MEDEC
CANADA'S MEDICAL TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

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January 2, 2018

Etienne Ouimette
Director General
Resource Management and Operations Directorate
Health Products and Food Branch, Health Canada
Ottawa, ON
K1A 0K9

Sent by electronic email: CRI_IRC_Consultations@hc-sc.gc.ca

RE: Cost Recovery Renewal Initiative – Consultation on Health Canada's Fee Proposal for Drugs and Medical Devices

Dear Mr. Ouimette,

On behalf of MEDEC, I am pleased to provide our comments for the consultation on Health Canada's Fee Proposal for Drugs and Medical Devices.

Overall, we are concerned the proposed fee increases will have a significant negative impact on industry and economic growth, and ultimately patient care – especially since the Department has explicitly stated that there will be no proposed changes to performance standards and reporting.

This Cost Recovery Renewal Initiative is an opportunity to make positive changes that will support industry and the government's shared goals to foster innovation, create good jobs in Canada and provide Canadians with better health outcomes.

Included in our submission are a number of recommendations to make that positive change. We look forward to further discussing them with you in late January/early February as part of the next steps outlined in your December 19, 2017 email to stakeholders.

Sincerely,

Brian Lewis
President & CEO

Cost Recovery Renewal Initiative

Consultation on Health Canada's Fee Proposal for Drugs and Medical Devices

January 2, 2018

MEDEC is the national association for Canada's innovative medical technology (medtech) industry.

Representing approximately 150 medtech companies (ranging from Canadian-owned to multinationals), MEDEC works closely with federal and provincial-territorial governments, health professionals, patients and other stakeholders to deliver a patient-centred, safe, accessible, innovative and sustainable, universal health care system supported by the use of medical technology.

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EXECUTIVE SUMMARY

MEDEC appreciates the opportunity to provide comments with respect to the *Fee Proposal for Drug and Medical Devices (for Consultation) October 2017*. We look forward to working in partnership with Health Canada to create a world-leading regulatory environment that is transparent, equitable and efficient. This is a golden opportunity for making positive changes that will support industry and government's shared goals to foster innovation, create good jobs in Canada and provide Canadians with better health outcomes.

Valued at more than US$6.7 billion,[1] the medical technologies sector makes significant contributions to Canada's economy. A thriving economy and a sustainable, high quality health care system go hand in hand; one cannot exist without the other. At MEDEC, we operate at the intersection of these two imperatives - our members create technologies that save patients' lives, improve the quality of patient outcomes, reduce costs in the health care system, and create thousands of high paying jobs. Our member companies employ over 35,000 Canadians in communities across the country with expertise in multiple disciplines, including manufacturing, sales and marketing, biomedical engineering, biological science, regulatory, professional services and health economics.

The timely approval and adoption of medical innovation and technology is essential to enhancing patient care, improving patient access to health care and enabling health care sustainability, while at the same time creating jobs and economic growth in Canada.

While we appreciate the goals for the changes outlined in the *Fee Proposal*, we are concerned the proposed fee increases will have a significant negative impact on the medical device industry and economic growth, and ultimately, patient care -– especially since the Department has explicitly stated that there will be no proposed changes to performance standards or reporting. It is disappointing the *Fee Proposal* fails to mention the ways Health Canada could leverage outcomes and evidence from trusted regulatory partners to reduce duplication of effort and improve review time.

There is limited information in the *Costing Companion Document for the Fee Proposal for Drugs and Medical Devices* to justify the steep cost increases for each fee line compared to current fees – in most cases the increases are over 100% and, in a couple of cases, over 400% - 500% **(**Appendix 1).

We understand the need for annual increases to keep pace with the cost of living. The current cost recovery fee schedule has a built-in annual increase for fees of 2% as well as a 50/50 ratio for public/private cost sharing. According to data from the Medical Devices Bureau the application volume has remained relatively stable in recent years (Table 4 – Page 8) therefore there shouldn't be an increase in workload to warrant the significant increases being proposed.

In *Budget 2017* the federal government announced its intent to modernize business fees by specifically stating businesses should pay their fair share for the services the government provides.[2]

MEDEC fully agrees with the "fair share" statements made in *Budget 2017*. We do not believe, however, that moving from industry paying 50% to paying 90-100% of the fees constitutes "fair share". Canadians accrue numerous benefits from the introduction of new

medical technologies: better healthcare and improved quality of life and outcomes, not to mention the economic impact of the commercial activity involved. New medical innovation can also help lower the incredible burden of health care costs on all levels of government.

Canada represents approximately 2% of the global market for medical technologies. The Canadian market is already less attractive to the medical technology industry compared to other countries. Canada ranked 60th across 75 countries on medical technology spending as a percentage of total health care budget and was ranked behind all other G7 countries.[3] When you couple this low spending on medical technologies with the proposed fee increases, small and medium sized companies (SMEs) as well as multinational organizations will question the value of bringing new innovations to the Canadian health care system.

The *Fee Proposal* runs counter to other key initiatives currently supported by the government that fall under the Federal Innovation Agenda. An innovative economy for medical technology requires a transparent, predictable regulatory pathway. Increasing fees by a very significant amount within a short timeframe, with the potential for further fee increases by Ministerial order, does not align with the Innovation Agenda. It is imperative that any fee increase be measured, transparent and have a strong, logical rationale behind it.

In addition, industry continues to have concerns over the time to approval for medical technologies in Canada. Industry's expectation is that revenue from increased fees would be invested in new processes to facilitate getting new products to market, and therefore to patients, faster; a more efficient and productive process. Combined with mutually agreed upon and transparent performance standards, industry and government can build a strong partnership to greatly improve Canada's regulatory framework which would enhance the value proposition for investment into Canada's medical technologies sector.

Lastly, we want to highlight concerns with the latest revised timeline from Health Canada for the *Fee Proposal* process sent to stakeholders on December 19, 2017. With such a short timeframe, we feel Health Canada is rushing this very important process. We don't believe a face-to-face stakeholder consultation period of approximately 4-6 weeks will allow for the opportunity to have the meaningful discussion with stakeholders that is required to properly consider the impact of this *Proposal*. We believe this process represents an opportunity for government and industry to work together to help lay the foundation for a regulatory process that leads the world in fostering innovation, improving the lives of patients, and creating economic growth for Canadians. As such, we would request that Health Canada strongly consider adding additional time to the face-to-face consultation period.

