Consumption of antimicrobial agents in Thailand in 2017

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First report

Thai working group on Health Policy and Systems Research on antimicrobial resistance (HPSR-AMR)[1]

[1] This publication is also supported by the Food and Agriculture Organization of the United Nations.

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Address : International Health Policy Program
Ministry of Public Health, Thailand
Tiwanon Rd. Nonthaburi 11000, Thailand
Phone: +66 (0) 2590-2366-7
Fax: +66 (0) 2590-2385

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Correspondence : Any correspondence relating to this report should be sent by e-mail to : hpsr_amr@ihpp.thaigov.net

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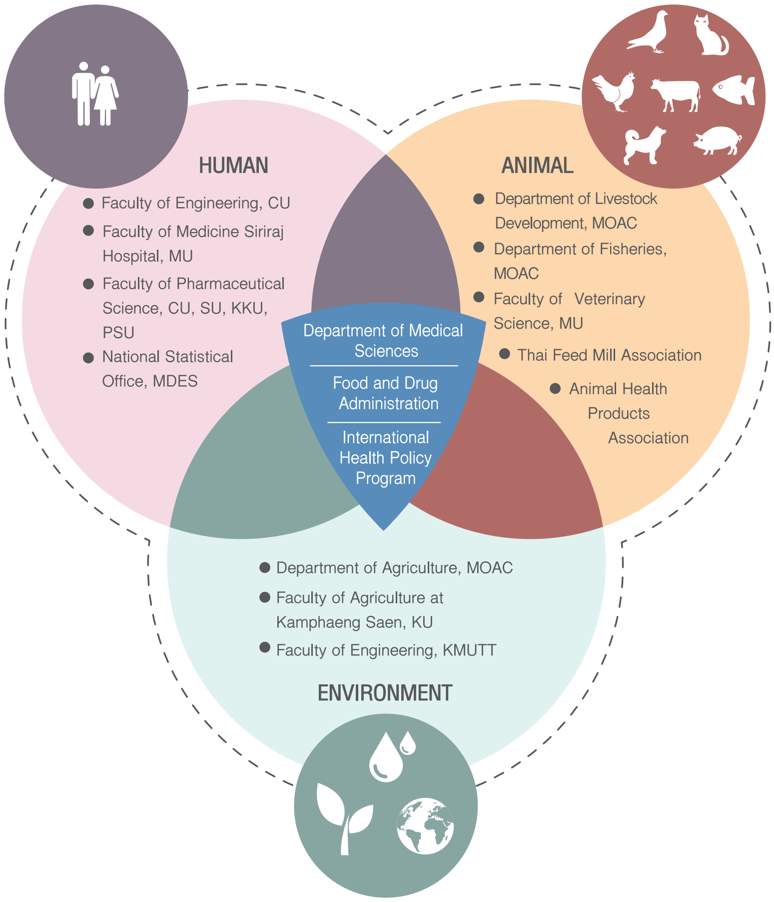
About the Health Policy and Systems Research on Antimicrobial Resistance

The "Thai Working Group on Health Policy and Systems Research on Antimicrobial Resistance (HPSR-AMR)" is a network of multi-disciplinary and multi-sectoral researchers using the One Health approach to strengthen and sustain the existing monitoring and evaluation of the National Strategic Plan on Antimicrobial Resistance (2017-2021) (NSP-AMR) platforms, and develop other essential platforms where needed. We naturally evolved from the working group of Development on Thailand Surveillance of Antimicrobial Consumption (Thailand SAC) in humans and animals since the mid-2015, well before the advent of the NSP-AMR (2017-2021). The initial goal of the Thailand SAC working group is to establish a sustainable system for monitoring the trend of antimicrobial consumption in humans and animals, which is comparable with international good practice (in particular the European Surveillance of Antimicrobial Consumption Network (ESAC-Net) and European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)) and supports policy decisions for optimizing consumption (1). Later, the working group was expanded to cover health systems and policy research related to Antimicrobial Resistance (AMR). There are more than 50 researchers from several institutes to form a unique trust-based collaboration for the benefit of the country; the International Health Policy Program (IHPP) of the Ministry of Public Health (MOPH) is the convener, coordinator and supporter which secures funding, conducts researches and ensures policy uptakes through its social network and long-standing exemplary institutional records and reputation among institutes involved in HPSR-AMR.

Addressing AMR requires multi-sectoral, multi-disciplinary researchers to work together. Mutual respect and recognition, team work and trust building are essential ingredients to build and sustain the research team. We fully applied trust-based working relations across different stakeholders who all had mutual respect for each other (2). We also focused on team building through empowerment so that all partners grew together in a non-exploitative manner. Full engagement and ownership of the research and uptake process will ensure commitment and long-term sustainability. An effective interface between evidence and policy decision-making is critical to address AMR. Based on its track record, IHPP is in a strong strategic position to ensure research uptake by multi-sectoral policy makers (1).



CU : Chulalongkorn University
DMSC : Department of Medical Sciences, Ministry of Public Health
FDA : Food and Drug Administration, Ministry of Public Health
IHPP : International Health Policy Program, Ministry of Public Health
KU : Kasetsart University
KKU : Khon Kaen University
KMUTT : King Mongkut's University of Technology Thonburi
MDES : Ministry of Digital Economy and Society
MOAC : Ministry of Agriculture and Cooperatives
MU : Mahidol University
PSU : Prince of Songkla University
SU : Silpakorn University

Multi-stakeholder engagement in developing the Thai Working Group on Health Policy and Systems Research on Antimicrobial Resistance using the One Health approach.

About the report

This is the first report on the surveillance of antimicrobial consumption in both humans and animals in Thailand. It provides baseline data in 2017 to monitor the NSP-AMR (2017-2021) goals, which are set at a 20% and 30% reduction of antimicrobial consumption in humans and animals, respectively. This report in veterinary antimicrobials focuses primarily on food-producing animals, excluding consumption in companion animals, for capturing the volume and value of imports and the local manufacture of all medicines including human and veterinary antimicrobials. This is legally mandated by article 85 of the 1987 Drug Act to Thai Food and Drug Administration (FDA); for which all pharmaceutical operators shall submit an annual report of the volume and value of antimicrobials it processes by March of the following year; this annual report covers all medicines licensed to them including antimicrobials. In order to ensure accuracy, peer reviews by external and internal experts were conducted not only in the methodology but also in the results and analysis of this report. The results were reported to the national steering committee on AMR at the end of 2018 (accepting the limitations of data that include exportation).

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01

Summary

1. Summary

1.1 Key findings

The Thailand Surveillance of Antimicrobial Consumption (Thailand SAC) was established to monitor the goals of the National Strategic Plan on Antimicrobial Resistance (2017-2021) (NSP-AMR) which aims to achieve a 20% and 30% reduction of antimicrobial consumption in humans and animals, respectively. This is the first national report, and provides baseline data about the consumption of antimicrobials in humans and animals in 2017.

The antimicrobial consumption data were captured by the Food and Drug Administration's (FDA) annual mandatory reporting system; for which a software program had been developed allowing electronic submission by pharmaceutical importers and manufacturers. The Defined daily dose (DDD) per 1000 inhabitants per day (DID) and mg of active ingredients (AI) per population correction unit modified by Thailand (mg/$PCU_{Thailand}$), were applied as the unit of measurement of antimicrobial consumption in humans and animals, respectively.

The scope of antimicrobials in humans was in line with the recommendations by the World Health Organization's (WHO) core list of antimicrobials: antibacterials (ATC Code J01), antibiotics for alimentary tract (A07AA) and nitroimidazole derivatives for protozoal diseases (P01AB). Thailand SAC also included the WHO optional list of antimicrobials: antifungals (J02), antimycotics (D01BA), antivirals (J05), antimycobacterials for treatment of tuberculosis (J04A), and antimalarials (P01B).

On animal consumption, the scope was in line with the World Organisation for Animal Health (OIE) and similar to that applied by the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC): antimicrobial agents for intestinal use (QA07AA; QA07AB; QA07AX), antimicrobial agents for intrauterine use (QG01AA; QG01AE; QG01BA; QG01BE QG51AA; QG51AG), antimicrobial agents for systemic use (QJ01) and antimicrobial agents for intramammary use (QJ51).

Consumption of human antimicrobials in Thailand in 2017 was 75.68 DDD/1,000 inhabitants/day. Of these, the antibacterials (J01) group was the highest consumption (69.98% of total), followed by antivirals (J05) (17.20%) and antifungals (J02) (6.58%). Of the antibacterials for systemic use (ATC group J01), amoxicillin was the largest consumption in ATC group J01-antibacterial for systemic use, at 15.10 DDD/1,000 inhabitants/day; followed by ceftriaxone (13.57 DDD/1,000 inhabitants/day); and tetracycline (3.55 DDD/1,000 inhabitants/day), respectively.

The consumption of veterinary antimicrobials by food-producing animals, expressed as mg/$PCU_{Thailand}$, was 711.56 mg/$PCU_{Thailand}$. The largest proportion of veterinary antimicrobial consumption was Penicillins (QJ01C) (24.93%), Intestinal anti-infective (QA07A) (21.64%) and Sulfonamides and trimethoprim (QJ01E) (17.55%). At the ATCvet level five, amoxicillin was the largest consumption 174.96 mg/$PCU_{Thailand}$ (24.59%), followed by halquinol (103.01 mg/$PCU_{Thailand}$, 14.48%), sulfadimidine (99.51 mg/$PCU_{Thailand}$, 13.98%), respectively. The top ten consumption of veterinary antimicrobials was a total of 621.96 mg/$PCU_{Thailand}$ or 87.40% of total national consumption by food-producing animals. Policy attention should be given to monitor the appropriate use of antimicrobials in these top ten, which will contribute to optimizing consumption.

In response to calls for rational use of antimicrobials and preservation of critically important antimicrobial items as the last resort, this report puts a special focus on the use of antimicrobial classes listed by WHO (5th revision (http://who.int/foodsafety/cia/en)) as the highest priority critically important antimicrobials (CIAs) for human medicine. They include Cephalosporins (3rd, 4th and 5th generation), Glycopeptides, Macrolides and ketolides, Polymyxins and Quinolones. The consumption of this antimicrobial class was 28.82% of total human antimicrobials and 13.99% of total animal antimicrobials in 2017. Antimicrobials including both the highest and high priority CIAs recommended to be preserved for humans as the last resort were used in human consumption at a rate of 43.63 DDD/1,000 inhabitants/day, or 57.65% of total national consumption; and in animal consumption at a rate of 308.09 mg/$PCU_{Thailand}$, or 43.30% of total consumption. Immediate policy actions must be introduced to strengthen antibiotics stewardship such as reclassifying the CIA items to restrict the distribution and use assuring rational use, and strengthening competencies regarding antibiotic among the health professionals.

1.2 Concluding remarks

The findings from this first national report on antimicrobial consumption in humans and animals should be interpreted with care, given the number of limitations of the database. The mandatory reports by importers and manufacturers are not fully validated for accuracy through on-site verification; which can be over- or under-reporting due to human errors. Mandatory reporting does not provide export volume, hence the consumption in this report is over-estimated. Mandatory reporting provides total import and manufacturing where total sales data are not available. Therefore, the Health Policy and Systems Research on Antimicrobial Resistance (HPSR-AMR) team has made an assumption that total annual imports and manufacturing are total annual consumption, assuming the stock is constant in an efficient market. Recognizing these limitations; the Thailand SAC team is in the process of rectifying these gaps.

Some countries produce Surveillance of Antimicrobial Consumption (SAC) by using national prescription data and provide breakdown by retail sector, primary care and hospital sector for human consumption and by animal species. Although efforts are being made to improve electronic submissions with more detail requested on distributional channels in humans and by animal species in future SAC reports, Thailand currently has these limitations.

Consumption in 2017 aims for in-country monitoring of optimizing consumption as mandated by NSP-AMR, it cannot benchmark Thailand with other international peers due to differences in a) data sources, b) human and animal epidemiology and disease burden, c) health and legal systems in relation to access to antibiotics and d) food animal production systems and profiles. Any un-careful interpretations lead to unnecessary disputes which are counter-productive and not the objective of Thailand SAC.

0 2

Introduction

2. Introduction

The increased trend of antimicrobial resistance (AMR) is recognized as one of the top global threats to human security, as it causes serious negative health and economic impact on humans, animals and the environment. Excessive and inappropriate use of antimicrobials is the main driver of the emergence of resistant bacterial strains. Massive international travel of humans accelerates the spread of AMR. Hence, combating AMR goes beyond the capacity of a single agency in a country or a nation. It requires inter-country multi-sectoral actions and global collective efforts using a 'One Health' approach.

Substantial evidence indicates AMR causes significant health and economic burdens. Globally, it causes approximately 700,000 deaths annually. Failing to tackle AMR will cause 10 million deaths by 2050 and the highest death toll of 4.7 million is forecast for Asia (3). In Thailand, it causes approximately 38,000 deaths annually and an economic burden of 1,200 million USD (1 USD = 35 Baht) (4).

The NSP-AMR (2017-2021) is the first Thai strategy to address AMR specifically. The Cabinet endorsed the NSP-AMR on 17 August 2016 and entrusts the mandate for effective cross-sectoral actions based on the One Health approach. The NSP-AMR goal is to achieve the reduction of morbidity, mortality and economic impacts due to AMR by 2021. Two out of the five targets of the NSP-AMR are 20% and 30% reduction in antimicrobial consumption in humans and animals respectively by 2021. To monitor the achievement of this goal, countries need to develop a monitoring system on antimicrobial consumption in humans and animals and disseminate this to policy decision-makers and the general public to increase awareness and encourage greater accountability of government sectors for optimizing consumption. The detail of NSP-AMR is summarized in figure 1. To achieve these five goals, the NSP-AMR applies six strategic actions. The strategic actions one to five cover key areas to resolve AMR, whereas strategic action six aims to develop governance mechanisms to implement and sustain AMR actions in accordance with the NSP-AMR.

Vision : Reduction of mortality, morbidity and economic impacts from AMR

Mission : Establish policies and national multi-sectoral mechanisms which support effective and sustained AMR management system

Goals :

1. 50% reduction in AMR morbidity
2. 20% reduction in antimicrobial consumption in humans
3. 30% reduction in antimicrobial consumption in animals
4. 20% increase in public knowledge on AMR and awareness of appropriate use of antimicrobials
5. Capacity of the national AMR management system is increased to level 4 as measured by the WHO's Joint Extemal Evaluation Tool (JEE) for International Health Regulations (2005)

Strategies :

1. AMR surveillance system using "One Health" approach
2. Regulation of antimicrobial distribution
3. Infection prevention and control and antimicrobial stewardship in humans
4. AMR prevention and control and antimicrobial stewardship in agriculture and companion animals
5. Public knowledge on AMR and awareness of appropriate use of antimicrobials
6. Governance mechanisms to implement and sustain AMR actions

Figure 1. Summary of National Strategic Plan on Antimicrobial Resistance (2017-2021)

To monitor the progress of optimizing the use of antimicrobial agents in humans and animals, as recommended by the WHO Global Action Plan, countries need to develop a sustainable system, which monitors antimicrobial consumption (5). To address this call, the Thailand Working Group on HPSR-AMR, coordinated by International Health Policy Program (IHPP), Ministry of Public Health (MOPH), Thailand was established in 2015. The goal of this Working Group is to generate evidence on antimicrobial consumption and embed a sustainable system for the continuous monitoring of the trend of consumption in humans and animals, compare with other international peers and support policy decision-making for optimizing consumption.

This report is the first annual report of surveillance of antimicrobial consumption in Thailand using 2017 consumption data.

03

Methods

3. Methods

3.1 Numerator

3.1.1 Data sources

In Thailand, by law, all medicines for human and veterinary use must be registered with the Thai FDA before production and importation. The Drug Act (1987) classifies most antibiotics as “dangerous drugs” which need to be dispensed by licensed pharmacists or veterinarians but which legally do not require prescription at licensed pharmacies. A few important antibiotics are classified as “special control” medicines, which are prescription-only medicine.

