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"Unacceptable secrecy" around potential safety risks of medicines

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Warnings should be publicly accessible, researchers say

Should new safety warnings about the potentially serious harmful effects of medicines be considered 'confidential business information'? University of Sydney researchers make a case for stronger regulation and full ongoing public access.

Rachel Fergus

Media and PR Advisor

Phone

+61 2 9351 2261

Mobile

+61 478 316 809

Email

rachel.fergus@sydney.edu.au

In *Pharmacoepidemiology and Drug Safety [https://onlinelibrary.wiley.com/doi/full/10.1002/pds.4762]* today, researchers describe their experience of failing to discover – despite persistent efforts – if safety warnings were issued to Australian clinicians for a large number of prescription medicines that were subject to publicly available safety warnings in Canada, the UK and the US.

‘Direct health professional communications’, as these letters to clinicians are called, often provide practical advice on how to reduce the risk of harm such as lowering doses or avoiding use by specific types of patients.

“Before new medicines hit the market they must undergo a series of trials to demonstrate their effectiveness and safety,“ explains co-author Associate Professor Barbara Mintzes [http://sydney.edu.au

/pharmacy/about/people/profiles/barbara.mintzes.php] from the Evidence, Policy and Influence Collaborative [https://sydney.edu.au/charles-perkins-centre/our-research/research-groups/evidence-policy-and-influence-collaborative.html] at the University of Sydney’s Charles Perkins Centre and School of Pharmacy.

“The trials are conducted on relatively small numbers of patients for relatively short periods of time and in highly selected groups. So it’s understandable that new and potentially serious safety problems can be identified once drugs have been marketed and used by larger numbers of people.

> *“What is less understandable is why letters issued to clinicians about new safety warnings for drugs already on the market are not on the public record – and why so many companies as well as the regulator refuse to provide them.”*
>
> – Associate Professor Barbara Mintzes

Failed requests for information

The research team identified 207 drugs from 39 companies that had no publicly available warnings in Australia, but that regulators in the UK, US and Canada had issued warnings about – including around increased risk of heart failure, seizures or death.

The researchers initially asked the Australian regulator – the Therapeutic Goods Association (TGA) – for copies of such warnings sent in Australia. After confirming it held no central file of letters, the TGA advised the team to request the information direct from the manufacturers.

Of the 39 companies the researchers contacted, 24 provided no letters or information on their existence. Nine companies refused requests for information by claiming it was “commercial in confidence” or “not provided to the general public”. Seven didn’t respond; five said they would respond, but didn’t. Three directed the researchers to contact the TGA (which had already instructed the researchers to instead contact the companies).

Fifteen companies provided information, either the letters themselves or confirmation that no warnings were sent out.

Ultimately, the TGA also refused two Freedom of Information requests for this information saying it would “divert resources” from its other operations.

A secret warning is no warning at all

“Our failed efforts demonstrate an unacceptable secrecy around potentially serious harmful effects of medicines, which has no place in modern medicine and should not be tolerated by regulatory agencies,” says Associate Professor Mintzes.

> *“We’re currently operating in a policy vacuum.”*
>
> – Associate Professor Barbara Mintzes

“The TGA regards these safety warnings as the property of the manufacturer and has no legislated authority over the communications, leaving companies free to choose whether to release them – or not.

“To ensure ongoing access to critical safety information we urgently need to develop explicit transparency policies on all postmarket safety communication, and ideally a publicly available searchable online database of all postmarket safety warnings on medicines.”

The research team included academics from the University of Sydney, Macquarie University and York University in Toronto, Canada.

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Commercial sensitivity or patient protection? Secrecy and medicine safety

Amanda Lyons

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Researchers have identified an information gap between pharmacological companies and Australian clinicians on the potential safety risks of medicines.

Researchers have identified an information gap in Australia about potential safety risks in medicines.

The researchers – who included academics from the University of Sydney, Macquarie University and York University in Canada – published a paper looking into the transparency of information given by manufacturers and regulators about post-market evidence of medicines' harmful effects.

They were very concerned by what they found.

'Our [findings] demonstrate an unacceptable secrecy around potentially serious harmful effects of medicines, which has no place in modern medicine and should not be tolerated by regulatory agencies,' Associate Professor Barbara Mintzes, study co-author from the University of Sydney's Charles Perkins Centre and School of Pharmacy, said.

