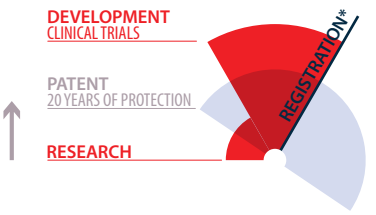
# 01 Life-cycle of a drug: from the research to the patient

To understand the relationship between intellectual property, drug prices and access to medicines and the options that exist to favor low price and universal access, one need to consider the full sequence of events and actions that take place from basic research, generally undertaken by public institutions, to the period where competition can exist on the market and patients can access generic versions of the products.

## 1

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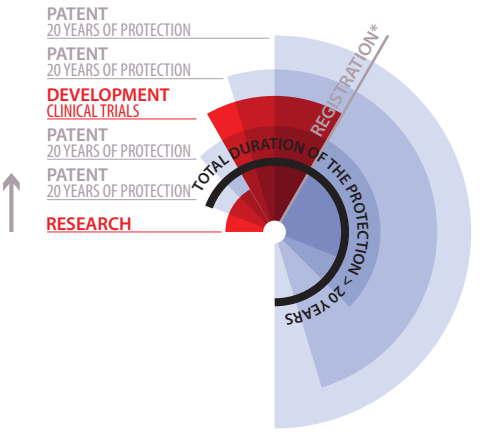
- The process of drug discovery and development begins with basic scientific research : to understand the disease at molecular level, to explore the pharmacological activity and therapeutic potential of chemical or biologic compounds, to turn active compounds into a form and strength suitable for human use and stable, and to assess the potential risk compounds poses to animals, tissue cultures, and other test systems prior to their human introduction.
- During this process of basic research, patents are granted to chemical compounds and medicines candidates.
- Each patent that is granted will last 20 years.
- This duration was set by the World Trade Organization (WTO) when it was created in 1995.
- During these 20 years the holder of the patent has a monopoly over the pharmaceutical product or the process to produce this product : nobody else can use it – that is, produce it, sell it, export it or import it.

## 2

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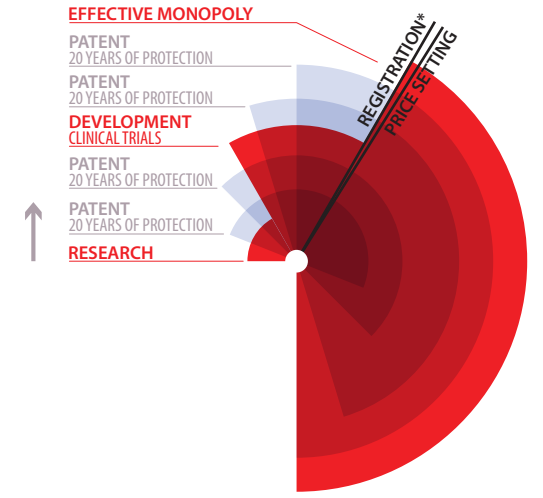
- After the research phase the candidate medicines is properly developed, which means that clinical trials are done to show whether a medical strategy, treatment, or device is safe and effective for humans.
- During the whole duration of the research and development, various patents can be granted (see factsheet n°X) for a single product, covering the chemical entity or the process to produce it.
- The total duration of the monopoly will go from the first day of the first patent that was granted to the last day of the 20 years of the last patent that was granted and that cover the same medicines.

## 3

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■ The period of effective monopoly only starts when the product is put on the market. In order for this to happen a marketing approval is granted by the competent regulatory authority, while a price is set according to a specific procedure.

■ Before the adoption of the WTO, in many countries, the duration of patents was set to 10 or 15 years. When the WTO adopted 20 years as a new standard of duration that all Member States had to respect, the calculation was that it would ensure a period of effective monopoly on the market sufficient.

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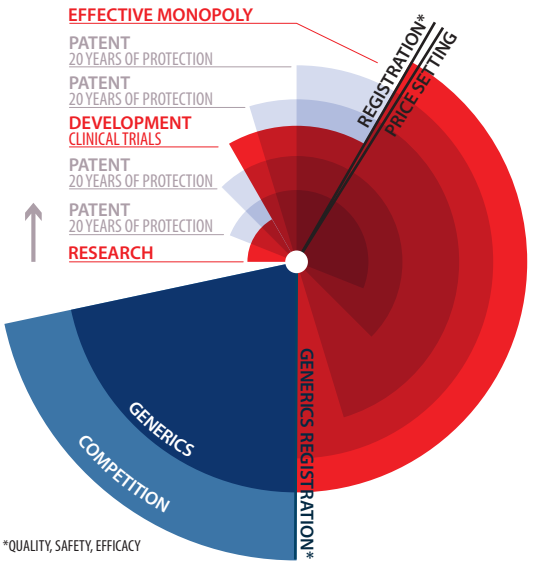


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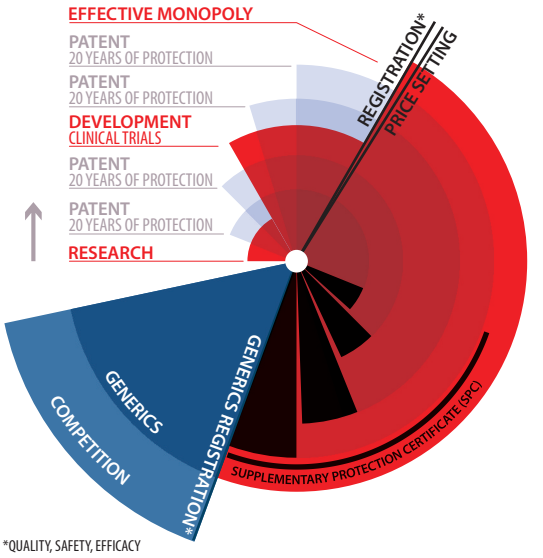
■ After the monopoly period, the work or invention falls into the public domain, anybody can make use of it – make use of the knowledge it describes.

■ Any generic medicines, however, needs to be registered in the country and get a marketing authorization. In order to do that the regulatory authority in the country usually ask the company selling the generic to provide the result of a bioequivalence study – proving that the medicines is clinically interchangeable with the original product (for which the result of clinical trials were provided), i.e. therapeutically equivalent, and work the same way in the body.

## 5




■ In several countries there are mechanisms to extend the duration of patent protection beyond the WTO standard of 20 years. The argument invoked is that in some cases the procedure to grand the patent or the procedure to grand a marketing approval take too long and therefore reduce the period of monopoly on the market for the patent owner. This is the case of the US and of EU (where the addition protection is called a complementary certificate of protection, CCP). These patent extension are then exported to other countries through Free Trade Agreement (FTA) (see factsheet on TRIPS+ provisions n°X).

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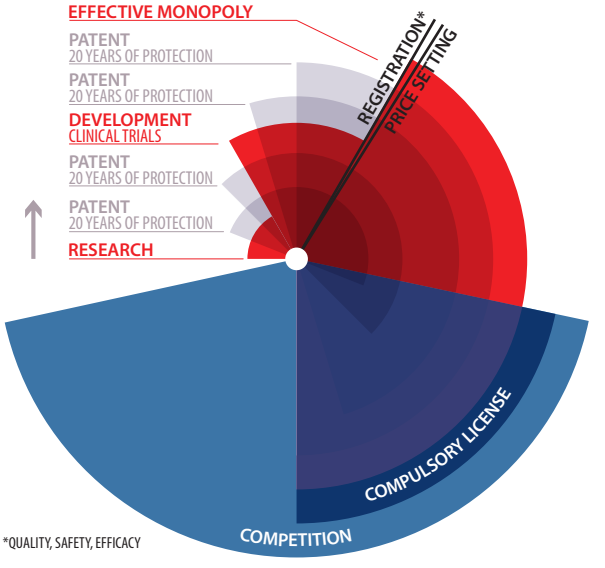
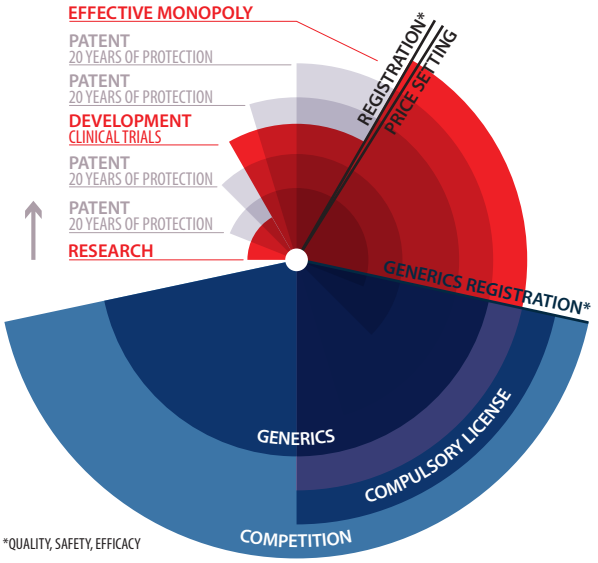



