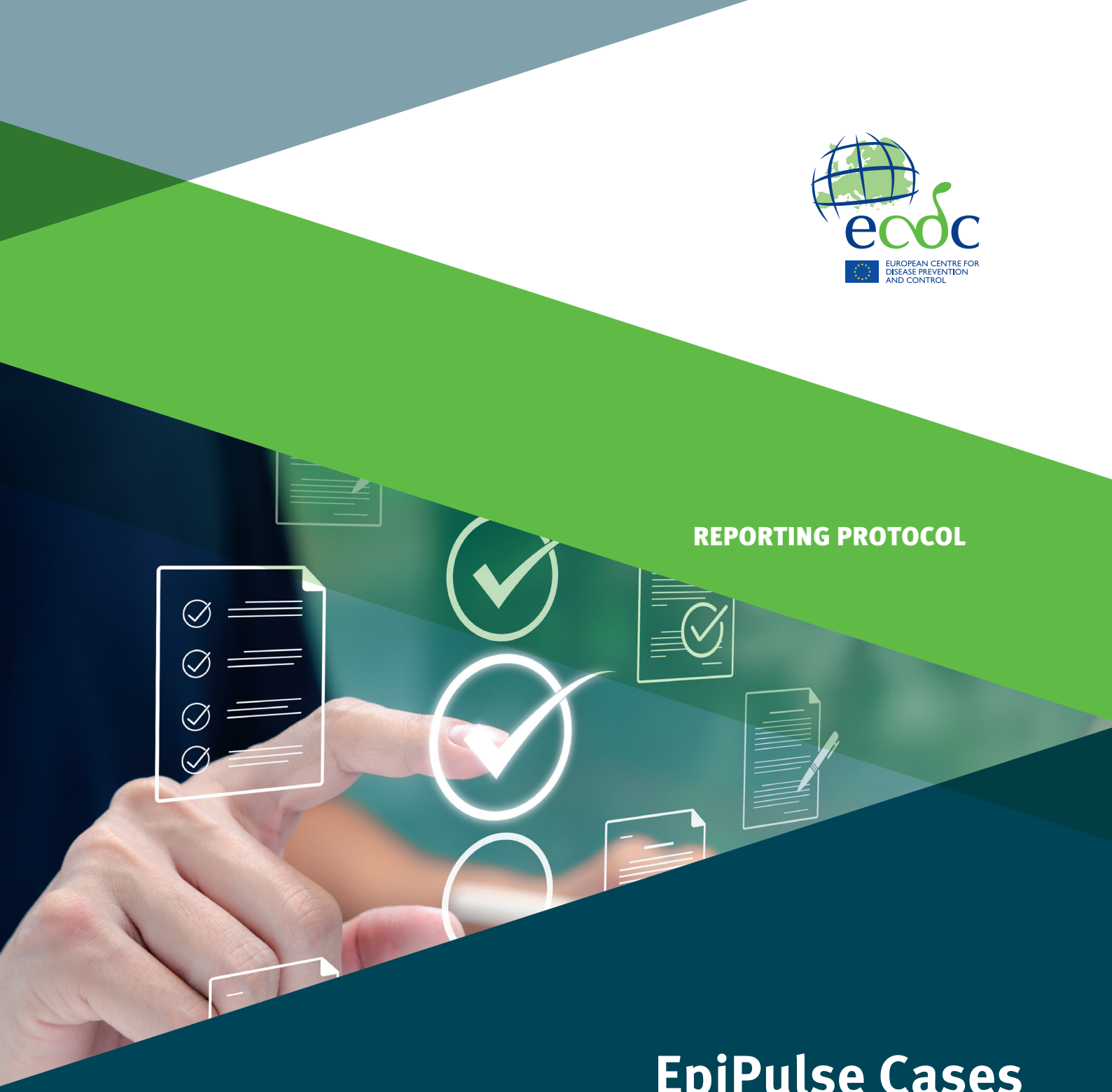

REPORTING PROTOCOL

EpiPulse Cases

Reporting Protocol 2025 for Antimicrobial consumption European Surveillance of Antimicrobial Consumption Network (ESAC-Net) surveillance data for 2024

April 2025

Contents

Introduction

This reporting protocol is for the 2025 data call for antimicrobial consumption (AMC) surveillance data, collected by the European Surveillance of Antimicrobial Consumption Network (ESAC-Net) for 2024, including updates of historical data. Starting 2025, surveillance data should be reported to EpiPulse Cases (EPC), which is replacing The European Surveillance System (TESSy).

Reporting protocols are data collection guidelines for the data managers of reporting countries and the protocol design is intended to improve user-friendliness by:

- introducing a uniform structure to make it easier for data managers to find data collection information across different subjects;
- removing information which is not relevant for data managers.

Since the data managers in reporting countries often have multiple roles, subject-specific material is sometimes distributed together with a reporting protocol. To maintain the uniform structure, this type of material is now included in Annex 2 and Annex 3.

How to use this document

This reporting protocol provides information for the data managers of reporting countries in four main sections:

- Reporting to EpiPulse Cases which contains guidelines on how to prepare data for submission to EpiPulse Cases, deadlines, subject-specific information (e.g. new changes to metadata), and links to further information.
- Annex 1 which contains subject-specific material relevant for distribution with the reporting protocol.
- Annex 2 which contains:
  - the metadata set for the subject(s) covered by this reporting protocol.
  - a list of metadata changes for the subject(s) covered by this reporting protocol.
- Annex 3 which contains subject-specific material relevant for distribution with the Reporting Protocol, for example contact information and the FWD data reporting frequency.

Finding further information

Updated links to all the schedules, documentation and training materials mentioned in this reporting protocol are included in the Documentation and Help pages, including links to:

- EpiPulse Cases Metadata
- EpiPulse Cases Machine to Machine Technical Documentation

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Reporting to EpiPulse Cases

Starting in April 2025, data on antimicrobial consumption should be reported to EpiPulse Cases, which is replacing The European Surveillance System (TESSy). This section provides both an overview of the EpiPulse Cases reporting process and tips on where you can find useful information.

The overall process is as follows:

- Familiarise yourself with the data collection deadlines.
- Prepare (export and transform) your data.
- Check that your data complies with the EpiPulse Cases metadata – see EpiPulse Help.
- Check that your data sources are up to date.
- Submit your file(s) to EpiPulse Cases.
- Finalise and approve your submission.

Checking the data collection schedule

A link to the current data collections schedule can be found in the EpiPulse Help section.

ESAC-Net AMC data should be reported once a year during the annual data call. The collection of 2024 AMC data starts in May 2025 and closes on 1 July 2025. It cannot be guaranteed that data submitted after the closure of data collection or not actively validated before 16 August 2025 will be included in the 2025 ESAC-Net data outputs.

Preparing data

After you have exported the data from your national database, you need to ensure that the data are in a format that EpiPulse Cases can accept. EpiPulse Cases accepts only CSV and XML files, optionally ZIP-compressed. The EpiPulse Cases metadata has been developed from the TESSy Metadata, with the aim to make only the minimal number of changes necessary, and to hopefully provide a better experience when reporting your datasets to ECDC.

A file converter tool is also available in EpiPulse Cases to support users in the transition period with the conversion of files in TESSy format to a format that would be compatible with EpiPulse Cases, see section 18 in the EpiPulse Cases Guide - see EpiPulse Help.

Specific guidelines for ESAC-Net AMC data collection, as well as for preparation for EpiPulse Cases, are provided in the Annexes.

Checking metadata

The metadata defines the fields and data formats that are valid as input to EpiPulse Cases for a given subject. The EpiPulse Cases metadata includes a section that compares and highlights the changes between TESSy and EpiPulse Cases, to facilitate the transition.

As the requirements for data to be shared among ECDC Stakeholders can change, the data format changes needed to support the new requirements are identified and agreed upon between the National Surveillance Contact Points, the Network Coordination Groups, and ECDC's Disease Experts. These changes are then implemented to the EpiPulse Cases metadata.

Changes to the metadata for the subject of this reporting protocol are described at the end in Annex 2.

The EpiPulse Cases metadata Excel file contains all the definitions and rules necessary to format data correctly. The 'READ ME' sheet of the Excel document explains how to work with the metadata. It can be downloaded from the EpiPulse Help. Filtering the fields in the file by subject will enable you to see the fields required for your subject and the rules that apply to these fields.

Checking your Surveillance System Descriptors

Before submitting file(s), please review your data source(s) in EpiPulse (in the menu, go to 'Report' -> 'Surveillance systems descriptors') and update the information as necessary.

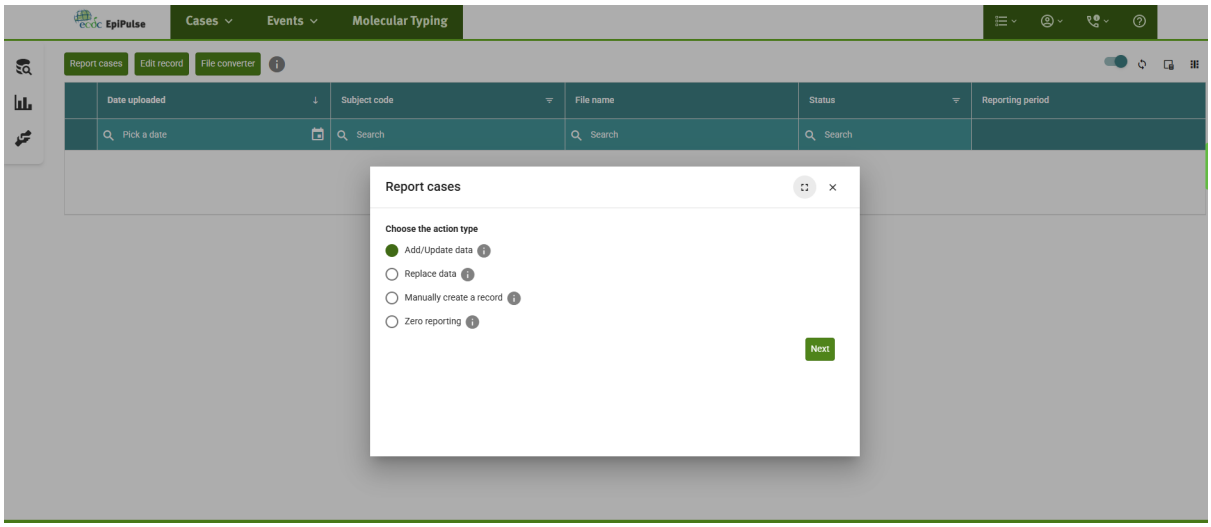
Complete and up-to-date data source information for each subject is important for improving the interpretation of data - each surveillance system has different features that need to be taken into account when comparing data at the European level.

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

Information on data sources is available in the EpiPulse Cases Guide – see EpiPulse Help.

