Safeguarding public health

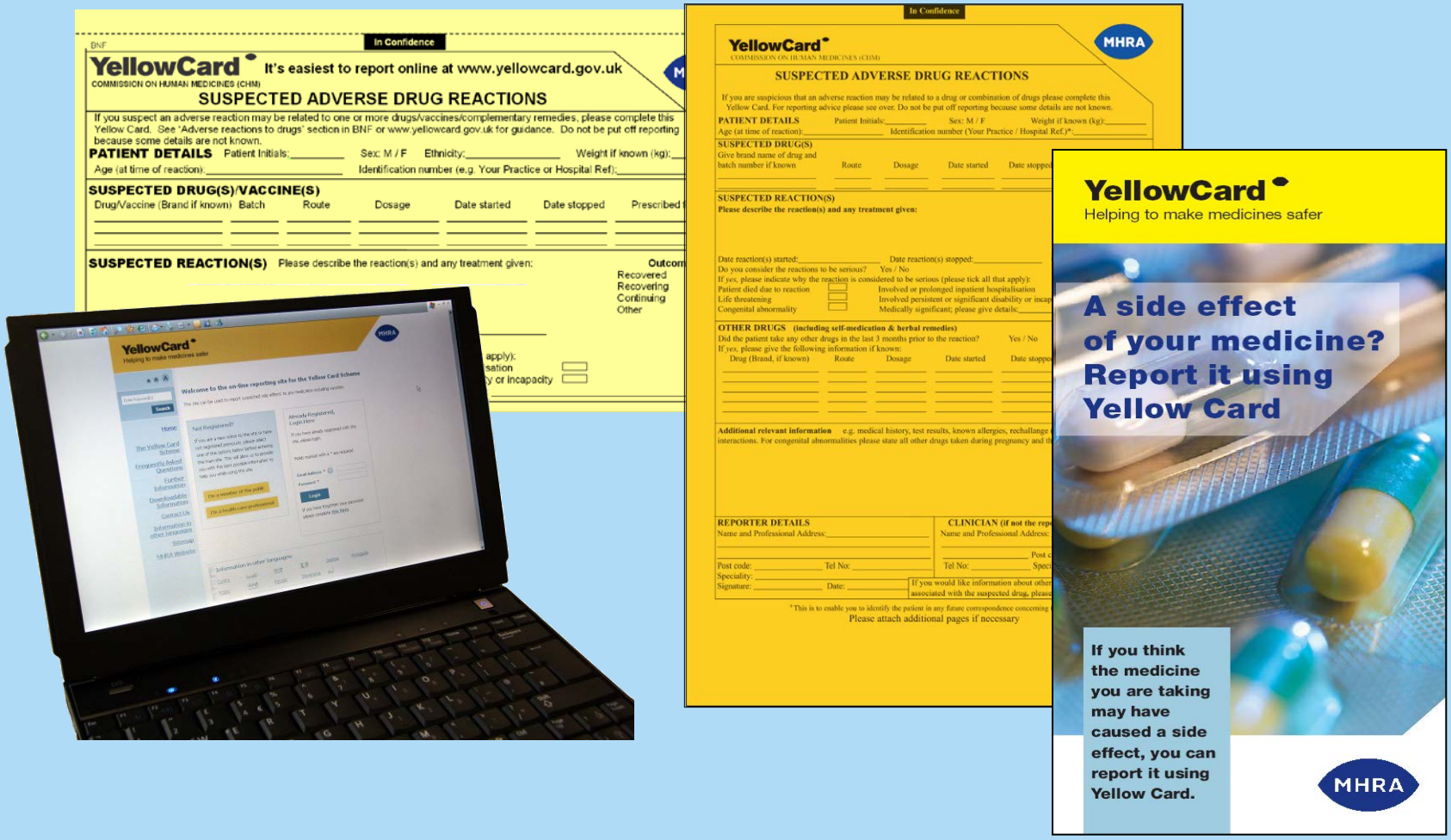
Reporting Medication Errors at National Level –
What should be reported and to whom

Mick Foy - MHRA
EMA Medication Error Workshop – 28th February 2013

Content

- New PV Legislation
- Scope of Change
- Incident Reporting in the UK
  - ADR reporting – Industry and HCPs/Patients
  - Medication error reporting
  - Other cases
- What happens in the rest of Europe?
- Raising awareness
- Summary

