5 things you should know about Pharmacovigilance (PV)

abpi
Bringing medicines to *life*
Pharmacovigilance Expert Network

1 What is pharmacovigilance?

The World Health Organization defines pharmacovigilance (PV) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

2 How does pharmacovigilance help to improve patient safety?

Medicinal products are authorised on the basis that the likely benefit outweighs the potential harm. Other and rare adverse drug reactions (ADRs) may only occur when the medicinal product is used in the wider population. On-going safety monitoring detects any changes in the risk profile so that the necessary steps to further optimise safe and effective use of the medicinal product can be taken.

All medicinal products come with information on how to minimise risk, such as how to use medicinal products properly, how to store them, whether they can be used with existing medication and whether there are any patients who should not use the product.

3 What tools are available to help reduce risk?

These tools are non-promotional and approved by the regulator

A Risk Management Plan (RMP) is designed to identify, prevent or minimise risks relating to a particular medicinal product.

The RMP documents the PV activities which are in place and the risk minimisation measures (RMMs) or tools needed to minimise risk by helping healthcare professionals (HCPs) and patients make informed decisions when prescribing or using a medicinal product.

All medicinal products require routine Risk Minimisation Measures (RMMs):

- Patient Information Leaflet (PIL)
- Labelling
- Summary of Product Characteristics (SmPC)
- The legal status of the medicinal product
- Pack size and design

How to access them

- In or on medicine packs
- By visiting the MHRA or EMA websites
- By visiting the eMC website

Some medicines require additional RMMs to further reduce risk of harm

- **Educational programmes and tools**
  - For HCPs to give guidance on prescribing, management of risks and reporting ADRs of special interest, e.g. prescribing checklists, dosage reference guides
  - For patients and carers to raise awareness of the signs and symptoms of specific ADRs e.g. patient diaries and patient alert cards
- **Controlled access programmes** e.g. patient screening and monitoring, medicinal product availability restricted to approved Pharmacies
- **Other measures**
  - Pregnancy prevention programmes
  - Direct Healthcare Professional Communication (DHPC)

How to access additional RMMs

- May be received in the post or in the pack with the medicinal product
- Can be requested from the Medical Information department of the Marketing Authorisation Holder (MAH)
- Many can also be found on dedicated websites or the eMC website

4 How can we work together to reduce risk?

Regulatory Authority

Approves the risk management system

- Agrees the RMP and approves medicinal products for marketing
- Publishes 'public friendly' RMP summaries
- Approves the additional RMMs
- Agrees a RMM communication plan with the MAH
- Evaluates RMM effectiveness and monitors medicine safety
- Oversees the additional monitoring for black triangle ▼ medicines

Pharmaceutical Company (or MAH)

Produces and supplies the RMP and RMM

- Creates a RMP for medicinal product
- Prepares RMM as directed by the Regulator and distributes them as agreed and appropriate
- Continually implements and updates the RMP during the lifecycle of the medicinal product, including the associated RMM

PATIENT SAFETY

Healthcare Professional

Prescribes/dispenses/administers medicinal products and keeps patients informed

- Selects the right medicinal product for the right patient taking account of any screening requirements or restricted access limitations
- Encourages patients to read labels, PILs (and additional RMMs if available) and helps them to understand any actions needed
- Monitors patients and manages suspected ADRs
- Reports any suspected ADRs with the use of a medicinal product (to the Yellow Card Scheme or directly to the MAH)
- Takes part in surveys to evaluate the effectiveness of additional RMMs

Patient / Caregiver

Feeds back information and becomes more aware of safety

- Understands and uses routine and additional RMMs to help manage or minimise ADRs
- Reports suspected side effects to HCPs, the MAH or the Regulator themselves e.g. through the Yellow Card Scheme
- Takes part in surveys to help evaluate the effectiveness of additional RMMs
- Takes or administers medicines as directed

5 What can I do to help improve patient safety?

- Report suspected adverse drug reactions promptly (via www.mhra.gov.uk/yellowcard or via the Yellow Card mobile app),
- Use the educational programmes for HCPs, patients and care givers,
- Provide feedback to help monitor the effectiveness of risk minimisation measures.

MAHs and Regulators are legally required to evaluate the success of risk minimisation activities. This ensures the contributions from all stakeholders are being used to maximise patient safety.

Where can I find out more...

For Risk Minimisation Activities see our quick reference guide and advice for pharmacists.

For Black Triangle see our quick reference guide and advice for pharmacists.

ROYAL PHARMACEUTICAL SOCIETY

Reference section

Pharmacovigilance. World Health Organisation, Geneva.
http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/

MHRA Yellow Card Scheme
https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals

Medicines and Healthcare products Regulatory Agency Medicines: information about specific products
https://www.gov.uk/government/publications/medicines-information-about-specific-products

Electronic Medicines Compendium
https://www.medicines.org.uk/emc/rmmdirectory