As mandated by the regulations in the 1987 Drug Act, all pharmaceutical importers and manufacturers shall submit an annual report of the volume and value (either price list or ex-factory price) of the total production and/or importation of medicines to the Thai FDA by 31 March of the following year. This report should cover all medicines licensed to them including antimicrobials. Therefore, the annual report database held by the Thai FDA covers the total consumption of antimicrobials in both human and veterinary drugs, which is based on total importation and production of antimicrobials in Thailand.

Figure 2 illustrates antimicrobial distribution through channels used by pharmaceutical operators as submitted in the annual reports to the Thai FDA including import and manufacture levels (6).

However, there are some limitations. The law does not require operators to report the total export, so the total consumption data also includes volumes which were actually exported. Future regulation will cover exportation in order to identify the net from total import and manufacturing, so that estimating total national consumption is possible. Although there is variation in annual stock, in an efficient pharmaceutical market, the stock level should be constant every year. Therefore, we assume that the total annual volume of import and manufactured antimicrobials equal total annual consumption. In addition, this consumption data cannot be disaggregated by target sector or by animal species as it is not mandated by the Drug Act 1987. In the future development of Thailand SAC, efforts will be given to mandatory reporting of disaggregated data in both human and animal sectors.

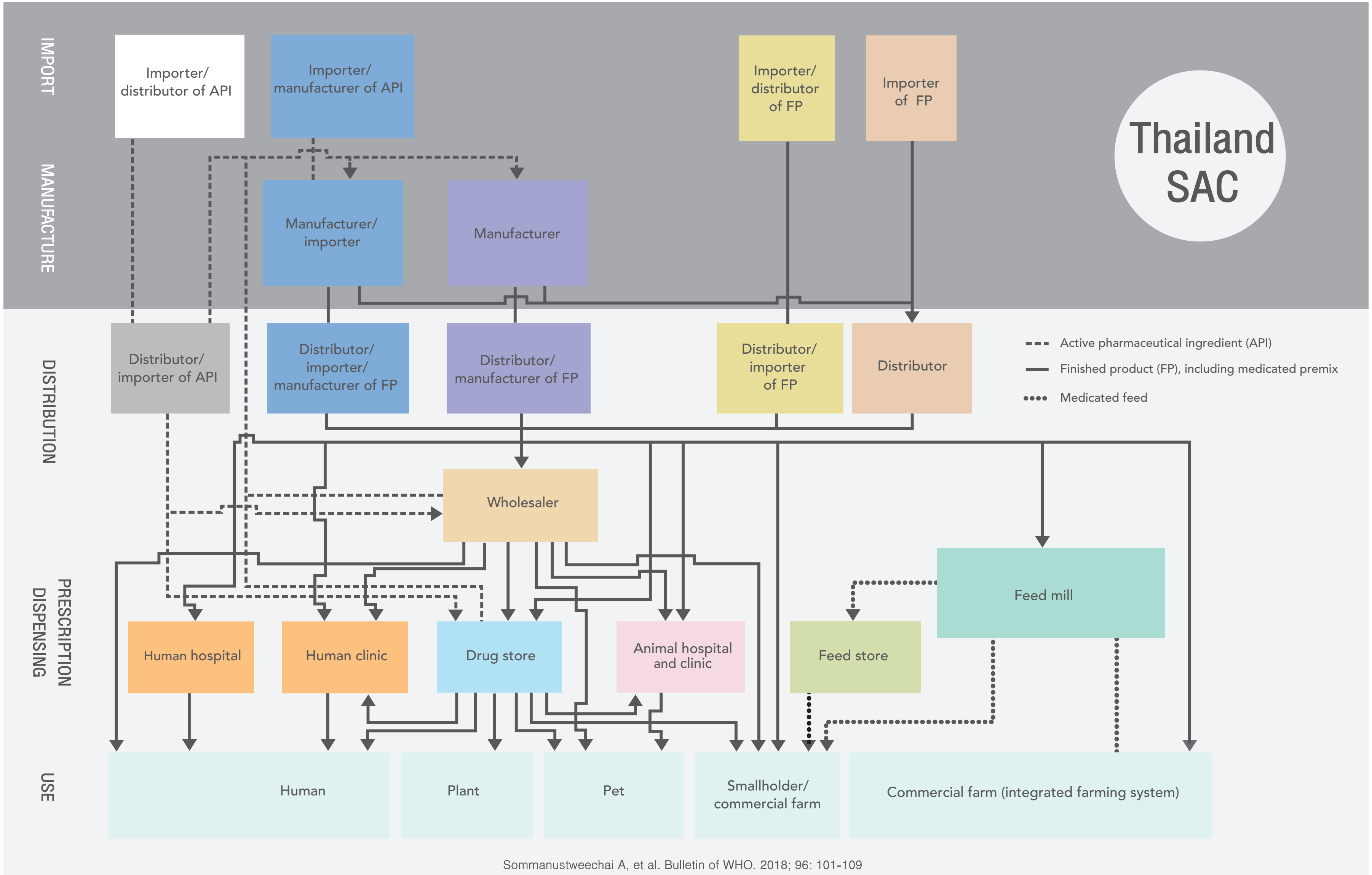

Figure 2. The annual report of Thai FDA included data from import and manufacture level

3.1.2 Drug Classification

Database in market authorization is categorized by the research term according to the Anatomical Therapeutic Chemical/Anatomical Therapeutic Chemical classification system for veterinary medicinal products (ATC/ ATCvet) classification system (7). For the ATC classification system, Defined Daily Dose (DDD) was employed as units of measurement. The ATC/DDD index of 2018 was used.

3.1.3 Inclusion criteria for antimicrobial consumption in Thailand SAC

For international comparison, the scope of antimicrobials included in the Thailand SAC for humans use includes the "core set" and "optional list" as recommended by WHO's methodology for a global programme on surveillance of antimicrobial consumption version 1.0 (8); it covers veterinary antimicrobials as recommended by OIE listed in the "OIE List of antimicrobial agents of veterinary importance" (9).

i. Human antimicrobials: core set and optional list

Groups of antimicrobial agents	ATC codes
I. Core set	
• Antibacterials	J01
• Antibiotics for alimentary tract	A07AA
• Nitroimidazole derivatives for protozoal diseases	P01AB
II. Optional list	
• Antifungals	J02
• Antimycotics	D01BA
• Antivirals	J05
• Antimycobacterials for treatment of tuberculosis	J04A
• Antimalarials	P01B

ii. Veterinary antimicrobials: antimicrobial agents for intestinal use, intrauterine use, systemic use, and intramammary use

Groups of antimicrobial agents	ATCvet codes
Antimicrobial agents for intestinal use	QA07AA; QA07AB; QA07AX
Antimicrobial agents for intrauterine use	QG01AA; QG01AE; QG01BA; QG01BE QG51AA; QG51AG
Antimicrobial agents for systemic use	QJ01
Antimicrobial agents for intramammary use	QJ51

Note : Dermatological preparations and preparations for sensory organs were excluded from the Thailand SAC as they are mostly used by companion animals.

3.1.4 Limitations

This report dose not cover export and illegal use of unregistered antimicrobials either through illegal imported or smuggling, manufacturing and sales.

3.2 Denominator

3.2.1 Human population

The mid-year population in Thailand in 2017 was estimated to be around 72,438,300 people (included migrant populations) (table 1) (10). Human population in Thailand SAC report includes Thai citizens and international migrants, while visitors and medical tourism who also consume antibiotics but data is unknown.

Table 1. Mid-year human population in Thailand, 2017

Thai population			Migrant population	Total
Male	Female	Total		
33,664,899	35,372,614	69,037,513	3,400,787	72,438,300

Source : World Bank, World Development Indicator 2017 Migrant population (10)

3.2.2 Animal population

3.2.2.1 Population correction unit modified by Thailand ($PCU_{Thailand}$)

Thailand has modified the population correction unit (PCU) methodology, which was established as a denominator for sales data by ESVAC (11). There are certain species of terrestrial food animals raised in Thailand but not raised in Europe; hence there is no data on the average weight at the time of treatment (Aw) for Thailand. Therefore, Thailand SAC developed its own $Aw_{Thailand}$ for estimating $PCU_{Thailand}$ for certain food animals not available in the ESVAC Aw; see details in table 2.

3.2.2.2 Calculation of PCU

On the calculation of PCU by ESVAC, the PCU for each animal category is equivalent to the number of livestock animals multiplied by Aw.

$$PCU = \text{Number of livestock animals} \times \text{average weight at the time of treatment (Aw)}$$

For Aw, Thailand refers to the ESVAC references (12). However, ESVAC does not provide Aw of certain food-producing animals in Thailand, in particular broiler breeders, layer breeders, laying hens, pullets, broiler duck breeders, broiler ducks, layer ducks, and dry cows. The Aw of these species equals to “final standing weight in kilogram” of each new animal category in table 2. This estimation has modified the original concept of PCU, which was previously established by ESVAC. Hence, the subscript “Thailand” is placed under PCU in $PCU_{Thailand}$ to indicate this modification. To facilitate future international comparison, ESVAC and OIE are requested to produce Aw for all animal species worldwide in consultation with relevant country experiences.

$$PCU_{Thailand} = \text{Number of livestock animals} \times \text{estimated the final standing weight at slaughterhouse } (Aw_{Thailand})$$

Total $PCU_{Thailand}$ is equivalent to total $PCU_{Thailand}$ Domestic and we assumed that 1 $PCU_{Thailand}$ = 1 kg of animal biomass. Note that the total $PCU_{Thailand}$ Export and $PCU_{Thailand}$ Import cannot be estimated; national data adjudicated by DLD in consultation with all relevant partners are only local production.

Table 2. Weights used to calculate the population correction unit modified by Thailand ($PCU_{Thailand}$)

Animal category	Weight in kg	Source	
		Eurostat	Thailand
Pigs			
Breeding pig	240	Eurostat*	-
Fattening pig	65	Eurostat*	-
Poultry			
Broiler breeder	4	-	Thailand
Broilers	1	Eurostat*	-
Layer breeders	2	-	Thailand
Laying hens	2	-	Thailand
Pullets	1.5	-	Thailand
Broiler duck breeders	3.5	-	Thailand
Integrated broiler ducks	3.3	-	Thailand
Free-market broiler ducks	3.3	-	Thailand
Integrated layer ducks	2.5	-	Thailand
Free-market layer ducks	2.5	-	Thailand
Cattle			
Dairy cows	425	Eurostat*	-
Dry cows	425	-	Thailand
Beef cows	425	Eurostat*	-

*Source ESVAC (12)

3.2.2.3 Animal species and categories included in the $PCU_{Thailand}$

The four main species including pigs, poultry, cattle and aquatic animals are included in $PCU_{Thailand}$. For the number of livestock animals, the data were collected by Department of Livestock Development (DLD). In aquaculture, the production volume (metric Tonnes) of fish and shrimp provided by the Department of Fisheries (DOF) were included in the report. Population statistics for animal populations are presented in table 3.

Table 3. Number of animals and population correction unit modified by Thailand ($PCU_{Thailand}$) by animal category included in the calculation, 2017

Animal category	Number of animals/Tonnes	$PCU_{Thailand}$ (kg)
Pigs (heads)		
Breeding pig	1,113,358	267,205,920.0
Fattening pig	18,411,401	1,196,741,065.0
Poultry (heads)		
Broiler breeder	18,100,000	72,400,000.0
Broilers	1,594,494,720	1,594,494,720.0
Layer breeders	719,900	1,439,800.0
Laying hens	55,643,971	111,287,942.0
Pullets	50,247,469	75,371,203.5
Broiler duck breeders	321,300	1,124,550.0
Integrated broiler ducks	32,130,000	106,029,000.0
Free-market broiler ducks	25,077,362	82,755,294.6
Integrated layer ducks	6,507,447	16,268,617.5
Free-market layer ducks	9,847,138	24,617,845.0
Cattle (heads)		
Dairy cows	245,505	104,339,625.0
Dry cows	273,279	116,143,575.0
Beef cows	4,876,228	2,072,396,900.0
Aquatic animals (tonnes)*		
Coastal aquatic animals	417,300	417,300,000.0
Fresh aquatic animals	329,014	329,014,000.0
Total $PCU_{Thailand}$		**6,588,930,057.6**

*Including only fish and shrimp

3.2.3 Limitations

There were some limitations due to no available data on the 2017 production of aquatic animals. Therefore, we estimated the total production of aquatic animals in 2017 by the extrapolation of 2014-2016 production of aquatic animals' data, already published by DOF.

3.3 Analysis and reporting of the data (Unit of measurement)

3.3.1 Human antimicrobials

The main indicator applied in this report to express the consumption of antimicrobials in humans by DDD per 1,000 inhabitants per day (DID):

$$\text{DDD Per 1,000 inhabitants per day (DID)} = \frac{\text{Defined daily dose (DDD)} \times 1{,}000}{\text{Mid-year population} \times 365}$$

Antimicrobial consumption data were collected according to the ATC classification system and DDD methodology developed by the WHO Collaborating Centre for Drug Statistics Methodology (13). For the analysis, DDD listed in the ATC Index with DDD 2018 were used (14). For combination antimicrobials used in humans, which do not provide DDD assignment, Thailand SAC decided to estimate consumption separately by different single drugs in these combined formulations. Where there are DDD for these combination medicines, we use WHO Collaborating Center's reference.

In 2017 in Thailand, the national consumption of both human and veterinary antimicrobials reported by importers and manufacturers did not disaggregate by retail sector, primary care and hospitals for humans or by species in the animal sector.

3.3.2 Veterinary antimicrobials

The national consumption data covered consumption of veterinary antimicrobials in food-producing animals, which included all pharmaceutical dosage forms of veterinary antimicrobials in the dataset, except tablets that are used almost solely by companion animals. The consumption of veterinary antimicrobials was measured by milligrams of active ingredient per population correction unit modified by Thailand (mg/$PCU_{Thailand}$):

$$\text{milligrams of active ingredient per population correction unit modified by Thailand (mg/}PCU_{Thailand}\text{)} = \frac{\text{Amount consumption in tonnes} \times 10^{9}}{PCU_{Thailand} \text{ in kilogram}}$$

In consultation with DLD and other partners in the animal sector in Thailand, in this report, the term food-producing species refers to the four main species, which are pigs, poultry, cattle and aquatic animals including fish and shrimp. The data are presented according to the classes/subclasses as defined by the ATCvet system. For combination preparations, each active ingredient was reported in the consumption according to the ATCvet class/subclass name for each single substance. However, the combined drugs were assigned the ATCvet code as combination drugs in order to reflect the real market authorizations in Thailand.

3.4 Validation, data integrity of the annual report

In 2017, the pharmaceutical operators submitted production and/or importation data by using an annual report's web-based submission tool (e-submission) operated by the Thai FDA. For the validation process, data were checked by the Thai FDA's staffs and HPSR-AMR team to identify outliers, mainly by checking the dosage form, the strength of each product and the calculation of active ingredients. However, this was the first time for operators to report on antimicrobial consumption in Thailand, so the data does not allow to cross-check against data in previous years.

To ensure the quality of mandatory reporting, HPSR-AMR initiated a project to develop a tool to assess the data quality of pharmaceutical operators who are mandated to provide annual reports to Thai FDA. The purposes of this project were to 1) verify the quality of the data; 2) assess the system that generates these data; and 3) develop a System Assessment Protocol (SAP) and Data Verification Protocol (DVP) to improve both data and systems which produce the data. The project selected a certain number of pharmaceutical operators. The purpose of the SAP was to identify potential challenges to data quality created by the data management and reporting systems in selected manufacturers and importers. The assessment of the data management and reporting systems took place in two stages: off-site desk review of documentation provided by the operator and on-site follow-up assessments. The outcome of this assessment was strengths and weaknesses for each functional area of the data management and reporting system, while the purpose of DVP was to trace and verify the data, to cross-check the reported results with other primary data sources and spot check if a sample of data had been accurately recorded. The data verification was conducted through in-depth verifications at the selected sites. The visited sites were purposely selected based on their size and the quality of their reported data. This project contributes to future quality assurance of pharmaceutical operator's information systems management, which finally contributes to the accuracy of mandatory reporting to the Thai FDA which is the Foundation of Thailand SAC. The SAP and DVP will be extended from pilot phase to larger samples, ensuring data integrity in the annual mandatory report.