At this time, MEDEC is pleased to provide comments for Health Canada's *Fee Proposal* and we look forward to meeting with you during the consultation period to ensure that our position and recommendations are clearly understood.

MEDEC RECOMMENDATIONS

Please refer to pages 5-22 for detailed comments regarding MEDEC recommendations.

Fee Proposal

1. Provide further clarity and justification for new fee unit costs and the rationale for a "fair share" 90-100% fee setting ratio at a meeting with MEDEC in late January/early February (as per the December 19 email to stakeholders with timelines for next steps).

2. Conduct an independent external review of Health Canada costs to instill confidence that the 2017 unit costs upon which the new fee setting ratios are applied are justified.

3. Consider a staggered implementation given the significant increases and impact on industry within a short period of time.

4. Seek further input from MEDEC with respect to the proposed fee structure. For consideration - add an administration-only fee for applications needing a limited or no data review (e.g. labelling only review, bundled submission); add a separate fee for Class IV Near Patient IVDD submission, similar to the proposal to maintain a separate Class III Near Patient IVDD fee line.

Annual Adjustment

5. Clarify when and how industry will be notified about the fee adjustment to take effect as of April 1st based on the CPI index. Industry is asking for at least 12 months advance notice in order to have the appropriate lead time to incorporate the fee increase into future operating budgets (i.e. notified April 1, 2019 for increase to take effect as of April 1, 2020).

Fee Mitigation

6. Continue with the current fee remission program for medical devices to ensure Canadians have a variety of options to address their medical needs.

7. Seek advice from MEDEC about possible solutions to address concerns with how companies currently qualify for fee remission and challenges with fee deferral.

8. Should Health Canada not accept MEDEC's recommendation to continue with the current fee remission program, we strongly encourage an assessment be conducted prior to moving ahead with the proposed program to reduce unintended consequences for patient care as a result of companies no longer qualifying for mitigation.

Performance Standards

9. Expand the current performance standard to include screening time as part of Time to First Decision.

10. Include MEDEC in the development of the upcoming "Stop the Clock" policy to leverage what is best practice from other regions and provide an opportunity for MEDEC to comment on the draft proposal. Discussion regarding this policy would also be relevant to determining how best to include screening time in the performance standard.

11. Engage with MEDEC to discuss process improvements to enable faster approvals and ultimately faster access to new devices for Canadians.

12. Formally explore Memorandums of Understanding (MoU) with similarly regulated regions to improve performance by reducing review complexities (i.e. partnering with similar regulators to exchange and accept "reviewer's notes", of course subject to final discretion by Health Canada).

Penalty Provision

13. Consider an approach similar to the FDA when the performance standard for a 510(k) submission is missed. Under the 510k process, if the FDA review reaches 100 days (10 days past their review target), written feedback is provided to the applicant to be discussed in a meeting or teleconference that includes all outstanding issues with the application preventing FDA from reaching a decision. The information provided reflects appropriate management input and approval, includes action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each party to complete their respective tasks.[4]

14. To encourage action and discourage a foreseeable possibility for prolonged delays of an application that has already missed its performance standard, consider a progressive escalation of serial penalties (or some equivalent).

Performance Reporting

15. Host an annual in-person stakeholder meeting with the medical technology sector to discuss areas of interest associated with medical device fees and related process improvements. These annual meetings should be separate from the regularly scheduled MEDEC Bilateral Meetings.

16. Performance reports (quarterly, annually) for medical devices should be posted publicly and in a timely fashion without a stakeholder needing to make a request. If website posting is a barrier then a separate newsletter sent to a stakeholder registry (opt-in) should be adopted. As a suggestion, Health Canada could leverage the existing database of stakeholders within the CSIMS registry.

17. "To better service your customers", Health Canada should have one publicly available medical device performance report (quarterly & annually) including the data provided at MEDEC Bilateral Meetings and include additional metrics that would be of value to the medical device industry. A list of proposed metrics can be found on Page 17.

FEE PROPOSAL FOR DRUGS AND MEDICAL DEVICES

MEDEC is pleased to provide these detailed comments to support our recommendations with respect to Health Canada's *Fee Proposal for Drugs and Medical Devices, October 2017.*

1. FEE SETTING RATIOS; ADDITIONAL FEE SPECIFIC CHANGES

The proposed fee changes for medical devices, as outlined in the *Fee Proposal for Drugs and Medical Devices* (Appendix 1) will have a significant negative financial impact on all manufacturers regardless of size and could result in a number of possible unintended consequences.

With the steep increases in the 2017 unit costs upon which the new fee setting ratio of 90-100% (from 50%) is applied, MEDEC estimates the impact to the industry will be:

- **$9,627,578 (137%)** - for new and amendment applications (Table 1)
    - Refer to Appendix 2 for full detail.

- **$4,431,750** - due to the Right to Sell fee increasing from $375 to $500 across 35,454 active medical device licenses. This doesn't take into consideration the financial impact associated with active licenses that would no longer qualify for the fee remission program where the Right to Sell fee for those devices is increasing from $61 to $500 (720% increase).

Table 1
Industry Impact Analysis - New Applications, Amendments
Current Fees vs Proposed Fees

	Current Fees	Proposed Fees	$ increase (%)
New Applications	$4,258,012	$9,843,468	**$5,585,456 (131%)**
Amendments	$2,776,740	$6,818,862	**$4,042,122 (146%)**
Total	$7,034,752	$16,662,330	**$9,627,578 (137%)**

Unintended Consequences

Health Canada should be aware of the possible unintended consequences if the government moves ahead with the proposed fee changes.

Negative impact on access to new innovations; new software-device clinical features

- With fees for new licence applications increasing by 127-233% and amendments by 429-595% (Appendix 1), manufacturers will reconsider bringing new and emerging health technologies and/or iterative innovations to Canada.
- Fee increases for amendments will significantly impact software-driven advances with new clinical features which are commonly released on an annual basis.

