EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines and Product Data Management

European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

Data Collection Protocol (version 3)

Background

The European Commission has requested the European Medicines Agency to take the lead in collating data collected on the use of antimicrobial agents in animals in the European Union and to manage the database. The European Medicines Agency was asked to develop a harmonised approach for the collection and reporting of data based on national sales figures as well as data on usage in at least major groups of animal species and to ensure comparability with the sale/use of antimicrobial agents in human medicine. The intended use of the surveillance data, both at national and Community level would be:

- To aid interpretation of patterns and trends regarding antimicrobial resistance (AMR);
- As input to risk profiling and risk assessment regarding AMR;
- For setting risk management priorities;
- For evaluation of the effectiveness of control measures being implemented;
- To identify emerging use of veterinary antimicrobial agents, e.g. of specific classes of antimicrobial agents such as those identified by WHO as critically important for human medicine;
- To aid comparison of usage of veterinary antimicrobial agents between human and veterinary medicine, time periods and countries;
- As a basis for focused and targeted research and development.

In the pilot phase (ESVAC- I; 2009-2011), the Agency will collect standardised data on overall national sales of veterinary antimicrobial agents from the Member States that are willing to participate in the project.

To allow for harmonised reporting of the data as well as comparison with data between time periods within and between different Member States (MSs) standardisation of the data collection is of vital importance, e.g. which veterinary antimicrobial agents to be included in the surveillance as well as which drug classification system and names of the active ingredients to be used. In order to obtain

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reliable and harmonised data in the ESVAC database and protocol (ESVAC Data Collection Protocol) and a standardised data collection form (ESVAC Data Collection Form – see Special Topics/Antimicrobial Resistance on the Agency's web pages) for the collection of data at national level have been developed, including which veterinary antimicrobial agents to be included in the ESVAC data. The ESVAC Data Collection Protocol and the ESVAC Data Collection Form have been developed together with the Technical Consultative Group on Monitoring of Sales of Veterinary Antimicrobial Agents (TCG) (Terms of reference and link to members in TCG - Special Topics/Antimicrobial Resistance on the Agency's web pages) and the protocol is harmonised with the protocol used by European Surveillance of Antimicrobial Consumption (ESAC) in human medicine.

ESVAC Data Collection Protocol

Selection of data source

The infrastructure of the distribution of veterinary antimicrobial agents may vary considerably from country to country; such medicinal products are dispensed to the end-users by wholesalers, pharmaceutical industry, pharmacies, veterinarians or a mixture of these. Wholesalers and pharmaceutical industry may also trade between each other and export veterinary antimicrobial agents to other MSs. The first step in setting up surveillance of veterinary antimicrobial agents in a MS is therefore to identify and describe of the distribution system for veterinary antimicrobial agents. To ensure that the collected data are reliable the representative of the selected data sources should be asked to provide data on sales to end-users within the MS in question such as veterinarians, farmers and wholesalers if possible.

Reporting the sales data to ESVAC should be accompanied with information on which source has been used to collect the data as the data coverage

Veterinary antimicrobial agents to be included in ESVAC

The classification system recommended to be used in the ESVAC project is the Anatomical Therapeutic Chemical (ATC) classification system for veterinary medicinal products, ATCvet. Brief information about the ATCvet system as well as the ATCvet codes for the included groups of antimicrobial agents is given in a separate document from the WHO Collaborating Centre for Drug Statistics Methodology (See Special Topics/Antimicrobial Resistance on the Agency's web pages).

The veterinary antimicrobial agents (ATCvet groups) that will have to be reported to the ESVAC database are shown in Table 1.

A description of deviation from these criteria, if any, should be provided to ESVAC together with the sales data.

Table 1. Groups of veterinary antimicrobial agents to be included in ESVAC

Groups of antimicrobial agents	ATCvet codes
Antimicrobial agents for intestinal use	QA07AA; QA07AB
Antimicrobial agents for intrauterine use	QG01AA; QG01AE; QG01BA; QG01BE QG51AA; QG51AG
Antimicrobial agents for systemic use	QJ01

Groups of antimicrobial agents	ATCvet codes
Antimicrobial agents for intramammary use	QJ51
Antimicrobial agents used as antiparasitic agents	QP51AG

Variables to be collected for each veterinary medicinal product (VMP)

