

Dr Delfy Góchez

Chargée de mission

Antimicrobial Resistance and Veterinary Products Department

Necessary Data to Obtain Kilograms of Active Ingredients

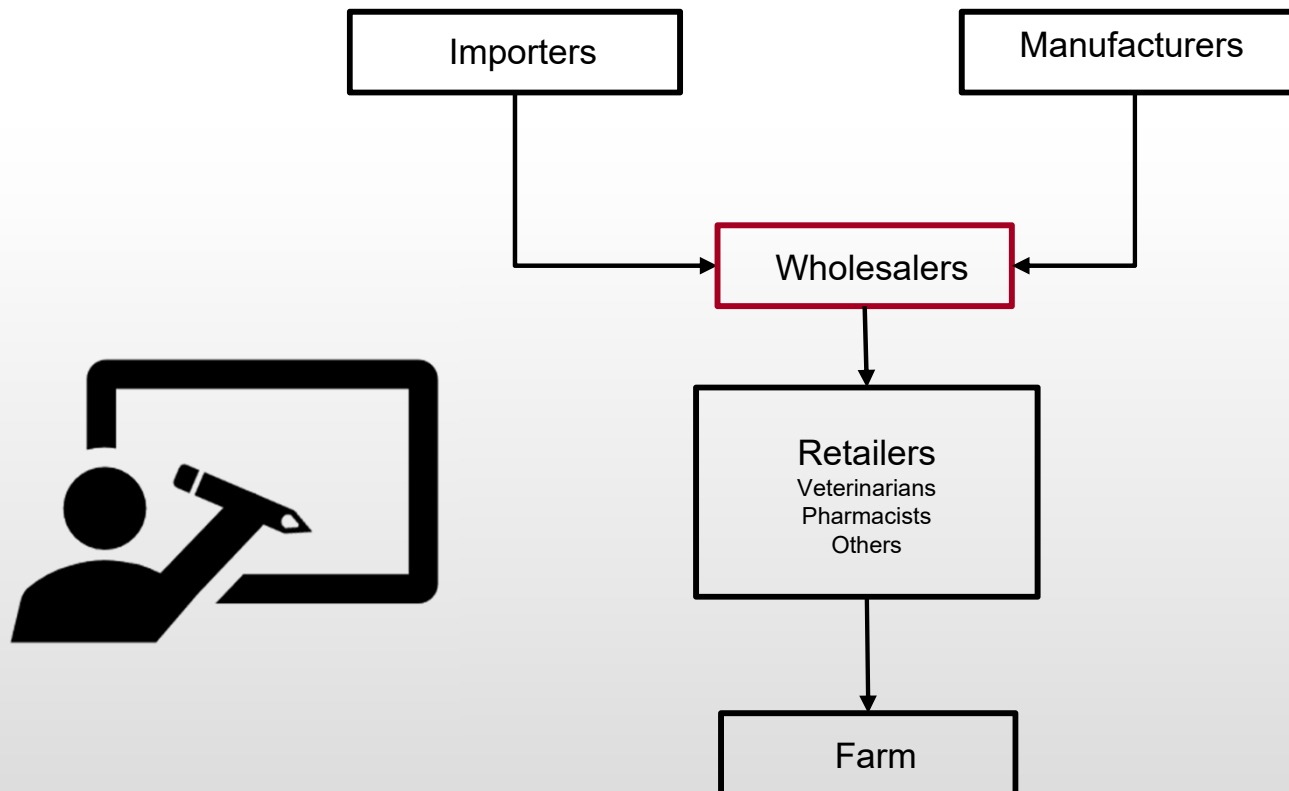
OIE Sub-Regional Workshop on the database on antimicrobial agents intended for use in animals in Eastern and Southern Africa

