Additional comments by Senator Xenophon

The human consequences of regulatory failure

Nick Xenophon, Independent Senator for South Australia

1.1 I would like to acknowledge the many witnesses who provided information to the committee of their own personal experiences with the PIP breast implant devices. This evidence was vital to the committee's understanding of the impact this recall has had on people who were implanted with these devices, and I thank these courageous individuals for their testimonies.

1.2 Many of the issues raised in this inquiry in relation to the Therapeutic Goods Administration were also raised in the previous inquiry into medical devices, undertaken by this committee. I am very concerned that there is a common thread of serious problems in relation to approval and post-market monitoring of devices, and communication of information to the public. While I acknowledge that the TGA has been much more forthcoming in this case in comparison to the withdrawal of the De Puy hip devices, I am concerned that evidence was provided to the committee which still demonstrates significant systematic failures in the TGA's systems.

1.3 It is very unfortunate that Medical Vision Australia refused to appear before the committee, or to provide information in any way. Engagement with the committee process would have shown a willingness on the part of MVA to be involved in discussing the failures of regulatory systems in Australia and overseas, and how they can be addressed. I also believe MVA's participation would have been meaningful for the individuals who have been affected by these implants.

1.4 I am also concerned about MVA's refusal to participate in the inquiry in light of the company's restructure last year. According to records from ASIC, in December 2011 the company appeared to separate its cosmetic arm from its other operations, forming two separate companies (Medical Vision Australia Cardiology & Thoracic Pty Ltd, and Medical Vision Australia Plastic & Cosmetic Pty Ltd)[1]. It would have been very useful for MVA to state on the record the reasons for this split, and the impact this split may have on individuals seeking legal redress, including whether it

[1] Australian Securities and Investments Commission, *ASIC Historical Company Extracts*, 24 January 2012 (attachment 1)

would make it more difficult for victims of the product MVA sponsored to seek compensation.

1.5 It is also important to note that the lack of a properly operating breast implant device registry added to the difficulties faced by the TGA and other bodies in collecting information on the PIP device. The new 'opt-out' registry discussed by Associate Professor Rodney Cooter, President of the Australian Society of Plastic Surgeons[2], should be strongly and immediately supported by the Government, as the previous inquiry into medical devices demonstrated the importance of a comprehensive, properly operating registry.

1.6 The arrangements in relation to the Special Access Scheme and informed consent are very concerning, and indeed appear woeful. While it evident that such a scheme should be in place to assist seriously ill patients who require specialist products, it is hard to see how the SAS would be relevant for breast implant devices, when there are already many approved devices to choose from. I support the committee's recommendation in this matter.

1.7 The TGA's lack of follow-up in relation to the provision of annual reports by sponsors of Class III medical devices, as required by the standard condition placed on sponsors when devices are listed on the Australian Register of Therapeutic Goods, is unacceptable. While I acknowledge that a follow-up system was established in 2011 and is now in place, it is vital that the TGA collect and analyse all missing information to ensure that there is no risk to Australian health consumers. This example also points to a lax attitude towards post-market monitoring within the TGA, which was also apparent during the previous inquiry into medical devices. While I note that the TGA has acknowledged this and is taking steps to create a more positive, pro-active stance, it does raise the question of how many problems we will be facing in the future because action was not taken in the past. I strongly endorse the committee's recommendation regarding this issue.

1.8 I note the committee's comments in relation to the fact that either the TGA or the sponsor of a device can take action in response to issues with a device. In response to the committee's report on the inquiry into medical devices, I raised concerns about the use of 'voluntary withdrawals' as opposed to recalls. It hints at a potentially

[2] Professor Rodney Cooter, Australian Society of Plastic Surgeons, *Committee Hansard,* 9 May 2012, p. 8

conflicted relationship between the TGA and the sponsor. The Hon. Dr Michael Armitage, of the Australian Health Insurance Association, provided evidence to that committee in relation to the importance of recalls as a type of sanction for companies[3]. A voluntary withdrawal obviously does not have the same impact.

Additional Recommendation: That an independent review of the TGA's processes relating to device withdrawals and recalls be conducted within the next 12 months, with a view to strengthening the TGA's position as an independent regulator

1.9 The previous committee inquiry also made several recommendations in relation to adverse event reporting, as noted in the committee's report. The Government has yet to respond to these recommendations. It is my position that the PIP breast implant device recall, and the issues surrounding it, emphasise the urgent need for reform in this area.

