TESSy - The European Surveillance System

Antimicrobial consumption (AMC) reporting protocol 2018

European Surveillance of Antimicrobial Consumption Network (ESAC-Net) surveillance data for 2017

April 2018

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Introduction

This reporting protocol is for the 2018 data call for antimicrobial consumption (AMC) surveillance data for 2017.

ECDC's Reporting Protocols are data collection guidelines for reporting countries' data managers, and the new Reporting Protocol design is intended to improve user-friendliness by:

- Introducing a uniform structure to make it easier for data managers to find data collection information across different subjects.
- Removing information not relevant to data managers.

The Reporting Protocols are supplemented by the *Technical Annex*, which contains updated generic information for each data collection.

Because reporting countries' data managers sometimes play multiple roles, it is sometimes relevant to distribute subject-specific material together with a Reporting Protocol. To maintain the uniform structure, this sort of material is now included in *Annex 2.*

How to use this document

This Reporting Protocol provides information for reporting countries' data managers in three main sections:

- *Reporting to TESSy* – contains guidelines on how to prepare data for submission to TESSy, deadlines, subject-specific information (e.g. new changes to metadata), and links to further information.
- *Annex 1* – contains:
    - The metadata set for the subject(s) covered by this Reporting Protocol.
    - A history of previous AMC metadata changes.
- *Annex 2* – contains AMC-specific material relevant for distribution with the Reporting Protocol, for example:
    - ESAC-Net objectives.
    - Reporting ESAC-Net data.
    - Examples.

Finding further information

 Paragraphs denoted by the information icon tell where you can find further information.

Updated links to all the schedules, documentation and training materials mentioned in this Reporting Protocol are included in the *Technical Annex*, including:

- Metadata sets and history.
- Tutorials for data transformation using respectively Excel and Access.
- TESSy user documentation.
- CSV and XML transport protocols.
- On country request, ECDC will offer webinars: ca 2hrs online teleseminars, and an individual coaching how to upload data to TESSy, incl. latest metadata changes etc. The webinars can be requested by the National focal points and will be available for the data managers in charge of uploading national consumption data.

Reporting to TESSy

This section provides both an overview of the TESSy reporting process and tips on where you can find useful information.

The overall process is:

1. *Familiarise yourself with the data collection deadlines*.
2. *Prepare (export and transform) your data*.
3. *Check that your data complies with the metadata*.
4. *Check that your data source profile is up-to-date*.
5. *Submit your file(s) to TESSy*.
6. *Finalise and approve your submission*.

Checking the data *collection* schedule

National reference data for antimicrobial consumption can only be reported once for one year, using AMC (preferred) or AMCLIGHT. Data from the community (primary care) and hospital sector should be reported separately rather than reporting total care data.

The collection of 2017 antimicrobial consumption data in TESSy started in March 2018 and close on 30 June 2018. After this date, the ECDC experts will subject the data to a final cleaning and validation before analysing them. Data submitted after data collection closure are not guaranteed to be included in the 2017 ESAC-Net data outputs on the occasion of the European Antibiotic Awareness Day (EAAD) in November 2018 and in the HTML reports at the ECDC website summarising the 2017 ESAC-Net data.
The uploaded 2017 ESAC-Net data will be released via the *ESAC-Net database* at the ECDC website on the occasion of the EAAD 2018.

 An updated link to the current data collections schedule is provided in the *Technical Annex.*

Preparing data

After you have exported the data from your national database, you need to ensure that the data are in a format that TESSy can accept. This applies both to the type of file submitted to TESSy (only CSV and XML files can be submitted) and to the format of the data in certain fields.

 Tutorials covering how you can transform your data to the correct TESSy format using Excel or Access are available on *the TESSy documents website*. Information on the file formats is available in the CSV Transport Protocol and XML Transport Protocol.

Checking metadata

The TESSy metadata define the fields and data formats that are valid as input to TESSy for a given subject.

As requirements to the data to be shared among TESSy users change, the data changes needed to support the new requirements, identified and agreed upon between the National Surveillance Contact Points, the Network Coordination Groups and ECDC's Disease Experts, and then implemented as changes to the TESSy metadata.

In order to ensure that your data can be saved correctly in TESSy, you therefore need to check that your data are correctly formatted according to the most recent metadata set.

Changes to the metadata for the subject of this Reporting Protocol are described in:

- *Changes to current metadata* – changes since the last Reporting Protocol.
- *AMC metadata change history* - all preceding changes.

It is especially important to focus on:

- **Field formats**
  Many fields require that data are formatted in a specific way. For example, dates must be in the YYYY-MM-DD format; dates in the DD/MM/YYYY format will be rejected.
- **Coded values**
  Some fields only permit the use of specific values (coded values). For example, **M**, **F**, **UNK**, or **Other** are the coded values for *Gender* and any other value in a *Gender* field will be rejected.

The metadata file contains all the definitions and rules you need to comply with to format your data correctly for every subject (in this case the antimicrobial consumption). The file can be downloaded as an Excel file from the TESSy documents website.

By filtering the fields in the file by subject, you can see the fields required for your subject and the rules applying to these fields.

The *Technical Annex* provides an overview of how you work with the metadata file, and the TESSy user documentation provides in-depth details on metadata.

Checking your data source profile

Before submitting your file(s), please review the profile for your data source(s) in TESSy (go to **Data Sources**), and update the information, if necessary.

Complete and up-to-date data source information for each subject is important for improving interpretation of data each surveillance system has different features that need to be taken into account when comparing data at an international level.

If your data source information is out-of-date and you do not have access rights to update it, please request your National Focal Point for Surveillance or National Coordinator to do so.

In-depth information on the data source variables is available in the TESSy user documentation.

Submitting your data

Data is submitted through the TESSy web interface (go to **Upload**).

The *Technical Annex* provides an overview of how you submit files to TESSy, and the TESSy user documentation provides in-depth descriptions of all the upload methods.

Finalising your submission

The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process.

The result of your upload – i.e. rejected or validated – is displayed immediately after the conclusion of the check in the **Validation details** webpage. Please review the result carefully:

- If your file has been rejected, there will be a message explaining each instance of non-compliance with the metadata that you need to correct.
- If your file has been validated, there might be warnings and remarks relating to possible data quality issues or to potential overwriting of existing records that you should consider.

When your file has been validated and you are satisfied that all corrections have been made, please ensure prompt approval – unapproved uploads can block for the approval of other uploads.

The TESSy user documentation provides information on reviewing validation results and adjusting reporting periods to avoid overwriting existing records.

TESSy HelpDesk

Email:	*TESSy@ecdc.europa.eu*
Telephone number:	**+46-(0)8-5860 1601**
Availability:	9:00 – 16:00 Stockholm time, Monday to Friday (except ECDC Holidays)

Changes to current antimicrobial consumption (AMC) metadata

ATC code for Combined Products

Products containing two or more active ingredients are regarded as combined products and their DDDs are expressed in unit dose (UD). According to the *list of combined products from the WHO Collaborating Centre for Drug Statistics Methodology, 2018*, different combined products sharing the same main active ingredients are usually given the same ATC code, though the active ingredients might be in different quantities.

For example three different combinations of the active ingredients ampicillin and cloxacillin are allocated to the same ATC code J01CR50:

a) J01CR50: ampicillin_0.25g – cloxacillin_0.25g → Tablets
b) J01CR50: ampicillin_0.25g – cloxacilin_0.25g → Powder for injection
c) J01CR50: ampicillin_0.5g – cloxacillin_0.5g → Powder for injection

Additionally, combinations of products of ampicillin with the active ingredients oxacillin or flucloxacillin, which belong to the same 4th ATC group J01CF (beta-lactamase resistant penicillins) like cloxacillin, are also allocated to the same ATC code J01CR50:

d) J01CR50: ampicillin_0.66g – oxacillin_0.33g → Powder for injection
e) J01CR50: ampicillin_0.125g – oxacillin_0.125g → Capsules
f) J01CR50: ampicillin_0.25g – flucloxacillin_0.25g → Tablets

Different DDDs are assigned to each of the combined products a) - f). The impossibility to distinguish them through the ATCCode, made it necessary to introduce a further variable in TESSy metadata. Therefore the variable CombinedProduct was created. It is composed of the ATC code adding a numerical element through the underscore symbol (_). The products of the previous example will be classified with the following codes of the variable CombinedProduct:

a) J01CR50_1

b) J01CR50_5

c) J01CR50_6

d) J01CR50_2

e) J01CR50_3

f) J01CR50_4

A list of all products that will report the new variable CombinedProduct can be found at the end of Annex 2. Additionally, *a practical example how to report consumption* for these combined products is provided on page 50.

ATC and DDD updates

New ATC codes, ATC changes, DDD updates and allocations of defined daily doses for combined products in TESSy are provided in the *end of Annex 2*.

The previous metadata changes are described in *AMC metadata change history*.

Information on changes to the metadata for other subjects is available on the TESSy documentation website.

Clarification on the variable SyrupForm

(It was already explained in the 2015 reporting protocol. However, only a few countries reported this variable in 2015 correctly (or adequately). Therefore, we are re-emphasising the usefulness of this variable. A correctly reported SyrupForm will enable estimations of proportions of paediatric consumption from the data reported to TESSy)

The variable *SyrupForm* used to track **all antimicrobials** that are administered **orally as a liquid**. The variable SyrupForm does not correspond to the pharmaceutical form syrup only but to all pharmaceutical forms that will produce a liquid and will be administered orally. Examples of pharmaceutical forms that should be reported as 'Y' (yes) for SyrupForm are **syrup, oral powder, oral solution** and **oral suspension**.

The variable is used for tracking paediatric consumption corresponding to all antimicrobials that are taken orally as a liquid.

Annex 1 Antimicrobial consumption (AMC) metadata

This section describes:

- *The antimicrobial consumption metadata*
- *Changes to the antimicrobial consumption metadata*

ESAC-Net data

Three subjects have been created to manage ESAC-Net data: AMC (to record antimicrobial consumption data), AMCDENOM (to record population data) and AMCDS (to record contextual data related to antimicrobial consumption).

For these three subjects, five record types have been defined. Three record types relate to the AMC subject:

- AMC: single (individual antimicrobials at the product level (case-based);
- AMC$PACKAGES: consumed packages at the product level (case-based);
-
- AMCLIGHT: antimicrobial consumption expressed at the substance level (aggregate).

The aggregate AMCDENOM record type for recording population data relates to the AMCDENOM subject. The AMCDS record type for recording contextual information relates to the AMCDS subject.

ESAC-Net record types

- The record type **AMC** contains the national registry data of all antimicrobials available in the country, even if not used during the reporting year. It includes 8 technical and 17 epidemiological variables.
- The record type **AMC$PACKAGES** contains case-based antimicrobial consumption data at the product level. It includes 3 technical and 7 epidemiological variables.
- The record type **AMCLIGHT** is an alternative for reporting the antimicrobial consumption data and contains aggregated antimicrobial consumption data based on DDD at the ATC substance level. It includes 6 technical and 12 epidemiological variables.
- The record type **AMCDENOM c**ontains denominator data; i.e. data on the population under surveillance. It is mandatory only if the Member State is not using Eurostat data. Additionally, data subdivided by sub-national area (NUTS classification), age class or gender can be optionally reported. This record type includes 6 technical and 5 epidemiological variables.
  The record type **AMCDS** contains information on the antimicrobial consumption data source. In particular, it includes information about whether the data represent national reference data and which groups of antimicrobials are included. Finally, two variables offer the possibility to share comments, either only with ECDC or publicly in the individual country summary sheets. The record type AMCDS includes 7 technical variables, 10 epidemiological variables on consumption and 3 denominator variables for each sector. Finally, it includes 5 summary variables on the inclusion of nursing homes, psychiatric hospitals and day care centres. Data should preferably be reported separately for the community (primary care) and the hospital sector. If data cannot be subdivided between the community and hospital sector, they can be reported for both sectors combined (total care).

