



**REPORT OF THE VIRTUAL MEETINGS OF THE WOAHS SUBGROUP OF THE WORKING GROUP ON ANTIMICROBIAL RESISTANCE ON THE REVISION OF CHAPTER 6.10. 'RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE'**

**December 2021- July 2022**

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## **1. Introduction**

Due to the Covid-19 pandemic, the WOAHS Subgroup from the Working Group on Antimicrobial Resistance (hereafter referred to as 'the Subgroup') met via video conference nine times between 24 January 2022 and 28 June 2022.

The list of participants is presented in [Annex I](#) and the Terms of Reference of the Working Group on Antimicrobial Resistance are presented [here](#).

The Subgroup was convened by WOAHS Deputy Director General following the request of the WOAHS Terrestrial Animal Health Standards Commission (hereafter referred to as 'Code Commission') to revise the Chapter 6.10. 'Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine' (hereafter referred to as 'the chapter').

The Working Group on Antimicrobial Resistance (hereafter referred to as 'AMRWG') discussed the potential content of the chapter during their meetings in April and October 2021 to provide support to the Subgroup. The Subgroup started the revision of the chapter remotely in December 2021 and took into consideration the Code Commission's recommendations and the latest version of the Code of Practice of the Codex Alimentarius (hereafter referred to as 'the Codex CoP'), which was finalised in October 2021. The revised chapter was presented for consideration of all members of the Working Group on Antimicrobial Resistance at its extraordinary meeting on 3 August 2022.

The following section of this report includes the Subgroup's proposed changes and associated rationale. The revised chapter will be provided to the Code Commission for its consideration at its September 2022 meeting.

## **2. Subgroup proposals**

### **Article 6.10.1. Purpose**

In the first paragraph, the Subgroup added 'in food and non-food producing animals' and 'minimising and containing antimicrobial resistance risks in the relevant animal' to align text with WOAHS terminology and with Codex CoP, and to emphasize the broadening of the scope of the chapter of promoting responsible and prudent use of antimicrobial in all animal species whilst considering the environment in which animals are kept and treated. The concept of 'One Health' was also included as previously missing from this chapter in alignment with the revised Codex CoP, paragraph 3.

In the second paragraph, the term 'animal owners' was added as this stakeholder was missing previously from the chapter and only food animal producers had been considered. Animal owners of non-food producing animals should also be considered in the chapter as they also use antimicrobial agents when caring for their sick animals. This has also been reflected in the creation of a new article 6.10.9. 'Responsibilities of animal

owners'. To represent the variety of the roles and responsibilities of the different stakeholders, it has been included: 'any or all of the following activities'. In the same paragraph, 'marketing authorization' was replaced with 'relevant regulatory approval' in line with the WOAHP terminology adopted in other chapters<sup>1</sup> of the WOAHP *Terrestrial Animal Health Code* and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. This change was applied across the whole chapter accordingly. The terms 'sales, advertising' were added to the list of activities as these are also within the remit of this chapter.

In the third paragraph, the term 'good agricultural practices' was replaced with 'animal husbandry practices' in line with Principle 2 of the Codex CoP.

At the end of the third paragraph a sentence was added to emphasize the need to focus on preventative measures to reduce reliance on antimicrobial agents to ensure animal health and welfare.

#### **Article 6.10.2. Objectives of responsible and prudent use**

In the first paragraph, 'practical and recommendations' was removed as the term 'measures' is sufficient.

In the first paragraph, 'Veterinary medical' was added in front of 'use' to reflect the current WOAHP terminology and Principle 12 of the Codex CoP. The wording 'of antimicrobial agents' was added to emphasise that the focus of this chapter is on these. It was decided by the Subgroup exclude recommendations on use of antimicrobial agents intended for growth promotion as they considered that the remit of this chapter should be on responsible and prudent use of antimicrobials intended for treatment, prevention or control of infectious diseases in animals<sup>2</sup>.

Furthermore, 'and resistance determinants in animals, humans and the relevant animal environment' was added to reflect the transfer of antimicrobial resistance across sectors and the need for a One Health approach.

