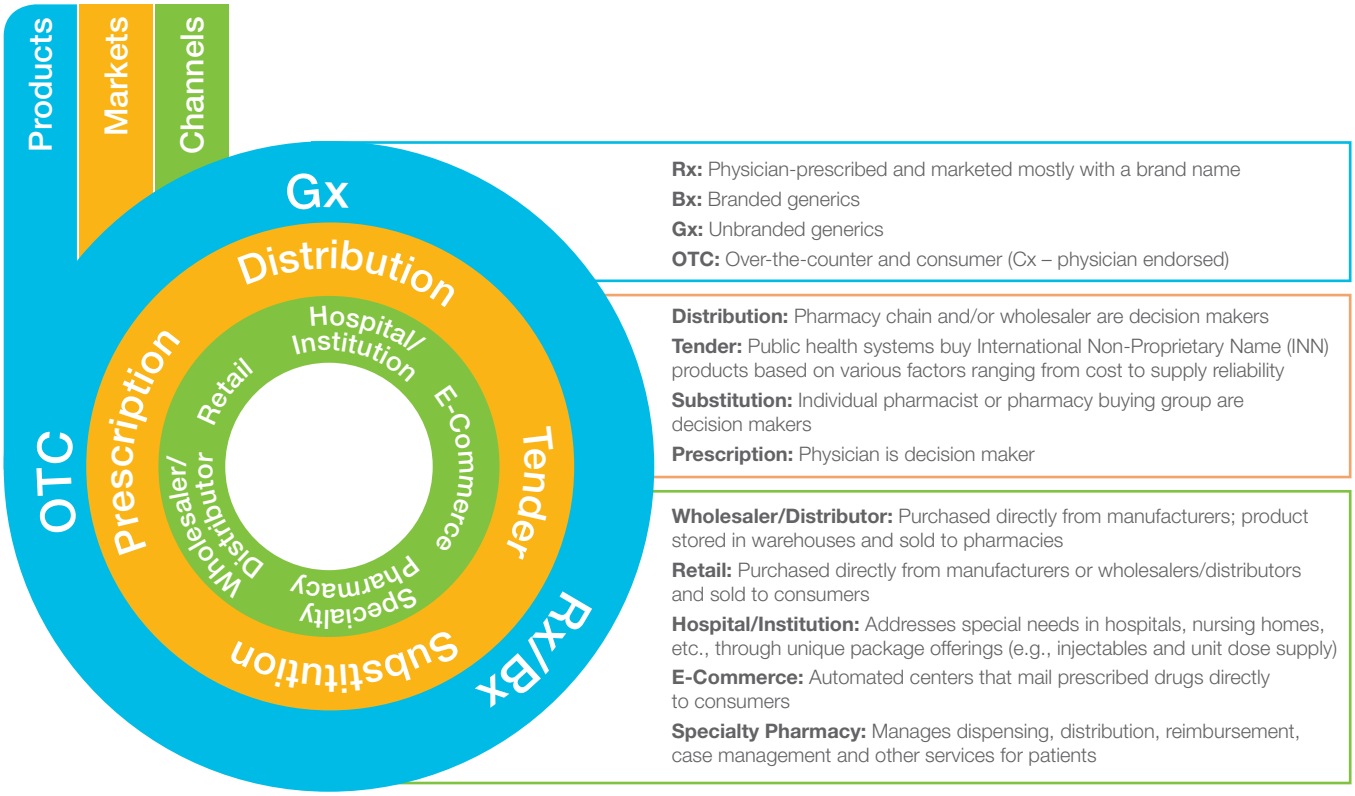
The Pharmaceutical Industry

Pharmaceuticals have long played an indispensable role in delivering better health around the world. They have virtually eliminated certain diseases, such as smallpox, that once killed tens of millions of people and have drastically reduced the number of deaths caused by other illnesses, such as influenza. More recently, pharmaceutical products have helped people with conditions such as cardiovascular disease, mental health and respiratory disorders, to name but a few, regain control of their lives. Today's wellness and lifestyle medicines offer opportunities to make everyone's journey healthier and more enjoyable.

