

Introduction to the ASU (Antimicrobial Sales and Use) Platform and collaboration with WOAH

Europe and Central Asia Workshop on ANIMUSE 7 – 9 November 2023

Presentation overview



Introduce the Antimicrobial Sales and Use (ASU) Platform and present the functionality that will enable users to download data in a compatible format for ANIMUSE.

1 Context of the ASU Platform

Design and functionalities of the ASU Platform

Using the ASU Platform to extract data for ANIMUSE



1. Context of the ASU Platform



Legal basis of the ASU Platform

Article 57 Regulation (EU) 2019/6

Article 5

Collection of data on antimicrobial medicinal products used in animals

 Member States shall collect relevant and comparable data on the volume of sales and on the use of antimicrobial medicinal products used in animals, to enable in particular the direct or indirect evaluation of the use of such products in food-producing animals at farm beach, in accordance with the Article and whitin the time limits set out in gengraph 5.

- 2. Member States shall send collated data on the volume of sales and the use per animal species and per types of autimixrobal medicinal products used in animals to the Agency in accordance with paragraph's and within the time limits referred to thereoff. The Agency altal Cooperar with other States and with other Union agrees to analyse those data and shall publish an animal report. The Agency shall take into account those data when adopting any relevant multilinear set account those data when adopting any relevant multilinear set account those data when adopting any relevant
- The Commission shall adopt delegated acts in accordance with Article 147, in order to supplement this Article, establishing the requirements as regards:
- (a) the types of antimicrobial medicinal products used in animals for which data shall be collected;
- (b) the quality assurance that Member States and the Agency shall put in place to ensure quality and comparability of data: and
- (c) the rules on the methods of gathering data on the use of the antimicrobial medicinal products used in animals and or the method of transfer of those data to the Agency.
- 4. The Commission shall, by means of implementing acts, set up the format for the data to be collected in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Collection and reporting of data on:

- volumes of sales per veterinary antimicrobial medicinal products
- use per animal species per antimicrobial medicinal products (both veterinary and human)



Delegated Regulation (EU) 2021/578

- Mandatory plus voluntary data collection based on ATC/ATCvet code
- Data quality
- Establishment of national data collection systems and IT tools for automated or semi-automated reporting and analysis

Implementing Regulation (EU) 2022/209

- Data collected at package level
- Data format
- Pre-filling of data entry fields by the Agency with information available from the Union Product Database (UPD)



Type of data being collected

Volume of Sales

- Veterinary Antimicrobial Medicinal Products
- Data providers: marketing authorisation holders, wholesalers, retailers, feed mills, pharmacies and/or veterinarians

Use

- Veterinary and Human Antimicrobial Medicinal Products
- Per animal species and categories
- Data providers: veterinarians, retailers, pharmacies, feed mills and/or end users (including farmers or breeders)
- Data sources: health records, treatment logbooks, delivery notes, farm invoices, prescriptions, pharmacy records, veterinary practice records

Stepwise scaling up of data collection, sending, and reporting

2023 EMA: Go-live

EMA: develop ASU Platform MS: Collect data



MS: Send sales & use data (cattle, pigs, chickens & turkeys) 30 September **2024**, then **30** June

EMA: Publish first annual sales & use data report **31** March 2025, then **annually** by **31** December



2027

MS: Send sales & use data (+ other foodproducing animal species)



2030

MS: Send sales & use data (all categories, incl. cats, dogs and fur animals)



2030+

Annual sending (30 June) and reporting (31 December)

