Medicines: mere generic facts

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Originator and generic medicines are often identified either by their generic name or their brand name. Good Manufacturing Practice (GMP) standards ensure that medicines are of high quality, and thus support policies of generic prescribing and generic substitution. The substitution model adopted in Malta promotes rational use and favours competition between different brands. Competition is essential for inducing innovation of medicines and for the sustainability of the pharmaceutical industry. The availability of medicines, the knowledge on these medicines and confidence in their use, are crucial for the rational use of medicines as well as for the strengthening of the medicines market.

Introduction

All medicines which are placed on the market have at least three names. The chemical name is based on its chemical structure. The generic name also known as international non-proprietary name (INN), reflects the active ingredient and the proprietary name is usually a registered trademark.[1,2]

An original medicinal product has a unique trade name for marketing purposes, also known as the brand name.[2] On the market, one finds branded generics or unbranded generics. The branded generics also have a specific trade name, while the unbranded generics use the INN and the manufacturer's name. Generic names indicate the medical class thus providing the health care professionals with the drug's pharmacology and classification. Generic names are international. Brand names for the same drug may vary between countries.[1,2]

Some doctors may be reluctant to prescribe the generic name while patients may not accept a different brand name than the usual.[3] The knowledge or lack of it, may be determining the attitude and behaviour of both health professionals and patients towards medicines, and this reflects on the rational or irrational use of medicines.

Originator and generic medicines

The originator medicinal product is the first version of a pharmaceutical, developed and patented by an originator pharmaceutical company which has exclusive rights to marketing the product in the European Union (EU) for 15 years.[2]

A generic medicine is a pharmaceutical product which is no longer protected by a patent and thus can be copied by other pharmaceutical companies and marketed either under its own brand or as an unbranded product, ideally at a cheaper price. These manufacturers do not face the risks and costs linked to the research and development (R&D) of innovative, originator medicines. The pre-clinical tests and clinical trials are not necessary. Instead bioequivalence studies are carried out.[4]

Thus, a company which decides to formulate and manufacture a generic medicine, has to ensure that it is bioequivalent to the original trade-name drug, and that appropriate active ingredients are used, and that it is manufactured according to Good Manufacturing Practice (GMP) standards.[5,6] Bioequivalence implies that two medicines are pharmaceutically equivalent and their bioavailability is similar to such a degree that their effect can be expected to be essentially the same.[2] The inactive ingredients used may be different and may, though rarely, cause unusual reactions in the body.[5]

Since the accession of Malta in the EU in May of 2004, the EU legislation with respect to medicinal products, their manufacture and supply, has been adopted. The transposition of the EU legislation into the national legislation – Medicines Act, 2003 and its subsidiary legislation – has provided a legal framework which ensures that both originator and generic medicines available in Malta, meet specific standards of quality, safety and efficacy.[7,8] This legislation deters medicinal products of dubious quality from reaching the market and boosts the confidence of healthcare professionals and patients in using any of the medicines available.

Prescribing of medicines

The discovery and development of new medicines is very costly. During the patented period, an innovator medicine is granted monopoly so that this period could possibly be one of high expense to the health service provider or the patient. In this period, the product is marketed extensively and by the time the patent expires the brand name is strongly associated with the generic name in many prescribers' minds.[1]

Active, continuous encouragement and promotion of generic prescribing has been shown to increase the rate of generic prescribing, which in turn promotes competition and exerts a downward pressure on the prices of medicines.[9] The prescription process could be an essential source of efficiency within a health care system.[10] In Malta, doctors are trained to prescribe by generic name, and in the Government Health Services, a 'generic prescribing policy' is

in place. The procurement of medicines by the Government Pharmaceutical Services, is based on the generic name of the medicine. Generic prescribing facilitates substitution when a medicinal product with a different brand name is made available.

Both the patient's therapeutic needs and the financial situation determine what medicines a doctor prescribes.[10] Generic prescribing may be limited by the belief that generic medicines are of poorer quality than their originator counterpart. Two preparations formulated by two different manufacturers cannot be exactly identical.[1] However, regulations regarding standards of manufacture and Marketing Authorisation ensure that they are bioequivalent and meet requirements of quality, safety and efficacy.[2,6] If an originator branded product is more expensive than the generic alternative, it does not mean that the originator brand is of superior quality or efficacy, and vice-versa.[1]

Substitution of medicines

The EU aims to make efficacious, high quality and safe medicines readily accessible to patients. Amongst its objectives, one finds the promotion of clinical and cost-effective prescribing and of the wider and appropriate use of generic medicines.[11]

Generic substitution is the practice of substituting a pharmaceutical, whether marketed under a trade name or generic name (branded or unbranded generic), by a pharmaceutical, often a cheaper one, containing the same active ingredient(s).[2] However, different policies and different models are adopted by the EU Member states.[11] One model allows the replacement by the pharmacist of the prescribed branded drug by a generic with the same active ingredient, possibly without consulting either the patient or the doctor. Some argue that doctors should be able to prescribe branded medicines as they know what is best for the patient. Substitution may induce the prioritization of economic considerations over patients needs, and a model which supports the substitution of originator brand with the generic medicine might give generics an unfair competitive advantage.[4,11]

