NATIONAL ONCOLOGY ALLIANCE

Submission to the Therapeutic Goods Advertising Code 2018 (*The Code*)

The National Oncology Alliance (NOA), comprising of representatives from patient groups, the pharmaceutical industry, medical oncology and research, as well as individual patients, welcomes the opportunity to provide comment on the update to the Therapeutic Goods Advertising Code (2018).

This submission will focus on the critical need for medical practitioners to be able to securely, reliably and quickly source information about various drug access schemes potentially available for patients, where such medicines are not currently reimbursed under the Pharmaceutical Benefits Scheme (PBS)**[1] and where these are set up by individual pharmaceutical companies. Often these drug access schemes are called different names, but the purpose of this submission is to deal with any access program (using the colloquial definition of the term "access") that precedes PBS subsidy.

Due to the length of the complex processes by which medicines are currently recommended and listed for subsidy on the PBS (i.e. for one indication and often for particular lines of treatment), we are aware of innumerable examples where patients never receive medicines that are ultimately listed on the PBS. Whilst they could be purchased by some individuals, the prohibitive costs of doing so for most of the community, means that most innovative drugs cannot be accessed until they are PBS listed or through one of these access programs (referred to above) which often provide drugs either free of charge or at a much-reduced cost.

However, because companies are not allowed to notify clinicians about these access programs (for fear of breach of the current Advertising Codes), many clinicians will not even be aware that such an access program has been established. As a result, their patients miss out. This is a particular problem for clinicians working in remote, rural or regional Australia, many of whom are much less likely than their metropolitan colleagues to meet up with representatives of the pharmaceutical industry who are willing to divulge information about their access programs if specifically asked for details. However, the issue is just as pertinent to city-based clinicians who cannot be expected to keep abreast of these programs as they open and close at various times and as each company is different, with varied cost-share arrangements according to the disease, drug, and other conditions.

As it currently stands, pharmaceutical companies are unable to inform the general public about these schemes as that would be in contravention of the Code. However, the NOA sees there being no legitimate reason for *health professionals* to be denied access to this information, as not only does the information constitute an urgent public health imperative, it also does not appear to be in contravention of existing regulation.

[1] **Please note this **does not** refer to the TGA's Special Access Scheme, but rather to the variously named forms of *compassionate* access schemes across pharmaceutical companies

Section 6 (2) of the Code clarifies that it's application refers *only* to advertising of therapeutic goods to the **public**, and that 'advertisements directed exclusively to health professionals [defined in s.42AA of the Act] are **not** subject to the requirements of the Code' (emphasis added).[2]

Additionally, the Code asserts that 'content provided online must be behind a secure firewall and can only be accessed once the AHPRA or other professional accreditation of the individual requiring access has been established.'[3]

The access scheme notification processes we are proposing would take the form of an encrypted online portal with clinician only login. A workshop involving a coalition of patients, clinicians, MOGA, HSANZ, Medicines Australia and the TGA to identify solutions to address the restricted information currently available to clinicians about these compassionate access programs is to be held in June, the results of which can hopefully be implemented shortly thereafter.

In addition to the argument that private publication of such information falls outside of the regulation of the Code, there is also a substantial argument to be made that such notification performs an informational rather than promotional function. Additionally, this informational function will only be available to highly qualified clinicians specialising in cancer treatment.

This proposal serves a great public health need.

Clinicians are currently unable to securely, reliably, and quickly obtain information about access schemes. Such a situation is very concerning for the many patients that are paying hugely expensive out-of-pocket costs for medicines and missing out on these schemes – or are unable to access these schemes *at all.* Access schemes exist as a last resort for the far too many patients that fall through the cracks of our health system.

The National Oncology Alliance is seeking either confirmation from the Therapeutic Goods Administration that the above interpretation of the Code would not prohibit encrypted content of access schemes to be available for clinicians. Alternatively, the National Oncology Alliance seeks any adjustment necessary to the Code to address this urgent public health need and empower clinicians with the information they require to best serve their patients.

We look forward to the Therapeutic Goods Administration's consideration of the above submission.

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[2] TGA, *Therapeutic Goods Advertising Code 2018 – Guidance on applying the Code when advertising therapeutic goods to the public* 2https://www.tga.gov.au/sites/default/files/draft-therapeutic-goods-advertising-code-guidance-2018.pdf 2018, p.13.

[3] Ibid. p. 14