Antibiotic distribution channels in Thailand: results of key-informant interviews, reviews of drug regulations and database searches

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Objective To analyse how antibiotics are imported, manufactured, distributed and regulated in Thailand.

Methods We gathered information, on antibiotic distribution in Thailand, in in-depth interviews – with 43 key informants from farms, health facilities, pharmaceutical and animal feed industries, private pharmacies and regulators—and in database and literature searches.

Findings In 2016–2017, licensed antibiotic distribution in Thailand involves over 700 importers and about 24,000 distributors—e.g. retail pharmacies and wholesalers. Thailand imports antibiotics and active pharmaceutical ingredients. There is no system for monitoring the distribution of active ingredients, some of which are used directly on farms, without being processed. Most antibiotics can be bought from pharmacies, for home or farm use, without a prescription. Although the 1987 Drug Act classified most antibiotics as “dangerous drugs”, it only classified a few of them as prescription-only medicines and placed no restrictions on the quantities of antibiotics that could be sold to any individual. Pharmacists working in pharmacies are covered by some of the Act’s regulations, but the quality of their dispensing and prescribing appears to be largely reliant on their competences.

Conclusion In Thailand, most antibiotics are easily and widely available from retail pharmacies, without a prescription. If the inappropriate use of active pharmaceutical ingredients and antibiotics is to be reduced, we need to reclassify and restrict access to certain antibiotics and to develop systems to audit the dispensing of antibiotics in the retail sector and track the movements of active ingredients.

Introduction

To address antimicrobial resistance, antibiotics should be used appropriately in human medicine. Patients should receive antibiotics “appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time”.⁴ Similar rules apply to the prudent use of antibiotics by all of the relevant stakeholders involved in veterinary medicine.⁵

The inappropriate use of antibiotics may involve the use of antibiotics for a health problem for which antibiotics are not indicated or the rational use of antibiotics either in doses that are inadequate or in the correct doses, but for an inadequate duration. As exposure of susceptible bacteria to low doses of antibiotics can lead to the selection of resistance,¹ there is a strong association between antimicrobial resistance and inappropriate use of antibiotics at both individual and population levels.²,³

In most developing countries, many antibiotics can be easily bought without prescription and self-medication with antibiotics, mostly bought from drugstores or pharmacies or left over from previous treatments, is common.⁶,⁷ Such self-medication is also found in some high-income countries.⁸ A major aim of the pharmaceutical market is to respond to increased demand. As the number of retail pharmacies and other outlets for the distribution of antibiotics increases, antibiotics become more widely and easily available. Health professionals may also be persuaded to over-prescribe antibiotics by financial incentives.⁹

In low- and middle-income countries most drug regulation is focussed on the quality of drugs and the process of licensing; relatively little attention is given to distribution, price and other aspects of market control. Furthermore, in such countries, the enforcement of the drug regulations that do exist is often poor and the sale of substandard over-the-counter antibiotics and weak pharmaco-vigilance are often common.¹⁰–¹²

One of the main aims of the Global Action Plan on Antimicrobial Resistance, which was adopted by the World Health Assembly in 2015, was to optimize the use of antibiotics in human and veterinary medicine.¹³ A key goal of Thailand’s subsequent National Action Plan on Antimicrobial Resistance, which was developed and endorsed by the Thai Cabinet in 2016, was to reduce antibiotic consumption, by 20% in human medicine and by 30% in veterinary medicine by 2021.

In 2009, the value of the antibiotics imported into Thailand or manufactured in the country was about 315 million United States dollars and this value represented about 10% of the total value of the medicines consumed in the country.¹⁴ There appears to be widespread and often unregulated use of antibiotics, not only for human and pet health, but also for the treatment of livestock both on farms and in household settings.

In 2016, we decided to investigate Thailand’s importation, manufacture, distribution and regulation of antibiotics. In interviews with key informants, we investigated the multiple channels for the distribution of antibiotics, from import and manufacture to retail sale, and the various issues that probably contribute to the inappropriate use of antibiotics.
Methods

We investigated antibiotic distribution and regulation in Thailand using a combination of key-informant interviews, a review of the relevant drug regulations and database searches.

