Submission addressing the Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

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Introduction

The Complementary Healthcare Council of Australia (the CHC) is appreciative of the opportunity to provide this submission on the Review to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), dated June 2012.

Complementary medicines and natural healthcare products are vitamins, mineral and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products, and natural cosmetics using herbals and botanicals. Roy Morgan Research[1] indicates that almost 75 per cent of Australians use complementary medicines. Recent research[2,3] showed that up to 2 billion dollars is being spent by consumers on complementary medicines and healthcare annually. With figures like these, it is clear that complementary medicines play a significant role in the health care choices of contemporary Australians.

There are over 300 complementary medicine companies in Australia generating around $2 billion in annual revenues. Australian companies export around $200 million in complementary medicines to more than 20 countries in Southeast Asia, Europe and The America's, and this continues to grow at higher rates than domestic consumption[4]. In Australia the industry generates around 5,000 highly-skilled manufacturing jobs, and indirectly supports a further 60,000 jobs. The global market has been estimated at $US 83 billion annually[5]. The production of complementary medicines in Australia is a substantial industry, with approximately 59 TGA approved manufacturing facilities for Listed medicines nationally (including CMs, sunscreens and over-the-counter medicines). Australia's medicines industry continues to lead the world in the development of global benchmark standards in safety, quality and efficacy.

The contribution made by complementary medicines to improving population health outcomes is supported by a large and constantly growing evidence base; this is particularly the case for major products such as multi vitamins, vitamin B, and fish oil, which together account for approximately 50 percent of complementary medicine sales in Australia. There are approximately 10 000 such medicines available on the Australian market. The evidence suggests that selected complementary medicine interventions are more cost-effective in dealing with minor conditions than the available pharmaceutical medicines on the market[6] (for some the cost differential is up to 70 per cent), and their efficacy has been recognised by the National Health and Medical Research Council (NHMRC).

[1] Roy Morgan Research 2008 Consumer Research, provided by Catalent Australia

[2] Stephen P Myers, Alastair H MacLennan, and Anne W Taylor - The continuing use of complementary and alternative medicine in South Australia: costs and beliefs in 2004 (MJA 2006; 184: 27–31)

3 Vitamins And Dietary Supplements in Australia, Published by: Euromonitor International, May 2009.

[4] CHC Complementary Medicines Industry Audit May 2011, available by request

[5] The Australian National Audit Office, Performance Audit Report No. 3 2011-2012, Therapeutic Goods Regulation: Complementary Medicines, pp13

6 NICM http://www.nicm.edu.au/content/view/159/276/

The CHC supports a review that aims to improve the efficiency and effectiveness of NICNAS by enhancing competition and innovation in industry, minimising the cost of and removing unnecessary regulation, while increasing consumer confidence in the regulatory system.

It is important to note the complexity of the Australian chemicals institutional and regulatory arrangements, involving some 140 pieces of legislation and multiple policy departments[7]. The regulatory process for therapeutic goods in Australia alone has it regulations scattered across 16 different guidelines. It should be noted, the Australian National Audit Office (ANAO) has recommended in its 2011 Performance Review, that Therapeutic Goods Administration (TGA) regulations be streamlined and guidance documents for industry updated and completed expeditiously[8]. This review of NICNAS is timely, and should consider the outcomes and initiatives of the TGA after having recently completed several major reviews across various regulatory areas.

There are obviously challenges to ensure that roles and responsibilities of the regulators are clear and that there is no duplication of effort in these processes. The CHC supports the proposal for the development of a body, such as a standing committee, to be established to ensure that regulation across various agencies is consistent and sufficient to protect public health and safety, and promote the safe use of chemicals in the work setting. This body could for example sit outside NICNAS but ensure that NICNAS, Australian Pesticides and Veterinary Medicines Authority (APVMA), Food Standards Australia and New Zealand (FSANZ), the TGA and the risk managers (for example, Safe Work Australia and the Poisons Scheduling area of DoHA) are consistent in their approach to chemicals assessment and management**.**

Importantly, the CHC encourages NICNAs to align its regulatory policies, where applicable, with International harmonisation in mind. For example the CHC believes that NICNAS should adopt lists of banned/restricted use chemicals in the EU, Canada, USA and UK to ensure that the Australian community is not exposed to such chemicals. NICNAS should also have the capacity to consider overseas assessments as opposed to creating unique Australian standards.

The CHC suggests that NICNAS consider the principles outlined by the TGAs Blueprint reforms: A Blueprint for TGA's Future, as some aspects may provide direction to address the enforcement issues experienced by the NICNAS.

Part 4 the Regulatory Framework for Industrial Chemicals

Stakeholders have previously noted the disconnect with the existing system in that there are approximately 5 Ministerial Councils and in excess of 36 different Commonwealth, state and territory agencies involved in policy setting, risk assessment or risk management in relation to industrial chemicals. Moreover, gaps in regulatory coverage and duplication in coverage would be greatly assisted by an overall review of the efficiency of the system that works in harmony with the 3 other chemical assessment and registration schemes.