Manufacturers may choose to delay individual upgrades and bundle multiple releases into one licence amendment to control costs.

Interruption of supply

- Companies will review the range of devices they currently sell in Canada and assess whether or not to renew their licence.

Negative economic impact

- Makes it more difficult for multinational organizations to advocate globally for investments in Canada.
- Increases the financial challenge for small to medium size organizations (SMEs) to launch new products in Canada – and without home market customers or case studies they are immensely challenged in securing domestic and foreign investment.
- Higher cost for medical devices as companies will either pass along incremental fee increases to payers or choose not to licence lower cost devices.

Surge in applications before new fees take effect

- With new fees proposed to take effect as of April 1, 2019, there could be a surge in applications before that date impacting both Health Canada's metrics and operational capabilities similar to what occurred prior to fees being increased in 2011 (Table 2).

Table 2
Number of New Medical Device Applications
2009/2010 to 2013/2014

	2009/2010[1]	**2010/2011**[1]	2011/2012[2]	2012/2013[2]	2013/2014[2]
New Applications	3054	**3508**	2587	2364	2061

1. MDB Metrics and Performance. MEDEC Regulatory & Legal Conf. J. Helmkay. Nov 2010
2. 2014 Review of the Fees in Respect of Drugs and Medical Device Regulations. Health Canada. October 27, 2014

Fee Ratio - Questioning Rationale for Shift from 50% to 90-100%

In *Health Canada's Proposal to Parliament for User Fees and Service Standards for Human Drugs and Medical Devices Programs (April 2010),* a concluding statement was: These efforts will support an appropriate balance of public-private cost sharing and will relieve the general Canadian taxpayer of the burden of subsidizing activities for which industry receives direct benefits.

A cost sharing ratio of 50/50 was considered the "appropriate balance" of public-private cost sharing.

In *Budget 2017,* the federal government announced its intent to modernize business fees, stating "businesses should pay their fair share for the services the government provides."

MEDEC agrees with the federal government that businesses should pay their "fair share" for services the government provides. We also agree with the approach taken in 2010 that a "fair share" ratio of 50/50 is considered appropriate.

The *Fee Proposal* and the *Costing Companion Document* fail to explain the change in perspective on public-private benefit that would result in "fair share" shifting from industry paying 50% to 90-100%.

The *Fee Proposal* cites international comparisons (Australia, Europe) as a rationale to justify a 90-100% fee setting ratio. The *Fee Proposal* fails to mention that in the United States, where the device framework is most similar, device program fees are approximately 40% recovered from industry.

The examples in the *Fee Proposal* of 100% cost recovery in Australia and 89% in Europe reflect medical device regulatory frameworks that differ substantially from that in Canada. In Europe, the referenced European Medicines Agency (EMA) reviews medicinal products for a fee, not medical devices. For medical devices, the bulk of fees are paid to independent third parties for conformity assessment and CE marking, which grants access to the entire European market. Furthermore, CE marking can be leveraged for other markets including Australia and Israel.

2017 Costing Analysis – More Information Needed to Justify Increases

Overall Program Costs

MEDEC is seeking clarity related to the device program costs described in the *Fee Proposal* compared to previous analyses conducted by Health Canada.

It is unclear why there are significant differences in the reported Medical Device Bureau costs in the 2016-2017 Departmental Performance Results Report (DPR) compared to the 2017 *Costing Companion Document.* Based on the data provided, it appears the DPR and *Costing Companion Document* comparisons for program costs are an 'apples to apples' comparison (even if the DPR doesn't include Capital Costs), yet some fee areas have greater than a 2.5 times difference in the cost analysis.

Specifically (Table 3):

- The 2016-2017 DPR Supplementary Tables note a 'Full Cost' of approximately $20 million for device licence evaluation activities whereas the *Costing Companion Document* lists the Program Costs (excluding Corporate costs) at ~$55 million - a difference of $35 million.

- Similarly, the 2016-2017 DPR Supplementary Tables note a 'Full Cost' of approximately $14 million for Device Right to Sell activities whereas the *Costing Companion* document lists Right to Sell Program Costs (not even including Corporate costs) at ~$55 million - a difference of $41 million.

Table 3
2016-2017 DPR "Full Cost" vs *Costing Companion* Program Costs

Cost Type	2016-2017 DPR 'Full Cost'[1]	*Costing Companion* 'Program Costs'	Difference
Licence Evaluation	$20,112,968	$55,061,000	**$34,948,032**
MDEL	$9,339,534	$9,962,000	$622,466
Right to Sell	$14,091,638	$54,926,000	**$40,834,362**

1. Supplementary Information Tables: 2016-2017 Departmental Performance Report, p.6

In addition, there are significant differences in the program costs outlined in the 2007-2011 cost recovery initiative documentation compared to the *Costing Companion Document*. For example, in the 2007 Official Notice the total cost to fund the Device Right to Sell program was estimated at $12.7 million[5] and in 2017 the *Costing Companion Document* estimates the cost to fund the Device Right to Sell program at $55 million, a difference of ~$43 million dollars.

More information is also required to justify the steep increases in program costs when the volume of applications has remained relatively stable over the last number of years (Table 4).

Table 4
# of Applications (New, Amendments) – 2013/14 to 2016/17

Type of Application	2013/14[1]	2014/15[2]	2015/16[2]	2016/17[3]
New	2364	2028	1982	1930
Amendments	2500	2446	2265	1845
Total	4864	4474	4247	3775

1. 2014 Review of the Fees in Respect of Drugs and Medical Device Regulations. Health Canada. October 27, 2014, p.19
2. TPD Yearly Medical Device Submission Performance Report. 2015/2016. p.8-9
3. Medical Devices Program. Performance Report. MEDEC Bilateral Meeting. June 2017.

Unit Cost Data

Health Canada has provided limited information for the unit cost data in the *Costing Companion Document*, however in preparing this submission MEDEC found a striking difference between the medical device unit costs in 2010 vs. 2017 (Table 5 – detail Appendix 3).

