Pharmaceutical Management Agency New Zealand Pharmaceutical Schedule

Section H Update for Hospital Pharmaceuticals

November 2023



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Summary of decisions EFFECTIVE 1 NOVEMBER 2023

- Barium sulphate oral liq 960 mg per g (96% w/w), 176 g bottle (Vanilla SilQ MD) and oral liquid 980 mg per g (98% w/w), 310 g bottle (Vanilla SilQ HD) new listing
- Bisoprolol fumarate (Bisoprolol Mylan) tab 2.5 mg and 5 mg delayed delisting date to 1 April 2024
- Bisoprolol fumarate (Ipca-Bisoprolol) tab 2.5 mg, 5 mg and 10 mg new listing and addition of PSS
- Bisoprolol fumarate tab 2.5 mg (Bisoprolol Viatris), tab 5 mg (Bisoprolol Viatris and Bosvate), tab 10 mg (Bisoprolol Mylan and Bisoprolol Viatris) to be delisted 1 April 2024
- Budesonide (Budesonide Te Arai) cap modified-release 3 mg amended presentation description, new listing and addition of PSS
- Calamine (Calamine-AFT) crm, aqueous, BP to be delisted 1 November 2023
- Captopril (DP-Captopril) oral liq 5 mg per ml, 100 ml new listing and addition of PSS
- Captopril (Capoten) oral liq 5 mg per ml, 100 ml to be delisted 1 April 2024
- Ciprofloxacin (Cipflox) tab 500 mg to be delisted 1 April 2024
- Clomipramine hydrochloride (Clomipramine Teva) cap 25 mg new listing
- Diclofenac sodium (Voltaren Ophtha) eye drops 0.1% to be delisted 1 December 2024
- Dulaglutide (Trulicity) inj 1.5 mg per 0.5 ml prefilled pen amended restriction criteria
- Escitalopram (Ipca-Escitalopram) tab 10 mg and 20 mg new listing and addition of PSS
- Escitalopram (Ethics) tab 10 mg and 20 mg to be delisted 1 April 2024
- Ezetimibe (Ezetimibe Sandoz) tab 10 mg removal of restriction criteria
- Ezetimibe with simvastatin (Zimybe) tab 10 mg with simvastatin 10 mg, tab 10 mg with simvastatin 20 mg, tab 10 mg with simvastatin 40 mg and tab 10 mg with simvastatin 80 mg removal of restriction criteria
- Glycomacropeptide and amino acid contains some phenylalanine (PKU Build 20 Chocolate, PKU Build 20 Raspberry Lemonade, PKU Build 20 Smooth, PKU Build 20 Vanilla, GMPro Ultra Lemonade, PKU sphere20 Lemon, PKU sphere20 Chocolate, PKU sphere20 Red Berry, PKU sphere20 Vanilla and PKU sphere20 Banana) amended chemical name
- Goserelin (Zoladex) implant 3.6 mg, syringe and 10.8 mg, syringe new listing and addition of PSS
- Goserelin (Teva) implant 3.6 mg, syringe and 10.8 mg, syringe to be delisted 1 April 2024

Summary of decisions - effective 1 November 2023 (continued)