Interviews

Between the July and November of 2016, we conducted in-depth interviews, lasting a mean of 90 minutes, with 43 key informants. Each interviewee had been selected using a purposive sampling technique in which relevant associations, i.e. Thailand’s Animal Health Products, Animal Feed Mill, Community Pharmacy and Pharmaceutical Manufacturers Associations, were asked to propose lists of their members who could provide information about antibiotic distribution. Each potential informant identified was asked if they were able and willing to participate in the study and, if so, they were asked to give their written informed consent. Our initial aim was to recruit at least three consenting informants from each of six main stakeholder groups, i.e. animal feed industries, farms, government authorities in the fields of human and animal health, health facilities, pharmaceutical industries and pharmacies. However, using the snowball technique, more key informants were interviewed until our data became saturated and no new information emerged (Table 1). To ensure consistency, the same individual (AS) interviewed each key informant.

All of the interviews were conducted face-to-face, in Thai. They were semi-structured, but based on open-ended questions. The informants were asked about the processes of antibiotic import, manufacturing, distribution, dispensing, prescription and use. For example, they were asked about the sources of active pharmaceutical ingredients used in the manufacture of finished products and about their sale patterns. All of the interviewees were asked about the licensing process and requirements for each distributor, the registration of medicines and the factors that might contribute to the excessive and inappropriate use of antibiotics. The informants representing the farming industry or health facilities were asked about their sources of antibiotics and the processes they followed to purchase such drugs or active pharmaceutical ingredients. The data recorded in each interview were kept confidential.

Database searches

We estimated the numbers of licensees involved in antibiotic distribution in the Thai market and in the regulation of such distribution by analysing the relevant databases held by the Thai Food and Drug Administration and the Thai Department of Livestock Development.

Drug regulations

We reviewed all of the regulations promulgated by both of the Acts that, in 2016, regulated the use of antibiotics and medicated feed through inspection, licensing and marketing: the 1987 Drug Act and the 2015 Animal Feed Quality Control Act.

The 1987 Drug Act, enforced by the Food and Drug Administration of the Thai Ministry of Public Health, regulates the finished products used in human and veterinary medicine and active pharmaceutical ingredients. The 2015 Animal Feed Quality Control Act is enforced by the Department of Livestock Development of the Thai Ministry of Agriculture and Cooperatives.

Data analysis

The data obtained from the key-informant interviews and document reviews were summarized to provide an overview of the distribution of antibiotics and identify weaknesses that could contribute to the inappropriate use of antibiotics. To assess the accuracy of the interview data, we used triangulation across the 43 interviewees. If information from one interviewee differed substantially from, and contradicted, the corresponding information from another interviewee, both pieces of information were ignored. Thailand’s antibiotic distribution channels were summarized as a system flowchart. The provincial numbers of licensed private pharmacies per 100,000 population were mapped using ArcGIS software (Esri, Redlands, United States of America).

Ethics

The study protocol was approved by the Research Ethics Committee at the Thai Ministry of Public Health’s Institute for Development of Human Research. Interviewees gave their written informed consent. Strict confidentiality was observed and interviewees could opt out from the interviews at any time.

Results

We created a flowchart, based on data from the key-informant interviews and reviews of the 1987 Drug Act and the 2015 Animal Feed Quality Control Act, to summarize the antibiotic distribution channels (Fig. 1). It 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.

Import, manufacture and distribution

Thailand imported active pharmaceutical ingredients, for local manufacturing into finished products. It also imported medicated premix for the manufacture

| Type                               | No. of informants | Ages (years) | Relevant work experience (years)* |
|------------------------------------|-------------------|--------------|----------------------------------|
| Regulator                          | 13                | 35–59        | 15.9 0.5–32.0                    |
| Representative of pharmaceutical companyb | 14                | 35–65        | 17.1 3.0–40.0                    |
| Representative of animal feed companyb | 5                 | 30–61        | 18.5 3.5–37.0                    |
| Health professional from human or animal health facility | 4                 | 35–54        | 14.3 1.0–31.0                    |
| Wholesaler or owner of retail drug store | 4                 | 36–70        | 25.5 11.0–42.5                   |
| Farmer                             | 3                 | 37–52        | 16.6 13.0–19.0                   |
| Total                              | 43                | 30–70        | 17.2 0.5–42.5                    |

* Recorded after rounding to the nearest half year.

