What is a medication?

The Federal Food, Drug and Cosmetic Act defines medication in general terms as a product intended for use in the cure, alleviation, treatment or prevention of disease.

**Why do identical medications have different names?**

The naming of medications is a complex process. Medications typically have three names: a chemical name, a generic name, and a brand name. For example, the brand name pain reliever Tylenol’s chemical name is n-acetyl-para-amino-phenol, and its generic name is acetaminophen.

The chemical name specifies the molecular structure of the medication and is used primarily by researchers. A medication’s chemical name is usually long and can be difficult to pronounce and remember, which is why consumers, physicians and pharmacists typically use its generic name.

The generic name is created when a new drug is ready to be marketed and is used internationally. It must be screened to ensure that it does not look or sound too similar to any other generic or brand-name product, and it also must be considered appropriate for the specific medication. The generic name must first be approved by the U.S. Adopted Name Council. After approving the generic name, the Council submits the name to the World Health Organization (WHO), which is responsible for final approval internationally.

The brand name for a medication is owned by the manufacturer and can be created as soon as the generic name is approved. Marketing motivates the choice of a brand name, since manufacturers want consumers and prescribers to easily remember the names of their products.

During the final stages of development of a new medication, the U.S. Food and Drug Administration (FDA) gives the final approval on a brand name. If the agency finds a new medication name to be confusing or inappropriate, it can reject the name.

**What is a generic medication?**

Generic medications are available for products that have lost their patent protection. This means other pharmaceutical companies not involved in the original development of the brand name medication can now produce a generic version of the medication. A generic medication is identical, or bioequivalent, to a brand-name medication in several ways: dosage form (tablet, capsule, liquid), safety, strength, route of administration, quality, performance
characteristics, and intended use. Although the medically active ingredients of
generic medications are chemically identical to their brand-name counterparts,
they are typically sold at substantial discounts. According to the Congressional
Budget Office, generic medications save consumers an estimated $8 billion to
$10 billion a year at retail pharmacies, with billions more saved when hospitals
use generics. Generic drugs are discussed in more detail in Chapter 8.

**Why are prescriptions required for most medications?**
As medications are developed to treat complicated illnesses such as serious
pain, mental conditions, life-threatening infections, and geriatric health issues,
the risk of improper use increases. Some medications can cause dependence
and can only be used safely and effectively if a proper diagnosis is made,
accompanied by close monitoring.

Because some medications can present risks to consumers, Congress
intervened in 1951 with a law that defined prescription medications. Included
in this definition was any medication that, “because of its toxicity or other
potentiality for harmful effect, or the method of its use, or the collateral
measures necessary to its use, is not safe for use except under the supervision
of a practitioner licensed by law to administer such drug.”
What are the requirements for selling prescription medications?
Individual state boards are responsible for regulating pharmacy and the other health professions, not the federal government. Though each state has enacted its own unique set of laws and regulations, they are similar nationwide and prescription medications can only legally be sold in licensed pharmacies.

When a medication is prescribed, a patient generally must be examined by a state-licensed health-care practitioner who determines the appropriate treatment and issues a prescription. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state requirements. Similar standards apply to the prescribing and dispensing of medications in hospitals by state-licensed physicians and pharmacists.

What are the requirements for over-the-counter medications?
Over-the-counter (OTC) medications are products available to consumers without a prescription. The FDA estimates there are more than 100,000 OTC drug products marketed, encompassing about 800 active ingredients. OTC products can be sold outside of state-licensed pharmacies in retailers such as grocery stores or variety shops. Generally, these alternative outlets must obtain a license from the state board of pharmacy before selling OTC medications.

The regulatory requirements for marketing OTC and prescription medications are similar, but there are important differences. For example, licensed professionals are not essential for the safe and effective use of an OTC medication. Like prescription products, the FDA must determine the benefits of OTC medications outweigh their risks. OTC medications also must have a low potential for misuse and abuse.

It is important to remember that OTC medications are not innocuous; they are potent medications, and the directions for their use must be carefully followed.

Key messages

- A medication is a product created to treat or prevent a disease.
- Medications have three names: chemical, generic and brand.
- The brand name is owned solely by the manufacturer.
- Generic medications must have the same amount of the active ingredient as the brand-name medication.
- Prescriptions and guidance by a licensed health professional are required for medications that are potentially toxic or harmful.