Ref. Ares(2025)897632 - 05/02/2025

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and Food Audits and Analysis

DG(SANTE) 2024-8108

FINAL REPORT OF AN AUDIT
OF POLAND
FROM 11 TO 21 OCTOBER 2024
IN ORDER TO ASSESS THE CONTROLS ON
ANTIMICROBIAL VETERINARY MEDICINAL PRODUCTS

In response to information provided by the competent authority, any factual error noted in the draft report has been corrected.

Executive Summary

This audit of Poland took place from 11 to 21 October 2024 and was undertaken as part of the Directorate-General for Health and Food Safety's audit programme. The overall objective of the audit was to verify the implementation of the measures proposed to address the recommendations of the audit that the European Commission carried out in December 2023 (DG(SANTE) 2023-7694).

Overall, the report concludes that there has been noticeable and significant progress in designing and implementing suitable controls to check compliance with the prudent use requirements of the Veterinary Medicinal Products Regulation (VMPR). However, there continues to be: i) a lack of designation of the competent authority responsible for checking that antimicrobials reserved for the treatment of certain infections in humans are not prescribed for animals, and ii) an inability to impose dissuasive penalties applicable to infringements of the VMPR. Both issues undermine the effectiveness of the new controls to ensure compliance with the prudent use requirements of the VMPR, which in turn affects the ability of the Polish authorities to fight antimicrobial resistance.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	**Explanation**
EU	European Union
GVI	General Veterinary Inspectorate – *Główny Inspektorat Weterynarii*
VMP	Veterinary medicinal product
VMPR	Veterinary Medicinal Products Regulation

1 INTRODUCTION

This audit of Poland took place from 11 to 21 October 2024 and was undertaken as part of the Directorate-General's Health and Food Safety's audit programme.

The audit team comprised two auditors from the Directorate-General for Health and Food Safety. An opening meeting was held remotely on 11 October with representatives from the different competent authorities with responsibilities in the areas under the scope of this audit (see table under point 2). At this meeting, the audit team confirmed the objectives of, and itinerary for, the audit and requested additional information required for its satisfactory completion.

2 OBJECTIVES AND SCOPE OF THE AUDIT

The objective of the audit was to verify the implementation of the measures proposed to address the recommendations of the audit that the European Commission carried out in December 2023 (DG(SANTE) 2023-7694) ([1]). That audit checked the appropriateness of the competent authorities' controls required by Article 123 ([2]) of the Veterinary Medicinal Products Regulation (VMPR) in relation to certain provisions concerning antimicrobial veterinary medicinal products (VMPs).

In terms of scope, the audit focused on checking the effectiveness of the measures proposed in the action plan of the 2023 audit to rectify the issues raised at that time.

In pursuit of the above-mentioned objectives, the audit team held the following meetings and visited the following sites:

COMPETENT AUTHORITY - CENTRAL LEVEL	4	Opening and closing meetings plus two additional working meetings
REGIONAL/LOCAL AUTHORITIES	2	Regional (*Voivodeship*) Veterinary Inspectorates of warminsko-mazurskie, kujawsko-pomorskie, Łódzkie and pomorskie District (*Powiat*) Veterinary Inspectorate of Sępólno Krajeńskie, Wieluń, Wieruszów and Zgierz

3 LEGAL BASIS FOR THE AUDIT

The audit was carried out under Article 124.

Full legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the last amended version at the time of the audit.

[1] https://ec.europa.eu/food/audits-analysis/audit-report/details/4754

[2] The articles mentioned throughout this report refer always to the VMPR.

4 FINDINGS AND CONCLUSIONS

4.1 COMPETENT AUTHORITIES

Legal requirements

Article 137(1).

Observations and findings

Report DG(SANTE) 2023-7694 concluded that the competent authorities responsible for carrying out controls in areas related to this audit had long been designated, with the exception of those responsible for checking that antimicrobials reserved for the treatment of certain infections in humans are not prescribed for animals.

The audit team noted the following:

1. According to personnel from the General Veterinary Inspectorate (GVI), the designation of the competent authority responsible for checking that antimicrobials reserved for the treatment of certain infections in humans are not prescribed for animals is contingent on having national legislation in place incorporating the requirements of the VMPR. Work is still in progress in that regard, and it is expected to be finished during the first half of 2026. This is not in line with Article 137(1).
2. The above said, and as reflected in the checklist used for the controls on the use of VMPs, voivodeship official veterinarians carrying out controls on veterinary practices are instructed to check whether the inspected veterinarian has prescribed these types of substances. One of these official veterinarians declared to the audit team that she systematically asks for this information when checking veterinary practices working with companion animals.
3. Currently, lacking both a designated authority and a system to impose fines by GVI, veterinarians found in breach of this requirement can only be referred to the veterinary chamber for disciplinary action (see point 12).

Conclusion on the competent authorities

4. Although the new instructions to conduct controls on the use of VMPs include the need to check whether antimicrobials in the reserved list have been prescribed, the competent authorities responsible for these types of checks have not been designated yet. Therefore, recommendation 1 of report DG(SANTE) 2023-7694 has not been addressed.

4.2 OFFICIAL CONTROLS ON THE USE OF ANTIMICROBIALS

Legal requirements

Articles 105(1) to (3), (5)(m) and (6), 106(1), 107(1) to (5) and (7) to (9), 108, 112 to 114, and 123.

