

Essential Medicine List



2009

Maldives Food and Drug Authority
Ministry of Health and Family, Male', Republic of Maldives

Maldives Essential Medicine List 2009

Essential medicines are those that satisfy the priority health care needs of the population. These medicines are selected with due regard to disease dominance, evidence on efficiency and safety, and relative cost-effectiveness. Also these medicines are intended to be available within the context of functioning health care systems at all times, in sufficient amounts, in the required dosage forms, with assured quality, and at a price affordable by the individuals and the community.

This Essential Medicine List has been formulated based on discussions held with doctors and specialists of major health discipline and in consultation with WHO consultants and Pharmaceutical Board. Every drug in this list is classified according to the category of medical officer or healthcare provider allowed to prescribe it.

Codes:

Can be used at all levels of health care (health post, health centre, hospital)	F
Should be used by a doctor only	Fd
Should be used by / under instruction of a specialist	Sp
Should be used by the Public Health Manager only	Ph

Key:

F: *Can be used at all levels of health care (health post, health centre, hospital)*

Fd: *Should be used by a doctor only*

Sp: *Should be used by / under instruction of a specialist*

Ph: *Should be used by the Public Health Manager only*

1. ANAESTHETICS				
1.1 General anaesthetics and oxygen				
	Sp		halothane	Inhalation.
	Sp		ketamine	Injection: 50 mg (as hydrochloride)/ml in 10-ml vial.
	Sp		nitrous oxide	Inhalation.
F			oxygen	Inhalation (medicinal gas).
	Sp		thiopental	Powder for injection: 0.5 g; 1.0 g (sodium salt) in ampoule.
1.2 Local anaesthetics				
	Sp		lidocaine	Injection for spinal anaesthesia: 5% (hydrochloride) in 2-ml ampoule to be mixed with 7.5% glucose solution.
	Sp		bupivacaine (heavy)	Injection for spinal anaesthesia: 0.5% (hydrochloride) in 4-ml ampoule with 7.5% glucose solution.
	Sp		lidocaine	Injection: 1%; 2% (hydrochloride) in vial topical forms: 2-4% (hydrochloride).
	Sp		bupivacaine (plain)	Injection: 0.25%; 0.5% (hydrochloride) in vial.
Fd			lidocaine + epinephrine (adrenaline)	Injection: 1%; 2% (hydrochloride) + epinephrine 1:200 000 in vial dental cartridge 2% (hydrochloride) + epinephrine 1:80 000.
	Sp		ephedrine	Injection: 30 mg (hydrochloride)/ml in 1-ml ampoule (For use in spinal anaesthesia during delivery to prevent hypotension).
1.3 Preoperative medication and sedation for short-term procedures				
F			atropine	Injection: 0.6 mg (sulfate) in 1-ml ampoule.
Fd			diazepam	Injection: 5 mg/ml in 2-ml ampoule. Oral liquid: 2mg/5ml. Tablet: 2mg; 5mg, suppository 2.5mg, 5mg, 10 mg.
	Sp		morphine	Injection: 10 mg (sulfate or hydrochloride) in 1-ml ampoule.
	Sp		midazolam	Injection: 5mg/ml in 2ml ampoule (hydrochloride).
	Sp		fentanyl	Injection: 50mg/ml ampoule.

2. ANALGESICS; ANTIPYREtics; NON-STERoidal ANTI-INFLAMMATORY MEDICINES (NSAIMs); GOUT AND RHEUMATOID DISORDER AGENTS (DMARDs)

2.1 Non-opioids and non-steroidal anti-inflammatory medicines

F				ibuprofen	Oral liquid: 100mg/5ml Tablet: 200 mg; 400 mg
F				paracetamol	Oral liquid: 120 mg/5ml Tablet: 500 mg Suppository:125 mg;250 mg
F				diclofenac sodium	Injection: 25 mg/ml in 3-ml ampoule Tablet: 25mg;50mg enteric coated Suppository: 12.5mg;50mg

2.2 Opioid analgesics

		Sp		morphine	Injection:10 mg(sulfate or hydrochloride) in 1-ml ampoule. Oral liquid: 10 mg (hydrochloride or sulfate)/5 ml Tablet: 10mg; 30mg modified release (sulfate).
		Sp		tramadol	Injection: 50 mg/ml in 2ml ampoule. Capsules: 50mg. Tablets: 50mg.
		Sp		pethidine	Injection: 50 mg/ml (hydrochloride).

2.3 Medicines used to treat gout

		Sp		allopurinol	Tablet:100 mg.
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2.4 Disease modifying agents used in rheumatoid disorders (DMARDs)

		Sp		methotrexate	Tablet: 2.5 mg (as sodium salt).
		Sp		chloroquine	Tablet: 150 mg base.

