DEPARTMENT OF LIVESTOCK DEVELOPMENT
MINISTRY OF AGRICULTURE AND COOPERATIVES

PROMOTING ACCESS TO HIGH QUALITY VETERINARY ANTIMICROBIALS

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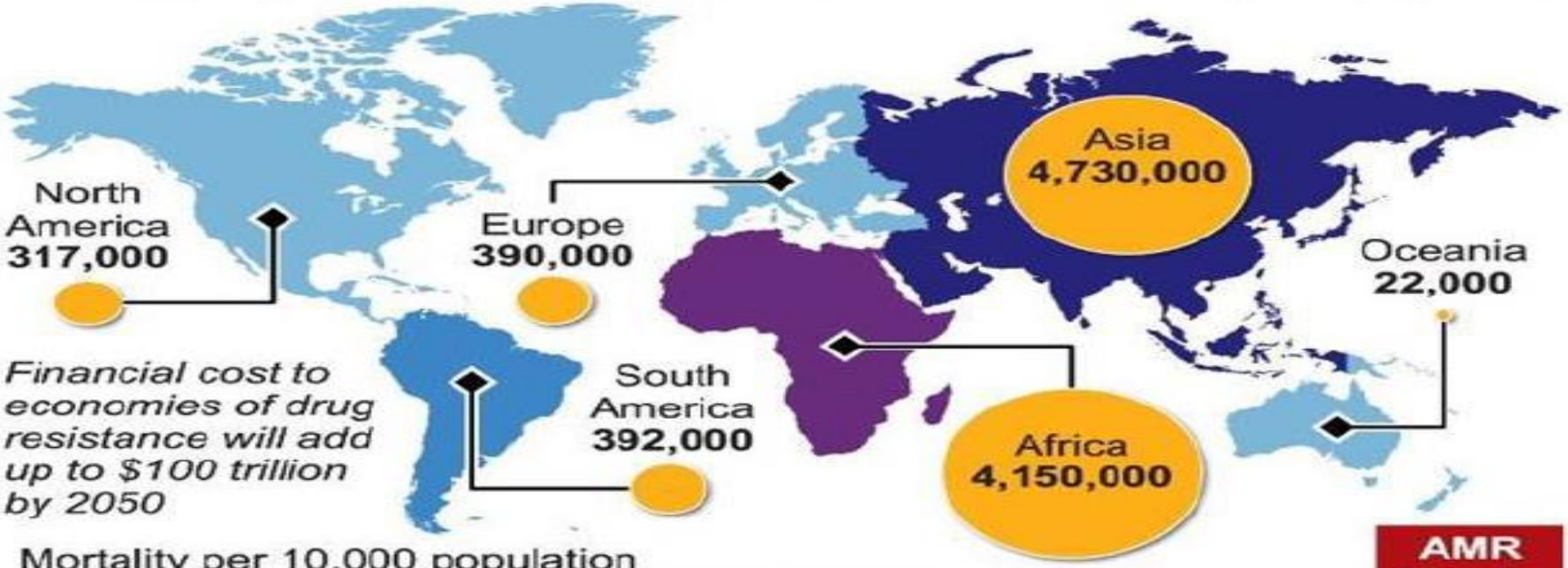
THAILAND

Superbugs "bigger risk than cancer"

An extra 10 million people could die every year by 2050 unless sweeping global changes are agreed to tackle increasing resistance to antibiotics

Deaths per year attributable to Antimicrobial Resistance (AMR) by 2050



Financial cost to economies of drug resistance will add up to $100 trillion by 2050

Mortality per 10,000 population

5 6 7 8 9 10 >

Deaths per year attributable to AMR compared to other major causes of deaths

Source: Review on Antimicrobial Resistance Picture: Associated Press

Addressing Antimicrobial Usage in Asia's Food Animal Production Sectors: Toward a Unified, One Health Approach to Preventing and Controlling Resistance

ABR in *E.coli* from Pigs

Class	Compound	AS	AU[1]	NZ[2]	US[3]	DK[4]	NL[5]	FI[6]	SW[7]
AMI	Gentamicin	24	3	0	1	1	2	0	1
	Kanamycin	36			1		1	0	1
	Streptomycin	66		32	15	42	60	15	16
CEP	Ceftiofur	<1	0	0		1		0	
	Cephalothin	18		2					
PEN	Amoxicillin	57		9	0				
	Ampicillin	57	35		13	29	25	7	13
PHE	Chloramph.	47	44	10	3	3	12	0	4
	Florfenicol	36	34			1	1	1	0
POL	Colistin	5				0			0
QUI	Ciprofloxacin	31	0		0	1	1	1	2
	Nalidixic acid	36	5	1	0	1	1	1	2
SUL	Sulfamethox.	60		33			45	12	
TET	Oxytetracycline	70	76						
	Tetracycline	87		49	47	36	56	18	8
TRI	Trimethoprim	26		8		22	37	12	11
	Trim-Sulfa	76	33						

