



Better Training for Safer Food *Initiative*

Antimicrobial Resistance One Health approach

**MONITORING AND REPORTING USE
OF ANTIMICROBIALS**

BTSEF

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Food safety

Malaga, Spain – 25-28 November 2019

Monitoring the consumption of antimicrobials

- Harmonization of the **source of data**
 - **In the public health sector**
 - **In the veterinary sector**
- Harmonization of the **measure units**
 - **In the public health sector**
 - **In the veterinary sector**
- Harmonization of the **data collection**
 - **In the public health sector**
 - **In the veterinary sector**



Harmonization of the source of data in the public health sector

Review of Data Sources

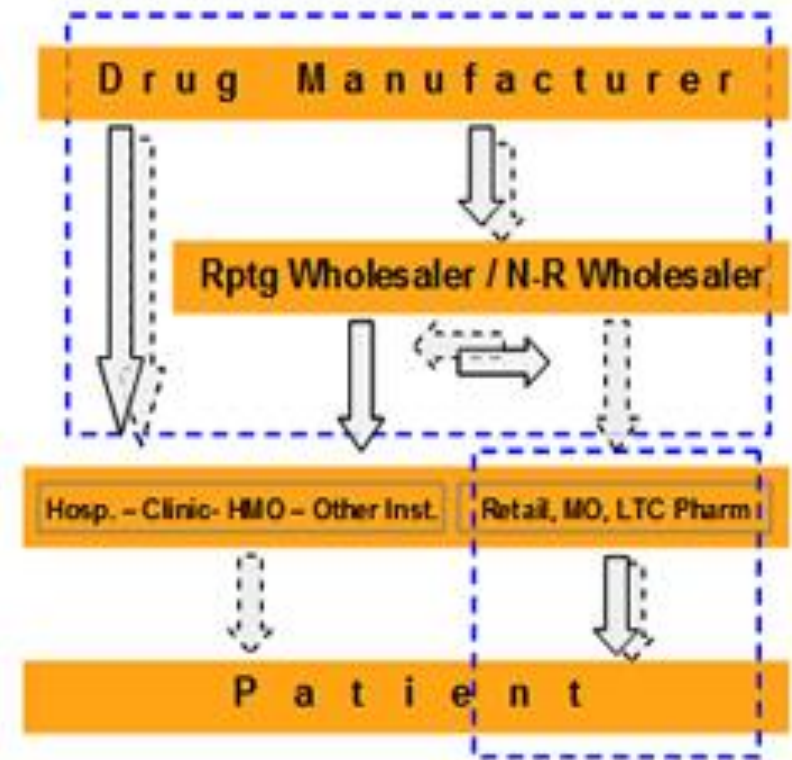
Sources of drug utilization data vary from country to country depending on the level of sophistication of record keeping, data collection, analysis and reporting and the operational considerations of the health care system. This section will provide a review of the different sources that can be used to assess antimicrobial consumption.

Collective Level

- Pharmaceutical industry **sales** (country/region)
- Pharmacy purchases (hospital)
- Pharmacy issues (unit/ward)

Patient level

- -**Prescriptions** (prescribing physician/patient)
 - -**Dispensation**
- National registers, e.g. Denmark (patient)
- **Reimbursement**



Sales data

Data Collected:

- Information from manufactures or wholesalers
 - Drug name and amount sold
 - Prescriptions + OTC drugs

Limitations:

- Sales data may only cover those drugs that are reimbursed by public insurance schemes
- They may be based on ex-factory or wholesale prices rather than retail prices
- Sales data may exclude drug consumption in hospitals

Useful for:

- Impact of pharmaceutical policies and interventions
- Comparisons



Prescription data

Data Collected:

- Information from health care providers
- Information about patient demography, drug name, dosage form, strength, dose, frequency of administration and duration of treatment. Even outcome
- Prescriptions + OTC drugs

Limitations:

- Requires structure data capture to ensure the accuracy and completeness of data collected
- Cost of implementation and maintenance
May vary from region to region

Useful for:

- Drug utilization studies
- Trends in utilization for specific drugs and diseases
- Determining some of the indicators of drug use



Dispensing data

Data Collected:

- Information from pharmacies
- Information about all dispensations of drugs prescription regardless reimbursement
- Information about drug name, dosage form, strength, amount dispensed, dates of prescribing and dispensing, cost, reimbursed cost and patient cost.
- May include information about the prescriber and setting

Limitations:

- Uncertainty around whether or not the patient will take the drug
- Alternative ways of obtaining medications

Useful for:

- Are considered more accurate than prescription data.



Reimbursement Data

Data Collected:

- Prescriptions that are submitted and recorded for reimbursement
- Information about patient demography, prescriber and pharmacy dispensing the drug, drug name, dosage form, strength, quantity, date of prescription and dispensation.

Limitations:

- Limited to those drugs that are reimbursed
- Changes in copayment may lead to distortions
- Information limited to insured individuals only
- Uncertainty around whether or not the patient will take the drug
- Alternative ways of obtaining medications

Useful for:

- Highly accurate for the information on the utilization of reimbursed drugs
- Drug utilization in routine clinical practice (factors influencing drug utilization, effect of health policy interventions)





Data source of antimicrobial consumption in Europe

Review of the different sources that are used to assess antimicrobial consumption in Europe and Comparison of antimicrobial consumption data from different countries/years

ESAC-net

- Coordinated by ECDC
- Coordination Group

Subprojects:

- HAI-Net
- HALT-2 project

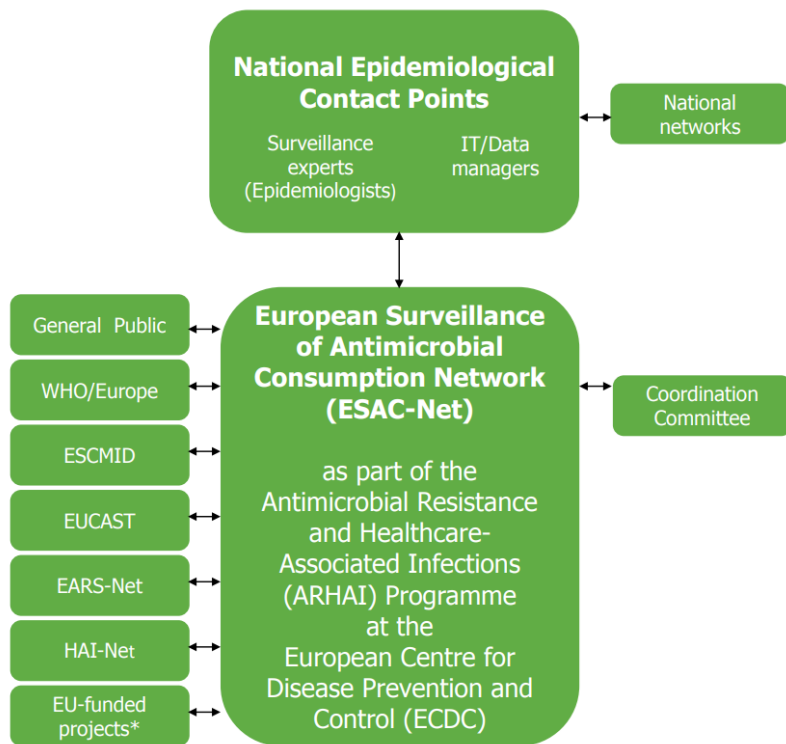
European Surveillance System (TESSy):

- antibacterials for systemic use
- antimycotics and antifungals
- antivirals

Data Sources:

- National Sales
- Reimbursement data

Figure 1.1. Organisation of ESAC-Net (2012)



* EU-funded projects on antimicrobial consumption, e.g. ARPEC and ESVAC.

