

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 13 & 15 February 2013

Question: E13-164

OUTCOME 1: Population Health

Topic: Titanium Dioxide in Sunscreen

Type of Question: Written Question on Notice

Senator: Senator Di Natale

Question:

- a) The TGA informed stakeholders last year that it had conducted a new review of the scientific literature on the safety of nanoparticulate titanium dioxide or zinc oxide in sunscreen. When will this review be published?
- b) Is the TGA aware of the study published by Bennett et al last year in PLOS ONE which found that sunlight causes clumps of titanium dioxide nanoparticles to disaggregate and to penetrate pig skin?
- c) Is the TGA aware of the study published by Virkutyte et al in the Chemical Engineering Journal last year which found that chlorine in swimming pools can strip the coating off titanium dioxide nanoparticles in sunscreens that protect against UV radiation, leaving them able to react with water to form free radicals?
- d) Is the TGA aware of the study published by Monopoli et al in Nature Nanotechnology last year which found that nanoparticles in contact with biological fluids are rapidly covered in a layer of proteins or lipids (termed a corona) with implications for skin penetration and the extent to which the nanoparticles are dissolved into ions?
- e) Does the TGA intend to revise its opinion regarding the safety of nano-ingredients in sunscreen on the basis of this new evidence?
- f) Is the TGA aware of the study published by Barker & Branch in Progress in Organic Coatings in 2008 which found that nanoparticles of anatase titanium dioxide in sunscreen were reacting with sunlight and breaking down the coating of Colorbond roofs in a matter of weeks?
- g) What action has the TGA taken to ensure that nanoparticles of anatase titanium dioxide are not used in sunscreen products?
- h) How many companies have the TGA told to stop advertising their sunscreen products as non nano or nano free within the past year and on what basis?
- i) What organisations and individuals are currently represented on the Complaints Resolution Panel which makes decisions about such complaints?

Answer:

- a) As part of its pharmacovigilance program, the Therapeutic Goods Administration (TGA) continues to actively monitor the safe use of sunscreens, as well as the emerging scientific literature in this area, to ensure that appropriate action is undertaken if any substantive safety concern is identified. The 2009 TGA review on the safety of sunscreens containing nanoparticles is currently being revised and, following consultation with other Australian Government agencies, including the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the review will be released in the near future.
- b) The TGA is aware of the study by Bennett *et al.*, (2012)¹ which is an *in vitro* (isolated tissue) study using slices of pig skin to investigate the effect of sunlight on clusters (clumps) of titanium dioxide (TiO₂) particles. The premise is that exposure to light causes large clumps of these nanoparticles to break down into smaller clumps which can easily diffuse through the skin.

The results showed that nanoparticle clusters or clumps of TiO₂ are in general resistant to disaggregation. Only a small percentage of the large clumps were broken down; the majority of the nanoparticle clumps remained as large clusters even after prolonged exposure to light.

The authors stated that, after a 90-minute exposure of the pig skin to the titanium clusters, only 0.1 per cent of the applied dose penetrated the pig skin. They confirmed that most of the applied material remained in large clusters or clumps. However, the material was referred to as 'titanium' and not 'titanium dioxide' so that no concrete conclusions can be drawn.

Titanium is a naturally-occurring substance found in foods and environmental materials and can be found naturally in human tissue (estimated as 0.123 mg/L).

This study is of interest but the results are of inconclusive significance. The TGA will continue to monitor any follow-up studies.

- c) The TGA is aware of the study by Virkutyte *et al.* published in 2012² conducted to determine whether chlorine from swimming pools can affect the aluminum hydroxide (Al[OH]₃) coating the TiO₂ nanoparticles in sunscreens and the consequences of this effect.

Aluminum hydroxide coating is often used in sunscreen formulations to shield against potential harmful effects of free radicals generated when TiO₂ nanoparticles are exposed to UV radiation. Free radicals (e.g., hydroxyl radicals) can cause damage to cells if their actions are not blocked.

The results showed that increasing concentrations of chlorine affected the integrity of the Al(OH)₃ coating of the nanoparticles, leaving nanoparticles uncoated, with the greatest effect observed from 3.5-7 parts per million (ppm) of chlorine. Hydroxyl radicals were formed in the presence of 5 ppm chlorine after seven days of exposure to the chlorine but this was not observed when untreated sunscreen was used. It should be noted that most swimming pools contain 1-3 ppm chlorine.

The TGA will continue to monitor these effects.