2.5 Medicines for intra-articular use

		Sp		methylprednisolone acetate	Injection: (depot).
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3. ANTIALLERGICS AND MEDICINES USED IN ANAPHYLAXIS

F				cetrizine	Oral liquid: 5mg/5ml Tablets: 10 mg
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	Fd			chlphenaramine	Injection: 10 mg (hydrogen maleate) in 1-ml ampoule Oral liquid: 2 mg/5 ml Tablet: 4 mg (hydrogen maleate)
	Fd			dexamethasone	Injection: 4 mg dexamethasone phosphate (as disodium salt) in 1-ml ampoule
F				epinephrine (adrenaline)	Injection: 1 mg (as hydrochloride or hydrogen tartrate) in 1-ml ampoule
	Fd			hydrocortisone	Powder for injection: 100 mg (as sodium succinate) in vial

4. ANTIDOTES AND OTHER SUBSTANCES USED IN POISONING

4.1 Non specific

F				charcoal; activated	Powder
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4.1 Specific

F				acetylcysteine	Injection: 200 mg/ml in 10-ml ampoule
		Sp		atropine	Injection: 0.6 mg; 1mg (sulfate) in 1-ml ampoule
		Sp		deferoxamine	Powder for injection: 500 mg (mesilate) in ampoule
	Fd			DL-methionine	Tablet: 250 mg
		Sp		flumazenil	Injection: mg/ml
	Fd			naloxone	Injection: 400 micrograms (hydrochloride) in 1-ml ampoule
	Fd			sodium nitrite	Injection: 30 mg/ml in 10-ml ampoule

4. ANTICONVULSANTS/ANTIEPILEPTICS

	Fd			carbamazepine	Oral liquid: 100mg/5ml Tablet (scored): 100 mg; 200 mg
	Fd			diazepam	Injection: 5 mg/ml in 2-ml ampoule intravenous; rectal solution
	Fd			lorazepam	Injection: 4 mg/ml in 1-ml ampoule Tablets 1mg; 2.5mg
		Sp		magnesium sulfate*	Injection; 500 mg/ml in 2-ml ampoule; 250mg/ml in 5-ml ampoule * for use in eclampsia and severe pre-eclampsia and not for other convulsant disorders.
	Fd			phenobarbital	Oral liquid: 15 mg/5ml Tablet:15-100 mg , injection 30mg/5ml

	Fd			phenytoin	Injection: 50 mg/ml(sodium salt) in 5-ml vial capsule: 25 mg; 50 mg; 100 mg (sodium salt) Tablet: 5 mg; 50 mg; 100 mg (sodium salt)
		Sp		valproic acid	Oral liquid: 200mg/5ml Tablet (enteric coated) : 200 mg; 500 mg (sodium salt)

6. ANTI-INFECTIVE MEDICINES

6.1 Anthelmintics

6.1.1 *Intestinal anthelmintics*

F				albendazole	Oral liquid: 200mg/5ml Tablet (chewable) 400 mg
F				pyrantel pamoate	Oral liquid: 50 mg (as embonate)/ml. Tablet (chewable): 250 mg (as embonate)

6.1.2 *Antifilarials*

	Fd			ivermectin	Scored tablet: 3 mg , 6 mg
	Fd			diethylcarbamazine	Tablet: 50 mg,100 mg

6.2 Antibacterials

6.2.1 *Beta Lactam medicines*

F				amoxicillin	Capsule or tablet; 250 mg; 500 mg (anhydrous) Powder for oral suspension:125 mg (anhydrous)/5 ml
	Fd			amoxicillin + clavulanic acid	Drops: 62.5mg/ml Oral liquid: 156mg/5ml; 228mg/5ml Powder for injection: 600 mg; 1.2 g in vial Tablet: 625 mg; 375mg
F				ampicillin	Powder for injection: 500 mg; 1 g (as sodium salt) in vial
	Fd			benzathine benzylpenicillin	Powder for injection: 1.44 g benzylpenicillin (=2.4 million IU) in 5-ml vial
	Fd			benzylpenicillin	Powder for injection: 600 mg (= 1 million IU); 3 g (= 5 million IU) (sodium or potassium salt) in vial
F				cloxacillin	Capsule: 500 mg; 1 g (as sodium salt) Powder for injection: 500 mg (as sodium salt) in vial Powder for oral solution:125 mg (as sodium salt)/5 ml
F				cefalexin	Capsules: 250mg;500mg Dispersible capsules: 125mg;250mg;500 mg Drops:100 mg/ml Oral liquids: 125mg/5ml ;250mg/5ml

