Dr Delfy Góchez

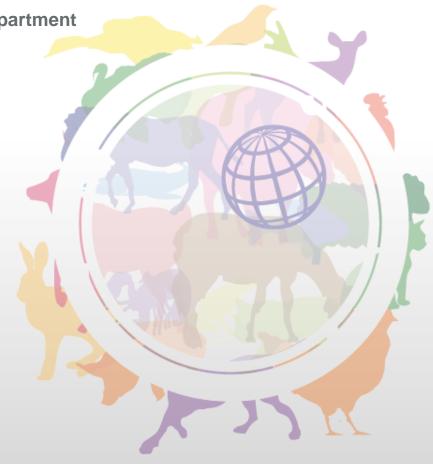
Chargée de mission

Antimicrobial Resistance and Veterinary Products Department

OIE AMU Data Collection

Template and Calculations

Webinar for Asia, Far East and Oceania 31 March 2020





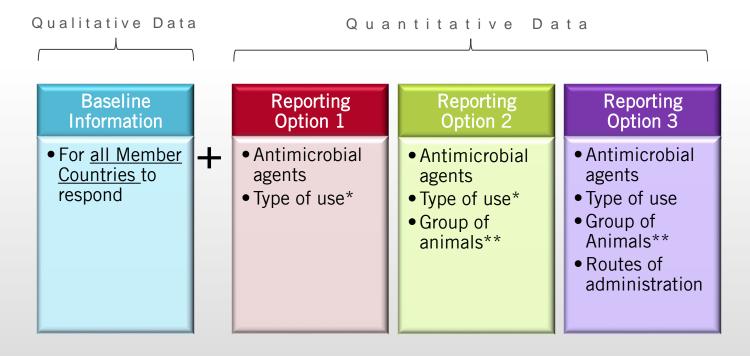
OIE Template





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.



^{*} Type of use: veterinary medical use or growth promotion

^{**}For the purposes of the OIE database, animal groups means: 'terrestrial food-producing animals', 'aquatic food-producing animals' or 'Companion animals'



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

Q		hould be completed by all OIE Member Countries *** dance document for further instructions.	Questions in bold are mandatory. Please provio this information as requested. Questions in <i>grey italics</i> are optional.	
	A. Contact Person for Anti	microbial Agents Use Data Collection		
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 the data are needed. Please select the appropriate 'Role with respect t the OIE' from the list.	
3	Role with respect to the OIE	☐ OIE Delegate ☐ OIE Focal Point for Veterinary Products ☐ Other		
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	eral Information		
(n in your country. Responses should not be linked to the year of al quantities reported.		
	Are data on the amount of antimicrobial agents	Amounts available - Yes		
9	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 rate of weight gain or the efficiency of feed utilisation.	
	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	<u>Delegate in copy,</u> to th <u>antimic</u>	this template, once validated by the OIE Delegate and with your OIE of the OIE Antimicrobial Use Team at: robialuse@oie.int please kindly complete Section C " Data Collection ".		
	27 7 7	obial Agents Intended for Use in Animals		
		or another year, please select the year from the list below ***	Please provide data for 2017. If you have data	
15	Year for which data apply	2017 (target year) 2018	another year, please select the year from the lis We will accept data for other years, but not fro before 2017. If you would like to provide data	

