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Research Article

Pre- and post-marketing quality surveillance of non-immunological veterinary medicinal products in Türkiye, 2018-2023

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ABSTRACT

Pharmaceutical quality studies of veterinary medicinal products at the pre- and post-marketing authorization stages are important for the pharmacoepidemiological assessment of product quality determining risk factors for non-compliance and the necessary measures. This study aimed to conduct a pharmacoepidemiological assessment of the results of quality control studies performed on non-immunological veterinary medicinal products pre- and post-marketing authorization. For this study, 1827 products were collected at pre-marketing authorization stage and 692 samples were collected at post-marketing stage. Non-compliance rates between pharmacological groups and between pre- and post-marketing stages were statistically evaluated with a 95% confidence level and a 0.05 margin of error. Significant differences were found the level of non-compliance between pre- and post-marketing authorization stages. Significant differences were found in terms of the level of non-compliance, between pharmacological groups. No statistically significant trend has been observed in the level of non-compliance over the years at the pre-marketing, post-marketing stages, combined non-compliance rates, and pharmacological groups' trends. Although the overall non-compliance rate is low, there have been notable increases in certain years for vitamins, minerals and antiparasitics. The non-compliance rates in Türkiye are at low levels thanks to the international harmonization of legislation of veterinary medicinal products, good manufacturing and distribution practices in the sector, and the operation of quality assurance, quality control and pharmacovigilance systems. However, non-compliant products may always exist in the market. This control and surveillance system should be continuously updated and maintained to reduce the risk and address problems.

Keywords: Non-immunological veterinary medicinal products, One Health, Pharmacoepidemiology, Quality control, Türkiye

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Introduction

Veterinary medicinal products (VMPs) are indispensable products used in animal health for the prevention, control, diagnosis, and treatment of diseases (5, 11, 12). When considered together with the concept of One Health, VMPs are also recognized to have an impact on the environment and human health (10, 18, 20).

Pharmaceutical quality controls, which are a legal obligation and constitute one of the key activities in the life cycle of a medicinal product, should be carried out by pharmaceutical companies and/or contracted organizations for at least "shelf life + 1 year" for each batch, starting from the pre-marketing authorization stage through the post-marketing authorization period (6, 9, 11, 14, 15). To monitor the safety of VMPs, the pharmaceutical quality characteristics of the products are also evaluated by regulatory authorities (6, 13, 14). The physical, chemical, and microbiological properties of the pharmaceutical product that need to be controlled, as well as their reference quality level are summarized in a specification (7, 8). For example, for the level of active substance among the chemical quality characteristics, a deviation of ± 5% is allowed at release and ± 10% during the shelf life of the finished product (5, 8, 9). Products with results outside the limits specified in the pharmacopeia monograph or product specifications in terms of pharmaceutical quality characteristics are called substandard, low-quality, or non-compliant products (11, 20). In a sector lacking independent quality controls, non-compliant products may be encountered more frequently (6, 14, 15). Such inappropriate products negatively affect animal, environmental, and human health, as well as the economy, leading to issues such as antimicrobial resistance, residues in food, and reduced disease control efficiency (10, 12, 18, 20, 21).

Survey studies are valuable as they provide the basic data required to evaluate the quality of VMPs, investigate the pharmacoepidemiological assessment of product quality, and establish sustainable quality control measures (5, 12, 20, 21). Through pharmacoepidemiological evaluation, it becomes possible to identify risk factors for non-compliance, the precautions to be taken, and weaknesses in supply chains (21). It is also reported that the implementation of a post-marketing survey helps to improve the quality of VMPs (11). On the other hand, non-compliant products are likely to be found at varying rates in all countries, regardless of development or income level (20). These products are withdrawn according to the degree of risk of non-compliance detected to eliminate the risks they may pose (14).

