



TESSy - The European Surveillance System

Antimicrobial consumption (AMC) reporting protocol 2023

**European Surveillance of Antimicrobial Consumption Network
(ESAC-Net) surveillance data for 2022**

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Abbreviation list

AMC	Antimicrobial consumption
ATC	Anatomical Therapeutic Chemical
DDD	Defined Daily Dose
ECDC	European Centre for Disease Prevention and Control
ESAC-Net	European Surveillance of Antimicrobial Consumption Network
EU/EEA	European Union/European Economic Area
INN	International Nonproprietary Names
IU	International unit
NUTS	Nomenclature of Territorial Units for Statistics
PCS	Pieces
TESSy	The European Surveillance System
UD	Unit dose
UNK	Unknown
WHO	World Health Organization

How to use this document

This reporting protocol provides information for the countries' data managers on how to report antimicrobial consumption (AMC) data, in four sections:

- **Introduction** – a general overview of the data and metrics used by The European Surveillance of Antimicrobial Consumption Network (ESAC-Net)
- **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 – AMC metadata:**
 - AMC metadata changes 2022;
 - The metadata set for the subject(s) covered by this reporting protocol;
 - A history of previous AMC metadata changes.
- **Annex 2 – AMC-specific material:**
 - Information on reporting combined products;
 - Information on reporting oral liquid pharmaceutical form;
 - Anatomical Therapeutic Chemical (ATC) and Defined Daily Dose (DDD) updates;
 - List of TESSy combined products codes with DDDs and weight;
 - Examples.

Introduction

The European Surveillance of Antimicrobial Consumption Network (ESAC-Net)

The European Surveillance of Antimicrobial Consumption Network (ESAC-Net) is a European Union (EU)/European Economic Area (EEA)-wide network of national surveillance systems, providing European reference data on antimicrobial consumption (AMC). The network is coordinated by the European Centre for Disease Prevention and Control (ECDC) and covers all EU/EEA countries.

The technical platform for reporting AMC data to ECDC is The European Surveillance System (TESSy), a system that includes features for web-based data submission, data storage and dissemination. This Reporting Protocol describes how AMC data should be reported to TESSy. The TESSy homepage contains [additional guidance](#) for using TESSy and [disease-specific guidance](#).

Antimicrobials under ESAC-Net surveillance

To ensure standardisation and comparability, ESAC-Net uses the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) / Defined Daily Dose (DDD) system to classify antimicrobial substances and measure consumption. The ATC/DDD Index is updated annually and is available from the WHO Collaborating Centre for Drug Statistics Methodology (http://www.whocc.no/atc_ddd_index).

Antimicrobials under surveillance by ESAC-Net include:

- Antibacterials for systemic use (ATC subgroup J01);
- Antimycotics for systemic use (ATC subgroup J02);
- Antifungals for systemic use (subgroup D01BA);
- Drugs for treatment of tuberculosis (ATC subgroup J04A);
- Antivirals for systemic use (ATC subgroup J05);
- Intestinal antiinfectives (ATC subgroup A07AA);
- Nitroimidazole derivatives used orally and rectally as antiprotozoals (ATC subgroup P01AB).

National data sources

National AMC data sources used for ESAC-Net are either national sales or reimbursement data, including information from national drug registers. National data should preferably be collected at the medicinal product level.

Data should be reported for the community (primary care) and hospital sectors separately. If consumption cannot be differentiated between the two sectors, data can be reported as 'total care' (including both community and hospital sectors combined). This is not the preferred option and is only acceptable if the data cannot be subdivided by sector.

By default, TESSy uses Eurostat population data as population denominators, assuming national consumption data are complete. If the consumption data do not correspond with 100% population coverage, this needs to be indicated with the submitted data and a separate data file (AMCDENOM) needs to be uploaded to TESSy.

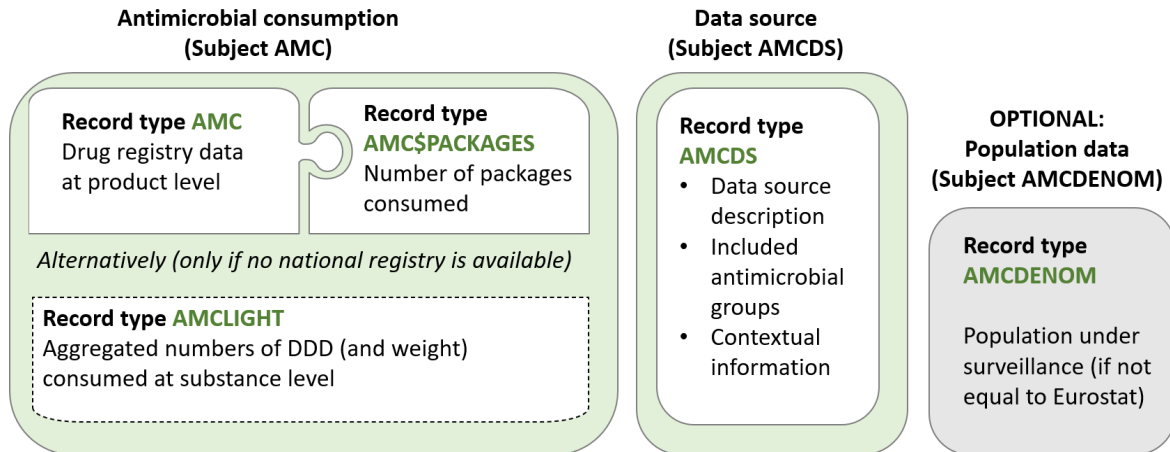
ESAC-Net data structure

TESSy includes three main surveillance subjects to capture ESAC-Net data:

- a) AMC to record consumption data;
- b) AMCDs to record contextual data source information;
- c) AMCDENOM to record population data associated with reported consumption data if different from Eurostat population.

An overview of the data subjects and the related record types is presented in Figure 1. The three subjects and their respective record types are described in more detail below, and a complete overview of all variables is available in Annex 1.

Figure 1. Overview of TESSy Subjects and Record Types used for ESAC-Net data



Antimicrobial consumption data

Antimicrobial consumption (Subject AMC) data can be reported through two options:

Option 1) Antimicrobial consumption at medicinal product level (preferred option)

For AMC, the preferred option is to provide data at the medicinal product level. This option includes two datasets:

- record type **AMC**: single (individual) antimicrobials at the product level. It contains the national registry data of all antimicrobials available in the country, even if not used during the reporting year;
- record type **AMC\$PACKAGES**: number of packages sold or reimbursed at the product level.

When using Option 1, TESSy will automatically calculate the number of DDDs and weight by linking the variable ParentId in record type **AMC\$PACKAGES** with the antimicrobial product listed in the record type **AMC** by using the variable RecordId.