Descriptions of all the ESAC-Net metadata variables can found in the TESSy system and in an Excel file, which is provided with the invitation letter for the data call. Additionally, all variables, including the respective coding and the associated validation rules, are described in *Metadata for antimicrobial consumption surveillance* on page 13.

Current record type versions

Table 1 shows the record types and record type versions to be used when uploading 2017 AMC surveillance data to TESSy.

Table 1: Accepted record types and record type versions

Subject		Record type version	Description
AMC	Standard (case-based)	AMC.4	National registry data of all antimicrobials available.
		AMC$PACKAGES.4	Antimicrobial consumption data linked to the national registry.
	Light (aggregated)	AMCLIGHT.2	Consumption data (based on DDD).
AMCDENOM (aggregated)		AMCDENOM.1	Denominator / population under surveillance.
AMCDS (aggregated)		AMCDS.3	Data source information for antimicrobial consumption data.

Metadata for antimicrobial consumption surveillance

The description of each variable used for reporting of the datasets of antimicrobial consumption data is presented in the following tables.

Please note that validation rules only check data within one record type. For this reason, it is theoretically possible to successfully upload data into TESSy, but no results are shown on the online reports. The latter could happen if, for example, antimicrobial consumption data are reported with the light version, but the healthcare sector or the denominator data are not reported accordingly in the record types AMCDENOM or AMCDS. If this is the case, no calculation or data analysis will be performed by TESSy.

In the tables, the following conventions are used:

VariableName Literal name of a variable. Never contains spaces.
Upper/lower case is only used to improve readability.

Code Code as accepted by the system.

Description Description of the meaning of a possible value for a specific variable.

Validation rule Function of validation rule (e.g., checking for the right format, checking for coded values, "look up" validation rules, expected values based on other rules).

Some variables are technically mandatory, i.e. TESSy will not accept the data submission unless the fields corresponding to these variables have been completed.

Record type AMC - national registry data for all available antimicrobials

Table 2: Technical variables for record type AMC

VariableName	**1 - RecordID**
Description	Unique identifier for the product within the year reported. Possible format: ReportingCountry + Year + ProductId.
Required (what happens if not submitted)	Yes (Error)
Data type	String (Max length: 80)
Validation rule	-
VariableName	**2 - RecordType**
Description	Structure and format of the data (case based reporting or aggregate reporting).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	AMC
Validation rule	-
VariableName	**3 - RecordTypeVersion**
Description	Indicates the version of the record type used in the reported batch. If no record type version is provided in the batch, it is automatically set with current version of the record type. The record type version is required when no metadata set is provided at upload or when a record type version, other than the current one, needs to be used.
Required (what happens if not submitted)	No
Data type	Numeric
Code	See ESAC-Net metadata (e.g. 1)
Validation rule	-
VariableName	**4 - Subject**
Description	Subject of the data reported (see Figure 1 on page 39).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	AMC
Validation rule	-
VariableName	**5 - DataSource**
Description	Data source (surveillance system) from which the record originates.
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	See ESAC-Net metadata

Validation rule	-
VariableName	**6 - ReportingCountry**
Description	Country reporting the record.
Required (what happens if not submitted)	Yes
Data type	Coded Value
Code	See ESAC-Net metadata
Validation rule	-
VariableName	**7 - DateUsedForStatistics**
Description	Year of reporting.
Required (what happens if not submitted)	Yes (Error)
Data type	Date
Code	Year (YYYY)
Validation rule	-
VariableName	**8 - Status**
Description	Status of reporting NEW/UPDATE or DELETE (inactivate). Default if left out: NEW/UPDATE. If set to DELETE, the record with the given RecordId will be deleted from the TESSy database (or better stated, invalidated). If set to NEW/UPDATE or left empty, the record is newly entered into the database.
Required (what happens if not submitted)	No
Data type	Coded Value
Code	NEW/UPDATE, DELETE
Validation rule	-

Table 3: Epidemiological variables for record type AMC

VariableName	**9 - ProductId**
Description	Product identifier (previously Medicinal Product Package Code Value - MPPCV). Must be a unique identifier of the medicinal product package (MPP). Because it is a key value in many tables, it must not change over time. Product identifiers that are no longer available on the market or that are no longer registered still can be identified in the TESSy database for historical purposes.
Required (what happens if not submitted)	No
Data type	String (Max length: 80)
Validation rule	-
VariableName	**10 - ProductLabel**
Description	The product label or medicinal product package label (e.g. Sovaldi® 400mg tablets
Required (what happens if not submitted)	Yes (Error)
Data type	String (Max length: 80)

Validation rule	-
VariableName	**11 - PackageSize**
Description	Package size or number of items (e.g., tablets) in the package. Do not provide the unit (e.g., not 60 tablets, it should be reported only as 60). Note that e.g. vials are quantified in number of items and not quantified by their volume (see *How to report medicinal products in vials or syrup forms*).
Required (what happens if not submitted)	No
Data type	Numeric
Validation rule	-
VariableName	**12 - PackageSizeUnit**
Description	Unit of the size (number of items) of a package.
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	PCS=pieces,
Validation rule	-
VariableName	**13 - Strength**
Description	Quantity of the ingredient in each unit. For multi-ingredient medicinal products, this field must contain the ingredient strength in which the DDD is expressed (e.g., amoxicillin/clavulanic acid combinations: strength expresses the strength of amoxicillin since DDD=1 g of amoxicillin). For combined products where the DDD is expressed in Unit Dose (UD), the strength should be reported in the number of UDs.
Required (what happens if not submitted)	Yes (Error)
Data type	String (Max length: 80)
Validation rule	Strength must be a positive integer or float (up to 3 decimals)
VariableName	**14- StrengthUnit**
Description	Unit of the strength reported. For the combined products where the DDD is expressed in Unit Dose the strength should be given in the number of UDs.
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	G = Gram, MG = Milligram, IU = International unit, MU = Million units, UD = Unit Dose
Validation rule	If ATCCode is reported different than A07AA02, A07AA05, J01XB01, J01CE01, J01CE02 and J01FA02, then StrengthUnit must be reported as G or MG. If ATCCode is reported as A07AA02, A07AA05 or J01XB01, then StrengthUnit must be reported as IU or MU. If ATCCode is reported as J01CE30, then StrengthUnit must be reported in G.
VariableName	**15 - AntimicrobialRoute**
Description	Route of administration of the substance.
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	O = Oral, P = Parenteral, R = Rectal, I = Inhalation, M = Implant
Validation rule	-

VariableName	**16- SyrupForm**
Description	Is the product a syrup? (The variable will be used for tracking paediatric consumption).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No, NA = Not applicable
Validation rule	If AntimicrobialRoute is reported different than 'O', then SyrupForm must be reported as NA. If AntimicrobialRoute is reported as 'O', then SyrupForm must be reported as Y/N.
VariableName	**17- InhalationForm**
Description	The galenic form of the drug for inhalation, i.e. inhalation powder or inhalation solution
Required	No
Data type	Coded value
Code	IP = Inhalation powder, IS = Inhalation solution
Validation rule	If Route is reported as 'I', InhalationForm should be reported as 'IP' or 'IS' If Route is reported as different from 'I', InhalationForm should not be reported
VariableName	**18- ATCCode**
Description	ATC code of the substance (ATC 5th level).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	List of ATC codes (only ATC 5th level codes) - (See *Annual ESAC-Net data collection*)
Validation rule	-
VariableName	**19- Salt**
Description	Salt associated with substance. Only used (required) for methenamine and for erythromycin. For methenamine, the associated salt (hippurate or mandelate) should be specified. For erythromycin, if the associated salt is ethylsuccinate and the galenic form is tablet, then ethylsuccinate must be specified. In all other cases (any other form than tablet and even if ethylsuccinate), the variable 'Salt' should be left empty.
Required (what happens if not submitted)	No
Data type	Coded value
Code	HIPP = Hippurate, MAND = Mandelate, ESUC = Ethylsuccinate, NA = Not applicable
Validation rule	If ATCCode is reported as J01XX05 (methenamine), then Salt must be reported as HIPP or MAND. If ATCCode is reported as J01FA01 (erythromycin) and AntimicrobialRoute is reported as O (oral), then Salt can only be reported as ESUC. If ATCCode is reported as J01FA01 (erythromycin) and AntimicrobialRoute is reported different than O (oral), then Salt must not be reported. If ATCCode is reported different than J01XX05 (methenamine) or J01FA01 (erythromycin), then Salt must not be reported.
VariableName	**20 - DPPNational**

Description	Number of DDD per package provided by the country. ECDC will compute the DPP from the package size, strength, basic quantity ingredient and WHO DDD.
Required (what happens if not submitted)	No.
Data type	String (Max length: 80)
Validation rule	DPPNational must be a positive integer or float (up to 3 decimals). DPPNational must be reported when DDDNational is reported different than UNK. If DPPNational is reported, then DDDNational must be reported different than UNK.
VariableName	**21 - DDDNational**
Description	Daily dose established by the country.
Required (what happens if not submitted)	No
Data type	String (Max length: 80)
Validation rule	DDDNational must be a positive integer or float up to 3 decimals (UNK is allowed). DDDNational is used to calculate the number of DDDs (for the current combination of ATCCode, AntimicrobialRoute and Salt) because the DDD value is missing in the WHO DDD table, www.whocc.no). If DDD national is reported as unknown, the number of DDDs will not be calculated
VariableName	**22- DDDNationalUnit**
Description	The unit used to express DDDNational.
Required (what happens if not submitted)	No
Data type	Coded value
Code	G = Gram, MG = Milligram, IU = International unit, MU = Million units, UD=Unit Dose, UNK = Unknown
Validation rule	If DDDNational is not reported or equals to UNK, then DDDNationalUnit must not be reported (UNK is allowed). If DDDNational is reported different than UNK, then DDDNationalUnit must be reported and be different than UNK.
VariableName	**23 - PackageContent**
Description	Package content provided by the country. ECDC will compute the package content from the package size and strength.
Required (what happens if not submitted)	No
Data type	String (Max length: 80)
Validation rule	PackageContent must be a positive integer or float (up to 3 decimals). If PackageContentUnit is different than G and MU, then PackageContent must be reported as integer. If PackageContent is not reported, then PackageContentUnit must not be reported. If PackageContent is reported, then PackageContentUnit must be reported.
VariableName	**24 - PackageContentUnit**
Description	Unit of the package content.
Required (what happens if not submitted)	No
Data type	Coded value
Code	G = Gram, MG = Milligram, IU = International unit, MU = Million units, UD= Unit Dose.
Validation rule	If StrengthUnit is reported as G or MG, then PackageContentUnit can only be reported as G or MG.

	If StrengthUnit is reported as IU or MU, then PackageContentUnit can only be reported as IU or MU.
VariableName	**25 – CombinedProduct**
Description	ATC code of the substance for combined products
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	List of ATC codes for combined products - (*Allocations of defined daily doses for combined products in TESSy*)
Validation rule	If ATCCode is not equal to the first 7 characters (before "_") of the code indicated in CombinedProduct.

Record type AMC$PACKAGES - antimicrobial consumption data linked to the national registry

Table 4: Technical variables for record type AMC$PACKAGES

VariableName	**1 - RecordID**
Description	Unique identifier for the product package consumption. Possible format: ParentId + PlaceOfNotification + PlaceOfNotification + AgeClass + Gender + Sector + Prescriber + Quarter.
Required (what happens if not submitted)	Yes (Error)
Data type	String (Max length: 80)
Validation rule	-
VariableName	**2 - RecordType**
Description	Structure and format of the data (case based reporting or aggregate reporting).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	AMC$PACKAGES
Validation rule	-
VariableName	**3 - ParentId**
Description	Unique identifier for the product within the year reported. Recommended format: ReportingCountry + Year + ProductId.
Required (what happens if not submitted)	Yes (Error)
Data type	String (Max length: 80)
Validation rule	ParentId exists in the AMC registry.

Table 5: Epidemiological variables for record type AMC$PACKAGES

VariableName	**4 - PlaceOfNotification**
Description	Sub-national area for which data are reported. Select the most detailed NUTS level possible. Leave empty for national data.

