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Review of Medicines and Medical Devices Regulation Secretariat
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NSW TAG RESPONSE TO THE EXPERT REVIEW OF MEDICINES AND MEDICAL DEVICES REGULATION OF COMPLEMENTARY REVIEW

This submission follows on from a joint submission made by NSW Therapeutic Advisory Group (TAG) and the Society of Hospital Pharmacists of Australia (SHPA), 9th January 2015.

This submission is provided in 4 sections:

1. Theme 1: Duplication of regulatory processes
2. Theme 2: Regulatory requirements are not commensurate with risk
3. Theme 3: Complex Regulatory Framework
4. Theme 4: Inadequate deterrents

NSW TAG wishes to make the general observations based on its expertise with regard to the quality use of medicines in NSW public hospitals, home medicines reviews, post-hospital discharge medicine reviews and pharmacist educator for attendees to the cardiac rehabilitation program of a large teaching hospital.

A review of the regulation of CM is pertinent given that it is reported that Australians spend $3.5 million annually on complementary medicines (CM) with 2 out of 3 Australians regularly take complementary medicines.

Theme 1: Duplication of regulatory processes

Issue 1 – Requirement of TGA assessment of ingredients approved overseas

Given the apparent differences in the definition of complementary medicines internationally and the level of pre-market assessment that they undergo, how might Australia determine 'trusted' regulators for the purpose of undertaking assessments of ingredients for use in listed products in Australia?

If a criteria based approach were to be adopted, what criteria should apply in determining whether an overseas regulator is 'trusted' for the purpose of undertaking assessments of ingredients for use in listed products in Australia?

NSW TAG recognises that medicine regulation is a global enterprise and endorses the removal of unnecessary duplication of effort but notes that there is innate risk in the use of any medicine

including CM given that their role (perceived or actual) is to exert pharmacological effects that may have both positive and negative consequences. Australia requires a regulatory system that facilitates the provision of accurate information about the therapeutic, safe and harmful effects of a CM. This allows consumers to make more informed decisions about the products they choose for themselves and their families based on constituents, quality, convenience and value for money.

The previous NSWTAG/SHPA submission to Expert Review Panel suggested criteria for a regulator to be considered 'trusted'; many of which would also apply to the regulation of CM.

- Having a track record with evidence of regulatory effectiveness
- Having similar structures/systems/approaches to regulation. (The Australian regulator would need to recognise differences of other regulators' processes and the limitations that that imposes including recognition of Australian context);
- Having post-marketing programs that can include CM monitoring;
- Having a similar risk tolerance threshold for CM;
- Having systems in place to detect and resolve problems with CM;
- Aligning with international harmonisation standards for CM; and,
- Ensuring transparency with regard to decision-making and access to documentation including supporting evidence, if required.

Additional criteria include

- Existence of a similar status of CM within the overseas health care system. It is noted that there may be differences between CM statuses in other jurisdictions compared to Australia. For example, Singapore may have greater use and different perceptions regarding the use of Chinese traditional medicine, sub-continental Asia with ayurvedic medicine and the United Kingdom with homeopathy because of historical perspectives and teachings and the evidence-free zone these products often occupy.
- Requirement of high level of evidence for safety and rigorous quality control for CM manufacture and a similar approach with regard to evidence for efficacy/effectiveness for approval; it may be that there should be increased approval categories in order to indicate the level of evidence for efficacy/effectiveness that a CM product may have in order for the consumer to be able to judge the value of such a product. Such categorisation could help educate the consumer and guide their selection along the lines of the food recommendations. (Please see page 10)

  A significant missing component in Australia's current evaluation of CM and regulatory framework is efficacy/effectiveness evaluation. It is possible that the trusted regulator may not have all components of the evaluation that Australia requires. Use of a trusted regulator who can provide information about safety but who does not evaluate efficacy/effectiveness may mean that greater focus on evaluation of efficacy /effectiveness could be undertaken by the TGA. The trusted regulator may wish to obtain the TGA's efficacy evaluation and as such an information sharing model between the two regulators (effectively a sharing of resources model) could be advantageous to both regulators.

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- Possibly similar governance of the health of vulnerable populations such as paediatric population, pregnant and breast-feeding women, geriatric populations, indigenous populations and potentially genetic subtypes in the future.

