

## Are Expired Medicines Safe to Consume?

**Bharati K\***

Health Policy Consultant-UNESCO, India

**\*Corresponding author:** Kaushik Bharati, Health Policy Consultant-UNESCO, India, Tel: +91-9910331170, Email: dr.kaushik.bharati@gmail.com

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### Abstract

There is much speculation and controversy about the utility of expiry dates on medicines. Questions about the quality of the drug after it crosses its expiry date and whether its pharmacological potency is as good as before are common in the minds of the general public. There are also scientific aspects that need to be addressed. These include drug stability, formulation, packaging, manufacturing date, among others. Other aspects of expired drugs that provide important clues on whether they can be consumed include the color of the tablets, their brittleness, glossiness, cloudiness in case of liquid formulations, and whether they were stored at the correct temperature and humidity. These are the major aspects that have been explored in the article in order to answer the question on whether expired medicines are safe for consumption.

### Introduction

Expiry dates on medicines ensure that they are safe to take by patients. The practice of labelling medicines with the expiry date started in 1979. By stating the expiry date, the drug manufacturer guarantees that the medicine will have full potency and be safe to take until that date. Additionally, even after reaching the expiry date, the medicine should still exhibit 90% of its original potency, when stored at standard conditions.

It is mandatory that all medicines must contain 90-100% of the active ingredient that is stated on the label. It takes around 1 to 5 years for a drug to expire from its date of manufacture. Since there is no stringent requirement for a pharmaceutical company to determine the potency of a drug after its

expiry date, this allows them flexibility to fix the expiry dates without having to conduct long-term drug stability studies. This means that the pharma company only has to provide evidence that the drug will maintain full-potency till the expiry date, which it chooses to fix. Importantly, it should be kept in mind that the expiry date doesn't in any way indicate that the drug will become ineffective and lose all of its potency as soon as the expiry date is reached. This hints at the fact that the medicine won't be harmful to take upon expiry.

### Expired Medicines can Sometimes be Useful

In certain circumstances, expired medicines may need to be taken, such as when there is no other

alternative or when there are financial constraints. It has been scientifically shown that epinephrine, injected by EpiPen auto-injectors still retains its potency even after reaching the expiry date. Based on these observations, it is now recommended that expired EpiPens may be used, when unexpired ones are not available. However, it should be checked that there is no precipitate formation or discoloration of the epinephrine solution contained in these EpiPens. This recommendation is based on the fact that the benefits far outweigh the risks. This is because epinephrine having a lower potency is better than no epinephrine at all, as it can be life-saving in certain situations.

### Scientific Studies on Expiry Date vs Potency

A drug doesn't lose its potency as soon as the expiry date is reached. Actually, its potency starts to decline from the date of manufacture and is in no way dependent on the expiry date. In fact, the expiry date is established on the basis of the manufacturing date, till the time its shelf-life stability is tested by the drug manufacturer.

Several scientific studies have established beyond doubt that the potency of a drug remains intact even after the expiry date. Two such studies are highlighted below:

- A study from USA found that 12 out of 14 drugs retained full potency even after 28 years post-expiry. Astoundingly, out of the 12 drugs, 8 of them retained their full potency up to a staggering 40 years after expiry!
- Another drug-stability study was conducted by the Shelf-Life Extension Program (SLEP) of the US Department of Defense. This study found that out of 122 different drugs kept under standard storage conditions, as per military specifications, 107 (88%) had their expiry

dates extended by more than a year, with an average extension of more than 5 years, and a maximum extension of 23 years.

### Drug Stability

As a general rule of thumb, medicines in liquid form are much less stable than those in solid form, such as tablets or capsules. It should be noted that drug stability is greatly decreased upon exposure to sunlight, high humidity, oxygen, and temperature fluctuations. Consequently, medicines are always labelled that they should be stored in a cool and dry place. This significantly increases the shelf-life of the drug.

