Australian Government

Department of Health
Therapeutic Goods Administration

Document No: D22-5504054
Submission No: RR17-045

The Managing Director
Australian Red Cross Lifeblood

Email: s22 [redacted] @redcrossblood.org.au

Attention: s22 [redacted]

Dear s22 [redacted],

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 3 months since last contact.

The proposed changes in this submission do not comply with:

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).

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.

The Lifeblood submission proposes a change to the donor deferral period from 12 months to 3 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)

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.

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.

The consent is effective from the date of this letter until the following conditions no longer remain true.

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 3-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

- 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 led 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 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.

Yours faithfully

Signed and authorised by

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

16 June 2022

Attachment 1 - Review rights

Attachment 1

Request for reconsideration of an initial decision

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 in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. 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 this function 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 making 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

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website <https://www.tga.gov.au/reconsideration-reviewable-initial-decisions> for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this 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: '**decision.review@health.gov.au**'

Subject: "**<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*"

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

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.