MHRA
Regulating Medicines and Medical Devices

Medical Devices
- Reporting to MHRA

Emma Rooke, December 2015

Medicines and Healthcare Products Regulatory Agency

Topics to be covered today:

- The MHRA and what we do
- What is a Medical Device?
- Adverse Incidents
- Reporting adverse incidents to the MHRA

Medicines and Healthcare Products Regulatory Agency

IRA

MHRA

The Medicines and Healthcare Products Regulatory Agency

CPRD

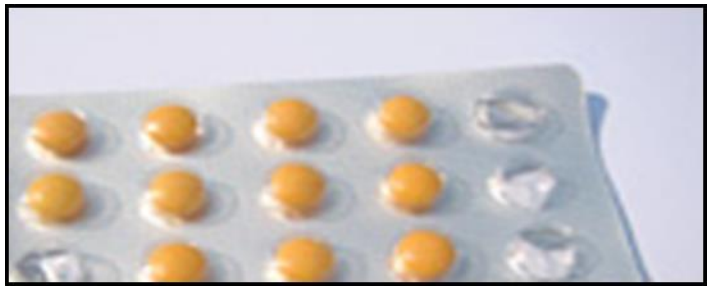
Clinical Practice Research Datalink

NIBSC

National Institute for Biological Standards and Control

What we do…(not exhaustive!)

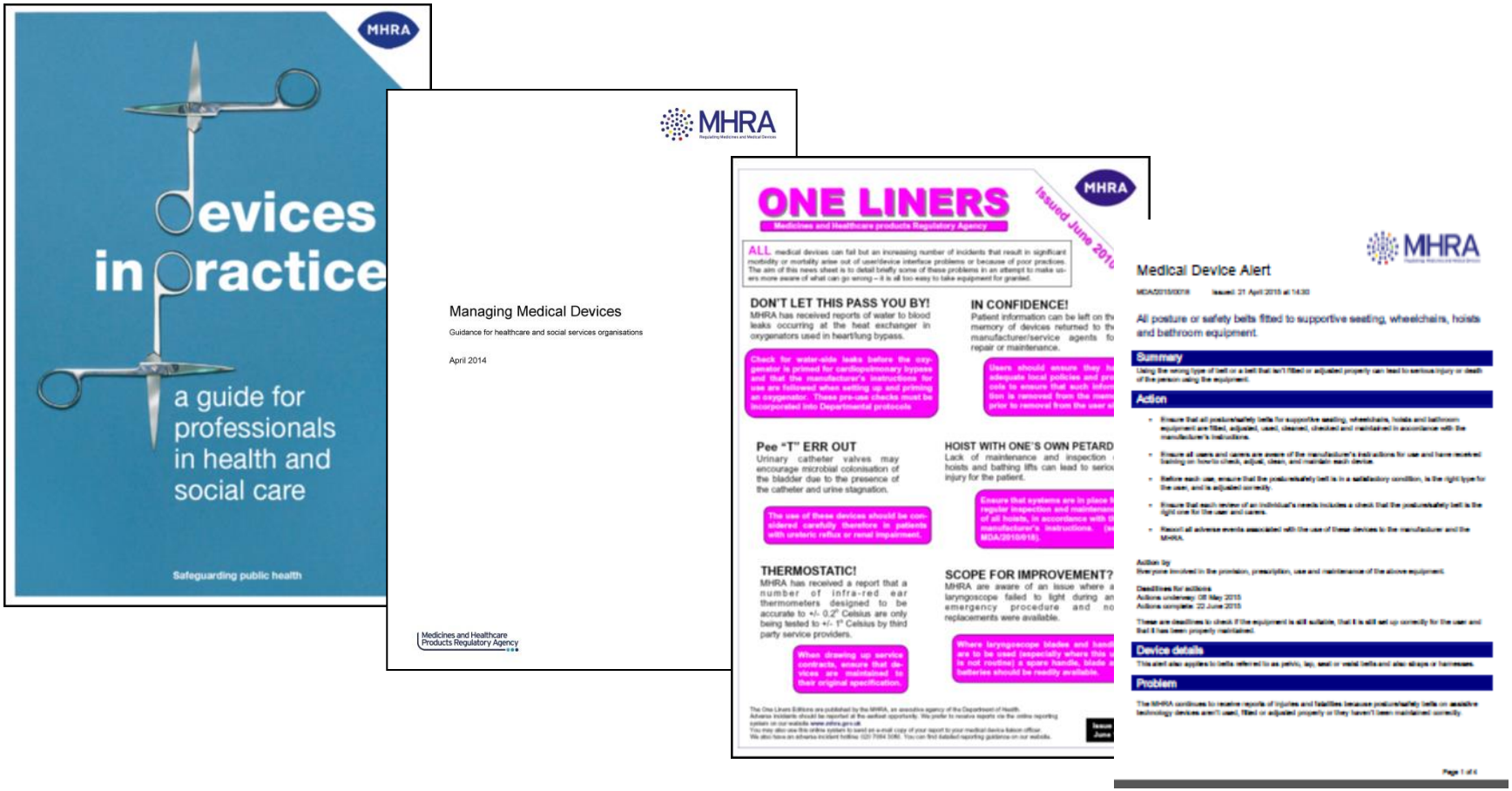
- Medicines (inc herbal and homeopathic)
  - Licence
  - Monitor adverse incidents
  - Enforce regulations



- Medical Devices
  - Monitor Notified Bodies
  - Monitor adverse incidents
  - Enforce regulations

- Blood Establishments & Blood Banks
  - Authorise
  - Monitor adverse incidents
  - Enforce regulations

MHRA Publications



What is a Medical Device?