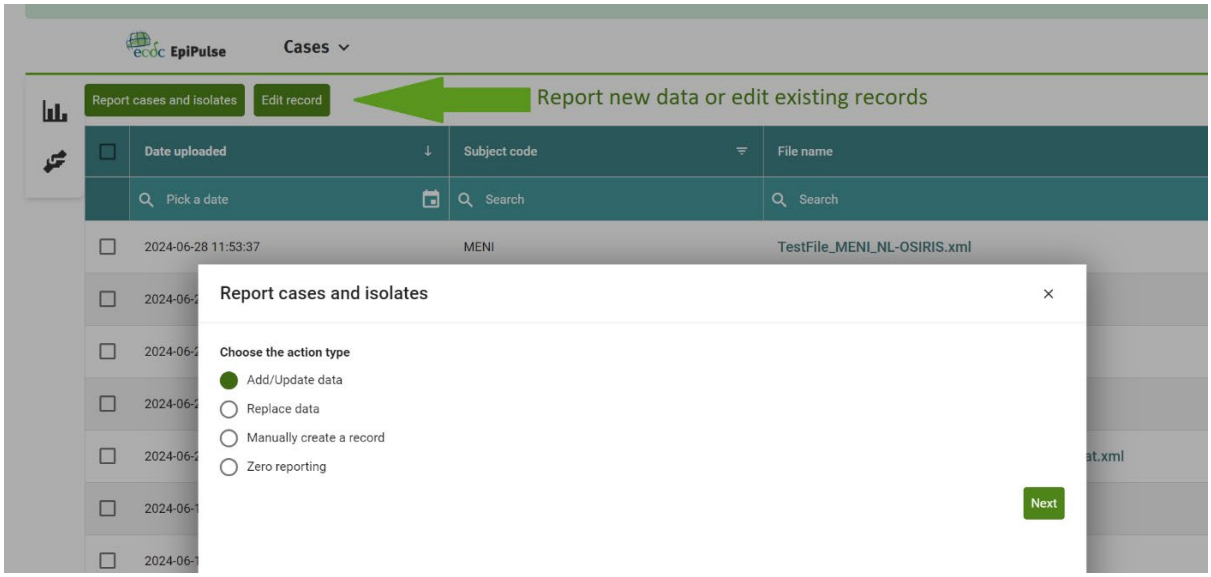
Uploading your data

Data is submitted through the EpiPulse web interface (in the menu, go to Report -> EpiPulse Cases).

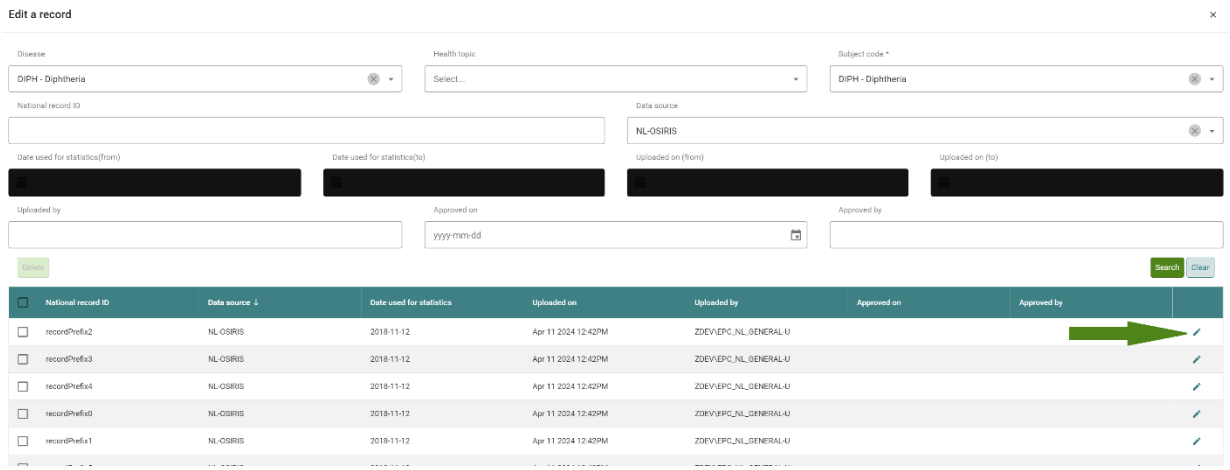


The visual interface for reporting new data and editing existing records has remained very similar to that of TESSy.

Similar to TESSy, you can Add/Update or Replace data with new uploads, using either CSV or XML files. You can also manually create records for some diseases, and report zero cases where appropriate.



The functionality for manually editing existing records is also a familiar experience. Search for the record you wish to edit, and modify the existing information as needed.



Finalising your submission

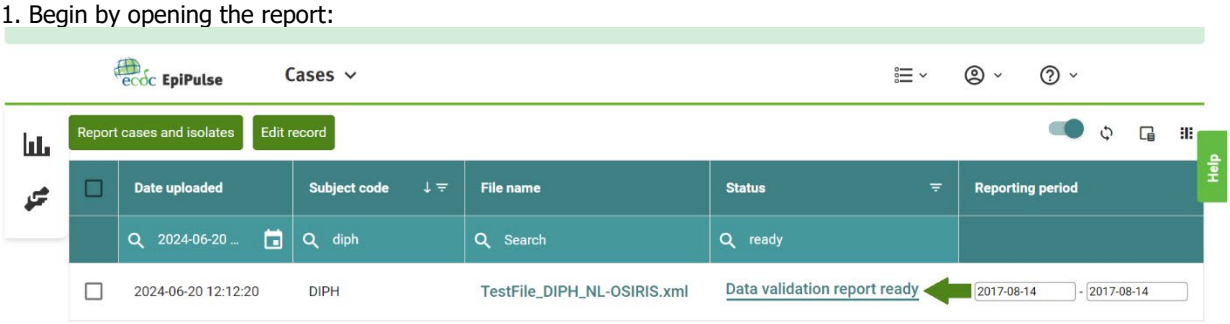
The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process. In EpiPulse Cases this process is called "Technical Validation", and it is the only step where your upload can be rejected, for severe data quality issues, such as the file format not being readable by the system, or (one of the few) mandatory variables having missing values.

If your file has been rejected, there will be a message explaining each instance of non-compliance with the metadata that needs correcting.

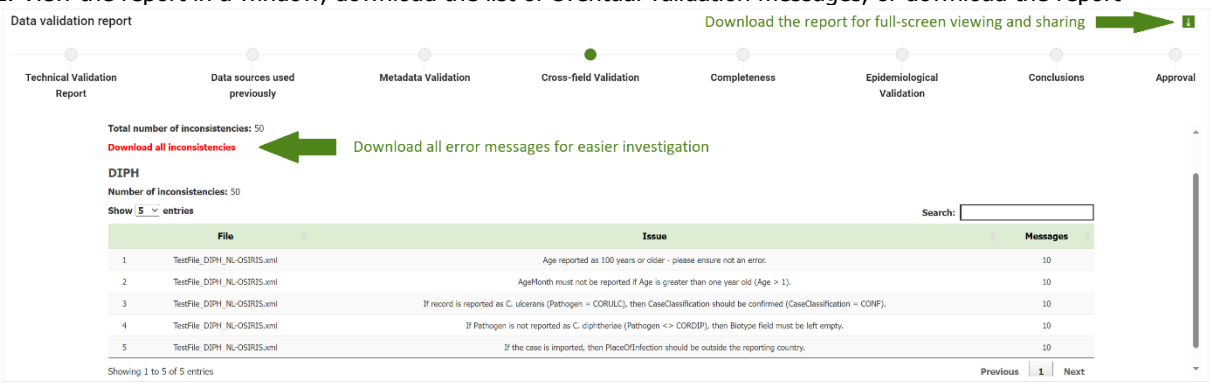
The significant new feature in EpiPulse Cases is the Data Validation Report, which puts your data in the context of the already existing information for the same disease or special health issue, and provides you with a detailed overview of the new data in the file you have just uploaded. The Data Validation reports will evolve and grow based on your feedback in collaboration with our Disease Experts. These reports will provide a new and better way of understanding and updating the information collected at European level, and will hopefully increase the quality and timeliness of the data, while reducing workloads.

Below you can find a few screenshots of the Data Validation Report.

1. Begin by opening the report:



2. View the report in a window, download the list of eventual validation messages, or download the report



3. Check data completeness; both for the new upload, and in the context of historical data

4. The downloaded report can be opened full screen for easier viewing and navigation. This is a preview of the currently developed epidemiological indicators/stratifications.

5. After reviewing the information in the Data Validation Report you can choose to approve or reject it.

If you choose to reject it, no data will be saved in the EpiPulse Cases system, but your file will remain visible should you wish to re-download it, or resubmit it for a new Data Validation at a later date or after further checks. Please check the Epi Validation Report carefully, there might be warnings and remarks relating to possible data quality issues or potential overwriting of existing records that you should consider.

When your file has been validated and you are satisfied that all corrections have been made, please ensure prompt approval or rejection. Unapproved uploads can block the approval of other related uploads.

Validation of ESAC-Net AMC calculations

The main indicator for monitoring the volume of AMC is DDD per 1 000 inhabitants per day. This is automatically calculated by EpiPulse using the latest WHO ATC/DDD index and the population provided by Eurostat (or if not applicable, using the data provided through **AMCDENOM**). In addition, the weight of the antibiotic substances in metric tonnes (t) is calculated to enable comparison with consumption in the animal sector. The latest available ATC/DDD index published by the WHO Collaborating Centre for Drug Statistics Methodology 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 calculations will be available for review in EpiPulse under the Explore/Surveillance dashboards/AMC section shortly after the data upload has been approved. Please ensure you review the results carefully and contact ECDC directly if you have any questions or note any inconsistencies.

EpiPulse Cases Helpdesk

Email: EpiPulseCases@ecdc.europa.eu

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

Availability: 9:00 – 16:00 Stockholm time, Monday to Friday (except ECDC holidays)

Annex 1. ESAC-Net AMC-specific material

ESAC-Net surveillance scope

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.

AMC refers to the volume of antimicrobials sold, dispensed or reimbursed within a setting. The data sources used for ESAC-Net AMC data are either national sales or reimbursement data, including information from national drug registers. National data should preferably be collected at the medicinal product level.

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 anti-infective (ATC subgroup A07AA).
- Nitroimidazole derivatives used orally and rectally as antiprotozoals (ATC subgroup P01AB).

Data should be reported for the community and hospital sectors separately, and the sector under which data from nursing homes and other long-term care facilities for the elderly are reported should be clearly specified. If it is not possible to differentiate between consumption in the community and hospital sectors, data can be reported as 'total care' (including both community and hospital sectors combined). However, this is not the preferred option and is only acceptable if the data cannot be subdivided by sector.

Depending on the context, ESAC-Net data will be presented as DDD and/or weight of active substance. EpiPulse uses Eurostat population data as the population denominator by default, 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 denominator data file needs to be uploaded by the reporting country.

