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Health Products and Food Branch Inspectorate

L'Inspectorat de la Direction générale des produits de santé et des aliments



MEDICAL DEVICE REGULATORY INSPECTION RESULTS / EXAMPLES

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Inspections Performed

- 2004/05 - 70 inspections performed
- 2005/06 - 89 inspections performed
- 2006/07 - 144 inspections performed

- currently about 1500 establishment licence holders

Noncompliances

April 1, 2005 to March 31, 2006



Labelling	57	10.2%
Device Licensing	75	13.4%
Establishment Licensing	267	47.8%
Complaint Handling	123	22.0%
Distribution Records	5	0.9%
Mandatory Problem Reports	2	0.4%
Recall	14	2.5%
Other	15	2.7%
Total	558	100.0%



Observations

April 1, 2005 to March 31, 2006

Labelling	71	23.8%
Device Licensing	105	35.2%
Establishment Licensing	49	16.4%
Complaint Handling	29	9.7%
Distribution Records	21	7.0%
Mandatory Problem Reports	8	2.7%
Recall	6	2.0%
Other	9	3.0%
Total	298	100.0%



Examples of Noncompliances Device Licensing

- manufacturer did not hold a valid device licence
- name/address of manufacturer on label did not match name/address on the device licence
- there was no manufacturer's name/address on the label
- device identifier on the label did not match the identifier on the device licence
- there was no device identifier on the label
- the device was labelled “not for sale in Canada or USA”
- establishment imported unlicensed devices for export



Examples of Noncompliances Advertising

- catalogues distributed/used by the company did not contain a statement that some devices may not be licensed for sale in Canada
- unlicensed devices were being advertised for sale in Canada on the company's website



Examples of Noncompliances Labelling

- manufacturer's name was not on the label (unlicensed)
- manufacturer's address was not on the label
- name of the device was not on the label (unlicensed)
- device identifier was not on the label (unlicensed)
- all of the above (unlicensed)

- the device identifier was not unique
- directions for use were not available in French



Examples of Noncompliances Establishment Licence (MDEL)

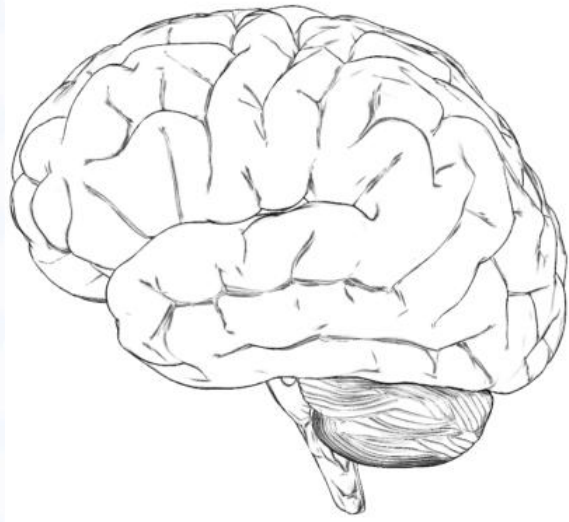
- establishment address was incorrect
- activities listed on MDEL application were incorrect
 - e.g., if you purchase from a Canadian source, even if manufacturer is outside Canada; you are a distributor
- manufacturers listed on MDEL application were incorrect or incomplete
 - list the manufacturers (as they appear on the label) of all devices sold
 - do not list your suppliers, unless they are also the manufacturer



Examples of Noncompliances Establishment Licence (MDEL)

- classes of devices listed on the MDEL application were incorrect
 - do not guess
 - do not select all classes just to be sure
- procedures attested to by the company were either not document, were inadequate, or were not “in place”
- **Important – Please retain copies of your past MDEL applications and renewals, including instructions provided.**

Examples of Noncompliances No Documented Procedure



If it is still in
here, the
procedure is not
documented





Examples of Noncompliances Inadequate Procedure

EXAMPLE

Maintenance of Distribution Record

Invoices are maintained for a period of 7 years. Our current year is kept on site and the remaining 6 years are stored off-site.

Note: An adequate procedure should address all elements required by the Act or Regulations



Examples of Noncompliances Procedures – Not In Place

- initial procedure was prepared after the attestation on the MDEL application (identified by dates)
- personnel were not aware of the procedure related to the activity they were performing



Examples of Noncompliances Distribution Records

- the procedure did not specify how long distribution records were retained, as required by section 55 of the Medical Devices Regulations
- the distribution records could not be retrieved in a timely manner (section 56)



Examples of Noncompliances Complaint Handling

- the company did not maintain records of reported problems
- the company did not retain records of actions taken in response to problems reported




Examples of Noncompliances Mandatory Problem Reporting

- the procedure did not adequately address mandatory reporting in Canada:
 - it did not identify the criteria in Canada for submitting a mandatory problem report (section 59)
 - there is no such thing as a voluntary MDR
- the importer did not submit the mandatory problem report (report by the manufacturer does not absolve the importer)



Examples of Noncompliances Recall

- the procedure did not adequately address recalls in Canada:
 - different definition of recall versus US or Europe
 - timeline for reporting recalls in Canada (on or before)
- the procedure did not address recall effectiveness (section 58 of the Medical Devices Regulations)
- the importer did not report the recall (report by the manufacturer does not absolve the importer)



Examples of Noncompliances Devices for Special Access

- label of the device did not state that it was imported or sold for special access
- the establishment imported devices prior to obtaining a special access authorization
- the establishment sold devices prior to obtaining a special access authorization
- importer did not return unused special-access devices to the manufacturer, as requested in the letter of authorization



Examples of Noncompliances Investigational Testing

- label of the device did not state that it was imported or sold for investigational testing (specific wording in section 86 of the Medical Devices Regulations)
- the establishment imported devices prior to obtaining an authorization for investigational testing

Other Examples of Noncompliances

- the company was selling expired medical devices
- the importer was modifying and repackaging a medical device, but reusing the original manufacturer's label