In point 1., the term 'responsible and prudent' replaced 'rational' in line with current WOAHP terminology. This change was applied across the chapter for consistency purposes. The term 'efficacy' was replaced with 'effectiveness' as this term is more accurate to describe what happens when using antimicrobials in animals in field conditions whilst 'efficacy' is used to assess antimicrobials in well controlled preclinical conditions prior to approval. The latter change was applied across the chapter accordingly.

In point 3., rephrased '... the environment and between animals and humans' to '...between animals, humans, and the relevant animal environment' to reflect better the transmission dynamics of antimicrobial resistance across sectors.

In point 4., removed '...and usefulness...' as already implied in the new wording proposed 'effectiveness'.

#### **Article 6.10.3. Responsibilities of the *Competent Authority***

The Subgroup added a new point '1. National Action Plan' to reflect the changes noted since the last revision of the chapter and the need to include national action plans as part of the responsibilities of the Competent Authority for addressing antimicrobial resistance as recommended in the Global Action Plan<sup>3</sup>. This new section is in alignment with the Codex CoP and what has been previously discussed by the WOAHP Working Group on Antimicrobial Resistance in April 2021. The new text included describes the roles and responsibilities of the Competent Authority in designing, implementing and evaluating progress of NAPs. The other points were renumbered accordingly.

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<sup>1</sup> [Terrestrial Code Chapter 4.18. Vaccination](#); [Terrestrial Manual Chapter 1.1.8. Principles of veterinary vaccine production](#); [Manual Chapter 2.3.2. The role of official bodies in the international regulation of veterinary biologicals](#); [Manual Chapter 2.3.4. Minimum requirements for the production and quality control of vaccines](#); [Manual Chapter 3.1.16. Q fever](#); [Manual Chapter 3.1.17 Rabies](#); and [Manual Chapter 3.1.24. West Nile fever](#)

<sup>2</sup> [TAHC Chapter 6.9. Article 6.9.2. Definitions](#)

<sup>3</sup> [Global Action Plan on Antimicrobial Resistance \(AMR\)](#) was adopted in 2015 by all countries through decisions in the World Health Assembly, the Food and Agriculture Organization of the United Nations (FAO) Governing Conference and the World Assembly of World Organisation for Animal Health (OIE) Delegates. Countries agreed to have a national action plan on AMR that is consistent with the Global Action Plan, and to implement relevant policies and plans to prevent, control and monitor AMR.

The second paragraph of the new section is in alignment with the Codex COP paragraph 17 on the creation and update of responsible and prudent use guidelines.

In point 2., the first paragraph was deleted as deemed inappropriate to start the point with this sentence.

In point 2., second paragraph, 'It' was replaced with '*Competent Authority*' for clarity and 'authorisation' was replaced with 'approval' in line with the previous made across the text for 'marketing authorisation'. This change was applied across the chapter.

In point 2., third paragraph, '...and proposed post-marketing surveillance program...' was added as part of relevant statutory registration checks to be conducted by Competent Authorities for VMPs containing antimicrobial agents. In the second sentence 'affect' was replaced with 'influence' as this term was deemed more adequate by the Subgroup.

In point 2b., 'and' was replaced with 'or' as the exporting and manufacturing country may not be the same for a specific VMP.

In point 2c., 'an' was added as 'Competent Authorities' was changed into singular and "relevant" was removed as redundant. The latter change was also applied across the chapter accordingly.

In point 2, paragraph 6, 'the' was replaced with 'a' and 'industry' was replaced with 'company' to focus on individual pharmaceutical companies rather than the industry in general, and 'other' was added as submissions may be made by applicants other than pharmaceutical companies. Order of text was changed to improve flow.

In point 2., paragraph 7, 'Member countries' was replaced with 'The Competent Authority' for accuracy purposes as this is the responsibility of the Competent Authority within a Member country. Furthermore, '...or require the use of...' was added to reflect the variations that may occur in national legislation across Members.

In point 2., paragraph 8, in the first sentence, 'potential' was removed as deemed not relevant and '... with particular focus on use in food-producing...' was removed to widen the scope of the article to all animal species. In the second sentence, 'should' was replaced with 'may' to allow flexibility of controls by Competent Authorities, and 'from one agent' was added to improve flow of the sentence. In the third sentence, 'usage' was replaced with 'use' as a more adequate term; this change was applied across the chapter accordingly. In the same sentence, 'species' was added after 'target' as this word was missing in the original text. Furthermore, a definition was included for dosage regimen and '..as relevant...' was added after 'withdrawal period' as this term would not apply to non-food producing animals. Additionally, 'and different duration of treatments that are proposed' was removed as already implied under the definition of dosage regimen.