Pharmaceutical products also help reduce the cost burden borne by individuals and society as a whole that results from sickness or injury. They do so by helping people avoid surgery and other expensive medical procedures. Moreover, by keeping people functional, medicines help keep them productive.

For all these reasons, it's important that the industry itself be healthy. The key to that, quite simply, is to make sure that innovation and competition both can flourish.

That said, the pharmaceutical industry is large and complex. How it functions, how it's regulated and how it provides patients access varies by location. In addition, the industry and the broader healthcare system are constantly evolving, and at paces that vary from place to place.



To help provide clarity, we have illustrated important industry characteristics, which center around product types; kinds of markets, which are a function of who makes key decisions around pharmaceutical prescribing, dispensing or buying; and channels, through which our products make their way to patients.

Just as wide-ranging are the types of companies operating within the industry. Historically, drugmakers focused either on developing new prescription products or on manufacturing generics, though many firms today do both.

Those focused on new products develop drugs that are sufficiently novel as to be protected by patents or other forms of exclusivity. As such, these drugs, which bear trade names, may be produced and sold only by those owning the rights, subject to certain available challenges. Developing new medicines takes years and significant investment. Only a few promising therapies ever enter clinical trials. Fewer still are approved for sale by health authorities, at which point marketing to healthcare providers (HCPs) and consumers begins.

Because patents and exclusivities last many years, they serve as an incentive to developers. During the periods protected, developers recoup their investments and earn a profit, typically by charging premium prices that reflect the benefits of their innovation. In many high-income countries, the brand business often is characterized by higher margins on lower volumes – especially when compared with generic manufacturers.

SUBSTITUTION

Many countries allow generic drugs to be substituted for brand-name medications.

But first, the two products must be proven to be therapeutically equivalent. To determine whether a generic product meets this standard, health authorities require evidence from an extensive series of studies.

The generic's maker compiles and submits the associated data, which typically includes a thorough scientific evaluation of both pharmaceutical equivalence and bioequivalence.

Pharmaceutical equivalence means that the generic and brand-name products are the same in terms of active ingredient, dosage form, dosage strength and route of administration. The generic drug also must be the same as the branded drug with respect to quality, purity, identity and potency.

Bioequivalence refers to how the drug is absorbed and distributed after it is taken by mouth, injected, infused, inhaled or otherwise administered. A generic drug and a branded medication are considered bioequivalent when there is no significant difference between the products in the speed and extent of delivery of the active ingredient to its site of action in the body.

When a generic medication meets these stringent requirements, it is considered therapeutically equivalent to the branded drug. This means the two medications would be expected to have the same clinical safety and efficacy, and that physicians, pharmacists and patients can substitute the generic for the branded product with confidence.

Generic drugmakers are held to the same standards of good manufacturing practices (GMP) by health authorities as brand drugmakers.

Generic pharmaceuticals are therapeutically equivalent versions of brand-name medicines. They generally become available once the patents and other exclusivities on their branded counterparts expire.

Generic drugmakers also invest significant sums in R&D and in manufacturing capacity. They also often incur substantial litigation expense as a result of challenging unwarranted brand patents or exclusivities. But because generics developers are not required to reproduce expensive clinical trials and seldom engage in product promotion, generic drugs typically cost far less than brand-name drugs. The generics business is characterized by lower margins on higher volumes, as most generic drugmakers offer a relatively large number of products.

Although generics companies have long been considered the industry's advocates for access, they also play substantial roles as innovators, in areas ranging from dosage forms to packaging.

Drugmakers also often contract with other, more specialized organizations for various products or services. Examples include producers of bulk compounds and chemicals used in producing drugs; biotechnology firms, which specialize in promising biological products; drug-delivery system suppliers; and packaging vendors.

Regardless of their heritage, all pharmaceutical companies – and the patients who ultimately depend on them – benefit when robust competition fuels innovation. Doing so means acknowledging each company's respective contributions and balancing their interests to preserve the industry's viability. Balance provides all participants with the opportunity to generate a reasonable profit and incentive to reinvest proceeds and grow in a sustainable manner. How individual companies approach that opportunity is defined by their choice of business model.

Mylan's model, discussed next, takes into account all aspects of the industry. It is built to allow the company to last and to holistically provide better health for a better world.