The discussion paper details the variation between regulators with regard to regulation of CM. Moreover regulators may vary with regard to specific CM groups. For example, the recent NHMRC review of homeopathy[1] showing no therapeutic value in a wide range of health conditions means that, in Australia, these should not be given the status of therapeutic goods (in contrast to their current classification). How the results of this NHMRC review should be translated into regulatory, commercial and clinical practice requires further thought but relegation of homeopathy to an as yet named class or as a consumer good should be considered. International regulators may have a different approach and assess these products differently.

It is unclear whether the approach to having 'trusted' regulator status should be 'all or nothing'. As stated above, there may be differences in the evaluations by some regulators with regard to specific CM groups e.g. homeopathy, and traditional Chinese herbs. Given these differences, it is likely these regulators could not be accorded the status of 'trusted' regulator although it is possible that their evaluations for some CM may be useful. Evaluation by the Australian regulator would be required for CM falling outside these regulators' perceived expertise.

Given the apparent differences, it may be useful to test a sample set of CM evaluations by overseas regulators through the TGA process and compare the consequences of such evaluations if any of these regulators' evaluations were to be adopted in Australia.

NSW TAG continues to recommend that the TGA does not lose its ability or capacity to independently assess new chemical entities whether prescription, OTC or complementary medicines. We also refer the Expert Panel to comments made in our previous submission with regard to the use of a 'trusted regulator' with regard to informing marketing approvals of new chemical entities.

NSW Therapeutic Advisory Group supports the use of a trusted regulator if they can meet the recommended criteria We acknowledge that there may be other worthwhile criteria identified by other submissions.

Should an ingredient only be considered to have been 'approved' by an overseas regulator if it has been subjected to some form of assessment? If yes:

- ***Should this assessment include quality, safety and efficacy?***

[1] National Health and Medical Research Council. 2015. *NHMRC Information Paper: Evidence on the effectiveness of homeopathy for treating health conditions*. Canberra: National Health and Medical Research Council; 2015
http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cam02a_information_paper.pdf

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- ***Should evidence standards be comparable with, or superior to, those currently applying in Australia?***

If Australia were to adopt approvals of ingredients provided by 'trusted' overseas regulators, what additional assessment, if any, should be conducted by the Australian regulator?

What value do you believe an assessment by the TGA adds in cases where such an assessment has already been undertaken by a 'trusted' overseas regulator?

Ideally the assessment should include quality, safety and efficacy and if the assessment comes from a trusted regulator, Australia could adopt the approved ingredient for the populations assessed by the trusted regulator. (See other comments in previous section regarding potential for information and resource sharing between regulators).

Evidence standards should be comparable with, if not superior to, those currently applying in Australia. NSW TAG notes that the NHMRC in its review of homeopathy[1] stated that 'when offering treatments for illness, all registered health practitioners must give consideration to the evidence for the effectiveness of such treatments.'

Whether additional assessments will be required will depend on the form of the assessment by the trusted regulator, noting the above comments as well as possible differences in cultures, sub-populations, CM status in the various countries, and storage conditions. Specific consideration should be undertaken with regard to the exposure of vulnerable populations to the CM e.g. paediatric, geriatric, indigenous, child-bearing populations and the governance of the health of these vulnerable populations. Further evaluation may be required for these populations by the Australian regulator. Australian conditions e.g. temperatures may differ substantially from those overseas and hence further product stability evaluations within a wider range of climate conditions may be required.

A recent study[2] investigating the quality and content of 32 fish oil supplements in New Zealand reported more than two-thirds of products had levels of omega-3 fatty acids that were at least 30% lower than their labels claimed. There were high levels of oxidised lipids that may accelerate atherosclerosis rather than attenuate it. Given the high use of these products and recommendations from organisations such as the Heart Foundation of Australia for their use, it is beholden on regulators to ensure that Australians can be assured that they are receiving what the label says they should be receiving and the amount they believe they are receiving. Otherwise these are misleading claims, and could be doing more harm than good in a substantial proportion of the Australian population. Such a study should be a trigger for the TGA to evaluate similar products on the Australian market as well as consider whether the existing quality standards or requirements are sufficient. Use of a trusted regulator has the potential to enable the TGA to provide greater resources to such evaluations.

