Dr Morgan Jeannin

Chargé de mission

**Antimicrobial Resistance and Veterinary Products Department** 

Introduction to the AMU Data Collection

**Template** 

Webinar for Europe 17 - 19 February 2021



# OIE 83<sup>rd</sup> General Session – May 2015

Resolution 26 "Combating AMR and Promoting the Prudent Use of Antimicrobial Agents in Animals"

The OIE develops a procedure and standards for data quality for collecting data annually from OIE Member Countries on the use of antimicrobial agents in food-producing animals with the aim of creating an OIE global database... – 25 –

#### RESOLUTION No. 26

#### Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals

#### CONSIDERING

- That antimicrobial agents are essential tools for protecting animal health and welfare and also contribute to meeting the increasing global demand for safe meat, milk, fish and eggs, and other products of animal origin.
- That antimicrobial resistance (AMR) is a significant global animal and human health threat that is influenced by the use of antimicrobial agents in some conditions,
- That during the 77th General Session 2009, the World Assembly of Delegates (the Assembly)
  adopted Resolution No. 25 on Veterinary Products, which considered previous Resolutions on
  harmonisation of registration requirements for veterinary drugs, their responsible and
  prudent use and monitoring of resistance.
- 4. The recommendations of the OIE Global Conference on the responsible and prudent use of antimicrobial agents in animals, held in March 2013 in Paris, France, including recommendation No.7 to collect harmonised quantitative data on the use of antimicrobial agents in animals with the view to establishing a global database,
- The recent update and development of OIE standards and guidelines related to antimicrobial resistance, which include references to the relevant standards developed by Codex Alimentarius,
- The tripartite agreement between FAO, OIE and WHO to address as a priority antimicrobial resistance and the important contribution of the OIE to the development and achievement of the WHO global action plan on antimicrobial resistance,
- The network of OIE National Focal Points for Veterinary Products and its role in supporting the global implementation of the OIE standards regarding veterinary products,
- 8. The importance of the PVS pathway in supporting compliance of national veterinary services with OIE standards including legislation, as a prerequisite to ensuring good governace covering production, registration, distribution and use of antimicrobial agents at the national level,
- The importance of appropriate Veterinary Education and Veterinary Statutory Bodies in the promotion of veterinary oversight to ensure responsible use of antimicrobial agents in animals.

#### THE ASSEMBLY

#### RECOMMENDS THAT

 The OIE continue to develop and update standards and guidelines related to antimicrobial resistance and the prudent use of antimicrobial agents including updating regularly the OIE List of Antimicrobial Agents of Veterinary Importance.

83 GS/FR - PARIS, May 2015





# OIE 84th General Session – May 2016

Resolution 36 "Combating AMR through a One Health Approach: Actions and OIE Strategy"

- The OIE actions to be compiled and consolidated within the OIE Strategy on antimicrobial resistance include:
  - The establishment and the management of a database for the collection of data on the use of antimicrobial agents in animals as well as the development of interpretation indicators

