Health Canada / Santé Canada

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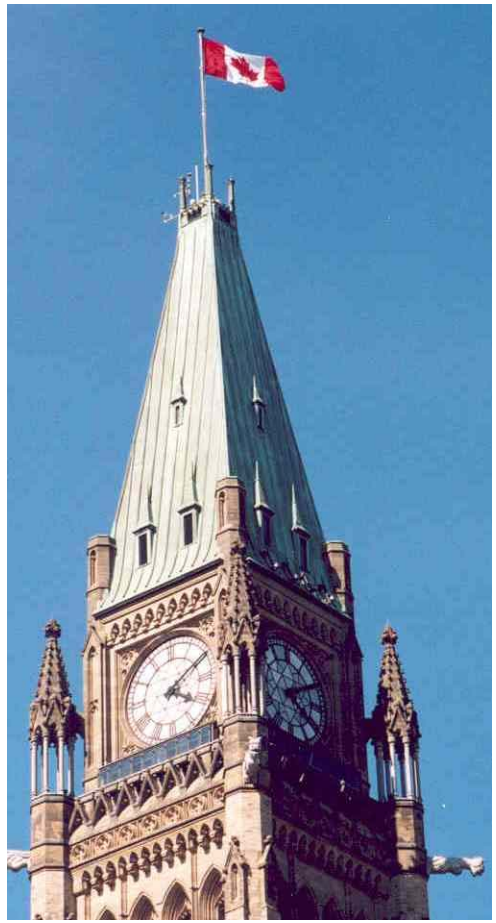
Medical Device Regulation

Authority is delegated by Canada's Parliament through the *Food and Drugs Act* and the *Medical Devices Regulations*



Key Features

- A risk-based approach to regulation
- Recognition of international consensus standards
- Quality management systems reviewed by independent, accredited auditors
- Post-market surveillance
- Global harmonization

Key Features

- Health Canada regulates the manufacture and sale, not the use of medical devices
- Manufacturers apply for a medical device licence authorizing the sale of the device in Canada
- Since 2000 Health Canada has received two applications for dental amalgam

Risk Class

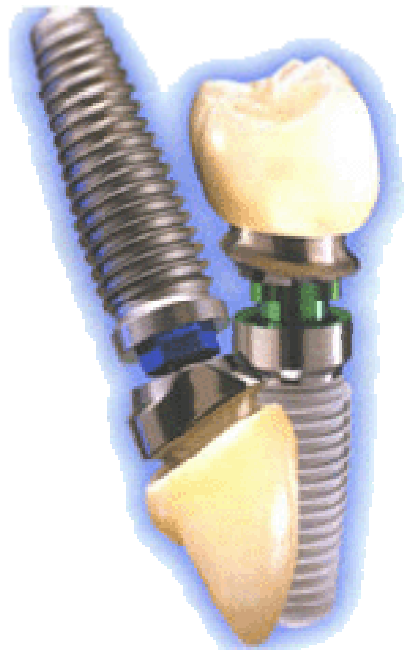
- Four risk classes
- Degree of pre-market scrutiny of the device depends on its risk class
- Class IV devices receive the highest level of scrutiny
- Dental Amalgam, Encapsulated Amalgam and Dental Mercury are Class III devices

Risk Class IV

- CNS and CVS devices
- Devices manufactured or derived from animal or human tissues
- Bone void fillers containing bovine collagen

Risk Class III

- Dental amalgam, dental mercury, encapsulated amalgam
- Endosseous dental implants
- Dental restorative materials
- Joint replacement devices
- Ceramic bone void fillers



Premarket Review Document

- Submitted by manufacturer in support of their medical device licence application
- Contains the objective evidence required to determine if the device licence application meets the safety and effectiveness requirements of the Medical Devices Regulations

Premarket Review Document

- Background Information
- Summary of Safety & Effectiveness Studies
- Labelling
- Quality Systems Requirements

Background Information

- Device description
  - Chemical composition
  - Physical/mechanical properties
- Design philosophy
- Marketing history
- Incident reports

Safety & Effectiveness Studies

- Each device licence application is reviewed on its own merits
- ≠ Substantial Equivalence of the 510(k) process

Safety & Effectiveness Studies

- Summary of all preclinical and clinical studies
- Conclusions drawn from studies
- Are conclusions reasonable, given the evidence?

