It takes an average of 10 years for a chemical compound to make the journey from the laboratory to reach the pharmacy shelf as a medicine.

The development of any new medicine requires a great deal of skill and expertise and costs millions. Thousands of promising compounds never make it out of the laboratory. On average, only one in 5000 will end up as a prescription medicine.

A new compound or new area for drug treatment needs to differ in some way from what has gone before, so that the unique recipe can be protected (patented) while development is taken forward.

Patents last for 20 years to enable drug companies to recoup the huge costs involved in developing their medicine. After this other companies can legitimately develop cheaper versions of the same medicine. These are called generics.

The first medicine of its type may be a trail-blazer. However, it is likely to be overtaken by other similar, but more effective versions.

**Who regulates medicines?**

Whether it’s cough mixture or cancer drugs, all medicinal products have to be licensed—given a marketing authorisation—before they can be put on the market.

A licence means that a medicine has been thoroughly tested and quality controlled, to make sure that it is acceptably safe and works as intended.

In the UK, licensing falls to the medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA).

The MHRA works closely with the European regulator, the European Medicines Agency (EMEA) (external link), which sits at the centre of a collaborative network of national regulatory bodies within the European Union (EU).
plus Liechtenstein, Norway and Iceland.

The EMEA is responsible for licensing “high-tech” medicines, such as gene therapy, and those that meet EU public health priorities, such as those for diabetes. This guarantees that these treatments are available across Europe rather than just in individual countries.

The regulation of medicines in the UK is covered by an Act of Parliament and European Directives.

The pharmaceutical industry also regulates itself through a code of practice, which sets out how companies can behave when they sponsor research and training, and how they can promote their products to healthcare professionals and the media.

**What does “acceptably safe” mean?**

Every medicine has some side effects (risks), ranging from minor to severe. In a life threatening condition, such as cancer, severe side effects may be an acceptable trade-off for the benefits the treatment brings. But severe side effects will not be acceptable in a medicine used to treat a minor ailment, such as hay fever.

Ultimately, with the help of healthcare professionals, patients have to decide whether they are prepared to put up with certain side effects in return for relief from painful symptoms, the slowing of a disease, or a cure.

**The life cycle of a medicine**

A medicine starts life as a chemical substance or compound. Many promising compounds turn out to be unsuitable—sometimes many years into development. This is because they have too many unwanted side effects or because they simply don’t work as well as at first thought.

Broadly, the life cycle of a medicine consists of:

- **The discovery stage**, when a compound is screened for its potential to be developed further and its make-up assessed in detail.
- Promising compounds are then tested in the laboratory and in living tissue in **pre-clinical research**. Thousands of compounds never go beyond this stage.
- Those that do are then tested on gradually increasing numbers of people in phased **clinical trials**, a stage of development that usually takes around six years.
- The manufacturers then apply to the regulator for a **marketing authorisation** (licence) so that the medicine can be put on the market.
- Once licensed, the effectiveness and safety of the medicine continue to be carefully tracked by the manufacturers, regulators, healthcare professionals, and the public. This **monitoring** may include further research, which can be carried out many years after a licence has been granted.
- Sometimes there will be **changes in the use of a medicine**, when it is shown to work well in different groups of patients or for different conditions.

**Who decides which medicines can be prescribed?**

Not every new medicine will be widely available to all patients across the UK. This is because different national bodies are responsible for recommending which treatments should be used in the National Health Service (NHS).

In England this is the job of the [National Institute for Health and Clinical Excellence (NICE)](https://www.nice.org.uk) (external link).

In Scotland, the Scottish Medicines Consortium, [NHS Quality Improvement for Scotland](https://www.scottishhealthquality.org) (external link) and the [Scottish Intercollegiate Guidelines Network (SIGN)](https://www.sign.ac.uk) (external link) take on this role.

Wales tends to follow NICE guidance, and the [Department of Health, Social Services, and Public Safety (DHSSPNI)](https://www.gov.wales) (external link) adapts it for patients in Northern Ireland.

Not all medicines will be assessed by these bodies. And the availability of certain medicines on the NHS will be influenced by other factors, such as local treatment priorities and budgets.