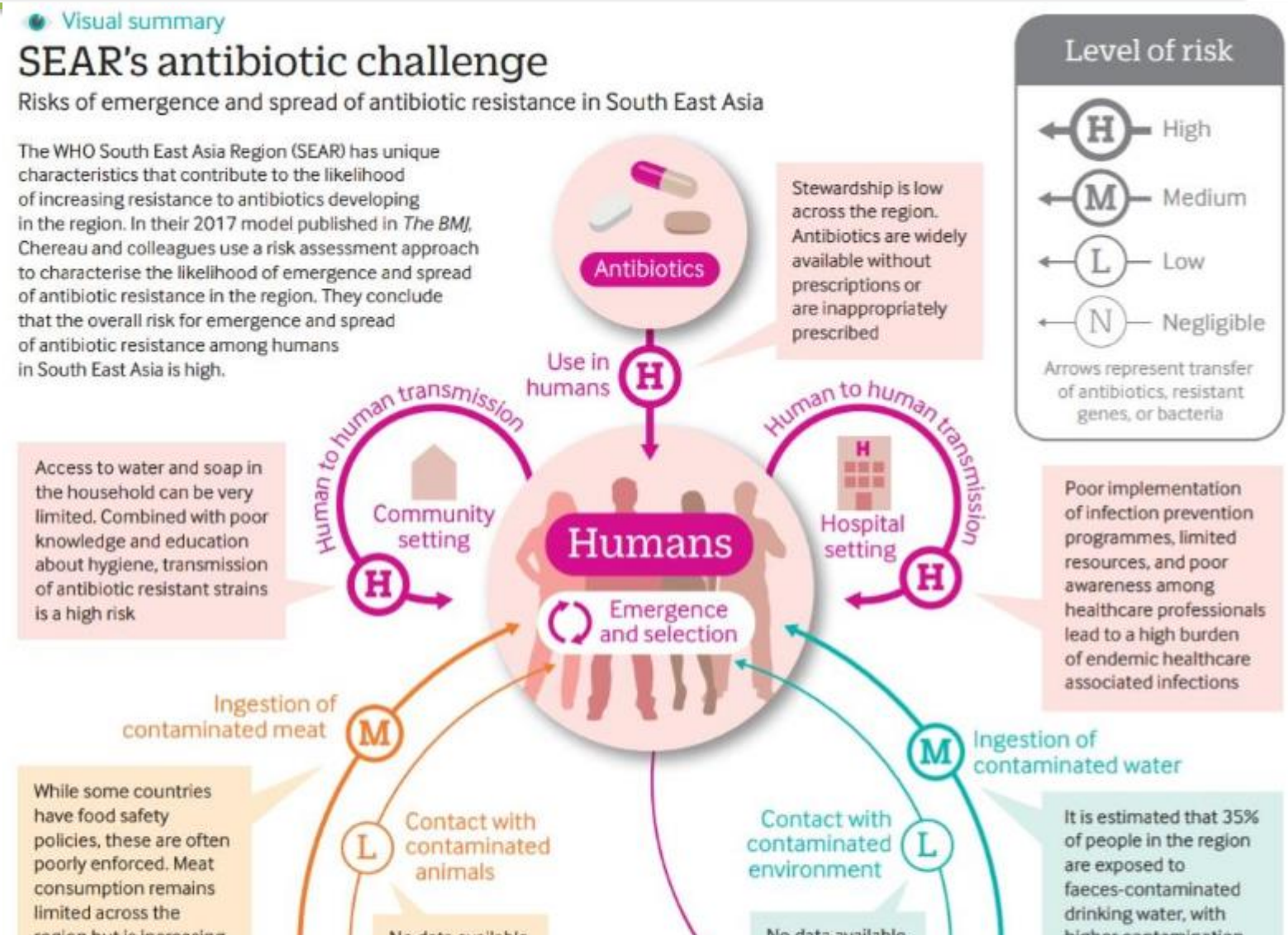
Low: ≤10% | Mod.: >10% to 20% | High: >20% to 50% | V. High: >50% to 70% | Ex. high: >70%

