Exton, Adam (HC/SC)

From: Wen, Vanessa (HC/SC)
Sent: 2020-07-28 8:10 PM
To: Nowers, Kathryn (HC/SC); Johnstone, Marnie (PHAC/ASPC)
Cc: Gordon2, Travis (HC/SC)
Subject: RE: Clinical trials for medical devices

Checking on this.

-----Original Message-----
From: Nowers, Kathryn (HC/SC) <kathryn.nowers@canada.ca>
Sent: 2020-07-28 5:28 PM
To: Wen, Vanessa (HC/SC) <vanessa.wen@canada.ca>; Johnstone, Marnie (PHAC/ASPC) <marnie.johnstone@canada.ca>
Cc: Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca>
Subject: Clinical trials for medical devices

Hi Vanessa,

Wondering if we can get some information on clinical trial requirements for medical devices like nasal swabs? Some of the manufacturers that have re-tooled to produce swabs are questioning the need for and feasibility of doing clinical trials in order to get their MDELS. In particular the key questions/concerns raised with us are:

1. Rationale for clinical trial requirement if swabs are considered class 1 : Argument being that that clinical trials are not required by FDA for market entry of swabs in the US, nor for foreign swabs currently entering Canada through distributors having an MDEL.. There is a concern that the Interim Order is inadvertently creating two standards for the same product in a way that disadvantages domestic producers by requiring them to meet a higher standard for data than you would need in order to import an equivalent product.. If a swab is a swab then they should all need clinical trials or not.

2. If clinical trials are required, what data are we seeking and what type of trial etc. We should be clear and transparent about what is needed and what the process is so that we are not slowing down progress unnecessarily.

Happy to do a call if that is easier.

Thanks