[redacted]

Response to the TGA Consultation:

Discontinuing pre-market evaluation of Herbal Component Names (HCNs)

November 2017

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Overview

[redacted] welcomes the opportunity to provide feedback on the Department of Health's Therapeutic Goods Administration (TGA) consultation on the Discontinuing pre-market evaluation of Herbal Component Names (HCNs), dated November 2017.

[redacted] believes the evaluation of HCN's by the TGA is required to maintain a consistent and controlled system of naming of herbal ingredients and components. This is to ensure consistency of presentation to consumers for these products and prevent misleading consumers with respect to the herbal components contained within the products.

Feedback sought

1. **Do you support Regulatory Option 1 or 2 as outlined in this paper or would you like to propose an additional option for consideration?**
2. **Do you have any specific concerns regarding discontinuation of the HCN evaluation process?**

[redacted] prefers Regulatory Option 1 over the alternative Option 2 proposed by the TGA in the consultation document, as we believe the naming of HCNs and subsequent use in labelling and advertising needs to remain under the control of the regulator. However, a cost recovery process for evaluation of new HCNs needs to be consulted with industry stakeholders and implemented as per the new ingredient evaluation with clear guidance documents for applicants and agreed timeframes and fees.

Consultation Considerations

1. **Past industry concerns**

The past industry concerns from 1999 are well out of date and not supported by [redacted].

2. **Risk**

The concerns raised under risk regarding the other applications using an available HCN without TGA assessment of their method of analysis are valid however this risk should be controlled via the requirements of GMP manufacturer requiring ingredients to be tested by a validated method. Oversight by TGA via post-market compliance review and by GMP auditors of laboratories should be included for applicants using a HCN and standardisation claim on labelled products. This

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requirement is no different to that for any low-risk listable ingredient used in listed medicines where the TGA does not individually verify each product prior to market supply.

3. Cost recovery

As with any new ingredient, a fee for application of a new HCN could be implemented to ensure cost recovery of TGA resources. This would need to be aligned with the process for new ingredients evaluation.

4. Applications for new HCNs

Removal of non-mandatory HCNs for new listed medicine applications will create a disparity between new applications and existing medicine entries still displaying the non-mandatory HCN. [redacted] believes creating a system with different requirements for new applications is not acceptable and can lead to existing medicine entries having an appearance of higher value with the inclusion of the HCN on the ARTG entry. The ARTG entry of medicines is used for support of registration for exporting products and all listed applications need to be controlled by the same regulatory requirements.

Additional concerns are held if the naming of non-mandatory HCNs is not controlled by the regulator, this could lead to the proliferation of a variety of names for the same herbal component dependent on the sponsor evaluation, causing confusion to consumers.