CMA Submission:

Exposure Draft of the Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017

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Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry. CMA members represent over 70% of all product sales and the entire value chain, including manufacturers, raw material suppliers, distributors, consultants, retailers, allied health professionals and educators. We promote industry advancement, whilst ensuring consumers have access to complementary medicines of the highest quality, contributing to improved population health outcomes. CMA is the principal reference point for members, the government, the media and consumers to communicate about issues relating to the complementary medicines industry.

Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to provide feedback on the exposure draft of the Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 (the draft Bill).

CMA notes that the draft Bill is part of the legislative response to the expert Panel Review of Medicines and Medical Devices Regulation (MMDR). CMA supports the main goals of the MMDR: that is, to improve the timely and safe access to therapeutic goods for consumers, ensuring that the regulatory framework is appropriately aligned to risk, and to remove unnecessary regulatory and administrative burden for businesses. There are a number of discussion points outlined in the Explanatory Memorandum accompanying the draft Bill that have been explored and many of which were agreed to in principle by the complementary medicines sector as a part of the MMDR consultation process. Despite this in principle agreement, there are matters relating to the implementation of these recommendations within the detail of the draft Bill where CMA has concerns about the impact of the newly proposed framework and the processes that underpin it.

CMA has a number of concerns regarding the procedural processes that are described in the draft Bill. Legal decisions that have a regulatory impact must have adequate checks and balances and these must be built in to legislation. CMA is also concerned there are proposed provisions that create barriers to or limit the natural justice of decisions that impact upon applicants and sponsors.

CMA believes it may be an unintended consequence of the way the Bill has been drafted that it will create barriers to listing, resulting in a less workable framework that could potentially drive sponsors to instead only focus on export medicines or to de-list and present products as foods. We understand that where a change in regulation is required a full Regulatory Impact Statement (RIS)

must be conducted and provided to the Office of Best Practice Regulation (OBPR). Amendments to the Act must not lead to a market that distorts the public use of complementary medicines and the cost-effectiveness for industry.

Consumer demand and interest in traditional and complementary medicines is growing worldwide and Australia's exporters are increasingly competing with companies from around the world. CMA supports the continued commitment by the Australian Government to improve our nation's competitiveness on the global stage and the minimisation of excessive red tape. An appropriate risk-based regulatory framework is vital in allowing the Australian industry to remain competitive, nationally and internationally, as well as provide significant economic and health benefits for our nation.

We are proud to represent an industry that supports individuals and communities to better care for their health. A sustainable and vibrant complementary medicines industry holds great potential to contribute further to individual and community health, and to the strength of high-skill local manufacturing, employment opportunities, research and growth in Australian exports.

CMA looks forward to continued collaboration with the TGA to develop and implement a regulatory framework that best reflects the goals of the Expert Panel Review of Medicines and Medical Devices Regulation.

Some of the more significant concerns identified with maintaining the healthy Australian complementary medicines industry are outlined in summary here.

Lack of clarity of the line between listed 26A and evaluated 26AE medicines, potentially risking that many 26A medicines become forced into the 26AE pathway, the requirements of which could not be met by many.

There is lack of adequate definition and clarity around what precisely constitutes a lower listable indication and what does not. There are some inconsistencies between what indications can be allowed in the lower pathway and the types of permitted indications persons are able to apply for. The drafted mechanisms, for example, include a provision that persons cannot apply for indications that alleviate ailments, which is a basic therapeutic use applicable to non-serious conditions that are principally considered to be listable indications. Such provisions have the potential to cause items that should be in the lower pathway to be forced into the intermediate pathway, for which there are significantly higher costs and evidentiary requirements that many products designed for the lower pathway will not be able to meet. This could result in a significant loss of products within industry and therefore a concurrent failure of the government to support industry in meeting the economy-boosting export demand for Australian complementary medicines.

Unfettered decision-making powers relating to industry access to ingredients and indications

The proposed framework provides that the Secretary (TGA delegate) has powers, upon the Secretary's own initiative, to make high-impact regulatory decisions relating to the approval of (or non-approval), banning of, and restrictions for listed medicine ingredients and indications, without adequate checks and balances (without regard to any specified criteria or considerations; without consultation with any specified persons) or right of reply (without the Secretary having to supply reasons and without a mechanism to appeal). The proposed provisions have gone further in specifying that the Secretary, in making these decisions, does not have limits as to the matters that may be regarded. CMA does appreciate that persons have been provided a separate and useful function to be able to request changes. However, it is a paid application that is not an appeal mechanism for and is a separate process from the Secretary's "own initiative" powers. To provide the Secretary with wide-ranging and unaffected powers to cause a significant impact upon the complementary medicine industry is not acceptable. Unfettered decision-making powers are not procedurally acceptable in any scenario, and the complementary medicine sector is one that some individuals hold bias against.

Requirement for crossover products (those with both intermediate and lower indications) to comply with efficacy requirements for the whole product when it is only suitable for intermediate risk indications.

The TGA is currently proposing that any product that has a TGA pre-assessed and ingredient-linked indication for the purpose of public health benefits (with approved restricted representations such as folate and neural tube defects), must be moved into the intermediate pathway because the indications are intermediate level. However, the draft Bill has prescribed that the entire medicine must conform to the 26A efficacy requirements for its therapeutic purpose. The result of this situation affects hundreds of products, which not only include the TGA pre-assessed indication but that also contain many other low level indications for which efficacy data is not available. This will cause a large proportion of these (public health benefit) indications to be removed as they will not be able to pass the prescribed test for their other indications. This will result in a significant reduction of health messages around things such as neural tube defects, osteoporosis etc. It will result in an inconsistent and confusing public health communication to consumers who will not be aware of the regulatory anomaly. It will also result in problems for pharmacists, retailers and health professionals who must compensate for inconsistent labelling and unexplained labelling changes. Finally, it will additionally result in a quality divide between products with the same ingredient where the intermediate pathway approval has been subject to additional quality requirements for that ingredient for which the lower pathway ingredient has not.

It is possible to make minor amendments to the draft Bill so that the lower pathway allows for TGA pre-approved indications that refer to reduction of risk of some forms of serious conditions in

relation to an ingredient under certain circumstances. CMA submits that this is the most desirable outcome for the public, the industry, and TGA resources. Sponsors will still have the option to utilise the intermediate pathway where they have the efficacy data to do so and wish to seek the additional recognition that the new pathway provides.

Please find specific commentary and suggestions to items in the draft Bill below.

Schedule 2 – Indications and Ingredients for Listed Medicines

Item 2

Paragraph 26A(2)(fe) - indication requirements must be fairly decided.

Paragraph 26A(2)(fe) – where there are requirements attached to indications that cannot be contravened by this part, it is necessary that the decision of the Secretary to apply those attached requirements is an adequately consulted or appealable decision.

- *Suggested Action*

Only include 26A(2)(fe) if the application of indication restrictions on behalf of the Secretary can be subject to a fair decision-making process: refer to further suggestions below relating to the discussion for 26BF within this submission.

Item 3

Opposed to proposed 26A(2)(j) – that evidence for claims on the Register cannot be required because claims cannot be included on the Register.

Paragraph 26A(2)(j)(i) relates to the requirement of a sponsor to hold evidence for any claim that is not an indication and is included on the Register.

There is no proposed mechanism (or intention to add a mechanism) by which to add claims that are not indications onto the Register - noting that 26BF only permits a determination to be made in relation to indications, and not claims.

Claims that currently exist on the Register are subject to a required phase-out due to the introduction of the 26BF determination. Where these existing claims are used in product advertising they are already subject to the advertising requirements: to be able to provide information or evidence to verify those claims.

The only other place it would be possible to suggest a claim is in the product name, but this is also subject to advertising requirements due to its presence on the label.

- *Suggested Action*

Proposed paragraph 26A(2)(j) should not be included.

Item 15 (related to Item 3 above)

Opposed to proposed 28(6) and (7) – that evidence for *claims* which are not indications must be held in accordance to an evidence guideline that specifically only relates to *indications*.

The conditions of listing described by the above subsection, that sponsors must hold evidence for claims that are not indications, in accordance with a proposed new legislative instrument that will capture the evidence guidelines for listed medicines, is not a logically valid proposal. The existing evidence guidelines are specifically and only in relation to therapeutic indications. They cannot be applied to non-indication claims, unless the evidence guidelines are subject to a complete rewriting, a process that has not been discussed or consulted with stakeholders.

Claims which are not indications are either factual statements or are advertising/marketing claims or both. They will not be able to be included on the Register in relation to listed medicines, and therefore it is only appropriate that these claims are covered by advertising provisions. Existing and proposed advertising provisions adequately cover these claims.