In case of multi-ingredient VMP, then the columns for the INGREDIENT variables have to be filled in for each ingredient. **Note that for products where it is indicated "powder for solution" in the name or in the SPC, the form ORAL SOLU-HERD or ORAL SOLU-IND should be given.**

Table 2. Variables to be collected for each VMP

	Variable	Description of variable	Justification if applicable
	COUNTRY	ISO Code (http://www.iso.org/iso/country_codes)	To identify place of collected sales data
	YEAR		To identify time period for collected sales data
PRODUCT INFORMATION	**MA**	**Marketing Authorisation Number**	To allow a unique identification of the Veterinary Medicinal Product (VMP) and enable link with other databases To allow for market analysis if all the products are available
	ID	**Medicinal Product Package Code Value** Digit code being a unique identifier for each package size, strength and formulation of the VMP. Because it is a key variable in many databases it has to be stable over time i.e. so that VMPs no longer available on the market or that are no longer registered still can be identified to allow for analysis of historical data	To allow for analysis of historical data
	NAME	**Medicinal Product Name (in national language)** E.g.: Harmony vet tablets 2 x 30; Harmony vet longacting injection 10 ml	For validation purposes To e.g. allow for analysis of use of e.g. longacting preparations and antimicrobial resistance
	FORM	**Pharmaceutical Form** Bolus (BOLUS), Injection (INJ), Intramammary (INTRAMAM), Intramammary dry cow treatment (INTRAMAM-DC), Oral solution individual treatment (ORAL SOLU-IND), Oral solution herd treatment (ORAL SOLU-HERD), Oral pasta (ORAL PASTA), Oral powder individual treatment (ORAL POWD-IND), Oral powder herd treatment (ORAL POWD-HERD) Premix (PREMIX), Capsules and Tablets etc (TABL), Intrauterine preparation (INTRAUT)	Important to avoid misinterpretation of pharmaceutical form if given in other language than English Allows for reporting of data as individual or flock treatment

	PACKSIZE	**Content Quantity in Package: Pack size (numerical only)** 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	To allow for calculation of the amount of active ingredient in each package/product
	PACKSIZEU	**Content Unit of Measurement** E.g.: ML, L, G, KG, PIECE (for e.g. tablets, capsules, bolus and intramammaries)	To allow for calculation of amount active ingredient in each package/product
	ATC_{vet} - 5th LEVEL	**ATC_{vet}: Anatomic Therapeutic Chemical (Classification) Veterinary** WHO ATCvet Code last version to be used	Generally, a classification system is necessary to have common language when reporting use and analysing data with data on AMR, e.g. for 3rd and 4th generation cephalosporins To have a common language for defining confidentiality of the data (can be converted into ATCvet 3rd level)
	SPECIES	**Animal Species** All the animal species for which the VMP is approved. E.g. cattle (CA), poultry (POU)	Optional
	NO SOLD	**Number of Packages Sold/Year/Country**	To calculate weight of active ingredient sold
INGREDIENT	**INGR**	**Active Ingredient Name (ATCvet name)** In case of multi-ingredient VMP the ATCvet name of all the ingredients has to be given	Important to avoid misinterpretation of ingredient name if given in other language than English. Use of ATCvet names facilitates the identification of active ingredients as well as standardised reporting
	SALT	**Salt of Active Ingredient** E.g.: Colistin sulfate and colistin methanesulfonate	**Only** in cases when the strength is given in IU, IU/ML or IU/UNIT and when different salts exists. To allow for conversion to weight of active ingredient
	PRODRUG	**Prodrug name (ATCvet name)** E.g.: Procaine penicillin that is prodrug for benzylpenicillin	Only in cases when a product contains a prodrug.