Observations and findings

Report DG(SANTE) 2023-7694 concluded that even though checks done in accordance with national legislation enacted before 2019 covered the trade and use of VMPs, the absence of planning and implementation of controls to verify compliance with most of the requirements under the scope of this audit, notably those on the use of antimicrobials, did not allow the competent authorities to contribute to a more prudent use of antimicrobials through the enforcement of the VMPR.

The audit team noted the following:

5. GVI drafted instructions in June this year detailing how inspectors from voivodeships must inspect so called animal treatment facilities (referred to in this report as veterinary practices or veterinarians) to check the relevant VMPR requirements described in Articles 105 to 107 and 112 to 114. In addition, these instructions reflect the requirements of Article 123(2) and (3) pertaining to the risk criteria to be used when selecting veterinarians to be inspected for these controls. Following these criteria, large animal practices are prioritised over companion animal ones.

6. Documentation checked showed that since the instruction came into force, voivodeship inspectors have already started checking compliance with the VMPR requirements above. As a result of these checks, a number of veterinarians were eventually found to be in breach of some of these requirements (see point 8).

7. In some cases, when checking veterinarians' treatment records and other relevant documents, inspectors suspected (and in a few cases already confirmed) non-compliance related to the use of VMPs (including antimicrobials) outside the terms of the marketing authorisation, unjustified metaphylactic or prophylactic use of antimicrobials, and to a lesser extent, the use of antimicrobials to compensate for poor hygiene or bad management.

8. To reach a conclusion, voivodeship inspectors, routinely asked the relevant powiat (district) veterinarians to go and inspect the concerned farm(s) and to gather the necessary information to corroborate (or not) what the records of the checked veterinarian suggested. In the examples seen, the powiat inspectors conducted the inspections in a short timeframe and swiftly reported the results back along with the relevant evidence. In most cases, these inspections proved that the suspicions (the voivodeship inspectors had) were well founded.

9. In most of the cases checked, inspectors drafted detailed reports and included the relevant evidence supporting their findings, such as copies of the treatment records from the inspected veterinarian.

Conclusion on official controls

10. Suitable controls to check compliance with the prudent use requirements of the VMPR have been planned and are being implemented. Therefore, recommendation 2 of report DG(SANTE) 2023-7694 has been satisfactorily addressed.

4.3 ACTIONS IN CASE OF NON-COMPLIANCE

Legal requirements

Article 135(1).

Observations and findings

Report DG(SANTE) 2023-7694 concluded that the current system in place to impose penalties applicable to infringements of the VMPR was not efficient enough to deter operators from prescribing or using antimicrobials in a non-prudent manner.

The audit team noted the following:

11. According to personnel from GVI, they will not be able to impose efficient penalties applicable to infringements of the VMPR until national legislation is in place, incorporating the requirements of the VMPR, which is not expected to happen before the first half of 2026 (see point 1). This is not in line with Article 135(1).

12. For disciplinary action, inspectors from the voivodeships can refer those veterinarians found to be in breach of the relevant requirements of the VMPR to the veterinary chamber in that voivodeship. This was the case in most of the examples seen: the voivodeship inspectors sent their reports (and the one from the powiat inspector) to the chamber along with associated evidence, and an accompanying letter specifying the articles of the VMPR that had been breached.

13. According to representatives of the regional veterinary chambers met, the first case relevant for this audit was received at the end of July. As the chambers have 3 months to complete their investigations, these cases are still being investigated and no conclusion has been reached so far. They added that a chamber can impose one of the following sanctions: i) a warning letter, ii) a reprimand, and iii) suspension of the right to practice, which can be temporary or permanent. They further stated that a sanction expires 3 years after being imposed and, providing the veterinarian does not reoffend, the file is removed from the concerned veterinarian's records.

Conclusion on actions in case of non-compliance

14. Despite the number of veterinarians referred to the relevant regional veterinary chambers, the lack of national legislation still prevents GVI to impose dissuasive penalties applicable to infringements of the VMPR. Therefore, recommendation 3 of report DG(SANTE) 2023-7694 has not been addressed.

5 OVERALL CONCLUSIONS

There has been noticeable and significant progress in designing and implementing suitable controls to check compliance with the prudent use requirements of the Veterinary Medicinal Products Regulation (VMPR). However, there continues to be: i) a lack of designation of the competent authority responsible for checking that antimicrobials reserved for the treatment of certain infections in humans are not prescribed for animals, and ii) an inability to impose dissuasive penalties applicable to infringements of the VMPR. Both issues undermine the effectiveness of the new controls to ensure compliance with the prudent use requirements of the VMPR, which in turn affects the ability of the Polish authorities to fight antimicrobial resistance.

6 CLOSING MEETING

During the closing meeting, held remotely on 21 October 2024, the audit team presented the main findings and preliminary conclusions to the competent authorities, who acknowledged them.

7 RECOMMENDATIONS

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below. The effectiveness of the actions taken to address such non-compliances will be assessed in future audits on this topic.

No.	Recommendations
1.	To designate the competent authorities responsible for controlling that antimicrobials or groups of antimicrobials listed in the Annex to Regulation (EU) 2022/1255 are not prescribed in animals, as required by Article 137(1) of Regulation (EU) 2019/6. *Recommendation based on conclusions No 4.* *Associated findings No 1.*
2.	To lay down rules on penalties applicable to infringements of Regulation (EU) 2019/6, that are effective, proportionate and dissuasive, as required by its Article 135(1). *Recommendation based on conclusion No 14.* *Associated finding No 11.*

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2024-8108

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 2022/1255	OJ L 191, 20.7.2022, p. 58–60	Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council
Reg. 2019/6	OJ L 4, 7.1.2019, p. 43–167	Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC