Clinical guideline

BRAND SPECIFIC MEDICINES – PRESCRIBING, DISPENSING AND SWITCHING BRAND

SETTING	University Hospitals Bristol and Weston NHS Trust and outsourced outpatient dispensaries
FOR STAFF	Prescribers and pharmacy staff working for University Hospitals Bristol and Weston NHS (UHBW) Trust or any outsourced dispensaries
PATIENTS	Any patients being prescribed or dispensed a brand specific medicine

Guideline

Although there is full interchangeability between brands of generic manufacturer's formulations containing the same generic drug there are some medicines and formulations of medicines containing the same generic drug which are not interchangeable. This is because their efficacy or tolerability has been found to vary too much when some patients are switched between them. These are normally referred to as brand specific medicines. It should be noted that in some cases, a medicine may not have an official brand name e.g. if there is a medicine manufactured as a Specials item or manufactured and labelled with only the manufacturer and the generic name. With these medicines, it is still important that they are considered and treated as a specific brand.

It is important for all pharmacy staff to be aware of which medicines are brand specific so that they do not unintentionally dispense a different brand (or manufacturer's product) which could clinically affect how well the medicine is working or cause toxicity to the patient.

This SOP seeks to

- Highlight the key medicines to be regarded as brand specific.
- Highlight the need for brand specific medicines to have their brand (or manufacturer) clearly defined within the pharmacy dispensing system (Wellsky/JAC)
- Highlight the actions to be taken if it becomes clear that, due to a medicines shortage, an unavoidable switch is necessary and is carried out in collaboration with the Trust clinical team, the pharmacy team and the patient or their representative.

How to identify if a medicine is brand specific?

There are multiple national publications that help pharmacy staff to identify which medicines are brand specific and it forms a key part of all pharmacy staff training, but it must be remembered that new medicines come onto the market all the time so there is no one key list which indicates all the medicines which should be brand specific. It is therefore important for all pharmacy staff and in particular the pharmacists and clinical pharmacy technicians to be aware of which medicines must be prescribed and dispensed by brand and also for staff to use the prompt available to them via the pharmacy dispensing system (Wellsky JAC) to help them when dispensing or screening to identify any such drugs particularly when working in a new area or dispensing a new medicine.

In order to support staff in identifying brand specific medicines it is a key requirement of any pharmacist or pharmacy staff member requesting for a new drug to be added onto the pharmacy dispensing system (Wellsky/JAC) to identify if the product requires brand (or manufacturer) specific prescribing. If it does, they must ensure that this is clearly identified in any drug file request.

Any new drug files requested by the specialist pharmacists are double checked by one of the pharmacists in the Pharmacy Informatics Team to ensure that they are also satisfied that the drug correctly contains a brand name or manufacturer when clinically required.

All pharmacy staff then using the pharmacy system to order, add suppliers or dispense medicines should be trained to monitor for drugs which have a brand name in their title as this will highlight to them when patients must stay on the same brand. It can also trigger appropriate management challenge of any prescription for these medicines where the brand or manufacturer is not clear. If a dispensing label has a brand in the title then the dispenser must ensure that both the generic drug name and brand (or manufacturer) match the product they are labelling.

Which are the key brand specific medicines groups?

The United Kingdom Medicines Information Service (UKMI) publishes a brand specific medicines in primary care summary on the Special Pharmacy Services (SPS) website. Key highlights from which can be find below but please see the website for the most up to date copy

Allergy and immunology

Adrenaline autoinjector

Prescribe by brand name to ensure patients receive an auto-injector device they have been trained to use. If switching between brands, patients should receive full training in use of the new device.

Licensed doses differ between brands of adrenaline auto-injectors.

Adrenaline bioavailability may be influenced by factors including formulation and needle length.

Anaesthesia and pain

Opioid patches

Buprenorphine

Buprenorphine transdermal patches are available as 72-hourly, 96-hourly and 7-day formulations. Brand name prescribing is recommended to reduce the risk of confusion and error in dispensing and administration.