Required (what happens if not submitted)	No
Data type	Coded value
Code	List of NUTS codes, country codes for non EU/EEA, UNK - Unknown
Validation rule	-
VariableName	**5 - AgeClass**
Description	Age class for which consumption data is reported. Leave empty if data are not reported by age class.
Required (what happens if not submitted)	No
Data type	Coded value
Code	See ESAC-Net metadata
Validation rule	AgeClass can only be reported for the community (primary care). For community (primary care), please report age class, if possible AgeClass can be reported only with a value from the following list: '00-<01', '01-04', '05-09', '10-14', '15-19', '20-24', '25-29', '30-34', '35-39', '40-44', '45-49', '50-54', '55-59', '60-64', '65-69', '70-74', '75-79', '80-84', '85+' or 'UNK'.
VariableName	**6 - Gender**
Description	Gender of the reported data. Leave empty if data are not reported by gender.
Required (what happens if not submitted)	No
Data type	Coded value
Code	M=Male, F=Female, O=Other, UNK=Unknown
Validation rule	Gender can only be reported for the community (primary care). For community (primary care), please report gender, if possible.
VariableName	**7 - Sector**
Description	Sector for which data are reported, i.e. community (primary care), hospital sector, or both healthcare sectors combined (total care).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	AC = community (primary care), HC = Hospital sector, TC = Total care
Validation rule	-
VariableName	**8 - Prescriber**
Description	Category of physicians prescribing the antimicrobials.
Required (what happens if not submitted)	No
Data type	Coded value
Code	GP = General Practitioners, SP = Specialists, GE = Geriatrics, DE = Dentists, PE = Paediatricians, OTH = Other, UNK = Unknown - not available.
Validation rule	Prescriber can only be reported only for the community (primary care). For community (primary care), please report prescriber, if possible.
VariableName	**9 - ReportQuarter**
Description	Use only when reporting quarterly data. Leave empty for annual data.
Required (what happens if not submitted)	No
Data type	Numeric
Validation rule	-

VariableName	**10 - NumberOfPackages**
Description	Number of packages used for the reported sector and period.
Required (what happens if not submitted)	Yes (Error)
Data type	String (Max length: 80)
Validation rule	NumberOfPackages must be an integer or float (up to 3 decimals).

Record type AMCLIGHT - antimicrobial consumption data (directly as a number of DDDs) AMCLIGHT record type

Table 6: Technical variables for record type AMCLIGHT

VariableName	**1 - RecordType**
Description	Structure and format of the data (case based reporting or aggregate reporting).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	AMCLIGHT
Validation rule	-
VariableName	**2 - RecordTypeVersion**
Description	Indicates the version of the record type used in the reported batch. If no record type version is provided in the batch, it is automatically set with current version of the record type. The record type version is required when no metadata set is provided at upload or when a record type version, other than the current one, needs to be used.
Required (what happens if not submitted)	No
Data type	Numeric
Code	See ESAC-Net metadata (e.g. 1)
Validation rule	-
VariableName	**3 - Subject**
Description	Subject of the data reported (see Figure 1 on page 39).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	AMC
Corresponding variable in the previous ESAC project dataset (notes)	(new variable)
Validation rule	-
VariableName	**4 - DataSource**
Description	Data source (surveillance system) from which the record originates.
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	See ESAC-Net metadata
Validation rule	-
VariableName	**5 - ReportingCountry**

Description	Country reporting the record.
Required (what happens if not submitted)	Yes
Data type	Coded Value
Code	See ESAC-Net metadata
VariableName	**6 - DateUsedForStatistics**
Description	Year of reporting.
Required (what happens if not submitted)	Yes
Data type	Date
Code	Year (YYYY, YYYY-Qq)

VariableName	**7 - PlaceOfNotification**
Description	Sub-national area for which data are reported. Select the most detailed NUTS level possible. Leave empty for national data.
Required (what happens if not submitted)	No
Data type	Coded value
Code	List of NUTS codes, country codes for non EU/EEA, UNK – Unknown.
Validation rule	-
VariableName	**8 - AgeClass**
Description	Age class for which consumption data is reported. Leave empty if data are not reported by age class.
Required (what happens if not submitted)	No
Data type	Coded value
Code	See ESAC-Net metadata
Validation rule	AgeClass can only be reported for the community (primary care) AgeClass can be reported only with a value from the following list: '00-<01', '01-04', '05-09', '10-14', '15-19', '20-24', '25-29', '30-34', '35-39', '40-44', '45-49', '50-54', '55-59', '60-64', '65-69', '70-74', '75-79', '80-84', '85+' or 'UNK'.
VariableName	**9 - Gender**
Description	Gender of the reported data. Leave empty if data are not reported by gender.
Required (what happens if not submitted)	No
Data type	Coded value
Code	M=Male, F=Female, O=Other, UNK=Unknown
Validation rule	Gender can only be reported for the community (primary care).
VariableName	**10 - Sector**
Description	Sector for which data are reported, i.e. community (primary care), hospital sector, or both healthcare sectors combined (total care).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	AC = community (primary care), HC = Hospital sector, TC = Total care

Validation rule	-
VariableName	**11 - Prescriber**
Description	Category of physicians prescribing the antimicrobials.
Required (what happens if not submitted)	No
Data type	Coded value
Code	GP = General Practitioners, SP = Specialists, GE = Geriatrics, DE = Dentists, PE = Paediatricians, OTH = Other, UNK = Unknown - not available.
Validation rule	Prescriber can only be reported for the community (primary care).
VariableName	**12 - ATCCode**
Description	ATC code of the substance (ATC 5th level).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	List of ATC codes (only ATC 5th level codes). See *Annual ESAC-Net data collection*).
Validation rule	-
VariableName	**13 - ATCName**
Description	ATC name of the substance (ATC 5th level).
Required (what happens if not submitted)	No
Data type	String (Max length: 80)
Validation rule	-
VariableName	**14 - AntimicrobialRoute**
Description	Route of administration of the substance.
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	O = Oral, P = Parenteral, R = Rectal, I = Inhalation, M = Implant
Validation rule	-
VariableName	**15 - Salt**
Description	Salt associated with substance. Only used (required) for methenamine and for erythromycin. For methenamine, the associated salt (hippurate or mandelate) should be specified. For erythromycin, if the associated salt is ethylsuccinate and the galenic form is tablet, then ethylsuccinate must be specified. In all other cases (any other form than tablet and even if ethylsuccinate), the variable 'Salt' should be left empty.
Required (what happens if not submitted)	No
Data type	Coded value
Code	HIPP = Hippurate, MAND = Mandelate, ESUC = Ethylsuccinate, NA = Not applicable.
Validation rule	If ATCCode is reported as J01XX05 (methenamine), then Salt must be reported as HIPP or MAND. If ATCCode is reported as J01FA01 (erythromycin) and AntimicrobialRoute is reported as O (oral), then Salt can only be reported as ESUC. If ATCCode is reported as J01FA01 (erythromycin) and AntimicrobialRoute is reported different than O (oral), then Salt must

	not be reported. If ATCCode is reported different than J01XX05 (methenamine) or J01FA01 (erythromycin), then Salt must not be reported.
VariableName	**16 - NumberOfDDD**
Description	Number of DDD used for the reported substance, healthcare sector and period. In the record type AMCDS (data source), specify whether NumberOfDDD is reported as WHO DDDs or national Daily Doses.
Required (what happens if not submitted)	Yes (Error)
Data type	String (Max length: 80)
Validation rule	NumberOfDDD must be a integer or float (up to 3 decimals).
VariableName	**17- NumberOfPackages**
Description	Number of packages used for the reported substance, healthcare sector and period.
Required (what happens if not submitted)	No
Data type	String (Max length: 80)
Validation rule	NumberOfPackages must be an integer or float (up to 3 decimals).
VariableName	**18 - CombinedProduct**
Description	ATC code of the substance for combined products.
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	List of ATC codes for combined products. See Annual ESAC-Net data collection).
Validation rule	If ATCCode is not equal to the first 7 characters (before "_") of the code indicated in CombinedProduct.

Record type AMCDENOM - Denominator / Population under surveillance

Table 7: Technical variables for record type AMCDENOM

VariableName	**1 - RecordType**
Description	Structure and format of the data (case based reporting or aggregate reporting).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	AMCDENOM
Validation rule	-
VariableName	**2 - RecordTypeVersion**
Description	Indicates the version of the record type used in the reported batch. If no record type version is provided in the batch, it is automatically set with current version of the record type. The record type version is required when no metadata set is provided at upload or when a record type version, other than the current one, needs to be used.
Required (what happens if not submitted)	No
Data type	Numeric

Code	See ESAC-Net metadata (e.g. 1)
Validation rule	-
VariableName	**3 - Subject**
Description	Subject of the data reported (see Figure 1 on page 39).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	AMCDENOM
Validation rule	-
VariableName	**4 - DataSource**
Description	Data source (surveillance system) from which the record originates.
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	See ESAC-Net metadata
Validation rule	-
VariableName	**5 - ReportingCountry**
Description	Country reporting the record.
Required (what happens if not submitted)	Yes
Data type	Coded Value
Code	See ESAC-Net metadata
Validation rule	-
VariableName	**6 - DateUsedForStatistics**
Description	Year of reporting.
Required (what happens if not submitted)	Yes
Data type	Date
Code	Year (YYYY)
Corresponding variable in the previous ESAC project dataset	YEAR
Validation rule	-

Table 8: Epidemiological variables for AMCDENOM

VariableName	**7 - PlaceOfNotification**
Description	Sub-national area for which data are reported. Select the most detailed NUTS level possible. Leave empty for national data.
Required (what happens if not submitted)	No
Data type	Coded value
Code	List of NUTS codes, country codes for non EU/EEA, UNK - Unknown
Validation rule	-
VariableName	**8 - AgeClass**
Description	Age class for which consumption data is reported. Leave empty if data are not reported by age class.

Required (what happens if not submitted)	No
Data type	Coded value
Code	See ESAC-Net metadata
Validation rule	AgeClass shall be reported only for the community (primary care).. For community (primary care), please report age class, if possible. AgeClass can be reported only with a value from the following list: '00-<01', '01-04', '05-09', '10-14', '15-19', '20-24', '25-29', '30-34', '35-39', '40-44', '45-49', '50-54', '55-59', '60-64', '65-69', '70-74', '75-79', '80-84', '85+' or 'UNK'.
VariableName	**9 - Gender**
Description	Gender of the reported data. Leave empty if data are not reported by gender.
Required (what happens if not submitted)	No
Data type	Coded value
Code	M=Male, F=Female, O=Other, UNK=Unknown
Validation rule	Gender can only be reported for the community (primary care). For community (primary care), please report gender, if possible.
VariableName	**10 - Sector**
Description	Sector for which data are reported, i.e. community (primary care), hospital sector, or both healthcare sectors combined (total care).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	AC = community (primary care), HC = Hospital sector, TC = Total care
Validation rule	-
VariableName	**11 - Denominator**
Description	Number of individuals in place of notification.
Required (what happens if not submitted)	No
Data type	Numeric
Validation rule	-

Record type AMCDS - data source information for antimicrobial consumption data

Table 9: Technical variables for record type AMCDS

VariableName	**1 - RecordType**
Description	Structure and format of the data (case based reporting or aggregate reporting).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	AMCDS
Validation rule	-
VariableName	**2 - RecordTypeVersion**

Description	Indicates the version of the record type used in the reported batch. If no record type version is provided in the batch, it is automatically set with current version of the record type. The record type version is required when no metadata set is provided at upload or when a record type version, other than the current one, needs to be used.
Required (what happens if not submitted)	No
Data type	Numeric
Code	See ESAC-Net metadata (e.g. 1)
Validation rule	-
VariableName	**3 - Subject**
Description	Subject of the data reported.(see Figure 1 on page 39)
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	AMCDS
Validation rule	-
VariableName	**4 – DataSource**
Description	Data source (surveillance system) from which the record originates.
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	See ESAC-Net metadata
Validation rule	-
VariableName	**5 - ReportingCountry**
Description	Country reporting the record.
Required (what happens if not submitted)	Yes
Data type	Coded Value
Code	See ESAC-Net metadata
Validation rule	-
VariableName	**6 - DateUsedForStatistics**
Description	Year of reporting.
Required (what happens if not submitted)	Yes
Data type	Date
Code	Year (YYYY)
Validation rule	-
VariableName	**7- NationalReferenceData**
Description	Are data reported as national reference data? If no, data reported shall provide additional information (e.g., reporting age class and gender from a different database than the National reference data).
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	-

