

**Guidelines for the application of
Specify Brand Advice
within Electronic Systems**

Te Tāhū Hauora
Health Quality & Safety
Commission



1. Best practice guidelines promote generic (nonproprietary) prescribing.^{1,2,3,4} In New Zealand the generic name is the International Nonproprietary Name (INN) from the New Zealand Medicines Terminology (NZMT).
2. However, there are some circumstances where it is preferable to prescribe by brand (trade) name. For example, where different brands of the same chemical have specific formulation release characteristics, or where products have multiple ingredients: situations that can result in therapeutic non-equivalence or confusion.
3. Specify Brand Advice (SBA) status is applied within the New Zealand Medicines Terminology (NZMT) dataset to medicines when in the interests of patient safety, practicality, and avoidance of confusion, the brand of the medicine should be used in addition to the generic name. The SBA status is assigned by the New Zealand Universal List of Medicines (NZULM) Editorial Team.
4. Prescribe by Brand status may be applied to some multi-ingredient products. In these cases, the brand name should be used instead of the generic name (eg, when generic prescribing is not practical or potentially ambiguous). The Prescribe by Brand flag is applied at an organisational or practice level.

Specify brand advice

5. SBA status is a general term to direct the prescriber to definitive recommendations to specify the brand for safety reasons.
6. This document describes the criteria for deciding whether a medicine should be designated SBA status. The process is illustrated in the Figure below; the SBA criteria are given in the Appendix.
7. The routine application of these criteria is the responsibility of the New Zealand Universal List of Medicines (NZULM) Editorial Team.
8. Recommendations / requests for additions, removals, or amendments to the specify brand list must be made to the NZULM Editorial Team.
9. Any areas of uncertainty (eg, whether a medicine meets the criteria for SBA status is unclear), controversy, or outliers, must be referred to the Te Tāhū Hauora Health Quality & Safety Commission National Medication Safety Advisory Group (NMSAG), through the Te Tāhū Hauora Advisor medication safety, by the NZULM Editorial Team for a considered decision.
10. SBA status information is distributed to software vendors and users through the standard NZULM release system.

¹ Te Tāhū Hauora Health Quality & Safety Commission. 2012. Medication Charting Standard, Version 3. Wellington: Te Tāhū Hauora Health Quality & Safety Commission.

² Medical Council of New Zealand. Good Prescribing Practice. September 2016.

³ de Vries TPGM, Henning RH, Hogerzeil HV, Fresle DA (1994). Guide to Good Prescribing A practical manual. World health Organisation. WHO WHO/DAP/94.11.

⁴ NHS Greater Glasgow and Clyde. GGC Medicines Adult Therapeutic Handbook, nd. (Accessed 23 April 2018). URL: <http://handbook.ggcmedicines.org.uk/guidelines/introduction/good-prescribing-practice-general-advice/>.

11. The NZULM publishes a list of medicines that have been assigned SBA status – see <https://sites.google.com/a/nzulm.org.nz/key-performance-indicators/policy-statements/specify-by--brand-policy/specify-by-brand-medicines-list>.⁵
12. A SBA alert should be available to software users for all presentations of a SBA medicine even if there is currently only one brand available in New Zealand.