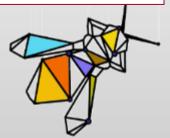
– 1 – RESOLUTION No. 36

#### Combating Antimicrobial Resistance through a One Health Approach: Actions and OIE Strategy

#### CONSIDERING

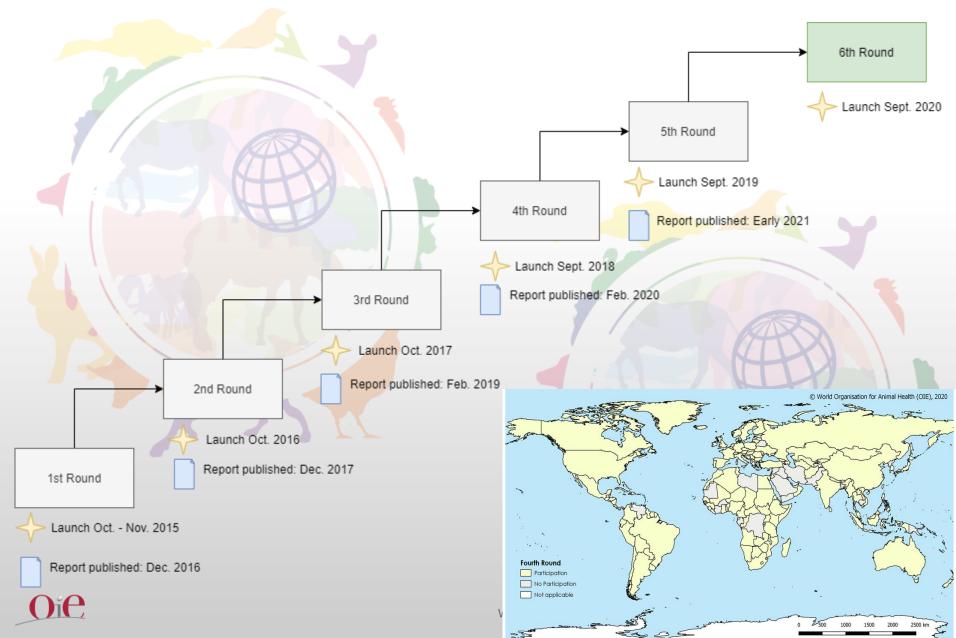
- That antimicrobial resistance (AMR) is both an animal and human health threat of growing concern which has been significantly considered by the OIE through the development and adoption of relevant and important standards and guidelines.
- 2. That during the 77th General Session (May 2009), the World Assembly of Delegates (the Assembly) adopted Resolution No. 25 on Veterinary Medicinal Products, which also considered previous Resolutions on the harmonising of registration requirements for veterinary drugs, their responsible and prudent use and the monitoring of resistance including recommended actions to be implementated.
- 3. The recommendations of the OIE Global Conference on the responsible and prudent use of antimicrobial agents in animals, held in March 2013 in Paris, France, including Recommendation No. 7 to collect harmonised quantitative data on the use of antimicrobial agents in animals with the view to establishing a global database, which was subsequently formally endorsed by the Assembly at the 83rd General Session (May 2015 through the adoption of Resolution No. 26,
- 4. The contribution of the OIE to the development of the World Health Organization's (WHO) Global Action Plan on Antimicrobial Resistance, under the framework of the Tripartite agreement between the Food and Agriculture Organization of the United Nations (FAO), the WHO and the OIE, which was adopted by the World Health Assembly of the WHO in May 2014.
- 5. The recommendation to Member Countries, to follow the guidance of the WHO Global Action Plan on Antimicrobial Resistance, in particular by developing national action plans, in respect of the use of antimicrobial agents in animals and ensuring close collaboration with public health officials, adopted through Resolution No. 26 of the S&rd General Session on Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals.
- 6. The importance of the capacities of the national Votorianry Services to comply with the relevant standards and the particular benefit of the OIE PVS Pathway in supporting the Member Countries to update their legislation, which is a prerequisite to ensure good governance covering registration, production, distribution, prescription and use as well as control and surveillance of antimicrobial agents at the national level,
- The role of the network of the OIE National Focal Points for Veterinary Products in supporting the global implementation of the OIE standards regarding veterinary products,
- The importance of appropriate veterinary and veterinary para-professional education in the promotion of veterinary oversight to ensure responsible use of antimicrobial agents in animals,
- The action of OIE to raise the awareness of the health risk posed by antimicrobial resistance by developing communication materials and organising sub-regional, regional and international groups.