Table 10: Epidemiological variables for record type AMCDS - community (primary care) data

VariableName	**8 - DS_DataProviderAC**
Description	Which authority/organisation/network was the provider for community (primary care) data?
Required (what happens if not submitted)	No
Data type	Coded Value
Code	MoH = Ministry of Health, HI = Health Insurance Company, CP = Community Pharmacists, HN = Hospital Network, MR = Marketing Research Company, MA = Medicines Agency, O = Other.
Validation rule	-
VariableName	**9 - DS_TypeOfDataAC**
Description	What is the type of community (primary care) data?
Required (what happens if not submitted)	No
Data type	Coded value
Code	S = Sales, R = Reimbursement, B = Both
Validation rule	If DS_DataProviderAC is reported, then all the information for the community (primary care), including DS_TypeOfDataAC, must be reported.
VariableName	**10 - DS_CoverageAC**
Description	What is the percentage of coverage of consumption data in the community (primary care)? (See *How to report data coverage in the AMCDS record type*)
Required (what happens if not submitted)	Yes (Error)
Data type	Numeric
Validation rule	If DS_DataProviderAC is reported, then all the information for the community (primary care), including DS_CoverageAC, must be reported.
VariableName	**11 - DS_CoverageExtrapolatedAC**
Description	Were the data extrapolated to obtain 100% coverage of the community (primary care) in the country?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderAC is reported, then all the information for the community (primary care), including DS_CoverageExtrapolatedAC, must be reported. If DS_EurostatDataAC = Y and DS_CoverageAC is less than 100, then DS_CoverageExtrapolatedAC must be reported as Y."
VariableName	**12 - DS_ATCVersionAC**
Description	Which version of the WHO ATC/DDD index was used for reporting consumption data in the community (primary care?
Required (what happens if not submitted)	Yes (Error)
Data type	Year
Code	YYYY
Validation rule	If DS_DataProviderAC is reported, then all the information for the community (primary care) including DS_ATCVersionAC, must be reported.

VariableName	**13- DS_ATCVersionAlteratedAC**
Description	Were other than official WHO ATC/DDD alterations applied?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderAC is reported, then all the information for the community (primary care), including DS_ATCVersionAlteratedAC, must be reported.
VariableName	**14 - DS_J01InclusionAC**
Description	Is consumption of substances in ATC groups J01 + A07AA + P01AB (i.e., antibacterials for systemic use + intestinal antiinfectives/antibiotics + nitroimidazole derivatives) included in the data reported for the community (primary care)?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderAC is reported, then all the information for the community (primary care), including DS_J01InclusionAC, must be reported.
VariableName	**15 - DS_J02InclusionAC**
Description	Is consumption of substances in ATC groups J02 + D01BA (i.e., antimycotics for systemic use + antifungals for systemic use) included in the data reported for the community (primary care)?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderAC is reported, then all the information for the community (primary care), including DS_J02InclusionAC, must be reported.
VariableName	**16- DS_J04InclusionAC**
Description	Is consumption of substances in ATC group J04A (drugs for the treatment of tuberculosis) included in the data reported for the community (primary care)?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderAC is reported, then all the information for the community (primary care), including DS_J04InclusionAC, must be reported.
VariableName	**17 - DS_J05InclusionAC**
Description	Is consumption of substances in ATC group J05 (antivirals for systemic use) included in the data reported for the community (primary care)?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderAC is reported, then all the information for the community (primary care), including DS_J05InclusionAC, must be reported.

Table 11: Denominator data for the community (primary care)

VariableName	**18- DS_EurostatDataAC**
Description	Are the reported population data from Eurostat? If no, national population data must be provided by the country.
Required (what happens if not submitted)	Yes (Warning)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_EurostatDataAC = N, then DS_DataProviderDenomAC must be reported
VariableName	**19- DS_DataProviderDenomAC**
Description	Which authority/organisation/network was the provider for population data for the community (primary care)?
Required (what happens if not submitted)	No
Data type	Coded value
Code	MoH = Ministry of Health, HI = Health Insurance Company, CP = Community Pharmacists, HN = Hospital Network, MR = Marketing Research Company, MA = Medicines Agency, O = Other.
Validation rule	If DS_EurostatDataAC = N, then DS_DataProviderDenomAC must be reported. If DS_EurostatDataAC = Y, then DS_DataProviderDenomAC must not be reported.
VariableName	**20 - DS_TypeOfDataDenomAC**
Description	What is the type of population data for the community (primary care)?
Required (what happens if not submitted)	No
Data type	Coded value
Code	POP = Population, INS = Insured population.
Validation rule	If DS_EurostatDataAC = N, then DS_TypeOfDataDenomAC must be reported. If DS_EurostatDataAC = Y, then DS_TypeOfDataDenomAC must not be reported.

Table 12: Epidemiological variables for record type AMCDS - Hospital care data

VariableName	**21 - DS_DataProviderHC**
Description	Which authority/organisation/network was the provider for hospital sector data?
Required (what happens if not submitted)	No
Data type	Coded Value
Code	MoH = Ministry of Health, HI = Health Insurance Company, NS = National Statistics Agency, O = Other, NA = Not applicable
Validation rule	-
VariableName	**22 - DS_TypeOfDataHC**
Description	What is the type of hospital sector data?
Required (what happens if not submitted)	No
Data type	Coded value
Code	S = Sales, R = Reimbursement, B = Both
Validation rule	If DS_DataProviderHC is reported, then all the information for the hospital sector, including DS_TypeOfDataHC, must be reported.

VariableName	**23 - DS_CoverageHC**
Description	What is the percentage of coverage of consumption data in the hospital sector?
Required (what happens if not submitted)	Yes (Error)
Data type	Numeric
Validation rule	If DS_DataProviderHC is reported, then all the information for the hospital sector, including DS_CoverageHC, must be reported.
VariableName	**24 - DS_CoverageExtrapolatedHC**
Description	Were the data extrapolated to obtain 100% coverage of the hospital sector in the country?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderHC is reported, then all the information for the hospital sector, including DS_CoverageExtrapolatedHC, must be reported. If DS_EurostatDataHC = Y and DS_CoverageHC is less than 100, then DS_CoverageExtrapolatedHC must be reported as Y.
VariableName	**25- DS_ATCVersionHC**
Description	Which version of the WHO ATC/DDD index was used for reporting consumption data in the hospital sector?
Required (what happens if not submitted)	Yes (Error)
Data type	Date
Code	Year (YYYY)
Validation rule	If DS_DataProviderHC is reported then all the information for the hospital sector, including DS_ATCVersionHC, must be reported.
VariableName	**26- DS_ATCVersionAlteratedHC**
Description	Were other than official WHO ATC/DDD alterations used?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderHC is reported, then all the information for the hospital sector, including DS_ATCVersionAlteratedHC, must be reported.
VariableName	**27 - DS_J01InclusionHC**
Description	Is consumption of substances in ATC groups J01 + A07AA + P01AB (i.e., antibacterials for systemic use + intestinal antiinfectives/antibiotics + nitroimidazole derivatives) included in the data reported for the hospital sector?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderHC is reported then all the information for the hospital sector, including DS_J01InclusionHC, must be reported.
VariableName	**28- DS_J02InclusionHC**
Description	Is consumption of substances in ATC groups J02 + D01BA (i.e., antimycotics for systemic use + antifungals for systemic use) included in the data reported for the hospital sector?

Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderHC is reported then all the information for the hospital sector, including DS_J02InclusionHC, must be reported.
VariableName	**29 - DS_J04InclusionHC**
Description	Is consumption of substances in ATC group J04A (drugs for the treatment of tuberculosis) included in the data reported for the hospital sector?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderHC is reported then all the information for the hospital sector, including DS_J04InclusionHC, must be reported.
VariableName	**30 - DS_J05InclusionHC**
Description	Is consumption of substances in ATC group J05 (antivirals for systemic use) included in the data reported for the hospital sector?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderHC is reported then all the information for the hospital sector, including DS_J05InclusionHC, must be reported.

Table 13: Denominator data for the hospital sector

VariableName	**31 - DS_EurostatDataHC**
Description	Are the reported population data from Eurostat? If no, national population data must be provided by the country.
Required (what happens if not submitted)	Yes (Warning)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_EurostatDataHC = N, then DS_DataProviderDenomHC must be reported
VariableName	**32 - DS_DataProviderDenomHC**
Description	Which authority/organisation/network was the provider for population data for the hospital sector?
Required (what happens if not submitted)	No
Data type	Coded value
Code	MoH = Ministry of Health, HI = Health Insurance Company, NS = National Statistics Agency, O = Other, NA = Not applicable
Validation rule	If DS_EurostatDataHC = N, then DS_DataProviderDenomHC must be reported. If DS_EurostatDataHC = Y, then DS_DataProviderDenomHC must not be reported.
VariableName	**33 - DS_TypeOfDataDenomHC**
Description	What is the type of the population data for the hospital sector?
Required (what happens if not submitted)	No

Data type	Coded value
Code	POP = Population, INS = Insured population.
Validation rule	If DS_EurostatDataHC = N, then DS_TypeOfDataDenomHC must be reported. If DS_EurostatDataHC = Y, then DS_TypeOfDataDenomHC must not be reported.

Table 14: Epidemiological variables for record type AMCDS Total care data

VariableName	**34- DS_DataProviderTC**
Description	Which authority/organisation/network was the provider for 'total care'data?
Required (what happens if not submitted)	No
Data type	Coded Value
Code	MoH = Ministry of Health, HI = Health Insurance Company, CP = Community Pharmacists, HN = Hospital Network, MR = Marketing Research Company, MA = Medicines Agency, O = Other.
Validation rule	-
VariableName	**35- DS_TypeOfDataTC**
Description	What is the type of 'total care' data?
Required (what happens if not submitted)	No
Data type	Coded value
Code	S = Sales, R = Reimbursement, B = Both
Validation rule	If DS_DataProviderTC is reported, then all the information for 'total care', including DS_TypeOfDataTC, must be reported.
VariableName	**36 - DS_CoverageTC**
Description	What is the percentage of coverage of consumption data for 'total care'?
Required (what happens if not submitted)	Yes (Error)
Data type	Numeric
Validation rule	If DS_DataProviderTC is reported, then all the information for 'total care', including DS_CoverageTC, must be reported.
VariableName	**37- DS_CoverageExtrapolatedTC**
Description	Were the data extrapolated to obtain 100% coverage of 'total care' in the country?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderTC is reported, then all the information for "total care", including DS_CoverageExtrapolatedTC, must be reported. If DS_EurostatDataTC = Y and DS_CoverageTC is less than 100, then DS_CoverageExtrapolatedTC must be reported as Y.
VariableName	**38 - DS_ATCVersionTC**
Description	Which version of the WHO ATC/DDD index was used for reporting consumption data in 'total care'?
Required (what happens if not submitted)	Yes (Error)
Data type	Date

Code	Year (YYYY)
Validation rule	If DS_DataProviderTC is reported, then all the information for 'total care', including DS_ATCVersionTC, must be reported.
VariableName	**39- DS_ATCVersionAlteratedTC**
Description	Were other than official WHO ATC/DDD alterations applied
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderTC is reported, then all the information 'total care', including DS_ATCVersionAlteratedTC, must be reported.
VariableName	**40 - DS_J01InclusionTC**
Description	Is consumption of substances in ATC groups J01 + A07AA + P01AB (i.e., antibacterials for systemic use + intestinal antiinfectives/antibiotics + nitroimidazole derivatives) included in the data reported for 'total care'?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderTC is reported, then all the information for 'total care', including DS_J01InclusionTC, must be reported.
VariableName	**41 - DS_J02InclusionTC**
Description	Is consumption of substances in ATC groups J02 + D01BA (i.e., antimycotics for systemic use + antifungals for systemic use) included in the data reported for 'total care'?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderTC is reported, then all the information for 'total care', including DS_J02InclusionTC, must be reported.
VariableName	**42- DS_J04InclusionTC**
Description	Is consumption of substances in ATC group J04A (drugs for the treatment of tuberculosis) included in the data reported for 'total care'?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderTC is reported, then all the information for 'total care', including DS_J04InclusionTC, must be reported.
VariableName	**43 - DS_J05InclusionTC**
Description	Is consumption of substances in ATC group J05 (antivirals for systemic use) included in the data reported for 'total care'?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_DataProviderTC is reported, then all the information for 'total care', including DS_J05InclusionTC, must be reported.

