

**Documents which are sent during the call to Provide Sales Data of antimicrobials**

*DOCUMENT 1 (Declaration)*

**Antimicrobial Sales Data Collection**

**Declaration by Data Provider**

I hereby declare that:

- **I have checked that the total quantities and calculations of veterinary medicinal products provided are correct.**
- **I have included all veterinary medicinal products that contain antimicrobial/s that are traded by the company I represent**
- **Information provided with regards to percentages of sales based on species is indicative and to the best of my knowledge**

Person compiling the data \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

## DOCUMENT 2 (Instructions)

### ANTIBIOTIC DATA COLLECTION

#### 1. Call for data

Prior to submission of antimicrobial data any veterinary medicinal products should be registered or authorised by Veterinary Medicines Section. The Data Collection Form contains lists to facilitate that the data are standardised and harmonised prior to the submission.

#### 2. Explanation of the Variables to be collected for each veterinary medicinal product (VMP) presentation

Variable	Description of variable	Comments	
PRODUCT INFORMATION	<b>MA</b>	<b>Marketing Authorisation Number</b>	The MA number from country of origin where the product is registered and procured.
	<b>MALTA VET NUMBER</b>	<b>Malta Vet Number</b>	The number given by the Veterinary Medicines Section (VMS) when a product is registered
	<b>NAME</b>	<b>Medicinal Product Name (in national language)</b> E.g.: Harmony vet 50 mg tablets 2 x 30; Harmony vet long acting 10 mg/ml injection 10 ml	Trade Name of the product which is registered with the VMS
	<b>FORM</b>	<b>Pharmaceutical Form</b> Boluses (BOLUS), injectable products (INJ), intramammary products for lactating cow treatment (INTRAMAM), intramammary products for dry cow treatment (INTRAMAM-DC), intrauterine products (INTRAUT), oral	

Variable		Description of variable	Comments
		<p>pastes (ORAL PASTE), oral solutions (ORAL SOLU), oral powders or granules (ORAL POWD), premixes (PREMIX), capsules and tablets (TABL).</p>	
	<b>PACKSIZE</b>	<p><b>Content Quantity in Package: Pack size (numerical only)</b>  E.g.: 100 for 100 tablets or 100 intramammaries; 10 for 10 ml injection; Package of 2 kg premix: 2; Box of 10 blisters of 30 tablets: 300; Box of 12 injectors: 12</p>	To allow for calculation of the amount of active ingredient in each VMP presentation
	<b>NO PACKS</b>	<b>Number of Packages Sold</b>	To calculate weight of active ingredient sold for each VMP presentation
PRODUCT INFORMATION	<b>INGR</b>	<b>Active Ingredient Name</b>	The Active Antimicrobial ingredient. Only active ingredient per cell
	<b>CLASS</b>	<p><b>Antibiotic Class</b>  Specify the antibiotic class the active ingredient belongs e.g. penicillin</p>	For Cephalosporin, please specify whether they are 1 <sup>st</sup> , 2 <sup>nd</sup> , 3 <sup>rd</sup> or 4 <sup>th</sup> Generation.
	<b>STRENGTH</b>	<p><b>Quantity of the Active Ingredient in Each Unit as declared in name (if not in name as in SPC): Strength (numerical only)</b>  E.g. 10 for 10 MG/TABLET, 10 IU/TABLET, 10 MG/ML, 10 IU/ML, 10 MG/PIECE or 10 IU/PIECE</p> <p>In case of a combination VMP</p>	To enable calculation of the amount of active ingredient in each package/product

Variable	Description of variable	Comments
	strengths has to be given for each ingredient in separate lines	
<b>STRENGTHU</b>	<p><b>Unit of Measurement for Strength</b> E.g.: IU, IU/G, IU/ML, IU/PIECE, G, G/KG, G/L, MG, MG/ML, MG/PIECE</p> <p>In case of a combination VMP unit of measurement strength has to be given for each ingredient in separate lines</p>	To enable calculation of the amount of active ingredient in each package/product
<b>CONTENTU</b>	<p><b>Unit of Active Ingredient in Package</b> To be given in gram (G) for all ingredients In case of combination VMP the content unit has to be given separately for each ingredient in separate lines</p>	e.g. Penicillin Antibiotic 10% x 50ml Concentration is 10mg per 100ml. since the product has 50ml then it is 5mg per vial.
<b>KG SOLD</b>	<b>Kilograms Sold of Active Ingredient</b>	
<b>STRATIFICATION</b>	<p><b>STRATIFICATION</b> Numbers should be in percentages</p>	Percentage sales for each species. If species is not listed, please specify in the 'Additional Information - Specify Species'

### 3. Data submission

Data have to be submitted as an excel document together with the pdf declaration form that will be sent together with the Data Collection Form.

### 4. Filling in the Antibiotic Sales Template

The sales data should always be recorded.

In case of combination VMPs, the columns for the INGREDIENT variables must be filled in for each ingredient in separate columns in the same row.

A product that has more than one presentation e.g. 100ml and 1000ml or 100g and 1000g bag should be filled in 2 separate rows and use the same VET number.

The following are not to be listed in the data input -:

- Enzyme inhibitors such as clavulanic acid
- Antifungals e.g. nystatin
- Anthelmintic (dewormers)
- Anti-parasitic e.g. coccidiostats that are classified as feed additives
- Biocides e.g. amitraz, fipronil, permethrin

## **MALTA VET NUMBER**

When this information is not available please contact Veterinary Medicines Section since this product needs to be newly registered.

### **Horse and Pigeon**

Please indicated if it is using for racing or food-producing or non-food producing in the *Additional Information - Specify Species* Section.

### **Checking the completeness of the sales data**

A verification that the sales data submitted to VMS are complete as possible and is expected by every wholesaler dealer.

1. MA and Malta Vet Number– check if ID is given for all lines;
2. FORM – filter by form and stepwise cross-check with product names;
3. Stratification of SPECIES – check if species information is filled in;
4. INGR – cross-check if ingredient name harmonise with the name of presentation, where it's possible; and check if filled in ingredient cells match the Malta Vet Number cells;
5. STRENGTH – check if strength is identical as in the name of VMP, when applicable; and check any peculiar strength reported;
6. STRENGTHU – filtering by PACK SIZEU, check if strength unit is given accurately (e.g. if packsize unit is provided in ML, then strength unit should be given as IU/ML or MG/ML); all strength units should be checked by line for all ingredients.
7. INGR CONTENT and KG SOLD – Please use the excel formula, **do not just input numbers** make sure that your working (formulae) is available for VMS to evaluate and in VMS can double check workings.

## **5. Confidentiality and security of submitted sales data**

Data published by the Veterinary Medicines Section, either on the web pages or as part of scientific or other publication, do not contain, or in any other way disclose, any commercially confidential information on specific veterinary medicinal products.

Veterinary Medicines Section has dedicated controls that adhere to the three main requirements related to the security of information: availability, confidentiality and integrity

*DOCUMENT 3 (Data collection form)*

MARKETING AUTHORISATION NUMBER
MALTA VET NUMBER
NAME
PHARMACEUTICAL FORM
PACKSIZE
PACKSIZE unit
NUMBER OF PACK SOLD
INGREDIENT 1 (ADDITIONAL ROWS IN CASE OF MORE THAN ONE INGREDIENT)
CLASS
STRENGTH
STRENGTH UNIT
INGR CONTENT (G)
Kg SOLD
Separate rows for cattle, pigs, poultry, sheep & Goats, fish, horses, rabbits, cats, dogs, pigeons, cage birds, All other animal species or unknown
Additional Information - Specify Species
Total, %