Source of data



Data Source

Community

Sales: 58%

Reimbursement: 29%

Both: 12%

Hospital

Sales: 60%

Reimbursement: 17%

Both: 21%

Country	Sector	Consumption							Population data source
		Data provider	Data type	Data Coverage (%) (population under surveillance)	Antibacterials for systemic use (ATC group J01) *	Antimycotics and antifungals for systemic use (ATC groups J02 & D01BA)	Antimycobacterials (ATC group J04)	Antivirals for systemic use (ATC group J05)	
Austria	C	Health insurance company	Reimbursement	100	Y	Y	Y	Y	Eurostat
Belgium	C	Health insurance company	Reimbursement	98	Y	Y	Y	Y	Eurostat
	HC	Health insurance company	Reimbursement	98	Y	Y	Y	Y	Eurostat
Bulgaria	C	Market research company	Sales	100	Y	Y	Y	Y	National Statistics Agency
	HC	Market research company	Sales	100	Y	Y	Y	Y	National Statistics Agency
Croatia	C	Health insurance company	Reimbursement	100	Y	N	N	N	National Statistics Agency
	HC	Ministry of Health	Reimbursement	100	Y	N	N	N	National Statistics Agency
Cyprus	TC	Ministry of Health	Sales	100	Y	Y	Y	Y	Eurostat
Czech Republic	C	Health insurance company	Reimbursement	100	Y	Y	Y	Y	National Statistics Agency
Denmark	C	Ministry of Health	Sales	100	Y	Y	Y	Y	Eurostat
	HC	Ministry of Health	Sales	100	Y	Y	Y	Y	Eurostat
Estonia	C	Medicines Agency	Sales	100	Y	Y	Y	Y	Eurostat
	HC	Medicines Agency	Sales	100	Y	Y	Y	Y	Eurostat
Finland	C	Medicines Agency	Sales	100	Y	Y	Y	Y	Eurostat
	HC	Medicines Agency	Sales	100	Y	Y	Y	Y	Eurostat
France	C	Medicines Agency	Sales	100	Y	Y	Y	Y	National Statistics Agency
	HC	Medicines Agency	Sales	100	Y	Y	Y	Y	National Statistics Agency
Germany	C	Health insurance company	Reimbursement	85	Y	Y	Y	Y	National Statistics Agency
Greece	C	Medicines Agency	Sales	100	Y	Y	Y	Y	Eurostat
	HC	Medicines Agency	Sales	100	Y	Y	Y	Y	Eurostat
Hungary	C	Health insurance company	Reimbursement	100	Y	Y	Y	Y	Eurostat
Iceland	TC	Medicines Agency	Sales	100	Y	Y	Y	Y	National Statistics Agency
Ireland	C	Market research company	Sales	100	Y	N	N	N	Eurostat
	HC	Hospital network	Sales/reimbursement	90	Y	Y	N	N	Eurostat
Italy	C	Medicines Agency	Sales	90	Y	Y	Y	Y	Ministry of Health
	HC	Medicines Agency	Reimbursement	100	Y	Y	Y	Y	Ministry of Health
Latvia	C	Medicines Agency	Sales	100	Y	Y	Y	Y	Eurostat
	HC	Medicines Agency	Sales	100	Y	Y	Y	Y	Eurostat
Lithuania	C	Medicines Agency	Sales	100	Y	Y	Y	Y	Eurostat
	HC	Medicines Agency	Sales	100	Y	Y	Y	Y	Eurostat
Luxembourg	C	Health insurance company	Reimbursement	94	Y	Y	Y	Y	Health insurance company
	HC	Hospital network	Sales	90	Y	Y	Y	Y	National Statistics Agency
Malta	C	Ministry of Health	Sales	100	Y	Y	Y	Y	Ministry of Health
	HC	Ministry of Health	Sales	100	Y	Y	Y	Y	Ministry of Health
Netherlands	C	Community pharmacists	Sales	92	Y	Y	Y	Y	Other
	HC	Hospital network	Sales	79	Y	N	N	N	National Statistics Agency
Norway	C	Other	Sales/reimbursement	100	Y	Y	Y	Y	National Statistics Agency
	HC	Hospital network	Sales/reimbursement	100	Y	Y	Y	Y	Other
Poland	C	Market research company	Sales	100	Y	N	N	N	Eurostat
Portugal	C	Ministry of Health	Sales	100	Y	Y	Y	Y	Ministry of Health
	HC	Ministry of Health	Sales/reimbursement	95	Y	Y	Y	Y	Ministry of Health
Romania	TC	Market research company	Sales	100	Y	Y	N	Y	National Statistics Agency
Slovakia	C	Medicines Agency	Sales	100	Y	Y	Y	N	Eurostat
	HC	Medicines Agency	Sales	100	Y	Y	Y	N	Eurostat
Slovenia	C	Other	Sales/reimbursement	100	Y	Y	Y	Y	National Statis
	HC	Hospital network	Sales/reimbursement	100	Y	Y	Y	Y	National Statistics Agency
Spain	C	Ministry of Health	Reimbursement	100	Y	N	N	N	National Statistics Agency
Sweden	C	Community pharmacists	Sales	100	Y	Y	Y	Y	National Statistics Agency
	HC	Other	Sales	100	Y	Y	Y	Y	National Statistics Agency
United Kingdom	C	Ministry of Health	Reimbursement	100	Y	N	N	N	National Statistics Agency

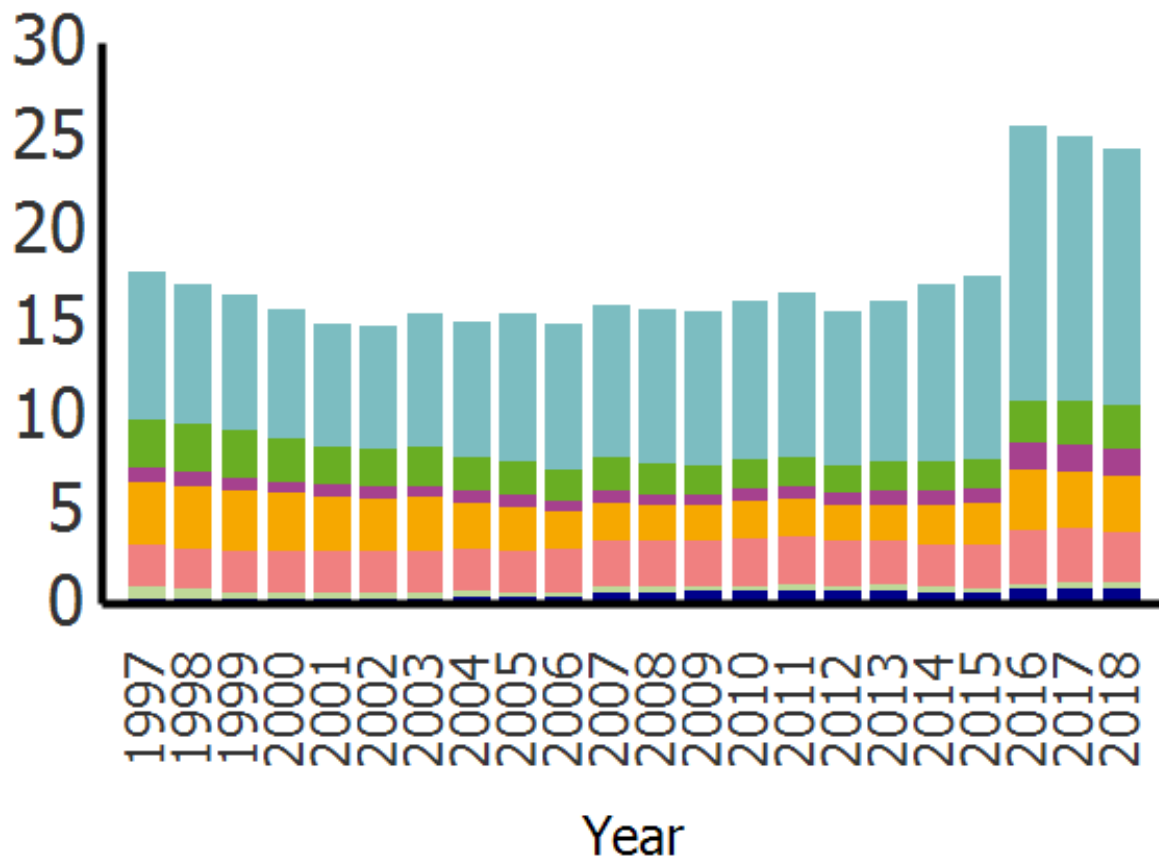
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Example