It is understandable that costs have increased due to yearly inflation adjustments and new department program costs (given that the 2010 report data was based on 2005 cost data[6]), however increases in the range of 113% to 558% raise important questions about how the 2017 unit costs were calculated.

Table 5
Unit Cost Comparisons - 2010 vs 2017

	2010 Unit Cost[1]	2017 Unit Cost	% Increase
Class III - Licence Application	$6,726	$15,401	129%
Class IV - Licence Application	$15,660	$33,403	113%
Class III - Changes in Manufacturing	$1,682	$11,062	558%
Class IV - Changes in Manufacturing	$1,682	$8,427	401%

1. Health Canada's Proposal to Parliament for User Fees and Service Standards for Human Drugs and Medical Devices Programs. Appendix B. April 2010

Medical Device Licence Application Fees

Each licence application is different and requires to some degree a varied amount of Health Canada resources to review, ultimately requiring applications to be grouped into representative fee categories. However, with the lack of transparency in the development of fee lines and new costs, a number of questions are raised in terms of the logic for some of the fee line costs and 'groupings'. For example:

- Manufacturing Change: It is not clear why an application for a Class III manufacturing change ($9,956) would be more expensive than a Class IV ($7,584). We understand that costs from Health Canada's SAP system were used to calculate the information, but logically it does not make sense that a lower risk device would incur a more expensive review.

- Class IV Licence Applications: It is not clear why Health Canada chose to combine current Class IV licence applications into one fee line (Table 6). MEDEC is concerned that less resource intensive applications will be subsidizing submissions that require more resources (e.g. Class IV Near Patient IVDD).

Table 6
Class IV Medical Device Licence Applications
Current Fees vs Proposed Fee

Class IV Medical Devices	Current Fees	Proposed Fee	% Increase
Licence Application	$13,235	$30,063	127%
Licence - Human, Animal Tissue	$12,347		143%
Licence - Near Patient IVDD	$22,560		33%

The proposed fee structure also does not account for Class III and Class IV submissions that have limited to no data review. In line with Health Canada's fee for service framework, a fee line should be created for Class III and IV submissions that are limited to an application form and labelling review (similar to a Class II medical device application). Examples of these types of submissions would include:

- Bundled submissions where one data set is reviewed for multiple licence applications submitted together.
- Adding a new legal manufacturer for a Class III or IV medical device (where the legal manufacturer has the same manufacturing process and specifications as the existing device) requires payment of the full application fee. As Health Canada resources required for this type of application are significantly less than a new Class III or IV medical device application, the fee should be reflective of the required resources. Payment of the full fee has deterred manufacturers to register additional legal manufacturers for supply continuity and flexibility, potentially limiting Canadians access to critical health products.

MEDEC RECOMMENDATIONS – Proposed Fees

1. Provide further clarity and justification for new fee unit costs and the rationale for a "fair share" 90-100% fee setting ratio at a meeting with MEDEC in late January/early February (as per the December 19 email to stakeholders with timelines for next steps).
2. Conduct an independent external review of Health Canada costs to instill confidence that the 2017 unit costs upon which the new fee setting ratios are applied are justified.
3. Consider a staggered implementation given the significant increases and impact on industry within a short period of time.
4. Seek further input from MEDEC with respect to the proposed fee structure. For consideration - add an administration-only fee for applications needing a limited or no data review (e.g. labelling only review, bundled submission); add a separate fee for Class IV Near Patient IVDD submission, similar to the proposal to maintain a separate Class III Near Patient IVDD fee line.

2. ANNUAL ADJUSTMENT

Predictability and transparency are two very important aspects for businesses preparing future operating plans either for investors or domestic/multinational organizations.

The current annual increase of 2% for fees is both predictable and transparent.

The proposal to adjust fees tied to the Consumer Price Index (CPI) doesn't clarify when the government would be announcing the fee adjustment to take effect every year as of April 1st or which twelve (12) month window the CPI would be based.

MEDEC RECOMMENDATIONS – Annual Adjustment

1. Clarify when and how industry will be notified about the fee adjustment to take effect as of April 1st based on the CPI index. Industry is asking for at least 12 months advance notice in order to have the appropriate lead time to incorporate the fee increase into future operating budgets (i.e. notified April 1, 2019 for increase to take effect as of April 1, 2020).

3. FEE MITIGATION

Since the implementation of user fees in the 1990's, Health Canada's approach to fee mitigation focused on facilitating the availability of health products to Canadians, and encouraging innovation and access to new products.

While we applaud Health Canada's initiative to support small businesses by proposing a small business waiver as a form of fee mitigation, Health Canada has overlooked the importance of fee remission to businesses that do not fit the Treasury Board definition of a small business and the degree to which the devices that currently qualify for fee remission will no longer be applicable.

Large companies have maintained medical device licences for products that generate little or no sales for one or more of the following reasons:

- Products intended to benefit small populations of Canadians.
- Earlier version of existing technology to meet the patient's and/or surgeon's needs. These products play a vital role especially in orthopedics, where a patient may require revision surgery.
- Products provided at no charge.
- Accessories of other medical devices that provide significant value to the physicians and/or overall patient outcome.

The current License Renewal Reduced Fee is $61 and the proposal is for this fee to increase to $500 (720% increase).

MEDEC member companies have been assessing the proposed change and the impact for a number of organizations will be an increase in Right to Sell fees in the range of $100,000 to $300,000. With this type of increase, manufacturers may have to discontinue the products in Canada, subject selected products to price increases, and/or decide not to bring innovations to Canada.

MEDEC RECOMMENDATIONS – Fee Mitigation

1. Continue with the current fee remission program for medical devices to ensure Canadians have a variety of options to address their medical needs.
2. Seek advice from MEDEC about possible solutions to address concerns with how companies currently qualify for fee remission and challenges with fee deferral.
3. Should Health Canada not accept MEDEC's recommendation to continue with the current fee remission program, we strongly encourage an assessment be conducted prior to moving ahead with the proposed program to reduce unintended consequences for patient care as a result of companies no longer qualifying for mitigation.

4. PERFORMANCE STANDARDS

Health Canada is proposing not to make any changes to the current performance standards framework for medical devices. MEDEC doesn't agree that performance standards should remain status quo.

