MHRA
Regulating Medicines and Medical Devices

Focus on : Notified Bodies
PMS
PMCF

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This session

Focus on

- Notified Bodies
- Post Market Surveillance
- Post Market Clinical Follow Up

Notified Bodies

- Included in Commissioner Dalli's recommendations following the PIP implant scandal was a requirement for Joint Inspections of Notified Bodies

- In addition Notified Bodies were also required to perform unannounced Audits

Joint Assessments

- Voluntary Phase – 2013
- Implementing Regulation 920/2013 brought in Mandatory Requirements
- Re-designation assessments of all Notified Bodies by October 2016
- Joint team consists of Commission (FVO), 2 other MS representatives and designating authority

Requirements

- independence and impartiality
- confidentiality
- limits on subcontracting
- competence
- quality system
- liability insurance

Activity to Date

- 24 Voluntary Assessments performed
- 20 Mandatory Assessments performed
- Number of Notified Bodies is dwindling fast (down to about 60 from 85). Numbers are expected to continue falling.

Actions Taken

- temporary suspension
- limitation in the scope of activities
- re-assessments of all certificates
- In one case a complete de-designation of the notified body followed
- Several other notified bodies stopped their activities without, or prior to, any joint assessment being announced.

Common Problems

The most common problems identified with regard to notified bodies relate to the:

– evidence of staff qualifications;

– thoroughness of the review of manufacturers clinical evaluations and

– sampling of technical files for class IIa and IIb devices.

Summary

- Number of Notified Bodies is dwindling fast (down to about 60 from 85). Numbers are expected to continue falling.

- FVO are doing an excellent job.

- MHRA have contributed to 7 joint audits to date with mixed experiences. Excellent feedback from FVO but stretching our resources.

- Bottleneck expected in 2016.

Unannounced Audits

Commission Recommendation 2013/473/EU

- At least every 3rd year
- Should be no less than 1 day and by 2 auditors
- Product focussed

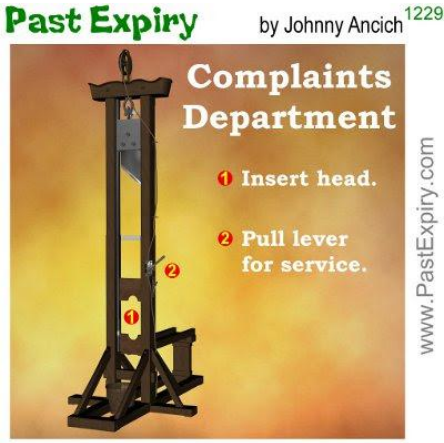
Post Market Surveillance

One of the key activity to come out of PIP implant scandal is the setting up of a monthly Vigilance telecon between all MSs.

This has proved to be extremely useful in co-ordinating vigilance activity amongst MSs and their communication with manufacturers.

PMS (cont)

- Complaints
- Customer Feedback
- Customer and user surveys
- Regulatory authority compliance related communications
- Peer reviewed journals
- Post market clinical follow up



Post Market Clinical Follow Up

While clinical evidence is an essential element of the premarket conformity assessment process to demonstrate conformity to Essential Requirements, it is important to recognise that there may be limitations to the clinical data available in the pre-market phase.

As part of the manufacturer's quality system, an appropriate post-market surveillance plan is key to identifying and investigating residual risks associated with the use of medical devices placed on the market. These residual risks can be investigated and assessed in the post-market phase through systematic Post-Market Clinical Follow-up (PMCF) study(ies).

PMCF (cont)

Clinical data obtained from post-market surveillance and during PMCF studies by the manufacturer are not intended to replace the pre-market data necessary to demonstrate conformity with the provisions of the legislation. However, they are critical to update the clinical evaluation throughout the life-cycle of the medical device and to ensure the long term safety and performance of devices after their placing on the market.

Indications for PMCF

- innovation, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are novel;

- significant changes to the products or to its intended use for which pre market clinical evaluation and re-certification has been completed;

- high product related risk e.g. based on design, materials, components, invasiveness, clinical procedures;

Indications for PMCF (cont)

- high risk anatomical locations;
- high risk target populations e.g. paediatrics, elderly;
- severity of disease/treatment challenges;
- questions of ability to generalise clinical investigation results;
- unanswered questions of long-term safety and performance;

Indications for PMCF (cont)

- results from any previous clinical investigation, including adverse events or from post-market surveillance activities;
- identification of previously unstudied sub populations which may show different benefit/risk-ratio e.g. hip implants in different ethnic populations;
- continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product;

Indications for PMCF (cont)

- risks identified from the literature or other data sources for similar marketed devices;
- interaction with other medical products or treatments;
- verification of safety and performance of device when exposed to a larger and more varied population of clinical users;
- emergence of new information on safety or performance;
- where CE marking was based on equivalence.

Methodologies

- the extended follow-up of patients enrolled in premarket investigations;
- a new clinical investigation;
- a review of data derived from a device registry; or
- a review of relevant retrospective data from patients previously exposed to the device.

Thank you

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