Position paper

31 August 2020

AnimalhealthEurope comments to the EMA advice on the format of the data to be collected on antimicrobial medicinal products used in animals

Implementing Act of Regulation 2019/6 article 57(4)

General Comments

AnimalhealthEurope is grateful for the opportunity to comment on this document. We have 3 major comments that are highlighted in bold below.

The principle that there should be a single input point/source of the information should be respected in order to avoid additional administrative burden and to avoid any possibility of contradictory information. Therefore, if a MS plans to require the pharmaceutical industry to provide the antimicrobial sales volume data then they must be required to source this from the Union Product Database (UPD) and specifically the sales volume data that have to be recorded there. The UPD design should be such that this is possible, for example it might be necessary to add a field for quantitative description of the package size (e.g. "10 (numerical value) Tablets (Unit)") - so this can be used in the calculation of the total amount of API involved.

A unique and stable identification for each package size of each antimicrobial product is needed which should be in the UPD and should be mapped in the ESVAC online data submission.

Product data should be drawn from the UPD based on the unique identifier to avoid inconsistencies. For example, product name, pharmaceutical form, ATCvet, APIs, strength, package sizes, marketing authorisation holder should all be drawn from the UPD.

Specific Comments

Page/Line Number	Comment
Page 4, point 9	**Comment:** Point 9 specifies: "For horses, cats, dogs, minks and foxes, which are kept or bred, Member States should be able to submit data on animal population". "Kept" is understood to be in the commercial sense rather than pet ownership. This means the data on animal population for cats and dogs should not be the total population but the subset which are kept or bred.
Page 9, point 3 & page 14, point 4)	**Comment:** "Marketing authorisation identification" this includes "or name of the marketing authorisation holder" -this raises the question of how the change of MAH during the calendar year is managed (but this is already a challenge today) if not drawn from the UPD. Given the stated purpose is to help with unique identification of the medicine and link to other databases a free text field is not appropriate, and it is important to consider that it is necessary to have a unique identifier for each package size of each antimicrobial veterinary product which won't change (see general comments).

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