North of Tyne & Gateshead Area Prescribing Committee

Medicines that are not suitable for Generic Prescribing[1] - updated January 2016.

Introduction

Prescribing medicines generically rather than by brand name can improve cost-effectiveness and is encouraged. However, there are some circumstances in which brand-name prescribing is preferred. These include:

- Where there is a clinically important difference in bioavailability between brands of the same medicine, particularly if the medicine has a narrow therapeutic index.
- Where modified release preparations are not interchangeable.
- Where there are important differences in formulation between brands of the same medicine.
- Where products contain multiple ingredients and brand name prescribing aids identification.
- Where administration devices (e.g. inhaler or self-injection) have different instructions for use and patient familiarity with the same product is important.
- Where the product is a biological rather than a chemical entity
- Where preparations of the same medicine have different licensed indications

Preparations of the same medicine have different licensed indications.
These should be considered on an individual medicine basis, taking into account the differences. If a medicinal product is supplied for an indication that is not licensed or is to be used in a way that is not licensed, patients should be made aware that the details in the package insert may not apply in their entirety to them.

Biological Medicines
Where the product is a biological rather than chemical entity, products with the same generic name may not always be equivalent. They may therefore need to be considered on an individual product basis.

[1] Many of the recommendations in this document are based on the recommendations in 'Which medicines are not suitable for generic prescribing in primary care?' UKMI Q&A 247.3, http://www.evidence.nhs.uk/search?q=%22Which+medicines+should+be+considered+for+brand%22

Recommendations

The following medicines may be considered suitable for brand-name prescribing. This table has been compiled based on recommendations in a Question and Answer Document from the UKMI with some local additions (in blue). Specific references for individual medicines are included where appropriate.

BNF	Drug or drug class	Reason for proprietary name prescribing	Specific references	Comments
1.1.1	Antacids preparations containing simeticone	To aid identification. Products contain multiple ingredients.	BNF	Exception - Co-simalcite 125/500 may be used as a generic name for Altacite plus as in BNF.
1.1.2	Compound alginates and proprietary indigestion preparations	To aid identification. Products contain multiple ingredients.	BNF	
1.5.1	Aminosalicylates (Mesalazine)	The delivery characteristics of oral mesalazine preparations may vary; these preparations should not be considered interchangeable.	BNF	
1.6.4	Macrogols (polyethylene glycols)	To aid identification. Products contain multiple ingredients.	Ref UKMI Q&A 67.4	Laxido is first line formulary choice
1.7.2	Compound haemorrhoid preparations	To aid identification. Products contain multiple ingredients.		
1.9.4	Pancreatin supplements	To aid identification. Products contain multiple ingredients.	-	Different products contain varying amounts of enzyme activity.
2.6.2	Diltiazem modified release preparations	Different versions of modified-release preparations containing more than 60 mg diltiazem hydrochloride may not have the same clinical effect. To avoid confusion between these different formulations of diltiazem, prescribers should specify the brand to be dispensed	BNF dm+d	Need to distinguish between once and twice daily preparations.

BNF	Drug or drug class	Reason for proprietary name prescribing	Specific references	Comments
2.6.2	Nifedipine modified release preparations	MR preparations have different release characteristics and are not interchangeable. To avoid confusion between these different formulations of nifedipine, prescribers should specify the brand to be dispensed.	BNF dm+d	Need to distinguish between once and twice daily preparations.
3.1	Inhaler devices – see general comment	Patient familiarity with one brand is important; instructions for use vary between preparations.	dm+d	Metered dose aerosol inhalers may generally be prescribed generically, providing particular attention is paid to particle size variations in formulation and bioavailability. Breath actuated, or dry powder, inhalers should be prescribed by brand name or generic name + device as instructions for use often vary between preparations.
3.1.1	Salmeterol metered dose inhalers	Patients with allergies to peanuts and soya	MHRA MIMS	The brands *Neovent*® and *Vertine*® are contraindicated in, and should not be supplied to, patients with allergies to peanuts and soya
3.1.3	Theophylline modified release preparations	MR preparations have different release characteristics and are not interchangeable. Theophylline has a narrow therapeutic index.	BNF	Products vary considerably and blood concentration needs to be maintained within narrow limits.
3.1.3	Aminophylline modified release preparations	MR preparations have different release characteristics and are not interchangeable. Aminophylline has a narrow therapeutic index.	BNF dm+d	As Theophylline.

