Report of the Meeting of WOAH Subgroup on the revision of Chapter 6.10. 'Responsible and prudent use of antimicrobial agents in veterinary medicine'

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1. Introduction

The WOAH Subgroup (hereafter 'the Subgroup') from the Working Group on Antimicrobial Resistance (hereafter 'AMRWG') met face-to-face on 29 March 2023 and subsequently via video conference three times on 6 April, 12 May and 30 June 2023.

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

The 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 as 'the Codex CoP'), which was finalised in October 2021.

2. Terms of reference and appointment of chair

Dr Ishibashi accepted to chair the Subgroup. The Subgroup adopted the agenda. The agenda and the list of participants are presented in Annex I and Annex 2 respectively and the terms of reference of the Working Group can be found here.

3. Update on the February 2023 Code Commission meeting

At its February 2023 meeting, the Code Commission discussed and addressed some of the Member comments. Regarding the comments on the establishment of clinical breakpoints, the Code Commission advised that these should be determined according to the guidance in the *Terrestrial Manual* Chapter 2.1.1. Laboratory methodologies for bacterial susceptibility testing. As a result this concept does not fall under the remit of Chapter 6.10. The Code Commission agreed not to circulate the revised draft Chapter for comments at this stage and requested that the AMRWG consider their feedback, discuss the remaining Member comments and submit a revised draft Chapter for the Code Commission's meeting in September 2023.

At its meeting on 29 March, the Subgroup acknowledged the Code Commission's support to continue its work to revise the Chapter taking into account Member comments received. The Subgroup also noted that the Code Commission welcomed the comments received from Members and directly addressed some of these comments as appropriate.

4. Review of comments on draft Chapter 6.10 'Responsible and prudent use of antimicrobial agents in veterinary medicine'

Overall, 140 Member comments were received from Brazil, Canada, China (People's Republic of), Chinese Taipei, Japan, New Caledonia, Singapore, Switzerland, the United Kingdom, (UK), and the European Union (EU).

The Subgroup considered the comments received and made amendments to improve clarity and readability, where relevant. Where amendments were of an editorial nature, no explanatory text has been provided in this report. In addition, the Subgroup did not consider comments that were difficult to interpret, that were not aligned with WOAH standards and guidelines, that had no rationale, or that were too specific in nature, for example when a comment was relevant to only one region.

This report includes the Subgroup's latest proposed changes and associated rationale in response to Member comments and recommendations from the Code Commission.

General comments

When considering a comment proposing to add 'whenever applicable' or 'whenever possible' where recommendations are more prescriptive than that of the Codex CoP, the Subgroup advised that the revised text should be aligned with the latest version of the Codex CoP. As such, the Subgroup recommended that the terms proposed should not be included in the text, as it is understood that Members should strive to adhere to WOAH standards whilst also considering their national context.

When considering a comment proposing to use 'producer' instead of 'animal breeders, owners and keepers', the Subgroup recommended the use of the latter term as it was deemed more inclusive. The Subgroup considers that the term 'animal breeders, owners and keepers' encompasses a wider range of individuals involved in caring for both food-producing and non-food producing animals and therefore this broader term is more appropriate for use in the context of the Chapter than 'producer' alone.

When considering a comment proposing to specify the content and scope of the National Action Plan (NAP), the Subgroup recommended that the text of the Chapter should include references to relevant documents (e.g. Global Action Plan or GAP).

When considering a comment proposing to define post-marketing surveillance programmes, the Subgroup recommended the editing of the text to avoid confusion between post-marketing surveillance of antimicrobial resistance (AMR) as part of pharmacovigilance and the general requirements for AMR surveillance programmes.

A comment noted that Article 6.10.3, point 8's requirements for environment risk assessment for AMR were too prescriptive and that 'animal environment' needed to be clarified. The Subgroup advised that whilst the recommendations in the Chapter should consider requirements for animal health rather than solely being focused on food safety and public health requirements stated in the Codex CoP. Moreover, the Subgroup noted that it is not within the scope of the Chapter to explicitly define the term 'animal environment'. The Subgroup considered that this will depend on the species and country context, and that the 'relevant animal environment' includes farms, animal transport vehicles, veterinary practices, lairages in slaughterhouses amongst others. The Subgroup recommended the adoption of this term across the chapter where deemed relevant.

When considering a comment proposing to separate the recommendations between food-producing animals and non-food producing animals due to the different purposes of rearing and treatment policy, the Subgroup recommended to flag up throughout the text, measures that should be applied to specific types of animals (food-producing or non food-producing animals such as companion animals), types of production systems and country regulatory contexts.

