Technician Tutorial:
Drug Expiration and Beyond-Use Dates

The dates after which meds should no longer be used can be a confusing subject in the pharmacy. There are a number of reasons for this, including misunderstandings about the differences between expiration dates and beyond-use dates and the wide variations in the “rules” for different types of drug products. Understanding how to interpret and assign dates after which meds should no longer be used is important for making sure your pharmacy meets legal and regulatory requirements and that patients get safe and effective treatment. In this technician tutorial, we’ll help you sort it all out.

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

The prescription is for latanoprost eye drops, with one drop to be placed in the right eye every evening. After the prescription is entered into the computer, you retrieve one latanoprost 2.5 mL bottle from the refrigerator.

What is the expiration date of a medication?
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) sets the standards that manufacturers must meet when determining expiration dates. The 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.

The manufacturer’s expiration date is printed, usually along with the lot number and manufacturer information, on stock bottles of medication, boxes containing pre-filled syringes, tubes containing topical medications, etc.

The manufacturer’s expiration date can be expressed as a month and year, or as a day, month, and year. In the U.S. and Canada, if just the month and year are indicated, the med can be used or dispensed until the last day of that month. For example, if the expiration date is written as 05/19, the med doesn’t actually “expire” until May 31, 2019. As such, the drug shouldn’t be used AFTER May 31, 2019.

How is the manufacturer’s expiration date determined?
Most meds get an expiration date of two to three years from the time of manufacture. This doesn’t mean that the med “goes bad” after the expiration date, or even that a med has full potency the day before it expires and has zero potency the day after. The drug company just has to be sure that, until the assigned expiration date, the med still meets requirements for safety and potency.
For example, a med might actually be good for ten years or more after its manufacture. But if the manufacturer gives the med an expiration date of three years, they just have to make sure it’s good for the first three years. The med may still be good after that time, but the manufacturer only has to have data to support up to three years in this example.

**What is a “beyond-use” date?**

An official definition for **beyond-use date (BUD)** 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 oral antibiotic’s labeling, past which the med should not be used. For instance, amoxicillin suspension has a beyond-use date of up to 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, doses of IV gentamicin may have a beyond-use date of ten days if they’re mixed in 5% dextrose and stored in the refrigerator.
- The 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 (e.g., compounded, reconstituted) or stored under certain conditions (e.g., room temp, refrigerated, frozen, outside the original packaging, etc), and how long a med can be expected to remain sterile (e.g., IV admixtures, compounded eye drops, etc).

**Will I ever see meds without expiration dates?**

You might see meds without expiration dates, especially if you work in a hospital. Investigational drugs are a good example of this. Testing for stability and potency are usually ongoing, so the shelf-life might not be established when meds are in the investigational phase. Typically a pharmacy that stocks investigational drugs will receive a notice to alert the pharmacist that certain lot numbers of an investigational product will need to be pulled from stock and returned at a certain time.

That being said, if you dispense a med without an expiration date, you will still need to give it a beyond-use date. The beyond-use date for an investigational drug would be found in the investigational protocol and paperwork. If you’re not sure about this, ask your pharmacist to help you find the information.

**How do I know what beyond-use date to assign to a med?**

Many meds that you dispense will require a beyond-use date. You’ll see that this includes all sorts of different drug preparations and products. An easy “mental list” to keep that will catch most meds that require a beyond-use date is meds stored in the refrigerator or freezer, some inhalers and nebulizer solutions, and meds that are compounded or reconstituted. You’ll see these discussed in more detail below, along with a few other examples.

Make sure you label meds with beyond-use dates in such a way that the label with the beyond-use date is securely attached to a part of the package that will not be discarded and that the label with the beyond-use date does not cover any other important information.
As mentioned, there are a number of **inhalers and nebulizer solutions** that have beyond-use dates shorter than the manufacturer’s expiration dates. One example is *Advair Diskus* (salmeterol/fluticasone), which is only good for one month after the foil pouch is removed. We have this information in our chart, *Correct Use of Inhalers* (U.S. subscribers; Canadian subscribers), and it can also be found in the package inserts, under the “How Supplied” or “Storage and Handling” sections.

There are also some **topicals** (e.g., benzoyl peroxide/clindamycin gel [*Duac-U.S.*, *Clindoxyl*, *Clindoxyl ADV-Canada*]-60 days, etc) and **ophthalmics** (e.g., azithromycin [*Azasite-U.S.*]-14 days, latanoprost [*Xalatan, etc.*]-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 inserts.

