



# Working group session

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

## *Introduction*

*G rard MOULIN*

[gerard.moulin@anses.fr](mailto:gerard.moulin@anses.fr)



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

8 rue Claude Bourgelat – Parc d’Activit s de la Grande Marche – Javen  - CS 70611 – 35306  
Foug res - France

# Tools for using the OIE template



1. Guidance for the Completion of the OIE template for the collection of data on antimicrobial agents used in animals

2. Annex to the Guidance for the Completion of ...

In case of questions contact the OIE Scientific and Technical department (SST) by email at [antimicrobialuse@oie.int](mailto: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

# Guidance for the Completion of the OIE template – Baseline information



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

- Who reported the data to the OIE – *we may need to clarify something*
- Year for which data are reported – *there may be reporting delays in some countries, plus we welcome a certain amount of historical 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 the Completion of the OIE template – Baseline information



- 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*
- Are quantitative data on sales available – *aims to encourage OIE MCs to collect what they already have and expand coverage to their whole country*
- 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*

# Guidance for the Completion of the OIE template – Baseline information



- 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*
- 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*

# Guidance for the Completion of the OIE template – free text in rept opt 1,2 3



- 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 transformations applied – *OIE MCs may carry out data transformation 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 OIE Scientific & Technical department ([antimicrobialuse@oie.int](mailto:antimicrobialuse@oie.int)) if conversion factors are missing



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## *Practical exercise*

*G rard MOULIN*

[gerard.moulin@anses.fr](mailto:gerard.moulin@anses.fr)



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# 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

This sheet of the OIE template should be completed by all OIE Member Countries

<b>Contact Point for data collection</b>	
Name (order: salutation, first name, surname)	<free text field>
Role with respect to the OIE	<free text field>
Organisation	<free text field>
Address	<free text field>
Phone number	<free text field>
Email address	<free text field>
<b>Year of data collection</b>	<free text field>
<b>Country</b>	<free text field>
<b>Are antimicrobial growth promoters authorised for use in your country?</b>	<input checked="" type="radio"/> Yes <input type="radio"/> No
<i>List of allowed antimicrobial growth promoters, if the answer to the previous question is - 'Yes'</i>	<free text field>
<b>Data source</b>	<input type="checkbox"/> Sales data - Wholesalers <input type="checkbox"/> Sales data - Retailers <input type="checkbox"/> Sales data - Marketing Authorisation Holders <input type="checkbox"/> Sales data - Registration Authorities <input type="checkbox"/> Sales data - Feed mills <input type="checkbox"/> Sales data - Pharmacies <input type="checkbox"/> Sales data - Farm shops/Agricultural suppliers <input type="checkbox"/> Sales data - Industry trade associations <input type="checkbox"/> Sales data - Veterinarian <input type="checkbox"/> Purchase data - Wholesalers <input type="checkbox"/> Purchase data - Retailers <input type="checkbox"/> Purchase data - Feed mills <input type="checkbox"/> Purchase data - Pharmacies <input type="checkbox"/> Purchase data - Agricultural Cooperatives <input type="checkbox"/> Purchase data - Producer organisations <input type="checkbox"/> Import data - Customs declarations - veterinary products <input type="checkbox"/> Import data - Customs declarations - active ingredients <input type="checkbox"/> Veterinary prescription data - Sales <input type="checkbox"/> Veterinary prescription data - Prescriptions <input type="checkbox"/> Veterinary prescription data - Dispensing <input type="checkbox"/> Antimicrobial use data - farm records <input type="checkbox"/> None <input type="checkbox"/> Other (further specified in 'Data source clarification')

# Different possible sources of DATA



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

## Practical exercise



- 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

## Step one



- Filling information on Veterinary medicinal product from the summary of Characteristics of the product
- For One product : Zolran

## Documents available



- 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



## Step two



- Filling information on number of présentations sold
- For all products in the table

## Documents available



- Sales declarations from Marketing Authorisation holders
- Table to be filled

**MARKETING AUTHORIZATION HOLDER : VERSUS**

**PRODUCT : COLDAROL**

<b>2015</b>		
<b>UNIT SIZE</b>	<b>Code</b>	<b>QUANTITY OF UNITS SOLD</b>
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	69008512	ZOLRAN													
MUSE	FR	2015	12517	69022933	ZOLRAN													

- Fill the blue column

## Step 3



- 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 trimethoprim)			
Tetracyclines			
Others			
Aggregated class data			

# Thank you for your attention!



**WORLD ORGANISATION FOR ANIMAL HEALTH**

*Protecting animals, preserving our future*