BNF	Drug or drug class	Reason for proprietary name prescribing	Specific references	Comments
3.4.3	Adrenaline pre-filled syringes	Patient familiarity with one brand is important; instructions for use vary between preparations.	BNF Dm+d	JEXT is the regional brand of choice
4.2.3	Lithium preparations	**Preparations vary widely in bioavailability**; changing the preparation requires the same precautions as initiation of treatment	BNF dm+d	Lithium concentrations need to be maintained within a relatively narrow range.
4.4	Methylphenidate modified release formulations	Different brands contain different proportions of immediate release and modified release methylphenidate and vary in their duration of action		Concerta XL®, Medikinet XL) and Equasym XL® are the brands currently on the formulary.
4.7.2	Morphine oral modified release preparations	MR preparations have different release characteristics. Patient familiarity with one brand is important.	DoH [2] RPSGB	. Zomorph capsules are the preferred brand for twice daily dosing.
4.7.2	Buprenorphine sublingual tablets	Differences is licensing between brands	SmPC	In the treatment of substance misuse the 400microgram strength should be prescribed as *Subutex*® to avoid a product licensed for pain relief being supplied.

2 *Building a Safer NHS for Patients - Improving Medication Safety*. Department of Health, London, pp. 105–111. Available from: www.dh.gov.uk/assetRoot/04/08/49/61/04084961.pdf states - Oral sustained-release opiates are a particular source of error and care should be taken to avoid any possible ambiguity when prescribing these drugs. Including the brand name on the prescription and dispensing label will aid in the identification of the correct formulation to be dispensed or administered.

BNF	Drug or drug class	Reason for proprietary name prescribing	Specific references	Comments
4.7.2	Fentanyl patches	Patches are available as matrix and reservoir formulations; Patient familiarity with one brand is important. Reservoir patches (e.g. *Tilofyl*) must not be cut because damage to the rate-limiting membrane can lead to a rapid release of fentanyl resulting in overdose. If the prescriber intends the patch to be cut (NB: unlicensed and not recommended by the MHRA) then the prescription must specify a brand of matrix formulation patch (e.g. *Durogesic DTrans*, *Matrifen*).		
4.7.2	Oxycodone	Confusion between the different formulations of oxycodone has resulted in clinical incidents.	MHRA	Confusion can arise between immediate (4 to 6 hourly) and modified release (twice daily) formulations. Prescribe by brand name. Also recommended that the liquid formulation is used if an immediate release formulation is needed. **OxyNorm® (immediate release) capsules are not recommended for use except in exceptional circumstances.**

4.8.1	Antiepileptic drugs	The MHRA has classified antiepileptic drugs (AEDs) into three categories of risk, based primarily on their therapeutic index and physiochemical characteristics (in particular solubility and permeability across membranes) indicative of potential differences between formulations. Category 1: Specific measures are necessary to ensure consistent supply of a particular product (which could be either a branded product or a specified manufacturer's generic product). Category 2: NB: By default, this category includes all AEDs not listed in categories 1 or 3. The need for continued supply of a particular manufacturer's product should be based on clinical judgement and consultation with patient and/or carer. Category 3: No specific measures are normally required and these AEDs can be prescribed generically and without specifying a specific manufacturer's product:	MRHA [3], [4]	NICE[5] recommends continuity of the same brand, or the same generic preparation, for patients with seizure disorders, unless the prescriber (in consultation with the patient and their family or carers) considers this not to be a concern. (For individual antiepileptic agents, see below.) **Note: When used for other indications (e.g. carbamazepine for pain) brand name prescribing is not necessary**