1.10 It is extremely concerning that evidence provided to the committee showed serious flaws in the TGA's original approval of the PIP devices. Presumably the processes relating to the clinical evaluator and the Medical Devices Evaluation Committee (as it was at the time) exist so that devices are only listed when the appropriate conditions and safeguards are in place. It is incomprehensible that the TGA would not follow the recommendations made by its own advisory committee (MDEC) in relation to comprehensive annual reports from the sponsor. It seems very unlikely that this expert committee, specifically set up to provide "independent medical and scientific advice to the Minister and the Therapeutic Goods Administration (TGA) on the safety, quality and performance of medical devices supplied in Australia including issues relating to premarket conformity assessment and post market monitoring"[4] would make these recommendations without reason. I believe the committee ought to have gone further and emphasised that this recommendation was not followed seems to indicate a 'low risk' attitude towards breast implant devices which is unacceptable given their Class III rating.

1.11 The fact that the approval for the device rested on the "arguments for essential similarity"[5] when there was limited clinical data is also very concerning.

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[3] The Hon. Dr Michael Armitage, AHIA, Community Affairs References Committee Hansard, 27 September 2011, p 4

[4] Therapeutic Goods Administration website: http://www.tga.gov.au/archive/committees-mdec.htm, retrieved 29 May 2012

[5] Department of Health and Ageing, *Submission 30*, p. 25

Recommendation 4 from the committee's previous inquiry into medical devices was a specific response to very real concerns that an increased number of very similar devices on the market do not necessarily equal better health outcomes[6]. In fact, thanks to the comprehensive data collected by the National Joint Replacement Registry, we know that many of the hip and knee prosthetic devices approved for use in Australia perform "worse, or no better than, those that are currently available"[7]. This fact refutes the very idea that a device should be approved on the grounds that it is 'essentially similar' to another device.

1.12 These circumstances raise particular concerns, especially when compared to the example of the Food and Drug Administration (FDA) in the US for a similar time period. As addressed in the committee's report, Dr Daniel Fleming of the Australasian College of Cosmetic Surgery provided evidence that, between 1992 and 2006, the FDA did not approve any silicone implants, and currently has only approved three brands. According to Dr Fleming, this is due to the FDA's requirement in relation to long-term pre-market approval studies[8].

1.13 It is also important to note that it is on the public record that surgeons were notifying the TGA of problems with these implants. In particular, Dr Tim Cooper, a plastic surgeon from Western Australia, stated on the ABC's *Background Briefing* program that he had written to the TGA with his concerns about the high failure rate of the device[9]. He was informed by the TGA that no further action would be taken at that time, and that they would continue to monitor the situation[10]. This was clearly an unsatisfactory response. Dr Cooper, and others like him, should be applauded for their efforts to encourage action on the part of the TGA in relation to these devices.

1.14 The committee also received evidence that some individuals with PIP implants were not contacted by their surgeons and, as a result, these individuals only became aware of problems with their devices through the media. This is totally unacceptable but, unfortunately, is consistent with evidence provided to the previous

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[6] Community Affairs References Committee, *Report on the regulatory standards for the approval of medical devices in Australia*, p. 99

[7] Ibid, p. 100

[8] Dr Feming, *Committee Hansard*, 9 May 2012, p. 23

[9] *Background Briefing*, 5 February 2012, online: http://www.abc.net.au/radionational/programs/backgroundbriefing/pip-implants/3804660#, retrieved 31 May 2012

[10] Ibid

inquiry on medical devices[11]. I support the committee's recommendation in relation to this, as well as the committee's advice that the TGA provide medical practitioners with written guidelines to outline their responsibilities in these situations.

1.15 I also support the committee's comments in relation to the TGA's reliance on their website as the primary form of communication with the public. An average health consumer cannot be expected to constantly check the website just in case the device they have been implanted with has been recalled. While I encourage the TGA's efforts to provide information and updates through their website, it is clear that a more comprehensive alert system is needed, particularly given the fact that surgeons do not (or cannot) always make contact with their patients to pass on information.