Source: Chuanchuen R et al., 2014

[1] AU: DAFF 2007; [2] NZ: MAF 2011; [3] US: NARMS 2011 (pork); [4] DK: DANMAP 2012; [5] NL: MARAN 2013; [6] FI: FINRES-VET 2007-2009; [7] SW: SVARM 2011

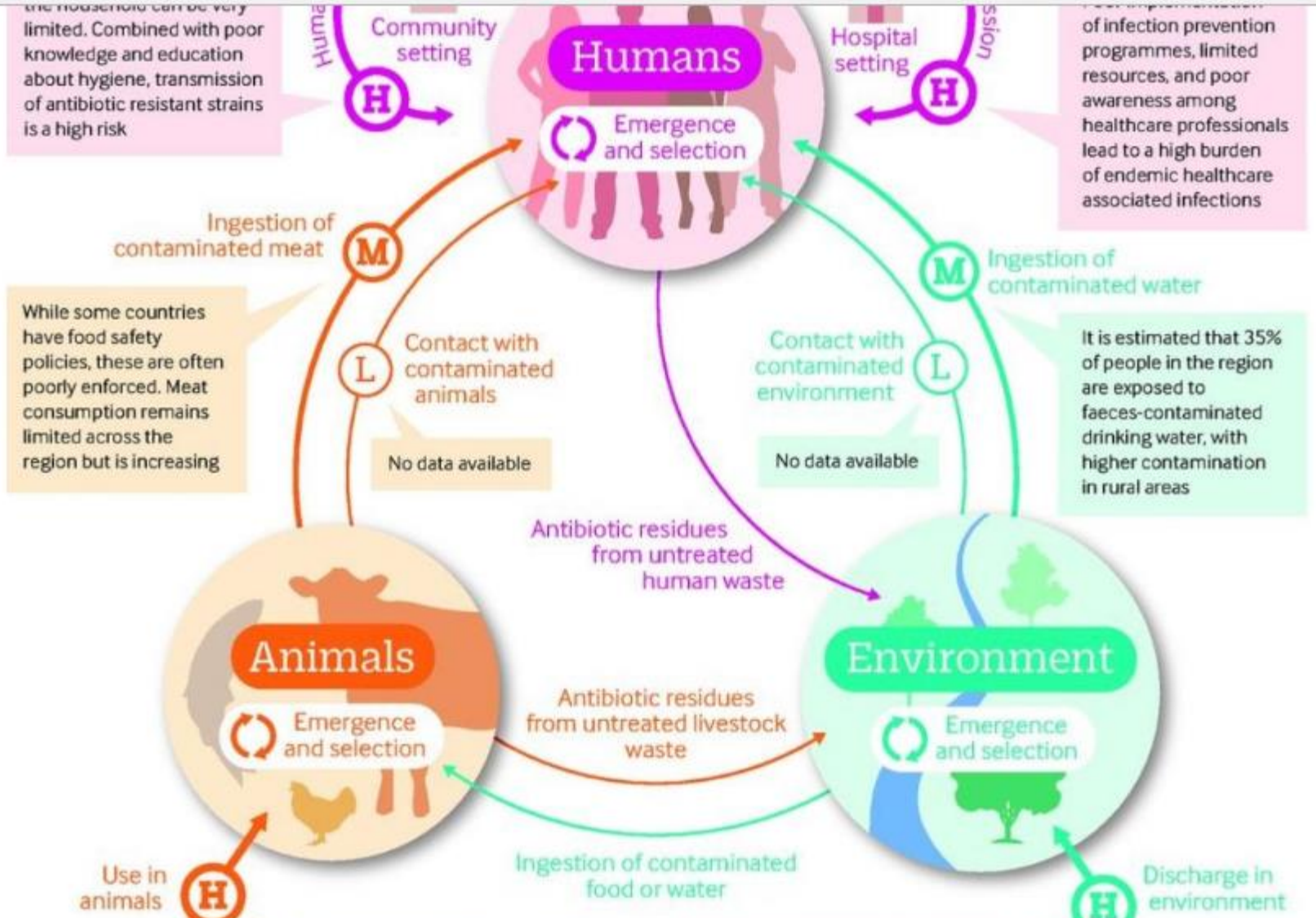
Overall risk for emergence and spread of ABR among people in SE ASIA is high (both hospital and community setting)

Risk assessment for antibiotic resistance in SE ASIA ,BMJ 2017



Risk from animal/environment (Medium,Low) But high use in animal

Risk assessment for antibiotic resistance in SE ASIA ,BMJ 2017



Main Issues

Active pharmaceutical ingredients

Medicated feed / Medicated premix
(Feed mill, farm mixer)

Custom -made vaccine

WHY ?