	STRENGTH	**Quantity of the Active Ingredient in Each Unit as declared in SPC/label: Strength (numerical only)** E.g. 10 for 10 MG/TABLET, 10 IU/TABLET, 10 MG/ML, 10 IU/ML, 10 MG/PIECE or 10 IU/PIECE In case of a multi-ingredient VMP strengths has to be given for each ingredient in separate lines	To allow for calculation of amount active ingredient in each package/product product and to validate INGR CONTENT
	STRENGTHU	**Unit of Measurement for Strength** E.g.: IU, IU/G, IU/ML, IU/PIECE, G, G/KG, G/L, MG, MG/ML, MG/PIECE In case of a multi-ingredient VMP unit of measurement strength has to be given for each ingredient in separate lines	To allow for calculation of the amount of active ingredient in each package/product and to validate INGR CONTENT
	CONV FACT IU	**Conversion Factor IU** When strength is given as IU, IU/ML or IU/PIECE	When strength is given as IU, IU/ML or IU/PIECE - to allow for calculation of weight of the active ingredient in package
	CONV FACT PRODR	**Conversion Factor Prodrug** Only when strength is given for the prodrug and not for the active ingredient (e.g. procaine penicillin that is prodrug for benzylpenicillin)	To allow for calculation of weight of the active ingredient in package
	INGR CONTENT	**Content of Active Ingredient in Package** In case of multi-ingredient VMP the content in the package has to be given separately for each ingredient in separate lines	Optional. To allow for validation of the ESVAC calculations
	CONT UNIT (G)	**Unit of Active Ingredient in Package** To be given in gram (G) for all substances In case of multi-ingredient VMP the content unit has to be given separately for each ingredient in separate lines	Optional. To allow for validation of the ESVAC calculations
	TONS SOLD	**Tons Sold of Active Ingredient**	
	TONS SOLD	**Tons Sold of Active Ingredient**	

Filling in the ESVAC Data Collection Form

General comments

The data should be delivered to ESVAC in the standardized Excel-spreadsheet developed within the ESVAC project – i.e. the ESVAC Data Collection Form (version 3).

Recommendations and examples on how to fill in the ESVAC Data Collection Form, including how to calculate weight of the active ingredient sold for each product are provided on the Agency's web pages (see Special Topics/Antimicrobial Resistance), further clarification on the use of the template is also provided in Annex I at the end of this document.

The original ESVAC Data Collection Form should always be used when filling in the data.

Several of the fields in the ESVAC Data Collection Form contain drop-down lists to ensure that the data are provided in a standardised manner. As the drop-down lists e.g. for Ingredient Name, are linked to other spreadsheets in the ESVAC Data Collection Form the original form should be used for filling in the data by all data providers.

For products containing 2 or more ingredients – information about each ingredient (name, strength, strength unit etc) have to be given in different columns.

At this stage ESVAC will not collect sales data per animal species from MSs and filling in the Species column is therefore optional. The purposes for including a column on which animal species the various products are approved for is that it might assist the interpretation of the data at national level for example if the product is intended for food producing or companion animals.

Please note that all the information for each product (ID) has to be aggregated in the same row. This is vital for the further processing of the data in the ESVAC database.

Comments on how to fill in the various fields variables

ID (Medicinal Product Package Code Value)

When this information is not available leave the field empty

ATCvet - 5th LEVEL (ATC_{vet}: Anatomic Therapeutic Chemical (Classification) Veterinary)

If an ATCvet code has not been assigned for the VMP in question apply the "code" "Not available". When receiving the data the ESVAC project team (PT) will ask the WHO Centre to provide a code for such products and the data set will be updated by ESVAC project team (PT) the when the codes have been assigned.

INGR [Active Ingredient Name (ATCvet name)]

If an ATCvet name has not been assigned for the VMP in question (not in drop down list) you include the ingredient name but then you have to use ATCvet code "not available". When receiving the data the ESVAC project team (PT) will ask the WHO Centre to provide the ATCvet name for such ingredients and the data set will be updated by ESVAC project team (PT) the when the ATCvet names have been assigned.

For preparations with more than one active ingredient the information on name has to be included for all the active ingredients (see also point 2 in Annex I).

CONV FACT IU (Conversion Factor IU) and CONV FACT PRODR (Conversion Factor Prodrug)

If Conversion Factor IU or Conversion Factor Prodrug for the ingredient/ Prodrug in question is not included in the ESVAC Data Collection Form, the ESVAC Project Team (ESVAC@eu.europa.eu) will provide the (standardised) value when validating the data.

Validation of the data by the national ESVAC representative

To ensure that all data have been submitted by the data providers (wholesaler, pharmacy, industry etc.):

- Check if all answers have been received from the data providers;
- If no sales are reported ask for a declaration form in order to avoid errors;
- Compare sales data with previous years results in order to detect major changes;
- In case of doubt contact the data provider for confirmation;
- If possible check from another source of data;
- In countries where data providers are required to declare the turnover for each product these data can be used to verify the sales data by comparing the data with the turnover declared for each product.

