A guide to the development and manufacture of medicines

Executive summary

Medicines are central to modern healthcare, preventing and treating disease, improving quality of life, and saving lives. In the UK, more than one billion medicines are prescribed each year from more than 18,000 licensed products, contributing to major gains such as improved cancer survival and reduced heart disease deaths, and transforming HIV/AIDS into a manageable long-term condition. The UK is a global leader in early-stage biomedical science, increasingly using tools such as artificial intelligence to identify potential targets and improve development decisions. Bringing a new medicine to patients is long, complex and high risk: development typically takes 10–15 years and often costs more than £1 billion per successful medicine.[1]

Attrition is substantial – on average, from 10,000 screened compounds, researchers identify only one or two compounds that will ultimately obtain market approval[1] - so early identification of safety, effectiveness or manufacturability issues is critical.

Discovery starts when a chemical or biological molecule shows desired activity in laboratory systems (such as antibodies or cultured cells). In preclinical development, 'lead' compounds are produced in small quantities and assessed for toxicity, stability, absorption and the feasibility of large-scale manufacture, with additional animal studies used to detect longer-term harms. Clinical trials then evaluate safety, dosing and effectiveness in staged phases.

In the UK, clinical trials require regulatory review by the Medicines and Healthcare products Regulatory Agency (MHRA) and ethics review by research ethics committees (RECs) coordinated by the Health Research Authority (HRA). Evidence continues to develop after licensing through post-marketing studies.

Manufacture occurs in two stages: primary manufacturing produces the active pharmaceutical ingredient (API) - via chemical technology or biotechnology and secondary manufacturing converts it into finished forms such as tablets, supported by stringent quality testing and controlled packaging lines. Finally, pharmacovigilance monitors benefits and harms throughout a medicine's lifecycle, including via the MHRA Yellow Card scheme. NHS availability depends on independent value assessments (such as National Institute for Health and Care Excellence (NICE) and devolved-nation equivalents), and promotion of prescription medicines is tightly regulated, including through the ABPI Code of Practice.

1. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA): Always Innovating - Pharmaceutical Industry Facts & Figures. Dec 2024.

Research and development of new medicines

The UK has a strong international reputation for medical research, underpinned by major advances in basic science that have transformed understanding of disease. The pharmaceutical industry invests around £9 billion each year in UK research and development to discover new medicines.[2]

Medicines development begins when a chemical or biological molecule is identified as a potential treatment. This candidate is first tested in the laboratory using systems such as antibodies or cultured cells to determine whether it shows the desired biological activity.

During preclinical development, promising compounds – known as 'leads' – are produced in small quantities and studied in greater detail. Initial tests on cell cultures assess toxicity and early therapeutic potential. At the same time, scientists evaluate how easily the compounds can be manufactured, how well they may be absorbed when taken orally, and whether large-scale production could present difficulties.

After several months of laboratory work, only a few of the most promising molecules progress to more extensive testing, including animal studies, to evaluate longer-term safety.

Such studies examine whether regular use could be toxic, cause serious side effects, or harm a developing foetus.

Before a compound can be tested in humans, it must be shown to be potentially effective, acceptably safe, chemically stable, and well understood in terms of how the body absorbs, distributes and eliminates it. These rigorous steps ensure that only the safest and most promising medicines proceed to clinical trials.

2. Office for National Statistics: Business enterprise research and development, UK: 2022 & 2023.

Clinical trials and the safety of new medicines

Before a new medicine can be tested in people, evidence from preclinical research is used to apply for permission to conduct clinical trials. In the UK, the MHRA assesses the quality, safety and scientific basis of the proposed study. In parallel, Research Ethics Committees, coordinated by the Health Research Authority (HRA), review whether participants' rights, safety, dignity and wellbeing are adequately protected. Clinical trials can only begin once all approvals are granted, and studies must be publicly registered to ensure transparency and support patient awareness.

Clinical trials usually begin with healthy volunteers for ethical and scientific reasons, although some early studies can involve patients. These first-in-human trials are followed by larger studies involving people with the relevant disease to assess effectiveness and monitor safety - with the NHS playing a central role in this research. Participants receive clear information about the trial, including potential risks and benefits, and decide whether to take part. As evidence grows, trials may expand across multiple hospitals and countries, lasting from weeks to many years. Trial data are submitted to regulators to support licensing decisions.

Clinical trials may reveal that medicines work better for certain groups, supporting targeted or personalised treatment approaches. Not all studies test medicines; observational and behavioural research also improves prevention and care. Research also continues after licensing through post-marketing (Phase 4) studies to examine long-term safety, optimal dosing, interactions and new uses. After licensing, medicines require approval for NHS use and are continuously monitored to identify rare or long-term side effects and inform future research.

