

Status of Transition in Canada

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Date:

Overview

- Outreach Activities
- 2017 Manufacturer Survey
- Progress of Transition

Outreach Activities

- Health Canada has been actively engaged in outreach activities over the last few years.
- More recently, webinars and teleconferences were held with MEDEC and the Canadian Council of Innovators (CCI).

Outreach Activities

- The Department continues to participate and present at various conferences (RAPS, OSMA, MEDEC, etc.)
- We have received considerable feedback from stakeholders about MDSAP and the transition.

Outreach Activities

- The feedback received contributed to the dialogue on the transition and helped shape some of the changes to our transition approach.

2017 Manufacture Survey

- In December 2017, Health Canada sent an electronic survey to all medical device licence holders.
- A total of 1455 companies responded.

2017 Manufacturer Survey

- When asked if they intended to transition to MDSAP:
 - 74% of respondents said yes
 - 14% said no
 - 12% were unsure

2017 Manufacturer Survey

- Of those indicating that they would transition:
 - 36% said during the first half of 2018
 - 42% said in the second half of 2018
 - 16% claimed difficulty scheduling their audit

Note: other answers are not included here

2017 Manufacturer Survey

- 61% of respondents indicating that they would not transition stated that this was because their sales in Canada do not justify the cost of the MDSAP transition.
- Another 16% stated that cost was the overall determinant.

2017 Manufacturer Survey

- A further analysis of the negative respondents revealed that for the most part these are small (and very small) companies with low sales in Canada.

2017 Manufacturer Survey

- The main factor under consideration for those unsure about the transition was cost (56%).

Progress of Transition

- To date, Health Canada has received about 170 MDSAP certificates
- This accounts for about 10% of licences.

Progress of Transition

- However, according to the Master List approximately 1800 facilities have been registered into the program.
- Over 1000 audits have taken place already.

Progress of Transition

- While it is understood that not all facilities are Legal Manufacturers, there appears to be a significant gap in the number of certificates

Progress of Transition

- It is understood that AOs are experiencing higher than normal certification volumes and that delays are frequent.

Progress of Transition

- Manufacturers are reminded to submit their MDSAP certificate to Health Canada if they have not done so already.