1.16 The issue of the type of information provided by the TGA also needs to be addressed. I commend the TGA for their increased efforts at transparency and public awareness, especially compared to their activities in relation to the De Puy hip devices. However, it is important that the TGA also provides the public with details of what further information they are seeking, what further testing they are undertaking, and so on. This will help to reassure health consumers that the TGA takes these types of issues seriously, and is acting accordingly. I support the committee's recommendation in relation to this.

1.17 One example of the TGA's poor communication is the response to a question on notice I received from the TGA in relation to the gel contained in PIP implants available in Australia. I asked whether the gel in the implants was in fact the same gel that was originally approved, and the TGA's response was that the gel "conform[ed] to the relevant international standards for this type of product" and that the samples tested had "superior physical properties to the approved gel"[12]. In response to another question on notice as part of this inquiry, the TGA finally provided a more satisfactory answer, which explained the issues with testing and detailed the TGA's methods and knowledge[13]. While I acknowledge the TGA may not have had as much information when it answered my original question in October 2010, an open and straightforward answer about what the TGA knew so far and what they were intending to find out would have been welcomed. This type of open communication is also much more

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[11] Community Affairs References Committee, *Report on the regulatory standards for the approval of medical devices in Australia*, p. 76

[12] Therapeutic Goods Administration, answer to question on notice, Budget Estimates June 2010, received 11 October 2010 (attachment 2)

[13] Therapeutic Goods Administration, answer to question on notice, received 23 May 2012

helpful to health consumers, as opposed to answers that appear to be constructed specifically to hide something, even if this is not the intention. I strongly agree with evidence provided by Ms Karen Carey of the Consumers Health Forum, who stated:

> *"Had the TGA been more active, mainstream and honest about what information it had and did not have, I think those expectations [of health consumers] would have been moderated."*[14]

1.18 The TGA's delay in finding examples of explanted PIP devices to examine is also concerning. The current testing regime, where devices can be tested by the TGA, the manufacturer or other parties, appears to disadvantage the TGA as it may not have had the opportunity to examine an explanted device before a recall or withdrawal. If this system had operated more effectively, the TGA would have been able to carry out tests on explanted devices already in their possession, rather than facing a delay while devices were procured.

1.19 I strongly support the committee's comments in relation to DOHA's assertion that "there will always be under-reporting" in relation to medical devices[15]. As the committee asserts, the National Joint Replacement Registry, operated by the Australian Orthopaedic Association, has an excellent history of data collection. Evidence from the NJRR was instrumental in the committee's previous inquiry into medical devices, and this registry should be considered as the benchmark in Australia. I also support the committee's recommendation in relation to this, although I believe it would be appropriate to aim for comprehensive registries for all implantable medical devices in Australia.

Additional Recommendation: That an independent inquiry be undertaken into the feasibility of establishing comprehensive registries for all implantable medical devices in Australia

1.20 I endorse the committee's comments in relation to the TGA's national hotline. While such a service could have been invaluable, the committee received evidence from heath consumers that the hotline did not provide them with the information and support they needed. The TGA should conduct an internal review into the operation of the hotline so that such a service can be offered more effectively in the future.

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[14] Ms Karen Carey, Consumers Health Forum, *Committee Hansard*, 9 May 2012, p. 4

[15] Department of Health and Ageing, *Submission*, p.31 footnote 26

Additional Recommendation: That the TGA conduct or commission a review into the operation of its National Hotline, with a view to improving the service in the future

1.21 I share the committee's concerns about the lack of Government action in implementing recommendations 13, 14 and 15 from the Review of the Health Technology Assessment, and I strongly support the committee's recommendation in relation to this. The PIP implant recall, coupled with the issues raised in this committee's previous inquiry into medical devices, point at serious flaws in the system. Recommendations 13, 14 and 15 of the HTA would go some way towards ensuring that Australian health consumers do not face another serious failure on the part of the regulator.