Article 6.10.1. Purpose

When considering a comment, the Subgroup advised against deleting 'relevant' in front of 'animal environment' in the first paragraph as it considered the proposed term would be too broad and outside the scope of this Chapter. The Subgroup considered that 'relevant animal environment' should be considered as part of a 'One Health' approach and relevant to the animal species and country context. This rationale was applied throughout the Chapter.

When addressing a comment concerning the third paragraph, the Subgroup advised to add the text '… importance of the antimicrobial agent to human medicine, the risk of development of antimicrobial resistance, the …' to emphasize the need to consider the importance of these antimicrobial agents deemed as critically important for human health and the fact that using antimicrobials in animals may contribute to the emergence of AMR in humans. These are important antimicrobial stewardship principles. In the last sentence, the Subgroup recommended to add 'and spread' for completeness.

Article 6.10.2. Objectives of responsible and prudent use

The Subgroup recommended the deletion of the first paragraph and to move part of the text to the end of the article. At the beginning of the article, the Subgroup advised the addition of a new sentence to introduce the objectives of responsible and prudent use: 'The objectives of responsible and prudent veterinary medical use of antimicrobial agents are to:', so that this article clearly states what are the objectives of responsible and prudent use and concludes with a paragraph that explains what measures should be adopted to achieve these.

In point 1), the Subgroup advised that the text 'ensuring the responsible and prudent rational use of antimicrobial agents in animals with the purpose of' should be deleted as it is redundant. When considering a comment, the Subgroup advised to replace 'optimising' with 'preserving' as a more appropriate term in the context of the sentence.

When considering a comment, the Subgroup advised against the addition of a new bullet point on 'advising on sound animal husbandry methods, hygiene procedure, …' as the proposed text was deemed by the Subgroup to be more related to antimicrobial stewardship than being an actual objective of responsible and prudent use of antimicrobials. Instead, the Subgroup proposed the addition of the proposed concept of preventative measures and good farming practices through the inclusion of a new sentence at the end of the last paragraph 'These measures include promotion of good animal husbandry practices, hygiene procedures, biosecurity and vaccination strategies which can help to minimise the need for antimicrobial use in animals'.

In the new last paragraph, when considering a comment, the Subgroup proposed the replacement of the term 'bacteria' with 'micro-organisms', as spelt in the Glossary. This change should be applied throughout the Chapter where the context is applicable to bacteria, fungi, microparasites and viruses; however, the term 'bacteria' should still be kept in sections of the text where the context was specific to antibacterial resistance (e.g., clinical breakpoints).

Article 6.10.3. Responsibilities of the Competent Authority

1) National Action Plan

When considering a comment, the Subgroup advised the addition in the title of the words 'for Antimicrobial Resistance' for clarity.

The Subgroup recommended that the text of the first paragraph should be divided into two paragraphs to make a clearer distinction between the role of Competent Authorities in the design and implementation of NAPs for AMR and the recommendations specific to NAPs. The Subgroup advised that the third paragraph should be merged with the newly created second paragraph to improve the flow of the text.

When considering a comment, the Subgroup proposed that in the first paragraph, the sentence 'considering the findings of the situational analysis of the country, the objectives of the Global Action Plan (GAP) for Antimicrobial Resistance and its existing guidance in the manual for developing National Action Plans for antimicrobial resistance' should be added as these criteria are relevant for the successful design of NAPs adapted to country's needs and are aligned with current recommendations from the quadripartite organisations for a One Health approach.

2) Regulatory approval

When considering a comment regarding point c), the Subgroup advised against adding 'science-based criteria, which could be aided through' before 'technical cooperation' as Members lacking adequate resources would not have the capacity to develop these criteria. The Subgroup noted that the Members should focus first on developing technical cooperation and partnerships to receive the support needed to address this gap.

When considering a comment, the Subgroup advised against the addition of a new paragraph to point 2 as the focus of the Chapter is on veterinary medical use of antimicrobials. As such, in the sixth paragraph, the Subgroup proposed the addition of the text 'for treatment, control and prevention of diseases and' to further emphasize the scope of the Chapter.

When considering a comment regarding the sixth paragraph, the Subgroup proposed the addition of the text 'based on the technical requirements for veterinary product registration' for clarity. The Subgroup also recommended the addition of the text 'consult and… as appropriate' and the deletion of the text 'or require the use of' to emphasize that WOAH recommends that Members should follow the Veterinary International Conference on Harmonization (VICH) guidelines whilst recognising that not all Members are VICH members.

