Expiration dates of drugs can be a confusing subject in the pharmacy. There are a lot of reasons for this, including the more specific terminology that’s been introduced in recent years, and the wide variations in the “rules” for different types of drug products. In this Technician Training Tutorial, we’ll sort it all out.

Barbara Dawes, a 58-year old female patient, comes in with the following Rx.

You fill the prescription with the Xalatan 2.5 mL bottle, which you retrieved from the refrigerator.

What does a manufacturer’s expiration date, or just expiration date, mean?

An official definition of the manufacturer’s expiration date is the “date beyond which ideally stored medications in the unopened manufacturer’s storage container or in most circumstances, the opened and intact manufacturer’s storage container, should not be used.” The United States Pharmacopeia (USP), says that the expiration date is “the time during which the article may be expected to meet the requirements of the pharmacopeial monograph provided it is kept under the prescribed conditions.” This refers to qualities like safety and potency of the drug.

An example of a manufacturer’s expiration date is the date that’s printed, usually along with the lot number and manufacturer, on a stock bottle of medication, on a box containing a pre-filled syringe, on a tube containing topical medication, etc.

The manufacturer’s expiration date can be expressed as a month and year, or as a day, month, and year. If just the month and year are indicated, the drug can be used or dispensed until the last day of that month. For example, if the expiration date is written as 05/11, the drug doesn’t actually “expire” until May 31, 2011.

How is the manufacturer’s expiration date determined?

Most drugs get an expiration date of two to three years from the time of manufacture. This doesn’t mean that the drug “goes bad” after the expiration date, or even that it’s any different at the time of expiration than it was immediately after it was manufactured. The drug company just has to be sure that, at the assigned expiration date, the drug still meets requirements for safety and potency. For example, a drug might be good for ten years or even for infinity. But if the manufacturer gives the drug an expiration date of three years, they just have to make sure that it’s still good at three years.
What is a “beyond-use date”?

An official definition for beyond-use date is the “date beyond which medications that have been manipulated and/or repackaged and stored or dispensed in a container other than the original manufacturer’s storage container should not be used.”

Here are some examples of beyond-use dates:

- The date that you would indicate on a reconstituted antibiotic’s labeling, past which the drug should not be used. For instance, *Amoxicil* suspension is good for 14 days after it’s mixed.
- The date that’s written on the label of an IV piggyback that you prepared, after which the piggyback should be discarded. For instance, IV gentamicin is usually good for seven days after a dose is mixed in normal saline (refrigerated).
- The “expiration” date that’s put on the label of a tablet that’s been unit-dosed from a bulk bottle. For instance, you will usually give a unit-dosed tablet a beyond-use date of one year after it’s packaged, if the manufacturer’s expiration date doesn’t come before then.

Generally, the term “beyond-use date” is appropriate for a product that has been dispensed. The beyond-use date takes into account things like how long a drug is stable after it has been mixed in a certain way (i.e., reconstituted or compounded medications) or stored under certain conditions (e.g., room temp, refrigerated, frozen, etc), and how long a drug can be expected to remain sterile (e.g., prepared IV admixtures, compounded eye drops, etc).

Will I ever see drugs without expiration dates?

You might, especially if you work in a hospital. Investigational drugs are a good example for this. Testing for stability and potency are usually ongoing and the shelf-life might not be established yet when drugs are in the investigational phase. A really current and more specific example is the IV peramivir that’s being used to treat U.S. hospitalized patients with H1N1. Of course it’s still investigational, and there’s not an expiration date on the vials. However, FDA is providing information on how long the vials can be used, based on lot number.

That being said, if you dispense a drug without an expiration date, you will probably still need to give it a beyond-use date. For example, peramivir doses are only good for 24 hours once they’ve been mixed.

How do I know what beyond-use date to give a drug?

Really, most products that you dispense will require a beyond-use date. Exceptions to this include many topicals, ophthalmics, otics, nasal sprays, and inhalers. These can be used up to the manufacturer’s expiration date. However, in the U.S. there are a few inhalers that have beyond-used dates shorter than the manufacturer’s expiration dates. One example is *Advair Diskus*, which is only good for one month after the foil overwrap is removed. We list these U.S. products in our Detail-Document, “Shortened Expiration Dating of Some Inhalation Products.”