Include Screening Time as Part of Performance Standard

The current Health Canada performance standard for licence evaluation is measured from the time of screening acceptance to the end of first review and doesn't include screening time. MEDEC strongly believes the Time to First Decision metric should reflect the time that the application is under review, including both screening and technical review. This approach would more accurately reflect a 'time to first decision' metric vs. the 'time in technical review' metric which is currently in place. Manufacturers are already paying for screening under the current cost recovery framework, with a retention of 10% of the service fee if the application is rejected at screening[7] (the current Fee Proposal includes the same provision[8]). Although screening is typically a shorter review cycle than the technical review, it is an important part of the overall time to market, often taking 30 days or more to complete. Variability in screening time challenges manufacturers to estimate the total review time and can ultimately impact time to market.

In comparison, the US FDA 510k acceptance review (equivalent to Health Canada screening process) is accounted for as part of the FDA review clock if the application is accepted for review. Per the FDA Guidance document on Refuse to Accept Policy for 510(k)s[9], the FDA review clock start date is *"the receipt date of the most recent submission or additional information that resulted in an acceptance designation for the 510(k)"*. In Canadian terms, if the original submission is accepted for review at Screening 1, the Screening 1 time would be included in the review clock. If the application receives a Screening Deficiency Notice (SD) and was subsequently accepted for review based on the response to the SD, the review clock would include the screening time of the Response to the SD (Screening 2).

The US FDA comparison is just one example of how to incorporate screening into performance accountability. There are a variety of other options that could be considered.

1. Include Screening as a stand-alone metric, separate from Review 1 timeline (i.e. add a new metric to the performance standard list)
2. Include Screening as part of the current Time to First Decision metric
    a. Using a similar process as the FDA i.e. once application been accepted for review, the last screening time is included in performance metric OR
    b. Follow similar logic to current Time to First Decision metric i.e. Screening is measured from the time Health Canada receives the application to the time they issue a Screening Acceptance/Deficiency letter

For many years, MEDEC has requested incorporating screening into performance metrics, and the response has been the current Cost Recovery Framework wouldn't allow this type of change. Now is the time to update the performance metric to include screening and accurately reflect Time to First Decision. MEDEC is very much willing to work with Health Canada to determine the best way to incorporate screening into the performance standard, balancing efficiency in reporting while ensuring Health Canada accountability.

"Stop the Clock" Policy Development

Recognizing the significant differences in review timelines and processes for drugs and devices, MEDEC would appreciate the opportunity to work with Health Canada in the development of the "Stop the Clock" policy.

To ensure Canadians have timely access to medical technology the policy needs to provide sufficient details for "stop the clock" criteria and not stifle the current process of discussion and informal information requests.

As an example, the FDA Guidance Document on FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment[10] provides details on the circumstances when stop the clock will occur, i.e. at the time of AI where *"additional information is not minor in nature and/or cannot be provided within a reasonable period of time (i.e., such that the review will not be delayed)"*; and when an informal request is more appropriate, *"the additional information is relatively minor in nature… and can be provided quickly".*

Medical Device Performance Improvements

At the medical device stakeholder meeting on November 20, 2017, Health Canada requested feedback on areas for improvement in the medical device program. Working with our member companies MEDEC has generated a number of suggestions that, if implemented, we believe would make a significant impact to the overall effectiveness of the Medical Devices Bureau as well as the efficiency and effectiveness of submission reviews and expedite getting new devices to market.

Interactive Review

In recent years, Health Canada has embraced an interactive approach in medical device application review, where the reviewer makes an informal request (via email, phone, etc.) for information that can be provided within a short period of time and not delay the review of the application. This approach has resulted in faster review times, leading to earlier availability of the product to Canadians. However, it appears this approach has not been adopted consistently across all sections, leading to differences in manufacturer's expectations. We believe if this approach could be implemented consistently across the Medical Devices Bureau it would be an efficiency improvement.

In addition, the interactive review approach would not affect the current formal request process (i.e. an Additional Information (AI) Request) if there is sufficient clarity on the criteria for an informal request versus formal request for information. Health Canada could consider including these criteria in the upcoming draft policy for "Stop the Clock".

Modular Submission Review

In a US FDA traditional PMA, similar to Health Canada device licence applications, the applicant submits all data at the same time (regardless of when testing is completed) and FDA begins its review only upon receipt of all the required information. In order to increase the efficiency of the PMA review process, FDA issued a policy in 1998 whereby applicants could submit "Modular PMAs"[11]. Under a Modular PMA the applicant can submit discrete

sections (modules) of the PMA submission to FDA for review soon after completing the testing and analysis – the sections or "modules" submitted at different times then cumulatively become a complete application, but can be reviewed by the agency as they are submitted. For example, a manufacturer could submit preclinical data and/or manufacturing information for review while still collecting, compiling, and analyzing the clinical data.

Enabling the ability to use a modular submission approach in Canada for certain novel high risk devices could reduce the overall Health Canada review time, specifically for devices when lengthy clinical studies and/or investigational testing are underway. Additionally, the modular approach would enable the manufacturer to potentially resolve any deficiencies noted by Health Canada earlier in the review process than would occur with a traditional licence application. Implementation of a modular submission could reduce time to market. Health Canada is already successfully utilizing a similar modular approach for Investigational Testing Authorization applications whereby certain regulatory requirements can be declared, “to come” or are already “attached” at time of submission

Instituting a modular submission review program would need to include the creation of a guidance document to outline the program framework. In addition, Health Canada has indicated development of a Stop the Clock provision, which could also include management of the modular submission review clock.

Guidance Document Development

Health Canada data shared at MEDEC Bilateral Meetings indicates over 50% of the time a submission has a screening deficiency. In 2018, MEDEC will be embarking on a Submission Quality Pilot Project to better understand the reasons for screening deficiencies as well as AI requests.

From what we already know, a published Guidance Document on Screening would ensure consistency on the type of screening questions a manufacturer could receive if the application does not meet Health Canada’s requirements. Guidance would reduce the number of potential screening questions and streamline the application review process, leading to an overall shorter time to decision. As work unfolds with the Pilot Project, we are also anticipating the need for product or topic specific guidance where the Bureau issues a large number of AI requests.

