AVICENNA
CONSULTING

AVICENNACO.COM.AU

INFO@AVICENNACO.COM.AU

PO BOX 2081

WODEN ACT 2606

TGA Consultation

Business process improvements supporting complementary medicines assessment pathways

30 October 2017

Dear Complementary Medicines Reform Section

Thank you for providing industry with the opportunity to comment on what will arguably be the largest reforms to the Australian complementary medicines framework in recent history.

We appreciate that a significant amount of work has gone into the drafting of these business improvements and thank the TGA's staff for their efforts.

Although generally supportive of the reforms, Avicenna Consulting will raise serious concerns about the proposed fees and the approach to introducing these new fees. We will also raise minor points for clarification.

Given the serious implications of the proposed fees for our clients – particularly our smaller business clients - Avicenna Consulting strongly recommends that the TGA reconsider the proposed fees. Failure to do so is likely to threaten the ability of some sponsors to conduct business in Australia.

Avicenna Consulting notes that the TGA is working to tight timeframes which will inevitably impact the way in which submissions are considered and actioned. For example, we note that the Exposure Drafts for the Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 and Therapeutic Goods (Charges) Amendment Bill 2017 were only opened for consultation for less than three business days. This is concerning particularly considering the long-term impact of these changes.

In the best interests of our clients, Avicenna Consulting will provide this submission to the Hon Greg Hunt MP, Minister for Health and request that adequate time is given to address these concerns.

The Board
Avicenna Consulting Pty Ltd
30 October 2017

Submission

Avicenna Consulting Pty Ltd

Background

Avicenna Consulting was born from the belief that sponsors needed frank, clear, and timely advice about the regulation of listed and complementary medicines. Our number one priority is to provide professional and courteous services to help sponsors maintain compliance with legal obligations and bring only the highest quality medicines to domestic and international markets.

With expert knowledge of the current regulatory requirements and the changes to the legislative framework that will affect the industry in the coming years, Avicenna Consulting is here to provide a responsive regulatory advice service unlike any other.

We offer our regulatory consulting services to new and existing sponsors, industry associations and regulators who seek risk-based, strategic advice.

Objectives

Avicenna Consulting provided comments in the context of the objectives listed on page 6 of the TGA's consultation paper, which stated that that objectives of these reforms are to:

1. Provide an appropriate benefit/risk model for the evaluation of complementary medicines.
2. Reduce duplication of regulatory effort through use of evaluation reports from overseas regulators of equivalent standard.
3. Improve the quality of complementary medicine applications.
4. Improve flexibility for applicants about the types of information that can be used to support pre-market applications.
5. Improve the efficiency of complementary medicines evaluations.
6. Provide consumers with timely access to high quality, safe and effective complementary medicines.
7. Deliver appropriate cost recovery of complementary medicines regulation.
8. Provide greater transparency and predictability of the regulatory process for all stakeholders.
9. Avicenna Consulting supports these objectives and has provided the following comments to help to achieve these aims.

Key Concern: Fees

Avicenna Consulting is supportive of changing the fee structure from one based on page-count to one based on risk-categories. However, we are seriously concerned about the fees being proposed by the TGA.

We categorically reject the TGA's stagged process for introducing new fees. Australian businesses should not be penalised with higher than necessary fees due to TGA's inability to accurately collect data or gauge the amount of work required to evaluate medicines in these new categories. If the TGA's aim is to test the time taken to evaluate medicines in the new categories, then there are alternative options which can be considered. For example, the TGA can implement a transition period where applications are evaluated via the new categories while fees continue to be charged based on page count until the required data is obtained. This is a far more favourable outcome than just increasing fees and hoping for the best.