Legislation Changes – ADR Reporting



ADR reporting

Directive 2010/84/EU – old definition

Article 1

Adverse reaction: A response to a medicinal product which is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function

ADR reporting

Directive 2010/84/EU – New definition

Article 1

Article 1 is amended as follows:

(a)Point 11 is replaced by the following

11. Adverse reaction: A response to a medicinal product which is noxious and unintended

Note: includes non serious, error, off-label, expected, patient, study reports

Member State Responsibilities

Member States should operate a pharmacovigilance system to collect information …. including information on suspected adverse reactions arising …within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, including overdose, misuse, abuse and medication errors, …. Member States should ensure the quality of the pharmacovigilance system through the follow-up of cases of suspected adverse reactions….. Member States should establish a permanent pharmacovigilance system, supported by the appropriate expertise, so that the obligations under this Directive can be fully met.

Incident Reporting in the UK

MHRA

VETERINARY MEDICINES DIRECTORATE VMD

NHS
National Patient Safety Agency
National Reporting and Learning Service

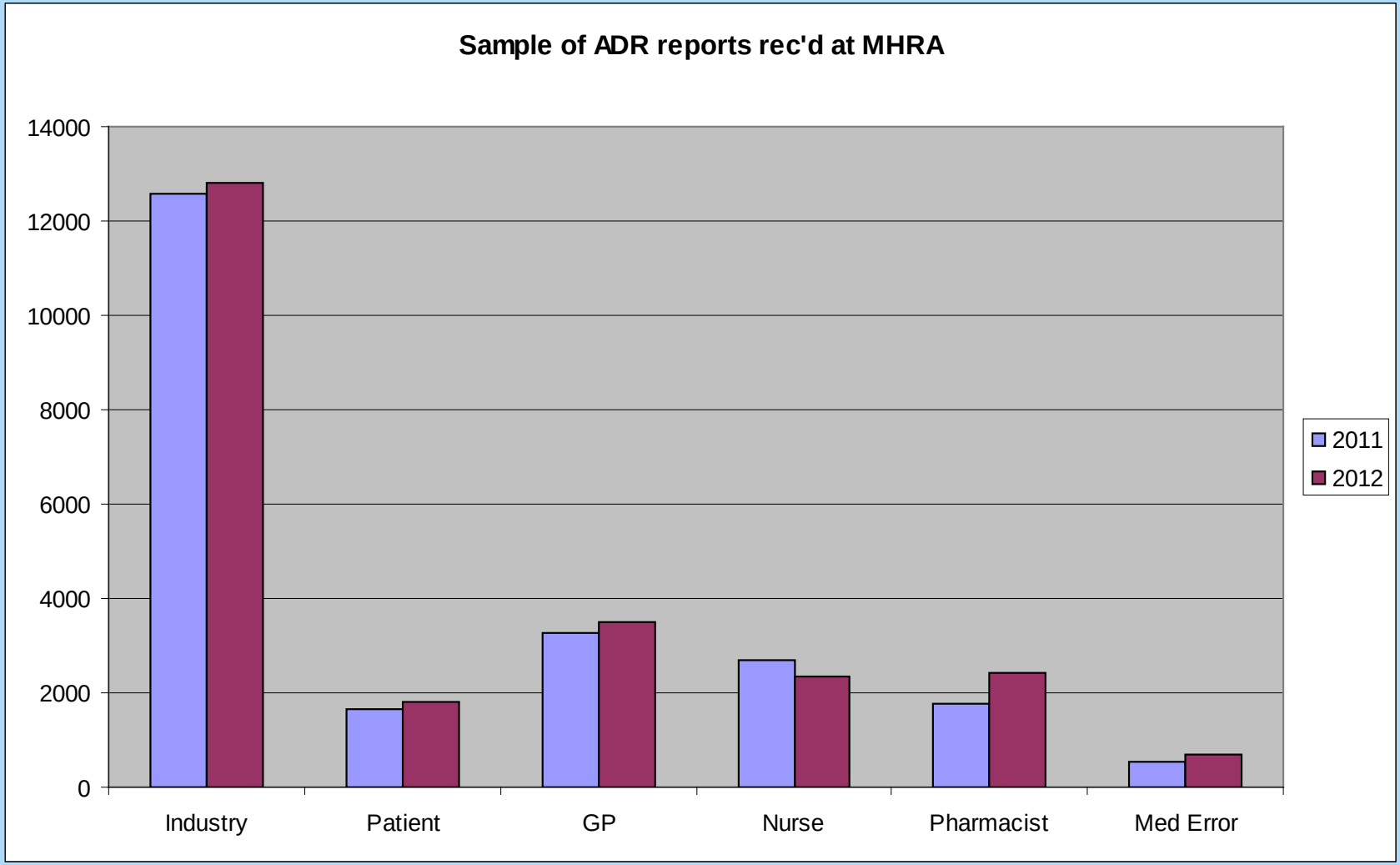
ts trading standards institute

MHRA

FOOD STANDARDS AGENCY

NHS
Commissioning Board

Understanding Reporting



Reports Received at MHRA

- Consultant wrote to GP asking to prescribe 6-mercaptopurine 50 mg once daily. GP misunderstood and prescribed mercaptopurine 50mg tablets 6 tablets daily.

- Is this an ADR?

- No, there is no evidence of harm

NHS
National Patient Safety Agency
National Reporting and Learning Service

Reports Received at MHRA

- On 16 Oct 2012, the patient on the ward had been given Klaricid IV as bolus in 10ml of saline and they didn't add the diluent.

- Is this an ADR?

- No, there is no evidence of harm

NHS
National Patient Safety Agency
National Reporting and Learning Service

Reports Received at MHRA

- Severe asthma attack that lasted over 4 hours, flying at high altitude, responded partially to Salbutamol and Seritide 250, most help when oxygen was administered. Patient felt chest discomfort ("like kicked in the chest") afterwards. Symptoms wheeze gradually receded over the next 48 hours, but problematic productive cough (sometimes severe) had persisted for now 12 days and still monitored.