There are also some U.S. topicals (e.g., benzoyl peroxide/clindamycin gel [*Duac*-two months, etc) and ophthalmics (i.e., azithromycin [*Azasite*-14 days, latanoprost [*Xalatan*-six weeks) that require beyond-use dates once they’re removed from the fridge and dispensed. These beyond-use dates can be found in the package insert. We have more on this in our chart, “Stability of Refrigerated and Frozen Drugs” (241001 [U.S. subscribers] or 241014 [Canadian subscribers]). We also have a Technician Training Tutorial, “Handling Refrigerated Drugs and Vaccines.”

The state where you work will determine the beyond-use date for most unit doses or prescription bottles of tablets or capsules. Usually, the rule is one year from the date of dispensing or the manufacturer’s expiration date, whichever comes first. For example, if you prepare an Rx for *Lasix* tablets on 02/01/10 and the tabs you are using expire on 10/31/10, you would make the beyond-use date 10/31/10 since it is SOONER than 02/01/11 (or one year from the date of dispensing).

Reconstituted products, either oral or parenteral, will have beyond-used dates specified by the manufacturer. These beyond-use dates can be found in the package insert. We also have more on this,
including information for storage conditions other than those specified by the manufacturer in our chart, “Pediatric Oral Antibiotic and Antifungal Suspensions and Liquids,” (231107 [U.S. subscribers] or 231122 [Canadian subscribers]).

Don’t forget about injectables (e.g., insulin, some neuromuscular blockers used in U.S. hospitals like cisatracurium [Nimbex]-21 days, rocuronium [Zemuron]-60 days, etc), that must be given beyond-use dates once they are removed from the fridge. This information can be found in the package insert for the product.

General guidelines for non-sterile compounded products are provided by what’s called USP Chapter 795. Here are the general rules for maximum recommended beyond-use dates for non-sterile compounded drug products:

Nonaqueous (don’t contain water) liquid and solid formulations: Six months maximum. (If the source of the ingredient(s) is a manufactured drug product, the beyond-use date is not later than 25% of the time remaining until the original product’s expiration date, or six months, whichever is earlier. If the source of the ingredient(s) is a USP or NF substance, the beyond-use date is not later than six months.) Examples of this might be preparing capsules from a dry powder or mixing two ointments together to make one product.

Water containing formulations: When prepared from ingredients in solid form, the beyond-use date should be not later than 14 days when stored at cold temperature. An example of this might be a pediatric oral suspension reconstituted with water.

All other formulations: Maximum of 30 days. (The beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.)

When you prepare a compound from a recipe, this information will usually be given to you. For more information, take a look at our Technician Training Tutorial, “Non-Sterile Compounding.”

General guidelines for sterile compounded products are provided in USP Chapter 797. It’s a bit complicated, as the beyond-use dates are based on different factors, including how soon a product will be used, the route of administration (e.g., epidural, intravenous, etc), and the conditions under which it will be stored. Know and follow your pharmacy’s policy on beyond-use dating for sterile compounded products.

Beyond-use dates also apply to vials of sterile medications that have been opened. This information also comes from USP Chapter 797. Know and follow your pharmacy’s policy on dating opened medication vials.

In addition to the “for use in the eye” sticker, you add an auxiliary label to Barbie’s Xalatan box, careful not to cover up any of the information on the label. This auxiliary label reminds her not to use the drops after 02/14/10, which is six weeks after the date of dispensing.

Are there other considerations for products with short beyond-use dating?

Make sure that when you dispense a product, it’s good long enough for the patient to complete the full course of therapy. In some cases, you may have to strategize to make this happen. For example, a patient could have a prescription for a reconstituted antibiotic that is good for ten days, while the prescriber has written for the patient to receive the drug for 14 days. You might need to reconstitute one bottle for dispensing, and dispense the other bottle without reconstituting it. (In this case, the pharmacist would give very specific instructions for the patient to reconstitute the suspension at home, after the first bottle has been used up.) Or, the patient might need to come back after the first bottle is finished to get the second bottle. If you’re not sure how to handle this, ask your pharmacist.

