



Catherine LAMBERT / Delfy GOCHEZ
Collaborating 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

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 Antimicrobial Agents Use Data Collection		
1	Title	<free text field>
2	Name (First name, SURNAME)	<free text field>
3	Role with respect to the OIE	<input type="checkbox"/> OIE Delegate <input type="checkbox"/> OIE Focal Point for Veterinary Products <input type="checkbox"/> Other
4	Organisation	<free text field>
5	Organisation's Address	<free text field>
6	Country	<free text field>
7	Phone Number	<free text field>
8	Email Address	<free text field>
B. General Information		
9	Are data on the amount of antimicrobial agents intended for use in animals available?	<input type="checkbox"/> Amounts available - Yes <input type="checkbox"/> 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 text field>
11	Are antimicrobial agents used for growth promotion purposes in animals in your country?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
12	Does your country have legislation/regulations on the use of antimicrobial agents as growth promoters in animals?	<input type="checkbox"/> Legislation/regulation exists - Yes <input type="checkbox"/> 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?	<input type="checkbox"/> All antimicrobial agents banned for use as growth promoters <input type="checkbox"/> Some antimicrobial agents banned for use as growth promoters <input type="checkbox"/> 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 text field>
<p>If your response to Question 9 is 'No', please kindly send this template, once validated by the OIE Delegate and with your OIE Delegate in copy, to the OIE Antimicrobial Use Team at: antimicrobialuse@oie.int.</p> <p>If your response to Question 9 is 'Yes', please kindly complete Section C "Data Collection".</p>		
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 ***		

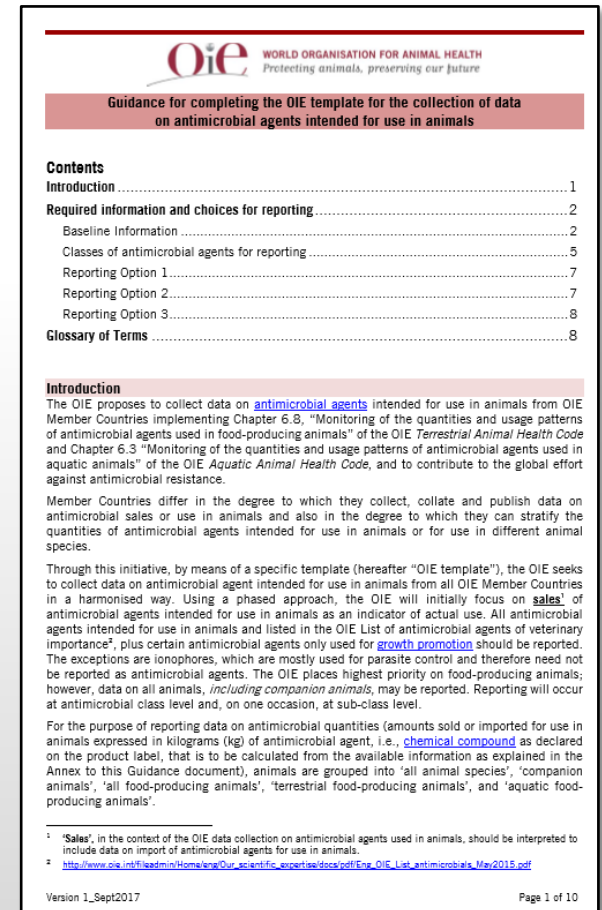
1. Guidance for completing the OIE template for the collection of data on antimicrobial agents intended for use in animals

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



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	✓	✓
Part B. General Information	✓	✓
Part C. Data Collection on the Use of Antimicrobial Agents in Animals.		✓

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	✓	✓

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

Baseline Information's part	Member Countries who could <u>not</u> provide amounts of antimicrobials	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 and 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
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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 aggregated data 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 'others' are reported under antimicrobial class list here the reported classes** – *we may have overlook something*
- **Please report here any additional calculations 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(antimicrobialuse@oie.int) if conversion factors are missing

Working group session

Practical exercise

Gérard MOULIN

gerard.moulin@anses.fr

French agency for food, environmental and occupational 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

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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-scientific-expertise/veterinary-products/antimicrobials/>

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

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 authorisation 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 Characteristics 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.

MAH	COUNTRY	YEAR	MA	ID presentation	NAME	FORM	PACKSIZE	PACKSIZEU	SPECIES	Combination	INGR	STRENGHT	STRENGHT U	CONV FACT	INGR CONTENT of the pack size	CONT UNIT (G)	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 Authorisation 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

MAH	COUNTRY	YEAR	MA	ID presentation	NAME	FORM	PACKSIZE	PACKSIZEU	SPECIES	Combination	INGR	STRENGHT	STRENGHT U	CONV FACT	INGR CONTENT of the pack size	CONT UNIT (G)	NO SOLD	TONS SOLD
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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 (Growth promotion + Therapeutic use)	Amount for Therapeutic use (including prevention of clinical signs)	Amount for Growth promotion
Antimicrobial class	All animal species (kg)	All animal species (kg)	All animal species (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 <i>trimethoprim</i>)			
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

