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Ad Hoc Codex Intergovernmental Task Force on Antimicrobial resistance (7th Session)

Pyeongchang, Republic of Korea, 9-13 December 2019

European Union comments on

Agenda Item 5:

Proposed draft revised Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005)

(CX/AMR 119/7/5)

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) would like to thank the United States, Chile, China, Kenya and the United Kingdom for leading the work on the revision of CXC 61-2005. The EUMS would like make the following comments on the draft text.

General comment

The scope of a number of provisions in the draft document is limited to medically important antimicrobial agents. The EUMS note that the new text in paragraph 11 clarifies that the CoP covers antimicrobials other than antibacterials where scientific evidence supports foodborne AMR risk to human health. The EUMS are of the view that this clarification allows the extension of prudent use recommendations to cover all antimicrobial agents within the scope of the CoP.

Specific comments

Paragraph 1

The EUMS support using the term “plant/crop production”. This is because the definition of the term “plants/crops” reads “a plant or crop that is cultivated or harvested as food or feed” which makes it clear that only plants/crops grown for food are covered by the CoP.

Paragraph 6

The EUMS support the 2nd bullet of paragraph 6 as currently drafted. It is important to refer to the entire WHO document although the emphasis in on the Annex.

Paragraph 11

The EUMS support the introduction of the new phrase "where scientific evidence supports foodborne AMR risk to human health" as it usefully clarifies the scope of the CoP as regards antiviral, antiparasitic, antiprotozoal and antifungal agents.

Definitions

Adverse health effects

The EUMS would prefer retaining the terms “of animal/crop origin” in the definition as the suggested definition is copied from the Guidelines for Risk Analysis of Foodborne AMR (CAC/GL 77-2011).

Competent authority(ies)

The EUMS are not in favour of having a definition for competent authorities. The term is self-explanatory while developing an all-encompassing definition for it would be very difficult. CCGP tried to develop such definition in the past but failed.

Food chain

The EUMS support adding “feed” in the definition of the food chain.

Food production environment

The term “immediate” is not clear and would need a definition of its own. Therefore, the EUMS support the definition for food production environment as currently written in the proposed draft guidelines for AMR monitoring and surveillance, i.e. “The vicinity of food, feed, plants/crops, animals to be harvested or processed that could contribute to foodborne AMR”.

Food of plant origin

The EUMS reiterate their comment that there is no need for a definition for “food of plant origin” as it not used in the document. Moreover, the CoP does not make any difference on risk management measures applied to edible and non-edible parts of plants/crops.

Therapeutic use

There is no need for a definition for “therapeutic use”. It is only used in principle 6 but that principle can be deleted. The term “therapeutic” has been added to paragraphs 33 and 54 but there it can be replaced with the original wording.

Principle 1

The EUMS suggest rewording the principle as follows:

“A one health approach should be ~~considered~~ **applied** wherever possible and relevant, for identifying, evaluating, selecting and implementing foodborne AMR risk management options.”

Rationale: The present text of this principle suggests that the one health approach can be ruled out beforehand. The One health approach, however, is a universal principle that should always be considered. What should be expressed is that in identifying, evaluating, selecting and implementing foodborne AMR risk management options, the one health principle should be applied wherever relevant.

Principle 5

This principle should read as follows:
Antimicrobial agents should not be granted regulatory approval for growth promotion and their use for growth promotion should be phased out.

Rationale: There is a growing international consensus that the use of antimicrobials for growth promotion should be phased out. This was recently confirmed by the Interagency Coordination Group on Antimicrobial Resistance (IACG) which in its report of April 2019 calls UN Member States to phase out the use of antimicrobials for growth promotion and emphasises that this should be complemented by the adoption of global standards.

Principle 6

This principle could be deleted as it essentially repeats what is already said in principle 5.

Principle 7

Principle 7 should be modified as follows:

When used for prevention/prophylaxis of a specific disease risk, ~~medically important~~ antimicrobials should only be administered in well-defined **and exceptional** circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration. **This use should not be systemic, nor routine, nor applied to compensate for poor hygiene or inadequate animal husbandry practices.**

Rationale: A clear principle is necessary to enshrine the conditions for preventive/prophylactic use of all antimicrobials, not only the medically important ones.

Principle 7bis

Principle 7bis should be modified as follows:

When used for the control of disease/metaphylaxis, ~~medically important~~t antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration.

Rationale:
A clear principle is necessary to enshrine the conditions for control/metaphylactic use of all antimicrobials, not only the medically important ones.

Principle 7ter

Principle 7ter should be modified as follows:

When used ~~for~~ **in** plant/crop ~~protection~~ **production**, ~~medically important~~ antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.