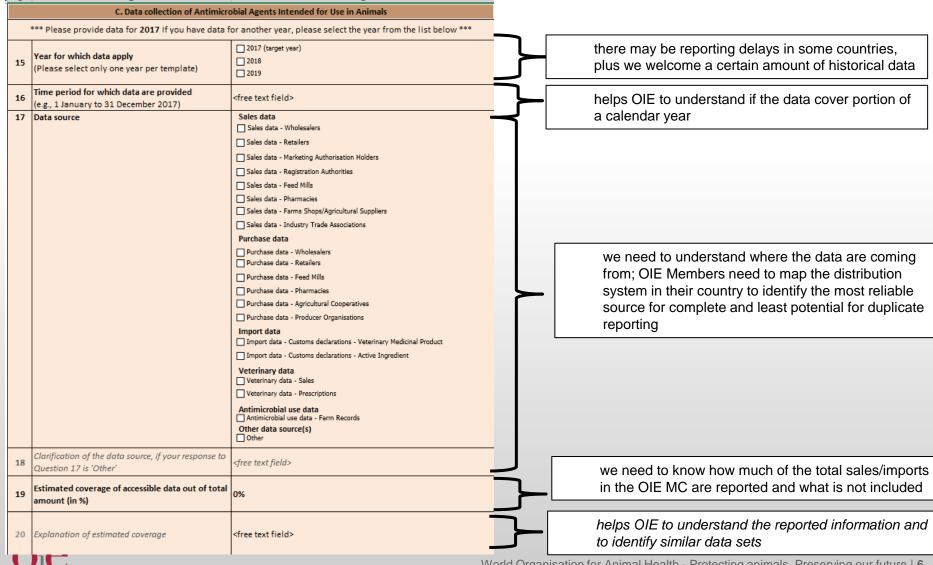


Preserving our future | 4

Part B- Questions 9-14

		Part D QUESTIONS 9-14		
	B. Gen	eral Information		
- 10		n in your country. Responses should not be linked to the al quantities reported.	year of	
9	Are data on the amount of antimicrobial agents intended for use in animals available?	Amounts available - Yes Amounts available - No	what ti	to encourage OIE Members to collect hey already have and expand coverage r whole country.
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>	If data	a are not available, OIE Members can be the barriers to provide such data
11	Are antimicrobial agents used for growth promotion purposes in animals in your country?	Yes No Unknown		
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		helps to understand the situation of the country
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	se	
14	Please provide a list of antimicrobial agents used or authorised as growth promoters, if any	<free field="" text=""></free>	pro	me substances are used for growth motion <u>and</u> medical use, the list helps se out such dual use
lf you	<u>Delegate in copy</u> , to the <u>antimic</u>	this template, once validated by the OIE Delegate and were OIE Antimicrobial Use Team at: robialuse@oie.int	rith your OIE	Protecting animals, Preserving our future 5

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



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

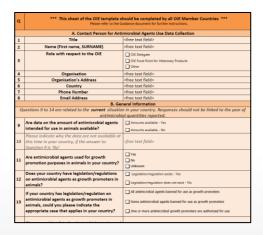
21	Is the information extrapolated from representative samples?	□ Data extrapolated from representatives samples - Yes □ Data extrapolated from representatives samples - No	helps OIE to understand what are the data provided
22	Explanation of extrapolations carried out, if your response to Question 21 is 'Yes'	<free field="" text=""></free>	
23	Can data be differentiated by animal group?	□ Data differentiated by animal group - Yes □ Data differentiated by animal group - No	
24	Animal groups <u>covered by the data</u>	Data with no differentiation (all animals combined) Data for terrestrial and aquatic food animals (all food-producing animals combined) Data for terrestrial food-producing animals and companion animals (combined) Data for terrestrial food-producing animals Data for aquatic food-producing animals Data for companion animals	refers to the categories in the different reporting options
25	Food-producing animal species <u>covered by the information on antimicrobial quantities</u>	Cattle Pigs - commercial Pigs - backyard Sheep Goats Sheep and goats (mixed flocks) Layers - commercial production for eggs Broilers - commercial production for meat Other commercial poultry Poultry - backyard	
		Buffaloes (excluding Syncerus caffer) □ Carvidae (farmed) □ Camelidae □ Equidae □ Rabbits □ Bees - Honey □ Fish - aquaculture production □ Crustaceans - aquaculture production □ Molluscs - aquaculture production □ Amphibians □ Reptiles (e.g., crocodiles) □ Other □ All	knowing differences in animals raised for food covered by the antimicrobial products helps OIE to collate appropriate data
26	Clarification of other species considered to be food- producing, if your response to Question 25 is 'Other commercial poultry' or 'Other'	<free field="" text=""></free>	World Organisation for Animal Health · Protecting animals, Preserving our future 7

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

27	Companion animal species <u>covered by</u> <u>antimicrobial quantities,</u> if any	□ Canines □ Felines □ Other
28	Clarification of other species considered to be companion animals, if your response to Question 27 is 'Other'	<free field="" text=""></free>
29	Can data be differentiated by route of administration?	□ Data differentiated by route of administration - Yes □ Data differentiated by route of administration - No
30	National report(s) on sales/use of antimicrobial	Report available on the web - Yes
30	agents in animals available on the web?	Report available on the web - No
31	Please provide the link to the report, if the answer to Question 30 is 'Yes'	<free field="" text=""></free>
	According to your responses to the questions abo	ove, you are invited to fill in the following Reporting Option:
	REPORTING OPTION	Appropiate for your Country
	Option 1	<u>NO</u>
	Option 2	NO.
	Option 3	<u>NO</u>



Documents on the OIE Website



OIE Template (questionnaire)



Guidance to complete the OIE Template



Annex to assist in **calculations**

https://www.oie.int/en/scientific-expertise/veterinary-products/antimicrobials/



Questions? (15 min)

Calculating Kilograms of Active Ingredients





Kilograms of Active Ingredients

	All Animal Species
Antimicrobial Class	All routes (kg)
Aminoglycosides	0
Amphenicols	0
Arsenicals	0
Cephalosporins (all generations)	0
1-2 gen. cephalosporins	0
3-4 gen cephalosporins	0
Fluoroquinolones	0
Glycopeptides	0
Glycophospholipids	0
Lincosamides	0
Macrolides	0
Nitrofurans	0
Orthosomycins	0
Other quinolones	0
Penicillins	0
Pleuromutilins	0
Polypeptides	0
Quinoxalines	0
Streptogramins	0
Sulfonamides (including trimethoprim)	0
Tetracyclines	0
Others	0
Aggregated class data	0
Total kg	0