Validation of calculations

- If possible perform 2 independent calculations.

When the ID number of a VMP changes

This is applicable only when the national ESVAC database is already established.

When the ID number change as a result of changes in e.g.,

- Composition of the VMP;
- Name of VMP;
- Market authorization extended to "new" target species;
- New sales presentation, e.g. change in package size;

the database will have to be updated accordingly (see example below).

Example: Change ID number because the market authorization has been extended from dog to dog and cat

In 2009

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACKSIZEU	ATCVET	SPECIES	NO SOLD	INGR	STRENGTH	STRENGTHU	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2009	12000	1111	"Amoxicillin-generic"	TABL	100	PIECE	QJ01CA04	DOG	100000	amoxicillin	200	MG/PIECE	20	G	2

Market authorization extended from dog to dog and cat will result in 2 different ID numbers in 2010 for the "same" product that will have to be reported in separate lines as shown below.

In 2010

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	SPECIES	NO SOLD	INGR	STRENGTH	STRENGTHU	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	12000	1111	"Amoxicillin-generic"	TABL	100	PIECE	QJ01CA04	DOG	0	amoxicillin	200	MG/PIECE	20	G	0
Data	XX	2010	12000	1112	"Amoxicillin-generic"	TABL	100	PIECE	QJ01CA04	DOG CAT	165000	amoxicillin	200	MG/PIECE	20	G	3.3

ANNEX I

The below examples are a compilation of answers to questions raised during the pilot phase. In case you have further queries please let us know sending an e-mail to: esvac@ema.europa.eu

1. How to fill in the template for products containing one active ingredient?

1.1. The strength of the active ingredient is given as IU (international units)

To do the calculation of the weight of the active ingredient the IU has to be converted into weight units. This is done by using the Conversion Factor–IU provided in the ESVAC Data Collection Form. Examples are shown below.

Example 1. "Spiramycin - generic"

Variables that can be filled in the template before performing any calculations

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	STRENGTH	STRENGTHU	CONV FACT IU	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	23456	876543	"Spiramycin-generic"	INJ	100	ML	QJ01FA02	3651	spiramycin	600000	IU/ML	0.000313		G	

Calculation of remaining variables:

$$\text{INGR CONTENT} = \frac{(\text{PACK SIZE}\ \text{PACK SIZEU} \cdot \text{STRENGTH}\ \text{STRENGTHU}) \cdot \text{CONV FACT IU}}{1000\ \text{MG/ML}}$$

$$= \frac{(100\ \text{ML} \cdot 600000\ \text{IU/ML}) \cdot 0.000313\ \text{MG/IU}}{1000\ \text{MG/G}} = 18.78\ \text{G}$$

Pack size unit and strength unit need to be identical to allow multiplication

TONS SOLD = **NO SOLD** · **INGR CONTENT** = 3651 · 18.78 G = 68566 G = 0.0686 TONS

How the data fields should look like after the calculations

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	STRENGTH	STRENGTHU	CONV FACT IU	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	23456	876543	"Spiramycin-generic"	INJ	100	ML	QJ01FA02	3651	spiramycin	600000	IU/ML	0.000313	18.78	G	0.07

Example 2. Salt: "Colistin + sulphate - generic"

Variables that can be filled in the template before performing any calculations

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	SALT	STRENGTH	STRENGTHU	CONV FACT IU	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	24567	765432	"Colistin + sulphate -generic"	PREMIX	20	KG	QA07AA10	6342	colistin	**sulphate**	1200000	IU/G	0.000049		G	

Calculation of remaining variables:

INGR CONTENT = (**PACK SIZE** **PACK SIZEU** · **STRENGTH** **STRENGTHU**) · **CONV FACT IU**
1000 MG/G

= (20000 G (20 KG) · 1200000 IU/G)) · 0.000049 MG/IU = 1176 G
1000 MG/G

Pack size unit and strength unit need to be identical to allow multiplication

TONS SOLD = **NO SOLD** · **INGR CONTENT** = 6342 · 1176 G = 7458192 G = 7.4582 TONS

How the data fields should look like after the calculations

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	SALT	STRENGTH	STRENGTHU	CONV FACT IU	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	24567	765432	"Colistin + sulphate - generic"	PREMIX	20	KG	QA07AA10	6342	colistin	sulphate	1200000	IU/G	0.000049	1176	G	7.46

2. How to fill in the template for products containing two or more active ingredients?

All active ingredients in a product have to be reported. The INGREDIENT variables are repeated for each active ingredient as illustrated below.

