Norwegian Veterinary Institute
Section of Epidemiology

Quality assessment of antibiotic use data in the Norwegian Veterinary Prescription Register for 2023

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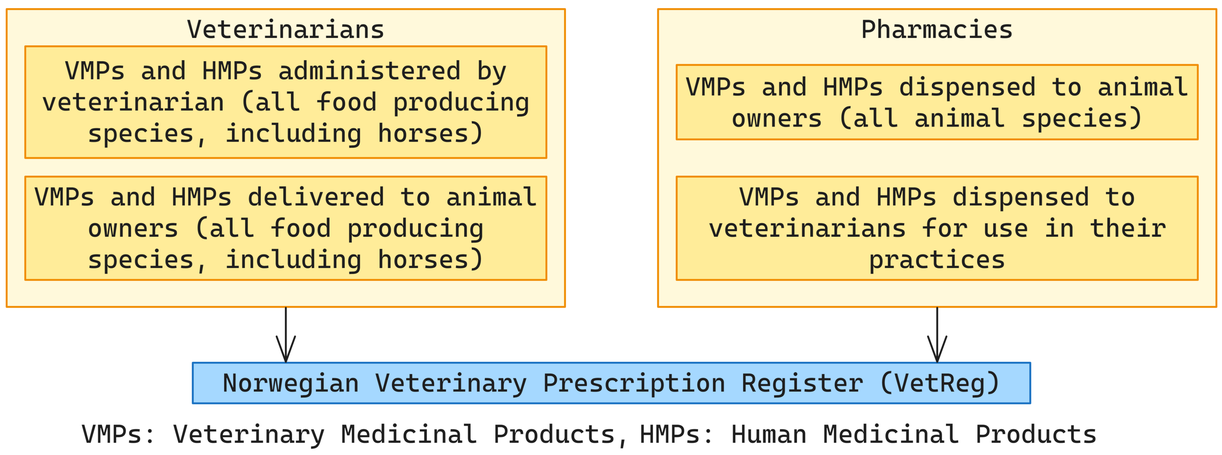
Objective and Description of Register

The main aim of this study was to evaluate the quality of antibiotics use data from the Veterinary Prescription Register (VetReg) for 2023, focusing on the data that has been used to fulfil the requirements of the first step of use data mandatory to be reported to European Medicines Agency (EMA) – i.e. for cattle, pigs, chicken and turkeys, according to Article 57 in regulation EU 2019/6. This includes developing and describing the methodology for the data cleansing steps performed.

Data on the use of medicinal products in animals in 2023 was collected by the Norwegian Food Safety Authority (NFSA) through the VetReg system. The figure below shows who reports data to VetReg and what types of data are mandatory to report.



Three attributes of the register were evaluated:
Accuracy of data, timeliness of reporting, and completeness of use data for VMPs compared to sales statistics from wholesalers.

Completeness Evaluation

Completeness was evaluated based on the extent to which data on all use or dispensed amounts is reported to VetReg, by comparing the use and sales data for antibiotic VMPs. The sales data of antibiotic VMPs were collected from the Norwegian Institute of Public Health (NIPH) as wholesalers are mandated to report their sales of VMPs (and HMPs) to pharmacies to NIPH.

Pharmaceutical form	Proportion of data reported by vets plus data reported dispensed from pharmacies to owners compared to sales data		Proportion of data reported dispensed from pharmacies to owners and animal health personnel compared to sales data	
	Number of records	Completeness (in %)	Number of records	Completeness (%)
Injection	130,401	86.19	8,421	56.79
Injection powder	12	Not present in sales data	0	Not present in sales or pharmacy data
Intramammary	26,912	78.26	2,467	64.90
Oral solution	141	93.10	115	90.78
Powder for oral solution	85	49.62	18	14.54
Oral paste	6,301	83.66	6,019	84.07
Oral powder	76	79.56	56	88.64
Tablet	85,797	91.21	86,396	92.23
Intrauterine	162	782.91	9	66.66
Total	**249,887**	**85.03**	**103,501**	**63.64**

The table shows completeness of use data of antibiotics VMPs compared to sales data per pharmaceutical formulation. The completeness is calculated for antibiotic data relevant for EMA reporting and for pharmacy data, separately.

Timeliness Evaluation

	Percent of records reported within the deadline of seven days
Records from Pharmacies	99.92%
Records from Veterinarians	70.63%

All veterinary records were reported within 225 days, and timeliness issues therefore affected the completeness of data, since data were extracted on the 15th of March 2024.

Accuracy Evaluations

Accuracy evaluation of several key variables was performed:

Animal Category:

Results of the evaluation	Number of VetReg records		
	Veterinarians' use	Pharmacies' dispensing to animal owners	Total number of records
No information provided	0	304	304
Animal species should be reported, but not reported per category	3,331	2,190	5,521
Animal species should be reported, and category can be specified	116,763	462	117,225
Total number of records	**120,094**	**2,956**	**123,050**

The table summarises records reported for cattle, pigs, chicken and turkeys . It is required to report antibiotic use per category to EMA for these species. Example for “Animal species should be reported, but not reported per category”: Record specified “cattle” but did not indicate whether they were categorized as “beef cattle”, “dairy cattle”, or “other cattle”.

Records Reported by Veterinarians: Amount of Medicinal Product Used and Associated Unit for Amount of Medicinal Product Given

Pharmaceutical formulation: Intramammary	
Results of evaluation	**Number of records**
Correct unit and amount reported by veterinarian	23,252
Correct amount BUT incorrect unit reported by veterinarian	2,874
Records excluded	114
Total numbers of records	**26,240**

Pharmaceutical formulation: Injection	
Results of evaluation	**Number of records**
Correct unit and amount reported by veterinarian	129,115
Correct amount BUT incorrect unit reported by veterinarian	3
Records excluded	229
Total numbers of records	**129,347**

Pharmaceutical formulation: Oral Paste	
Results of evaluation	**Number of records**
Correct unit and amount reported by veterinarian	585
Correct amount BUT incorrect unit reported by veterinarian	5
Records excluded	18
Total numbers of records	**608**

Pharmaceutical formulations: Tablets, Intrauterine, Oral Solution, Oral Powder, Powder of Oral Solution, Injection Powder and Infusion powder	
Results of evaluation	**Number of records**
Correct unit and amount reported by veterinarian	1,908
Correct amount BUT incorrect unit reported by veterinarian	3
Records excluded	37
Total numbers of records	**1,948**

Records were excluded when the number of applicators dosed per animal (for intramammary) / quantity reported used per animal (for all other formulations) exceeded either the cut-offs for dosing set based on information from the Summary of Product Characteristics (SPC) for each VMP OR statistical test (Grubbs test) identified the record as an outlier. Records were also excluded when a reporting unit of unknown size was used by veterinarian. Additionally, in case of intramammaries, records were excluded when number of applicators dosed per animal could not be calculated into a whole number.

CONCLUSION: The quality evaluation of VetReg data for 2023 showed that all records from pharmacies and most records from veterinarians on antibiotic use in cattle, pigs, chickens, and turkeys were suitable for reporting to the EMA. However, not all data could be reported per animal category required by EMA. Less than full completeness of use data is most likely also caused by some degree of underreporting and timeliness issues.

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