- Is this an ADR?

- No, it was an insect repellent

Reports Received at MHRA

• On 22 Jan 2009, the patient received isoflurane for maintenance of anesthesia via inhalation while undergoing ovariohysterectomy. She initially induced with triple combination injection of Ketamine, Medetomidine and Butorphanol. During the procedure, the feline was place on gaseous anesthesia with isoflurane. Shortly thereafter, she experienced respiratory arrest with significant airway resistance noted when manually ventilated. Cardiac arrest followed was unable to be resuscitated. The patient expired.

• Is this an ADR?

• Yes, of course

• However the patient was described as
  - Female Domestic Shorthair Feline

Reports Received at NRLS

- Patient was admitted to EAU on 2.2.11 by on - call SHO . Noted to have high potassium (K 6.1) with tall T waves on ECG . SHO prescribed Insulin / dextrose which was given to the patient. Shortly after being given this infusion , the patient suffered a seizure - where she fractured her humerus . During the seizure, her BM was found to be 0.8 . It was terminated by giving IV dextrose .

- Is this an ADR?

- Yes,

Reports Received at NRLS

- True ADRs sent to NRLS are often difficult to detect
- Important, validating information not always present
  - Patient details
  - Reporter details
  - Drug information
  - Reaction information
  - Follow up is problematic

ADRs should be reported on Yellow Cards

Report what to whom

- If there is harm on a human medicinal product – MHRA regardless

- If there is no harm but a medication error – NRLS

- If it is not a human, or a cosmetic, or a food – Another body i.e. FSA, Trading Standards

Report what to whom

- Patient safety bodies need to have data sharing arrangements in place to ensure the cases reported get to the right agency. Confidentiality issues need to be addressed.

- MHRA – NRLS data sharing has been in place since 2009

- MHRA screen weekly the data we receive for medication errors and supply each month

- We look for the signals of a drug safety issues whereas the NHS look for incidents that the service can learn from to avoid error

- We know there is a lot of confusion in the UK and need to put out clear messages

- Is the UK representative of the rest of Europe?

