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Submission: Draft Guidance Document: Labelling Veterinary Medicines
Date: 16 August 2022
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DRAFT GUIDANCE DOCUMENT: LABELLING VETERINARY MEDICINES: APHANZ SUBMISSION

Introduction

Animal and Plant Health NZ (APHANZ) welcomes the opportunity to provide feedback on the Draft Guidance Document: Labelling Veterinary Medicines. This submission represents the views of the animal health industry members of APHANZ which encompasses the majority of animal health products registered in NZ.

Overall, APHANZ is generally supportive of the Guidance Document: Labelling Veterinary Medicines, noting that there are a number of areas where we consider clarifications or amendments are needed, along with some suggestions on areas for further discussion.

Key recommendations

APHANZ recommends:

a. Inclusion of vials and ampules in section 5 (7)
b. Clarification of the requirements for including potency on labels in Section 5.4
c. Amendments to the proposed labels statements for parasiticides in relation to resistance to provide greater clarity
d. Wider discussion on how QR codes and similar technologies could potentially facilitate better labelling of veterinary medicines.

Section 5 Mandatory label information

We understand some of our member companies have provided comments on primary packaging labels of restricted size. In support of these comments, under Section 5 (7) we request that vials and ampoules be added to the products for which ACVM will consider reduced information requirements on a case-by-case basis. We note that vials have special storage requirements i.e., store frozen, which mean they cannot be re-labelled for the New Zealand market. Similarly,

ampoules are very small (smaller than vials) and are often stored in liquid nitrogen. It is not possible to add custom text for the New Zealand market, or over-label in these circumstances.

Section 5.4 Active ingredient(s) and quantities

The draft guidelines state:

"(5) For biological products, potency should be stated unless justified otherwise."

While we understand that potency on vaccine labels is required in a number of other countries it's unclear what benefits this will provide. This statement is also somewhat vague and open for interpretation by ACVM assessors and registrants and there is concern that adding this information may cause confusion. We suggest that:

- more guidance be provided on the reasons for requiring potency on a vaccine label and on the criteria that might be accepted for not putting this on vaccine labels.
- consideration be given to using "dose per vial/bottle" rather than PFUs, CFUs and ID50 (as outlined in more detail in member submissions).
- listing the antigens and potency should be optional on primary packs due to space constraints.

Section 5.7 Registration statement, registration number and MPI website address

We note there is now the requirement to have the full registration statement on one component of labelling, versus currently not requiring "Registered pursuant to the ACVM Act (1997)…". We question whether this statement means much to users, compared with just having the ACVM registration number. However, as the full statement is only required on one labelling component, we have no major issues with this proposed change.

Section 5.9 Registrant/NZ Agent contact information

We are pleased to see that the registrant contact information can now be "physical, postal, email or website". The current guide says, "name address, phone number". We understand this means registrants will no longer have to include the registrant postal address, which has been a bit cumbersome and of little practical use.

Section 5.8 Withhold period statements

We understand that the changes to the milk WHP statement are simply an illustration of how withholding statements should be worded, rather than a requirement to have three different milk WHPs for every product. i.e., for once-a-day milking, twice-a-day milking and three-times-a-day milking. We suggest the wording of this section be reviewed to make this clearer.

If it is intended to make the three different milking frequency WHPs mandatory this would be of concern, noting that the data required to support additional WHPs is not required for product registration, and generating this data would require new residue studies to be done at considerable cost.

We also note that while milk WHPs may vary based on milking frequency for some products (e.g., intramammary), it would be more common for milk residues (and, therefore, milk WHPs) to have been generated based on time from treatment. For these products, adding milking frequency WHPs would not be relevant.

Section 6 Mandatory label information for specific product classes

Section 6.1 Resistance

We agree that there should be labels statements for parasiticides in relation to resistance. However, the layout proposed seems inefficient and this statement would be more effective and user-friendly if it was simplified and shortened. Long statements on the label can lead to smaller text making it harder to read and/or longer explanatory leaflets, which are unlikely to be effective in managing risk.

For a ruminant anthelmintic, the label would have to contain the statement in 6.1(8), plus then all the statements shown under 6.1.1(5), which are overly wordy. Too many words will have a negative impact on user compliance. We would suggest that the resistance statement be closest to 6.1.1(5)(a) and (b), plus the recommendation to contact your veterinarian or animal health advisor – delete (c) and (d), and don't require 6.1(8) where these other statements are included. The recommendation in (c) about refugia picks out one good strategic recommendation but ignores others. That level of detail should be conveyed by other means, such as the vet, education programs, product detailers, etc. It runs the risk of cluttering the label and distracting from more important product information. The warning in (d) about single/dual/triple resistance ignores the problem that impartial data on this issue is not frequently updated, and even then labels may remain unchanged in the marketplace for several years, giving poor information.

Sections 6.1.3 and 6.1.4 relate to "External Parasiticides" – is this referring to ectoparasiticides, or to externally-applied parasiticides? It would be good to make sure this is clear.

Section 6.1.11 proposes new mandatory label statements for abamectin products. We suggest that these statements be given more flexibility to fit with trial work noting that the details of trial data may sometimes vary from the prescriptive statements proposed. In the past, ACVM has been flexible on most label statements, but we consider the labelling guide should reflect that. We suggest adding the wording "Mandatory label statements may be varied where supported by data".

Section 6.9 In-water and in-feed medications

In Section 6.9 the changes proposed are:

Addition of (1)(c) requirement for maximum period between preparation and consumption of prepared feed and water

We note the comments that have been expressed directly by one of our members regarding an exemption for in-water vaccines.

Section 8 APVMA harmonised labels

Section 8(3): This suggests that the WHPs need to be listed in bold. Is this correct, or can the WHPs themselves be in regular (non-bold) text? We suggest that while the headings should certainly be in bold, we don't think that this is necessary for the species/commodity and time.

Sections 8(4) and 8(5): Since the statement "RESTRICTED VETERINARY MEDICINE" and "RVM" are expected to be printed in bold, it would be better for these to be in bold when mentioned in the guidelines also.

Section 8(6), harmonized label with Australia: the guide now states that the NZ WHP "should" be in line with the AU WHP – is there still scope for differing WHPs, given each country does its own assessment?

Section 9.1 Implementation

This section needs more clarity on what stage of production "implementation" refers to – is it manufacturing, or supply from our warehouse? ACVM generally considers this to refer to supply from warehouse. If so, then 12 months is too short. There will be product in warehouses for more than 12 months. And it can take 3 months to go from ACVM approval to having a label printed and ready to use. If the implementation period refers to supply from warehouse, it should be 2 years. If it refers to manufacture of new batches, then 12 months is OK.

Section 9.5 References to Websites or Social Media, including QR codes

We note the proposed addition of this section and in particular section (2) (c) on QR Codes and similar technologies which states that:

"Information which is required to be on the label (as per this labelling guidance) cannot be replaced by use of a QR code or similar type technologies"

While we understand the intent of the proposed change we think it would be timely to have a more in-depth discussion of how QR codes and similar technologies could potentially facilitate better labelling of veterinary medicines.

We note that Japan has recently instituted a system where all prescription animal health products must have an electronic (not paper) leaflet by end of July 2023. We understand this is the first market where this is happening with veterinary medicines but several markets have this system for human medicines.

The new labels only say:

- Species
- Ingredient
- Storage conditions
- Manufacturer information
- Bottle size/ dose (e.g., 100mL/50 doses)
- Expiry and batch #

All other information is supplied via a QR code which links to the regulator's website. This applies to prescription animal health products only. OTC products are still required to have the full label information provided as per usual.

Our concern is product labels are getting longer, with more and more text being added, and with the text becoming smaller. We need a better way of ensuring that the key messages are getting across to end users. Adding more and more label information to small containers, fold outs or leaflets causes issues with readability for the user and increases the cost of packaging, noting that packaging size is to some extent determined by the requirement to include label information in full or the addition of inserts. This results in costs both for businesses and the environment. Greater use of QR codes could allow more flexibility thereby supporting efforts towards more sustainable packaging, in keeping with government priorities for veterinary medicine product stewardship. It could also offer the means to provide rich content such as videos, which may be of benefit to users.

Further discussion on the use of QR codes would also enable consultation with veterinarians as to what a minimum label information is needed and whether there is sufficient connectivity to support greater use of QR codes in the field.