	Fd			cefazolin (surgical prophylaxis only)	Injection: 500 mg; 1g
	Fd			cefuroxime	Injections: 250 mg; 500 mg Tablets: 125 mg; 250 mg (as cefuroxime axetil)
		Sp		ceftazidime	Powder for injection: 250 mg (as pentahydrate) in vial
		Sp		cefotaxime	Injection: 250mg; 500 mg; 1g
		Sp		meropenem	Injection: 500 mg
	Fd			phenoxycephalpenicillin	Tablet: 250 mg (as potassium salt) Powder for oral suspension: 250 mg (as potassium salt)/5 ml

6.2.2 Other antibacterials

	Fd			azithromycin	Capsule: 250 mg Oral liquid: 200g/15ml (for restricted indications only)
	Fd			ciprofloxacin	Tablet: 250 mg (as hydrochloride), 500mg, Injection 200 mg
	Fd			clarithromycin	Tablets: 250mg; 500 mg
	Fd			clindamycin	Capsule: 150mg, 300mg
	Fd			doxycycline	Capsule or tablet: 100 mg (hydrochloride)
	Fd			erythromycin	Capsule or tablet: 250 mg (as stearate or ethyl succinate) Powder for injection: 500 mg (as lactobionate) in vial Powder for oral suspension: 125 mg (as stearate or ethyl succinate)
	Fd			gentamicin	Injection: 10 mg; 40 mg (as sulfate)/ml in 2-ml vial
		Sp		amikacin sulphate	Injection: 250 mg in 2ml aqueous solution in vial for pediatric use
	F			metronidazole	Injection: 500 mg in 100-ml vial Oral suspension: 200 mg (as benzoate)/5 ml Tablet: 200-500 mg Suppository: 500 mg; 1g
	Fd			nitrofurantoin	Tablets: 50 mg; 100 mg
	Fd			norfloxacin	Tablet: 400 mg (urinary tract infections)
	Fd			sulfamethoxazole + trimethoprim	Oral suspension: 200 mg + 40 mg/5 ml Tablet: 100 mg + 20 mg; 400 mg + 80 mg
	Fd			vancomycin	Powder for injection: 250 mg (as hydrochloride) in vial

		Sp		chloramphenicol	Capsules: 250mg Oral suspension: 150mg (as palmitate) /5ml , Powder for injecton: 1g (sodium succinate)/ml in 2-ml I ampoule.
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6.2.3 Antileprosy medicines (*Medicines used in the treatment of leprosy should never be used except in combination. Combination therapy is essential to prevent the emergence of drug resistance.)*

		Ph	clofazimine	Capsule: 50 mg; 100 mg
		Ph	dapsone	Tablet: 25 mg; 50 mg; 100 mg
		Ph	rifampicin	Capsule or tablet: 150 mg; 300 mg

6.2.4 Antituberculosis medicine

		Ph	ethambutol	Tablet: 100mg; 400 mg (hydrochloride)
		Ph	isoniazid	Tablet: 100mg; 300mg Tablet: (scored): 50 mg
		Ph	isoniazid + ethambutol	Tablet: 150 mg + 400 mg
		Ph	pyrazinamide	Tablet: 400 mg. Tablet (dispersible):150 mg Tablet (scored): 150 mg
		Ph	rifampicin	Capsule or tablet: 150 mg; 300 mg
		Ph	rifampicin + isoniazid	Tablet: 60 mg + 30 mg; 150 mg + 75 mg; 300 mg + 150 mg 60 mg + 60 mg (for intermittent use three times weekly) 150 mg + 150 mg (for intermittent use three times weekly)
		Ph	rifampicin + isoniazid + ethambutol	Tablet: 150 mg + 75 mg + 275 mg.
		Ph	rifampicin + isoniazid + pyrazinamide + ethambutol	Tablet: 150 mg + 75 mg + 400 mg + 275 mg.
		Ph	streptomycin	Powder for injection: 1 g (as sulfate) in vial

Reserve second - line drugs for the treatment of multidrug-resistant tuberculosis (MDR-TB) should be used adhering to WHO standards for TB control

		Ph	amikacin	Powder for injection: 1000 mg in vial
		Ph	capreomycin	Powder for injection: 1000 mg in vial
		Ph	cycloserine	Capsule or tablet: 250 mg
		Ph	ethionamide	Tablet: 125 mg; 250 mg

		Ph	kanamycin	Powder for injection: 1000 mg in vial
		Ph	ofloxacin	Tablet: 200 mg; 400 mg * Levofloxacin may be an alternative based on availability
		Ph	p-aminosalicylic acid	Granules: 4 g in sachet Tablet: 500 mg

