

Catherine LAMBERT / Delfy GOCHEZ

Collaborrating Center

Working group session

Filling the OIE template for the collection of data on antimicrobials used in animals Introductions

Beirut, November 8th 2017



Tools for using the OIE template

A. Contact Person for Antimicrobial Agents Use Data Collection Title	es ***	hould be completed by all OIE Member Countri idance document for further instructions.		Q							
Role with respect to the OIE Role with respect to the OIE Antimicrobial Use Team at: antimicrobial use@oie.int.		microbial Agents Use Data Collection	A. Contact Person for Anti								
Role with respect to the OIE Role with respect to the OIE OIE Delegate OIE Focal Point for Veterinary Products Other 4 Organisation 4 Free text field> 5 Organisation's Address 6 Country 7 Phone Number 8 Email Address B. General Information Are data on the amount of antimicrobial agents intended for use in animals available? Please indicate why the data are not available at this time in your country, if the answer to Question 9 is 'No' 11 Are antimicrobial agents used for growth promotion purposes in animals in your country? Does your country have legislation/regulations on the use of antimicrobial agents as growth promoters in animals? If your country has legislation/regulation on the use of 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 in animals, could you please indicate the appropriate case that applies in your country? All antimicrobial agents banned for use as growth promoters in animals, could you please indicate the appropriate case that applies in your country? Please provide a list of antimicrobial agents authorised as growth promoters, if any If your response to Question 9 is 'No', please kindly send this template, once validated by the OIE Delegate and Delegate in copy, to the OIE Antimicrobial Use Team at: antimicrobial use@oie.int.		<free field="" text=""></free>	Title	1							
Organisation Other Ot		<free field="" text=""></free>	Name (First name, SURNAME)								
Some antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country? Some antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country? Please provide a list of antimicrobial agents and peleagate in copy, to the OIE Antimicrobial Use Team at: Antimicrobial Use Team at: Antimic		OIE Focal Point for Veterinary Products	Role with respect to the OIE	3							
Country <free field="" text=""> </free>		<free field="" text=""></free>	Organisation	4							
7 Phone Number sfree text field> 8 Email Address S. General Information 9 Are data on the amount of antimicrobial agents intended for use in animals available? Amounts available - Yes 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' 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 the use of antimicrobial agents as growth promoters in animals? Legislation/regulation does not exist - No 13 If your country has legislation/regulation on the use of antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country? One or more antimicrobial growth promoters are authorised for your response to Question 9 is 'No', please kindly send this template, once validated by the OIE Delegate and Delegate in copy, to the OIE Antimicrobial Use Team at: antimicrobial use@oie.int.		<free field="" text=""></free>	Organisation's Address	5							
B. General Information 9		<free field="" text=""></free>	Country	6							
B. General Information 9		<free field="" text=""></free>	Phone Number	7							
Are data on the amount of antimicrobial agents intended for use in animals available? Please indicate why the data are not available at this time in your country, if the answer to Question 9 is 'No' Are antimicrobial agents used for growth promotion purposes in animals in your country? Are antimicrobial agents used for growth promoters in animals? If your country have legislation/regulations on the use of antimicrobial agents as growth promoters in animals? If your country has legislation/regulation on the use of antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country? Please provide a list of antimicrobial agents authorised as growth promoters, if any Amounts available - Yes Amounts available - No Fyes No Unknown Legislation/regulation exists - Yes Legislation/regulation does not exist - No All antimicrobial agents banned for use as growth promoters in animals, could you please indicate the appropriate case that applies in your country? Please provide a list of antimicrobial agents authorised as growth promoters, if any f your response to Question 9 is 'No', please kindly send this template, once validated by the OIE Delegate and Delegate in copy, to the OIE Antimicrobial Use Team at: antimicrobial use@oie.int		<free field="" text=""></free>	Email Address	8							
intended for use in animals available? Please indicate why the data are not available at this time in your country, if the answer to Question 9 is 'No' Are antimicrobial agents used for growth promotion purposes in animals in your country? Does your country have legislation/regulations on the use of antimicrobial agents as growth promoters in animals? If your country has legislation/regulation on the use of antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country? Please provide a list of antimicrobial agents and belease to All antimicrobial growth promoters are authorised for use as growth promoters and this in your country? Please provide a list of antimicrobial agents authorised as growth promoters, if any fyour response to Question 9 is 'No', please kindly send this template, once validated by the OIE Delegate and Delegate in copy, to the OIE Antimicrobial Use Team at: antimicrobial use@oie.int		neral Information	B. Gen								
this time in your country, if the answer to Question 9 is 'No' Are antimicrobial agents used for growth promotion purposes in animals in your country? Does your country have legislation/regulations on the use of antimicrobial agents as growth promoters in animals? If your country has legislation/regulation on the use of antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country? Please provide a list of antimicrobial agents anthorised as growth promoters, if any f your response to Question 9 is 'No', please kindly send this template, once validated by the OIE Delegate and Delegate in copy, to the OIE Antimicrobial Use Team at: antimicrobial use@oie.int.			_	Q I							
Are antimicrobial agents used for growth promotion purposes in animals in your country? Does your country have legislation/regulations on the use of antimicrobial agents as growth promoters in animals? If your country has legislation/regulation on the use of antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country? Please provide a list of antimicrobial agents agrowth promoters authorised as growth promoters, if any Please provide a list of antimicrobial agents and please indicate the authorised as growth promoters, if any Please provide a list of antimicrobial agents are authorised for use as growth promoters are authorised for		<free field="" text=""></free>	this time in your country, if the answer to Question	10							
the use of antimicrobial agents as growth promoters in animals? If your country has legislation/regulation on the use of antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country? Please provide a list of antimicrobial agents agrowth promoters authorised as growth promoters, if any Please provide a list of antimicrobial agents agrowth promoters are authorised for use as growth p		No		11 I							
use of antimicrobial agents as growth promoters in animals, could you please indicate the appropriate case that applies in your country? Please provide a list of antimicrobial agents authorised as growth promoters, if any f your response to Question 9 is 'No', please kindly send this template, once validated by the OIE Delegate and Delegate in copy, to the OIE Antimicrobial Use Team at: antimicrobial use@oie.int			the use of antimicrobial agents as growth	12							
authorised as growth promoters, if any f your response to Question 9 is 'No', please kindly <u>send this template</u> , once validated by the OIE Delegate and <u>Delegate in copy</u> , to the OIE Antimicrobial Use Team at: antimicrobialuse@oie.int_	romoters	Some antimicrobial agents banned for use as growth p	use of antimicrobial agents as growth promoters in animals, could you please indicate the	13							
<u>Delegate in copy</u> , to the OIE Antimicrobial Use Team at: <u>antimicrobialuse@oie.int</u>			authorised as growth promoters, if any	14							
antimicrobialuse@oie.int_	e and with your			you							
If your response to Question 9 is 'Yes', please kindly complete Section C " Data Collection ".											
	<u>ı</u> ".	please kindly complete Section C " <u>Data Collection</u>	If your response to Question 9 is 'Yes ', p								
C. Data collection of Antimicrobial Agents Intended for Use in Animals		obial Agents Intended for Use in Animals	C. Data collection of Antimicro								