When considering a comment regarding the eighth paragraph, the Subgroup recommended the addition of the text 'treatment options' as there could be alternative options to antimicrobials, but with the following additional edits '… or treatment options, including alternatives to antimicrobials,…' as it is important to emphasize to Competent Authorities that they are also responsible for the regulatory approval of Veterinary Medicinal Products that are alternatives to antimicrobials for treatment of infectious diseases in animals.

3) Quality of antimicrobial agents and veterinary medicinal products containing antimicrobial agents

In point c), the Subgroup proposed to edit the sentence to improve the flow of the text to 'that antimicrobial agents are stable and compatible when mixed with feed and water;'.

4) Assessment of therapeutic effectiveness

When considering a comment, the Subgroup advised against the proposed deletion of the term 'therapeutic' in the title, and advised to replace the word 'efficacy' with 'effectiveness' as this is the appropriate terminology associated with the use of antimicrobials in animals. The Subgroup recommended that this change should be applied throughout the Chapter where applicable.

When considering a comment, the Subgroup advised against the deletion of the second indent in point a) i), as its content is not covered elsewhere. The Subgroup noted that the third indent is not suitable to replace the second indent, as it refers to the capacity for an antimicrobial agent of selecting for AMR and does not cover the spectrum of activity of antimicrobials.

When considering a comment regarding point a) ii), second indent, the Subgroup recommended the addition of the words 'concentration (MIC)', 'minimum' and '(MBC)' for clarity and to be consistent with accepted terminology.

When considering a comment the Subgroup advised against to the deletion 'time or' In point a) ii), fourth indent, as it would change the meaning of the sentence; instead the Subgroup proposed the addition of the word 'time-' by 'time-dependent' to improve clarity and to align text with current terminology.

When considering a comment regarding point a) ii), fifth indent, the Subgroup advised against the deletion of the entire indent as it was not deemed to be a duplication of third indent of a) iii); instead, the Subgroup proposed the addition of the words 'and concentration' as this is an important parameter that veterinarians should consider when selecting antimicrobial agents for animal therapy.

When considering a comment regarding point a) iii), the Subgroup recommended replacing 'established' with 'informed' as pharmacokinetic investigation should not be the only parameter considered for dosage regimen estimation. The Subgroup furthermore proposed adding the words 'and pharmacodynamic' for completeness and clarity.

When considering a comment regarding point a) iii), first indent, the Subgroup advised that the sentence should be reorganised by moving the text 'metabolism and elimination and' to the first half of the sentence to improve readability.

When considering a comment regarding point a) iii), the Subgroup recommended that a new paragraph should be added to highlight the fact to Competent Authorities that types of studies other than pharmacokinetic and pharmacodynamics studies may be used for dose determination.

5) Assessment of the potential of antimicrobial agents to select for resistance

When concerning a comment regarding point b), the Subgroup advised against the deletion of the whole text in this point to avoid a possible duplication with point a). The Subgroup noted that points a) and b) refer to different criteria that are relevant for the assessment of the potential of antimicrobial agents to select for AMR; whilst a) refers to the concentration of active metabolites in the gut of the animal, b) refers to the actual (spectrum) of activity of the antimicrobial agent in the intestinal environment.

When considering a comment regarding point c), the Subgroup advised adding 'relevant' in front of 'animal environment' for consistency. The Subgroup advised adding ', antimicrobial resistance determinants' for completeness as genetic resistance traits, such as genes and plasmids are important in the epidemiology of AMR and should not be overlooked.

When considering a comment, regarding point d), the Subgroup recommended adding 'co-selection' to improve technical accuracy as it is a relevant mechanism through which AMR can be transmitted.

When considering a comment regarding point e), the Subgroup proposed replacing 'pre-existing' with 'acquired' and editing the sentence so that it would be better aligned with current terminology. The sentence's meaning would change to the need to assess risk of selection for resistance from a particular antimicrobial agent taking into consideration the baseline levels of both intrinsic and acquired resistance.

6) Establishment of clinical breakpoints

The Subgroup proposed moving point 6 'Establishment of clinical breakpoints' to point 12.

When considering a comment regarding the first sentence, the Subgroup recommended replacing 'there is a need for' with 'the Competent Authority should support the development of' to provide clarity on the role of the Competent Authority.