European picture

• 2012 survey answered by IT, NO, FR, DK, FI, SI, BE, IE, HU, LV, PT & ES

- 11:12 collected medication error reports within the Pv system
- 7:12 have separate public bodies to address error (no harm)
- 4:12 have local hospital & poisons unit based centres
- All have low levels of reporting of medication error
- None have specific signal detection methodologies for these reports
- 5:12 planned to make changes to their collection systems, data sharing arrangements or IT to accommodate new requirements

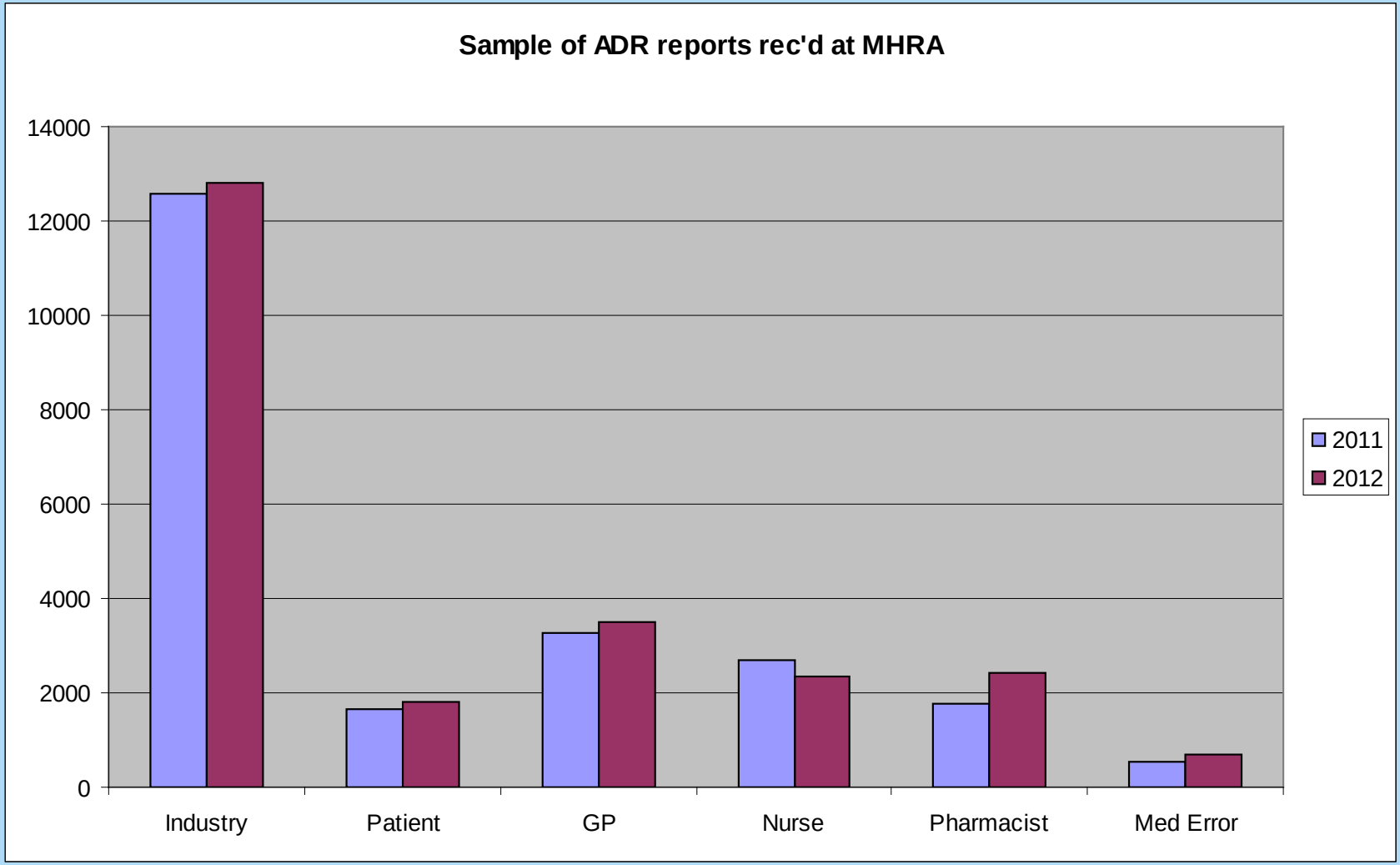
Raising Awareness
- ‘take all appropriate measures’

“Directive 2010/84/EU… Article 102. The Member States shall:

….take all appropriate measures to encourage patients, doctors, pharmacists and other health-care professionals to report suspected adverse reactions to the national competent authority; for these tasks, consumer organisations, patients organisations and healthcare professionals organisations may be involved as appropriate.”