Table 15: Denominator data for the total care sector

VariableName	**44- DS_EurostatDataTC**
Description	Are the reported population data from Eurostat? If no, national population data must be provided by the country.
Required (what happens if not submitted)	Yes (Warning)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	If DS_EurostatDataTC = N, then DS_DataProviderDenomTC must be reported
VariableName	**45 - DS_DataProviderDenomTC**
Description	Which authority/organisation/network was the provider for the population data for 'total care'?
Required (what happens if not submitted)	No
Data type	Coded value
Code	MoH = Ministry of Health, HI = Health Insurance Company, NS = National Statistics Agency, O = Other, NA = Not applicable
Validation rule	If DS_EurostatDataTC = N, then DS_DataProviderDenomTC must be reported. If DS_EurostatDataTC = Y then DS_DataProviderDenomTC must not be reported.
VariableName	**46 - DS_TypeOfDataDenomTC**
Description	What is the type of the population data for 'total care'?
Required (what happens if not submitted)	No
Data type	Coded value
Code	POP = Population, INS = Insured population.
Validation rule	If DS_EurostatDataTC = N, then DS_TypeOfDataDenomTC must be reported. If DS_EurostatDataTC = Y, then DS_TypeOfDataDenomTC must not be reported.

Table 16: Summary variables

VariableName	**47 - DS_PSYHOSP_Inclusion**
Description	In which sector, i.e. community (primary care), hospital sector, or both), are data from psychiatric hospitals reported?
Required (what happens if not submitted)	No
Data type	Coded value
Code	AC = Community (primary care), HC = Hospital care, BOTH = Community and hospital care, NONE = Not included.
Validation rule	-
VariableName	**48 - DS_HALT_Inclusion**
Description	In which sector, i.e. community (primary care), hospital sector, or both, are data from nursing homes and other long-term care facilities for the elderly reported?
Required (what happens if not submitted)	No
Data type	Coded value
Code	AC = Community (primary care), HC = Hospital sector, BOTH = Community and hospital care, NONE = Not included.

Validation rule	-
VariableName	**49- DS_DayCare_Inclusion**
Description	In which sector (AC and/or HC), data from day care centres (for young children) are reported?
Required (what happens if not submitted)	No
Data type	Coded value
Code	AC = Community (primary care), HC = Hospital sector, BOTH = Community and hospital sector, NONE = Not included.
Validation rule	-
VariableName	**50 - DS_CommentECDC**
Description	General comments for ECDC. Any information that is important or useful when analysing the data, these comments will not be published.
Required (what happens if not submitted)	No
Data type	String variable
Validation rule	-
VariableName	**51 - DS_CommentPublic**
Description	General comments for public display. Any remark that should be included when presenting data.
Required (what happens if not submitted)	No
Data type	String variable
Validation rule	-

AMC metadata change history

Metadata changes prior to 2016 can be found on the TESSy documents website.

-

2016 AMC metadata changes

Changes for the 6th ESAC-Net data call (2015 data) were:

- A new variable CombinedProduct enables reporting consumption of combined products according the ATC/DDD index of the WHOCC.

  Products containing two or more active ingredients are regarded as combined products and their DDDs are expressed in unit dose (UD). According to the *list of combined products from the WHO Collaborating Centre for Drug Statistics*, different combined products sharing the same main active ingredients are usually given the same ATC code, though the active ingredients might be in different quantities.

  Therefore a new variable, called CombinedProduct was created. It is composed of the ATC code adding a numerical element through the underscore symbol (_).

  The new variable applies to AMC and AMCLIGHT.

Table 17: Summary of implemented changes in case-based record types for Antimicrobial Consumption (AMC)

Year	Subject	Description
2014	**AMC$PACKAGES** **AMCDS**	Update name of variables: - Ambulatory Care (AC) is replace by Community; - Hospital Care (HC) is replaced by Hospital sector; - TC (total care) is replaced by Total care. This has no impact on data reporting since the technical variable names are not changed (only 'full name' and 'description' are changed). Some descriptions also improved.
	AMCDS	Addition of a remark to ask the users in providing explanations when data comes from both sales and re-imbursement sectors.
	AMC	ATC codes: update of a coded value list using the ATC coding system.
	AMC	A variable is added to collect information on the galenic form of antimicrobial agents used for inhalation (powder or solution) to comply with WHO coding standards.
	AMC	Validation rule associated to the new variable.
	All	Update NUTS codes according to the NUTS Codes 2010 classification from EUROSTAT
2016	**AMC**	New variable CombinedProduct
	AMCLIGHT	New variable CombinedProduct
	AMCDS	Error message for: - DS_ATCVersionAC(HT,TC) - DS_ATCVersionAlteratedAC(HT,TC) - DS_CoverageAC(HT,TC) - DS_J01InclusionAC(HT,TC) - DS_J02InclusionAC(HT,TC) - DS_J04InclusionAC(HT,TC) - DS_J05InclusionAC(HT,TC) If DS_DataProviderAC(HT,TC) and one of the previous variables is not reported Warning message if DS_EurostatDataAC(HT,TC)=N and DS_DataProviderDenomAC(HT,TC) is not reported

Annex 2 Antimicrobial consumption (AMC) specific material

This section covers:

- *ESAC-Net* – the network's history and objectives.
- *Overview of AMC data collection and analysis* – AMC-specific information on uploading data to TESSy and the annual AMC data collection.
- *Reporting ESAC-Net data* – tips for reporting for certain categories of data.
- *Examples* – examples of reporting data on the consumption of fluids, and on consumption and population coverage.
- *Antimicrobials under ESAC-Net surveillance*
- *ATC and DDD updates*.

ESAC-Net

The European Surveillance of Antimicrobial Consumption Network (ESAC-Net) is a Europe-wide network of national surveillance systems, providing European reference data on antimicrobial consumption. ESAC-Net collects and analyses data on antimicrobial consumption from EU/EEA countries, both in the community and in the hospital sector.

The specific objectives of ESAC-Net are:

- To validate antimicrobial consumption data from the community (primary care) and the hospital sector derived from national surveillance networks, including data from the national drug registers;
- To analyse trends in antimicrobial consumption overall and for the different ATC groups, as well as provide comparisons between countries and regions;
- To make information on antimicrobial consumption in Europe publicly accessible through an ESAC-Net interactive database.

ESAC-Net covers all EU/EEA countries in agreement with Decision 1082/2013/EU of the European Parliament and the Council of 22 October 2013 on serious cross-border threats to health.

The data sources are either national sales or reimbursement data, including information from national drug registers. The WHO Anatomical Therapeutic Chemical (ATC) classification system is used for the allocation of antimicrobials into groups. National reference data are preferably collected at the medicinal product level. The preferred units of measurement are the number of DDDs and the numbers of packages. The main indicators describing antimicrobial consumption are the number of DDDs per 1 000 inhabitants and per day, and the number of packages per 1 000 inhabitants and per day.

Data covering the period 1997-2009 were uploaded into TESSy after termination of the ESAC project using the historical project database that was transferred from the University of Antwerp to ECDC.

Overview of AMC data collection and analysis

Following data management at country level, antimicrobial consumption data from each healthcare sector – for example, national sales data for the community (primary care) – are provided by uploading defined datasets as described in Figure 1.

For each healthcare sector, the datasets to be uploaded comprise the three subjects AMC, AMCDENOM and AMCDS.

Figure 1: Overview of ESAC-Net metadata for each data source.

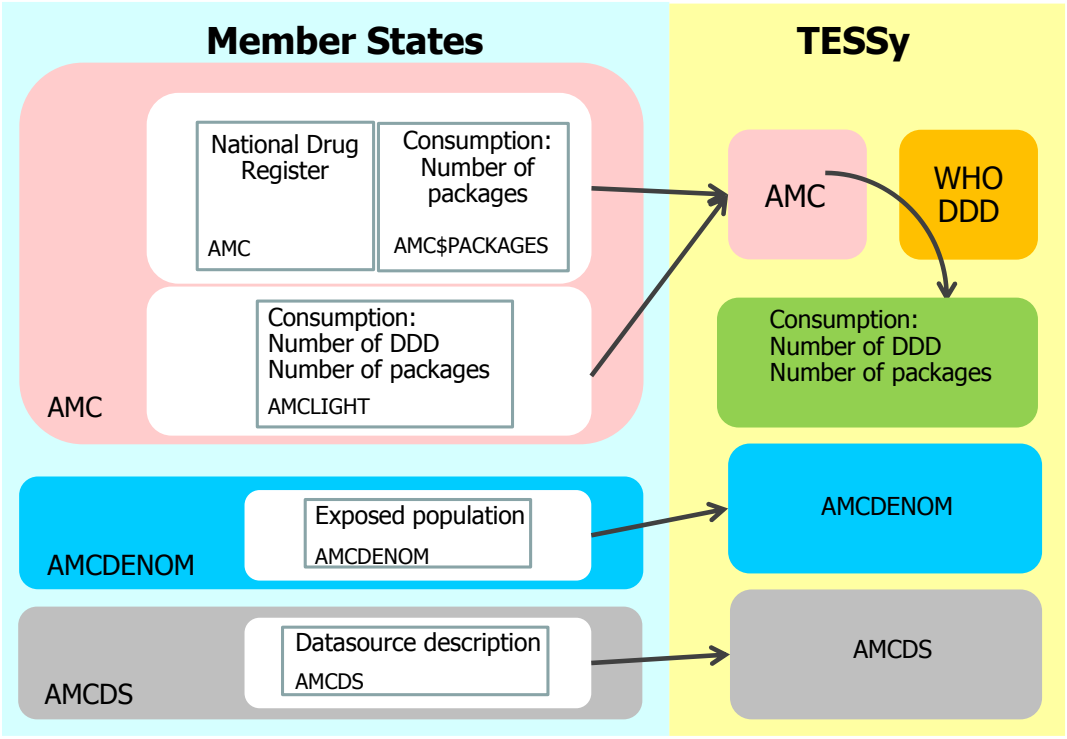

Figure 1 illustrates that different datasets for the subjects AMC, AMCDENOM and AMCDS must be uploaded from different data sources. For antimicrobial consumption, the preferred option is to provide data at the medicinal product level (record types AMC and AMC$PACKAGES), or alternatively aggregated data at the substance level (record type AMCLIGHT). Data on the denominator (population, record type AMCDENOM) and on data sources (record type AMCDS) must always be provided.

Denominator data (subject AMCDENOM with record type AMCDENOM) and description of the data source (subject AMCDS with record type AMCDS) are essential to enable TESSy to calculate the number of DDDs per 1 000 inhabitants and per day and produce online reports. Uploading data only for the subject AMC (record types AMC and AMC$PACKAGES, or record type AMCLIGHT) is not sufficient.

There are four possible situations depending on whether the country provides data at medicinal product level (preferred option) or at the substance level, and on whether the country uses Eurostat or its own population data:

- Countries providing data at the medicinal product level and using Eurostat data must provide three datasets (record types AMC, AMC$PACKAGES and AMCDS);
- Countries providing data at the medicinal product level and using their own denominator data must provide four datasets (record types AMC, AMC$PACKAGES, AMCDENOM and AMCDS);
- Countries providing data at the ATC substance level and using Eurostat data must provide two datasets (record types AMCLIGHT and AMCDS);
- Countries providing data directly at the ATC substance level and using their own denominator data must provide three datasets (record types AMCLIGHT, AMCDENOM and AMCDS).