With respect to developing new Guidance documents, we suggest Health Canada continue to work with MEDEC to establish timelines and responsibilities in order for documents to be completed in a time efficient manner.

Increased Health Canada/Industry Interaction

Health Canada publishes newly issued guidance and notices on their website but rarely holds webinars or other interactive forums with device manufacturers to provide an overview of Health Canada expectations and enable manufacturers to ask clarification questions. The US FDA CDRH has developed a robust and predictable program of holding webinars when a new guidance is issued, where the FDA’s relevant subject matter expert reviews the guidance details and provides an opportunity for industry to ask questions. Interactive webinars on new guidance or other topics of interest where industry

can engage could help to educate industry and ultimately improve submission applications.

Other opportunities for increased Health Canada engagement with industry (beyond the current forums such as the MEDEC Bilateral Meetings and yearly MEDEC MedTech conference) are also important to explore. Some examples drawn from the US FDA include an Experiential Learning Program (where Health Canada staff can target learning about product technologies/industry processes) or hosting Vendor Days (an educational activity that allows device manufacturers to display and provide product demonstrations to Health Canada highlighting the technical and scientific basis for the device).

Opportunities for Health Canada and industry engagement are extremely valuable not only in increasing education but also fostering improved communications, providing both organizations with a better understanding of the health issues involved with medical device technology.

Leveraging International Approvals

Recognizing Health Canada's existing mechanisms within the costing framework there is the capability to consider information through an attestation model. MEDEC proposes to leverage foreign approvals as an opportunity to streamline Health Canada's operational burden.

Both the "Declaration of Conformity" (DoC) and "Memorandums of Understanding" (MoU), are existing mechanisms that could potentially reduce administrative and review burdens without impacting final jurisdictional regulatory authority or additional costs. Expanding the existing DoC framework would not introduce additional cost-burdens to Health Canada and would fall well within existing review stages already under cost recovery.

Additionally, MEDEC recognizes the importance for regulatory cooperation and the efficient transparent exchange of communications between regulators, as enabled by additional MoUs with pre-approved regulatory jurisdictions. This would facilitate an inter-governmental exchange of "reviewer notes" and "reviewer reports" for example, towards demonstrating openness and enabling regulatory cooperation, for the expedited review of medical device technologies that have already been subject to appropriate regulatory scrutiny and already found to be favorable on the balance of risk-benefit.

MEDEC recognizes the need to balance reducing review complexities with Health Canada's capability to establish an evidence-based regulatory decision as Canada's national health regulatory authority. Towards the shared MEDEC and Health Canada goal to enable timely access to approved medical technologies for Canadians, the proposed expansion of DoC and MoU capabilities would offer a balanced cooperative approach to facilitate Health Canada's risk-based assessments while improving medical device market access.

MEDEC RECOMMENDATIONS – Performance Standards

1. Expand the current performance standard to include screening time as part of Time to First Decision.
2. Include MEDEC in the development of the upcoming "Stop the Clock" policy to leverage what is best practice from other regions and provide an opportunity for

MEDEC to comment on the draft proposal. Discussion regarding this policy would also be relevant to determining how best to include screening time in the performance standard.

3. Engage with MEDEC to discuss process improvements to enable faster approvals and ultimately faster access to new devices for Canadians.
4. Formally explore Memorandums of Understanding (MoU) with similarly regulated regions to improve performance by reducing review complexities (i.e. partnering with similar regulators to exchange and accept "reviewer's notes", of course, subject to final discretion by Health Canada).

5. PENALTIES

The *Fee Proposal* includes a one-time 25% penalty for not achieving a performance standard for each single application, however there is no mechanism to address the application delay after the penalty has occurred.

Manufacturers are most concerned about the total time it takes for Health Canada to license a medical device. This can be particularly important to a small business where investors are waiting for a new innovation to generate revenue.

To prevent the possibility for prolonged delays with an application after a penalty has occurred, we encourage Health Canada to consider an approach similar to the FDA for 510(k) submissions and establish escalating penalties should action not be taken to address issues with a particular application in a timely manner.

MEDEC RECOMMENDATIONS - Penalties

1. Consider an approach similar to the FDA when the performance standard for a 510(k) submission is missed. Under the 510k process, if the FDA review reaches 100 days (10 days past their review target) written feedback is provided to the applicant to be discussed in a meeting or teleconference that includes all outstanding issues with the application preventing FDA from reaching a decision. The information provided reflects appropriate management input and approval, includes action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each party to complete their respective tasks.[12]
2. To encourage action and discourage a foreseeable possibility for prolonged delays of an application that has already missed its performance standard, consider a progressive escalation of serial penalties (or some equivalent).

6. PERFORMANCE REPORTING

MEDEC is pleased that the *Fee Proposal* states: Health Canada understands accountability is important in its relationship with stakeholders and is planning to host annual stakeholder meetings.

While we appreciate performance metrics are available both in quarterly, as well as annual reports, and shared at the MEDEC Bilateral Meeting, the information isn't easily accessible by all and often not in a timely manner. Quarterly and annual reports are only

provided based on a stakeholder request to an email address and often take days to receive - a process which the *Fee Proposal* indicates would continue. The MEDEC Bilateral Meeting data is provided separately, some of which is not included in the quarterly or annual reports.

There are also metrics not yet reported but would be important for industry when developing business cases for bringing new innovations to Canada. Our request for this type of data is not different from what is currently provided in the Health Canada Drug Submission Performance Reports and what the US FDA provides to the medical device industry.