Need to raise general awareness of legislation

Understanding Reporting



Yellow Card Strategy – revised

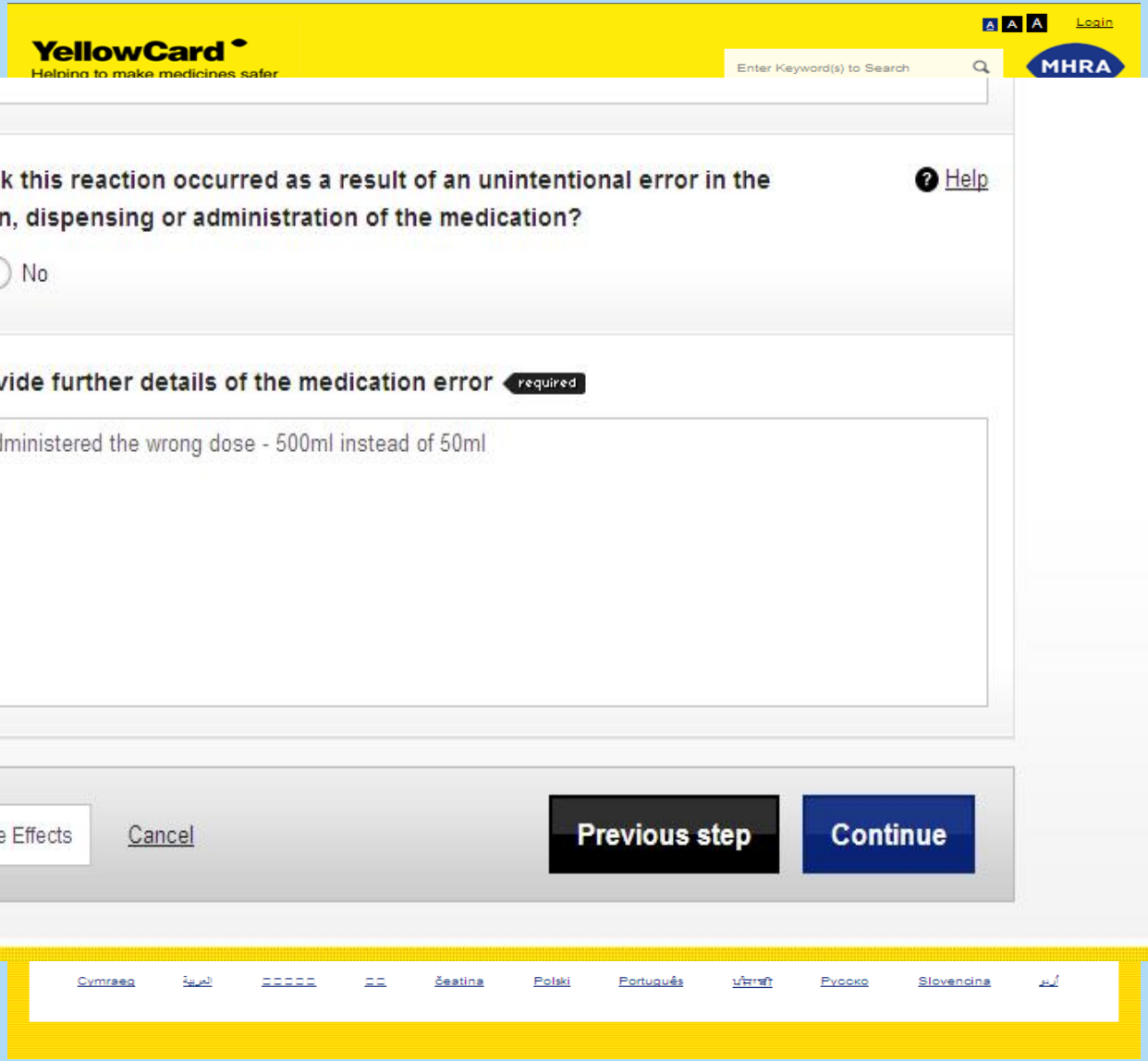
Raise awareness and understanding of the Yellow Card Scheme and increase reporting

- **Facilitation** – Increasing access to the scheme to meet the needs of reporters e.g. integration with clinical systems
- **Clarity** – What to report and when
- **Impact** – How Yellow Card reporting makes a positive difference
- **Promotion** – Develop and maintain promotion and communication strategies for the scheme