Impact of the different sources used to assess antimicrobial consumption

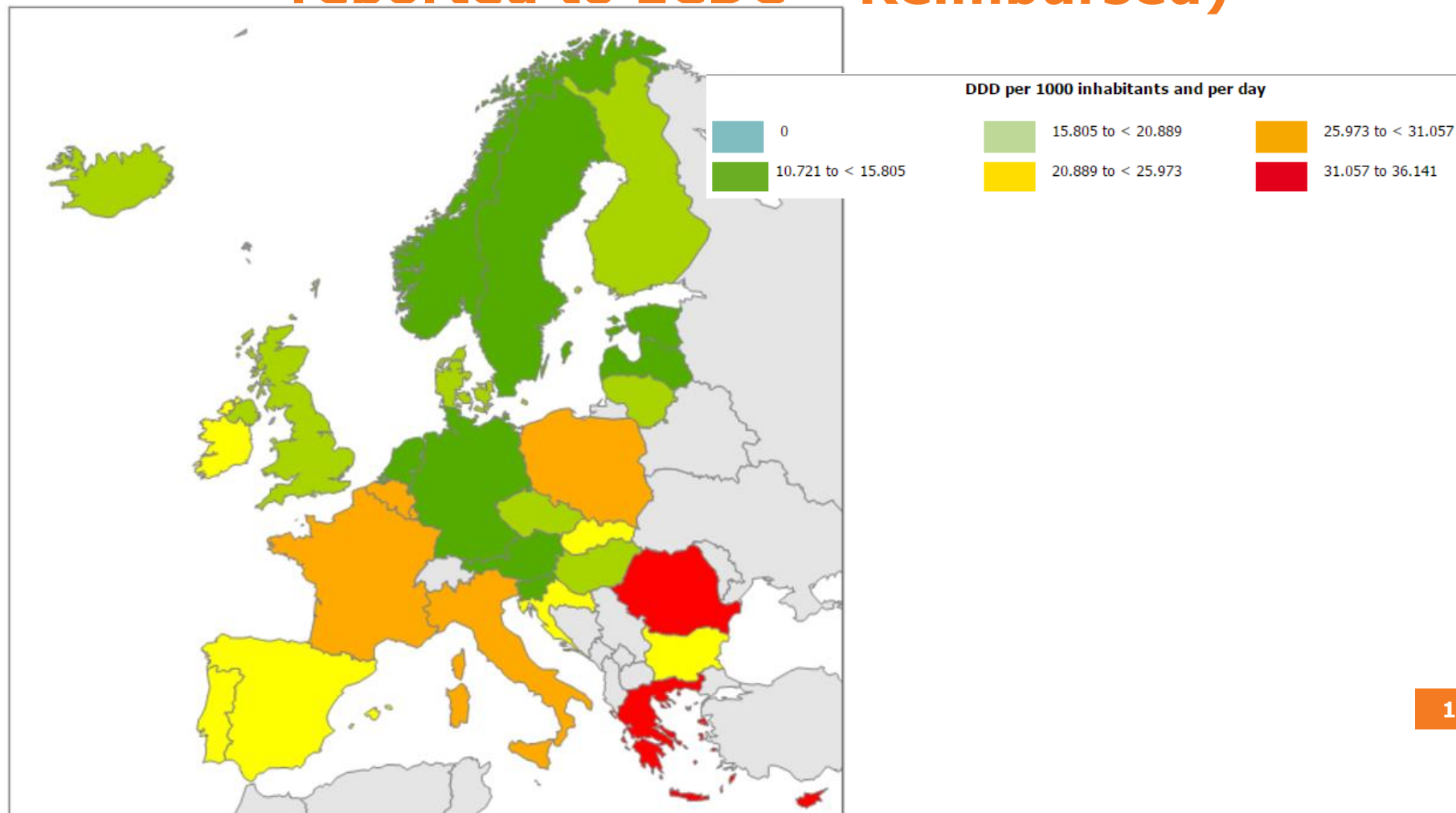
Trends in antibiotic consumption in the community sector Spain 1997-2018 (DHD)





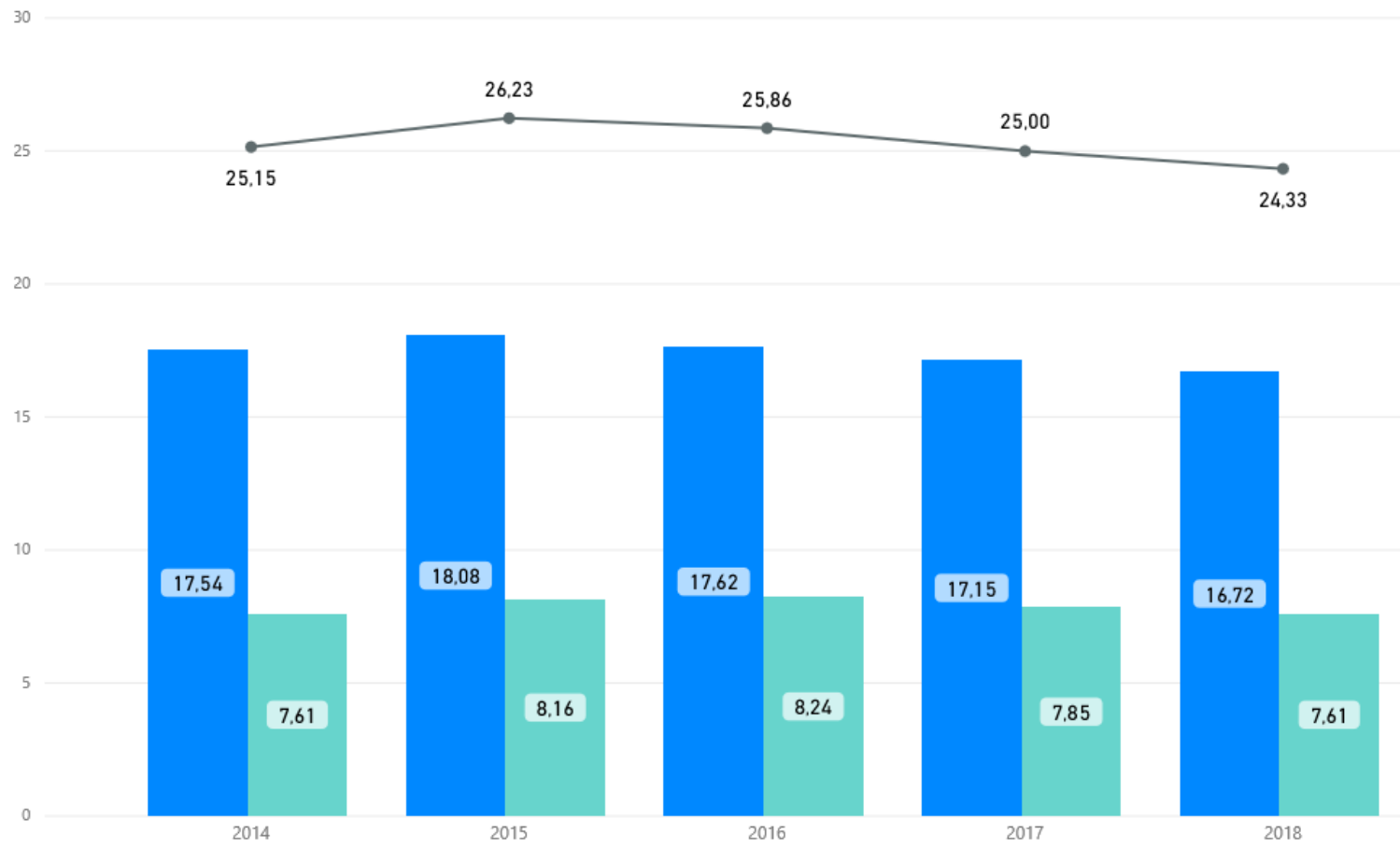
European
Commission

Antibiotic consumption in primary care (data reported to ECDC – Reimbursed)