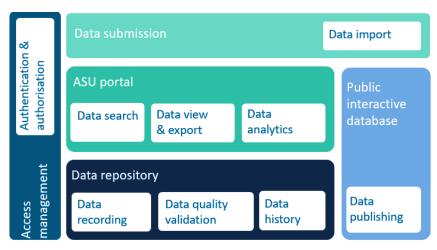




2. Design and functionalities of the ASU Platform



ASU Platform: IT system overview

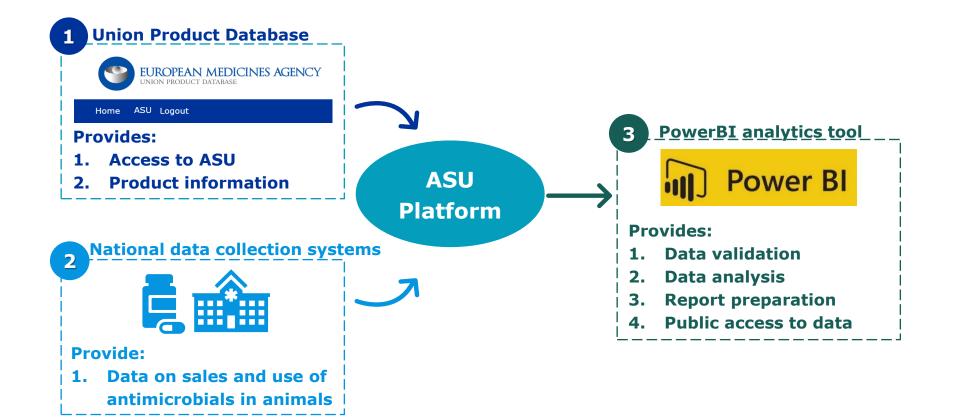


ASU concept

- In line with legal requirements
- Provide an environment for MSs to submit data in a standardised format
- Leveraging existing capabilities for sales data collection
- Functionalities prioritised in cooperation with MSs to enable legislative compliance
- Support harmonisation and data quality
- Improve User Interface and Experience
- Provide a public interactive database and support data analytics

How does the ASU Platform work?







ASU Platform users

Data managers (NCA users)

During reporting cycle (Q1-Q2):

- Upload sales, use and animal population data to ASU Platform.
- Validate uploaded data in the ASU Power BI Application.
- Submit the data on the ASU Platform.

EMA (Admin users)

- Q1-Q2: assist with data submission and validation.
- Q3-Q4: analyse submitted data and prepare annual publication

Workflow for ASU data managers

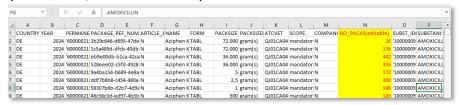
1. Access the ASU Platform via UPD



2. Download sales and use data templates prefilled with products and product information at package level from the UPD



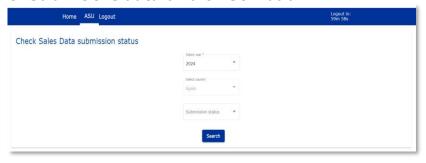
3. Complete downloaded templates with the number of packs sold/used for each product



4. Upload the sales and use templates to the ASU Platform

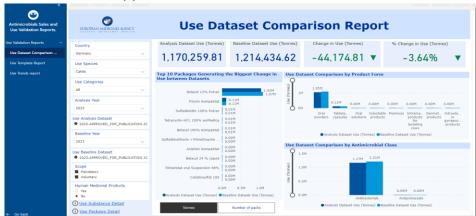


6. Submit the data on the ASU Platform



5. Validate the uploaded data in the

ASU Power BI Application





3. Using the ASU Platform to extract data for ANIMUSE

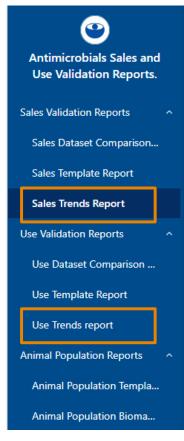


ASU Power BI Data Validation Reports

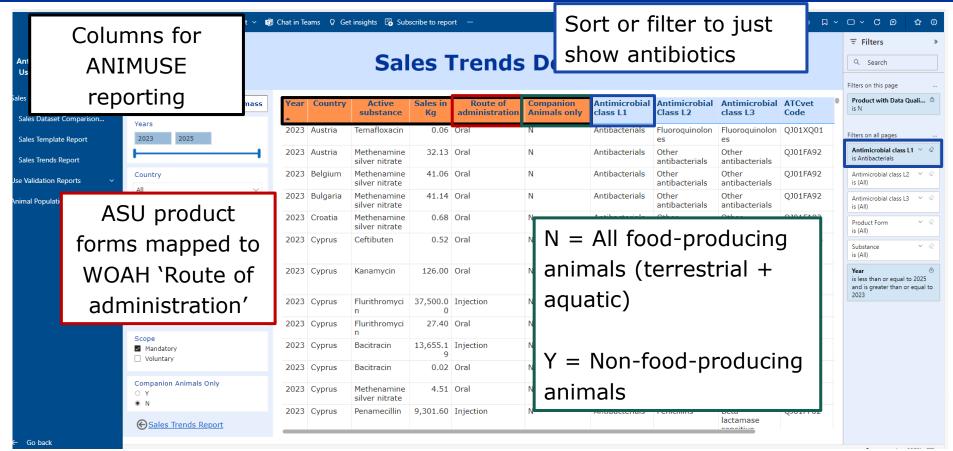
 Help Member States validate the data uploaded to the ASU Platform and ensure that it meets the quality standards indicated in the legislation.











