



## Quiz

The regulation of autologous stem cell therapies

1. What are autologous stem cells?
  - a. Donated cells
  - b. Cells derived from a patient's own body
  - c. Cells derived from a patient's next of kin
  - d. Cells created in a developed in a lab or clinic
2. Which of the following bodies recently announced proposed amendments to the regulatory regime around autologous stem cell therapies?
  - a. The Australian Health Practitioner Regulation Agency
  - b. The Australian Medical Board
  - c. The Therapeutic Goods Authority
  - d. The Australian Competition and Consumer Commission
3. Which of the following is the only disorder for which a safe and effective stem cell treatment has been proven?
  - a. Leukemia
  - b. Ligament repair
  - c. Dementia
  - d. Arthritis

4. What condition must be met for the supply of autologous stem cell therapy without approval by the TGA as provided by item 4Q of the *Therapeutic Goods (Excluded Goods) Order No 1 of 2011*?
- a. That the cells are collected from a patient who is in the clinical care and treatment of a registered medical practitioner
  - b. That the cells are being manufactured by the practitioner or someone under the medical practitioner's supervision
  - c. That the cells are for therapeutic application or treatment in a single course of treatment by the same practitioner or someone under the practitioner's supervision
  - d. All of the above
5. Which of the following was a proposed change to the regulatory framework in regard to autologous stem cell therapies?
- a. That a substantial proportion of autologous stem cell products would be subject to TGA regulation;
  - b. That the direct advertising of stem cell therapies is to be prohibited
  - c. That clinics cannot use colloquial terms such as 'stem cells'
  - d. All of the above

**Answers:**

**1. B 2. C 3. A 4. D 5. D**