

Not just left to your own devices !

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Medicines and Healthcare products Regulatory Agency

- Executive Agency of the Department of Health.
- Ensures that medicines and medical devices work and are acceptably safe.



What Is a Medical Device?

Any product, other than medicines, which is used for the diagnosis, prevention, monitoring, treatment and alleviation of illness or injury or the prevention of conception.

MHRA's Roles



- Regulator
- Incident investigation
- Source of information

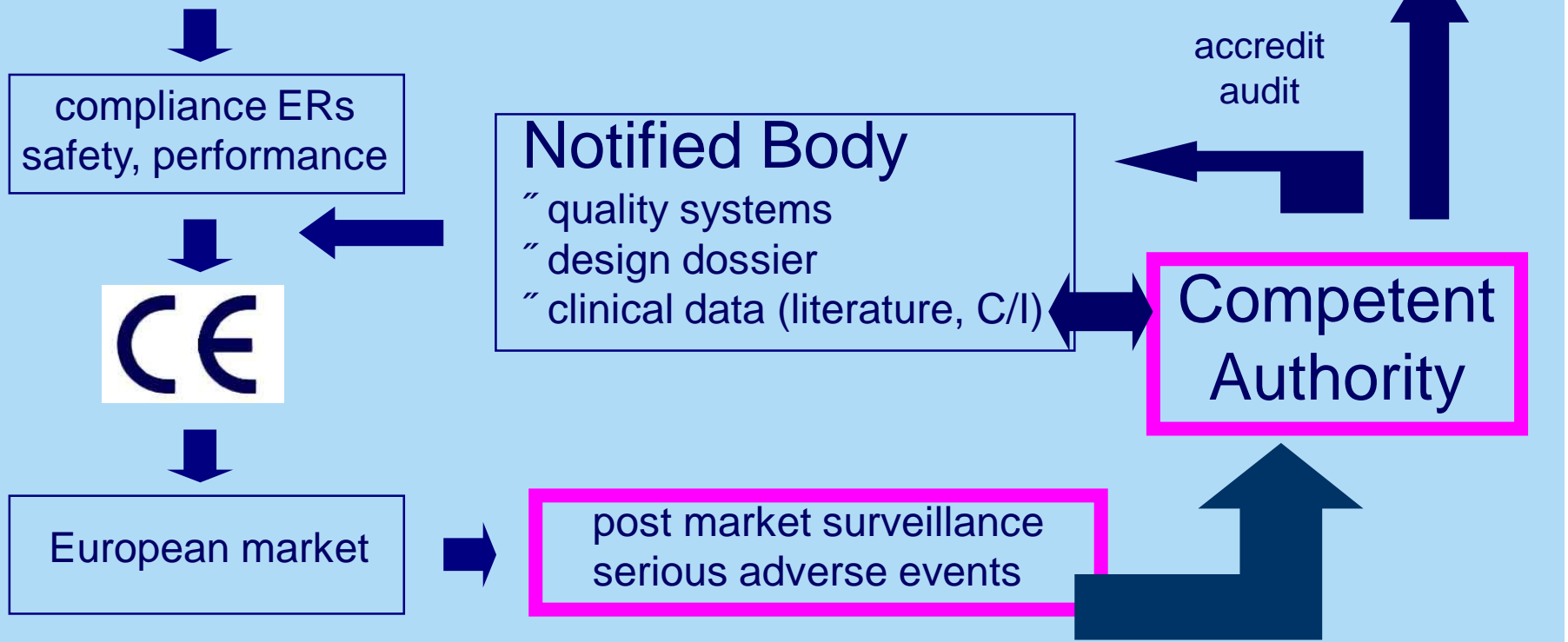
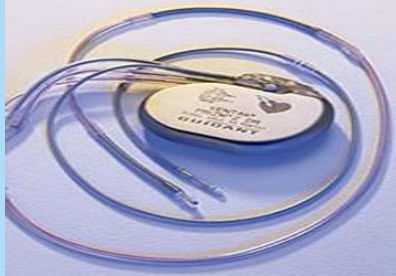
Regulations

MHRA

- patient health and safety
- user safety
- manufacturer protection
- commercial level playing field