TESSy will use the least level of detail common between AMC and AMCDENOM subjects for reporting. For example, if consumption was reported by age and gender, but population was only reported overall for the whole country, then TESSy will aggregate consumption data before reporting.

Following successful upload of data, TESSy users have access to the TESSy online reports. Based on these TESSy reports and following consultations with MS, ECDC publishes an annual chapter (HTML report) on antimicrobial consumption in Europe in ECDC's Annual Epidemiological Report.

Summary of the TESSy AMC data upload and validation process

1. The national data manager revises and compiles the data from national sales and/or reimbursement databases.
2. The nominated national focal point for antimicrobial surveillance or the national operational contact point with TESSy rights to upload and/or approve data uploads the compiled data into TESSy. At the end of this process, the complete uploaded file will be saved in a specific environment which is different from the one used to generate the online reports.
3. TESSy provides a validation report to the country user for approval. This report shows the correctness of the data uploaded based on the validation rules defined in the ESAC-Net metadata. At this stage, neither the calculation nor the volume of DDD reported is validated. The country user checks the validation report and approves or rejects the uploaded file.
4. After approval by the country user, the file is automatically transferred into the TESSy data warehouse where the number of DDDs per 1 000 inhabitants and per day are calculated for each ATC substance and each sector. At this stage the data are available in the TESSy online reports for antimicrobial consumption and can be downloaded by the country user. These online reports are automatically refreshed at least every hour. The outputs (maps, graphs and tables) of TESSy online reports are produced with the same methods and programmes used for the final reports and web application outputs.
5. The user should validate the figures shown in the TESSy online reports. The reports contain detailed results for the country referring down to the ATC 5th level. Additionally, the contact points who uploaded the data will receive via email a comparative summary of the data including data from the previous three years.
6. It is important that the user informs the ESAC-Net experts at ECDC via email on the status of the data to avoid ECDC using incorrect data.
7. In case mistakes are found or records must be updated the user should repeat all previous reporting steps.

Annual ESAC-Net data collection

The complete calendar year is the temporal basis for data reporting and analysis.

The annual national consumption data derived from sales or reimbursement data can be reported:

- Either using the record type AMC$PACKAGES with reporting of all consumed packages at the product level based on the national registry data given in the parent record type AMC. The number of DDDs will subsequently be calculated by TESSy. This is the preferred option,
- or using the record type AMCLIGHT for reporting aggregated numbers of Defined Daily Doses (DDDs) at the ATC substance level.

Denominator data (record type AMCDENOM) and information on the data source for antimicrobial consumption data (record type AMCDS) must be reported whatever option is chosen to report consumption data.

Reporting ESAC-Net data

As described in *Overview of AMC data collection and analysis*, there are two options for reporting ESAC-Net data:

- The preferred standard version: Reporting national antimicrobial consumption data at the medicinal product level, including national registry data, using the record types AMC and AMCPACKAGES. If data are delivered with this preferred standard version:

  - For erythromycin and methenamine, the associated salt must be provided (see ESAC-Net metadata);
  - For combined products, a new variable, CombinedProducts, has to be reported to distinguish and to define them. A detailed explanation is reported in *ATC code for Combined products* and a complete list of the products with the new variable can be found in *Table 22*.
- A light version: Reporting national antimicrobial consumption data at the ATC substance level using the record type AMCLIGHT.

Reporting for different healthcare sectors

The preferred approach is to report national reference data of antimicrobial consumption separately for each healthcare sector: community (primary care) and hospital sector. If the same data source is used, it can be uploaded as one batch file (see Figure 1 on page 39).
If otherwise not possible, the national reference data can be reported on both healthcare sectors combined, i.e. total care (= community plus hospital sector).
When using the AMCLIGHT record type, data on the number of packages can be omitted for the hospital sector.

Reporting the variables age class, gender and prescriber

If possible, ESAC-Net encourages reporting of community (primary care) antimicrobial consumption data stratified by age class, gender and prescriber.
It is possible to report data for the variables age class, gender and prescriber using a data source different from that of the main consumption data, thus allowing double reporting to TESSy. However, only one data source can be assigned as being the national reference data, which is necessary to ensure comparison of antimicrobial consumption between different Member States.
In cases where national reference data (without reporting for age class, gender and/or prescriber) are reported in the preferred standard reporting (record types AMC, AMCPACKAGES) and additional data for age class and gender are reported in the light version (record type AMCLIGHT), the reporting country must create two TESSy data sources (one for the national reference data and another for the additional data) and refer to the correct data source in the record types. Otherwise, TESSy will not be able to separate the data coming from the different sources and will provide wrong results.

Reporting population (number of inhabitants)

Eurostat population denominator data are preferred.
Available from: *http://ec.europa.eu/eurostat/data/database*
TESSy maintains an up-to-date copy of the Eurostat population data in its own database.

- If the surveillance coverage is compatible with Eurostat data, it is not necessary to submit any population denominator data to TESSy via the record type AMCDS. By default, TESSy uses Eurostat population data.
- If the surveillance coverage is not compatible with Eurostat data or if data providers disagree with TESSy using Eurostat data, it is necessary to provide denominator data at the same level as the level of consumption data (healthcare sector, NUTS, age class and gender). For more detailed information, please consult *Examples*.

Reporting historical data from the former ESAC project

Data covering the period 1997-2009 were uploaded into TESSy after termination of the ESAC project using the historical project database that was transferred from the University of Antwerp to ECDC.

If necessary, Member States can update these data in the same way that they have uploaded data for the year 2010 and onward; however, in this case use TESSy's **Replace** function instead of its **Update** function.

Examples

This section provides examples of reporting data on the consumption of fluids, and on consumption and population coverage.

How to report medicinal products in vials or syrup forms

Medicinal products in a vial or syrup form have either a strength expressed as a concentration (for instance 250mg/5mL, 80mg/mL), or their content is expressed as the total amount (for instance 250mg/vial). TESSy cannot handle data for the variable Strength expressed as a concentration. Below indications are provided how to fill in the AMC record type for such products. Based on these data, TESSy calculates the content of vials or syrup forms and allocates the correct DDD.

Variables to be reported for both vials and syrup forms:

Variable	
PackageSize:	Number of items in the box (either the number of vials or the number of bottles of syrup)
PackageSizeUnit:	PCS
Strength:	Total amount of active substance in one item (either a vial or a bottle of syrup)
StrengthUnit:	G/MG/IU/MU
SyrupForm:	Yes or No or NA

Two options for computing data for the variable Strength

- Original strength (e.g. 500 mg per vial) expressed as the total amount of the active substance in one item.
  The strength to be reported is the original strength.
- Original strength expressed as a concentration of an active substance per volume (e.g. 100mg per 5 ml).
  The strength to be reported is the result of the calculation of the numerator of the original strength (e.g. 100 mg) divided by the denominator of the original strength (e.g. 5 ml) and multiplied by the volume of the item (e.g. bottle or vial).

Based on this information, TESSy will compute the content of the active substance for a vial or syrup bottle and allocate DDD accordingly.

Formula for computing the content of a medicinal product:

TESSy uses the following formula to compute a medicinal product's active substance content:

Content = PackageSize x Strength

Three examples for computing the content of product A (vials) and products B and C (syrup forms)

Example 1

The presentation of the product A is defined as 5 vials of 500 mg of amoxicillin each. For product A the information to be provided is:

PackageSize:	5
PackageSizeUnit:	PCS
Strength:	500
StrengthUnit:	MG
SyrupForm:	NA

Based on this information, TESSy will compute the following content of the active substance for product A and allocate DDD:

Content of product A = 5 PCS x 500 mg = 2500 mg (2.5 g)

Example 2

The presentation of the product B is defined as 1 bottle of syrup of 60mL of amoxicillin at a concentration of 125mg/5mL. For product B the information to be provided is:

PackageSize:	1
PackageSizeUnit:	PCS
Strength:	125/5x60=1500
StrengthUnit:	MG
SyrupForm:	Y

Based on this information, TESSy will compute the following content of the active substance for product B and allocate DDD:

Content of product B = 1 PCS x 1500 mg = 1500 mg (1.5 g)

Example 3

The presentation of the product C is defined as 12 bottles of syrup each of 60mL of amoxicillin at a concentration of 125mg/5mL. For product C the information to be provided is:

PackageSize:	12
PackageSizeUnit:	PCS
Strength:	125/5x60=1500
StrengthUnit:	MG
SyrupForm:	Y

Based on this information, TESSy will compute the following content of the active substance for product C and allocate DDD:

Content of product C = 12 PCS x 1500 mg = 18000 mg (18 g)

How to report data coverage in the AMCDS record type

TESSy calculates DDD or packages per 1000 inhabitants and per day. Therefore, TESSy has to divide the consumption figures by the population figures. The figures provided for the consumption and for the population should cover the same population. Now, some countries provide consumption figures for the whole population, others provide them only for a sample. The information about the coverage for consumption and population is stored in the record type AMCDS and should be provided for each health sector for which data are delivered.

Examples of all possible cases are provided below. The examples provided show data reported to TESSy for the sector community (primary care).

Country A reports data for the whole population from overall sales

The relevant variable names and the data reported in the record type AMCDS are as follows:

For the consumption data:

DS_CoverageAC:	100%
DS_CoverageExtrapolatedAC:	No

The actual data coverage stored in TESSy is 100%.

For the population data:

Country A has the choice to use preferentially Eurostat data or its own national statistics database.

If country A chooses Eurostat data, TESSy will use Eurostat to retrieve the population figures. Country A reports in the record type AMCDS as follow:

DS_EurostatDataAC: Yes

If country A chooses not to use Eurostat data, it reports in the record type AMCDS as follow:

DS_EurostatDataAC: No

Additionally, it provides population data using the AMCDENOM record type.

Country B reports data extrapolated for the whole population from a sample representing 70% of the total population

Country B has collected data from a sample representing 70% of its total population. Then it has extrapolated the data to 100% of the population. The relevant variable names and the data reported in the record type AMCDS are as follows:

For the consumption data:

DS_CoverageAC: 70% (as its original data covered only 70% of the population)

DS_CoverageExtrapolatedAC: Yes

The actual data coverage in TESSy is 100% because Country B has extrapolated the data.

For the population data:

Country B, because it has extrapolated its original data to 100% of the population, can use preferentially Eurostat data or its own national statistics database. See example of *country A* for details.

Country C reports data for a sample representing 70% of the total population without any extrapolation

Country C has collected data from a sample representing 70% of its total population. It has not extrapolated the data to 100% of the population like Country B. The relevant variable names and the data reported in the record type AMCDS are as follows:

For the consumption data:

DS_CoverageAC: 70% (as its original data covered only 70% of the population)

DS_CoverageExtrapolatedAC: No

The actual data coverage in TESSy is 70% because Country C has not extrapolated the data.

For the population data:

Because the submitted consumption data represents only 70% of the total population, country C cannot use Eurostat data. The relevant variable names and the data reported in the record type AMCDS are as follows:

DS_EurostatDataAC: No

Additionally, it provides population data corresponding to the sample using the record type AMCDENOM.

Country D reports data from a sample of 80% from the insured population covering itself 90% of the total population

Country D receives the consumption data from an insurance company that collected data only in a sample of the insured population representing only 80% of it. The insured population represents itself

90% of the total population. Country D has four different options to report the consumption data to ECDC. The choice of the options is up to countries:

Option 1: the sample has been extrapolated to the whole insured population

Country D submits the data extrapolated to the insured population. The relevant variable names and the data reported in the record type AMCDS are as follows:

For the consumption data:

DS_Coverage: 90% (data extrapolated to the insured population)

DS_CoverageExtrapolated: No

The actual data coverage in TESSy is 90% because Country D has not extrapolated the data to the total population.

For the population data:

Country D with option 1 is in the same situation as Country C.

