Expired drugs: statistics, factors and mitigation strategies of med-gate pharmaceuticals and tan pharmacy up to 31/07/2021

David Nyagah^{1*}, Aldress Njagi² and Milcah Nyaga³

¹ Med-gate Pharmaceuticals Limited, Wang'uru, Kenya
² Tan Pharmacy Limited, Embu, Kenya
³ Embu University, Embu, Kenya
Correspondence Author: David Nyagah
Received 19 Mar 2022; Accepted 25 Apr 2022; Published 17 May 2022
DOI: <u>https://doi.org/10.64171/[AES.2.2.09-11</u>

Abstract

Background: Expired drugs are a route to significant financial losses, but most factors leading to expiry are avertable. These drugs should be safely disposed of. This short communication aims to establish the statistics, factors, and mitigation strategies of Med-Gate Pharmaceuticals and Tan Pharmacy up to 31/07/2021.

Methods: Expired drug data were collected utilizing a stock-taking sheet and analyzed by a Point of Sale (PoS) system. Key informant interviews were used to establish reasons for expiry. Content analysis was used to examine qualitative data.

Results: The estimated cost of expired drugs and their disposal amounted to Kenya Shillings 49, 772.49/=. The main reason for expiry was poor stock control practices such as not implementing First in First Out (FIFO), First Expired First Out (FEFO), and overstocking. Landfill and waste encapsulation were the primary methods of disposal.

Conclusions: Implementing good stock control practices such as FIFO and FEFO, quantifying drug needs using morbidity and consumption methods, stock inspection during delivery, not accepting short-dated stocks, and ordering drugs from suppliers that accept return of short-dated stock are highly recommended to minimize wastage through expiry.

Keywords: expired drug, FIFO, FEFO, key informants (KI)

Introduction

An expired item refers to a product that has completed its mandated shelf life by the manufacturer; therefore, it should not be consumed or used as it could be ineffective, contaminated or harmful ^[1]. The expiration date is the period in which a manufacturer assures the stability of the product when stored under specified conditions. Stability factors may include purity, potency, efficacy and quality ^[2]. Use by date is the expected amount of time a drug will be viable for consumption and applies typically to reconstituted, compounded or extemporaneous preparations such as eyedrops, prepared antibiotic mixtures and creams. This date is determined by the Pharmacist/compounder and is labelled on the products' package ^[3].

Drugs expire for several reasons: chemical degradation over time, the interaction of excipients used, adequateness of preservatives, changes in storage conditions, namely light intensity, temperature fluctuations, humidity levels and repackaging, which may lead to exposure to contaminants ^[4]. Facility-related practices may also lead to expiry; this includes; failure to implement FEFO, overstocking, receiving donations that do not align with the facility's needs, communication gap between procurement officer, warehouse manager and supplier, inadequate monitoring system of stock at hand and understaffing ^[5].

The food and drug administration (FDA), through the Shelf-Life Extension Programme (SLEP), conducted the pharmaceutical analysis to determine the efficacy, potency and stability of a sample of expired drugs. The results revealed that some drugs such as ciprofloxacin and morphine sulfate injection were still viable for use up to 15 years after expiry. However, the study showed that it was difficult for consumers and healthcare providers to identify drugs with an extended shelf life ^[4]. It is imperative not to use expired drugs before conducting pharmaceutical analysis or to avoid them due to the following risks: disease progression, infection causation, toxicity and allergies. Such drugs include insulin and biological products ^[4, 6].

Expired drugs lead to loss of revenue through combating effects experienced by the patient, loss of stock and disposal costs incurred by health facilities and suppliers. Alen (2017) reported that hospitals in the United States of America (USA) discard drugs worth \$800 million annually ^[7]. Minimising losses through expiry can be managed by implementing a better stock management system which includes FIFO, FEFO, regular stock takes, procuring drugs according to the facility needs, bridging the communication gap ^[8]. Expired drugs are considered pharmaceutical waste; hence they should be disposed of safely adhering to disposal guidelines from regulatory bodies. Disposal methods vary based on the dosage form and pharmacologic class. They include landfill, encapsulation, incineration ^[9].

Methods

Med-gate Pharmaceuticals Limited was established in 2019 and has a strong track record in pharmaceutical distribution and retailing. Established in 2019, Tan Pharmacy limited is a Page | 9 consulting, compounding and homecare pharmacy based in Embu town, Embu County. With over 1000 clients spanning five counties, the companies established a Central Purchasing Unit (CPU) in Wangu'uru, Kirinyaga County.