Fentanyl

Fentanyl transdermal patches are available as matrix and reservoir formulations. Reservoir patches 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) then the prescription must specify a brand of matrix formulation patch.

Opioids MR

Morphine, oxycodone, tramadol

These medicines are available as 12-hourly and 24-hourly oral formulations. Brand-name prescribing is recommended to reduce the risk of confusion in dispensing and administration.

Cardiovascular

Diltiazem MR

Different versions of diltiazem modified-release preparations containing more than 60mg may not have the same clinical effect.

Nifedipine MR

Different versions of nifedipine modified-release preparations may not have the same clinical effect.

Endocrinology

Insulins

NICE guidance recommends insulins are prescribed by brand name.

It is important to ensure patients receive an administration device they have been trained to use.

Manufacturers advise any switch between brands or formulation of insulin should be done under strict supervision; a change in dose may be required.

Gastrointestinal

Mesalazine

The BNF states there is no evidence that any one oral preparation of mesalazine is more effective than another; however, delivery characteristics of mesalazine preparations may vary.

If switching to a different brand of mesalazine, advise the patient to report any changes in symptoms.

Further information on the differences between mesalazine preparations are at oral mesalazine and non-oral mesalazine.

Mental health

Lithium

Lithium has a narrow therapeutic index and preparations vary widely in bioavailability. Changing the preparation requires the same precautions as initiation of treatment.

Methylphenidate MR

Methylphenidate modified-release (MR) preparations contain both immediate-release (IR) and MR methylphenidate. The proportion of IR and MR methylphenidate differs between brands; different preparations may not have the same clinical effect.

Neurology

Antiepileptics for epilepsy

NICE epilepsy guidelines recommends consistent supply of the same 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 further information on the MHRA requirements for which antiepileptics need to be prescribed by brand please see the trust guideline on MHRA guidance on formulation switching of antiepileptic drugs

Organ transplantation

Ciclosporin

Patients should be stabilised on a particular brand of oral ciclosporin because switching between formulations without close monitoring may lead to clinically important changes in blood ciclosporin concentration.

Switching between a brand and generic formulation, or between generic formulations, should be initiated only by a transplant specialist. If switching is necessary, the patient should be monitored closely for changes in blood-ciclosporin concentration, serum creatinine, blood pressure, and transplant function.

Mycophenolate

Switching between a brand and generic formulation, or between generic formulations, should be initiated only by a transplant specialist as it requires careful monitoring. *(NB it should be noted that at UHBW very little of the mycophenolate prescribing is for transplant indications and therefore the requirement to remain on a specific brand is not required for many of the patients currently on this therapy)*

Tacrolimus

Inadvertent switching between oral tacrolimus products has been associated with reports of toxicity and graft rejection. Oral tacrolimus products should be prescribed and dispensed by brand name only.

Switching between a brand and generic formulation, or between generic formulations, should be initiated only by a transplant specialist as it requires careful monitoring of levels and transplant function.

Respiratory

Inhalers

NICE CKS asthma guidelines advise generic prescribing of inhalers should be avoided as it can lead to people with asthma being given an unfamiliar device, affecting usage and adherence.

Corticosteroids: beclometasone, budesonide, fluticasone

Beclometasone dipropionate CFC-free pressurised metered-dose inhalers are not interchangeable; *Qvar* and *Kelhale* have extra-fine particles and are more potent than *Clenil Modulite* and *Soprobec*. MHRA advice to prescribe beclometasone inhalers by brand name was issued in 2008.

