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To whom it may concern;

Blood and Tissues Unit
Standards and Code of GMP
Office of Devices Blood and Tissues
Therapeutic Goods Administration
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Comment on the "Draft Therapeutic Goods Order: Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies"

Schedule 5(3)

(3) In cases where a human blood and blood component, human tissue or human cellular therapy is manufactured from a donor with repeatedly reactive mandatory screening tests, with the intended purpose of reintroduction into that donor

(a) segregation and quarantine must be applied to that human blood and blood component, human tissue or human cellular therapy and cross-contamination is to be avoided; and

(b) records must be available to demonstrate the rationale for the use of the product. Authority for the release of this product must also be documented.

Comment

There should be no requirement to segregate blood and cellular therapy products that are stored in TGA approved freezing bags in vapour phase liquid nitrogen based on positive serology or microbiology testing results.

Risk assessments show that there is no risk of cross contamination of such products stored in approved freezing containers in vapour phase liquid nitrogen. Furthermore, products may be compromised by being moved into and out of separate quarantine and long-term storage locations before and after test results are available. The requirement to store products with positive serology that are intended for autologous use separately to those with negative serology introduces an unnecessary level of complexity to product storage and increases the chances of mix-ups or of products being compromised, while having no impact on the risk of cross contamination for products in vapour phase liquid nitrogen storage, as there is no identifiable risk of such cross contamination.

Suggested Change

An exemption from this clause for products stored in vapour phase liquid nitrogen and in approved storage containers should be added to the Regulations.

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