APEC Conference on Strategies Against the Evolving Threats from Antimicrobial Resistance:

From Awareness to Concrete Action

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Introduction

In the Philippines, majority of the infections are caused by MDR *Pseudomonas* aeruginosa, Acinetobacter spp., Streptococcus pneumoniae, methicillin-resistance Staphylococcus aureus, Neisseria gonorhoeae, MDR TB and XDR TB.

Creation of the Inter-Agency Committee on Antimicrobial Resistance

In 2014, former President Benigno Aquino signed the Administrative Order no. 42 series of 2014 entitled "Creating an Inter-agency Committee for the Formulation and Implementation of a National Plan to Combat Antimicrobial Resistance (AMR) in the Philippines."











Composition of the Inter-Agency Committee on Antimicrobial Resistance (ICAMR):

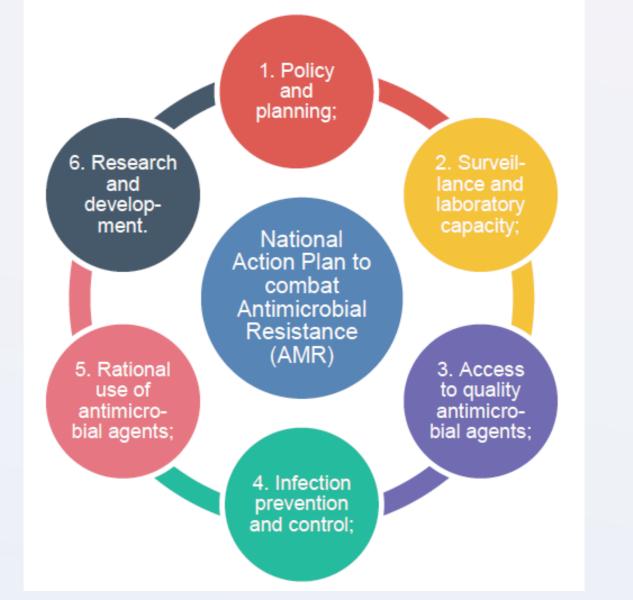
	Agency	Functions
Chair	Department of Health (DOH)	Primarily functions to provide technical secretariat support to the committee
		Responsible for establishing policies that address AMR
		Ensure that quality antimicrobials are accessible and affordable
		Regulate antimicrobials in the market
		Create essential medicines lists, treatment guidelines, systems, platforms, risk communication plans and IEC materials for human use
		Establish AMR and antimicrobial use surveillance programs
	Department of Agriculture (DA)	Responsible for establishing policies that address AMR
		Ensure that quality antimicrobials are accessible and affordable
Co-chair		Regulate antimicrobials in the market
		Create essential medicines lists, treatment guidelines, systems, platforms, risk communication plans and IEC materials for veterinary use
		Establish AMR and antimicrobial use surveillance programs
Members	Department of Trade and In- dustry (DTI)	Strengthen surveillance systems and laboratory detection capacity for AMR and their use in humans and animals
		Ensure the laboratories conform to international standards
	Department of Science and Technology (DOST)	Lead in the prioritization of AMR in health agendas and researches aimed to develop new antimicrobials and innovative technologies to improve diagnosis and treatment
	Department of the Interior and Local Government (DILG)	Coordinate and implement AMR policies to the local governments to ensure that strategies to address AMR reach communities and household level

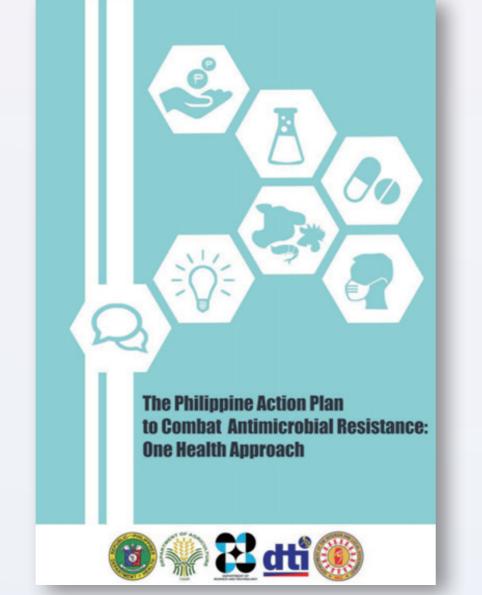
The ICAMR is tasked to oversee the implementation of a unified, comprehensive, and a sustainable National Action Plan adhering to the WHO Six-Point Policy Package.

In 2016, the ICAMR, through the DOH, established a partnership with the Department of Education (DepEd) to include the concepts of AMR and rational use of antimicrobials in the elementary and high school curriculum. The Professional Regulatory Commission (PRC) and the Commission on Higher Education were also encouraged to include the rational use of antimicrobials and medicines in the undergraduate curriculum of the healthcare professionals.

Development of the Philippine Action Plan to Combat Antimicrobial Resistance

The major actionable areas in the document entitled: "Philippine Action Plan to Combat Antimicrobial Resistance: One Health Approach" are as follows:



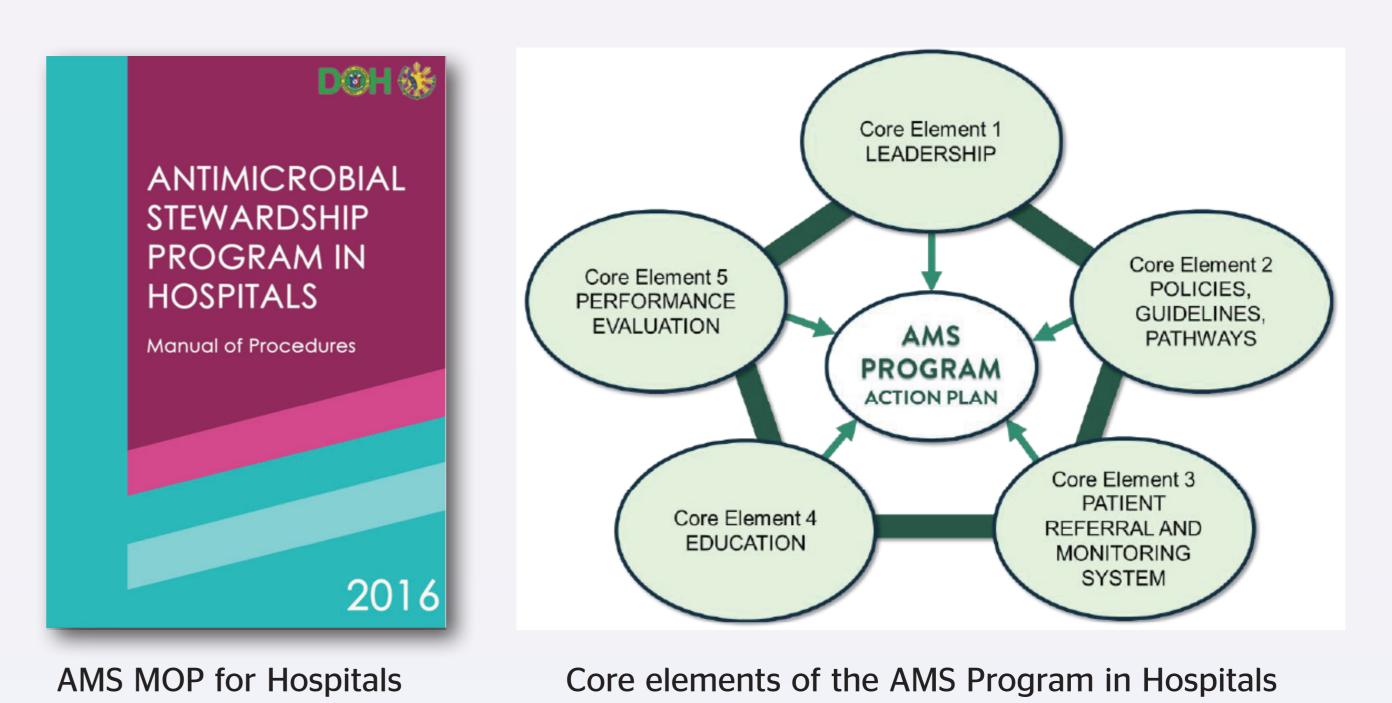


Photos during the celebration of the 1st Philippine AMR Summit in November 2015

Since 2015, the country observes the Philippine Antibiotic Awareness Week every November in time for the celebration of the World Antibiotic Awareness Week.

National Antimicrobial Stewardship Program

In light of the global and national agenda to address the multi-sectoral threats of AMR, the DOH institutionalize the Antimicrobial Stewardship (AMS) Program in hospitals as part of the overarching Country Action Plan to combat AMR. This is to ensure rational prescribing, dispensing and use of antimicrobials. As such, the DOH selected two clinical pharmacists among the AMS pilot sites in 2015 to undergo the AMS training program in Singapore from 29 February to 18 March 2016. Moreover, the AMS Manual of Procedures (MOP) was developed in 2016 to facilitate the effective and systematic implementation of the program to all public and private hospitals in the country.



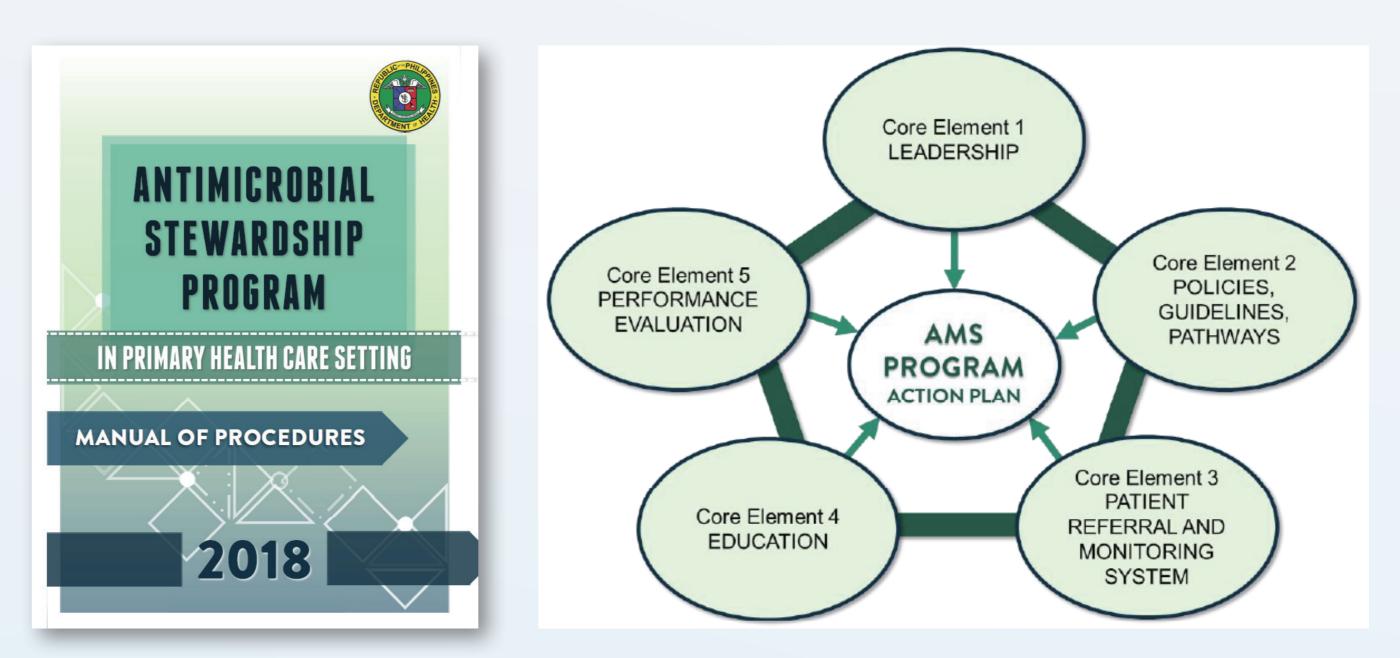
AMS in the Community Settings

In 2018, the DOH with support from the WHO, has developed the AMS MOPs for community settings which follows similar principles of the AMS program in hospitals. It also aims to strengthen the network between the hospitals and the primary care settings.

Actionable Areas in the Philippine AMR Plan

Cover Page of the Philippine AMR Action Plan launched in November 2015

The strategies, timeline, performance indicators, responsible agencies, and budget for each program and activity are also specified in the action plan.