Tiotropium

To ensure patients receive an inhaler they have been trained to use, tiotropium capsules and administration devices should be prescribed by brand name

Additional Hospital only brand specific medicines

In addition to the UKMI list above there are also many hospital only medicines *which must be prescribed by brand, most of these fall into the following groups*

Biosimilars, biologics and Advanced Therapeutic Moiety Products (ATMP's)

Biosimilars by their very name are biologic medicines which are highly similar to one another but are not the same as they involve a biological source in their development. Many Biologic medicines also fulfil the criteria to be known as Advanced therapeutic moiety products *(note some cell therapies don't meet the ATMP criteria despite being biologics).* Therefore, as they cannot be seen as interchangeable, medicines in these groups are normally brand specific. Examples include the drugs with names needed with the suffix mab such as adalimumab, rituximab, infliximab, insulins (as already listed above), filgrastim and related agents, Low molecular weight heparins (LMWH) like enoxaparin, and etanercept.

In terms of the most advanced genetic therapy ATMP's these medicines may be prescribed by brand e.g. Zolgensma although will be issued for a named patient's use only or may be so advanced that they are tailor-made using patient's own cells so a dose will only be suitable for the patient whose cell its biologic component was extracted from (e.g. CAR T)

Formulation differences of some brand specific medicines

It should also be noted that there are a few brand specific medicines where the dose of the medication may need to change if a patient changes formulation of the drug even though the brand remains the same. Such differences are clearly described in the BNF / BNFC and also in the product literature. Examples here would include pozaconazole (liquid v tablets), itraconazole (Liquid v tablets) carbamazepine (tablets v suppositories), phenytoin (liquid v capsules). For a fuller list of products please refer to UKMI guidance here

Prescribing, Dispensing and checking responsibility of staff in relation to brand specific medicines.

All registered pharmacy staff and prescribers are encouraged through their initial training, induction and through ongoing professional development to learn which medicines are brand specific. In addition, day-to-day recognition of brand specific medicines can also be prompted through the pharmacy dispensing system, as mentioned above.

Prescriber responsibilities

Prescribers through their own professional development should be aware of which medicines are brand (or manufacturer) specific and should include the brand name or manufacturer's name when prescribing in addition to the normal generic name which is used to prescribe all medicines in UHBW unless they are combination medicines with no generic names e.g. multivitamin products like Abidec. When a prescriber makes a decision to change a patient's brand (or manufacturer) specific medicine they are also responsible for ensuring that

- The patient (or carer) is aware of this change and the risks that such a change may pose
- A plan for the patients necessary monitoring is made and shared with the patient and any staff who will need to be involved.
- All these things are documented clearly in the patient notes.

Pharmacist responsibilities

Pharmacists should clinically screen all orders for medicines before they are dispensed and at this point should ensure that any order or prescription for a brand specific medicine contains the necessary brand or manufacturer. Brands and manufacturers are not required for medicines which do not clinically need to be prescribed by brand. If it is unclear what brand is required, or If at any point the prescriber requests a change to the brand or manufacturer that they have written on the prescription, then a new prescription should be requested rather than an alteration made by the pharmacist (For outpatient brand switches the Outpatient Pharmacy Brand Switch Record on the patients careflow should be completed by the Boots team). If a change to the original prescription is made on an electronic prescription then the old prescription will need to be excluded from the medway record so that only the most up to date one is visible. This is to ensure there is a clear ownership by the prescriber that they are asking for a brand change for any medicine which should be brand specific. If an owing is generated in the pharmacy for a brand specific medicine then the pharmacist should ensure that it is clear to all staff who may then process that owing as to which brand should be dispensed when processed.

Pharmacy Dispenser Responsibilities

Dispensers should dispense according to the brand on the prescription and should not substitute a brand or manufacturer without querying with a pharmacist and getting their prescription changed to match the brand they are supplying. If the dispenser or labeller becomes aware that a drug which should be brand (or manufacturer) specific has been prescribed, dispensed or ordered without the prescription clearly stating the brand, or if the dispenser identifies that this supply is asking for a different brand than that previously dispensed for the patient then the dispenser should query this with the pharmacist to clarify what brand, manufacturer or formulation is needed. A prescription containing the appropriate brand should then be sourced from the prescriber if needed. If an owing is generated in the pharmacy for a brand specific medicine then the dispenser should ensure that its clear to all staff who may then process that owing as to which brand should be dispensed when processed.

