sales	NA <sup>a</sup>
Medicine wholesalers	Pharmaceutical sales	NA <sup>a</sup>
<b>Retail drug stores or pharmacies</b>		
• Selling all medicines	Pharmaceutical sales	NA <sup>a</sup>
• Selling only ready-packed medicines	Pharmaceutical sales-ready-packed medicines only	3164 <sup>a</sup>
• Selling only ready-packed medicines for animals	Pharmaceutical sales-packed medicines for animals only	763 <sup>a</sup>
Human health facilities	Health facility	11 560 <sup>b</sup>
Importers of animal feed	Animal feed import	323 <sup>c</sup>
Animal feed mills	Animal feed manufacture	299 <sup>c</sup>
Animal feed stores	Animal feed sales	27165 <sup>c</sup>
Animal health facilities	Animal health facility	2058 <sup>d</sup>
<b>Unlicensed individuals</b>		
Households involved in the rearing of livestock	None	3 102 530 <sup>e</sup>

NA: not available.

<sup>a</sup> In 2017, according to the Thai Food and Drug Administration's records, there were 19 934 individuals holding full pharmaceutical sales licenses in Thailand.

<sup>b</sup> Data from the Thai Ministry of Public Health's records for 2016.

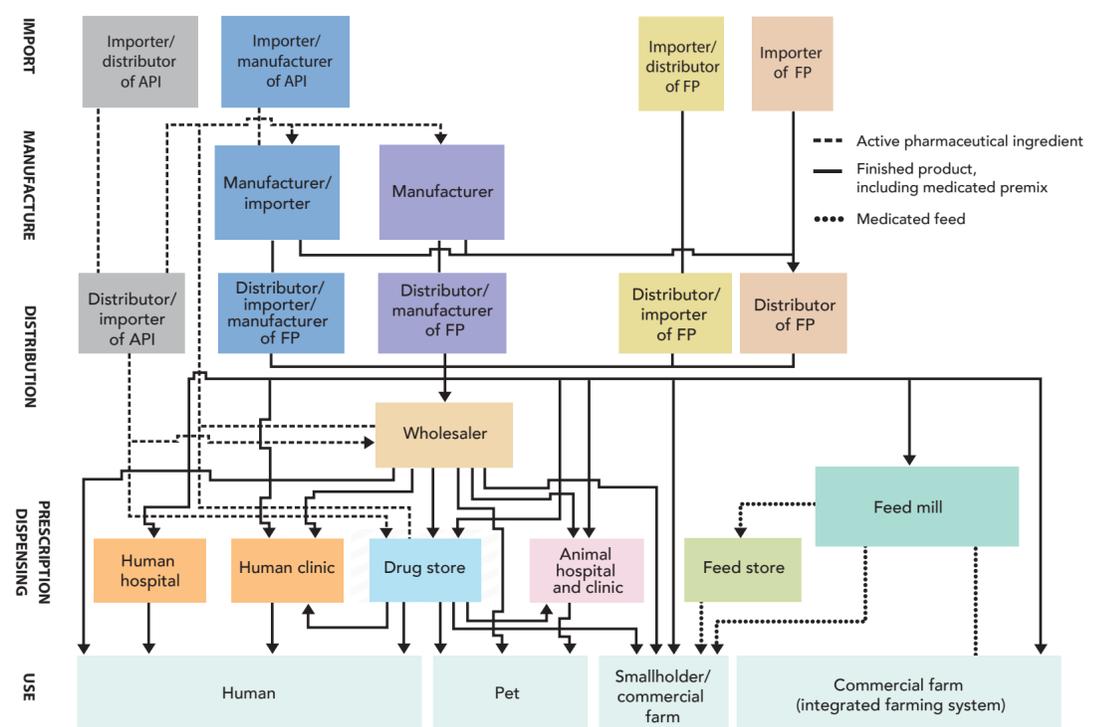
<sup>c</sup> Data from the Thai Department of Livestock Development's records for 2016.

<sup>d</sup> Data from the Thai Department of Livestock Development's records for 2016.

<sup>e</sup> The estimated number of households involved in the rearing of livestock

Figure 1 illustrates the complexity of the distribution of active pharmaceutical ingredients, finished products and medicated feed, from the importers and local manufacturers to final consumption by humans, livestock or pets.

**Fig. 1.** Complex channels of antibiotic distribution, Thailand



Food and Drug Administration classifies most antibiotics as "dangerous drugs" that can only be dispensed by licensed pharmacists in pharmacies but can be obtained, legally, without a prescription and placed no restrictions on the quantities of antibiotics sold to customers. Only a few antibiotics are classified as prescription-only medicines.

## Discussion

The study synthesizes key challenges that made access to antibiotics too easy: demand and supply sides of the antibiotic market, health systems and the regulatory environment (3, 4). Strengthening regulatory enforcement is a key entry point for controlling the distribution of antibiotics (5). (Fig. 2)

**Fig. 2.** Factors potentially contributing to the excessive and/or inappropriate use of antibiotics, Thailand

### Regulations and enforcement capacity

- Unregulated leakage of API into the market, allowing their potential abuse in agricultural sector
- No limitation on antibiotic purchasing leading to use without health professional supervision
- Only a very few antibiotics categorized as prescription-only by Thai FDA
- Lack of audits on prescription and dispensing records

### DEMAND

#### People:

- Misconceptions and lack of knowledge on appropriate use of antibiotics
- Cheaper for households to seek antibiotics from private pharmacies than clinics, hospitals and other formal providers for common ailments

#### Farmers and animal owners:

- Use of illegal and unregistered antibiotics

Widely available and easy access leading to inappropriate use of antibiotics by communities and farmers

### SUPPLY

#### Pharmaceutical industry and health professionals:

- Profits from pharmaceutical sales
- Decision on antibiotic prescription based on opinion and experiences
- Non-clinical issues may influence the health professional's decision on antibiotic prescription

### Health systems

- Lack of information systems to capture magnitude of self-medication of antibiotics
- Lack of AMR surveillance system to support decision of health professionals

## Conclusions

Most antibiotics are widely available and easily accessible from retail pharmacies, without a prescription. If the inappropriate use of active pharmaceutical ingredients and antibiotics is to be reduced, the government needs to:

- reclassify and restrict access to certain antibiotics,
- develop systems to audit prescription and dispensing of antibiotics in the retail sector and
- track and control distribution of the highest-priority critically important antimicrobial of antibiotics and active pharmaceutical ingredients.

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