## 5 things you should know about Pharmacovigilance (PV)

### 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 safety 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 medicines and whether there are any patients who should not use the product.

### 3. What tools are available to help reduce risk?

1. **Patient Information Leaflet (PIL)**
2. **Labeling**
3. **Summary of Product Characteristics (SmPC)**
4. **Pack size and design**
5. **Additional tools and systems**

#### Patient Information Leaflet (PIL)

- Helps patients identify and report ADRs
- Encourages patients to read labels, PILs (and additional RMMs)

#### Labeling

- Helps patients 
- Helps healthcare professionals

#### Summary of Product Characteristics (SmPC)

- Describes the medicinal product
- Provides information necessary to use the medicinal product safely

#### Pack size and design

- helps to improve medication adherence

### 4. How can we work together to reduce risk?

#### Regulatory Authority

- Agrees the RMP and approves medicinal products for marketing
- Publishes guidance freely (EFPH summaries)
- Approves the additional RMMs
- Ensures RMM effectiveness and monitors medicinal product safety

#### Healthcare Professional

- Takes part in surveys to help evaluate the effectiveness of additional RMMs
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- Encourages patients to read labels, PILs and additional RMMs
- Understands and uses routine and additional RMMs

#### Patient/Caregiver

- Feeds back information and becomes more aware of safety
- Takes steps as directed at the time of the advice by the Healthcare Professional (HCP) and/or by the MAH

### 5. What can I do to help improve patient safety?

- Report suspected adverse drug reactions promptly

- Use the educational programmes for HCPs, patients and care givers

- Provide feedback to help monitor the effectiveness of risk minimisation measures

### Reference section

- MIIRA Yellow Card Scheme
- Medicines and Healthcare products Regulatory Agency Medicines: information about specific products

### Where can I find out more...

- EMA websites
- MHRA websites
- Electronic Medicines Compendium
- MIIRA Yellow Card Scheme
- EMA websites
- Medicines and Healthcare products Regulatory Agency Medicines: information about specific products

### PATIENT SAFETY

- Black Triangle

### Electronic Medicines Compendium

https://www.medicines.org.uk/emc/