Summer Educational Program Minutes

Location: Renaissance Montreal Downtown Hotel · Montreal, Canada (Places-des-Arts/McGill)

Date: Thursday, July 19th, 2018

Time: 8:15am – 5pm EST

Attendees: (See Attachment 2)

Agenda Topic	Presenter
Welcome, Introductions, Reading of Meeting Guidelines & Meeting Logistics	Sharon Starowicz

Sharon called the meeting to order and welcomed attendees. Sharon read the meeting guidelines verbatim and reviewed the meeting and dinner logistics, and attendees (both OSMA members and guests) introduced themselves. Sharon introduced Jeanine Redden to present the guest speakers.

Brexit Update	Phil Brown

QUESTIONS

Practical example for orthopedic instruments under EU MDR, there will be a requirement to mark with NB number. If some items are under EU NB, then the number will likely change. What is the likelihood that that number will change? Is there a scenario to have it negotiated to remain the same?

(*The following response is an update from what was previously communicated at the meeting).

- There is no change in number for a Notified Body when being designated under the MDR from the MDD. So, TUV-Sud for example, will remain as CE0123 under the MDR.
- Current UK-based NBs will have to change number however, as a result of the Brexit issues and their 'Plan-Bs'. As they will be designated by a different 'Member State', by moving to the EU 'mainland', they will need this new number. So, BSI, for example, who are currently CE0086, will have to change. There is no news at the moment, as to what these new numbers are.
- The number change will affect BSI, LRQA, SGS and UL.
- As for labeling, manufacturers should also consider the change to Authorized Representative if they currently have a UK-based one.

Where do we get further information on this?
This will likely come from your trade association such as MedTech Europe and NBOG. It is well understood at ABHI.

Could you please expand on Custom Devices?
This will be more defined in the EU MDR. "Custom made", for example, if you are thinking about hospital manufacturing or refurbishing of a product, as soon as you change a device significantly, you are developing a device. You require a CE mark. For example, an additive manufacturing company came to ABHI recently and described a custom manufacturing process where a surgeon will send the additive manufacturing company a

CAD file, with a cranium implant and will fit it perfectly to a patient. CE marking is the manufacturing process itself.

MEDEC RA Update: Key Priorities, Issues and Opportunities to Partner — Diana Johnson

There are several videos on MEDEC's website that highlight advances in technology (for example, retired hockey player with a hip replacement). MEDEC has participated in harmonization initiatives such as moving contact lenses from drugs to devices. They have also participated in protecting the health and safety of Canadians via Vanessa's Law.

What is Vanessa's Law?
There was an incident where a young girl was prescribed a device that resulted in an unfortunate death. At the time, the device did not have to be recalled. Due to Vanessa's Law, there is more transparency with device use and the incident would now result in a recall.

Cost Recovery (with Federal Affairs Committee)
The initial proposal was 50/50. MEDEC met with Health Canada to assess more reasonable fees. The second version was released in April of this year and the fees were reduced by 75%. It is a phased in approach, spread over 4 years. No more than 25% increase per year. The right to sell is no more than 50%. There are further provisions for small to medium sized enterprises. Health Canada explained the changes via Webex and accepted comments until mid-June. MEDEC submitted comments on behalf of their membership. At this time, MEDEC is awaiting feedback from Health Canada, which is expected sometime next week.

Draft ITA Guidance
MEDEC submitted 18 pages of comments. Recommended HC adopt a similar process as drugs. You can get approval for protocol, while still seeking ethics committee approval. As each ethics committee gets their approvals in, sponsor maintains ethics approval and communicates it back to Health Canada; therefore, only having manufacturers issuing ITAs. It is burdensome to modify an ITA. Another issue is bilingual labeling when the device doesn't require bilingual labeling on the final commercial product.

MDSAP
Recordings are available on the MEDEC website.

Issues Being Addressed
Reg and health innovation – These are far reaching, future direction and pain points that need to be addressed.
MDR Serious Adverse Events – The draft is currently out for comment. The main issue is how do we tie in serious medical incidents that get reported directly to the government to match the events reported internally and/or avoid duplication?

What was the largest deficiency according to the Submission Quality Project?
Labeling was the largest deficiency. In addition, IFUs could have generic devices that are not licensed or sold in Canada, but it appears like promotion of a non-licensed device since they are included.

Medical Devices Bureau: Key Initiatives/Priorities, Aspects of R2D2 and Cost Recovery — David Boudreau

Cybersecurity
Health Canada established an inter departmental agreement with NRC and Communications Security. There was a kick-off meeting in May. The goal is to build a workforce of reviewers. To date, staffed two senior positions out of the 5. Hoping to have a total of 10. The priority is to create work tools and guidance documents.

Revising the way reviewers currently deal with the internal review of applications. One reviewer will look at the same file from beginning to end. The goal is to change the process to have two individuals (general administrative review prior) and then a digital health reviewer. More of a team approach.
Digital health would be able to provide support to other divisions.

