[redacted]

[redacted]

TGA Consultation

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

8 January 2018

Dear Complementary and OTC Medicines Branch

Thank you for providing industry with the opportunity to offer feedback on proposed changes to the HCN evaluation process. In response to the two questions posed, we offer the following.

Question 1

We support regulatory option 2 and the discontinuation of the HCN pre-approval process. The pre-market evaluation of HCNs is inconsistent with the broader regulatory framework for listed medicines in which evidence for claims made by the product is reviewed in a post-market setting. Further, HCN evaluations often delay product release as the process requires input from several lines areas of the TGA who, depending on the component, have varying requirements and interest in the process.

We would expect sponsors to be able to continue to make claims relating to these standardised components as it allows for product differentiation. Our clients are currently collating evidence relating to specific standardised components of approved ingredients in order to sell unique ingredients and products to their consumers. Our clients feel that the use of HCNs is one of the key tools used by sponsors to gain market edge.

Question 2

Guidelines and responsibility

The current evaluation process for HCNs can involve a significant amount of internal consultation by different areas of the TGA. Our clients feel that the process can vary significantly from component to component based on the interest of different line areas. We are concerned that the removal of the pre-market evaluation process and reliance on post-market compliance may create further confusion about the expected evidence requirements to support HCN claims. We request that the TGA provide comprehensive guidelines about the evidence required to support a HCN claim or indication.

We also suggest that these evaluations be undertaken by COMB to ensure consistency in the interpretation of requirements and the decisions.

Existing HCNs

We would like clarity about the status of existing HCNs; that is, will they be subjected to post-market review despite already being approved by the TGA? We suggest that this would be a waste of TGA's limited resources as many existing HCNs have already been evaluated and approved for use by TGA.

We recognise that it may be necessary to review all HCN claims to ensure that any new uses of the components, particularly by other sponsors, are supported by evidence. Thus; if existing HCNs are subjected to the same level of post-market review, we suggest that evidence already evaluated by the TGA as part of the original approval process should be considered sufficient by the TGA.

Compliance

Finally, we would like to highlight that clients are concerned that a small number of sponsors may take advantage of the removal of the pre-market evaluation process and make claims about components that are not present in an ingredient, exaggerate the truth, or make HCN claims without holding evidence. This can negatively impact the industry by allowing products to compete on false pretences, and by reducing consumer confidence in the industry. We suggest that the listed medicines post-market review process should include an assessment of any claims made about HCNs. Such a regime would not increase the regulatory burden on sponsors who already hold evidence for the claims that are made.

We thank the TGA, and particularly the Complementary Medicines Evaluation Section, for their work on this proposal as it provides a helpful business process improvement. We look forward to working the TGA to finalise the details for this proposal.

Yours sincerely

[redacted]