

Who can report?

All healthcare professionals including, physicians, dentists, pharmacists, nurses or patients as well as others should report the drug quality defects to the National Pharmacovigilance and Drug Safety Center.

What should be reported?

Product quality defects that should be reported include the following:

- Therapeutic failures.
- Suspected counterfeit product.
- Suspected contamination.
- Questionable stability.
- Defective components.
- Poor packaging and labeling.
- Wrong data on labels, packaging or leaflets.
- Product mix-up (e.g. wrong pre - filled syringes in boxes).
- Wrong quantity.
- Difficult to use (e.g. open the container).
- Re -labeling error (e.g. wrong expiry date on peeling back over- label).

How to report pharmaceutical products quality defects?

Fill the product quality reponing form and send it to the Saudi Food and Drug Authority through the following:

Online: www.sfda.gov.sa/npc

E-mail: npc.drug@sfda.gov.sa

Call NPC at + 966 11 2038222

Ext-2317 - 2356 - 2354 Or 5785

Toll Free Number: 8002490000

Fax: +966 11 2057662

Mail:

National Pharmacovigilance and Drug Safety Center
Vigilance and Crisis Management Excutive Directorate
Saudi Food and Drug Authority -Drug Sector
3292 Northern Ring Road AlNafal District
Riyadh 13312 - 6288
Kingdom of Saudi Arabia

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Guide for pharmaceutical Products Quality Reporting

Introduction

Pharmaceutical products play an important role in improving the health and promoting the well-being of every individual.

The issue of drug quality is in the interest of the following parties, because each has a stake in them: a) consumers - cure and cost; b) prescribers - patient trust, future visits, and future income; c) pharmaceutical companies - reputation, trust in their products, and future profits; and d) governments - protection of public health and prevention of increased public expenditure of drugs.

Drug quality is a source of great concern worldwide, particularly in many developing countries. Recent reports indicated that the availability of substandard and counterfeit (fake) drugs has reached a disturbing proportion. The rising cost of drugs generally creates a corresponding increase in incentive to produce counterfeit drugs because of profit margin. Use of poor quality drugs has serious health implications and waste resources.

What is drug quality and why is it important?

Poor quality medications do not meet official standards for strength, quality, purity, packaging and/or labeling. They may be legally registered innovator or generic products, or they could be counterfeited-deliberately mislabeled for identity, strength or source. Whether counterfeit or unintentionally substandard, poor quality drugs could result in serious health implications including treatment failure, adverse effects, increased morbidity, mortality, development of drug resistance and wasted resources.

What are the consequences of using poor quality drugs?

Use of poor quality drugs bears serious health implications such as treatment failure, adverse reactions, drug resistance, increased morbidity and mortality. Poor quality drugs can affect public trust and confidence resulting in reduced investment in the pharmaceutical industry. It also can severely affect the business of the manufacturer whose products are being copied through loss of confidence as well as revenue.

What are the benefits of pharmaceutical products quality reporting?

The benefits of quality defects reporting system are as follow:

- Improving the quality of care offered to patients.
- Monitoring the safety and quality of pharmaceutical products throughout their lifetime.
- Reducing drug-related problems, leading to better treatment outcomes.
- Improving the manufacturing quality of products.

What are the consequences of product quality defect under-reporting?

Under reporting may delay the recognition of new product quality defect and leads to the perception that injuries from product quality defect are less common than they really are. In product quality defect reporting, not only the quantity but also the relevance of case reports and the quality of data are important.