Any instrument, apparatus, appliance, material or other article…to be used for human beings for the purpose of:

- - diagnosis, prevention, monitoring, treatment or alleviation of disease,
- - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- - investigation, replacement or modification of the anatomy or of a physiological process,
- - control of conception,
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

Adverse Incidents

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.*

What to report

Report to MHRA when

a) the problem involves a medical device

and

b) the problem with/failure of the product has caused or could have caused injury

If in doubt, please report it!

Medical devices you may come across can include:

- Powered wheelchairs
- Mobility Scooters
- Oxygen Concentrators
- Electrically powered medical devices

Who should report and when?

Anyone! Clinicians, Suppliers, Patients, Medical Device Liaison Officers, Manufacturers…

If you would like to discuss it first, get in touch:

MHRA Adverse Incident Centre

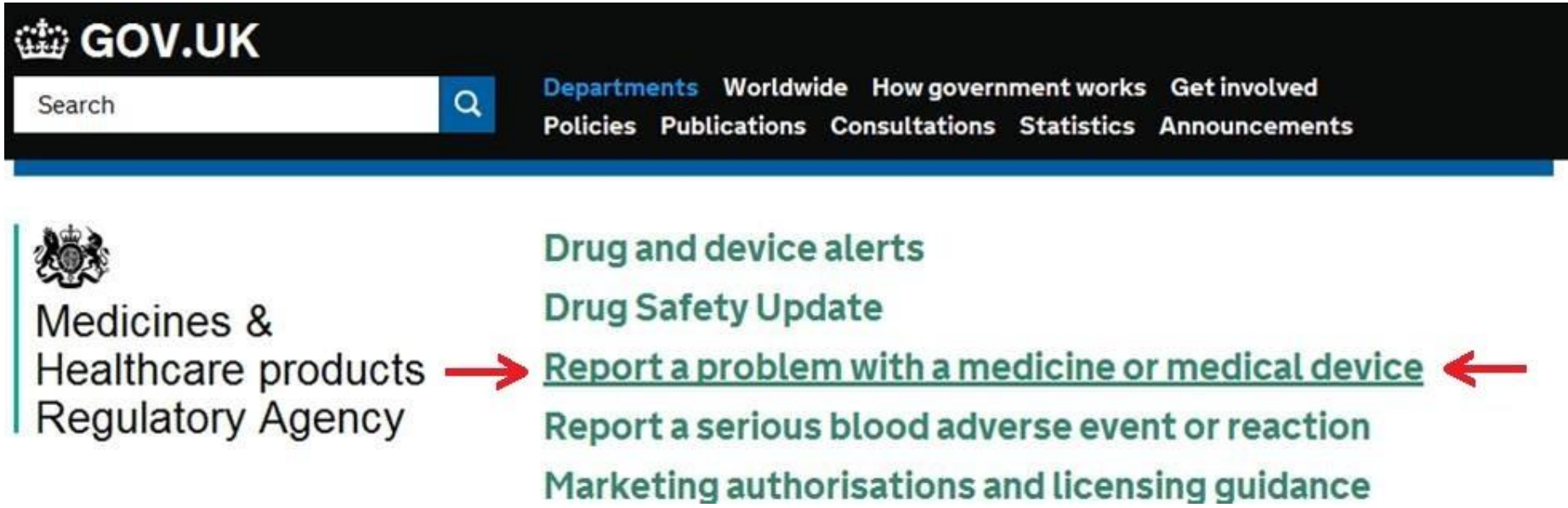
Tel: 020 3080 7080, aic@mhra.gsi.gov.uk

Please report any issues as soon as possible, providing as much detail as you can

