Members Health
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10 December 2021

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Dear Ms Duffy

RE: Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia

Members Health is pleased to submit its response to the TGA's consultation on the *Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia*.

As a peak body for value driven health funds that put people first, Members Health welcomes the opportunity to contribute towards reforms of the Medical Device industry to help protect Australian lives.

All the evidence points to increased scrutiny and regulation of the medical device industry being long overdue and overwhelmingly in the public interest.

The revelation that in 2020 alone, the TGA received 6,000 reports of adverse impacts arising from implantable medical devices, is deplorable. It is horrifying that the above figure is likely to be far greater because many thousands of adverse events are presently going unreported by health care professionals and facilities and are hidden from public view.

The urgent need for greater regulation of the medical devices industry is compelling. The largest women's health class action in Australia's history recently took place over a widely used pelvic mesh product. Thousands of women were left in debilitating pain, their lives were destroyed, because of the actions of these international device companies and a regulatory failure by Government.

We find it difficult to comprehend how or why medical device manufacturers have succeeded in avoiding scrutiny over the performance, quality and safety of their products for so long.

The medical device industry is dominated by large multinational corporations and this consultation is Australia's chance to introduce new regulations to hold them to account for the safety of their products. It is Australians' and the healthcare industry's opportunity to stand collectively and demand that the items we place into our bodies are not unfit for purpose".[1]

[1] Lawyers Weekely, 21 November 2019: *'Lives were destroyed': Shine wins 'largest' health class action in Australia's history*. Quoted as judgment by Justice Anna Katzmann.

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Every Australian should be able to trust that the devices being put into their bodies are safe and of clinically efficacy. Likewise, they should be able to trust that their doctor or health practitioner is going to look out for them should things go wrong. Therefore, every health practitioner and facility has a responsibility to the Australian people to report every instance of an adverse event arising from an implantable device and this must be facilitated by Government through a rigorous mandatory scheme that is transparent to the public.

Members Health represents 26 of Australia's not-for-profit and member owned health insurers. Collectively, our member funds cover the health needs of more than 4 million Australians. This consultation – and the wider issue of ensuring efficacy, safety and scrutiny on medical devices – is one that demands a humane, moral and outcomes focused response.

Therefore we see it as essential that government move quickly and decisively to introduce refrom requiring the reporting of adverse events on a single register that is publically avaible online and easy to navigate. That the data be incorporate into the Medical Costs Finder website and individual patient records, discharge summaries, implant registries, and MyHealth records.

Again, Members Health is pleased to provide its views on this consultation in the below submission. We look forward to these changes to mandatory reporting being made as swiftly as possible to avoid another 6,000 lives or more being damaged.

Yours Sincerely,

MATTHEW KOCE

CEO, Members Health

cc: *The Hon. Greg Hunt MP, Minister for Health*

Christopher Fechner, CEO, Digital Transformation Agency

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Discussion

From the outset, Members Health notes its position as an industry peak body, not a health care service provider. Therefore, it does not have direct expertise in existing adverse event reporting processes and systems currently used across the wide variety of healthcare facilities in operation in Australia.

We therefore do not intend to contribute to the questions listed in the discussion paper that related directly to the current landscape of adverse event reporting processes and systems, and how they may be leveraged for a mandatory notification system.

However, a number of private health insurance providers, including some Members Health funds, are direct providers of healthcare services and operators of healthcare facilities (e.g., dental, optical and allied health centres). We suggest those organisations will be better placed to provide the TGA further insights into the matter.

For the purposes of strengthening patient safety, Members Health broadly agrees with more comprehensive post-market monitoring, analysis and scrutiny of medical device safety, as well as reporting of adverse events, in the Australian marketplace.

Among other initiatives, we commend the Government's persistent efforts to streamline (and make more comprehensive and transparent) the reporting of medical device adverse events. Along with the ongoing reforms to the Prostheses List, which seeks fairer pricing of devices for consumers, we believe the proposal for mandatory reporting is another positive step towards protecting the health interests and seeking equitable care for Australians.

Despite these efforts, however, there remain critical issues affecting the Government's capacity to identify, monitor and act upon adverse events arising from medical devices.

The particularly disturbing figures provided in the Discussion Paper – that last year alone, the TGA received 6,000 reports of medical device adverse events – as well as the overwhelming class action concerning transvaginal mesh are case in point for more stringent regulation in this area.