In point 2., paragraph 9, 'expedite' was replaced with 'consider expediting' and 'need' was replaced with 'needs' to improve flow of text. Wording was added to make it clear that Competent Authorities should be aware of the OIE list of antimicrobials of veterinary importance and that they should make decisions and provide guidance based on international standards.

In the title of point 3., the word 'control' was removed as not relevant within the context of the responsibilities of the Competent Authority. The term 'VMP' was changed to plural to 'VMPs'; this change was conducted across the chapter as appropriate.

In point 3., first paragraph and in points 3b. to 3d. the wording was modified to improve clarity and flow of the text.

In point 3a. the current text was moved to new point 3d., and new text 'to ensure the specifications of antimicrobial agents' was added and merged with part of the text in 3b minus the segment 'to ensure that analysis specifications of *antimicrobial agents*' was deleted. This change is to encourage Competent Authorities to follow existing guidance (e.g. VICH) where possible when conducting assessment of quality of VMPs containing antimicrobial agents and it is in line with current international guidance for approval of VMPs

The point 3c. became 3b .

The point 3d became 3c. The term ‘and compatibility’ was added after ‘stability’ as this is an important factor to consider for antimicrobials that are intended to be added to feed or water.

The point 3e became 3d. The text ‘purity in order to guarantee their safety and efficacy’ was deleted and text from 3a was added to be in line with Paragraph 20 of the Codex CoP that states that “Competent authorities should ensure that quality controls are carried out in accordance with national or international guidance and in compliance with the provisions of good manufacturing practices.”

In point 4, a new first paragraph was added to improve clarity and flow of text.

In point 4a. i. in the second bullet point, ‘pre-existing resistant’ was removed and ‘and strains with acquired resistance’ was added as relevant to consider together with intrinsic resistance. In the third bullet point. a sentence was added to emphasize the existing gaps in knowledge for clinical breakpoints for specific animal species, pathogens and antimicrobial agent combinations that need to be addressed.

In point 4.a. ii., a new third bullet point was added ‘time-kill kinetics when appropriate’ as this type of assay was deemed relevant as it is used to study the activity of an antimicrobial agent against a bacterial strain and can determine the bactericidal or bacteriostatic activity of an agent over time.

In point 4a. ii. and iii., ‘pharmacodynamics’ was replaced with ‘pharmacodynamic investigation’ as more accurate in the context of this section and ‘criteria’ was replaced with ‘characteristics’ as this text refers to the intrinsic characteristics of the antimicrobial agents that should be considered when determining their activity.

In point 4a. iii., ‘levels’ was replaced with ‘concentrations’ as a more accurate scientific term and ‘investigation’ was added after ‘pharmacokinetic’. The two sentences in this point were merged into one and edited accordingly to improve flow of the text. In the first bullet point was removed ‘bio-availability in accordance with the route of administration;’. The second bullet point, was rephrased, merged with the third bullet point and the fourth bullet point to reflect better the characteristics of antimicrobial agents at site of infection that should be assessed as part of pharmacokinetics investigations.

A new last bullet point was added to account for any potential routes of administration that are proposed by the applicant.

In the last paragraph of point 4a. ‘Any proposed’ was added for clarity.

In point 5., second sentence of the first paragraph ‘The party applying for market authorisation’ was replaced with ‘The applicant for regulatory approval’ in line with current WOAH terminology.

In the second paragraph, the word ‘assessment’ was added for clarity.

In point 5a. removed ‘either’ and added ‘and, where appropriate, active’ as active metabolites of antimicrobial agents are the agents most likely to induce antimicrobial resistance in the gut flora of animals and taking into account that some metabolites will become inactive when binding with fibres or other particles and therefore will not interfere with gut flora. The wording ‘bacteria and commensal flora’, was added as relevant for consideration in the context of antimicrobial resistance.

Added new point 5b. ‘the antimicrobial activity of the antimicrobial agents and metabolites in the intestinal environment’ as range of activity of the antimicrobial agents and metabolites may be affected by different concurring factors present in the intestine environment.