1.22 It is also concerning that some evidence provided to the committee seemed to indicate a 'commoditisation' of healthcare in relation to cosmetic surgery. Professor Rod Cooter, President of the Australian Society of Plastic Surgeons, stated that many of the PIP implants were inserted by cosmetic surgeons, who are unlikely to be credentialled at major public hospitals. According to Professor Cooter, this then creates problems if "things go wrong", as patients end up in the public system and are taken on as patients by specialist surgeons who are credentialled to work in public hospitals[16]. On the other hand, Dr Daniel Fleming of the Australasian College of Cosmetic Surgery pointed out that as there is no specialty of cosmetic surgery, qualifications in this area are not given the same weight as qualifications in plastic surgery or other specialties[17]. Many health consumers would not be aware of these factors and, given the increase in popularity of cosmetic surgery procedures, it would be appropriate for guidelines or regulations to be developed in relation to disclosure to patients. This would ensure that patients knew exactly what type of care their practitioner could provide and where this care would take place, and prevent the establishment of 'one stop shops' for cosmetic surgery procedures.

Additional Recommendation: That the Department, in conjunction with relevant industry groups, establish regulations for patient disclosure relating to the specific qualifications of and services provided by their surgeon

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[16] Prof. Rod Cooter, Australian Society of Plastic Surgeons, *Committee Hansard*, 9 May 2012, p. 7

[17] Dr Daniel Fleming, Australasian College of Cosmetic Surgery, *Committee Hansard*,, 9 May 2012, p. 21

1.23 The issue of compulsory insurance for sponsors of medical devices was also raised during the hearing, with the TGA stating that there is currently no requirement for sponsors to have medical indemnity insurance[18]. However, the representatives of the Consumers Health Forum pointed out that in the past, the Government has become the default insurer for adverse events, and that requiring medical indemnity insurance would have a double benefit as insurers would also seek to limit risks[19]. Given the fact that in this case, the manufacturer of the device is bankrupt and the sponsor has restructured its company (although I note that MVA declined to provide evidence in relation to the reasons behind their restructure), compulsory insurance would have given individuals implanted with PIP devices some peace of mind.

Additional Recommendation: That all sponsors or manufacturers of medical devices listed on the ARTG be required to hold medical indemnity insurance

1.24 It is clear that there are many similarities between this case and the matters raised during the previous inquiry into medical devices. In both cases, serious systemic flaws have been highlighted and recommendations have been made to address these. It is very disappointing that the Government has not yet responded to the previous inquiry or taken steps towards implementing recommendations 13, 14 and 15 of the HTA, which has been recommended in both inquiries.

1.25 Australian health consumers have been let down once again by systemic failures on the part of the regulator. Evidence provided to the committee illustrated, once again, serious flaws in the approval and post-market monitoring processes for medical devices. Individual submitters also expressed their anger and disappointment at the TGA's level of communication with them and the public as a whole, and this matter needs to be addressed as a matter of urgency.

1.26 These two examples (PIP breast implants and De Puy hip prostheses) have illustrated the serious problems, and with it the untold pain and suffering for thousands of Australians, which could well have been avoided. While the TGA and DOHA can make changes for the future processing and monitoring of medical devices, we do not know what harm will still be caused by these past and current bad

[18] Dr Brian Richards, Therapeutic Goods Administration, *Committee Hansard*, 9 May 2012, p. 30

[19] Ms Karen Carey, Consumers Health Forum, *Committee Hansard*, 9 May 2012, p. 3

practices. Ultimately, Australians should not have to pay for the regulator's failures with their own health.

Additional Recommendation: That the Government implement the recommendations of this inquiry and the previous inquiry into medical devices as a matter of urgency

NICK XENOPHON
Independent Senator for South Australia

Senator Xenophon additional comments- attachments

Attachment 1: Australian Securities and Investments Commission, *ASIC Historical Compony Extracts*, 24 January 2012

Attachment 2: Therapeutic Goods Administration, answer to question on notice, Budget Estimates June 2010, received 11 October 2010

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ACN (Australian Company Number): 084 706 338
Registered in: South Australia
Previous State Number:
Registration Date: 12/10/1998
Next Review Date: 12/10/2012
Company bound by:
Australian Business Number: 87 084 706 338

Current Organisation Details

Name : MEDICAL VISION AUSTRALIA PTY LTD 014127807
Name Start: 12/10/1998
Status : Registered
Type : AUSTRALIAN PROPRIETARY COMPANY
Class : LIMITED BY SHARES
Subclass : PROPRIETARY COMPANY