There are three studies on the pharmacoepidemiological evaluations of the post-marketing surveys conducted in South Korea between 2008 and 2021. In the surveys, the quality performance of over a thousand products collected from manufacturers, importers, wholesalers, veterinary pharmacies, and veterinary hospitals in the categories of antibacterial, other chemicals, and biologicals were investigated. The researchers analyzed the change in the rate of non-compliant products over the years and across non-compliance groups, and the major causes of non-compliance (5, 11, 12). In the VMPs survey conducted in Tanzania between 2014 and 2017, a total of 231 products, mostly containing oxytetracycline, collected from pharmacies, veterinary clinics, and veterinary accredited medicine distribution points. These products were collected using a convenience sampling method from 9 regions of the country, which were selected using a random sampling method, and were subsequently checked. The researchers determined that 11% of the products were non-compliant and examined the reasons for non-compliance (10). In Ethiopia, a pre- and post-marketing survey of 953 products conducted between 2016 and 2021 revealed that 6.9% were non-compliant in terms of active substance content, and 8.2% were non-compliant in one or more parameters. Researchers shared that non-compliance may be caused by a lack of good practices in production, storage, and supply chains (18). In the European Union (EU), selected VMPs, based on risk analysis, are subject to annual data collection through audits and are controlled by the European Official Medicines Control Laboratories (OMCL). In France, the rate of non-compliant products was reported to be 13% in 2020, 4.8% in 2021, and 1.8% in 2022 (1, 2).

In Türkiye, the procedures regarding the production, import, export, use, packaging, labeling, promotion, transport, storage, sale, approval, control, and supply of VMPs have been carried out by the Republic of Türkiye Ministry of Agriculture and Forestry (TC-TOB) since the early 2000s in line with EU legislation (13). In this sector, where good manufacturing practices (GMP), good distribution practices (GDP), and pharmacovigilance systems are in place, there are 1,780 non-immunological and 627 immunological veterinary medicinal products (17). The distribution of non-immunological products by pharmacological group is as follows; antibacterials and combinations (46%), antiparasitics (27%), vitamins and minerals (11%), and others (antihistamines, antispasmodics, anaesthetics-sedatives, antifungals, hormones, etc. 16%). TC-TOB uses electronic prescriptions and tracking systems for medicines and vaccines to ensure the traceability of VMPs. The electronic prescription system enables the tracking of prescription density by region and province, as well as the collection of information on food safety and animal diseases. The medicine tracking system provides statistical data on the production, distribution and retail sale of VMPs and raw materials, which can be used for tracking and control purposes (16). In 2021, 57 million boxes of VMPs were prescribed, accounting for 2.4 million prescriptions. Antibacterials and VMPs combinations were the most commonly prescribed pharmacological effect group, accounting for 22 million boxes (3).

The distribution of VMPs is carried out through 233 licensed veterinary pharmaceutical warehouses (16). Transactions related to the sales and applications of VMPs are recorded using electronic distribution and prescription systems (14). For the quality performance controls of VMPs, a control program consisting of all products at the application stage and a risk-based control program consisting of selected products are applied. In addition, this method is updated based on scientific evaluation, pharmacovigilance, and field requests. Under the coordination of its central organization, TC-TOB maintains a network capable of performing control and surveillance activities nationwide through 81 provincial and district directorates (13, 16). An association called the Veterinary Health Products Industrialists' Association (VİSAD), which represents the sector in Türkiye, carries out activities in cooperation with TC-TOB, international authorities, professional, and sectoral organizations (19). However, no previously published large-scale survey study or pharmacoepidemiological evaluation of VMPs has been reported in Türkiye.

This study aimed to retrospectively examine the results of quality control studies conducted by TC-TOB on non-immunological VMPs, from a pharmacoepidemiological perspective, pre- and post-marketing authorization between 2018 and 2023. Specifically, it investigated whether the non-compliance rates within and between groups during the marketing authorization periods were statistically different and whether they showed an increasing or decreasing trend over the six-year period. Additionally, the study investigated whether there were statistically significant differences in the non-compliance rates within and between pharmacological groups, as well as whether there were significant increasing or decreasing trends over the six-year period. Finally, the aim was to identify high-risk pharmacological groups.