Regarding the denominator ($PCU_{Thailand}$) data, data gathered by the DLD and DOF, reached consensus among all stakeholders including Thai Feed Mill Association (TFMA), Animal health Products Association (AHPA) and HPSR-AMR.

3.4.1 Limitations

The selected pharmaceutical operators were aware before the officers came to their sites. Therefore, it may have allowed them to prepare themselves, resulting in tending to overestimate capabilities.

3.5 Summary of included data sources/types

Information profile for which Thailand SAC 2017 was generated such as years of data collection, legal basis for the data collection at national level, systems for distribution of antimicrobial, sources from which the data were obtained, type of data, and the limitation were described in table 4.

Table 4. Summary of information on year of data collection, legal basis for collecting data at national level, national data provider, type and sources for consumption data and limitation

Year of data collection	2017
Legal basis	Mandatory to report
National data provider	Thai FDA for which Thailand SAC systems will be embedded in Thai FDA
Type of data	Consumption data
Sources for consumption data	Importers (n=185) and manufacturers (n= 148)
Limitation	Export included which result in high estimation of consumption.

Box 1. Most important technical remarks on interpretation of Thailand SAC

1. Careful interpretation of results in this report is required. As sales data is not available, hence Thailand SAC assumes stock remains constant across years and that the total production and importation equal total consumption. This assumption needs verifications. Reports to FDA do not a) cover certain unknown size of illegal importation and production of finished products, b) provide export volume, c) conduct on-site verification of potential under-reporting and inaccuracy, and d) verify the potential double counting.

All these limitations can result in either over- or under-estimate of total consumption. HPSR-AMR recognizes these limitations and decides that they will be gradually overcome in future reports.

2. This report provides 2017 baseline for monitoring progress to achieve 20% and 30% reduction in antimicrobial consumption in humans and animals.

3. Consumption in 2017 cannot benchmark Thailand with other international peers due to differences in a) data sources, b) human and animal epidemiology and disease burden, c) health and legal systems in relation to access to antibiotics and d) food animal production systems. Any careless interpretations lead to unnecessary disputes which are counter-productive and not the objective of Thailand SAC.

0 4

Results

4. Results

4.1 Human antimicrobials

4.1.1 Total consumption of human antimicrobials (DDD/1,000 inhabitants/day)

Overall, the consumption of human antimicrobials (within the scope of Thailand SAC) in Thailand in 2017 was 75.68 DDD/1,000 inhabitants/day (table 5). The consumption in each group of human antimicrobials was shown in table 6. Of these, the antibacterials (J01) group was the highest consumption in humans, with the amount of 52.96 DDD/1,000 inhabitants/day, followed by antivirals (J05) with the amount of 13.02 DDD/1,000 inhabitants/day and antifungals (J02) with the amount of 4.98 DDD/1,000 inhabitants/day.

Table 5. Consumption, in DDD, of human antimicrobials, population and consumption in DDD/1,000 inhabitants/day, in 2017

	Consumption (DDD)	Human population	Consumption (DDD/1,000 inhabitants/day)
Thailand	2,001,014,477	72,438,300	75.68

Footnote :

a. Careful interpretation of results in this report is required. As sales data is not available, hence Thailand SAC assumes stock remains constant across years and that the total production and importation equal total consumption. This assumption needs verifications. Reports to FDA do not a) cover certain unknown size of illegal importation and production of finished products, b) provide export volume, c) conduct on-site verification of potential under-reporting and inaccuracy, and d) verify the potential double counting. All these limitations can result in either over- or under-estimate of total consumption. HPSR-AMR recognizes these limitations and decides that they will be gradually overcome in future reports.

b. This report provides 2017 baseline for monitoring progress to achieve 20% and 30% reduction in antimicrobial consumption in humans and animals.

c. Consumption in 2017 cannot benchmark Thailand with other international peers due to differences in a) data sources, b) human and animal epidemiology and disease burden, c) health and legal systems in relation to access to antibiotics and d) food animal production systems and profiles. Any un-careful interpretations lead to unnecessary disputes which are counter-productive and not the objective of Thailand SAC.

Table 6. Consumption of human antimicrobials in Thailand, expressed as DDD/1,000 inhabitants/day, core set and optional list by ATC code, 2017*

Targeted human antimicrobial	Consumption (DDD/1,000 inhabitants/day)
1. Core set	
1.1 Antibacterials (J01)	52.96
1.2 Antibiotics for alimentary tract (A07AA)	0.04
1.3 Nitroimidazole derivatives for protozoal diseases (P01AB)	0.58
2. Optional list	
2.1 Antifungals (J02)	4.98
2.2 Antimycotics (D01BA)	0.40
2.3 Antivirals (J05)	13.02
2.4 Antimycobacterials for treatment of tuberculosis (J04A)	2.22
2.5 Antimalarials (P01B)	1.48
Total consumption	**75.68**

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

4.1.2 Consumption of targeted human antimicrobial groups

1. Core set

1.1 Consumption of antibacterials for systemic use (ATC group J01) in DDD/1,000 inhabitants/day

Of the total consumption of major subgroups of antibacterials for systemic use (ATC level 2 group J01) in 2017, the most frequently used antibacterials at ATC level 3, expressed as DDD/1,000 inhabitants/day, was Beta-lactams, Penicillins (21.30), followed by other Beta-lactam antibacterials (15.98), Tetracyclines (6.04) and Quinolones antibacterials (4.18) (table 7 and figure 3).

Table 7. Consumption of antibacterials for systemic use (ATC group J01) by ATC level 3 in Thailand, 2017, expressed as DDD/1,000 inhabitants/day*

ATC level 3	Groups of substances	Consumption (DDD/1,000 inhabitants/day)
J01A	Tetracyclines	6.04
J01B	Amphenicols	0.11
J01C	Beta-lactams, Penicillins	21.30
J01D	Other beta-lactam antibacterials	15.98
J01E	Sulfonamides and trimethoprim	1.63
J01F	Macrolides, lincosamides and streptogramins	3.40
J01G	Aminoglycoside antibacterials	0.25
J01M	Quinolones antibacterials	4.18
J01X	Other antibacterials	0.07
Total (ATC group J01)		**52.96**

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

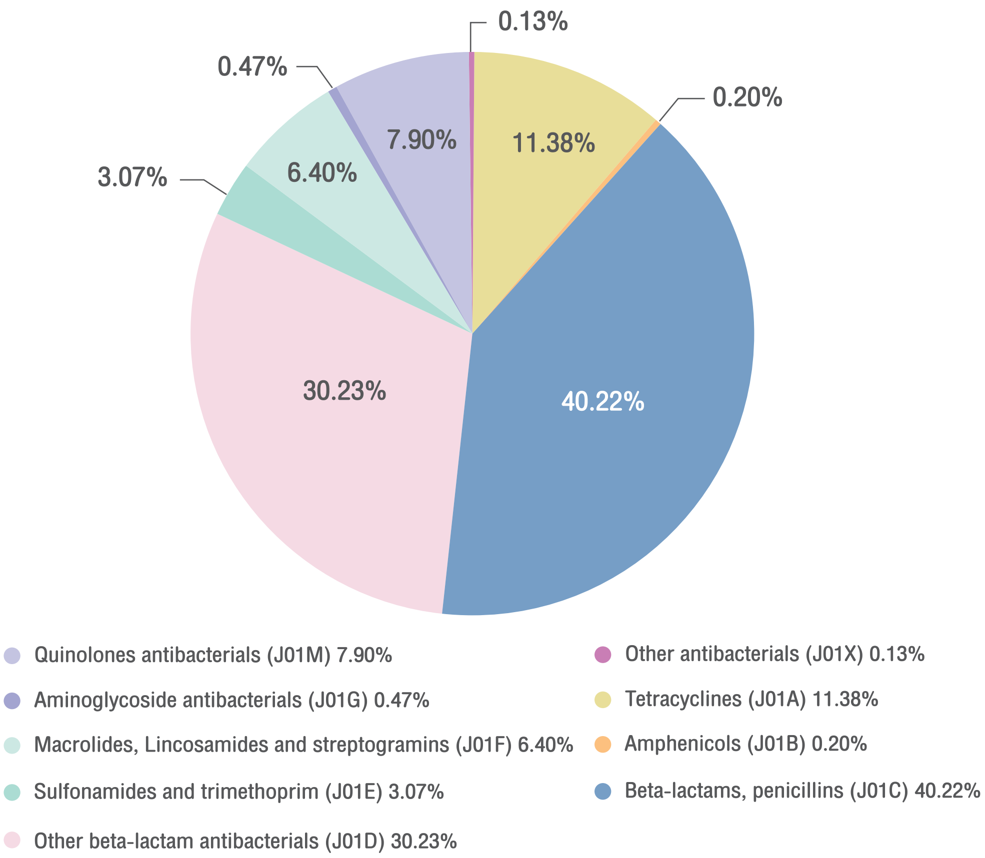

Figure 3. Relative amount of antibacterials consumption for systemic use (ATC group J01) classified by ATC level 3 in Thailand, 2017, expressed as percentages of the total consumption in DDD

In ATC level 4, Penicillins with extended spectrum (J01CA) was the highest consumption, it was 16.56 DDD/1,000 inhabitants/day, followed by Third-generation Cephalosporins (J01DD) (14.87 DDD/1,000 inhabitants/day) and Tetracyclines (J01AA) (6.04 DDD/1,000 inhabitants/day) (table 8).

Table 8. Consumption of antibacterials for systemic use (ATC group J01) by ATC group level 3 and 4 in Thailand, 2017, expressed as DDD/1,000 inhabitants/day*

	ATC group level 3		ATC group level 4	Consumption (DDD/1,000 inhabitants/day)
J01A	Tetracyclines	J01AA	Tetracyclines	6.04
J01B	Amphenicols	J01BA	Amphenicols	0.11
J01C	Beta-lactams, penicillins			21.30
		J01CA	Penicillins with extended spectrum	16.56
		J01CE	Beta-lactamase sensitive penicillins	0.15
		J01CF	Beta-lactamase resistant penicillins	2.08
		J01CG	Beta-lactamase inhibitors	<0.01
		J01CR	Combinations of penicillins, incl. beta-lactamase inhibitors	2.51
J01D	Other beta-lactam antibacterials			15.98
		J01DB	First-generation cephalosporins	0.74
		J01DC	Second-generation cephalosporins	0.28
		J01DD	Third-generation cephalosporins	14.87
		J01DE	Fourth-generation cephalosporins	<0.01
		J01DH	Carbapenems	0.09
J01E	Sulfonamides and trimethoprim			1.63
		J01EA	Trimethoprim and derivatives	<0.01
		J01EB	Short-acting sulfonamides	0.02
		J01EC	Intermediate-acting sulfonamides	0.16
		J01ED	Long-acting sulfonamides	0.02
		J01EE	Combinations of sulfonamides and trimethoprim, incl. derivatives	1.43
J01F	Macrolides, lincosamides and streptogramins			3.40
		J01FA	Macrolides	2.74
		J01FF	Lincosamides	0.66
J01G	Aminoglycoside antibacterials			0.25
		J01GA	Streptomycins	0.05
		J01GB	Other aminoglycosides	0.20
J01M	Quinolones antibacterials	J01MA	Fluoroquinolones	4.18
J01X	Other antibacterials			0.07
		J01XA	Glycopeptide antibacterials	0.01
		J01XB	Polymyxins	0.01
		J01XD	Imidazole derivatives	0.03
		J01XE	Nitrofuran derivatives	0.01
		J01XX	Other antibacterials	0.01
Total (ATC group J01)				52.96

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

Analysis by ATC level 5, amoxicillin was the largest consumption of antibacterials for systemic use (ATC group J01) in humans in Thailand, at consumption levels of 15.10 DDD/1,000 inhabitants/day, followed by ceftriaxone at 13.57 DDD/1,000 inhabitants/day, and tetracycline at 3.55 DDD/1,000 inhabitants/day (table 9).

Table 9. Top ten antibacterials for systemic use (ATC group J01), in DDD/1,000 inhabitants/day, analyzed by ATC level 5 in Thailand, in 2017*

Rank	ATC level 5	Antibacterials for systemic use (ATC group J01)	Consumption (DDD/1,000 inhabitants/day)
1	J01CA04	amoxicillin	15.10
2	J01DD04	ceftriaxone	13.57
3	J01AA07	tetracycline	3.55
4	J01CR02	amoxicillin and enzyme inhibitor	2.46
5	J01AA02	doxycycline	2.42
6	J01MA06	norfloxacin	2.07
7	J01FA06	roxithromycin	1.59
8	J01CA01	ampicillin	1.46
9	J01EE01	sulfamethoxazole and trimethoprim	1.43
10	J01CF01	dicloxacillin	1.38
		Total top ten of consumption	**45.03**

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

1.2 Consumption of antibiotics for alimentary tract and metabolism (ATC group A07AA) in DDD/1,000 inhabitants/day

In 2017, consumption of antibiotics for alimentary tract and metabolism (ATC group A07AA) was 0.04 DDD/1,000 inhabitants/day (table 10). In 2017, consumption of nystatin and neomycin were similar, it was 0.02 DDD/1,000 inhabitants/day.

Table 10. Consumption of antibiotics for alimentary tract and metabolism (ATC group A07AA) in Thailand in 2017, expressed as DDD/1,000 inhabitants/day, analyzed by ATC level 5*

ATC level 5	Substances	Consumption (DDD/1,000 inhabitants/day)
A07AA01	neomycin	0.02
A07AA02	nystatin	0.02
	Total (ATC group A07AA)	**0.04**

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

1.3 Consumption of Nitroimidazole derivatives (ATC group P01AB) in DDD/1,000 inhabitants/day

In 2017, the consumption of substances used to treat protozoal diseases (ATC group P01AB) was 0.58 DDD/1,000 inhabitants/day. The highest consumption of nitroimidazole derivatives drugs in this group was metronidazole, at 0.55 DDD/1,000 inhabitants/day, and small amount of tinidazole at 0.03 DDD/1,000 inhabitants/day.

Table 11. Consumption of Nitroimidazole derivatives (ATC group P01AB) in Thailand in 2017, expressed as DDD/1,000 inhabitants/day, analyzed by ATC level 5*

ATC level 5	Substances	Consumption (DDD/1,000 inhabitants/day)
P01AB01	metronidazole	0.55
P01AB02	tinidazole	0.03
Total (ATC group P01AB)		**0.58**

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

2. Optional list

2.1 Consumption of antimycotics and antifungals for systemic use (ATC groups J02 and D01BA) in DDD/1,000 inhabitants/day

In 2017, Thailand consumption of antimycotics and antifungals for systemic use (ATC groups J02 & D01BA) was 5.38 DDD/1,000 inhabitants/day (table 12). Ketoconazole was the most consumed antimycotics and antifungals for systemic use in Thailand, showing 4.31 DDD/1,000 inhabitants/day. Consumption of other antimycotics in this group is insignificant.