Option 2) Antimicrobial consumption aggregated at substance level

This option provides the opportunity to report national AMC data at ATC substance level as an aggregated number of DDDs per 1 000 inhabitants per day. It is only acceptable when national registry data are not available.

The aggregated data option includes one dataset: record type **AMCLIGHT**, which contains aggregated antimicrobial consumption data expressed in DDD at the ATC substance level.

DDD and weights must be calculated by the national data managers before upload. Please note that in case of changes in DDD value, TESSy will not be able to automatically update historical data.

Please ensure that:

- For erythromycin and methenamine, the associated salt is provided (see ESAC-Net metadata);
- For combined products, a variable, CombinedProducts, must be reported to distinguish them and to assign appropriate DDDs. A detailed explanation can be found on [the ATC/DDD Index website](#) and a complete list of the products with DDDs can be found in Table 24.

Data source

The record type **AMCDS** contains information on the antimicrobial consumption data source, healthcare sectors covered (community, hospital or 'total care' sector), whether the data represent national reference data, and which groups of antimicrobials are included. Two variables offer the possibility to share comments on the data, either only with ECDC or publicly.

AMCDS data must be reported regardless of the option chosen to report consumption data. The level to which the data should be reported (community, hospital or 'total care') must reflect how data are reported for Subject AMC. Description of the data source (subject AMCDS with record type **AMCDS**) is essential to enable TESSy to calculate the number of DDDs per 1 000 inhabitants 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.

Population data (optional)

Eurostat population denominator data are preferred, and TESSy uses Eurostat populations as default population values. If the surveillance coverage is compatible with the Eurostat population, it is not necessary to submit any population denominator data to TESSy.

If the surveillance coverage is not compatible with the Eurostat population, it is necessary to provide denominator data at the same level as the level of consumption data (i.e., healthcare sector) through the record type **AMCDENOM**.

Metrics calculated by TESSy

The latest available ATC/DDD index is used for reporting data, and only antimicrobial substances with a designated ATC code and a corresponding DDD allocation will be included in ESAC-Net outputs.

The main indicator for monitoring the volume of AMC is DDD per 1000 inhabitants per day. This is calculated by TESSy using the latest WHO ATC/DDD index and the population provided by Eurostat (or if not applicable using the data provided through the Record type **AMCDENOM**).

In addition, the weight of the antibiotic substances in metric tonnes (t) is calculated to enable comparison with consumption in the animal sector.

Finding further information

Paragraphs denoted by the information icon  indicate 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](#), (accessible at the TESSy homepage with restricted access) that contains:

- Metadata sets and history.
- Tutorials for data transformation using respectively Microsoft Excel and Access.
- TESSy user documentation.
- CSV and XML transport protocols.

Reporting to TESSy

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

Important steps:

1. Data collection schedule
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.


Data collection schedule

National reference data for AMC should be reported once per year during the annual data call. The collection of 2022 AMC data in TESSy starts in March 2023 and closes on 1 July 2023. Data submitted after data collection closure and not actively validated before 20 August 2023 are not guaranteed to be included in the 2023 ESAC-Net data outputs.

 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 (only CSV and XML files can be submitted). This applies both to the type of file submitted to TESSy 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

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

To ensure that your data can be saved correctly in TESSy, you 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, **O**, **P**, **R**, **I** and **M** are the coded values for *AntimicrobialRoute* and any other value in a *AntimicrobialRoute* 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 AMC, AMCDs, and AMCDENOM). 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](#), (accessible at the TESSy homepage with restricted access) provides an overview of how you work with the metadata file, and the TESSy user documentation provides in-depth details on metadata.


Checking 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 should be considered 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 data

The data are 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 and approving 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 all necessary corrections regarding the TESSy warnings have been made, please ensure prompt approval – **unapproved uploads can block the approval process for uploads of other countries**.

 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 (always include esac-net@ecdc.europa.eu in copy)

Telephone number: **+46-(0)8-5860 1601**

Availability: 09:00 – 16:00 Stockholm time, Monday to Friday (except ECDC Holidays)

On country request, ECDC will offer webinars and individual coaching how to upload data to TESSy, as well as the latest metadata changes. The webinars can be requested by the National Focal Point and will be available for the data managers in charge of uploading national consumption data.

Annex 1: Antimicrobial consumption (AMC) metadata

AMC metadata changes 2023


For the 2023 metadata, **the following variables have been removed** from the record types **AMC\$PACKAGES** and **AMCLIGHT**:

- PlaceOfNotification
- AgeClass
- Gender
- Prescriber

These variables were previously optional and were not used for any analyses due to inconsistent reporting and inability to derive useful findings from them.

Each year, the AMC metadata is updated with the latest ATC/DDD Index. These updates are outlined in Tables 19–23 of Annex 2. TESSy updates historical DDD values and calculated AMC rates (expressed as DDD per 1 000 inhabitants per day) based on the most recent ATC/DDD index when record type **AMC** is reported. For record type **AMCLIGHT**, calculations are not updated as DDD values are calculated and reported by the countries themselves.

In 2019, the ATC/DDD index included several updates with DDD alterations for nine frequently consumed antimicrobial agents ([WHO Collaborating Centre, Annual Epidemiological ESAC-Net report 2018](#)). ECDC manually updated reported aggregated DDD numbers for all historical ESAC-Net data reported, i.e., for all years before 2019 for which countries had reported AMC data using **AMCLIGHT**.

 Information on changes to the metadata for other subjects is available on the TESSy documentation website. Previous metadata changes are described in Table 18 this Annex.

Current record type versions

Table 1 shows the record types and record type versions that must be used when uploading 2022 AMC surveillance data to TESSy. As there have been changes to the variables for Subject AMC, the record type versions for **AMC**, **AMC\$Packages**, and **AMCLIGHT** have been updated this year.

Table 1. Accepted record types and record type versions

Subject		Record type version	Description
AMC	Standard (case-based)	AMC.6	National registry data of all antimicrobials available.
		AMC\$PACKAGES.6	AMC data linked to the national registry.
	Light (aggregated)	AMCLIGHT.4	Consumption data (expressed as DDD).
AMCDENOM (aggregated)		AMCDENOM.1	Denominator / population corresponding to AMC coverage.
AMCDS (aggregated)		AMCDS.3	Data source information for AMC data.

Metadata for antimicrobial consumption surveillance

The description of each variable used for reporting of the datasets of AMC 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, AMC 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.
Description	Description of a possible value for a specific variable.
Required	Whether variable is mandatory or not.
Data type	Textual, numeric, coded value.
Code	Code as accepted by the system.
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 corresponding fields have been completed.

Record type AMC - national registry data for all available antimicrobials

Table 2. Technical variables for AMC record type.