Reporting Option 1

- Antimicrobial agents
- Type of use*

Reporting Option 2

- Antimicrobial agents
- Type of use*
- Group of animals**

Reporting Option 3

- Antimicrobial agents
- Type of use
- Group of Animals**
- Routes of administration

Annex to the Guidance for the Completion of the OIE template

- Explains the calculations necessary to provide the data required by the OIE template:
 - Conversion of different weight units into kilograms
 - Calculation of amounts to be reported
 - For active chemical substances as reported on the label
 - For prodrugs and certain long-acting derivatives that require conversion into the active antimicrobial entity (moiety)
 - From numbers of packs and content of antimicrobial agent per unit to kg
 - Always contact the Antimicrobial Use Team
 (antimicrobialuse@oie.int) if conversion factors are missing



Mandatory Product Information



- 1. Active substance (e.g., Enrofloxacin)
- 2. Concentration, content and units (e.g., 50 mg each 1 ml)
- 3. Package size (e.g., 100 ml)
- 4. Number of times the product presentation has been imported, sold, prescribed or used

Necessary data to use Reporting Option 1



Desirable Product Information



1. Route of administration(e.g., parenteral)

Necessary data to use in Reporting Option 3

2. Target species(e.g., canines and felines)

Necessary data to use in Reporting Option 2 and additionally in Reporting Option 3



Calculations

General calculation:

• Active substance concentration * Package size Concentration content X Number of times the product has been sold, imported or prescribed



- 1. Active substance (e.g., Enrofloxacin)
- 2. **Strength, strength and content** (e.g., 50 mg each 1 ml)
- 3. Package size (e.g., 100 ml)
- 4. Number of times the product presentation has been imported: 25 0000

$$= \frac{50 mg *100 ml}{1 ml} X 25 0000$$

- = 125 000 000 mg
- = 125 000 000 mg / 1 000 000
- = 125 kg to be reported under Fluoroquinolones class



Conversion Factors for International Units (IU), Long-acting and Produg Conversion Factors

If the chemical compound as declared on the product label is in **IU**, please use the following conversion factors (**Table 2** of the Annex to the guidance)

Antimicrobial agent in the veterinary medicine	Antimicrobial active entity for reporting to OIE	International Units per mg	Conversion factor to mg for multiplication
Bacitracin	Bacitracin	74	0.013514
Benzylpenicillin (penicillin G)	Benzylpenicillin	1666.67	0.0006
Chlortetracycline	Chlortetracycline	900	0.001111
Colistin methane sulfonate sodium (colistimethate sodium INN)	Colistin	12700	0.000079
Colistin sulfate	Colistin	20500	0.000049
Dihydrostreptomycin	Dihydrostreptomycin	820	0.00122
Erythromycin	Erythromycin	920	0.001087
Gentamicin	Gentamicin	620	0.001613
Kanamycin	Kanamyoin	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	Rifamyoin	887	0.001127
Spiramycin	Spiramycin	3200	0.000313
Streptomycin	Streptomycin	785	0.001274
Tobramycin	Tobramycin	875	0.001143
Tylosin	Tylosin	1000	0.001
Tetracycline	Tetracycline	950	0.001

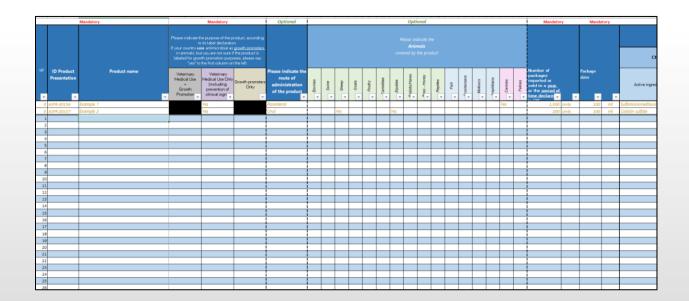
If the antimicrobial agent is a **long-acting salt** (example: benethamine benzylpenicillin) or a **prodrug** (example: penethamate hydroiodide), please use the following conversion factors (**Table 3** of the Annex to the guidance)

e 3: Conversion of content stated in lats in the veterinary product into correct OIE, based on the ESVAC conversion	esponding mg, g or kg antimicro	
Antimicrobial agent (prodrug)	Active entity	Prodrug conversion factor for multiplication
Benethamine benzylpenicillin	Benzylpenicillin	0.65
Benzathine benzylpenicillin	Benzylpenicillin	0.74
Cefapirin benzathine	Cefapirin	0.41
Cefalexin benzathine	Cefalexin	0.36
Cloxacillin benzathine	Cloxacillin	0.43
Oxacillin benzathine	Oxacillin	0.69
Penethamate hydroiodide	Benzylpenicillin	0.63
Procaine benzylpenicillin	Benzylpenicillin	0.61



Additional assistance in calculations

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



For more Information, please contact antimicrobialuse@oie.int



Questions? (10 min)



12, rue de Prony, 75017 Paris, France www.oie.int media@oie.int - oie@oie.int









