



Drugs Expiration Date Dilemma!

Padideh Ghaeli^{1*}

¹ Professor of Clinical Pharmacy, Faculty of Pharmacy and Roozbeh Hospital, Tehran University of Medical Sciences, Tehran, Iran.

ARTICLE INFO

Article type:
Editorial

J Pharm Care 2014; 2 (1): 1-2.

► Please cite this paper as:

Ghaeli P. Drugs Expiration Date Dilemma!. J Pharm Care 2014; 2(1): 1-2.

A law passed in 1979 by the Food and Drug Administration (FDA) required all drug manufacturers to provide the expiration dates on their products (1). The Expiration date of a drug is given based on its stability in its original container and shows the time over which the potency and integrity of a drug in its sealed container are intact. Several factors, including types of the active and inactive ingredients as well as the storage conditions, can influence the expiration date of a drug. Drug companies would guarantee the safety as well as the full potency and stability of any of their products up to the expiration date noted on that product. It is important to note that the expiration date provided on the sealed container does not apply after the container is opened. Therefore, the expiration date of most drugs does not necessarily show their instability, ineffectiveness or lack of safety after that date.

There have been questions and discussions on the accuracy and truthfulness of drug expiration dates that are given by drug manufacturers. It has been even speculated that the labelled expiry dates given by the industries are another way to sell more drugs despite the stability of drugs beyond their printed expiry dates. Even though it has been reported that the actual shelf lives of many drugs are longer than their printed expiration dates (2), some

medications may harm patients if taken after this date. For example, consumption of tetracycline, an antibiotic with a broad spectrum, has been specifically mentioned to be dangerous if used after its expiration date.

A joint program, called Shelf Life Extension Program (SLEP), has been administered by the U.S. Department of Defense (DoD) and U.S. Food and Drug Administration (FDA) to test medications in a controlled condition for their safety and stability for an extended period of time (3). This program has found that most of the tested medications would remain stable and effective beyond their expiration dates and some even for years past the printed date on the products.

It is important to note that drugs differ in terms of their forms, dosage, and stability. Usually, drugs in liquid forms (e.g. solutions and suspensions) are not as stable as those in the solid forms (e.g. tablets and capsules). For example, it has been reported that bioavailability of EpiPen® (epinephrine auto-injectors) were reduced when administered between 1 to 90 months after the labelled expiration date compared with those that were not yet expired (4). Interestingly, the expired auto-injectors in that study were not discolored and did not contain precipitates.

It should be kept in mind that improper storage of a medication (e.g. exposure of a medicine to oxygen, light, heat, and/or humidity) may result in losing its full potency and/or safety before the printed expiration time on that product. For example, nitroglycerin should not be exposed to light. Another familiar example is the storage of medications by many people in their medicine

* Corresponding Author: Dr Padideh Ghaeli

Address: Professor of Clinical Pharmacy, Faculty of Pharmacy and Roozbeh Hospital, Tehran University of Medical Sciences (TUMS), Tehran, Iran, Postal Code: 13337-95914. Tel:+982155412222, Fax:+98215541-9113.

E-mail: mmppg@yahoo.com

cabinet at their bathrooms. However, the high humidity of the bathrooms can result in a quicker breakdown of drugs.

In summary, if a patient is in a situation when there is no other choice except for taking an outdated medication that has been kept under proper conditions, that drug may work. However, despite the fact that expired drugs may not be dangerous in most cases, they still can cause harm. It is wise to pay attention to the expiration dates seriously in patients who rely on medications for life threatening illnesses such as cardiovascular diseases. Besides, expiry dates of drugs become very important in many cases when patients have to take medications that are fully stable and effective. For example, certain drugs such as insulin, epinephrine auto-injectors, nitroglycerine, vaccines, as well as blood and biological products may be susceptible to degradation or loss of potency after their expiration

dates. Additionally, tetracycline safety is questionable after its expiration date. It should also be kept in mind that medications that are disintegrated, have a strong smell or are dried up (e.g. tubes of cream or ointment) should not be used.

References

1. CFR Code of Federal Regulations Title 21. US Food and Drug Administration website. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrcfr/CFRSearch.cfm?fr=211.137>
2. American Medical Association. "Pharmaceutical Expiration Dates." Report 1 of the Council on Scientific Affairs (A-01). July 25, 2001. Accessed November 18, 2011. <http://www.ama-assn.org/resources/doc/csaph/csaa-01.pdf>
3. Anon. Drugs Past Their Expiration Date. *Med Lett Drugs Ther* 2009; 51:101-2.
4. Simons FE, Gu X, Simons KJ. Outdated EpiPen and EpiPen Jr autoinjectors: past their prime? *J Allergy Clin Immunol* 2000;105:1025-30.