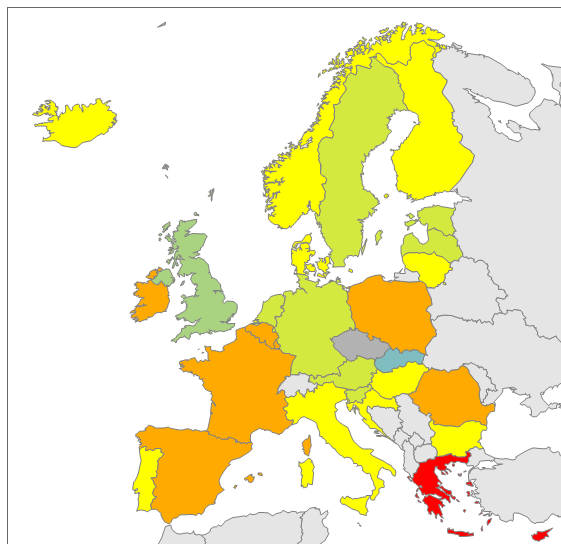


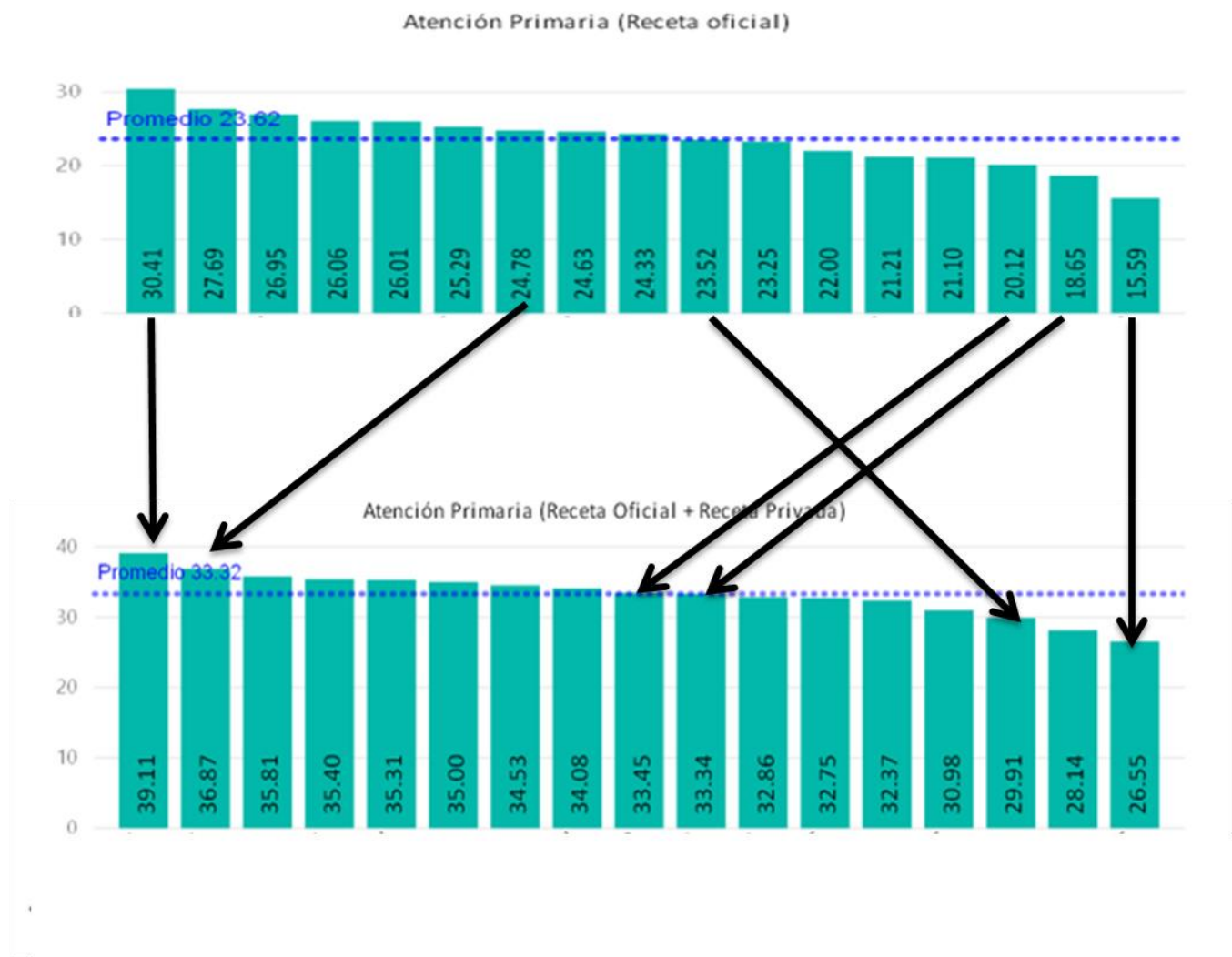
Total Antibiotic Sales in Spain



Europe: Consumption of Antibacterials for systemic Use in the community(2018)-DHD

Consumption of Antibacterials for systemic use (ATC group J01) in the community (primary care sector) in Europe, reporting year 2018







Harmonization of the source of data in the veterinary sector

Monitoring and reporting of sales/use of veterinary antimicrobials

Current systems and future perspectives
Veterinary field



WHY

Monitoring/surveillance of sales/use?

To know

The extent and trends of the use

To investigate

How the use of antimicrobials correspond to AMR*

To evaluate

Effectiveness of measures

To raise

Awareness of overuse if is the case

To benchmark

To do

Measures to lower the use to the level allowing to:

- **keep sustainable animal husbandry with healthy animals**
 - impact on quality of food of animal origin => public health concerns
- **combating of development and spread of AMR** => animal/public health concerns
- **lower the load for environment**

* Note: Please consider the complexity – e.g. Co-selection of AMR not only by „true“ ATM ...routes of spread of AMR



WHAT?

Monitoring: Monitoring refers to a continuous, dynamic process of **collecting data** intended to be further analysed and used.

Surveillance: Surveillance refers to a specific extension of the monitoring process where **obtained data/analysed information are used** and **measures are taken** if certain threshold values have been passed.

... and by WHOM?

Sales



Raw data from sources close to end user if possible **MAHs, wholesalers / feed mills, pharmacies** – e.g. ESVAC data on variables - one of them packages of certain VMP sold per country.

Mandatory according to Article 57(3) of Regulation (EU) 2019/6

Use



Data from **end-user (vets/farmers)** – e.g. data on exact use from farm level (delivery notes, prescriptions, no of packages administered, no of empty packages checked)

Mandatory according to Article 57(3) of Regulation (EU) 2019/6

Consumption →

Calculated amount of active ingredients (antimicrobials) should be linked with explanation of the data source



ESVAC European Surveillance of Veterinary Antimicrobial Consumption

Interactive ESVAC database

complements the annual ESVAC report on the sales of veterinary antimicrobials, allowing users to access a summary of the specific ESVAC data they are interested in, including data for a specific country or sales of a particular antimicrobial class



- Annual report on sales of veterinary antibiotics
- Collection of overall sales data
 - **Report 2017 data (31 EU/EEA countries) released October 2019**

https://www.ema.europa.eu/en/documents/report/sales-veterinary-antimicrobial-agents-31-european-countries-2017_en.pdf

- Stratifying sales data by animal species

Population correction unit

Standardised units of measurement

Reporting data by animal species

ESVAC strategy 2016 - 2020



What was gained from ESVAC sales data?

Harmonised sales data template + sales data protocol

Covering the AMC in Europe :

From 9 countries (2009) ... to 31 countries (2019)

Amount of ATM / harmonised PCU

Estimation of the species consumption (JIACRA II)

Special analysis performed with the sales data:

...attention to CIAs, mass medication, pharmaceutical forms, food producing vs. pet (tablets), trends analysis ...





