On 19 December 2018, the TGA announced the inclusion of Kymriah (Tisagenlecleucel) on the Australian Register of Therapeutic Goods (ARTG). Therapeutic goods entered in the ARTG can be lawfully supplied in Australia [1]. The approval extends to three clinical sites in the first instance – Royal Prince Alfred Hospital (New South Wales), Peter MacCallum Cancer Centre (Victoria) and the Royal Children’s Hospital (Victoria). The Australian government is currently considering a funding application through the Medical Services Advisory Committee (MSAC). MSAC considered Kymriah but the outcome has yet to be published.

On 11 January 2019, the TGA announced that it is seeking comments on a pilot Good Clinical Practice (GCP) Inspections Program of 12 months duration that will inform a routine GCP Inspections Program. The purpose of the consultation is to outline the rationale for introducing a domestic GCP Inspections Program for clinical trials conducted under Australia’s Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes. The aim is to enhance the TGA’s ability to identify risk over the life of clinical trials and ensure compliance with international GCP guidelines and the Therapeutic Goods Regulations 1990, while also continuing to build and protect Australia’s competitive advantages in the clinical trials sector. The consultation closes on 22 February 2019 [2].

The second meeting of the TGA’s Therapeutic Goods Advertising Consultative Committee is scheduled for March 2019. The Committee includes representatives from consumer, health professional, industry, media and government bodies. It provides input and advice on a range of matters, including the administration of the Therapeutic Goods Advertising Code 2018, emerging issues, complaints handling and reporting, and education and compliance priorities. The first meeting was held in October 2018 [3].

References

3. Therapeutic Goods Advertising Consultative Committee (TGACC)
   https://www.tga.gov.au/committee/therapeutic-goods-advertising-consultative-committee-