Materials and Methods

Chemicals and Reagents: Certified reference standards purchased from approved suppliers such as European Pharmacopoeia, US Pharmacopoeia, Sigma-Aldrich, Dr. Ehrenstrofer were used for studies controlling active substance limits. All chemicals and reagents used in the analyses were high performance liquid chromatography (HPLC) grade and purchased from approved suppliers such as Sigma-Aldrich, and Merck. Purified water obtained by the Purelab® system (Flex-3, ELGA, UK) was used in the analyses.

Analytical Instruments: Chromatographic analyses were performed on an HPLC instrument (Dionex Ultimate 3000, Thermo Scientific, Waltham, Massachusetts, USA) equipped with a Charged Aerosol Detector (Corona™ Veo™, Thermo Scientific, Waltham, Massachusetts, USA) for aminoglycoside group active substances and a Diode Array Detector (Dionex Ultimate 3000, Thermo Scientific, Waltham, Massachusetts, USA) for other active substances and Chromeleon software (Version 7.2.9, Thermo Scientific, Waltham, Massachusetts, USA). Mineral analyses were performed by inductively coupled plasma-mass spectrometry (NexION 350X, Perkin Elmer, USA) and Syngistix software (Version 2.2, Perkin Elmer, USA).

Physicochemical Methods of Analysis: Tests of the products were performed using European Pharmacopoeia, United States Pharmacopeia, or validated in-house methods were used. The amount of active substance was evaluated in terms of 90 to 110% limits specified in the shelf life specifications of the products (4, 8).

Survey Method: For the pre-marketing survey, samples were collected from products in the import and marketing authorization application period. Approximately 300 series of non-immunological VMPs are inspected annually in this context. TC-TOB aims to conduct post-marketing pharmaceutical quality performance controls on at least 5% of non-immunological VMPs in the legal supply chain each year, ensuring continuous monitoring. A risk-based selection method is used to compile the list of products to be monitored. Non-immunological VMPs are assessed for risk based on data obtained from reports such as pre- and post-marketing survey results from previous years, pharmacovigilance reports, veterinary reports, pharmaceutical factory inspections and inspections of veterinary pharmaceutical warehouses. Non-immunological VMPs assessed as high risk include those with unstable active substances, those requiring sensitive storage and transport conditions, and those with high sales and/or prescription counts in the medicine tracking system and electronic prescription system.

Veterinary pharmaceutical warehouses from which these products will be obtained are selected using a stepwise random selection technique, based on the locations with high sales or prescription counts for these products in the medicine tracking and electronic prescription systems. 2,519 non-immunological VMPs, whose distribution is shown in Table 1, were collected during the pre-and post-marketing surveys conducted between 2018 and 2023. A pharmacological group classification has been made according to the Anatomical Therapeutic Chemical classification system for Veterinary medicinal products (ATCvet) in products where active substances are used in combination. (For example, a product containing antibacterial and corticosteroid active substances is shown in Table 2 under the antibacterials and combinations group). Pharmaceutical quality tests were performed at the Pendik Veterinary Control Institute Pharmaceutical Quality Control Laboratory, a national reference laboratory with a quality management system under ISO/IEC 17025 standard. In pharmaceutical quality performance checks, products with results outside the limits according to pharmacopeia monograph and product specifications were considered non-compliant.

Table 1. Non-compliance rates (%) of non-immunological VMPs controlled between 2018-2023 in Türkiye pre-and post-marketing stage.