ESAC-Net AMC subject codes and data structure

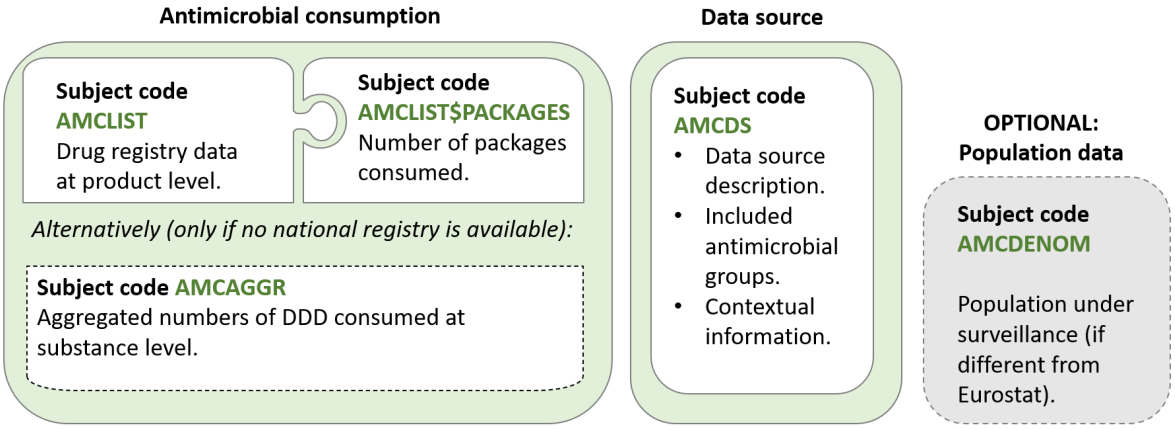
EpiPulse Cases (EPC) includes ESAC-Net AMC data under the Health Topic 'AMC'. The Health Topic 'AMC' consists of three main modules with a number of related subject codes:

- Antimicrobial consumption data (subject codes **AMCLIST, AMCLIST$PACKAGES** and **AMCAGGR)**;
- Contextual data source information (subject code **AMCDS**);
- Population data associated with reported consumption data, if different from Eurostat population (subject code **AMCDENOM**).

For the Health Topic 'AMC', reporting should be done in accordance with the latest ATC/DDD index, so it is important to check that your list of ATC codes, DDD assignments and combined product codes are up to date before extracting the data. See Annex 3 for details.

An overview of the Health Topic 'AMC' and its related subject codes is presented in Figure 1, with more detailed descriptions of the structure of each module, including examples, further below. A complete list of all included variables, data format and validation rules are available in Annex 2.

Figure 1. Overview of EpiPulse Cases the Health Topic 'AMC' with related reporting modules and subject codes used for reporting of ESAC-Net AMC data



ESAC-Net antimicrobial consumption data

Subject code reporting options

There are two options for reporting ESAC-Net antimicrobial consumption data to EPC:

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

The preferred option is to provide data at the medicinal product level. This option includes two datasets: **AMCLIST** which is based on product level registry data, and **AMCLIST$PACKAGES** which is including the product-specific number of packages sold or reimbursed. Example **AMCLIST** and **AMCLIST$PACKAGES** file extracts can be found in Figure 2 and Figure 3.

When using the **AMCLIST** option, EpiPulse will automatically calculate the number of DDDs and the weight of active substance by linking the variable ***ParentNationalRecordId*** in **AMCLIST$PACKAGES** with the antimicrobial product listed in **AMCLIST**, using the variable ***NationalRecordId***. Calculations will be based on the latest DDD/ATC index and will also include updates of historical data to reflect the latest version of the index.

Figure 2. Example of an AMCLIST file.

NationalRecordId	Status	SubjectCode	HealthTopic	DataSource	DateUsedForStatistics	ReportingCountry	ATCCode	CombinedProduct	AntimicrobialRoute	MedicinalProductCode	MedicinalProductName	Strength	StrengthUnit	PackageSize	Formulation	InhalationForm	Salt	SyrupForm
12345678	NEW/UPDATE	AMCLIST	AMC	XX-AMC	2024	XX	J01CR02	N/A	P	123456	Product label name	500	MG	100				
12345679	NEW/UPDATE	AMCLIST	AMC	XX-AMC	2025	XX	J01RA04	J01RA04_2	O	123457	Product label name	1	UD	30				0
12345680	NEW/UPDATE	AMCLIST	AMC	XX-AMC	2026	XX	A07AA02	N/A	O	123458	Product label name	10000000	IU	1				1
12345681	NEW/UPDATE	AMCLIST	AMC	XX-AMC	2027	XX	J02AA01	N/A	P	123459	Product label name	0.05	G	10	LIP			
12345682	NEW/UPDATE	AMCLIST	AMC	XX-AMC	2028	XX	J02AA01	N/A	P	123460	Product label name	0.05	G	1	CON			
12345683	NEW/UPDATE	AMCLIST	AMC	XX-AMC	2029	XX	J01GB01	N/A	I	123461	Product label name	0.028	G	224		IP		
12345684	NEW/UPDATE	AMCLIST	AMC	XX-AMC	2030	XX	J01GB01	N/A	I	123462	Product label name	0.08	G	10		IS		
12345685	NEW/UPDATE	AMCLIST	AMC	XX-AMC	2031	XX	J01XX05	N/A	O	123463	Product label name	1	G	100			HIPP	0
12345686	NEW/UPDATE	AMCLIST	AMC	XX-AMC	2032	XX	J01FA01	N/A	O	123464	Product label name	100	MG	50			ESUC	1

An extract of an AMCLIST sample file based on a national registry of antimicrobial products. Each row and NationalRecordId represents one individual product and its related package size. Data are coded as specified in Annex 2. The variables CombinedProduct, Formulation, InhalationForm, Salt and Syrup form have been completed where relevant, and left empty when not applicable.

Figure 3. Example of an AMCLIST$PACKAGES file for a country reporting data separated by sector and quarter.

NationalRecordId	ParentNationalRecordId	SubjectCode	NumberOfPackages	ReportQuarter	HealthcareSector
55890439	12345678	AMC$Packages	55	1	HOSP
55890440	12345678	AMC$Packages	10	2	HOSP
55890441	12345678	AMC$Packages	6	3	HOSP
55890442	12345678	AMC$Packages	25	4	HOSP
55890443	12345679	AMC$Packages	7886	1	COM
55890444	12345679	AMC$Packages	4451	2	COM
55890445	12345679	AMC$Packages	3256	3	COM
55890446	12345679	AMC$Packages	6164	4	COM
55890447	12345680	AMC$Packages	80	1	HOSP
55890448	12345680	AMC$Packages	6	2	HOSP
55890449	12345680	AMC$Packages	15	3	HOSP
55890450	12345680	AMC$Packages	10	4	HOSP

An extract of an AMCLIST$PACKAGES sample file. Each ParentNationalRecordId refers to the product with the same NationalRecordId in the AMCLIST file, with multiple rows per product to differentiate reporting by sector and quarter.

Option 2) Antimicrobial consumption aggregated at substance level

This option provides the opportunity to report national AMC data as an aggregated number of DDDs at ATC substance level through the **AMCAGGR** file. This option is only acceptable when national registry data are not available.

DDDs must be calculated by the national data managers before being uploaded to EPC, and should be based on the latest available ATC/DDD index. Please note that in the event of changes in DDD assignments, EpiPulse will not be able to automatically update historical data. It is the responsibility of the country to ensure access to the latest ATC/DDD index as well as updating and re-uploading historical data if there have been any major changes in ATC codes or DDD assignments.

When using the **AMCAGGR** option, it is important to ensure the following in order for EpiPulse to calculate the weights (tonnes) of active substance correctly:

- Each ***ATCCode -AntimicrobialRoute -Sector*** variable combination should be reported in a separate line with a separate ***NationalRecordId***.
- Each ***CombinedProduct***, ***Salt***, ***Formulation***, and ***InhalationForm*** variable response should be reported in a separate line with a separate ***NationalRecordId***.

An example of an AMCAGGR file excerpt can be found in Figure 4.

Figure 4. Example of an AMCAGGR file for a country reporting data separated by sector and quarter.

SubjectCode	HealthTopic	DataSource	DateUsedForStatistics	ReportingCountry	HealthcareSector	ATCCode	CombinedProduct	AntimicrobialRoute	Formulation	InhalationForm	Salt	SyrupForm	NumberOfDDD
AMCAGGR	AMC	XX-AMC	2024-Q1	XX	COM	A07AA02		O				0	23908
AMCAGGR	AMC	XX-AMC	2024-Q2	XX	COM	A07AA02		O				0	22816
AMCAGGR	AMC	XX-AMC	2024-Q3	XX	COM	A07AA02		O				0	23057
AMCAGGR	AMC	XX-AMC	2024-Q4	XX	COM	A07AA02		O				0	21714
AMCAGGR	AMC	XX-AMC	2024-Q1	XX	COM	J01EE01	J01EE01_2	O				1	11038
AMCAGGR	AMC	XX-AMC	2024-Q1	XX	HOSP	J01EE01	J01EE01_2	O				1	218
AMCAGGR	AMC	XX-AMC	2024-Q2	XX	COM	J01EE01	J01EE01_2	O				1	6673
AMCAGGR	AMC	XX-AMC	2024-Q2	XX	HOSP	J01EE01	J01EE01_2	O				1	141
AMCAGGR	AMC	XX-AMC	2024-Q3	XX	COM	J01EE01	J01EE01_2	O				1	6126
AMCAGGR	AMC	XX-AMC	2024-Q3	XX	HOSP	J01EE01	J01EE01_2	O				1	173
AMCAGGR	AMC	XX-AMC	2024-Q4	XX	COM	J01EE01	J01EE01_2	O				1	9447
AMCAGGR	AMC	XX-AMC	2024-Q4	XX	HOSP	J01EE01	J01EE01_2	O				1	236
AMCAGGR	AMC	XX-AMC	2024-Q1	XX	COM	J01GB01		I		IS			1960
AMCAGGR	AMC	XX-AMC	2024-Q3	XX	COM	J01GB01		I		IS			2165
AMCAGGR	AMC	XX-AMC	2024-Q4	XX	COM	J01GB01		I		IS			2091
AMCAGGR	AMC	XX-AMC	2024-Q4	XX	HOSP	J01GB01		I		IS			19
AMCAGGR	AMC	XX-AMC	2024-Q1	XX	COM	J02AA01		P	CON				405
AMCAGGR	AMC	XX-AMC	2024-Q1	XX	COM	J02AA01		P	LIP				69
AMCAGGR	AMC	XX-AMC	2024-Q2	XX	COM	J02AA01		P	CON				235
AMCAGGR	AMC	XX-AMC	2024-Q2	XX	COM	J02AA01		P	LIP				51
AMCAGGR	AMC	XX-AMC	2024-Q3	XX	COM	J02AA01		P	CON				226
AMCAGGR	AMC	XX-AMC	2024-Q3	XX	COM	J02AA01		P	LIP				65
AMCAGGR	AMC	XX-AMC	2024-Q4	XX	COM	J02AA01		P	CON				248
AMCAGGR	AMC	XX-AMC	2024-Q4	XX	COM	J02AA01		P	LIP				74
AMCAGGR	AMC	XX-AMC	2024-Q2	XX	COM	J01FA01		O			ESUC	1	115552
AMCAGGR	AMC	XX-AMC	2024-Q2	XX	HOSP	J01FA01		O			ESUC	1	10

An extract of an AMCAGGR sample file for a country reporting data separated by sector and quarter. Each row represents one individual ATC code, quarter, healthcare sector and route of administration. Data are coded as specified in Annex 2. The variables CombinedProduct, Formulation, InhalationForm, Salt and Syrup form have been completed where relevant, and left empty when not applicable.