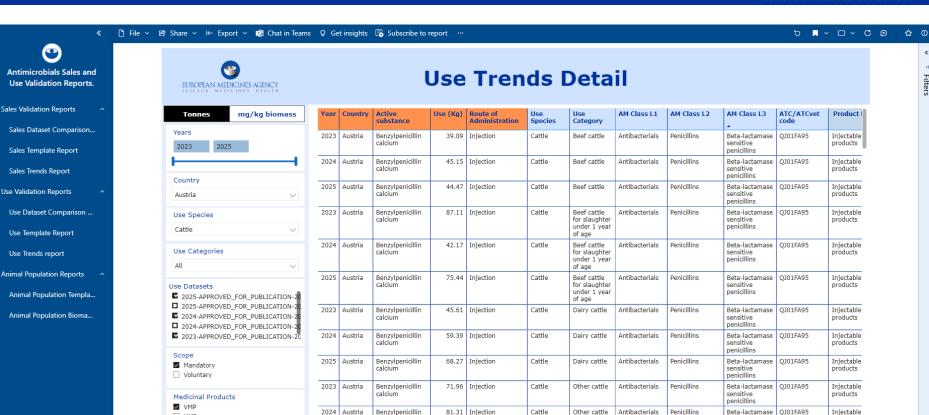
products

Injectable

sensitive

penicillins

Reta-lactamase 0101FA05



47 30 Injection

Cattle

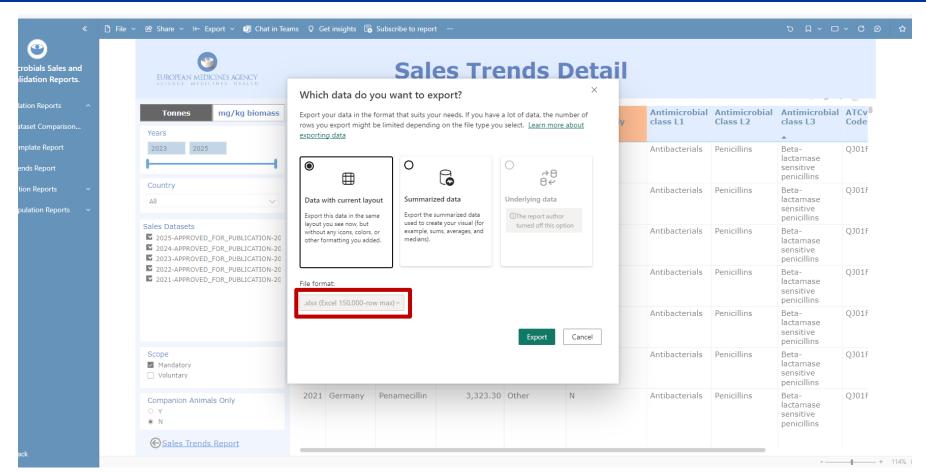
Other cattle Antihacterials Denicilling

calcium

2025 Austria Benzylnenicillin

☐ HMP

Use Trends Report



ı, ıál	\ All EMA aff a	nd Contractors	•	•	Private	Public	Internal + Confidenti	ial ▼ Restricted					
	-	-			-	G	Н	I I	J	K	L	M	
ar	Country	Active substance	Sales in Kg	Route of administration	Companion Animals only	ntime class L1	Antimicrobial Class L2	Antimicrobial class L3	ATCvet Code	Product Form			
202	23 Austria	Amoxicillin	78,58 I	Injection	N	ntibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA04	Injectable products			
202	23 Austria	Amoxicillin	5,49 I	Injection	N	intibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA91	Injectable products			
202	23 Austria	Amoxicillin	25.870,28	Oral	N	intibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA04	Tablets, capsules			
202	23 Austria	Amoxicillin	0,28	Oral	N	intibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA91	Oral powders			
202	24 Austria	Amoxicillin	116,88	Injection	N	ntibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA04	Injectable products			
202	24 Austria	Amoxicillin	17,52	Injection	N	intibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA91	Injectable products			
202	24 Austria	Amoxicillin	15,02	Oral	N	ntibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA04	Oral powders			
202	24 Austria	Amoxicillin	1.411,86	Oral	N	intibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA04	Oral solutions			
202	24 Austria	Amoxicillin	32,54 (Oral	N	intibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA04	Tablets, capsules			
202	24 Austria	Amoxicillin	97,28	Other	N	intibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA04	Intramammary products for lactating cows			
202	25 Austria	Amoxicillin	62.047,42	Injection	N	intibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA04	Injectable products			
202	25 Austria	Amoxicillin	34,20	Injection	N	intibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA91	Injectable products			
202	25 Austria	Amoxicillin	5.141,59	Oral	N	intibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA04	Oral powders			
202	25 Austria	Amoxicillin	0,03	Oral	N	intibacterials	Penicillins	Penicillins with extended spectrum	QJ01RA04	Tablets, capsules			
202	23 Austria	Bacitracin	13.655,19	Injection	N	intibacterials	Other antibacterials	Other antibacterials	QJ01RA01	Injectable products			
202	23 Austria	Bacitracin	0,02	Oral	N	intibacterials	Other antibacterials	Other antibacterials	QJ01RA01	Tablets, capsules			
202	24 Austria	Bacitracin	6,48	Injection	N	ntibacterials	Other antibacterials	Other antibacterials	QJ01RA01	Injectable products			
202	25 Austria	Bacitracin	0,87	Injection	N	intibacterials	Other antibacterials	Other antibacterials	QJ01RA01	Injectable products			