Years	Pre-marketing stage			Post-marketing stage			Average		% NC
	Sample	NC	% NC	Sample	NC	% NC	Sample	NC	
2018	323	3	0.92	95	0	0.00	418	3	0.71
2019	392	4	1.02	92	2	2.17 *	484	6	1.23
2020	282	4	1.41	97	5	5.17 *	379	9	2.37
2021	369	0	0.00	212	8	3.77 *	581	8	1.37
2022	232	0	0.00	87	0	0.00	319	0	0.00
2023	229	1	0.34	109	3	2.75 *	338	4	1.18
Mean	304.5	2	0.65	115.3	3	2.60	419.83	5	1.19 *

* P<0.05 indicates statistically significant difference in at least one of the applied tests (Fisher's exact test, Freeman–Halton [Monte Carlo approx., 20 000], Cochran–Mantel–Haenszel (CMH), or Generalized Linear Model (GLM, binomial logit)). % NC (non-compliance rate)

Table 2. Pharmacological group and non-compliance rates (%) of non-immunological VMPs controlled between 2018-2023 in Türkiye.

Years	Antibacterials and combinations			Antiparasitics			Vitamins and minerals			Others		
	Sample	NC	% NC	Sample	NC	% NC	Sample	NC	% NC	Sample	NC	% NC
2018	214	3	1.40	107	0	0.00	65	0	0.00	32	0	0.00
2019	375	1	0.26	62	2	3.22	28	3	10.71 *	19	0	0.00
2020	291	6	2.06	44	3	6.81 *	15	0	0.00	29	0	0.00
2021	436	3	0.68	70	1	1.42	36	4	11.11 *	39	0	0.00
2022	252	0	0.00	36	0	0.00	14	0	0.00	17	0	0.00
2023	259	4	1.54	35	0	0.00	22	0	0.00	22	0	0.00
Mean	304.5	2.83	0.92	59.00	1	1.69	30.00	1.16	3.86	26.33	0	0.00

*Statistically significant at P<0.05 in at least one of the applied tests (Fisher's exact test, Freeman–Halton (Monte Carlo approximation, 20,000), Cochran–Mantel–Haenszel (CMH), or Generalized Linear Model (GLM, binomial logit)). % NC (non-compliance rate)

Statistical Analysis: For the pre- and post-marketing stages and pharmacological groups, the annual percentage non-compliance rates (%) within groups were statistically compared using a Fisher–Freeman–Halton exact test (Monte Carlo, 20,000). Additionally, the Cochran-Mantel-Haenszel (CMH) test was used to compare the non-compliance rates (%) within groups and to control for variability from year to year.

A trend analysis was conducted using a generalized linear model (GLM) with year as a continuous predictor to determine whether a statistically significant trend existed in the non-compliance rates (%) for the pre-marketing, post-marketing, and pharmacological groups between 2018 and 2023. The results were visualized by a line graph in the Excel® software program (2010 version, Microsoft, Washington, USA). Additionally, to minimize confusion arising from year-to-year variability, the presence of specific high-risk categories for pharmacological groups was investigated using the CMH analysis, which involves comparing one group with each of the other groups in turn and is stratified by year). Statistical evaluations were conducted at a 95% confidence level (5% error margin, two-tailed, α = 0.05) using SPSS Statistics version 26.

Results

The physical and chemical properties of 2,519 batches of non-immunological VMPs, representing different pharmaceutical forms and pharmacological action groups, were tested across 27,024 parameters. As summarized in Table 1, annual non-compliance rates varied between 0.7% and 2.4% across the years 2018–2023. Similarly, as summarized in Table 2, the annual non-compliance rates across pharmacological groups ranged from 0.0% to 11.11% between 2018 and 2023.

There was no statistically significant difference in non-compliance rates across the years at the pre-marketing stage (P=0.166). Similarly, at the post-marketing stage (P=0.126), there was no statistically significant difference in non-compliance rates over the years. However, a statistically significant difference was found when comparing the pre-marketing and post-marketing non-compliance rates (P<0.001).