The proposed subsections are not only superfluous due to the advertising controls but are also impossible to implement under current evidence guidelines. CMA agrees it is logical to repeal the existing 28(6) and (7) of the Act, however there is no necessity to replace them as the situation is sufficiently covered by permitted indications and advertising provisions.

- *Suggested Action*

Repeal existing subsections; do not replace.

Items 4, 5, 16 and 18 – Evidence requirements for indications

Opposed to 26A(2B) – A legislative Instrument for evidence guidelines has not been agreed upon in consultation.

The insertion of 26A(2B), the provision of a legislative instrument to specify requirements relating to information or evidence for indications, has previously only been agreed to as a guideline and not as a legislative instrument.

CMA has previously expressed concerns with the requirements contained within the current evidence guidelines, which bear similarity to those for registered over-the-counter medicines. The requirements are disproportionate for low-risk listed medicines that may only make limited health claims, and in their current form it is not appropriate to underpin them in legislation.

It is also worth noting that the TGA's current suggested format requirements for evidence are very lengthy forms that do not provide significant clarity over sponsor developed formats. The suggested forms have been found to take up to 4x longer to prepare and express the same information, which places a significant and unnecessary burden upon sponsors and similarly should not be underpinned in a legislative instrument.

- *Suggested Action*

Proposed subsection 26A(2B) should not be included.

Item 6

Requires modification – the proposed implementation of the Secretary's power to create ingredient restrictions and controls without sufficient checks and balances.

Paragraph 26BB(2A) proposes that particular ingredients included in a 26BB determination may be required to be contained in particular medicines only under specified circumstances.

CMA agrees in principle with the provision, but not with the implementation.

Paragraph 26BC of the Act provides that a 26BB determination may be varied at the Secretary's own initiative. Paragraphs of 26BB including 26BB(2A) above relate to restriction and controls over the use of ingredients within the entire class of listed medicines.

Where the Secretary has decided to vary a 26BB determination under paragraph 26BC, there is no mechanism to make a submission prior to the decision, or to appeal a decision, or for any other party other than the Secretary to consider the matter. In addition, there are no specified requirements that the Secretary must take into consideration when making a 26BC decision. This significantly increases the potential regulatory impact of 26BB(2A) above.

CMA appreciates that persons have been provided the ability to make ingredient applications under 26BE, but notes it is a separate process that does not constitute a natural justice provision to the Secretary's 26BC powers. Applications by a person under 26BE are not intended to be, nor are they, a suitable appeal mechanism for the Secretary's decisions under 26BC.

A comparative example of where restrictions and controls over ingredients in medicines is made by the Secretary's own initiative is 52D(3) of the Act which relates to the Poisons Standard. Here, adequate natural justice provisions have been included. Such decisions must be made with regard to considerations outlined in 52E, including matters relating to the appropriate use of medicines, and with the Secretary taking the advice of a specified committee. Whilst CMA is not necessarily

suggesting the use of a committee for 26BB decisions, the issue remains that there are not sufficient checks and balances in relation to the wide-ranging influence of the powers under 26BC of the Act, including the power to make ingredient restrictions in the newly proposed 26BB(2A).

- *Suggested Action*
  1. Add a provision requiring a targeted consultation as part of 26BC where the Secretary proposes decisions that have a regulatory impact, specifically:
     a. ingredient removals;
     b. ingredient restrictions.

  2. Add a provision that the 26BE applications can be used as a mechanism to request a reconsideration of a decision made under 26BC, in circumstances where the decision has resulted in the removal of or the restriction of an ingredient. As it would relate to a situation where it is thought that a decision by a delegate was not adequately considered, there should not be a fee associated with this type of application.

Items 9 and 10

Opposed to the implementation of the power under 26BE(2B) to lapse 26BE new substance applications for the specified reasons.

Considering the considerable expense of an application under 26BE, CMA is concerned about the addition of the clause under proposed 26BE(2B) to allow an application to lapse due to the requirement to provide information of a kind that is unspecified within existing or proposed 26BE paragraphs. There is no clarity around what the definition of lapsing is and what effect it has upon the application, whether it is indefinitely paused or whether it is deemed invalidated. For example, by common definitions lapsing could be taken to mean 'pausing', it can also mean 'the expiration or invalidation of'.

(Note: CMA supports TGA's ability to stop the evaluation clock where necessary.)