** Involved in the import, manufacturer and/or distribution of antibiotics.

*** Running a feed mill or feed store.

Table 1. Types, ages and years in relevant work of the 43 key informants, Thailand, 2016
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of medicated feed by feed mills. Active pharmaceutical ingredients were imported either by manufacturers or by licensed importers that then sold the ingredients to manufacturers. Most of the manufacturers either purchased active pharmaceutical ingredients from licensed importers or imported such ingredients themselves – rather than buying them, at a greater cost, from drugstores. The antibiotics produced by the manufacturers were sold to distributors, retail outlets and/or wholesalers. The imported finished products were distributed, by importers who were licensed to distribute or by distributors, to drugstores, farms, feed mills, health facilities, veterinary facilities and/or wholesalers. Our data indicated that the import and manufacture of human medicines were very similar to those of veterinary medicines, because the Thai Food and Drug Administration regulated all of these processes.

Several interviewees, representing regulators, retailers and wholesalers, described the illegal distribution of both finished products and certain active pharmaceutical ingredients. The 1987 Drug Act stipulates that all active pharmaceutical ingredients must be used by manufacturers to produce finished products. However, a few informants reported how drug inspectors had confiscated active pharmaceutical ingredients that were being used directly on livestock in farms. The interviewees that represented the farming industry reported how the high cost of buying medicated feed had persuaded some farmers to mix active pharmaceutical ingredients into their animal feed. The farmers who produced their own medicated feed did not have quality control and, in the interviewees’ opinion, the feed they produced was unlikely to have an even distribution of active pharmaceutical ingredients. Although the 2015 Animal Feed Quality Control Act prohibited such direct use of active pharmaceutical ingredients in animal feed, inadequate inspection allowed farmers to purchase such ingredients from drugstores or wholesalers.

According to our interviews with key informants representing the country’s health providers, every private and public clinic and hospital had a pharmacy section in which antibiotics were dispensed to inpatients and outpatients according to the prescriptions of doctors. Although most of these prescriptions were not required by law, the routine issuing of prescriptions, even for drugs that were not, legally, prescription-only, had become the tradition of most health facilities. Antibiotics were also dispensed directly to consumers.
and pet owners by licensed pharmacists in wholesalers or drugstores.

Informants representing animal feed companies reported how feed mills mostly purchased medicated premix, from importers, manufacturers or distributors, to produce medicated feed that was then sold to farms either directly or via feed stores. According to the key informants from the farming industry, most of the antibiotics that farmers used were given to livestock in medicated feed, either for treatment or for prophylaxis during periods of increased vulnerability, e.g. when livestock were transferred to new environments.

The large number of licensed individuals involved in the antibiotic supply chains can be categorized according to the type of license granted to them under the 1987 Drug Act or 2015 Animal Feed Quality Control Act. According to the licenses issued in 2016–2017, these chains involved 793 drug importers, 187 drug manufacturers, 323 animal feed importers, 299 animal feed mills, 27,165 feed stores and about 24,000 other individuals involved in the antibiotic supply chain, either for treatment or for prophylaxis during periods of increased vulnerability.

