

Potential health risk from counterfeit drugs

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Worldwide, an estimated 10% of all medicines are counterfeit. The true extent of the problem is unknown.

Counterfeit medicines are those that are deliberately and fraudulently mislabeled with respect to identity and source. Poor quality medicines is a term inclusive of counterfeit, substandard, and degraded medicines and also for medicines that fail chemistry analysis but with insufficient information to determine whether they are counterfeit, substandard, or degraded. Counterfeit medicines have a disastrous effect on global health and on individual patient safety, including patient injury, non treatment, and death.

The scenarios are different in developing and developed countries. The impact of counterfeits in essential drug stocks has a profound and disproportionate impact in resource poor countries. This includes increased morbidity and mortality, adverse effects, therapeutic failure, inaccurate reports of drug resistance due to substandard medicines, and rise of drug-resistant pathogens.

A counterfeit drug may contain no active ingredient, so the drug fails to help the patient get better, which can ultimately harm the patient. The counterfeit drug may have no active ingredient and any number of harmful ingredients. Wrong drug may be used in the counterfeit agent. A counterfeit drug may contain the wrong concentration or wrong dose of the drug. Drugs may be contaminated with other substances. Microbiological contaminations may occur.

So counterfeit/substandard drugs pose a serious health concern from several perspectives. A formulation with no active ingredient or with insufficient active ingredient lead to a lack of clinical response and possibly, death. Adverse events also occur due to drug–drug interactions. The inadvertent use of suboptimal doses of drugs is likely to be one of the key factors contributing to antimicrobial resistance and thereby leading to the wider spread of disease (malaria, tuberculosis, helminthiasis, HIV).

Counterfeit drugs create uncertainty, confusion, loss of trust and confidence in healthcare stakeholders/system doubts about the value of the real drug, and may lead to the use of alternative, less-desirable drugs or therapies.