3D Printing for Implants
Surgeons have specific software to have MRIs/stats to put together model for patient specific implant. Health Canada was invited to visit the 3D printing lab in Quebec.

Scientific Advisory Board
Looking for a sounding board – current members with various backgrounds to help inform future initiatives (guidance documents, etc.) Published a call for interest in June. Closed last week. Lots of interest. Received over 100 applications for this scientific advisory committee. Ideally, want 5 to 6 members. May have a core member and then have subcommittees. First meeting will be this Fall and plan to discuss cybersecurity.

Survey
On April 16th, Health Canada launched a 2-minute survey for all authorizations issued. OSMA members are encouraged to complete the brief survey. The email letter has a link to the survey.

On the fee increase, when do you expect the 4-year transition to begin?
It will start April 1, 2019. There is a webinar scheduled for Monday, July 23rd to review the proposal.

What are the training plans for new employees?
Health Canada has an onboarding program for new reviewers. For example, 3 new junior reviewers were hired for digital health. They will be assigned a mentor for job shadowing. The onboarding program is a three-year process.

Is there a pathway for expedited review?
No, there is only one process. It would be good to have two tracks but not there yet. Files are prioritized as needed. The file may be considered by the Bureau based on rationale. Shortages on the market can also be re-prioritized, if needed.

Health Canada Update: MDSAP — Frederic Hamelin

Criteria for reduction in length of audit
-long term implantable devices are not considered for this reduction

Guidance documents for surveillance audits will hopefully drive more consistency amongst future audits.

Over 1,000 responses received to the MDSAP survey

- 75% said no issues
- 12% undecided
- Some said no, not going to do it

60 different manufacturers met with regulators at the May 9th meeting in Ottawa. Received feedback to the program. MEDEC has those webinars posted on their website.

Health Canada Update: Investigational Testing Authorization — Chris Schmidt

Health Canada website has a search function for active medical device licenses. It also contains archived devices within the search function.

IT Application Requirements
Class III – should contain a summary of V&V activities
Class IV – should contain data and signed reports. Studies should include pass/fail criteria and end points along with statistical characteristics.

What are the greatest deficiencies?
One of the biggest deficiencies is how manufacturers response to the questions "Number of Units". This should include all components, including accessories to the device. Also, the number of devices requested and/or the number of patients. The form has been updated. This has been a large improvement as the form is more structured.

Can you submit this form with the results for the device license?
These are two different processes. Health Canada won't compile it for you but you can leverage the information and submit it with the device license.

Is the ethics board approval a condition of the ITA?
It is right now. Health Canada is looking at regulation changes that allow for ITA authorization prior to receiving the ethics approval.

Can you submit ITA in parallel?
We need the ethics board approval prior. It will be requested if not submitted initially. It would cause a screening deficiency or additional information request. Class II devices require ethics board approval but do not need to provide evidence. Still legally required to have it.

Industry has highly requested Health Canada provide a means for amendments to an existing ITA instead of submitting new ITA's. This would be a significant change.

Highly encouraged OSMA members to complete the Client Satisfaction Survey.

When you receive a deficiency, it stops the review clock. The sponsor has 60 calendar days to provide a response. When Health Canada receives the response, the clock re-starts (get 30 days to complete the review).
69% of accepted ITAs met the 30 Target days

Estimated timeline for regulatory changes?
Initially, hoping to group them into existing changes. Looking to some outside the box – policy approach instead of regulatory approaches. No timeline at this time; exploring options. Assessing the best approach with the quickest result.

Advice about trials in Canada?
Health Canada encourages pre-ITA meetings to understand requirements and so Health Canada can better understand the technology prior.

Timelines?
Looking to be more consistent in the future, especially for early access trials that other countries are doing.

For the submission, is the 30 days interactive?
Once the ITA has been submitted and there are concerns with the design of the study, then additional information questions are used to address those concerns. This prompts the clock to stop. That allows the back and forth discussions. It is a more formalized process for discussion purposes. Likely have multiple rounds. The number of rounds that pass influence the feasibility of authorizing the device.

For special access, any info or direction for manufacturers?
Manufacturers are largely consulted. Process doesn't exist. It is more of a case by case basis. Recommend coming in for a meeting prior.

Tips for submissions?
Summarize the data. The process is designed for quick responses. It is important to summarize the data and ensure it addresses the specific needs that have been requested by the physician.

Clinical Data Transparency — Sally Prawdzik

Vanessa's Law – mandated to increase transparency initiatives in the past 3 to 4 years.

Data transparency will start with drugs and phased in over 4 years.

Creation of Stakeholder Reference Group
Health Canada, legal and industry met 5 times. Medtronic and J&J participated on the device side. Lot of different opinions and overall a great process.

Key difference between Regulation and Guidance Document in this case, the regulation gives Health Canada the power to release confidential clinical data. Once Health Canada has granted or refused a license then the process kicks off. The timeline hasn't been finalized yet. Guidance timelines are specific to drugs (60-day timelines) regardless of market. The data remains confidential during development but once the device obtains a license, data could be released.