Table 2. The types and numbers of individuals involved in the distribution of antibiotics and other medicines, Thailand, 2016–2017

| Type                         | License held                  | No. of individuals |
|------------------------------|-------------------------------|--------------------|
| **Licensed providers**        |                               |                    |
| Medicine importers           | Pharmaceutical import         | 793*               |
| Medicine manufacturers       | Pharmaceutical manufacture    | 187*               |
| Medicine distributors        | Pharmaceutical sales          | NA*                |
| Medicine wholesalers         | Pharmaceutical sales          | NA*                |
| Retail drug stores or pharmacies |                            |                    |
| Selling all medicines        | Pharmaceutical sales          | NA*                |
| Selling only ready-packed medicines |                   | 3164*              |
| Selling only ready-packed medicines for animals | pharmaceutical sales – ready-packed medicines only | 763* |
| Human health facilities      | Health facility               | 11,560*            |
| Importers of animal feed     | Animal feed import            | 323*               |
| Animal feed mills            | Animal feed manufacture       | 299*               |
| Animal feed stores           | Animal feed sales             | 27,165*            |
| Animal health facilities     | Animal health facility        | 2058*              |
| **Unlicensed individuals**   |                               |                    |
| Households involved in the rearing of livestock | None                          | 3,102,530*         |

* In 2017, according to the Thai Food and Drug Administration’s records, there were 19,934 individuals holding full pharmaceutical sales licenses in Thailand.12

* Data from the Thai Ministry of Public Health’s records for 2016.31

* Data from the Thai Department of Livestock Development’s records for 2016.36

* The estimated number of households involved in the rearing of livestock.14

The 793 importers involved in antibiotic distribution, 675 (85%) were located in Bangkok, the capital city where the main air and sea ports are located.32 From Bangkok, many medicines, including antibiotics, are distributed throughout the country by importers, manufacturers and wholesalers, with sales driven, as usual, by market forces. In 2016, the provinces of Bangkok, Chonburi and Phuket had more than 61 licensed private pharmacies per 100,000 population (Fig. 2).

Our database searches revealed how, in 2015, about 3.1 million Thai households raised chickens (n = 2.4 million), ducks (n = 0.4 million), buffalo (n = 0.2 million) and/or pigs (n = 0.2 million).14

**Market authorization and licensing**

Overall, 5371 antibiotics were registered in the Thai Food and Drug Administration’s database for 2016.34 Of these, 3371 (63%) were registered for human use and the rest for use on livestock and pets, some as medicated premix. The database records did not distinguish between imported antibiotics and those produced in Thailand.

The importation of any drugs must be registered and pre-approved by the Thai Food and Drug Administration. By law, active pharmaceutical ingredients must only be sold by licensed importers and manufacturers. At customs, the licensed importers of active pharmaceutical ingredients are required to notify the Thai Food and Drug Administration before gaining approval for imports.

The 1987 Drug Act regulates pharmacists working in pharmacies, on aspects such as working hours and the dispensing of special-control drugs. However, most of the dispensing of antibiotics classified as dangerous drugs is not legally regulated and the quality of dispensing is largely reliant on the competences of the doctors, pharmacists and veterinarians involved. Historically, there have been no legal requirements for the keeping of records on the types and quantities of antibiotics dispensed within the retail sector. At the time of our study, prescriptions were routinely issued in hospitals, but no prescription audits were required.

**Discussion**

Our study was triggered by the Global Action Plan on Antimicrobial Resistance. In this study, we identified a few key challenges, on both the demand and supply sides of the market as well as in health facilities and the regulatory environment, that perhaps made access to antibiotics too easy (Fig. 3).

**Demand by patients and farmers**

Self-medication with antibiotics obtained without a prescription is a common practice in most developing countries.16 Although such self-medication may appear to be a relatively cheap option for the sick and their household caretakers, the societal cost of such treatment, often associated with inappropriate drugs or appropriate drugs in inadequate or suboptimal doses, and with a lack of counselling by the drug provider, can be relatively high. In China and Viet Nam, inadequate knowledge and lack of awareness of antimicrobial resistance, in both patients and providers, were recognized as important factors contributing to the irrational use of antibiotics.17 Inadequate regulation of drug distribution and sales may result in easy access, especially when, as is often
the case in Thailand, prescriptions are not required. In turn, easy access may boost the inappropriate use of drugs by households.18,19

