Review Article

Effectiveness, Safety and Disposal of Medications Beyond Expiry Dates: Brief Review

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ABSTRACT

The increasing prevalence of chronic illnesses, over-prescription, and pharmaceutical waste has led to concerns about the disposal of expired medications. While expiration dates indicate the period during which a drug's potency and safety are guaranteed, research suggests that many medications remain effective beyond their labeled expiration dates. Studies, including those conducted by the FDA for the U.S. military, have found that approximately 90% of tested drugs retain their potency for years beyond their stated expiry. However, certain drugs, such as nitroglycerin, insulin, and tetracycline, degrade more quickly and should not be used past expiration. The FDA's Shelf-Life Extension Program (SLEP) has demonstrated the feasibility of extending drug expiration dates, resulting in significant cost savings. Despite this, regulatory constraints and financial interests limit the widespread implementation of extended drug use. Proper disposal of expired medications remains a critical issue due to potential environmental hazards. A globally standardized approach to monitoring, regulating, and repurposing expired medications could reduce pharmaceutical waste, lower healthcare costs, and enhance drug accessibility, particularly in resource-limited settings.

Keywords: Expiry date, Economy, Pharmaceutical industry, Ethics.

INTRODUCTION

In recent decades, the prevalence of illnesses and chronic diseases, coupled with over-prescription, altered prescriptions, treatment cancellations, drug misuse, and excessive pharmaceutical production, has led to increased drug consumption and significant pharmaceutical waste. Many unused medications are either discarded or destroyed. Another factor contributing to drug disposal is the expiration of their shelf life. The high costs associated with storing or disposing of expired drugs, which amount to billions of dollars,[1] have prompted researchers to examine the safety and efficacy of these expired medications[2].

Drug expiration dates[3,4,5] indicate the period during which a manufacturer guarantees a drug's potency and safety. Consumers can determine a drug's shelf life by referring to its packaging. While certain medications, including nitroglycerin, insulin, epinephrine, and tetracycline, degrade more quickly, most drugs stored under proper conditions maintain at least 70–80% of their original potency for one to two years beyond the expiration date, even after being opened.[6] Research conducted by the Food and Drug Administration (FDA) for the military revealed that approximately 90% of over 100 tested medications,[7] both prescription and over-the-counter, remained effective up to 15 years after their expiration dates, suggesting that expiration dates do not necessarily mark the point at which drugs become ineffective or hazardous .[8]

EXPIRATION DATES AND SHELF LIFE

A drug's expiration date signifies the last point at which the manufacturer ensures its full potency and safety [9,10]. The term "shelf life" differs slightly, referring to the duration a drug remains safe and effective for use. Most pharmaceuticals expire within two to three years, and manufacturers generally discourage usage beyond this period. However, some drugs have been found effective for over five years, as confirmed by independent laboratories. Notably, expiration dates are often set by manufacturers without regulatory oversight, except for a limited number of selected medications .[11]

The concept of shelf life was introduced in 1979 when the FDA mandated expiration dates on pharmaceutical products to guarantee their safety and effectiveness. Manufacturers determine a drug's shelf life by conducting stability tests under specific environmental conditions. These tests include an accelerated stability study at 40°C and 75% humidity for six months and a real-time study under normal conditions (30°C/65%) for at least 24 months. These studies establish tentative expiration dates, optimal storage conditions, and retest periods .[12]

The European Medicines Agency (EMA) allows for expiration date extensions based on additional stability data.[13] However, extending expiration dates requires substantial supportive data, making it a complex process.

DURABILITY OF PHARMACEUTICALS BEYOND EXPIRY DATES

The term "expiration date" is sometimes misinterpreted. Drug manufacturers guarantee a drug's safety and efficacy until this date, but this does not imply that the medication is ineffective immediately afterward. Many drugs, when stored appropriately, remain highly potent for extended periods .[14] For instance, a 2006 study published in the Journal of Pharmaceutical Sciences found that two-thirds of 122 expired drugs retained stability and safety for months to years beyond their expiration dates. Some of these drugs had their expiration dates extended by an average of 66 months.[15]

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While many medications remain potent, certain drugs, such as nitroglycerin, insulin, epinephrine, and some antibiotics like Tetracycline degrade more rapidly and should not be used beyond their expiration dates.[16] expired oral antibiotic tetracycline, resulting in toxic reactions, including kidney failure, specifically Fanconi syndrome [17,18]. Many attributes this toxicity to degradation products of tetracycline (such as epi-anhydrotetracycline or anhydrotetracycline). Patients experienced symptoms such as nausea, vomiting, and metabolic acidosis within 2 to 8 days of taking the expired antibiotic. It is recommended that expired medications be returned to pharmacies or hospitals for proper disposal rather than being discarded in the trash or flushed down the drain, which can have environmental consequences.[19]

POTENCY AND EFFICACY

Drug potency begins to decline upon manufacturing but does not diminish abruptly after the expiration date. The expiration date guarantees that the medication retains its labeled potency until that time. Studies indicate that many drugs maintain 90% of their potency for at least five years after expiration and sometimes even longer.[20] Solid formulations such as tablets and capsules are more stable post-expiration, while liquid medications or reconstituted suspensions may lose efficacy sooner.