The TGA has claimed that

> *"The fees have been designed to reflect the amount of work required to complete the relevant applications and evaluations, based on the circumstances of the different application categories and the complexity of documentation associated with them."*[1]

It is therefore unfathomable that the TGA would consider it appropriate to charge the same fee across different risk categories involving a different amount of effort and weeks and weeks of difference in work. For example, the TGA has proposed a fee of $15,050 for IN1 and IN2 despite the evaluation times being 70 and 120 days respectively. Although we recognise that these timeframes do not reflect the actual days of work taken for each application, it cannot be possible that the evaluation of an international report will take the same amount of actual work as a partial *de novo* assessment. Therefore, the same fee should not be charged across categories under any circumstances.

It is our view that the proposed fee structure fundamentally contradicts the TGA's cost-recovery model which is based on actual work effort – not as a way to guess said effort.

Additionally, given the increase in fees, the TGA's proposal implies that the evaluation of applications through new categories based on international evaluation reports will take longer than current evaluations and require higher fees. In our view, these fees contradict objective 5 (improve efficiency of complementary medicines evaluations) and objective 7 (deliver appropriate cost-recovery) of the reforms. If this process aims to reduce the duplication of work effort and reduce evaluation times, the lower-risk application categories should take less time and therefore cost less than current evaluations.[2]

We also note that the evaluation fees are highly inconsistent. For example, a C4 evaluation would cost a total of $9950 and would consist of 170 days of evaluation time and the assessment of safety and/or efficacy

---

[1] *Consultation: Business process improvements supporting complementary medicine assessment pathways*, TGA, September 2017, p 25.

[2] Although not officially reported in TGA's last *Annual performance statistics report: July 2016 to June 2017,* our clients indicate that the current average evaluation times for ingredients can range from 12-18 months.

data.[3] It is therefore unclear why an L(A)2 which is assessing an international evaluation report of efficacy should cost $15,160 (with 60 days assessment time) and the assessment of an international evaluation report of safety and quality via IN1 should cost $15,050 (with 70 days assessment time). The fees, timeframes and reasoning are illogical and inconsistent, and we are at a loss as to how we should explain these fees to our clients. This lack of transparency and predictability also contradicts objective 8). When lining up the fees based on timeframes, they become even more confusing, as shown below:

Category	Time	Cost ($)	Evaluation
C1	20	1,380	Nil
L(A)1	45	2,070	Clone
RCM1	45	3,590	Clone
L(A)2	60	15,160	International report
C2	64	4,690	Quality
IN1	70	15,050	International report
RCM2	90	22,410	International report
IN2	120	15,050	Quality
C3	120	6,970	Quality, safety and efficacy
IN3	150	25,670	Safety
L(A)3	150	15,160	Efficacy
RCM3	150	22,410	Quality and safety/efficacy
C4	170	9,950	Safety and efficacy
IN4	180	25,670	Quality and safety
RCM4	180	30,330	Two of safety, quality or efficacy
RCM5	210	38,270	Safety, quality and efficacy

Our clients have raised serious concerns about their ability to bring new products to the Australian market through these new categories, with cost being the number one prohibitive factor. Our clients were looking forward to reduced evaluation times associated with the use of international evaluation reports and what they hoped would be a decrease in cost.

We would like to take this opportunity to remind the TGA that these reforms are implementing recommendations from the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) which stem from the Government's 'Cutting Red Tape' deregulation agenda. These reforms were presented to business in the context of the Industry Innovation and Competitiveness Agenda which had the primary ambition of providing 'a lower cost, business friendly environment with less regulation,[4] lower taxes and more competitive markets.'[5]

A sharp increase in fees is not justifiable in this context, nor does it contribute to enhancing the industry's business practices and ability to remain competitive domestically and internationally.

In summary, we advise that the TGA seriously reconsider the proposed fee structure and implementation strategy in the interest of industry innovation and ensuring that Australians have access to new products.

[3] *Consultation: Business process improvements supporting complementary medicine assessment pathways*, TGA, September 2017, p 24.

[4] Of course, less regulation in this context means 'better regulation' as per the Australian Government Guide to Regulation.

[5] *Industry Innovation and Competitiveness Agenda: Action plan for stronger Australia,* Australian Government, p III.