2 Albert BB, Derraik JGB, Cameron-Smith D, et al. Fish oil supplements in New Zealand are highly oxidised and do not meet label content of n-3 PUFA. Nature Scientific Reports, 2015 5: 7928. Published 21 January 2015

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NSW TAG also notes that applications for approval of an ingredient/CM product may come to Australia prior to another international regulator and hence the skills and expertise required and the capacity for the full assessment of a CM must be maintained and augmented in Australia. It may also be that the therapeutic product derives from Australia e.g. bush tucker and hence would likely be evaluated in Australia prior to international evaluation.

NSW TAG sees no advantage to an additional/duplicated assessment by the TGA in cases where there are no differences between the assessment approaches (e.g. same evidence hierarchy/quality requirements, risk appetite, population surveillance) between the ideal Australia assessment (incorporating quality, safety and efficacy assessments) and that of the trusted regulator . However, as this is unlikely, there will need to be a determination of the differences in order for the TGA to address any assessment gaps.

In summary, if the CM ingredient/product meets the required standards after assessments of quality, safety and efficacy by the trusted regulator, the ingredient may have tentative approval. Further assessments by the Australian regulator are likely to be required as determined by a gap analysis of differences between the Australian and trusted regulators but are likely to include quality control for stability under a wide range of temperatures

Issue 2 – Interface between advertising and listing evidence requirements

How might evidence requirements for listing on the ARTG and for advertising pre-approval of complementary medicines be harmonised? What changes to evidence requirements would be required

The requirements for advertising pre-approval should be the same as the requirements for listing i.e. the evidence requirements for the indications associated with listing must be met for pre-advertising approval rather than simply satisfying the claim that it is not false or misleading. As therapeutic management becomes more complex, the bar should be set higher not lower. Whether the current requirements for listing are sufficient is arguable.

Theme 2: Regulatory requirements are not commensurate with risk

Issue 1 – Interface between complementary medicines and pharmaceuticals

Is the current regulatory regime for complementary medicines in Australia appropriate and commensurate with the risk posed by these products? If not, why not?

Should complementary medicines in Australia be regulated under a separate legislative framework? If yes, what should be the key features of the framework?

NSW TAG recommends a strengthening of the legislative framework for CM regulation to improve the rigour of the evaluation process (which may be augmented by the use of a trusted regulator and enable the TGA to address current gaps). The framework should enable CM evaluation to be more comprehensible to sponsors, consumers and health professionals. Improved evaluation of efficacy,

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communication to consumers and health professionals and post market monitoring are required. CM stratification according to risk profile and efficacy may be useful. Amendments to the current framework which provide stratification of CM to meet the various levels of risk of harm, evidence for efficacy and indications would be useful. This could assuage sponsors' concerns re red tape as well as provide an opportunity to educate the consumers and health professionals about CM given that adverse effects of many CM are not appreciated by many health professionals or consumers. The current regulatory regime is partly to blame for this poor understanding.

Issue 2 – Threshold for therapeutic goods

Should low-risk complementary medicines be regulated as general consumer goods, removing the requirement for listing on the ARTG? If yes, why? If not, why not?
What criteria should be used to determine whether a complementary medicine should be regulated as a therapeutic good?

If the product is designated a 'general consumer good', it should not be called a 'medicine'. The use of the term 'medicine' inherently means that it exerts a pharmacological effect and once this is true, it may exert positive and/or negative effects, affect health and interact with disease conditions and other medicines. In order to be designated a 'general consumer good' rather than a medicine, it must be not have any pharmacological activity in the doses that are recommended. Any product making a therapeutic claim cannot be classed as a 'general consumer good'.

Issue 3 – Interface between complementary medicines and foods

Should certain dietary supplements, such as water soluble vitamins, be regulated as foods or as general consumer goods rather than as therapeutic goods? If yes, should such goods be regulated as foods or consumer goods?

What criteria should be applied to determine whether a product should continue to be regulated as a therapeutic good?

NSW TAG agrees that regulatory uncertainty and inconsistency – where similar products with only limited differences in their claims can be regulated under different regimes by different regulators- should be reduced or removed as much as possible.