Two complementary sets of activities

- healthcare professionals
- the public

ADR Reporting Site



Electronic reporting direct from systems

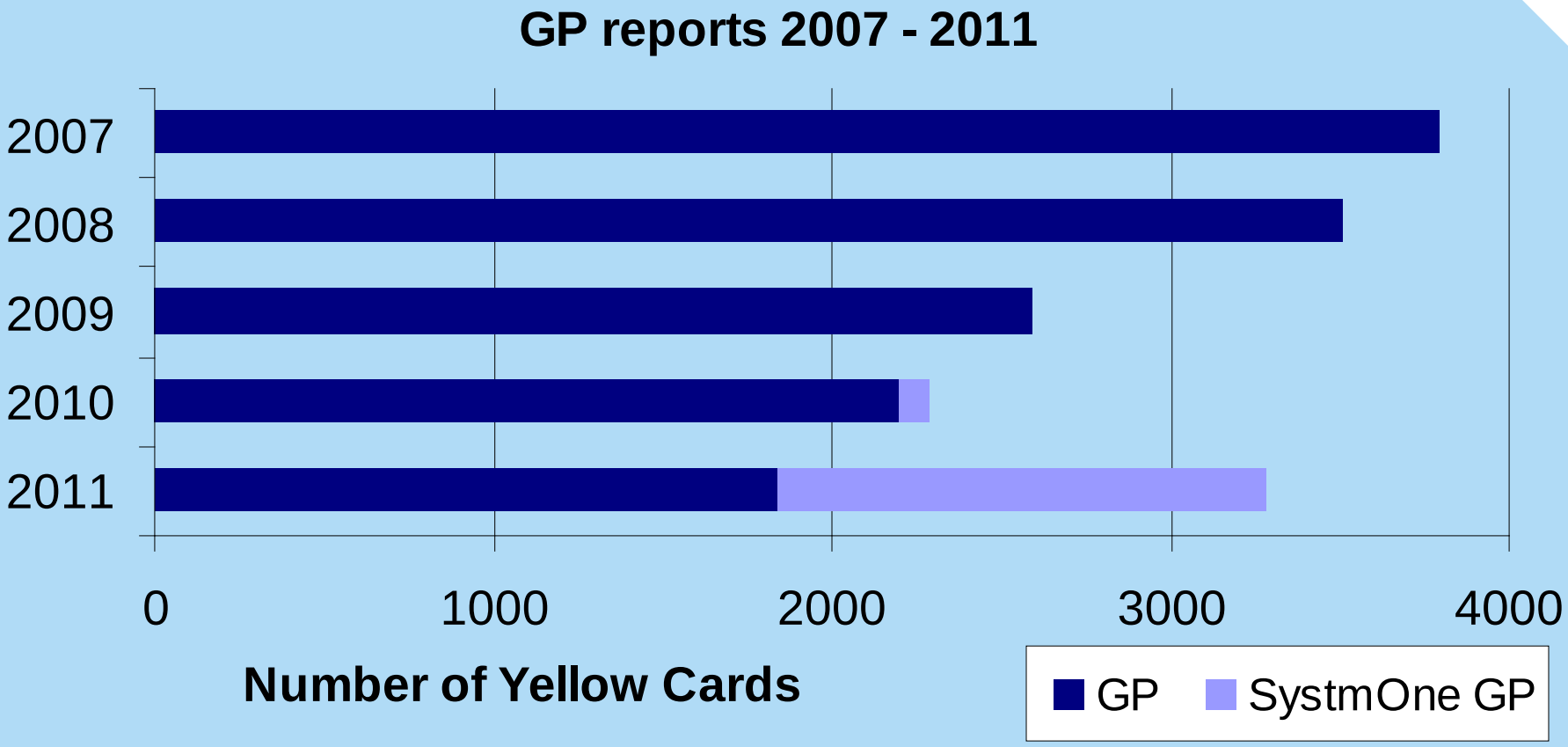
- SystmOne (GP system) (15-20% England GP practices)
  - Reported >2,200 since end of November 10
  - Over 1700 received in one year
  - ~50% increase in GP reporting

