Operationalizing Post Market Surveillance

CASE STUDY TWO

MedCon 2014
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Case Study 2 – "Pain Free Implantable Neurostimulation Device"

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The firm received reports that its "Pain Free" implantable neurostimulation device was showing premature battery life depletion resulting in ineffective pain therapy and explantation to replace the device.

Labeling for the "Pain Free" device states the minimum expected life of the device is 5 years and patients and their physicians are advised explanation is required for replacement of the device.

Patients selected for implantation of this device receive training on the maintenance of the device, specifically a requirement to wear an external generator for 1 hour every week to recharge the implanted device.

Labeling for the "Pain free" device also clearly states premature battery failure could occur if the implanted device is not recharged per instructions.

Case Study 2 – "Pain Free Implantable Neurostimulation Device" Cont'd

The firm's investigation of these battery life complaints showed that some patients were not following the instructions for recharging the device and this was the primary reason for early life failure of the device.

However, the firm's testing of explanted devices showed some of the devices were beyond the expected 5-year device life and the battery had electrolyte leakage near the terminals and that this could also be a factor in some of these ineffective pain therapy complaints.

Questions:

1. *What actions should the firm take?*

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- *Complaints on device with premature battery life depletion resulting in ineffective pain therapy.*
- *User requirement to wear an external generator for 1 hour every week to recharge the implanted device and maintain expected battery life.*
- *Labeling for the "Pain Free" device states the minimum expected life of the device is 5 years.*
- *Primary cause: Users not following recharging instructions.*
- *Secondary cause identified: Some of the devices were beyond the expected 5-year device life.*

Questions:

What actions should the firm take?

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What actions should the firm take?

1. Evaluate for MDR reportability. Device fails to deliver therapy; although investigation shows user compliance as a factor, premature explantation is considered a serious injury. Event is reportable as a MDR.

2. Did the device malfunction?
   - Does the firm have data e.g. charge session logs to show users were not compliant?

3. Utilize risk assessments for determination of whether the hazardous situation has been reduced to As Low as Reasonably Practicable.
   - Investigate adequacy of the design to prevent User non-compliance.
   - Labeling alone or relying on training may be inadequate for this device and intended use.

4. Evaluate claims around end of life – how does the device signal end of life? Design issue?

5. Does the firm have a potential recall?