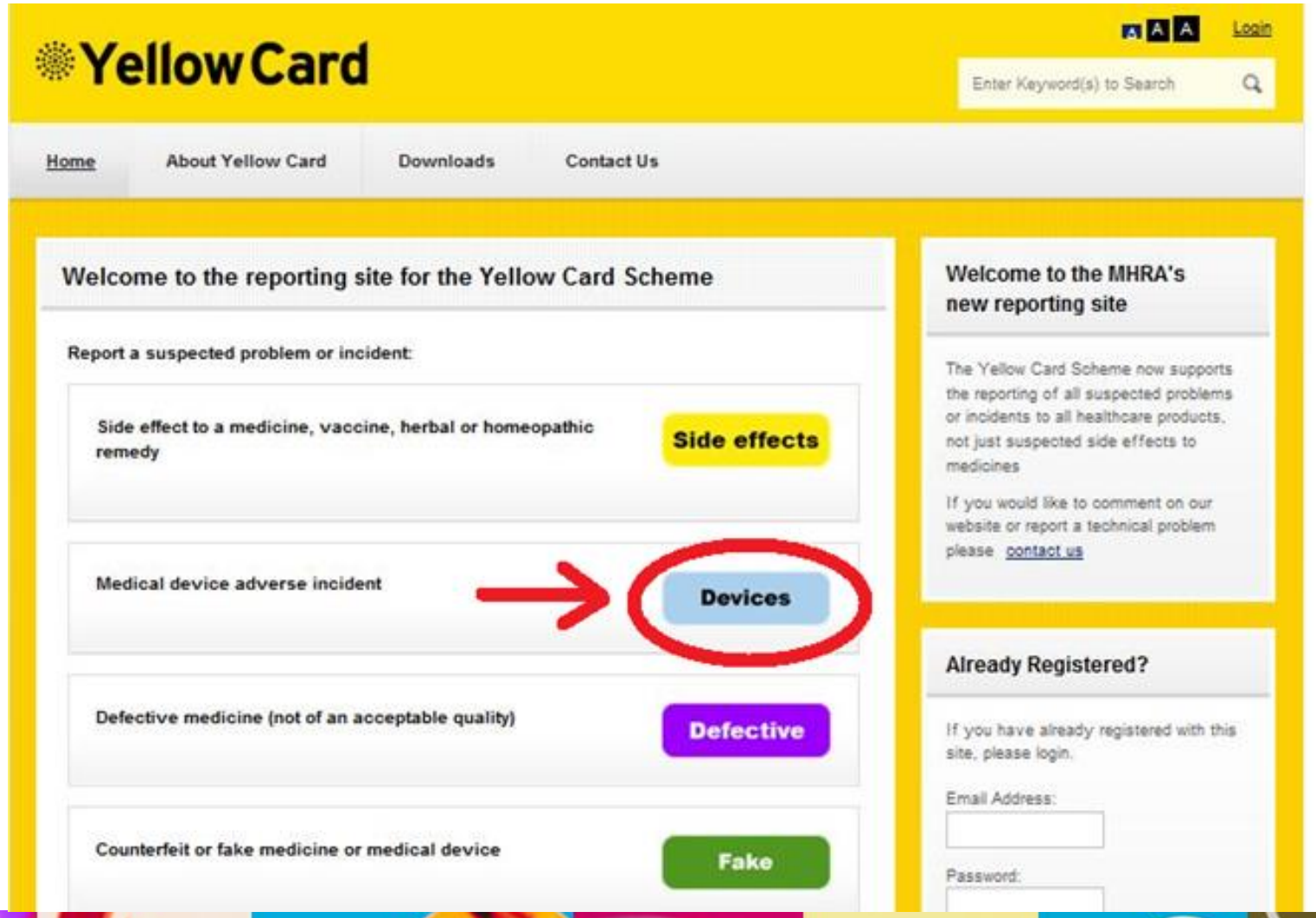
How to report

Visit our website

www.mhra.gsi.gov.uk



Yellow card scheme
- now covers Medical Devices too



Please include:

- Manufacturer, device type and model name
  - Without these
    - the manufacturer cannot investigate
    - MHRA will not be able to determine whether your report is part of a wider problem
- Details of what happened
- Who MHRA and the manufacturer can contact for further information about the incident report

What happens next?

We will tell you within 10 working days of receipt of your report what we plan to do

We will always:

- send your report to the manufacturer for their internal investigation

- add your report to our database

Our database is reviewed regularly to identify patterns where further action is needed

We do not investigate every report

Therefore, please do not automatically expect updates from us

The manufacturer will carry out an internal investigation

Please provide them with any details they request, and contact them for their findings

When do MHRA investigate?

- When we receive a report of death or serious injury

or

- When the manufacturer's investigation indicates a wider problem

or

- When we detect a pattern in reported problems

If we decide to do this, we will let you know and keep you informed of our progress

What does an MHRA investigation involve?

We may

- ask the manufacturer for details of their findings
- ask them to investigate further
- ask them to consider corrective action

Why should I report?

If problems are not reported, they won't be resolved

MHRA investigations can result in:

- Changes to design/instructions
- Safety related warnings/advice being issued
- Education to reduce "use-errors"
- Field Safety Corrective Actions
- Removal from the market

Why your report counts

Receipt of **13,282*** reports in 2014 resulted in the following actions:-

- **104** design modifications
- **130** labelling/instructions-for-use changes
- **26** cases of production being ceased
- **341** manufacturer undertakings to manufacturing process and quality assurance
- **42** medical device alerts issued

*Total incidents reported – includes periodic summary reports

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If you have any questions, please get in touch

MHRA Adverse Incident Centre

aic@mhra.gsi.gov.uk

Tel: 020 3080 7080

Thank you