Table 12. Consumption of antimycotics and antifungals for systemic use (ATC groups J02 and D01BA) in Thailand in 2017, expressed as DDD/1,000 inhabitants/day*

ATC level 5	Substances	Consumption (DDD/1,000 inhabitants/day)
J02AA01	amphotericin B	0.01
J02AB02	ketoconazole	4.31
J02AC01	fluconazole	0.36
J02AC02	itraconazole	0.29
J02AC03	voriconazole	0.01
J02AC04	posaconazole	<0.01
J02AX04	caspofungin	<0.01
J02AX05	micafungin	<0.01
J02AX06	anidulafungin	<0.01
D01BA01	griseofulvin	0.40
D01BA02	terbinafine	<0.01
Total (ATC group J02 and D01BA)		**5.38**

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

2.2 Consumption of antivirals for systemic use (ATC group J05) in DDD/1,000 inhabitants/day

In 2017, there were 316,600 people living with HIV/AIDS who are on antiretroviral treatment (15) fully subsidized by the three public health insurance schemes; and free at point of service. In 2017, the consumption of antivirals for systemic use (ATC group J05) was 13.02 DDD/1,000 inhabitants/day (table 13). Of these, the most consumed antivirals for systemic use (ATC group J05) in Thailand was efavirenz, observing 3.08 DDD/1,000 inhabitants/day.

Table 13. Consumption of antivirals for systemic use (ATC group J05) in Thailand in 2017, expressed as DDD/1,000 inhabitants/day*

ATC level 5	Substances	Consumption (DDD/1,000 inhabitants/day)
J05AB01	acyclovir	0.17
J05AB06	ganciclovir	<0.01
J05AB09	famciclovir	<0.01
J05AB11	valaciclovir	<0.01
J05AB14	valganciclovir	<0.01
J05AE08	atazanavir	0.05
J05AE10	darunavir	0.01
J05AF01	zidovudine	0.82
J05AF02	didanosine	<0.01
J05AF04	stavudine	0.15
J05AF05	lamivudine	2.73
J05AF06	abacavir	0.11
J05AF07	tenofovir disoproxil	2.16
J05AF08	adefovir dipivoxil	0.01
J05AF09	emtricitabine	1.66
J05AF10	entecavir	0.09
J05AF11	telbivudine	0.02
J05AG01	nevirapine	1.18
J05AG03	efavirenz	3.08
J05AG04	etravirine	<0.01
J05AG05	rilpivirine	0.19
J05AH01	zanamivir	<0.01
J05AH02	oseltamivir	0.04
J05AP01	ribavirin	0.02
J05AP07	daclatasvir	<0.01
J05AP08	sofosbuvir	<0.01
J05AR10	lopinavir and ritonavir	0.52
J05AX05	inosine pranobex	<0.01
J05AX08	raltegravir	0.01
J05AX09	maraviroc	<0.01
J05AX12	dolutegravir	<0.01
	Total (ATC group J05)	13.02

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

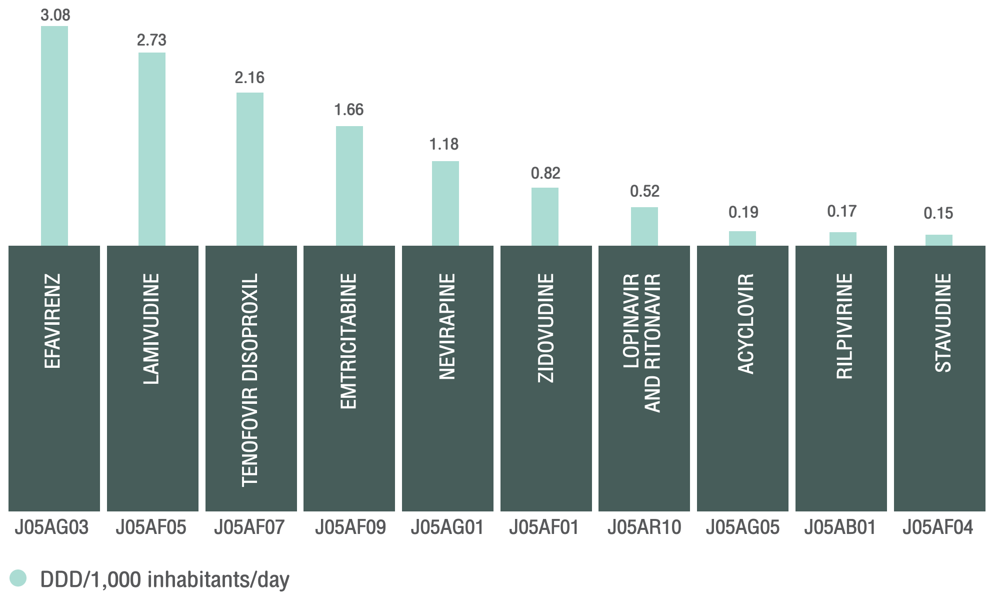

Figure 4. Top ten consumption of antivirals for systemic use (ATC group J05) in Thailand in 2017, expressed as DDD/1,000 inhabitants/day*

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

2.3 Consumption of drugs for treatment of tuberculosis (ATC group J04A) in DDD/1,000 inhabitants/day

Thailand is one of the high tuberculosis burden countries; the total tuberculosis incidence was estimated at 108,000 in 2017 (with an uncertainty interval of 82,000-138,000). The tuberculosis treatment coverage, as measured by the number of tuberculosis notified divided by the estimated incidence, was 74% in 2017 (16). In 2017, Thailand's consumption of drugs for treatment of tuberculosis (ATC group J04A) was 2.22 DDD/1,000 inhabitants/day (table 14). The major consumption of drugs for the treatment of tuberculosis group (ATC group J04A) was isoniazid, illustrating 0.89 DDD/1,000 inhabitants/day.

Table 14. Consumption of drugs for treatment of tuberculosis (ATC group J04A) in Thailand in 2017, expressed as DDD/1,000 inhabitants/day, by ATC level 5*

ATC level 5	Substances	Consumption (DDD/1,000 inhabitants/day)
J04AA02	sodium aminosalicylate	0.01
J04AB01	cycloserine	<0.01
J04AB02	rifampicin	0.81
J04AB30	capreomycin	<0.01
J04AC01	isoniazid	0.89
J04AD03	ethionamide	0.02
J04AK01	pyrazinamide	0.26
J04AK02	ethambutol	0.23
	Total (ATC group J04A)	2.22

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

2.4 Consumption of antimalarials (ATC group P01B) in DDD/1,000 inhabitants/day

In 2017, Thailand consumed antimalarials (ATC group P01B) at the amount of 1.48 DDD/1,000 inhabitants/day (table 15). Of these, chloroquine was the highest consumption in this group, showing 0.75 DDD/1,000 inhabitants/day.

Table 15. Consumption of antimalarials (ATC group P01B) in Thailand in 2017, expressed as DDD/1,000 inhabitants/day*

ATC level 5	Substances	Consumption (DDD/1,000 inhabitants/day)
P01BA01	chloroquine	0.75
P01BA02	hydroxychloroquine	0.19
P01BA03	primaquine	0.02
P01BA06	amodiaquine	<0.01
P01BC01	quinine	0.04
P01BC02	mefloquine	<0.01
P01BD01	pyrimethamine	0.48
P01BF01	artemether and lumefantrine	<0.01
	Total (ATC group P01B)	**1.48**

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

4.1.3 Consumption by critically important antibiotics by ATC level 3/4/5

In 2016, WHO has updated the antimicrobials classes list of the CIAs for human medicine (12,17). Detailed criteria for WHO's classification of CIAs can be found in annex 4 and table 16. The total consumption of antimicrobials classes list of the CIAs for human medicine in Thailand was 43.63 DDD/1,000 inhabitants/day. Of these, the highest priority CIA was 21.81 DDD/1,000 inhabitants/day, while the high priority CIAs consumed 21.82 DDD/1,000 inhabitants/day. See table 16.

On the highest priority CIAs group, in 2017, Cephalosporins (3rd, 4th and 5th generation) (14.87 DDD/1,000 inhabitants/day) was the highest consumption among the highest priority CIAs for human medicine, followed by Quinolones (4.18 DDD/1,000 inhabitants/day), Macrolides and ketolides (2.74 DDD/1,000 inhabitants/day), Glycopeptides (0.01 DDD/1,000 inhabitants/day) and Polymyxins (0.01 DDD/1,000 inhabitants/day), respectively.

Among the high priority critically important antimicrobial group; Penicillins (natural, aminopenicillins and anti-pseudomonal) had the highest consumption at 19.22 DDD/1,000 inhabitants/day; this was followed by drugs used solely for the treatment of tuberculosis and other mycobacterial diseases at 2.22 DDD/1,000 inhabitants/day.

Table 16. Consumption of antimicrobials class listed as the highest and high priority critically important antimicrobials (CIAs) for human medicine, in DDD/1,000 inhabitants/day in Thailand in 2017*

Critically Important Antimicrobials	Consumption (DDD/1,000 inhabitants/day)
Highest priority	**21.81**
Cephalosporins (3rd, 4th and 5th generation)	14.87
Glycopeptides	0.01
Macrolides and ketolides	2.74
Polymyxins	0.01
Quinolones	4.18
High priority	**21.82**
Aminoglycosides	0.27
Ansamycins	-
Carbapenems and other penems	0.09
Glycylcyclines	0.01
Lipopeptides	-
Monobactams	-
Oxazolidinones	<0.01
Penicillins (natural, aminopenicillins, and antipseudomonal)	19.22
Phosphonic acid derivatives	0.01
Drugs used solely to treat tuberculosis or other mycobacterial diseases	2.22
Total	**43.63**

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

4.2 Veterinary antimicrobials

4.2.1 Total national consumption per population-corrected unit for food-producing animals, by antimicrobial class

The consumption of veterinary antimicrobial agents for food-producing animals, expressed as mg consumption per population correction unit modified by Thailand ($PCU_{Thailand}$), was 711.56 mg/$PCU_{Thailand}$. The consumption patterns of the antimicrobial classes are shown in table 17. Of the national consumption of veterinary antimicrobials in 2017, the largest amount, expressed as mg/$PCU_{Thailand}$, was Penicillins (QJ01C) (177.42 mg/$PCU_{Thailand}$, 24.93%), followed by Intestinal antiinfectives (QA07A) (154.00 mg/$PCU_{Thailand}$, 21.64%), and Sulfonamides and Trimethoprim (QJ01E) (124.89 mg/$PCU_{Thailand}$, 17.55%), respectively. Overall, these three classes contributed to 64.12% of total national consumption in Thailand.

Table 17. Consumption, in tonnes of active ingredient of veterinary antimicrobial drugs marketed mainly for food-producing animals, and population correction unit modified by Thailand ($PCU_{Thailand}$) and consumption in mg/$PCU_{Thailand}$, 2017

	Consumption (tonnes) for food-producing animals	$PCU_{Thailand}$ (1,000 tonnes)	Total national consumption mg/$PCU_{Thailand}$
Thailand	4,688.41	6,588.93	711.56

Footnote:

a. Careful interpretation of results in this report is required. As sales data is not available, hence Thailand SAC assumes stock remains constant across years and that the total production and importation equal total consumption. This assumption needs verifications. Reports to FDA do not a) cover certain unknown size of illegal importation and production of finished products, b) provide export volume, c) conduct on-site verification of potential under-reporting and inaccuracy, and d) verify the potential double counting. All these limitations can result in either over- or under-estimate of total consumption. HPSR-AMR recognizes these limitations and decides that they will be gradually overcome in future reports.

b. This report provides 2017 baseline for monitoring progress to achieve 20% and 30% reduction in antimicrobial consumption in humans and animals.

c Consumption in 2017 cannot benchmark Thailand with other international peers due to differences in a) data sources, b) human and animal epidemiology and disease burden, c) health and legal systems in relation to access to antibiotics and d) food animal production systems and profiles. Any un-careful interpretations lead to unnecessary disputes which are counter-productive and not the objective of Thailand SAC.

Table 18. Consumption of antimicrobial agents by food-producing animals, in mg per population correction unit modified by Thailand ($mg/PCU_{Thailand}$), of the various veterinary antimicrobial classes by ATCvet level 3 and level 4 in Thailand in 2017*

ATC group level 3		ATC group level 4		Consumption ($mg/PCU_{Thailand}$)
QA07A	Intestinal antiinfectives			154.00
		QA07AA	Antibiotics	50.99
		QA07AX	Other intestinal antiinfectives	103.01
QG51A	Antiinfectives and antiseptics for intrauterine use	QG51AA	Antibacterials	<0.01
QJ01A	Tetracyclines	QJ01AA	Tetracyclines	110.14
QJ01B	Amphenicols	QJ01BA	Amphenicols	0.01
QJ01C	Beta-lactam antibacterials, Penicillins			177.42
		QJ01CA	Penicillins with extended spectrum	175.25
		QJ01CE	Beta-lactamase sensitive Penicillins	2.04
		QJ01CF	Beta-lactamase resistant Penicillins	<0.01
		QJ01CR	Combinations of Penicillins, incl. beta-lactamase inhibitors	0.13
QJ01D	Other Beta-lactam antibacterials			0.98
		QJ01DC	Second-generation Cephalosporins	<0.01
		QJ01DD	Third-generation Cephalosporins	0.22
		QJ01DE	Fourth-generation Cephalosporins	0.76
QJ01E	Sulfonamides and Trimethoprim			124.89
		QJ01EA	Trimethoprim and derivatives	21.99
		QJ01EQ	Sulfonamides	102.90
QJ01F	Macrolides, Lincosamides and Streptogramins			58.30
		QJ01FA	Macrolides	54.67
		QJ01FF	Lincosamides	3.64
QJ01G	Aminoglycosides antibacterials			22.61
		QJ01GA	Streptomycins	1.97
		QJ01GB	Other aminoglycosides	20.64
QJ01M	Quinolone and Quinoxaline antibacterials	QJ01MA	Fluoroquinolones	10.85
QJ01X	Other antibacterials			52.30
		QJ01XQ	Pleuromutilins	48.54
		QJ01XX	Other antibacterials	3.76
QJ51A	Tetracyclines for intramammary use	QJ51AA	Tetracyclines	<0.01

	ATC group level 3		ATC group level 4	Consumption ($mg/PCU_{Thailand}$)
QJ51C	Beta-lactam antibacterials, Penicillins for intramammary use			0.05
		QJ51CA	Penicillins with extended spectrum	0.02
		QJ51CF	Beta-lactamase resistant penicillins	0.03
QJ51D	Other beta-lactam antibacterials, Penicillins for intramammary use			<0.01
		QJ51DB	First-generation cephalosporins	<0.01
		QJ51DE	Fourth-generation cephalosporins	<0.01
QJ51G	Aminoglycoside antibacterials for intramammary use	QJ51GB	Other aminoglycosides	<0.01
		Total		711.56

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

Of the total consumption of all classes, amoxicillin was the largest veterinary antimicrobial used in food-producing animals in Thailand, (174.96 $mg/PCU_{Thailand}$, 24.59%), followed by halquinol (103.01 $mg/PCU_{Thailand}$, 14.48%), sulfadimidine (99.51 $mg/PCU_{Thailand}$, 13.98%), respectively. The top ten consumption in table 19 was 621.96 $mg/PCU_{Thailand}$ which was 87.40% of total national consumption by food-producing animals. Policy attention should be given to monitor the appropriate use in these top ten ATCvet level 5 will contribute to optimizing of consumption.

