



Legal Path To Launch: Regulatory Approval, Device Funding, Pricing & Setting Up Your Business

Canadian Medical Device Market Access & Government Affairs

Eileen McMahon & Cheryl Reicin

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- > Regulatory approval
 - Which bodies
 - Timing
 - The process
- > Device funding
 - Which bodies
 - Timing
 - The Process

- > Pricing
 - How does pricing work
 - Factors to consider
- > Setting up your business
 - What are the choices
 - Timing
 - Costs
 - Tax issues

- > Get a handle on all legal and operational requirements to launch
- > Determine the “rate limiting steps”
- > Typically, seeking regulatory approval is the first step

Legal Path to Launch – Regulatory Approval

- > Determine
 - Claims you wish to make for device (in marketing and advertising)
 - Classification for the device
- > Other helpful information:
 - Classification in other countries
 - Ease of approval in other countries
 - Claims for devices in other countries

> Canada

- Four risk classes for devices (see Medical Devices Regulations), Class I lowest perceived risk, Class IV highest perceived risk
- Oversight by Medical Devices Bureau
- Medical Device Active License Search (Classification of Competitors' Devices)
 - <http://webprod3.hc-sc.gc.ca/mdll-limh/prepareSearch-preparerRecherche.do?type=active&lang=eng>
- If uncertain about classification, it is possible to seek classification ruling

- > Medical Devices Bureau
 - Pre-submission meeting
 - Pre-submission call
 - Regulatory submission – common errors
 - Submission not based on Medical Device Regulations and guidance documents
 - Subjects not addressed
 - Copy (or excerpts) of submission made to another country
 - Thorny issues (if any) not dealt with in advance (before submission filed)

- > Medical Devices Bureau
 - Regulatory submission
 - Make is easy for Bureau to comment/approve
 - » Regulatory approvals in other countries
 - » History of safety and efficacy
 - » History of adverse events
 - » Layout of submission conforms to Canadian requirements

- > Timelines for review and approval
 - Class I: (none)
 - Class II: Target (15 days)
 - Class III: Target (75 days)
 - Class IV: Target (90 days)
- > Actual often differ from target (depends on backlog)

- > Quality systems certificate – ISO – 13485
- > Steps and timelines required to obtain that certificate
- > What to do if there are delays in regulatory approval (or if the regulatory review is not proceeding smoothly)?

Legal Path to Launch – Regulatory Approval

- > Other approvals to consider
 - electrical (CSA)
 - technical acceptance certificate (Industry Canada) for radiofrequency devices

- > Reimbursement for device
- > Reimbursement for time of healthcare professional using device

- > Reimbursement for device
 - Determine market
 - public
 - private
 - Where will device be used
 - hospitals
 - clinics
 - physicians offices

- > Reimbursement for device
 - If market is public hospitals, consider
 - group purchasing organizations (for hospitals)
 - purchasing department (of hospitals)
 - support for device (within hospitals) – key opinion leaders

> Reimbursement for device

- If market is private clinics or individual physicians, consider
 - marketing approach – why is it in the interest of the clinic or physician to pay for the device out of their budget

- > Reimbursement for time of healthcare professional using device
 - Each province determines which activities of professionals are reimbursable
 - Codes which apply to healthcare professionals' use of the device
 - Need to ensure that professionals' will be properly reimbursed for their time (otherwise, not incentivized to use device)

- > How does pricing work
 - Market driven (pricing of devices not regulated)
 - Pricing pressure
 - GPOs
 - purchasing departments
 - agreements in place with existing suppliers
 - » exclusive or non-exclusive
 - » value added products or services to include in agreement
 - » what distinguishes your device and your offering from competitors?

- > What are the choices
 - Go it alone
 - Appoint exclusive distributor
 - Appoint non-exclusive distributors
 - Combination of the foregoing (you distribute and they distribute)
 - Appoint co-marketer

Legal Path to Launch – Setting Up the Business

- > The choice drives the legal structure
 - Standalone Corporation v. Branch
 - Distribution Agreement
 - Joint Venture
 - License
- > Timing and costs
- > Tax issues

- > Compensation Issues for standalone entities
 - Salary
 - Stock Options
 - Other Benefits

- > Incentives to set-up in Canada
 - Next Generation of Jobs Fund
 - Grant up to 15% of company budget for approved companies investing at least \$25 M or creating at least 100 jobs
 - 45 day application process
- > SRED credits for R&D conducted in Canada up to 50%, up to 70% with OBRI

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