Notes of a discussion with Dr Ken Harvey, Transparency Review Panel

Our public consultations provided the option for a participant (or a person who could not attend) to talk privately with a panel member about a relevant issue of concern.

After our Melbourne meeting, I was approached by Georgia Miller, Friends of the Earth (FoE) Australia, who wanted to discuss therapeutic goods advertising issues in general and a specific determination of the Complaint Resolution Panel (CRP) about a sunscreen advertisement in particular.

I meet with Georgia and her colleague, Elena McMaster at FoE in Brunswick on Thursday, March 3, 2011.

Both Georgia and Elena found the therapeutic goods advertising complaint procedures complex and convoluted. I was able to provide them with the attached flow chart (which confirmed the complexity) but the flow chart was silent on their query about how a determination could be clarified (or appealed against) and what happens when the CRP refers a complaint to the TGA and/or ACCC.

Georgia and Elena are both involved in a FoE Nanotechnology Project.1 They, and others, are concerned that the health risks posed by manufactured nanoparticles (compared with conventional materials based on the same chemical composition) have not yet been properly studied.2,3 Given this uncertainty, they believe that consumers have a basic right to know whether therapeutic goods contain nanoparticles.

Sunscreens provide a specific example of their concern. About one-third of the 1000 sunscreen products are marketed in Australia currently incorporate engineered nanoparticles (ENPs) and this proportion is increasing.

In approving such products, the Therapeutic Goods Administration (TGA), has stated that to-date (2009), “the current weight of evidence suggests that titanium dioxide and zinc oxide nanoparticles do not reach viable skin cells; rather, they remain on the surface of the skin and in the outer layer of the skin that is composed of non-viable cells” and “Given the outcome of the recent review of the scientific literature, the TGA does not require any specific warnings about nanoparticles to be placed on labels of sunscreens”.4

Despite the TGA’s stance, existing research does not comprehensively ensure the safety of all ENPs in sunscreens, particularly ENPs less than 40 nm in size applied long-term to human skin that is immature, aged, diseased, damaged, hairy or covering flexural creases.5

A New South Wales Government committee has recommended that, for regulatory purposes, ENPs be considered new chemical entities that require increased safety data.6

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1 http://nano.foe.org.au/
Recently, the CRP upheld a complaint against a sunscreen by a competitor on a number of grounds, including that promoting the product as “Not Nano” and, “recommended as a NANO-FREE sunscreen by Friends of the Earth” was a breach of Section 4(2)(d) of the Therapeutic Goods Advertising Code which prohibits advertisements which, “abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress.”7

FoE were concerned that this particular prohibition set a dangerous precedent for consumers’, “right to know”. As the TGA does not require mandatory labelling about ENPs, many consumers who are concerned about nano-sunscreen safety rely on sunscreens that have been labelled as "not nano” voluntarily by manufacturers.

FoE were also concerned that the CRP refused to provide any further information about the complaint resolution process, the reasoning behind the decision, or what this meant for other nano-free manufacturers. They note that a retraction has been called for, but that the attachment said to contain the required retraction cannot be found on the CRP web site.

They also commented that the members of the CRP, including consumer representatives, were not named on the CRP web site. As the CRP is a government co-regulatory body, they believed that its membership should be transparent and its decision-making open to further explanation (if requested) and also possible appeal.

I agreed to put their concerns in writing and pass them on to other members of the panel.

Dr Ken Harvey
CHOICE
March 7, 2011

7 http://www tgacrp com au/index cfm?pageID=13&special=complaint single&complaintID=1691
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.

Response

Friends of the Earth welcomes this review of the transparency of the Therapeutic Goods Administration (TGA). A key focus of the work of our organisation’s nanotechnology project has been sunscreen safety, specifically the use of manufactured nanoparticles in sunscreen. We have been frustrated and disappointed at the lack of transparency in the TGA’s activities in relation to nano-sunscreens.

Key areas of concern for us include a lack of transparency in relation to:

Information on the manufactured nanoparticle content of therapeutic goods (specifically sunscreens) on the market

The TGA published statements regarding the widespread sale of nano-sunscreens in 2006. However it has refused to make available information regarding which sunscreens contain these ingredients in nanoparticle form. This has been especially concerning in light of the BlueScope Steel study which found that several sunscreens tested contained nanoparticles that acted as extreme photocatalysts. For people with sensitive or damaged skin, who may be at increased risk of skin penetration by nanoparticles, information regarding the presence of nanoparticle ingredients is especially important. Nonetheless, the TGA has rejected calls for information on nano-ingredients made on the grounds of both public health and consumer choice.

Further, although the TGA made very specific statements in 2006 about the percentage of sunscreens that used nanoparticles, in response to Freedom of Information (FoI) requests it subsequently stated that it did not have accurate or complete information in relation to this. It is unclear what information the TGA actually had when it made these statements. In relation to a
specific question from Friends of the Earth the TGA said that it is not a requirement to information on nanoparticle content when listing a sunscreen on the Australian Register of Therapeutic Goods; it appears that nano-content surveys had been carried out on a voluntary response basis. This casts doubt over the accuracy and reliability of the original statements, which FoE notes have now been removed from the TGA website.

