

Attachment 2: EML Secretariat proposal to amend square box listings on the EML and EMLc

Section	Medicine	ATC code	Indication	Restrictions / Limitations	Limited to:	Secretariat recommendation
GROUP 1: Listings without square box but with asterix denoting accepted alternatives - propose convert these to qualified square box listings						
1.1.2	propofol*	N01AX10	general anaesthesia	Yes*	thiopental	Add square box specifying thiopental as an alternative and remove asterix/note
6.2.2	meropenem*	J01DH02	cIAI, high-risk febrile neutropenia	Yes*	imipenem + cilastatin	Add square box specifying imipenem+cilastatin as alternative for cIAI and FN. Maintain asterix/note to specify square box does not apply to meropenem for acute bacterial meningitis in neonates.
6.2.5	cycloserine*	J04AB01	MDR-TB	Yes*	terizidone	Add square box specifying terizidone as an alternative and remove asterix/note
6.2.5	ethionamide*	J04AD03	MDR-TB	Yes*	prothionamide	Add square box specifying prothionamide as an alternative and
6.2.5	meropenem*	J01DH02	MDR-TB	Yes*	Imipenem + cilastatin	Add square box specifying imipenem+cilastatin as an alternative and remove asterix/note
6.4.2.5	efavirenz + emtricitabine* + tenofovir	J05AR06	HIV FDCs	Yes*	lamivudine (for emtricitabine)	Add square box to emtricitabine component of this FDC, specifying lamivudine as alternative and remove asterix/note
6.4.2.5	emtricitabine* + tenofovir	J05AR03	HIV FDCs	Yes*	lamivudine (for emtricitabine)	Add square box to emtricitabine component of this FDC, specifying lamivudine as alternative and remove asterix/note
10.3	deferoxamine*	V03AC01	Iron overload in sickle cell disease	Yes*	deferasirox (oral formulation)	Add square box specifying deferasirox as an alternative and remove asterix/note. This change should also be applied to the listing for deferoxamine in Section 4.2.
21.5	atropine*	S01FA01	mydriatics	Yes*	homatropine hydrobromide cyclopentolate hydrochloride (EMLc only)	Add square box to the EMLc listing for atropine, specifying homatropine and cyclopentolate as alternatives.
GROUP 2: Listings without square box but with asterix denoting accepted alternatives - propose add independent listings for accepted alternatives						
6.2.1	sulfamethoxazole + trimethoprim	J01EE01	lower urinary tract infection	Yes*	Trimethoprim	Add independent listing for trimethoprim for treatment of lower UTI, remove asterix/note from SMX-TMP
6.2.2	clarithromycin	J01FA09	pharyngitis (2nd choice) EMLc	Yes*	Erythromycin	Add independent listing for erythromycin to the EMLc for second choice treatment of pharyngitis. Remove asterix/note
GROUP 3: Unrestricted square box listings where accepted alternatives are described in TRS recommendations - propose convert to qualified square box listings						
2.3	ondansetron	A04AA01	nausea and vomiting	TR51021	granisetron tropisetron dolasetron palonosetron	Alternatives described in TRS. Include in list as qualified square box: granisetron, tropisetron, dolasetron, palonosetron
3	loratidine	R06AX13	allergy / anaphylaxis	TR5985	cetirizine, fexofenadine	Alternatives described in TRS. Include in list as qualified square box: cetirizine, fexofenadine
6.4.1	aciclovir	J05AB01	herpes simplex/zoster infection	TR5920	valaciclovir	Alternative described in TRS. Include in list as qualified square box: valaciclovir
6.5.1	metronidazole	P01AB01	antiamoebic / anti-giardiasis	TR5950	tinidazole	Alternative described in TRS. Include in list as qualified square box: tinidazole