 $84~\mathrm{GS/FR}-\mathrm{PARIS},\,\mathrm{May}~2016$ 





### Rounds of the OIE AMU Data Collection



# Then...TrACSS?





- an annual Tripartite AMR country self-assessment survey (TrACSS)
- Multisectoral (so you should be involved!)
- an open data (available at: <a href="https://amrcountryprogress.org/">https://amrcountryprogress.org/</a>)

- Tracking countries progress on AMR objectives
- for Demonstrating incremental progress

Related to

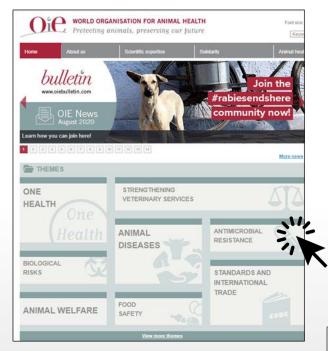
- Secretary General report to the United Nations **General Assembly**
- GAP AMR M&E framework
- OIE AMU Data Collection (40% inconsistency)

# OIE AMU Template





#### **Documents on the OIE Website**





#### OIE Template, Guidance and Calculations

The OIE considered the experience and feedback from Member Countries and annually update the template and guidance document based on requests for clarification from responding Members. The current version of these documents, are available below.







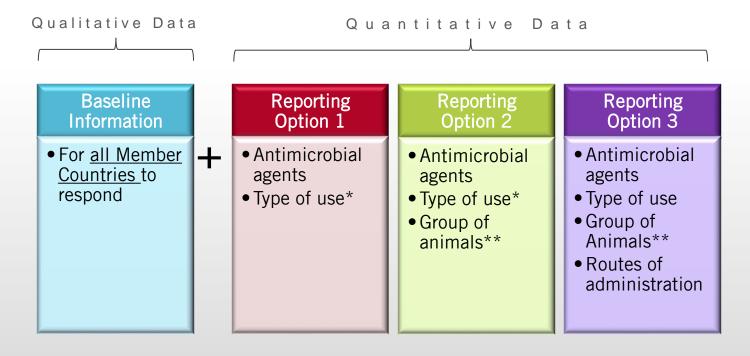
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Guidance for completing the OIE template Annex to assist in calculations



# **Reporting Options**

The sections of the OIE Template named 'Reporting Options' 1, 2 and 3, collect the quantities of antimicrobial agents intended for use in animals.



<sup>\*</sup> Type of use: veterinary medical use or growth promotion

<sup>\*\*</sup>For the purposes of the OIE database, animal groups means: 'terrestrial food-producing animals', 'aquatic food-producing animals' or 'Companion animals'



### **Baseline Information**

All OIE Members can provide information to Parts A and B- Questions 1-14

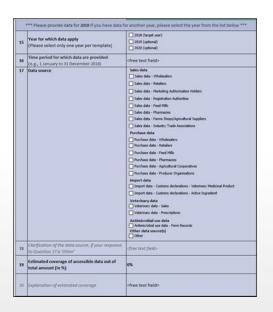
Q	*** This sheet of the OIE template should be completed by all countries ***  Please refer to the Guidance document for further instructions.		Questions in <b>bold</b> are mandatory. Please provide this information as requested.  Questions in <i>grey italics</i> are optional.
•	A. Contact Person for Anti		
1	Title	<free field="" text=""></free>	Please provide the contact information of the
2	Name (First name, SURNAME)	<free field="" text=""></free>	person completing this template. He/she will be contacted by the OIE in case any clarifications on
3	Role with respect to the OIE	OIE Delegate OIE Focal Point for Veterinary Products Other	the data are needed.  Please select the appropriate 'Role with respect to the OIE' from the list.
4	Organisation	<free field="" text=""></free>	
5	Organisation's Address	<free field="" text=""></free>	
6	Country	<free field="" text=""></free>	
7	Phone Number	<free field="" text=""></free>	Please provide the telephone number in the
8	Email Address	<free field="" text=""></free>	format " (country code) phone number ".
	B. Ger	neral Information	
Q		n in your country. Responses should not be linked to the year of	
		al quantities reported.	
9	Are data on the amount of antimicrobial agents	Amounts available - Yes	
	intended for use in animals available?	Amounts available - No	
10	Please indicate why the data are not available at this time in your country, if the answer to Question 9 is 'No'	<free field="" text=""></free>	
11	Are antimicrobial agents used for growth promotion purposes in animals in your country?	Yes No Unknown	Growth Promotion means the administration of antimicrobial agents to animals only to increase the rate of weight gain or the efficiency of feed utilisation.
12	Does your country have legislation/regulations on antimicrobial agents as growth promoters in animals?	Legislation/regulation exists - Yes Legislation/regulation does not exist - No	
13	If your country has legislation/regulation on antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country?	All antimicrobial agents banned for use as growth promoters  Some antimicrobial agents banned for use as growth promoters  One or more antimicrobial growth promoters are authorised for use	
14	Please provide a list of antimicrobial agents used or authorised as growth promoters, if any	<free field="" text=""></free>	
If you	ur response to Question 9 is ' <b>No</b> ', please kindly <u>sen</u> <u>OIE Delegate in copy,</u> to <u>antimic</u> If your response to Question 9 is ' <b>Yes</b> ', p  C. Data collection of Antimicro	Please provide data for 2018. If you have data for	
15	*** Please provide data for 2018 If you have data for Year for which data apply (Please select only one year per template)	or another year, please select the year from the list below ***  2018 (target year) 2019 (optional) 2020 (optional)	another year, please select the year from the list. We will accept data for other years (2020 or 2019), but not from before 2018. If you would like to provide data for additional years, please fill out one template per year of data. If you have found calculation errors in data

