Australian Government
Department of Health
Therapeutic Goods Administration

Document No: D20-3008284

The Chief Executive Officer
Australian Red Cross Lifeblood
Level 3, 417 St Kilda Road Melbourne VIC 3004
GPO Box 5103 Melbourne VIC 3001

Attention: s22
Email: s22 @redcrossblood.org.au

Dear s22

REQUEST UNDER SECTIONS 14 AND 14A FOR CONSENT TO SUPPLY THERAPEUTIC GOODS THAT DO NOT CONFORM WITH A STANDARD

I refer to your request under sections 14 and 14A of the Therapeutic Goods Act 1989 (the Act) dated 26 June 2020 in relation to proposed changes to the Guidelines for the Selection of Blood Donors (GSBD) for sexual activity based risk factor deferral periods (RR17-045).

The proposed changes to the Guidelines for the Selection of Blood Donors in this current application are to reduce the deferral period for donors with a sexual activity risk factor from 12 months to three months since last contact.

I note the previous Lifeblood application of 17 March 2020 and TGA decision letter of 8 April for the changes to the donor deferral periods for whole blood donors only at D20-359363. This approval decision supersedes that previous decision.

The proposed changes in this submission do not comply with:

Therapeutic Goods Order No. 88 - Standards for donor selection, Part 3 section 9(4), Table 1 (k): A donor whose sexual practices put them at increased risk of acquiring infectious diseases that can be transmitted by blood, cells or tissues. Ineligible for 12 months from last contact.

Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019 Subsection 7(1) that specifies the requirements in relation to blood and blood components as those set out in the Council of Europe Guide (CoE Guide) for the preparation, use and quality assurance of blood components (19th edition):
Standards for selection of donors, Chapter 2, section 4, table 2.1
- Persons whose sexual behaviour puts them at a high risk of acquiring severe infectious diseases that can be transmitted by blood must be deferred permanently.

- Current sexual partners of people with HIV must be deferred. Previous sexual partners of people with HIV are acceptable 12 months after the last sexual contact.

You have asked for the Secretary's consent to supply all blood components as per the Technical Master File (TMF) in Australia, including clinical components and plasma for fractionation, notwithstanding they do not conform to the requirements of Therapeutic Goods Order 102 or Therapeutic Goods Order 88.

The Lifeblood submission proposes a change to the donor deferral period from 12 months to three months for donors 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)
- 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)

Donors currently receiving pre-exposure prophylaxis HIV prevention (PrEP) treatment are outside the scope of this submission, and the deferral period for those donors remains unchanged at 12 months post PrEP.

Lifeblood proposes that the deferral period for donors with new partners from HIV risk areas remains at 12 months as the deferral 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 the need for deferral for a set period after every sexual contact with their long-term partner. After 12 months the sexual partner is no longer defined as 'new' and the deferral will no longer apply.

The scope of any change in donor deferrals resulting from this submission is restricted to Lifeblood and does not apply to other sponsors/products.

Decision

As a delegate to the Secretary of the Department of Health under sections 14 and 14A of the Act, I consent under those sections to the supply in Australia of the product that does not conform to the requirements of subsection 7(1) of Therapeutic Goods Order 102 and Part 3 section 9(4), Table 1 (k) of Therapeutic Goods Order 88.

This decision has been made based on the risk analysis supplied by Lifeblood that demonstrates recipient safety remains within accepted risk tolerance parameters. It is noted that the minimal increase in sufficiency of blood products due to this change in donor deferral periods is not considered a significant factor in the decision.

This consent is effective from the date of this letter. As a delegate under section 15 of the Act, I impose under subsection 15(1) the following conditions on that consent:

- Should new information become available in the future that indicates the risk of transmission of infectious diseases from donors has increased, Australian Red Cross Lifeblood must submit this information to the TGA and obtain approval to continue with this consent.
- Due to uncertainty regarding the impact of this change on the rate of non-compliance to donor selection questions for Australian donors, Lifeblood should

assess the non-compliance rate of high-risk donors and monitor the return rate for donors, and provide this information to the TGA for review within two years of the date of this approval.

It is an offence under section 15 of the Act, and a civil penalty under section 15AA of the Act may be payable, for breach of a condition of this consent.

The Act can be found online at the following link:
https://www.legislation.gov.au/Series/C2004A03952

Material considered in the decision making:

- Information submitted by Australian Red Cross Lifeblood; and
- Advice from the Advisory Committee on Biologicals (ACB)

Reasons for decision

The proposed change to a three month donor deferral period for donors with sexual activity based risk factors is supported, based on the evidence provided in the Lifeblood submission and the advice received from the Advisory Committee on Biologicals including:

- the proposed donor deferral period of three months is approximately twice the longest test window period for relevant TTIs (HTLV and syphilis) and considerably longer for other relevant TTIs (HIV, HCV, HBV)
- the results of mathematical modelling suggest the risk of HIV transmission remains acceptable, noting that HIV transmission constitutes the largest risk for any TTI in any group subject to sexual activity based deferrals and has the highest concern based on societal, political and clinical concerns
- changes to donor deferral criteria for Australian sourced plasma from Lifeblood do not have an impact on final product risk assessments for CSL Behring's plasma-derived medicinal products, as the controls and processing procedures ensure the required level of safety for product and patients
- the proposed donor deferral of three months is also approximately three times the incubation period of HAV infection prior to symptom onset and is acceptable
- experience from other jurisdictions such as the UK where similar deferrals have been implemented have not lead to significant changes in HIV incidence in blood donors.

Publication of particulars of decision

Particulars of this decision will be published on the website, as soon as practicable.

You are reminded that the product in relation to which this consent is given must comply with all other applicable parts of Therapeutic Goods Order 102, Therapeutic Goods Order 88, and other applicable standards.

Review rights

Details of review rights for the decisions are provided at **Attachment 1**. Please do not hesitate to contact me if you have any further queries regarding this matter.

Sincerely

Signed Electronically

Signed and authorised by

s22 [redacted]
Delegate of the Secretary
Scientific Evaluation Branch
infectiousdiseasesafety@health.gov.au

28 July 2020

Attachment 1

Review of the decision to impose conditions

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation. Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:
Email: '**minister.hunt.DLO@health.gov.au**' and '**decision.review@tga.gov.au**'

Where a request for reconsideration includes dossiers (or similar bulk material) that cannot easily be attached to the request given by email, the supporting documentation and original (signed) request for reconsideration can then be sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 41
c/- Parliament House
CANBERRA, ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.