Access Programs and Why We Need to Tell Physicians About New Medicines Available to Patients

When it comes to healthcare, Australians are fortunate.

We have a world-class health care system that includes an amazing government initiated and managed scheme to ensure that new drugs – perhaps already approved internationally — can be made available in this country, with the approval and supervision of treating doctors.

This scheme is known as the Special Access Scheme (SAS) and was introduced by Australia's Therapeutics Goods Administrations (TGA) "in recognition that there are circumstances where patients need access to therapeutic goods that are not on the ARTG". (https://www.tga.gov.au/form/special-access-scheme).

The motive driving the TGA to initiate the SAS scheme is laudable. However, I continue to hear of many cases, specifically in oncology and haematology, where physicians are completely unaware that special access programs exist.

I recently heard about a patient with a life-threatening illness who sold his home

to import and fund access to a new, innovative and expensive cancer therapy that was not yet approved for use in Australia.

But unbeknownst to both the patient and his physician, there was a special access program – fully compliant with Australia's laws – that would have enabled him access to this unapproved medicine with significantly less financial sacrifice.

Further, this access program was initiated by the pharmaceutical company that developed, manufactured and ultimately imported the drug into Australia for the specific purpose of enabling Australians access to this cancer therapy prior to its regulatory approval.

And herein lies one of the great dilemmas facing pharmaceutical companies developing specialty medicines.

Under the Medicines Australia Code of Conduct, proactively communicating information to a medical professional about the availability of any unapproved drug via an access program under the auspices of the TGA SAS is forbidden, as it is seen to be advertising or promoting an unapproved specialist medicine.

This is where I say – and many of my medical oncologist and haematologist colleagues agree– that there has to be a rethink.

MA must acknowledge that there is a significant difference between advertising and informing.

At the very least, we must have absolute confidence in the decision making process our health care professionals undertake when considering prescribing an unapproved therapy.

These decisions are being made by highly educated, intelligent professionals who have dedicated their lives to medicine. These doctors are not going to provide a medicine to a patient just because they have heard about an access program. They will research information to make the right decision, for the right patient, at the right time.

Given the tremendous workloads of specialist physicians, it is unreasonable to expect that they would be fully aware of all available access programs. And there are many, as numerous innovative therapies have emerged in recent years. My company alone has several access programs in place.

The pharmaceutical industry should be encouraged to ensure all appropriate physicians are made aware of any access programs responsibly, and without making any promotional claims about the efficacy and safety of these medicines.

This information will enable physicians and patients to make informed and timely decisions about whether they wish to access the unapproved drug.

More broadly, patient and public health lobbyists are also calling for access program information to be available via a central national database, so physicians and patients are aware which new therapies might be available, albeit with special provisions.

Such a database would ensure that the intent of the TGA's SAS is fully realised, ensuring all Australians have the opportunity to access innovative but unapproved new medicines, when deemed appropriate by their physician and when strictly supplied by legitimate medicine manufacturers and developers.