Supply problems

Any economic incentives offered by pharmaceutical companies to boost their market share may contribute to the excessive provision of antibiotics.17 Some pharmaceutical companies support clinicians by sponsoring continuing professional education, financing international travel for conferences and leisure or offering generous speaking fees.20–22 In an attempt to break the link between such incentives and the preferential dispensing of drugs produced by the company providing the incentives, Denmark has decoupled the prescribing and dispensing of medicines by veterinarians.23 Almost all medicines used in the livestock sector in Denmark are now sold directly to the farmers by pharmacies.23

In much of Asia, the quality of the pharmaceutical services provided by retail pharmacies is often poor. The staff in such pharmacies may offer no counselling or history taking and may recommend inappropriate presumptive treatments, e.g. antibiotics for the treatment of the symptoms of a common cold or influenza, or appropriate drugs in suboptimal doses.24 Suboptimal doses may be all that the patient can afford. In Peru and central Thailand, private retail pharmacies, where dispensing could not be guided by the antibiotic-resistance profiles of the causative agents, were found to be the most common source of antibiotics for the treatment of sexually transmitted diseases.25,26

In Thailand, we identified about 24 000 distributors, retailers and wholesalers who were fully licensed for pharmaceutical sales in 2017. At the time of our study, the records of the Thai Food and Drug Administration did not differentiate between such licensed distributors, retailers and wholesalers. In consequence, there was no easy way to monitor or control the sale of large quantities of antibiotics to individual patients or farmers. We found that, if they could afford it, Thai farmers could easily buy very large amounts of finished products and active pharmaceutical ingredients from drug retailers or wholesalers.

Regulatory environment

The focus of drug regulation in low- and middle-income countries, e.g. Ethiopia, Thailand, the United Republic of Tanzania and Zimbabwe, is on drug quality and licensing rather than availability and distribution channels.10–12

In Thailand, the 1987 Drug Act did attempt to regulate the availability of some antibiotics, by dividing antibiotics into a large group of “dangerous drugs not requiring prescriptions” and a much smaller group of “special-control drugs requiring prescriptions”.30 This categorization meant that most antibiotics could be dispensed, by licensed pharmacists in retail pharmacies, without a prescription. Furthermore, the Act made no attempt to regulate the quantity of antibiotics that could be distributed to any individual or to control the excessive use of antibiotics in livestock. Later, the 2015 Animal Feed Quality Control Act prohibited direct use of active pharmaceutical ingredient in the animal feeds. However, our interviews indicated that, many Thai farmers were, illegally, adding active pharmaceutical ingredients to animal feeds, probably as a cost-saving measure.

Following a series of public consultations, the Thai Food and Drug Administration is working on a reclassification of antibiotics in which a larger proportion of the drugs will be categorized as special-control/prescription-only, in line with the recommendations made by the World Health Organization in its 20th Model List of Essential Medicines.27 Compared with access to antibiotics, access to active pharmaceutical ingredients appears to be less well regulated, leading to inappropriate use by farmers. In Thailand, all drugs have to be registered with the Food and Drug Administration before production or importation. There is, however, no corresponding requirement for the

Fig. 2. Provincial numbers of private licensed retail pharmacies per 100 000 population, Thailand, 2016

Source: Based on data from the Thai Food and Drug Administration's records for 2017.32
Factors potentially contributing to the excessive and/or inappropriate use of antibiotics, Thailand, 2016

Table: Regulations and enforcement capacity

- Leakage of illegal API into the market, potential abuse in agricultural sector
- Unregulated leakage of API into the market, allowing their potential abuse in agricultural sector
- Antibiotics classified by Thai-FDA as pharmacy dispensing only and no prescription requirement
- Lack of audits on prescription and dispensing records

Table: 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

In conclusion, this study appears to be the first published study in Thailand to investigate antibiotic distribution, for human and animal health. The thousands of drug distributors, drug wholesalers, retail pharmacies and animal feed stores that have arisen in the country, as a result of market forces, and the small number of antibiotics that are classified as special-control/precription-only make most antibiotics easily and widely available in both the human and animal health sectors. Such wide availability probably leads to frequent inappropriate use. A general lack of enforcement of the legislation covering the distribution of active pharmaceutical ingredients facilitates the direct use of such ingredients on farms.