Article 57(3) of Regulation (EU) 2019/6: NEW MANDATORY "USE" DATA COLLECTION

- **January 2023 (reporting to EMA 2024)** Member States should start collection of data on **AM use** in species/categories included in Com Implementing Decision 2013/652/EU:
 - **cattle** (all categories, specifying use in bovines under 1 year of age),
 - **pigs** (all categories including fattening pigs),
 - **chickens** (all categories or stages of chickens including broilers and laying hens) and turkeys (all categories including fattening turkeys)
- **January 2026 (reporting to EMA 2027)** Member States should start collection of data on **AM use** for the rest of food-producing animal species:
 - **other poultry (ducks, geese),**
 - **sheep, goats,**
 - **finfish, horses, rabbits** (food-producing) and any **other food-producing** animals
- **January 2029 (reporting to EMA 2030)** Member States should start collection of data on **AM use** for the following non-food-producing animal species:
 - **dogs,**
 - **cats**
 - **fur animals (minks and foxes)**



Recommendation to prioritise the collection of sales and use data of the antimicrobials EU level

- **mandatory** collection at EU level sales and use data:
 - **all categories AM as currently in ESVAC sales project:**
antidiarrheals, intestinal anti-inflammatory/anti-infective agents, gynaecological anti-infectives and antiseptics, anti-infectives and antiseptics for intrauterine use, antibacterials for systemic use, antibacterials for intramammary use, antiprotozoals with antibacterial effect,
 - **in addition mandatory** collection of **sales** data antibiotics and chemotherapeutics for **dermatological** use, other **nasal** preparations (that contain antimicrobials), **antimycobacterials** for intramammary use, , **ophthalmological** anti-infectives and **otological** anti-infectives
- **MSs may voluntarily extend** the collection to **sales** data for other antiprotozoals, antifungals, antimycotics, antimycobacterials and antivirals and use data for antibiotics and chemotherapeutics for dermatological use, antimycobacterials for intramammary use, antimycotics, antimycobacterials, nasal preparations, ophthalmological anti-infectives, otological anti-infectives, other antiprotozoals, antifungals, antimycotics, antimycobacterials and antivirals.



Use data ... WHO and HOW?

Governmental / Private

Survey systems / Permanent record system

Partial coverage / Full coverage

Possible sources for use data:

- Health records, treatment log books, delivery notes / invoices;
- Prescriptions or pharmacy records;
- Veterinary practice records.

Data on antimicrobial use collected in the form of:

- The treatment schedule used or prescribed, including the number and weight of animals treated, VMP/medicated feed;
- The number of packages per VMP presentation used for the treatment/observation;
- The total quantity of a VMP (premix) mixed into medicated feed.

EU technical requirement under development



Benefits of monitoring the use – national level

- Policy makers insight into the effect of implemented measures (e.g. national responsible use and treatment GL)
- Risk managers can identify risk factors and tools for risk assessment as well as risk management:
 - At a national/regional level
 - Animal sector
 - Farm level(depending on the data collection system in each country)
- Extent of possibilities for further analysis and work with data can be broadened by collection of additional data



Working with data on USE at national level (II)

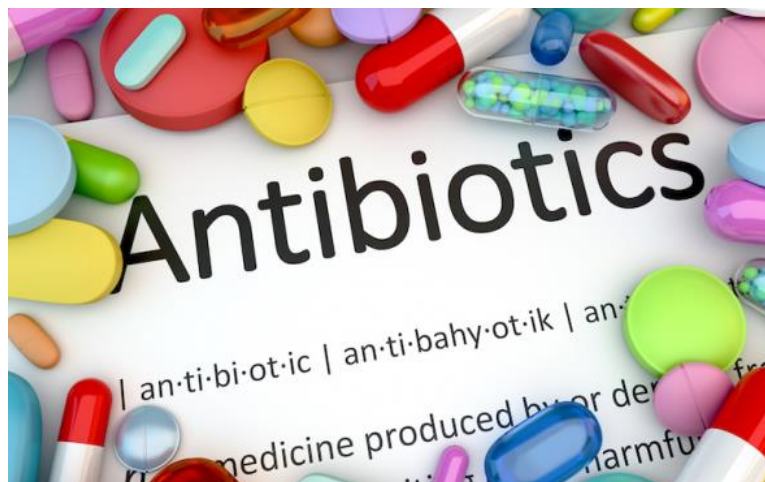
- **Trends** monitoring

- In several years validated/stable collecting system
- Analysis in relation to AMR data of relevance to:
 - Animal and public health (surveillance of zoonotic, indicator and/or commensal pathogens) – EU programs co-financed (EFSA)
 - Animal health + effective treatment (surveillance of target veterinary pathogens (nationally specific programs, national budgets)
 - Availability of both datasets (ATM use + AMR data)
 - From the farms and collected at the relevant time framework:
 - › Same time as the use data or
 - › Follow up dataset... monitoring what happened after certain changes (e.g. switch-off use of certain ATM)

Introduction – MEASURE UNITS

Why measure antibiotic consumption?

- To define best levels of consumption, including local disease prevalence, susceptibility patterns, antibiotic prescribing practices.
- To better understand trends in antibiotic prescribing.
- To identify where interventions to improve prescribing are most needed.
- To measure progress.





Harmonization of the measure units in the public health sector

To facilitate the ability to compare consumption information across time and geography, different technical units of measurement can be used



Defined Daily Doses (DDD)

- Assigned by the WHO Collaborating Centre for Drug Statistics Methodology, Oslo (Norway)
 - DDD = average maintenance dose per day for a drug used for its main indication in adults
 - Expressed in grams (or I.U.) of the active substance
- **Technical measurement unit that allows comparisons**

$$\text{No. DDD} = \frac{\text{No. packages} \times \text{No. tablets per package} \times \text{No. g per tablet}}{\text{DDD of antimicrobial in grams}}$$



Advantages of DDDs

Allow comparisons with others (countries, hospitals and wards)

- Independent from price and package size
- Easy to calculate



Limitations of DDDs

- Not everyone agrees with the DDD correction factor
- Not patient level information
- Cannot be used in paediatric wards
- It does not always correspond to the dose used in clinical practice (e.g. intensive care units, renal dysfunction, surgery prophylaxis)
- It does not necessarily correspond to the dose effectively received by the patient (Days of Therapy)
- Many use institution-specific correction factors (Prescribed Daily Dose)
- DDD can change with time



Prescribed Daily Doses (PDDs)

Defined locally, **Do NOT allow inter-hospital comparisons!**

Days of Therapy

Can be used in children and not influenced by changes in the DDD standards. Not subject to differences in institutional preference. Based on Patient-specific information → **More difficult to measure without computerized records**

Number of Packages

Useful in assessing differences in antimicrobial prescribing habits or impact of awareness campaigns in countries dispensing complete packages. **Does not reflect the variations in strengths**



Indicators used in the public health sector

To facilitate the ability to compare consumption information across time and geography, different technical units of measurement can be used.

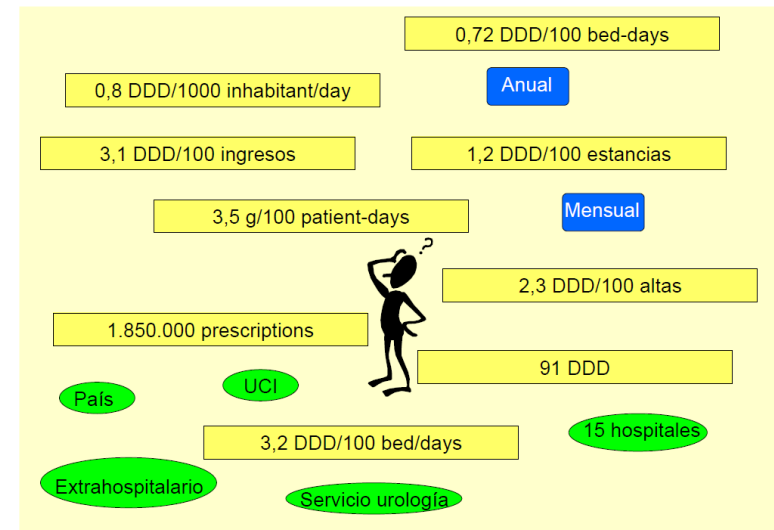
Indicators for Antimicrobial Use

Rate:

Total Units of drug

Specified Period of Time

Population





Available Denominators for Measuring Antibiotic Use

Patient-days, per 100 or 1,000 patient-days (country/region)

