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The Therapeutics Goods Administration (TGA) continues to ensure compliance with the Australian Therapeutic Goods Advertising Code (No.2) 2018. It published a communique from the meeting of the Therapeutic Goods Advertising Consultative Committee held on 13 June [1], rules about safety claims in advertising [2], and guidance on the use of the word ‘natural’ in advertising [3]. On 23 July 2019, it also published on ruling of the Federal Court of Australia, which ordered Peptide Clinics Australia (Peptide Clinics Pty Ltd) to pay $10 million to the Commonwealth for breaches of the mandatory rules for advertising of medicines, including the ban on advertising prescription-only medicines to the public [4].

On 9 July, the TGA published information about new regulations for stem cell treatments in Australia that came into effect on 1 July 2019 following a one-year transition period. The new regulations maintain consumer access to established stem cell treatments while protecting consumers from unproven and harmful treatments. Under the new regulations, all providers of cell and tissue products who operate outside of hospitals will need to meet the TGA's requirements for safety, quality, and effectiveness. Providers who fail to meet the requirements may face criminal charges [5].

The TGA has also published information on the Australian regulatory guidelines for biologicals (ARGB) [6], guidance on testing applicable to biological medicines during and after registration in the Australian Register of Therapeutic Goods (ARTG) [7], and an overview of how specific overseas assessments and approvals can be used as support for a possible abridged assessment of an application for a TGA conformity assessment certificate, or as documentation to be provided with applications for inclusion of medical devices (including IVDs) in the ARTG [8]. Therapeutic goods entered in the ARTG can be lawfully supplied in Australia. There are also new guidelines on the regulation of disinfectants [9] and on the implications of the implementation of European Medical Device and IVD Regulations in Australia [10].

The TGA announced on 17 July 2019, that Pembrolizumab (KEYTRUDA) has become the first medicine to have additional indications registered on the ARTG via the TGA's provisional approval pathway. Pembrolizumab’s indications now include the treatment of patients with metastatic colorectal carcinoma (bowel cancer) and other solid tumours with certain types of mutations (deficient mismatch repair). Provisional approval allows the TGA to approve some prescription medicines for a limited time while more research is conducted. The continued approval of pembrolizumab for these new indications will depend on further evidence of clinical benefit from clinical trials being provided by the product sponsor. [11]

On 11 July 2019, the TGA published advice to health professionals regarding Tocilizumab and hepatotoxicity [12].


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