

GENERIC PRESCRIBING

SUMMARY

- + Generic prescribing is cost effective.
- + Generic prescribing reduces the potential for confusion when prescribing .
- + Generic prescribing should be encouraged for all drugs except modified-release preparations, combination products and drugs with narrow therapeutic indices such as cyclosporin and lithium.

INTRODUCTION

Prescribing a drug generically has been identified as an indicator of good prescribing practice and may have an economic advantage.^{1,2} There is a lower rate of generic prescribing in the Republic of Ireland compared to England and Northern Ireland with less than one in five drugs prescribed for General Medical Services patients being written generically. In contrast, the proportion of prescriptions written in general practice in England, where there is a similar range of medicines available, using the generic name increased from 35% in 1985 to 69% in 1998.³ Prescribers here are concerned about the reliability or quality of generic products on the market, possible legal liabilities associated with their use and the fact that pharmacists may legally dispense proprietary preparations in the case of private prescriptions written generically⁴.

TERMINOLOGY

Every marketed drug has at least three names: a chemical name, a generic name and a proprietary (or brand) name which is usually a registered trademark. In addition, formulations containing two or more drugs in fixed ratios sometimes have generic titles e.g co-proxamol, co-amoxyclov⁵. While the patent is valid, the manufacturer who invented and developed the drug will derive income whenever it is prescribed, irrespective of whether the generic or proprietary name appears on the prescription. Following patent expiry, competitors can manufacture and market the drug. These drugs may be licensed using either the generic name or alternative proprietary names (Branded Generics). If the drug is then prescribed generically, a pharmacist has a choice of products to dispense and often the sales of the original brand will fall. If the competing products are cheaper, this competition benefits the purchaser but damages

the innovator, who has had at most 15 yrs to recover the investment necessary to bring the drug to market. Since 1993 there has been an option available to pharmaceutical manufacturers to apply for an extension of the patent term protection within the European Community which has eased the effects of the process on the innovator to some extent. The high rate of generic prescribing in the United Kingdom does not appear to have impinged on the growth of research based pharmaceutical companies located there.

REASONS TO PRESCRIBE GENERICALLY

Prescribing generically offers the following advantages:

1. It saves money, as generic products are almost always cheaper than branded products. The switch to fundholding (where general practitioners are in charge of their own prescribing budget) in England and Northern Ireland led to an increase in generic prescribing with a consequent reduction in prescribing costs^{6,7}. Recent increases in the prices of generic products in the United Kingdom have led to calls to regulate the generic market⁸. However, writing a generic prescription does not ensure that a non-branded product will be dispensed. The growth of the branded generic market has reduced the potential savings which may accrue from generic prescribing. **(Table 1)**
2. Generic prescribing reduces the potential for confusion as only one name for a drug is used. Errors have occurred with products of similar names such as Losec[®]/Lasix[®] ⁹.
3. The generic name provides a guide to the drug's pharmacology as the name normally indicates its chemical class. For example, all beta-blockers end in -ol and ACE-inhibitors end in -pril.
4. It increases the likelihood of undergraduate and post-graduate education influencing practice since generic names are commonly used universally. Generic names are also used routinely in medical and scientific publications.
5. The pharmacist can also reduce the number of brands which are stocked if the prescription is written generically. This in turn reduces the inconvenience to patients if the community pharmacist does not stock the brand prescribed.

FACTORS TO BE CONSIDERED WHEN PRESCRIBING GENERICALLY

Quality

Pharmaceutical products formulated by different manufacturers are unlikely to be identical in every respect. However different products may be considered equivalent. Equivalence may be expressed in several ways:

- a. Chemical equivalence- containing the same amount of the same therapeutically active ingredient
- b. Biological (bio-) equivalence- delivering the same amount of active drug to the site of action
- c. Therapeutic (clinical) equivalence- producing the same clinical effects.

Two products can be chemically equivalent but bio-inequivalent, because they contain different adjuvant ingredients that alter their dissolution and absorption properties. To obtain a product authorisation (PA), a generic manufacturer must in addition to providing evidence of safety, efficacy and quality, satisfy the Irish Medicines Board that the bioavailability of its product matches that of the original proprietary brand¹⁰.

For drugs with a wide therapeutic index e.g. penicillins, inhaled bronchodilators, whose efficacy would not be compromised and whose toxicity would not be enhanced by minor differences in plasma concentration, bioequivalence ensures therapeutic equivalence. For drugs with a narrow therapeutic index, especially those whose efficacy and/or toxicity, are critically dependent on the drug's plasma concentration, differences in bioequivalence may result in changes in clinical effects. Examples include carbamazepine, phenytoin, theophylline, cyclosporin and lithium. In these patients it is recommended that the same formulation, either proprietary or generic (where available) be prescribed on each occasion.