There are no checks and balances or right of reply as to whether the kind of information being requested is reasonable or sufficiently relevant to the application. In other places in the Act where reasonable time-frames are requested to supply information, it is in relation to information that a sponsor should already hold about a medicine. In this instance, the kind of information that is being requested is in relation to a proposed new ingredient; therefore, it may need to be sought out. There is very little reassurance as to whether it can be provided in such a period that the Secretary provides as reasonable, and the consequence of failing to provide such information in such a time is severe if it is the invalidation of a highly expensive application.

If the applicant is subject to requests for further information, where failure to respond to those requests has the ability to lapse their application, they must have the right of reply where that applicant has reasons to believe that the information requested isn't necessary for the Secretary to be satisfied that the recommendation can be made. A relevant similarity in the Act is a request for information under s.31, which is an appealable decision.

Therefore, CMA believes that the proposed paragraph 26BE(2B) must be better defined, or must not be included in the Act if it means that an application is essentially invalidated. The section must be amended to allow for the resumption of a lapsed application where new or additional information becomes available. Due to the unchanging nature of ingredients and the time periods involved in scientific studies, CMA suggest that a significantly lengthy period is provided in which to allow for the resumption of a lapsed application.

- *Suggested Action*
  1. Define the term 'lapsing' and its effect upon an application.

  2. Provide a right of reply mechanism where the applicant feels the information is not necessary or relevant to the recommendation.

  3. Provide for the resumption of lapsed applications at no additional fee where relevant information becomes available.

In relation to the Explanatory Memorandum and 26BB, 26BC, and 26BE generally.

Page 6 of the Explanatory Memorandum describes the MMDR recommendations 15 and 17, that the TGA make greater use of assessments from comparable overseas regulators in assessing medicines and medical devices, while continuing to be responsible for final regulatory decisions. It goes on to say that whilst the changes have been made for medical devices, that it was not needed for medicines because it is already compatible with provisions in the Act relating to medicines. This may be true of certain registered medicines but is not true of ingredients used in listed medicines. Comparable overseas regulators such as Health Canada have very relevant assessments relating to complementary medicine ingredients and the ability to utilise them has not been referenced anywhere in 26BB, 26BC, or 26BE. Therefore, reports of overseas regulators are unable to be used to minimise the regulatory burden on the regulator and the industry, and the MMDR recommendations have not been adequately met in our view.

CMA strongly recommends that provisions are included to enable the Secretary to utilise the work of comparable overseas regulators in assessing new complementary medicine substances for inclusion in the legislative instrument under 26BB.

- *Suggested Action*

Include provisions into 26BB, 26BC and 26BE that assessments of comparable overseas regulators can be used to influence and inform new ingredient approvals.

Item 14

"Serious form" must be defined for 26BF(2)(d)

In relation to 26BF(2)(d): there is no associated definition as to what a 'serious form' of a disease, ailment, defect, or injury means. Without definition, there is no clarity and no legislative agreement as to the interpretation or exactly how the Secretary must exercise the powers in relation to deciding to make a particular indication available. CMA suggests that a definition must be included and be clear and unambiguous, to ensure that the test to be applied is sufficiently objective as to be reasonably applied by both industry and the TGA.

- *Suggested Action*
  1. Define 'serious form' as a disease, ailment, defect or injury that is generally accepted to require ongoing treatment and regular evaluation by a healthcare professional; and
  2. Clarify that 'Serious form' does not include a disease, ailment, defect or injury that is generally accepted to be suitable to be self-managed and/or symptomatically treated after an initial diagnosis (or without a diagnosis) by a healthcare professional.

In addition, for reasons outlined in our summary introduction and in relation to the discussion regarding 26BJ(3) and Schedule 5 26AE(1)(c) below, it is imperative that groups of medicines that include indications with ingredient-linked public health interest indications are not mandatorily required to transition into the intermediate pathway where there exists requirements that cannot be met for all ingredients. The most functional scenario is to allow for the Secretary to pre-approve indications under particular circumstances where those indications are beneficial for public health interest within a self-medication format. Failure to do so will result in many medicines staying in the lower pathway but losing the indication, which will cause public and health professional/retailer confusion and a quality divide between medicines with the same ingredients (because higher requirements are likely to be attached to intermediate medicines). If medicines are allowed to remain in the lower pathway the same quality requirements can be attached with a condition of listing (like *Ginkgo biloba*), but the public health risk of consumers being confused, inadequately informed, or choosing a cheaper medicine because it has the same ingredient (but without realising it is not of the same quality) is eliminated.