Antibiotic APIs (leak to farm)

Medicated feed

Autogenous vaccine

- High demand
- Specific issues in animal sector
- Borderline products

(Unclear/weak regulation)

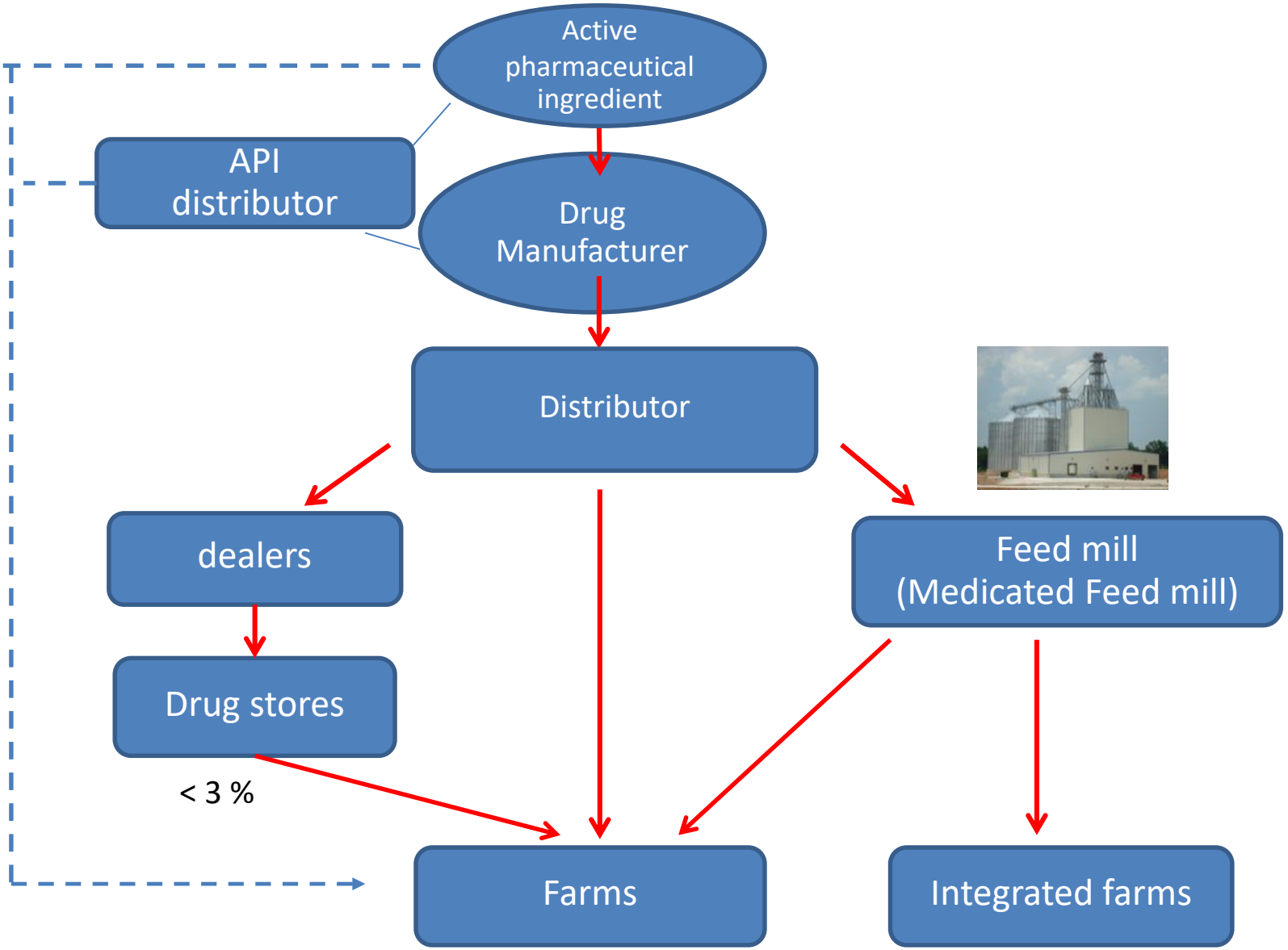
Identified AMU / AMR problem in Food producing animals

