

From: s22
To: s22
Cc: s22; Infectious Disease Safety; (AUS) Regulatory Affairs and Audit Team; s22
Subject: RE: Request for additional information: Donor deferral period submission [SEC=UNOFFICIAL]
Date: Thursday, 12 March 2020 12:02:51 PM
Attachments: [image001.gif](#)

Hi s22

Thank you for the follow up phone call yesterday. Please see a corrected extract of the proposed guideline change, with a strike out through "*sexual contact with a new partner from a HIV high prevalence country*" which is in line with Q2 from your earlier email.

Proposed guidelines

Apply a 3-month deferral to anyone reporting the following activities:

- for male donors: male-to-male sex
- for female donors: sex with a man who has ever had sex with a man
- for transgender donors: sexual contact with a male
- sex work
- sexual contact with a sex worker (male or female)
- ~~sexual contact with a new partner from a HIV high prevalence country~~
- overseas sexual contact with a resident of a HIV high prevalence country
- sexual contact with an injecting drug user (current or past)
- sexual contact with a partner known to be infected with a blood-borne virus (HIV, HBV, HCV or HTLV)

Apologies for any confusion. Please let me know if there is anything further that you need from the team.

Regards

s22
s22

Manufacturing and Quality Division

Australian Red Cross Lifeblood

P: s22 or s22
M: s22

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From: s22
Sent: Tuesday, 3 March 2020 9:49 AM
To: s22; s22@health.gov.au; s22@health.gov.au>
Cc: s22@health.gov.au>; Infectious Disease Safety <infectiousdiseasesafety@health.gov.au>; (AUS) Regulatory Affairs and Audit Team <DL-RegulatoryAffairs@redcrossblood.org.au>; s22@redcrossblood.org.au>; s22@redcrossblood.org.au>
Subject: RE: Request for additional information: Donor deferral period submission [SEC=UNOFFICIAL]

Hi s22,

Thank you for your email. Please find attached the responses to your questions.

1. *Page 4/41: A statements in support of a 3-month deferral is not referenced. For example "Hepatitis A virus (HAV) outbreaks have occurred in multiple states in which male-to-male sex was the predominant mode of transmission. In the absence of HAV donation testing, a 3-month deferral period provides appropriate risk mitigation for hepatitis A among MSM. " While this may be true, the scientific basis for the statement in this second sentence is not stated, nor on page 15/55 where it mentioned again. Can Lifeblood please provide the reference to this statement?*

Lifeblood response – The evidence to this statement is detailed in the risk modelling and supplementary literature used in the HAV risk modelling section (Appendix A) on page 23 and page 25 in the submission.

2. *Page 28/41 in the GSBD. In this entry for 'HIV risk area contact, new partner' the deferral period remains at 12 months. Can Lifeblood please confirm that this deferral period is not intended to change to three months in line with the changes for other groups? For example, the deferral period for 'HIV risk contact, while overseas', has changed from 12 to three months for whole blood donors. If the deferral period for 'HIV risk area contact, new partner' is to remain at 12 months, can Lifeblood please provide the rationale for this?*

Lifeblood response – Lifeblood can confirm that the deferral period for "HIV risk area contact, new partner" is intended to remain at 12 months while the deferral period for "HIV risk contact, while overseas" is intended to change to 3 months. The rationale for this that the "new partner" deferral differs from the other sexual activity deferrals – including the "while overseas" deferral – in that it is not a "post-contact" deferral. Instead, it only applies for the first 12 months of an ongoing sexual relationship. This allows donors who are in an ongoing relationship with a person from a HIV risk area to regain eligibility to donate without being deferred for a set period after every sexual contact with their long-term partner.

Therefore the 12-month deferral period in this case is to cover the highest risk period for transmission of HIV during a long-term sexual relationship between an Australian donor and a former resident of a HIV risk area. Because this "highest risk period" is not directly influenced by the duration of the testing window period for HIV, Lifeblood sees no justification for decreasing this 12-month exclusion period for donors with a new sexual partner from a HIV risk area and therefore this existing policy will not be changed.

Meanwhile, Lifeblood proposes that the deferral period for overseas sexual contact with a resident of a HIV risk area be decreased from 12 months to 3 months. This is consistent with other "post-contact" deferrals that are applied from the date of last sexual contact - on the basis that the required deferral period is directly related to the duration of the testing window period for HIV.

Regards

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From: s22 [REDACTED] <s22@health.gov.au>

Sent: Monday, 24 February 2020 9:52 AM

To: s22 [REDACTED] <s22@redcrossblood.org.au>

Cc: s22 [REDACTED] <s22@health.gov.au>; (AUS) Regulatory Affairs and Audit Team <DL-RegulatoryAffairs@redcrossblood.org.au>

Subject: Request for additional information: Donor deferral period submission
[SEC=UNOFFICIAL]

Hi s22 [REDACTED]

As discussed, the Advisory Committee on Biologicals met on Friday 21 February to discuss the Lifeblood submission 'Proposed changes to the Guidelines for the Selection of Blood Donors (GSBD) for sexual activity based risk factor deferral periods'.

The Committee suggested to the TGA delegate that some further information/comment be sought from Lifeblood on a couple of issues to clarify the details of the submission. I have provided the queries from the ACB member(s) below.

1. Page 4/41: A statements in support of a 3-month deferral is not referenced. For example "Hepatitis A virus (HAV) outbreaks have occurred in multiple states in which male-to-male sex was the predominant mode of transmission. In the absence of HAV donation testing, a 3-month deferral period provides appropriate risk mitigation for hepatitis A among MSM. " While this may be true, the scientific basis for the statement in this second sentence is not stated, nor on page 15/55 where it mentioned again. Can Lifeblood please provide the reference to this statement?
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We will be in touch with further updates and if any addition requests for information arise during the ratification of the Minutes for the ACB meeting. I thought it would be useful to get these initial questions to you as soon as possible, with the timeframe of 31 March for the TGA Delegate's decision still the target.

Please let me know if you require any further information.

Kind regards.

s22 [REDACTED]

s22 [REDACTED]

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