9	biperiden	N04AA02	Parkinson disease	TRS985	trihexylphenidyl	Alternative described in TRS. Include in list as qualified square box: trihexylphenidyl
12.3	lisinopril + amlodipine (FDC)	C09BB03	hypertension	TRS1021	other ACEI, dihydropyridine CCB	Lisinopril: Propose qualified square box with all alternatives within C09AA with DDD as alternatives. Amlodipine: Propose qualified square box with alternative dihydropyridine CCBs as alternatives
12.3	lisinopril + hydrochlorothiazide (FDC)	C09BA03	hypertension	TRS1021	Other ACEI, thiazide/thiazide-like diuretics	Lisinopril: Propose qualified square box with all alternatives within C09AA with DDD as alternatives. HCTZ: Propose qualified square box with commonly used thiazide and thiazide-like diuretics: indapamide, chlorthalidone, chlorothiazide
12.3	telmisartan + amlodipine (FDC)	C09DB07	hypertension	TRS1021	Other ATRA, DHP CCB	Telmisartan: Propose qualified square box with all alternatives within C09CA with DDDs as alternatives; amlodipine: Propose qualified square box with alternative dihydropyridine CCBs as alternatives
12.3	telmisartan + hydrochlorothiazide	C09DA07	hypertension	TRS1021	Other ATRA, thiazide/thiazide-like diuretics	Telmisartan: Propose qualified square box with all alternatives within C09CA with DDDs as alternatives; HCTZ: Propose qualified square box with commonly used thiazide and thiazide-like diuretics: indapamide, chlorthalidone, chlorthiazide
12.6	simvastatin	C10AA01	hyperlipidaemia	TRS946	atorvastatin pravastatin fluvastatin lovastatin	Alternatives described in TRS. Include in list as qualified square box: atorvastatin, pravastatin, fluvastatin, lovastatin
13.4	podophyllum resin	N/A	warts	TRS770	podophyllotoxin	Alternative described in TRS. Include in list as qualified square box: podophyllotoxin
13.5	benzyl benzoate	P03AX01	scabies, head and body lice	TRS882	precipitated sulfur	Alternative described in TRS. Include in list as qualified square box: precipitated sulfur (topical ointment)
15.1	ethanol	D08AX08	antiseptic	TRS895	propanol	Alternative described in TRS. Include in list as qualified square box: propanol
15.1	povidone iodine	D08AG02	antiseptic	TRS850	iodine	Alternative described in TRS. Include in list as qualified square box: iodine
15.2	chloroxylenol	D08AE05	disinfectant	TRS882	"other phenolic disinfectants"	Alternatives described in TRS. Include in list as qualified square box alternatives within D08AE
16	hydrochlorothiazide	C03AA03	diuretic	TRS685	"any other thiazide-type diuretic currently in broad clinical use"	Alternatives described in TRS. Include in list as qualified square box: indapamide, chlorthalidone, chlorothiazide
17.2	ondansetron	A04AA01	nausea and vomiting	TRS1021	granisetron tropisetron dolasetron palonosetron	Alternatives described in TRS. Include in list as qualified square box: granisetron, tropisetron, dolasetron, palonosetron
17.3	sulfasalazine	A07EC01	inflammatory bowel conditions	TRS850	mesalazine (for patients allergic to sulfonamides)	Alternative described in TRS. Include in list as qualified square box: mesalazine
17.4	senna	A06AB06	constipation	TRS685	any mild stimulant laxative (either synthetic or of plant origin)	Alternatives described in TRS. Include in list as qualified square box: bisacodyl

18.4	medroxyprogesterone acetate	G03DA02	endometriosis, dysfunctional uterine bleeding	TRS965	norethisterone	Alternative described in TRS. Include in list as qualified square box: norethisterone
18.5	gliclazide	A10BB09	diabetes mellitus	TRS965	second-generation sulfonylureas	Alternatives described in TRSPropose qualified square box with all alternatives within A10BB with DDD as alternatives
21.1	gentamicin	S01AA11	ophthal infection	TRS825	other aminoglycosides	Alternatives described in TRS (other aminoglycosides). Include in list as qualified square box: tobramycin
21.1	ofloxacin	S01AE01	ophthal infection	TRS965	other fluoroquinolones	Alternatives described in TRS (other fluoroquinolone). Include in list as qualified square box alternatives within S01AE
22.6	ibuprofen	C01EB16	mgmt of patent ductus arteriosus	TRS958	indomethacin	Alternative described in TRS for this indication. Include in list as qualified square box: indomethacin
24.2.1	fluoxetine	N06AB03	depressive disorders	TRS1021	other SSRIs	Alternatives described in TRS (other SSRIs). Include in list as qualified square box: citalopram, escitalopram, fluvoxamine, paroxetine, sertraline
25.1	budesonide + formoterol	R03AK07	asthma	TRS1006	ICS + LABA combinations	Alternatives described in TRS (ICS + LABA combination). Include in the list as qualified square box said combinations within R03AK that are indicated for use in asthma: budesonide+salmeterol, budesonide+salmeterol, beclometasone+formoterol, mometasone+formoterol, fluticasone+formoterol, fluticasone furoate +vilanterol
25.1	tiotropium	R03BB04	COPD	TRS1021	LAMAs	Alternatives described in TRS (LAMAs). Include in the list as qualified square box: aclidinium, umeclidinium, glycopyrronium
27	ergocalciferol	A11CC01	prevention/treatment vitamin D deficiency	TRS950	colecalfiferol	Alternative described in TRS. Include in list as qualified square box: colecalfiferol

GROUP 4: Unrestricted square box listings where a qualified square box listing for specific limited alternatives is proposed by the Secretariat

3	prednisolone	H02AB06	allergy / anaphylaxis	No		Propose qualified square box with prednisone as alternative. Other glucocorticoids (hydrocortisone, dexamethasone listed separately in this section)
5	lorazepam	N05BA06	status epilepticus	No		Propose qualified square box with parenteral diazepam and parenteral midazolam as alternatives. Rectal diazepam and oromucosal midazolam are listed separately for SE
8.2.4	bicalutamide	L02BB03	metastatic prostate cancer	No		Propose qualified square box with nilutamide and flutamide as alternatives
8.2.4	leuprorelin	L02AE02	early breast cancer metastatic prostate cancer	No		Propose qualified square box with goserelin and triptorelin as alternatives

8.2.4	prednisolone	H02AB06	CLL DLBCL Hodgkin lymphoma Follicular lymphoma ALL Burkitt lymphoma MCRPC Multiple myeloma	No	Propose qualified square box with prednisone as alternative. Other glucocorticoids (hydrocortisone, dexamethasone, methylprednisolone listed separately)
9	carbidopa	N04BA	Parkinson disease	No	Propose qualified square box with bensazide as alternative, allowing levodopa combinations with other decarboxylase inhibitor
12.3	hydrochlorothiazide	C03AA03	hypertension	No	Propose qualified square box with commonly used thiazide and thiazide-like diuretics: indapamide, chlorthalidone, chlorothiazide
12.4	furosemide	C03CA01	heart failure	No	Propose qualified square box with alternative loop diuretics within C03CA with DDD as alternatives: bumetanide, torasemide
12.4	hydrochlorothiazide	C03AA03	heart failure	No	Propose qualified square box with commonly used thiazide and thiazide-like diuretics: indapamide, chlorthalidone, chlorothiazide
13.1	miconazole	D01AC02	topical antifungal	No	Propose qualified square box with commonly available imidazole antifungals as alternatives: clotrimazole, econazole, isoconazole, tioconazole, ketoconazole, sulconazole, fivonazole, oxiconazole, fenticonazole, omoconazole, sertaconazole
14.1	tropicamide	S01FA06	ophthalmological mydriatic	No	Propose qualified square box with alternative short-acting mydriatics specified: atropine, cyclopentolate
21.1	tetracycline	S01AA09	ophthal infection	No	Propose qualified square box with all tetracycline alternatives within S01AA: chlortetracycline, oxytetracycline
21.2	prednisolone	S01BA04	ophthal inflammation	No	Propose qualified square box with alternatives within S01BA that are available in drop formulations: betamethasone, dexamethasone, fluorometholone, hydrocortisone,, lotependol, rimexolone, others? Review?
21.4	pilocarpine	S01EB01	glaucoma	No	Propose qualified square box with carbachol as specified alternative (only other parasympathomimetic indicated for glaucoma)
21.4	timolol	S01ED01	glaucoma	No	Propose qualified square box with non-combination alternatives within S01ED: betaxolol, levobunolol, metipranolol, carteolol, bufunolol
22.3	ergometrine	G02AB03	post partum haemorrhage	No	Propose qualified square box with methylergometrine as specified alternative
25.1	salbutamol	R03AC02	asthma/copd	No	Propose qualified square box with with terbutaline as alternative (only SABA within R03AC in common clinical use)

25.1	beclometasone	R03BA01	asthma/copd	No	Propose consolidation of the listigs for beclometasone and budesonide by using a qualified square box with alternatives within R03BA with DDD as alternatives. Budesonide as the representative agent (greatest availability) and including as alternatives: beclometasoneflunisolide, fluticasone, mometasone, ciclesonide.
25.1	budesonide	R03BA02	asthma (children)	No	Propose consolidation of the listigs for beclometasone and budesonide by using a qualified square box with alternatives within R03BA with DDD as alternatives. Budesonide as the representative agent (greatest availability) and including as alternatives: beclometasoneflunisolide, fluticasone, mometasone, ciclesonide.
28	ciprofloxacin	S02AA15	otitis externa (children)	No	Propose qualified square box with alternative fluoroquinolone within S02AA, ofloxacin