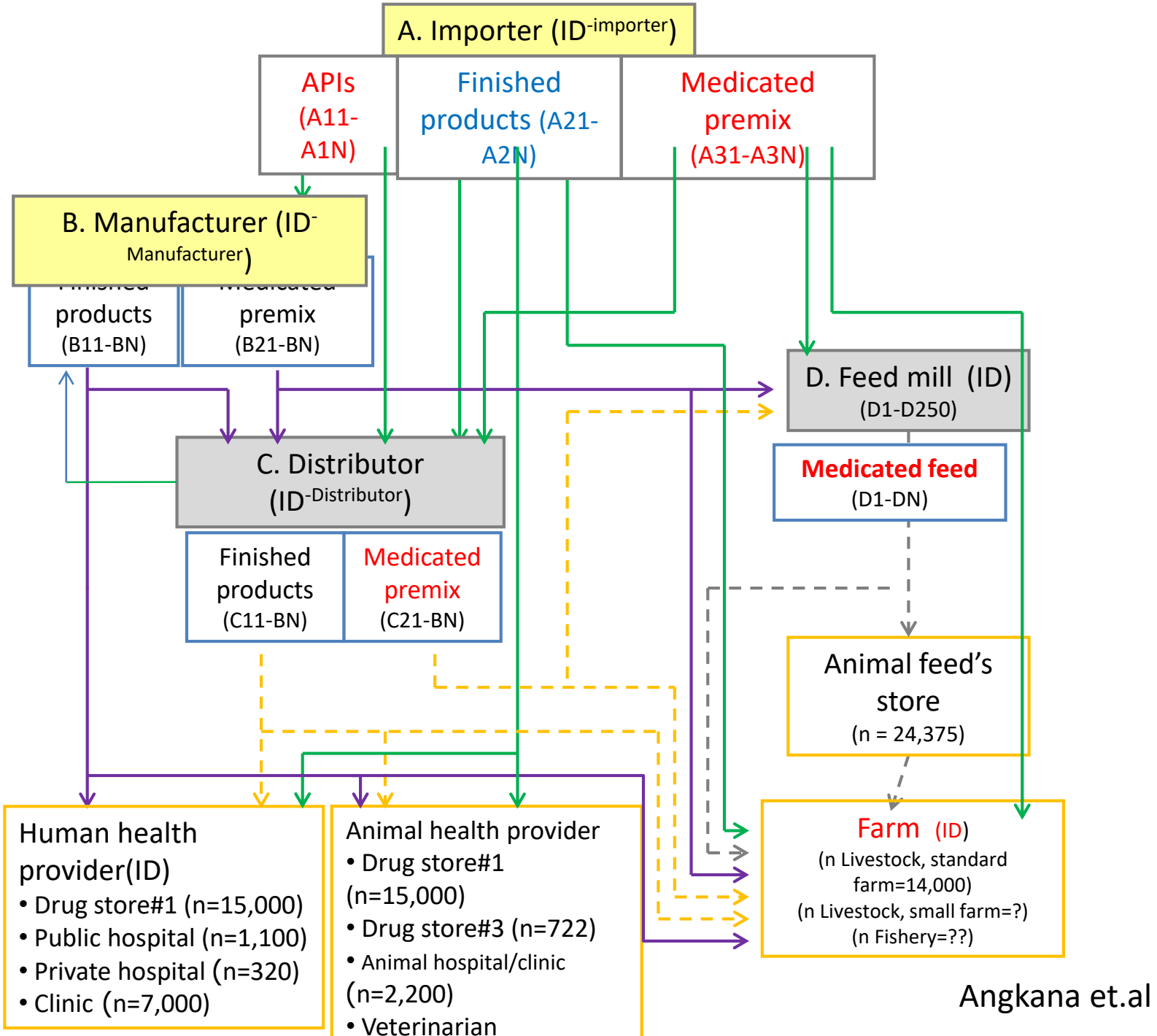
Communique of Tokyo meeting of Health Ministers on AMR in ASIA / WHO Bi-Regional meeting
14 -16 April 2016

Strengthen

"Regulating production and domestic/international distribution of active pharmaceutical ingredients of antimicrobials, medicated feed production, and registration of antibiotics to be used in animals, based on scientific risk assessment

