Regulation of autologous cell and tissue therapies in Australia

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Human cell and tissue products (HCTs) can be derived and used as part of medical practice or supplied as products manufactured for therapeutic use. Medical practice and therapeutic products are overseen by different regulatory frameworks, with therapeutic products regulated under the *Therapeutic Goods Act 1989* (the Act) by the Therapeutic Goods Administration (TGA).
Some autologous HCTs are currently excluded from regulation by TGA through provisions outlined in the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 (the Order). This provision was intended to facilitate individual medical practitioners performing accepted procedures. Increased public and professional scrutiny raised concerns that some autologous 'stem cell' therapies, in particular, are being provided without adequate evidence for efficacy or safety of the treatments. TGA released a discussion paper for consultation in January 2015. The purpose of the discussion paper was to canvas the views of the public on potential options for regulating autologous stem cell therapies currently excluded from regulation by TGA by way of Item 4(q) of the Order. This presentation outlines some of the findings of the consultation and the current regulatory status of autologous and allogeneic human cell and tissue therapies.