Reporting package size and strengths

Some examples on how to report of the variables ***PackageSize***, ***Strength*** and ***StrengthUnit*** are provided in Figure 5 and detailed further below. It is important to ensure these variables are reported correctly, as EpiPulse will compute the content of the active substance and allocate DDDs when applicable based on the information provided.

The variable ***PackageSize*** refers to the number of items in the package (e.g., number of tablets, vials, bottles etc). Do not report the volume (ml, litre etc.) of the item as ***PackageSize***.

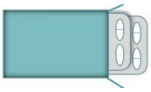
The variable ***Strength*** refers to the total quantity of the active ingredient in each single item:

- For tablets, capsules etc.: provide the amount of active ingredients per item (e.g. tablet, capsule, bottle, vial, etc.).
- For bottles, ampules etc.: Do not report the concentration (e.g. mg/ml etc.) as Strength. Instead, report the total amount of the active ingredients of the item. Examples on how to calculate this is available in Figure 5.
- For multi-ingredient medicinal products: Strength must refer to the ingredient strength in which the DDD is expressed. When in doubt, check the latest ATC/DDD index at the website of the WHO Collaborating Centre for Drug Statistics Methodology (https://atcddd.fhi.no/atc_ddd_index/).

The variable ***StrengthUnit*** refers to the unit of the strength reported, and must be consistent with what is specified in the latest ATC/DDD index:

- For combined products: ***StrengthUnit*** should be reported as unit doses (UD), with the exception of ATC code 'J01CE30' that should be reported in gram (see Figure 6 and Table 14 for details).
- For ATC codes reported as 'A07AA02' (nystatin)', 'A07AA05' (oral polymyxin B), 'A07AA10' (oral colistin) or J01XB01 (parenteral or inhalation colistin), ***StrengthUnit*** must be reported as 'IU' or 'MU'.

Figure 5. Examples of reporting of package size, strength and strength unit

	Tablets	Syrup	Injectables
Example 1: Single unit package			
	1 tablet per package. 20 mg /tablet.	1 bottle of 50 ml per package. 20 mg/ml.	1 vial of 1 ml per package. 10 mg/ml.
Package size	1	1	1
Strength and strength unit	20 mg (20 mg/tablet * 1 tablet)	1000 mg (20 mg/ml*50ml*1bottle)	10 mg (10 mg/ml*1 ml* 1 vial)
Example 1: Multiple unit package			
	20 tablets per package. 20 mg /tablet.	3 bottles of 50 ml each per package 20 mg/ml.	5 vials of 1 ml each per package. 10 mg/ml.
Package size	20	3	5
Strength and strength unit	20 mg (20 mg/tablet * 1 tablet)	1000 mg (20 mg/ml*50ml*1bottle)	10 mg (10 mg/ml*1 ml* 1 vial)

Reporting combined products

Products containing two or more *active* ingredients are regarded as combined products. Combined products classified within the same ATC5 group can have different quantities of active ingredients even per the same route of administration. The ***CombinedProduct*** variable is used to differentiate between these products so the DDD and weight of active substance can be correctly calculated by EpiPulse. The ***CombinedProduct*** variable consists of the ATC code and an additional numerical element after an underscore symbol (_), e.g. J01CR50_2. A list of all combined products, including the related codes can be found in Table 14.

For countries using the **AMCLIST** reporting option, the ***StrengthUnit*** for combined products is given in unit dose (UD) and indicates how much of combined product expressed in UD is equal to 1 DDD. According to the latest ATC/DDD index, all combined products should have the ***StrengthUnit*** expressed in UD, with the exception of J01CE30_1 (benzylpenicillin/procaine -benzylpenicillin/ benzathine benzylpenicillin) that should be reported in grams (g). A list of UD allocations is available in Table 14. Examples on how to report combined products and calculate the UD is given in Figure 6. Based on the information provided, EpiPulse will compute the content of the active substance and allocate DDDs when applicable.

For countries reporting though the **AMCAGGR** option, the conversion from UD to DDD must be performed by before upload to EPC, and should be based on the UD allocations in Table 14.

Figure 6. Examples of reporting combined products using the AMCLIST reporting option

Example 1: A package with 10 vials of 1 ml infusion concentrate, each vial containing sulfamethoxazole 80 mg and trimethoprim 16 mg.

ATCCode	**J01EE01**	
CombinedProduct	**J01EE01_1**	1 Report the ***CombinedProduct*** code as specified in Table 14 (see relevant excerpt at the bottom of this Figure).
PackageSize	**10**	Report the number of items (i.e. vials) in the package, see Figure 5 for details on reporting package size.
StrengthUnit	**UD**	The strength unit for combined products should always be reported in Unit Dose.*
Strength	**1**	2 Report the strength per item as per Table 14 (see relevant excerpt at the bottom of this Figure). The active ingredients per one UD for this combined product is sulfamethoxazole 80 mg/ trimethoprim 16 mg. Hence, in this example the strength of one item equals one UD and should be reported as 1.

3 EpiPulse will calculate the DDD based on what you have reported: One package containing a total of 10 UDs (10 vials of 1 UD each). As one DDD equals 20 UD for this combined product, one package contains 0.5 DDD.

Example 2: A package with 8 bottles of 5 ml mixture each containing sulfamethoxazole 0.2 g and trimethoprim 40 mg.

ATCCode	**J01EE01**	
CombinedProduct	**J01EE01_2**	1 Report the ***CombinedProduct*** code as specified in Table 14 (see relevant excerpt at the bottom of this Figure).
PackageSize	**8**	Report the number of items (i.e. bottles) in the package, see Figure 5 for details on reporting package size.
StrengthUnit	**UD**	The strength unit for combined products should always be reported in Unit Dose.*
Strength	**1**	2 Report the strength per item as per Table 14 (see relevant excerpt at the bottom of this Figure). The active ingredients per one UD for this combined product is sulfamethoxazole 0.2g / trimethoprim 40 mg. Hence, in this example the strength of one item is one UD and should be reported as 1.

3 EpiPulse will calculate the DDD based on what you have reported: One package containing a total of 8 UD (8 bottles of 1 UD each). As one DDD equals 8 UD for this combined product, one package contains 1 DDD.

Example 3: A package of 8 tablets with sulfamethoxazole 0.4 g and trimethoprim 80 mg.

ATCCode	**J01EE01**	
CombinedProduct	**J01EE01_3**	1 Report the ***CombinedProduct*** code as specified in Table 14 (see relevant excerpt at the bottom of this Figure).
PackageSize	**8**	Report the number of items (i.e. tablets) in the package, see Figure 5 for details on reporting package size.
StrengthUnit	**UD**	The strength unit for combined products should always be reported in Unit Dose.*
Strength	**1**	2 Report the strength per item as per Table 14 (see relevant excerpt at the bottom of this Figure). The active ingredients per one UD for this combined product is sulfamethoxazole 0.2g / trimethoprim 40 mg. Hence, in this example the strength of one item is one UD and should be reported as 1.

3 EpiPulse will calculate the DDD based on what you have reported: One package containing a total of 8 UD (8 tablets of 1 UD each). As one DDD equals 4 UD for this combined product, one package contains 0.5 DDD

Excerpt from Table 14:

ATC code	CombinedProduct (variable to be reported) 1	Variable description in EPC metadata	Active ingredients per one unit dose (UD) 2	Dosage form	Brand name	Conversions used for EPC calculations 3	
						Weight per one DDD	No. of UD* per one DDD
J01EE01	J01EE01_1	sulfamethoxazole_80mg - trimethoprim_16mg	In 1mL: sulfamethoxazole 80 mg / trimethoprim 16 mg	Inf conc	Bactrim, Eusaprim, Trimetoprim-sulfa	1.6 gram 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 gram 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 gram sulfamethoxazole 0.32 gram trimethoprim	4 UD (=4 tab)

** For CombinedProducts: StrengthUnit should be reported as unit doses (UD), with the exception of J01CE30_1 (benzylpenicillin/procaine -benzylpenicillin/benzathine benzylpenicillin) that should be reported in grams (g). See Table 14 for details).*

Ensuring correct formulation-specific DDD assignments

For some antimicrobials within the same ATC5 group, there are differences in DDD assignments depending on factors related to formulation, inhalation form or inclusion of salts. To enable EpiPulse to correctly calculate the DDD and weight of active substance for these products, it is important to ensure that the following variables are completed and correctly specified:

- ***InhalationForm*** (inhalation powder or inhalation solution) for ATC code J01GB01 (tobramycin) when ***AntimicrobialRoute*** is reported as 'I' (Inhalation).
- ***Salt*** for ATC codes 'J01FA01' (erythromycin) and 'J01XX05' (methenamine) when ***AntimicrobialRoute*** is reported as 'O' (oral).
- ***Formulation*** (conventional or lipid) when the ATC code is reported as 'J02AA01'.

Some examples on how to report inhalation form, salt and formulation through **AMCLIST** and **AMCAGGR** is available in Figure 2 and Figure 4. Based on the information provided, EpiPulse will compute the content of the active substance and allocate DDDs when applicable.

Reporting consumption data aggregated by quarter

If AMC data aggregated by quarter are available, reporting at this level can facilitate analyses of seasonal variations in AMC. If quarterly data are only available for AMC data from one sector, it is possible to report annual AMC data for one sector and quarterly AMC data for the other.

Reporting AMC by quarter is optional, and the way to report differs for **AMCLIST**/**AMCLIST$PACKAGES** and **AMCAGGR** reporting:

- **AMCLIST**/**AMCLIST$PACKAGES**: Report all variables for **AMCLIST$PACKAGES**, including the optional variable ***ReportQuarter***. Separate lines (with separate ***RecordID***s) should be created to report ***NumberOfPackages*** for each ***ReportQuarter*** -***ParentId***- ***Sector*** combination. Quarter should be reported using a single digit number corresponding to the quarter of the year for which the package volume is being reported: 1, 2, 3, or 4. As the ***ParentId*** in **AMCLIST$PACKAGES** corresponds with the ***RecordID*** in the **AMCLIST** dataset (national drug registry), no adjustments for quarterly reporting is needed in the **AMCLIST** file.
- **AMCAGGR**: Report variable ***DateUsedForStatistics*** in **AMCLIGHT**. Separate lines should be created to report ***NumberOfDDD*** for each ***DateUsedForStatistics*** -***Sector*** -***ATCCode***-***AntimicrobialRoute***- (***CombinedProduct***|***Salt***|***InhalationForm***) combination. Quarter is reported in ***DateUsedForStatistics*** using a single digit (1, 2, 3, or 4) directly following the uppercase letter 'Q' in the format 'YYYY-Q_'.

Some examples on how to report quarterly data through **AMCLIST$PACKAGES** and **AMCAGGR** are given in Figure 2 and Figure 4.

ESAC-Net AMC descriptive data (AMCDS)

AMCDS contains information on the antimicrobial consumption data source, healthcare sectors covered (community, hospital or 'total care' sector), under which sector data from nursing homes and other long-term care facilities are reported, whether the consumption data covers the total national population, and which groups of antimicrobials are included. Two variables offer the possibility to share comments on the data, either publicly or only with ECDC.

AMCDS data must be reported regardless of the option chosen for reporting consumption data. The level at which the data should be reported (community, hospital or 'total care') must reflect how the antimicrobial consumption data (**AMCLIST** or **AMCAGGR**) are reported.

To enable EpiPulse to correctly calculate the DDD per 1 000 inhabitants per day, the figures provided for the consumption and the population should cover the same population. Some countries provide consumption figures for the whole population, while others provide them only for a sample. The information about the coverage for consumption and population is stored in the **AMCDS** and should be provided for each health sector for which data are delivered.

EpiPulse uses the latest Eurostat national population data by default. If the consumption data reported to EPC do not cover the total national population, or if you wish that another national population figure should be used, you need to indicate this under variable ***UseEurostatPopulation*** and upload a separate **AMCDENOM** file.

Some examples on how to report coverage population are available in Table 1. An example **AMCDS** file can be found in Figure 7.

Table 1. How to report data coverage in AMCDS

Example 1: Country A reported consumption data covering the total national population (100% population coverage)			
HealthcareSector	COM	HOSP	If the consumption data in **AMCLIST/AMCAGGR** is reported differentiated by sector, the related information in **AMCDS** also needs to be provided by sector.
ProportionPopulationCovered	100%	100%	Indicates that the original consumption data collected covered 100% of the national population.
ExtrapolatedCoverage	0	0	The consumption data have not been extrapolated as indicated by 0=No.
UseEurostatPopulation	1	1	As the population coverage of the reported consumption data covers 100% of the national population, EpiPulse can use the Eurostat population data for calculations of DDD per 1000 inhabitants per day. This is indicated by 1=Yes.
Example 2: Country B collected consumption data from a sample representing 70% of its total population. They then extrapolate the data to represent 100% of the population before reporting to EPC.			
HealthcareSector	COM	HOSP	If the consumption data in **AMCLIST/AMCAGGR** is reported differentiated by sector, the related information in **AMCDS** also needs to be provided by sector.
ProportionPopulationCovered	70%	70%	Indicates that the original consumption data collected only covered 70% of the national population.
ExtrapolatedCoverage	1	1	The consumption data reported to EpiPulse were extrapolated by the country to cover 100% of the national population as indicated by 1=Yes.
UseEurostatPopulation	1	1	As the population coverage of the reported consumption data covers 100% of the national population after the extrapolation, EpiPulse can use the Eurostat population data for calculations of DDD per 1000 inhabitants per day. This is indicated by 1=Yes.
Example 3: Country C collected data from a sample representing 70% of its total population. They did not extrapolate the data to 100% of the population before reporting to EPC.			
HealthcareSector	COM	HOSP	If the consumption data in **AMCLIST/AMCAGGR** is reported differentiated by sector, the related information in **AMCDS** also needs to be provided by sector.
ProportionPopulationCovered	70%	70%	Indicates that the original consumption data collected only covered 70% of the national population.
ExtrapolatedCoverage	0	0	The consumption data reported to EpiPulse were not extrapolated to cover 100%, and the actual data coverage in EPC remain as 70%. This is indicated by 0=No.
UseEurostatPopulation	0	0	Because the submitted consumption data only represent 70% of the total population, EpiPulse cannot use Eurostat data for country C. This is indicated by 0=No. Country C needs to provide population data corresponding to the sample using the subject **AMCDENOM**
Example 4: 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 two different options to report the consumption data to ECDC:			
Option 1: Country D submits the data extrapolated to the total insured population (but not the total population).			
HealthcareSector	COM	HOSP	If the consumption data in **AMCLIST/AMCAGGR** is reported differentiated by sector, the related information in **AMCDS** also needs to be provided by sector.
ProportionPopulationCovered	90%	90%	Indicates that the data has been extrapolated to the insured population which represents 90% of the total population.
ExtrapolatedCoverage	0	0	Although extrapolated to reflect the insured population, the consumption data reported to EpiPulse are still based on a sample as it does not cover 100% of the total population. This is indicated by 0=No.
UseEurostatPopulation	0	0	Because the submitted consumption data only represent 90% of the total population, country D cannot use Eurostat data. This is indicated by 0=No. Country D should provide population data corresponding to the sample and indicate that this refers to the insured population using the subject **AMCDENOM** (variables *Population* and *InsuredPopulation*)
Option 2: Country D submits the original sample of the insured population without extrapolating to the total insured population or the total population.			

HealthcareSector	COM	HOSP	If the consumption data in **AMCLIST/AMCAGGR** is reported differentiated by sector, the related information in **AMCDS** also needs to be provided by sector.
ProportionPopulationCovered	72%	72%	As data covers 80% of the insured population (which is representing 90% of the total population) and have not been extrapolated, the total population covered is 80% of 90% = 72%.
ExtrapolatedCoverage	0	0	The actual data coverage has not been extrapolated to cover the total population. This is indicated by 0=No.
UseEurostatPopulation	0	0	Because the submitted consumption data only represent 72% of the total population, country D cannot use Eurostat data. This is indicated by 0=No. Country D should provide population data corresponding to the sample and indicate that this refers to the insured population using the subject **AMCDENOM** (variables *Population* and *InsuredPopulation*)

Figure 7. Example of an AMCDS file for a country reporting data separated by sector

SubjectCode	HealthTopic	DateUsedForStatistics	DataSource	ReportingCountry	PublicHealthSector	DataProvider	OriginOfData	UseEurostatPopulation	ProportionPopulationCovered	ExtrapolatedCoverage	J01Inclusion	J02Inclusion	J04Inclusion	J05Inclusion	IncludesPSYHOSP	IncludesHALT	IncludesDayCare	CommentsECDC	CommentsPublic
AMCDS	AMC	2024	XX-AMC	XX	HOSP	HN	S	1	100	0	1	1	1	1	1	0	0	Sample text	Sample text
AMCDS	AMC	2024	XX-AMC	XX	COM	CP	R	1	100	0	1	1	1	1	0	1	0	Sample text	Sample text

ESAC-Net AMC population data (AMCDENOM, optional)

Eurostat population denominator data are preferred, and EpiPulse 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 EPC. If the surveillance coverage is not compatible with the Eurostat population, it is necessary to indicate this in the **AMCDS** file and provide denominator data at the same level as the consumption data (i.e. healthcare sector) through a **AMCDENOM** file.

An example **AMCDENOM** file can be found in Figure 8.

Figure 8. Example of an AMCDENOM file for a country reporting data separated by sector

SubjectCode	HealthTopic	ReportingCountry	DataSource	DateUsedForStatistics	PublicHealthSector	DataProvider	InsuredPopulation	Population
AMCDENOM	AMC	XX	XX-AMC	2024	HOSP	NS	0	12345678
AMCDENOM	AMC	XX	XX-AMC	2024	COM	NS	0	12345678

Annex 2. Antimicrobial consumption (AMC) metadata

This section describes:

- The ESAC-Net AMC metadata set for AMCLIST (Table 2), AMCLIST$PACKAGES (**Table 3**), AMCAGGR (**Table 4**), AMCDS (Table 5) and AMCDENOM (Table 6).
- Changes to the ESAC-Net AMC metadata.

An overview of the EPC Health Topic 'AMC' and its related surveillance subjects used to report ESAC-Net AMC data is available in Figure 1. The description of each variable per respective surveillance subject is presented in the tables below, including the corresponding validation rules when applicable. Some variables are technically mandatory (i.e. EPC will not accept the data submission unless the corresponding fields have been completed).

Please note that validation rules only check data within one subject type (i.e. **AMCLIST**, **AMCLIST$PACKAGES, AMCAGGR, AMCDS and AMCDENOM**). For this reason, it is theoretically possible to successfully upload data into EPC, although no results are shown in the online reports. For example, this could happen if AMC data are reported with the aggregated version **AMCAGGR**, but the healthcare sector or the denominator data are not reported accordingly in the subject **AMCDENOM** or **AMCDS.**

Table 2. AMCLIST - national registry data for all available antimicrobials

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

VariableName	**1 - NationalRecordId**
Description	Unique identifier for each record within and across the national surveillance system –selected and generated by the country. **NationalRecordId represents the unique identifier for each record of the variable ParentNationalRecordId within the "AMCLIST$PACKAGES" reporting.**
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Text; max length: 80 characters
Validation rule	-
VariableName	**2 - SubjectCode**
Description	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	AMCLIST = Antimicrobial consumption product list
Validation rule	-
VariableName	**3 - DataSource**
Description	The data source (surveillance system) that the record originates from. The DataSource value must be a special reference value from EpiPulse Cases metadata.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	DATASOURCE
Code	See EPC metadata
Validation rule	-
VariableName	**4 - ReportingCountry**
Description	The country reporting the record.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	LOCATION
Code	See EPC metadata
Validation rule	-
VariableName	**5 - DateUsedForStatistics**
Description	The reference date used for standard reports that is compared to the reporting period. The date used for statistics can be any date that the reporting country finds applicable, e.g. date of notification, date of diagnosis or any other date.

Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Date
Code	Year (YYYY)
Validation rule	-
VariableName	**6 - Status**
Description	The Status value is used to provide the functionality for a record within EpiPulse Cases database. Default value: NEW/UPDATE. If set to DELETE, the record with the specified NationalRecordId is deleted (invalidated) from EpiPulse Cases database, if it exists. If set to NEW/UPDATE, the record is inserted into the database: If the same NationalRecordId already exists for the same data source and subject code, then the current submitted record updates (replaces) the existing one.
Required (what happens if not submitted)	No
Data type	Coded value
Code	NEW/UPDATE, DELETE
Validation rule	-
VariableName	**7 - MedicinalProductCode**
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, 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 EpiPulse Cases database for historical purposes.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Text; max length: 400 characters
Validation rule	-
VariableName	**8 - MedicinalProductName**
Description	The product label or medicinal product package label (e.g. Sovaldi tablets 28 x 400 mg).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Text; max length: 1000 characters
Validation rule	-
VariableName	**9 - PackageSize**
Description	The number of items in the package (e.g. number of tablets, vials, bottles) in the package. Do not provide the unit (e.g. not 60 tablets, it should be reported only as number: 60). Note that vials and bottles are quantified in number of items and not quantified by their volume.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Numeric (minimum value: 1; no decimals allowed)
Validation rule	-
VariableName	**10 – Strength**
Description	The strength of the active substance of each individual item (e.g. tablet, bottle, vial) as defined in PackageSize. For multi-ingredient medicinal products, this field must contain the ingredient strength in which the DDD is expressed (e.g., amoxicillin/clavulanic acid combinations: strength expresses the strength of amoxicillin since DDD = 1000 mg amoxicillin). For combined products where the DDD is expressed in Unit Dose (UD), the strength should be reported in the number of UD with the exception of J01CE1 that is expressed in grams.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Numeric (minimum value: 0; maximum number of decimals: 3)
Validation rule	
VariableName	**11- StrengthUnit**
Description	Unit of the strength reported. For the combined products where the DDD is expressed in Unit Dose (UD), the strength should be given in the number of UD, with the exception of J01CE1 which is expressed in grams.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value

Code	G = Gram, MG = Milligram, IU = International unit, MU = Million units, UD = Unit dose
Validation rule	- StrengthUnit should be reported as G or MG apart from all combined products (except 'J01CE30'), and for 'A07AA02', 'A07AA05', 'A07AA10' or 'J01XB01'. - If ATCCode is reported as 'A07AA02', 'A07AA05', 'A07AA10' or 'J01XB01', then StrengthUnit must be reported as 'IU' or 'MU'. - If combined products are reported, then StrengthUnit must be reported as 'UD' (Unit Doses) with the exception of ATC code 'J01CE30' that should be reported in grams.
VariableName	**12 - AntimicrobialRoute**
Description	The route of administration of the substance.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	I = Inhalation; M = Implant; O = Oral; P = Parenteral; R = Rectal
Validation rules	- If ATCCode is reported as 'J01GB01' and AntimicrobialRoute is reported as 'I' (Inhalation), then InhalationForm must be reported as 'IS' (Inhalation solution) or 'IP' (Inhalation powder). This is to ensure that the DDD can be calculated.
VariableName	**13 - SyrupForm**
Description	Is the product a syrup?
Required (what happens if not submitted)	No
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	- If AntimicrobialRoute is reported as 'O', then SyrupForm must be reported. - If AntimicrobialRoute is reported different than 'O', then SyrupForm must not be reported.
VariableName	**14- InhalationForm**
Description	The galenic form of the drug for inhalation, i.e. inhalation powder or inhalation solution.
Required	No
Data type	Coded value
Code	IP = Inhalation powder; IS = Inhalation solution
Validation rule	- If ATCCode is reported as 'J01GB01' and AntimicrobialRoute is reported as 'I' (Inhalation), then InhalationForm must be reported as 'IS' (Inhalation solution) or 'IP' (Inhalation powder). This is to ensure that the DDD can be calculated.
VariableName	**15- ATCCode**
Description	ATC code of the substance (ATC 5th level).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	See EPC metadata
Validation rule	-
VariableName	**16- Salt**
Description	Salt associated with substance. Only used (required) for methenamine and erythromycin. For 'J01XX05' (methenamine), the associated salt (hippurate or mandelate) should be specified. For 'J01FA01' (erythromycin), if the associated salt is ethylsuccinate and the galenic form is tablet, then ethylsuccinate must be specified. In all other cases (any other form than tablet 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
Validation rule	- If ATCCode is reported as 'J01FA01' (erythromycin) and AntimicrobialRoute is reported as 'O' (oral), then Salt -if reported- can only be reported as 'ESUC'. - If ATCCode is reported as 'J01XX05' (methenamine), then Salt must be reported as 'HIPP' or 'MAND'.

VariableName	17 - Formulation
Description	To differentiate formulation-specific DDDs. Note that lipid formulations (e.g. liposomal, lipid complex) of 'J02AA01' (amphotericin B) have been assigned a separate, higher DDD from the conventional formulations due to a considerably higher dosage.
Required (what happens if not submitted)	No
Data type	Coded value
Code	LIP = Liposomal CON = Conventional
Validation rule	- If ATCCode is reported as 'J02AA01', then Formulation must be reported.

VariableName	18– CombinedProduct
Description	Identifier for products with a specific combinations of substances in order to allocate DDD for combined products. Please find a list with all CombinedProduct codes in **Table 14**.
Required (what happens if not submitted)	No
Data type	Coded value
Code	consult the reference values for SubjectCode = AMCLIST and Variable = CombinedProduct
Validation rule	-

Table 3. AMCLIST$PACKAGES - AMC data linked to the national registry (as reported under AMCLIST)

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

VariableName	**1 - NationalRecordId**
Description	Unique identifier for each record within and across the specified surveillance system (data source) – selected and generated by the country reporting the record.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Text; max length: 80 characters
Validation rule	-
VariableName	**2 - SubjectCode**
Description	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	AMCLIST$PACKAGES = Antimicrobial consumption product list - packages
Validation rule	-
VariableName	**3 - ParentNationalRecordId**
Description	The corresponding parent identifier for each record (should exist in the upper level, i.e. NationalRecordId in **AMCLIST**). **A record with no corresponding parent identifier will be ignored and it will not be added to EpiPulse Cases database.**
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Text; max length: 80 characters
Validation rule	-
VariableName	**4 - HealthcareSector**
Description	Healthcare sector level for which consumption data are reported, i.e. community (primary care), hospital sector, or both healthcare sectors combined (total care).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	COM = Community care HOSP = Hospital care TOTAL = Total care
Validation rule	-
VariableName	**5 - ReportQuarter**
Description	Report quarter. Use only when reporting quarterly data. Leave empty for annual data.
Required (what happens if not submitted)	No
Data type	Numeric (minimum value: 1; maximum value: 4; no decimals allowed)
Validation rule	-
VariableName	**6 - NumberOfPackages**
Description	Number of packages used for the reported healthcare sector and period.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Numeric (minimum value: 0; maximum decimals: 3)
Validation rule	

Table 4. AMCAGGR - (aggregated number of DDDs reported)

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

VariableName	**1 - SubjectCode**
Description	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	AMCAGGR = Antimicrobial consumption aggregated
Validation rule	-
VariableName	**2 - HealthTopic**
Description	The code of the health topic that is being reported.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	AMC = Antimicrobial consumption
Validation rule	-
VariableName	**3 - DataSource**
Description	The data source (surveillance system) that the record originates from. The DataSource value must be a special reference value from EpiPulse Cases metadata.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	DATASOURCE
Code	See EPC metadata
Validation rule	-
VariableName	**4 - ReportingCountry**
Description	The country reporting the record.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	LOCATION
Code	See EPC metadata
Validation rule	-
VariableName	**5 - DateUsedForStatistics**
Description	The reference date used for standard reports that is compared to the reporting period. The date used for statistics can be any date that the reporting country finds applicable, e.g. date of notification, date of diagnosis or any other date.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Date
Code	Year (YYYY, YYYY-Qq)
Validation rule	-
VariableName	**6 - HealthcareSector**
Description	Healthcare sector level for which consumption data are reported, i.e. community (primary care), hospital sector, or both healthcare sectors combined (total care).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	COM = Community care HOSP = Hospital care TOTAL = Total care
Validation rule	-
VariableName	**7 – ATCCode**
Description	ATC code of the substance (ATC 5th level).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	See EPC metadata
Validation rule	
VariableName	**8 – CombinedProduct**
Description	Identifier for products with a specific combination of substances in order to allocate DDD for combined products.

Required (what happens if not submitted)	No
Data type	Coded value
Code	See EPC metadata
Validation rule	
VariableName	**9 - AntimicrobialRoute**
Description	The route of administration of the substance.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	I = Inhalation M = Implant O = Oral P = Parenteral R = Rectal
Validation rule	- No DDDs have been assigned to AntimicrobialRoute 'M', and 'R' in the current ATC/DDD index. - If ATCCode is reported as 'J01GB01' and AntimicrobialRoute is reported as 'I' (Inhalation), then InhalationForm must be reported as 'IS' (Inhalation solution) or 'IP' (Inhalation powder). This is to ensure that the DDD can be calculated.
VariableName	**10 - Salt**
Description	Salt associated with substance. Only used (required) for methenamine and erythromycin. For methenamine, the associated salt (hippurate or mandelate) should be specified. For erythromycin, if the associated salt is ethylsuccinate and the galenic form is tablet, then ethylsuccinate must be specified. In all other cases (any other form than tablet 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
Validation rule	- If ***ATCCode*** is reported as 'J01FA01' (erythromycin) and AntimicrobialRoute is reported as 'O' (oral), then Salt -if reported- can only be reported as 'ESUC'. - If ***ATCCode*** is reported as 'J01XX05' (methenamine), then Salt must be reported as 'HIPP' or 'MAND'
VariableName	**11 - NumberOfDDD**
Description	Number of DDDs used for the reported substance, healthcare sector and period.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Numeric (minimum value: 0; maximum decimals: 3)
Validation rule	NumberOfDDD must be an integer or float (up to three decimals).
VariableName	**12- SyrupForm**
Description	Is the product a syrup?
Required (what happens if not submitted)	No
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	- If ***AntimicrobialRoute*** is reported as 'O', then ***SyrupForm*** must be reported. - If ***AntimicrobialRoute*** is reported different than 'O', then ***SyrupForm*** must not be reported.
VariableName	**13- InhalationForm**
Description	The galenic form of the drug for inhalation, i.e. inhalation powder or inhalation solution.
Required (what happens if not submitted)	No
Data type	Coded value
Code	IP = Inhalation powder, IS = Inhalation solution
Validation rule	- If ***ATCCode*** is reported as 'J01GB01' and ***AntimicrobialRoute*** is reported as 'I' (Inhalation), then ***InhalationForm*** must be reported as 'IS' (Inhalation solution) or 'IP' (Inhalation powder). This is to ensure that the DDD can be calculated.
VariableName	**14 - Formulation**
Description	To differentiate formulation-specific DDDs. Note that lipid formulations (e.g. liposomal, lipid complex) of amphotericin B have been assigned a

	separate, higher DDD from the conventional formulations due to a considerably higher dosage.
Required (what happens if not submitted)	No
Data type	Coded value
Code	LIP = Liposomal CON = Conventional
Validation rule	- If ***ATCCode*** is 'J02AA01', Formulation must be reported.

Table 5. AMCDS (data source information for antimicrobial consumption data)
Green cells represent variables that are mandatory to report, grey cells represent optional variables.

VariableName	1 – SubjectCode
Description	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	AMCDS = Antimicrobial consumption - data source
Validation rule	-
VariableName	**2 - HealthTopic**
Description	The code of the health topic that is being reported.
Required (what happens if not submitted)	No
Data type	Coded value
Code	AMC = Antimicrobial consumption
Validation rule	-
VariableName	**3 – DataSource**
Description	The data source (surveillance system) that the record originates from. The DataSource value must be a special reference value from EpiPulse Cases metadata.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	DATASOURCE
Code	See EPC metadata
Validation rule	-
VariableName	**4 - ReportingCountry**
Description	The country reporting the record.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	LOCATION
Code	See EPC metadata
Validation rule	-
VariableName	**5 - DateUsedForStatistics**
Description	The reference date used for standard reports that is compared to the reporting period. The date used for statistics can be any date that the reporting country finds applicable, e.g. date of notification, date of diagnosis or any other date.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Date
Code	Year (YYYY)
Validation rule	-
VariableName	**6 - HealthcareSector**
Description	Healthcare sector level for which consumption data are reported, i.e. community (primary care), hospital sector, or both healthcare sectors combined (total care).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	COM = Community care HOSP = Hospital care TOTAL = Total care
Validation rule	
VariableName	**7 - DataProvider**
Description	Which authority/organisation/network was the provider of population data for the reported healthcare sector?
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	CP = Community Pharmacies HI = Health Insurance Company HN = Hospital network MA = Medicines Agency MoH = Ministry of Health MR = Market Research Company NS = National Statistics Agency OTH = Other

Validation rule	- If DataProvider is reported, then all the information for the reported healthcare sector, including ExtrapolatedCoverage, must be reported. - If DataProvider is reported, then all the information for the reported healthcare sector, including J01Inclusion, must be reported. - If DataProvider is reported, then all the information for the reported healthcare sector, including J02Inclusion, must be reported. - If DataProvider is reported, then all the information for the reported healthcare sector, including J04Inclusion, must be reported. - If DataProvider is reported, then all the information for the reported healthcare sector, including J05Inclusion, must be reported. - If DataProvider is reported, then all the information for the reported healthcare sector, including OriginOfData, must be reported. - If DataProvider is reported, then all the information for the reported healthcare sector, including ProportionPopulationCovered, must be reported.
VariableName	**8 - OriginOfData**
Description	What is the origin of consumption data for the reported healthcare sector? In case "BOTH" is selected, please provide information on how the consumption data reported to EpiPulse Cases are based on sales and reimbursements in the "CommentsECDC" variable.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	BOTH = Both (reimbursements and sales) R = Reimbursements S = Sales
Validation rule	- If OriginOfData is reported as 'BOTH', then additional information should be provided in CommentsECDC variable.
VariableName	**9 - ExtrapolatedCoverage**
Description	Were the data extrapolated to obtain 100% coverage of the reported healthcare sector in the country?
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	- If UseEurostatPopulation is 1 (TRUE) and ProportionPopulationCovered is less than 100, then ExtrapolatedCoverage must be reported as 1 (TRUE).
VariableName	**10 - J01Inclusion**
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 consumption data for the reported healthcare sector?
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	-
VariableName	**11 - J02Inclusion**
Description	Is consumption of substances in ATC groups J02 + D01BA (i.e., antimycotics for systemic use + antifungals for systemic use) included in the consumption data for the reported healthcare sector?
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	-
VariableName	**12 - J04Inclusion**
Description	Is consumption of substances in ATC group J04A (drugs for the treatment of tuberculosis) included in the consumption data for the reported healthcare sector?
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	-
VariableName	**13 – J05Inclusion**
Description	Is consumption of substances in ATC group J05 (antivirals for systemic use) included in the consumption data for the reported healthcare sector?

Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	-
VariableName	**14 - IncludesPSYHOSP**
Description	Is data from psychiatric hospitals included for the reported healthcare sector?
Required (what happens if not submitted)	No
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	
VariableName	**15 - IncludesHALT**
Description	Is data from nursing homes and other long-term care facilities for the elderly included for the reported healthcare sector?
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	
VariableName	**16 - IncludesDayCare**
Description	Is data from day care centres (for young children) included for the reported healthcare sector?
Required (what happens if not submitted)	No
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	

VariableName	17 - UseEurostatPopulation
Description	Should EpiPulse Cases use Eurostat as source of population data? If no, national population data must be provided by the country.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	- If UseEurostatPopulation is 1 (TRUE) and ProportionPopulationCovered is less than 100, then ExtrapolatedCoverage must be reported as 1 (TRUE).
VariableName	**18 - ProportionPopulationCovered**
Description	What is the percentage of coverage of population under surveillance for the reported healthcare sector compared to the whole population in the country?
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Numeric (minimum value 0; maximum value: 100; maximum number of allowed decimals: 2)
Validation rule	- If UseEurostatPopulation is 1 (TRUE) and ProportionPopulationCovered is less than 100, then ExtrapolatedCoverage must be reported as 1 (TRUE).
VariableName	**19 – CommentECDC**
Description	General comments for ECDC, these comments will not be published publicly. Any information that is important or useful when analysing the data can be included here.
Required (what happens if not submitted)	No
Data type	Text
Validation rule	- If OriginOfData is reported as 'BOTH', then additional information should be provided in CommentsECDC variable.
VariableName	**20 - 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	Text
Validation rule	-

Table 6. AMCDENOM (denominator/population under surveillance)

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

VariableName	**1 - SubjectCode**
Description	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	AMCDENOM = Antimicrobial consumption - denominator
Validation rule	-
VariableName	**2 - HealthTopic**
Description	The code of the health topic that is being reported.
Required (what happens if not submitted)	No
Data type	Coded value
Code	AMC = Antimicrobial consumption
Validation rule	-
VariableName	**3 - DataSource**
Description	The data source (surveillance system) that the record originates from.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	DATASOURCE
Code	See EPC metadata
Validation rule	-
VariableName	**4 - ReportingCountry**
Description	The country reporting the record.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	LOCATION
Code	See EPC metadata
Validation rule	-
VariableName	**5 - DateUsedForStatistics**
Description	The reference date used for standard reports that is compared to the reporting period.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Date
Code	Year (yyyy)
Validation rule	-
VariableName	6- **HealthcareSector**
Description	Healthcare sector level for which consumption data are reported, i.e. community (primary care), hospital sector, or both healthcare sectors combined (total care).
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	COM = Community care HOSP = Hospital care TOTAL = Total care
Validation rule	-
VariableName	**7 - Population**
Description	Population at place of notification.
Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Numeric (minimum value: 1; no decimals allowed)
Validation rule	-
VariableName	**8 - DataProvider**
Description	Which authority/organisation/network was the provider of population data for the reported healthcare sector?

Required (what happens if not submitted)	Yes (upload will be rejected)
Data type	Coded value
Code	CP = Community Pharmacies HI = Health Insurance Company HN = Hospital network MA = Medicines Agency MoH = Ministry of Health MR = Market Research Company NS = National Statistics Agency OTH = Other
Validation rule	
VariableName	**9 - InsuredPopulation**
Description	Is the type of population data based on the insured population?
Required (what happens if not submitted)	No
Data type	Boolean (yes/no)
Code	0 = No; 1 = Yes
Validation rule	

ESAC-Net AMC metadata changes

2025 metadata changes and EpiPulse Acses transition

Starting in April 2025, data on antimicrobial consumption should be reported to EpiPulse Cases (EPC), which is replacing The European Surveillance System (TESSy). The EPC AMC metadata set can be found here: EpiPulse Help. Differences between TESSy Metadata and EPC Metadata Variables are listed in Metadata set sheet 'TESSy vs EpiPulse Cases'. Select the Health Topic AMC and find and the explanation of changes under the 'Variable Status' ('Content change', 'Name change', 'Content change', 'Name change', 'New variable', 'No change', or 'Remove variable!').

A complete list of updates on reference values are available by selecting the Health Topic AMC in the Metadata sheet 'ReferenceValue'.

Metadata change history

The previous metadata changes from 2020–2024 are described in Table 7 below. Metadata changes prior to 2016 can be found on the TESSy documents website.

In addition to these changes, the AMC metadata is updated with the latest ATC/DDD Index on an annual basis. These updates are outlined in Tables 19–24 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 subject code **AMCLIST** is reported. For subject code **AMCAGGR**, calculations are not updated as DDD values are calculated and reported by the countries. 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). The ESAC-Net team 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 **AMCAGGR**.

Table 7. Implemented changes in record types for AMC 2016–2024

Year	Record types	Variable(s)	Description
2024	**AMC**	*StrengthUnit*	**Validation rule added**. If ATCCode is A07AA10 or J01XB01, StrengthUnit must be reported as IU or MU
	AMCDS	*DS_HALT_Inclusion*	**Change from optional to required variable**. Essential for understanding antimicrobial consumption reported from the long-term care sector.
	AMC, AMCLIGHT	*Formulation*	**Variable added** to differentiate formulation-specific DDDs.
	AMCLIGHT	*InhalationForm (powder/solution)*	**Variable added.** Needed to determine the weight of substances consumed when weight per DDD varies for different inhalation forms (e.g. tobramycin J01GB01).
	AMCLIGHT	*Weight, WeightUnit*	**Variables removed.** Weight is automatically calculated from the reported DDD.
	AMCDENOM	*PlaceOfNotification, Gender and AgeClass*	**Variables removed.** These optional variables have not been used for any analyses due to inconsistent reporting and inability to derive useful findings from them.
	AMCDS	*NationalReferenceData*	**Variables removed.** The optional variable has not been used for any analyses.
2022	**AMC$PACKAGES** **AMCLIGHT**	*PlaceOfNotification* *AgeClass* *Gender* *Prescriber*	**Variables removed.** These optional variables have not been used for any analyses due to inconsistent reporting and inability to derive useful findings from them.
2019	**AMC**	*DPPNational* *DDDNational* *DDDNationalUnit*	**Variables 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*	**Variables 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*	**Validation rule added** to validate the correct uploading of the strength unit for combined products.
	AMCLIGHT	*SyrupForm*	**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*	**Variables were added as mandatory variables** They will be used as indicators 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**

Annex 3. DDD and ATC updates and DDDs for combined products

This annex covers:

- ATC and DDD updates.
- DDDs for combined products.

ATC and DDD updates

The ATC/DDD index 2025 should be used for reporting AMC data during the 2025 call for data (referring to 2024 data). 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/

DDD calculations based on data reported under the AMCLIST reporting option will automatically be based on the latest DDD/ATC index, including updates of historical data. For data reported under the AMCAGGR option, it is the responsibility of the reporting country to ensure access and use to the latest ATC/DD index as well as updating and re-uploading historical data if there have been any major changes in ATC codes or DDD assignments.