Registered Office

RINALDI & CO 100 GREENHILL ROAD UNLEY SA 5061 014127830
Start Date: 21/10/1998

Previous Registered Office

5 TH LEVEL 76 WAYMOUTH STREET ADELAIDE SA 5000 014127807
Start Date: 12/10/1998 Cease Date: 20/10/1998

Principal Place of Business

99 KING WILLIAM STREET KENT TOWN SA 5067 1E6948521
Start Date: 29/10/2010

Previous Principal Place of Business

35 NORTH TERRACE HACKNEY SA 5069 1E0608225
Start Date: 19/01/2005 Cease Date: 28/10/2010

UNIT 6 174 PAYNEHAM ROAD EVANDALE SA 5069 014127830
Start Date: 12/10/1998 Cease Date: 18/01/2005

LEVEL 5 76 WAYMOUTH STREET ADELAIDE SA 5000 014127807

Start Date: 12/10/1998 Cease Date: 12/10/1998

Directors

ZDENKO RACIC 017082126
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 12/10/1998

Previous Directors

ROSIE RACIC 017082126
6 KENT ROAD HIGHBURY SA 5089
Born: 05/07/1962 - CALABRIA ITALY
Appointment Date: 12/10/1998 Cease Date: 05/04/2004

DAVID GARRY 014127807
LOT 12 WILHELM ROAD LITTLEHAMPTON SA 5250
Born: 14/06/1950 - UNITED KINGDOM
Appointment Date: 12/10/1998 Cease Date: 12/10/1998

Secretary

ZDENKO RACIC 0E9752685
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 05/04/2004

Previous Secretary

ROSIE RACIC 017082126
6 KENT ROAD HIGHBURY SA 5089
Born: 05/07/1962 - CALABRIA ITALY
Appointment Date: 12/10/1998 Cease Date: 05/04/2004

DAVID GARRY 014127807
LOT 12 WILHELM ROAD LITTLEHAMPTON SA 5250
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Class: ORD 1E0853745
ORDINARY SHARES
Number of Shares/Interests Issued : 10
Total Amount (if any) Paid / Taken to be Paid: 200008.00
Total Amount Due and Payable : 0.00

Members

Class : ORD No. Held: 2 1E0853745
Beneficially Held: NO Paid : FULLY
** JOINT MEMBER **
GIOVANNI POLITO
4 BIRKENHEAD COURT PARA HILLS SA 5096

GABRIELLA POLITO
4 BIRKENHEAD COURT PARA HILLS SA 5096

Class : ORD No. Held: 4 1E0853745
Beneficially Held: YES Paid : FULLY
ROSALBA RACIC
6 KENT ROAD HIGHBURY SA 5089

Class : ORD No. Held: 4 1E0853745
Beneficially Held: YES Paid : FULLY
ZDENKO RACIC
6 KENT ROAD HIGHBURY SA 5089

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ASIC Charge Number : 689418 Status : Registered
Date and time Registered : 31/03/1999 15:41:00 Fixed/floating : Both Fixed & Floating
Date Created : 19/03/1999
Chargee/Trustee : 004 044 937 NATIONAL AUSTRALIA BANK LIMITED
Documents Received

Form Type	Description	Date Lodged	Proc'd	No. Pages	Document No
309	NOTIFICATION OF DETAILS OF A CHARGE	31/03/1999	YES	41	014900995

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484C	Change to Company Details Change of Principal Place Of Business (Address)				
484	19/04/2005	19/04/2005	3	13/04/2005	1E0853745
484	Change to Company Details				
484O	Changes to Share Structure				
484G	Notification of Share Issue				
484N	Changes to (Members) Share Holdings				
484	25/01/2005	25/01/2005	2	19/01/2005	1E0608225
484C	Change to Company Details Change of Principal Place Of Business (Address)				
484	08/04/2004	08/04/2004	2		0E9752685
484E	Change to Company Details Appointment or Cessation of A Company Officeholder				
316	31/01/2003	06/03/2003	3	20/11/2002	0E8531086
316L	Annual Return Annual Return - Proprietary Company				(AR 2002)
304	12/12/2001	18/12/2001	2	11/12/2001	017082126
304C	Notification of Change of Name or Address of Officeholder				
316	12/12/2001	08/01/2002	3	10/12/2001	08470633L
316L	Annual Return Annual Return - Proprietary Company				(AR 2001)

316 31/01/2001 12/02/2001 3 10/01/2001 08470633K
316L Annual Return Annual Return - Proprietary Company (AR 2000)