The FDA's Shelf-Life Extension Program (SLEP), conducted for the U.S. Department of Défense, found that 88% of 122 drugs tested under ideal conditions had expiration dates that could be extended by an average of 66 months, with some lasting up to 278 months .[21] A drug labelled to expire five years after manufacture is so labelled because it only had stability testing up to that point (Coffey, 2013)[22]. Unless further testing is done, its true shelf life is unknown, and the drug may retain its potency for many more years**.** It is also almost impossible to assess what is the actual potency of the active ingredient in the product (Ette, 2004).[23]

However, certain drugs, particularly those with narrow therapeutic indices, should not be used past their expiration dates due to the risk of reduced pharmacological activity.

REGULATION OF EXPIRED DRUG DISPENSING

In most countries, pharmacists and healthcare providers are legally prohibited from dispensing expired drugs (World Health Organization [WHO], 2019).[24] In one case, a North Carolina pharmacy received a reprimand for dispensing expired medications. Various nations have established guidelines for proper disposal,[25] but a globally harmonized system remains absent. The WHO outlines several disposal methods, including returning drugs to manufacturers, high-temperature incineration, waste encapsulation, and chemical decomposition (WHO, 2020)[26]. The European Commission has considered revising expiration date regulations, but no uniform approach exists internationally (CPME, 2021).[27]

ADVANTAGES OF USING EXPIRED PHARMACEUTICALS

Discarding expired medications has several drawbacks. Many low- and middle-income countries face medication shortages and struggle to afford essential drugs. Instead of wasting medications proven to be safe and effective, these drugs could be redirected to areas in need, enhancing accessibility and affordability for disadvantaged populations. Expired medications could also serve in emergency situations where immediate supply is critical. Additionally, extending shelf life would reduce costs for healthcare systems and insurance providers.

PHARMACEUTICAL COMPANIES' FINANCIAL INTERESTS

Manufacturers are aware that many drugs remain effective beyond their expiration dates. However, they rarely conduct extension studies due to the associated costs and regulatory barriers. Without legal mandates to extend shelf life, pharmaceutical companies lack incentives to pursue such studies, as expired medications drive sales of replacement products. Some argue that focusing on shelf-life extension may reduce research and development investments and limit access to new drugs.

THE SHELF-LIFE EXTENSION PROGRAM

In response to high medication replacement costs, the FDA and the U.S. Department of Défense introduced the SLEP in the late 1980s. This initiative evaluates stockpiled medications to determine whether their expiration dates can be safely extended. Studies confirm that many drugs remain viable well beyond their original expiration dates, and no adverse effects have been reported from their use.[28] In emergencies, the FDA may authorize the use of expired medications under the Emergency Use Authorization (EUA), particularly for chemical, biological, radiological, nuclear, and explosive (CBRN) threats.[29] Each year the federal government saved USD 600 million to USD 800 million because it did not have to replace expired medication.

Table 1: List of essential drugs and their average extension time.

Drug type	Drug generic name	Average extension time in month (range)
Analgesics	Morphine sulphate (injectable)	89(35-119)
	Fentanyl citrate (injectable)	84(70-96)
	Ketamine Hcl (injectable)	64(42-87)
	Naproxen Tablets	52(46-62)
Antibiotic	Ciprofloxacin (tablets)	89(35-119)
	Doxycycline hyclate (capsules)	84(70-96)
	Cephalexin (capsules)	64(42-87)
	Ceftriaxone (powder)	60 (44-69)
Intravenous fluids	Sodium chloride	50 (12-113)
	Dextrose (5%)	65 (13-128)
	Sodium lactate	53 (20-87)

Source: Lyon et al., 2006; Next Generation Combat Medic, 2018

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Extension greatly depends on the individual drug, its production batch, and its storage conditions (Culbertson et al., 2011).[30] Excluding nitroglycerin, insulin, and liquid antibiotics, most medications are as long-lasting as the ones tested by the military.[31]

CONCLUSION

Given the evidence that many pharmaceuticals remain effective beyond their expiration dates, a globally standardized approach to monitoring, regulating, and repurposing expired medications is necessary. Expanding the shelf life of proven safe drugs could reduce pharmaceutical waste, lower healthcare costs, and improve access to essential medications in underprivileged regions.

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