

18 December 2019

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Blood and Infectious Disease Safety Unit
Biological Science Section
Scientific Evaluation Branch
Therapeutic Goods Administration
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Dear §22

Proposed changes to the Guidelines for the Selection of Blood Donors for sexual activity based risk factor deferrals

Australian Red Cross Lifeblood proposes to reduce the deferral period for all donors with a sexual activity-based risk factor from twelve to three months since the last sexual contact.

There is strong supportive evidence for a change from the existing 12 months to a 3-month deferral period for all the proposed sexual activity-based deferrals. The evidence base includes a robust body of local and international epidemiological data and improved testing technology, and is consistent with a number of overseas blood establishments.

Most importantly, predictive risk modelling indicates that a 3-month deferral period for male-to-male sex would keep the risk of transfusion-transmitted HIV well below the tolerable threshold. Because no other sexual activity-based risk group carries a higher burden of any TTI than HIV among MSM, this modelling also establishes the safety of applying the same 3-month deferral period to all sexual activity-based exposure risks. Lifeblood anticipates that adopting this proposal would yield a modest sufficiency gain without affecting patient safety.

We have been consulting with CSL Behring (CSLB) about our planned change to the deferral, in accordance with our agreement relating to plasma-for-fractionation. We are yet to receive formal acknowledgement from CSLB of the proposed change, or their risk assessment of the impact on plasma derived medicines. We understand that CSLB would need to make a separate TGA submission for those products.

Our preference is to simultaneously implement this change for both components for direct transfusion as well as for plasma for fractionation. However should CSLB not seek a change in the deferral period for their products (and only accept plasma that is from donors with a 12-month deferral period), we are confident that we could still implement the reduced deferral period for whole blood donations.

By utilising functionality associated with the recently implemented electronic donor questionnaire, Lifeblood has identified a robust mechanism which supports the collection of whole blood from donors with a 3 month deferral for sexual activity. Plasma recovered from these whole blood donations would be prevented from entering the CSLB plasma stream.

The proposed approach is summarised below:

- All donors would be required to answer the current sexual activity-based risk factor questions which would identify such activity within the last 12 months.

- If a donor answers yes to any of these questions, the electronic donor questionnaire will then require the donor to answer whether the risk activity occurred within the last 3 months. If the risk activity occurred within the last 3 months, the donor will be deferred. If the risk activity occurred within the 3 to 12 month timeframe they will only be eligible to give a whole blood donation.
- Our National Blood Management System will automatically restrict the use of their recovered plasma to research use only; it will not be able to be supplied to CSLB or for clinical use. Red cells and platelets manufactured from these whole blood donations will be able to be used for direct transfusion.

We look forward to discussing this approach with you further if required.

Yours sincerely,

