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Drug Expiration Dates
Patients often have questions about drug expiration dates: Can they take a medication if it has reached the drug expiration date? Are there recommendations about the best way to store medications? Are there certain drugs that should never be used past their expiration date? For many patients, these questions arise because medications can be expensive, and it is costly to frequently replace expired but unused medications.

What does an expiration date mean?
The expiration date is the final day that the manufacturer guarantees the full potency and safety of a medication. Drug expiration dates exist on most medication labels, including prescription, over-the-counter (OTC) and dietary (herbal) supplements. U.S. pharmaceutical manufacturers are required by law to place expiration dates on prescription products prior to marketing. For legal and liability reasons, manufacturers will not make recommendations about the stability of drugs past the original expiration date.1

The expiration date of a drug is estimated using stability testing under good manufacturing practices as determined by the Food and Drug Administration (FDA). Drug products marketed in the US typically have an expiration that extends from 12 to 60 months from the time of manufacturer. Once the original container is opened, either by the patient or the health care provider who will dispense the drug, that original expiration date on the container can no longer be relied upon.2 However, the actual shelf life of the drug may be much longer, as stability studies have shown.3

At the pharmacy, "beyond-use" dates are often put on the prescription bottle label given to the patient. These dates often say "do not use after..." or "discard after..." and are required by the Board of Pharmacy in many states. These dates are typically one year from the date on the stock bottle. But why would these expiration dates be different? According to the manufacturer, the stability of a drug cannot be guaranteed once the original bottle is opened. Therefore, the United States Pharmacopeia (USP), the body that sets the standards for pharmaceutical quality in the U.S., recommends using "beyond use" dates. The "beyond use" date would never be later than the expiration date on the manufacturer's bottle.4

Do expired medications lose their potency?
The American Medical Association (AMA) concluded in 2001 that the actual shelf life of some products is longer than the labeled expiration date. The AMA stated the best evidence resides in the Shelf Life Extension Program (SLEP) undertaken by the FDA for the Department of Defense.5 The original purpose of the SLEP program was twofold: to determine the actual shelf life of stockpiled military medications for future use, and to save government dollars.5 Over 3000 lots, representing 122 different drug products, were assessed in the SLEP program. Based on stability data, expiration dates on 88 percent of the lots were extended beyond their original expiration date for an average of 66 months. Of these 2652 lots, only 18 percent were terminated due to failure. Examples of common drug
products that were tested with no failures included amoxicillin, ciprofloxacin, diphenhydramine, and morphine sulfate injection. Drug expiration extension dates on these products ranged from 12 to 184 months.

These results suggest that many drug products may have extended shelf lives beyond their expiration date. However, it is difficult for any one consumer or health care provider to know which product could have an extended shelf life. The ability for a drug to have an extended shelf life would be dependent upon the actual drug ingredients, presence of preservatives, temperature fluctuations, light, humidity, and other storage conditions. Additionally, the drug lots tested in the SLEP program were kept in their original packaging. Once a drug is repackaged into another container, as often happens in the pharmacy, the shelf-life might decline.3

Is it safe to take expired medications?
There are no specific reports linking expired medication use to human toxicity. In 1963, a report was published that tied degraded tetracycline use with a form of renal tubular damage known as "Fanconi Syndrome"; however, that formulation of tetracycline in no longer marketed in the U.S.1

Solid dosage forms, such as tablets and capsules, appear to be most stable past their expiration date. Drugs that exist in solution or as a reconstituted suspension, and that require refrigeration (such as amoxicillin suspension), may not have the required potency if used when outdated. Loss of potency can be a major health concern, especially when treating an infection with an antibiotic. Additionally, antibiotic resistance may occur with sub-potent medications.

Drugs that exist in solution, especially injectable drugs, should be discarded if the product forms a precipitant or looks cloudy or discolored.1 EpiPen autoinjectors should not be used after the expiration date as the epinephrine has been shown to lose its potency.1 EpiPens are used in life-threatening situations like anaphylaxis, so there is a major health threat with an expired EpiPen.6 Expired medications that contain preservatives, such as ophthalmic (eye) drops, may be unsafe past their expiration date.1 Outdated preservatives may allow bacterial growth in the solution.

Insulin is used to control blood sugar in diabetes and may be susceptible to degradation after its expiration date. Oral nitroglycerin (NTG), a medication used for angina (chest pain), may lose its potency quickly once the medication bottle is opened. Vaccines, biologicals or blood products could also be subject to quick degradation once the expiration date is reached. If a patient finds a medication is powdery or crumbling, has a strong smell, or has dried up (as in the case of or ointments or creams), these drugs should be discarded.7

Proper storage of medications may help to extend their potency. The bathroom and medicine cabinet are not ideal places to store medications due to heat and humidity. Similarly, medications should not be left in a hot car. Medications remain most stable in dry, cool spaces away from light. Keep the prescription bottle caps tightly closed and always keep medications out of reach of children and pets.

What is the bottom line?
Should patients use expired medications or not? If a medication is needed, and the patient
is not able to replace the expired medication, there is no evidence that it is unsafe to take the medication in most cases. However, if a medication is essential for a chronic and potentially life-threatening disease, for example, a heart condition, seizure, or life-threatening allergy, it is probably wise to get a new prescription once expired.

If an expired medication is for a minor health problem, for example, for a headache, hayfever, or mild pain, it may also be safe to take it, although drug potency might not be 100 percent. Research has shown many military stockpile medications retained 90 percent of their potency in their original stock bottle. However, storage conditions of these medications were optimized for temperature and humidity, and probably do not mimic the typical storage conditions of the average household prescription bottle.

If an expired medication is taken, and the patient notices the drug has limited or no therapeutic effect, the medication should be replaced. If the medication is a biologic product, insulin, EpiPen, refrigerated liquid, eye drop, injectable, or looks like it is degraded or cloudy, it should be discarded and replaced. If questions still remain about how to handle an expired medication, it is wise to speak with your pharmacist or physician, who can offer additional information and advice.

References

Last updated: 2012-12-28 by Leigh Anderson, PharmD.