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# Bad hips spotlight lip service on TGA

The government  
stands accused of a  
wimpy response to  
protecting consumers

NATASHA BITA  
CONSUMER EDITOR



AS a nurse, Stuart Cain had blind faith in the nation's medicines regulator to protect his patients.

He reassured them that the DePuy hip replacements approved by the Therapeutic Goods Administration were perfectly safe — until he had one implanted to repair the damage wrought by years of rugby in his youth.

After four years of “constant pain and little sleep”, and two operations to replace the dodgy prosthesis, the Brisbane nurse is learning once more how to walk.

“There were massive problems with these joints yet the TGA, through their process of not having to clinically trial something to approve it, was allowing them to still be used in Australia,” he says of the agency's tardiness in banning the heavy metal-leaching false hips.

“It doesn't matter if it is a drug or a piece of equipment; we should be able to use any product in Australia knowing it is thoroughly tested and is safe. The TGA is there to protect patients, but they failed dismally.”

The Gillard government commissioned a rash of reviews

into the TGA after recent health scandals involving the dangerous DePuy metal hip replacements — recalled only after they were implanted in 5500 Australian patients — and Fluvax, the CSL flu vaccine banned for young children after triggering febrile fits in some.

Independent senator Nick Xenophon, who instigated last month's Senate inquiry into the Johnson & Johnson DePuy debacle, describes the TGA as “a watchdog in need of a guide dog”.

“There are some seriously ill people in this country who have gone through hell and back with surgery and ongoing complications as a result of the TGA — the watchdog — not doing its job properly,” he says. “Unless we reform it, it will continue to put Australian lives at risk.”

Eight inquiries and reviews in the past year alone have made 93 recommendations for reform, from the way it is funded to its secretive system of approving and monitoring medicines and its byzantine bureaucracy.

This week, the federal government fobbed off much of

the expert advice, delaying key reforms for “consultation with stakeholders” while giving the TGA four years to implement the findings of a “transparency review”. The theme of the government response is it “prefers to maintain the current self-regulatory focus”. The status quo.

Consumers Health Forum chief executive Carol Bennett is furious the government has refused to force companies to sign up to an industry code of conduct as a prerequisite for TGA approval of their products.

“Now the cowboys in the industry will continue to do whatever they like,” she says. “Who is the TGA's client, after all? It is the consumer, yet the industry remains its core client.”

To Australian National University medical professor Peter Collignon, the government's “wishy-washy” response fails to deal with the inherent conflicts of interest that put patient health at risk.

“We've got major examples of harm and nothing is being done to

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# Bad hips spotlight lip service

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address fundamental flaws in the system. The TGA and government seem to be unduly captured by lobbyists and industry.”

Collignon, head of the infectious disease unit at Canberra Hospital, cites the national shortage of penicillin created when Australian drug giant CSL — which makes Fluvax — asked hospitals to ration supplies for the rest of the year after a shipment failed to arrive in August.

“The (TGA) rules protect the (existing) supplier, so competitors can’t bring in alternative products from overseas,” he says. “The regulations are there to protect the manufacturers much more than the consumers.”

Collignon blames the funding model: under Howard government reforms in 1998, the TGA must source its entire \$105 million budget from industry levies, which range from \$200,000 to approve a new chemical entity to \$76,000 for a generic product.

“It is fundamental for the independence of the regulator that it is funded by the Treasury,” he says. “It may well be that if the TGA decides to stop a drug or a product being sold in Australia, its funding would go down. That’s an entirely improper way to fund a regulator.”

Xenophon agrees the user-pays funding makes the TGA beholden to the pharmaceutical industry it is supposed to regulate: “It just seems all too cosy.”

Just which companies pay how

much is a secret: a Freedom of Information request for a list of sponsors and how much they contributed reveals that 3205 companies paid fees to the TGA last year, but the amounts were blacked out.

The Australian Medical Association, too, has demanded taxpayer funding for the TGA, with AMA president Steve Hambleton arguing that “if the TGA can’t do what it needs to do, we need to ask why”.

This week, the government ruled out taxpayer funding of the agency, revealing it would impose a “modest increase” in the TGA’s fees and charges to industry.

Parliamentary secretary for health Catherine King told Inquirer yesterday that industry funding “is not a conflict”.