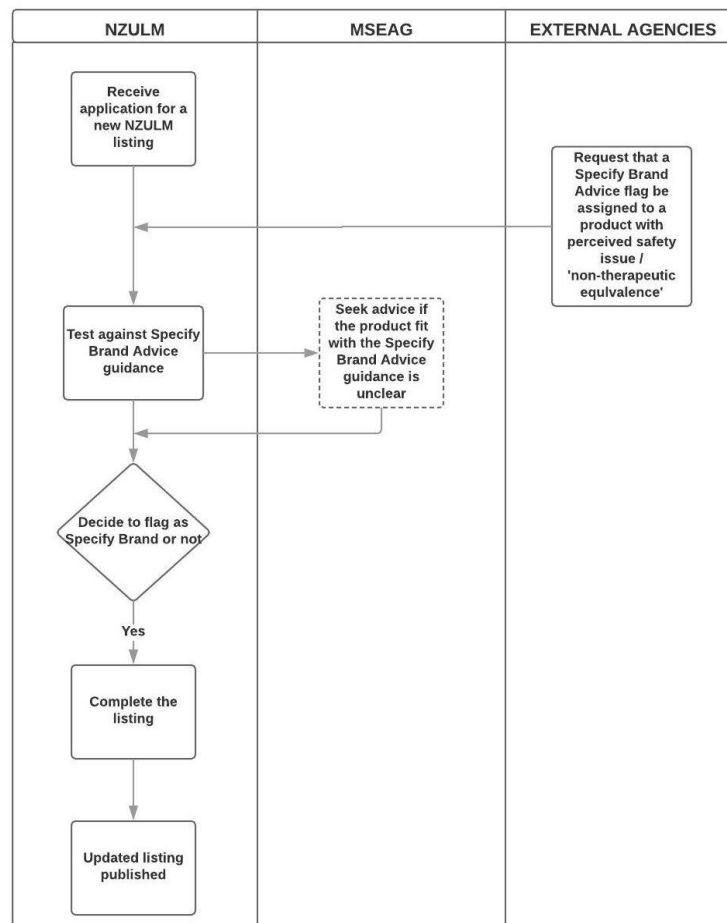


Figure. Process for assigning a specify brand advice (SBA) flag by the New Zealand Universal List of Medicines (NZULM)

Prescribe by Brand

13. The identification of multi-ingredient products is handled in clinical software at an organisational or practice level (rather than at the NZULM level).
14. Generic prescribing for multi-ingredient products (containing four or more active substances; typically, with long and confusing names, eg, multi-vitamin products, parenteral nutrition, oral rehydration salts) can be hazardous because it can be hard to remember the composition of these products, and it is very easy to select a similar product to the target product if one prescribes, dispenses or administers generically. Prescribing by brand name aids identification.
15. 'Prescribe by Brand' products should only be presented to users through vendor systems by the brand name.

⁵ Please note that in the NZULM dataset, specify by brand medicines are indicated through the use of a flag - «prescribe_by_brand». It can be found in the following tables: MPUU_dump.csv; MPP_dump.csv; charting_term_index_dump.csv; and prescribing_term_index_dump.csv. It is not practical to change the name of the flag as this would force vendors to make significant changes to their systems to accommodate the change.

Appendix. Criteria for Specify Brand Advice (SBA) with illustrative examples

Criteria	Examples	Notes
The responsibility of the New Zealand Universal List of Medicines (NZULM) Editorial Board		
1. Narrow therapeutic index Drugs with a narrow therapeutic index where differences in bioavailability may lead to a clinically significant difference in a patient's response (sub-therapeutic or toxic).	Levothyroxine	To assign this criterion there must be published guidance / evidence of a clinically significant change in bioavailability and/or change in clinical effect of a medicine between brands. The decision to apply SBA may be directed by Medsafe.
2. Different appearance creates risk Where the appearance (eg, different coloured dose forms of the same strength medicine) is considered to bring high risk to patients.	Warfarin	This criterion will be applied in exceptional circumstances.
3. Formulation release characteristics clinically significant Where the release characteristics vary between different formulations of the same chemical and the difference is clinically significant. a. When different formulations of the same chemical have different dosing and/or rates of administration. b. When there are different brands which have different dose regimens for the same indications. c. When different formulations (including modified release [MR]) of the same chemical have different release characteristics. d. When a brand name for a MR formulation may help to differentiate it from an immediate release formulation.	Amphotericin (systemic) – amphotericin B infusion <ul style="list-style-type: none"> amphotericin B deoxycholate (conventional formulation) complex phospholipid (<i>Abelcet</i>) liposomal (<i>AmBisome</i>) bi. Botulinum Toxin type A <ul style="list-style-type: none"> <i>Botox</i> <i>Dysport</i> <i>Xeomin</i> bii. Beclomethasone dipropionate (BDP) inhaled <ul style="list-style-type: none"> <i>Beclazone</i> <i>Qvar</i> (extra-fine BDP) biii. Leuprorelin (<i>Lucrin & Eligard</i>) Oestradiol transdermal patch (<i>Estradot & Climara</i>) c. Diltiazem Buprenorphine patches Fentanyl patches Mesalazine (<i>Asacol, Asamax, Pentasa</i>) Methylphenidate Nifedipine c. Morphine Oxycodone	eg, morphine modified release (m-Eslon SR) 10 mg

