



Australian Government
Department of Health
Therapeutic Goods Administration

[REDACTED]
Chief Executive
Australian Red Cross Blood Service
417 St Kilda Rd
Melbourne VIC 3004

Our Reference: R13/982015

Dear [REDACTED]

RE: Proposal for changes to blood donor deferral guidelines

Earlier this year, the Blood Service formally requested TGA to relax blood donor deferral periods for a number of sexual activity-based behaviours from 12 months to 6 months. In particular, you requested consideration of a reduced deferral period for male-to-male sex (MSM) and bisexual contact (women having sex with MSM) practices.

The Blood Service Technical Master File requires demonstration of compliance to a number of standards, including Therapeutic Goods Order No 88: *Standards for donor selection, testing and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products*. The standard currently stipulates ineligibility to donate for 12 months from last contact for ‘a donor whose sexual practices put them at increased risk of acquiring infectious diseases that can be transmitted by blood, cells or tissues’.

We have considered your request on the basis of risk-benefit to the blood supply. In simple terms, we considered potential risks and potential benefits in terms of the possibility of increased risk of infected blood entering the blood supply and the potential increase in the blood supply from an increased pool of donors.

Based on this analysis, it is not proposed at this time to alter the deferral period.

Several factors were taken into account. In discussions between the TGA and the Blood Service, and in our consultations with a wider group of health care professionals, it was agreed that a change in the donor deferral period to 6 months from the current 12 month period would be unlikely to provide a significant increase in the blood supply.

While we are mindful of the range of measures in place by the Blood Service to address the risk of transfusion-transmissible infection (TTI), newly-diagnosed HIV cases increased by 10 per cent in Australia in 2012, predominantly among gay men and men who have sex with men. This is the largest annual increase in new cases in 20 years and can only partly be explained by increased HIV testing.

The five national strategies, which provide a framework to guide Australia's response to HIV, hepatitis B, hepatitis C, sexually transmissible infections and Aboriginal and Torres Strait Islander blood-borne viruses and sexually transmitted infections are currently under review. The strategies will address the key challenges and underlying reasons for the rising rates of infections, including the need to reinvigorate safe sex messages as the foundational response. It is expected that the Standing Council on Health will consider the strategies during 2014.

We agree that donor compliance is central to the management of risk. We welcome the Blood Service's recent efforts in conducting a survey of TTI-negative male donors in Australia which identified that 1.2% of respondents had not revealed deferrable activity on their pre-donation questionnaire, including 0.23 % MSM.

However, we are most concerned that there is no clear explanation for the differences in rates of non-compliance found in several overseas surveys and the Blood Service results, as the greatest risk would be from donations that take place during that period following a risk activity. As we have discussed, similar surveys in other countries (US, Canada and Hong Kong) revealed 4-10 times higher levels of non-compliance (0.8, 1.4 and 2.3% respectively) than the levels that your survey found. While it has been speculated that the shorter donation deferral period that current exists in Australia than these other countries may lead to increased compliance by potential donors, such an assertion is difficult to objectively prove.

As you are aware, there are a range of donor deferral periods in different countries for sexual activity-based behaviours, and the 12 month deferral period in Australia is at the lower end of these. The periods range from indefinite deferrals for MSM in the United States and several European countries, 5 years in Canada and New Zealand, 12 months in the UK. Only two countries have 6 month deferrals - South Africa and Japan. Technical recommendations from the WHO Guidelines on Assessing Donor Suitability for Blood donation (2012) advise that individuals whose behaviour put them at high risk of transfusion transmissible infections should be deferred permanently.

We appreciate your patience and cooperation over the last few months while we have consulted more widely on the proposal, and my colleagues at TGA and I look forward to working closely with the Blood Service during 2014.

Yours sincerely



Prof John H Skerritt
National Manager
13 December 2013