- *Suggested Action*
  3. Add a paragraph (e): "*an indication that refers to the reduction of risk or alleviation of a serious form of a disease, ailment, defect or injury, where the indication has been*

approved by the Secretary for purposes of subsections 26BH or 26BJ under prescribed circumstances."

Opposed to the implementation of 26BF(3), 26BH, 26BG, 26BF(4) and 26BJ(13)

CMA is very concerned about the addition of paragraph 26BF(3) that provides the Secretary with unlimited matters with which to regard, and therefore unlimited powers, to make a decision on whether to approve a new indication or not. Considered in light of the matter outlined above for 26BF(2)(d), there is a concurrent situation where there is a significant lack of clarity on what is acceptable and unlimited powers of behalf of the Secretary's delegate. The proposed powers with regard to unlimited matters are also proposed in 26BJ(13).

There are significant concerns with the provision of 26BH that provides the Secretary with unaffected powers to not approve indications under 26BF(2) / (3), to restrict them under 26BF(4), or to specifically ban them under 26BG. Allowing the Secretary to make unilateral decisions about the above has not taken into consideration the negative impact these powers could have upon industry if applied injudiciously or with bias that does not account for accurate consideration about the effect of an indication in the self-medication space. Natural justice considerations and the limitations on the ability for individuals within a government organisation to hold unilateral decision-making powers are traditionally built into legislative Acts because decisions might be made under some circumstances where there is conscious or unconscious cognitive bias in a delegate or where an adequate reasoning process has not been conducted.

It is worth noting here that paid applications by a person under 26BJ are not intended as nor are they a suitable appeal mechanism where non-reasonable or unfairly applied decisions have been made under 26BH for purposes of 26BF and 26BG. However, if specifically stated in the Act and not accompanied with a fee, they could be used as a de facto mechanism to request the review of a decision where a person feels that the reasons for the decision were not adequately considered.

CMA provides that there are significant problems with the proposed scenario; in summary, that the Secretary can ban, refuse to approve, or restrict certain indications without regard to any criteria, or any checks or balances such as consultation or committee, or any right of reply, without even the ability of affected parties to be provided reasons for the Secretary's decision or to submit for a reconsideration of the decision.

- *Suggested Action*
  1. Add a requirement for a targeted consultation as part of 26BH where the Secretary proposes decisions that have a regulatory impact, specifically:
     a. indication removals
     b. indication restrictions.

2. Add a provision that the 26BJ applications can be used as a mechanism to request a review of a decision made under 26BH, in circumstances where the decision has resulted in the removal of or the restriction of an indication. As it would relate to a situation where it is thought that a decision by a delegate was not adequately considered, there should not be a fee associated with this type of application.

Opposed to proposed 26BJ(2)(a), that an indication application must be in a specified form.

As described in the paragraphs above, there is not sufficient interpretation or criteria set for the decisions to be made for the purposes of 26BF. The application form that is currently proposed by the TGA contains matters that relate to policy and not to legislation. The legislation is not sufficiently clear to set criteria within a form. It is not acceptable that a form can be prescribed under legislation where that form refers to policy criteria and not to legislative criteria, when the applicant's paid application can be rejected upon the basis of the policy content of that form.

In addition, there is no reason an applicant shouldn't be able to provide an application in their own format rather than the suggested format, if they feel it is a better format for their submission.

- *Suggested Action*

Remove proposed 26BJ(2)(a).

Amendments required to proposed 26BJ(3), (4) and (5), in particular paragraph (d)

Paragraph (d) provides that an application cannot be made for an indication that refers to "preventing" or "alleviating" any disease, ailment, defect or injury. Paragraph (d) is in direct contradiction to paragraph 26BF(2) which allows for indications to be made in relation to therapeutic use in relation to a disease, ailment, defect or injury, other than a serious form.

a. 'Alleviating' a disease, ailment, defect or injury precludes any therapeutic use that is not maintaining or enhancing health. This is not in the spirit of allowing indications for use on medicines, even low risk medicines. As stated above it is also inconsistent with 26BF(2).

b. 'Prevention' may be interpreted to include 'reduction of risk', but reduction of risk is an acceptable claim that is available for use for listed medicines. Prevention of non-serious conditions and reduction of risk of conditions are appropriate for low risk medicines.