The unnecessary and inappropriate use of antibiotics will probably lead to an increase in the problem posed by antimicrobial resistance in Thailand. A system for recording antibiotic dispensing at retail pharmacies should be established and then carefully audited by pharmacists. The continued professional education of retail pharmacists should be promoted, as a means of reducing the inappropriate use of antibiotics, and other drugs. The sales of large quantities of antibiotics to individuals need to be restricted by differentiating wholesalers from retailers in the licensing system. This includes prohibiting wholesalers from selling large quantities of antibiotics to farmers, or others who are not licensed retail outlets, and carefully restricting the sale by retailers of large quantities of such drugs to individuals. The ongoing policy to reclassify more antibiotics as special-control/precription-only drugs in Thailand should be rapidly implemented. A national system for tracking active pharmaceutical ingredients should be established immediately, to prevent the direct use of such ingredients on farms.

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Antimicrobial resistance; API: active pharmaceutical ingredients; FDA: Food and Drug Administration.

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могут быть отпущены одному лицу. Некоторые положения закона распространяются на фармацевтов, работающих в аптеках, но ограничения по количеству антибиотиков, в которых они могут лекарственные средства, отпускаемые по рецепту, и отсутствуют этом документе лишь некоторые из них классифицированы как лекарственные средства, отпускаемые по рецепту, и отсутствуют ограничения по количеству антибиотиков, в котором они могут быть отпущены одному лицу. Некоторые положения закона распространяются на фармацевтов, работающих в аптеках, но количество их назначения и отпуска лекарственных средств, по-видимому, в значительной степени зависит от их компетенции.

Вывод В Таиланде большинство антибиотиков легко и широко доступны в розничных аптеках, где их можно приобрести без рецепта. Чтобы сократить ненадлежащее использование активных фармацевтических ингредиентов и антибиотиков, необходима повторно их классификация, ограничить доступ к определенным антибиотикам и разработать системы контроля отпуска антибиотиков в розничном секторе и отслеживания движения активных ингредиентов.

Resumen
Canalåes de distribución de antibióticos en Tailandia: resultados de entrevistas con informantes clave, revisiones de regulaciones de medicamentos y búsquedas en bases de datos

Objetivo Analizar cómo se importan, fabrican, distribuyen y regulan los antibióticos en Tailandia.

Métodos Recopilamos información sobre la distribución de antibióticos en Tailandia, en entrevistas en profundidad, con 43 informadores clave (granjas, centros de salud, industria farmacéutica y alimentación animal, farmacias privadas y reguladores, y en búsquedas de datos y bibliografía.)

Resultados En 2016-2017, en la distribución autorizada de antibióticos en Tailandia participan más de 700 importadores y alrededor de 24 000 distribuidores, p.e. farmacias minoristas y mayoristas. Tailandia importa antibióticos y sustancias farmacéuticas activas. No existe un sistema para controlar la distribución de los ingredientes activos, algunos de los cuales se usan directamente en las granjas, sin ser procesados. La mayoría de los antibióticos se pueden comprar en farmacias, para uso doméstico o agrícola, sin receta médica. Aunque la Ley de Medicamentos de 1987 clasificó la mayoría de los antibióticos como “drogas peligrosas”, solo clasificó algunos de ellos como medicamentos de venta con receta y no restringió las cantidades de antibióticos que podrían venderse a cada persona. Los farmacéuticos que trabajan en farmacias están cubiertos por algunas de las normas de la Ley, pero la calidad de su dispensación y prescripción parece depender en gran medida de sus competencias.

Conclusión En Tailandia, la mayoría de los antibióticos están disponibles de forma fácil y general en farmacias minoristas, sin receta médica. Para reducir el uso inapropiado de sustancias farmacéuticas activas y antibióticos, debemos volver a clasificar y restringir el acceso a ciertos antibióticos y desarrollar sistemas para auditar la dispensación de antibióticos en el sector minorista y llevar a cabo un seguimiento de los movimientos de los ingredientes activos.

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