Due to large stockpiles in the CPU, the companies work hand in hand to curb the loss of merchandise through expiry. Regular physical stock checks and analysis of alerts by the point of sale (PoS) system notify employees of short-dated stock. Under the guidance of the PPB and mentorship of the PSK, the companies have been vigilant in sensitising patients, clients and the community to handle and dispose of expired drugs. Data was collected from July 2020 to July 2021 through quarterly and bi-monthly stock checks in the CPU and outlets, respectively, utilising stock take sheets. This data was fed into the company's PoS system to establish the source, receipt date and value of expired drugs. Purposive sampling sampled Key Informants (KI). KI interviews were conducted with the procurement officer, two warehouse managers and two retail outlet superintendents to determine the reasons for expiry. Responses were transcribed and analysed through content analysis. The PPB pharmaceutical waste management guidelines were used in the disposal ^[10].

Results

Table 1: List of expire	d medicine indicating the o	uantity, total cost, reasons	and methods of disposal

Item name	Quantity	Price	Exit price	Reasons	Method of disposal
Maxitrol drops 5ml	4	180.00	720.00	Ordering currently expensive items in bulk	Waste encapsulation
Erythromycin tablets 500mg	213	5.40	1 150.20	Overstocking	Landfill
Tuspress 100ml	2	118.90	237.8	Poor stock control system-not implementing FIFO/FEFO	Waste encapsulation
Tuspress 60ml	3	82.38	247.14	Poor stock control system-not implementing FIFO/FEFO	Waste encapsulation
P Alaxin Suspension 80ml	2	194.00	388.00	Disease no longer prevalent in the region	Incineration
Vegon 50mg tablets	8	6.50	52.00	Receiving short-dated stocks	landfill
Febrex Plus syrup	1	110.00	110.00	Preference of Cheaper alternatives	Waste encapsulation
Nextcal-d tablets	30	5.00	150.00	Unwanted donation	Landfill
Recartix-Forte tablets	1	57.00	57.00	Slow-moving product	Landfill
Reunite tablets	20	54.80	1096.0	Late stock delivery	Landfill
Ivermectin tablets 3's	2	135.00	270.00	Overstocking	Landfill
Ascoril Exp 100ml	1	166.00	166.00	Poor stock control system-not implementing FIFO/FEFO	Waste encapsulation
URS_10T strips	1	600.00	600.00	Stock arrangement-item placed in the wrong section	Waste encapsulation
Betamed cream	8	36.00	288.00	Overstocking	Waste encapsulation
Cefuroxime 125mg/5ml	1	220.00	220.00	Slow-moving product	Waste encapsulation
Erythromycin 60ml	89	37.00	3 293.00	Late stock delivery	Waste encapsulation
Aurocal Dm eye drops	6	72.00	432.00	Overstocking	Waste encapsulation
Panadol Baby Suspension 100ml	1	205.00	205.00	Overstocking	Waste encapsulation
X-beta n eye/ear drops	4	48.50	194.00	Poor stock control system-not implementing FIFO/FEFO	Waste encapsulation
Momate ointment	3	455.00	1 365.00	Preference for Cheaper alternatives	Waste encapsulation
Dobesil_H Ointment	1	665.00	665.00	Poor stock control system-not implementing FIFO/FEFO	Waste encapsulation
Zupricin B Ointment	1	477.00	477.00	Poor stock control system-not implementing FIFO/FEFO	Waste encapsulation
Choice-72 tablets	9	17.15	154.35	Receiving short-dated stocks	Landfill
Calcigard retard tablets	1 400	1.00	1 400.00	Preference of Cheaper alternatives	Landfill
Cephalexin 250mg capsules	5 040	2.30	11 592.00	Overstocking	Landfill
Thiovent 100ml	1	88.00	88.00	Poor stock control system-not implementing FIFO/FEFO	Waste encapsulation
Lawash Intimate Hygiene 100ml	5	252.00	1 260.00	Medicine takes too long to be replenished	Waste encapsulation
Domi Suspension 30ml	1	68.00	68.00	Poor stock control system-not implementing FIFO/FEFO	Waste encapsulation
Brimochek-T drops 5ml	3	490.00	1 470.00	Poor coordination between warehouse management and procurement officers	Waste encapsulation
Co_Amoxiclav 375 tablets	50	9.27	463.50	Poor stock control system-not implementing FIFO/FEFO	Landfill
Tinilox MPS Suspension 100ml	1	165.00	165.00	Preference of Cheaper alternatives	Waste encapsulation
Tofen 100ml	3	220.00	660.00	Ordering currently expensive items in bulk	Waste encapsulation
Amoxicillin 250mg 1000's tablets	1 000	0.89	890.00	Poor stock control system-not implementing FIFO/FEFO	Landfill
Cotrimoxazole 480mg tablets	1	28.50	28.50	Poor stock control system-not implementing FIFO/FEFO	Landfill
Aurocal Dm Eye drops	1	72.00	72.00	Receiving short-dated stocks	Incineration
Casodex 50mg	28	285.0	7980.00	Slow-moving product	Incineration
Augmentin 1gm	14	157.0	2198.00	Preference of Cheaper alternatives	Landfill
Cardiocare	60	65.00	3900.00	Poor stock control system-not implementing FIFO/FEFO	Landfill
Subtotal			44,772.49	· · · ·	
	Cost of d	isposal	5,000.00		
Total		_	49,772.49		