Dr Evan Ackermann, a GP with an interest in the regulation of the pharmaceutical industry, believes the study highlights a serious problem.

'The Sydney University team should be congratulated for exposing a national flaw in our drug safety regulations and practices,' he told *newsGP*.

'This is a very important finding in the development of comprehensive drug safety practices in Australia.'

Medicines must undergo a series of trials before their release into market, but the research team was concerned about what happens after they have been cleared for use in the field.

'[Pre-market] trials are conducted on relatively small numbers of patients for relatively short periods of time an... highly selected groups, so it's understandable that new and potentially serious safety problems can be identified once drugs have been marketed and used by larger numbers of people,' Associate Professor Mintzes explained.

Medicine risks 'hidden from doctors'

SUE DUNLEVY

SERIOUS adverse reactions to medicines, including death, heart failure and pancreatitis, are being hidden from Australian doctors and patients and a new study says that it is "unacceptable".

In the decade between 2007 and 2016 doctors in Canada, the US and the UK received 207 warning letters about medicine serious side effects.

But when Sydney University researchers investigated whether Australians had been informed, it found our medicines watchdog the Therapeutic Goods Administration (TGA) did not post these letters on its website. Regulators in the UK, US and Canada do publish these letters.

Things got worse when researchers asked the TGA to provide copies of the letters to show they had been sent to doctors in Australia and they were told the agency had no central file of the letters.

The TGA told them to approach the 39 pharmaceutical companies who manufactured the medicines, says Dr Barbara Mintzes whose research is published in the journal *Pharmacoepidemiol Drug Safety*.

When they did so, they found only four companies would provide proof that they had sent out the letters in Australia.

Eleven companies said they did not send out the warning letters to Australian doctors.

Fifteen companies that manufactured 83 drugs with safety warnings did not provide any information at all.

Nine companies that produced 87 drugs subject to safety advisories actively refused to provide researchers with copies of the safety warning letters, with some claiming the information was "commercial in confidence".

These companies were Amgen, Astra Zeneca, Aspen, Bayer, Janssen-Cilag, Eli Lilly, Roche, LEO and Pfizer.

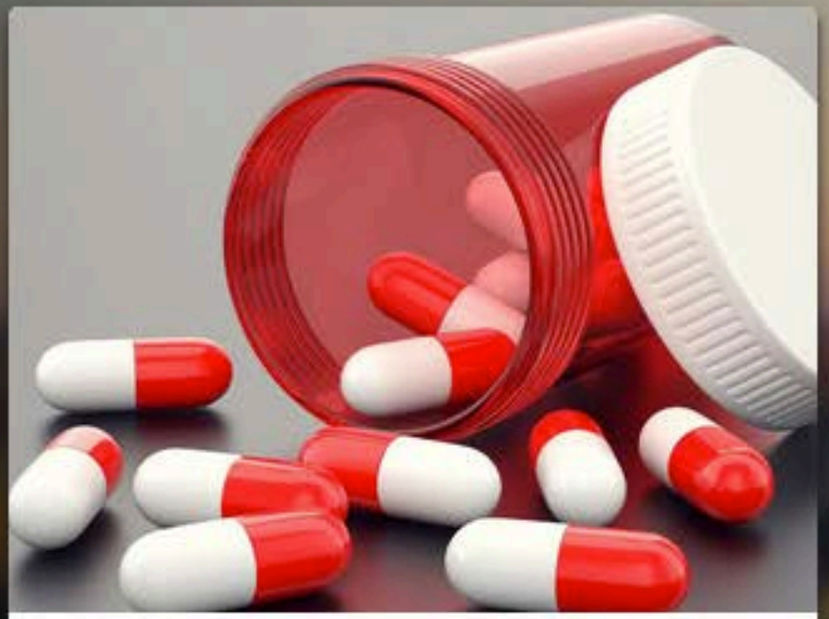
"We were certainly shocked to have that response from some companies," Dr Mintzes said.

"The idea that a warning letter that has gone out to thousands of individual health professionals would be considered confidential is counterintuitive.

"A secret warning is no warning at all."

Prof Mintzes said the study highlighted a serious policy vacuum in which companies were free to choose whether or not to release their safety warning letters.

The Daily Telegraph



SECRET MEDICAL DRUG WARNINGS KEPT FROM AUSSIES

Australian patients are being kept in the dark about serious adverse reactions to medicines including pancreatitis, heart failure and even death.