Transparency review of the TGA

Terms of Reference

The panel will consider and report on:

- The current arrangements for disclosure of information or advice in relation to all therapeutic goods currently on the market in Australia or previously approved for marketing in Australia;
- Opportunities for increased provision of public information on therapeutic goods currently on the market in Australia or previously approved for marketing in Australia;
- Opportunities for improved public understanding of the procedures for ongoing monitoring of products already on the market and the evaluation, assessment and testing of new products;
- The timeliness of the provision to the public of information regarding the evaluation, assessment and testing of new products;
- Any constraints on the release of further information, including possible implications for public health or safety, which might influence future arrangements;
- Arrangements for the public disclosure of information utilised by other comparable international regulators; and
- Opportunities to improve public access to information through enhancements to web-based and other information dissemination mechanisms.

Preliminary Outline Paper Requested

The Chair, Professor Dennis Pearce, has asked each stakeholder organisation to provide a brief perspective on the current arrangements for the disclosure of information by the TGA and a list of topics to be canvassed during the review (in order of priority).

Response

First of all, it is acknowledged that the TGA is making an effort to improve the transparency of a number of its processes and provide more information to assist consumers and health professionals. This is evidenced by the creation and publication of Australian Public Assessment Reports (AusPAR) for prescription medicines, the availability of approved Product and Consumer Medicine Information on the TGA main web site and access to ARTG information, including public summary documents, on the TGA’s eBS web site. In addition, the TGA’s new policy of publishing the outcome of “certain” investigations into complaints about advertising which have been referred by the Complaints Resolution Panel is welcome (although insufficient). Furthermore, current TGA consultations in a number of areas of concern, such as Internet site redevelopment, improving advertising arrangements for therapeutic goods and reforms in the medical devices regulatory framework are noted. The Trimmer Working Group on Promotion of Therapeutic Products is also of relevance.

Regardless, there remain a number of opportunities for the TGA to increase the public provision of information about the assessment, quality, safety and efficacy of therapeutic goods. Additional information would improve competition in the therapeutic goods market place and facilitate quality use of therapeutic products by both health professionals and consumers. The latter has been defined by the Trimmer Working Group as selecting diagnostic and treatment options wisely,
Transparency review of the TGA

choosing suitable therapeutic products if this is considered necessary, and using therapeutic products safely and effectively.

It is suggested that the following topics should be dealt with by the Pearce review (in order of priority):

1. **Transparency, currency and accuracy of information provided by AusPAR, the Australian Register of Therapeutic Goods (ARTG), approved Product Information (PI), Consumers Medicines Information (CMI), Public Summary documents and the TGA with regard to pre- and post-marketing assessment and surveillance.**

   1.1. Although TGA transparency about these matters is improving it still appears to be far behind the US FDA\(^1\) and the European Medicines Agency (EMEA)\(^2,3,4\) who have also been asked to move forward.\(^5\) In particular, the interpretation of the “commercial-in-confidence” clause in the National Health Act by Australian bureaucrats appears far more restrictive than that of the EMEA.

   At the EMEA, “commercially confidential information” may include confidential intellectual property, “know-how” and trade secrets (e.g. formulas, programmes, process or information contained or embodied in a product, unpublished aspects of trademarks and patents); and commercial confidences (e.g. structures and development plans of a company).

   However, “Any information encompassing nonclinical and clinical development of the medicinal product and the subsequent assessment by the CHMP (Committee for Medicinal Products for Human Use ) is recognised as not commercially confidential and, therefore, its deletion cannot be accepted as a general rule”\(^6\).

   1.2. Although PI and CMI for prescription medicines are accurate at the time of marketing, this information can rapidly get out of date and thus provide erroneous information.\(^7\) A mechanism is required to update this information in the light of changing knowledge that does not depend on the pharmaceutical industry.

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1.3. The TGA does not assess so-called “lower-risk” therapeutic goods for efficacy and sponsors currently populate the ARTG and the public summary documents themselves, with only occasional (and non-transparent) checking of this information by the TGA. The end result is numerous products on the ARTG (and in the market place) with indications and/or claims that lack an evidence base, erroneous and misleading information contained in public summary documents and an overloaded complaint system. In addition, despite important and well-known adverse interactions between a number of complementary and conventional medicines, the TGA does not require information about such matters to be added to public summary documents, labels or promotional material.