Core elements of the AMS program in the primary care settings

Antimicrobial Resistance Surveillance Program

As the country's response to the recommendation of the World Health Organization (WHO) Working Group on the Regional Information Network on Antimicrobial Resistance that a surveillance program be initiated among member states of the Western Pacific Region to contain and prevent resistance to antimicrobials, the Philippine Committee on Antimicrobial Resistance Surveillance Program was created in 1988 by the Department of Health's Department Order 339-J. The program aims to provide critical inputs to the Department of Health's effort to promote rational drug use by determining the status and developing trends of antimicrobial resistance of selected bacteria to specific antimicrobials.

The publication of yearly ARSP data which will help the health practitioners in making clinical decisions to treat patients used as basis in the preparation and revision of Clinical Practice Guidelines, selection of antibiotics for inclusion in the National Formulary, identification of emerging antimicrobial resistant strains, and identification of outbreaks of antimicrobial resistant microorganisms.

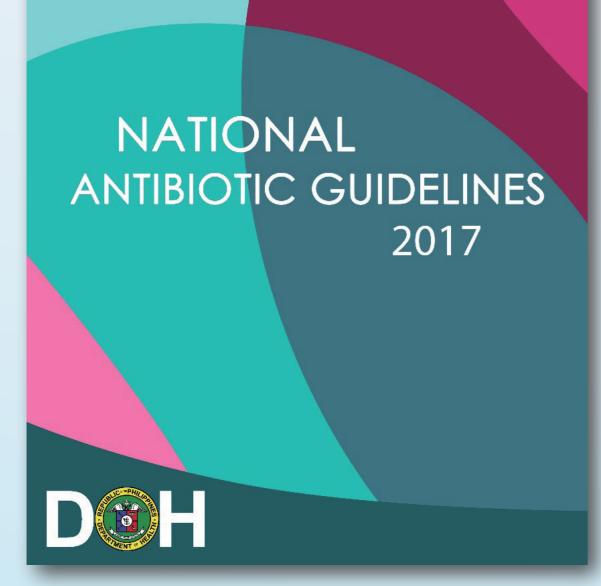
Point Prevalence Survey in Hospitals

In 2017, the Philippines has undertaken the conduct of point prevalence survey in hospitals which aims to: determine the prevalence of inpatient antimicrobial use in selected hospitals in the Philippines; identify targets for improvement in quality of antimicrobial prescribing; and, guide policy makers develop interventions to promote prudent antimicrobial use. The first dissemination forum on PPS data to relevant stakeholders (ICAMR member agencies, hospitals, professional organizations, medical associations, patient groups and civil society organizations) was conducted in June 13, 2018.

Advocacy Materials

The Philippines, with support from development partners, is able to develop information, education, and communication materials for AMR which are available in various media format.

PAAW 2016



National Antibiotic Guidelines

The National Antibiotic Guidelines aims to provide information on the treatment of choice or recommendations for selected pathogen-specific conditions based on recent evidences of clinical effectiveness, adverse effects, cost, and patterns of resistance; as well as the necessary dosing and monitoring guidelines for specific antimicrobials. The guidelines should be able to cover infectious diseases commonly observed in the country. The guidelines are also divided per organ system and will be published online every time the NAGCom has finished discussing a particular system.

National Antibiotic Guidelines published in 2017

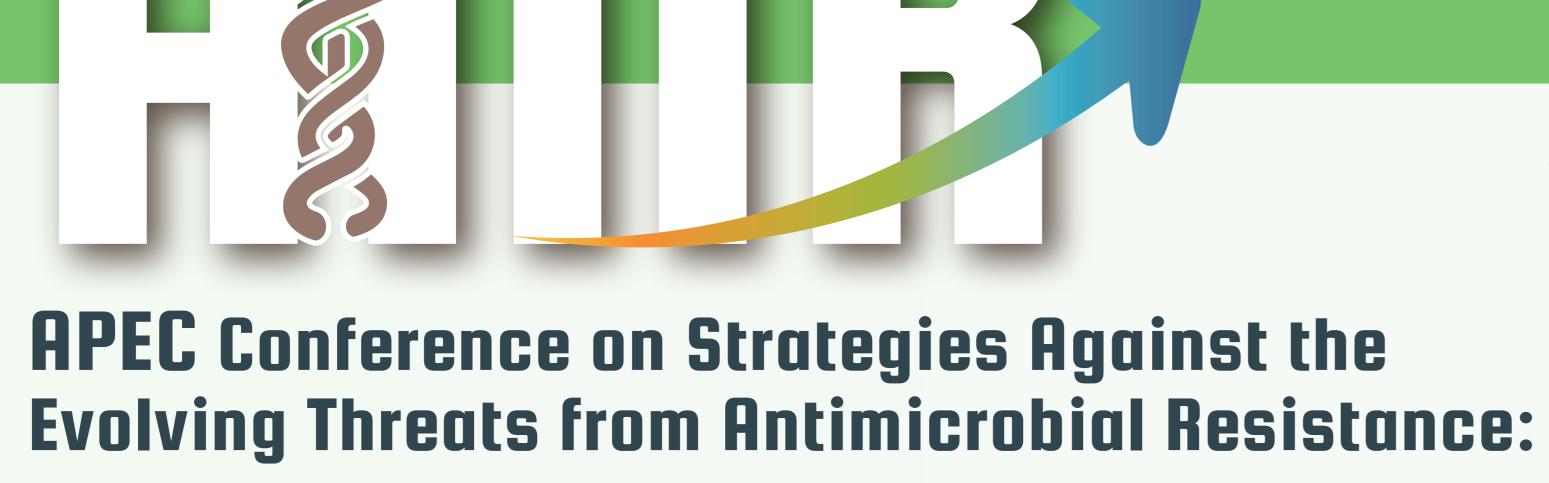
Philippine AMR Summit

The 1st Philippine AMR Summit was organized by the PD in cooperation with the WHO, a two-day activity which commenced on 24-25 November 2015. This served as an avenue to showcase the programs that the country has been implementing since the signing of AO 42 in 2014. The tripartite global agencies - WHO, Food and Agriculture Organization (FAO) and the World Organization for Animal Health (OIE), who initially pushed the global movement to address AMR, as well as high-level officials of the ICAMR member agencies and international luminaries, graced this prestigious event. The highlight of the Summit was the formal launch of "The Philippine Action Plan to Combat Antimicrobial Resistance: One Health Approach." This was jointly developed by the inter-agency committee on AMR. During the Summit, a press conference was held to increase awareness on the threats of AMR and the importance of responsible use of antibiotics.









From Awareness to Concrete Action

Thailand's Activities and National Strategic Plan on Antimicrobial Resistance (2017-2021): **The Animal and Agriculture Sector**

Dr.Mintra Lukkana

Veterinarian, National Bureau of Agricultural Commodity and Food Standards, Ministry of Agriculture and Cooperatives

Vision

4. Implement antimicrobial stewardship in animal hospitals and clinics

Reduction of mortality, morbidity and economic impact of Antimicrobial Resistance (AMR)

Mission

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

Goals

By the year 2021

- 1. 50% reduction in AMR morbidity
- 2. 20% reduction in antimicrobial use in human
- 3. 30% reduction in antimicrobial use in animal

The national databases of annual reports of veterinary medicine production and importation that pharmaceutical companies report to the Thailand Food and Drug Administration will be the main source of data for the assessment of antimicrobials used in animal. The amount of antibiotic used is calculated in terms of kilogram of active ingredient per Population Correction Unit (PCU), the calculation would be in comparison with the amount used in animals in the past three years

- 4. 20% increase of public knowledge on AMR and awareness of appropriate use of antimicrobials
- 5. AMR management system meets universally accepted standards

Thailand's National Strategic Plan on AMR consists of 6 strategies

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

Strategies 1-5 aim at resolving different aspects of AMR in an integrated manner. Strategy 6 aims at developing structures and mechanisms to implement Thailand's National Strategic Plan on AMR 2017-2021. Monitoring and evaluation of the implementation of Thailand's National Strategic Plan on AMR 2017-2021 will be based on the developmental evaluation approach, including the measurement of progress towards defined National Strategic Plan milestones, targets and goals in reference to an established baseline.

The National Strategic Plan on AMR 2017-2021 is Thailand's first national strategy that is specifically targeted towards addressing AMR issues. It sets clear and measurable goals as well as establishing an integrated framework to resolve AMR issues. It is also responsive to the national situation with an emphasis 5. Educate relevant stakeholders in food animals and agriculture regarding appropriate use of antimicrobials

Activities and ongoing works on AMR: The Animal and Agriculture Sector

Strategy 1 AMR surveillance system using a 'One-Health' approach

Strategic actions	Activities
Develop the national integrat- ed system of AMR surveillance and signaling	 Surveillance of AMR bacteria livestock: Salmonella spp., Campylobacter spp., E. coli and Enterococcus spp. fisheries: Salmonella spp., E. coli and Vibrio cholera
Strengthen capacity and net- working of microbiology labo- ratories	 Enhancing laboratory capacities of AMR detection in livestock and fisheries harmonize and implement standard method for AMR testing provide the training courses on AMR detection for lab- oratory staffs

Strategy 2 Regulation of antimicrobial distribution

	Strategy 2 Regulation of antimicrobial distribution				
Strategic actions Activities Strengthen the antimicrobial dis- <i>Cooperation between the Ministry of Public Health</i>					
	oth (MoPH) and the Ministry of Agriculture and Coop-				
humans and animals	eratives (MoAC)				
	- Reclassify and control distribution channel of antimi-				
	crobials - Develop program of National Drug Account (NDA)				
	and Thai Surveillance Antimicrobial Consumption				
	(Thai-SAC) (Monitor values, consumption rates and				
Strategy 4 AMR prevention and	distribution of all medicines) control and antimicrobial stewardship in agriculture and				
animals	control and antimicrobial stewardship in agriculture and				
Strategic actions	Activities				
Reduce use of antimicrobials	Reduce use of antimicrobials in livestock farming				
in livestock farming and fish- eries	- Develop the regulations to control of manufacture, im-				
enes	port, sale and use of medicated feed				
	- "Raised without antibiotics in livestock animal" project				
	 - "Reduction of antibiotic used in livestock animal" project Training veterinarians who responsible for a mixing of 				
	antimicrobial drugs at feed mills				
	- Training farm veterinarians who control the use of anti-				
	microbial drugs at farms				
	 Develop the guidelines of Rational Drug Use (RDU) in livestock and fisheries 				
	- Training staff on the RDU in fisheries				
	- Training staff on the regulation about Drugs Act and				
	Food Act Bost marketing surveillance of antimicrobial drugs				
	Post marketing surveillance of antimicrobial drugs & Residue monitoring plan in livestock and fishery				
	products				
	- Post marketing surveillance of veterinary drugs using in				
	livestock				
	 Monitoring plan of drug residues in livestock and fishery products 				
	Develop alternative ways to reduce antimicrobial use				
	 Study project in the use of herbs and alternative prod- ucts in livestock animals 				
	Cooperation between MoAC and MoPH to develop				
	the regulation for monitoring the use of vaccines at				
Deduce entimicrobial reaso	farm-level				
Reduce antimicrobial resis- tant bacteria in the food pro-	Develop regulations and measures about food safety in the food production chain				
duction chain	- Develop mandatory agricultural standard for Good Agri-				
	cultural Practices (GAP) farming				
	- Develop agricultural standard for carcass transportation				
	 Develop regulations in accordance with Control of Ani- mal Slaughter for the Distribution of Meat Act, B.E. 2559 				
	(2016)				
	- Promote national & international standards of slaughter-				
Establish surveillance of anti-	house e.g. Good Manufacturing Practice (GMP)				
microbial use in crop produc-	 Study project in the use of alternative products to cure greening disease in mandarin oranges 				
tion	- Develop the guideline on RDU in oranges				
	- Implement antimicrobial stewardship in animal hospitals				
	and clinics				
-	- Develop guideline on RDU in pets				
ardship in animal hospitals and clinics	- Project on RDU in small animal teaching hospital				
Educate relevant stakehold-	- Research project about AMR in livestock products and				
-	education/communication with relevant stakeholders				
use of antimicrobials	- Training course/Public relations for staff and farmers to raise awareness about the problems of AMR				
าเขาร่วมใครงา	S				

on multi-sectoral collaboration through the One Health approach and takes into account both national and international policies in order to systematize actions to address AMR. Thailand's National Strategic Plan on AMR 2017-2021 is also aligned with the Global Action Plan, reflecting the country's commitment to join forces internationally in resolving AMR issues.

Expected results:

Overall achievement

Successful implementation of Thailand's Strategic Plan on AMR 2017-2021 will be measured by two achievements as follows;

- 1. Achievement of the defined goals of the strategic plan
- 2. Achievement of the anticipated positive impacts that would be the result such as better health and safety for the public, compliance with the country's vision "stability, prosperity and sustainability" and Thailand's international commitment and responsibility on AMR problem solving.

