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ASMI Submission

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

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About ASMI

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. More information about ASMI and our membership is available on our website.

Principles

ASMI notes that the objective of the consultation is to support the discontinuation of the receipt and pre-market evaluation of herbal component names (HCNs) by the TGA. The purpose of this proposal is to reduce the regulatory burden to reflect the low risk category of listed medicines, to improve business predictability, to remove regulatory processes that are not legally underpinned, and to better allocate resources within the cost-recovery framework. ASMI is supportive of the principles underpinning this proposal and acknowledges that the proposed mechanism is consistent with these objectives.

ASMI Position

ASMI is supportive of the proposal to remove herbal components names (for non-mandatory components) from the listing system and for the TGA to cease pre-market evaluation of herbal component names. In order to ensure the removal of this mechanism as a reduction in regulatory burden commensurate with low risk medicines, the ASMI support is conditional on three main criteria:

- The ability of sponsors to use of herbal components on their labels is retained (as per the current proposal), and that this mechanism is safeguarded in the future to ensure that consumers continue to have access to this valuable product information.
- Clear guidance documents are produced to enable sponsors to accurately identify, label and communicate meaningful herbal components, and understand how the content of these should be verified. Clear communication and dissemination of these changes will be needed to ascertain how the responsibilities of manufacturers and sponsors will intersect without these components being underpinned in the market authorisation.
- Consistent principles and processes are implemented within the TGA to ensure predictability between pre and post-market functions, along with inspection by the manufacturing quality branch.

ASMI is therefore supportive of these changes, however further consultation and development of the surrounding regulatory and technical guidance is necessary to ensure that expectations and responsibilities are clearly articulated. This will help minimise any resultant non-compliance that could undermine the credibility of the industry and compromise the quality of products available to consumers.

In addition to the three conditional criteria, consideration needs to be given to the following functional aspects of this proposal:

- Greater clarity is required regarding the proposed transition arrangements for existing products.
- Greater clarity is required regarding the expression of herbal extracts, and whether these would continue to be defined as 'herbal extract' and 'standardised extract' within the ARTG in the absence of a listed standardised marker.
- Consideration of the appropriate expression of mandatory components on the ARTG, particularly when the component may also have a therapeutic function. The purpose of the herbal component, whether for safety or efficacy, influences the appropriate expression i.e. whether an upper limit or target input is more meaningful. In the context of a marker with dual functions, such as caffeine or kavalactones (active components with upper safety limits), the practical implications of the impact of expression on manufacturing controls, marketing materials and consumer understanding needs to be taken into account.
- Clarity will also need to be provided regarding whether GMP licence and clearance requirements for testing laboratories will be retained in the context of a 'marketing claim' that is not represented or certified in the market authorisation. For instance, removal of herbal components from the market authorisation may alter how these are underpinned in the PIC/S Guide to Good Manufacturing Practice for Medicinal Products.

Savings associated with the removal of the herbal component name from the ARTG include time cost and regulatory burden in pursuing an HCN approval. Flow-on cost savings could also result from reducing the number of variation/grouping applications, and removing one of the criteria that would result in a separate and distinct good. This is advantageous for industry, as it allows a greater degree of flexibility and reduces the associated costs with changes to listings, however this flexibility needs to be balanced with the need for transparency for the consumer. Systems and guidance need to be in place to ensure the consumer is purchasing consistent product that meets all regulatory requirements. Considering the cost recovery framework and the availability for HCNs to be used in alternative herbal extracts, and therefore not tied back to the applicant, ASMI is particularly supportive of discontinuing the current HCN application system if a fee is to be attached.

There are many advantages to the acceptance of this proposal, however the details of how this will be implemented and underpinned in the regulations need to be clearly expressed to ensure consistency and predictability for industry, as well as maintain the rigorous quality standards that Australian consumers expect. Ongoing consultation with industry will be vital to ensure guidance and processes are developed that enable these outcomes while reducing regulatory burden.

Conclusion

In light of these considerations, ASMI is supportive of option 2 and the proposal for industry and the TGA to collaboratively develop a workable mechanism that enables the discontinuation of pre-market evaluation of HCN applications. As highlighted in this response, there are several areas of the regulatory system and the guidance that will need to be worked through in detail to ensure that the outcome is viable for industry, sustainable, and able to support transparency and ongoing consumer confidence in complementary medicines.