316 31/01/2000 22/02/2000 3 18/01/2000 08470633J
316L Annual Return Annual Return - Proprietary Company (AR 1999)

316 26/03/1999 26/03/1999 3 25/03/1999 08470633I
316L Annual Return Annual Return - Proprietary Company (AR 1998)

304 15/10/1998 16/10/1998 1 12/10/1998 014127869
304A Notification of Change to Officeholders of Australian Company

207 14/10/1998 15/10/1998 1 12/10/1998 014127833
207 Notification of Share Issue

370 14/10/1998 15/10/1998 2 14/10/1998 014127832
370 Notice of Retirement or Resignation By Director or Secretary

284 14/10/1998 15/10/1998 1 12/10/1998 014127831
284A Notification of Share Cancellation Redeemable Preference Shares

203 14/10/1998 15/10/1998 1 12/10/1998 014127830
203 Notification Of
203A Change of Address
203G Change of Address - Principal Place of Business

201 12/10/1998 12/10/1998 2 12/10/1998 014127807
201C Application For Registration as a Proprietary Company

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Year	Return Due Date	Extended Due Date	AGM Due Date	Extended AGM Date	AGM Held Date	O/Stand
1998	31/01/1999	30/04/1999				N
1999	31/01/2000					N
2000	31/01/2001					N
2001	31/01/2002					N
2002	31/01/2003					N

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154 907 310 MEDICAL VISION AUSTRALIA HOLDINGS PTY LTD **Document No**

ACN (Australian Company Number): 154 907 310
Registered in: South Australia
Previous State Number:
Registration Date: 22/12/2011
Next Review Date: 22/12/2012
Company bound by:

Current Organisation Details

Name : MEDICAL VISION AUSTRALIA HOLDINGS PTY LTD 027298911
Name Start: 22/12/2011
Status : Registered
Type : AUSTRALIAN PROPRIETARY COMPANY
Class : LIMITED BY SHARES
Subclass : PROPRIETARY COMPANY

Registered Office

RINALDI & CO 100 GREENHILL ROAD UNLEY SA 5061 027298911
Start Date: 22/12/2011

Principal Place of Business

99 KING WILLIAM STREET KENT TOWN SA 5067 027298911
Start Date: 22/12/2011

Directors

ZDENKO RACIC 027298911
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 22/12/2011

Secretary

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Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 22/12/2011

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Class: ORD 027298911
ORDINARY SHARES
Number of Shares/Interests Issued : 100
Total Amount (if any) Paid / Taken to be Paid: 100.00
Total Amount Due and Payable : 0.00

Members

Class : ORD No. Held: 80 027298911
Beneficially Held: NO Paid : FULLY
054 945 621 Z & R RACIC PTY. LTD.
6 KENT ROAD HIGHBURY SA 5089

Class : ORD No. Held: 20 027298911
Beneficially Held: NO Paid : FULLY
** JOINT MEMBER **
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201C Application For Registration as a Proprietary Company					

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(International Standard ISO 9001).

154 921 829 MEDICAL VISION AUSTRALIA CARDIOLOGY & THORACIC PTY LTD Document No

ACN (Australian Company Number): 154 921 829
Registered in: South Australia
Previous State Number:
Registration Date: 23/12/2011
Next Review Date: 23/12/2012
Company bound by:

Current Organisation Details

Name : MEDICAL VISION AUSTRALIA CARDIOLOGY & THORACIC PTY LTD 027298923
Name Start: 23/12/2011
Status : Registered
Type : AUSTRALIAN PROPRIETARY COMPANY
Class : LIMITED BY SHARES
Subclass : PROPRIETARY COMPANY

Registered Office

RINALDI & CO 100 GREENHILL ROAD UNLEY SA 5061 027298923
Start Date: 23/12/2011

Principal Place of Business

99 KING WILLIAM STREET KENT TOWN SA 5067 027298923
Start Date: 23/12/2011

Directors

ZDENKO RACIC 027298923
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 23/12/2011

Secretary

ZDENKO RACIC 027298923
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 23/12/2011

Share Structure

Note: For each class of shares issued by a proprietary company, ASIC records the details of the top twenty members of the class (based on shareholdings). The details of any other members holding the same number of shares as the twentieth ranked member will also be recorded by ASIC on the database. Where available, historical records show that a member has ceased to be ranked amongst the top twenty members. This may, but does not necessarily mean, that they have ceased to be a member of the company.

