

The generic name is a shorthand way of referring to a specific chemical substance. It does not describe some of the therapeutically significant physical attributes of the substance; i.e., it does not tell if it is amorphous, crystalline, coarse, or fine. Neither does it describe its degree of purity beyond minimum legal standards.

For these and other reasons, the often-used phrase "generic drug product" is no more than a misleading term.

The term "generic name," properly used, refers only to the pharmacologically active chemical ingredient of a finished product, and not to the finished product itself. To be dispensed and used, the chemical ingredient must be combined with other carefully selected substances and embodied in a finished product (dosage form such as a tablet, an ampule, or a suppository. Therefore, in the case of finished drugs (dosage form), application of the same "generic" name to two or more products does not and cannot mean that they are necessarily identical.

The brand name or trademark

Pharmaceutical companies generally adopt brand names or trademarks to identify their products. No official rules control this nomenclature. The objective is to coin a name which is useful, dignified, easily remembered, and individual or proprietary.

After it is finally put into use in interstate commerce, the brand name is generally registered with the U.S. Patent Office.

To continue the example cited above, one manufacturer of a product based on hydrochlorothiazide gave its finished product the brand name, HydroDiuril, suggesting partly the chemical name and partly its diuretic properties. Another manufacturer, for other reasons, chose to name its product containing hydrochlorothiazide Esidrix; a third, Oretic.

These names are quite different, which is proper since they are intended to identify different products produced by different companies. But in order to avoid confusion and simplify the physician's and pharmacist's task of remembering the main therapeutic ingredient of the many products on the market, the generic name of the principal ingredient appears on product labels in advertising and in other communications about the product. Hence, the names mentioned above may be referred to this way in written communications.

HydroDiuril (hydrochlorothiazide)

Esidrix (hydrochlorothiazide)

Oretic (hydrochlorothiazide)

There is the alternate method of using the company name, initials, or symbol along with the generic name. The following examples, based on a fictitious John Doe Drug Co., illustrate the method:

hydrochlorothiazide, Doe

or

hydrochlorothiazide, DDC

B. Legally acceptable and other standards

For more than 100 years, drug standards established by non-governmental bodies have played a major role in the continuing effort to obtain uniformity in therapeutic agents. Their existence, however, does not *guarantee* therapeutic uniformity of products from manufacturer to manufacturer. But since these standards have frequently been cited as a readymade foundation for a system of so-called generic name prescribing, it is important to understand their exact coverage and function.

The *Pharmacopeia of the United States* and *National Formulary* are "official" publications of the U.S. Pharmacopeial Convention and the American Pharmaceutical Association respectively. They are recognized as registers of legal standards to which drugs and some ingredients used in making medicines should conform. These lists are specified by the U.S. Government under the Food and Drug Act, as amended, as setting minimum standards. Lists are periodically compiled by other organizations, too, each designed to serve specific needs.

Pharmacopeia of the United States (U.S.P.).—This compendium was the first of two published in the 19th century covering the broad practice of pharmacy, to guide pharmacists and drug manufacturers. The first edition of U.S.P. was printed in 1820 under the auspices of the U.S. Pharmacopeial Convention, a private assemblage of physicians, pharmacists, chemists and others. It is an authoritative source of minimal standards for therapeutic substances "the utility