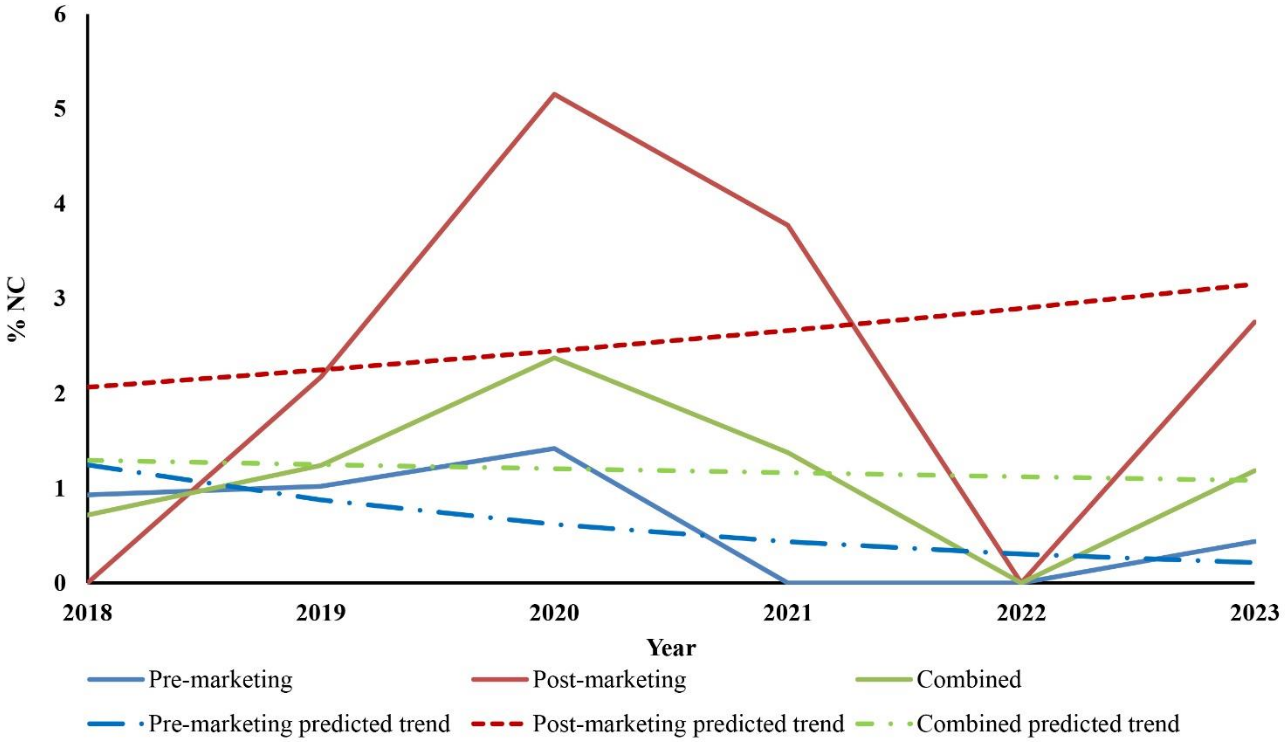

Figure 1. Pre-marketing, post-marketing, and combined non-compliance rates (%) and predicted trends of non-immunological VMPs between 2018-2023 in Türkiye. Statistically, no significant trend (P > 0.05) was observed in any of the plotted lines.