DS_EurostatDataAC: No

Additionally, it provides population data corresponding to insured population using the record type AMCDENOM.

Option 2: the sample has not been extrapolated to the whole insured population

Country D submits the original sample in the insured population without extrapolating to the total insured population. The relevant variable names and the data reported in the record type AMCDS are as follows:

For the consumption data:

DS_Coverage: 72% (data not extrapolated to the insured population, i.e. 80% of 90% = 72%)

DS_CoverageExtrapolated: No

The actual data coverage in TESSy is 72% because Country D has not extrapolated the data to the total population.

For the population data:

Country D with option 2 is in the same situation as Country C.

DS_EurostatDataAC: No

Additionally, it provides population data corresponding to 80% of the insured population which finally represents 72% of the total population using the record type AMCDENOM.

How to report combined products

From 2017, combined products under surveillance in ESAC-Net (as defined in the *list of the WHO Collaborating Centre for Drug Statistics Methodology*) reported for the antimicrobial consumption have to contain the new variable CombinedProduct;

CombinedProduct: an additional code, based on the ATC classification and adjusted in order to distinguish and precisely define one particular product.

The updated Table 22 contains the new variable assigned to all combined products under surveillance in ESAC-Net and a description of the product details.

Variables to be reported for combined products in the record type 'AMC'

(TESSy needs this information to calculate the number of DDD per package. Please, see also Tab. 22 Allocations of defined daily doses for combined products.)

ATCCode:	ATC code of the substances (5th level)
CombinedProduct:	ATC code of the substances for the combined product
AntimicrobialRoute:	Route of administration of the substance; e.g. oral or parenteral)
Package Size:	Number of items (e.g. tablets, bottles, ampules) in the package
PackageSizeUnit:	Unit of the size (item) of a package. Provided as pieces (PCS).
Strength:	Quantity of the ingredient in each item (provided as the number of UDs)
StrengthUnit:	Unit of the strength reported (UD)
ProductLabel:	The product label or medicinal product package label

Examples

The product A, B and C, all containing sulfamethoxazole and trimethoprim in different amounts were previously reported with *ATCCode J01EE01*.

Now for each of the products A, B and C it has to be reported, additional to the ATCCode, also the CombinedProduct variable which makes them distinguishable.

Product A:
A package with 10 ampules of 1 ml infusion concentrates.
Each ml infusion concentrate contains ulfamethoxazole 80mg - trimethoprim 16mg. ml
(According to Tab. 22, 20 ml of an infusion concentrate with a combination of sulfamethoxazole 80mg and trimethoprim 16mg per ml are equal to 20 UD = 1 DDD).

ATCCode: J01EE01

CombinedProduct: J01EE01_1

Antimicrobial route: Parenteral

PackageSize: 10

PackageSizeUnit: PCS

Strength; 1

StrengthUnit; UD

The content of a package of product A contains 10 UD and is equal to 0.5 DDD.
In the ESAC-Net metadata there are as well two other related variables. I.e. the variable PackageContent (it is has to be reported as 10) and the variable PackageContentUnit (it has to be reported as UD).

Product B:
A package with 8 vials of 5 ml mixture containing each sulfamethoxazole 0.2 g and trimethoprim 40 mg.
(According to Tab. 22, 40 ml of mixture containing a combination of sulfamethoxazole_0.2 g - trimethoprim_40 mg per 5 ml are equal to 8 UD = 1 DDD) .

ATCCode: J01EE01

CombinedProduct: J01EE01_2

Antimicrobial route: Parenteral

PackageSize: 8

PackageSizeUnit: PCS

Strength: 1

StrengthUnit: UD

The content of a package of product B contains 8 UD and is equal to 1 DDD.
In the ESAC-Net metadata there are as well two other related variables. I.e. the variable PackageContent (it is has to be reported as 8) and the variable PackageContentUnit (it has to be reported as UD).

Product C:
A package with 8 tablets and each tablet containing sulfamethoxazole 0.4 g and trimethoprim 80 mg. (According to Tab. 22, 4 tablets containing a combination of sulfamethoxazole_0.4 g - trimethoprim_80 mg are equal to 4 UD = 1 DDD) .

ATCCode: J01EE01

CombinedProduct: J01EE01_3

Antimicrobial route: Oral

PackageSize: 8

PackageSizeUnit: PCS

Strength: 1

StrengthUnit: UDThe content of a package of product C contains 8 UD and is equal to 2 DDD.
In the ESAC-Net metadata there are as well two other related variables. I.e. the variable PackageContent (it is has to be reported as 8) and the variable PackageContentUnit (it has to be reported as UD).

Antimicrobials under ESAC-Net surveillance

The following antimicrobials are under ESAC-Net surveillance:

- Antibacterials for systemic use (ATC therapeutic subgroup J01);
- Antimycotics for systemic use (ATC therapeutic subgroup J02);
- Antifungals for systemic use (ATC chemical subgroup D01BA);
- Drugs for treatment of tuberculosis (ATC pharmacological subgroup J04A);
- Antivirals for systemic use (ATC therapeutic subgroup J05);
- Nitroimidazole derivatives used orally and rectally as antiprotozoals (ATC chemical subgroup P01AB);
- Intestinal antiinfectives (ATC chemical subgroup A07AA)
  (All ATC codes should be reported including vancomycin used orally as intestinal antiinfectives).

The ATC/DDD index 2018 should be used (http://www.whocc.no/atc_ddd_index).

The latest update of the ATC/DDD index can be found at:

http://www.whocc.no/atc_ddd_index/updates_included_in_the_atc_ddd_index/

ATC and DDD updates

ATC updates

Table 18: New ATC codes

Year	ATC Code	ATC Name
2016	J01DD52	ceftazidime, combinations
	J01DI54	ceftolozane and enzyme inhibitor
	J01MB08	nemonoxacin
	J01XX11	tedizolid
	J02AC05	isavuconazole
	J05AR15	atazanavir and cobicistat
	J05AR16	lamivudine and raltegravir
	J05AR17	emtricitabine and tenofovir alafenamide
	J05AR18	emtricitabine, tenofovir alafenamide, elvitegravir and cobicistat
	J05AR19	emtricitabine, tenofovir alafenamide and rilpivirine
	J05AX16	dasabuvir
	J05AX65	sofosbuvir and ledipasvir
	J05AX66	dasabuvir, ombitasvir, paritaprevir and ritonavir
	J05AX67	ombitasvir, paritaprevir and ritonavir
2017	J01FA16	solithromycin

	J05AF13	tenofir alafenamide
	J05AX68	elbasvir and grazoprevir
	J05AX69	sofosbuvir-velpatasvir
2018	J01DD63	ceftriaxone and beta-lactamase inhibitor
	J05AP56	sofosbuvir, velpatasvir and voxilaprevir
	J05AP57	glecaprevir and pibrentasvir
	J05AR20	emtricitabine, tenofovir alafenamide and bictegravir
	J05AR21	dolutegravir and rilpivirine
	J05AR22	emtricitabine, tenofovir alafenamide, darunavir and cobicistat

No ATC changes in 2016 and in 2017.

Table 19: ATC name changes

Year	ATC Code	Old ATC name	New ATC name
2016	No changes		
2017	No changes		
2018	J01CR01	ampicillin and enzyme inhibitor	ampicillin and beta-lactamase inhibitor
	J01CR02	amoxicillin and enzyme inhibitor	amoxicillin and beta-lactamase inhibitor
	J01CR03	ticarcillin and enzyme inhibitor	ticarcillin and beta-lactamase inhibitor
	J01CR05	piperacillin and enzyme inhibitor	piperacillin and beta-lactamase inhibitor
	J01DD51	cefotaxime, combinations	cefotaxime and beta-lactamase inhibitor
	J01DD52	ceftazidime, combinations	ceftazidime and beta-lactamase inhibitor
	J01DD54 (split of code into J01DD54 and J01DD63)	ceftriaxone, combinations	ceftriaxone, combinations (excl.beta-lacatamse inhibitor)
	J01DD62	cefoperazone, combinations	cefoperazone and beta-lactamase inhibitor
	J01DH51	imipenem and enzyme inhibitor	imipenem and cilastatin
	J01DI54	ceftolozane and enzyme inhibitor	ceftolozane and beta-lactamase inhibitor

Table 20: ATC code changes

Year	Old ATC Code	ATC name	New ATC code
2016	No changes		
2017	No changes		
2018	J05AB04	ribavirin	J05AP01
	J05AE11	telaprevir	J05AP02

	J05AE12	boceprevir	J05AP03
	J05AE13	faldaprevir	J05AP04
	J05AE14	simeprevir	J05AP05
	J05AE15	asunaprevir	J05AP06
	J05AX14	daclatasvir	J05AP07
	J05AX15	sofosbuvir	J05AP08
	J05AX16	dasabuvir	J05AP09
	J05AX65	sofosbuvir and ledipasvir	J05AP51
	J05AX66	dasabuvir, ombitasvir, paritaprevir and ritonavir	J05AP52
	J05AX67	ombitasvir, paritaprevir and ritonavir	J05AP53
	J05AX68	elbasvir and grazoprevir	J05AP54
	J05AX69	sofosbuvir and velpatasvir	J05AP55

DDD updates

Table 212: New DDD allocations and alterations of DDD

Year	ATC code	Route	Salt	Inhalation Form	DDD value	DDD unit
2016	J01XB01	I		IP	3	MU
	J05AE14	O			0.15	g
	J05AX14	O			60	mg
	J05AX16	O			0.5	g
2017	J01CR01	P			6	g
	J01DI54	P			3	g
	J01XA04	P			1.5	g
	J01XE03	O			0.3	g
	J01XX11	O,P			0.2	g
	J02AC04	O,P			0.3	g
	J02AC05	O,P			0.2	g
	J04AB05	O			0.11	g
2018	J01DD52	P			6	g
	J05AF13	O			25	mg

P: parenteral, I: inhalation, IP: inhalation powder, IS: inhalation solution.

Defined daily doses for combined products, 2018

Table 223: List of DDDs for combined products in TESSy (adapted from WHO Collaboration Centre for Drug Statistics Methodology)

ATC code	CombinedProduct (variable to be reported)	Variable description in TESSy metadata	Active ingredients per one unit dose (UD)	Dosageform	No. of UD* per one DDD	Brand name
J01AA20	J01AA20_1	Tetracycline - chlortetracycline - demeclocycline	tetracycline 115.4 mg/ chlortetracycline 115.4 mg/ demeclocycline 69.2 mg	Tab	2 UD (=2 tab)	Deteclo
J01CA20	J01CA20_1	Pivampicillin_0.25g - pivmecillinam_0.2g	pivampicillin 0.25 g/ pivmecillinam 0.2 g	Tab	3 UD (=3 tab)	Miraxid
J01CA20	J01CA20_2	Pivampicillin_0.125g - pivmecillinam 0.1g	pivampicillin 0.125 g/ pivmecillinam 0.1 g	Tab	6 UD (=6 tab)	Miraxid mite
J01CE30	J01CE30_1	Benzylpenicillin/procain - benzylpenicillin/benzathine benzylpenicillin	benzylpenicillin/procain- benzylpenicillin/benzathine benzylpenicillin	Powder for inj	3.6 g* expressed as benzylpenicillin	Bicillin C-R, Bicillin A-P, Bicillin
J01CR50	J01CR50_1	Ampicillin_0.25g - cloxacillin_0.25g	ampicillin 0.25 g/ cloxacillin 0.25 g	Tab	4 UD (=4 tab)	Ampiclox
J01CR50	J01CR50_2	Ampicillin_0.66g - oxacillin_0.33g	ampicillin 0.66 g/ oxacillin 0.33 g	Powder for inj	2 UD (= 2 g)	Ampoxium
J01CR50	J01CR50_3	Ampicillin0.125g - oxacillin_0.125g	ampicillin 0.125g/ oxacillin 0.125 g	Caps	8 UD (= 8 caps)	Ampoxium
J01CR50	J01CR50_4	Ampicillin_0.25g - flucloxacillin_0.25g	ampicillin 0.25 g/ flucloxacillin 0.25 g	Tab	4 UD (=4 tab)	Co-fluampicil
J01CR50	J01CR50_5	Ampicillin_250mg - cloxacillin_250mg	ampicillin 250 mg/ cloxacillin 250 mg	Powder for inj	4 UD (=2 grams of powder for injection)	Viccillin-S