¹ Bennet SW, Zhou D, Mielke R & Keller AA. (2012) Photo induced disaggregation of TiO₂ nanoparticles enables transdermal penetration. *PLOS One*. 7:1-7.

² Virkutyte J, Al-Abed SR & Dionysiou DD (2012) Depletion of the protective aluminum hydroxide coating in TiO₂-based sunscreens by swimming pool water ingredients. *Chemical Engineering Journal*. 191:95-103.

- d) The TGA is aware of the report by Monopoli *et al.* (2012)³ and has been monitoring the emerging scientific literature in the area of nanoparticle coronas.
- e) Australia has a robust regulatory framework in place to ensure the safety of sunscreens, and on current evidence, the TGA does not believe there is a need to change the current framework.

The relevance of these studies to humans has not been established and further research is required. These studies do not alter the current TGA position, and the internationally held opinion, that nanoparticulate TiO₂ is safe as an ingredient in sunscreens.

There is currently no evidence to suggest that sunscreen products which incorporate nanotechnologies pose greater safety risks than conventional products.

The TGA actively monitors any emerging scientific literature and works with other Government agencies and international medicines regulators in this area, to ensure that appropriate action is undertaken if any substantive safety concern is identified.

The health risks of excessive sun exposure are well-documented and far outweigh unproven theoretical risks related to nanoparticles.

- f) The TGA is aware of the paper by Barker & Branch (2008)⁴ who investigated effects of application of 10 different sunscreens containing nano-TiO₂, nano-ZnO or other approved organic UV filters to flat, pre-painted Colorbond roof panels. Accelerated weathering of the coating of the roof panels were attributed to the presence of an anatase form of TiO₂ in sunscreen by a photocatalytic degradation mechanism.

Titanium dioxide can be manufactured to form two crystal structures: anatase and rutile forms. Studies have shown that the anatase form of TiO₂ is the more photocatalytic form.

This study examined chemical effects only in the absence of biological system(s) or tissues. The study appears of little relevance to safety in humans.

- g) The TGA is aware of the studies conducted by the National Measurement Institute (NMI) in which there was an indication that anatase TiO₂ may be present in a number of sunscreen products. However, the NMI confirmed that the studies only proved the ingredient to be in nano form but were unable to definitively conclude that the anatase form of TiO₂ is present in the sunscreen.

The TGA requires that the labelling of medicines, including sunscreens, must declare the identity and quantities of active ingredients in the product.

The TGA aims to ensure that information about the health, safety and environmental impacts of nanotechnology is based on medical and scientific evidence.

At this time, the TGA has no sound evidence that nanoparticles of anatase TiO₂ are used in sunscreen products.

- h) The TGA has not ordered any company within the past year to stop advertising their sunscreen products as non nano or nano free.

³ Monopoli MP, Aberg C, Salvati A & Dawson KA. (2012) Biomolecular coronas provide the biological identity of nanosized materials. *Nature Nanotechnology*. 7:779-786.

⁴ Barker PJ & Branch A. (2008) The interaction of modern sunscreen formulation with surface coatings. *Progress in Organic Coatings*. 62: 313-320.

- i) The organisations represented on the Complaints Resolution Panel (the Panel) are prescribed in the Therapeutic Goods Regulations 1990 (the Regulations).

Subregulation 42T(1) of the Regulations prescribes the Panel's membership as follows:

- (a) a chairperson nominated by the Therapeutic Goods Advertising Code Council;
- (b) 3 members, comprising 1 person nominated by each of the following bodies:
 - (i) the Complementary Healthcare Council of Australia;
 - (ii) the Australian Self Medication Industry;
 - (iii) the Medical Technology Association of Australia;
- (c) 2 consumer members, comprising 1 person nominated by each of the following bodies:
 - (i) the Australian Consumers Association;
 - (ii) the Consumers' Health Forum;
- (d) 3 health care professional members comprising:
 - (i) 1 person nominated by the Australian Traditional Medicines Society; and
 - (ii) 1 person nominated jointly by the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia; and
 - (iii) 1 person nominated by the Royal Australian College of General Practitioners.

Regulation 42X of the Regulations prescribes the following organisations as observers:

- (1) The Therapeutic Goods Administration.
- (2) Food Standards Australia New Zealand.

The identities of the individual members and observers of the Complaints Resolution Panel are kept confidential in order to minimise the possibility of any attempt either to obtain confidential information or to compromise the considerations of the Panel through inappropriate lobbying, or influence on, any representative. However, their names can be provided to the Senator Di Natale on a confidential basis, if required.