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Canada's Switch From CMDCAS To MDSAP Went Off Without A Hitch – Despite 403 Firms Leaving The Market

by Shawn M. Schmitt

It's been one full month since the Medical Device Single Audit Program officially replaced the traditional Canadian Medical Devices Conformity Assessment System (CMDCAS) audits, and Health Canada is claiming success. Although 403 device-makers withdrew from the Canadian market because of the switch to MDSAP, it's nothing to be concerned about, a Health Canada spokesperson says.

It's been one full month since Health Canada's deadline for manufacturers to be certified to the Medical Device Single Audit Program came and went, and the message from that regulator is clear: All systems normal.

MDSAP – which allows firms to undergo one audit by an accredited third party to satisfy quality regulations for Canada, the US, Brazil, Japan and Australia – officially replaced the traditional Canadian Medical Devices Conformity Assessment System (CMDCAS) audits on Jan. 1. (Check out *Medtech Insight*'s *Interactive Timeline* to stay abreast of global regulatory deadlines.)

> ***"The MDSAP transition deadline has passed without incident," Health Canada's Geoffroy Legault-Thivierge says.***

That means MDSAP is now the sole mechanism to demonstrate compliance with Canadian quality management system requirements. Firms that fail to undergo an MDSAP audit cannot

sell product in the country.

"The MDSAP transition deadline has passed without incident," Health Canada spokesperson Geoffroy Legault-Thivierge confirmed in a Jan. 31 email to *Medtech Insight*. "As of the transition deadline, approximately 90% of manufacturers have initiated or completed the transition to MDSAP."

That's roughly 3,000 companies that make and/or sell product in Canada, he noted. The regulator originally announced the transition to MDSAP in December 2015. (Also see "*Canada Sets Jan 2019 Deadline For Mandatory Adoption Of MDSAP Within Medtech Framework*" - Medtech Insight, 29 Dec, 2015.)

To smooth the transition, Health Canada *softened some requirements for small manufacturers*. And the regulator has said it *won't take enforcement action* against device-makers that didn't obtain a valid MDSAP certificate by the end of 2018, but are able to demonstrate that they underwent an MDSAP audit before Jan. 1, 2019.

"Given the progress, with approximately 90% of manufacturers having initiated or completed the transition, Health Canada does not intend to make further changes to transition requirements at this time," Legault-Thivierge said.

Despite steps by Health Canada to soften the switch from CMDCAS to MDSAP, some device-makers were always expected to stop selling product there because of it.

While "manufacturers are not required to indicate the reason for cancelling a medical device licence," Legault-Thivierge said, "some manufacturers indicated to us [in 2018] that they were withdrawing their products from Canada because of MDSAP."

Specifically, 403 firms withdrew from the Canadian market – but that's nothing to be concerned about, he said.

"Most of the manufacturers that have indicated that they are exiting the

MDSAP Is A Snap If Your Firm Follows Quality Systems Standard ISO 13485, Auditor Says

By Shawn M. Schmitt

31 Jan 2019

NSF International's Brian Ludovico explains why device-makers that already follow international quality systems standard ISO 13485 shouldn't be nervous about taking part in the Medical Device Single Audit Program. Ludovico also shares MDSAP participation numbers and says firms should feel at ease knowing that the program's auditing organizations undergo a rigorous process to become recognized by the MDSAP Regulatory

Canadian market as a result of MDSAP had very low sales or no sales in Canada," Legault-Thivierge said. "To put this figure in context, in any given year, between 1,200 and 1,600 [medical device] licences are canceled or withdrawn for a variety of reasons."

From the editors of The Gray Sheet

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