New ATC codes, ATC changes, DDD updates and allocations of defined daily doses for combined products in EpiPulse are provided in Table 8–Table 13**.**

Table 8. New ATC codes 2025

Year	ATC code	ATC Name (active substance; International Non-proprietary Names (INN))
2024	J01DC52	cefuroxime and beta-lactamase inhibitor
	J01DD58	cefixime and beta-lactamase inhibitor
	J01DE51	cefepime and beta-lactamase inhibitor
	J05AE16	ensitrelvir
	J05AP13	Ravidasvir
	J05AR28	stavudine and lamivudine

J01DD58, J01DE51 and J05AR28 do not yet have an assigned DDD.

Table 9. New DDD allocations 2025

Year	ATC code	ATC Name (active substance; INN)	Route	DDD value	DDD unit
2024	A07AA13	rifamycin (sodium salt)	O	0.8	g
	J01AA13	eravacycline	P	0.14	g
	J01DC52	cefuroxime and beta-lactamase inhibitor*	O	0.5	g
	J01DI04	cefiderocol	P	6	g
	J02AA01	amphotericin B (lipid formulation)	P	210	mg
	J02AC06	oteseconazole	O	21	mg
	J04AK08	pretomanid	O	0.2	g
	J05AE16	ensitrelvir	O	0.175	g
	J05AH04	laninamivir	Inhal.solution	0.16	g
	J05AP13	ravidasvir	O	0.2	g
	J05AX10	maribavir	O	0.8	g
	J05AX24	tecovirimat	O	1.2	g
	J05AX28	bulevirtide	P	2	mg
	J05AX31	lenacapavir	O	0.19	g
	J05AX31	lenacapavir	P	5.1	mg

O: oral, P: parenteral
** Refers to cefuroxime.*

Table 10. ATC alterations 2025

Year	Previous ATC Code	ATC Name (active substance; INN)	New ATC Code
There are no ATC alterations defined in the 2025 ATC/DDD index.			

Table 11. ATC level name alterations 2025

Year	Previous ATC level name	ATC code	New ATC level name
There are no ATC level name alterations defined in the 2025 ATC/DDD index.			

Table 12. DDD alterations 2025

Year	ATC Code	ATC Name (active substance; INN)	route	Old DDD	New DDD	
There are no DDD alterations defined in the 2025 ATC/DDD index.						

List of EpiPulse Cases combined product codes

Table 13. New combined products codes in EpiPulse Cases, 2025

ATC code	CombinedProduct (variable to be reported)	Variable description in EpiPulse Cases metadata	Active ingredients per one unit dose (UD)	Dosage form	Brand name	Conversions used for EPC calculations	
						Weight per one DDD	No. of UD per one DDD
There are no new combined products codes in the 2025 ATC/DDD index.							

Table 14. Complete list of combined products codes in EpiPulse Cases *(adapted from WHO Collaboration Centre for Drug Statistics Methodology)*

ATC code	CombinedProduct (variable to be reported)	Variable description in EpiPulse Cases metadata	Active ingredients per one unit dose (UD)	Dosage form	Brand name	Conversions used for EPC 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	Deteclo	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 gram	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 gram	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 gram	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 gram	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 gram	2 UD (= 2 g)
J01CR50	J01CR50_3	Ampicillin_0.125g - oxacillin_0.125g	ampicillin 0.125g / oxacillin 0.125 g	Caps	Ampoxium	2 gram	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 gram	4 UD (=4 tab)
J01CR50	J01CR50_5	ampicillin_250mg - cloxacillin_250mg	ampicillin 250 mg / cloxacillin 250 mg	Powder for inj	Viccillin-S	2 gram	2 UD (=2 grams of powder for injection)
J01CR50	J01CR50_6	ampicillin_500mg - cloxacillin_500mg	ampicillin 500 mg / cloxacillin 500 mg	Powder for inj	Viccillin-S	2 gram	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 gram	8 UD (=8 tab)
J01CR50	J01CR50_8	ampicillin_250mg - cloxacillin_250mg	ampicillin 250 mg / cloxacillin 250 mg	Tab	Betaclox	2 gram	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 gram	4 UD (=4 tab)

ATC code	CombinedProduct (variable to be reported)	Variable description in EpiPulse Cases metadata	Active ingredients per one unit dose (UD)	Dosage form	Brand name	Conversions used for EPC calculations	
						Weight per one DDD	No. of UD* per one DDD
J01EE01	J01EE01_1	sulfamethoxazole_80mg - trimethoprim_16mg	In 1mL: sulfamethoxazole 80 mg / trimethoprim 16 mg	Inf conc	Bactrim, Eusaprim, Trimetoprim-sulfa	1.6 gram 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 gram 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 gram 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)
J01EE03	J01EE03_1	sulfametrole_0.8g - trimethoprim_0.16g(tab)	sulfametrole 0.8 g / trimethoprim 0.16 g	Tab	Lidaprim	1.6 gram 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 gram 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/	spiramycin 1.5 MU / (1MU=0.31g) metronidazole 250 mg	Tab	Bidontogyl	1.395 gram spira 0.75 gram metro	3 UD (=3 tab)
J01RA04	J01RA04_2	metronidazole 250 mg	spiramycin 0.75 MU / metronidazole 125 mg	Tab	Orogyl	1.395 gram 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 gram	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 gram	4 UD (=4 tab)
J01RA09	J01RA09_1	ofloxacin_200mg - ornidazole_500mg(tab)	ofloxacin 200 mg / ornidazole 500 mg	Tab	Oflox Oz	1.4 gram	2 UD (=2 tab)
J01RA10	J01RA10_1	ciprofloxacin_500mg - metronidazole_200mg(tab)	ciprofloxacin 500 mg / metronidazole 200 mg	Tab	Cipramed	1.4 gram	2 UD (=2 tab)
J01RA11	J01RA11_1	ciprofloxacin_500mg - tinidazole_300mg(tab)	ciprofloxacin 500 mg / tinidazole 600 mg	Tab	Ciprotini	2.2 gram	2 UD (=2 tab)
J01RA11	J01RA11_2	ciprofloxacin_250mg - tinidazole_300mg(tab)	ciprofloxacin 250 mg / tinidazole 300 mg	Tab	Ciptin	2.2 gram	4 UD (=4 tab)

ATC code	CombinedProduct (variable to be reported)	Variable description in EpiPulse Cases metadata	Active ingredients per one unit dose (UD)	Dosage form	Brand name	Conversions used for EPC calculations	
						Weight per one DDD	No. of UD* per one DDD
J01RA12	J01RA12_1	ciprofloxacin_500mg - ornidazole_500mg(tab)	ciprofloxacin 500 mg / ornidazole 500 mg	Tab	Simprasole	2 gram	2 UD (=2 tab)
J01RA13	J01RA13_1	norfloxacin_400 mg - tinidazole_600 mg	norfloxacin 400 mg / tinidazole 600 mg	Tab	Actiflox-T	2 gram	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 gram	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 gram	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 gram	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 gram	6 UD (=6 tab)
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 gram	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 gram	4 UD (=4 tab)
J04AM06	J04AM06_2	rifamp._0.45g -pyrazin._0.75g - ethambutol_0.8g - isoniazid_0.3g	rifampicin 450 mg (1 tab) / pyrazinamide 750 mg (2 tab) / ethambutol 800 mg+isoniazid 300 mg (1 tab) (combination package)**	Tab	AK-4	3.05 gram	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 gram	4 UD (=4 tab)
J05AP51	J05AP51_1	sofosbuvir - ledipasvir	sofosbuvir 400 mg / ledipasvir 90 mg	Tab	Harvoni	0.49 gram	1 UD (=1 tab)

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						Weight per one DDD	No. of UD* per one DDD
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)
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)
J05AP55	J05AP55_2	sofosbuvir_150mg - velpatasvir_37.5mg	sofosbuvir 150mg / velpatasvir 37.5mg	granules, single dose sachets	Epclusa	0.562 gram	3 UD (=3 sachets)
J05AP55	J05AP55_3	sofosbuvir_200mg - velpatasvir_50mg	sofosbuvir 200mg / velpatasvir 50mg	granules, single dose sachets	Epclusa	0.5 gram	2 UD (=2 sachets)
J05AP55	J05AP55_4	sofosbuvir_200mg - velpatasvir_50mg	sofosbuvir 200mg / velpatasvir 50mg	Tab	Epclusa	0.5 gram	2 UD (=2 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	0.42 gram	3 UD (=3 tab)
J05AP57	J05AP57_2	glecaprevir_50mg - pibrentasvir_20mg	glecaprevir 50mg / pibrentasvir 20mg(tab)	granules, single dose sachets	Maviret/ Mavyret	0.42 gram	6 UD (=6 sachets)
J05AP57	J05AP57_3	glecaprevir_100mg - pibrentasvir_40mg	glecaprevir 100mg / pibrentasvir 40mg (tab)	Tab	Maviret/ Mavyret	0.42	3 UD (=3 tab)
J05AR01	J05AR01_1	lamivudine - zidovudine	lamivudine 0.15 g / zidovudine 0.3 g	Tab	Combivir	0.9 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 gram	2 UD (=2 tab)
J05AR05	J05AR05_1	lamivudine - nevirapine - zidovudine	lamivudine 150 mg / nevirapine 200 mg / zidovudine 300 mg	Tab	Lamivudine/Nevirapine/ Zidovudine	1.3 gram	2 UD (=2 tab)

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						Weight per one DDD	No. of UD* per one DDD
					150mg/200mg/ 300mg		
J05AR06	J05AR06_1	emtricitabine - tenofovir disoproxil - efavirenz	emtricitabine 0.2 g / tenofovir disoproxil 0.245 g / efavirenz 0.6 g	Tab	Atripla	1.045 gram	1 UD (=1 tab)
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 disoprxil - efavirenz	lamivudine 300 mg / tenofovir disoproxil 300 mg (fumarate) / efavirenz 600 mg	Tab	Efavirenz/lamivudine/tenofovir	1.2 gram	1 UD (=1 tab)
J05AR12	J05AR12_1	lamivudine - tenofovir disoproxilo	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/ Prezcobix	0.95 gram	1 UD (=1 tab)
J05AR15	J05AR15_1	atazanavir - cobicistat	atazanavir 0.3 g / cobicistat 0.15 g	Tab	Evotaz	0.45 ram	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 - tenofovir alafenamide - elvitegravir - cobicistat	emtricitabine 200 mg / tenofovir alafenamide 10 mg / elvitegravir 150 mg / cobicistat 150 mg	Tab	Genvoya	0.51 gram	1 UD (=1 tab)
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)

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						Weight per one DDD	No. of UD* per one DDD
J05AR20	J05AR20_2	emtricitabine - tenofovir alafenamide - bictegravir	emtricitabine 120 mg / tenofovir alafenamide 15 mg / bictegravir 30 mg	Tab	Biktarvy	0.33 gram	2 UD (=2 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 gram	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, J05AP55, J05AP57, J05AP58, J05AR20, J05AR26 and J05AR27 do not have an assigned DDD (2024 ATC/DDD index).

DDD: Defined daily Dose; 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 dosage 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' is 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'.