10 Sample Mock ABPI Exam Questions from PharmacyCPA.com

Join our ABPI Exam Course today!

Why is pharmacovigilance important even after a medicine is marketed?
a) To monitor the safety of medicines throughout their marketed life, as some adverse drug reactions may not be seen until a large number of people have received the medicine.
b) To conduct further clinical trials to test the medicine's efficacy.
c) To compare the medicine with new medications that are developed after its marketing.
d) To reduce the cost of the medicine over time.

The correct answer is a. *Pharmacovigilance is crucial post-marketing to ensure the ongoing safety of medicines. Adverse reactions can sometimes only emerge once a medicine is used by a larger population, making continuous monitoring essential. For more information have a look at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9532191/*

Which of the following is NOT a component of pharmacovigilance?
a) Monitoring the use of medicines in everyday practice to identify previously unrecognised adverse effects.
b) Assessing the risks and benefits of medicines to determine necessary actions for safe use.
c) Providing information to healthcare professionals and patients to optimise the safe and effective use of medicines.
d) Conducting initial clinical trials to test the efficacy of new medicines.

The correct answer is d. *Conducting initial clinical trials is not a component of pharmacovigilance. Pharmacovigilance focuses on monitoring the safety of medicines after they are marketed. For more information see .gov details on the Yellow Card scheme.*

When is a medicine considered safe?
a) When its expected benefits are greater than any associated risks of harmful reactions.
b) When it causes no reactions at all.
c) When it is only used by a small number of people.
d) When it has been on the market for a long period of time.

The correct answer is a. *A medicine is considered safe when its expected benefits outweigh any associated risks of harmful reactions.*

Which of the following is NOT a source of information used for pharmacovigilance?
a) Spontaneous adverse drug reaction (ADR) reporting schemes, such as the Yellow Card Scheme.
b) Clinical and epidemiological studies.
c) Worldwide published medical literature.
d) Patient self-diagnosis forums.

The correct answer is d. *Patient self-diagnosis forums are not a formal source of information used for pharmacovigilance. While patients may share their experiences and concerns on such forums, the information is not systematically collected or verified for pharmacovigilance purposes.*

What can be a consequence of identifying unexpected adverse drug reactions (ADRs) through pharmacovigilance?
a) Complete removal of the medicine from the market.
b) Changes in the marketing authorisation license of the medicine, such as restrictions in use or changes in the specified dose.
c) Mandatory participation in clinical trials for all patients taking the medicine.
d) Immediate cessation of all production of the medicine.

The correct answer is b. *Identifying unexpected adverse drug reactions (ADRs) through pharmacovigilance can lead to changes in the marketing authorization license of the medicine, such as restrictions in use or changes in the specified dose, to ensure its safe use. Complete removal of the medicine from the market or immediate cessation of all production would be extreme measures taken in rare cases where the risk is deemed too high to manage effectively. Mandatory participation in clinical trials for all patients taking the medicine is also not a typical consequence of identifying unexpected ADRs. For more info, read "Pharmacovigilance in perspective"*

Which of the following is NOT a regulatory action that the MHRA may take to minimise the risk associated with a medicine?
a) Changes to warnings in the product information or on the package label.
b) Restricting the indications for use of a medicine.
c) Changing the legal status of a medicine, for example, from over-the-counter to prescription only.
d) Increasing the price of the medicine to discourage its use.

The correct answer is d. *Increasing the price of a medicine is not a regulatory action typically taken by the MHRA to minimize the risk associated with a medicine. Regulatory actions usually focus on changes to warnings, restrictions on indications, or changes in legal status to ensure safe use.*

What is the role of the Willingness to Pay (WTP) threshold in pharmacoeconomic evaluations?
a) The WTP threshold is used to determine the point at which a new intervention is considered affordable and an efficient use of limited resources, based on the comparison of the incremental cost-effectiveness ratio to an accepted threshold.
b) The WTP threshold is used to calculate the direct costs associated with a healthcare intervention.
c) The WTP threshold is solely used to measure the quality of life improvements provided by an intervention.
d) The WTP threshold is a fixed value that is the same across all healthcare interventions and countries.

The correct answer is a. *The WTP threshold is a crucial concept in pharmacoeconomic evaluations. It represents the maximum amount society is willing to pay for a unit of health gain. It helps decision-makers determine whether a new intervention is cost-effective by comparing its incremental cost-effectiveness ratio to the WTP threshold.*

How does the MHRA provide feedback on pharmacovigilance to healthcare professionals and patients?
a) By conducting personal interviews with all healthcare professionals.
b) By hosting annual pharmacovigilance conferences.
c) By updating patient information leaflets (PILs) and Summaries of Product, Characteristics (SPCs), sending letters with urgent warnings, publishing safety information in the 'Drug Safety Update' bulletin, providing fact sheets on major safety issues, and publishing safety alerts on the MHRA website.
d) By requiring all healthcare professionals to take a yearly pharmacovigilance exam.

The correct answer is c.

What is the primary purpose of evaluating Yellow Card reports in the context of pharmacovigilance?
a) To immediately ban all medicines reported to have adverse effects.
b) To determine whether any regulatory action is required to allow medicines to be used more safely and effectively, and to identify previously unrecognised concerns that may warrant further action.
c) To publicly disclose the names of patients who have reported adverse effects.
d) To increase the sales of medicines by proving their safety.

The correct answer is b.

What is the purpose of a budget-impact analysis (BIA) in pharmacoeconomic evaluations?
a) To estimate the impact of implementing or adopting a new intervention or technology on a designated healthcare budget.
b) To determine the economic burden of a disease or condition on a given population or region/country.
c) To assess the least costly among alternative technologies that are assumed to produce equivalent healthcare outcomes.
d) To reproduce events and possible consequences due to alternative policy options using a mathematical/statistical framework.

The correct answer is a. *A budget-impact analysis (BIA) is used to estimate the financial impact of adopting a new intervention or technology on a specific healthcare budget. It helps decision-makers understand the financial consequences of incorporating the new intervention into the healthcare system.*

What is the purpose of statistical analysis of Yellow Card data in signal detection?

a) To immediately withdraw all medicines with reported adverse effects from the market.
b) To identify 'signals'—drug-reaction combinations that occur more frequently than expected when compared to the background frequency of other drug-reaction combinations in the database.
c) To determine the price of medicines based on their safety profile.
d) To track the geographical distribution of adverse drug reactions.

The correct answer is b.