The *Discussion Paper* appropriately identifies fundamental pitfalls in the current reporting system as: 1) Mandatory adverse event reporting requirements exist only for device manufacturers and sponsors, not all health care service providers; and 2) Longer term device failures, which are more likely to have serious clinical impacts years after implantation, often present themselves in a different healthcare setting.

Similar to the soft approach to reforming the Prostheses List thus far, which has failed to stop manufacturers charging private patients outrageous prices for their products, we suggest self-reporting of adverse events grants device makers the same luxury of lax scrutiny and accountability – albeit at the physical and financial detriment of all Australians.

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Recommendations

Importance of data and transparency:

1. Make a public register/record of the reported adverse events from medical devices more accessible to the public and health care providers.
2. Incorporate the database into the Medical Costs Finder website currently in development.
3. Incorporate this database into individual patient records, discharge summaries, implant registries, and MyHealth records.

Members Health supports efforts to ensure that public and private health services effectively and efficiently complement each other. The private health system reduces pressure on the already overstretched public hospital system by providing fast and efficient access to high quality care at a much lower cost to Government.

In addition to a publically conducted annual premium setting process, the full gamut of operations of private health insurers are made publically available through quarterly and annual APRA reports as well as the annual *'State of the health funds report'* published by the Commonwealth Ombudsman. This report details the financial and operational performance of each health insurer, including their Management Expense.

The result of having such transparency imposed on the private health insurance industry is – above all – accountability. Health funds' operations and products are constantly debated, compared and scrutinized in the public arena. And this is due to the availability of the data.

Consumers have many Government and non-government resources to help them choose the right health fund for them based on premium or price, coverage, inclusions or exclusions, additional wellbeing programs, geographical area, industry or community segment.

As a result, the private health insurance industry receives vastly fewer ombudsman complaints as a share of the market compared to general insurance, telecommunications or energy. Their consumers are informed, empowered with choice and – based on recent growth figures – eager to join and seize control of their health care decisions.

Unfortunately the oversight and very high transparency and accountability standards applied to private health insurers do not extend to other players in the health system.

In this particular case, such an environment renders insurers as *passive payers* of overpriced and in thousands of cases, high risk medical devices. Data around the efficacy and performance of medical devices are not readily or easily available.

While the TGA currently has a searchable database of adverse event reports on its website, the problem with it is (i) it is difficult to navigate; and (ii) the underlying data is not integrated with healthcare provider systems – thus, its utility to the public and healthcare providers rely largely on them proactively searching the database for device-specific information.

Therefore consumers and their specialists are unable to make informed and empowered choices around their care.

Given that service providers are the core drivers of health inflation and insurance premium increases, and are central to patient care and treatment, we support transparency measures concerning the efficacy and performance for all medical costs.

Such work supports the Government's Medical Costs Finder website, and has the potential to achieve greater transparency, improved patient literacy and empower patients and clinicians alike with accurate pricing and performance information.

With the above principles in mind, Members Health suggests that a public register/record of the reported adverse events from medical devices be made available to the public. Such a database would be an appropriate addition to the Medical Costs Finder website currently in development.

Likewise, we have long been a supporter of the Government's initiatives to operate e-health records and to improve data sharing and transparency across the health system, empowering all parties in the healthcare journey to make informed and above all, safe clinical decisions.

We are therefore in firm agreement with the proposal to incorporate this database into individual patient records, discharge summaries, implant registries, and MyHealth records.

Efficient and cost effective regulation

1. Develop reasonable estimates of resultant additional compliance costs such that they may be accounted for by healthcare facilities and healthcare funders (who ultimately pay to cover the additional compliance costs).

Members Health recognises and agrees that greater patient/consumer and system benefits would accrue from more timely and complete provisioning of data and information regarding suspected or actual adverse events arising from medical devices and that healthcare facilities should play a more active role than they currently do in providing such data/information to the TGA.

However, one of Members Health's foundational priorities is for fit-for-purpose, efficient and cost effective regulation from government and agencies.

With that, we acknowledge that mandatory notification obligations placed on healthcare facilities will likely add to regulatory compliance costs. But it is assumed that the benefits to both the public and the healthcare system more widely will significantly outweigh the additional compliance costs.

Our overarching objective remains that the TGA persist with the most appropriate, accurate and timely method for collecting this information to ensure better patient safety and positive healthcare outcomes.

However, in designing an appropriate mandatory notification structure for healthcare facilities, we encourage the TGA to develop reasonable estimates of resultant additional compliance costs such that they may be accounted for by healthcare facilities and healthcare funders (who ultimately pay to cover the additional compliance costs) and measured against estimates of patient and system benefits.