When considering a comment regarding the second sentence, the Subgroup advised adding 'and, whenever possible, accepted by internationally-recognised antimicrobial susceptibility testing committee(s) in accordance with the *Terrestrial Manual*.' to reinforce what is already stated in WOAH's Terrestrial Manual Chapter 2.1.1.

7) Establishment of acceptable daily intake (ADI), maximum residue limit (MRL) and withdrawal periods in food-producing animals

When considering a comment regarding point a), the Subgroup recommended replacing the word 'microbiome' with 'microbiota' as more accurate and in accordance with current terminology.

8) Assessment of the impact on the relevant animal environment

When regarding a comment, the Subgroup advised to Point 8 "Assessment of the impact on the relevant animal environment" to after current point 5 to improve the flow of the text.

When regarding a comment, the Subgroup advised that risk assessment requirements by applicants should be kept in the text as Competent Authorities may consider asking applicants submitting veterinary medicinal products containing antimicrobial agents for regulatory approval to include the environmental dimensions of AMR into their risk assessment. It is up to the Competent Authority to decide on the type of risk assessment (i.e., qualitative, semi-quantitative or quantitative) that should be conducted.

When considering a comment regarding the second paragraph, the Subgroup proposed adding a new sentence 'Consideration should be given to performing a qualitative risk assessment instead of a quantitative risk assessment when quantitative data are sparse in accordance with risk analysis principles.' to allow Competent Authorities some flexibility on the types of risk assessment that can be conducted considering the variability across countries on access to and quality of data concerning AMR in relevant animal environments.

When considering a comment, the Subgroup advised against the addition a sentence at the end of the second paragraph regarding the need to establish an action plan to address the issue as it did not add value to the text.9) Establishment of a summary of product characteristics or equivalent for each VMP veterinary medicinal product containing antimicrobial agents

When considering a comment regarding point s), the Subgroup recommended adding the concept of responsible use of antimicrobials and editing the sentence to include 'responsible and prudent use of antimicrobials and minimising the development…' as deemed more relevant to the context of the information that may be included in the Summary of Product Characteristics (SPC) or equivalent by the applicant.

When considering a comment, the Subgroup recommended adding a new point u) 'known signs of overdosage and particulars of its treatment' as this may be relevant information for Competent Authorities to consider whether to include in the SPC or equivalent.

9) Post-marketing antimicrobial resistance surveillance

When considering a comment regarding point b), the Subgroup recommended modifying the text of this point to improve readability and clarify recommendations for specific surveillance, which may be required as part of post-marketing AMR surveillance if supported by scientific evidence.

10) Distribution and administration of antimicrobial agents or veterinary medicinal products containing antimicrobial agents

When considering a comment regarding point d), the Subgroup advised adding the text 'or by direction' to account that individuals other than veterinarians and other animal health professionals such as animal breeders and keepers may administer antimicrobials to animals under their care following the instructions of their veterinarian or equivalent.

11) Control of advertising

In the first paragraph, the Subgroup recommended replacing 'must' with 'should' for consistency.

Regarding a comment regarding point b), the Subgroup advised against deleting it and replacing it with text 'in accordance with national legislation'. Instead, the Subgroup recommended adding a new point c), 'and their promotion is done in a manner consistent with specific regulatory recommendations for the product' to address any potential issues that could lead to the inappropriate use of antimicrobials in animals in contravention of good antimicrobial stewardship practices.

When considering a comment regarding point b), the Subgroup recommended adding 'or to persons permitted to supply veterinary medicinal products' to include relevant individuals able to properly assess the information related to veterinary medicinal products containing antimicrobial agents based on their knowledge and training in animal health.

12) Training related to the use of antimicrobial agents and antimicrobial resistance

When considering a comment regarding point d), the Subgroup advised against the deletion of the text 'new methodologies for molecular detection of resistance (…)' as it was clearly stated at the beginning of the section that this is only one of several training options that the Competent Authority should consider promoting. The Subgroup proposed adding new text to reinforce the need for training in new and existing methodologies for detection and characterisation of AMR, the interpretation of laboratory tests and their use in risk assessment.

13) Monitoring of antimicrobial use

When considering a comment, the Subgroup recommended adding a new point e) to reiterate the need for monitoring of antimicrobial use in animals to promote antimicrobial stewardship and ensure accessibility of safe and effective antimicrobial agents for humans and animals.

When considering a comment regarding the last paragraph, the Subgroup advised against adding a sentence to clarify that sales and imports of antimicrobial data should be provided, as data collated by the WOAH Animal Antimicrobial Use Global Database (ANIMUSE) are already mainly composed by imports and sales data.