Rationale:
A clear principle is necessary to enshrine the conditions for use of all antimicrobials, not only the medically important ones, when used in plant/crop production. The EUMS further suggest replacing "plant/crop protection" with "plant/crop production" to make it clear that antimicrobials should not be used prophylactically in plant/crop production.

Principle 12

The EUMS support retaining principle 12 and reiterate their comment that principle 12 should be modified as follows:

~~Medically important a~~**A**ntimicrobials should be administered, prescribed, or applied only by, or under the direction of veterinarians, plant/crop health professionals or other suitably trained persons authorized in accordance with national legislation.

Rationale: The Codex guidance should be consistent with the corresponding OIE guidance. According to Article 6.10.3.(9) of the OIE Terrestrial Animal Health Code, all antimicrobial agents should be prescribed by a veterinarian or other suitably trained person in accordance with national legislation.

Paragraph 14

The EUMS support maintaining the reference to the VICH guidelines as this is useful information.

Paragraph 17

In order to promote responsible and prudent use of antimicrobial agents, it is important to encourage the use development, and availability, and use of validated, rapid, reliable diagnostic tools, where available, to support veterinarians and plant/crop health professionals **in diagnosing the disease and** in selecting the most appropriate antimicrobial**, if any,** to be administered/applied.

Rationale: To clarify that there is an alternative not to use antimicrobials. The diagnosis of a disease should also be covered as this is an essential step for prudent use of antimicrobials.

Paragraph 18

Following risk analysis, the competent authorities should determine appropriate labelling, including the conditions that will minimize the development of foodborne AMR while still maintaining efficacy and safety~~, when this information is available~~. Furthermore, the professional judgement of the veterinarian or plant/crop health professional, who holds the responsibility of oversight, should be considered when competent authorities develop guidance for approved product labelling.

Rationale: When product specific information is not available, general information on the need to apply prudent use, and to follow national or regional guidance and guidelines can be given.

Paragraph 20

The EUMS suggest deleting the last sentence of this paragraph as the evaluation of good pharmacovigilance practices is not part of the assessment of efficacy.

Paragraph 22

The EUMS support retaining the former paragraph 18 reading:

"Competent authorities should assess the impact of proposed antimicrobial agent use on the environment in accordance with national guidelines or recognized international guidelines."

Rationale: It is important to assess the impact of antimicrobial agent use on the environment. This also recommended in the Article 6.10.3(6) of the OIE Terrestrial Animal Health Code.

Paragraph 23

The EUMS support extending the scope of this paragraph to plant/crop protection products.

Paragraph 25

The EUMS suggest rewriting the last sentence of this paragraph as follows:

The information collected through the pharmacovigilance program can contribute to a comprehensive strategy to minimize antimicrobial resistance in ~~food~~ **the food chain**.

Rationale: Also AMR occurring not (only) on food as a result of veterinary use can have significant impact on public health like LA-MRSA which is predominantly transferred to humans through contact with animals.

Paragraph 27

The EUMS reiterate their comment that paragraph 27 should be modified as follows:

Competent authorities should make sure approved antimicrobial agents are distributed through **licensed or authorised** ~~appropriate~~ distribution systems **and prescribed** in accordance with national legislation~~, including that medically important antimicrobials are distributed to appropriately~~ **by** credentialed/registered veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.

Rationale: The Codex guidance should be consistent with the corresponding OIE guidance. According to Article 6.10.3.(9) of the OIE Terrestrial Animal Health Code, the relevant authorities should ensure that all antimicrobial agents are supplied only through licensed or authorised distribution systems and all antimicrobial agents should be prescribed by a veterinarian or other suitably trained person in accordance with national legislation.

Paragraph 32

The EUMS support the revised text in paragraph 32. The EUMS also support retaining the list of examples as they provide useful and informative guidance.

Paragraph 33

The last bullet point of paragraph 33 should be modified as follows:

Determine the potential transfer to animals and plants/crops of resistant microorganism and resistance determinants due to agricultural chemical use, **including environmental effects.**

Rationale: To clarify that the use of antimicrobials could have environmental effects (which could lead to secondary effects for the human health such as shortage of food due to destroyed soil).

Paragraph 41

The EUMS reiterate their comment that paragraph 41 should be modified as follows:

It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 30-31 on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not advertise ~~medically important~~ antimicrobials to farmers or producers.

Rationale: The Codex guidance should be consistent with the corresponding OIE guidance. According to Article 6.10.4.(3) of the OIE Terrestrial Animal Health Code, the industry should not advertise any antimicrobial agent directly to the food animal producer.