- Hydrocortisone acetate (Colifoam) rectal foam 10%, CFC free (14 applications), 21.1 g to be delisted 1 April 2024
- Levonorgestrel intra-uterine device 52 mg (Mirena) and intra-uterine device 13.5 mg (Jaydess) addition of HSS
- Liraglutide (Victoza) inj 6 mg per ml, 3 ml prefilled pen amended restriction criteria
- Macrogol 3350 with potassium chloride and sodium chloride (Glycoprep Orange) powder for oral soln 755.68 mg with potassium chloride 10.55 mg, sodium chloride 37.33 mg and sodium sulphate 80.62 mg per g, 70 g sachet, 3 sachets and 12 sachets – amended chemical name, presentation description and brand name
- Macrogol 3350 with potassium chloride and sodium chloride (e.g. Glycoprep Orange) powder for oral soln 755.68 mg with potassium chloride 10.55 mg, sodium chloride 37.33 mg and sodium sulphate 80.62 mg per g, 210 g sachet – amended chemical name, presentation description and example brand name
- Metoprolol succinate (Myloc CR) tab long-acting 23.75 mg, 47.5 mg, 95 mg and 190 mg new listing and addition of PSS
- Metoprolol succinate (Betaloc) tab long-acting 23.75 mg, 47.5 mg, 95 mg and 190 mg to be delisted 1 April 2024
- Ocrelizumab (Ocrevus) inj 30 mg per ml, 10 ml vial amended restriction criteria
- Ondansetron (Ondansetron Kabi) inj 2 mg per ml, 4 ml ampoule to be delisted 1 November 2023
- Phenobarbitone (Noumed Phenobarbitone) tab 15 mg new listing and addition of PSS
- Phenobarbitone (PSM) tab 15 mg to be delisted 1 May 2024
- Simvastatin (Simvastatin Mylan) tab 20 mg removal of PSS and to be delisted 1 March 2024
- Simvastatin (Simvastatin Viatris) tab 20 mg addition of PSS
- Sumatriptan (Clustran) inj 12 mg per ml, 0.5 ml prefilled pen new listing and addition of PSS
- Sumatriptan (Imigran) inj 12 mg per ml, 0.5 ml prefilled pen to be delisted 1 April 2024
- Thiotepa (Tepadina) inj 15 mg vial and 100 mg vial new listing and addition of PSS

Changes to General Rules

We have made amendments to Pharmaceutical Schedule Rules to align funding with the Misuse of Drugs Amendment Regulations (No 2) 2023.

A summary of the changes is provided below (only relevant parts of the criteria are shown).

Part 1 - Prescribing and initiating Subsidies for Community Pharmaceuticals

- 1.2 Community Pharmaceuticals Pperiods of supply for Subsidy: For Community Pharmaceuticals:
 - 1.2.1 periods of supply are as follows (note that legislative and regulatory requirements regardingperiods of supply must also be met): Only a quantity sufficient to provide treatment up to the legal period of supply limit will be Subsidised as specified in the Medicines Act 1981 and Medicines Regulations 1984 and the Misuse of Drugs Act 1975 and Misuse of Drugs Regulations 1977.
 - 1.2.2 Where there is no legal period of supply limit, only a quantity sufficient to provide treatment for a period up to 3 Months will be Subsidised.
 - 1.2.1 Only a quantity sufficient to provide treatment for a period of up to 3 Months will be Subsidised, and only if the Prescription under which the Community Pharmaceutical has been dispensed waspresented to the Contractor within 3 Months of the date on which the Prescription was written, subject to the following exceptions:
 - a Class B Controlled Drugs: Other than methylphenidate hydrochloride and dexamfetamine sulfate, only a quantity sufficient to provide treatment for a period of up to 1 Month in total (or up to 5 days when prescribed by a Dentist) will be Subsidised.
 - b Oral Contraceptives: The Prescriber must specify on the Prescription the period of treatment for which the oral contraceptive is to be supplied. To be eligible for Subsidy, this period must not exceed 6 Months. Where the Oral Contraceptive is prescribed for non-contraceptive indications, then the Subsidised period of supply is up to 3 Months per Prescription.
 - e Nicotine Replacement Therapy on Quiteard: Only a quantity sufficient to provide treatment for a period of up to 3 Months with nicotine patches, lozenges or gum will be eligible for Subsidy.