14) Knowledge gaps and research

When considering a comment regarding point b), the Subgroup recommended deleting the first 'transmission' and replacing 'dissemination' with 'transmission' as it is more accurate in the context of the sentence. The Subgroup also advised adding the text 'between animals, humans and the relevant animal environment' and replacing 'and' with 'including' to broaden the scope of the sentence to other relevant animal environments such as those occupied by non-food producing animals (e.g., veterinary practices).

When considering a comment regarding point g), the Subgroup recommended replacing 'resulting from antimicrobial use' with 'in the animal environment' to reiterate the importance of understanding the role of the environment in the epidemiology of AMR and adding 'relevant' for consistency in terminology used throughout the Chapter.

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

When considering a comment regarding point 1c), the Subgroup recommended that the concept of timeliness of reporting pharmacovigilance information should be included and proposed replacing 'regularly' with 'timely'.

When considering a comment regarding point 1d), the Subgroup recommended merging bullet points c) and d), as these are interconnected: point d) refers to isolation and identification of bacteria that is consistent with what would be required for specific surveillance for resistant bacteria noted in point c). This will also provide alignment with the corresponding text on Regulatory Approval under Article 10.6.3..

When considering a comment regarding point 1d), the Subgroup advised against elaborating further on data needed and on how the data should be analysed, as this falls within the scope of the Terrestrial Manual Chapter 2.1.1.

When considering a comment regarding point 2b), the Subgroup recommended replacing 'quality certificate' with 'certificate of quality' for clarity.

In point 2d), the Subgroup recommended adding the text 'pharmaceutical industry should provide the' to the beginning of the sentence to improve flow of text and create an active sentence.

When considering a comment regarding point 3b) the Subgroup advised that the whole sentence should be revised in order to aligned it with point 11 of Article 6.10.3., to 'advertise in accordance with national legislation or policies. Advertising and promotion of antimicrobial agents should be done in a manner consistent with specific regulatory requirements of the product'.

Article 6.10.5. Responsibilities of wholesale and retail distributors

When considering a comment regarding point 2c), the Subgroup advised against providing further clarification on the term 'user' as it is implicit that the user is the individual named in the prescription.

Article 6.10.6. Responsibilities of veterinarians

When considering a comment regarding the first paragraph, first sentence, the Subgroup advised that minor edits should be conducted to improve clarity and flow.

When considering a comment regarding the second paragraph, second sentence, the Subgroup advised against expanding the text to include a description of the differences between non antimicrobial options and alternatives to antimicrobials. Instead, the Subgroup proposed replacing 'non-antimicrobial options or' with 'safe and effective'. This was to avoid confusion and to emphasize to veterinarians and other animal health professionals that only alternatives to

antimicrobials for which there is evidence of their safety and effectiveness should be considered when selecting these for use in animals for disease prevention and control.

When considering a comment regarding point 2b), the Subgroup recommended adding a sentence 'Veterinarians should maintain where possible laboratory records of bacterial isolation, identification and susceptibility testing obtained from isolates of the animals under their care.'. This sentence was to align the text with a the new edit proposed by the Subgroup when considering a comment to align the text with the Codex CoP under article 6.10.8. Responsibilities of food animal breeders, owners and keepers, point 2j) 'maintain, or have their veterinarian maintain, all the laboratory records…'.

When considering a comment regarding point 3., second paragraph, the Subgroup proposed replacing 'Critically' with 'Medically' per the current terminology adopted by the World Health Organisation (WHO) and adding 'or relevant national lists, where available' at the end of the first sentence to account for countries that have already established lists based on scientific evidence to promote responsible and prudent use of antimicrobials in animals.

When considering a comment regarding point 3., fifth paragraph, the Subgroup recommended adding the text 'and of a compounded product' as these products are, by definition, always used off- or extra-label in animals.

When considering a comment, the Subgroup advised against adding a new paragraph on 'prudent and responsible use of antimicrobial agents in animals does not include their use for the purposes of growth promotion', and advised instead adding the text 'for treatment, control and prevention of diseases,' in the first sentence of the fourth paragraph as this is the sole purpose for which off-label and extra-label of antimicrobials in animals should be considered.

When considering a comment regarding point 4a), the Subgroup advised adding the word 'commercial' for clarity.

When considering a comment regarding point 4, the Subgroup advised adding a new bullet point b) 'name of the antimicrobial agents in the veterinary medicinal products' to provide further specification on which data to collect.

When considering a comment regarding point 4g) the Subgroup advised adding 'duration of' for completeness.