Distribution channel of APIs and Finished drugs



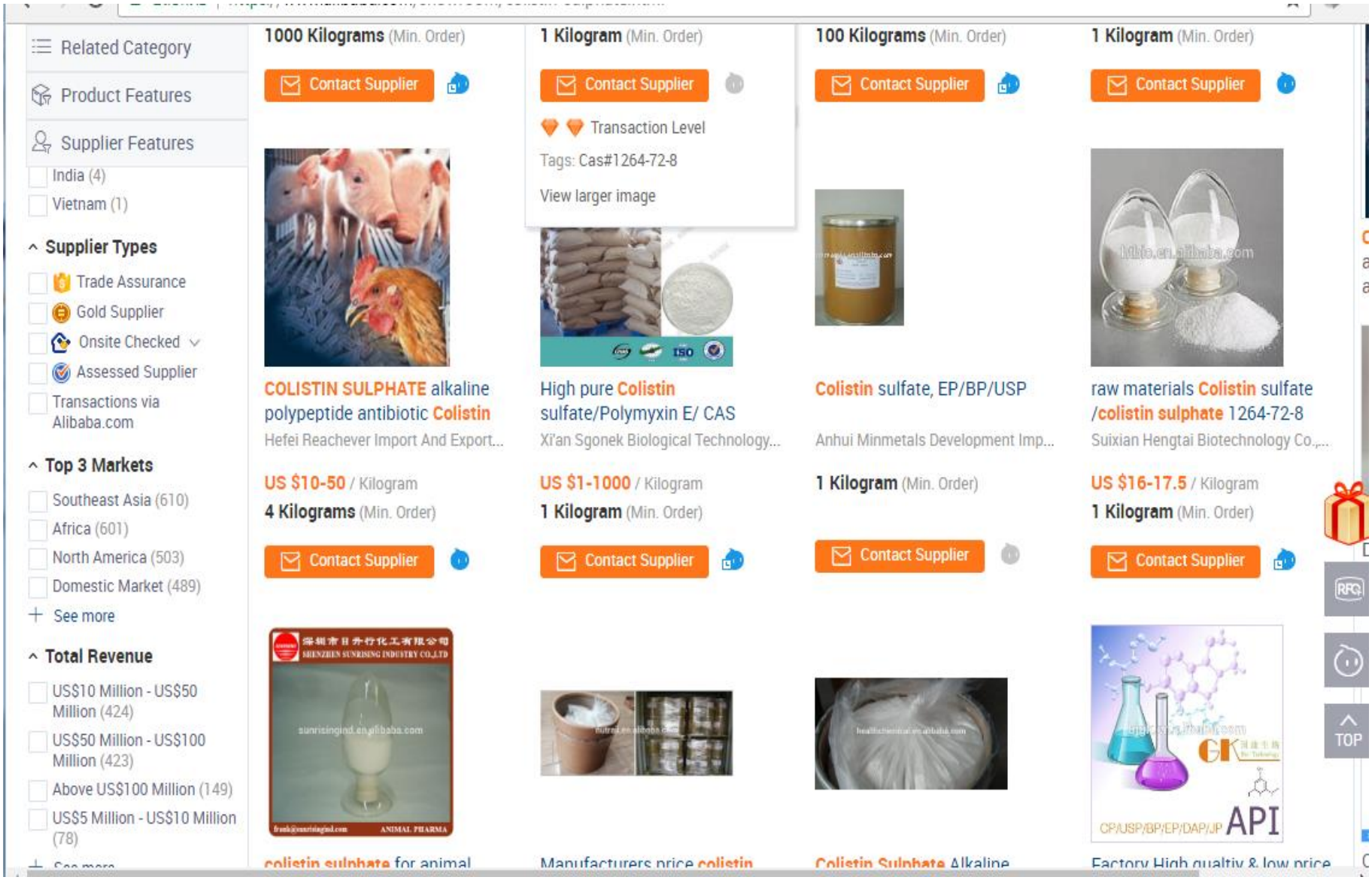

A. Importer (ID-importer)
APIs (A11-A1N)
Finished products (A21-A2N)
Medicated premix (A31-A3N)
B. Manufacturer (ID-Manufacturer)
products (B11-BN)
premix (B21-BN)
D. Feed mill (ID) (D1-D250)
Medicated feed (D1-DN)
C. Distributor (ID-Distributor)
Finished products (C11-BN)
Medicated premix (C21-BN)
Animal feed's store (n = 24,375)
Human health provider(ID)
• Drug store#1 (n=15,000)
• Public hospital (n=1,100)
• Private hospital (n=320)
• Clinic (n=7,000)
Animal health provider
• Drug store#1 (n=15,000)
• Drug store#3 (n=722)
• Animal hospital/clinic (n=2,200)
• Veterinarian
Farm (ID)
(n Livestock, standard farm=14,000)
(n Livestock, small farm=?)
(n Fishery=??)
Angkana et.al