“It is perfectly feasible to have an independent regulator continue to do its job with 100 per cent cost recovery,” she says.

The chairman of the TGA transparency review, former commonwealth ombudsman Dennis Pearce, agrees the source of funding is not as important as the amount.

Although the TGA and industry “certainly depend on each other”, Pearce says, “I don’t think it necessarily follows that because the industry pays for the regulator, it has somehow or other has control over the regulator.”

The industry relies on the TGA’s approval as much as the TGA relies on the industry’s

money.

“(The companies) are making billions,” he says. “Unless their product meets the standards the TGA requires, it is not going to be listed in the Pharmaceutical Benefits Scheme.”

Although the TGA needs more money to do its job, Pearce says, governments do not have the money: “Are they going to take money away from hospitals?”

Epidemiologist Emily Banks, who chairs the TGA’s advisory committee on the safety of medicines, defends the TGA’s record, given its level of resourcing.

“The FDA (US Food and Drug Administration) has 17,000 staff and the TGA has about 500, and they pretty much deal with the same number of drugs, so the TGA is doing an amazing job when you think about that difference,” Banks says. “TGA approval is like when you first get your car registered and someone checks the brakes, but then a lot of accidents are caused by driver error. The TGA doesn’t regulate that; it has quite a restricted role.”

At the crux of many of the complaints about the TGA is that it is required only to assess the quality, safety and efficacy of “higher risk” products, such as prescription medicines. What it rates as low risk, such as over-the-counter medicines and vitamins, does not have to be assessed to see if it actually works.

“Medical devices”, ranging from heart valves to hip implants



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‘The regulations are there to protect the manufacturers much more than the consumers’

PETER COLLIGNON  
ANU MEDICAL PROFESSOR

and bandages, merely have to comply with what the TGA describes as “internationally agreed essential principles for their quality, safety and performance”.

In short, the TGA does not require clinical trials of everything it approves, so for many products it is a case of buyer beware. Banks wants the TGA to require a logo to be placed on newly approved products so the public knows to be vigilant for side effects.

“The earlier a drug is in its life, the less is known about its safety,” she says. “It is reasonable for the public to be informed when a drug is early in its post-marketing life.”

Part of the TGA’s job is to audit pharmaceutical companies to ensure they comply with manufacturing regulations. Last year it carried out 256 audits. The TGA reported deficiencies in all but three of the 139 laboratories it inspected in 2009, yet the results remain secret. When *The Australian* sought the outcome of audits of CSL’s Melbourne laboratory in the aftermath of the Fluvax scare, it was told the FOI request would cost more than \$20,000. Yet when

this newspaper sought the results of the FDA’s own damning audits of CSL, the American regulator posted them, free of charge, within a week of the request.

Releasing the government’s Blueprint for TGA’s Future on Thursday, King accepted all the transparency review’s recommendations to publicise the outcomes of its investigations and to let the public search its database of reported side effects. Yet the TGA has been given four years to comply, by which time it will be subsumed by a new bilateral Australia New Zealand Therapeutic Products Agency.

King insists that “the TGA does a good job”, although “there are obviously very complex areas in this space, and there is always room for improvement”.

Citing the TGA’s safety regulation of “complementary medicines”, such as vitamins and minerals and other homeopathic products, she says “we obviously are concerned they are not being complied with as much as we would like”.

Another key reform will be the

introduction of a more efficient surveillance scheme to alert the TGA to side effects of vaccines. When Fluvax sent children into fits, the TGA took weeks to suspend the flu immunisation program because the “adverse events” reports took so long to trickle in.

“The government accepts absolutely the need to improve adverse events reporting and surveillance,” King says.

The changes have come too late for Cain, who suffered heavy metal poisoning from his DePuy hip replacement and still requires physiotherapy three times a week.

Once a proponent of “doctor knows best”, Cain now empathises with patients who prefer to research over the internet rather than trust the regulator.

“I’m not a massive fan of people using the internet to get medical advice because you get promotional and advertising material and not facts,” he says. “But it is very, very hard when you’ve got a regulatory authority that appears to be letting us all down.”



Peter Collignon says the TGA must be funded by Treasury

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LYNDON MECHIESEN

After four years of pain and two operations to replace his hip prosthesis, Brisbane nurse Stuart Cain is learning how to walk again