Pharmacy Checker responsibilities

Dispensing Accuracy Checkers – when final accuracy checking dispensed medicine, the checking staff have to ensure that the drug name on the label matches the product which it has been attached to and also matches the prescription. If a brand or manufacturer or specific formulation is listed on the drug name section of the dispensing label then the product it is attached to must fully match the brand, manufacturer or formulation listed and both items should also fully match the prescription.

Stock Specialist / Pharmacy Purchasing staff responsibilities

Stock Specialists – any staff who have the ability to add a new supplier onto an existing Wellsky/JAC drug file must be trained to ensure that they do not add a new supplier for a medicine to an existing file if the supplier's product does not meet the full description of the product. For example, the only supplier that should be added to the drug file name Tacrolimus (unlicensed) (Tacrose) 5mg/5ml suspension is Rosemont. A new drug file should be requested in collaboration with the pharmacist and the Trust Pharmacy Informatics team if the dispensing system does not already have a file for that particular brand or manufacturers formulation of a brand specific product.

Responsibilities for staff if errors occur

If it becomes apparent that any error has occurred in the processes and responsibilities described above then this should be highlighted to a pharmacist and recorded on the trusts incident reporting system Datix by the staff member who identifies the issue.

Switching brand specific medicines

If considering a switch to a patient's brand specific medicine, then please adhere to the following

- Wherever possible branded medicines should not be switched, and all attempts should be made to secure a new supply before the patient runs out.
- If it becomes clear a supply cannot be made before the patient runs out (e.g. due to a long term supply issue) then no brand specific medicine can be switched without full agreement of the prescriber and explanation to the patient as to the risks and what to monitor for. Pharmacists must ensure that both these requirements have been done before sending the prescription or related order for dispensing.
- Prescribers must physically change or rewrite the prescription for any brand specific medicine in which the brand is being intentionally changed rather than expect the pharmacist to make the change through an annotation. If a prescriber is changing the brand or manufacturer due to a clinical issue (e.g. patient wished to move from a liquid to a tablet) rather than a supply problem then it is good practice add a note to the prescription to help indicate to the screening pharmacists as to why it's being changed.
- Decisions to deliberately change a patients brand specific medicine should be written in the patients notes by the prescriber or pharmacist indicating the reason for change and the actions being taken to ensure the patient is fully aware of what it means for them, and any monitoring is in place.
- Prescribers must take ownership for talking to their patients about brand specific medicines changes. Although pharmacy outpatient teams will give basic counselling on the drug and the dose to take when patients pick up medicines it must be understood that the person handing out may not be aware of any changes to the therapy so will not be expected to fully counsel the patient on the significance and risks of changing brand.

- Pharmacists may after discussion with the prescriber and if they feel confident agree to assist the prescriber in fully counselling the patient as to the risks, change to administration process (device, volume changes etc) and monitoring for any switch but this should be documented in the patient notes and must be completed before the medicine is handed out or received by the patient via a delivery.

Table A

REFERENCES	UKMI - Example medicines to prescribe by brand name in primary care. Karoline Brennan, Published 27 March 2022. SPS website
RELATED DOCUMENTS AND PAGES	MHRA guidance on formulation switching of antiepileptic drugs http://nww.avon.nhs.uk/dms/download.aspx?did=19187
AUTHORISING BODY	Medicines Governance Group
SAFETY	Prescribing and dispensing brand specific medicines in a safe way that prevents any unintentional switches as laid out in this document should prevent incidents of avoidable toxicity or reduced efficacy of therapy in patients which in some circumstances could cause major harm such as transplant rejection in patients accidentally switched brands of immunosuppressants. This SOP was generated in response to a serious incident.
QUERIES AND CONTACT	Pharmacy Medicines Information ext 29283