The generics substitution should promote the rational use of medicines so that patients receive medications appropriate to their clinical needs (Table 1), in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community.[12]

Table 1. Situations where generic substitution may not be appropriate[1,3,5]

- The medicine has a narrow therapeutic window e.g. digoxin, warfarin
- Plasma levels have to be measured and the dose of the medicine has to be carefully titrated against clinical effect
- The pharmaceutical preparation is a modified-release preparation
- The inhalers are CFC free
- The preparation has many active ingredients
- The patient suffers from an intolerance to an excipient
- There is an issue of patient compliance
- Patient may not be reassured and will not accept a substitute to the usual brand

The model of medicines substitution adopted in Malta supports the rational use of medicines. In fact according to the current legislation,

"Upon presentation of a prescription for a medicinal product, unless the prescriber specifically requests a particular branded product by writing "branded" or "®" on the prescription, a pharmacist can dispense the medicinal product prescribed or an equivalent medicinal product having the same chemical entity, dose, dosage form, formulation and dosage frequency as the medicinal product indicated on the prescription."
(Article 80, Medicines Act, 2003).[7]

Thus, in Malta the prescriber can prescribe a particular branded product where it is deemed necessary. On the other hand, the pharmacist may substitute the prescribed medicine with a less expensive alternative, which could be either the originator or a generic medicine. This model provides several advantages to pharmacists, doctors and patients. Community pharmacists do not need to stock several different brands of the same medicine as the pharmacist has a choice over which brand may be dispensed. Thus, wastage of money and expired medicines is less likely. A pharmacist may buy one brand in bulk thus ensuring that the generic drug is always available for the patients. A delay in the start of treatment and inconvenience to the patients are avoided when a generic equivalent to the prescribed medicine is available.[1] Those patients who cannot afford certain branded medicinal products can be offered an alternative which aids in lowering their financial burden.

Similarly to other policies which promote rational use, generic substitution can be quite controversial and thus may encounter opposition.[13] Doctors and pharmacists could have a financial interest in prescribing or dispensing those medicines with the highest profit margins. Doctors may see generic substitution as an interference with their freedom to prescribe. The prescribing and dispensing of newly marketed or expensive medicines could be associated with a certain status.[13] Inappropriate promotion and lack of information for health professionals and consumers can result in misunderstandings which in turn lead to irrational use of medicines.

In Malta, besides the legislation governing the substitution of medicines, there are also the Advertising Regulations which govern the promotion of medicines.[14] These regulations help to decrease the influences which misleading claims and financial incentives may have on the rational prescribing, dispensing and use of medicines. Information on the medicines authorized and marketed in Malta is provided by the Malta Medicines List published on the website of the National Medicines Policy & Audit Unit (NMPAU) within the Ministry for Health, the Elderly and Community Care (MHEC).[15] This list is classified by the Anatomic Therapeutic Chemical (ATC) code and enables the identification of alternatives available.

Medicines expenditure

The key objectives of a government's medicines policy should include the identification of medicines that bring the greatest benefit to patients, ensuring early access to medicines and providing choice of high value medicines.[16] Affordable prices are an important prerequisite for ensuring access to good quality essential medicines.[13,17] Affordability depends on pricing policies, price negotiations and

the promotion of competition.[13] A study which analysed the policy environment surrounding the retail market of generic medicines in 11 European Union countries concluded that if the 10 most commonly prescribed and used medicines were replaced by generic medicines, government spending on medicines could be reduced by between 27% and 48%.[18] In the EU, the rate of spending on medicines is growing faster than the economies and thus the promotion of the use of cheaper alternatives would help governments contain drug expenditure. Cheaper alternatives are a result of the price competition induced by safe, effective, high quality generic medicines. The latter also provide an incentive for the development of innovative medicines and a reduction in the prices of the originator brands.[19]

Products which are still patented are affected by price competition, as most often the drug whose patent has expired would be a therapeutic alternative for still patented drugs. Thus, the effects of generic substitution are not limited to the generics market. It also affects the competition in an entire therapeutic area. Generic substitution can thus reach its full benefits within an efficient marketplace where there is free competition.[20]

The uptake of generics can be stimulated effectively by efficient and fast regulatory procedures, legislation, generic substitution, information campaigns, reference-pricing systems, reimbursement systems and prescribing budgets. These same instruments must be also effective in stimulating competition between different brands, so as to ensure long-term sustainability of the medicines industry.[10] The latter also depends on the creation of an environment that encourages pharmaceutical innovation and fosters the research-based development of new and better medicines.[21]

Practice points

1. Medicines have three names: chemical name, generic name and brand name.
2. In the ATC classification system pharmaceuticals are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.[2]
3. In Malta, substitution of a medicinal product with an equivalent alternative can be done.[11]
4. As increasing demands are being made on healthcare services, generic medicines provide a major benefit to society by ensuring patient access to quality, safe and effective medicines.[4]
5. Any medicines policy must take into account the need to have an environment which supports the research and development of innovative medicines, which are essential for patients as well as for the sustainability and general equilibrium of the medicines market.[4]

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