Criteria	Examples	Notes
4. Biological medicine / biosimilar Biological medicines / biosimilars. All biosimilars <u>except</u> where there is proven therapeutic equivalence across the full range of all brands of the biosimilar (eg, different brands of enoxaparin currently available are considered to be therapeutically equivalent).		The UK Medicines and Healthcare Products Regulatory Agency ⁶ (MHRA), and the New Zealand Formulary ⁷ (NZF), recommend that it is good practice to prescribe biological products by brand name to ensure that substitution of a biosimilar product does not occur. Medsafe have a position statement / guidance on the interchangeability of biosimilar medicines. ⁸
5. Specific brand indications When there is a specific brand for a specific indication and when confusion between the two may be unsafe or lead to a clinically significant difference in clinical response.	Leuprorelin (<i>Lucrin & Eligard</i>)	
6. Antibody / antibody-conjugate confusion risk When there could be confusion between an antibody and an antibody-drug conjugate.	Trastuzumab Trastuzumab emtansine	
7. Delivery device continuity Where continuity with the same delivery device is in the interests of the patient; eg, different devices for the same chemical have different operating instructions.	Adrenaline autoinjectors Insulin delivery devices (pens, cartridges)	
8. Brand name differentiates between release type forms Depot preparations when the brand differentiates between formulations.	<i>Clopixol Acuphase</i> <i>Clopixol Conc</i> <i>Clopixol Depot</i> <i>Depo-Medrol</i> <i>Solu-Medrol</i>	Normally inclusion of the word 'depot' will be sufficient if the brand name is the same (eg, Haldol depot).
9. Same or similar generic names create error risk Where there are many preparations that include the same, or very similar, generic name which could lead to prescribing, dispensing and administration errors.	All insulins Doxorubicin hydrochloride (as pegylated liposomal)	
10. Vaccines with varying strains or immunisation regimens Certain vaccines when strains, components or immunisation regimen vary.	HPV vaccines (<i>Cervarix & Gardasil</i>) Pneumococcal (<i>Synflorix, Prevenar 13, Pneumovax 23</i>) Rotavirus (<i>Rotateq, Rotarix</i>)	

⁶ Medicines and Healthcare Products Regulatory Agency. Drug Safety Update Feb 2008; Vol 1, Issue 7: 8. (Accessed 1 May 2018). URL: <https://www.gov.uk/drug-safety-update/biosimilar-products>

⁷ New Zealand Formulary (NZF). NZF v71. 2018. (Accessed 1 May 2018). URL: http://nzf.org.nz/nzf_70473.

⁸ Medsafe. Medsafe position on biosimilar medicines, nd. (Accessed 30 May 2018). URL: <http://www.medsafe.govt.nz/profs/RIss/Medsafe%20position%20on%20biosimilars.pdf>

Criteria	Examples	Notes
11. Effects of changing brand during course not assessed When the effects on clinical response of changing brands during a defined duration course of treatment has not been assessed.		A 'catch all' category to remind people that products are not interchangeable until they are proven to be.

Prescribe by brand

Criteria	Examples	Notes
To be implemented in clinical software at an organisational or practice level		
12. Multi-ingredient preparations (four or more active substances in the product ⁹).	Multi-vitamin products Nutritional supplements Oral rehydration salts Pancreatic enzyme products Parenteral nutrition	In these examples prescribe by brand name in the interests of practicality and safety.

Special notes

Chemical	Examples	Notes
Zolendronic acid	Aclasta (5 mg/100 mL) Zometa (4 mg/5 mL)	The current zolendronic acid products do not meet the threshold for 'confusion between brands may be unsafe or lead to a clinically significant difference in clinical response'.

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⁹ Australian Commission on Safety and Quality in Health Care. National guidelines for on-screen display of medicines Information. Sydney: ACSQHC, 2017. (Accessed 30 May 2018). URL: <https://www.safetyandquality.gov.au/wp-content/uploads/2016/03/National-guidelines-for-onscreen-display-of-clinical-medicines-information.pdf>. Section 6.1.3: 'The brand name may be displayed alone for combination products, or multi-ingredient or multi-component products with four or more active ingredients or components'. It is anticipated that this standard will be adopted by New Zealand.