■ One way of the only options to lift the monopoly established by the patent is the granting of a compulsory license.

■ Compulsory licenses is a legal provision of the international intellectual property system, described by the WTO agreement on intellectual property (Trade-Related Aspects of Intellectual Property Rights, TRIPS) that gives the possibility to a State to authorize a third party or a state entity to use – meaning to make, use, offer for sale, sell, or import – a patent without the authorization or the patent holder. To put it simply, it lifts the monopoly rights that the national authority (usually a patent office or office of industrial property, see factsheet n°X) has allocated to a patent holder when it granted the patent. In the case of compulsory licensing, as in the case of voluntary licensing, royalties have to be set and paid to the patent owner to compensate for the use of the patent.

## 7




■ When a compulsory license is granted generic version of the patented drug can be put on the market and given to patients.

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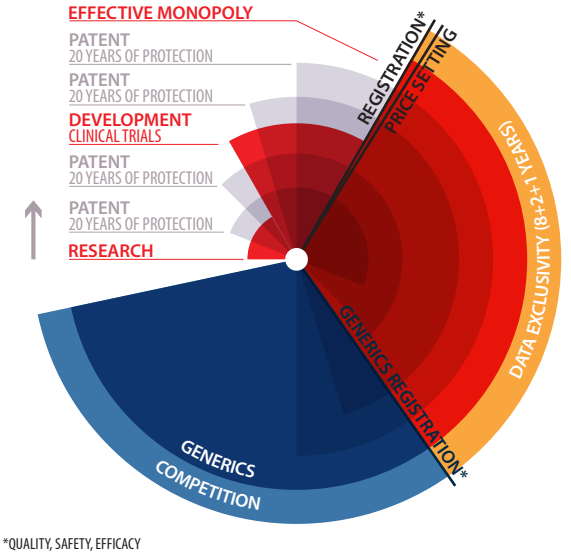


■ In some countries, States provide companies with another way to get marketting monopoly than monopoly. It is called data exclusivity (See factsheet n°X).

■ To obtain marketing approval for a new product, pharmaceutical companies must submit data proving the absence of toxicity and the effectiveness of the product to drug regulation authorities. Such data are referred to as "registration data" or "marketing approval data" and result from tests and clinical trials on animals and human beings. When a company wants to market a generic version of a pharmaceutical product already on the market, the regulatory authorities do not ask it to undertake the same clinical trials (which would be unethical); they ask the company to provide the results of bioequivalent tests proving that the product is chemically equivalent and has the same action in the human body as the brand-name product (bioequivalent). The authorities rely on the data on toxicity and effectiveness provided for the marketing of the first product to be registered. Data exclusivity establishes a marketing monopoly as it prevents competitors from marketing their product unless they conduct new clinical trials.

■ Moreover, this provision can render useless the granting of compulsory licensing to allow access to generic versions of patented products: even if a license is issued and the drug is produced or imported, it will not be able to enter the market. Even old products, unpatented products can benefit from a monopoly under this provision, as long as they have not already been marketed yet.