



**SUBMISSION TGA
CONSULTATION:**

**INCENTIVES FOR
INNOVATION -
PROTECTION
MECHANISMS FOR
EVIDENCE-BASED,
PRE-ASSESSED
COMPLEMENTARY
MEDICINES**

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NICM

The science of integrative medicine



INTRODUCTION

The Expert Committee on Complementary Medicines in the Health System (2003) outlined in section 6.1 of "Complementary Medicines in the Australian Health System (Report to the Parliamentary Secretary to the Minister for Health and Ageing)" that: *"a viable, innovative and responsible complementary medicines industry is dependent on research to support quality, safety, efficacy, and cost-effectiveness, and to develop new products. There is currently little or no incentive to support the development of complementary medicines if there is no possibility of data protection and/or market exclusivity."*

The report further noted: *"there is a need to identify ways to support innovation and complementary medicine research by industry, especially for products which are not patentable or 'off patent' (as is the case for many complementary medicines). Currently, there is little or no financial incentive to support the development of new indications and new complementary medicines if there is little or no possibility of market exclusivity or protection of data."*

Subsequent to this, the Expert Panel in the "Review of Medicines and Medical Devices Regulation Stage 2 Report on the Regulatory Frameworks for Complementary Medicines and Advertising of Therapeutic Goods (2015)" consider the incentives for innovation and reported that the: *"Panel recognises the concerns of stakeholders that the current system does not encourage industry investment in generating greater evidence in relation to complementary medicines ingredients and products. The Panel agrees with the view of stakeholders that encouraging greater development of evidence relating to complementary medicines would have the benefits of greater consumer confidence in the efficacy of complementary medicines, and the improved reputation and competitiveness of the sector domestically and internationally."*

The TGA Consultation Paper on Reforms to the Regulatory Framework for Complementary Medicines - Assessment Pathways (2017) in the section on market protection proposed that a limited period of data protection be provided to

applicants of medicines approved by the new pathway [now identified as AUST L(A)], however, they noted that the Expert Panel in the 2015 report did not make a specific recommendation for any particular mechanism.

Market exclusivity and data protection - key mechanisms to incentivise innovation.

The TGA Consultation Paper noted above provided definitions of 'Data Protection' and 'Market Exclusivity' as mechanisms to incentivise innovation. Data Protection was defined as: *"a form of secrecy that prevents access to and use of data that supported a product approval from being used for a subsequent evaluation of competitor's similar product."*

While Market Exclusivity was defined as: *"a form of protection that concerns a product or an ingredient, and prevents any other person from using the ingredient or obtaining an approval for the product during the exclusivity period."*

Importantly the consultation paper noted that: *"Data protection and exclusivity are not mutually exclusive and could possibly be used in combination to encourage innovation by protecting investment in developing new ingredients; new indications supported by new clinical investigations or new product formulations."*

After consultation with key stakeholders and the community, legislation was passed in 2018 permitting a successful applicant for a new permitted ingredient to have exclusive use of that ingredient (the protected ingredient) for a specified period of time - that is, granting the sponsor 'market exclusivity' (See: Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017). The proposed exclusivity period is two years. NICM supported this important reform in a previous submission to the TGA (2017).

In this submission, NICM outlines a proposal for a limited period of data protection on successful applicants for the AUST L(A) pathway who meet specific criteria and proposes a simple to implement mechanism to achieve this objective.

WHY DATA PROTECTION IS AN IMPERATIVE FOR INNOVATION

Prior to the development of the new pathway and the opportunity for data protection, there has been a disincentive for sponsors of complementary medicines to undertake clinical research in Australia.

Specifically, a sponsor who did undertake research on a product that was not patentable or 'off patent' was unable to recover the expense of the research except through product sales in a competitive market.

A significant risk was a second sponsor could enter the same market with the same product, having no research expenses, and commence profiting immediately; this placed the sponsor who undertook the original research at a competitive disadvantage.

Sponsors realising this financial disincentive made decisions to minimise their engagement in clinical research. In some cases, sponsors, who were unable to see any return for investing in high-quality Australian research, invested instead in low-cost clinical research in developing countries without consideration of the generalisability of the study findings to the Australian population.

The Expert Committee on Complementary Medicines in the Health System (2003) noted that: *"sponsors who undertake R&D on either an AUST L or AUST R product soon find they gain limited benefit from their investment. This is apparent in the lack of marketplace advantage for their scientifically validated product. Specifically, competitors can make similar claims on their AUST L product as the company which conducted the R&D (on either an AUST L or AUST R product) without incurring these R&D costs, rather basing their evidence on (potentially weaker) publically available data."*

WIDENING THE SCOPE OF DATA PROTECTIONS

The Consultation Paper on Reforms to the Regulatory Framework for Complementary Medicine - Assessment Pathways (2017) defined Data Protection as: *"a form of secrecy that prevents access to and use of data that supported a product approval from being used for a subsequent evaluation of competitor's similar product."*

In this proposal, NICM has a broader definition of Data Protection and defines it as: **"a method to securely ensure that data used to support a specific product approval cannot be used for a subsequent evaluation of a competitor's similar product."**

While secrecy may be required in the application process for data protection, NICM considers that administrative arrangements can be implemented that do not require ongoing secrecy to ensure data protection. In this way, many of the concerns regarding data protection preventing the data from being peer-reviewed and available to health consumers can be alleviated.

A fundamental principle underpins this broader definition of data protection, which is that the data relates to a **specific product** which has been demonstrated to have efficacy in a specific condition in a well conducted clinical trial. As such, the **specific product** used in the clinical trial, and only that product, should be assessed for efficacy. A competitor's similar product would require its own well conducted clinical trial in order to make similar claims.