1. Guidance for completing the OIE template for the collection of data on antimicrobial agents intended for use in animals

2. Annex to the Guidance for Completing the OIE template for ...

In case of questions contact the Antimicrobial Use Team by email at antimicrobialuse@oie.int

Guidance for the Completion of the OIE template

- Explains the set up of the OIE template:
 - Brief explanation of the concepts applied
 - The different sheets of the template
 - Difference between the sheets
 - The individual fields
 - The nature of the information collected in each field

world organisation for animal health Protecting animals, preserving our future
Guidance for completing the OIE template for the collection of data on antimicrobial agents intended for use in animals
Contents
Introduction
Required information and choices for reporting
Baseline Information
Classes of antimicrobial agents for reporting
Reporting Option 1
Reporting Option 2
Reporting Option 38
Glossary of Terms

Introduction

The OIE proposes to collect data on antimicrobial agents intended for use in animals from OIE Member Countries implementing Chapter 6.8, "Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals" of the OIE Terrestrial Animal Health Code and Chapter 6.3 "Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals" of the OIE Aquatic Animal Health Code, and to contribute to the global effort against antimicrobial resistance.

Member Countries differ in the degree to which they collect, collate and publish data on antimicrobial sales or use in animals and also in the degree to which they can stratify the quantities of antimicrobial agents intended for use in animals or for use in different animal species.

Through this initiative, by means of a specific template (hereafter "OIE template"), the OIE seeks to collect data on antimicrobial agent intended for use in animals from all OIE Member Countries in a harmonised way. Using a phased approach, the OIE will initially focus on <u>sales</u> of antimicrobial agents intended for use in animals as an indicator of actual use. All antimicrobial agents intended for use in animals and listed in the OIE List of antimicrobial agents of veterinary importance², plus certain antimicrobial agents only used for growth promotion should be reported. The exceptions are ionophores, which are mostly used for parasite control and therefore need not be reported as antimicrobial agents. The OIE places highest priority on food-producing animals; however, data on all animals, including companion animals, may be reported. Reporting will occur at antimicrobial class level and, on one occasion, at sub-class level.

