

Fact Sheet: Making a medicine – Safety surveillance and life-cycle management

Marketing and post-marketing safety surveillance

The marketing process involves sharing the information about the new medicine with doctors and other health care professionals so that they are aware of the effects of the new medicine, and may prescribe it in cases where they believe patients can benefit.

However, the development process does not stop there. There is still a need to collect and analyse the information about the safety of the medicine when it is used in 'real-life' (called pharmacovigilance). This is because:

- In clinical trials (which are designed to give clear answers), patients ideally only have the illness being studied and are not taking any other medicines.
- In real-life, a large number of patients take the new medicine. They may have several other illnesses and take a variety of other medicines.

Both the clinical trials and real-life data are necessary to fully understand the real benefit-risk relationship.

Life-cycle Management.

Finally, the development process continues to explore:

- other possible uses (indications) for the medicine. For example, if the initial use was for patients with asthma, a new indication might be for patients with a different type of lung disease, e.g. chronic obstructive pulmonary disease.
- improved ways of making and using the medicine (new formulations). For example, a special formulation for children.

All of these activities are known as 'life-cycle management'.

Other changes in the life cycle of a medicine

When a medicine is first marketed, it is protected by a 'patent'. This means that other companies cannot market a similar medicine. At the end of the patent or data protection period other companies will manufacture and market the same product. When this happens, the product is called a 'generic' or, in the case of a biologic product, a 'biosimilar'.

New medicines are usually licensed as Prescription-Only Medicines (POM). This means that healthcare professionals can supervise their use in the first few years. Where it is appropriate and safe to do so, the medicine can then be made available as an Over-The-Counter (OTC) medicine. This involves a change in the Regulatory status of the medicine and a new licence is required. Patients can buy the OTC medicine directly from a pharmacy or supermarket.