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

VariableName	1 - RecordID
Description	Unique identifier for the product in the reported year. Possible format: ReportingCountry + Year + ProductId. The Record ID represents the variable ParentId of the record type AMC&PACKAGES
Required (what happens if not submitted)	Yes (Error)
Data type	String (Text; max length: 80 characters)
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., 6)
Validation rule	-
VariableName	4 - Subject
Description	Subject of the data reported (see Table 1)).
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 (Error)
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 AMC record type

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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)	Yes (Error)
Data type	String (Text; max length: 80 characters)
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 (Text; max length: 80 characters)
Validation rule	-
VariableName	11 - PackageSize
Description	Package size or number of single items (e.g., tablets) in the package. Tablets/capsules: Do not provide the unit (e.g., if a package contains 60 tablets, just report "60", not "60 tablets"). Bottles, vials and inhalators: Note that vials, bottles and inhalators are quantified in number of items and not quantified by their volume. Ensure that the variable "Strength" refers to the total quantity of the active ingredients See How to report medicinal products in vials or syrup forms)
Required (what happens if not submitted)	Yes (Error)
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 single item. Tablets/capsules: Provide the amount of active ingredients per tablet/capsule. Bottles, vials and inhalators: Ensure the total amount of the ingredients in the package is reported. For multi-ingredient medicinal products, this field must contain the ingredient strength in which the DDD is expressed (e.g., for the parenteral route of administration, amoxicillin/clavulanic acid combinations: strength expresses the strength of amoxicillin since DDD=3 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 (Text; max length: 80 characters)
Validation rule	Strength must be a positive integer or float (up to 3 decimals)
VariableName	14- StrengthUnit
Description	Unit of the strength reported.
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 as A07AA02, A07AA05 or J01XB01, then StrengthUnit must be reported as IU or MU. If ATCCode is reported different than A07AA02, A07AA05, J01XB01 then StrengthUnit must be reported as G or MG. If combined products are reported, then StrengthUnit must be reported as Unit Doses (UD) with the exception of ATC code J01CE30, where StrengthUnit is reported in grams (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 rules	1. If Antimicrobial Route is reported as "I", then Inhalation Form should be reported as "IP" (inhalation powder) or "IS" (inhalation solution). 2. If Antimicrobial Route is reported different than "I", then Inhalation Form should not be reported. 3. If ATCCode is reported as J01FA01 (erythromycin) and AntimicrobialRoute is reported as O (oral), then Salt -if reported- can only be reported as ESUC (ethylsuccinate). 4. If ATCCode is reported as J01FA01 (erythromycin) and AntimicrobialRoute is reported different than O (oral), then Salt must not be reported.

	<p>5. If AntimicrobialRoute is reported different than "O" then SyrupForm must be reported as NA.</p> <p>6. If AntimicrobialRoute is reported as "O" then SyrupForm must be reported as Y/N.</p>
VariableName	16- SyrupForm
Description	All antimicrobials administered orally as a liquid (syrup, oral powder, oral solution, oral suspension) (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 pharmaceutical form of the drug for inhalation, i.e., inhalation powder or inhalation solution. Note that for tobramycin (J01GB01), the DDD differs by inhalation form.
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)
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 pharmaceutical 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 – 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 - (<i>Allocations of defined daily doses for combined products in TESSy</i>)
Validation rule	If ATCCode is not equal to the first 7 characters (before “_”) of the code indicated in CombinedProduct.

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

Table 4. Technical variables for AMC\$PACKAGES record type

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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 (Text; max length: 80 characters)
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 in the year reported. Recommended format: ReportingCountry + Year + ProductId. ParentId represented by the corresponding variable RecordID exists in the AMC record type.
Required (what happens if not submitted)	Yes (Error)
Data type	String (Text; max length: 80 characters)
Validation rule	-

Table 5. Epidemiological variables for record type AMC\$PACKAGES

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

VariableName	4 - 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	5 - 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	6 - NumberOfPackages
Description	Number of packages consumed the reported sector and period.
Required (what happens if not submitted)	Yes (Error)
Data type	Numeric
Validation rule	NumberOfPackages must be an integer or float (up to 3 decimals).

Record type AMCLIGHT - (aggregated number of DDDs reported)

Table 6. Technical variables for record type AMCLIGHT

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

VariableName	1 - RecordType
Description	Structure and format of the data (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., 4)
Validation rule	-
VariableName	3 - Subject

Description	Subject of the data reported
Required (what happens if not submitted)	Yes (Error)
Data type	Coded Value
Code	AMC
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 (Error)
Data type	Coded Value
Code	See ESAC-Net metadata
VariableName	6 - DateUsedForStatistics
Description	Year of reporting, with option of reporting by quarter.
Required (what happens if not submitted)	Yes (Error)
Data type	Date
Code	Year (YYYY, YYYY-Qq)

Table 7. Epidemiological variables for AMCLIGHT record type

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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 - 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).
Validation rule	-

VariableName	9 - ATCName
Description	ATC name of the substance (ATC 5th level).
Required (what happens if not submitted)	No
Data type	String (Text; max length: 80 characters)
Validation rule	-
VariableName	10 – 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 - (<i>Allocations of defined daily doses for combined products in TESSy</i>)
Validation rule	If ATCCode is not equal to the first 7 characters (before “_”) of the code indicated in CombinedProduct.
VariableName	11 - 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	12 - 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 pharmaceutical 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	13 - NumberOfDDD
Description	Number of DDD used for the reported substance, healthcare sector and period.
Required (what happens if not submitted)	Yes (Error)
Data type	String (Text; max length: 80 characters)
Validation rule	NumberOfDDD must be an integer or float (up to 3 decimals).

VariableName	14 - Weight
Description	Number of weight units (total weight corresponding to the reported NumberOfDDD).
Required (what happens if not submitted)	Yes (Error)
Data type	String (Text; max length: 80 characters)
VariableName	15 - WeightUnit
Description	Unit of the weight.
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	G = Gram; IU = International unit; MG = Milligram; MU = Million units; UD = Unit dose
Validation rule	
VariableName	16- SyrupForm
Description	All antimicrobials administered orally as a liquid (syrup, oral powder, oral solution, oral suspension) (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

Record type AMCDENOM - Denominator / Population under surveillance

Table 8. Technical variables for record type AMCDENOM

This record type must only be reported in case TESSy is not using Eurostat data as denominator. Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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

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 (Error)
Data type	Coded Value
Code	See ESAC-Net metadata
Validation rule	-
VariableName	6 - DateUsedForStatistics
Description	Year of reporting, with option of reporting quarters.
Required (what happens if not submitted)	Yes (Error)
Data type	Date
Code	Year (yyyy, yyyy-Qq)
Validation rule	-

Table 9. Epidemiological variables for AMCDENOM

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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 - 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 10. Technical variables for record type AMCDS

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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., 3)
Validation rule	-
VariableName	3 - Subject
Description	Subject of the data reported
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 (Error)
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 (Error)
Data type	Date
Code	Year (YYYY)
Validation rule	-
VariableName	7- NationalReferenceData
Description	Are data reported as national reference data?
Required (what happens if not submitted)	Yes (Error)
Data type	Coded value
Code	Y = Yes, N = No
Validation rule	-

Table 11. Epidemiological variables for record type AMCDs - community (primary care)
Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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)?
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_ATCVersionAlteredAC
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_ATCVersionAlteredAC, 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 12. Denominator data for record type AMCDs - community (primary care)

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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 13. Epidemiological variables for record type AMCDs - Hospital care

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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_ATCVersionAlteredHC
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_ATCVersionAlteredHC, 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 14. Denominator data for record type AMCDs - Hospital care

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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 15. Epidemiological variables for record type AMCDs – ‘Total care’

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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_ATCVersionAlteredTC
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_ATCVersionAlteredTC, 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 16. Denominator data for record type AMCDs – 'Total care'

Green cells represent variables that are mandatory to report, grey cells represent optional variables.

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 17. Summary variables for record type AMCDS

Green cells represent variables that are mandatory to report, grey cells represent optional 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

Table 18. Implemented changes in record types for AMC through 2022

Year	Record types	Variable(s)	Description
2022	AMC\$PACKAGES	PlaceOfNotification AgeClass	These variables were removed.
	AMCLIGHT	Gender Prescriber	These optional variables have not been used for any of the analyses due to inconsistent reporting and inability to derive useful findings from them.
2019	AMC	DPPNational DDDNational DDDNationalUnit	These variables were removed. The possibility to report nationally DDDs was important in the early days of ESAC-Net when the WHO Collaborating Centre for Drug Statistics Methodology had not yet allocated a DDD for all antimicrobial agents. These variables are now obsolete because nearly all antimicrobial agents have been assigned a WHO DDD.
	AMC	PackageContent PackageContentUnit	These variables were removed. The variables were originally created for internal validation purposes. However, they are now obsolete. TESSy computes the package content from other existing variables: the package size, strength and basic quantity ingredient.
	AMC	CombinedProduct	A validation rule was added to validate the correct uploading of the strength unit for combined products.
	AMCLIGHT	SyrupForm	The variable was added as mandatory variable for the oral route of administration. It will help assess the paediatric consumption for all ESAC-Net AMC data. A similar variable exists in the standard version of reporting ESAC-Net AMC data.
	AMCLIGHT record type:	Weight WeightUnit	These variables were added as mandatory variables They will be used as indicator in the ECDC Atlas of Infectious Diseases and are also required for the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Report (European Commission request; comparison with the animal consumption).
2016	AMC	CombinedProduct	New variable
	AMCLIGHT		
	AMCDS	Error message for: <ul style="list-style-type: none"> - DS_ATCVersionAC(HT,TC) - DS_ATCVersionAlteredAC(HT,TC) - DS_CoverageAC(HT,TC) - DS_J01InclusionAC(HT,TC) - DS_J02InclusionAC(HT,TC) - DS_J04InclusionAC(HT,TC) - DS_J05InclusionAC(HT,TC) <p>If DS_DataProviderAC(HT,TC) and one of the previous variables is not reported</p> <p>Warning message if DS_EurostatDataAC(HT,TC)=N and DS_DataProviderDenomAC(HT,TC) is not reported</p>	

Metadata changes prior to 2016 can be found on the TESSy documents website.
There were no metadata changes in 2017, 2018 and 2021.

Annex 2: Antimicrobial consumption (AMC) specific material

This annex covers:

- Reporting combined products
- Reporting oral liquid pharmaceutical form
- ATC and DDD updates
 - DDDs for combined products
 - Examples – examples of reporting data on the consumption of liquids, and on consumption and population coverage

Reporting combined products

Products containing two or more active ingredients are regarded as combined products and their DDDs are expressed in unit doses (UD). According to the [list of combined products from the WHO Collaborating Centre for Drug Statistics Methodology](#), 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, four different combinations of the active ingredients such as 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 – cloxacillin_0.25g → Powder for injection
- c) J01CR50: ampicillin_0.5g – cloxacillin_0.5g → Powder for injection
- d) J01CR50: ampicillin_0.125g – cloxacillin_0.125g → Tablets

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

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

Different DDDs are assigned to each of the combined products a) - g) above. As it is impossible to distinguish them by ATC code, a further variable is necessary in the TESSy metadata.

Thus, the variable CombinedProduct was created. This variable is composed of the ATC code and the addition of a numerical element after an underscore symbol (_). The products of the previous example are classified with the following codes of the variable CombinedProduct:

- a) J01CR50_1
- b) J01CR50_5
- c) J01CR50_6
- d) J01CR50_7
- e) J01CR50_2
- f) J01CR50_3
- g) J01CR50_4

A list of all products that require values for the CombinedProduct variable can be found in Table 24 in this annex. In addition, [a practical example how to report consumption](#) for these combined products is provided in the last section of this annex.

Reporting oral liquid pharmaceutical form (variable SyrupForm)

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

The variable *SyrupForm* is used for **all antimicrobials** that are administered **orally as a liquid**. The variable SyrupForm does not only correspond to the pharmaceutical form 'syrup' 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**.

ATC and DDD updates

The ATC/DDD Index 2023 should be used for reporting AMC data during the call for data during 2023 (referring to 2022 data).

In addition to new ATC codes and DDD allocations for the ATC/DDD Index 2023, the TESSy metadata this year will also include new ATC codes and DDD allocations that have been finalised for publication in the ATC/DDD Index 2024 (for example, DDD for J01DI04 cefiderocol).

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/

New ATC codes, ATC changes, DDD updates and allocations of defined daily doses for combined products in TESSy are provided in Tables 19–23.

ATC/DDD updates 2023

Table 19. New ATC codes

Year	ATC code	ATC Name (active substance; INN)
2023	J01RA16	cefixime and azithromycin
	J02AX07	ibrexafungerp
	J02AX08	rezafungin acetate
	J04BA50	dapsone and rifampicin
	J04BA51	dapsone, rifampicin and clofazimine
	J05AB18	molnupiravir
2024*	J05AE30	nirmatrelvir and ritonavir
	J01DC52	Cefuroxime and beta-lactamase inhibitor
	J01DE51	Cefepime and beta-lactamase inhibitor

INN: international Nonproprietary Name

* Preliminary codes to be published in 2024 are included as they have been finalised by the WHO Collaborating Centre for Drug Statistics Methodology and consumption and may already be reported by countries.

