

Advisory Committee on Biologicals (ACB) Meeting 3, 19 September 2013 Minutes

9.30 am – 2.40 pm Conference room 1, TGA, Canberra

Members present

[REDACTED]

Apologies

[REDACTED]

TGA attendees

[REDACTED]

Principal Medical Adviser
Head, Market Authorisation Group
Head, Office of Scientific Evaluation (OSE)
Senior Medical Adviser, OSE
Director, Biological Science Section (BSS)/(OSE)
Senior Medical Advisor, BSS/OSE
Medical Advisor, BSS/OSE
Unit Head, Cell and Tissue Therapies Unit,

Secretariat

[REDACTED]

BSS/OSE
BSS/OSE
BSS/OSE

Observers

For all or part of the meeting

[REDACTED]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

4. Other items

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

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[Redacted]

[Redacted]

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[Redacted]

[Redacted]



4.2. Proposed changes to the blood donor deferral period for sexual behaviour

TGA introduced the Australian Red Cross Blood Service (ARCBS) request to relax the donor deferral period for individuals who engage in certain sexual behaviours from 12 months to 6 months.

TGA assured the Committee that they are an advisory body and TGA is the decision maker and will seek advice from a number of sources before making a decision.

Therapeutic Goods Order no. 88 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'.

The majority of the Committee agreed that current screening technology is robust enough to detect HBV, HCV and HIV infections in blood samples from donors in relatively early stages of infection and that there is little difference between the ability of the tests to detect infection in blood collected from a donor who has been deferred for 6 months and one who has been deferred for 12 months. Based on window periods alone the deferral period could be reduced to 3 months. A 6 month deferral may be considered reasonable as this would double the theoretical window period for detection of HCV which has the longest window period of the infections in question.

It was noted that a 6 month deferral period would still be considered as discriminatory by some sectors of the community as a 12 month deferral period, but that the shorter deferral period better reflects the science underpinning screening for transfusion transmissible infections. The Committee also noted that a 6 month deferral period will not have a significant effect on the supply of blood products.

An alternative approach to stratify the risks further to better address the discrimination concerns was generally not supported by the Committee.

It was noted to TGA they should be mindful of how other jurisdictions and countries approach this problem. Internationally it is often viewed that in the past Australia has been a leader, not a follower, in the control of HIV and other blood borne infections.

The Committee agreed that changing the deferral period is as much an ethical and legal issue as one of science. Maintaining confidence in the blood supply is crucial and the Committee acknowledged that the community may have substantial concerns with what may be perceived as a significant relaxation of requirements. The Committee noted that these concerns were likely to arise from misperceptions about blood safety and testing.

Comments were made on the human propensity to be untruthful when completing donor surveys. It was suggested that the Blood Service consider alternative approaches for collection of personal information to improve compliance. It was noted that IV drug users were more often non-compliant with donor deferral periods.

A Committee member advised that organ donation and milk banking are also triggered off this donor questionnaire and that the potential for affecting organ donation and milk banking rates should be considered by TGA when making a decision.

Resolutions:

In response to the advice sought:

