Information session for members of industry on swabs

Meeting Summary

Introduction

On May 29, 2020, Health Canada hosted an information session with Innovation, Science and Economic Development (ISED) and the National Research Council Canada (NRC), on the overview of the quality requirements and testing criteria for swabs submitted for authorization under the *Interim Order Respecting the Importation of Sale of medical Devices for Use in Relation to Covid-19*.

The purpose of the information session was to provide swab manufacturers, in particular, manufacturers of novel swabs (e.g. 3D printed) and those new to medical device sector, with an overview of Health Canada evidence requirements for IO applications, as well as NRC testing approaches and processes.

Points of Discussion

Background

- Health Canada seeks to facilitate access to COVID-19 related medical devices, and must ensure those devices are safe and effective
- The best way to reopen the economy is to help ensure high quality swabs are available for public health authorities to handle icreased testing.
- The Minister of Heatlh approved an Interim Order (IO) in mid-March to expedite access to COVID devices, and the IO authorization is valid for 1 year from approval.
- A key feature of the IO is that it allows Health Canada to review Class I devices that would normally not undergo pre-market review.
    - Although the IO pathway is a parallel approach to the existing Medical Device Establishment License (MDEL) pathway, Health Canada strongly encourages manufacturers of nasopharyngeal and orthopharyngeal swabs to apply through IO pathway.
    - IO application reviews can help mitigate potential human harm and potential COVID testing invalidation.

Quality Criteria

- Labelling requirements apply to the swab packaging, as well as any included documentation.
- Swab description should include diagrams, pictures, and an explanation of how the swab is made as well as the materials used in its production.
- Quality manufacturing system requirements include either an ISO 13485 or equivalent certification.

    - Alternatively, a description of the planned activities that will ensure the design, planning, records, purchasing, manufacturing, corrective actions, post-market activities of the swab demonstrates good manufacturing practices.
- Design verification must be conducted on sterilized swabs and show that the dimensional, flexibility, strength/breakpoint and surface property specifications set by the manufacturer, are met.
- Design validation must demonstrate the swab is able to collect a specimen sample that is comparable to a commercially available swab, as well as demonstrate swab compatibility with PCR.
- Clinical/field testing must demonstrate the proposed swab is as safe and effective as a commercially available swab. The primary endpoint is condordance of PCR test results.
- Post-market requirements require manufacturers to notify Health Canada within 10 days of the occurrence of an incident involving the proposed swab.
- Sterilization validation must be demonstrated to a Sterility Assurance Level of at least 10^{-6}. Alternatively, an adoption rationale may be submitted to leverage an existing sterilization validation.
- Packaging validation must show the packaging system can maintain a sterile barrier for the duration of the stated shelf-life of the packaged swab.
    - Alternatively, an adoption rationale may be submitted to leverage an existing packaging validation.
- Biocompatibility per ISO 10993-1 must be demonstrated on sterilized swabs.
    - Alternatively, a scientifically based rationale may be submitted that demonstrates the material constituents of the proposed swab are identical to those incorporated into a swab that is commercially available in Canada.

<u>NRC Process Map of NRC/NML Swab Testing:</u>

- Step 1 - Mechanical testing of sterilized swabs (NRC Bourcherville for physical testing and NRC Winnipeg for mechanical testing and simulation testing in the Airway Trainer).
    - Swabs that pass Airway training are sent to NML for further testing.
    - Swabs that don't pass airway trainer: NRC Boucherville will use results of physical testing to assist applicants/manufactuers with swab prototype, design and material modifications.
- Step 2 - Dip testing and PCR compatibility validation by NML.
- Step 3 - Clinical trial validation.
- Step 4 - Health Canada will assess information against IO swab quality criteria.

<u>Questions & Answers Session</u>

Question: Is there a timeline associated with each of the validation steps for planning purpose?
Answer: The process is expected to take a few days.

Question: If a company manufactures swabs and contracts other companies to package and sterilize the swabs, will each company involved need an IO?
Answer: No, an IO is required by the manufacturer of the swabs.

Question: If a swab has already passed regulatory requirements of the USFDA, will the process be different in Canada?
Answer: The US FDA regulates swabs as Class I devices, which are not subject to pre-market review. What makes the Canadian regulatory process different is that safety and performance need to be established before swabs may be imported or sold in Canada.

Question: Can in-house testing be used to support design verification requirements?
Answer: Yes, the requirements are designed to allow for flexibility in testing approach.

Question: ISO 13485 certification usually takes six months or longer. How can companies obtain this or equivalent certification if they don't already have it?
Answer: Because Health Canada recognizes the urgent need for swabs and the time required to obtain certification, manufacturers may submit a description of their quality systems, which should be similar to existing certified systems (described in the Health Canada Interim Order guidance found online: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19/guidance-medical-device-applications.html).

Question: To meet the biocompatility requirements, can a manufacturer leverage existing peer-reviewed clinical data for another country?
Answer: We would accept a scientifically-based rationale based on studies obtained in other jurisdictions. Clinical data may not be the best to capture those outcomes, but leveraging other toxicology study data that demonstrate no cytotoxic, sensitization and irritation potential would be accepted for review.

Question: Is the ISO 13485 requirement a must for Class I swabs?
Answer: In a recent update to the published IO application guidance, a considerable list of items was added to better explain the role and need for quality systems. These were largely applicable to IVDD test kits. While every item may not be applicable, it provides a general overview.

Question: If a company has a MDEL for swabs, do they have to submit an amendment?
Answer: Health Canada asks that those companies submit an IO application.

Question: Is sterilization by autoclave acceptable?
Answer: Sterilization processes are acceptable if the applicant can demonstrate a minimum sterility assurance level (SAL) of 10^{-6} without affecting swab safety or performance. Also, Health Canada is aware of reports that claim autoclave sterilization of 3D printed swabs may render them brittle.

Question: Does a pharmacist that is compounding VTM (according to applicable standards/practices) meet the definition of a medical device manufacturer, and is an IO authorization required to sell the VTM?
Answer: Yes, the pharmacist would meet the definition of a manufacturer, and while both the IO and MDEL pathways are options, Health Canada recommends applying for a Medical Device Establishment License (MDEL). For more information, please refer to Health Canada's alert

regarding expedited access and the, “Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licence Fees (GUI-0016)”.

Question: As it relates to the ISO 10993-1 standard for biocompatibility and 3D printed swabs, will Health Canada accept clinical trials from outside Canada?
Answer: We would accept clinical data to support the clinical feasility requirement, but clinical data itself may not address all issues of biocompatilibty. Therefore, either test data or a scientific rationale in lieu of test data are required. The rationale should clearly demonstrate that the exact materials used in the proposed swab have a history of safe use (e.g. are and have been used in other commercially available swabs).

Question: If a manufacturer has an IO for a swab and applies for a MDEL for manufacturing, would that create interference with the MDEL process?
Answer: No.