Table 19. Top ten veterinary antimicrobial consumption in food-producing animals, in mg per population correction unit modified by Thailand ($mg/PCU_{Thailand}$), of the various veterinary antimicrobial classes by ATC level 5 in Thailand in 2017*

Rank	ATCvet level 5	Veterinary antimicrobial drugs	Consumption ($mg/PCU_{Thailand}$)
1	QJ01CA04	amoxicillin	174.96
2	QA07AX91	halquinol	103.01
3	QJ01EQ03	sulfadimidine	99.51
4	QJ01AA03	chlortetracycline	58.19
5	QJ01XQ01	tiamulin	48.54
6	QJ01AA02	doxycycline	39.31
7	QA07AA10	colistin	33.05
8	QJ01FA91	tilmicosin	23.76
9	QJ01EA01	trimethoprim	21.99
10	QJ01GB03	gentamicin	19.64
Total top ten veterinary antimicrobial consumption			621.96

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

4.2.2 Consumption by WHO critically important antimicrobials

Throughout this report, there is a special focus on antimicrobials classes listed in the WHO list (5th revision (http://who.int/foodsafety/cia/en)) (15) of CIAs for human medicine. Detailed criteria for WHO's classification of highest priority CIAs can be found in annex 4. The total consumption of these antimicrobial classes in the CIAs list in Thailand by food-producing animals was 308.09 mg/$PCU_{Thailand}$ (43.30% of the total national consumption of veterinary antimicrobial in 2017). Of these, the consumption of the highest priority CIA by food-producing animals was 99.55 mg/$PCU_{Thailand}$, (13.99% of total national consumption) while the high priority CIA consumed 208.54 mg/$PCU_{Thailand}$ (29.31% of total national consumption). The proportion of consumption, in mg/$PCU_{Thailand}$, of these classes/subclasses in Thailand is shown in figure 5.

On the highest priority CIAs group, the consumption (mg/$PCU_{Thailand}$) of 3rd and 4th generation Cephalosporins, Macrolides, Polymyxins, and Fluoroquinolones accounted for 0.98 mg/$PCU_{Thailand}$ (0.14%), 54.67 mg/$PCU_{Thailand}$ (7.68%), 33.05 mg/$PCU_{Thailand}$ (4.64%) and 10.85 mg/$PCU_{Thailand}$ (1.53%), of the total consumption in Thailand in 2017, respectively.

Table 20. Consumption of antimicrobials class listed as the critically important antimicrobials (CIAs) for human medicine, in mg per population correction unit modified by Thailand (mg/$PCU_{Thailand}$), in food-producing animals in Thailand, 2017*

Groups of substances	Consumption (mg/$PCU_{Thailand}$)
Highest priority	**99.55**
Cephalosporins (3rd, 4th and 5th generation)	0.98
Glycopeptides	-
Macrolides and ketolides	54.67
Polymyxins (colistin)	33.05
Fluoroquinolones	10.85
High priority	**208.54**
Aminoglycosides	29.56
Ansamycins	-
Carbapenems and other penems	-
Glycylcyclines	-
Lipopeptides	-
Monobactams	-
Oxazolidinones	-
Penicillins (natural, aminopenicillins, and antipseudomonal)	177.47
Phosphonic acid derivatives	1.51
Drugs used solely to treat tuberculosis or other mycobacterial diseases	-
Total	**308.09**

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

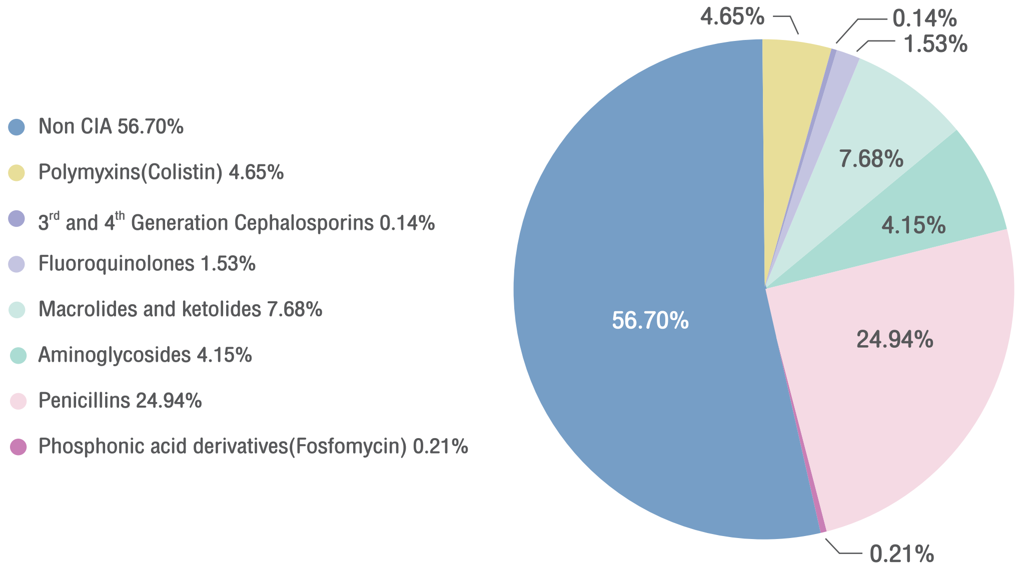

Figure 5. Proportion of the total consumption of antimicrobials in WHO's critically important antimicrobials (CIAs) list in food-producing animals, expressed as percentages of the total consumption in mg in Thailand in 2017

4.2.3 Consumption of veterinary antimicrobial agents for food-producing animals by route administration

The consumption of veterinary antimicrobial agents for food-producing animals stratified by pharmaceutical forms is shown in figure 6.

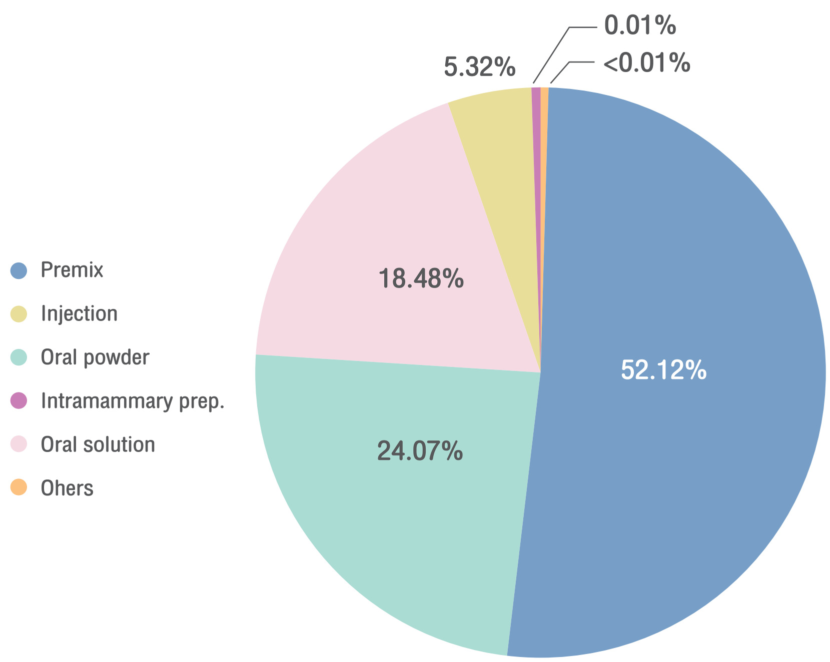

Figure 6. Distribution of consumption of veterinary antimicrobial agents for food-producing animals, in mg per population correction unit modified by Thailand (mg/$PCU_{Thailand}$), by pharmaceutical form in Thailand for 2017

The consumption (mg/$PCU_{Thailand}$) of medicated premixes accounted for 52.12% of the total national consumption of veterinary antimicrobial, while 24.07% were in oral powders, 18.48% oral solutions, 5.32% injection, 0.01% as intramammary preparations and less than 0.01% was others including oral pastes, vaginal tablets and intrauterine preparations.

The consumption of CIAs by pharmaceutical form in Thailand was shown in figure 7 where a great variation was noted. A majority, 87.73% of Polymyxins (colistin) and 65.31% of Macrolides and ketolides consumption were through medicated premix. Third and fourth generation of Cephalosporins were almost solely administered through injection of individual animal (99.91%), while 82.99% of Quinolones was administered through oral solution.

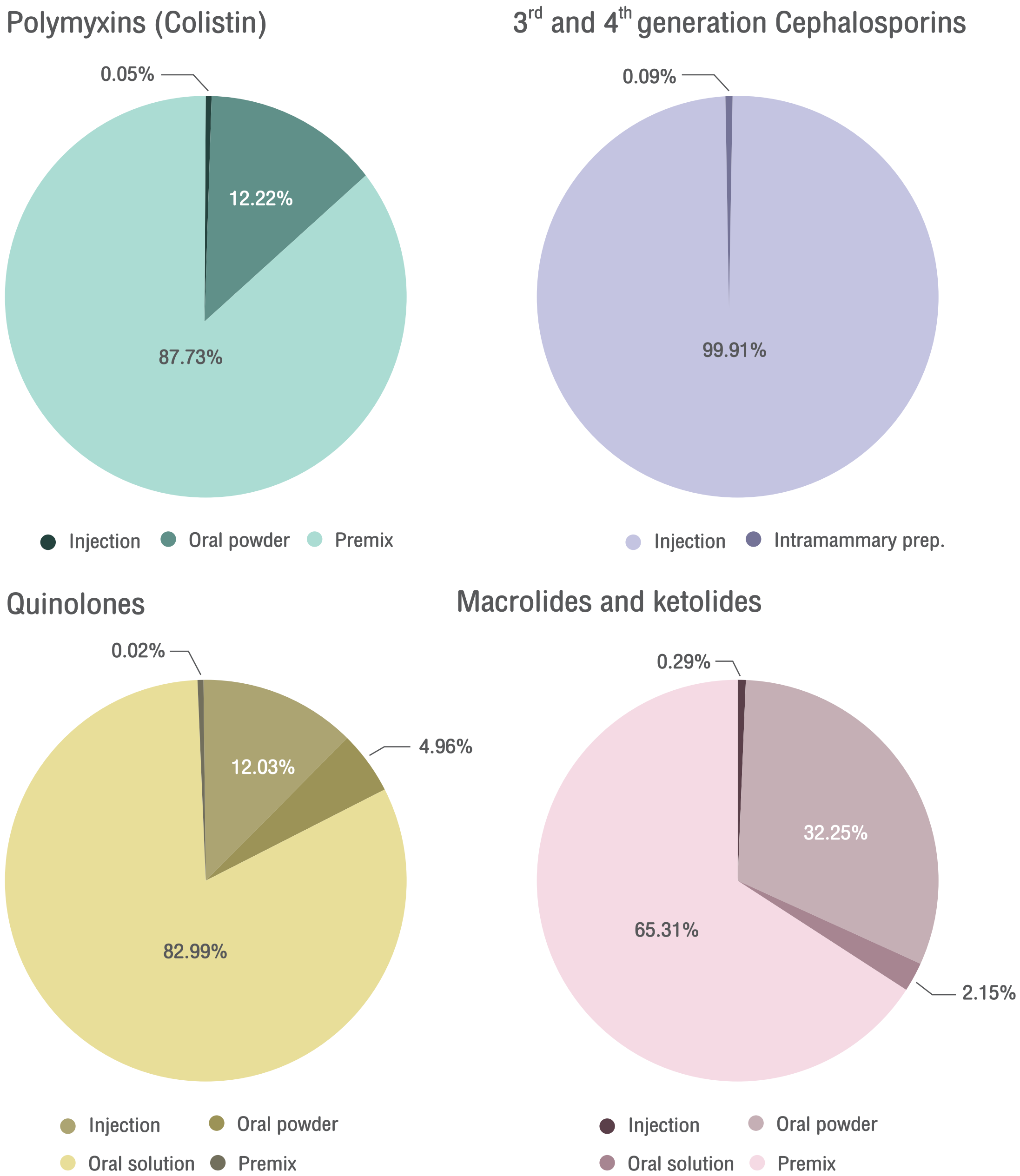

Figure 7. Distribution of consumption of WHO highest priority CIAs for food-producing animals by five forms of pharmaceutical administration, 2017

4.3 Consumption of critically important antimicrobials in humans and animals

Alarmingly, the preserved items for humans as a last resort was used in human consumption at a rate of 43.63 DDD/1,000 inhabitants/day, or 57.65% of total national consumption; and 308.09 mg per $PCU_{Thailand}$, or 43.30% of total consumption in the animal sector.

Table 21. Consumption of critically important antibiotics: highest and high priority by humans and food-producing animals, 2017 Thailand*

Human consumption	DDD/1,000 inhabitants/day	%
• Highest priority CIA	21.81	28.82%
• High priority CIA	21.82	28.83%
Total CIA use by human sector	43.63	57.65%
Total national consumption in human	75.68	
Consumption in food producing animals	**mg /$PCU_{Thailand}$**	**%**
• Highest priority CIA	99.55	13.99%
• High priority CIA	208.54	29.31%
Total CIA used by animal sector	308.09	43.30%
Total national consumption in animal	711.56	

* Interpretation and use of the data in this table should take into account the limitation described in Box 1 page 18.

05

Annex

Annex 1 Terminology

Acronyms

AI	Active ingredient
AMR	Antimicrobial Resistance
AMU	Antimicrobial Use
API	Active Pharmaceutical Ingredient
ATC	Anatomical Therapeutic Chemical
ATCvet	Anatomical Therapeutic Chemical classification system for veterinary medicinal products
Aw	Average weight at the time of treatment
CIA	Critically Important Antimicrobials
DDD	Defined Daily Dose
DID	Defined Daily Doses/1000 inhabitants/day
DLD	Department of Livestock Development
DOF	Department of Fisheries
ESAC-Net	European Surveillance of Antimicrobial Consumption Network
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
FAO	Food and Agricultural Organization
FDA	Food and Drug Administration
GDP	Gross Domestic product
HPSR-AMR	Health Policy and Systems Research on Antimicrobial Resistance
IHPP	International Health Policy Program
MOAC	Ministry of Agriculture and Cooperatives
MOPH	Ministry of Public Health
NSP-AMR	National Strategic Plan on Antimicrobial Resistance
OIE	World Organization for Animal Health
PCU	Population correction unit
Thailand SAC	Thailand Surveillance of Antimicrobial Consumption
VMPs	Veterinary Medicinal Products
WHO	World Health Organization

Annex 2 Methods used for calculation of numbers of food-producing animals

Livestock animals

The Department of Livestock Development, Ministry of Agriculture and Cooperatives provides the data on the numbers of food-producing animals, and collects from four sources;

1. Animal surveys by provincial/district Livestock officers
2. Data from producers especially large-scale private companies which imported Grandparent stocks (GP) and Parent stocks (PS) for producing commercial animals such as poultry and swine.
3. Data from E-movement system of DLD, which aims at animal movement management and control to ensure safe imports and exports. As stipulated by the Animal Epidemic law B.E. 2499 (1956) and its revision B.E. 2542 (1999), neither animal nor animal products shall be allowed for importation into, or exportation from, or transit in Thailand without permission from the Director General (DG), Department of Livestock Development or an authorized person designated by DG. The domestic movement of livestock is also subjected to a permission of the DG or his appointees. The data from E-movement system of DLD was mainly used for providing the data and cross-checking data before going to the data verification process.

Data verification was done by national level committees such as the egg board and pig board for finalizing the estimated number of commercial products in the whole market in Thailand in order to formulate an animal producing policy in our country.

Table A1. Summary of methods used for calculation of numbers of food-producing animals in each species.

Animal category	Data source			Data verification
	Animal survey by provincial/district Livestock officers	Data from producers	Cross-checked data by E-movement system of DLD	
Pigs				
Breeding pigs	/		/	Pig board
Fattening pigs*		/**	/	Pig board
Poultry				
Layer breeders			/***	Egg board
Laying hens*		/****	/	Egg board
Pullets			/	Egg board
Broiler breeders			/***	Broiler board
Broilers*		/*****	/	Broiler board
Broiler duck breeders			/***	-
Integrated broiler ducks*	/		/	-
Free-market broiler ducks	/		/	-
Integrated layer ducks	/		/	-
Free-market layer ducks	/		/	-
Cattle				
Dairy cows	/		/	Milk board
Dry cows	/		/	Milk board
Beef cows	/		/	-

*Variations from Government policies, economic conditions, disease situation

**Number of fattening pigs = number of breeders x 19.8 piglets/sow/year (9 survival piglets /sow x 2.2 litters/year)

***Importing data on numbers of Grandparent stocks (GP) & Parent stocks (PS)

****Number of laying hens = number of breeders x 90 chicks/hen/year x 95% survival rate during brooding period x 95% survival rate during growing period x Estimate number of laying hen/year (52 weeks)

*****Number of broiler chickens = Number of breeders x 129 chicks/hen/year x 95% survival rate during growing period

Aquatics animals

Data about production of aquatic animals were published by Fisheries Development Policy and Strategy Division, DOF. The data collection methods are as follows:

1. Production of aquatic animals of registered farms were reported by provincial fisheries office.
2. Sampling from listing survey farms, which include information of farm (e.g. capacity, species and type).
3. Survey sampling was done by using stratified sampling method (species and type are strata).