NSW TAG believes it is reasonable for dietary supplements such as water soluble vitamins or minerals to be regulated as foods when they are used in doses that are commensurate with dietary supplementation rather than as medicines. However we note that justifications for the use of CM are often made because a supposed deficiency is causing a condition/symptom where outcome data does not show that correction of the deficiency improves the condition/symptom e.g. Co-enzyme Q 10 and statin-induced myalgia. Was it the horse or the cart? Further, if there is evidence of potential harm with the use of a 'dietary supplement' formulation e.g. Vitamin E-containing formulations, it should be treated as a therapeutic good. Any product that solely relies on homeopathic principles should not be given the status of a therapeutic good. Non-oral aromatherapy could also be removed as a therapeutic good if it does no harm and makes no therapeutic claim.

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If a therapeutic claim for any health conditions that are chronic, serious or could become serious is made, no matter what the dose, the product must be treated as a therapeutic good. If a CM product can interact with any drug that has a narrow therapeutic index e.g. warfarin, it should also be treated as a therapeutic good. As a therapeutic good, sponsors would need to meet certain requirements regarding evidence for claimed indications, quality and safety as well as advertising and that claims made by the sponsor would be available to the public. Therapeutic goods designated as above should be accompanied by Product Information and Consumer Complementary Medicines Information leaflets. This would mean that non evidence-based use of a therapeutic good would be discouraged. For example, formulations delivering high dose Vitamin C, touted for cancer, coronary artery disease and asthma, would be a therapeutic good not a dietary supplement. Furthermore if there is evidence that harm could be done with the use of a dietary supplement they should be classed as a dietary supplement. Such an example may be promotion of Vitamin E supplementation as a product that reduces risk of coronary heart disease should be treated as a therapeutic good because such a claim is not based on evidence and could do more harm than good.

Given the varying approaches made by overseas regulators, it would be useful to know if there has been any harm (to public health or the individual) arising from their different approaches to the classification of dietary supplements as foods or therapeutic goods. It is possible that assessment of whether a product is a general consumer good, food or therapeutic good may need to be made on a case by case basis to capture all eventualities. In the event that this is too difficult, the position should be that all are classified therapeutic goods.

Should the TGA introduce a modified registration pathway for complementary medicines seeking to make higher level health claims that would allow it to only assess the evidence to support the higher level claims?

This could be reasonable if:

- the product's components have a proven safety profile in the majority of the population
- the product is only marketed for the health claim it is making and
- the labelling of the product identifies the indication(s) for which it claims therapeutic value.

However the reality is that there would likely be widespread 'off-label' use, which may pose a further consideration of potential harm (physical, mental and financial). Potential for harm may be mitigated using consumer and health professional education and compliance with strict labelling requirements that should include a Consumer Complementary Medicines Information leaflet.

Issue 4 – Evidence requirements

Are the current evidence requirements for listed medicines overly onerous? If so, in what way?

How could the current evidence requirements for listed medicines be altered to reduce the burden on sponsors without reducing consumer confidence that complementary medicines are safe, efficacious and comply with quality standards?

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In general, NSW TAG does not believe the evidence requirements for listed medicines are too onerous. We note that the question suggests that consumer confidence is high or at an adequate level. NSW TAG would suggest that if it is high, it is misguided and that many consumers do not have an adequate level of knowledge to support their level of confidence in CM use.

There should be a high level evidence base for any therapeutic claim for chronic, serious or potentially serious conditions as detailed in the Discussion Paper.

NSW TAG notes that many CM products are now claiming both scientific and traditional evidence as a base for their use. It is likely that the majority of consumers do not know what either term means.

For those products not making therapeutic claims for chronic, serious or potentially serious conditions, NSW TAG believes that ranking of evidence levels in respect of these products should be undertaken. Traditional evidence should be of lower rating than scientific rating. Evidence rating should be partnered with safety rating. Consumers should be able to understand and have access to the rating system. Given that provision of evidence is a sponsor responsibility, incentive(s) for sponsors to provide higher quality evidence could be considered (see page 10 for suggestion with respect to implementation of a CM rating system). (NB a product may have high quality evidence for a chronic condition but may be unsafe for a certain group of the population and consumers and health professionals would need to be aware of this if the product was listed).

Issue 5 – Compliance with GMP

Should Australia remove the requirement for manufacturers of low risk products or ingredients to comply with medicinal Good Manufacturing Practice (GMP) standards?