1.4. There is a great discrepancy between the pre- and post-market assessment of medical devices (and the information made publically available) compared to prescription medicines. For example, no AusPAR documentation is provided about “high-risk” medical devices added to the ARTG and medical devices lack regular reports on adverse events provided by the Advisory Committee on the Safety of Medicines (ACSOM).

1.5. There is concern that the current systems used to collect, report and give advice on adverse events to immunisation are dysfunctional, as evidenced by recent problems with febrile convulsions in children in WA following seasonal influenza vaccination. In addition, the TGA response appeared defensive rather than constructive.

2. Educating the public (and health professionals) about limitations of the current “risk-based” TGA assessment procedures.

Consumer research has shown that the public do not understand that AUST L labelled medicines have not been evaluated for efficacy.

A number of submissions to the TGA consultation on improving advertising arrangements for therapeutic goods suggested that, by default, all therapeutic goods not assessed for efficacy by the TGA or a comparable national authority must contain an appropriate warning on their ARTG public summary document, the product label and all promotional material, for example, “The claims made for this product have not been assessed by Australian health authorities”.

In addition, the current Listing system has allowed the misconception that all complementary medicines containing the same ingredients are equally effective. The reality is that complementary medicines especially herbal medicines are complex products with numerous biologically active components. This means that evidence of benefits (and risks) are specific to the product tested and cannot necessarily be extrapolated.

The “generic” concept which is valid for conventional medicines, for example the interchangeability of paracetamol containing products, is invalid for complementary medicines. A prescription for “St John’s wort” for example, is not reliable as St John’s wort is not one substance. In addition, meta-analyses and systematic reviews of a “substance”, such as a herb,
or glucosamine, are easily misinterpreted because the products made from that “substance” can be so different that any conclusions drawn can only be applied to the specific products trialled. A recent report on the cost-effectiveness of complementary medicines by Access Economics, commissioned by the National Institute of Complementary Medicine, noted that, “the results of this review apply only to the preparations tested in the studies included, and possibly to extracts with similar characteristics” and “if St John’s wort was to be sold in Australia with ‘depression’ as a therapeutic indication, a higher level of regulatory approval would be required”.

More education of consumers and health professionals about these matters is required.

3. **Making it easier for consumers and health professionals to know which products have been added to, or removed, from the ARTG.**

At the moment it is difficult (or impossible) to know that a product has been removed from the ARTG. This can occur when a TGA review finds that the sponsor cannot substantiate indications listed on the ARTG, or a sponsor de-lists a product themselves rather than face a review. The end result is that de-listed products continue to be used. Information about all products that have been added to, removed from, or who have had information changed on the ARTG, should be made publically available, either on the TGA web site or via subscription to a TGA email alert system.

4. **ALL complaints about the promotion of therapeutic goods referred to the TGA by Complaint Resolution Committee (CRP), the Complaint Resolution Committee (CRC) of the Complementary Health Care Council, or handled direct should be made publically available as should the action taken, the time line and the outcome.**

The TGA’s “new” policy only concerns publishing the outcome of “certain” investigations into complaints about advertising which have been referred by the CRP. All complaints referred to the TGA should be dealt with expeditiously and transparently. Alternatively, the CRP should handle all complaints and be given the power to enforce sanctions.

5. **Clusters of complaints upheld by the CRP in areas such as Listed products for weight loss, arthritis and cognitive enhancement should trigger a product class review that is timely, efficient and reaches regulatory conclusions.**

This has not been the experience to-date. For example, in 2007, the TGA was asked to review the efficacy of all ingredients used in Listed weight loss products in the hope that up-stream evaluation would reduce the need for down-stream complaints. It was suggested that all ingredients that lacked evidence of efficacy for weight loss should be proscribed for use in such products until such time as a sponsor convinced the Complementary Medicines Evaluation Committee that new evidence was available. Industry concern apparently watered down the scope of this review to a draft document (released in February 2009) that merely reviewed the evidence that might support a claim for weight loss products. A number of consumer and health professional organisations wrote submissions expressing concerns about the limitations of the draft document, especially the lack of any implementation plan. A public consultation was held, in Canberra, on October 26, 2009. Many concerns were reiterated and the TGA promised to revise the document. Twelve months later no more has been heard.