BNF	Drug or drug class	Reason for proprietary name prescribing	Specific references	Comments
4.8.1	Carbamazepine, phenytoin, phenobarbital and primidone	Different preparations may vary in bioavailability.	BNF MHRA Nov 2013	Doctors are advised to ensure that their patient is maintained on a specific manufacturer`s product .
4.8.1	Valproate, lamotrigine, perampanel, retigabine, rufinamide, clobazam, clonazepam, oxcarbazepine, eslicarbazepine, eslicarbazepine, zonisamide and topiramate		MHRA Nov 2013	Doctors are advised to use their judgement (in consultation with their patient/carer) to determine whether it would be advisable for them to be maintained on a specific manufacturer`s product.
4.9.1	Apomorphine pre-filled syringe	Patient familiarity with one brand is important; instructions for use vary between preparations.	dm+d	
4.9.3	Botulinum toxin type A	Preparations are not interchangeable due to differences in potency. Preparations have different licensed indications.	BNF	
6.1.1	Insulin	Patient familiarity with the same brand is important; training is required in the use of specific devices for self-injection.	dm+d	

[3] Medicines and Healthcare products Regulatory Agency. Antiepileptic drugs: new advice on switching between different manufacturers' products for a particular drug. Drug Safety Update November 2013; 7 (4): A1. Accessed at: www.mhra.gov.uk/home/groups/dsu/documents/publication/con336729.pdf on 3/12/2013.

[4] Medicines and Healthcare products Regulatory Agency. Formulation switching of antiepileptic drugs: A report on the recommendations of the Commission on Human Medicines from July 2013. Accessed at http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con341226.pdf on 3/12/2013.

[5] National Institute for Health and Clinical Excellence. Clinical guideline 137: The epilepsies – the diagnosis and management of the epilepsies in adults and children in primary and secondary care. January 2012. Accessed at www.nice.org.uk/nicemedia/live/13635/57779/57779.pdf on 4/9/2013.

BNF	Drug or drug class	Reason for proprietary name prescribing	Specific references	Comments
6.4.1	Hormone replacement therapy	Different brands of the same formulation are available. Patient familiarity with one brand is often important. Other single component products e.g. tibilone, conjugated oestrogens - see comments		Combination products should be prescribed by brand name. Some single ingredient tablets e.g. conjugated oestrogens & tibolone can be prescribed generically but where instructions may be product specific and patient familiarity is considered important e.g. oestradiol transdermal patches, then brand prescribing is appropriate.
6.5.1	Somatropin injection cartridges	Patient familiarity with the same brand is important and training is required in the use of specific devices for self-injection. Some somatropin preparations are licensed as 'biosimilar' medicines.	dm+d, BNF	
7.3.1	Combined oral contraceptive	Different brands of the same formulation are available. Patient familiarity with one brand is important.	-	Generic prescribing is may cause confusion .
7.3.2	Progestogen only oral contraceptive	Different brands of the same formulation are available.	-	Branded prescribing is not necessary with single component products unless patient familiarity with one brand is deemed important. Where a prescriber decides to implement branded prescribing, the brand initiated should be maintained.
7.3.2.3	Levonorgestrel-releasing intrauterine systems	Products have different indications, durations of use, and introducers.	MHRA Jan 2016[6]	
7.4.5	Alprostadil injection	Instructions for use vary between preparations.	dm+d	Caverject® Dual Chamber preferred presentation for ease of use and lower cost.