Mombasa, Kenya, 29-31 Oct. 2019



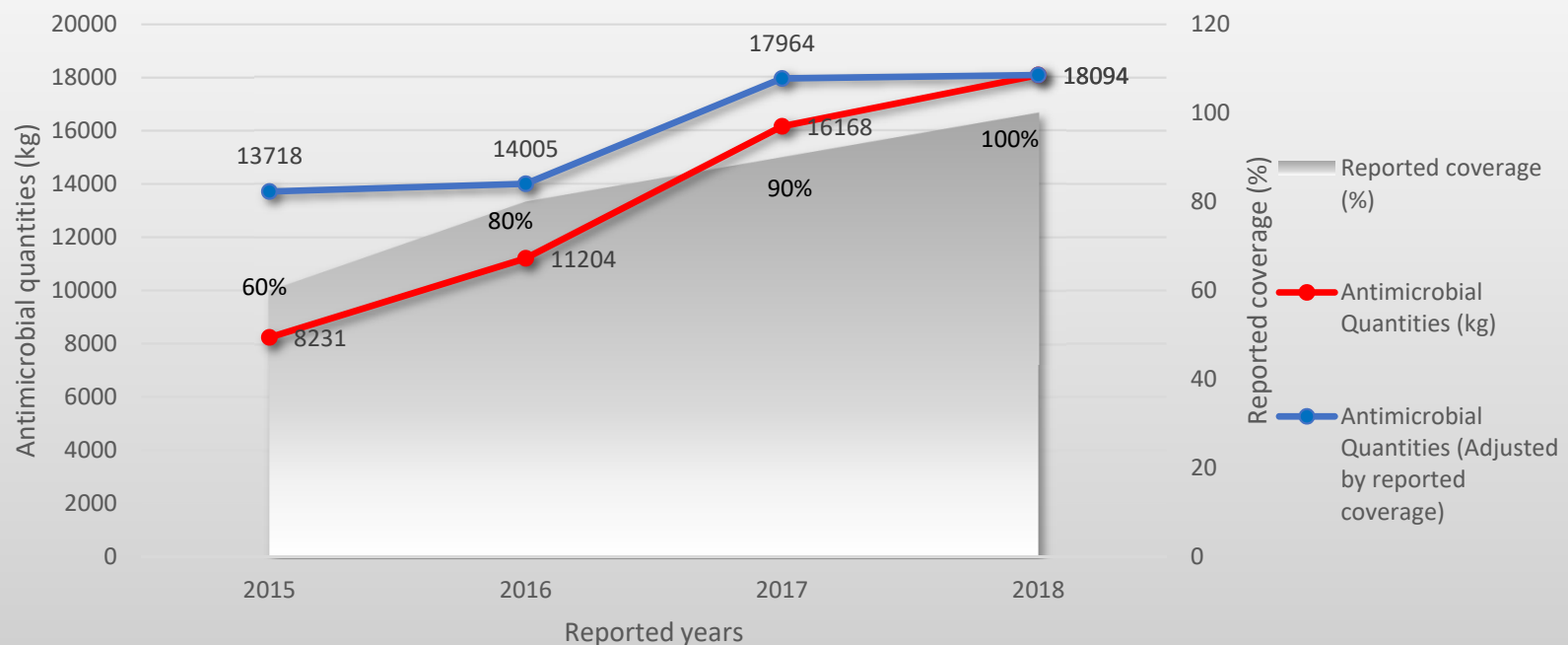
Step 1 – Establish the Data Source

Prepare a simplified mapping of the distribution system in your country



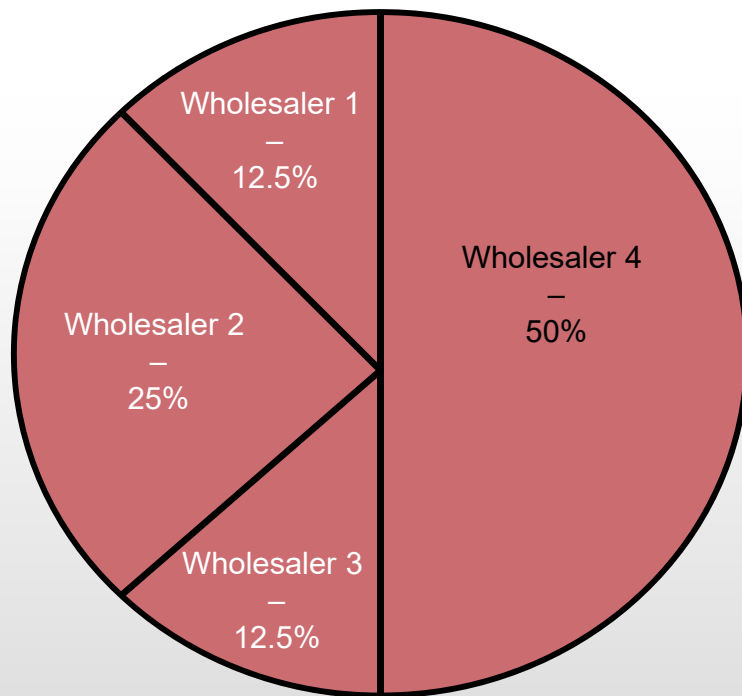
Step 2 – Estimate the Coverage of the Data