Class: ORD 027298923
ORDINARY SHARES
Number of Shares/Interests Issued : 100
Total Amount (if any) Paid / Taken to be Paid: 100.00
Total Amount Due and Payable : 0.00

Members

Class : ORD No. Held: 100 027298923
Beneficially Held: NO Paid : FULLY
154 907 310 MEDICAL VISION AUSTRALIA HOLDINGS PTY LTD
99 KING WILLIAM STREET KENT TOWN SA 5067

Documents Received

Form Type	Date Received	Date Processed	No. Pages	Effective Date	
201	23/12/2011	23/12/2011	8	23/12/2011	027298923
201C Application For Registration as a Proprietary Company					

Note: Where the expression "Unknown" is shown, the precise date may be available from records taken over on 1 january 1991 and held by the ASIC in paper or microfiche.

*** End of Extract ***

ASIC Current and Historical Extract as at Date: 24 Jan 2012 Time: 12:46:26

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Section 1274B
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154 921 892 MEDICAL VISION AUSTRALIA PLASTIC & COSMETIC PTY LTD **Document No**

ACN (Australian Company Number): 154 921 892
Registered in: South Australia
Previous State Number:
Registration Date: 23/12/2011
Next Review Date: 23/12/2012
Company bound by:

Current Organisation Details

Name : MEDICAL VISION AUSTRALIA PLASTIC & COSMETIC PTY LTD 027298921
Name Start: 23/12/2011
Status : Registered
Type : AUSTRALIAN PROPRIETARY COMPANY
Class : LIMITED BY SHARES
Subclass : PROPRIETARY COMPANY

Registered Office

RINALDI & CO 100 GREENHILL ROAD UNLEY SA 5061 027298921
Start Date: 23/12/2011

Principal Place of Business

99 KING WILLIAM STREET KENT TOWN SA 5067 027298921
Start Date: 23/12/2011

Directors

ZDENKO RACIC 027298921
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 23/12/2011

Secretary

ZDENKO RACIC 027298921
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 23/12/2011

Share Structure

Note: For each class of shares issued by a proprietary company, ASIC records the details of the top twenty members of the class (based on shareholdings). The details of any other members holding the same number of shares as the twentieth ranked member will also be recorded by ASIC on the database. Where available, historical records show that a member has ceased to be ranked amongst the top twenty members. This may, but does not necessarily mean, that they have ceased to be a member of the company.

Class: ORD 027298921
ORDINARY SHARES
Number of Shares/Interests Issued : 100
Total Amount (if any) Paid / Taken to be Paid: 100.00
Total Amount Due and Payable : 0.00

Members

Class : ORD No. Held: 100 027298921
Beneficially Held: NO Paid : FULLY
154 907 310 MEDICAL VISION AUSTRALIA HOLDINGS PTY LTD
99 KING WILLIAM STREET KENT TOWN SA 5067

Documents Received

Form Type	Date Received	Date Processed	No. Pages	Effective Date	
201	23/12/2011	23/12/2011	8	23/12/2011	027298921
201C Application For Registration as a Proprietary Company					

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*** End of Extract ***

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2010-2011, 2 and 3 June 2010

Question: E10-109

OUTCOME 1: Population Health

Topic: BREAST IMPLANT RECALL

Hansard Page: CA 87

Senator Xenophon asked:

Can the TGA provide advice on whether the gel that was initially approved for use in PIP breast implants was the same gel found in independent testing by the TGA?

Answer:

Both the TGA and French regulatory authorities have been undertaking product sample testing to ensure the implants meet quality and safety requirements. TGA's test results to date indicate that the PIP breast implants supplied in Australia conform to the relevant international standards for this type of product including gel cytotoxicity and shell strength.

The TGA undertook further tests on the gel contained within the implant. The approved gel and the gel in the PIP implants were polysiloxane-based materials. The samples tested by TGA contained a gel that had superior physical properties to the approved gel. Specifically, if the shell were to rupture the viscosity of the gel was such that it would be less likely to leak when compared to the originally approved gel material.

The French Authorities are currently testing samples of gel that were taken during their audit. They have agreed to release those results to the TGA and other regulatory agencies as soon as they are available.