In point 5c. moved ‘the’ to the beginning of the sentence to improve flow of the text, and added ‘and antimicrobial residues in the environment’, as missing from text and deemed relevant.

In point 5d. replaced ‘degree’ with ‘presence of and potential for’ as more appropriate and added ‘co-resistance and’ as co-resistance is more important than cross-resistance as it refers to when a particular resistance trait confers resistance to other antimicrobial classes.

In point 5e., added 'commensal and food-borne pathogenic bacteria' in alignment with current VICH terminology and replaced 'agents' with 'bacteria' due to the animal and public health importance worldwide of antimicrobial resistance in bacteria. Replaced 'concern' with 'relevance' as more in line with current terminology in international guidance.

Added new point '6. Establishment of clinical breakpoints' and a paragraph as this is an important gap in knowledge that needs to be addressed.

In point 7a. 'biological' was replaced with 'microbiological' to reflect impact on bacterial populations derived from antimicrobial use and 'flora' was replaced with 'microbiome' to reflect current scientific terminology. Furthermore, 'to derive ADI' was added at the end of the sentence for clarity. In 7b. 'for use in food-producing animals' was added as withdrawal periods are only applicable to these animal species.

In point 8. title 'Protection' was replaced with 'Assessment' and 'impact of on the relevant animal' was added to reflect the changes on the text in this section, where more detail has been provided on environmental risk assessment following existing national and international guidance based on the paragraph 23 of the Codex CoP. In the first paragraph, it was added 'risk to' and 'relevant' and 'accordance with national or international guidelines'.

A new paragraph was added in this section emphasizing the need for using outputs of environmental risk assessments to inform policy and interventions by Competent Authorities.

In point 9, title, 'or equivalent' was added as it was recognised that not all Members are familiar with or use the term Summary of Product Characteristics or SPC. This change has been applied across the chapter for consistency purposes. In the same sentence, 'package insert and labelling' were also included as these should also contain relevant information concerning the specific VMPs containing antimicrobial agents.

The first paragraph was edited as the relevant information of VMPs containing antimicrobial agents should be included.

The second sentence of the first paragraph was edited to reflect that not all information may be relevant for all VMPs containing antimicrobial agents and that Competent Authorities should decide which to include based on their own judgement.

Five new points were added under 9. (9.a., 9.c., 9.d., 9.p., and 9.q.) including relevant information that should be captured in the SPC or equivalent for the specific VMP -if deemed appropriate- concerning its commercial name and characteristics of the formulation, recommendations for use to prevent negative impact of the environment and flagging up potential restrictions for use in specific types of food animal production systems.

Line 9.t. was edited to the plural as more adequate 'contraindications'.

In point 10, 'resistance' was added to the title for clarity. In the same point, in the first paragraph, 'The *Competent Authority* should assess' was added to emphasise the role of the Competent Authority in assessing post-marketing surveillance data. 'Surveillance' was added to the same sentence for clarity. In the second sentence 'These information sources' and 'detect and' were added for clarity.

In point 10a. 'relevant authorities' was replaced with '*Competent Authority*' as per current WOAHP terminology.

In point 10b. first sentence, 'antimicrobial agent' was replaced with 'VMP' as deemed more adequate in the context proposed. In the following sentence, 'pathogenic agents' was replaced with 'pathogens' as more concise, and 'other relevant zoonotic pathogens' was added to broaden the scope of the post-marketing surveillance remit to include pathogens that affect human health following a One Health approach.

In point 11, 'Supply' was replaced with 'Distribution' as this term was deemed to be more reflective of the need to take into account the whole of the supply chain of VMPs containing antimicrobial agents. The first paragraph was edited for clarity.

The order of points a. to d. was modified and content of points was extensively edited to reflect the logical steps observed in a supply chain of VMPs containing antimicrobials and the responsibility of the *Competent*

*Authority* at each of the steps, taking into account Codex CoP paragraph 29. In line 11.d. ‘authorised’ has been replaced with ‘suitably trained’ to reflect WOAHA terminology and ‘animal owners and animal food producers as appropriate’ was added to reflect that these stakeholders are also end users of antimicrobial agents.