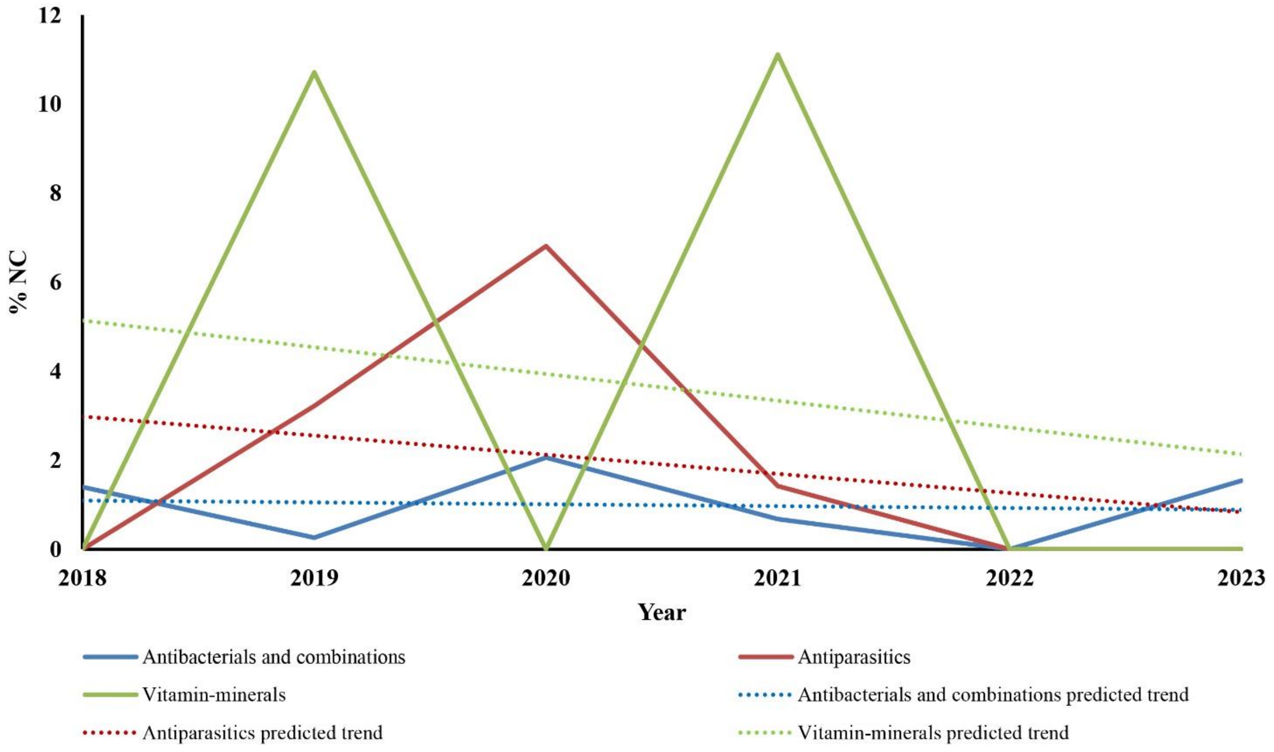

Figure 2. Pharmacological groups non-compliance rates (%) and predicted trends of non-immunological VMPs between 2018-2023 in Türkiye. Significant differences (P < 0.05) were found between some pharmacological groups; however, no significant overall trend was detected.

As shown in Figure 1, there was no significant increasing or decreasing trend in the non-compliance rates during the pre-marketing (P=0.0817), post-marketing (P=0.5693), and combined (P=0.7468) stages between 2018 and 2023.

Between 2018 and 2023, no non-compliant products were detected in the "Others" group. Therefore, no statistical comparison could be made due to the lack of variance. For antibacterials and combinations (P=0.052), the non-compliance rate showed a borderline result, slightly exceeding the threshold for statistical significance. Antiparasitics (P=0.045) and vitamins and minerals (P=0.017) showed statistically significant differences in non-compliance rates between years at the 5% level of significance.

According to the combined data for 2018–2023, statistically significant differences were identified in the year-stratified pairwise comparisons of overall non-compliance rates between pharmacological groups (P=0.0056). This difference was determined to originate from the antibacterials and combinations (P=0.028) and vitamins and minerals groups (P=0.00013). For antibacterials and combinations (P=0.85), antiparasitics (P=0.57), and vitamins and minerals (P=0.70) groups, no significant trend in increasing or decreasing in medical product quality performance (NC rates) was observed between 2018 and 2023.