Reporting Option 1 Reporting Option 2



#### **Baseline Information**

#### Part C- Questions 14-31 that are related to the antimicrobial quantities



20	Explanation of estimated coverage	cfree text field>
21	as the information extrapolated from representative samples?	Sata extrapolated from representatives samples - Yes     Outs extrapolated from representatives samples - No
22	Explanation of extrapolations carried out, if your response to Question 21 is "Yes"	-free text fields
23	Can data be differentiated by animal group?	Data differentiated by animal group - Yes Data differentiated by animal group - No
24	Animal groups covered by the data	Objective or differentiation jall animate contained;  Data for function and squatch floor animate jall hood-producing entimate.  Data for function and squatch floor animate jall hood-producing entimate.  Data for function floor-producing entimate completion animate journal of the foreign animate completion animate journal of the foreign animate completion animate journal of the squatch floor-producing entimate of the particular animate completion
25	Food-producing animal species (opened by the information on antimicrobial quantities)	Terrentini finder producing selemble   Gotte   Type - commercial

31	Please provide the link to the report, if the answer to Question 30 is 'Yes'	<pre>free text field&gt;</pre>
30	National report(s) on sales/use of antimicrobial agents in animals available on the web?	Report available on the web - Yes Report available on the web - No
29	Can data be differentiated by route of administration?	Data differentiated by route of administration - Yes Data differentiated by route of administration - No
28	Clarification of other species considered to be companion animals, if your response to Question 27 is 'Other'	free text field>
27	Companion animal species <u>covered by</u> <u>antimicrobial quantities</u> , if any	Canines   Felines   Other
26	Clarification of other species considered to be food-producing, if your response to Question 25 is 'Other commercial poultry' or 'Other'	<pre>free text field&gt;</pre>

According to your responses to the questions abo	According to your responses to the questions above, you are invited to fill in the following Reporting Option:	
REPORTING OPTION	Appropiate for your Country	
Option 1	<u>NO</u>	
Option 2	<u>NO</u>	
Option 3	<u>NO</u>	

