

Pharmaceutical Benefits Scheme (PBS) prescription —bioequivalent allowed indicator, code A

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Pharmaceutical Benefits Scheme (PBS) prescription —bioequivalent allowed indicator, code A

Identifying and definitional attributes

Metadata item type:	Data Element
Short name:	Bioequivalent allowed indicator
Synonymous names:	Bioequivalent indicator; Brand equivalent allowed indicator
METEOR identifier:	605962
Registration status:	Commonwealth Department of Health , Standard 17/12/2015
Definition:	An indicator of whether a bioequivalent brand of a medicinal product is allowed to be substituted for the brand prescribed from the Schedule of Pharmaceutical Benefits, as represented by a code.
Data Element Concept:	Pharmaceutical Benefits Scheme (PBS) prescription—bioequivalent allowed indicator
Value Domain:	Bioequivalent allowed indicator code A

Value domain attributes

Representational attributes

Representation class:	Code
Data type:	String
Format:	A
Maximum character length:	1

	Value	Meaning
Permissible values:	a	Able to be substituted with other 'a flagged' brands
	b	Able to be substituted with other 'b flagged' brands
Supplementary values:	blank	Not able to be substituted with other brands

Collection and usage attributes

Guide for use: The permissible values for this value domain should be reported in lowercase only.

CODE a Able to be substituted with other 'a flagged' brands

This code is used to identify those medicinal products for which either:

1. the sponsor of the brand has submitted evidence to the Therapeutic Goods Administration (TGA) that the medicinal product has been demonstrated to be bioequivalent or therapeutically equivalent, or
2. justification for not needing bioequivalence or therapeutic equivalence data has been provided to and accepted by the TGA.

CODE b Able to be substituted with other 'b flagged' brands

This code is used to identify those brands of medicinal products that are considered to be bioequivalent or therapeutically equivalent, but for which it is not known if there is equivalence between brands marked 'a' and those marked 'b'.

More information about brand equivalence is available from the relevant section of the 'Symbols used in the Schedule' page of the Schedule of Pharmaceutical Benefits - see the Reference documents section below.

Source and reference attributes

Submitting organisation: Department of Health

Reference documents: Department of Health 2015. Schedule of Pharmaceutical Benefits. Department of Health, Canberra. Viewed 18 September 2015, <http://www.pbs.gov.au/info/healthpro/explanatory-notes/section2/section-2-symbols>

Data element attributes

Collection and usage attributes

Guide for use:

This data element is used to identify different brands of the same drug, form and strength that can be substituted by the pharmacist. The underlying assumption is that the brand has been declared as bioequivalent by the Therapeutic Goods Administration (TGA), following a request by the manufacturer.

Within the Schedule of Pharmaceutical Benefits, bioequivalent medicinal products are flagged as being either 'Brand equivalent a' or 'Brand equivalent b'.

'Brand equivalent a' medicinal products are those for which either:

1. the sponsor of the brand has submitted evidence to the TGA that the medicinal product has been demonstrated to be bioequivalent or therapeutically equivalent, or
2. justification for not needing bioequivalence or therapeutic equivalence data has been provided to and accepted by the TGA.

'Brand equivalent b' medicinal products are those brands that are considered to be bioequivalent or therapeutically equivalent, but for which it is not known if there is equivalence between brands marked 'a' and those marked 'b'.

More information about brand equivalence is available from the relevant section of the 'Symbols used in the Schedule' page of the Schedule of Pharmaceutical Benefits - see the Reference documents section below.

Source and reference attributes

Submitting organisation: Department of Health

Reference documents: Department of Health 2015. Schedule of Pharmaceutical Benefits. Department of Health, Canberra. Viewed 18 September 2015, <http://www.pbs.gov.au/info/healthpro/explanatory-notes/section2/section-2-symbols>

Relational attributes

Implementation in Data Set Specifications: [Pharmaceutical Benefits Scheme \(PBS\) state/territory data extract 2013-14 Commonwealth Department of Health](#), Standard 17/12/2015

Implementation start date: 01/07/2013

Implementation end date: 30/06/2014

DSS specific information:

Variable name = BQVLNT_IND