Non-compliance rates according to pharmacological effect group were as follows: antibacterials and combinations 0.93%, antiparasitics 1.69%, and vitamins and minerals 3.88%. Regarding pharmaceutical form, the most common non-compliances were observed in solutions or suspensions for injection (n=14), intramammary ointments (n=12), and oral/intrauterine tablets (n=4). Thirty non-compliant products were detected during the six years. Ten products were non-compliant only in terms of active substance limits and fifteen products were non-compliant only in terms of physical parameters. Four products were non-compliant with active substance limits and pH, and one product was non-compliant with active substance limits and density. Hardness and friability non-compliance were found together in the three products. The physical parameters showing non-compliance included pH (n=9), density (n=5), friability (n=4), hardness (n=3), and volume (n=2).

In pre-marketing surveys; seven products were non-compliant only in terms of physical parameters, four products were non-compliant only in terms of active substance limits, and one product was non-compliant in terms of both parameters. In post-marketing surveys; eight products were non-compliant only with physical parameters, six products only with active substance limits, and four products with both parameters.

Non-compliance with active substance limits was detected in the vitamins and minerals group for vitamin B12 (n=1) and vitamin A (n=3). In the antibacterials and combinations group, non-compliant products included benzylpenicillin (n=1), clavulanic acid (n=2), ampicillin (n=1), and dicloxacillin (n=1). In the antiparasitic group, only ivermectin (n=3) showed products that did not meet the minimum limits. In the other pharmacological effect group, products with low concentrations were detected for prednisolone (n=4) and bromhexine (n=1).

Discussion and Conclusion

Deviations in the pharmaceutical quality characteristics of VMPs, which have an important place in terms of animal health, livestock industry and public health protection, may lead to issues within One Health framework (10, 18, 20). Sustainable survey practices carried out with correct techniques and efficient use of resources are important for the detection of non-compliant medicinal products.

In Türkiye, non-compliant non-immunological VMPs were detected in pharmacological groups such as vitamins and minerals, antiparasitics, and antibacterials and combinations, which are widely used on the market. This study demonstrated a statistically significant difference in non-compliant products between the pre-marketing and post-marketing phases of VMP. Non-compliance was more frequently observed in the post-marketing phase, primarily due to deviations from active ingredient limits. Formulation or packaging defects, as well as inappropriate transportation or storage conditions, are likely the main causes of active ingredient degradation and deviation from limits during shelf life. Although pre-marketing, post-marketing, and combined non-compliance rates fluctuated over the years, no significant overall trends were identified.

Statistically significant annual differences in non-compliance rates were found for the antiparasitic and vitamin–mineral groups. For antibacterials and combinations, the difference was borderline and not statistically significant, and thus should be interpreted with caution. On the other hand, year-stratified pairwise comparisons of overall non-compliance rates among pharmacological groups revealed significant differences originating primarily from the antibacterials and combinations, and vitamins and minerals groups. Although the overall non-compliance rate was low, marked fluctuations, including sudden increases, were observed in certain years, particularly for vitamins, minerals, and antiparasitics.

In previous studies, there were reports of non-compliance with antibacterials and combination products such as beta-lactams, macrolides, aminoglycosides, tetracyclines, fluoroquinolones, and phenicols (5, 10-12). Although antibacterials and combination products from all mentioned groups were tested in this study, only non-compliant products with respect to levels of ampicillin, dicloxacillin, benzyl penicillin, and clavulanic acid were detected. Low-limit ivermectin products were identified within the antiparasitic group, confirming previous reports (5, 11). Non-compliance with vitamins A, C, D, E, and B12 (5, 11, 12) was reported in previous studies. This study only detected non-compliant products; vitamin A limits were violated pre-market, and vitamin B12 limits were violated post-marketing. Previous studies concur with our findings of non-compliance regarding prednisolone limits in various pharmacological product groups, including analgesics, anesthetics, corticosteroids, antihistamines, and hormones (11, 12). In addition, one product was found to be non-compliant in terms of bromhexine limits, which has not been previously reported in this group of products.