In addition, subsection 26BJ(5) refers to a serious form of a disease (cancer), therefore the inclusion of serious forms must be added to (d) for clarity.

If there are public health related exemptions for listed medicines and the prevention of skin cancer, then also allow for public health related exemptions for the prevention (or reduction of risk) of TGA accepted restricted representations such as neural tube defects and osteoporosis. These are currently allowed for certain ingredients in listed medicines. Just like sunscreens, it is not necessary to move these products into a higher category of medicines with a significantly increased regulatory burden where the TGA has already pre-approved indications with consideration of the available scientific evidence and public health criteria. Allow for others that may become relevant (e.g. antibiotic-associated diarrhoea). This approach is also harmonious with a functional framework for MMDR recommendation 46 relating to monographs which is due for consideration in the third Bill.

Comments below on paragraph 26AE(1)(c) are also relevant to this consideration.

- *Suggested Action*
  1. Amend paragraph as follows: "*unless subsection (5) applies – an indication that refers to curing a disease, ailment, defect or injury, or to preventing a serious form of a disease, ailment, defect or injury".*

  2. Definition of 'serious form' would be applicable as outlined above for 26BF(2)(d) and 26BJ(9). This incidentally enables the removal of prevention of dietary deficiency from 26BJ(5)(a).

  3. Include an exception clause for 26BJ(3)(b) – restricted representations – in the same way as paragraphs (c) and (d). Include neural tube defects and osteoporosis as exceptions, which are indications connected to certain ingredients in the 26BB determination.

  4. Make an additional paragraph in subsection 26BJ to allow the ability to make an application for an indication that includes an exception, and make it a requirement for the applicant to provide a rationale based on public health interest criteria in order for the exception to be allowed in certain circumstances.

Opposed to implementation of lapsing as proposed in 26BJ(6), (7) and (8)(c)

CMA is opposed to the 26BJ(7) lapsing of a paid application for a recommendation for the same considerations outlined for 26BE(2B) above.

Similarly, applicants that are subject to 26BJ(6) requests for further information, where failure to respond to those requests have the ability to lapse their application, must have the right of reply where that applicant has reasons to believe that the information requested isn't necessary for the Secretary to be satisfied that the recommendation can be made. A relevant similarity in the Act is requests for information under s.31, which is an appealable decision.

(Note: CMA supports the TGA's ability to stop the evaluation clock where necessary.)

- *Suggested Action*
  1. Define the term 'lapsing' and its effect upon an application.

  2. Provide a right of reply where the applicant feels the information is not necessary or relevant to the recommendation.

  3. Provide for the resumption of lapsed applications at no additional fee where relevant information becomes available.

Amend proposed 26BJ(9)

For 26BJ(9) discussion, please refer to the concerns discussed in our introductory statement and in relation to 26BJ(3) and 26BF(2)(d), both above, regarding the appropriateness and necessity of the TGA allowing pre-approved indications under certain circumstances in 26A listed medicines.

- *Suggested Action*

Add to 26BJ(9): "*an indication that refers to the reduction of risk or alleviation of a serious form of a disease, ailment, defect or injury, where prescribed circumstances make it acceptable for use as a self-medication that benefits public health*."

Item 17

Move items (fba), (fd), and (fe) from 30(1)(e) to 30(2)(ba)

The item proposed by item 17 provides that the Secretary can cancel a listed medicine under 30(1)(e) and therefore without consideration of subsection 30(3) – a proposal to cancel – in the situation where the sponsor has made an indication on the label or the Register that is not in the 26BF determination or does not comply with the requirements thereof.

Sponsors should always be afforded sufficient procedural fairness in the event that it is alleged they are making indications that are not in the 26BF determination. This is particularly the case because the TGA has provided that "words to the effect" will be allowed for indications, but has not provided any criteria or guidance as to what "words to the effect" means. It is not a safety/QUM issue unless a prohibited or restricted representation is made, and therefore it does not warrant such an extreme level of regulatory oversight such that the sponsor's right to make a submission under 30(3) is removed.

The CMA also has concerns that the "words to the effect" issue may not have been adequately considered for the advertising penalties and sanctions described in Schedule 6 where the sponsor advertises an indication not accepted on the Register.

Where a sponsor makes an indication that is a prohibited or restricted representation and it is not an allowable indication, that would be sufficient grounds for cancellation under 30(1)(e) and the provisions should be amended to reflect that this is the only scenario where it is appropriate to cancel under 30(1)(e).