Conclusions

The value of expired drugs and their disposal amounted to an estimate of KES. 49,772.49. The cost of disposing of expired drugs was high, primarily where waste encapsulation was used. Most medicines expired due to insufficient stock control practices such as not implementing FIFO/FEFO, overstocking and ordering items currently expensive in bulk. Wastage through expiry is bound to increase if the companies do not follow strict pharmaceutical waste minimisation practices recommended by the PPB.¹⁰ These include; stock inspection during delivery, avoid receiving short-dated stocks from medical representatives, suppliers or donors, ordering drugs from manufacturing companies that accept return of shortdated stock and implementing good stock control practices such as FIFO and FEFO. The WHO⁸ recommends that expensive drugs wait until the next order if buffer stock is available. An overstocked premise has a risk of short-dated stock. To counter overstocking, drug needs should be estimated using these WHO-recommended methods; morbidity and consumption method. Thus, precise consumption data should be available and obtainable. The company should also invest in better stock management systems and improve communication between the warehouse management and procurement officers. Cooperation from all stakeholders is highly recommended to minimise wastage through expiry. These statistics are the first of their kind for communication and future knowledge.

Acknowledgements

The authors would like to thank the participants for their valuable input.

Declaration of conflict of interest

The authors declare no conflict of interest.

Funding declaration

No funding source is to be declared.

Ethics declaration

None.

References

- 1. Tardi C. Expiration Date. Investopedia, 2021. https://www.investopedia.com/terms/e/expirationdate.asp (accessed 12 May 2021).
- United States Food and Drug Administration. Expiration Dates - Questions and Answers. The United States of America, 2018. https://www.fda.gov/drugs/pharmaceutical-qualityresources/expiration-dates-questions-and-answers (accessed 10 May 2021).
- 3. National Health Service. Why do medicines have expiry dates? The United Kingdom, 2020. https://www.nhs.uk/common-healthquestions/medicines/why-do-medicines-have-expirydates/ (accessed 16 June 2021).
- Anderson AL. Drug Expiration Dates Are Expired Drugs Still Safe to Take? Drugs.com, 2021.

https://www.drugs.com/article/drug-expiration-dates.html (accessed 2 July 2021).

- Gabremariam ET, Gebregeorgise TD & Fenta GT. Factors contributing to medicines wastage in public health facilities of South West Shoa Zone, Oromia Regional State, Ethiopia: a qualitative study. Journal of Pharmaceutical Policy and Practice, 2019, 12(29). https://doi.org/10.1186/s40545-019-0192-z
- Entertainment Times. What happens to your body when you consume expired medicines. Times of India, India, 2020. https://timesofindia.indiatimes.com/lifestyle/health-fitness/health-news/what-happens-to-yourbody-when-you-consume-expiredmedicines/articleshow/74824996.cms(accessed 14 August 2021).
- 7. Allen M. That Drug Expiration Date May Be More Myth Than Fact. NPR, 2017. https://www.npr.org/sections/healthshots/2017/07/18/537257884/that-drug-expiration-datemay-be-more-myth-than-fact (accessed 5 May 2021).
- World Health Organization. Practical Pharmacy for Developing Countries. Hai Africa, 2010; 21:1-10. http://origin.who.int/management/resources/drugs/practic alpharmacy21b.pdf (accessed 5 August 2021).
- Nyagah DM, Njagi A, Nyaga MN. Pharmaceutical waste: overview, management and impact of improper disposal. Journal of Peerscientist, 2020; 3(2):e1000028. https://doi.org/10.5281/zenodo.4088224.
- Pharmacy and Poisons Board. Guidelines for the safe management of pharmaceutical waste. Pharmacy and Poisons Board, Nairobi, 2018; 1(1):1-21. https://pharmacyboardkenya.org/files/?file=Safe_manage ment_of_pharmaceutical_waste_guidelines.pdf (accessed 20 May 2021).