Status of Transition in Canada

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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.