Strengths of the Veterinary Medicinal Products (registered medicated premix)

Active Ingredient	Animal Species	Premix Concentration		
		South East Asia	Japan (MAFF)	European Union (EMEA)
Colistin	Pig	- 40% premixes	-1%, 2%, 4% premixes	-1%, 2%, 4% premixes
Amoxicillin	-Pig -Poultry	- 50 % premix	-	- 10, 20% premixes

High concentration of premix is like APIs. It is cheaper when compare to low concentration. Does it could go directly to the farm and attribute the irrational use of drugs in feed. Besides, farm mixers may have no suitable capability of mixing it well. APIs and high concentration of medicated premix including uncontrolled access to antibiotics can attribute to high rate of AMR

Advertise and sale online



Medicated feed in the EU (2008)

European Commission
Directorate General for Health and Consumers

Evaluation of the EU Legislative Framework in the Field of Medicated Feed

Framework Contract for evaluation
and evaluation related services - Lot 3: Food Chain
(awarded through tender n° 2004/S 243-208899)

	Production of medicated feed ('000 tonnes)	Production of medicated feed as percentage of production of compound feed [a]	Most common route of oral administration of VMPs [b]	Evolution of the use of medicated feed over the last 5 years [b]
Belgium	300	4.8 %	Top dressing/ incorporation of ready-to-use VMPs in the feed and mixing into water	Increased fairly significantly
Czech Republic	99	3.4 %	Medicated feed and mixing into water	Decreased fairly significantly
Denmark	12 [c]	0.2 % [c]	Top dressing/ incorporation of ready-to-use VMPs in the feed and mixing into water	Increased very significantly [d]
France	800 – 1,000	3.5 % – 4.4 %	Medicated feed	Remained the same
Germany	12	0.1 %	Top dressing/ incorporation of ready-to-use VMPs in the feed and mixing into water	Decreased very significantly
Italy	1,330	9.1%	Medicated feed and mixing into water	n.a. [e]
Poland	n.a.	n.a.	Medicated feed	Increased very significantly
Portugal	n.a.	n.a.	Medicated feed	Increased fairly significantly
Spain	2,000 [f]	6.6 % [f]	Medicated feed	Remained the same
UK	500	4.0 %	Medicated feed	Decreased fairly significantly

Notification of Ministry of Agriculture and Cooperative : Control of manufacture, import sale and use of medicated feed 2018

Trainning

“Farm veterinarian (FV)” means a veterinarian who has a license and certify by DLD to control an animal farm according to the regulation of the Department of Livestock Development concerning to use veterinary medicinal products and manage animal health issues for food safety

“Medicated feed mill veterinarian (MFMV)” means the veterinarian who is assigned by feed business operator to control the medicated feed production system and notify to DLD