Preclinical Studies

- List of standards
- Declaration of Conformity to internationally recognized consensus standards
- Preclinical bench testing
- Animal studies

Preclinical Studies

- Biocompatibility
- Sterilization validation
- Shelf-life, packaging validation

Clinical Evidence

- Controlled clinical trials
- Clinical case reports
- Bibliography of published reports
- Critical review of the literature
- Marketing history
- Experience with comparable devices

Clinical Evidence

- Are the manufacturer's conclusions reasonable?
- Consistent with the objective evidence?
- Are there internal discrepancies?
- Quality of data
- Trial protocol and design meet accepted practices?

Labelling

- Device identifier
- Device details
- Expiry date
- Medical conditions, purposes and uses for which the device is manufactured, unless self-evident to intended user
- Instructions for use

Quality Systems Requirements

- Valid ISO 13485:2003 Quality System Certificate
- Issued by a registrar accredited by the Standards Council of Canada and recognized by Health Canada
- Accreditation under the provisions of the Canadian Medical Devices Conformity Assessment System (CMDCAS)

S & E for Dental Amalgam

- Health Canada does not currently have a Guidance Document or Policy on dental restorative materials
- Conformity to international consensus standards
- Detailed chemical composition

S & E for Dental Amalgam

- Physical/mechanical properties and bench testing that demonstrate adequate strength
- Validation of mercury vapour escape during amalgamation
- Evidence of biocompatibility
  - Critical review of the literature

Regulatory Background

- 1996: Stakeholder Review Committee
- 1996: Health Canada Position Paper
- 1998: Amalgam subject to premarket review as a Class III medical device
- 2004: *Mercury: Your Health & the Environment: A Resource Tool* published

Stakeholder Review Committee

- Convened in 1996 to provide Health Canada with advice in developing a position statement on the safety of amalgam
- Access to both published and unpublished material

Stakeholder Review Committee

Membership:

- Consumer health advocates
- Provincial public health officials
- Dentists
- Dental scientists
- Dental industry
- Dental public health
- Amalgam-free dentists
- Environmental advocates

Stakeholder Review Committee

- Committee made eight policy recommendations to Health Canada
- Resulted in the publication of the *1996 Position Paper on the Safety of Dental Amalgam*

1996 Position Paper

- Six conclusions based on:
  - The Government of Canada's overall strategy for the reduction of human exposure to mercury
  - Canadian environmental policies
  - The Stakeholder Committee Report
  - Precautionary Principle
  - Published and unpublished materials

Position Paper Conclusions

1) While dental amalgam contributes detectable amounts of mercury to the body, this exposure is not causing illness in the general population
2) Current evidence does not indicate mercury contributes to Alzheimer's disease, amyotrophic lateral sclerosis, multiple sclerosis or Parkinson's disease

Position Paper Conclusions

3) Mercury can cross the placental barrier, and can impair kidney function at sub-clinical levels of exposure. Therefore it is advisable to avoid procedures involving amalgam in pregnant women or individuals with kidney disease
4) The environmental policies of Canada favour a reduction in the use of mercury in all products. It is prudent to reduce human exposure to mercury where safe and practical alternatives exist

Position Paper Conclusions

5) … currently available clinical data are not reliable enough to permit making a confident estimate of Tolerable Daily Intake for mercury from amalgam
6) Evidence does not warrant the removal of existing amalgam fillings from individuals who have no indications of adverse events

Mercury Issues Task Group

- *Mercury, Your Health and the Environment: A Resource Tool*
- Published 2004
- Membership includes experts in biology, toxicology, epidemiology, dentistry, medical devices
- Retains recommendations from 1996 Position Paper