Manufacturing medicines

Medicines are manufactured in two main stages: primary and secondary manufacturing, with the overall aim of producing safe, effective and high-quality products for patients.

Irrespective of the final form of a medicine, such as tablet, capsule, injectable or ointment, primary manufacturing involves producing the API - although present in small amounts, the API is the most critical component of a medicine, since it is responsible for treating the disease. APIs are produced using either chemical technology or biotechnology. In chemical manufacturing, chemists and chemical engineers design and optimise reactions to produce the API with high purity and yield. Environmental considerations are increasingly important, including reducing energy use and choosing safer, water-based solvents. Processes are first tested at small scale before moving to full production. As chemical reactions generate by-products, the API must be isolated and purified using methods such as filtration and crystallisation. This approach is commonly used to produce small-molecule medicines for conditions including asthma, heart disease and pain.

Biotechnology uses living organisms or biological systems to manufacture medicines. Advances such as genetic engineering allow human genes to be inserted into bacteria, fungi or animal cells to produce proteins including insulin, growth hormone and monoclonal antibodies. These biologic medicines are used in vaccines and to treat conditions such as cancer, arthritis and transplant rejection.

Secondary manufacturing converts the API into a finished medicine, such as tablets, by combining it with inactive ingredients known as excipients which play important supporting roles such as aiding absorption. This stage includes mixing, granulation, drying and tablet pressing, with careful quality checks to ensure accurate dosing, strength, purity and reliable breakdown in the body. Some tablets are coated to improve stability, control release or aid swallowing. Together, both stages ensure medicines meet strict quality standards.

Packaging of medicines

Before medicines are supplied to hospitals and pharmacies, they must be carefully and securely packaged. The packaging used depends on whether the medication comes in the form or tablets, or one of the many non-tablet delivery mechanisms such as capsule, suspension, inhaler, patch or cream. For tablets, blister packs are among the most common packaging. They are safe, easy to use and allow patients to see the tablets without opening the pack. Capsules can be packaged in a similar way. To reduce costs and avoid frequent machinery changes, many manufacturers use standard-sized blister packs. Some packs are perforated so individual doses can be separated; in these cases, essential information such as the medicine name and expiry date must be printed on each section. Blister packs must also remain flat during packaging, particularly when being placed into cartons, which requires careful design and engineering.

Packaging takes place on controlled production lines, with tablets entering at one end and finished cartons leaving at the other. Strict quality controls operate throughout the process. For example, camera systems check that every blister cavity contains a tablet, and faulty packs are automatically rejected.

Cartons are supplied as flat printed sheets and folded during packaging. Both blister packs and cartons are printed with batch numbers and expiry dates to ensure traceability. Each pack also includes a patient information leaflet explaining dosage, warnings and possible side effects. Finished cartons are weighed to confirm they contain the correct contents before being grouped, wrapped and placed into larger outer cartons for distribution. These steps ensure medicines are safe, clearly labelled and ready for patient use.

Medicines safety, regulation and access

No medicine is completely risk free. Before a medicine is licensed, extensive research and testing are carried out to minimise risks, but very rare side effects may only become apparent once it is used by large numbers of patients.

In the UK, medicines must receive marketing approval from the MHRA before they can be prescribed. This requires detailed evidence on manufacturing processes, quality standards, and safety and effectiveness, often compiled into extensive documentation. Once approved, the medicine is issued with a product licence number that appears on every pack.

MHRA approval does not automatically guarantee NHS availability. Medicines are assessed for cost effectiveness by independent bodies such as NICE, the Scottish Medicines Consortium and the All Wales Medicines Strategy Group. These assessments consider benefits such as improved quality of life, independence and reduced hospital use. NICE approval supports consistent NHS access.

Even once approved, and available to NHS patients, robust ongoing monitoring takes place. Medicines safety, or pharmacovigilance, involves detecting, assessing, understanding and preventing side effects. Safety scientists continuously collect and analyse information from patients and healthcare professionals to monitor a medicine's risks and benefits. Monitoring takes place throughout the medicine's life cycle, during clinical trials, after licensing and for as long as the medicine is in use. Suspected side effects can be reported through the MHRA's Yellow Card scheme or directly to manufacturers.

The promotion of prescription medicines is tightly regulated. Advertising to the public is prohibited and marketing to healthcare professionals is strictly controlled. Most companies also follow the ABPI Code of Practice, which sets standards and drives ethical, transparent and responsible communication.

About the ABPI

The ABPI exists to make the UK the best place in the world to research, develop and access medicines and vaccines to improve patient care.

We represent companies of all sizes that invest in making and discovering medicines and vaccines to enhance and save the lives of millions of people around the world.

In England, Scotland, Wales and Northern Ireland, we work in partnership with governments and the NHS so that patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, our members partner with healthcare professionals, academics and patient organisations to find new solutions to unmet health needs.

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