This part is linked to your responses to previous questions



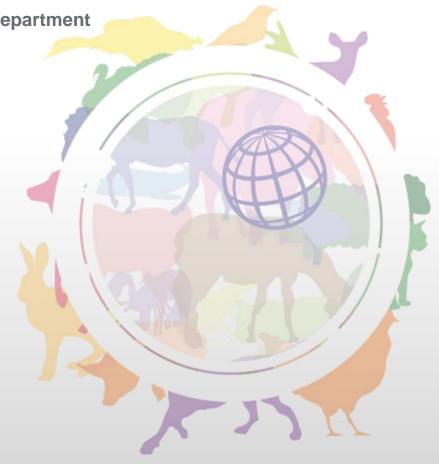
#### **Dr Delfy Góchez**

Chargée de mission

**Antimicrobial Resistance and Veterinary Products Department** 

# **OIE AMU Data Collection Calculations**

Webinar for the Middle East 7 December 2020





Calculating Kilograms of Active Ingredients Ingredients



# **Kilograms of Active Ingredients**

Antimicro	obial Class
Anumicre	DDIAI CIASS
Aminogly	
Amphenic	
Arsenical	s
Cephalos	porins (all generations)
	1-2 gen. cephalosporins
	3-4 gen cephalosporins
Fluoroqui	nolones
Glycopep	tides
Glycopho	spholipids
Lincosam	ides
Macrolide	s
Nitrofurar	ıs
Orthosom	ycins
Other qui	nolones
Penicillin:	s
Pleuromu	tilins
Polypepti	des
Quinoxali	nes
Streptogr	amins
Sulfonam	ides (including trimethoprim)
Tetracycl	ines
Others	
Aggregat	ed class data
	Total kg

#### **OTHER**

All other antibiotics not covered by the antimicrobial classes already listed. This could include novobiocin, fusidic acid, kirromycins, fosfomycin, rifamycins, etc.

# AGGREGATED CLASS DATA

This is for **confidential** data only, not for products having more than one antibiotic. If in your country the data for one antimicrobial class needs to remain confidential, then the data can be reported under this category by using the AGG letters and report the names of the classes to the OIE.

# Which data do you need to have for obtaining kilograms of active ingredients?

### Mandatory data by product

- Active ingredients Molecule name (e.g. enrofloxacin)
- Active ingredients Concentration and units (e.g. 100 mg each 1ml)
- Package size (e.g. 1 L)
- Number of units imported, sold, prescribed or used for the period of time declared to the OIE (e.g. 1500 units)

### Optional data by product

- Target species (e.g. poultry)
- Route of administration (e.g. Oral)



### **General Calculation**

 $Active\ substance\ concentration* Package\ size$ 

Concentration content

X Number of units sold, imported, prescribed or used

Example 1

Product Name: Product premix

Package size: 500 g

Sales during a year: 1 500 units

Molecules and concentrations:

Tetracycline 40 mg / 1 g

• Neomycin 20 mg / 1 g

Active Ingredient 1

Tetracycline

$$= \frac{0.04 \ g *500 \ g}{1 \ g} \times 1500$$

 $= 30\ 000\ g\ /\ 1\ 000$ 

= 30 kg reported for tetracyclines class

Active Ingredient 2

Neomycin

$$= \frac{0.02 g *500 g}{1 g} \times 1500$$

= 15000 g / 1000

= 15 kg reported for aminoglycosides class

Example 2

Product Name: Doggy tabs

Package size: 1 box with 3 blisters (each blister has 10 tabs)

Imports during a year: 950 boxes

Molecules and concentrations:

Metronidazole 125 mg / 1 tablet

Spiramycin 700 000 IU / 1 tablet

**Active Ingredient 1** 

Metronidazole

$$= \frac{125 mg *30 piece}{1 piece} \times 950$$

= 3 562 500 mg / 1 000 000

= 3. 6 kg reported for the Other class

Active Ingredient 2

Spiramycin

$$\frac{700\ 000\ IU *30\ piece}{1\ piece} \times 950$$

= 19 950 000 000 **IU** x **0.000313** 

= 6 244 350 mg/ 1 000 000

= 6. 2 kg reported for macrolides class

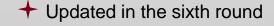
#### **Conversion Factors**

#### For International Units (IU)

Antimicrobial agent in the veterinary	Antimicrobial active entity for	International Units	Conversion factor to mg
medicine	reporting to OIE	per mg	for multiplication
Apramycin 🔶	Apramycin	556	0.0018
Bacitracin	Bacitracin	74	0.013514
Benzylpenicillin (penicillin G)	Benzylpenicillin	1666.67	0.0006
Chlortetracycline	Chlortetracycline	900	0.001111
Colistin methane sulfonate sodium	Colistin	12700	0.000079
(colistimethate sodium INN)			
Colistin sulfate	Colistin	20500	0.000049
Dihydrostreptomycin	Dihydrostreptomycin	820	0.00122
Erythromycin	Erythromycin	920	0.001087
Gentamicin	Gentamicin	620	0.001613
Kanamycin	Kanamycin	796	0.001256
Neomycin	Neomycin	755	0.001325
Neomycin B (Framycetin)	Neomycin B (Framycetin)	670	0.001492
Oxytetracycline	Oxytetracycline	870	0.001149
Paromomycin	Paromomycin	675	0.001481
Polymyxin B	Polymyxin B	8403	0.000119
Rifamycin	Rifamycin	887	0.001127
Spiramycin	Spiramycin	3200	0.000313
Streptomycin	Streptomycin	785	0.001274
Tetracycline 👉	Tetracycline	982	0.00102
Tobramycin	Tobramycin	875	0.001143
Tylosin	Tylosin	1000	0.001

#### For Derivates or Compounds

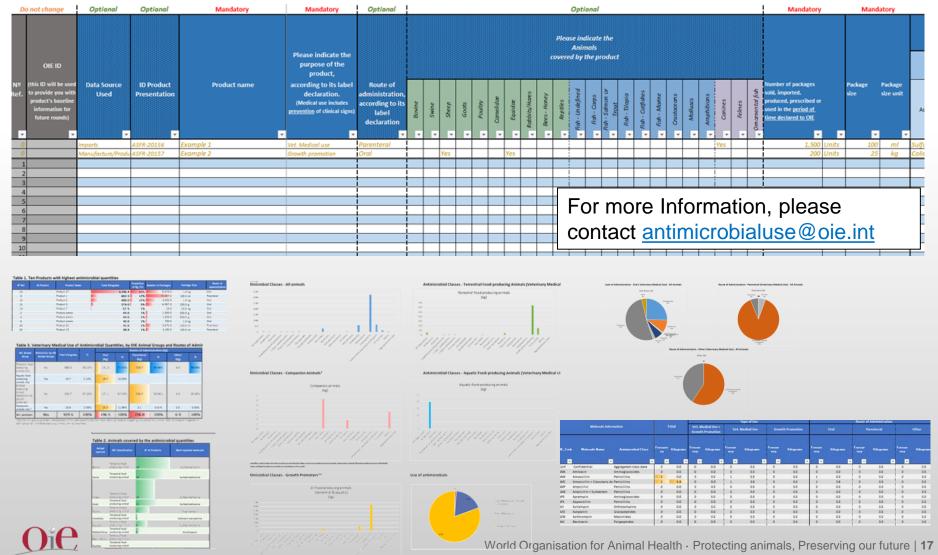
Derivate or compound	Active entity	Conversion factor for multiplication
Benethamine benzylpenicillin+	Benzylpenicillin	0.61
Benzathine benzylpenicillin	Benzylpenicillin	0.74
Cefapirin benzathine	Cefapirin	0.78
Cefalexin benzathine	Cefalexin	0.74
Cloxacillin benzathine	Cloxacillin	0.78
Oxacillin benzathine	Oxacillin	0.77
Penethamate hydriodide	Benzylpenicillin	0.60
Procaine benzylpenicillin	Benzylpenicillin	0.57





#### Additional assistance in calculations

The OIE Antimicrobial Use Team has developed a tool to assist countries in obtaining kilograms of active ingredients





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