2.1. The strength is given as MG/ML, MG/G, MG/PIECE, G/KG, G/L, or G/PIECE

Example 1. "Chlortetracycline + Sulfadimidine"- generic

Variables that can be filled in the template before performing any calculations

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	STRENGTH	STRENGTHU	INGR CONTENT	CONT UNIT (G)	TONS SOLD	INGR	STRENGTH	STRENGTHU	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	65432	234567	"Chlortetra-cycline + Sulfadi-midine - generic"	PREMIX	25	KG	QJ01AA53	220765	chlortet-racycline	60	MG/G		G		sulfadi-midine	80	MG/G		G	

Calculations of remaining variables:

Chlortetracycline

$$\text{INGR CONTENT} = \frac{\text{PACK SIZE PACK SIZEU} \cdot \text{STRENGTH STRENGTHU}}{1000\ \text{MG/G}} = \frac{25000\ \text{G (25 KG)} \cdot 60\ \text{MG/G}}{1000\ \text{MG/G}} = 1500\ \text{G}$$

Pack size unit and strength unit need to be identical to allow multiplication

$$\text{TONS SOLD} = \text{NO SOLD} \cdot \text{INGR CONTENT} = 220765 \cdot 1500\ \text{G} = 331147500\ \text{G} = 331.1475\ \text{TONS}$$

Sulfadimidine

$$\text{INGR CONTENT} = \frac{\text{PACK SIZE PACK SIZEU} \cdot \text{STRENGTH STRENGTHU}}{1000\ \text{MG/G}} = \frac{25000\ \text{G (25 KG)} \cdot 80\ \text{MG/G}}{1000\ \text{MG/G}} = 2000\ \text{G}$$

$$\text{TONS SOLD} = \text{NO SOLD} \cdot \text{INGR CONTENT} = 220765 \cdot 2000\ \text{G} = 441530000\ \text{G} = 441.5300\ \text{TONS}$$

How the data fields should look like after the calculations

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	STRENGTH	STRENGTHU	INGR CONTENT	CONT UNIT (G)	TONS SOLD	INGR	STRENGTH	STRENGTHU	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	65432	234567	"Chlortetra -cycline + Sulfadi- midine- generic"	PREMIX	25	KG	QJ01AA53	220765	chlortet- racycline	60	MG/G	1500	G	331.15	sulfadi- midine	80	MG/G	2000	G	441.53

2.2. The strength of the active ingredients is given as IU (international units)

To do the calculation of the weight of the active ingredients the IU has to be converted into weight units. This is done by using the Conversion Factor - IU provided in the ESVAC Data Collection Form. Examples are shown in 1.1.

3. How to fill in the template when the strength is given for the Prodrug (not the active ingredient)?

A Prodrug is a compound that must undergo chemical conversion by metabolic processes before becoming an active pharmacological agent. To calculate the weight of the active ingredient (G) converted from the Prodrug the Conversion Factor – Prodrug provided in the ESVAC Data Collection Form has to be used. Examples are shown below.

3.1. Prodrug strength is given as MG/ML, MG/G, MG/PIECE, G/KG, G/L or G/PIECE

Example 1. "Procaine penicillin"- generic (procaine penicillin is a prodrug for benzylpenicillin)

Variables that can be filled in the template without any calculations

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	PRODRUG	STRENGTH	STRENGTHU	CONV FACT PRODRUG	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	56789	101112	"Procaine penicillin-generic"	INJ	100	ML	QJ01CE09	5843	benzyl penicillin	procaine penicillin	300	MG/ML	0.61		G	

Calculation of remaining variables:

$$\text{INGR CONTENT} = \frac{(\text{PACK SIZE} \cdot \text{PACK SIZEU}) \cdot \text{STRENGTH}}{\text{STRENGTHU}} \cdot \text{CONV FACT PRODRUG} = \frac{(100\ \text{ML} \cdot 300\ \text{MG/ML}) \cdot 0.61}{1000\ \text{MG/G}} = 18.3\ \text{G}$$

$$\text{TONS SOLD} = \text{NO SOLD} \cdot \text{INGR CONTENT} = 5843 \cdot 18.3\ \text{G} = 106927\ \text{G} = 0.1069\ \text{TONS}$$