202	25 Austria	Bacitracin	18,91	Oral	N	intibacterials	Other antibacterials	Other antibacterials	QJ01RA01	Oral solutions			
202	23 Austria	Bacitracin	1.505,82	Injection	N	intibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Injectable products			
202	23 Austria	Bacitracin	49,66	Oral	N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Oral powders			
202	23 Austria	Bacitracin	0,33 (Oral	N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Tablets, capsules			
202	24 Austria	Bacitracin	741,07	Injection	N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Injectable products			
202	24 Austria	Bacitracin	171,63 (•	N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Oral powders			
202	24 Austria	Bacitracin	0,37		N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Tablets, capsules			
202	25 Austria	Bacitracin	1.318,65	Injection	N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Injectable products			
202	25 Austria	Bacitracin	206,91	Oral	N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Oral powders			
202	25 Austria	Bacitracin	0,36		N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Tablets, capsules			
	23 Austria	Bacitracin	0,28		N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Tablets, capsules			
	23 Austria	Bacitracin	2,67		N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CR02	Tablets, capsules			
	23 Austria	Bacitracin	0,09		N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Intrauterine or gynaecological products			
	24 Austria	Bacitracin	0,39		N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Tablets, capsules			
	24 Austria	Bacitracin	2,62		N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CR02	Tablets, capsules			
	24 Austria	Bacitracin	0.06		N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Intrauterine or gynaecological products			
	25 Austria	Bacitracin	0.06		N	ntibacterials	Other antibacterials	Other antibacterials	QJ01CA04	Tablets, capsules			
201	E Austria	Basitrasia	0.94	Oral	NI.	ntibacterials	Other antibacterials	Other antibacterials	OJ01CR02	Tablets cansules			



Any questions?

Further information

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands Telephone +31 (0)88 781 6000

Send us a question Go to www.ema.europa.eu/contact

Follow us on **9 @EMA_News**

Useful links

- Regulation (EU) 2019/6
- Commission Delegated Regulation (EU) 2021/578 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals
- Commission Implementing Regulation (EU) 2022/209 of 16 February 2022 establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council
- Antimicrobial use data reporting per animal categories (numerator) Manual for reporting Veterinary
 Medicinal Products Regulation | European Medicines Agency (europa.eu)
- https://www.ema.europa.eu/documents/scientific-guideline/guideline-reporting-antimicrobial-sales-use-animals-eu-level-denominators-indicators en.pdf
- Union Product Database | European Medicines Agency (europa.eu)