Short-term achievement

Time period	Achievements		
By three months	 Establishment of National Committee on Antimicrobial Resistance (The commit- tee consists of representatives from the Ministry of Public Health and the Min- istry of Agriculture and Cooperatives, academic sector, professional societies and civil society organizations) 		
	Establishment of national policy on promoting rational drug use in hospitals, that integrates appropriate use of antimicrobials		
By six months	 Promulgation of a legislative order on withdrawal of antimicrobials from a household remedy list 		
By twelve months	4. An initiative on the integrated AMR surveillance system at least in two hospitals		
	An initiative to establish an integrated system for AMR management in 24 pro- vincial and regional hospitals in 12 area health systems		
	6. Promulgation of a legislative order on antimicrobial reclassification		
	7. Promulgation of a Ministry of Agriculture and Cooperatives Ministerial Order on regulation of the production, sales, and use of medicated feed Drugs, including antibiotics, are after mixed into feed referred to as medi- cated feed.		
	8. An initiative on antimicrobial stewardship in two animal hospitals		





The first meeting of National Committee on Antimicrobial Resistance on July 13, 2017 at the Government House (Photo: http://www.thaigov.go.th/news/contents/details/5183)

Highlighted strategic plan associated with the animal and agriculture sector

Strategy 4

"AMR prevention and control and antimicrobial stewardship in agriculture and animals" Objective: Integrated and harmonized systems of AMR management and reduction of antimicrobial use

in agricultural and animal sectors are applied to both public and private sectors. Strategic action

- 1. Reduce use of antimicrobials in livestock farming and fisheries
- 2. Reduce antimicrobial resistant bacteria in the food production chain
- 3. Establish surveillance of antimicrobial use in crop production

The kick-off meeting of "Raised without antibiotics in livestock animal" project took place in Bangkok, Thailand on August 7, 2018 (Photo: http://secretary.dld.go.th/webnew/index.php/th/news-menu/headnews-menu/3860-5-3)

References

www.fda.moph.go.th

The National Strategic Plan on AMR 2017-2021, www.amrthailand.net www.thaigov.go.th www.moac.go.th www.dld.go.th www.acfs.go.th www.fisheries.go.th www.doa.go.th www.vetcouncil.or.th







National Strategic Plan on Antimicrobial Resistance 2017-2021

Ms.Rathar Benchapalanont

Pharmacist, Food and Drug Administration, Ministry of Public Health

At a glance

Ministry of Public Health Ministry of Agriculture and Cooperatives



In collaboration with National Health Commission Offi ce of Thailand National Health Security Offi ce Thai Health Promotion Foundation Health Systems Research Institute International Health Policy Program Drug System Monitoring and Development Program Food and Agriculture Organization of the United Nations World Health Organization









World Health Organization

National Strategic Plan on Antimicrobial Resistance 2017-2021 Thailand

The National Strategic Plan on Antimicrobial Resistance (2017-2021) (NSP-AMR) is the first Thailand's strategy which addresses AMR specifically. It was developed by the AMR Coordination and Integration Committee (AMR-CIC), a multisectoral committee appointed by the Ministry of Public Health (MOPH) through a ministerial order in May 2015.

The drafting process began in the mid of 2015 with full participation of and engagement by multi-stakeholders. The draft versions have gone through several rounds of public consultation including through the 2015 National Health Assembly (NHA)¹ and the 2016 formal public hearing forum. Synergizing the NSP-AMR development process, a NHA Resolution on the integrated approach addressing antibacterial resistance crisis was adopted in December 2015. Through these processes, the draft of NSP-AMR was finalized in the second half of 2016. Finally, through a joint proposal by MOPH and Ministry of Agriculture and Cooperatives (MOAC), the NSP-AMR was endorsed by a Cabinet resolution in August 2016.

The NSP-AMR is guided by two underlying concepts: **'One Health' approach** which recognizes the interconnectivity across human, animal and environmental health; and **'Triangle that Moves the Mountain' concept** which emphasizes the importance of resolving complex intersectoral issues through policy engagement and social movement driven by evidence from knowledge generation.

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 use in human
- 30% reduction in antimicrobial use in animal
- 4 20% increase of public knowledge on AMR and awareness of appropriate use of antimicrobials
- 5 Capacity of the national AMR management system is improved to level 4²

Strategies

- 1 AMR surveillance system using 'One Health' approach
- 2 Regulation of antimicrobial distribution
- 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

hree guiding principles shape the contents of NSP-AMR

- **Action oriented** with measurable goals and targets by implementing the NSP-AMR in stepwise manner leading toward continued advancement
- Synergistic efforts which orchestrate and promote coherence of the existing policies, processes and actions across relevant stakeholders
- **Political engagement** to ensure effective and sustainable implementation.

¹ The National Health Assembly (NHA), mandated by the National Health Act 2007, is a bottom-up, evidence-based participatory public policy process through inclusive engagements by government sector, the academia, private and people sectors across all 77 provinces of Thailand.

6 Governance mechanisms to develop and sustain AMR-related actions

Monitoring and Evaluation

The monitoring and evaluation (M&E) will include a few key actions such as, establishing baseline indicators for 2016 and strengthening the infrastructure and the functioning of M&E systems which contribute to monitoring progresses of each goal against each of five targets. Evidence on AMR and magnitudes of antimicrobial use in human and animal will be regularly shared with prescribers in human and agriculture sectors, in order to change course of actions, general public and decision makers.

² This is measured by the WHO's Joint External Evaluation Tool (JEE) for International Health Regulations (2005)

Milestones on the NSP-AMR development

2012 AMR as an issue in the 8 Oct Multi-sectoral meeting 6 May Appointment of AMR-CIC **18 Jan** Revision of AMR-CIC by to map roles of agencies and to develop NSP-AMR having a joint MOPH and MOAC National Drug Development Strategy 2012-2016 develop an integrated framework secretariat team Aug Multi-sectoral brainstorming on AMR actions 2013 AMR as an issue in the workshop for NSP-AMR Apr-May Public hearing of the National Strategic Plan on Dec 2014- Jan 2015 Informal development draft NSP-AMR **Emerging Infectious Disease** meetings between MOPH and **Nov** AMR-CIC launched a 25 Jul A joined proposal on National 2013-2016 MOAC full report on 'Landscape of NSP-AMR from MOPH and AMR situations and actions in MOAC to the Cabinet Thailand' **17 Aug** The NSP-AMR was **Dec** NHA resolution regarding endorsed by the cabinet antibacterial resistance **Prior to 2014** 2014 2016 2015 16 Apr Communiqué of Tokyo Sep 2011 Jaipur Declaration on **Sep** Thailand as a contributing 8 May Hosting a regional GHSA country on AMR in GHSA meeting consisting of AMR Meeting of Health Ministers on AMR AMR in Asia session **Nov** AMR as a flagship priority Dec 2011 World Health Day on identified by SEARO Regional 21 Sep High level meeting on AMR **19 May** Co-founding the Alliance of Champions fighting AMR in UNGA Director against AMR during WHA 68th **19 May** Organizing the ministerial side event on AMR

Interna

AMR – Antimicrobial Resistance; AMR-CIC – AMR Coordination and Integration Committee; FAO – Food and Agriculture Organization of the United Nations; FPGH – Foreign Policy and Global Health; GAP-AMR – Global Action Plan on Antimicrobial Resistance; GHSA – Global Health Security Agenda; MOAC – Ministry of Agriculture and Cooperatives; MOPH – Ministry of Public Health; NHA – National Health Assembly; NSP-AMR – National Strategic Plan on Antimicrobial Resistance; OIE - World Organisation for Animal Health; SEARO – WHO South-East Asia Regional Office; WHA – World Health Assembly; WHO – World Health Organization; UNGA – United Nations General Assembly

- during WHA 68th on behalf of FPGH countries
- **20 May** WHA resolution on GAP-AMR
- **26 May** OIE resolution on combating AMR and promoting the prudent use of antimicrobial agents in animals
- Jun FAO resolution on AMR in food and agriculture
- Nov World Antibiotic Awareness Week

World Health Organization

Printing support is provided by WHO







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Implementation of Intersectoral "One Health" Antimicrobial Resistance (AMR) **Containment Programme in Malaysia**

Suraya A.H¹, Azman A.B¹, PAA MNAR¹, Norazah A², Noraini M³, Noor Amelia A.R¹, Puteri Fajariah¹, Hazimah H³, Nor Farah B¹, Mardhiyah K³, Suhaily O¹, Rohana O¹, RozanahS⁴

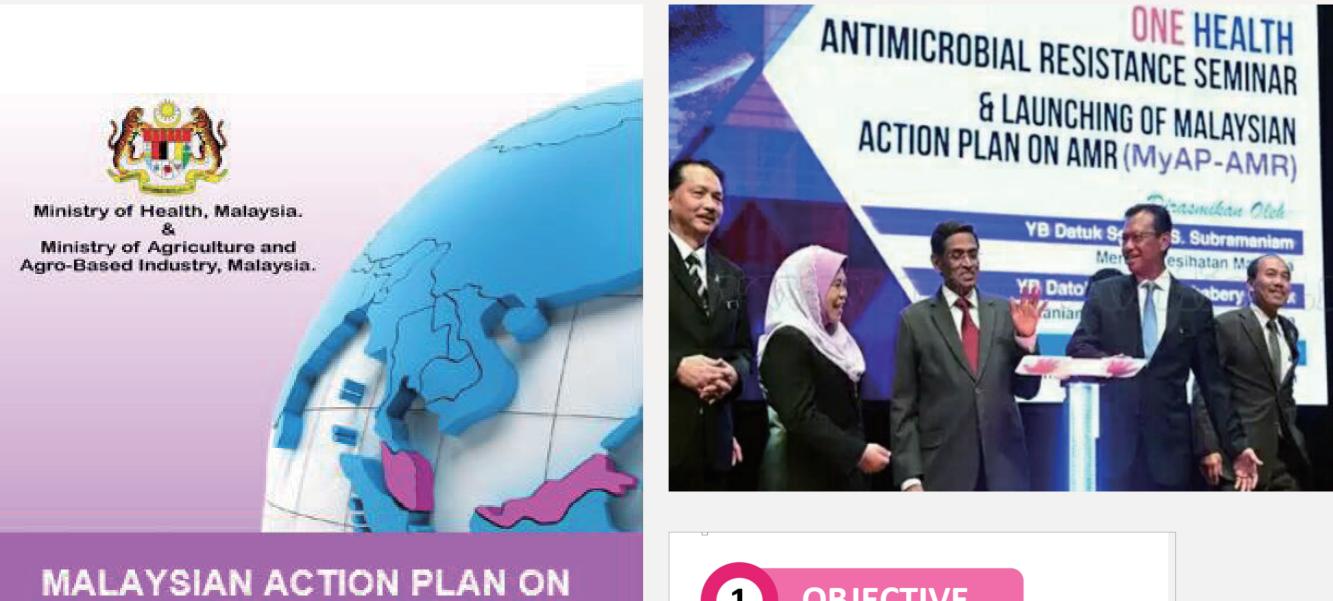
¹Medical Development Division, MOH, Malaysia, ²Institute for Medical Research, MOH, Malaysia, ³Pharmaceutical Services Division, MOH, Malaysia, 4Department of Veterinary Services, MOA, Malaysia

Introduction

The incidence of AMR is increasing around the world and is affecting all levels of society, thus making AMR a global health threat of grave concern. AMR is a complex epidemiological problem due to the fact that various causal factors are intertwined. Generally, resistant organisms exists in humans, animals, food and the environment and they act as the key drivers of the occurrence of AMR. Thus, AMR is a major issue that requires a comprehensive and holistic "One Health" approach.

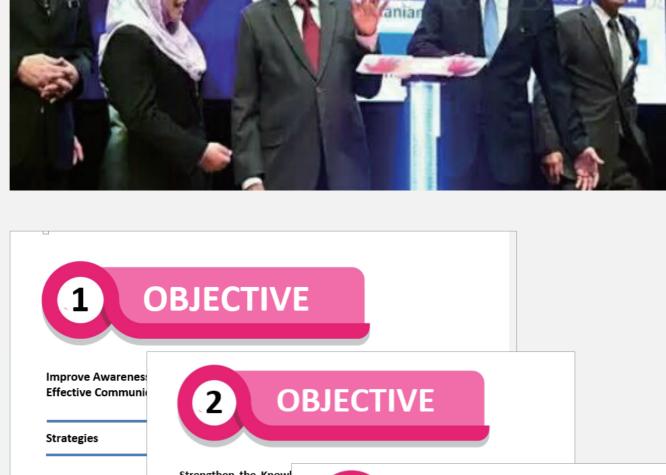
In 2016, the MOH steered the initiatives of One Health approach involving various ministries and agencies in combating AMR.