- Provide an estimate of the extent to which the quantitative data you report are representative of the overall antimicrobials for use in animals.

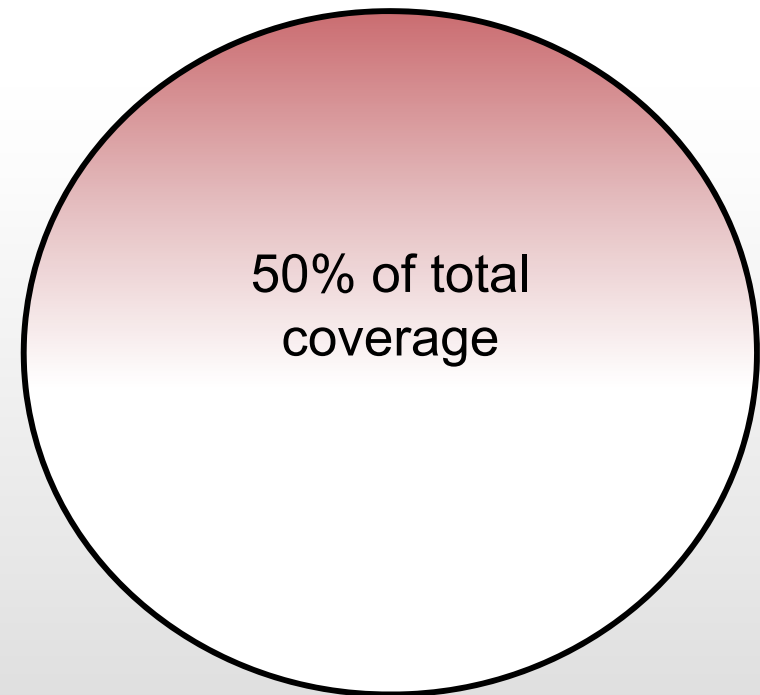


Step 2 – Estimate the Coverage of the Data

Country A –
4 Wholesalers in the country



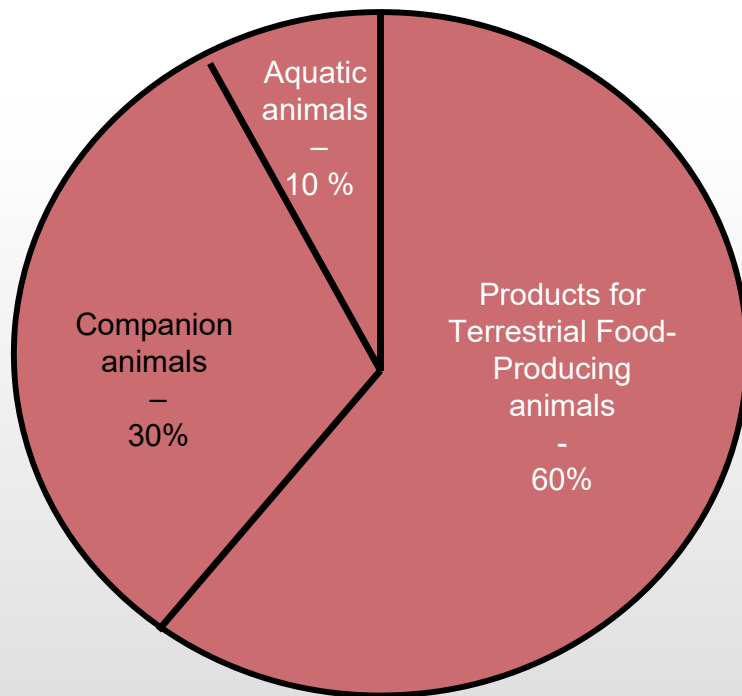
Country A –
3 Wholesalers provided data



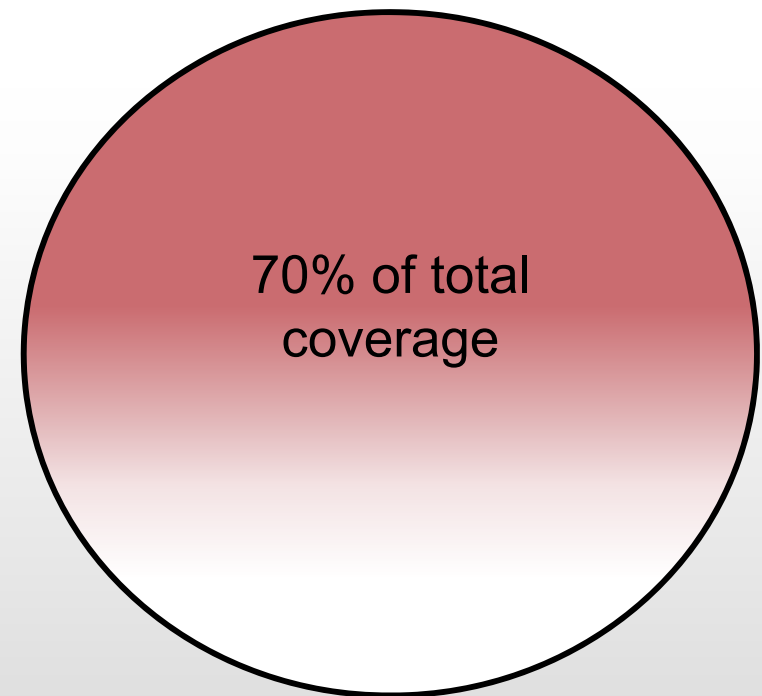
=

Step 2 – Estimate the Coverage of the Data

Country B –
Import data



Country B –
Data only for aquatic and terrestrial
food-producing animals

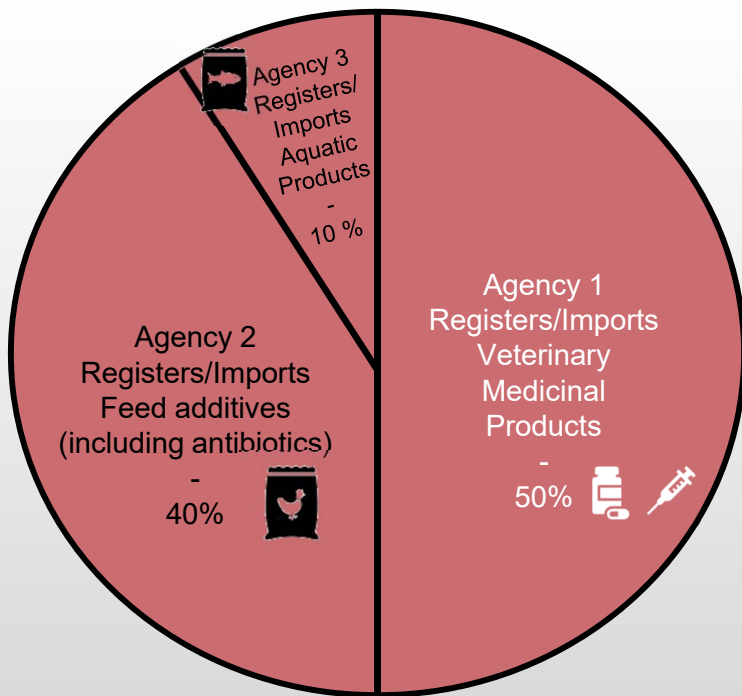


=

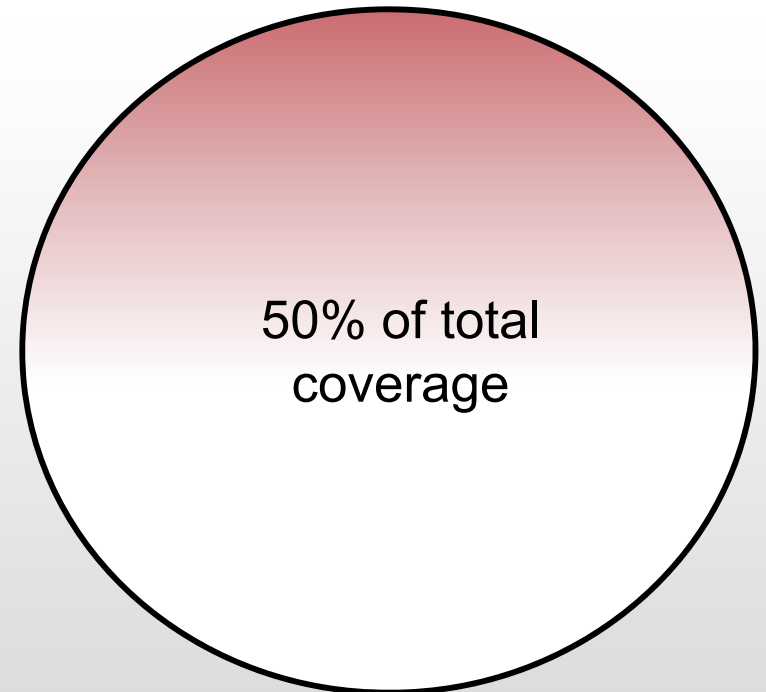
Step 2 – Estimate the Coverage of the Data

Country C –
Different registration/import
agencies

Country C –
Data only for Veterinary Medicinal
Products



=



Step 3 – Mandatory Product Information



1. **Active substance** (e.g., Enrofloxacin)
2. **Strength, 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

Step 3.1 – 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

Step 4 – Calculations

■ General calculation:

- $\frac{\text{Active substance strength} * \text{Package size}}{\text{Strength content}} \times \text{Number of times the product has been sold, imported or prescribed}$



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**

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

$$= 125 \text{ 000 000 mg}$$

$$= 125 \text{ 000 000 mg} / 1 \text{ 000 000}$$

$$= \mathbf{125 \text{ kg}}$$
 to be reported under **Fluoroquinolones class**

Step 5.1 – Conversion Factors for International Units (IU)

- 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)

Table 2: Conversion of International Units (IUs) of certain antimicrobial agents into mg and relevant active entities, based on the ESVAC conversion factors¹

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	Kanamycin	796	0.001266
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	3403	0.000119
Rifamycin	Rifamycin	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

- Product X: Colistin Sulfate
- Strength: 10 000 000 UI / ml
- Package size: 50 ml
- Number of times imported: 20 000
- **Conversion factor of IU to mg: 0.000049**

- $$= \frac{10\,000\,000\text{ UI} * 50\text{ ml}}{1\text{ ml}} \times 20\,000$$
- $$= 10\,000\,000\,000\,000\text{ UI}$$
- $$= 10\,000\,000\,000\,000\text{ UI} * \mathbf{0.000049}$$
- $$= 490\,000\,000\text{ mg}$$
- $$= 490\,000\,000 / 1\,000\,000$$
- $$= \mathbf{490\text{ kg}}$$

Step 5.1 – Long-acting Salts and Prodrug Conversion Factors

- 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)

Table 3: Conversion of content stated in mg, g or kg of long-acting salts and prodrugs of antimicrobial agents in the veterinary product into corresponding mg, g or kg antimicrobial active entity for reporting to the OIE, based on the ESVAC conversion factors²¹

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

- Product X: Cloxacillin benzathine
- Strength: 700 mg / 10 ml
- Package size: 10 ml
- Number of times imported: 30 000
- **Conversion factor: 0.43**

- $= \frac{700 \text{ mg} * 10 \text{ ml}}{10 \text{ ml}} \times 30\ 000$
- = 21 000 000 mg
- = 21 000 000 mg m* **0.43**
- = 9 030 000 mg
- = 9 030 000 mg / 1 000 000
- = **9.03 kg**



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



WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future