An additional paragraph was added to reflect the need to ensure access to sufficient VMPs and the need for the public sector to work closely together with the pharmaceutical industry to prevent drug shortages that could compromise animal health and welfare.

In point 12a., ‘or equivalent’ was added to account for country variation in documentation available for VMPs containing antimicrobial agents.

In point 12b., ‘and under the supervision of a veterinarian’ was removed as use of antimicrobials by veterinary paraprofessionals should be according to national legislation.

In point 13., title, ‘related to the use’ and ‘and antimicrobial resistance’ were added to improve flow of the text and to broaden the scope of the training to also include the epidemiology of antimicrobial resistance to raise awareness and provide better understanding on the reasons why it is important to promote responsible and prudent use of antimicrobials.

In point 13., first paragraph, a sentence was added to improve clarity. In the second sentence ‘stakeholders’ ‘and paraprofessional education establishments’ and ‘paraprofessional’ were added to update the terminology. The last sentence was simplified to reflect the variety of training activities that may or not be included in training programs. The training requirements were edited taking into account the recommendations from the revised Codex CoP paragraph 33.

A new point 14. was added as this is part of the competencies of the Competent Authority focusing on the need for collation of antimicrobial use data in an harmonised manner, risk assessment and monitoring of effectiveness of interventions and policies. Moreover, this point also emphasized the responsibility of the Competent Authority to collect and provide antimicrobial use data to WOAHA’s global database (ANIMUSE).

In point 15., the title was modified to include ‘Knowledge gaps and’. The first paragraph and the content of this section were edited taking into account the recommendations from the revised Codex CoP, paragraph 18.

#### **Article 6.10.4. Responsibilities of the veterinary pharmaceutical industry with regards to VMPs containing antimicrobial agents**

In point 1a. replaced ‘supply’ with ‘provide’ and added ‘as specified in Article 6.10.3’ for clarity.

In point 1c. added ‘and regularly report on’ as the veterinary pharmaceutical industry should share their pharmacovigilance data with the Competent Authorities on a regular basis so that AMR can be detected early for specific antimicrobial agents.

A new point 1d. was added to acknowledge the need to promote private-public partnerships and the importance of sharing of information across sectors to address knowledge gaps on antimicrobial resistance. It is also acknowledged that this may not be an option for some companies in the pharmaceutical sector nor feasible for all Members.

In point 2. a new point c. was added in line with what was added also in Article 6.10.3. to note that some aspects of this responsibility may be shared between the veterinary pharmaceutical industry and the Competent Authority; in particular, follow-up of drug shortages were therefore also included in the Competent Authority’s responsibilities.

In point 3. first paragraph, ‘standards’ was replaced with ‘practices’ in line with current terminology.

In point 3b, ‘and animal owner’ was added as owners of non-food producing animals should also not be targeted directly by advertisement campaigns for VMPs containing antimicrobial agents.

In point 4. first paragraph, the reference made to the training requirements source was changed to '13' to reflect current structure of the revised chapter. This change was applied accordingly across the chapter.

#### **Article 6.10.5. Responsibilities of wholesale and retail distributors.**

In point 1., order of text was changed to improve flow and 'and under the supervision of a veterinarian' was deleted as this should be included under national legislation.

In point 2., added 'for an appropriate period' in relation to the period of time for which records related to VMPs containing antimicrobial agents should be kept, as this will vary across Members. The point 2i. was added to account for variation of requirements for record keeping across Members.

#### **Article 6.10.6. Responsibilities of veterinarians**

In the first paragraph, added 'antimicrobial stewardship' as part of the role of veterinarians to be guardians of antimicrobials. Antimicrobial stewardship includes a coherent set of integrated actions taken to promote the responsible and prudent use of antimicrobial agents across sectors, to help mitigate the risk of antimicrobial resistance and preserve the effectiveness of antimicrobials. Replaced 'identification' with 'detection and diagnosis' as more technically accurate when referring to animal diseases.

In the second paragraph, a sentence was added to emphasize that veterinarians should consider non-antimicrobial options during their decision-making process when selecting animal therapy whenever possible.

A third paragraph was added as in some Members, veterinary paraprofessionals and other suitably trained persons are important stakeholders in delivering animal health services and are contemplated in the national legislation.