- For antimicrobial consumption in hospitals
- Means \approx an occupied bed one day
- Theoretically: day of admission + day of discharge = 1 single day
- But in practice: administrative bed-days

Number of beds x occupancy x Number of days
(during a specified period)



Available Denominators for Measuring Antibiotic Use

Admissions or discharges

- For antimicrobial consumption in hospitals
- More stable
- Used for calculating % patients exposed to antimicrobials and reflecting hospital activity

Inhabitant-days (per 1,000 inhabitant-days)

- For antimicrobial consumption in primary health care
- NOT to be used for consumption in hospitals



Indicators of AMC in humans (ECDC_EMA_EFSA JIACRA)

Primary indicator:

- Total consumption of all antimicrobials for systemic use (DDD per 1,000 inhabitants and per day)

Secondary indicators:

- Ratio of consumption of broad-spectrum penicillins, cephalosporins, macrolides and fluoroquinolones to the consumption of narrow-spectrum penicillins, cephalosporins and macrolides;
- Consumption of glycopeptides, 3rd and 4th generation cephalosporins, monobactams, carbapenems, fluoroquinolones, polymyxins, piperacillin and enzyme inhibitors, linezolid, tedizolid and daptomycin (DDD per 1,000 inhabitants and per day, and as proportion of the total hospital use).



Conclusions

- There are many different ways to measure antibiotic use, each with distinct advantages and disadvantages.
- Important considerations when selecting a metric include:
 - Availability of data and ease of access
 - Institutional vs. patient- level data
- Hospital setting
 - Patient-level data for time-limited studies only
 - To measure ecological pressure and for benchmarking with other institutions and other countries:
 - DDD / 1,000 inhabitant-days (EU-ESAC)
 - **DDD/100 patient-days** (WHO, EU-ARPAC)*
- Primary care
 - **DDD / 1,000 inhabitant-days** (WHO, EU-ESAC)
 - **No Packages / 1000 inhabitants-day** (EU-ESAC)



Harmonization of the measure units in the veterinary sector

IN SYSTEMS OF MONITORING OF USE/SALES DATA

Current systems and future perspectives
Veterinary field



Sales of VMPs – ESVAC units (I)

Published sales data: antimicrobial classes summarising all relevant active ingredients used in VMPs **expressed in**
tonnes **and** **mg/PCU**

NUMERATOR = sales data for antimicrobial agents

DENOMINATOR = all food-producing species (including horses) - the food producing animal population 'at risk' of being treated with antimicrobials

PCU as a technical unit of measurement and not a real value for the animal population that could potentially be treated with antimicrobial agents.

Stratification of the PCU value among the food producing animal species in the various countries to be considered.



Use of VMPs – ESVAC units (II)

Standardised units of measurement - consumption in specific animal species: pigs, cattle, broilers

Indicators of use of antimicrobials

- **mg** of active substance normalised by **animal biomass** (expressed in kilograms)
- **Number** of Defined Daily Doses for animals (DDDvet) normalised by animal biomass (expressed in kilograms)
- **Number** of Defined Course Dose for animals (DCDvet) normalised by animal biomass (expressed in kilograms)



Interpretation and communication of reported outcomes

Indicators are not intended to exactly reflect the practices in a given country, species and year.

- **DDDvet** and **DCDvet** are technical units of antimicrobial use measurement
- The **denominator** is a proxy for the animal population, biomass at risk

Reported outcomes are to be interpreted with caution

- Systematic differences between data collection systems and sources
- Related factors (e.g. production characteristics, climate) differing between species and countries



PCU = Population Correction Unit

- **PCU** = purely a technical unit of measurement
- Used only to estimate sales corrected by the animal population in individual countries;
- **1 PCU = 1 kg** of different categories of livestock and slaughtered animals

Methodology for the calculation of PCU / each animal category /:

- Calculated by **multiplying numbers**:
 - **of livestock animals** (dairy cows, sheep, sows and horses)
 - **slaughtered animals** (cattle, goat, pigs, sheep, poultry, rabbits, turkeys)
 - By the **theoretical weight** at the most likely time for treatment.
- Data sources used / methodology for the calculation of PCU comprehensively described in ESVAC-EMA website
 - Animal categories and raw data of PCU are available in Eurostat :
<http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/themes>
 - Data on import / export considered in PCU calculations



DDDvet

...

DCDvet

ARE intended for the **reporting of antimicrobial consumption data**,

NOT to be assumed to reflect the daily and course doses **recommended or prescribed**,

NOT applicable for **commercial use** (pricing and analyses of costs); assigned DDDvet and DCDvet often a consensus/compromise values.

The lists of DDDvet and DCDvet value separately:

- **pigs**
- **cattle** (with specific iIMM lactating/dry cow treatment and IUT)
- **broilers** (poultry)

Set based on SPCs of VMPs as authorized in 9 MSs volunteered to provide the data on dosing for pigs, broilers and cattle:

CZ, DE, DK, ES, FI, FR, NL, SE, UK (Voluntary countries)



DDDvet ... DCDvet

DDDvet / DCDvet take account of differences in:

- dosing,
- pharmaceutical form
- route of administration used **in the different species.**

Administration routes/forms	Units
oral and injectable products	milligram per kilogram of animal
lactating cow intramammary products	units per teat
dry cow intramammary products	units per udder
intrauterine products	units per animal

* There are some exceptions

CATEGORIES

Introduction – Public health

Global data vs Specific Data

- Will depend on the question being asked. E.g.
- Comparisons between countries, regions and health facilities.
- To determine whether there is a trend towards use of higher strengths of antibiotics
- To determine the relative use of an antibiotic group
- Down to level patient based analysis to direct interventions in specific groups (age, wards)
- Diagnosis-linked or non-diagnosis-linked analysis.

Global Data analyses

Information on antimicrobial consumption, and in particular the consumption of antibacterials, can be an important source for healthcare professionals and policy makers monitoring progress towards a more prudent use of antibiotics.

Specific Data analyses

Specific data are collected from certain specific groups, such as patients hospitalised and in long-term care facilities that are collected through the Healthcare-Associated Infections Surveillance Network (HAI-Net). Other examples of data collection in specific populations, such as Worldwide Antibiotic Resistance and Prescribing in European Children (ARPEC) or BIFAP (Spanish Farmacoepidemiological Investigation Database) are presented.

Antimicrobial consumption in Europe ESAC-net Report

ECDC reports yearly antimicrobial consumption data
from the community (primary care sector) and the
hospital sector

Data Sources:

- National Sales
- Reimbursement data

Indicators:

DDD per 1 000 inhabitants and per day
Packages per 1 000 inhabitants and per day

Quality indicators:

Specific antibiotic groups

SURVEILLAN



Surveillance of ant consumption

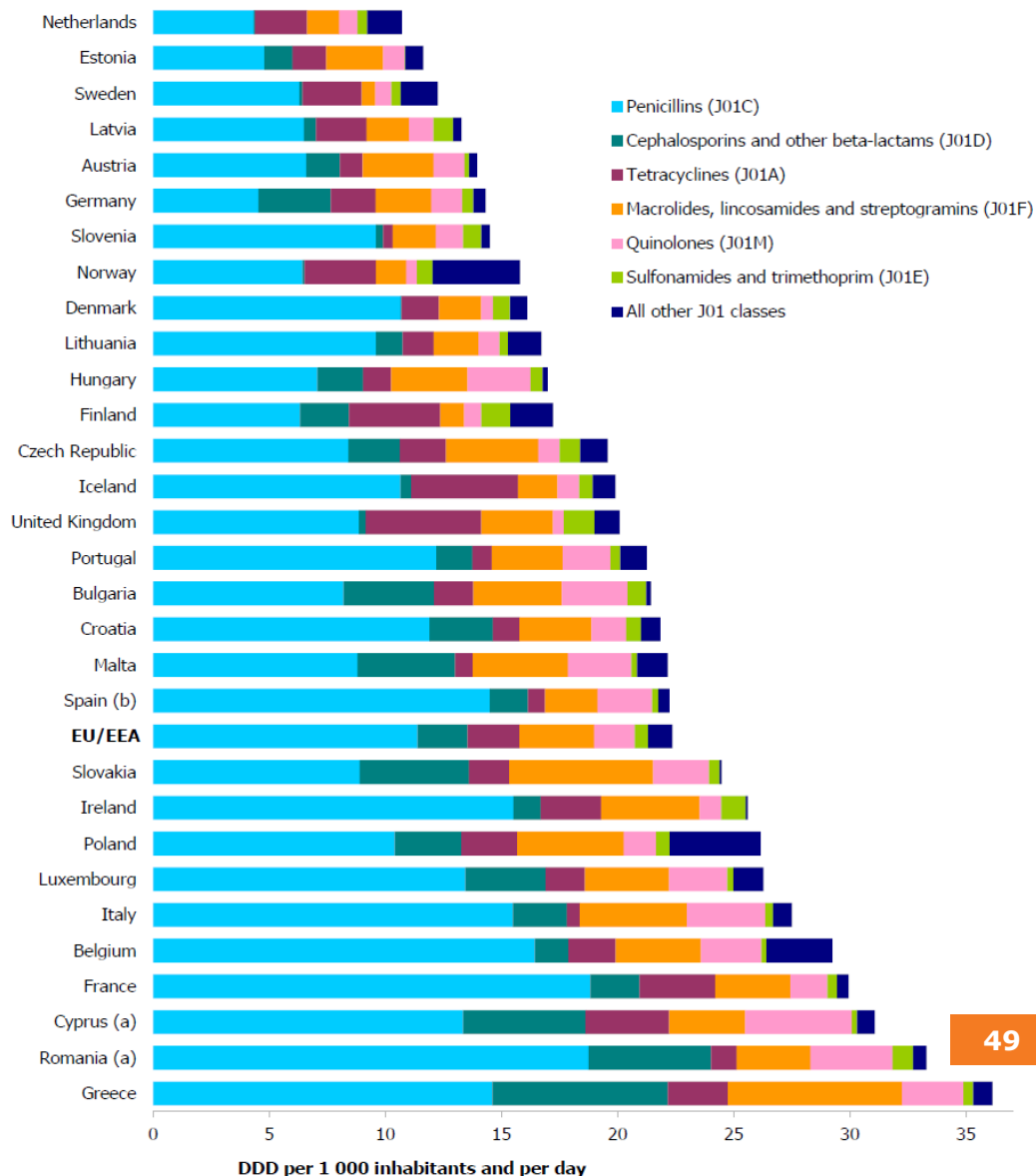


Indicators for Antimicrobial Use Global data

Type of global data:

- 1. From the community
- 2. From hospitals
- 3. Multidrug resistant bacteria

Consumption of antibiotics for systemic use in the **community** by antibiotic group, EU/EEA countries, 2015 (expressed in **DDD per 1 000 inhabitants and per day**)





Indicators for Antimicrobial Use Global data

Trends in consumption of
antibiotics for systemic use
within the **community**, EU/EEA
countries, 2011–2015
(expressed as
**DDD per 1 000 inhabitants
and per day**)

Country	2011	2012	2013	2014	2015	Trends in antimicrobial consumption, 2011–2015	Average annual change 2011–2015	Statistically significant trend
Netherlands	11.4	11.3	10.8	10.6	10.7		-0.21	<
Estonia	12.2	11.7	11.7	11.7	11.6		-0.11	
Sweden	14.3	14.1	13.0	13.0	12.3		-0.51	<
Latvia	12.8	13.0	13.5	12.6	13.3		0.06	
Austria	14.5	14.0	16.3	13.9	14.0		-0.12	
Germany	13.9	14.8	15.7	14.6	14.3		0.07	
Slovenia	14.4	14.3	14.5	14.2	14.5		0.01	
Norway	16.5	16.9	16.2	15.9	15.8		-0.24	
Denmark	17.4	16.4	16.4	15.9	16.1		-0.32	
Lithuania	19.0*	16.2	18.5	16.0	16.7			N/A
Hungary	15.9	15.0	15.5	16.2	17.0		0.33	
Finland	20.1	19.5	18.3	18.1	17.2		-0.71	<
Czech Republic	18.5	17.5	19.0	19.2	19.6		0.38	
Iceland	22.3*	22.1*	21.9*	19.3	19.9			N/A
United Kingdom	18.8	20.1	20.6	20.8	20.1		0.35	
Portugal (a)	23.2	22.7	19.6†	20.3†	21.3†			N/A
Bulgaria	19.5	18.5	19.9	21.2	21.4		0.67	
Croatia	19.4	21.7	21.1	21.4	21.8		0.45	
Malta	23.4	22.5	23.8	23.7	22.2		-0.14	
Spain	20.9†	19.7†	20.3†	21.6†	22.2†		0.47	
EU/EEA	21.5	21.7	22.2	21.9	22.4		0.19	
Slovakia	23.8*	20.0	23.6	20.9	24.5			N/A
Ireland	22.6	23.0	23.8	23.1	25.6		0.60	
Poland (a)	21.7†	22.9	23.6	22.8	26.2			N/A
Luxembourg	27.8	27.7	27.7	25.8	26.3		-0.48	
Italy	28.2	27.6	28.6	27.8	27.5		-0.12	
Belgium	29.0	29.8	29.6	28.4	29.2		-0.09	
France	28.7	29.7	30.1	29.0	29.9		0.18	
Cyprus	32.0*	29.7*	28.3*	26.1*	31.1*		-0.54	
Romania	30.9*	30.4*	31.6*	31.2*	33.3*		0.56	
Greece	35.7	32.5	32.2	35.1	36.1		0.34	

PPS of healthcare-associated infections and antimicrobial use in European acute care hospitals

To estimate the prevalence of HAIs and antimicrobial use in acute care hospitals in the EU

To describe HAIs (sites, microorganisms including markers of antimicrobial resistance) and antimicrobials prescribed (compounds, indications):

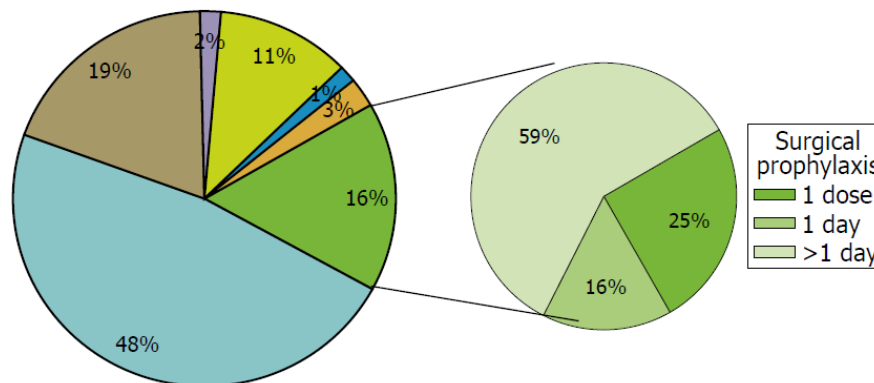
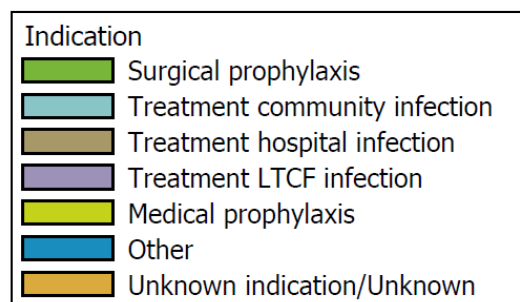
- by type of patients, specialties or healthcare facilities
- by EU country

SURVEILLANCE



Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals

Figure 55. Indications for antimicrobial use in European acute care hospitals, ECDC PPS 2011-2012



PPS Healthcare-associated infections, antimicrobial use and indicators of infection prevention in long-term care facilities in EU/EEA Member States HALT Project

To estimate the prevalence of HAIs and
antimicrobial use in LTCFs at national and European
level

To describe HAIs (sites, microorganisms including
markers of antimicrobial resistance) and antimicrobials
prescribed (compounds, indications)

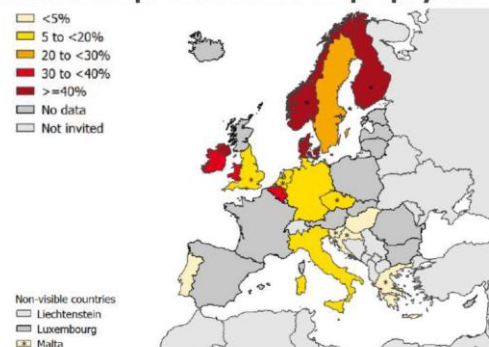
SURVEILLANCE RE



oint prevalence surv
ssociated infections
microbial use in Euro
long-term care faci

% antimicrobials prescribed for uroprophylaxis (22%)

- <5%
- 5 to <20%
- 20 to <30%
- 30 to <40%
- >=40%
- No data
- Not invited



The Antibiotic Resistance and Prescribing in European Children (ARPEC)

European paediatric and neonatal antimicrobial web-based point prevalence survey in 73 hospitals within Europe and globally in 2011.



