To
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THERAPEUTIC GOODS ORDER NO. XX - *Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products*

We have reviewed the updated version of the standards within the context of our current licensed activities – ie autologous products including HPC(A), HPC(M) and ACI.

Part 3
8 1(b): the interview must occur no more than 7 days prior to or 30 days after collection.

Previously a 30 day rule applied for HPC which we consider more compatible with patient treatment. In the context of products required for rescue following high dose therapy a 7 day timeframe may compromise patient assessment processes. The scheduling of interviews closer to patient conditioning will also make treatment planning very difficult.

9 2 (a) Blood sampling of a living donor must take place 7 days prior to or 7 days after collection of blood, blood components, cells or tissues.

This specification if accurate is far too restrictive. The requirement to test 7 days prior to collection has potential to compromise patient assessment and product quality especially in situations where patient preconditioning occurs in the week preceding administration. In the allogeneic setting donor suitability must be established prior to commencing conditioning – the 7 day timeframe in many cases would be insufficient.

9.4 (a) all donors must be tested by serology at the time of collection
and (b) NAT testing for HIV, HCV and HBV must be performed at the time of collection to exclude a window period infection.

Once again the 30 day rule applied for HPC is more compatible with patient treatment and product manufacture. Ito meet these requirements processing could not commence until donor testing is complete thereby compromising product quality by extending the period between collection and processing. Alternatively processing could commence under quarantine - which is never guaranteed 100% effective - until test results are complete. Either scenario severely compromises product quality in direct contrast the aims of these standards.

We therefore request consideration be given to further changes to ensure increased product safety is achieved.

Prepared on behalf of the Therapeutic Products Facility
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