Part 4 – Community Pharmaceutical Dispensing Quantities for Subsidy

- 4.4 Community Pharmaceuticals identified in the Schedule without the *** or ▲ symbols
 - 4.4.1 Default dispensing is Monthly Lots, or 10 day Lots for Class B opioid Controlled Drugs, other than methylphenidate hydrochloride and dexamfetamine sulfate, in which case default dispensing is-Monthly Lots.
 - 4.4.2 A Community Pharmaceutical, other than methylphenidate hydrochloride and dexamfetamine sulfate, may be dispensed in one Lot, where legally permitted, in the following circumstances:
 - a a patient or their representative signs the Prescription to qualify for single Lot dispensing. In signing the Prescription, the patient or their nominated representative must certify which of the following criteria the patient meets:
 - i they have limited physical mobility
 - ii they live and work more than 30 minutes from the nearest pharmacy by their normal form of transport
 - iii they are relocating to another area, or
 - iv they are travelling and will be away when the repeat Prescriptions dispensings are due.
 - b A Class B **opioid** Controlled Drug with default dispensing of 10 day Lots may be dispensed in Monthly Lots if the patient meets the requirements of the criteria in 4.4.2.a.

	Price Brand or (ex man. Excl. GST) Generic \$ Per Manufacturer
Se	ction H changes to Part II
	ctive 1 November 2023
ALIN	MENTARY TRACT AND METABOLISM
5	BUDESONIDE (amended presentation description, new listing and addition of PSS) → Cap modified-release 3 mg – 5% DV Apr-24 to 2025
6	HYDROCORTISONE ACETATE (delisting) Rectal foam 10%, CFC free (14 applications)26.55 21.1 g Colifoam Note – Colifoam rectal foam 10%, CFC free (14 applications), 21.1 g to be delisted 1 April 2024.
11	DULAGLUTIDE (amended restriction criteria) Note: Not to be given in combination with a funded SGLT-2 inhibitor or other GLP-1 agonist. → Inj 1.5 mg per 0.5 ml prefilled pen115.23 4 Trulicity Restricted Initiation All of the following Either: 1 For continuation use; or 2 Patient has previously had an initial approval for an SGLT-2 inhibitor; or 2 All of the following 2.1 Patient has type 2 diabetes; and 2.2 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of ALL of the following funded blood glucose lowering agents for a period of least 6 months, where clinically appropriate: empagliflozin, metformin, and vildagliptin (see note a)*; and 2.32:-2: Any of the following: -2:-2:-2:-2:-3: 1 Patient is Mãori or any Pacific ethnicity*; or -2:-2:-2: 3: Patient has an absolute 5-year cardiovascular disease or risk equivalent (see note b a)*; or -2:-2:-2: 3: Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or
	 2-2-2.3.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or 2-2-2.3.5 Patient has diabetic kidney disease (see note c b)*.; or 3.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood glucose lowering agent (e.g., metformin, vildagliptin, or insulin) for at least 3 months. Notes: *Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.
	 a) Due to the ongoing supply issues with GLP-1 agonists, we strongly urge prescribers to consider initiating patients on other hypoglycaemic agents, provided they are not contraindicated. Please also consider discontinuing GLP-1 agonist treatment where the patient is not receiving clinicall meaningful benefit. b a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypase grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heaa failure or familial hypercholesterolaemia. c b) Diabetic kidney disease defined as: persistent albuminuria (albumin: creatinine ratio greater than o equal to 3 mg/mmol, in at least two out of three samples over a 3–6-month period) and/or eGFR less

equal to 3 mg/mmol, in at least two out of three samples over a 3–6-month period) and/or eGFR less than 60 mL/min/1.73m² in the presence of diabetes, without alternative cause.