MEDEC and AdvaMed are concerned industry won't go to Health Canada until all key markets are established with a device. There is a threat that competitors would reverse engineer devices. Canada is not the biggest market in the world. If this process is not implemented correctly, companies may not come to Canada.
Come to HC, data is on the website, competitors can reverse engineer devices

Last week, there was a court decision in Canada in the case where Academic sued Health Canada to get access to submission data on a drug (Tamiflu). Health Canada said no, we can't release the info, it's confidential per regulations. It developed into a legal battle. The court ruled in the favor of academic and said Health Canada was required to release the confidential information. This ruling will likely be challenged thru appeals, etc. However, this is a good example of the fact that data transparency is not going away. Should it be done, it needs to be done appropriately. There is still a load of concerns.

On the drug side, transparency has been done in Europe. FDA has a pilot, not as significant but similar for drugs. It's new for devices but not going away.

Clinical investigation reports will be posted publicly via the EU MDR

The ATI process is like the US Freedom of Information Act. For the ATI process, confidential items can be blacklined, but you must provide justification for each black line.

IMDRF and ToC Update — Sally Prawdzik

The IMDRF working group has proposed a set of common definitions (terms such as patient-specific, custom made and personalized) and hopefully these will be released at the Beijing meeting in Sept 2018. Health Canada will adopt the same definitions via a guidance document that is scheduled to be released before the end of the year. It was very challenging to take into consideration all the comments received.

UDI
Application guide recently released on the IMDRF website

Good Regulatory Review Practices
Developing principles of labeling for medical devices and IVDs – just posted online as well

Regulated Products Submissions (RPS)
ToC

What is the primary difference between STED and ToC?

- ToC is more easy to use than STED
- Health Canada is going to let go of STED.
- STED has similar vision and similar format
- ToC format is more well accepted

Mostly the same information but it is formatted differently.
Electronic version can be utilized with XML based submission
STED wasn't as granulated
Comments from staff are very positive
Regulators are quite positive with ToC

Is the long-term intent for all 10 countries to recommend ToC?
Per David, at the June 27th IMDRF meeting, Health Canada was the only one willing to embark and mandate the ToC format in their jurisdiction. Health Canada will allow for STED for some transition period but the Health Canada and ToC will be the preferred and recommended format. It was unfortunate that the other countries could not collectively collaborate and leverage the work that is being done within IMDRF for this purpose.

In some countries, predicate device comparison is required.. Would there be a step in order to adopt this ToC into their process?
They would need to do some regulation changes.

Moving forward with ToC, is it possible that some of the countries will continue to add specific requirements to the Toc? Experienced that with STED and other initiatives. Is that part of their reluctance to adopt ToC?
A lot of work has been done to harmonize it. Agreed on the format. Also, understand that there are some issues with specific jurisdictions. It is foreseen that countries could potentially add to it. They are in the stage that everyone agreed to the format.

How does the ToC align with the new EU MDR?
Not there yet. The EU said they would look at it in 2019. Too busy with the EU MDR changes.

What do the IMDRF meetings look like?
Anyone can attend the Stakeholder Day. It is available to anyone in the industry. Sign up officially to attend and the link is posted on the IMDRF website. The remaining two days of meetings are closed door. At these meetings, each management committee member provides an update. The afternoon generally has a planned event. Last year, there was a cybersecurity and real-world evidence panel discussion. There is normally a cocktail reception that provides a great networking opportunity with key regulators across the jurisdictions.

How do you get a work item added?
Submit a work item proposal that includes the objective and the expected outcome. It would be discussed at the committee table (at the Day 2 meeting). The Chair would be able to participate in a designated segment of the meeting to present, sell, explain and discuss the desired proposal. Committee members will discuss and debate the proposal. IMDRF received two work item proposals related to Cybersecurity that will be discussed at the September meeting. One of the proposals was submitted by DITTA and the other came from China. There is a lot of behind the scenes work that must occur before a proposal would be submitted. It is imperative that there are advocates at the table prior to a proposal being accepted for discussion.

Task Force Meeting	
Task Force Effectiveness	Geeta Chatfield

Refer to the presentation for a detailed update of discussion items.

Implementation of the new OSMA TF Scorecard
-Geeta will schedule a WebEx with all of the current TF chairs to review the new scorecard and answer questions.
-All TF Chairs should draft the scorecard prior to the Fall meeting
-All TF Chairs should reach out to current TF members to assess their level of participation. Only contributing members should maintain a TF member status.
-Geeta will add a revision level for the scorecard to drive consistency

Task Force Pre-Planning Efforts
-The workstream will work to create a process that defines the objective, desired metrics and deliverables that need to be completed and reviewed prior to the initiation of a TF group

Website
-Assess the setup permissions for individuals to get notifications from certain TF group postings
-Assess the ability to establish TF groups online for members to add/remove themselves

Incorporate the expectations of participating in a Task Force into the bylaws.

Refer to the Summer Business Meeting Minutes for a list of the action items captured.

Attachments	
No.	Name
1	OSMA Summer Business Meeting Presentation
2	Attendee List