- Pilot ongoing with Cerner - Newcastle NHS Trust

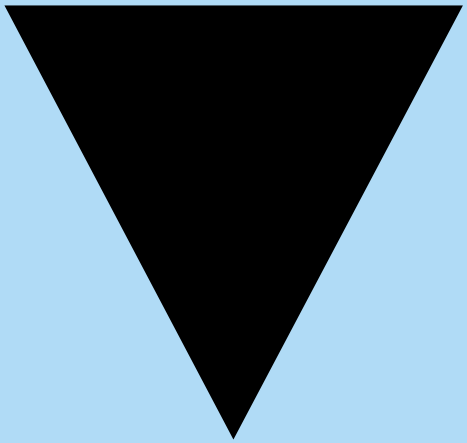
- NHS information Standard – ISB 1582 electronic Yellow Card reporting
  - GP Systems of Choice

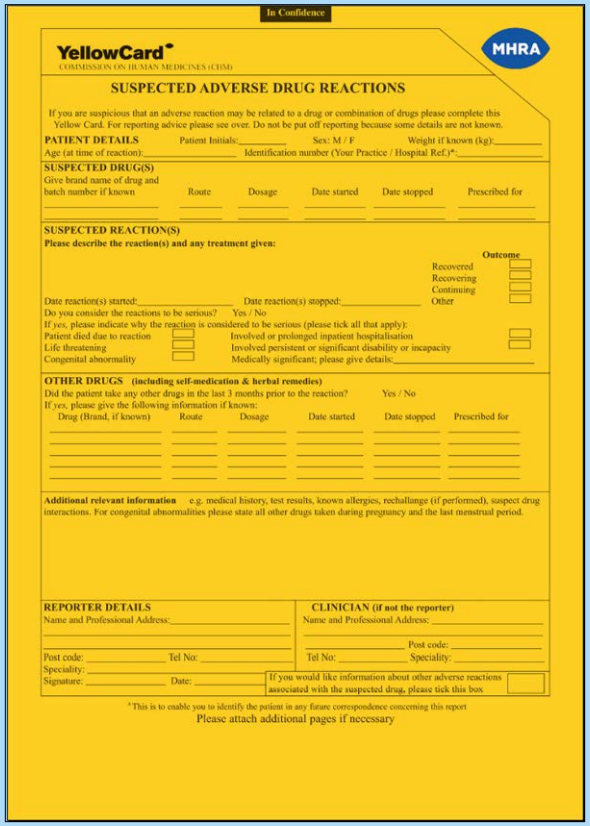
- UKMI Centres went live in 2010

GP Reporting



Key Changes – Additional Monitoring





In Confidence

YellowCard
COMMISSION ON HUMAN MEDICINES (CHM)

MHRA

SUSPECTED ADVERSE DRUG REACTIONS

If you are suspicious that an adverse reaction may be related to a drug or combination of drugs please complete this Yellow Card. For reporting advice please see over. Do not be put off reporting because some details are not known.

PATIENT DETAILS Patient Initials:_____ Sex: M / F Weight if known (kg):_____
Age (at time of reaction):_____ Identification number (Your Practice / Hospital Ref.)*:_____

SUSPECTED DRUG(S)
Give brand name of drug and batch number if known | Route | Dosage | Date started | Date stopped | Prescribed for

SUSPECTED REACTION(S)
Please describe the reaction(s) and any treatment given:

Outcome
Recovered ☐
Recovering ☐
Continuing ☐
Other ☐

Date reaction(s) started:_____ Date reaction(s) stopped:_____
Do you consider the reactions to be serious? Yes / No
If yes, please indicate why the reaction is considered to be serious (please tick all that apply):
Patient died due to reaction ☐ Involved or prolonged inpatient hospitalisation ☐
Life threatening ☐ Involved persistent or significant disability or incapacity ☐
Congenital abnormality ☐ Medically significant; please give details:_____

OTHER DRUGS (including self-medication & herbal remedies)
Did the patient take any other drugs in the last 3 months prior to the reaction? Yes / No
If yes, please give the following information if known:
Drug (Brand, if known) | Route | Dosage | Date started | Date stopped | Prescribed for

Additional relevant information e.g. medical history, test results, known allergies, rechallange (if performed), suspect drug interactions. For congenital abnormalities please state all other drugs taken during pregnancy and the last menstrual period.