				Price (ex man. Excl. GST)		Brand or Generic		
				\$	Pe	er	Manufacturer	

Changes to Section H Part II – effective 1 November 2023 (continued)

11 LIRAGLUTIDE (amended restriction criteria)

Restricted

Initiation

Any of the following Either:

- 1. For continuation use; or
- 2 Patient has previously received an initial Special Authority approval for either an SGLT-2 inhibitor or GLP-1agonist; or
- 2. All of the following
 - 2.1 Patient has type 2 diabetes; and
 - 2.2 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of ALL of the following funded blood glucose lowering agents for a period of least 6 months, where clinically appropriate: empagliflozin, metformin, and vildagliptin (see note a)*; and
 - 2.32.2 Any of the following:
 - 2.2.2.3.1 Patient is Māori or any Pacific ethnicity*; or
 - **2.2.2.3.2** Patient has pre-existing cardiovascular disease or risk equivalent (see note ba)*; or
 - 2.2.2.3.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or
 - 2.2.2.3.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or
 - 2.2.2.3.5 Patient has diabetic kidney disease (see note cb)*.; or

3.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least oneblood-glueose lowering agent (e.g., metformin, vildagliptin, or insulin) for at least 3 months.

Notes: *Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes. Indication marked with ** is an unapproved indication.

- a) Due to the ongoing supply issues with GLP-1 agonists, we strongly urge prescribers to consider initiating patients on other hypoglycaemic agents, provided they are not contraindicated. Please also consider discontinuing GLP-1 agonist treatment where the patient is not receiving clinically meaningful benefit.
- ba) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
- cb) Diabetic kidney disease defined as: persistent albuminuria (albumin: creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3–6-month period) and/or eGFR less than 60 mL/min/1.73m² in the presence of diabetes, without alternative cause.
- 14 MACROGOL 3350 WITH ASCORBIC ACID, POTASSIUM CHLORIDE AND SODIUM CHLORIDE (amended chemical name, presentation description, brand name and example brand name)

Powder for oral soln 755.68 mg with ascorbic acid 85.16 mg, potassium chloride 10.55 mg, sodium chloride 37.33 mg and sodium sulphate 80.62 mg per g, 70 g sachet		
– 5% DV Aug-22 to Jun 2024 13.68	3	Glycoprep-O Glycoprep Orange
54.72	12	Glycoprep-O Glycoprep Orange
Powder for oral soln 755.68 mg with ascorbic acid 85.16 mg, potassium chloride 10.55 mg, sodium chloride 37.33 mg		u u
and sodium sulphate 80.62 mg per g, 210 g sachet		e.g. Glycoprep-O Glycoprep Orange

Price		Brand or
(ex man. Excl. G	Generic	
`\$	Per	Manufacturer

Changes to Section H Part II – effective 1 November 2023 (continued)

CARDIOVASCULAR SYSTEM

43	CAPTOPRIL (new listing and addition of PSS) → Oral liq 5 mg per ml – 5% DV Apr-24 to 2026
46	BISOPROLOL FUMARATE (delayed delisting date) Tab 2.5 mg
46	BISOPROLOL FUMARATE (new listing and addition of PSS) Tab 2.5 mg – 5% DV Apr-24 to 2026
47	METOPROLOL SUCCINATE (new listing and addition of PSS) Tab long-acting 23.75 mg - 5% DV Apr-24 to 2026 4.20 90 Myloc CR Tab long-acting 47.5 mg - 5% DV Apr-24 to 2026 3.65 90 Myloc CR Tab long-acting 95 mg - 5% DV Apr-24 to 2026 5.24 90 Myloc CR Tab long-acting 190 mg - 5% DV Apr-24 to 2026 9.76 90 Myloc CR Note - Betaloc CR tab long-acting 23.75 mg, tab long-acting 47.5 mg, tab long-acting 95 mg and tab long-acting 190 mg to be delisted from 1 April 2024. 90.87 100
52	 EZETIMIBE (removal of restriction criteria) → Tab 10 mg - 5% DV Dec-23 to 20261.76 30 Ezetimibe Sandoz Restricted Initiation All of the following: Patient has a calculated absolute risk of cardiovascular disease of at least 15% over 5 years; and 2 Patient's LDL cholesterol is 2.0 mmol/litre or greater; and Any of the following: 3.1 The patient has habdomyolysis (defined as muscle aches and creatine kinase more than 10 × normal) when treated with one statin; or 3.2 The patient is intolorant to both simvastatin and atorvastatin; or 3.3 The patient has not reduced their LDL cholesterol to less than 2.0 mmol/litre with the use of the maximal

3.3 The patient has not reduced their LDL cholesterol to less than 2.0 mmol/litre with the use of the maximaltolerated dose of atorvastatin.

