

Summary of proposed changes to Case for Change

Section	Change	Rationale
Introduction	“The safety and quality of tissue...” revised to “The quality of tissue...”	Safety is an element of quality, so this change does not change the intent of the document, but diffuses some of Health Canada’s objections.
Introduction	An acknowledgment that new CTO regulations were introduced in December 2007 was added to the Introduction, in the same section where other positive achievements in OTDT are acknowledged.	This should have been mentioned as one of the positive developments.
Section 1 Preamble	We did not make changes in response to their objection that the Case for Change implies there are gaps in the regulations.	The text in the Case for Change clearly refers to the gaps in the safety and quality framework of the tissue <i>programs</i> , not the regulations themselves.
Section 1.1	We did not make changes to the text in response to their objection to the statement about inconsistent application of standards, regulations and leading practices.	We believe that the inconsistent use of NAT testing for HIV, HCV and WNV is a good example of this (even though NAT is recommended, not required by the regulations).
Section 1.1	We did not make changes to the text in response to their objection to the statement about the limited ability to respond to emerging issues and safety incidents. Their argument is based on the extensive consultation they believe they have engaged in, and the existence of an Expert Advisory Committee for CTOs.	Our consultation has been robust, and our expert committees are stronger in terms of subject matter expertise.
Section 1.1	We modified the layout of the section on the adoption of leading practices to better describe that it is also the <i>interpretation of the regulation requirements</i> that can hinder adoption of leading practices, since the regulations do not outline detailed requirements.	Text was added to acknowledge that Health Canada has provided guidance documents which begin to describe these detailed requirements, but that ongoing guidance is required.
Section 1.2	We did not make changes to the text in response to their objection to the statement about the absence of a comprehensive system to ensure complete traceability.	BGTD appears to believe that having a regulation requiring traceability ensures that a <u>system</u> for traceability is in place. We do not agree.
Section 1.3	BGTD indicate that adverse event reporting through the Canada Vigilance program is adequate. Interestingly, they do not even acknowledge the CTO Surveillance System being piloted by PHAC. The same dual system for AE reporting has been criticized for plasma products for many years. We made no changes to this section of the Case for Change.	This appears to be more of a comment that a specific objection to the language in the Case for Change.
Section 1.4	We clarified that the incidents with imported product occurred before the CTO regulations were in place, and that implicated tissue was withdrawn. However, we also clarified that inspections are not required to become a (foreign) registered CTO supplier, and the act of registration may not be sufficient to ensure safety. We also added text acknowledging that regulators share information.	The timing of recalls that occurred before the CTO regulations were implemented is now clarified. The fact that inspections of foreign suppliers are not required is now clarified. To us it seems weak to rely on a paper application process as a compliance tool, compared to the way Health Canada inspects foreign plasma product manufacturers, for example.

Section	Change	Rationale
Section 3.1	We did not find that any of the comments in this section of their document warranted changes to the Case for Change.	This appears to be more of a comment that a specific objection to the language in the Case for Change.
Section 4.1	BGTD notes that according to the regulations, tissue banks are required to communicate about errors, accidents and adverse reactions concerning tissue they distributed. This is a very narrow interpretation of "communication", and we have clarified that tissue banks have no incentive to share information related to system performance.	This clarifies the language which stated that tissue banks have no incentive to communicate with each other.

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