They randomly select the farms in each stratum using systematic random sampling (10 percent of total number of farms in each stratum) to estimate the total production of aquatic animals.

Aquatic animals including in this report	Scientific name
Nile tilapia	*Oreochromis niloticus*
Common carp	*Cyprinus carpio*
Common silver barb	*Barbonymus gonionotus*
Snakeskin gourami	*Trichogaster pectoralis*
Hybrid catfish	*Clarias microcephalus, C.gariepinnus*
Striped snake-head fish	*Channa striata*
Striped catfish	*Pangasius hypopthalmus*
Giant freshwater prawn	*Macrobrachium rosenbergii*
Other fishes (not indicated)	
Other aquatic animals: Softshell turtle	*Pelodiscus sinensis*
Frog	*Haplobatrachus rugulosus*

Annex 3 Statistics of annual report and Market Authorization in 2017

Statistics of annual report in 2017 only for targeted antimicrobials

Type of report	List of products	Type of licensing	
		No. of drug import licensee (N=188)	No. of drug produce licensee (N=150)
Annual report	Antimicrobials operators that have already submitted annual report to Thai FDA by 31 March 2018	185 (98.40%)	148 (98.67%)

Statistics of Market Authorization in 2017

Antimicrobials	No. of market authorization	No. of reported market authorization	No. of analyzed market authorization
Human antimicrobials	4,062	2,180	2,172*
Veterinary antimicrobials	1,634	948	948
Total	**5,696**	**3,128**	**3,120**

*8 market authorizations have no ATC/DDD (single drug/combined drug).

The proportion between single and combined drugs containing one, two, three and four active ingredients in reported market authorization

The proportion of the total consumption in 2017 of combined drugs containing three or more active ingredients in both humans and animals was relatively low. Of these pharmaceutical forms, 84.62%, 4.68%, 9.52%, 0.99% and 0.19% were single drugs, combined drugs containing one, two, three and four active ingredients, respectively.

Table A2. Number of single and combined drugs containing one, two, three and four active ingredients consumed in Thailand, for 2017

Antimicrobials	Single targeted antimicrobial drugs	Combined targeted antimicrobial drugs				
		1 antimicrobial ingredient	2 antimicrobial ingredients	3 antimicrobial ingredients	4 antimicrobial ingredients	Total
Human antimicrobials	1,830	132	186	19	5	2,172
Veterinary antimicrobials	810	14	111	12	1	948
Total	**2,640**	**146**	**297**	**31**	**6**	**3,120**

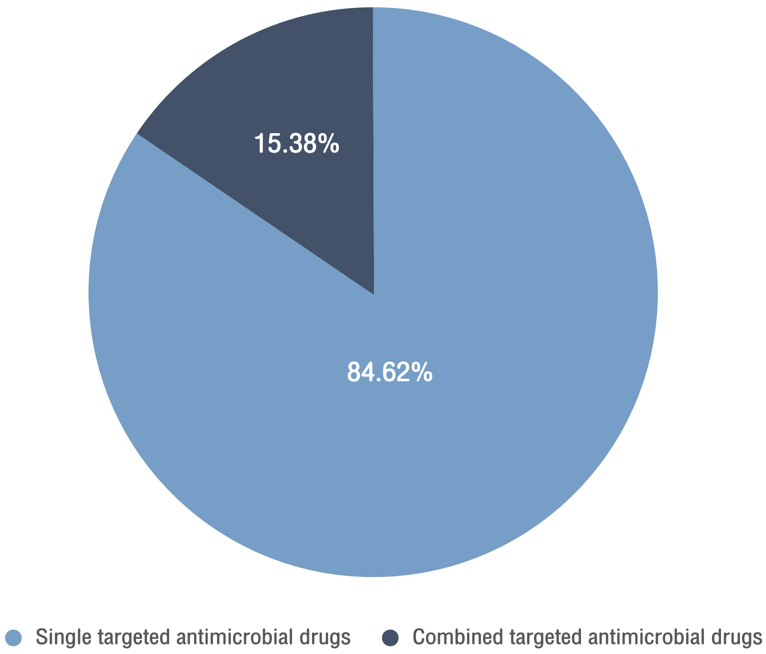

Figure A1. Percentages of single and combined targeted antimicrobial drugs consumed in both humans and animals in Thailand, 2017

Annex 4 WHO list of critically important antimicrobials (CIAs) for human medicine

WHO has produced a list of 'Critically Important Antimicrobials for Human Medicine' since 2005 and the updated WHO list of CIA was announced in 2017. Regarding the most updated list in 2017, all antimicrobials currently used for human medicine are prioritized to assist in addressing AMR and promote the prudent use in both human and veterinary medicine (15).

WHO criteria for including antimicrobial substances in critically important antimicrobials require that two parameters are fulfilled (WHO, 2017):

1. The antimicrobial class is the sole, or one of limited available therapies, to treat serious bacterial infections in people.
2. The antimicrobial class is used to treat infections in people caused by either: (1) bacteria that may be transmitted to humans from non-human sources, or (2) bacteria that may acquire resistance genes from non human sources.

Three prioritization criteria are used to categorize antimicrobial substances in the critically important antimicrobials into two groups; Highest Priority CIA and High Priority CIA (WHO, 2017):

1. High absolute number of people, or high proportion of use in patients with serious infections in health-care settings affected by bacterial diseases for which the antimicrobial class is the sole or one of few alternatives to treat serious infections in humans.
2. High frequency of use of the antimicrobial class for any indication in human medicine, or high proportion of use in patients with serious infections in health-care settings, since use may favour selection of resistance in both settings.
3. The antimicrobial class is used to treat infections in people for whom there is evidence of transmission of resistant bacteria (e.g. non-typhoidal *Salmonella* and *Campylobacter* spp.) or resistance genes (high for *E. coli* and *Enterococcus* spp.) from non-human sources.

The highest and high priority of WHO list of CIAs in human medicine was captured to identify antimicrobial classes that are highlighted in the report (table A3).

Table A3. Antimicrobial classes in WHO Critically Important Antimicrobials mentioned in the report

WHO classification	Antimicrobial class
Highest priority Critically Important Antimicrobials	Cephalosporins (3rd, 4th and 5th generations)
	Glycopeptides
	Macrolides and ketolides
	Polymyxins
	Quinolones
High priority Critically Important Antimicrobials	Aminoglycosides
	Ansamycins
	Carbapenems and other penems
	Glycylcyclines
	Lipopeptides
	Monobactams
	Oxazolidinones
	Penicillins (natural, aminopenicillins, and antipseudomonal)
	Phosphonic acid derivatives
	Drugs used solely to treat tuberculosis or other mycobacterial diseases

Annex 5 The calculation method in human antimicrobials

Antimicrobial consumption in humans was measured in DDD/1,000 inhabitants/day using the following calculation formula.

$$\text{DDD per 1,000 inhabitants per day (DID)} = \frac{\text{Defined daily dose (DDD)} \times 1{,}000}{\text{Mid-year population} \times 365}$$

DDD or defined daily dose is a measurement of drug utilization. DDD is the average adult dose per day of a drug for its main indication. DDD may not reflect the recommended dose for a particular patient or group of patients and it depends on patient characteristics such as age, weight, ethnicity, type and severity of disease as well as pharmacokinetics considerations.

The number of DDD (DDDs) equals the overall consumption of a particular drug in a specific time period divided by its DDD. This unit of utilizations allows consumption trends monitoring and comparison among different groups of the population, because it is independent from price, value of money, pack size, and strength of drug.

Steps to calculate DDD/1000 inhabitants/day

1. The important data elements required for calculation are WHO/ATC/DDD, standardized strength, standardized strength unit, WHO defined route of administration (to assign DDD) and manufacturing and importing quantities reported to the Thai FDA for the year 2017.
2. Calculated active ingredient (AI) from the reported manufacturing and importing quantities using standardized strength of drug. There are three calculation situations corresponding to different dosage forms. For example:
   a. amoxycillin 500 mg/capsule reported quantities = 100,000 capsules
      AI = 500 mg x 100,000 capsules = 50,000,000 mg
   b. amoxycillin suspension 125 mg/5 ml reported quantities = 8,600 bottles (60 ml each)
      AI = (125 mg / 5 ml) x (8,600 bottles x 60 ml) = 12,900,000 mg
   c. lincomycin injection 300 mg/ml reported quantities 7,000 vials (2 ml each)
      AI = 300 mg x (7,000 vials x 2 ml) = 4,200,000 mg
3. Calculate number of DDD (DDDs) from AI divided by DDD of each drug. For example AI of amoxycillin = 50,000,000 mg, and oral amoxycillin's DDD = 1 g. The same measurement unit of AI and DDD is required.
4. Calculate DDD/1,000 inhabitants/day by each level of ATC of targeted antimicrobial drugs.
5. For combined drugs, there are two different calculation methods. First, for those combined drugs with DDD of the combination, DDDs were calculated using combination DDD. For example, a combination of sulfamethoxazole and trimethoprim 400 mg/80 mg in each tablet has its combination DDD = 4 tablets, and 20,000 tablets were manufactured. DDDs = 20,000 tablets/4 tablets = 5,000 DDDs. Second, in case of no DDD assigned for the combination, DDDs were calculated using DDD of each single drug in the combination. For example, combination of lamivudine 150 mg (DDD = 0.3 g), and zidovudine 300 mg (DDD = 0.6 g) reported 5,000 tablets manufacturing.

Annex 6 The calculation method in veterinary antimicrobials

Methodology for veterinary consumption calculation

Before processing data from the database of the FDA, the integrity and completeness of the data must be achieved first. In this study, there were two sources of data, registration database and annual reports. The first one included essential information on veterinary medicinal products (VMPs) for calculation such as active pharmaceutical ingredient (API), the amount of API, strength unit the amount of a finished product, pharmaceutical dosage form, and ATC vet code. As for annual reports, the type of pack size, pack size, number of packs, and quantity of import or manufacture were compulsorily reported and electronically recorded. Part of the information from both of sources was retrieved.

Prior to the calculation process, the data from both the sources were mapped into two single Excel worksheets depending on the type of VMP: single VMP (sVMP), the VMP that contains only one antimicrobial API; or combination cVMP), the VMP that contains at least one antimicrobial API. Then, the calculation process was performed using Microsoft Excel version 2013. Generally, the steps of calculation were as follows:

1. Check for unit agreement. This step was to identify the unit agreement between strength unit and pack size in terms of solids (milligram, gram, or kilogram) or liquids (milliliter or liter).
2. Calculate the amount of API using the following formula:

$$\text{Amount of API} = \frac{\text{Strength}}{\text{Strength unit}} \times \text{Quantity of import or manufacture}$$

3. Adjust unit. In this calculation, the amount of API was calculated and converted into grams.
4. Subtract the amount of APIs from out-of-scope VMP (oVMP) and tablets. Some out-of-scope pharmaceutical dosage forms (dermatological preparations and preparations for sensory organs) needed to be excluded due to their insignificance in terms of antimicrobial consumption or primary use in companion animals (tablets).
5. Subtract the amount of API from non-target ATC vet codes. For cVMP, many cVMPs contained non-antimicrobial APIs or APIs that were already included in another code such as clavulanic acid. The results were the amount of target API (tAPI).

After the process had been finished, the data were classified and presented into two aspects: pharmaceutical dosage form and ATC vet code. Furthermore, as both the aspects originated from the same source of data, the total amount of tAPI calculated must have been balanced. If any irregularity was detected, it needed to be addressed and rectified to make all sheets balanced as they should.

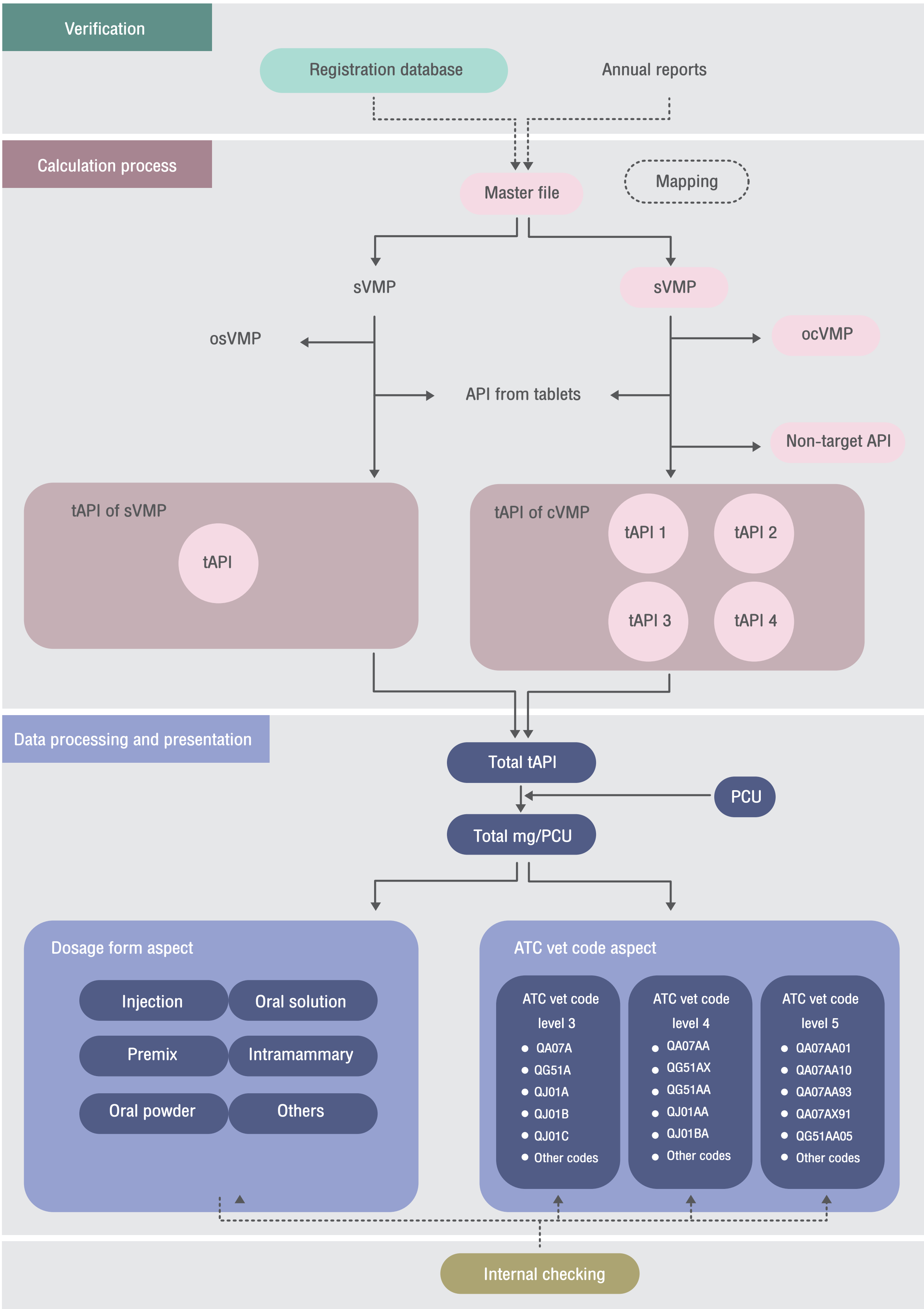

Figure A2. Methodology for veterinary consumption calculation

Annex 7 Validation for human antimicrobials

Method

Validation of the number of DDD as estimated by the working group was conducted independently by an external peer reviewer. The reviewer used STATA 14.0 for calculating the DDDs per uniquely-identified registering of numbers of drugs that were distinguished by two key attributes: (1) level-5 ATC and (2) dosage form plus route of administration (table A4).

Table A4. Data elements and sources for validating the DDD calculation

Five data elements	Three data sources		
	1. Industry's report	2. FDA's registration	3. WHO's ATC/DDD
A. Qualification			
1. *Unique identifier*	Register number	Register number	Register number
2. *Attribute 1*	Branded name	Active ingredient(s)	ATC level 5 & variant
3. *Attribute 2*		Dosage form - Oral solid - Oral liquid - Injection	Administration route - Oral (O) - Parenteral (P)
B. Quantification			
4. *Storage type 1 (numeric)*	**Quantity (Q)**	**Strength (S)**	**Defined daily dose (DDD)**
5. *Storage type 2 (string)*	**Unit of Q** - mg., g., units - cap., tab. - ml.	**Unit of S** - mg., g., units - mg./ …cap., …tab. - mg./ …ml.	**Unit of DDD** - mg., g., units - cap., tab.

In addition to the three qualitative elements, data for calculation of the DDD was obtained from three sources, including: 1) industry's report on quantity (Q); 2) FDA's registered strength (S); and 3) WHO's ATC/DDD system, based on the formula: DDDs = Q x S / DDD. Working data were divided into two major subsets; 1) single drugs; and 2) combined drugs. Each was distinguished by the units of quantity reported, including mg. or g.; capsule or tablet (for oral solid form); and ml. (for oral liquid form). Thirteen registered items of single source with the strength reported in "units (MU)", those with missing data on strength, and those with the data corrected in-between by the FDA were omitted from the validation process.

Finding

A total of 2,316 and 408 registered items of single and combined drugs respectively was subject to the validation. Of 229, 1,676, and 398 items of single drugs reported the quantity in mg or g, capsules or tablets and ml, respectively; 9, 1, and 2 items were found to have discrepancy in the DDD through validation by the external review process. For the combined drugs, 298 items with DDD available for the overall ATC; 0, 0, and 2 items of those reported the quantity in mg. or g., capsules or tablets, and ml, respectively were found to have a DDD discrepancy. Out of 109 items of the combined drugs with separate DDD of the first ATC; 1 of 11, 28 of 85, and 0 of 9 items were found to have the DDD discrepancy for those reported the quantity in mg or g, capsules or tablets, and ml, respectively. Out of 76 items of the combined drugs with separate DDD of the second ATC; 0 of 10, 9 of 57, and 0 of 8 items were found the DDD discrepancy for those reported the quantity in mg or g, capsules or tablets and ml, respectively. A total of 24 items of the combined drugs with separate DDD of the third ATC reported the quantity in capsules or tablets, of which six items were found to have the DDD discrepancy. For three items with the fourth ATC of combined drugs with separate DDD, all strength data were missing, hence none were validated.

The external reviewer advised the priority need for conventions of ATC/DDD for unconventional ATC/DDD, standardization for strength and strength units and aggregation levels of the DDD calculation for further development.

Annex 8 Validation for veterinary antimicrobials

Method

Validation on the consumption of antimicrobial agents used in animals as estimated by the working group was conducted independently by an external peer reviewer. The reviewer used Stata 13.1 for calculating the quantity of active ingredients per uniquely identified register numbers of drugs that were distinguished by two key attributes: 1) level-5 ATC; and (2) dosage form plus route of administration. In addition to the two qualitative elements, data for calculation of the number of active ingredients was obtained from two sources including: 1) industry's report on quantity (Q); and 2) FDA's registered strength (S) based on the formula: total AIs = Q x S. Working data were divided into two major subsets: 1) single drugs; and 2) combined drugs.

First of all, the process started with eligible criteria in which all ineligible drugs were removed. Then the unit of drug strength, the size of product package, and the import quantity of each record were reviewed. All items with mismatched units were checked individually and all incorrected data were verified. Afterwards, the quantity of active ingredients per register numbers and total consumption were calculated and compared with the result calculated by the working group. Then, unequal results were reviewed individually. Lastly, the list of incorrect results and total number of consumption were informed to the working group.

Finding

A total of 1,019 registered items of single drugs were subjected to the validation. Two items of single drugs were excluded because of ineligible criteria. A total of 58 records had mismatched units, as 5.70% of the total items. All mismatched records were verified and amended with both external peers and the working group's consensus. The pitfalls were incorrect data entries from the FDA and industries. After data amendments, the 49 of 1,107 items were found to have AI discrepancy from the previous calculation. However, all differences were less than 1% of the number of calculated AI, between -0.00001% and 0.00001%.

A total of 223 registered items of combined drugs were subjected to the validation. Of 223; 11 items were excluded because of eligible criteria. A total of 11 had mismatched units, as 5.19% of total items. All mismatched records were verified and amended with both external peers and the working group's consensus. The pitfalls were incorrect data entries from the FDA and industries. After data amendments, the 67 of 1,107 items were found to have AI discrepancy from the previous calculation. However, most were minor discrepancies; 64 differences were not more than 5% of the number of calculated AI, between -1.83% and 5.00%. There were three items having high discrepancy because of a wrong formula used, and were 1.42% of total items. The external reviewer had reported these errors to the working group for recalculation.

The external reviewer advised the working group to: 1) standardize drug strength pattern which should distinguish between strength and concentration; 2) verify data from both industries' reports and FDA's registration; 3) consider a mismatch of unit patterns in strength, packaging and imported quantity; and 4) note all amendments systematically for further development.

Annex 9 Total consumption of veterinary antimicrobials (tonnes)

The overall national consumption data covers the consumption of veterinary antimicrobials for use in food-producing animals (all other pharmaceutical dosage forms) and that of tablets which are exclusively used in companion animals. However, injectable veterinary antimicrobial agents are registered for both food-producing and companion animals and use in companion animals is limited based on the amount of active ingredients; such consumption is included in the statistics for food-producing animals. Overall, consumption of tablets using in companion animals in 2017 represented 0.04 % of the total consumption in tonnes, which accounted for a minor proportion of the total consumption of veterinary antimicrobials in 2017.

Table A5. Distribution of overall consumption, in tonnes of active ingredient, divided into tablets (used exclusively in companion animals) and all other pharmaceutical dosage forms (used mainly in food-producing animals) in Thailand, 2017

	Tablets		All other pharmaceutical dosage forms		Total tonnes
	Tonnes	% of total consumption in tonnes	Tonnes	% of total consumption in tonnes	
Thailand	1.71	0.04	4688.41	99.96	4690.12

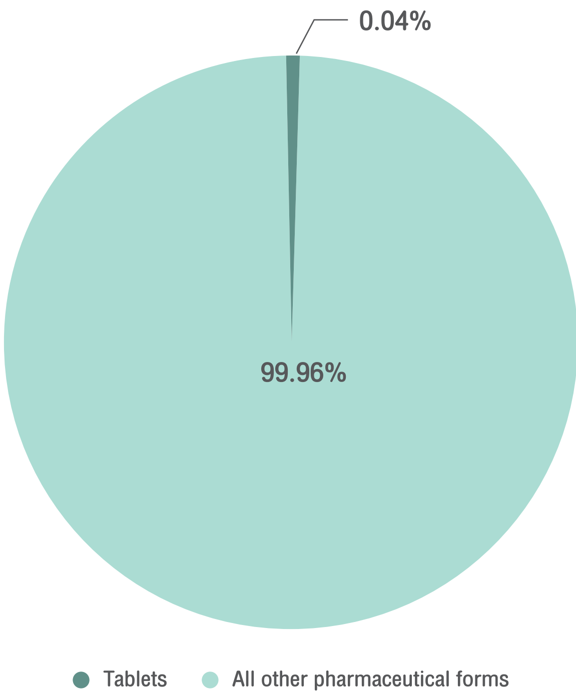

Figure A3. Distribution of consumption, in tonnes of active ingredients, divided into tablets (used exclusively in companion animals) and all other pharmaceutical forms (used mainly in food-producing animals) in Thailand, 2017

Annex 10 All veterinary antimicrobials used as premix for medicated feeding stuff in food-producing animals

Table A6. All veterinary consumption as premix for medicated feeding stuff in food-producing animals, 2017

Rank	ATC level 5	Antimicrobial drug	Total consumption (tonnes)
1	QA07AX91	halquinol	678.72
2	QJ01AA03	chlortetracycline	380.29
3	QJ01CA04	amoxicillin	375.47
4	QJ01XQ01	tiamulin	300.89
5	QA07AA10	colistin	191.04
6	QJ01FA91	tilmicosin	148.80
7	QJ01AA02	doxycycline	134.25
8	QA07AA93	bacitracin	69.63
9	QJ01FA90	tylosin	58.37
10	QJ01AA06	oxytetracycline	31.22
11	QJ01FA93	kitasamycin	24.40
12	QJ01FF02	lincomycin	15.04
13	QJ01XX01	fosfomycin	9.97
14	QJ01EQ03	sulfadimidine	7.14
15	QJ01EQ10	sulfadiazine	6.12
16	QJ01FA07	josamycin	3.61
17	QA07AA96	bambermycin	2.79
18	QJ01EA01	trimethoprim	1.85
19	QJ01XX04	spectinomycin	1.76
20	QJ01CE02	phenoxymethylpenicillin	1.14
21	QJ01EQ17	sulfamerazine	0.51
22	QJ01GB90	apramycin	0.30
23	QJ01FA01	erythromycin	0.04
24	QJ01MA90	enrofloxacin	0.01
25	QJ01MA98	sarafloxacin	<0.01
26	QJ01XQ02	valnemulin	<0.01
	Total		2,443.38

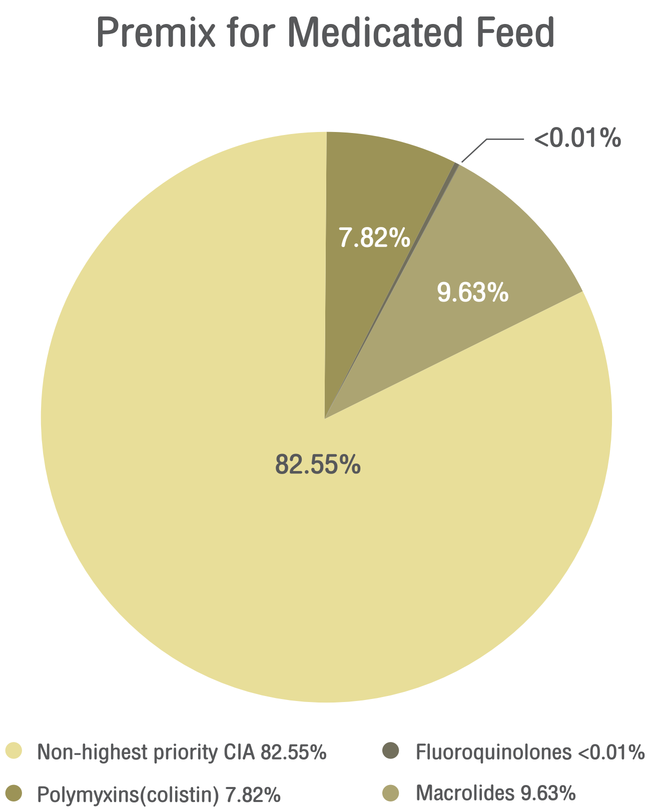

Figure A4. Distribution of consumption of WHO highest priority CIAs for veterinary antimicrobials used as premix for medicated feeding stuff in food-producing animals, 2017

Annex 11 Lists of consumption by ATC level 5 (human antimicrobials)*

Rank	ATC level 5	Antimicrobial drug	Total consumption (DDDs)	DID	%
1	J01CA04	amoxicillin	399,189,828.25	15.10	19.95%
2	J01DD04	ceftriaxone	358,905,231.75	13.57	17.94%
3	J02AB02	ketoconazole	113,958,190.00	4.31	5.70%
4	J01AA07	tetracycline	93,750,626.50	3.55	4.69%
5	J05AG03	efavirenz	81,536,302.50	3.08	4.07%
6	J05AF05	lamivudine	72,096,324.87	2.73	3.60%
7	J01CR02	amoxicillin and enzyme inhibitor	64,959,098.97	2.46	3.25%
8	J01AA02	doxycycline	63,888,050.00	2.42	3.19%
9	J05AF07	tenofovir disoproxil	57,017,735.51	2.16	2.85%
10	J01MA06	norfloxacin	54,687,807.75	2.07	2.73%
11	J05AF09	emtricitabine	43,908,000.00	1.66	2.19%
12	J01FA06	roxithromycin	42,155,308.33	1.59	2.11%
13	J01CA01	ampicillin	38,670,455.75	1.46	1.93%
14	J01EE01	sulfamethoxazole and trimethoprim	37,833,324.65	1.43	1.89%
15	J01CF01	dicloxacillin	36,573,941.00	1.38	1.83%
16	J01MA02	ciprofloxacin	34,340,130.10	1.30	1.72%
17	J05AG01	nevirapine	31,159,440.00	1.18	1.56%
18	J01DD02	ceftazidime	24,611,839.63	0.93	1.23%
19	J04AC01	isoniazid	23,639,337.50	0.89	1.18%
20	J05AF01	zidovudine	21,689,453.67	0.82	1.08%
21	J04AB02	rifampicin	21,492,317.50	0.81	1.07%
22	P01BA01	chloroquine	19,810,665.50	0.75	0.99%
23	J01CF02	cloxacillin	18,587,523.75	0.70	0.93%
24	J01DB01	cefalexin	16,461,676.50	0.62	0.82%
25	J01FA10	azithromycin	14,709,218.95	0.56	0.74%
26	P01AB01	metronidazole	14,474,322.50	0.55	0.72%
27	J05AR10	lopinavir and ritonavir	13,640,581.50	0.52	0.68%
28	P01BD01	pyrimethamine	12,675,010.00	0.48	0.63%
29	J01FF01	clindamycin	12,293,341.42	0.46	0.61%
30	D01BA01	griseofulvin	10,694,250.00	0.40	0.53%
31	J01MA01	ofloxacin	10,636,731.50	0.40	0.53%
32	J01FA09	clarithromycin	10,442,278.40	0.39	0.52%
33	J02AC01	fluconazole	9,569,516.75	0.36	0.48%
34	J01MA12	levofloxacin	9,548,146.50	0.36	0.48%
35	J02AC02	itraconazole	7,537,904.50	0.29	0.38%
36	J04AK01	pyrazinamide	6,802,062.33	0.26	0.34%