What if patients ask if they can use expired meds?

Again, drugs past their expiration dates don’t just “go bad.” In fact, harm from taking expired drugs has only been linked to degraded tetracycline. There are rare reports of kidney damage in patients who took outdated tetracycline in the 1960s. Tetracycline products have since been reformulated and the
Stability of tetracycline appears to have been improved. Current tetracycline products do not seem to cause this problem.

Refer patients who ask if they can use meds past the expiration or beyond-use date to the pharmacist. The answer might depend on a variety of factors, including how the drug was stored, how it was handled, how far past the expiration or beyond-use date it is, and any additional information that’s available on the stability of the drug past the expiration or beyond-use date from the manufacturer or other references.

One of the rare examples of when a drug is actually recommended for use past its manufacturer expiration date is Tamiflu (oseltamivir) oral suspension for H1N1 flu. Certain lot numbers were recently given extended expirations by FDA. We have these on our website in a chart, “Tamiflu Expiration Date Extension.”

When Barbie comes in later in the day to pick up her Xalatan, the pharmacist tells her she will need to throw away whatever is left in this bottle and come back for a new one in six weeks. Barbie pulls the Xalatan box out, and regards both the beyond-use date and the manufacturer’s expiration date on the box. Barbie says, “I got laid off from my job and I’m freelancing now…so I lost my insurance and I’m paying cash. At 85 bucks a pop, I’d hate to throw any of this stuff out. In fact, it would be fantastic for me if I could just get it every other month. Is there any way I could eek out an extra two weeks?”

The pharmacist does a quick calculation of how many drops are actually in the 2.5 mL bottle. There are about 80 drops. Then he looks at the Pharmacist’s Letter chart “Stability of Refrigerated and Frozen Drugs.” There’s no information to suggest that the drug should be used after six weeks.

The pharmacist tells Barbie, “You know, I’d love to tell you to use up every last drop. But I can’t guarantee that it’s safe, so you will need to come back for a new bottle in six weeks. Let’s take a look through your other medications and see if we can save you money some other way, a way that we know is safe for you!”

What are some strategies for avoiding dispensing expired drugs or drugs with short expiration dates?

Your pharmacy, whether in the retail or hospital setting, probably has a policy or practice to rotate stock so that the oldest stock gets used up first. Otherwise, new stock would get used up as it comes in and the old stuff would just sit in the back getting even older and closer to its expiration date.

The specific policy or practice at your workplace will likely depend on your wholesaler’s policy. Generally, the wholesaler will accept returns of products that are within a certain window, say three months, from expiring.

Here are some really general strategies that you might be able to incorporate at your workplace if you see that there are currently problems with rotating stock:

• Use colored stickers to indicate how close a drug is to expiring.
• If a particular product is consistently expiring, try to figure out why. Are you keeping too much of it on-hand?
• Place newer product on the shelves BEHIND old product, so that product with the shorter expiration date is in the FRONT.
• Assign someone or set up a schedule to check expiration dates.
• Always check expiration dates as you dispense.
• Avoid using short-dated drugs in situations where the drugs might not be used for a long period of time (e.g., E-cart trays, rapid sequence kits, stat boxes, etc).
• Make sure not to stock short-dated drugs in automated dispensing cabinets or on patient care units.
When and how should I return expired meds?

Your distributor and sometimes a drug manufacturer might dictate when and how you return expired meds. If you’re unsure, check with your pharmacist, or with the person who is designated to take care of stock (i.e., inventory specialist).

In the hospital setting, you may need to return expired meds or nearly expired meds from your pharmacy satellite, patient care areas, or automated dispensing machines to the main pharmacy. Check with your pharmacy’s inventory specialist for the policy on this (e.g., which meds should be pulled, where they should be placed in the main pharmacy area or stock room, etc).

Resources