- *Suggested Action*

Paragraphs relating to 26A(fba), (fd) and (fe) should be moved to 30(2) to be commensurate with the level of risk it poses (unless a prohibited or restricted representation is included, which would be a different drafted provision).

Item 23

23(9) refers to 26AB(1)(g) which appears not to be drafted

Item 23(9) refers to 26AB(1)(g) which appears not to be in the existing Act or in the draft Bill, which ends at 26AB(1)(f).

Schedule 3 – New Pathway for Listed Medicines

Item 4

Requires clarity for 26AB(1)(d), why medicines cannot be listed under 26A.

26AB deals with the legislative framework application requirements for medicines that have low risk ingredients with intermediate risk indications. It is not clear from 26AB(1)(d) that the differentiation is in relation to indications only. Also, as discussed in items above relating to the permitted indication determination, the line between the two pathways has not been appropriately delineated in the drafting.

- *Suggested Action*

Amend the provision so it is clear that the medicine cannot be listed under 26A because it does not conform to the provisions of 26A for one or more indications that is proposed for the medicine.

Requires clarity for 26AB(2)(a) that medicine is eligible in relation to 26AE.

26AB(2) relates to the certifications that sponsors must make in order to include an evaluated medicine in relation to 26AE. The certification described in (a) is that the sponsor must certify that the medicine is eligible for listing, but there are now two pathways for listing and the medicine will only be eligible for one. Therefore the sponsor will be making an incorrect certification.

- *Suggested Action*

Amend the provision so it says that the medicine is eligible for listing in relation to 26AE.

26AE and related provisions do not include provision for a claimer.

The TGA and industry have agreed that medicines listed under 26AE of the Act will be allowed to have a claimer to the effect that the medicine has been evaluated. There is no provision that we can see within 26AE or related provisions that allow for the claimer as per the agreed position.

- *Suggested Action*

Add a provision to 26AE to allow for a claimer.

26AD definition of 'lapsing' and what effect it has on the evaluation not adequately described.

Paragraph 26AD(1) describes the lapsing of an application under certain circumstances but there is no definition or clarity as to what lapsing means in relation to the application, specifically what effect it has upon the application. For example, by common definitions lapsing could be taken to mean 'pausing', it can also mean 'the expiring of'.

(Note: CMA supports TGA's ability to stop the evaluation clock where necessary.)

- *Suggested Action*
  1. Define the term 'lapsing' and its effect upon an application.

26AE(1)(c) must only be in relation to indications that are not eligible for inclusion in the permitted indications determination.

Paragraph 26AE(1)(c) describes that efficacy must be established for the purposes for which the medicine is to be used, but has not taken into account that, while efficacy can be established for all indications where available, *it is only a risk-commensurate requirement that efficacy is established for certain (intermediate) indications*.

The only proposed difference between 26A listed medicines and 26AE evaluated medicines is the strength of indication (low level or intermediate level), but the format and formulation of the medicines in all other respects are to be the same. By nature many complementary medicines have a range of therapeutic uses, many relating to health enhancement, as well as multiple ingredients that further broaden the range of use. There are and will be many 'crossover' medicines that have both intermediate indications (suitable for efficacy assessment in the intermediate pathway) as well as low level indications for which it is not feasible to be assessed at the efficacy level unless a clinical trial has been conducted on the whole formulation. The TGA is currently requiring that a wide range of existing medicines that have only one intermediate indication (such as folate and neural tube defects) are transitioned to the intermediate pathway on the understanding that low level indications are assessed, but only at the appropriate low level requirement, and not at the level required for intermediate level indications. To mandate otherwise would be to create 'red tape' requirements that are not commensurate with the level of risk posed by those indications.

- *Suggested Action*
  1. *Where the intermediate indications have been pre-approved by the TGA and linked to an ingredient in 26BB.*
     In the situation where the TGA has pre-approved indications for public health benefit under certain circumstances, CMA has already outlined in this submission that as the

indications are already pre-approved because of TGA evaluated evidence, they should remain in the lower pathway.

2. *Where the efficacy evaluation relates to ingredients of the medicine.*
   If number one does not occur, and in the case of other medicines with some intermediate and some low level indications, 26AE(1) must be amended so that efficacy requirements only relate to indications which are not eligible for inclusion in the permitted indications determination or have not been pre-approved by the Secretary. (Noting here that the eligibility for inclusion must be clearly defined as previously discussed.) Efficacy evaluations can be applied to low level indications if that information is available (see next point), but it should not be mandated where it is not commensurate with risk.