Table 20. New DDD allocations

Year	ATC code	ATC Name (active substance; INN)	Route	DDD value	DDD unit
2023	J01GB06	amikacin	Inhal.solution	0.59	g
	J05AB18	molnupiravir	O	1.6	g
	J05AE30	nirmatrelvir and ritonavir*	O	0.6	g
2024**	J01AA13	eravacycline	P	0.14	g
	J01DC52	cefuroxime and beta-lactamase inhibitor	O	0.5	g
	J01DI04	cefiderocol	P	6	g
	J05AH04	laninamivir	Inhal.solution	0.16	g
	J05AX28	bulevirtide	P	2	mg

O: oral, P: parenteral

*refers to nirmatrelvir

** Preliminary DDDs to be published in 2024 are included as they have been finalised by the WHO Collaborating Centre for Drug Statistics Methodology and consumption and may already be reported by countries.

Table 21. ATC alterations

Year	Previous ATC Code	ATC Name (active substance; INN)	NewATC Code
There are no ATC alterations defined in the ATC/DDD Index 2023.			

Table 22. ATC level name alterations

Year	Previous ATC level name	ATC code	New ATC level name
There are no ATC level name alterations defined in the ATC/DDD Index 2023.			

Table 23. DDD alterations

Year	ATC Code	ATC Name (active substance; INN)	route	Old DDD	New DDD
There are no DDD alterations defined in the ATC/DDD Index 2023.					

List of TESSy combined product codes, 2023

Table 24. List of combined products codes 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)	Dosage form	Brand name	Conversions used for TESSy calculations	
						Weight per one DDD	No. of UD* per one DDD
J01AA20	J01AA20_1	tetracycline - chlortetracycline - demeclocycline	tetracycline 115.4 mg / chlortetracycline 115.4 mg / demeclocycline 69.2 mg	Tab	Deteco	0.6 gram	2 UD (=2 tab)
J01CA20	J01CA20_1	pivampicillin_0.25g - pivmecillinam_0.2g	pivampicillin 0.25 g / pivmecillinam 0.2 g	Tab	Miraxid	1.35 grams	3 UD (=3 tab)
J01CA20	J01CA20_2	pivampicillin_0.125g - pivmecillinam_0.1g	pivampicillin 0.125 g / pivmecillinam 0.1 g	Tab	Miraxid mite	1.35 grams	6 UD (=6 tab)
J01CE30	J01CE30_1	benzylpenicillin/procaine - benzylpenicillin/benzathine benzylpenicillin	benzylpenicillin/procaine-benzylpenicillin/benzathine benzylpenicillin	Powder for inj	Bicillin C-R, Bicillin A-P, Bicillin	3.6 grams	3.6 g* expressed as benzylpenicillin
J01CR50	J01CR50_1	ampicillin_0.25g - cloxacillin_0.25g	ampicillin 0.25 g / cloxacillin 0.25 g	Tab	Ampiclox	2 grams	4 UD (=4 tab)
J01CR50	J01CR50_2	ampicillin_0.66g - oxacillin_0.33g	ampicillin 0.66 g / oxacillin 0.33 g	Powder for inj	Ampoxium	1.98 grams	2 UD (= 2 g)
J01CR50	J01CR50_3	Ampicillin_0.125g - oxacillin_0.125g	ampicillin 0.125g / oxacillin 0.125 g	Caps	Ampoxium	2 grams	8 UD (= 8 caps)
J01CR50	J01CR50_4	ampicillin_0.25g - flucloxacillin_0.25g	ampicillin 0.25 g / flucloxacillin 0.25 g	Tab	Co-fluampicil	2 grams	4 UD (=4 tab)
J01CR50	J01CR50_5	ampicillin_250mg - cloxacillin_250mg	ampicillin 250 mg / cloxacillin 250 mg	Powder for inj	Vicillin-S	2 grams	2 UD (=2 grams of powder for injection)

ATC code	CombinedProduct (variable to be reported)	Variable description in TESSy metadata	Active ingredients per one unit dose (UD)	Dosage form	Brand name	Conversions used for TESSy calculations	
						Weight per one DDD	No. of UD* per one DDD
J01CR50	J01CR50_6	ampicillin_500mg - cloxacillin_500mg	ampicillin 500 mg / cloxacillin 500 mg	Powder for inj	Viccillin-S	2 grams	2 UD (=2 grams of powder for injection)
J01CR50	J01CR50_7	ampicillin_125mg - cloxacillin_125mg	ampicillin 125 mg / cloxacillin 125 mg	Tab	Viccillin-S	2 grams	8 UD (=8 tab)
J01CR50	J01CR50_8	ampicillin_250mg - cloxacillin_250mg	ampicillin 250 mg / cloxacillin 250 mg	Tab	Betaclox	2 grams	4 UD (=4 tab)
J01EC20	J01EC20_1	sulfacarbamide - sulfadiazine - sulfadimidine	sulfacarbamide 0.167 g / sulfadiazine 0.167 g / sulfadimidine 0.167 g	Tab	Trisulfamid	2.004 grams	4 UD (=4 tab)
J01EE01	J01EE01_1	sulfamethoxazole_80mg - trimethoprim_16mg	In 1mL: sulfamethoxazole 80 mg / trimethoprim 16 mg	Inf conc	Bactrim, Eusaprim, Trimetoprim-sulfa	1.6 grams sulfamethoxazole 0.32 gram trimethoprim	20 UD (=20 ml)
J01EE01	J01EE01_2	sulfamethoxazole_0.2g - trimethoprim_40mg	In 5 mL: sulfamethoxazole 0.2 g / trimethoprim 40 mg	Mixt	Bactrim, Eusaprim, Trimetoprim-sulfa	1.6 grams sulfamethoxazole 0.32 gram trimethoprim	8 UD (= 40 ml)
J01EE01	J01EE01_3	sulfamethoxazole_0.4g - trimethoprim_80mg	sulfamethoxazole 0.4 g / trimethoprim 80 mg	Tab	Bactrim, Eusaprim Trimetoprim-sulfa	1.6 grams sulfamethoxazole 0.32 gram trimethoprim	4 UD (=4 tab)
J01EE02	J01EE02_1	sulfadiazine_0.205g - trimethoprim_45mg	sulfadiazine 0.205 g / trimethoprim 45 mg	Mixt	Triglobe, Trimin Sulfa	0.82 gram sulfa. 0.18 gram trim.	4 UD (=20 ml)
J01EE02	J01EE02_2	sulfadiazine_0.41g - trimethoprim_90mg	sulfadiazine 0.41 g / trimethoprim 90 mg	Tab	Triglobe, Trimin Sulfa	0.82 gram sulfa. 0.18 gram trim.	2 UD (=2 tab)

ATC code	CombinedProduct (variable to be reported)	Variable description in TESSy metadata	Active ingredients per one unit dose (UD)	Dosage form	Brand name	Conversions used for TESSy calculations	
						Weight per one DDD	No. of UD* per one DDD
J01EE03	J01EE03_1	sulfametrole_0.8g - trimethoprim_0.16g(tab)	sulfametrole 0.8 g / trimethoprim 0.16 g	Tab	Lidaprim	1.6 grams sulfa. 0.32 gram trim.	2 UD (=2 tab)
J01EE03	J01EE03_2	sulfametrole_0.8g - trimethoprim_0.16g(powd)	sulfametrole 0.8 g / trimethoprim 0.16 g per vial	Powder for inj	Lidaprim	1.6 grams sulfa. 0.32 gram trim.	2 UD (defined as 2 vials)
J01EE06	J01EE06_1	sulfadiazin - tetroxoprim	sulfadiazin 0.25 g / tetroxoprim 0.1 g	Tab	Sterinor	0.5 gram sulfa. 0.2 gram tetro.	2 UD (=2 tab)
J01EE07	J01EE07_1	sulfamerazin - trimethoprim	sulfamerazin 0.12 g / trimethoprim 80 mg	Tab	Berlocombin	0.48 gram sulfa. 0.32 gram trim.	4 UD (=4 tab)
J01RA04	J01RA04_1	spiramycin 1.5 MU - metronidazole 250 mg	spiramycin 1.5 MU / (1MU=0.31g) metronidazole 250 mg	Tab	Bidontogyl	1.395 grams spira. 0.75 gram metro.	3 UD (=3 tab)
J01RA04	J01RA04_2	spiramycin 0.75 MU - metronidazole 125 mg	spiramycin 0.75 MU / metronidazole 125 mg	Tab	Orogyl	1.395 grams spira. 0.75 gram metro.	6 UD (=6 tab)
J01RA05	J01RA05_1	levofloxacin_250mg - ornidazole_500mg(tab)	levofloxacin 250 mg / ornidazole 500 mg	Tab	Duobact	1.5 grams	2 UD (=2 tab)
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	Safocid	3.15 grams	4 UD (=4 tab)
J01RA09	J01RA09_1	ofloxacin_200mg - ornidazole_500mg(tab)	ofloxacin 200 mg / ornidazole 500 mg	Tab	Oflox Oz	1.4 grams	2 UD (=2 tab)
J01RA10	J01RA10_1	ciprofloxacin_500mg - metronidazole_200mg(tab)	ciprofloxacin 500 mg / metronidazole 200 mg	Tab	Cipramed	1.4 grams	2 UD (=2 tab)
J01RA11	J01RA11_1	ciprofloxacin_500mg - tinidazole_300mg(tab)	ciprofloxacin 500 mg / tinidazole 600 mg	Tab	Ciprotini	2.2 grams	2 UD (=2 tab)

ATC code	CombinedProduct (variable to be reported)	Variable description in TESSy metadata	Active ingredients per one unit dose (UD)	Dosage form	Brand name	Conversions used for TESSy calculations	
						Weight per one DDD	No. of UD* per one DDD
J01RA11	J01RA11_2	ciprofloxacin_250mg - tinidazole_300mg(tab)	ciprofloxacin 250 mg / tinidazole 300 mg	Tab	Ciptin	2.2 grams	4 UD (=4 tab)
J01RA12	J01RA12_1	ciprofloxacin_500mg - ornidazole_500mg(tab)	ciprofloxacin 500 mg / ornidazole 500 mg	Tab	Simprasole	2 grams	2 UD (=2 tab)
J01RA13	J01RA13_1	norfloxacin_400 mg - tinidazole_600 mg	norfloxacin 400 mg / tinidazole 600 mg	Tab	Actiflox-T	2 grams	2 UD (=2 tab)
J01RA13	J01RA13_2	norfloxacin_0.4 g - tinidazole_0.6 g	norfloxacin 0.4 g / tinidazole 0.6 g	Tab	Tricogyn- N, Norzol	2 grams	2 UD (=2 tab)
J01RA16	J01RA16_1	cefixime_200 mg – azithromycin 250 mg	cefixime_200 mg / azithromycin 250 mg	Tab	Zifi-Az	0.9 gram	2 UD (= 2 tab)
J04AM02	J04AM02_1	rifampicin_0.3g - isoniazid_0.15g	rifampicin 0.3 g / isoniazid 0.15 g	Tab	Rifinah	0.9 gram	2 UD (=2 tab)
J04AM02	J04AM02_2	rifampicin_0.15g - isoniazid_0.1g	rifampicin 0.15 g / isoniazid 0.1 g	Tab	Rifinah	1 gram	4 UD (=4 tab)
J04AM02	J04AM02_3	rifampicin_0.15g - isoniazid_75mg	rifampicin 0.15 g / isoniazid 75 mg	Tab	Rimactazid	0.9 gram	4 UD (=4 tab)
J04AM05	J04AM05_1	rifampicin_0.12g - isoniazid_50mg - pyrazinamide_0.3g	rifampicin 0.12 g / isoniazid 50 mg / pyrazinamide 0.3 g	Tab	Rifater	2.82 grams	6 UD (=6 tab)
J04AM05	J04AM05_2	rifampicin0.15g - isoniazid_75mg - pyrazinamide_0.4g	rifampicin 0.15 g / isoniazid 75 mg / pyrazinamide 0.4 g	Tab	Rimcure	2.5 grams	4 UD (=4 tab)
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	R-cinex	2.25 grams	6 UD (=6 tab)

ATC code	CombinedProduct (variable to be reported)	Variable description in TESSy metadata	Active ingredients per one unit dose (UD)	Dosage form	Brand name	Conversions used for TESSy calculations	
						Weight per one DDD	No. of UD* per one DDD
J04AM05	J04AM05_4	rifampicin_60mg - pyrazinamide_150 mg - isoniazid_30mg(tab)	rifampicin 60 mg / pyrazinamide 150 mg / isoniazid 30 mg	Tab	RHZ 60	2.4 grams	10 UD (=10 tab)
J04AM06	J04AM06_1	rifampicin - ethambutol - isoniazid - pyrazinamide	rifampicin 0.15 g / ethambutol 0.275 g / isoniazid 75 mg / pyrazinamide 0.4 g	Tab	Rimstar	3.6 grams	4 UD (=4 tab)
J04AM06	J04AM06_2	rifampicin_0.45g - pyrazinamide_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	AK-4	3.05 grams	4 UD (=4 tab)
J04AM07	J04AM07_1	rifampicin_150mg - ethambutol_275mg - isoniazid_75mg (tab)	rifampicin 150 mg / ethambutol 275 mg / isoniazid 75 mg	Tab	3-FDC	2.0 grams	4 UD (=4 tab)
J05AP51	J05AP51_1	sofosbuvir - ledipasvir	sofosbuvir 400 mg / ledipasvir 90 mg	Tab	Harvoni	0.49 gram	1 UD (=1 tab)
J05AP51	J05AP51_2	sofosbuvir - ledipasvir	sofosbuvir 150 mg / ledipasvir 33.75 mg	granules, single dose sachets	Harvoni	0.551 gram	3 UD (=3 sachets)
J05AP51	J05AP51_3	sofosbuvir - ledipasvir	sofosbuvir 200 mg / ledipasvir 45 mg	granules, single dose sachets	Harvoni	0.49 gram	2 UD (=2 sachets)
J05AP51	J05AP51_4	sofosbuvir - ledipasvir	sofosbuvir 200 mg / ledipasvir 45 mg	Tab	Harvoni	0.49 gram	2 UD (=2 tab)
J05AP53	J05AP53_1	ombitasvir - paritaprevir - ritonavir	ombitasvir 12.5 mg / paritaprevir 75 mg / ritonavir 50 mg	Tab	Technivie, Viekirax	0.275 gram	2 UD (=2 tab)