Malaysian Action Plan on AMR (MyAP-AMR) 2017-2021

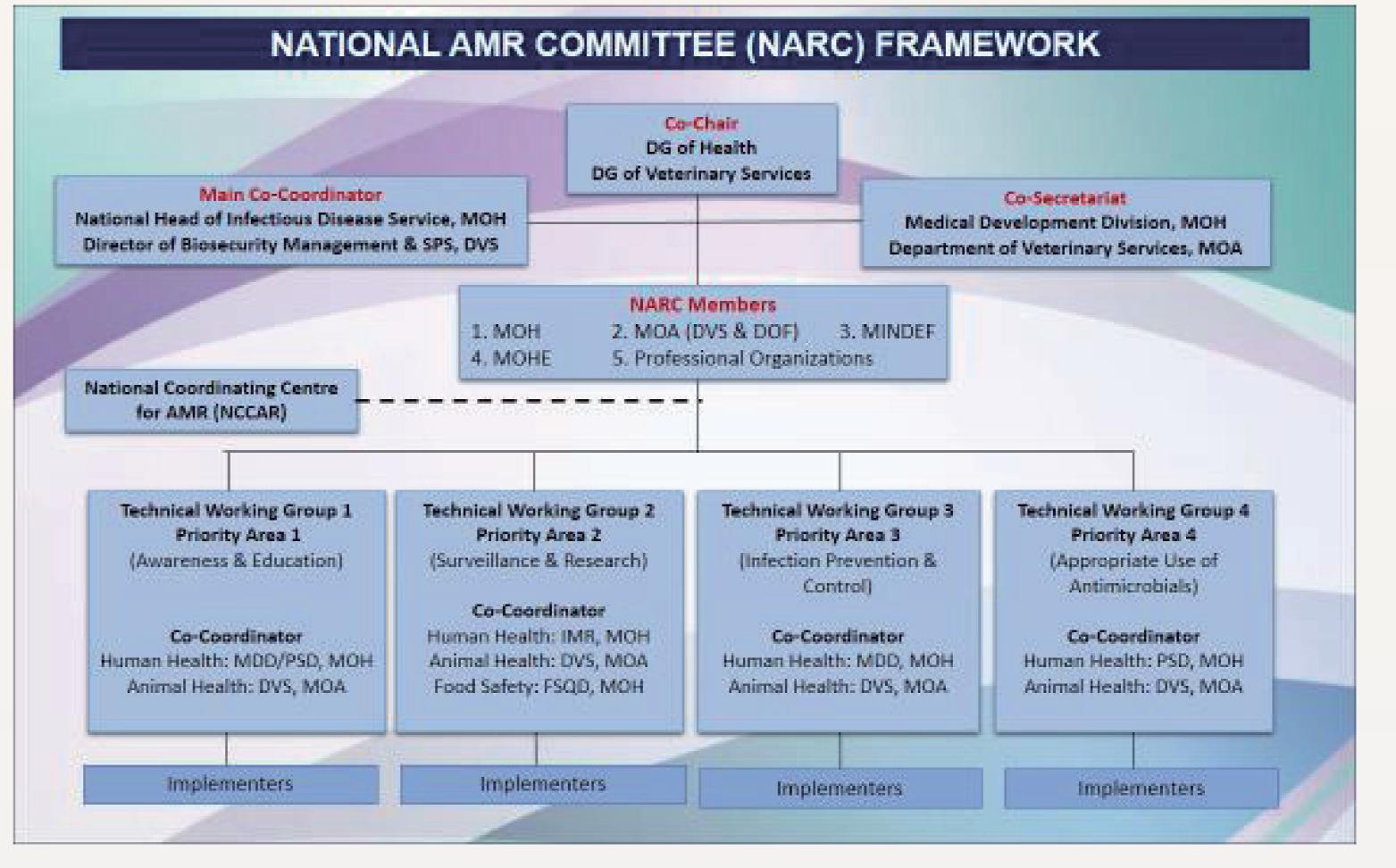


ANTIMICROBIAL RESISTANCE (MyAP-AMR) 2017-2021





IntersectoralAMR Governance



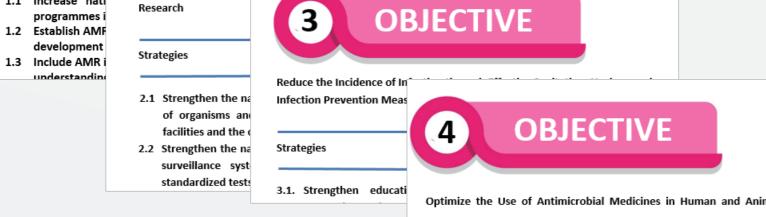
The National AMR Committee (NARC) was established in March 2017 and acts as a coordinating body to govern the intersectoral AMR containment activities and its implementation.

Under the NARC framework, there are 4 technical working groups responsible for implementing the strategies and activities set in the MyAP-AMR

AMR One Health Activities

Nationwide World Antibiotic Awareness Week (WAAW) Campaign:





MyAP-AMR was launched in 27th Feb 2018 by the Ministers of Ministry of Health and Ministry of Agriculture and Agro-based Industry

- 4 Key Priority Areas in MyAP-AMR:
- i) Awareness and education;
- ii) Surveillance and research;
- iii) Infection prevention and control;
- iv) Appropriate use of antimicrobials.

- a) Printed media
- b) Mass media
- c) Electronic media
- d) Social media
- e) Training/conference/seminar/workshop





Conclusion

MR is becoming an increasingly urgent challenge and a public health threat for Malaysia. We recognize the need to reduce the impact of AMR on morbidity, mortali-Ty, costs and burden on health systems.

Intersectoral coordination has been set up to oversee the implementation of activities in the national action plan. Regulation and enforcement of relevant products have been reinforced especially with regard to the prescription of human and veterinary medicines in the agro-industries. Malaysia has intensified the awareness and education program as well as strengthened the infection control, the antimicrobial stewardship programme and the surveillance system including the development of integrated AMR surveillance. The success of these measures can only be achieved through One Health approach.









JAPAN

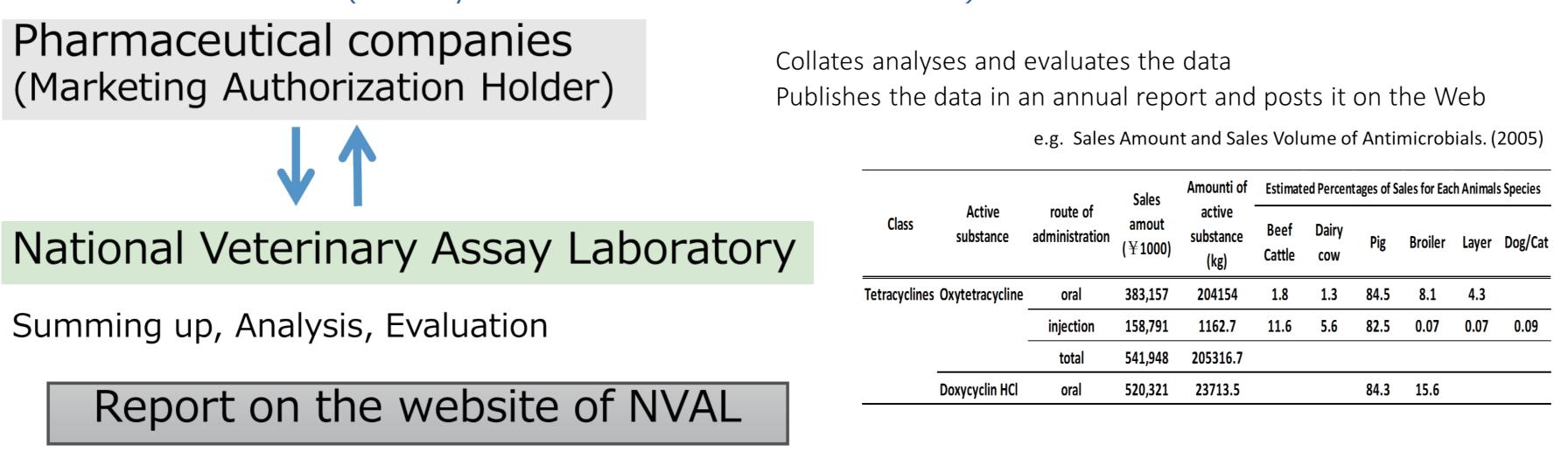
Surveillance of AMR and Antimicrobial Use Japanese Veterinary Antimicrobial Resistance Monitoring(JVARM)

Mr. Takahiro Shirakawa

Inspector, National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries

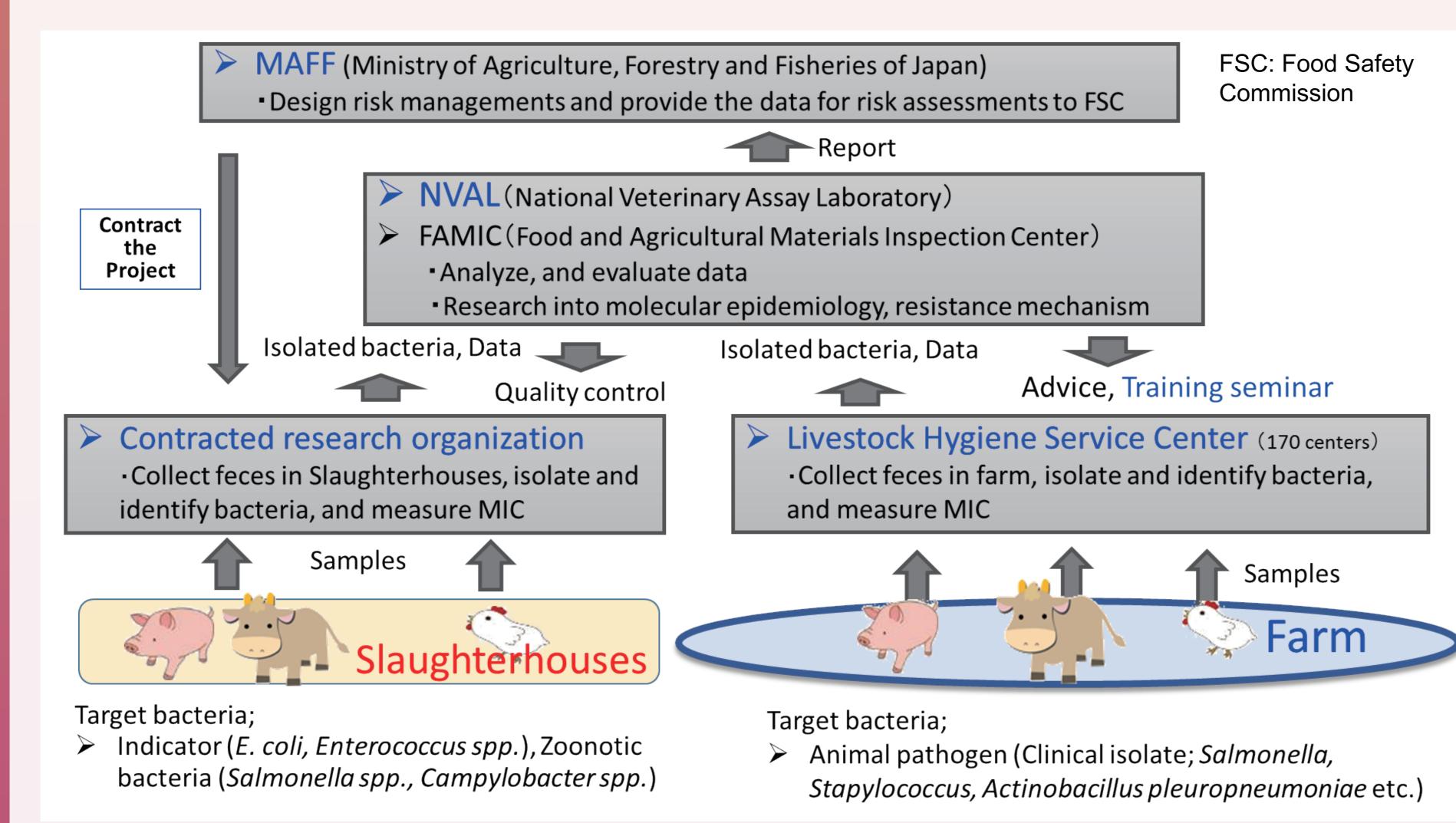
Monitoring of Antimicrobial Sales

Under the Pharmaceutical and Medical Device Act (formerly known as Pharmaceutical Affairs Law)