3. *Where the efficacy evaluation relates to a clinically trialled whole formulation.*
   In this instance it is appropriate for the efficacy requirements to apply to the whole medicine irrespective of whether indications are lower or intermediate level.

26AE(1)(d) Matters which the Secretary considers relevant must be reasonable.

As the matters referred to in paragraph 26AE(1)(d) are undefined and unprescribed, it is necessary for the due consideration of an applicant's appeal rights that the matters considered are reasonable to the evaluation of the medicine.

- *Suggested Action*

Insert 'reasonable' so that paragraph 26AE(1)(d) reads:

"*..the Secretary must evaluate the medicine having regard to: …, (d) such other <u>reasonable</u> matters (if any) as the Secretary considers relevant*."

Schedule 4 – Preliminary Assessment of Applications

Part 1 – Therapeutic Goods

Item 6

Opposed to 23C(2)(e) – samples unable to be delivered

Paragraph 23C(2)(e) proposes that where the Secretary requires, an applicant for a listed (lower pathway) medicine must provide samples of the goods in order to pass preliminary assessment. The application and listing of goods is in almost every case conducted prior to the manufacturing and packaging and labelling of the goods: it is not feasible to enter into full production of goods that do not already have an approved 26A listing on the Register. Sponsors will not be able to provide samples and consequently would be prevented from listing medicines.

Where the Secretary requires samples of a listed medicine, it can continue to be done after the medicine is listed onto the Register (and the medicine has been manufactured) under the provisions of section 31 of the Act.

- *Suggested Action*

Proposed paragraph 23C(2)(e) must be removed.

Consultation required regarding proposed 23C(3)

Any such legislative instrument proposed under 23C(3) for the types of information that must be included in a form for an application for a listing of a medicine under 26A must be consulted with industry to determine whether the content has a regulatory impact in comparison to the current listing form. If such a legislative instrument were to be created, changes that have an impact on sponsors should also be subject to a targeted consultation.

Schedule 6 – Advertising

CMA agrees in principle with most of the proposed advertising amendments, but has identified some following issues. Not all issues may have been identified due to the short consultation period.

Item 35

Paragraphs 42DL(9) and 42DLB(6) must be amended to allow for 26AE medicine claimer.

Paragraphs 42DL(9) and 42DLB(6) relating to advertising offences and penalties is as follows.

> 'This subsection applies to the advertisement if it contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than:
>
> (a) a statement of the availability of the goods as a pharmaceutical benefit; or
>
> (b) a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority); or
>
> (c) a statement, pictorial representation or design prescribed by the regulations for the purposes of this paragraph.'

The TGA and industry have agreed that medicines listed under 26AE of the Act will be allowed to have a claimer to the effect that the medicine has been evaluated (wording yet to be decided). Such a claimer, although authorised by the TGA, will breach paragraphs 42DL(9) and 42DLB(6) in their proposed forms.

- *Suggested Action*

Include an exclusion paragraph for these items to the effect of "*other than a reference authorised or required by a government or government authority*".

Item 38

42DR(3) should be extended to 20 days

42DR(3) provides that an advertiser is given not less than 14 days to respond to a notice requesting specified information or documents relating to an advertisement.

Considering there are many small enterprise sponsors (even sole traders), and that a period of leave or travel is frequently 1-3 weeks, and that there are serious offences and penalties attached under 42DS, 14 days is not a reasonable period.

- *Suggested Action*

Amend the minimum period in 42DR(3) from 14 days to 20 days.

In relation to advertising powers over generic advertising

The new advertising provisions provide significant powers over the advertisers of generic information. It is understood that the likely intention is to capture problematic medicine/device sponsors that attempt to circumvent other advertising provisions. However, CMA notes that these powers could be applied to persons who are exercising their freedom of speech whilst going about their business in a manner that does not relate to the sale of medicines or medical devices. For example, herbalists in the act of sharing generic herbal information that they have genuine cause to be interested in and wish to participate in public education or free speech about, including their personal businesses that may involve web blogs, etc.

CMA would suggest that the human rights analysis is re-examined in detail in regard to this issue. Amendments should be made in relation to these provisions with consideration of such individuals who are conducting free speech in a lawful fashion and without prejudice to the sale of manufactured therapeutic good products.