ATC code	CombinedProduct (variable to be reported)	Variable description in TESSy metadata	Active ingredients per one unit dose (UD)	Dosage form	Brand name	Conversions used for TESSy calculations	
						Weight per one DDD	No. of UD* per one DDD
J05AP54	J05AP54_1	elbasvir_50mg - grazoprevir_100mg	elbasvir 50 mg / grazoprevir 100 mg	Tab	Zepatier	0.15 gram	1 UD (=1 tab)
J05AP55	J05AP55_1	sofosbuvir_400mg - velpatasvir_100mg	sofosbuvir 400 mg / velpatasvir 100 mg	Tab	Epclusa	0.5 gram	1 UD (=1 tab)
J05AP56	J05AP56_1	sofosbuvir_400mg - velpatasvir_100mg - voxilaprevir_100mg	sofosbuvir 400 mg / velpatasvir 100 mg / voxilaprevir 100 mg	Tab	Vosevi	0.6 gram	1 UD (=1 tab)
J05AP57	J05AP57_1	glecaprevir_100mg - pibrentasvir_40mg(tab)	glecaprevir 100 mg / pibrentasvir 40 mg	Tab	Maviret	0.14 gram	3 UD (=3 tab)
J05AR01	J05AR01_1	lamivudine - zidovudine	lamivudine 0.15 g / zidovudine 0.3 g	Tab	Combivir	0.42 gram	2 UD (=2 tab)
J05AR02	J05AR02_1	abacavir - lamivudine	abacavir 0.6 g / lamivudine 0.3 g	Tab	Kivexa	0.9 gram	1 UD (=1 tab)
J05AR03	J05AR03_1	emtricitabine - tenofovir disoproxil	emtricitabine 0.2 g / tenofovir disoproxil 0.245 g	Tab	Truvada	0.445 gram	1 UD (=1 tab)
J05AR04	J05AR04_1	zidovudine - lamivudine - abacavir	zidovudine 0.3 g / lamivudine 0.15 g / abacavir 0.3 g	Tab	Trizivir	1.5 grams	2 UD (=2 tab)
J05AR05	J05AR05_1	lamivudine - nevirapine - zidovudine	lamivudine 150 mg / nevirapine 200 mg / zidovudine 300 mg	Tab	Lamivudine/ Nevirapine/ Zidovudine 150mg/200mg/ 300mg	1.3 grams	2 UD (=2 tab)
J05AR06	J05AR06_1	emtricitabine - tenofovir disoproxil - efavirenz	emtricitabine 0.2 g / tenofovir disoproxil 0.245 g / efavirenz 0.6 g	Tab	Atripla	1.045 grams	1 UD (=1 tab)

ATC code	CombinedProduct (variable to be reported)	Variable description in TESSy metadata	Active ingredients per one unit dose (UD)	Dosage form	Brand name	Conversions used for TESSy calculations	
						Weight per one DDD	No. of UD* per one DDD
J05AR08	J05AR08_1	emtricitabine - tenofovir disoproxil - rilpivirine	emtricitabine 0.2 g / tenofovir disoproxil 0.245 g / rilpivirine 0.025 g	Tab	Eviplera, Complera	0.47 gram	1 UD (=1 tab)
J05AR09	J05AR09_1	emtricitabine - tenofovir disoproxil - elvitegravir - cobicistat	emtricitabine 200 mg / tenofovir disoproxil 245 mg / elvitegravir 150 mg / cobicistat 150 mg	Tab	Stribild	0.7465 gram	1 UD (=1 tab)
J05AR11	J05AR11_1	lamivudine – tenofovir disoproxil - efavirenz	lamivudine 300 mg / tenofovir disoproxil 300 mg (fumarate) / efavirenz 600 mg	Tab	Efavirenz/Lamivudine/Tenofovir	1.2 grams	1 UD (=1 tab)
J05AR12	J05AR12_1	lamivudine - tenofovir disoproxil	lamivudine 300 mg / tenofovir disoproxil 300 mg (fumarate)	Tab	Lamivudine and Tenofovir	0.6 gram	1 UD (=1 tab)
J05AR13	J05AR13_1	lamivudine - abacavir - dolutegravir	lamivudine 300 mg / abacavir 600 mg / dolutegravir 50 mg	Tab	Triumeq	0.95 gram	1 UD (=1 tab)
J05AR14	J05AR14_1	darunavir - cobicistat	darunavir 800 mg / cobicistat 150 mg	Tab	Rezolsta, Prezcofix	0.95 gram	1 UD (=1 tab)
J05AR15	J05AR15_1	atazanavir - cobicistat	atazanavir 0.3 g / cobicistat 0.15 g	Tab	Evotaz	0.45 gram	1 UD (=1 tab)
J05AR17	J05AR17_1	emtricitabine - tenofovir alafenamide	emtricitabine 200 mg / tenofovir alafenamide 10 mg	Tab	Descovy	0.21 gram	1 UD (=1 tab)
J05AR17	J05AR17_2	emtricitabine - tenofovir alafenamide	emtricitabine 200 mg / tenofovir alafenamide 25 mg	Tab	Descovy	0.225 gram	1 UD (=1 tab)
J05AR18	J05AR18_1	emtricitabine -	emtricitabine 200 mg / tenofovir alafenamide 10 mg /	Tab	Genvoya	0.51 gram	1 UD (=1 tab)