The state where you work will usually determine the beyond-use date for most **unit doses or prescription bottles of capsules or tablets**. The general rule is one year from the date of dispensing or the manufacturer’s expiration date, whichever comes first. This may help take into consideration the fact that meds may not be kept at ideal conditions after they are dispensed, such as at controlled room temperature. For example, if you prepare an Rx for furosemide tablets on 12/01/17 and the tabs you are using expire on 10/31/18, you would make the beyond-use date 10/31/18 since it is SOONER than one year from the date of dispensing, which would be 12/01/18.

Keep in mind that some oral caps or tabs such as dabigatran (*Pradaxa*) actually require beyond-use dates once their bottles are opened, as specified by the manufacturer. Dabigatran is good for four months. Use our chart, *Oral Meds to Keep in Original Containers*, and our technician tutorial, *Dispensing Meds in Original Containers*, to find out more about storage requirements for these oral meds. Once again, these beyond-use dates can also be found in the package inserts.

**Reconstituted products, either oral or injectable**, will have beyond-use dates specified by the manufacturer. These beyond-use dates can be found in the package inserts. The beyond-use date for reconstituted injectables will also depend on USP Chapter <797>, as described below.

Don’t forget about **injectable solutions and suspensions that don’t need to be reconstituted** (e.g., insulin, neuromuscular blockers such as rocuronium [*Zemuron*], etc), but must be given beyond-use dates once they’re removed from the fridge. This information can be found in the package inserts. For example, most insulin vials are usually good for 28 days after they’re removed from the fridge and stored at room temperature.

In the U.S., general guidelines for **non-sterile compounded preparations** are provided by what’s called USP Chapter <795>. In Canada, NAPRA has published guidance documents for pharmacy compounding of non-sterile preps. (Canadian subscribers can see a summary of the NAPRA guidance in our *Non-sterile Compounding Cheat Sheet*.) Below are the **general rules** from the 2019 USP Chapter <795> for maximum recommended beyond-use dates for non-sterile compounded preparations in the U.S.:

- **Aqueous (contains water) dosage forms without a preservative**: Up to 14 days if stored in the refrigerator.
- **Aqueous dosage forms with a preservative**: Up to 35 days stored at room temp or in the refrigerator.
- **Non-aqueous (don’t contain water) dosage forms (e.g., ointments, suppositories)**: Up to 90 days stored at room temp or in the refrigerator.
- **Solid dosage forms (e.g., capsules, tablets)**: Up to 180 days stored at room temperature or in the refrigerator.
Keep in mind that if you use an ingredient with a shorter BUD or expiration date than the max allowed for the type of preparation, the shorter BUD or expiration date will need to be used as the BUD for the preparation. Also, when you prepare a compound from a recipe, such as Magic Mouthwash, the beyond-use date should be included on the recipe, or more formally, the “Master Formulation Record.”

General guidelines for sterile compounded preparations are provided in USP Chapter <797>. It’s a bit complicated, as the beyond-use dates are based on different factors, including where a compound is made, how soon it will be used, and the conditions under which it will be stored. Know and follow your pharmacy’s policies on beyond-use dating for sterile compounded preparations.

Beyond-use dates must also be assigned to vials of sterile medications, single-dose and multidose, that have been entered. This information also comes from USP Chapter <797>. Know and follow your pharmacy’s policies on beyond-use dating for in-use vials.

In addition to the “for use in the eye” sticker, you add an auxiliary label to Barbara’s Xalatan bottle, careful not to cover up any of the information on the label. This auxiliary label reminds her not to use the drops after 12/13/17, 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 preparation or 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. 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 outdated meds? Again, drugs past their expiration dates don’t just “go bad” and may not even be harmful. In fact, the only documented harm from taking a med past the manufacturer’s expiration date is linked to degraded tetracycline. There were 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. However, this might be a different story when it comes to beyond-use dates. Since beyond-use dates are used to help ensure qualities such as stability and sterility of IV meds, using meds past the beyond-use date might be more likely to cause patient harm in some cases.

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.

When Barbie comes in later in the day to pick up her latanoprost, 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 latanoprost 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 20 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 eke 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 checks a couple of references that he has handy. 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 outdated meds or meds with short expiration or beyond-use dates?

Your pharmacy, whether in the community 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. Plus, states and provinces may have regulations on stock rotation as well.

The specific policy or practice at your workplace will likely depend to some degree on your wholesaler’s policy. Generally, the wholesaler will accept returns of products that are within a certain window, say three months, from expiring. Be sure to quarantine these meds once they are pulled from stock, so they don’t get dispensed to a patient by accident.

Here are some 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 med is to being out-of-date.
- If a particular product is consistently going out-of-date, 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 or beyond-use date is in the FRONT.
- Check for short dates as you put inventory on shelves.
- Assign someone or set up a schedule to check expiration and beyond-use dates.
- Always check expiration and beyond-use dates as you dispense.
- Avoid using short-dated meds in situations where the meds might not be used for a long period of time (e.g., crash cart trays, rapid sequence intubation (RSI) kits, stat boxes, etc).
- Make sure not to stock short-dated meds in low-use automated dispensing cabinets.

When and how should I return expired meds?

Depending on your practice setting, supplier, and product, the method of return for expired meds may vary. As mentioned, your pharmacy will likely return expired or nearly expired meds to your warehouse or primary vendor. In some cases, a reverse distributor is used to return and destroy expired meds. Sometimes a manufacturer will dictate when and how you return expired meds. If you’re unsure about returning expired meds at your pharmacy, 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 outdated meds or nearly outdated meds from your pharmacy satellite, patient care areas, or automated dispensing machines to the central or main pharmacy. Then the pharmacy inventory specialist will follow through with returning them as described above. Be familiar with your pharmacy’s policy on this (e.g., which meds should be pulled, where they should be placed in the main pharmacy area or stock room, etc). Or if you have to dispose of an outdated med in-house, be aware of your options with our technician tutorial, Medication Disposal in the Hospital.
In the U.S., special paperwork is required for Schedule II controlled substances that are expired. We have more information about this in our technician tutorial, *Dispensing C-II Controlled Substances*.

If a patient needs to dispose of unneeded or outdated meds, use our chart, *Drug Disposal Options*, to find more information about drug disposal requirements in the U.S. We also have a U.S. patient education handout, *Medication Disposal Guide*, you can give to your patients.

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---Please continue to the next page for a Cheat Sheet on drug expiration and beyond-use dates---
“Cheat Sheet” on Drug Expiration and Beyond-Use Dates

Why is it important to only dispense meds that are in-date?
- Meds are guaranteed to have full potency up to the manufacturer’s expiration date.
- Beyond-use dates help guarantee additional important qualities such as stability and sterility of meds.
- State or province laws and regulatory agencies expect you to only dispense in-date meds.

How do I interpret a drug expiration date that only has the month and year?
- If a manufacturer’s expiration date only has a month and a year, the med is good until the last day of that month.

What types of meds commonly require beyond-use dates that are shorter than the manufacturer’s expiration date?
- Non-sterile compounds (e.g., oral suspensions)
- Sterile compounds (e.g., IV piggybacks)
- Meds that are reconstituted
- Meds that are repackaged
- Opened multidose and single-dose vials
- Some meds that are removed from their original packaging (e.g., inhalers)
- Some meds that are removed from the fridge or freezer and stored at room temp (e.g., eye drops, insulin)

Where can I find info on a med’s beyond-use date?
- Package insert or med labeling
- USP Chapter <795> for non-sterile compounds
- USP Chapter <797> for sterile compounds
- NAPRA guidance document for non-sterile compounding (Canada only)
- Pharmacy policies and procedures

Are there any meds that don’t have expiration dates?
- Investigational drugs may not have expiration dates. But they’ll still require a beyond-use date when they’re dispensed.

What are some things that can be done to prevent dispensing of outdated meds?
- Check for short-dated meds when you receive an order in the pharmacy.
- Rotate old stock to the front of pharmacy shelves and place new stock in the back.
- Use strategies such as colored stickers so meds that are going out-of-date can be spotted easily.
- Be aware of meds that require beyond-use dates, and always remember to assign them.
- Check expiration and beyond-use dates whenever you fill an order or Rx.
- Pull short-dated meds from low-use areas, so they don’t slip through the cracks.
- Quarantine outdated meds in the pharmacy, so they don’t get dispensed by accident.

What are some things that can be done to prevent administration of outdated meds?
- Attach beyond-use dates securely to med packaging, not to an outer cover that could be discarded.
- Alert your pharmacist if a med you dispense won’t be good for long enough for a patient to complete a course of therapy. They can help come up with a good strategy so the patient has an adequate supply of the med that is not outdated.
- Refer patients who ask if they can use outdated meds to the pharmacist.

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