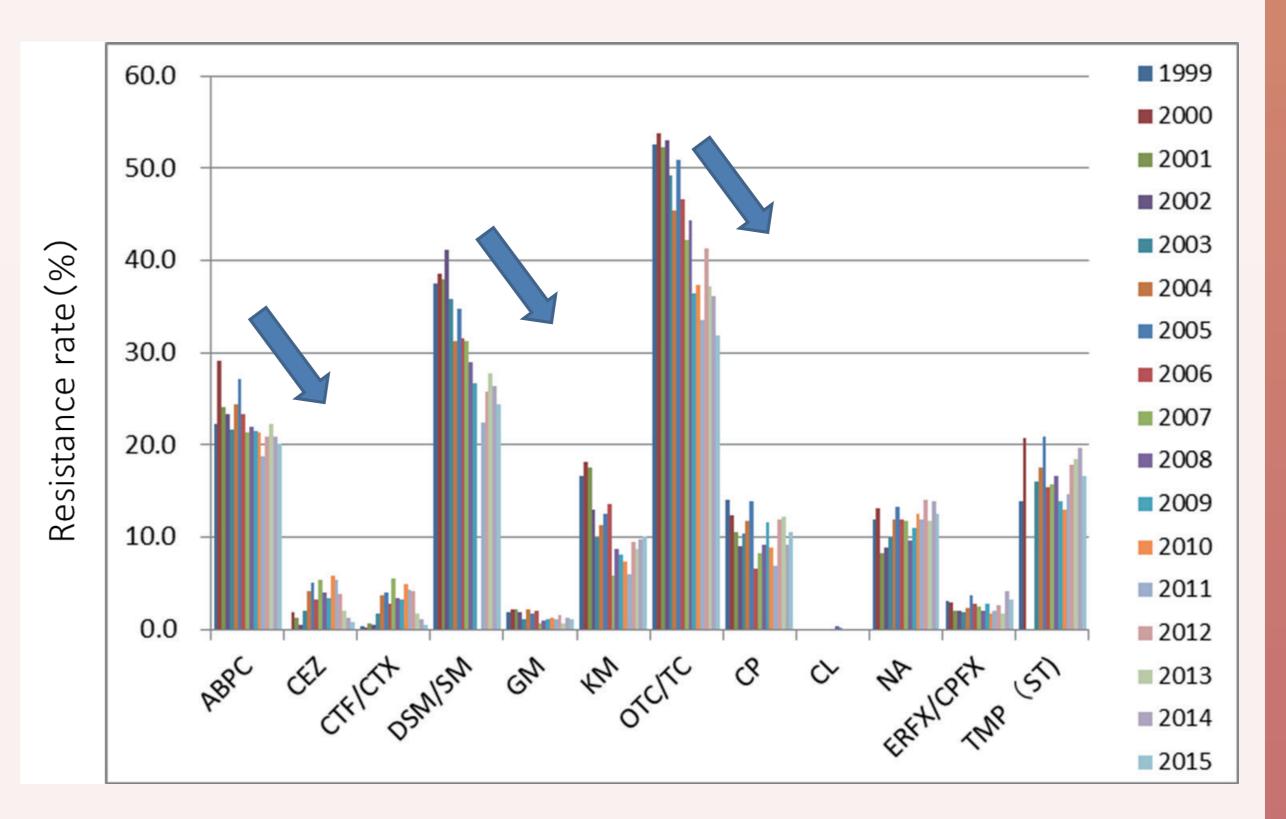


http://www.maff.go.jp/nval/iyakutou/hanbaidaka/attach/pdf/h27-koukinzai_re.pdf

Monitoring of AMR



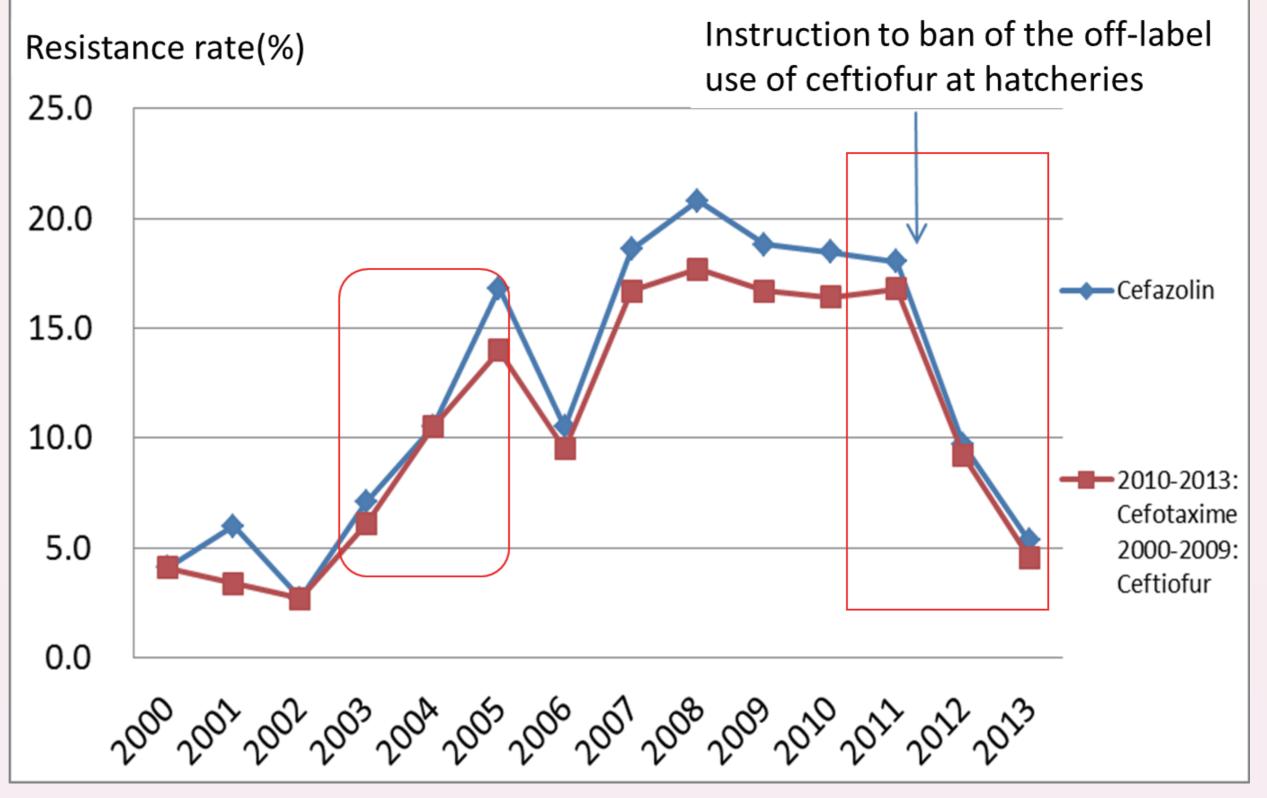
Antimicrobial resistance rates in *E.coli* isolated from healthy food producing animals(JVARM)



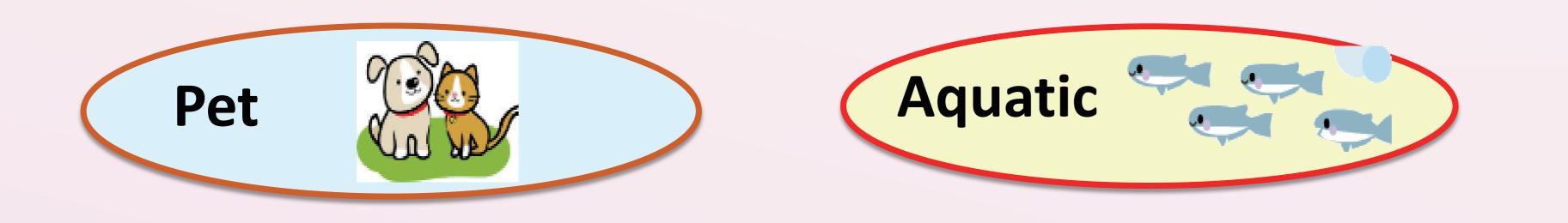
Resistant rates were higher in tetracyclines, streptomycins and Ampicillin, and the resistant rates for these drugs have been decreasing.

As for the cephalosporins and fluoroquinolones, which are very important as human drugs, resistance rates remain low, at comparable levels to those in EU and USA.

Resistance rate of cephalosporin in *E. coli* **isolates from healthy broilers(JVARM)**



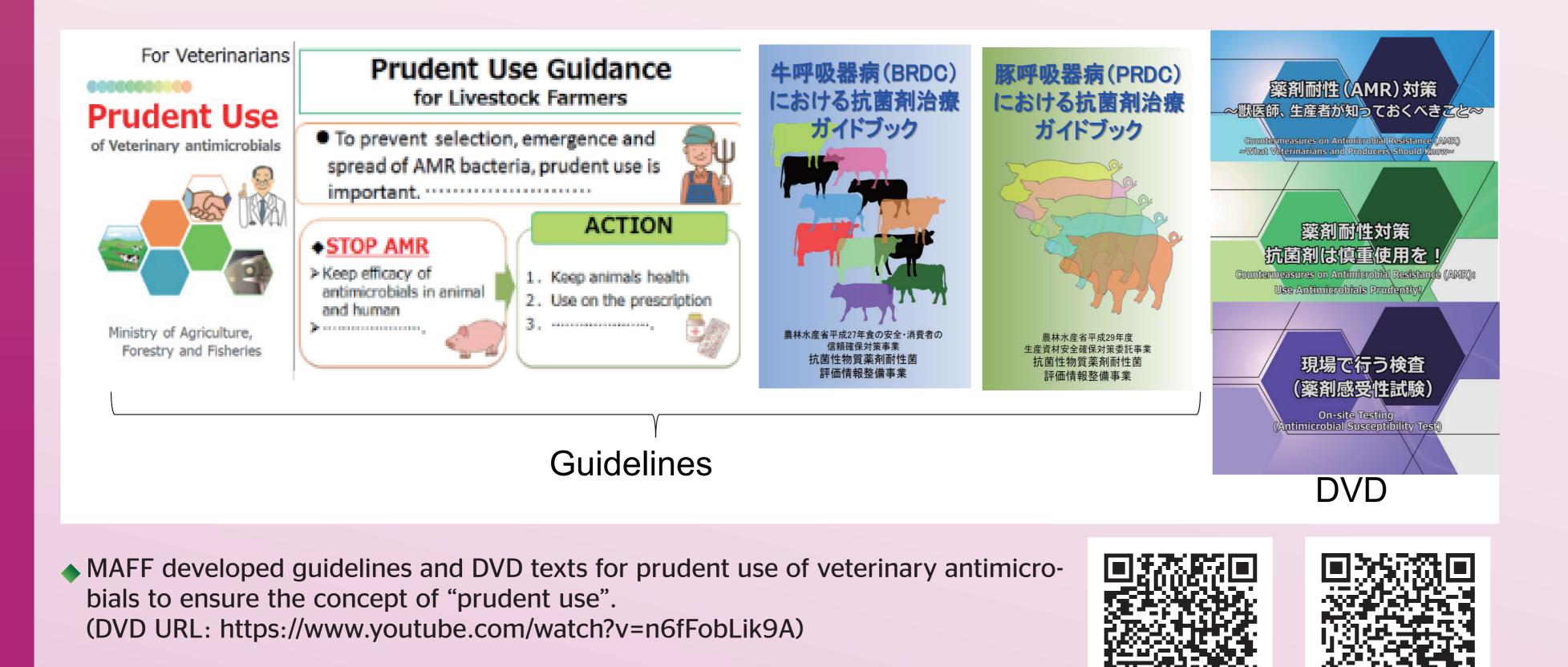
- ◆ JVARM was established in1999 and has continuously conducted nation-wide monitoring.
- JVARM report are published in Japanese every year and in English every few years (http://www.maff.go.jp/nval/English/index. html).
- Monitoring of AMR on companion animals has launched since last year.
 Monitoring of AMR on aquatic animals has been strengthened since last year.



Hiki M et al. Foodborne Pathog Dis. 2015 Jul;12(7):639-43.