The aims of the survey were:

- To develop a standardized method for surveillance of antimicrobial use in hospitals within Europe and globally;
- To determine the quality and quantity of antibiotic drug use by indication;
- To identify targets for quality improvement.

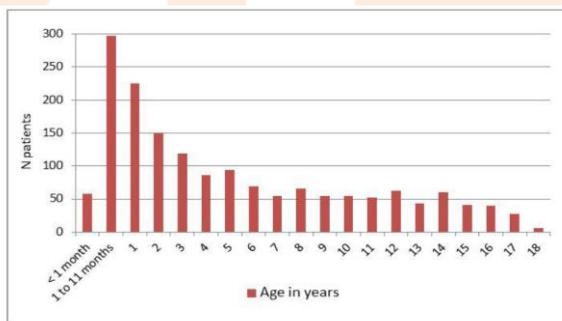


Figure 2: Number of patients, admitted on a paediatric ward, receiving antimicrobial treatment by age.

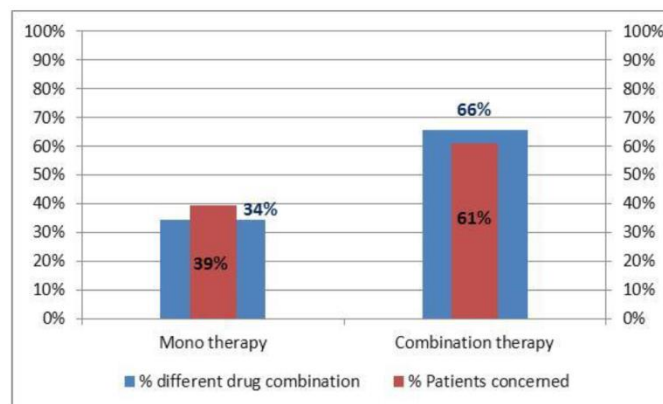


Figure 7: Proportion of antibiotic combination therapies and its related proportion of patients admitted on a neonatal ward.

Conclusions

Tools for assessing interventions to improve antibiotic prescribing

Meaningful comparisons...

- Uniformity of data collection
- Implementation of common methodology
- Opportunity to stimulate local networking
 - ...toward data interpretation
- Quantifiable outcome measures and targets for quality improvement of antibiotic treatment and prophylaxis
- Interpretation of antimicrobial consumption data at different levels
- Creation of reference database for scientific research and hypothesis formulation at national and international level
- Data-sharing



VMP legislation Reg 2019/6 - what to consider

- Until now, the use and sales data collection is **not mandatory under the EU rules**.
- The Commission proposal for the new VMP Regulation is to provide mandatory collection of data on sales and use of veterinary antimicrobials:
 - **first phase „USE“ data delivery to EMA 2024!**
- Collecting the use data by animal species is demanding as for **human/budgetary resources** => for some MSs difficult to reach **„full coverage VALID data“** on term
- Member States:
 - Lack of resources – **phased approach ... 2024 – 2027 – 2030**
 - Some of the systems considering the exact purpose might collect **more data** than just the data on use (e.g. groups of animals, indications...)
- **Pragmatic approach necessary**
 - COST/BENEFIT
 - Analysis at farm/national/EU level ... measures at farm level
 - Taking into consideration already existing systems
 - What is already collected / used (e.g. For benchmarking ... setting measures ... communication) by some MSs.

What to describe and collect if harmonised

ALREADY PROPOSED in Advice on implementing measures EMA/CVMP/131097/2019

1. Animal species / categories / years of phases „USE“ data collection/delivery (see slide above)
2. Data collection period / frequency (yearly)
3. Antimicrobials to be involved (see slide above)

TO BE FURTHER SPECIFIED by the next Advice on Format of the data collection

1. Variables to be collected (to be precised by DA)
2. Models / Coverage (to be precised by DA)
3. Animals population data (to be precised by DA)
4. Sources / Data integrity and quality control:
minimal quality requirements
(completeness, accuracy, correctness, validity and reliability) to be met
5. Communication/reporting





Rules on the methods of gathering the required data and of transferring it to the EMA enabling surveillance

Detailed rules dependent on the chosen systems for collecting/transferring/storing data on AM consumption.

The **sales** and **use** data to be submitted to EMA each year, by MSs for calendar year:
The data should be validated by MS before sending to EMA (technical specifications described in relevant legislation and relevant guidance including manuals, protocols, templates and/or electronic forms)

The source of **sales** data submitted to EMA may vary per MS (marketing authorisation holders, wholesalers, retailers, etc.) : should cover all the sales of all relevant VMP sold or placed on their market during the calendar year covering the data collection.

To collect harmonised and standardised **use** data per animal species (Article 57) MSs set up a continuous (semi)automated data collection system or other appropriate systems that enable in particular direct or indirect evaluation of the use of such products in food-producing animals at farm level.

Data provided to EMA: number of packages per presentation of the veterinary or human medicinal product per animal species or category used in the MSs during calendar year. The collected raw data on use of antimicrobials in animals should be aggregated at national level at each presentation level into the total per animal species or category.

The submission of the collected data on sales and on use of antimicrobials in animals from MSs to EMA should be carried out by electronic means.

6. Animal population data

Biomass of animal population at risk of being treated with antimicrobials:

- Standard weights established (as for ESVAC sales PCU);
- Mixture of slaughter and/or live animal numbers per sector;
- Denominator: multiplying number of animals with standard weights.

Considered if could take appropriate species elements from composition of PCU:

- Census → national data is easily available from Eurostat/TRACES.
- Sample survey → what data is easily available at farm level?
- Are additional categories needed?

2.2.2. Animal population data

EMA would report use data by animal species/category adjusted by a standardised denominator for that species/category. This denominator, the estimated animal biomass, represents the animal population at risk of being treated with antimicrobials in the country or on the sample farms during the data collection period.

The estimated animal biomass would be calculated for each animal species/category separately by multiplying the number of animals by the standardised, average weight at treatment for each category (see Table 4). The standardised weights are derived from EMA guidance⁵, as already established for the calculation of the ESVAC sales Population Correction Unit (PCU).

Table 4. Animal species and categories with definition and standardised average weight at treatment (kg)

Animal species and category	Definition	Standardised weight (kg)
Pigs		
Breeding sows	Live breeding sows with a live weight of 50 kg and over ⁶	240
Pigs for slaughter	Slaughtered domestic animals of the species <i>Sus scrofa domestica</i> (no breakdown into categories) ⁶	65
Pigs imported/exported certified as slaughter	Live swine (no breakdown into categories) ⁷	65
Pigs imported/exported certified as fattening	Live swine (no breakdown into categories) ⁷	25

7. Sources / Data integrity and quality control

Description of the system

Characteristics of the national data collection system

- Data collection approach
- Coverage
 - Farms
 - Production
- Data sources
 - For antimicrobials use data
 - For animal population data
- Quality controls
- Additional comments

Data protection / confidentiality

Data collected and reported: aggregated by species

→ No information on individual farms, prescribers, pharmacists, data suppliers.

Authorities should have access to the raw data/work with raw data holders

→ Arrangements and provisions between authorities and data holders to ensure confidentiality



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