EU Regulatory System



Essential Requirements

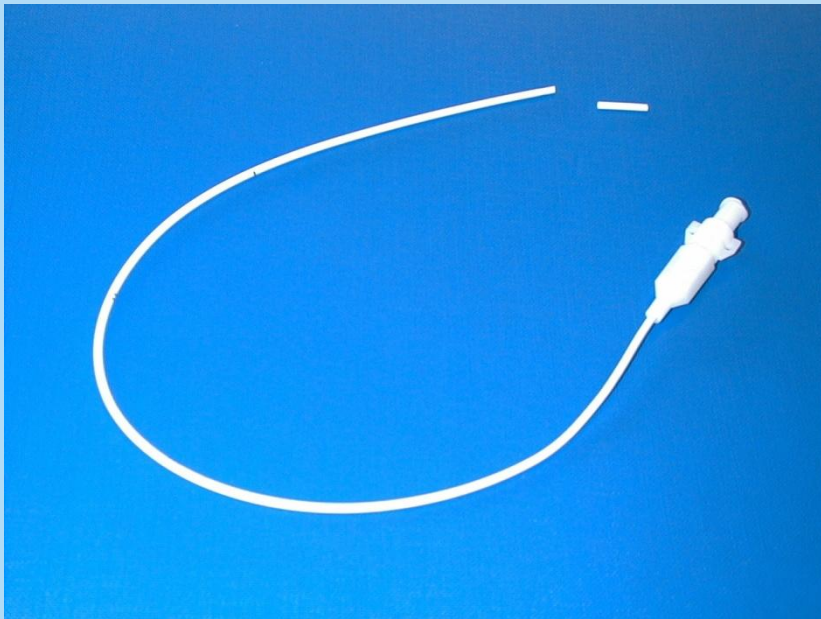
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“the devices must be designed in such a way that....they will not compromise the clinical condition or SAFETY of patients.....provided that any RISKS which may be associated with their use constitute acceptable RISKS when weighed against the benefits....”

.....devices must achieve the performances intended by the manufacturer.....

...Once on the market

- post market surveillance
- vigilance
- safeguard action





MHRA as a source of information

- Provides information to device users
- Device alerts
- Device bulletins
- Posters
- Leaflets



What Is an Adverse Incident?

An event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons.



Investigating Adverse Incidents

Can result in:

- Change in design/instructions
- Removal from the market
- Education to reduce “user-errors”



Causes of Adverse Incidents - Manufacturer Problems

Problem with the device itself:

- Design
- Production

Information accompanying device

- Not complete
- Confusing
- Not attached to the device

Recent manufacturer problems



- Leaking IV burette.
- Infusion pump software problems.
- Suction catheter detachments.
- Paediatric tracheostomy tube problems.
- Breaches in packaging of sterile devices.



Causes of Adverse Incidents - User Error

- Incorrect device
- Incorrect use
- Inadequate training
- Local modification
- Too complex
- Inappropriate accessories
- Not monitored

Identified problems



- Inadequate decontamination
- Material alteration
- Mechanical failure
- Potential for cross-infection
- Reaction to bacterial residue (endotoxins)
- Residues from chemicals

Reported incidents

- Urodynamic pressure monitoring device - single-use component reused on several patients resulting in cross contamination and serious infection.
- Spinal needle - single-use needle bent at first attempt, straightened and inserted again resulted in needle breaking and tip left in epidural space between patients vertabrae.



How to Report

- As soon as possible
- Serious cases by fastest means
- As much detail as possible-but don't delay
- Forms available on website (www.mhra.gov.uk)
- Report to adverse incident centre
- Quarantine device and keep

Overview Of Outcomes: 2008

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- Investigation of **8,902** reports received in 2008 resulted in the following actions:-
 - É **88** medical device alerts issued
 - É **96** notifications to authorities in EU member states
 - É **568** manufacturer field safety corrective actions
 - É **250** other manufacturer field actions
 - É **363** cases requiring the provision of advice on safer device use or improved staff training
 - É **822** manufacturer undertakings to improve designs, manufacturing processes and quality systems



How Best Should Devices Be Managed?

- Safe systems approach requires the integration of
 - Organisational responsibility
 - Develop and implement safe systems of work
 - Individual responsibility
 - Adhere to these procedures
 - Perform to adequate professional standard
 - Be aware of own/device limitations

How Best Should Devices be Managed?

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- Safe system includes:
 - Procurement
 - Safe use
 - Record keeping
 - Maintenance and repair
 - Training professionals and patients/carers when appropriate
 - Adverse event reporting

Conclusions



- Buy it right!
- Use it right!
- Keep it right!



If all else fails...

.....Read the instructions!

Telephone and Web-site Details



- Telephone 020 7084 2000
- <http://www.mhra.gov.uk>