Generic medicines

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Introduction

When chemical medicines are first developed and approved, they are sold by a pharmaceutical company under a brand name. Once the protection of the product expires (for example, patents or regulatory protection such as data exclusivity), the company no longer has exclusive rights to sell the medicine. Other companies can then manufacture and sell a comparable medicine with the same active pharmaceutical ingredient (API). This new version is often referred to as a ‘generic’.

What are generic medicines?

A generic medicinal product is defined as a medicinal product that has:

- The same composition (qualitative and quantitative) in active substances as the original (reference medicinal) product (typically brand-name products);
- The same pharmaceutical form (tablet, syrup, inhaler, etc.) as the reference medicinal product; **and**
- Has been shown to interact with the body in a similar manner to the reference medicinal product (bioavailability studies and bioequivalence)

Chemically, there is **no difference** between the original branded medicine and the generic. As with all medicines, generics must comply with appropriate regulatory approval processes assessing and ensuring quality, safety, and efficacy. Approved generics are regulated in the same way that original medicines are regulated.

Generic names

The original medicine and the generic medicine will have different brand names, appearances, and packaging but contain the same active ingredients. Effectively,

they can be considered the same medicine. This could cause confusion were it not for the generic name (International Nonproprietary Name, INN) which is shared by all brands of the medicine. This is common for pain medications – for instance, active ingredients such as paracetamol and ibuprofen are used as the basis for many of the painkillers that can be bought in pharmacies.

Cost and quality of generic medicines

The key benefit of generics – and the reason that they are preferred by many patients, doctors, and hospitals – is that they often cost much less than original branded medicines.

Because of their comparatively low cost, it is common for the equality of generics and original medicines to be questioned by patients. Primarily, generic medicines cost less than the original medicine because the costs of research and development have been covered by the company that marketed the original medicine. The generic company does not need to demonstrate non-clinical or clinical test results for their products before obtaining a marketing authorisation. However, approved generic medicines are regulated in the same way as the original medicines. Manufacturing facilities and conditions must be of a very high standard. The generic medicine is tested to ensure that it has the same properties as the original. Following the approval of a generic medicine, the company producing it must commit to the collection and reporting of additional post-marketing safety data (pharmacovigilance).

There have been problems reported by patients who changed from the original medicine to its generic, and vice versa. In most cases, these problems seem to stem from variation in the inactive ingredients (for instance, a patient may have an allergy to an inactive ingredient used in a generic formulation). Other problems seem to come as a result of the amount of active ingredient in the different version.