J01CR50	J01CR50_6	Ampicillin_500mg - cloxacillin_500mg	ampicillin 500 mg/ cloxacillin 500 mg	Powder for inj	2 UD (=2 grams of powder for injection)	Viccillin-S
J01EC20	J01EC20_1	Sulfacarbamide - sulfadiazine - sulfadimidine	sulfacarbamide 0.167 g/ sulfadiazine 0.167 g/ sulfadimidine 0.167 g	Tab	4 UD (=4 tab)	Trisulfamid
J01EE01	J01EE01_1	Sulfamethoxazole_80mg - trimethoprim_16mg	In 1mL: sulfamethoxazole 80 mg/ trimethoprim 16 mg	Inf conc	20 UD (=20 ml)	Bactrim, Eusaprim, Trimetoprim-sulfa
J01EE01	J01EE01_2	Sulfamethoxazole_0.2g - trimethoprim_40mg	In 5 mL: sulfamethoxazole 0.2 g/ trimethoprim 40 mg	Mixt	8 UD (= 40 ml)	Bactrim, Eusaprim, Trimetoprim-sulfa
J01EE01	J01EE01_3	Sulfamethoxazole_0.4g - trimethoprim80mg	sulfamethoxazole 0.4 g/ trimethoprim 80 mg	Tab	4 UD (=4 tab)	Bactrim, Eusaprim Trimetoprim-sulfa
J01EE02	J01EE02_1	Sulfadiazine_0.205g - trimethoprim_45mg	sulfadiazine 0.205 g/ trimethoprim 45 mg	Mixt	4 UD (=20 ml)	Triglobe, Trimin Sulfa
J01EE02	J01EE02_2	Sulfadiazine_0.41g - trimethoprim_90mg	sulfadiazine 0.41 g/ trimethoprim 90 mg	Tab	2 UD (=2 tab)	Triglobe, Trimin Sulfa
J01EE03	J01EE03_1	Sulfametrole_0.8g - trimethoprim_0.16g(tab)	sulfametrole 0.8 g/ trimethoprim 0.16 g	Tab	2 UD (=2 tab)	Lidaprim
J01EE03	J01EE03_2	Sulfametrole0.8g - trimethoprim_0.16g(powd)	sulfametrole 0.8 g/ trimethoprim 0.16 g per vial	Powder for inj	2 UD (defined as 2 vials)	Lidaprim
J01EE06	J01EE06_1	Sulfadiazin - tetroxoprim	sulfadiazin 0.25 g/ tetroxoprim 0.1 g	Tab	2 UD (=2 tab)	Sterinor
J01EE07	J01EE07_1	Sulfamerazin - trimethoprim	sulfamerazin 0.12 g/ trimethoprim 80 mg	Tab	4 UD (=4 tab)	Berlocombin

J01RA05	J01RA05_1	levofloxacin_250mg - ornidazole_500mg(tab)	levofloxacin 250 mg/ ornidazole 500 mg	Tab	2 UD (=2 tab)	Duobact
J01RA07	J01RA07_1	azithromycin_1000mg-fluconazole_150mg-secnidazole_1000mg(tab)	azithromycin 1000 mg (1 tab)/ fluconazole 150 mg (1 tab)/ secnidazole 1000 mg (2 tab) (combination package)	Tab	4 UD (=4 tab)	Safocid
J01RA09	J01RA09_1	ofloxacin_200mg - ornidazole_500mg(tab)	ofloxacin 200 mg/ ornidazole 500 mg	Tab	2 UD (=2 tab)	Oflox Oz
J01RA10	J01RA10_1	ciprofloxacin_500mg - metronidazole_200mg(tab)	ciprofloxacin 500 mg/ metronidazole 200 mg	Tab	2 UD (=2 tab)	Cipramed
J01RA11	J01RA11_1	ciprofloxacin_500mg - tinidazole_300mg(tab)	ciprofloxacin 500 mg/ tinidazole 600 mg	Tab	2 UD (=2 tab)	Ciprotini
J01RA11	J01RA11_2	ciprofloxacin_250mg - tinidazole_300mg(tab)	ciprofloxacin 250 mg/ tinidazole 300 mg	Tab	4 UD (=4 tab)	Ciptin
J01RA12	J01RA12_1	ciprofloxacin_500mg - ornidazole_500mg(tab)	ciprofloxacin 500 mg/ ornidazole 500 mg	Tab	2 UD (=2 tab)	Simprasole
J04AM02	J04AM02_1	Rifampicin_0.3g - isoniazid_0.15g	rifampicin 0.3 g/ isoniazid 0.15 g	Tab	2 UD (=2 tab)	Rifinah
J04AM02	J04AM02_2	Rifampicin_0.15g - isoniazid_0.1g	rifampicin 0.15 g/ isoniazid 0.1 g	Tab	4 UD (=4 tab)	Rifinah
J04AM02	J04AM02_3	Rifampicin_0.15g - isoniazid_75mg	rifampicin 0.15 g/ isoniazid 75 mg	Tab	4 UD (=4 tab)	Rimactazid
J04AM05	J04AM05_1	Rifampicin_0.12g - isoniazid_50mg - pyrazinamide_0.3g	rifampicin 0.12 g/ isoniazid 50 mg/ pyrazinamide 0.3 g	Tab	6 UD (=6 tab)	Rifater

J04AM05	J04AM05_2	Rifampicin0.15g - isoniazid_75mg - pyrazinamide_0.4g	rifampicin 0.15 g/ isoniazid 75 mg/ pyrazinamide 0.4 g	Tab	4 UD (=4 tab)	Rimcure
J04AM05	J04AM05_3	rifampicin_225mg - pyrazinamide_750mg - isoniazid_150mg(tab)	rifampicin 225 mg (1 tab)/ pyrazinamide 750 mg (1 tab)/ isoniazid 150 mg (1 tab) (combination package)	Tab	6 UD (=6 tab)	R-cinex
J04AM05	J04AM05_4	rifampicin_60mg - pyrazinamide_0.4g - isoniazid_30mg(tab)	rifampicin 60 mg/ pyrazinamide 150 mg/ isoniazid 30 mg	Tab	10 UD (=10 tab)	RHZ 60
J04AM06	J04AM06_1	Rifampicin - ethambutol - isoniazid - pyrazinamide	rifampicin 0.15 g/ ethambutol 0.275 g/ isoniazid 75 mg/ pyrazinamide 0.4 g	Tab	4 UD (=4 tab)	Rimstar
J04AM06	J04AM06_2	rifamp._0.45g-pyrazin._0.75g-ethambutol_0.8g–isoniazid_0.3g	rifampicin 450 mg (1 tab)/ pyrazinamide 750 mg (2 tab)/ethambutol 800 mg+isoniazid 300 mg (1 tab) (combination package)	Tab	4 UD (=4 tab)	AK-4
J04AM07	J04AM07_1	rifampicin_150mg - ethambutol_275mg - isoniazid_75mg(tab)	rifampicin 150 mg/ ethambutol 275 mg/ isoniazid 75 mg	Tab	4 UD (=4 tab)	3-FDC
J05AP51	J05AP51_1	sofosbuvir - ledipasvir	sofosbuvir 400 mg/ ledipasvir 90 mg	Tab	1 UD (=1 tab)	Harvoni
J05AP53	J05AP53_1	ombitasvir - paritaprevir ritonavir	ombitasvir 12.5 mg/ paritaprevir 75 mg/ ritonavir 50 mg	Tab	2 UD (=2 tab)	Technivie / Viekirax
J05AP54	J05AP54_1	elbasvir_50mg - grazoprevir_100mg	elbasvir 50 mg/ grazoprevir 100 mg	Tab	1 UD (=1 tab)	Zepatier

J05AP55	J05AP55_1	sofosbuvir_400mg - velpatasvir_100mg	sofosbuvir 400 mg/ velpatasvir 100 mg	Tab	1 UD (=1 tab)	Epclusa
J05AP57	J05AP57_1	glecaprevir_100mg - pibrentasvir_40mg(tab)	glecaprevir 100 mg/ pibrentasvir 40 mg	Tab	3 UD (=3 tab)	Maviret
J05AR01	J05AR01_1	Lamivudine - zidovudine	lamivudine 0.15 g/ zidovudine 0.3 g	Tab	2 UD (=2 tab)	Combivir
J05AR02	J05AR02_1	Abacavir - lamivudine	abacavir 0.6 g/ lamivudine 0.3 g	Tab	1 UD (=1 tab)	Kivexa
J05AR03	J05AR03_1	Emtricitabine - tenofovir disoproxil	emtricitabine 0.2 g/ tenofovir disoproxil 0.245 g	Tab	1 UD (=1 tab)	Truvada
J05AR04	J05AR04_1	Zidovudine - lamivudine - bacavir	zidovudine 0.3 g/ lamivudine 0.15 g/ abacavir 0.3 g	Tab	2 UD (=2 tab)	Trizivir
J05AR05	J05AR05_1	Lamivudine - nevirapine - zidovudine	lamivudine 150 mg/ nevirapine 200 mg/ zidovudine 300 mg	Tab	2 UD (=2 tab)	Lamivudine/Nevirapine/ Zidovudine 150mg/200mg/ 300mg
J05AR06	J05AR06_1	Emtricitabine - tenofovir disoproxil - efavirenz	emtricitabine 0.2 g/ tenofovir disoproxil 0.245 g/ efavirenz 0.6 g	Tab	1 UD (=1 tab)	Atripla
J05AR08	J05AR08_1	Emtricitabine - tenofovir disoproxil - rilpivirine	emtricitabine 0.2 g/ tenofovir disoproxil 0.245 g/ rilpivirine 0.025 g	Tab	1 UD (=1 tab)	Eviplera, Complera
J05AR09	J05AR09_1	Emtricitabine - tenofovir disoproxil - elvitegravir - cobicistat	emtricitabine 200 mg/ tenofovir disoproxil 245 mg/ elvitegravir 150 mg/ cobicistat 150 mg	Tab	1 UD (=1 tab)	Stribild

J05AR13	J05AR13_1	Lamivudine - abacavir - dolutegravir	lamivudine 300 mg/ abacavir 600 mg/ dolutegravir 50 mg	Tab	1 UD (=1 tab)	Triumeq
J05AR14	J05AR14	Darunavir -cobicistat	darunavir 800 mg/ cobicistat 150	Tab	1 UD (=1 tab)	Rezolsta/Prezcobix
J05AR15	J05AR15	Atazanavir - cobicistat	atazanavir 0.3 g/ cobicistat 0.15 g	Tab	1 UD (=1 tab)	Evotaz
J05AR17	J05AR17_1	Emtricitabine - tenofovir alafenamide	emtricitabine 200 mg/tenofovir alafenamide 10 mg	Tab	1 UD (=1 tab)	Descovy
J05AR17	J05AR17_2	Emtricitabine - tenofovir alafenamide	emtricitabine 200 mg /tenofovir alafenamide 25 mg	Tab	1 UD (=1 tab)	Descovy
J05AR18	J05AR18_1	Emtricitabine – tenofovir alafenamide - elvitegravir - cobicistat	emtricitabine 200 mg/ tenofovir alafenamide 10 mg/ elvitegravir 150 mg/ cobicistat 150 mg	Tab	1 UD (=1 tab)	Genvoya
J05AR19	J05AR19_1	Emtricitabin – tenofovir alafenamide - rilpivirine	emtricitabine 200 mg/tenofovir alafenamide 25 mg/rilpivirine 25 mg	Tab	1 UD (=1 tab)	Odefsey

Tab: tablet, Powder for inj: powder for injection, Caps: capsule, Mixt: Mixture, Inf conc: Infusion concentrate
*: for J01CE30 the StrengthUnit is given in grams

No DDDs were assigned for the ATC codes J05AP52 and J05AP56.

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