For the purpose of reporting data on antimicrobial quantities (amounts sold or imported for use in animals expressed in kilograms (kg) of antimicrobial agent, i.e., chemical compound as declared on the product label, that is to be calculated from the available information as explained in the Annex to this Guidance document), animals are grouped into 'all animal species', 'companion animals', 'all food-producing animals', 'terrestrial food-producing animals', and 'aquatic food-producing animals'.

Version 1_Sept2017

Page 1 of 10

Sales, in the context of the OIE data collection on antimicrobial agents used in animals, should be interpreted to include data on import of antimicrobial agents for use in animals.

http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pd

Information that clarifies the reference points and provides the background for interpretation

Baseline Information's part	Member Countries who could <u>not</u> provide amounts of antimicrobials	Member Countries who provided amounts of antimicrobials
Part A. Contact Person for Antimicrobial Agents Use Data Collection	\checkmark	✓
Part B. General Information	✓	✓
Part C. Data Collection on the Use of Antimicrobial Agents in Animals.		✓

	Member Countries	Member Countries
Descline Information/s work	who could <u>not</u>	who provided
Baseline Information's part	provide amounts of	amounts of
	antimicrobials	antimicrobials
Part A. Contact Person for Antimicrobial Agents Use Data Collection	✓	✓

• Who reported the data to the OIE – we may need to clarify something

Member Countries who provided amounts of antimicrobials

Part B. General Information

- Are quantitative data on sales available aims to encourage OIE MCs to collect what they already have and expand coverage to their whole country. If data are not available, OIE MCs can describe the barriers to provide such data
- Are Growth promoters allowed or used helps where only overall amounts are used
- List of allowed Growth promoters some substances are used for growth promotion <u>and</u> therapeutic use, the list helps tease out such dual use

Guidance for completing the OIE template – Baseline information

Baseline Information's part

Member Countries who could <u>not</u> provide amounts of antimicrobials

Member Countries who provided amounts of antimicrobials

Part C. Data Collection on the Use of Antimicrobial Agents in Animals.



- Year for which data are reported there may be reporting delays in some countries, plus we welcome a certain amount of historical data
- Time period helps OIE to understand if the data cover portion of a calendar year
- Data source we need to understand where the data are coming from; OIE MCs need to map the distribution system in their country to identify the most reliable source for complete and least potential for duplicate reporting

Baseline Information's part	Member Countries who could <u>not</u> provide amounts of antimicrobials	Member Countries who provided amounts of antimicrobials
Part C. Data Collection on the Use of Antimicrobial Agents in Animals.		✓

- Estimated coverage of the data we need to know how much of the total sales in the OIE MC are reported and what is not included
- Is the information extrapolated from representative samples helps OIE to understand what are the data provided
- Explanations of estimate coverage and extrapolations carried out
 helps OIE to understand the reported information and to identify
 similar data sets
- Animal groups covered refers to the categories in the different reporting options and helps OIE identify like and like when only total amounts are reported

Baseline Information's part	

Member Countries who could <u>not</u> provide amounts of antimicrobials

Member Countries who provided amounts of antimicrobials

Part C. Data Collection on the Use of Antimicrobial Agents in Animals.



- Animals raised in your country and considered as food-producing knowing differences in animals raised for food helps OIE to collate appropriate data
- National report available on the web? helps OIE to get an overview on the data available in an OIE MC

- If <u>aggregated data</u> are reported, please list here the classes combined helps OIE to understand which substances are used in a country, and which cannot be individually reported and if substances are included that OIE does not require
- If '<u>others</u>' are reported under antimicrobial class list here the reported classes we may have overlook something
- Please report here any <u>additional calculations</u>
 applied OIE MCs may carry out data calculation over and above those described in the annex, OIE needs to know which calculations were carried out

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(<u>antimicrobialuse@oie.int</u>) if conversion factors are missing

Working group session

Practical exercise

Gérard MOULIN



gerard.moulin@anses.fr

French agency for food, environmental and occupationnal safety National agency for veterinary Medicinal Products

8 rue Claude Bourgelat – Parc d'Activités de la Grande Marche – Javené - CS 70611 – 35306 Fougères - France

Step 0

Fill the OIE template for your country

- Sheet 1 baseline information
- Prepare a simplified mapping of the distribution system in your country.