Rank	ATC level 5	Antimicrobial drug	Total consumption (DDDs)	DID	%
37	J04AK02	ethambutol	6,175,451.46	0.23	0.31%
38	J01DD16	cefditoren	5,659,995.00	0.21	0.28%
39	P01BA02	hydroxychloroquine	5,057,918.60	0.19	0.25%
40	J01FA01	erythromycin	5,022,144.75	0.19	0.25%
41	J01FF02	lincomycin	4,990,130.00	0.19	0.25%
42	J05AG05	rilpivirine	4,963,140.00	0.19	0.25%
43	J01DC04	cefaclor	4,536,976.38	0.17	0.23%
44	J05AB01	aciclovir	4,469,497.51	0.17	0.22%
45	J01EC02	sulfadiazine	4,215,356.85	0.16	0.21%
46	J01GB03	gentamicin	4,068,397.92	0.15	0.20%
47	J05AF04	stavudine	3,963,358.80	0.15	0.20%
48	J05AF06	abacavir	3,015,943.10	0.11	0.15%
49	J01DC02	cefuroxime	2,939,096.00	0.11	0.15%
50	J01DB04	cefazolin	2,776,015.17	0.10	0.14%
51	J01BA02	thiamphenicol	2,732,578.33	0.10	0.14%
52	J01CE02	phenoxymethyl penicillin	2,603,834.88	0.10	0.13%
53	J01DD08	cefixime	2,378,975.00	0.09	0.12%
54	J05AF10	entecavir	2,285,310.00	0.09	0.11%
55	J01DH02	meropenem	1,838,019.25	0.07	0.09%
56	J01DD15	cefdinir	1,434,247.08	0.05	0.07%
57	J05AE08	atazanavir	1,414,060.00	0.05	0.07%
58	J01AA03	chlortetracycline	1,278,150.00	0.05	0.06%
59	J01GA01	streptomycin	1,219,540.00	0.05	0.06%
60	P01BC01	quinine	1,138,656.93	0.04	0.06%
61	J05AH02	oseltamivir	1,005,355.96	0.04	0.05%
62	J01CE09	procaine benzylpenicillin	995,010.00	0.04	0.05%
63	J01GB04	kanamycin	921,455.73	0.03	0.05%
64	J01MA14	moxifloxacin	869,652.00	0.03	0.04%
65	J01XD01	metronidazole	869,532.67	0.03	0.04%
66	P01AB02	tinidazole	848,624.50	0.03	0.04%
67	J01CR05	piperacillin and enzyme inhibitor	780,973.36	0.03	0.04%
68	J05AF11	telbivudine	607,936.00	0.02	0.03%
69	A07AA02	nystatin	563,359.79	0.02	0.03%
70	P01BA03	primaquine	503,500.00	0.02	0.03%
71	A07AA01	neomycin	485,295.29	0.02	0.02%
72	J05AP01	ribavirin	430,164.00	0.02	0.02%
73	J04AD03	ethionamide	399,166.67	0.02	0.02%
74	J05AE10	darunavir	367,860.00	0.01	0.02%

Rank	ATC level 5	Antimicrobial drug	Total consumption (DDDs)	DID	%
75	J01DH03	ertapenem	366,415.00	0.01	0.02%
76	J05AF08	adefovir dipivoxil	362,490.00	0.01	0.02%
77	J01EB02	sulfamethizole	351,146.88	0.01	0.02%
78	J01DD01	cefotaxime	341,448.25	0.01	0.02%
79	J01DD62	cefoperazone, combinations	327,985.63	0.01	0.02%
80	J05AX08	raltegravir	304,530.00	0.01	0.02%
81	J01GB06	amikacin	290,009.00	0.01	0.01%
82	J01XA01	vancomycin	284,142.25	0.01	0.01%
83	J02AA01	amphotericin B	265,450.00	0.01	0.01%
84	J01CE01	benzylpenicillin	248,801.91	0.01	0.01%
85	J01XX01	fosfomycin	239,014.00	0.01	0.01%
86	J01XE01	nitrofurantoin	232,500.00	0.01	0.01%
87	J01MA17	prulifloxacin	225,083.33	0.01	0.01%
88	J01MA21	sitafloxacin	225,000.00	0.01	0.01%
89	J01EB03	sulfadimidine	221,977.50	0.01	0.01%
90	J01AA06	oxytetracycline	221,257.00	0.01	0.01%
91	J01DH51	imipenem and enzyme inhibitor	212,764.50	0.01	0.01%
92	J04AA02	sodium aminosalicylate	211,785.71	0.01	0.01%
93	J01ED05	sulfamethoxypyridazine	200,000.00	0.01	0.01%
94	J01CR01	ampicillin and enzyme inhibitor	165,746.26	0.01	0.01%
95	J01CR04	sultamicillin	163,183.00	0.01	0.01%
96	J01ED07	sulfamerazine	152,768.04	0.01	0.01%
97	J01BA01	chloramphenicol	129,763.33	< 0.01	0.01%
98	J01XB01	colistin	119,117.73	< 0.01	0.01%
99	J01DB05	cefadroxil	118,192.00	< 0.01	0.01%
100	J01AA12	tigecycline	110,000.00	< 0.01	0.01%
101	J02AC03	voriconazole	107,902.50	< 0.01	0.01%
102	J05AB11	valaciclovir	93,413.33	< 0.01	<0.01%
103	J05AG04	etravirine	91,260.00	< 0.01	<0.01%
104	D01BA02	terbinafine	91,042.00	< 0.01	<0.01%
105	J01DC01	cefoxitin	90,150.50	< 0.01	<0.01%
106	J01AA08	minocycline	85,225.00	< 0.01	<0.01%
107	J04AB01	cycloserine	75,583.33	< 0.01	<0.01%
108	J05AP07	daclatasvir	57,596.00	< 0.01	<0.01%
109	J05AF02	didanosine	56,250.00	< 0.01	<0.01%
110	J01DE01	cefepime	52,616.50	< 0.01	<0.01%
111	J01DH05	biapenem	41,205.00	< 0.01	<0.01%
112	J05AX12	dolutegravir	40,500.00	< 0.01	<0.01%

Rank	ATC level 5	Antimicrobial drug	Total consumption (DDDs)	DID	%
113	J01DD12	cefoperazone	36,883.75	< 0.01	<0.01%
114	J05AB06	ganciclovir	29,025.00	< 0.01	<0.01%
115	J05AP08	sofosbuvir	28,000.00	< 0.01	<0.01%
116	J05AB09	famciclovir	23,803.50	< 0.01	<0.01%
117	J02AC04	posaconazole	22,974.00	< 0.01	<0.01%
118	J05AB14	valganciclovir	22,350.00	< 0.01	<0.01%
119	J01GB07	netilmicin	14,957.71	< 0.01	<0.01%
120	J01XX08	linezolid	14,640.00	< 0.01	<0.01%
121	J05AX09	maraviroc	12,720.00	< 0.01	<0.01%
122	J01AA04	lymecycline	10,752.00	< 0.01	<0.01%
123	J01CE10	benzathine phenoxymethylpenicillin	10,714.50	< 0.01	<0.01%
124	J01XA02	teicoplanin	8,567.50	< 0.01	<0.01%
125	J02AX05	micafungin	8,400.00	< 0.01	<0.01%
126	J01CG01	sulbactam	7,908.00	< 0.01	<0.01%
127	J05AX05	inosine pranobex	7,400.00	< 0.01	<0.01%
128	J01EA01	trimethoprim	6,000.00	< 0.01	<0.01%
129	J02AX06	anidulafungin	3,600.00	< 0.01	<0.01%
130	J02AX04	caspofungin	894.00	< 0.01	<0.01%
131	J04AB30	capreomycin	470.00	< 0.01	<0.01%
132	J01DC03	cefamandole	166.67	< 0.01	<0.01%
133	P01BA06	amodiaquine	150.00	< 0.01	<0.01%
134	P01BC02	mefloquine	128.00	< 0.01	<0.01%
135	P01BF01	artemether and lumefantrine	1.71	< 0.01	<0.01%
136	J05AH01	zanamivir	1.00	< 0.01	<0.01%
137	J01XX04	spectinomycin	0.67	< 0.01	<0.01%
		Total	**2,001,014,476.80**	**75.68**	**100%**

* Interpretation and use of the data in this table should take into account on the limitation as expressed on page 18.

Annex 12 Lists of consumption by ATCvet level 5 (veterinary antimicrobials)*

Rank	ATCvet level 5	Antimicrobial drug	Total consumption (mg)	$mg/PCU_{Thailand}$	%
1	QJ01CA04	amoxicillin	1,152,774,290,521.18	174.96	24.59%
2	QA07AX91	halquinol	678,724,080,000.00	103.01	14.48%
3	QJ01EQ03	sulfadimidine	655,646,053,731.52	99.51	13.98%
4	QJ01AA03	chlortetracycline	383,436,281,595.90	58.19	8.18%
5	QJ01XQ01	tiamulin	319,807,631,471.50	48.54	6.82%
6	QJ01AA02	doxycycline	259,011,988,899.36	39.31	5.52%
7	QA07AA10	colistin	217,760,220,850.19	33.05	4.64%
8	QJ01FA91	tilmicosin	156,532,478,630.00	23.76	3.34%
9	QJ01EA01	trimethoprim	144,874,338,900.00	21.99	3.09%
10	QJ01GB03	gentamicin	129,375,458,475.00	19.64	2.76%
11	QJ01FA90	tylosin	125,759,987,925.46	19.09	2.68%
12	QJ01AA06	oxytetracycline	83,185,926,644.04	12.63	1.77%
13	QJ01MA90	enrofloxacin	71,133,806,701.00	10.80	1.52%
14	QA07AA93	bacitracin	69,628,493,165.78	10.57	1.49%
15	QJ01FA93	kitasamycin	53,876,060,000.00	8.18	1.15%
16	QA07AA01	neomycin	45,822,650,532.94	6.95	0.98%
17	QJ01FF02	lincomycin	23,958,917,816.80	3.64	0.51%
18	QJ01EQ10	sulfadiazine	18,795,328,143.75	2.85	0.40%
19	QJ01XX04	spectinomycin	14,831,169,060.08	2.25	0.32%
20	QJ01FA92	tylvalosin	12,966,000,000.00	1.97	0.28%
21	QJ01GA90	dihydrostreptomycin	12,033,751,259.69	1.83	0.26%
22	QJ01XX01	fosfomycin	9,973,460,000.00	1.51	0.21%
23	QJ01CE09	procaine benzylpenicillin	8,989,294,998.26	1.36	0.19%
24	QJ01FA01	erythromycin	7,233,377,676.95	1.10	0.15%
25	QJ01GB04	kanamycin	5,916,020,800.00	0.90	0.13%
26	QJ01DE90	cefquinome	5,031,452,500.00	0.76	0.11%
27	QJ01FA07	josamycin	3,613,500,000.00	0.55	0.08%
28	QJ01CE08	benzathine benzylpenicillin	3,232,807,666.87	0.49	0.07%
29	QA07AA96	bambermycin	2,786,000,000.00	0.42	0.06%
30	QJ01CA01	ampicillin	1,963,483,598.19	0.30	0.04%
31	QJ01DD90	ceftiofur	1,423,974,000.00	0.22	0.03%
32	QJ01EQ11	sulfamethoxazole	1,152,880,000.00	0.17	0.02%
33	QJ01CE02	phenoxymethylpenicillin	1,144,638,000.00	0.17	0.02%
34	QJ01EQ09	sulfadimethoxine	983,759,447.40	0.15	0.02%
35	QJ01GA01	streptomycin	939,484,617.01	0.14	0.02%
36	QJ01CR02	amoxicillin and enzyme inhibitor	829,749,900.00	0.13	0.02%

Rank	ATCvet level 5	Antimicrobial drug	Total consumption (mg)	mg/$PCU_{Thailand}$	%
37	QJ01EQ17	sulfamerazine	512,000,000.00	0.08	0.01%
38	QJ01GB90	apramycin	470,480,000.00	0.07	0.01%
39	QJ01EQ13	sulfadoxine	462,660,000.00	0.07	<0.01%
40	QJ01MA93	marbofloxacin	274,198,000.00	0.04	<0.01%
41	QJ01EQ15	sulfamethoxypyridazine	231,712,000.00	0.04	<0.01%
42	QJ51CF02	cloxacillin	216,478,492.16	0.03	<0.01%
43	QJ01GB05	neomycin	208,122,729.83	0.03	<0.01%
44	QJ01EQ16	sulfazuinoxaline	185,270,904.10	0.03	<0.01%
45	QJ01FA94	tulathromycin	129,700,000.00	0.02	<0.01%
46	QJ01MA92	danofloxacin	93,620,000.00	0.01	<0.01%
47	QJ51CA01	ampicillin	81,932,400.00	0.01	<0.01%
48	QJ01FA95	gamithromycin	74,925,000.00	0.01	<0.01%
49	QJ01BA90	florfenicol	74,820,000.00	0.01	<0.01%
50	QJ01CE01	benzylpenicillin	68,146,706.68	0.01	<0.01%
51	QJ01AA07	tetracycline	64,694,000.00	<0.01	<0.01%
52	QJ01EQ18	sulfamonomethoxine	27,697,853.60	<0.01	<0.01%
53	QJ51DB90	cefalonium	27,085,000.00	<0.01	<0.01%
54	QJ01DC02	cefuroxime	14,460,000.00	<0.01	<0.01%
55	QJ51DB01	cefalexin	8,353,330.90	<0.01	<0.01%
56	QJ01FF01	clindamycin	8,007,500.00	<0.01	<0.01%
57	QJ51DE90	cefquinome	5,577,750.00	<0.01	<0.01%
58	QJ51AA07	tetracycline	5,474,887.73	<0.01	<0.01%
59	QJ01EQ07	sulfathiazole	3,985,830.00	<0.01	<0.01%
60	QJ01MA98	sarafloxacin	3,652,000.00	<0.01	<0.01%
61	QJ51DB08	cefapirin	2,619,162.00	<0.01	<0.01%
62	QJ01DD91	cefovecin	2,426,880.00	<0.01	<0.01%
63	QJ01XQ02	valnemulin	2,200,000.00	<0.01	<0.01%
64	QG51AA05	cefapirin	900,000.00	<0.01	<0.01%
65	QJ01XX10	bacitracin	800,539.74	<0.01	<0.01%
66	QJ01FA02	spiramycin	545,440.00	<0.01	<0.01%
67	QJ51GB03	gentamicin	281,867.71	<0.01	<0.01%
68	-	ormethoprim	100,000.00	<0.01	<0.01%
69	QJ01CF06	nafcillin	77,870.48	<0.01	<0.01%
70	QJ01CF02	cloxacillin	6,854.33	<0.01	<0.01%
		Total	**4,688,411,810,528.12**	**711.56**	**100%**

* Interpretation and use of the data in this table should take into account on the limitation as expressed on page 18.

Annex 13 Health Policy and Systems Research on antimicrobial resistance working group members

Ministry of Public Health

International Health Policy Program

Viroj Tangcharoensathien

Angkana Lekagul

Sunicha Chanvatik

Wanwisa Kaewkhankhaeng

Food and Drug Administration

Varavoot Sermsinsiri

Kritsada Limpananont

Chutamas Luangaroonchai

Pischa Lusanandana

Chaiporn Pumkam

Supapat Kirivan

Sitanan Poonpolsub

Ministry of Agriculture and Cooperatives

Department of Livestock Development

Thanida Harintharanon

Sasi Jareonpoj

Bunyoung Suangthamai

Julaporn Srinha

Suchana Sukklad

Natthapong Supimon

Porjai Rattanapanadda

Department of Fisheries

Thitiporn Laoprasert

Chanotit Nakmanoc

Narintha Boonkuang

Jutamas Auewongaree

Suppaluck Chambang

Faculty of Pharmaceutical Sciences, Chulalongkorn University

Rungpetch Sakulbumrungsil

Faculty of Pharmacy, Silpakorn University

Inthira Kanchanaphibool

Faculty of Pharmaceutical Sciences, Khon Kaen University

Nussaraporn Kessomboon

Faculty of Pharmaceutical Sciences, Prince of Songkla University

Khunjira Udomaksorn

Contributors

Faculty of Veterinary Science, Mahidol University

Walasinee Moonarmart

Boonrat Chantong

Sarin Suwanpakdee

Anuwat Wiratsudakul

Thai Feed Mill Association

Boonyita Rujtikumporn

Wichai Thermphonboon

Chaiwat Suwannatad

Sompong Harnuthaikij

Krisada Rithichaidumrongkul

Yamuna Patthong

Sureemas Nitikanchana

Pranee Pirompud

Pattama Sritiangtrong

Animal Health Products Association

Nackanun Chitaroon

Panitan Suwannapetch

Eagaluk Theerakornsakul

Varisara Jirathitivong

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Health Policy and Systems Research on antimicrobial resistance (HPSR-AMR)
International Health Policy Program, Thailand
Ministry of Public Health, Tivanond Road,
Muang District, Nonthaburi 11000
Telephone + 66 2 590 2366, 590 2367
Fax + 66 2 590 2385
Website: www.ihppthaigov.net