REPORTER DETAILS
Name and Professional Address:_____
Post code:_____ Tel No:_____
Speciality:_____
Signature:_____ Date:_____

CLINICIAN (if not the reporter)
Name and Professional Address:_____
Post code:_____
Tel No:_____ Speciality:_____

If you would like information about other adverse reactions associated with the suspected drug, please tick this box ☐

* This is to enable you to identify the patient in any future correspondence concerning this report

Please attach additional pages if necessary

New pharmacovigilance legislation, July 2012

Printer friendly version (new window)

In July 2012, new pharmacovigilance legislation come into effect across the EU as a result of changes set out in:

- Regulation (EU) No1235/2010 (external link)
- Directive 2010/84/EU (external link)

The changes introduced by the Directive will be transposed into UK law in the Human Medicines Regulations 2012, which also consolidate nearly all other UK medicines legislation.

The legislation will be underpinned by an EC Implementing Measures Regulation and a series of modules on Good Pharmacovigilance Practice.

Find out more about the implementation of the legislation in the introduction page below.

We have developed a series of questions and answers (Q&As) (below), from the MHRA's perspective, to support marketing authorisation holders (MAHs) with the introduction of the new legislation. Information is grouped into six themes. This information will be developed over the coming weeks and months, and MAHs are advised to keep an eye out for updated information.

A Q&A document on the new Pharmacovigilance legislation is also available from the European Medicines Agency (EMA) (external link)

For further questions or comments specifically regarding MHRA's implementation of the new legislation, email pv2012@mhra.gsi.gov.uk. Please note, however, that not all enquiries will be answered directly and may instead be used to develop further questions and answers on this webpage. The EMA also has an email for enquiries regarding the legislation: p-pv-helpdesk@ema.europa.eu

Introduction

This page provides information about the new pharmacovigilance legislation.

Go to the introduction

Questions and answers

This section provides questions and answers about the new pharmacovigilance legislation.

Go to the questions and answers

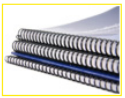
accordance with Directive 2010/84/EU (the new pharmacovigilance legislation).

The MHRA holds data for medicines that are licensed at a national level. Some medicines are licensed centrally by the European Medicines Agency (EMA). For product information on these medicines, please consult the EMA website:

- European Medicines Agency (external link)

If you have any questions or comments on this list of product information, please contact our Customer Services Team, email: info@mhra.gsi.gov.uk, telephone: 020 3080 6000.

Drug Analysis Prints (DAPs)



DAPs contain complete listings of all suspected adverse drug reactions or side effects, which have been reported by healthcare professionals and patients to the MHRA, via the Yellow Card Scheme. Each DAP lists all of the reactions reported by health professionals and patients for a particular medicine

Go to the Drug Analysis Prints (DAPs)

Drug Safety Update (DSU)

Drug Safety Update is our monthly newsletter for healthcare professionals, bringing you information and clinical advice on the safe use of medicines.

Go to Drug Safety Update (DSU)

Public Assessment Reports

The MHRA's assessment of a medicine is available in a Public Assessment Report (PAR), albeit with commercially or personally confidential information removed. PARs are typically prepared for products that were granted licences after 30 October 2005. We also publish safety Public Assessment Reports, which summarise the evaluation of a safety issue that has been identified with a medicine and the action taken to ensure that any risks are minimised and the benefits always outweigh them.

Go to the Public Assessment Reports (PARs)

Summaries of Product Characteristics (SPCs) and patient information leaflets (PILs)

This page contains product information. Every medicine pack includes a patient information leaflet (PIL), which provides information on using the medicine safely. PILs are based on the Summaries of Product Characteristics - a description of a medicinal product's properties and the conditions for its use.

Go to the Summaries of Product Characteristics (SPCs) and patient information leaflets (PILs)

Summaries of Risk Management Plans

A Risk Management Plan (RMP) is a document which describes all the available knowledge about the safety and efficacy of a medicinal product.

Go to the summaries of risk management plans

Yellow Card

The Yellow Card Scheme is run by the MHRA and the Commission on Human Medicines (CHM), and is used to collect information from both health professionals and the general public on suspected side effects or ADRs to a medicine. Its continued success depends on the willingness of

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Summary

- The ADR definition is now much broader and PV systems should be capturing new and important safety information
- National reporting systems however are often complex with a number of organisations involved
- Where harm occurs from a medicine though it should be reported to the NCA for pharmacovigilance
- Member States need to communicate these changes and other important messages to stakeholders

Conclusions

Thank You!

Questions?