Modified-release formulations

Problems may arise with modified-release formulations, whose composition and pharmacokinetic characteristics are more difficult to standardise compared to standard-release formulations. Use of a modified release preparation is only justified if it offers advantages over the standard-release version. Modified-release preparations are often more expensive than standard-release preparations. The Medicines Control Agency (MCA), UK advises that all modified-release preparations should be prescribed by their brand name. In addition, the British National Formulary

advises that modified-release forms of nifedipine and diltiazem should be prescribed by their brand name. It is therefore recommended that all modified-release formulations are prescribed by their brand names and that substitution does not occur once treatment has been initiated.

Product Liability

Concerns regarding litigation have been put forward as a reason for not prescribing generically. Liability for any injury caused by a defect in a product lies with the manufacturer. If the manufacturer cannot be identified, then the supplier is liable. The dispenser of the product should be satisfied with the quality of the medicine supplied and to be able to identify the source of supply. Most generic manufacturers now have unique company and/or product identification codes on all solid dosage forms enabling easier identification of the manufacturer¹¹.

Patient Acceptability

Problems may arise when a generic product is substituted after a patient has become familiar with the name, shape, colour and taste of the branded product. Although any patient information leaflet supplied must be written in English, further confusion can arise in the case of licensed parallel imports, part of whose packaging may be labelled in a foreign language. Any unexpected contrast may cause concern that a mistake has occurred or that quality has been sacrificed in the interests of economy. Patient acceptability of a generic product (whether in tablet or inhaler form) may be increased if the reasons behind the substitution are explained and reassurances about quality assurance and therapeutic equivalence are given¹². Acceptability may also be increased if the appearance of the generic product is not too dissimilar from the branded product (e.g. salbutamol inhalers are usually blue, and beclomethasone inhalers are usually brown) but even this need not be an obstacle if the patient is forewarned about any differences. In some instances, no amount of reassurance will convince some patients that a generic medicine, or an alternative brand, is equivalent to their previous medication. In such instances, prescribing a branded product may be the only way to ensure that patients continue to take their medication as directed.

In conclusion the incidence of generic prescribing in Ireland is still relatively low. Prescribers can be assured that generic prescribing with few exceptions will result in a clinically equivalent, but cheaper product compared with the original proprietary drug leading to significant cost-savings. With patient counselling and liaison with the community pharmacist, generic substitution need not present any difficulties. Generic prescribing should be encouraged for all drugs (including branded generics), except for modified-release preparations, combination products and drugs with a narrow therapeutic index.

Table 1: Prescribing Costs - Proprietary vs Generic (GMS May 2000)

Drug	Proprietary Cost (Cost of 30 days)	Generic Cost (Cost of 30 days)	Potential Cost Saving
Gastrointestinal			
Ranitidine 150mg BD	£31.96	£18.11	£13.85
Cimetidine 400mg BD	£20.55	£8.95	£11.60
Cardiovascular			
Fruzemide 20mg OD	£1.41	£0.67	£0.74
Atenolol 50mg OD	£6.21	£3.74	£2.47
Captopril 25mg BD	£13.90	£8.64	£5.26
Anti-Infectives			
Amoxycillin 250mg TDS for 5 days	£7.88	£1.53	£6.35
Co-amoxyclav 375mg TDS for 5 days	£8.74	£7.42	£1.32
Central Nervous System			
Fluoxetine 20mg OD	£21.41	£17.12	£4.29
Respiratory			
Beclomethasone metered dose inhaler 100mcg (200 dose)	£11.61	£9.58	£2.03
Salbutamol metered dose inhaler (200 dose)	£2.66	£2.15	£0.51
Gout			
Allopurinol 300mg OD	£9.11	£5.21	£3.90

REFERENCES	
1. HMSO 1994;	7. BMJ 1995;311:1347-1350
2. BMJ 1988;297:1596	8. BMJ 2000;320:131-132.
3. Statistical Bulletin 2000;1998/15	9. Pharmacy in Practice 1995(Apr):173
4. IMJ 1997;90:146-147	10. DTB 1997;35:9-11
5. Prescribers' Journal 1997;37:133-137	11. MeReC Bulletin 1996;7:37-40
6. BMJ 1997;315:166-170	12. Br.J.Gen.Pract 1994;44:139-140.