painaustralia

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health
PO Box 9848
CANBERRA ACT 2601

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Dear Adjunct Prof Skerritt

Thank you for the opportunity to comment on the draft Therapeutic Goods Administration (TGA) complaints management process regarding advertising of therapeutic goods to the public.

Painaustralia has a keen interest in ensuring the regulation, compliance and enforcement of therapeutic goods enables the most effective and safe use of all medicines be they prescribed, over the counter and/or self-selected. This must be underpinned by effective complaint management processes that strengthen transparency for industry and the public.

Pain is one of the most prevalent conditions for which consumers seek medical attention and chronic pain impacts a significant portion of the Australian population (one in five Australians lives with chronic pain). People in pain are vulnerable to targeted by industry promoting a diverse range of therapeutic goods. This includes a broad range of complementary medicines and treatments, and increasingly consumers are using these medicines - while the mechanisms, side effect profiles, and efficacy of these alternative therapies remains unknown and untested.[i]

It is vital that consumers, prescribers and health practitioners are equipped with factual, evidence-based information to make informed choices about their treatment options to prevent unintended consequences arising from misuse or the pursuit of ineffective medicines that averts consumers from seeking evidence-based treatment pathways.

Painaustralia is concerned that the proposed TGA complaints handling model provides less transparency and accountability than the current system. Our concerns are in line with many others in the health and medical research community that the proposed system is too reliant on the word of industry and places too much onus on complainants to follow up the progress of their complaint.

Specifically, we would like to see the following issues addressed in the new model. Some of these elements are features of the current complaints system:

- **Greater transparency about the inquiry complaints process** regardless of priority level determined by TGA (low, medium, high or critical priority) by actively informing complainants:
  - if their allegations of code breaches were agreed with;
  - the priority level that their complaint has been registered as; and
  - the inquiry outcome – that includes what breaches were justified and if a 'regulatory notice' was issued and achieved compliance. This alleviates complainants of the need to follow up the outcome of their complaint.

- **Enhanced reporting and monitoring** about the total number and nature of complaints, that includes an assurance that all complaints, including low priority cases will be reported on an

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annual basis. This should include reference to the conditions that products are seeking to alleviate. This information can then be provided in a transparent way to the public and include:
- details of the product involved for all levels of complaint, not just high priority cases; and
- which alleged Code breaches were determined by the TGA to be justified.

- **Enhanced reporting of the actions of product sponsors** in responding to alleged breaches including publishing details of how they have responded and if these actions achieved compliance or not on specific products. It also includes compliance achieved by negotiations between the TGA and sponsors, not just compliance reached through regulatory enforcement.

- In general, **more transparency in the way the TGA reports and monitors trends in compliance activity by industry** including:
  - details of the most non-compliant companies, updated on a regular basis;
  - total number of complaints received, not just percentages;
  - separate reporting of targeted and random reviews of products and how that impacts on the trends on compliance; and
  - more details on the categories of products targeted by random reviews so consumers are more easily able to identify information that is relevant to them and their condition.

Painaustralia is keen to see the current complaints system strengthened, not weakened, yet we remain concerned that protecting the interests of consumers are not paramount in the draft model.

The effective regulation of therapeutic goods is critical to ensuring consumers access best practice evidence-based care. For people living with chronic pain this encompasses an interdisciplinary approach that embraces a combination of medical, physical and psychological therapies and can reduce reliance on pain medications. Our concern is that for the millions of Australians living with chronic pain, the pursuit of ineffective medications and treatments divert them from accessing best practice care that has the best chance of improving quality of life and restoring function.

Thank you again for the opportunity to provide feedback on the draft model. We look forward to receiving more information about the next steps and are happy to be engaged further in the finalisation of the model.

Yours sincerely

[i] https://www.ncbi.nlm.nih.gov/pubmed/21063917

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