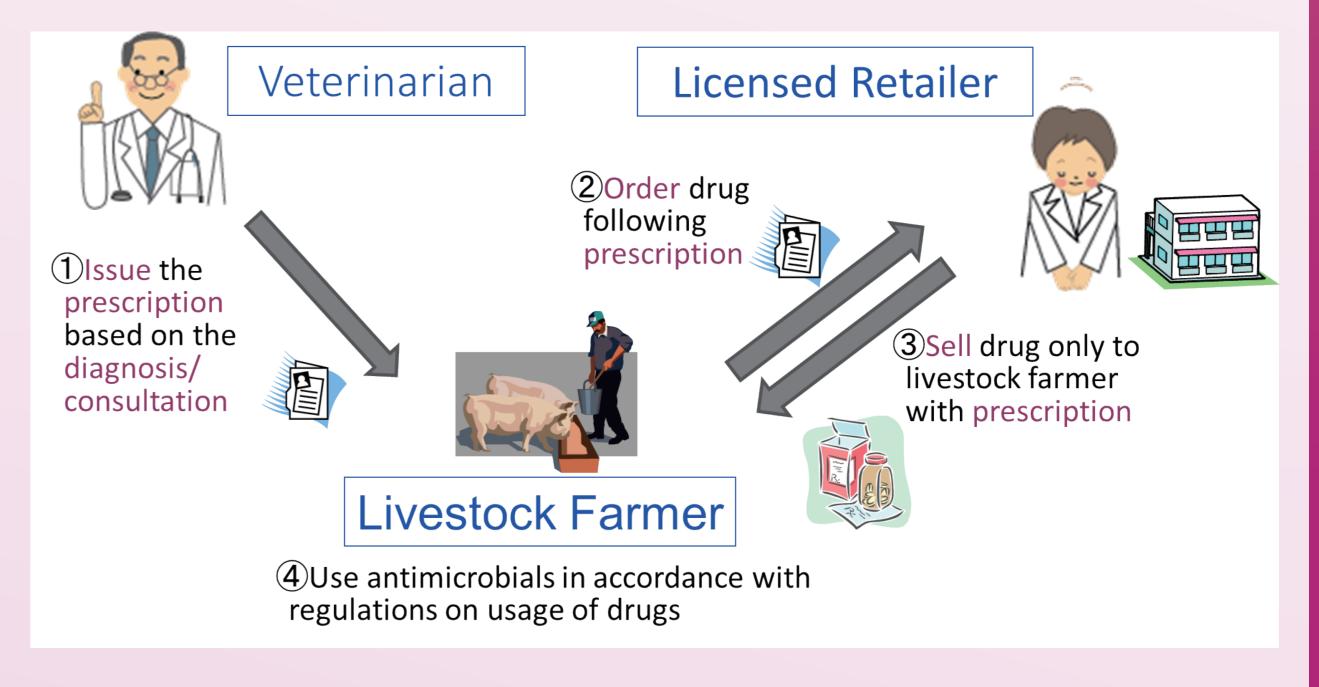
- In some hatcheries, the off-label use of ceftiofur had been performed for in ovo vaccination or vaccination of 1-day-old chickens.
- MAFF showed these JVARM data to poultry industries, and instructed to ban of the off-label use of ceftiofur at hatcheries.
- The prevalence of broad-spectrum cephalosporin resistance in *E.coli* significantly decreased thereafter.

Prudent Use of Antimicrobials



Veterinary Legislation

Prescription system











APEC Conference on Strategies Against the **Evolving Threats from Antimicrobial Resistance:**

From Awareness to Concrete Action



Regulatory collaboration to combat to AMR

Dr. Junko Sato Director, Office of international cooperation, Pharmaceuticals and Medical Devices Agency

Challenge for Development of anti-AMR Product

Limited number of patients

- Sporadically occurrence of patients
- Urgency to initiate therapy
- Complications in patients background

Collaboration between EMA, FDA and PMDA

FDA U.S. FOOD & DRUG ADMINISTRATION EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH	Pinda	
MEETING SUMMARY		
Tripartite meeting held between the EMA, FD EMA, London, on 1-2 September 2016 to d approaches for the evaluation of antiba		
The EMA, FDA and PMDA consider that a robust response to t resistance must be multi-facetted and that the regulatory approa antibacterial agents is only one element of the total response the accelerate new antibacterial drug development to meet patient r	FDA U.S. FOOD & DRUG ADMINISTRATION EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH	Pinda
These three regulatory agencies recognize that:	MEETING SUMMARY	
 It is appropriate to exercise flexibility with regard to the development programmes for antibacterial agents, espective used to treat patients with limited treatment options b resistance; There is benefit in further convergence on the data requirantibacterial agents; 	Tripartite meeting held between the EMA, PMD Vienna, on 26-27 April 2017 to discuss regulatory the evaluation of antibacterial agen The EMA, FDA and PMDA consider that a robust response to the problem of	EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES AGENCY
 It may be appropriate to accept a greater degree of uncerisk balance when developing new antibacterial agents t patients with limited treatment options, e.g. it may be ac smaller numbers of patients than would usually be requi It is important to conduct sound analyses of the pharmac relationship for the purposes of selecting dose regimens 	must be multi-facetted and that the regulatory approach for the evaluation of a element of the total response that is required to encourage and accelerate new development to meet patient needs. Following on from the meeting of Septem of the three agencies met for the second time. Progress was made as follows:	MEETING SUMMARY
 including regimens that may minimize the risk of select There is value in developing clinical trial networks to fa antibacterial agents and the development of such networ There is value in continuing the discussions that were in the EMA; further discussions proposed for Spring 2017 	 EMA, PMDA and FDA discussed in detail clinical trial recommendations urinary tract, intra-abdominal, and skin infections, as well as for drugs inte multi-drug resistant infections. A number of areas of similarity were identified with regard to clinical trial such as patient selection criteria, and endpoints for certain types of infection 	discussions on recommended clinical trial designs for evaluating antibacterial drugs and ways to further enhance collaboration in this
the pre-approval clinical development programmes but a post-approval period.	 Areas were identified where a move to convergence was agreed. For exam selection and response in urinary tract and intra-abdominal infection trials. Some aspects of clinical development programs for drugs intended to treat multi-drug resistant bacteria were agreed. EMA, PMDA, and FDA will be working to update guidance documents to 	 The discussions at this meeting built on the work of prior meetings leading to further alignment on a number of clinical trial design elements for key indications for antibacterial drugs, such as the approaches for studying antibacterial drugs for uncomplicated gonorrhoea and uncomplicated urinary tract
	 ENA, PMDA, and PDA will be working to update guidance documents to convergence. In the meantime, EMA, PMDA, and FDA will provide advice is consistent with the agreements reached. Prior advice on drug developme Areas were identified where currently differences remain. For example, while regarded as primary in community-acquired bacterial pneumonia and skin scientific discussion and sharing of information may help to achieve conver- 	 The importance of adequately characterizing pharmacokinetic and pharmacodynamic relationships, particularly for drugs that are developed to address serious infections with unmet need was reiterated
		 The importance of obtaining clinical data in pediatric patients was recognized along with the challenges of gathering such data in a timely fashion. The three Agencies will work together

Workshop on development of antibacterial medicinal products for paediatric patients



Date: 21th-22th June, 2018 Venue: EMA(London) Hosts: EMA, PMDA, FDA Discussion points

General considerations on regulatory requirements Challenges with paediatric trials ✓ Efficacy Assessment Safety Assessment
 Studying neonates

Discussion points in EMA-FDA-PMDA meeting

Utilization of Modeling and Simulation

TM

9

to explore options to streamline pediatric antibacterial drug

 Monitoring benefit-risk throughout the lifecycle of a product was recognized as an important activity, particularly for drugs

To respond to unmet medical needs in the antibacterial area.

EMA, FDA and PMDA will continue to work together under their

approved based on a more limited clinical program.

development

EUROPEAN MEDICINES AGENCY

Recognition of three regulatory agencies

There is benefit in further convergence on the data requirements for the approval of antibacterial agents.

It may be appropriate to accept a greater degree of uncertainty regarding the benefit-risk balance when developing new antibacterial agents that can be used to treat patients with limited treatment options, e.g. it may be acceptable to conduct trials in smaller numbers of patients than would usually be required.

It is important to conduct sound analyses of the pharmacokinetic-pharmacodynamics relationship for the purposes of selecting dose regimens for study in clinical trials, including regimens that may minimize the risk of selecting for resistant organisms.

There is value in developing clinical trial networks to facilitate the evaluation of new antibacterial agents and the development of such networks is encouraged.

Follow-Fiber simulation Monte Carlo Simulation PK/PD modeling etc. Utilization of Clinical Network Paediatric development Pathogen focused development?

For acceleration of anti-AMR product development

Regulatory convergence Well collaboration among stakeholders Internationally Over disciplinary in own region Utilization of alternative methods

Go forward for patients !









The National Action Plan on Antimicrobial Resistance

Mr. Victor Fiestas Solórzano Infectious Disease Specialist, National Institute Health

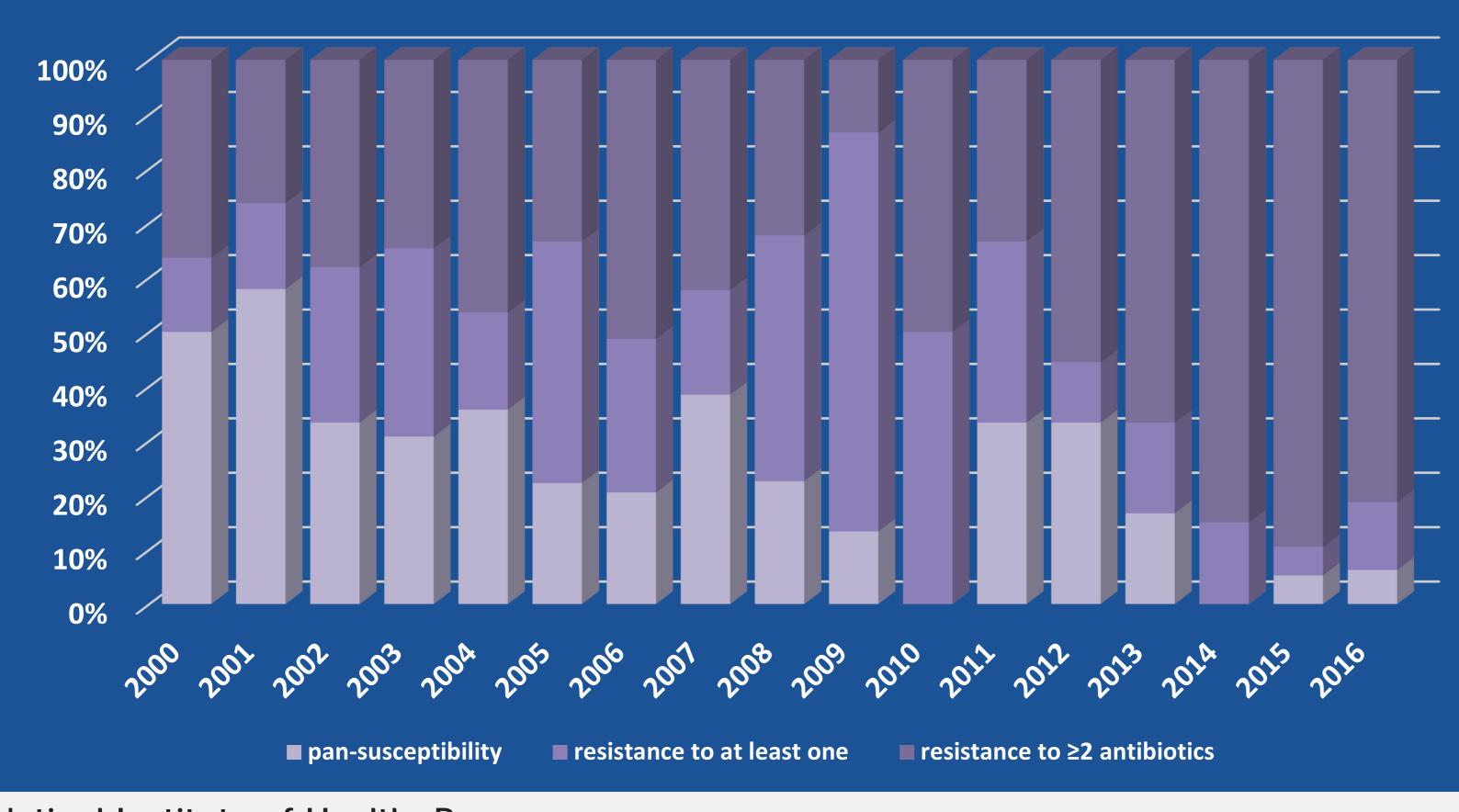
The Ministry of Health of Peru through the National Institute of Health (INS) initiated surveillance of antimicrobial resistance in 1997 and since 2002, our country participates in the in the regional laboratory-based surveillance systems of the Pan American Health Organization (PAHO): SIREVA (Sistema Regional de Vacunas) and later SIREVA II (Sistema de Redes de Vigilancia de Agentes Bacterianos Causantes de Meningitis y Neumonías) and the Latin Amer-