ATC code	CombinedProduct (variable to be reported)	Variable description in TESSy metadata	Active ingredients per one unit dose (UD)	Dosage form	Brand name	Conversions used for TESSy calculations	
						Weight per one DDD	No. of UD* per one DDD
		tenofovir alafenamide - elvitegravir - cobicistat	elvitegravir 150 mg / cobicistat 150 mg				
J05AR19	J05AR19_1	emtricitabine - tenofovir alafenamide - rilpivirine	emtricitabine 200 mg / tenofovir alafenamide 25 mg / rilpivirine 25 mg	Tab	Odefsey	0.25 gram	1 UD (=1 tab)
J05AR20	J05AR20_1	emtricitabine - tenofovir alafenamide - bictegravir	emtricitabine 200 mg / tenofovir alafenamide 25 mg / bictegravir 50 mg	Tab	Biktarvy	0.275 gram	1 UD (=1 tab)
J05AR21	J05AR21_1	dolutegravir – rilpivirine	dolutegravir 50 mg / rilpivirine 25 mg	Tab	Juluca	0.075 gram	1 UD (=1 tab)
J05AR22	J05AR22_1	emtricitabine - tenofovir alafenamide - darunavir - cobicistat	emtricitabine 200 mg / tenofovir alafenamide 10 mg / darunavir 800 mg / cobicistat 150 mg	Tab	Symtuza	1.16 grams	1 UD (=1 tab)
J05AR24	J05AR24_1	lamivudine - tenofovir-disoproxil - doravirine	lamivudine 300 mg / tenofovir disoproxil 245 mg / doravirine 100 mg	Tab	Delstrigo	0.645 gram	1 UD (=1 tab)
J05AR25	J05AR25_1	lamivudine - dolutegravir	lamivudine 300 mg / dolutegravir 50 mg	Tab	Dovato	0.35 gram	1 UD (=1 tab)

J01RA14, J01RA15, J05AP58, J05AR26 and J05AR27 do not have an assigned DDD (ATC/DDD Index 2021).

Tab: tablet, Powder for inj: powder for injection, Caps: capsule, Mixt: Mixture, Inf conc: Infusion concentrate

*: for J01CE30 the StrengthUnit is given in grams

** For 'combination packages', the variable 'active ingredients per one unit dose' (UD) refers to single items (e.g., tablets) contained in a package and thus 'combination packages' have more than one UD. UDs comprising a 'combination package' are ready to use single dosing and are administered at the same time.

If one 'combination package' is the usual recommended daily dose as defined by WHO CC, then one DDD is equal to the number of UDs in a 'combination package'.

If more than one 'combination package' are recommended as a daily dose, then one DDD is equal to the product of the number of 'combination packages' comprising a daily dose and the number of UDs contained in a single 'combination package'.

Examples

This section provides examples of reporting data on the consumption of liquids, on data and population coverage, and on consumption of combined products.

Reporting of liquid medicinal products in vials or bottles

Liquid medicinal products in a vial or a bottle 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 are instructions on how to fill in the **AMC** record type for such products. Based on these data, TESSy calculates the content of vials or bottles and allocates the correct DDD.

Variables to be reported for liquid medicinal products in both vials and bottles:

Variable

PackageSize:	Number of items in the box (either the number of vials or the number of bottles of syrup)
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

- If original strength is expressed as the *total amount of the active substance in one item* (e.g., 500 mg per vial): The strength to be reported is the *original strength*.
- If original strength is 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., 3 ml 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:

$$\text{Content} = \text{PackageSize} \times \text{Strength}$$

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

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
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
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
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)**

Reporting data coverage in the AMCDS record type

TESSy calculates DDD per 1000 inhabitants per day. Therefore, TESSy divides the consumption figures by the population figures. The figures provided for the consumption and for the population should cover the same population. 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 community sector (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:

<u>DS_CoverageAC</u> :	100%
<u>DS_CoverageExtrapolatedAC</u> :	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 follows:

<u>DS_EurostatDataAC</u> :	Yes
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If country A chooses not to use Eurostat data, it reports in the record type **AMCDS** as follow:

<u>DS_EurostatDataAC</u> :	No
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Additionally, population data should be provided 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 collected data from a sample representing 70% of its total population. Then it 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:

<u>DS CoverageAC:</u>	70% (as original data only covered 70% of the population)
<u>DS CoverageExtrapolatedAC:</u>	Yes

The actual data coverage in TESSy is 100% because Country B extrapolated the data to the total population.

For the population data:

Country B, because it 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 collected data from a sample representing 70% of its total population. It did not extrapolate 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:

<u>DS CoverageAC:</u>	70% (as original data only covered 70% of the population)
<u>DS CoverageExtrapolatedAC:</u>	No

The actual data coverage in TESSy is 70% because Country C did not extrapolate the data to the total population.

For the population data:

Because the submitted consumption data only represent 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:

<u>DS EurostatDataAC:</u>	No
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Additionally, Country C should provide population data corresponding to the sample using the record type **AMCDENOM**.

Country D reports data from a sample of 80% from the insured population; insurance covers 90% of the total population

Country D receives the consumption data from an insurance company that collected data on only a sample covering 80% of the insured population. The insured population represents itself 90% of the country's total population. Country D has four different options to report the consumption data to ECDC:

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:

<u>DS Coverage:</u>	90% (data extrapolated to the insured population)
<u>DS CoverageExtrapolated:</u>	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

For this option, Country D should provide 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

For this option, Country D should provide population data corresponding to 80% of the insured population, which 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](#)) must be reported with the variable CombinedProduct, an additional code based on ATC classification and adjusted in order to distinguish and precisely define one particular product.

The CombinedProduct variable assigned to all combined products under surveillance in ESAC-Net and a description of the product details is available in Table 24 in this annex.

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

(TESSy needs these data to calculate the number of DDD per package. Please refer to Table 24.)

ATCCode: ATC code of the substance (5th level)
 CombinedProduct: ATC code of the substance 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, ampoules) in the package
 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 products A, B and C, all containing sulfamethoxazole and trimethoprim in different amounts and all share the [ATCCode J01EE01](#). The CombinedProduct variable makes them distinguishable.

Product A: A package with 10 ampoules of 1 ml infusion concentrates. Each ml infusion concentrate contains sulfamethoxazole 80mg and trimethoprim 16mg.

According to Table 24, 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
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 two other related variables: the variable PackageContent (must be reported as 10) and the variable PackageContentUnit (must 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 Table 24, 40 ml of mixture containing a combination of sulfamethoxazole_0.2 g - trimethoprim_40 mg per 5 ml is equal to 8 UD = 1 DDD.

ATCCode: J01EE01
CombinedProduct: J01EE01_2
Antimicrobial route: Parenteral
PackageSize: 8
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 two other related variables: the variable PackageContent (must be reported as 8) and the variable PackageContentUnit (must 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 Table 24, 4 tablets containing a combination of sulfamethoxazole 0.4 g and trimethoprim 80 mg are equal to 4 UD = 1 DDD.

ATCCode: J01EE01
CombinedProduct: J01EE01_3
Antimicrobial route: Oral
PackageSize: 8
Strength: 1
StrengthUnit: UD

The content of a package of product C contains 8 UD and is equal to 2 DDD.
 In the ESAC-Net metadata, there are two other related variables: the variable PackageContent (must be reported as 8) and the variable PackageContentUnit (must be reported as UD).