In point 1, the title was modified as most of the text in this section relates to the criteria that veterinarians should consider when deciding on the animal therapy for the animals under their care.

The first paragraph was edited to complete the listing of tasks that veterinarians are responsible for in order to inform their selection of antimicrobial therapy.

In point 1a., 'dispense' was added as for some Members, national legislation allows veterinarians to directly dispense antimicrobials to animal owners and 'to treat, control or prevent infectious diseases in animals' was added to align with the definition of veterinary medical use. The order of the wording of the sentence was modified to improve flow. The rest of the first sentence was moved to line c.

A new point 1b. was added as to emphasize the important role that veterinarians have in the promotion of good animal husbandry practices to their clients.

Point 1c was re-written to reflect the need for veterinarians to follow national responsible and prudent use guidelines, the OIE list of antimicrobial agents of veterinary importance and principles of antimicrobial stewardship. Consideration would need to be given as to whether such guidelines have regulatory or non-regulatory implications, the need to keep such guidelines updated, and the consideration of international standards during the development of national guidelines.

In point 1d, 'where possible' was moved to account that in some circumstances and contexts across Members it may not be able to conduct antimicrobial susceptibility testing to inform antimicrobial selection due to lack of access to laboratories, cost of testing or other factors.

In point 1e., the term '(if applicable)' was added as withdrawal periods will not be applicable when target species is a non-food producing animal species. In the same sentence, 'times' was removed and replaced with 'period' in accordance with current terminology.

A new point 1f. was added to acknowledge that therapeutic success can also be influenced by non-antimicrobial, supportive therapy and that these also play a role in ensuring animal health and welfare.

In point 2., current point 2a. was converted into a paragraph and the list of items was renumbered with letters instead of 'i' for consistency with the structure of the chapter.

In point 2b., 'antibiogram' was replaced by 'antimicrobial susceptibility testing' as this was deemed more appropriate in the context of the process that veterinarians should follow when choosing an antimicrobial agent for animal therapy.

In point 2c., the wording 'properties of the selected antimicrobial agent' was added for clarity. In point 2f. text was added for clarity to the factors affecting effectiveness of treatment and 'pathogenic agents' was replaced with 'pathogens' in alignment with the rest of the chapter.

The second paragraph was edited extensively to reflect the stepwise, evidence-based approach that should be followed by veterinarians when in the presence of therapeutic failure or disease reoccurrence. The investigation conducted by the veterinarian may include revision of the clinical history and laboratory test results (if any) of the sick animal(s), further clinical and laboratory examinations and exploration of therapeutic options that may include non-antimicrobial agents if adequate.

In the third paragraph, the focus was broadened from 'Emergencies' and the text edited accordingly to 'In particular situations' to reflect circumstances in which empirical antimicrobial use may occur in the absence of a confirmed diagnosis. Text 'without the recourse to' was removed and 'results are available' was added to reflect this.

In the last paragraph, 'for their synergistic effect' was deleted as the terminology may not be confluent with the way in which it is understood nowadays.

In point 3., title, the term 'selected' was added and the word 'chosen' was deleted being superfluous.

In point 3., the first paragraph was edited to indicate all the information that should be included in the prescription issued by the veterinarian so as that clear instructions are provided to end users (i.e., food animal producers and animal owners), and misuse of antimicrobials in animals is avoided.

Two new paragraphs were added as paragraph 2 and 3. The first added paragraph highlighted the need for veterinarians to consider categorisation of antimicrobial agents according to their importance in human and animal health, emphasizing the need for a One Health approach. The second paragraph, reiterated the important role of the veterinarian in educating animal owners in how to use veterinary products properly.

In the penultimate paragraph, it was added 'certain' to 'appropriate circumstances' to indicate that their use should be exceptional and 'periods to be used, if applicable' was shortened to 'period, as applicable' to improve flow of text.

In the last paragraph, text was added to the last sentence to remind Members of WOA's recommendations<sup>4</sup>.

In point 4. a new point 'a' was added 'Name of the VMP' to indicate the need for veterinarians to record the commercial name of the VMP as formulations of VMPs may vary.

In point 4b., 'on or supplied to each food producing holding or animal owner' was added to reflect the situation of countries where veterinarians are allowed to dispense VMPs directly to animal owners and food animal producers and to reflect the broadening of the scope of the chapter to also include non-food producing animals

The terms 'per animal species' were removed from 4b., but the concept of animal species was added onto a new point 4d.