The requirement for manufacturers of low risk products or ingredients to comply with medicinal Good Manufacturing Practice (GMP) standards should remain if a product falls under the category of a therapeutic good/medicine. Relaxation of these standards as suggested by the Complementary Medicines Australia (CMA) with development of complementary medicine-specific GMP guidelines, may be of some merit but further details are required. A detailed 'business case' is required with a clear risk profile and risk mitigation strategies included.

NSW TAG is frequently alerted by the TGA and international regulatory organisations to the poor quality of certain CM products which frequently contain additional components such as sildenalfil, phenylbutazone, steroids.

Issue 6 – Pre-publication approval for advertising

Should Australia continue to require compulsory pre-vetting of complementary medicines advertised direct-to-consumers or should it move towards a self-regulatory model or combined statutory and self-regulatory models such as that operating in the UK?

Should listed complementary medicines be required to include a disclaimer in all advertising materials and on product labels advising consumers that statements/claims have not been independently assessed by the TGA?

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In theory, NSW TAG supports some form of industry self-regulation by making pre-vetting of advertisements a requirement of industry associations for product advertising or marketing campaigns. This is because the current process is not working. However we are concerned that when sponsor companies are not a member of an industry group they may circumvent the system. Further advertising for non-approved indications should not be allowed.

NSW TAG supports a model such as the UK system that has more risk based pre-vetting requirements, combined with self-regulation.

Use of disclaimers: With regard to the UK-required statement for homeopathic products or any other traditional herbal medicines basing their claim on traditional evidence: this statement is not sufficient. It should also be mandated that a statement regarding the lack of proven value compared to placebo/scientific evidence (in terms that can be understood) and potential for harm (as previously outlined) also be included on the product and in advertising. Inclusion of non-assessment by the TGA should also be considered although it is unclear what the consumer may understand by such a statement. It is also possible that advertising could also refer to a CM rating system for consumer (see page 10).

Theme 3: Complex Regulatory Framework

Issue 1 – Lack of understanding of requirements for listing

Should sponsors of complementary medicines have to undergo compliance training before being able to list a product on the ARTG? If yes:

- ***What evidence is there that such a scheme would increase compliance?***
- ***What would the impact of this be on sponsors in terms of additional costs and time to market? Would it delay consumer access to new products?***

If not, what other strategies might be put in place to increase sponsors' understanding of regulatory requirements and/or increase compliance with regulatory requirements?

Is current guidance material user friendly and easily understood by sponsors?

NSW TAG supports a model that includes compliance training of CM sponsors prior to product listing as current compliance rates are poor. In the long term, NSW TAG does not believe this would have a significant impact on costs to sponsors or delay access to new products. It has the potential to facilitate listing as it may improve transparency and increase sponsor understanding.

NSW TAG is not familiar with the current guidance material and cannot comment on its user friendliness or understanding by sponsors. However it would seem a direct training workshop approach with additional education materials is more likely to achieve compliance.

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Issue 2 – Poor consumer understanding

Is the regulation of complementary medicines transparent enough in terms of informing health consumers about the level of scrutiny that the medicine has undergone? If not, how could it be improved?

NSW TAG believes poor consumer understanding is a major issue with the use of CM including what is and can be inferred by Australia's regulation of CM products. There is also poor understanding by many health professionals.

Consumers would be assisted with an online Therapeutic Panel Calculator/Quality, Safety and Evidence Star Rating Calculator similar to that provided for food products. Examples of food rating schemes that could be used as a template for CM products include the Australian federal department of Health's new Health Star rating system[3], Food Standards of Australia rating system[4] and Food Switch developed and maintained by the George Institute[5]. Such a system could rate evidence and safety for every listed and registered CM obtained as a result of the scrutiny (whether by the TGA or the trusted regulator) that the CM has undergone. It could also act as a portal for other important information for consumers including alerts regarding harmful CM products that are sourced from overseas rather than the current TGA website that consumers are unlikely to be aware of. We would recommend a stand-alone portal rather than going through a TGA website for ease of access. While this will mean a sizeable initial investment on the part of government, NSW TAG believes that it will be a very valuable long term initiative, leading to more judicious, appropriate, safe and effective use of CM with reduced loss of opportunity costs and increased productivity. If it can be done for food products, it should be possible for CM products.

