DRUG SAFETY AND PHARMACOVIGILANCE
SAQs

Postgraduate Course in Pharmaceutical Medicine
Module 10 – Revision Module
etc venues Marble Arch, London – 16th-18th July 2019

Dr Kristina Strutt
Head of Pharmacovigilance, China and Emerging Markets Global Business Unit
Sanofi

Short Answer Question – 2017 2.

a) What is a medication error? **2 marks**

b) For the following 4 different potential sources of medication errors (prescribing, storing, dispensing, preparing/administering medicinal products) give 2 examples of medication errors and briefly describe how routine and additional risk minimisation measures can be used to prevent them. **8 marks**

SAQ – 2017 2. : suggested approach

a) 'A medication error is an **unintended** failure in the **drug treatment process** that leads to, or has the potential to lead to **harm to the patient**.'

b)

	Example 1	Example 2
Prescribing	Inadvertently prescribed in pregnancy despite contraindication ARMM: restricted access only for patients complying with pregnancy prevention programme	Missing a new warning and precaution re concomitant medications ARMM: DHPC
Storing	Stored at the wrong temperature/humidity RRMM: clear instructions in the SmPC ± on the packaging	Stolen from the transporter lorry ARMM: special training and instructions for the transport company
Dispensing	Confusing the drug name with another RRMM: Clearly differentiated naming	Accidental ingestion by children RRMM: dispense in child-proof containers
Preparing/administering	Mistakes with complex reconstitution methodology ARMM: reconstitution to be performed only by specialist pharmacists who are certified on specific training	Patient crushes a modified-release formulation RRMM: clear instructions in the Patient Package Insert

Short Answer Question – 2017 3.

a) List the minimum information required for an adverse event report to be valid. **2 marks**

b) Briefly describe what MedDRA is and its intended purpose. **3 marks**

c) What is a safety signal? **2 marks**

d) List 6 potential sources of safety signals for a marketed product. **3 marks**

SAQ – 2017 3. : suggested approach

a) The four criteria for a valid case are:
a product; an event; an identifiable patient; an identifiable reporter

b) - The **Med**ical **D**ictionary for **R**egulatory **A**ctivities has become the standard reference to standardise medical terminology (e.g. adverse event terms) for the sharing of regulatory information internationally for medical products used by humans
- Developed by ICH in the late 1990s
- Maintained and kept up-to-date by the ICH MedDRA Management Committee
- Multilingual – in additional to English, it is translated and maintained in Chinese, Czech, Dutch, French, German, Hungarian, Italian, Portuguese, Russian, and Spanish.
- Standardised MedDRA Queries (SMQs) are are validated, pre-determined sets of MedDRA adverse event terms used for signal detection and evaluation.

c) A signal is:
"*Information that arises from one or multiple sources (including observations and experiments), that suggests a* ***new potentially causal association****, or a* ***new aspect of a known association****, between an intervention and an event or set of related events, either adverse or beneficial, that is* ***judged to be of sufficient likelihood to justify further action to verify***."

d) Clinical trials; post-marketing non-interventional studies; post-marketing spontaneous reports; literature review; non-clinical data (toxicology, genotoxicity studies etc); patient support programmes; epidemiology databases; reports for products in the same class; quality defects; etc

Short Answer Question – 2018 8.

a) Briefly describe the role of the European Union Qualified person for Pharmacovigilance (EU QPPV). **2 marks**

b) Briefly describe the requirements a company must meet when appointing an EU QPPV. **5 marks**

c) What is the Pharmacovigilance Risk Assessment Committee (PRAC) and its role? **3 marks**

SAQ – 2018 8. : suggested approach

a) The QPPV is responsible for establishing and maintaining the MAH PV System, having an overview of the safety profiles of all their **EU-authorised products**, and acting as a single point of contact on a 24-hour basis for the competent authorities

b) - Location: should reside and work in an EU (EEA) Member State
- Notification: shall inform the EMA and the Member States of the name and 24-hour contact details of the EU QPPV
- Ensure that the QPPV has sufficient authority to influence the performance of the PV System
- Ensure that the QPPV has access to the PSMF, and can access all the information that they consider relevant (related to the benefit-risk of the products, processes, audit and inspection reports etc)
- Ensure that if the EU QPPV is appropriately qualified, and that if they are not medically qualified, they have access to a medically qualified person
- Ensure that back-up procedures are in place

c) The PRAC is the European Medicines Agency's (EMA) committee responsible for assessing and monitoring the safety of human medicines. It comprises experts in medicines safety from the regulatory authorities in each Member State, plus scientific experts and representatives of patients and healthcare professionals nominated by the European Commission.
Responsible for assessing all aspects of **risk management of human medicines**, including:

- the detection, assessment, minimisation and communication of the risk of adverse reactions, while taking the therapeutic effect of the medicine into account; (*i.e. benefit-risk*!)
- design and evaluation of post-authorisation safety studies
- pharmacovigilance audit