EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Focus on Pharmacovigilance

## Introduction

SME workshop: 19 April 2012

**Dr June Raine**
**Chair, Pharmacovigilance Working Party**

# Focus on pharmacovigilance

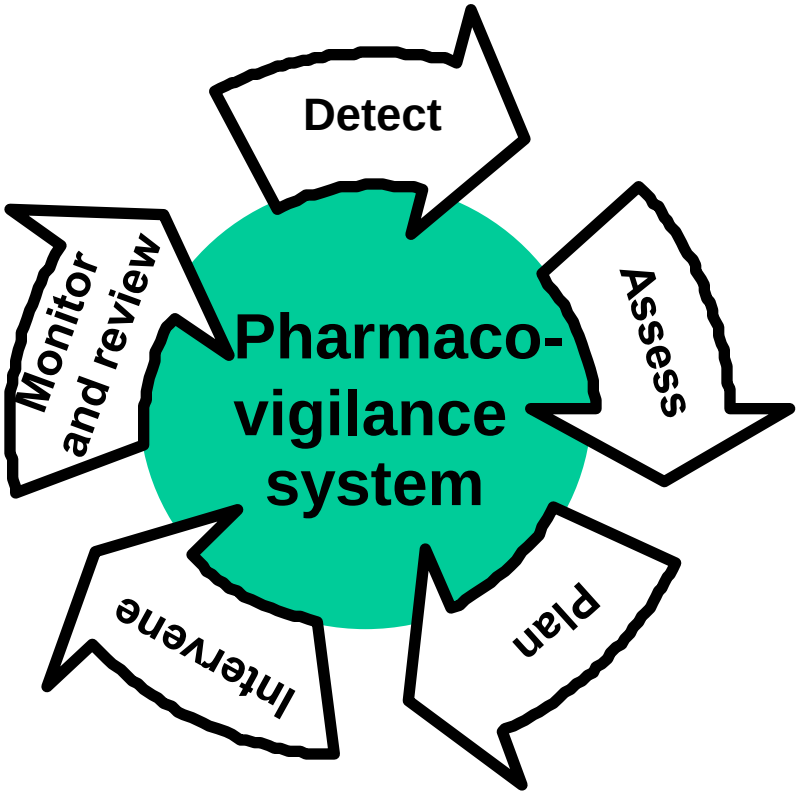
- Pharmacovigilance

  - a vital public health function

- New EU legislation

  – why and how being introduced?