Examples of metrics that would be of value to the medical device industry, in addition to what is currently available in public reports and from MEDEC Bilateral Meetings include:

- Total approval time – by Class, by Division – mean, median, mode
- # of applications by all fee lines
- # of applications that incur a penalty – by Class, by Division, by fee line
- Screening time – by Class, by Division – mean, median, mode
- Reasons for screening deficiencies – by Class, by Division
- Reasons for AI requests – by Class, by Division
- Backlog data e.g. time for screening to review; time from question response to review

MEDEC RECOMMENDATIONS – Performance Reporting

1. Host an annual in-person stakeholder meeting with the medical technology sector to discuss areas of interest associated with medical device fees and related process improvements. These annual meetings should be separate from the regularly scheduled MEDEC Bilateral Meetings.
2. Performance reports (quarterly, annually) for medical devices should be posted publicly and in a timely fashion without a stakeholder needing to make a request. If website posting is a barrier then a separate newsletter sent to a stakeholder registry (opt-in) should be adopted. As a suggestion, Health Canada could leverage the existing database of stakeholders within the CSIMS registry.
3. “To better service your customers”, Health Canada should have one publicly available medical device performance report (quarterly & annually) incorporating the data provided at MEDEC Bilateral Meetings and include additional metrics that would be of value to the medical device industry.

REFERENCES

1. Innovation, Science and Economic Development Canada. Medical Devices Industry Profile. https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html.

2. Government of Canada. Budget 2017 Building a Strong Middle Class. Chapter 4 – Tax Fairness for the Middle Class, Modernizing Business Fees. March 22, 2017.

3. Canadian Health Policy Institute. Medical Devices and Health Care Costs in Canada and 74 Other Countries, 2010 to 2015. Oct 2015

4. FDA. MDUFA Performance Goals and Procedures, Fiscal Years 2018 through 2022. Dec 2016. Pg 8. https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.

5. Health Canada's Proposal to Parliament for User Fees and Service Standards for Human Drugs and Medical Devices Programs. April 2010. Pg 19.

6. Health Canada's Proposal to Parliament for User Fees and Service Standards for Human Drugs and Medical Devices Programs. April 2010. Pg 6.

7. Fees in Respect of Drugs and Medical Devices Regulations. Section 42 (b)(i).

8. Fee Proposal for Drugs and Medical Devices. Health Canada. October 2017. Pg 12.

9. FDA Guidance for Industry and Food and Drug Administration Staff- Refuse to Accept Policy for 510(k)s, August 2015. https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf

10. FDA Guidance Document on FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment. https://www.fda.gov/OHRMS/DOCKETS/98fr/03d-0538-gdl0001.pdf

11. FDA Guidance: Premarket Approval Application Modular Review. Nov 2003. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089764.htm

12. FDA. MDUFA Performance Goals and Procedures, Fiscal Years 2018 through 2022. Dec 2016. Pg 8. https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.

Appendix 1
Medical Devices - Analysis of Proposed Fee Changes
Source: Fee Proposal for Drugs and Devices. Health Canada. October 2017

Name of Fee	Current Fee	New Fee	% increase	$ increase	New Performance Standard
New Applications					
Class II - Licence Application	$397	$627	**58%**	$230	**No change**
Class III - Licence Application	$5,691	$13,861	**144%**	$8,170	**No change**
Class III - Licence Application for near patient IVDD	$9,687	$32,267	**233%**	$22,580	**No change**
Class IV - Licence Application	$13,235	$30,063	**127%**	$16,828	**No change**
Class IV – Licence Application for near patient IVDD	$22,560	$30,063	**33%**	$7,503	**No change**
Class IV – Licence Application human, animal tissue	$12,347	$30,063	**143%**	$17,716	**No change**
Private label applications and amendments	$0	$172	**NEW**	$172	**No change**
Amendments					
Class II	$0	$320	**NEW**	$320	**No change**
Class III - Changes in Manufacturing	$1,433	$9,956	**595%**	$8,523	**No change**
Class III - Significant Change (not related to manufacturing)	$5,330	$11,127	**109%**	$5,797	**No change**
Class IV - Changes in Manufacturing	$1,433	$7,584	**429%**	$6,151	**No change**
Class IV - Significant Change (not related to manufacturing)	$6,073	$15,907	**162%**	$9,834	**No change**
Other					
Establishment Licence	$8,109	$4,500	**-45%**	($3,609)	**No change**
Annual fee for right to maintain a device	$375	$500	**33%**	$125	**No change**

Appendix 2
Medical Devices - Industry Impact Analysis
Current vs Proposed Fees – New and Amendment Applications

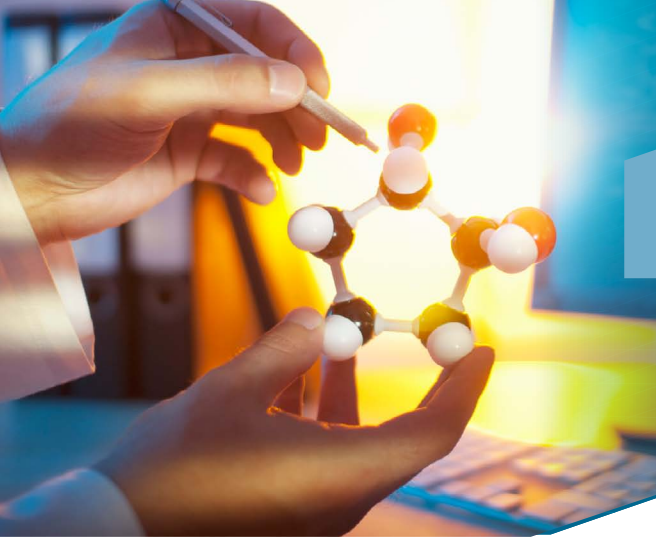
		# Applications[1]	Application Fees		Impact (Total $, %)			
			Current	Proposed	Current $	Proposed $	$ increase	% increase
New Applications								
Class II		1397	$397	$627	$554,609	$875,919	$321,310	58%
Class III	CV	23	$5,691	$13,861	$130,893	$318,803	$187,910	144%
	GR	149	$5,691	$13,861	$847,959	$2,065,289	$1,217,330	144%
	MS	209	$5,691	$13,861	$1,189,419	$2,896,949	$1,707,530	144%
	IVD	56	$5,691	$13,861	$318,696	$776,216	$457,520	144%
Class III	IVD Near Patient	11	$9,687	$32,267	$106,557	$354,937	$248,380	233%
Class IV	CV	46	$13,235	$30,063	$608,810	$1,382,898	$774,088	127%
	GR	12	$13,235	$30,063	$158,820	$360,756	$201,936	127%
	MS	2	$13,235	$30,063	$26,470	$60,126	$33,656	127%
	IVD	8	$13,235	$30,063	$105,880	$240,504	$134,624	127%
Class IV	New Tissue	17	$12,347	$30,063	$209,899	$511,071	$301,172	$143%
Sub-total – New Applications					**$4,258,012**	**$9,843,468**	**$5,585,456**	**131%**
Amendments								
Class II		1315	$0	$320	$0	$420,800	$420,000	NEW
Class III	Manufacturing	15	$1,433	$9,956	$21,495	$149,340	$127,845	595%
	All other	370	$5,330	$11,127	$1,972,100	$4,116,990	$2,144,890	109%
Class IV	Manufacturing	21	$1,433	$7,584	$30,093	$159,264	$129,171	429%
	All other	124	$6,073	$15,907	$753,052	$1,972,468	$1,219,416	162%
Sub-total - Amendments					**$2,776,740**	**$6,818,862**	**$4,042,122**	**146%**
Total – New Applications + Amendments					**$7,034,752**	**$16,662,330**	**$9,627,578**	**137%**