GROUP 5: Unrestricted square box listings where qualified square box listings with alternatives defined by ATC4 are proposed by the Secretariat

6.2.1	cloxacillin	J01CF02	bone and joint infections Skin/soft tissue infections sepsis in neonates/children	No	Propose qualified square box with all alternatives within J01CF as alternatives. Retain note regarding clox/diclox/fluclo preferred for oral administration
8.2.4	anastrozole	L02BG03	early/metastatic breast cancer	No	Propose qualified square box with all alternatives within L02BG as alternatives
12.3	enalapril	C09AA02	hypertension	No	Propose qualified square box with all alternatives within C09AA with DDD as alternatives
12.3	losartan	C09CA01	hypertension	No	Propose qualified square box with all alternatives within C09CA with DDDs as alternatives
12.4	enalapril	C09AA02	heart failure	No	Propose qualified square box with all alternatives within C09AA with DDD as alternatives
12.4	losartan	C09CA01	heart failure	No	Propose qualified square box with all alternatives within C09CA with DDDs as alternatives
13.3	betamethasone (valerate)	D07AC01	topical corticosteroid	No	Propose qualified square box with all alternatives within D07AA as alternatives
13.3	hydrocortisone (acetate)	D07AA02	topical corticosteroid	No	Propose qualified square box with all alternatives within D07AC as alternatives
16	furosemide	C03CA01	diuretic	No	Propose qualified square box with all alternatives within C03CA with DDD as alternatives
17.1	omeprazole	A02BC01	GORD, peptic ulcer disease	No	Propose qualified square box with all alternatives within A02BC with DDD as alternatives
17.1	ranitidine	A02BA02	GORD, peptic ulcer disease	No	Propose qualified square box with alternatives within A02BA with DDD as alternatives: cimetidine, famotidine, nizatidine
21.3	tetracaine	S01HA03	ophthal anaesthetic	No	Propose qualified square box with alternatives within S01HA (excent cocaine?)

GROUP 6: Unrestricted square box listings where removal of the square box is proposed by the Secretariat

12.1	isosorbide dinitrate	C01DA08	angina	No		Remove square box. Formulation listed is short-acting sublingual isosorbide dinitrate for acute treatment of angina (not prevention). Only other short-acting nitrate is GTN which is listed separately.
13.3	calamine lotion	N/A	topical antipruritic	No		Remove square box - no suitable alternatives
15.2	chlorine base compound	N/A	disinfectant	TRS882	"various formulations can be used"	Remove square box and add note indicating various formulations of chlorine base compound as alternatives
17	pancreatic enzymes	A09AA02	pancreatic enzyme insufficiency	TRS958	Age-appropriate formulations and doses including lipase, protease and amylase	Remove square box and add note indicating age-appropriate formulations including lipase, protease and amylase
17.3	hydrocortisone retention enema	A07EA02	inflammatory bowel conditions	TRS895	prednisolone retention enema	Remove square box and add independent listing for prednisolone retention enema
22.6	prostaglandin E		to maintain patency of the ductus arteriosus	TRS958	E1 or E2	Remove square box. Replace with separate listings for prostaglandin E1 and prostaglandin E2 (as described in formulations part of list)
26.2	sodium lactate compound solution	B05BB01	IV fluid/electrolyte replacement	No		Remove square box. Alternative IV fluids listed separately (eg normal saline, 5% dextrose, glucose).
27	nicotinamide	A11HA01	pellagra	No		Remove square box. No suitable alternatives

GROUP 7: Unrestricted square box listings prosed by the Secretariat for a review of suitable alternatives (no change at this time)