- Goals of today's Workshop




# Pharmacovigilance – a continuous process

# EU pharmacovigilance - aims

Maximising benefit, minimising risk of medicines

Evidence-based information available in a timely way to all stakeholders

Demonstrable public health outcomes

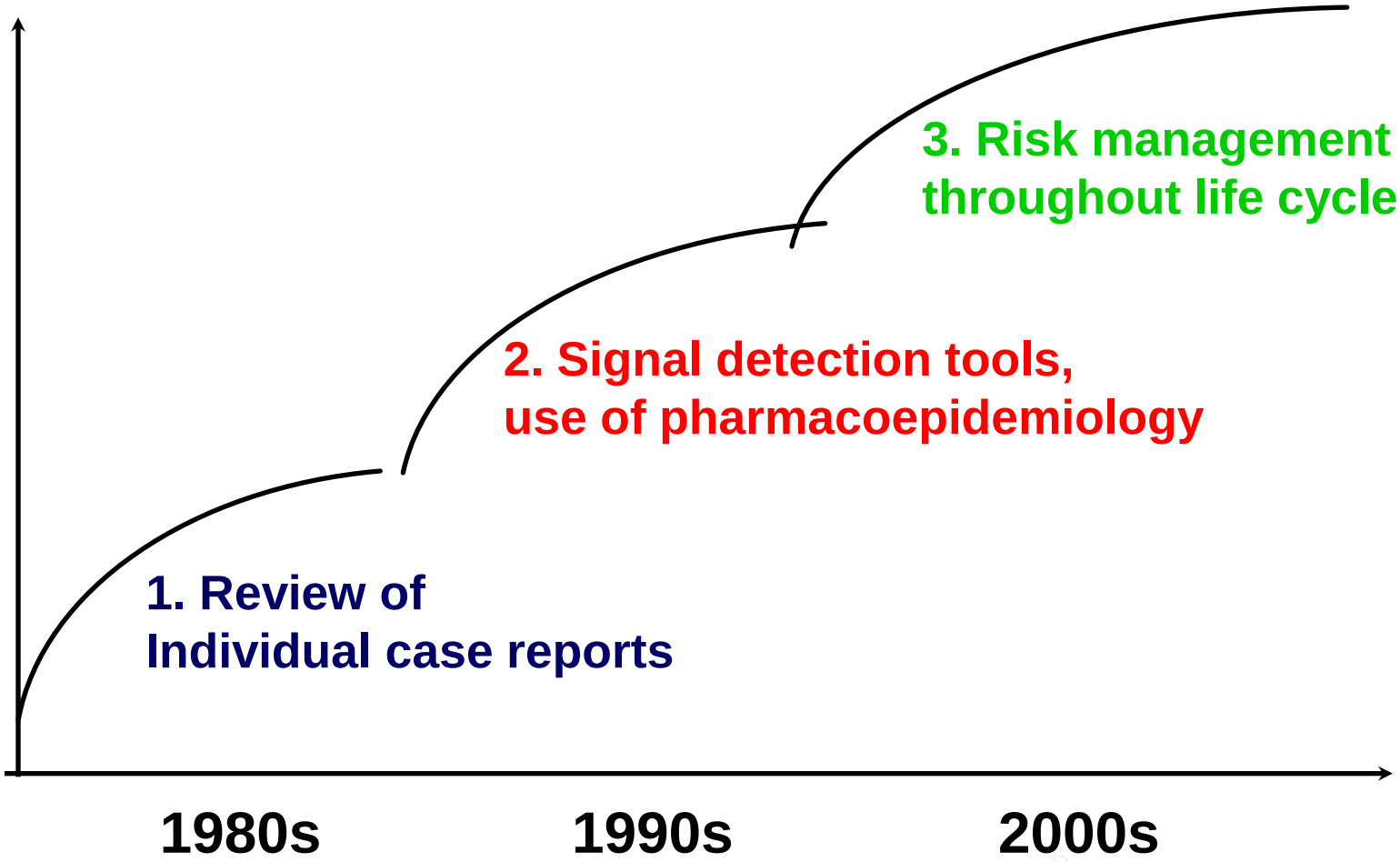

- Pre-clinical (animal studies)
- Phase I-III clinical studies
- Specialised studies eg genetics

- Highly controlled
- Few thousand patients

- Spontaneous adverse events
- Health information databases
- Registries etc

- Less controlled
- Many thousands of patients

# Pharmacovigilance evolution

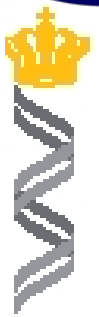


# A European network…












# Why need to strengthen PhVig?

High-profile drug safety issues – Vioxx, SSRIs

Independent review by European Commission

Findings highlighted weaknesses in systems

# European Commission identified:

- Lack of clear roles and responsibilities
- Lack of proactive and proportionate monitoring
- Duplicative AR reporting rules
- Lack of inclusiveness of stakeholders
- Slow decision-making
- Low levels of transparency

# Introducing new EU legislation

- Formal adoption, published 31 December 2010
- Transposition over 18 months
  - Implementing measures
    - EC Consultation
  - National legislation
  - Good Vigilance Practice (GVP)
- Effective from July 2012
  - some transitional arrangements

# Who is doing what in the new system?

**European Commission:** Making the law – Regulation, Directive, Implementing Measures, Transitional Arrangements

**EMA**: Developing the guidance, supporting the system, engaging stakeholders – GVP, Committee structure, Eudravigilance, EU web portal

**NCAs:** Operating the systems - scientific expertise, work-sharing, audit, HCP and patient communications

**HCPs:** Engagement with system - reporting ADRs, acting on advice

**Patients:** Awareness and engagement – reporting, acting on information

**MAHs:** Compliance with the system, delivering the benefits

# Core MAH Responsibilities

- New legislation affects all MAHs regardless of size, EU country of operation, or product portfolio
- Cuts across product lifecycle from MAA to ongoing monitoring & signal detection
- Will affect procedures, systems & resources
- Most of this is covered today's programme …….

# Goals of today's programme

To provide an update on pharmacovigilance

Focus on the key changes in the new legislation

How to prepare for its implementation