

Senate Economics Legislation Committee
ANSWERS TO QUESTIONS ON NOTICE
Treasury Portfolio
Budget Estimates 2014
3 June to 5 June 2014

Department/ Agency: Australian Securities and Investments Commission

Question: BET 816-817

Topic: Medical Device Sponsors

Reference: Written – 12 June 2014

Senator: Xenophon

Question:

816. Does ASIC have any specific monitoring process in relation to medical device sponsors – that is, companies that import medical devices but do not necessarily manufacture them?
817. In 2012, the Senate Community Affairs committee conducted an inquiry into the recall of PIP breast implants. The implant sponsor was Medical Vision Australia Pty Ltd, based in Adelaide. As ASIC may be aware, following the withdrawal of the devices from the Australian market, Medical Vision Australia Pty Ltd went into administration and split its business into two arms, Medical Vision Australia Cardiology & Thoracic Pty Ltd, and Medical Vision Australia Plastic & Cosmetic Pty Ltd. These companies are: The manufacturer of the device has also been arrested in France. Subsequent legal action on behalf of women who had received the PIP implants found that Medical Vision Australia did not carry product liability insurance. This, coupled with the company's decision to enter into administration, meant they could not receive compensation from the company. I understand the company's liquidator reported them to ASIC and requested an investigation to determine if there had been any breaches of the Corporations Act.
- a. Did ASIC investigate and what stage is the investigation at?
- b. If a breach of law were found, would ASIC discuss the matter with the TGA in relation to the company's suitability to be a device sponsor?
- c. Are there any specific consumer protection or similar provisions that would allow ASIC to take a harder line against a company where that company deals in medical matters (such as device sponsorship), where the health impacts for consumers could be significant?

Answer:

816. A sponsor, as defined in the Therapeutic Goods Act 1989 (**TG Act**), is a person or company who does one or more of the following:
- exports/imports therapeutic goods from/to Australia
 - manufactures therapeutic goods for supply in Australia or elsewhere
 - arranges for another party to import, export or manufacture therapeutic goods.

The TG Act is administered by the Therapeutic Goods Administration (**TGA**) which is part of the Australian Government Department of Health. Broadly, the TGA is responsible for regulating therapeutic goods including medical devices, prescription medicines, vaccines, sunscreens, vitamins and minerals, blood and blood products.

If a sponsor is registered as a company under the *Corporations Act 2001* (**Corporations Act**) or is constituted as some other form of body corporate, it will be subject to the

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Corporations Act. ASIC's regulatory oversight of such a sponsor would extend only to its compliance with the Corporations Act. Sponsors are not otherwise distinguished from the broader population of entities regulated by ASIC.

817.

- a. Before ASIC investigates an allegation of misconduct in relation to a company in liquidation, generally the liquidator will conduct its own inquiries and make a recommendation to ASIC. This is because of the liquidator's unique position and level of knowledge in relation to the affairs of a company; they are often better placed to make a recommendation on alleged misconduct.

Where a liquidator, during the course of performing their duties, becomes concerned that a company may be guilty of misconduct they are required to provide a report to ASIC (section 533 of the Corporations Act).

Liquidators may also make an application to the Assetless Administration Fund for funding to complete an investigation into potential misconduct in the company, in circumstances where the company lacks funds to undertake the investigation. ASIC will review applications in accordance with our policy set out in Regulatory Guide 109 *Assetless Administration Fund: Funding criteria and guidelines and appendices 1 to 10*. If an application for funding is approved, a report will then be commissioned by the liquidator and forwarded to ASIC along with a recommendation on whether or not action should be taken.

Because reports by liquidators may involve untested allegations of misconduct against company officers, such reports not made publically available. Where ASIC receives reports of potential misconduct, we will consider the information and make a decision as to whether to start an investigation. ASIC's decision whether or not to conduct an investigation, as well as the stage of an investigation, is generally confidential until certain milestones are reached. This is to protect the integrity of our investigations.

- b. Discussions and information-sharing between ASIC and the Department of Health or the TGA occurs on an ad hoc basis, as required. ASIC consults with federal and state government departments and agencies where it would add useful information to each of our deliberations, and vice versa.
- c. ASIC does not regulate sponsors, except as to their compliance with the Corporations Act. The Corporations Act regulates all companies and body corporates and does not differentiate treatment for companies based on their business or the industry in which they operate. Industry regulators and industry specific legislation provides this function and is better placed for such protections due to the level of specific knowledge and expertise required to regulate for certain industries.

The *Australian Securities and Investments Commission Act 2001*, another Act which ASIC regulates, provides for some further consumer protection mechanisms in relation to financial services, in the area of unconscionable conduct, unfair contract terms, false or misleading statements or misleading and deceptive conduct. These consumer protection mechanisms work in conjunction with those in the Corporations Act and those regulated by other government agencies such as the Australian Consumer Law, governed by the Australian Competition and Consumer Commission.