1. Medical Devices Program. Performance Report. Fiscal 2016/2017. MEDEC Bilateral Meeting. June 2017.

Appendix 3
Medical Devices Unit Cost Analysis – 2010 vs 2017

	2017 Fee Proposal				Unit Cost Comparison		
	Current	**New**	**Unit Cost**	**Ratio**	**2010[1]**	**2017**	**% increase**
New Applications							
Class II Licence	$397	$627	$696	90%	$459	$696	52%
Class III Licence	$5,691	$13,861	$15,401	90%	$6,726	$15,401	129%
Class III Licence – Near Patient IVDD	$9,687	$32,267	$35,852	90%	$11,456	$35,852	213%
Class IV Licence	$13,235	$30,063	$33,403	90%	$15,660	$33,403	113%
Class IV Licence – Human, Animal Tissue	$12,347	$30,063	$33,403	90%	$14,609	$33,403	129%
Class IV Licence – Near Patient IVDD		$30,063	$33,403	90%	$26,694	$33,403	25%
Amendments							
Class II	$0	$320	$355	90%	$0	$355	New
Class III – Changes in Manufacturing	$1,433	$9,956	$11,062	90%	$1,682	$11,062	558%
Class III – Significant Changes	$5,330	$11,127	$12,363	90%	$6,307	$12,363	96%
Class IV – Changes in Manufacturing	$1,433	$7,584	$8,427	90%	$1,682	$8,427	401%
Class IV – Significant Changes	$6,073	$15,907	$17,674	90%	$7,187	$17,674	146%
Establishment Licence							
Application for new and renewal of licences	$8,109	$4,500	$4,503	100%			-47%
Right to Sell							
Annual fee for right to maintain a device	$375	$500	$556	90%	$641	$556	-13%

1. Health Canada's Proposal to Parliament for User Fees and Service Standards for Human Drugs and Medical Devices Programs. Appendix B. April 2010.



ABOUT **MEDEC**

"THE VOICE OF CANADA'S MEDICAL TECHNOLOGY INDUSTRY"

Established in 1973, MEDEC is the national association representing Canada's innovative medical technology (medtech) industry.

Representing approximately 150 medtech companies (ranging from Canadian-owned to multinationals), MEDEC works closely with the federal and provincial-territorial governments, health professionals, patients and other stakeholders to deliver a patient-centred, safe, accessible, innovative and sustainable, universal healthcare system supported by the use of medical technology.

MEDEC is governed by a Board of Directors representing the diverse perspectives and experiences of its members from across the country.

OUR VISION

Serving as an essential partner in providing better health and more sustainable healthcare for Canadians.

OUR MISSION

MEDEC speaks with one voice for Canada's medical technology companies in advocating for a responsive, safe and sustainable healthcare system that is enabled by the use of Medical Technology.

For more than 40 years, MEDEC has delivered essential programs and services to its member companies (members), including:

- Serving as a trusted thought leader on current issues affecting the medtech industry, the healthcare system and international trade;
- Providing access and strategic opportunities for collaboration with government and other health partners;
- Delivering timely communications and advocacy tools on key issues that matter to members;
- Hosting timely educational sessions to keep members current on industry trends, legislative and policy initiatives at the federal and provincial-territorial level;
- Hosting practical forums to accelerate knowledge transfer and the exchange of best practices; and
- Promoting broad awareness about medical technology's contributions to patient care, the healthcare system and to the broader economy.

CANADA'S MEDICAL TECHNOLOGY INDUSTRY AT A GLANCE

- MEDEC represents over 150 medtech companies in Canada involved in the research, supply and manufacturing of medical technologies.
- The size of the Canadian medical device market in 2011 was valued at approximately $6.3 billion, up from $4.5 billion in 2006.[1]
- More than 1,700 medtech companies operate in Canada.[2]
- Medtech companies are located across Canada with the highest concentration in Ontario and Quebec.[3]
- Canada exports approximately 1.835-million of medical technology and imports $6.5-billion.[4]
- The largest markets for export are the United States Europe, Middle East South America and China.[5]
- The Canadian medtech industry employs more than 35,000 Canadians[6] with expertise across multiple disciplines, including but not limited to: life sciences, professional services, biomedical engineering, biological sciences, health economics, information technology, law, manufacturing, nursing, physical sciences, regulatory and quality, sales and marketing, and public affairs.

[1] Industry Canada. *2013. Medical Device Industry Profile 2013* – Canadian Life Sciences Industries. http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html
[2] Health Canada, *2013. http://webprod5.hc-sc.gc.ca/el-le/start-debuter.do?lang=eng*
[3] Industry Canada. *2013. Medical Device Industry Profile 2013* – Canadian Life Sciences Industries. http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html
[4] Industry Canada. *2011. Medical Device Industry Profile 2013* – Canadian Life Sciences Industries. http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html
[5] MEDEC Industry Market Data Survey, 2013.
[6] Health Canada, 2011. *http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md_notice_software_im_avis_logicels-eng.php*

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