Health Canada Santé Canada

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To manage and deliver a national compliance and enforcement program for blood and donor semen; cells, tissues and organs; drugs (human and veterinary); medical devices and natural health products, collaborating with and across all regions

Health Products and Food Branch Inspectorate

Summary Report: Stakeholder Consultation Workbook for the Cells, Tissues and Organs Programs Inspection Strategy

Period of Consultation:
December 8, 2011 to February 21, 2012

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Canada

Table of Contents

1.0 Introduction

Health Canada is in the process of developing an inspection strategy to be used for scheduling inspections of registered cells, tissues and organ (CTO) programs in Canada. The goal is to implement an inspection strategy in which a risk based approach would be used to determine the frequency of inspections. As part of the implementation process, Health Canada consulted with stakeholders from December 2011–February 2012. In total 15 stakeholders provided comments and suggestions and this report provides a summary of that feedback.

2.0 Consultation

As part of the consultation workbook stakeholders were asked to comment on three options for scheduling inspections, as described below:

Option 1: Pre-Determined Inspection Cycle

In this inspection model, all registered Canadian programs would be inspected as per a fixed cycle. For example, all programs, regardless of activities or previous compliance history, would be inspected every 2 years.

Option 2: Annual Targeted Inspection

In this inspection model, Health Canada would develop an inspection plan annually which would outline the programs subject to an inspection in that given year. The determination of programs to prioritize for inspections in a given year would be based on data such as compliance history, international issues, errors and accidents as well as adverse reactions.

Option 3: Inspection frequency based on activities and previous inspection results

This model would determine the inspection frequency based on two factors, namely (1) the intrinsic risk of the activities being conducted and (2) the results of the last two inspections.

In Option 3, the determination of the inspection frequency is a three step process:

1. Assess the intrinsic risk of the program activities;
2. Assign a designation based on the last two inspection results;
3. Determine inspection frequency.

3.0 Summary of Comments Received

3.1 Option 1: Pre-Determined Inspection Cycle

Over 30 % of the respondents were in support of this option.

In general, the respondents viewed the fixed cycle as being ideal for consistency and predictability for CTO establishments, especially for those establishments still becoming accustomed to the regulatory oversight by Health Canada. There was a consensus that an inspection period longer than 3 years would be too infrequent to add any value to the process and less than two years could present an operational burden. One establishment highlighted that program changes and/or staff turnover could affect an establishment's ability to comply with CTO Regulations, and that a period of 36 months before the next inspection could present a risk to the transplant recipient's safety. It was noted that much of the industry is already accustomed to a fixed inspection cycle approach as most other accreditation and international regulatory bodies follow a regular inspection cycle.

A number of respondents indicated that a pre-determined inspection cycle would provide structure, planning and firm timelines. In addition, it would unify the regulatory inspection framework across Canada.

One respondent noted that a strong internal quality assurance function would ensure adequate implementation of the regulations and monitoring of the status of compliance; it would also drive continuous improvement within the establishment.

A number of respondents emphasized that there is a need for timely follow-up in situations where establishments are found to be *Non-compliant* and that three years was too long between inspections for those Non-Compliant rated establishments.

As a hybrid of option 1 and 3, a two to three year pre-established inspection cycle and a shorter interval for programs with compliance issues was proposed.

3.2 Option 2: Annual Targeted Inspection

Overall, Option 2 was not supported by the respondents, however, a hybrid of option 2 and 3 was proposed by one respondent. This option would consider the intrinsic risk of the activity (option 3), but also errors and accidents and adverse reactions (option 2). In addition, it was proposed that a minimum inspection timeline be set, regardless of the assigned risk.

3.3 Option 3: Inspection frequency based on activities and previous inspection results

Over 46 % of the respondents were in support of this option.

Overall, the participants were in support of a regulatory inspection schedule based on risk of activities performed and past performance history. Several stakeholders expressed the need for risk based inspections incorporating the level of risk of the activities being conducted and the results of the last two inspections. A number of respondents indicated that, in their view, this option could provide a more precise method for evaluating the safety of the CTO, with clear direction and timelines. The approach was also seen to be equally beneficial for both the CTO establishments and Health Canada.

For the most part participants were satisfied with the proposed timelines for Option 3. If an establishment is deemed compliant, a two or three year cycle is appropriate but longer than three years would be too infrequent to be valuable and more frequent then two years would be an operational burden and hence its value would be diminished. It was also noted that a good internal audit system or program would maintain the establishment's compliance from year to year, and every two to three years Health Canada would verify compliance through the inspection process.

Participants agreed that if an establishment received an NC rating, a timely re-inspection would be appropriate. It was suggested that Major observations should be re-examined within a 3-6 month time frame and critical observations should be corrected immediately with notification to the Inspectorate when corrective actions were implemented. One participant commented that Health Canada should focus on programs that do not meet quality and safety guidelines instead of spending equal resources and time on programs which are compliant.

4.0 General Comments

The majority of the respondents indicated that the following criteria should be considered when developing an inspection strategy:

- Intrinsic Risk and the level of risk associated with the activity being performed,
- Past compliance history; and,
- Inspection frequencies which are in line with international regulatory accreditation bodies.

It was expressed that compliance with the CTO Regulations needs to become a higher priority for all establishments, especially hospital based programs that are challenged with competing priorities within their institutions.

Participants suggested that inspections not only "ensures the safety of CTO for transplantation, but is also a valuable learning tool for the programs. Inspections allow for greater understanding of the regulations and their interpretation".

Participants thought it was important that each establishment be inspected on a standard pre-determined inspection cycle with the cycle being shorter for facilities that have a non-compliant rating.

It was noted that some respondents believed that all facilities should be assessed equally without assigning risk and that importers have an equal responsibility to ensure that imported tissues are safe. Given the importance of the quality and safety of CTO used for transplantation, some respondents suggested that the same risk be assigned to all programs regardless of the type of activities, e.g. source establishments or importers.

It was also indicated that once the regular inspection program has been implemented, programs would have a better understanding of the regulatory requirements.

When asked about an alternative option, two proposals to the aforementioned three options were suggested, summing up to a total of 12.5 % of the respondents (see option 1 and option 2 for further details).

5.0 Next Steps:

Further to the comments received during the consultation, Health Canada has developed an *Inspection Strategy for Cells, Tissues and Organs Establishments* (POL-0057) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/cell/pol-0057_doc-eng.php) based on Option #3, as outlined in the consultation workbook. This was the preferred option by the majority of the stakeholders and is reflective of Health Canada's approach to a risk based inspection model.