The National Action Plan on Antimicrobial Resistance,

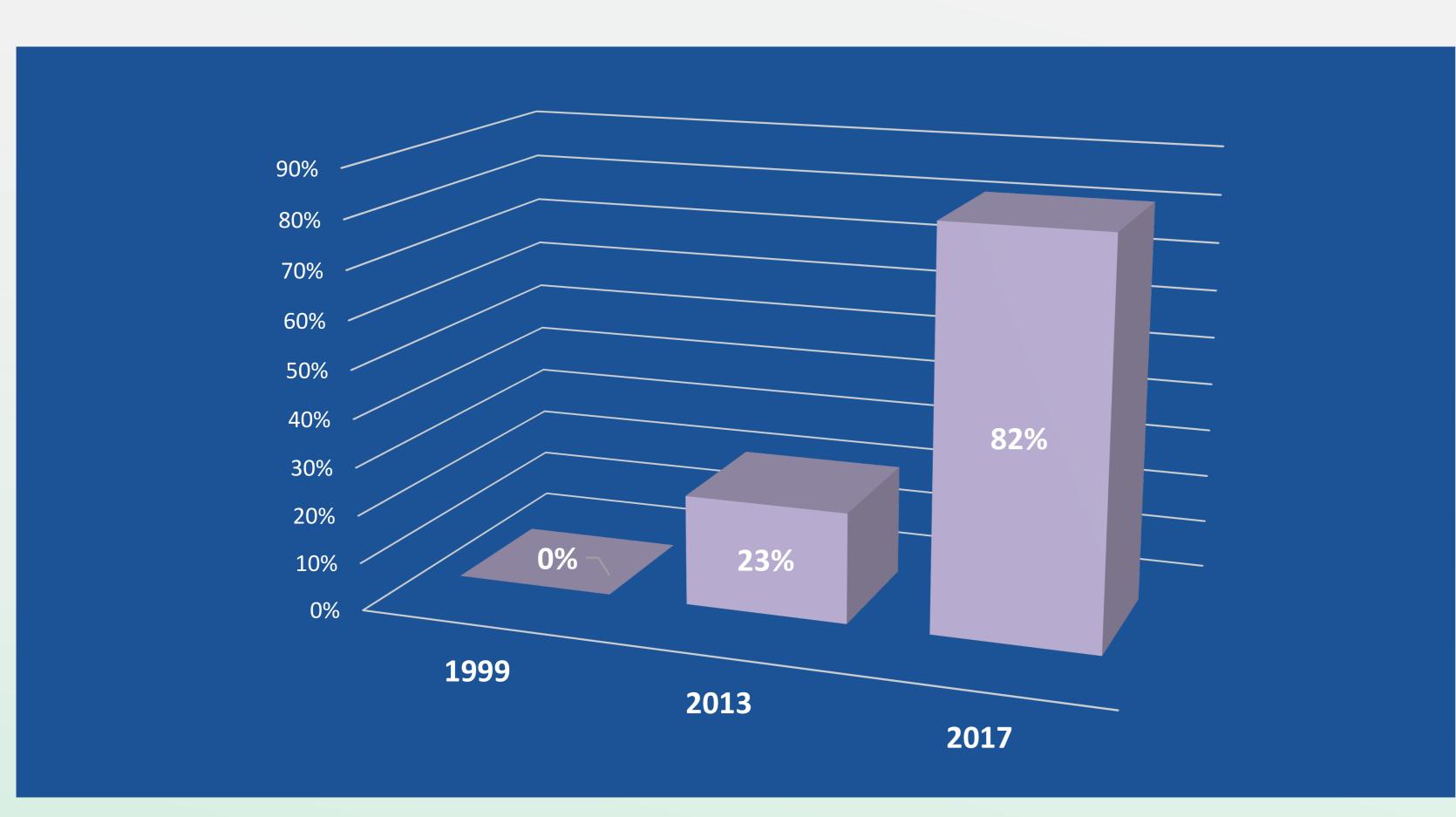
ican Antimicrobial Resistance Surveillance Network (ReLAVRA).

Antimicrobial resistance Streptococcus pneumoniae in Peru



Natinal Institute of Health, Peru

Neisseria gonorrhoeae ciprofloxacin resistance in Peru



2018-2021

Peru has deployed initiatives over more than two decades to address antimicrobial resistance; however, these initiatives have not had the expected results

In 2016, the Ministry of Health commissioned the National Institute of Health to prepare the national plan, taking as a framework the WHO Global Action Plan on Antimicrobial, which integrates a multisectoral (Ministry of Agriculture, Ministry of Environment, Ministry of Education) response under the "One Health" approach.



1st workshop, National Institute of Health September 2016

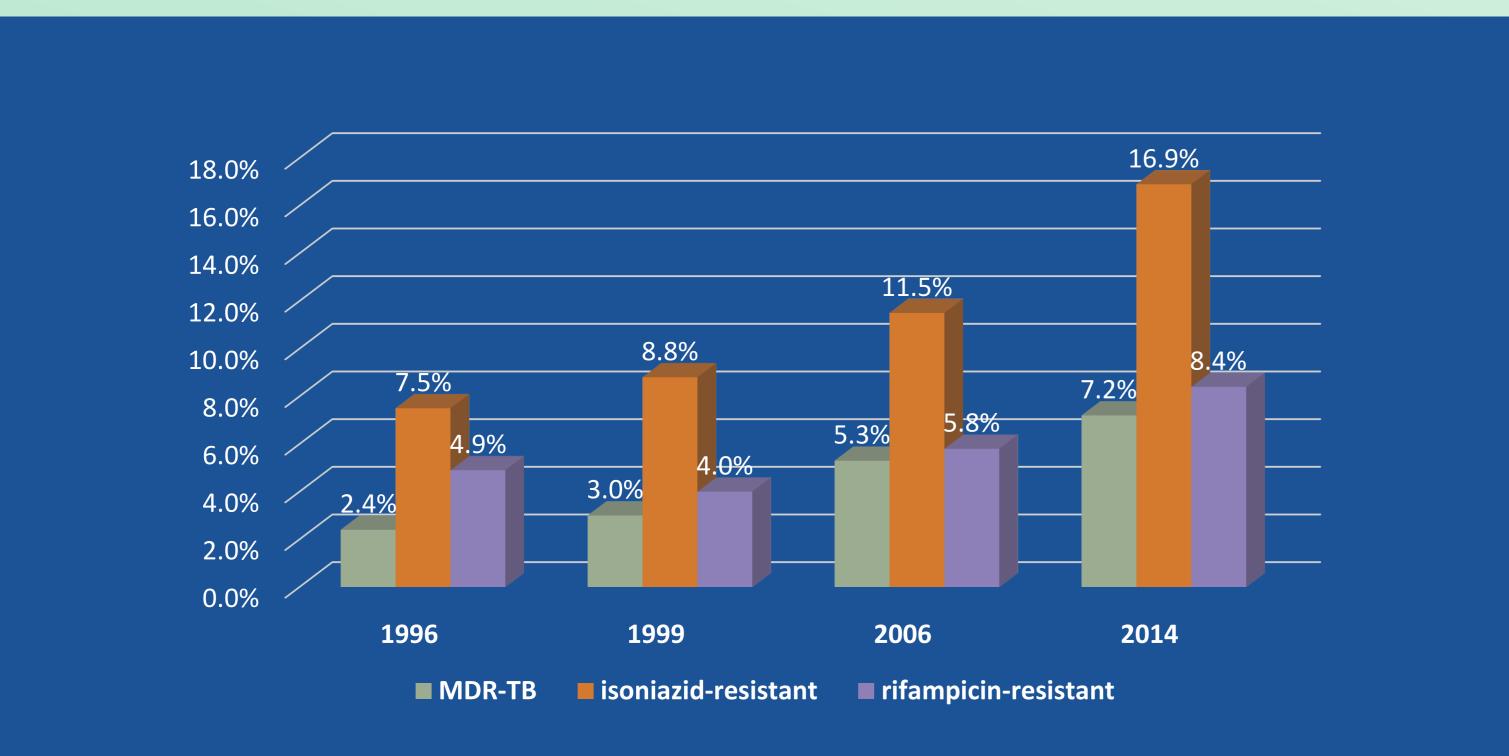
		DIGEMID	
	Ministry o Health	DIGESA	
		Oficina General de Cooperación y Asuntos Internacionales	
		Centro Nacional de Epidemiología	
		Instituto Nacional de Salud	
		Dirección General de Intervenciones Estratégicas en Salud Públic	
		Seguro Integral de Salud	
		Secretaria de Coordinación del Consejo Nacional de Salud	
		SUSALUD	
Human health		Oficina General de Planificación y Presupuesto	
		Dirección General de Personal de la Salud	
		Oficina General de Comunicaciones (MINSA)	
		Unidad Funcional de Gestión de la Calidad en Salud (MINSA)	
	MINDEF	Dirección de Sanidad de las Fuerzas Armadas	
	MINTRA	ESSALUD	
	Colegios profesionales	Colegio Médico del Perú	
		Colegio de Químicos Farmacéuticos	
	Universidades	Instituto de Medicina Tropical D.A. Carrión UNMSM	
		Instituto de Medicina Tropical Alexander Von Humbolt -UPCH	
	MINAGRI	SENASA	
Animal health	PRODUCE	SANIPES	
	Colegios profesionales	s Colegio Médico Veterinario del Perú	
Enviroment MINAM		Ministerio del Ambiente	
	MINSA	DIGESA	
Food	MINAGRI	SENASA	
	PRODUCE	SANIPES	

1.Portilla J. Susceptibilidad antimicrobiana in vitro de cepas de Neisseria gonorrhoeae procesadas en el Instituto Nacional de Salud, Lima-Perú 1998-1999. Rev Peru Med Exp Salud Publica. 2003; 20(4): 216-9

2.Tsai AY et al. The U.S. military's Neisseria gonorrhoeae resistance surveillance initiatives in selected populations of five countries. MSMR. 2013; 20(2): 25-7

3.Jorge-Berrocal A, Mayta-Barrios M & Fiestas-Solorzano V. Antimicrobial resistance of Neisseria gonorrhoeae in Peru. Rev Peru Med Exp Salud Publica. 2018; 35(1): 155-156

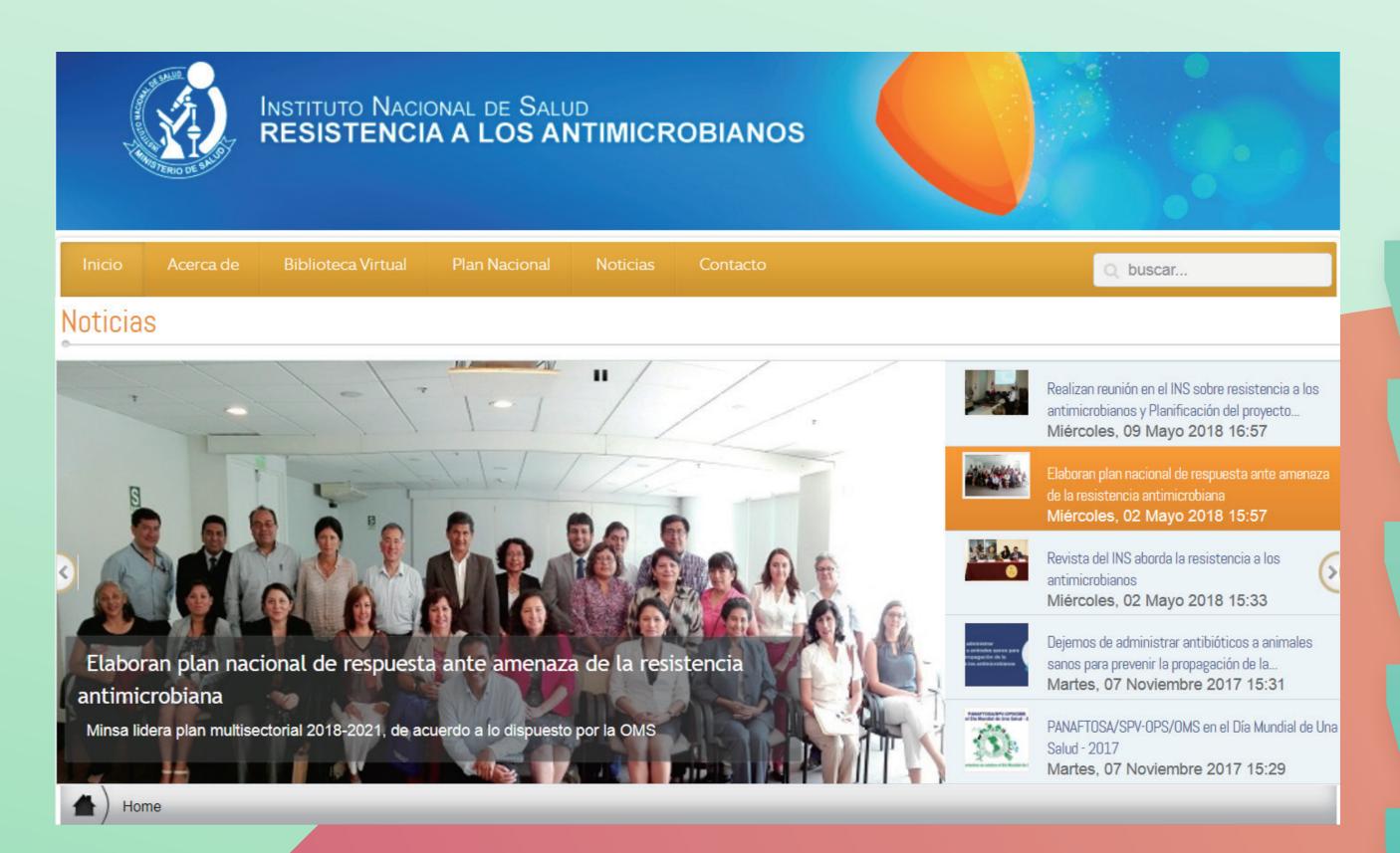
Anti-tuberculosis drugs resistance among new patients, Peru 1996-2014





Last workshop, Colegio Médico del Perú April 2018

The plan will be made official through a Supreme Decree with the signature of the President and the ministers of the corresponding sectors.