	,	Price		Brand or
	((ex man. Excl. G \$	Per	Generic Manufacturer
Chan	ges to Section H Part II – effective 1 Novembe	r 2023 (cont	inued)	
52	EZETIMIBE WITH SIMVASTATIN (removal of restriction criter			
02	→ Tab 10 mg with simvastatin 10 mg		30	Zimybe
	→ Tab 10 mg with simvastatin 20 mg		30	Zimybe
	→ Tab 10 mg with simvastatin 40 mg		30	Zimybe
	-> Tab 10 mg with simvastatin 80 mg		30	Zimybe
	Restricted Initiation All of the following:			-
	1 Patient has a calculated absolute risk of cardiovascular di 2 Patient's LDL cholesterol is 2.0 mmol/litre or greater; and		st 15% ove	er 5 years; and
	3 The patient has not reduced their LDL cholesterol to less tolerated dose of atorvastatin.		(litre with tl	ne use of the maximal
52	SIMVASTATIN (removal of PSS and delisting)			
	Tab 20 mg – 5% DV Mar-24 to 2026 Note – Simvastatin Mylan tab 20 mg to be delisted from 1 M		90	Simvastatin Mylan
52	SIMVASTATIN (addition of PSS)			
	Tab 20 mg – 5% DV Mar-24 to 2026	2.54	90	Simvastatin Viatris
DERN	NATOLOGICALS			
68	CALAMINE (delisting) Crm, aqueous, BP – 5% DV May-22 to 2024		100 g	Calamine-AFT
	Note – Calamine-AFT crm, aqueous, BP to be delisted 1 Nov	/ember 2023.		
GENI	TO-URINARY SYSTEM			
75	LEVONORGESTREL (addition of HSS)			
	Intra-uterine device 52 mg – 1% DV Nov-23 to 31 Oct 2024	260 50	1	Mirena
	Intra-uterine device 13.5 mg	209.30	1	WIIICIIA
	– 1% DV Nov-23 to 31 Oct 2024	215.60	1	Jaydess
HORI	MONE PREPARATIONS			
82	GOSERELIN (new listing and addition of PSS) Implant 3.6 mg, syringe – 5% DV Apr-24 to 2026 Implant 10.8 mg, syringe – 5% DV Apr-24 to 2026		1	Zoladex Zoladex
	Note – Teva implant 3.6 mg syringe and 10.8 mg syringe to		-	
INFE	CTIONS			
93	CIPROFLOXACIN (delisting)			
	→ Tab 500 mg Note – Cipflox tab 500 mg to be delisted from 1 April 2024.	3.40	28	Cipflox