[6] https://www.gov.uk/drug-safety-update/levonorgestrel-releasing-intrauterine-systems-prescribe-by-brand-name

BNF	Drug or drug class	Reason for proprietary name prescribing	Specific references	Comments
8.2.1	Mycophenolate	Different formulations of the same immunosuppressant may vary in bioavailability and to avoid reduced effect or excessive side-effects, it is important not to change formulation except on the advice of a transplant specialist.	BNF, PJ2010; 285 (7630): 659-660,, Renal News 2011; 2: 3-4	Mycophenolate mofetil and mycophenolate sodium preparations are not interchangeable.
8.2.2	Ciclosporin	Preparations are not interchangeable and should be prescribed by brand-name to avoid inadvertent switching. It is important not to change formulation except on the advice of a transplant specialist. Ciclosporin has a narrow therapeutic index.	BNF & MHRA Drug Safety Update Dec 2009	*Neoral*® is the preferred brand of oral ciclosporin in the Formulary for routine use.
8.2.2	Tacrolimus	Tacrolimus has a narrow therapeutic index. Oral tacrolimus products: prescribe and dispense by brand name only, to minimise the risk of inadvertent switching between products, which has been associated with reports of toxicity and graft rejection.	MHRA Drug Safety alert June 2012	The growing number of oral tacrolimus products available on the market increases the potential for inadvertent switching between products, which has been associated with reports of toxicity and graft rejection. Therefore, to ensure maintenance of therapeutic response when a patient is stabilised on a particular brand, oral tacrolimus products should be prescribed and dispensed by brand name only. If a prescriber considers that switching a patient to a different brand of oral tacrolimus would be of benefit, the change requires careful supervision and therapeutic monitoring by an appropriate specialist
8.2.4	Interferon pre-filled disposable devices Peginterferon injection pre-filled disposable devices	Patient familiarity with one brand is important; instructions for use vary between preparations.	dm+d	Products are not interchangeable, dosage varies and variation in injection devices.

BNF	Drug or drug class	Reason for proprietary name prescribing	Specific references	Comments
9.1.3	Erythropoietins	Patient familiarity with the same brand is important and training is required in the use of specific devices for self-injection. Some epoetin preparations are licensed as 'biosimilar' medicines.	BNF	
9.1.6	Granulocyte-colony stimulating factors Filgrastim, lenograstim and Pegfilgrastim	Patient familiarity with the same brand is important and training is required in the use of specific devices for self-injection. Generic filgrastim has been approved as a 'biosimilar' medicine.	dm+d,	
9.2.1	Oral rehydration salts	To aid identification. Products contain multiple ingredients.	-	Different products are made to different formulae and have different flavours.
9.5.1	Calcium salts	To aid identification.	-	Single ingredient products should be prescribed by generic name. Brand names should only be used where a specific product is needed (e.g. for patient acceptability).
9.6.4	Vitamin D with Calcium preparations	Brand name may aid identification and products contain multiple ingredients, but some listed generically in Drug Tariff.	-	Products vary in composition, flavour and method of administration.
9.6.7	Multivitamin preparations	Composition of proprietary products varies widely	-	Except where there is an official generic preparation e.g. Vitamins capsules in the BNF. **The terms Multivitamin tablets and Multivitamin capsules should not be used.**
12.3.5	Saliva replacement products	To aid identification. Products contain multiple ingredients.	-	Products contain multiple ingredients and recommendations on use differ.

BNF	Drug or drug class	Reason for proprietary name prescribing	Specific references	Comments
13.1-13.10	Preparations for skin and scalp conditions containing multiple ingredients	To aid identification. Products contain multiple ingredients. Also, potency of topical corticosteroids preparations is a result of the formulation as well as the corticosteroid.	-	Brand names should be used for combination products, unless there is an official combination.
13.5.3	Ciclosporin	See section 8.2.2	BNF	
14.4	Human papillomavirus vaccine	*Cervarix* (bivalent vaccine) and *Gardasil* (quadravalent vaccine) are not considered interchangeable.	BNF	
Appendix 5	Wound formulary	Consistency of supply and ease of dispensing	North of Tyne & Gateshead APC	Where several brands are available for a generic description,brand prescribing will help ensure consistency of supply. Dressings should be prescribed by brand where named as such in the formulary.

Abbreviations
MHRA = Medicines & Healthcare Products Regulation Agency
PCF = Palliative Care Formulary
dm+d = The NHS Dictionary of Medicines and Devices

Note – this list may not be completely comprehensive.