Introduction of risk-based application categories

Use of domestic evaluation reports

The TGA has discussed the 'use of international evaluation reports' as a way to streamline evaluations. However, domestic regulators, such as Food Standards Australia New Zealand (FSANZ) or the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) have or will undertake assessment of the safety, quality or efficacy of ingredients that have the potential to be used in listed medicines. In keeping with objective 2 (reducing duplication of regulatory effort), we suggest that the TGA accept evaluation reports from domestic comparable regulators to allow for abridged assessment through the new categories.

Proposed application categories for assessed listed medicines

The TGA has not clarified how it will treat existing registered medicines which sponsors would like to move into the new pathway and whether these would be considered clones, generics or subject to full *de novo assessment*. Our clients would consider moving registered medicines which meet the criteria into the new pathway to reap the incentives of the claimer. Given that the TGA has already assessed these medicines for safety, quality, and efficacy and that the L(A) medicines would have lower-level claims, we propose that the TGA consider such medicines to fall within the L(A)1 category, as a second *de novo* assessment by the TGA does not seem to be appropriate based on risk and would contradict objective 4 (improving flexibility about the information that can support an application).

Proposed business processes & legislated assessment timeframes

Requests for information

The TGA is proposing that requests for information (RFI) will be limited to a single round. OTC medicines that are not generic medicines are allowed two RFIs. We propose that all complementary medicine categories be provided with two rounds of RFI to ensure that sponsors are given the opportunity to provide additional information and prevent the need for re-application wherever possible, keeping in line with objective 6 (timely access to complementary medicines), especially while the TGA adjusts to the new categories.

Legislated timeframes

The TGA should clarify whether ingredients which are approved for use in listed medicines can be used by sponsors at the decision phase or whether sponsors must wait for implementation in the Permissible Ingredients Determination. If sponsors can only use ingredients at implementation, we suggest that the TGA extend legislative timeframes to capture the point at which sponsors can use the ingredients or use an alternative mechanism to guarantee certainty about when ingredients will become available and improve predictability per objective 8 (providing greater predictability)

The TGA has suggested that pre-screen of ingredients and registered complementary medicines may take up to 25 days. This is an excessive number of days given that that pre-screen is assessing whether all the data required to complete an evaluation is present. It's unclear why the pre-screen of an ingredient involving safety and quality only should take as long as the pre-screen for an RCM5 requiring safety, quality and efficacy

data. In line with objective 5 (improve efficiency of complementary medicines evaluations), the TGA should consider reducing the maximum number of evaluation days for a registered complementary medicine to 10 days and reducing the maximums for other categories respectively.

Criteria and mechanisms for acceptance of reports from comparable overseas regulators and alternate sources of evidence for de novo assessments

Submission of original data

The TGA has not stated whether the dossier provided to the comparable regulator will need to also be submitted to the TGA per Recommendations 36 and 40 of the MMDR.

Justification & additional data

The TGA has stated that consideration will be given to accepting reports from comparable overseas regulators that may not meet all criteria, provided the applicant can provide adequate justification or additional data as required.[6] The TGA should clarify whether these medicines will continue to be evaluated through the lower risk categories to ensure clarity for sponsors per objective 4 (improving flexibility of types of information to support applications) and objective 8 (providing greater predictability).

Criteria for regulators

We note that criteria 1 for the regulators is that they have a track record for approving (emphasis added) '**low risk** food, chemical or medicinal substances'.[7] We suggest that any regulator with an established track record for approving these substances be permitted.

Strategies to enhance post-market monitoring and compliance scheme for listed medicines

Sponsor education

We are very supportive of any initiatives to increase sponsor understanding of their regulatory requirements following these changes. We welcome the suggestion of regular sponsor training days post-implementation of the reforms.

[6] *Consultation: Business process improvements supporting complementary medicine assessment pathways*, TGA, September 2017, p 17.

[7] Ibid.