### Expired Medicines: Safety and Toxicity Issues

It is commonly believed that expired medicines are unsafe and toxic. However, there is a dearth of scientific evidence to support this belief. In fact, till date, there is only one reliable scientific publication, which has reported that expired medicines can be unsafe and toxic. This particular paper documented that degradation products arising from expired tetracycline gave rise to Fanconi syndrome, which is characterized by reversible renal tubular damage. Although there is a lack of evidence on the deleterious effects of expired medicines, it should be kept in mind that very little research has been conducted on the toxicity of expired drugs.

### Expiry Date is Critical for Certain Drugs

Certain drugs have a narrow therapeutic index, meaning that the pharmacological activity of these drugs is optimal within a very narrow range. Thus, the correct dosage is vital, as otherwise there may be severe clinical consequences, which can be life-threatening in certain cases. Therefore, the expiry date of these drugs should be strictly adhered to.

Some of these drugs include digoxin, warfarin, theophylline, insulin, nitroglycerin, paraldehyde, phenobarbital, thyroid hormones, procainamide, anticonvulsants, oral contraceptives, and ophthalmic solutions. Besides these, antibiotics should also be taken before the expiry date, as otherwise, antibiotic resistance will inevitably emerge.

### Is there a Commercial Angle to Expiry Dates?

It is believed by some people that the use of expiry dates on medicines could lead to financial gains for pharma companies, as this will compel patients to buy new medicines and discard the old ones, thereby making them rich at the expense of poor patients.

Although this is one way of looking at the dilemma, there is also another way. Expiry dates are highly conservative, so that the full potency of the drugs is ensured. Importantly, if pharma companies had to carry out drug-stability and shelf-life studies longer than the usual 2-3 years, it would significantly slowdown their pipeline of new drugs, having improved formulations. Keeping in mind that a single drug molecule requires at least 12 years to develop, this would lead to stagnation in the drug-development pipeline, thereby halting the production of new drugs. This could prove to be disastrous for life-saving drugs, such as antibiotics, which are fast-becoming resistant and therefore need to be urgently replenished by newer and improved ones.

### Factors to be Considered Before Taking Expired Medicines

Before deciding to take expired medicines, the following factors should be taken into consideration:

#### Appearance of the Medicine

Whether to take or not take the medicine, relies heavily on its appearance. It would be prudent to avoid taking an expired medicine if the following are observed:

- If a tablet is brittle, discoloured, or has lost its glossiness (in case of coated tablets)
- If an injectable drug is cloudy or a precipitate is seen at the bottom of the vial
- If an ophthalmic solution has become cloudy (indicative of microbial contamination)

#### Length of Time from Manufacturing Date

The potency of the drug will be higher if it is used nearer to the manufacturing date.

#### Storage Conditions

Storage at optimal conditions, as recommended by the drug manufacturer, is crucial for ensuring the stability of the drug. The stability of the drug will be significantly higher if it is stored in a cool and dry place and remains unopened.

#### Type of Packaging

The stability and longevity of a drug also depends on the type of packaging used. Thus, airtight strips/blister packs of tablets or capsules will remain much more stable and will be preserved for far longer periods than if they are kept in a screw-capped container.

#### Formulation

Correct formulation of the drug will ensure that it remains stable for longer periods of time. In general, solid formulations are far more stable than liquid formulations.

### Expired Medicines – To Take or Not to Take, that is the Question!

Thus, based on the foregoing discussion, what

should be the “bottom line” or “take home” message? Should we take an expired medicine or not? It is now quite clear that expired medicines are not as harmful as is usually believed. Their potency remains at almost 90% of the original potency at the time of manufacture. Hence, it may be advised that in case of common symptoms, such as headaches, constipation, stomach cramps, muscle spasms, sprains, and similar mundane symptoms, expired medicines could be taken, as none of these are life-threatening. However, for life-threatening conditions, for which 100% potency is a must, it would be wise to take new medicines instead of expired ones. This is evidently because “*it’s better to be safe than sorry*”.

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