Paragraph 46

The EUMS reiterate their comment that paragraph 46 should be modified as follows:

Wholesalers and retailers distributing ~~medically important~~ antimicrobial agents should only do so on the prescription of a veterinarian or order from a plant/crop health professional or other suitably trained person authorized in accordance with national legislation. All distributed products should be appropriately labelled.

Rationale: To bring the text in line with section 5 of CAC/RCP 61-2005. There is no justification to limit this provision only to medically important antimicrobial agents. The Codex guidance should also be consistent with the corresponding OIE guidance. According to Article 6.10.5.(1) of the OIE Terrestrial Animal Health Code, distributors of all antimicrobial agents should do so on the prescription of a veterinarian or other suitably trained person authorized in accordance with national legislation.

Paragraph 49

Paragraph 49 should be modified as follows:

Veterinarians and plant/crop health professionals should identify new recurrent disease problems and ~~work toward~~ develop~~ing~~ strategies to prevent, control, or treat infectious disease. These may include, but are not limited to, biosecurity, improved production practices, and safe and effective alternatives to antimicrobial agents, including vaccination or integrated pest management practices where applicable/available.

Rationale: To clarify that veterinarians and plant/crop health professionals should develop strategies.

Paragraph 51

The EUMS reiterate their comments on the bullets of paragraph 51:

The 1st bullet of paragraph 47 should be modified as follows:

"A prescription, order for application, or similar document for ~~medically important~~ antimicrobial agents should indicate the dose…"

The 3rd bullet of paragraph 47 should be modified as follows:

"All ~~medically important~~ antimicrobial agents should be prescribed…"

Rationale: To bring the text in line with section 6 of CAC/RCP 61-2005. There is no justification to limit these provisions only to medically important antimicrobial agents.

Paragraph 52

Paragraph 52 should be modified as follows:

For food-producing animals, the appropriate use of antimicrobial agents in practice is a clinical decision that should be based on the experience of the prescribing veterinarian and epidemiological and clinical knowledge **and, if available, based on adequate diagnostic procedures.** When a group of food-producing animals ~~may~~ have been exposed to pathogens, they may need to be treated without recourse to a laboratory confirmed diagnosis based on antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.

Rationale: To include a sentence on adequate diagnostic procedures which has been deleted. This is relevant as there are cases when diagnostics is part of good veterinary practice. However, it is also clarified that the clinical decision should be based on diagnostic procedures when available. Prevention should not be used if the food producing animals have not been exposed to pathogens.

Paragraph 53

The EUMS suggest modifying the paragraph as follows:

For plant/crop production, the appropriate use of ~~medically important~~ antimicrobial agents to manage disease/pests should be based on the principles of integrated pest management (IPM), consultation with a plant/crop health professional, historical and epidemiological knowledge of the disease/pest situation, and monitoring of the current disease/pest status. Only authorized products should be used following label directions. Alternatives to ~~medically important~~ antimicrobials should be considered when available and their safety and effectiveness has been determined. ~~Medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.~~

Rationale: It is unclear why the provisions of this paragraph should be limited only to medically important antimicrobial agents. The last sentence repeats principle 7ter.

Paragraph 54

The last sentence of the 3rd sub bullet of the 1st bullet should be modified as follows:
Should a first antimicrobial administration fail, or should the disease recur, the use of a second antimicrobial agent should ~~ideally~~ be based on the results of microbiological susceptibility tests derived from relevant samples.

The last bullet of paragraph 54 should be modified as follows:

If the label conditions allow for flexibility, the veterinarian or plant/crop health professional should consider a **dosage** ~~therapeutic~~ regimen that is long enough to allow an effective treatment, ~~but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms.~~ **and no longer than necessary so that selection of resistance is minimised.**

Rationale: The selection for AMR occurs even if the dosage regimen is very short.

Paragraph 59bis

A new paragraph 59bis should be introduced:

Veterinarians and plant health professionals should assist the relevant authorities in surveillance programs related to antimicrobial use and antimicrobial resistance, as appropriate.

Rationale: This is an important duty/task of veterinarians and plant health professionals.

Paragraph 62

The 6th bullet point in paragraph 62 should be reintroduced with the following text:

to address farm biosecurity measures and take basic hygiene precautions as appropriate

Rationale: The argument to delete this bullet point is due to an overlap with OIE guidance. However, biosecurity is important to address and there are other parts as well in this document that overlap with OIE. The bullet point could be amended to be more in line with the OIE guidance in order to be more readable:

The 8th sub bullet of the 11th bullet should be reintroduced as follows:

daily dose and number of treatment days in case of food producing animals

Rationale: This should remain in the text to ensure records of dose, quantity and duration. Quantity (sub bullet point below) could be the record of the total quantity for the treatment, and is not the same as the daily dose.