Document available:

OIE template

Q	*** This sheet of the OIE template should be completed by all OIE Member Countries *** Please refer to the Guidance document for further instructions.										
	A. Contact Person for Anti	imicrobial Agents Use Data Collection									
1	Title	<free field="" text=""></free>									
2	Name (First name, SURNAME)	<free field="" text=""></free>									
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>									
8	Email Address	<free field="" text=""></free>									
	B. General Information										
9	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									
12	Does your country have legislation/regulations on the use of 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 the use of 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 authorised as growth promoters, if any	<free field="" text=""></free>									
If your response to Question 9 is "No", please kindly <u>send this template</u> , <u>once validated by the OiE Delegate and with your OiE Delegate in copy</u> , to the OiE Antimicrobial Use Team at: <u>antimicrobialuse@oie.int</u> . If your response to Question 9 is "Yes", please kindly complete Section C " <u>Data Collection</u> ".											
C. Data collection of Antimicrobial Agents Intended for Use in Animals											
*** Please provide data for 2015 If you have data for another year, please select the year from the list below ***											

http://www.oie.int/our-scientificexpertise/veterinaryproducts/antimicrobials/

- Imports
- Prescription / delivery,
- Usage data,
- Wholesalers declarations,
- Marketing Authorisation holders declarations...

l		

-
Sales data
Sales data - Wholesalers
Sales data - Retailers
Sales data - Marketing Authorisation Holders
Sales data - Registration Authorities
Sales data - Feed Mills
Sales data - Pharmacies
Sales data - Farms Shops/Agricultural Suppliers
Sales data - Industry Trade Associations
Purchase data
Purchase data - Wholesalers
Purchase data - Retailers
Purchase data - Feed Mills
Purchase data - Pharmacies
Purchase data - Agricultural Cooperatives
Purchase data - Producer Organisations
Import data
Import data - Customs declarations - Veterinary Medicinal Product
Import data - Customs declarations - Active Ingredient
Veterinary data
Veterinary data - Sales
Veterinary data - Prescriptions
Antimicrobial use data Antimicrobial use data - Farm Records
Other data source(s) Other

 Data source : Declaration of sales by Marketing autorisation holders

Example for one antimicrobial class:
 Macrolides

(invented names and sales figures)

Data needed?

 Information on Veterinary Medicinal Products

 Sales figure for sale package for each VMP containing Antimicrobials Filling information on Veterinary medicinal product from the summary of Characteristics of the product

For One product : Zolran

- Summary of product Characteritics for Zolran
- Table to be filled

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZACTRAN 150 mg/ml solution for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Gamithromycin 150 mg

Excipient:

Monothioglycerol 1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection. Colourless to pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

МАН	COUNTRY	YEAR	MA	ID presentatio n	NAME	FORM	PACKSIZE	PACKSIZEU	SPECIES	Combination	INGR	STRENGHT	STRENGHT U	CONV FACT	INGR CONTENT of the pack size	CONT UNIT	NO SOLD	TONS SOLD
MUSE	FR	2015	12517	69008220	ZOLRAN													
MUSE	FR	2015	12517	69008221	ZOLRAN													
MUSE	FR	2015	12517	69008512	ZOLRAN													
MUSE	FR	2015	12517	69022933	ZOLRAN													

 Fill cells in red from information included in the SPC Filling information on number of presentations sold

For all products in the table

 Sales declarations from Marketing Autorisation holders

Table to be filled

MARKETING AUTHORIZATION HOLDER: VERSUS

PRODUCT: COLDAROL

2015									
UNIT SIZE	Code	QUANTITY OF UNITS SOLD							
25 bags of 30 g	68731146	3300							

МАН	COUNTRY	YEAR	MA	ID presentatio n	NAME	FORM	PACKSIZE	PACKSIZEU	SPECIES	Combination	INGR	STRENGHT	STRENGHT U	CONV FACT	CONT UNIT	NO SOLD	TONS SOLD
	FR	2015	12517	69008220	ZOLRAN												
MUSE	FR	2015	12517	69008221	ZOLRAN												
MUSE	FR	2015	12517	69008512	ZOLRAN												
MUSE	FR	2015	12517	69022933	ZOLRAN												

Fill the blue column

Step Three

Make the calculations:

- Calculate the ingredient content of the pack side for ZOLRAN and COLDAROL
- Calculate the number of tons sold for each product (Green column)
- Calculate the Total number of tons sold for Macrolides

Step 4

- Fill the OIE template
 - Sheet 2 « reporting option 1 » for macrolides

Document available:

OIE template

OIE template for the collection of data on antimicrobial agents for use in animals Reporting option 1 - Overall amount sold for/used in animals by antimicrobial class; with the possibility to separate by type of use Overall amount Amount for Amount for Therapeutic use (including **Growth promotion** (Growth promotion + Therapeutic use) prevention of clinical signs) Antimicrobial class All animal species All animal species All animal species (kg) (kg) (kg) Aminoglycosides Amphenicols Arsenicals Cephalosporins (all generations) 1-2 gen. cephalosporins 3-4 gen cephalosporins Fluoroquinolones Glycopeptides Glycophospholipids Lincosamides Macrolides Nitrofurans Orthosomycins Other quinolones Penicillins Pleuromutilins Polypeptides Quinoxalines Streptogramins Sulfonamides (including Tetracyclines Others Aggregated class data





WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

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