Pack size unit and strength unit need to be identical to allow multiplication

How the data fields should look like after the calculations

	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	PRODRUG	STRENGTH	STRENGTHU	CONV FACT PRODRUG	INGR CONTENT	CONT UNIT (G)	TONS SOLD
	XX	2010	56789	101112	"Procaine penicillin-generic"	INJ	100	ML	QJ01CE09	5843	benzyl penicillin	procaine penicillin	300	MG/ML	0.61	18.3	G	0.11

Example 2. "Penethamate hydriodide - generic" (Penethamate hydriodide is a prodrug for benzylpenicillin)

Variables that can be filled in the template without any calculations

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	PRODRUG	STRENGTH	STRENGTHU	CONV FACT PRODRUG	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	34567	141516	"Penethamate hydriodide - generic"	INJ	10	PIECE	QJ01CE90	3112	benzyl penicillin	penethamate hydriodide	5	G/PIECE	0.63		G	

Calculation of remaining variables:

INGR CONTENT = (**PACK SIZE** **PACK SIZEU** · **STRENGTH** **STRENGTHU**) / 1000 MG/G · **CONV FACT PRODRUG**

Pack size unit and strength unit need to be identical to allow multiplication

= (10 PIECES · 5 G/PIECE) · 0.63 = 31.5 G

Not divided on 1000 mg/g because the denominator already is in grams

TONS SOLD = **NO SOLD** · **INGR CONTENT** = 3112 · 31.5 G = 98028 G = 0.0980 TONS

How the data fields should look like after the calculations

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	PRODRUG	STRENGTH	STRENGTHU	CONV FACT PRODRUG	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	34567	141516	""Penethamate hydriodide - generic"- generic"	INJ	10	PIECE	QJ01CE90	3112	benzyl penicillin	penethamate hydriodide	5	G/PIECE	0.63	31.5	G	0.09

3.2. Prodrug strength is given as IU/ML, IU/G or IU/PIECE

Example. "Benzathine phenoxymethylpenicillin-generic" (benzathine phenoxymethylpenicillin is a prodrug for benzylpenicillin)

Variables that can be filled in the template before any calculations

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	PRODRUG	STRENGTH	STRENGTHU	CONV FACT IU	CONV FACT PRODRUG	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	21222	324252	"Benzathine phenoxymet-hylpenicillin - generic"	INJ	100	ML	QJ01CE10	7854	benzyl penicillin	benzathine phenoxymet-hylpenicillin	200000	IU/ML	0.000599			G	

Note that when the strenght for a prodrug is given as IU it refers to the active ingredient therefore conversion factor prodrug should not be applied.

Calculation of remaining variables:

Step 1.

INGR CONTENT = ingredient content in IU / 1000 MG/G · **CONV FACT IU** = (100 ML · 200000 IU/ML / 1000 MG/G · 0.000599 MG/IU = 11.98 G

Pack size unit and strength unit need to be identical to allow multiplication

TONS SOLD = **NO SOLD** · **INGR CONTENT** = 7854 · 11.98 G = 94090.92 G = 0.09409092 TONS

How the data fields should look like after the calculations

Variables	COUNTRY	YEAR	MA	ID	NAME	FORM	PACK SIZE	PACK SIZEU	ATCVET	NO SOLD	INGR	PRODRUG	STRENGTH	STRENGTHU	CONV FACT IU	CONV FACT PRODRUG	INGR CONTENT	CONT UNIT (G)	TONS SOLD
Data	XX	2010	21222	324252	"Benzathine phenoxymet-hylpenicillin - generic"	INJ	100	ML	QJ01CE10	7854	benzyl penicillin	benzathine phenoxymet-hylpenicillin	200000	IU/ML	0.000599		11.98	G	0.094

4. How to fill in the template for products that contain enzyme inhibitors (e.g. clavulanic acid)?

Enzyme inhibitors such as clavulanic acid are not active ingredients but it is important to quantify use of e.g. amoxicillin+ clavulanic acid. But if the ATCvet code for the combination with active ingredients is given (e.g. QJ01CR02 for amoxicillin+ clavulanic acid) it is not necessary to include clavulanic acid in a separate line in the template.