When considering a comment regarding point 4i) the Subgroup advised adding the text 'the animal or' for accuracy and to include treatment of individual and groups of animals by veterinarians.

When considering a comment regarding point 4j), the Subgroup recommended replacing 'lack of response due to possible antimicrobial resistance' with 'lack of effectiveness' as it is not easy for veterinarians to know whether the lack of response was caused by AMR.

In point 4j), second sentence, the Subgroup recommended adding 'holder of the regulatory approval and/or' and 'according to national legislation' to account for potential variations across countries on the requirements for reporting of adverse reactions for food-producing and non-food producing animals (e.g., companion animals) as per national legislation.

In point 6, in the title, the Subgroup recommended replacing 'continued' with 'continuing' per current terminology.

Article 6.10.7. Responsibilities of animal feed manufacturers

When considering a comment regarding point 1, the Subgroup advised adding 'or equivalent' for broadening the scope to other animal health professionals such as veterinary paraprofessionals and community animal health workers that are important providers of animal health services in some countries.

Article 6.10.8. Responsibilities of food animal producers

In point 2d), the Subgroup recommended replacing 'relevant' with 'Competent' for consistency and according to WOAH terminology.

When considering a comment regarding point 2f), the Subgroup recommended adding 'extra-label/off-label use of veterinary medicinal products containing antimicrobial agents should be in line with the relevant national legislation and the instructions of the prescribing veterinarian' to broaden antimicrobial use to include extra- or off-label use of veterinary medicine products containing antimicrobial agents considering that they are allowed in some countries under national legislation and it should follow responsible and prudent use principles.

When considering a comment regarding point 2i), the Subgroup advised against deleting the whole text as the WOAH Glossary clearly includes medicated premixes as 'veterinary medicinal products' and reiterated that medicated premixes can be used in groups of animals for veterinary medical purposes.

When considering a comment regarding point 2j), the Subgroup advised adding the text ‘or have their veterinarian maintain’ to account that in some countries, veterinarians may keep the laboratory test results of animals under their care for follow up and to inform animal health management. This is aligned with point 2b) in Article 6.10.6.

When considering a comment regarding point 2k) i), the Subgroup proposed adding ‘and’ and deleting ‘and expiry date’ to improve flow of text.

When considering a comment regarding point 2k) ii), the Subgroup proposed adding ‘and contact details’ as this may be relevant for traceability and accountability.

When considering a comment regarding point 2k) v), the Subgroup advised replacing ‘clinical conditions’ with ‘disease’ as deemed more accurate.

When considering a comment regarding point 2k) vi), the Subgroup proposed adding ‘(including dose, dosing interval and duration of treatment)’ to clarify the meaning of the term ‘dose regimen’.

When considering a comment regarding points 2k) viii), 2k) ix) and 2k) x) the Subgroup advised to remove them as these points are not an essential part of records that should be maintained by breeders, owners and keepers of food-producing animals and to align the text in terms of requirements of record keeping with the Codex CoP.

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

When considering a comment regarding point 3), the Subgroup advised that this point should be divided into two points. The Subgroup also proposed the deletion of the text ‘leftover and expired’, replacing ‘animal’ with ‘veterinary’ from point 3 and creating a new point 4 ‘not administer unused and expired human and veterinary antimicrobials agents to their animals’ as using stronger wording is more likely to discourage the use of unused and expired antimicrobial agents.

5. Next steps

The Secretariat informed the Subgroup that the revised draft Chapter and the Subgroup report will be submitted to the AMRWG for its consideration at its next extraordinary meeting on 28 July 2023. Any changes proposed by the AMRWG will be included in the revised draft Chapter and the rationale for their proposed changes will be included in the AMRWG meeting report. The revised draft Chapter will be submitted to the Code Commission for its consideration at its September 2023 meeting.

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…/Annexes

Annex 1. Adopted Agenda

MEETING OF WOAH SUBGROUP ON THE REVISION OF CHAPTER 6.10. 'RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE'

Paris, 29 March 2023, Virtual April-June 2023

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1. Introduction
2. Terms of Reference and appointment of Chair
3. Update on the February 2023 Code Commission meeting
4. Review of comments on draft Chapter 6.10 'Responsible and prudent use of antimicrobial agents in veterinary medicine'
5. Next steps

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Annex 2. List of Participants

MEETING OF WOAH SUBGROUP ON THE REVISION OF CHAPTER 6.10. 'RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE'

Paris, 29 March 2023, Virtual April-June 2023

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