efcg EUROPEAN FINE CHEMICALS GROUP

THE VALUE OF
ACTIVE PHARMACEUTICAL INGREDIENTS

HOW IS A PHARMACEUTICAL SPECIALTY DEVELOPED?

The development of a new pharmaceutical specialty is **long** and **costly** and can last up to ten years.

10 YEARS

5 PHASES

DISCOVERY

PRECLINICAL PHASE

3 phases of **CLINICAL EXPERIMENTATION** on an increasingly large number of subjects

1/1000

In order to produce a single medicinal product, **several hundred or sometimes thousand molecules are subjected to preliminary laboratory tests.** This entails top level R&D engagement.

During this **preclinical phase,** the selected molecules are are subjected to a **very comprehensive pharmacological screening.**

The 3 screening phases include: **pharmacology, toxicology** and **in vivo clinical trials**

AN ACTIVE INGREDIENT MUST

- Demonstrate its therapeutic activity
- Have a good delivery system
- Be absorbed once delivered or be effective where required
- Reach its target(s)
- Perform its action and be subsequently eliminated

At the end of this selection process, **only a few molecules remain that can proceed to Clinical Phases 1, 2 and 3 subject to prior authorisation by the competent national bodies**

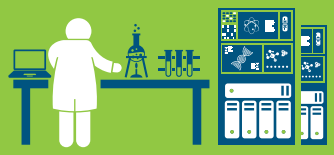
HOW IS AN ACTIVE PHARMACEUTICAL INGREDIENT PRODUCED?

APIs ARE PRODUCED ACCORDING TO GOOD MANUFACTURING PRACTICES (GMP) DEFINED BY REGULATORY AUTHORITIES. THE ENTIRE SYSTEM IS CONTROLLED BY VERY STRICT REGULATORY PROCEDURES.

License to manufacture certifying that the company works **in accordance** with the **requirements** of the **EU legislation** on GMP

A plant that has the **adequately trained personnel, premises** and **equipment** for the production and the conservation of each and every product

Quality systems and **processes** that **guarantee** the proper functioning of **the equipment** and **the consistency** and **quality** of the APIs produced

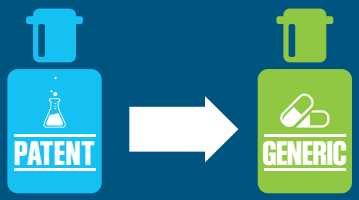


It is crucial for the API manufacturer to have a **cutting-edge Research & Development (R&D) facility,** enabling the **transition from laboratory scale** to **pilot plant** and then **to full industrial scale.** To achieve this an **excellent level of technology is needed.**

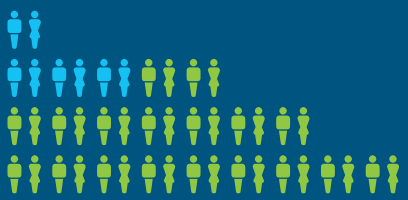
GMP standards require from manufacturers, inter alia, the **validation of their equipment, processes, analytical methods** and **cleaning methods**

Strict **environmental, health and safety (EHS) standards** are required to operate manufacturing plants

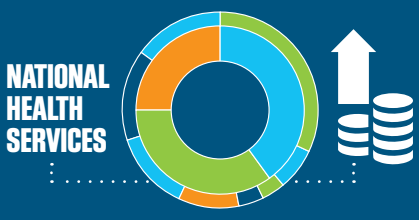
"Gold standards" are applied to meet excellence in **industrial safety, environmental protection** and **health & safety** at work



At the expiry of its patent the **active ingredient can be used for the production of generic drugs,**



allowing **access to healthcare** to a **wider population**



and **reducing the cost for health services** and insurers thus **freeing up resources for innovative therapies**

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