Using the NICM definition associated with appropriate administrative arrangements will minimise the period of secrecy required to the submission process, when the unique identifier of the clinical trial submitted for review by the TGA can be captured. Once the clinical trial is captured and related to a specific complementary medicine then administratively it cannot be used for the evaluation of competitor's product.

PATENTS

The Expert Committee on Complementary Medicines in the Health System (2003) noted that many complementary medicines are either not patentable or off patent.

The report stated that: *"complementary medicines are rarely able to be patented because they cannot meet the requirements of novelty and secrecy, given their history of use is often in the public domain. As a result, a company which prepares a novel formulation of medicinal herbs and undertakes research to establish its effectiveness is often unable to prevent other companies from copying this formulation."*

As such, the use of patents as the only way to provide data protection is not a feasible option.

DATA PROTECTION PROPOSAL

NICM proposes that data protection is given to Australian sponsors who are successfully granted registration in the AUST L(A) pathway for a specific complementary medicine based on a clinical trial that is undertaken on the product under registration for the condition specified in the claim(s) where they are the primary funding agent. Provided that the medicine is:

1. not subject to a patent;
2. is not under licence from an international supplier; and
3. that the clinical research has been undertaken by an Australian contract research organisation (CRO) and prospectively registered on the Australian and New Zealand Clinical Trial Register (ANZCTR)

To implement this data protection, NICM recommends that the TGA establish a database of the clinical trials that have successfully been assessed for the AUST L(A) pathway.

The primary identifier for the clinical trial should be the unique registration number from the ANZCTR. No further application for the AUST L(A) pathway from a different sponsor can apply the same clinical trial registration number for consideration.

Once the application has been submitted to the TGA with the unique ANZCTR registration number entered into the database as under assessment, the Sponsor should be then eligible to have the clinical trial published in the peer review literature.

This will alleviate concern that data protection could discourage publication of clinical trials which should be subject of peer review and in the public domain to play a role in the understanding and use of complementary medicines by consumers.

THE SCOPE OF APPLICATIONS FOR AUST L(A)

NICM recommends that the scope of applications for inclusion in the AUST L(A) pathway should be as broad as possible and should not be limited to new active ingredients.

NICM considers that finding new therapeutic uses of existing complementary medicine substances to be a key area of innovation where scientific research excels. Research based on the plausibility of identified constituents, putative or demonstrated mechanisms of action coupled with innovative thinking gives rise to novel discoveries. Such research is critical to growing a viable, innovative and responsible complementary medicines industry.

Given that new therapeutic uses are required to be demonstrated in rigorous clinical trials, NICM strongly recommends that new therapeutic uses of existing complementary medicine substances should be eligible for data protection under in the new AUST L(A) pathway.

LENGTH OF DATA PROTECTION

NICM recommends that medicines that are successfully registered in the AUST L(A) pathway be given five years of data protection if they meet the criterion established and are successfully assessed by the TGA.

NICM considers this to be more reflective of the costs and time associated with adequate research and development to secure a sound scientific evidence base.

The investment and work required in undertaking a clinical trial are much higher than the cost and work required for the Listing approval of a new ingredient which has been proposed to be granted two years protection.

PRODUCT DIFFERENTIATION

The TGA has proposed an optional logo-style claimer to allow better differentiation of products that belong to the AUST L(A) class to those in the AUST L class. NICM supports this concept as an essential component of providing effective consumer recognition of the TGA assessment of efficacy and the AUST L(A) class of therapeutic goods.

NICM considers that it is highly likely that companies who have not invested money in clinical research will attempt to trade off those products produced by companies that have made this investment. Ways that companies could conceivably do this is by copying the formulation, using a similar sounding name and packaging the product in similar colours. Such a situation sets up unfair competition and may affect the financial viability of an AUST L(A) product with a period of data protection.

The most notable of these methods of poaching customers away from products that have successfully applied for AUST L(A) registration and data protection is by copying the formulation and making a “me too” product or a “pseudo-generic”. These products would be accompanied by a marketing campaign to convince consumers and suppliers that this product is the same as the AUST L(A) product with the advantage of being offered at a lower price point.

NICM considers that it is the TGA’s responsibility to provide a mechanism that discourages this behaviour by companies that operate at the edges of ethical business practice. The optional logo-style claimer which provides a unique point of differentiation is a critical mechanism in the effective regulation of the new pathway. It will also provide an incentive to companies that make the investment in Australian clinical research that they have TGA support to effectively differentiate their products.

NICM recommends that the TGA implement the optional logo-style claimer as clear method of product and registration class differentiation.

NICM recommends that the TGA in consultation with industry also explore options for the protection of novel formulas that are successfully meet the criteria for AUST L(A) registration.

PRODUCTS CURRENTLY ON THE ARTG

NICM recommends that products currently on the ARTG as listed products (AUST L) should be eligible for AUST L(A) listing with data protection if they meet the criterion established and are successfully assessed by the TGA.

Patented and internationally licenced products would be eligible for AUST L(A) registration without data protection.

REFERENCES

- Consultation Paper on Reforms to the Regulatory Framework for Complementary Medicines -Assessment Pathways (2017). Therapeutic Goods Administration, Department of Health, Commonwealth of Australia, Canberra, ACT.
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- NICM Submission to TGA Consultation: Reforms to the regulatory framework for complementary medicines - Assessment pathways (2017). NICM Health Research Institute, Western Sydney University, Campbelltown, NSW.
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