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VMDA COMMENTS ON AGVET CHEMICAL REGULATIONS AMENDMENTS 2018

PROPOSED CHANGES TO TIMESHIFT APPLICATIONS AND OTHER MEASURES, AND TO SUPPORT OPERATIONAL EFFICIENCY.

The VMDA supports Proposals 1 thru 7, 9, 10, 11 and 14 as presented.

Note that we accept Proposal 7 on the basis that the practical outcome is that any further 'protected information' or 'restricted information' will apply only to any 'new or extended use' and that all other information that is not protected or restricted, including any for which the protection or restriction period has expired, may be used by the APVMA to assess and register the product.

The VMDA comments on the other proposals as follows:

Proposal 8:

The concurrent assessment of active constituents with product registration applications for Item 7 and 8 Applications should be included along with the other application Item numbers proposed.

Since the products are required to be closely similar, and therefore the actives must be the same as in the reference products, the applicant must demonstrate 'close similarity' between the proposed active and the active in the reference product.

This is usually achieved by way of specifications and certificates of analysis, which do not require significant resources to evaluate and are assessed in any case as part of the 'closely similar' test.

The VMDA asserts that this process is sufficient to approve those active constituents.

Proposal 12:

We do not accept the APVMA preference for 'information requiring technical assessment to not be prescribed through this mechanism'.

In particular, the VMDA suggests that using this mechanism to accept and assess additional stability data is entirely practical. Since any initial stability data submitted with the application will have been assessed and the evaluator therefore familiar with the data, the task of assessing further data on the same product and presumably therefore simply an extension of the earlier data in both format and content, should not be overly burdensome.

Proposal 13:

Improving application quality is a laudable aim, and the VMDA in general supports this proposal. We do however have concerns as to the definition of 'poor quality applications' and also the mechanism that may be used to make such a determination.

While this would be a 'reviewable decision', as we are all aware, the process of review is lengthy and complex, especially once it reaches the level of the AAT (if necessary). We do not believe that this proposal offers sufficient clarity as to the decision-making process.

February 15, 2019.