The TGA’s strong resistance to calls for mandatory listing of nano-ingredients on sunscreen product labels have been a further barrier to transparency. We note that the European Union has recently passed new laws that will require most manufactured nanoparticles in sunscreens and cosmetics to pass safety testing prior to commercial sale, and to face mandatory labelling. The fact that the TGA resists similar regulatory measures here is in opposition to calls for mandatory labelling from the NSW Parliamentary Inquiry into Nanotechnology, cosmetics and sunscreen industry body ACCORD, the Cancer Council, the Australian Council of Trade Unions, Choice, Friends of the Earth and other community groups.

Procedures for ongoing monitoring of products already on the market and the evaluation, assessment and testing of new products; specifically, the TGA’s review of the adequacy of regulatory arrangements in relation to nanotechnology

The TGA has refused to provide information regarding its monitoring of commercially available nano-sunscreens. Further, the TGA has been highly non-transparent in relation to its evaluation, assessment and testing of nano-sunscreens. We question whether any such evaluation, assessment or testing has taken place, or whether the TGA has simply relied on its literature review concluding that the risk of skin penetration by nanoparticles is negligible to justify a failure to evaluate, assess and test the safety and efficacy of nano-sunscreens.

We are particularly concerned at the lack of transparency associated with the TGA’s review of its regulation of nano-products. The TGA website statement dated 9 July 2008 asserts that "...the TGA is conducting a comprehensive review of current regulatory arrangements to ensure that those arrangements remain adequate to assess and manage the risks that may be associated with products manufactured using increasingly sophisticated nanotechnologies".

It is of concern to Friends of the Earth that this regulatory review was carried out without public comment or input from community stakeholders. We note that other regulators such as NICNAS have carried out focussed stakeholder consultation as well as broadly advertised public consultation in relation to the need for its regulations to be updated to address nanotechnologies.

We are also concerned that the outcomes of the review were not made public (and were perhaps never intended to be made public). We note that in response to a question from Friends of the Earth, the Office of Non-Prescription Medicines advised in December 2009 that: “The TGA is in the process of finalising an internal analysis of the regulatory capture of therapeutic products incorporating nanotechnologies. This project did not seek public comment. On finalising this analysis early next year, the TGA will determine the appropriate next steps”. Close to three years after the conduct of the TGA regulatory review, there is still no public information about its conclusions.

Process and actions of the Complaints Resolution Panel:

The process and actions of the Complaints Resolution Panel (CRP) in relation to the promotion of therapeutic products are highly non-transparent. The participants of the CRP are not listed on the
CRP website (as is customary for most decision making committees), only the organisations they represent. The website does not state how regularly the CRP meets, whether decision making is by consensus or majority, whether a quorum is required, the timeline of decision making or basic processes about complaints referral and enforcement. Two telephone requests for this information made to the CRP secretariat have been met with blunt refusal to provide this information and a degree of inexplicable hostility.

We note the TGA’s “new” policy to publish the outcome of “certain” investigations into advertising complaints which have been referred by the CRP. However we suggest that all complaints referred to the TGA should be dealt with transparently and the information relating to them made publicly available.

Friends of the Earth hold specific concerns about complaint number 2010-07-006. This complaint, upheld by the CRP, is in relation to a company labelling its products as “micronised not nano”. We are concerned that the complaint is not about the accuracy of this statement, but that labelling as “not nano” is a breach of Section 4(2)(d) of the Therapeutic Goods Advertising Code which prohibits advertisements which “abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress.” We note that European cosmetics law will require all nano-ingredients in sunscreens and cosmetics to face mandatory labelling from 2012-13 and that Australian industry body ACCORD has called for similar labelling requirements here. We are concerned that the CRP, a TGA co-regulatory body, has made a determination that voluntary disclosure of nano status is not permitted in Australia. This is a breach of the community’s right to know and a further erosion of transparency in therapeutic good content.

We are also concerned at the lack of transparency surrounding decision making by the CRP in relation to this complaint. When contacted by telephone, the secretary of the CRP refused to provide any further information about the complaint resolution process, the reasoning behind the decision, or any avenues for appeal. We note that the CRP has called on the company to issue a retraction, but that this is not available on the CRP web site.

**Freedom of information:**

We are concerned that the TGA’s standard practice in dealing with FoI requests is focused on obstruction and delay, without due regard for the public interest, and with undue emphasis on protecting companies’ commercial interests. Despite requests from several parties, the TGA has consistently refused to clarify which sunscreens contain ingredients in nanoparticle form. Instead the TGA has emphasised that information on nanoparticle content is commercially sensitive, and has asserted that even under FoI, companies’ have the right to require the TGA to not release this information.

We are also concerned that documents made available through the FoI process are incomplete. For example a broad ranging FoI request about TGA decision making in relation to nano-sunscreens resulted in the provision of very few internal memos, emails and documents, and no information related to the regulatory review.

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