NSW TAG also refers to the Expert Review Panel to the Council of Australian Therapeutic Advisory Groups (CATAG) *Position Statement for the Use of Complementary and Alternative Medicines* [6]due to be published on the CATAG website in April 2015. This position statement addresses issues identified in the management of hospital patients with respect to complementary medicines (CM) and recommends an approach to their management. Such an approach is required because it is recognised that patients often do not report their use of complementary medicines to hospital clinicians and general practitioners, have not received adequate education regarding the safety and effectiveness of a specific CM they may be using and do not understand the potential harms that the use of some CM may represent to their health. Such harms not only include physical and mental adverse effects but also a waste of money and hence potential opportunity loss for more effective use of the money (essentially a potential loss of productivity on the part of the consumer). This is, in part, due to the poor understanding of CM that the general public has such that they perceive potential benefit and no potential harm from the CM, the marketing power of the CM industry and the overwhelming number of CM products available on the Australian market. Regulatory authorities, as do others, have a responsibility to ensure appropriate and adequate consumer

[3] http://www.healthstarrating.gov.au/internet/healthstarrating/publishing.nsf/content/home
[4] http://www.foodstandards.gov.au/industry/npc/Pages/Nutrition-Panel-Calculator-introduction.aspx
[5] http://www.foodswitch.com.au/
[6] www.catag.org.au

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knowledge of any product advancing a therapeutic claim or potentially exerting a pharmacological effect that may be detrimental to a consumer if it is to be marketed in Australia. It is not uncommon on home visits to patients recently discharged from hospital or during home medicines reviews to find that they are taking up to 10 additional CM products in addition to their 10 prescription medicines. Many of the CM products have overlapping constituents and potential interactions. The huge range of CM products also adds to confusion and makes judicious and appropriate product selection difficult for consumers. For example, how can consumers obtain independent advice to assess the benefits and potential harms of omega-3 fatty acid-containing products and compare the vast array of fish oil, krill oil and calamari oil products. How do consumers assess products that contain OMEGA BRAIN (concentrated fish oil) 'maintains mental and cognitive function', Red Krill Oil 'for active joints' and Deep Sea Krill oil with triple action: 'helps support joint & heart health, antioxidant'. The amounts of omega-3 fatty acids listed in the products are 600mg, nil and 102.5mg, respectively. (Pictures of these products are available, if required)

The CATAG Position Statement recommends an evidence-based approach when considering endorsing the continuation of a CAM while the patient is in hospital. Importantly it emphasises a scientific evidence-based approach to CM use. The fact that such an approach has not been adopted by the consumer when they initiated/continued the CM is likely to be due to the lack of education regarding what an evidence-based approach means. Moreover currently there is no incentive for that evidence to have been developed by sponsors and hence the consumer may not appreciate the paucity of evidence and why such a paucity of evidence exists. Whilst NSW TAG and CATAG recognise the patient's right to self-determination in medical treatment, CM use by the consumer may often rely on the lack of definitive information rather than any proven benefit and the consumer's lack of awareness of such facts. Notwithstanding the acknowledgment of the placebo effect that CM may represent, a lot of money is spent on such an effect. Consumers are not aware of the questions they should ask when considering use of a CM.

Theme 4: Inadequate deterrents

Does the current legislative framework provide sufficient deterrents to prevent sponsors from knowingly listing non-compliant complementary medicines on the ARTG? If not, what additional measures should be considered?

Should complementary medicines that are withdrawn from the ARTG require some form of assessment before being able to be re-listed?

How effective are the current post-market compliance reviews of complementary medicines in minimising exposure of consumers to non-compliant complementary medicines?

Therapeutic goods should not be listed on the ARTG prior to regulatory evaluation- with the use of a trusted regulator, and the ability to 'grandfather' evaluations of constituents, this should not mean a great delay in listing.

It is clear that there are not sufficient deterrents for 'gaming' the system. The use of an on-line portal for consumers and health professionals to learn about CM products may be an opportunity to improve compliance including reasons why a product has been withdrawn from listing. Some form of

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assessment prior to re-listing may also be a useful deterrent. Random or targeted reviews do not appear to be sufficient deterrent. NSW TAG recommends adequate resourcing of the Australian regulator to ensure that it can conduct these reviews comprehensively and whenever required to ensure quality use of CM.

Currently the media is the most effective deterrent method but their involvement will be episodic and does not provide a sufficiently effective deterrent for less sensational non-compliance.

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