Injectable products and intramammary products were the most frequent non-compliant pharmaceutical forms. This may be attributed to degradation of active substances caused by the loss of protective properties of packaging materials and/or excipients (antioxidants, antimicrobial preservatives, pH buffers) over time. The high rate of non-compliance with active ingredient limits in post-marketing and parenteral products, especially those tested near the end of their shelf life, highlights this concern.

In previous studies, non-compliances were most commonly observed in active substance limits, followed by physical properties such as pH and friability (1, 11, 18). In this study, it was determined that the non-compliances detected in physical parameters such as hardness, friability, density, and volume in the pre-marketing stage were mostly due to errors in the creation of specifications. On the other hand, a high level of non-compliance was detected in the pH determination parameter, especially in the post-marketing stage. pH non-compliance was most frequently encountered in products with non-compliant ivermectin limits. pH is an important parameter, particularly concerning the solubility, stability, bioavailability, and patient compliance of active substances, as well as interactions between active substances and packaging. Products that are found to be non-compliant in terms of active substance limits have negative effects on animal health, the environment, human health, and the economy, such as antimicrobial resistance, residues in foods, and low levels of disease control (10, 12, 18, 20, 21).

Because of differences in production and distribution infrastructure, product diversity, pharmacological group distribution, and survey methodologies, studies comparing pharmacological groups and overall non-compliance rates are not directly comparable across countries (1, 2, 5, 10–12, 18). Likewise, it has been reported that the main causes of non-compliance include the absence of robust quality control systems, inadequate adherence to GMP or GDP standards, and the use of substandard active ingredients by manufacturers (10, 11, 18). Therefore, it is more meaningful for each country to monitor its annual non-compliance rates and assess its effectiveness in reducing these over time.

This study has several limitations. First, the risk-based sampling approach may have introduced bias, as products perceived to be at higher risk were more likely to be sampled, potentially limiting representativeness. Second, multiple statistical comparisons across pharmacological groups and years increased the risk of Type I errors, despite applying appropriate significance thresholds. Third, pharmacological groups were classified according to the ATCvet system, which posed challenges in accurately categorizing certain combination products. For instance, non-compliance associated with prednisolone was evaluated within the antibacterial group with which it was combined. Finally, this study was limited to non-immunological VMPs, as the laboratory's scope of responsibility did not include immunological products.

This study summarized six years of pre- and post-marketing quality control data on non-immunological VMPs in Türkiye to determine the extent and rate of non-compliance and to inform future quality control strategies. Through the harmonization of TC-TOB with international legislation, the adoption of GMP and GDP, and the establishment of company-level quality assurance systems and control units, significant and sustainable progress has been achieved in enhancing VMP quality. Although the overall non-compliance rate of non-immunological VMPs in Türkiye was low between 2018 and 2023, notable fluctuations were observed in the vitamin–mineral and antiparasitic groups. These findings indicate that risk-based control programs should prioritize these categories. Strengthening stability testing, optimizing storage and distribution practices, and maintaining harmonization with international regulations will be crucial to sustaining low non-compliance levels. Ultimately, such measures will help protect animal health, support food safety, and enhance public health within the One Health framework.

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Conflict of Interest

The authors declared that there is no conflict of interest. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the Republic of Türkiye Ministry of Agricultural and Forestry. The Ministry of Agriculture and Forestry cannot be held responsible for them.

Author Contributions

OD conceived the idea and planned the manuscript. OD, FT, MA, ME, GKA, and MK contributed to sample analysis. OD, EOÇ, TÇ, PE, and MD have provided scientific support and contributed to the interpretation of the results. All authors helped to shape the manuscript.

Data Availability Statement

The data supporting this study's findings are available from the corresponding author.

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