1.2	bupivacaine	N01BB01	local and spinal anaesthesia	No		Review suitable alternatives
1.2	lidocaine	N01BB02	local and spinal anaesthesia	No		Review suitable alternatives
1.3	midazolam	N05CD08	pre-operative sedation	No		Review suitable alternatives
7.2	propranolol	C07AA05	migraine prophylaxis	No		Review suitable alternatives
10.2	warfarin	B01AA03	anticoagulant	No		Review suitable alternatives
11.2.2	coagulation factor VIII	B02BD02	haemophilia A	No		Review suitable alternatives
11.2.2	coagulation factor IX	B02BD04	haemophilia B coagulation defects	No		Review suitable alternatives
12.3	amlodipine	C08CA01	hypertension	No		Review suitable alternative CCBs (dihydropyridine and non-dihydropyridine)
14.2	amidotrizoate (diatrizoic acid)	V08AA01	radiocontrast	No		Review suitable alternatives
14.2	iohexol	V08AB02	radiocontrast	No		Review suitable alternatives
14.2	meeglumine iotroxate (iotroxic acid)	V08AC02	radiocontrast	No		Review suitable alternatives
15.1	chlorhexidine	D08AC02	antiseptic	No		Review suitable alternatives
20	atracurium	M03AC04	skeletal muscle relaxant	No		Review suitable alternatives
20	vecuronium	M03AC04	skeletal muscle relaxant	No		Review suitable alternatives
22.1.1	ethinylestradiol + levonorgestrel	G03AA07	oral contraceptive	No		Review suitable alternatives
22.1.2	ethinylestradiol + norethisterone	G03AA07	oral contraceptive	No		Review suitable alternatives
24.1	chlorpromazine	N05AA01	schizophrenia / psychoses	No		Review suitable alternative typical antipsychotics
24.1	fluphenazine	N05AB02	schizophrenia / psychoses	No		Review suitable alternative typical antipsychotics
24.1	haloperidol	N05AD01	schizophrenia / psychoses	No		Review suitable alternative typical antipsychotics
24.2.1	amitriptyline	N06AA09	depressive disorders	No		Review suitable alternative tricyclic antidepressants

24.3	diazepam	N05BA01	anxiolytic	No		Review suitable alternative benzodiazepines for anxiety
28	budesonide	R01AD05	allergic rhinitis (children)	No		Review suitable alternatives corticosteroids for allergic rhinitis, including use in adults
28	xylometazoline	R01AA07	topical nasal decongestion (children)	No		Review suitable alternative sympathomimetic nasal sprays for nasal congestion, including use in adults.

GROUP 8: Qualified square box listing - no changes proposed

2.2	morphine	N02AA01	pain	yes	hydromorphone oxycodone	No change proposed
6.4.4.2.1	pangenotypic direct-acting antiviral combinations	J05AP	chronic hepatitis C infection	yes	daclatasvir, sofosbuvir (in combination) gleaprevir + pibrentasvir sofosbuvir + velpatasvir	No change proposed
8.1	adalimumab	L04AB04	rheumatoid arthritis Crohn disease juvenile idiopathic arthritis ankylosing spondylitis	yes	certolizumab pegol (EML) etanercept (EML/EMLc) golimumab (EML) infliximab (EML/EMLc) (including biosimilars)	No change proposed
8.2.2	erlotinib	L01EB02	EGFR+ non-small cell lung cancer	yes	afatinib gefitinib	No change proposed
8.2.3	nivolumab	L01XC17	metastatic melanoma	yes	pembrolizumab	No change proposed
10.1	erythropoiesis-stimulating agents	B03XA	anaemia of chronic disease	yes	epoetin alfa (EML/EMLc) epoetin beta (EML/EMLc) epoetin theta (EML/EMLc) darbepoetin alfa (EML/EMLc) methoxy polyethylene glycol- epoetin beta (EML) (including biosimilars)	No change proposed
10.2	dabigatran	B01AE07	venous thromboembolism, stroke prevention in atrial fibrillation	yes	apixaban edoxaban rivaroxaban	No change proposed
10.2	enoxaprin	B01AB05	venous thromboembolism, acute coronary syndromes	yes	dalteparin nadroparin	No change proposed
12.1	bisoprolol	C07AB07	angina	yes	carvedilol metoprolol	No change proposed
12.2	bisoprolol	C07AB07	cardiac arrhythmia	yes	carvedilol metoprolol	No change proposed
12.3	bisoprolol	C07AB07	hypertension	yes	atenolol carvedilol metoprolol	No change proposed
12.4	bisoprolol	C07AB07	heart failure	yes	carvedilol metoprolol	No change proposed
18.7	methimazole	H03BB02	hyperthyroidism	yes	carbimazole	No change proposed
24.5	methadone	N07BC02	opioid dependence	yes	buprenorphine	No change proposed