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6. **Sanctions available to the TGA for breaches of the Therapeutic Goods Act (including Therapeutic Goods Advertising Code) should be transparent, pursued and improved if found wanting.**

There was considerable confusion in submissions to the TGA consultation on improving advertising arrangements as to what sanctions were available to the TGA for breaches of the Therapeutic Goods Act and whether or not they were adequate. For example, Section 42(DM) of the Therapeutic Goods Act, 1989 says: “(1) A person is guilty of an offence if: (a) the person publishes or broadcasts an advertisement about therapeutic goods; and (b) the advertisement does not comply with the Therapeutic Goods Advertising Code. Penalty: 60 penalty units”. Some understood this provision to be ineffectual because the TGA has to put a criminal case to the public prosecutor to get action and the latter has more important priorities. Other believed that existing penalties, such as removal of a product from the ARTG were adequate. All penalties available should be transparent and, if they have limitations, these should be addressed.

7. **TGA “consultations” such as those recently undertaken on listed weight loss medicines should be inclusive, transparent and be brought to a conclusion.**

The initial consultation is invariably with industry in-confidence. This sets the agenda. Public submissions are then invited but, unlike most other government and departmental inquiries, until the latest advertising consultation, the TGA has not made such submissions public. Often, the TGA has not even provided a summary of what issues were raised. For example, the revised draft version of the weight loss product guideline paper\(^\text{14}\) does not detail the many changes that were made from the previous version in response to submissions, let along explain why some things were changed and why many other suggestions were ignored. As a consequence, one has no idea who, or what, has influenced the changes. In addition, when public meetings are called on these matters they have traditionally been held in Canberra with no support for consumer or other poorly resourced groups to appear. The inevitable result is that industry views predominate. This perception is reinforced when the TGA fails (after 3 years) to complete the weight loss medicine consultation, apparently because of industry objections.

8. **FOI requests.**

There is concern that the TGA’s standard practice in dealing with such requests is bureaucratic and focused on obstruction and delay. For example, initial requests (and information provided) that a request is in the public interest have been ignored and charges insisted upon without giving any reason as to why the information provided by the applicant was insufficient. Commercial-in-confidence considerations appear to be interpreted very differently to EMEU guidelines. In addition, FOI requests have been refused on the grounds that industry might be financially disadvantaged and their co-operation with the TGA might be impaired. Once again, such experiences create the perception that the TGA places the commercial interests of the therapeutic goods industry ahead of consumer and health professional interests.


HOT ISSUE BRIEF

IN-CONFIDENCE

COMPLEMENTARY MEDICINES – COMPLIANCE ISSUES

Key Information

- The majority of complementary medicines are approved for supply through an Electronic Listing Facility. Premarket review is limited with most focus on post market reviews.

- Based on 2009-10 data, as many as 90 per cent of products reviewed are found to be non-compliant with regulatory requirements, with a significant number of products requiring removal from the Australian Register of Therapeutic Goods (ARTG). This information is not publically available.

Background

- There are approximately 10,250 Listed complementary medicines included on the ARTG comprising mainly of vitamins, minerals and herbal preparations. In 2009-2010 the Therapeutic Goods Administration monitored or reviewed approximately 400 or 26 per cent of newly listed medicines.

- Approved standard statements or claims (called coded indications) are permitted for use on the label of Listed medicines and in advertisements. The sponsor may also choose their own wording for such claims. Regulatory restrictions are placed on claims for Listed medicines. There are some claims that cannot be made. The sponsor is responsible for ensuring the accuracy and truthfulness of these claims. Claims may mislead consumers if they are inappropriate or not true.

- Compliance issues identified in reviews may result from a lack of regulatory understanding by some sectors of industry and/or the unwillingness or inability of some industry members to adhere to the regulatory framework.

- The majority of sponsors take appropriate corrective actions when compliance issues are brought to their attention. However, a small percentage of industry is consistently non-compliant.

- The high level of regulatory compliance irregularities presents a major risk to confidence in the Australian Government’s regulatory framework for complementary medicines and the complementary industry itself.

- The Complementary Healthcare Council of Australia and the Australian Self Medication Industry, peak industry bodies, agree that this situation needs to be addressed.

Handling Strategy

- A number of options for correcting the rate of non-compliance have already been identified by both the Therapeutic Goods Administration and industry.

- The Therapeutic Goods Administration will provide a Minute proposing a process to address the risks posed to government through this non-compliance that involves key consumer and industry stakeholders. This will include managing the potential risks to public health and the risk of a loss of confidence in the regulatory system.

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