Promotion of rational use of antibiotics in the community

The National Drug Regulatory Authority (Dirección General de Medicamentos, Insumos y Drogas, DIGEMID) developed guidelines for the rational use of medicines (including antibiotics) in the community

http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Publicaciones/URM/P22_2012-09-17_Manual_comunidad.pdf MANUAL SOBRE USO ADECUADO DE LOS MEDICAMENTOS EN LA COMUNIDAD Para Agentes Comunitarios de Salud



Web page about the National Action Plan on Antimicrobial Resistance: antimicrobianos.ins.gob.pe



Asia-Pacific Economic Cooperation



Centers for Disease Control



Progress on AMR Control Programme in Indonesia

Dr. Triya Novita Dinihari Head Section for Early Warning, Dg for Diseases Prevention and Control, Ministry of Health

INTRODUCTION

Data on AMR have been patchy, sporadic and selective \rightarrow few university labs (unconnected)

Some independent studies on AMR and AMU conducted

35.2% households keep medicines (including AM) at home for various reason

INDONESIA





(Basic Health Research, 2013)

80% AB use in animal husbandry was in poultry

Most of commercial poultry in Indonesia are owned by people with low biosecurity level

National Action Plan on AMR Indonesia 2017-2019 has already in place since May 2017, developed by multisectoral collaboration, in-line with GAP AMR One Health approach, supported by WHO and FAO (http://www.who.int/antimicrobial-resistance/national-action-plans/library/en/)

National Action Plan on AMRIndonesia 2017 -2019



GOAL

To ensure continuity of successful treatment and prevention of infectious diseases with effective and safe medicines that are quality-assured, used in a responsible way and accessible



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Cerdas Gunakan C
 @gemacermat

@gemacermat
 @cerdasgunaka
 @diskusiobat

1. Improve awareness and understanding

Public awareness campaigns through the Community Movement on Smart Use of Medicines (GeMa CerMat) program, prioritized in AMR and prudent use of antibiotics

Nationwide dissemination of information and educational material for increasing public awareness and knowledge, through printed, electronic, and social media

2. Strengthen knowledge through surveillance & research

18 surveillance sites in referral hospitals coordinated by MoH/ARCC AMR surveillance on livestock conducted by National Veterinary Product Assay Laboratory



Policy and regulation on AMR

STRATEGIC OBJECTIVES

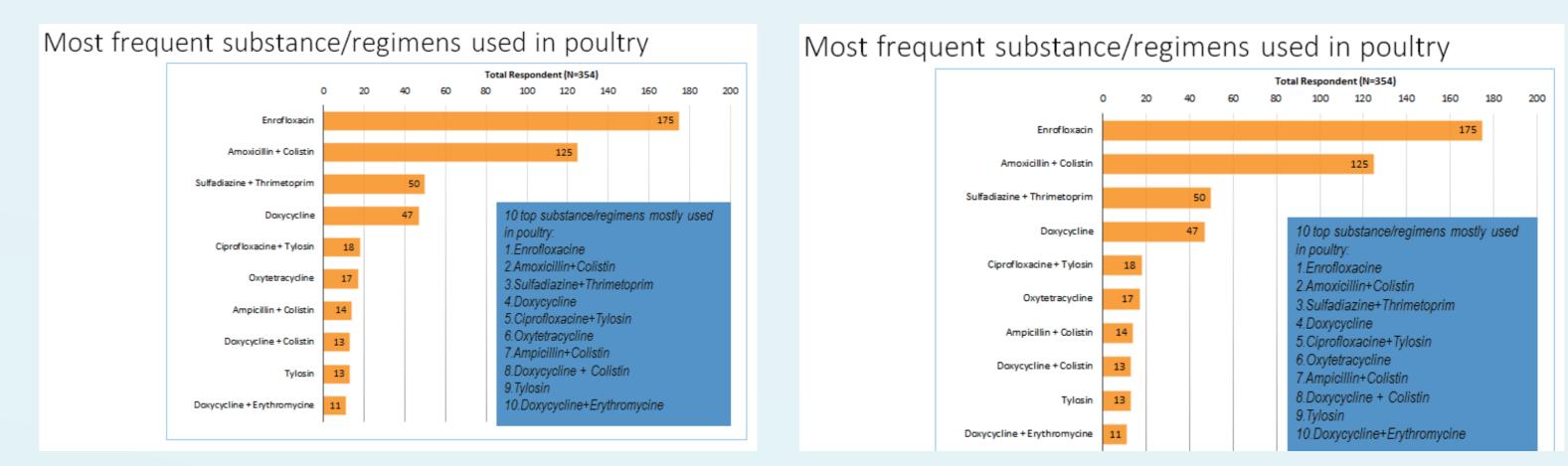
Improve awareness and understanding of antimicrobial resistance through effective communication , education and training	Strengthen the knowledge and evidence base through surveillance and research	Reduce the incidence of infection through effective sanitation, hygiene and infection prevention measures	Optimize the use of antimicrobial medicines in human and animal health	Increase investments in new medicines, diagnostic tools, vaccines and other interventions to reduce antimicrobial use
SO-1	SO-2	SO-3	SO-4	SO-5

Public awareness has been implemented to farmers, veterinary medicine association, feed production association, and student of faculty of veterinary medicine through stadium generale. Antibiotic awareness week has

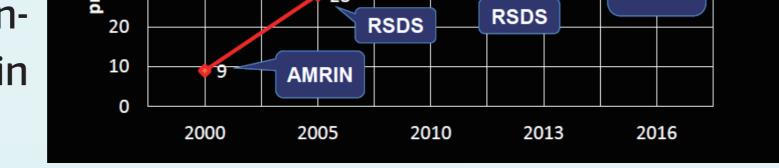


been done routinely support by MoH with WHO, some hospitals and pharmacist association and MoA with FAO and university.

AMR and AMU survey (2017 and 2018) in poultry conducted



8 Regional Disease Investigation Centers for surveillance including AMR in animal health.



Pomeran

Aunan

atan

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National reference laboratory for

AMR surveillance for human and animal health has not established yet. Preparation phase of Global Surveillance on ESBL Producing E.Coli (Tricycle project) with One Health approach, collaborative work between MoH, Min. of Agriculture and Min. of Environmental and Forestry.

3. Reduce incidence of infection

2017: Health Minister decree no.27/2017 infection prevention and control in health facilities guideline

2015: Health Minister decree no.8/2015 antimicrobial resistance control programme in hospital

Infection Prevention and Control (IPC) program in healthcare settings available, including regulations and guidelines, committees in healthcare settings both for referral (hospital) and primary (health center) healthcare, and trained personnel

AMR, IPC and HAI include in national accreditation for hospital

Hand hygiene already implemented in healthcare facilities (hospital and health center) primary health care

Large-scale farms have now been awarded free AI compartment certificates, one of the indicators in the audit is the implementation of biosecurity in the farm.

Policy and guidelines biosecurity in the farm have been established.

4. Optimize use of antimicrobial medicines

als

The Essential Medicines List and National Formulary with its restriction for the reference of antimicrobials use in healthcare facilities are available Guideline on Antibiotic Use has been in place

Some hospitals have capacity to produce AMR patterns and the use of antimicrobials (AMU)

Regulation and policy on the Antimicrobial Stewardship Programme (AMSP) for health center is under development (apakah yang dimaksud PPRA di RS?) AMR is included in trainings, workshops and seminars for health profession-

Regulation No. 18 /2009 and regulation No. 41 /2014: prohibit use of certain AB for animal that to be consumed by human and for AGP Minister of Agriculture decree No. 14/2017: prohibit use of certain AB for animal (detail)

5. Ensure sustainable investment for R&D and implementation of control measures

NIHRD-MoH focuses on vaccine development under vaccine consortium (TB and Dengue) and antimalarial which consist of the government, industry, and academic

CHALLENGES

Misuse and overuse on AB in human, livestock and agriculture

Common and unnecessary prescription of ABs by doctors

High rates of self-medication

OTC purchase

Antibiotics use without prescribing

Weak of environmental sector engagement in AMR programme

National reference laboratory (NRL) and national coordinating center (NCC) on AMR have not established yet

Weak policy enforcement and poor governance (maksudnya ?)

Lack of awareness

CONCLUSION

Continue and expand the public awareness to all the community level, and educate more health professionals and other stakeholders

Need to establish Inter-ministerial committee for AMR control for coordinated actions to achieve NAP deliverables

Multisectoral national action plans on AMR are fundamental but sustainable implementation is a major challenge

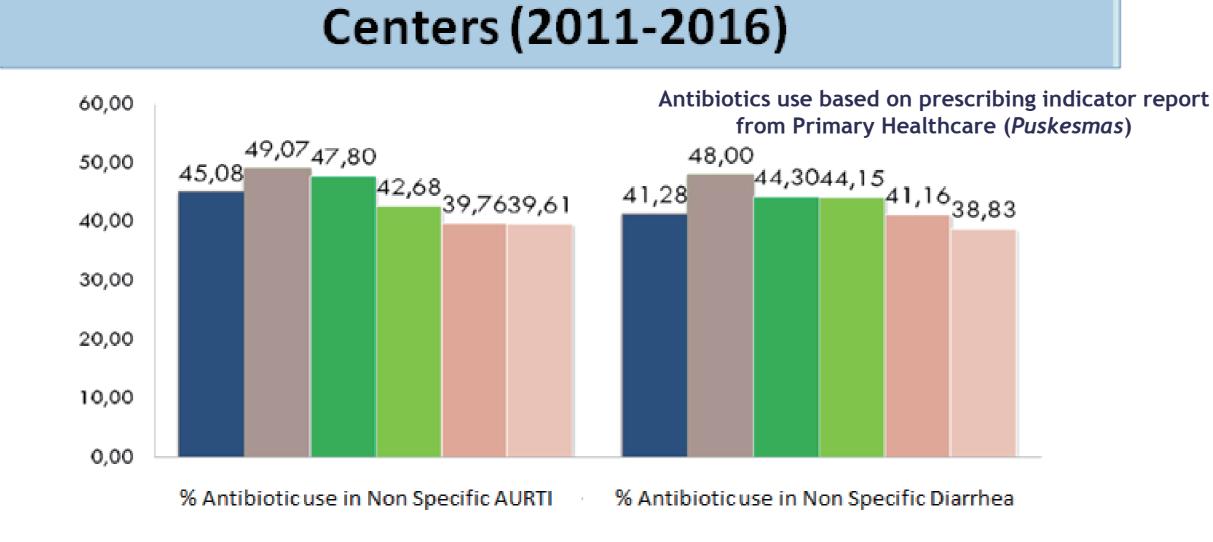
AB use for growth promoter was banned since 1 Jan 2018

Antimicrobial use (AMU) monitoring in health center (for non-pneumonia ARTI and acute diarrhea) has been regularly reported.

NADFC conducts pre and post market control of antimicrobial medicines as part of quality assurance activities.

GMP, GDP, GPP control has already performed on the production, distribution and healthcare facilities

Antibiotic Prescription Monitoring in Health



■ 2011 ■ 2012 ■ 2013 ■ 2014 ■ 2015 ■ 2016

Apakah yang dimaksudkan data di primary healthcare?