		(ex man. Excl. G	ST) Per	Generic Manufacturer
Char	nges to Section H Part II – effective 1 Novem	1ber 2023 (conti	nued)	
NER	VOUS SYSTEM			
125	CLOMIPRAMINE HYDROCHLORIDE (new listing) Cap 25 mg	11.19	28	Clomipramine Teva
126	ESCITALOPRAM (new listing and addition of PSS) Tab 10 mg – 5% DV Apr-24 to 2026 Tab 20 mg – 5% DV Apr-24 to 2026 Note – Escitalopram (Ethics) tab 10 mg and 20 mg to b	1.49	28 28 oril 2024.	lpca-Escitalopram lpca-Escitalopram
128	PHENOBARBITONE (new listing and addition of PSS) Tab 15 mg – 5% DV May-24 to 2026	248.50	500	Noumed Phenobarbitone
	Note - PSM tab 15 mg to be delisted from 1 May 2024.			, nonobarbhono
130	SUMATRIPTAN (new listing and addition of PSS) Inj 12 mg per ml, 0.5 ml prefilled pen – 5% DV Apr-24 to 2025 Note – Imigran inj 12 mg per ml, 0.5 ml prefilled pen to		2 April 2024.	Clustran
131	ONDANSETRON (delisting) Inj 2 mg per ml, 4 ml ampoule Note – Ondansetron Kabi inj 2 mg per ml, 4 ml ampoule		5 vember 20	Ondansetron Kabi 023.
137	OCRELIZUMAB (amended restriction criteria – amended Note: Treatment on two or more funded multiple scleros → Inj 30 mg per ml, 10 ml vial Continuation – Primary Progressive Multiple Sclerosis Any relevant practitioner Patient has had an EDSS score of 2.0 to less than or eq (ie patient has walked 20 metres with bilateral assistance	sis treatments simult 9,346.00 qual to 6.5 (inclusiv	aneously i 1 e) at any ti	Ocrevus ime in the last six months
ONC	OLOGY AGENTS AND IMMUNOSUPPRESSANTS	5		
147	THIOTEPA (new listing and addition of PSS) Inj 15 mg vial – 5% DV Apr-24 to 2026 Inj 100 mg vial – 5% DV Apr-24 to 2026		1 1	Tepadina Tepadina
SENS	SORY ORGANS			
251	DICLOFENAC SODIUM (delisting brand only) Eye drops 0.1% – 5% DV Nov-21 to 2024 Note – Voltaren Ophtha eye drops 0.1% to be delisted fr			Voltaren Ophtha
VARI	OUS			
262	BARIUM SULPHATE (new listing)	520.00	04	Vanilla SilO MD

Price

Brand or

02	Dianow Coel Inate (new insting)		
	Oral liq 960 mg per g (96% w/w), 176 g bottle	 24	Vanilla SilQ MD
	Oral liq 980 mg per g (98% w/w), 310 g bottle	 24	Vanilla SilQ HD

Price		Brand or
(ex man. Excl. G	iST)	Generic
\$ Per		Manufacturer

Changes to Section H Part II – effective 1 November 2023 (continued)

SPECIAL FOODS

286 Other Supplements for PKU (amended chemical name)

AMINO ACID FORMULA (WITHOUT PHENYLALANINE) GLYCOMACROPEPTIDE AND AMINO ACID CONTAINS SOME PHENYLALANINE

→ Powder 20 g protein, 1.7 g carbohydrate per 32 g sachet 898.56	30	PKU Build 20 Chocolate PKU Build 20 Raspberry Lemonade PKU Build 20 Smooth PKU Build 20 Vanilla
→ Powder 20 g protein, 4.9 g carbohydrate per 33.4 g sachet936.00	30	PKU GMPro Ultra Lemonade
→ Powder 20 g protein, 6.0 g carbohydrate per 35 g sachet930.00	30	PKU sphere20 Lemon
→ Powder 20 g protein, 6.3 g carbohydrate per 35 g sachet930.00	30	PKU sphere20 Chocolate PKU sphere20 Red Berry PKU sphere20 Vanilla
→ Powder 20 g protein, 6.7 g carbohydrate per 35 g sachet930.00	30	PKU sphere20 Banana

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Pharmaceuticals and brands

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Budesonide Te Arai	6
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Calamine-AFT	
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Clomipramine Teva	10
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SODIUM CHLORIDE	7
MACROGOL 3350 WITH POTASSIUM CHLORIDE	
AND SODIUM CHLORIDE	7
METOPROLOL SUCCINATE	8
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Myloc CR	-
N	0
Noumed Phenobarbitone	10
0	
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Te Kāwanatanga o Ao<u>tear</u>oa New Zealand Government

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