** DLD may set criteria to issue the license for MFMV in line with this MoA notification as necessary in the future

Autogenous vaccine

1 to 3 weeks

1 Farmer or owner: Detection of sick animals

2 Veterinarian: Clinical diagnosis and sampling

3 Laboratory: Isolation and identification of the strains

4 Veterinarian: Prescription of an autogenous vaccine

5 4 to 5 weeks Manufacturing of the autogenous vaccine

6 Veterinarian and farmer: Delivery of the autogenous vaccine and administration to animals

EU perspective: recent developments

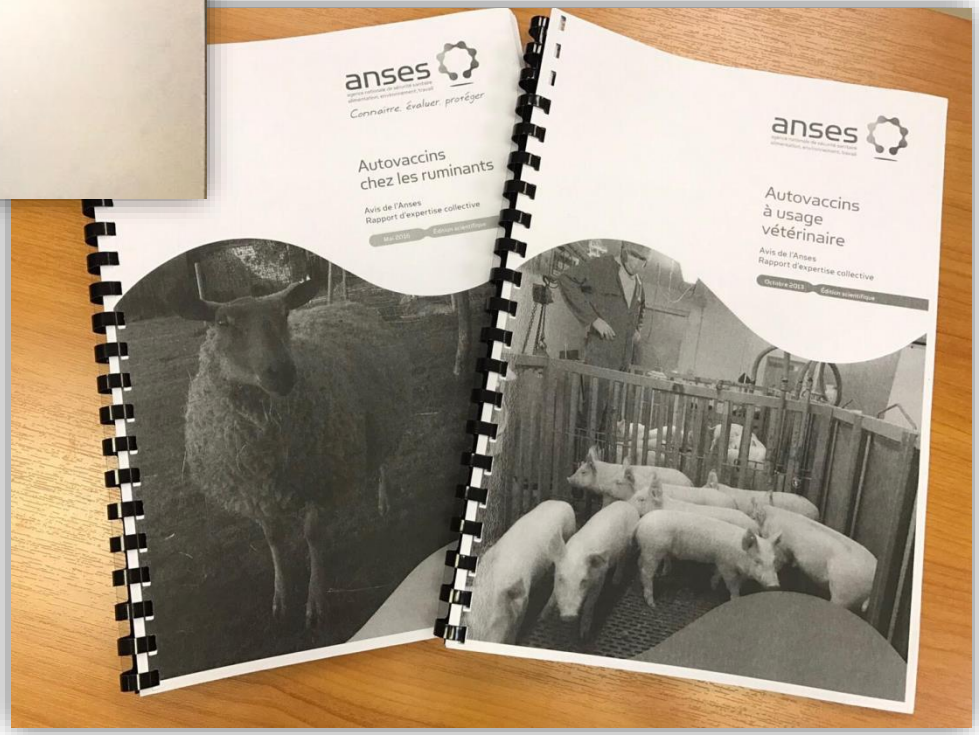
CMDv

Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

Recommendations for the use, manufacture and control of inactivated autogenous veterinary vaccines within the EEA

(To be validated by HMA)

Harmonized in EU



Together, beyond animal health

WHO ARE WE? ▪ AUTOGENOUS VACCINES ▪ REAGENTS

- Home
- Autogenous Vaccines
- Autogenous swine vaccines
- Autogenous Avian vaccines
- Autogenous vaccines for other species
- Know-how
- Practical information

Products

Custom Made Vaccines (Autogenous Biologics)

Custom Made Vaccines have been used for many years to help address livestock diseases. Newport

Custom-made vaccine
Drug Act

- The Drug Act in Thailand controls both human and veterinary medicinal products.

- Require licensing for manufacturing, importing, selling and registration of all medical products.

- No specific clause to control autogenous vaccine
- However, the Drug law has some exemptions. For example:

Drug Act (exemption for licensing)

- The production of medicinal products for individual patient by medical doctor or individual animal by vet prescription

(They do not require the licensing to produce medicinal product for individual patient or individual animal.

how to interpret this exemption under drug law for custom-made vaccine in farm animals !!

ASEAN Guideline

AUTOGENOUS VACCINES

Standard requirements for the use and production of AUTOGENOUS VETERINARY VACCINES

Autogenous Vaccine

	USA	EU	Canada
Production			
•Licensing	✓	✓	✓
•For an approved list of pathogens and animal species			
Specific criteria for Use	✓	✓	✓
• Prescription			
• No licensed Vac.			
•Lack of efficacy of licensed vac.			
etc			

Autogenous vaccine Company	Country	Link
1. Ceva animal health	France	https://www.biovac.ceva.com/en/Autogenous-vaccines/
2. Newportlabs	USA	http://www.newportlabs.com/custom-made-vaccines
3. MPV laboratory	USA	http://www.mvplabs.com/products/autogenous-bovine-vaccines
4. ARKO laboratory	USA	http://www.arkolabs.com/pb/wp_5cfca004/wp_5cfca004.html
5. Anicon	Germany	https://www.anicon.eu/en/pages/show/impfstoffe
6. Harris vaccines	USA	http://www.harrisvaccines.com/
7. Phibro vaccine	USA	http://www.mvplabs.com/products/autogenous-specialty-vaccines
8. vaxxinova	Germany	https://en.vaxxinova.no/services/autogenous-vaccines

Conclusion

Promote High quality Veterinary Antimicrobials ?

- Prevent leak APIs

  (regulation / IT system, control distribution channel and international movement of antibiotic APIs)

- Strengthen regulation for medicated feed mills / medicated premix

- Set the appropriate place for autogenous vaccine

Recommendation / Requirement

- API (antibiotics)

  political commitment and global action plan specific to APIs

- Medicated feed / medicated premix

  International guideline to control the production

  Capacity building for testing method of drug after mix into feed

  Training (OIE animal feed / Veterinary medicinal collaborating Center)

- Custom –made vaccine

  OIE guideline / recommendation to control the use

  and manufacture of autogenous vaccine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THANK YOU FOR YOUR ATTENTION