New points 4c., 4e. and 4f. were added to allow the assessment of the appropriateness of the therapy selected.

In point 4g., 'or animal owner' was added to align with the broadening of the scope of the chapter to include also non-food producing animals.

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<sup>4</sup> <https://www.woah.org/app/uploads/2021/06/a-oie-list-antimicrobials-june2021.pdf>



In point 4k., 'to' was replaced with 'associated with' to improve syntax.

In point 6., 'and paraprofessional' was added in the two sentences to recognise the need to include these animal health professionals in training and continuous professional development initiatives as these play an important role in the provision of animal health services in some Member countries and regions.

#### **Article 6.10.7. Responsibilities of animal feed manufacturers**

This article was previously Article 6.10.8. but was moved to earlier in the chapter in order to respect the logic from Competent Authority to end-users of antimicrobial agents.

In point 1., in the first sentence, text 'manufacturing and' was added as a task under the direct responsibility of feed manufacturers. In the second sentence, 'and under the supervision of a veterinarian' was removed as already implied within the national legislation.

Point 2., was extensively edited and shortened to include mention of medicated feed and premixes. It was noted that records should be kept for a suitable period of time (as specific time periods may be defined by the Competent Authority and/or national legislation).

In point 3., 'medications' was replaced with 'pharmaceutical products' and 'drug' was replaced with 'medicated' as more scientifically accurate use of terminology.

In point 4., 'intended' was replaced with 'target' in line with the rest of the chapter.

In point 5., 'appropriate production' was replaced with 'good manufacturing' in line with current WOAH terminology.

A new point 6. was included to address the need of these stakeholders to receive training on responsible and prudent use of antimicrobials and antimicrobial resistance.

#### **Article 6.10.8. Responsibilities of food animal producers**

This article was previously Article 6.10.7. but was moved to respect the logic from Competent Authority to end-users of antimicrobial agents.

In point 1, text was added to provide clarity on the rationale for the need to focus on preventative measures.

In point 2, a new point 2b. was added and 2d. was created using part of 2c. following the rationale that food animal producers should focus on preventative measures to reduce burden of animal diseases in their animals, therefore reducing their reliance on antimicrobial agents to protect animal health and welfare.

Point 2e., was edited as to reflect that in some countries veterinary paraprofessionals and other suitably trained persons may also be able to prescribe, provide and administer antimicrobial agents to animals under their care according to existing national legislation.

In point 2f., the term 'attending' was replaced with 'prescribing' as instructions for use of antimicrobial agents should be included in the prescription provided by the veterinarian responsible for the animal(s) care.

In point 2g., 'and record' was removed as already covered in point 2l. vii.

In point 2h., 'according to the SPC or equivalent, or relevant national legislation' was added as to reflect the proposed changes in earlier text and to emphasize the need for animal food producers to consider environmental impact when using antimicrobial agents.

A new point 2i. was added to cover the use of medicated premixes in farm settings.

In point 2k. iv. 'of the animal or group' was replaced with 'and the number' for clarity.

In point 2k. vi. 'dosage' was replaced with 'dose regimen' as this term is broader and includes dosage, frequency and duration of treatment.

In point 2k. viii. 'result' was converted into plural.

A new point 2k. x. was added for the recording of 'suspected adverse events' due to the use of VMPs containing antimicrobial agents by food animal producers.

**Article 6.10.9. Responsibilities of owners of non-food producing animals**

This article was created as antimicrobial agents may also be used by these stakeholders when caring for their sick animals and therefore falls into their responsibility to use these in a responsible manner.

Points 1. to 5. cover the responsibility of the animal owner to follow recommendations by their veterinarian regarding disease prevention and control including responsible and prudent use of antimicrobials, and communication to the veterinarian or veterinary paraprofessional of any adverse reactions or treatment failures that may be observed after the administration of VMPs containing antimicrobial agents.

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**MEETING OF THE WOH SUBGROUP OF THE WORKING GROUP ON ANTIMICROBIAL RESISTANCE ON THE REVISION OF CHAPTER 6.10. 'RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE'**

**Virtual, December 2021 - July 2022**

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