The CHC supports the creation of an ongoing Government cross-portfolio group that would consider chemical policy issues and work to minimise duplication between the Australian Government agencies and a co-ordinated approach to risk. The CHC suggests comparing the principles of the TGA's risk based model for harmonisation purposes.

The CHC supports the development of a manual, undertaken in consultation with industry, that would detail industrial chemicals risk assessment and management, to clarify the roles and responsibilities of the

7 Discussion paper: Review of the National Industrial Chemicals Notification and Assessment Scheme, June 2012

8 The Australian National Audit Office, Performance Audit Report No. 3 2011-2012, Therapeutic Goods Regulation: Complementary Medicines, p. 19-20.

Australian Government agencies and expand on NICNAs' approach to risk assessment and management. This manual should be user-friendly, clear and concise to be an effective communicative tool for industry and the wider community.

Part 5 New Industrial Chemicals

NICNAS currently undertakes both a risk assessment and risk management function in relation to lower risk chemicals. It is the CHC's understanding that many of the chemicals used by the complementary medicine industry, such as natural cosmetics, contain these lower risk chemicals and therefore has no specific comment to make, at this time, on the risk management functions for higher risk chemicals.

In general the CHC supports the NICNAS position that the list of exemptions is outdated and overly restrictive for industry. In general the permit system can be confusing for industry and should be more flexible for improved outcomes.

The CHC believes that NICNAS should be provided with a limited risk management/regulatory role in relation to higher risk chemicals. It is unreasonable, from a public health and safety perspective, that there can be gaps in regulatory control purely because NINCAS can not refuse an assessment certificate and risk managers may not make an immediate decision. It would seem reasonable that in cases where there is no direct risk manager that NICNAS be able to enforce any necessary condition of use in order to minimise safety and protect the environment.

The CHC supports a review to increase current volume thresholds, data requirements and applicability criteria with a view to harmonising these with overseas arrangements, where possible. Steps should be identified that clarify and harmonise data requirements which will potentially reduce the complexity for industry.

Part 6 Existing Industrial Chemicals

The CHC understands that from July 2012, NICNAS will asses existing chemicals following the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework, a framework that was developed in consultation with industry and aims to better asses and priorities existing chemicals.

The CHC strongly supports that any reform in this area ensures there is transparency in the decision-making processes. In principle, the CHC supports the idea that NICNAS broaden the mandatory information-gathering powers to enable better risk assessment activities and to adequately manage AICS. The circumstances under which NICNAS may request information from industry would need to be tightly defined and proportional to the risk. This mechanism could be used for NICNAS to seek information regarding those chemicals that have been introduced into Australia over the last 5 years as part of recommendation C5, for example.

Part 7 Post Market Monitoring and Enforcement

It is concerning that there are approximately 39,000 chemicals on the AICS that have not been assessed by NICNAS for their health and environmental impacts and, therefore, post-market monitoring does not occur. Of particular concern is, for those chemicals that have not been assessed by NICNAS there is no effective system of adverse effects reporting.

Moreover, there appears to be a lack of a graduated compliance response between the extremes of warning letters or minor fines to that of imprisonment. Again, the CHC recommends NICNAS considers the approaches taken by other regulatory agencies, such as the TGAs risk based model that is currently being reviewed. Any penalty provisions for non compliance should acknowledge the degree of risk and aim to create a level playing field for all industry participants.

The CHC understands that NICNAS undertakes compliance and enforcement activity related to registrations, exemptions, permit conditions and annotations on the Australian Inventory of Chemical Substances (AICS) and establishes and enforces national standards for cosmetics imported into, or manufactured in Australia. The CHC supports regulatory reform that, where applicable, aims to increase international harmonisation, and as the 1991 Baume report identified, should not aim to create unique Australian only regulatory conditions.

Other general comments

The CHC notes, in general, there are references on the NICNAS website that are linked to out-dated documents or are in draft from. For example, the Customer Service charter could be updated and the link to the Annual Regulatory Plan (under the brochure tab) directs the user to an out-dated plan and should be reviewed. There are sections of the NICNAS Handbook for Notifiers that have been in draft form since 2009.

The CHC would like to highlight its recent work with industry and the government to raise the awareness of the potential for some precursor chemicals in the complementary medicine supply chain to be diverted into the illicit drug manufacturer. There has been a lot of media highlighting the counterfeit medicine trade recently and the CHC is actively involved in alerting industry to the risks of purchasing their medicines online from overseas websites. We actively promote information to industry as to the advantages of purchasing therapeutic products in Australia where they are generally registered on the Australian Register of Therapeutic Goods (ARTG) and display an AUST L or AUST R number on the label.

Conclusion

The CHC values the opportunity to make this submission as we are supportive of reforms that aim to improve the overall regulatory framework for industrial chemicals. The CHC encourages a closer examination of the intersection between evidence-based industry-focused research and robust policy development to achieve lasting outcomes that will provide for improved population health.

The CHC has encouraged its membership to provide NICNAS with information on the likely impacts, including any costs or benefits, should the reforms be adopted. We look forward to further detail of these reform options and the regulatory impact statements that are to be developed as a consequence of this consultation.

Yours sincerely,

Complementary Healthcare Council