6.3 Antifungal medicines

		Sp		fluconazole	Injection: 2 mg/ml in vial Capsule: 50-150 mg Oral suspension: 50 mg/5-ml
	Fd			griseofulvin	Capsule or tablet: 125 mg; 250 mg
	Fd			nystatin	Lozenge: 100 000 IU Pessary: 100 000 IU Tablet: 100 000; 500 000 IU Oral Drops: 100 000 IU
		Sp		potassium iodide	Saturated solution
		Sp		amphotericin B Liposomal	Injection: 50 mg/ml; 100 mg/ml in vial

6.4 Antiviral medicines

6.4.1 Antiherpes medicines

	Fd			aciclovir	Cream: 3% Powder for injection: 250 mg (as sodium salt) in vial Tablet: 200 mg; 400 mg, 800 mg, ointment 5%, suspension 40 mg/5 ml
			Ph	oseltamivir phosphate (under PH programme only)	Tablet: 25 mg

6.4.2 Antiretrovirals

6.4.2.1 Nucleoside/Nucleotide reverse transcriptase inhibitors

			Ph	abacavir (ABC)	Oral liquid: 100 mg (as sulfate)/5 ml. Tablet: 300 mg (as sulfate)
			Ph	lamivudine (3TC)	Oral liquid: 50 mg/5 ml, tablet: 150 mg
			Ph	tenofovir disoproxil fumarate (TDF)	Tablet: 300 mg (tenofovir disoproxil fumarate equivalent to 245 mg tenofovir disoproxil)

			Ph	zidovudine (ZDV or AZT)	Capsule: 100 mg; 250 mg. Oral liquid: 50 mg/5 ml. solution for IV infusion Injection: 10 mg/ml in 20-ml vial. Tablet: 300 mg.
6.4.2.2 Non-nucleoside reverse transcriptase inhibitors					
			Ph	efavirenz (EFV or EFZ)	Capsule: 50 mg; 100 mg; 200 mg Oral liquid: 150 mg/5 ml Tablet: 600 mg
			Ph	nevirapine (NVP)	Oral liquid: 50 mg/5 ml Tablet: 200 mg
6.4.2.3 Protease inhibitors					
			Ph	lopinavir + ritonavir (LPV/r)	Capsule: 133.3 mg + 33.3 mg Oral liquid: 400 mg + 100 mg/5 ml
			Ph	nelfinavir (NFV)	Oral powder: 50 mg/g Tablet: 250 mg (as mesilate)
			Ph	ritonavir	Oral liquid: 400 mg/5 ml Oral solid dosage form: 100 mg
6.4.2.4 Fixed Dose Combinations					
			Ph	efavirenz + emtricitabine* + tenofovir	Tablet: 600 mg + 200 mg + 300 mg * FTC is an acceptable alternative to 3TC; based on knowledge of the pharmacology; the resistance patterns and clinical trials of antiretrovirals
			Ph	emtricitabine* + tenofovir	Tablet: 200 mg + 300 mg * FTC is an acceptable alternative to 3TC; based on knowledge of the pharmacology; the resistance patterns and clinical trials of antiretrovirals
			Ph	stavudine + lamivudine + nevirapine	Tablet: 30 mg + 150 mg + 200 mg
			Ph	zidovudine + lamivudine	Tablet: 300 mg + 150 mg
			Ph	zidovudine + lamivudine + nevirapine	Tablet: 300 mg + 150 mg + 200mg

6.5.3 Antimalarial medicines				
		Ph	mefloquine	Tablet: 250 mg
		Ph	quinine	Tablet: 100 mg, Syrup:150mg/ml, Injection:300 mg
		Ph	chloroquine	Tablet:150 mg
		Ph	sulphadoxine	Tablet:500 mg
		Ph	primaquine	Tablet:7.5 mg,15 mg
		Ph	artesunate	Tablet: 150 mg ,injection 150 mg
		Ph	artemether	Tablet: 80 mg, injection: 80 mg
6.5.4 Anti -pneumocystosis and antitoxoplasmosis				
		Ph	sulphadiazine	Tablets: 500mg, 12.5 mg syrup
		Ph	pyrimethamine	Tablets: 25mg
		Ph	spiramycin	Tablets: 1.5 miu; 3 miu
7. ANTIMIGRAINE MEDICINES				
7.1 For treatment of acute attack				
F			acetyl salicylic acid	Tablet: 300mg
F			paracetamol	Oral liquid: 120 mg/5ml Tablet: 500 mg Suppository:125 mg;250 mg
	Fd		sumatriptan	Injections: 6mg/0.5ml Nasal spray: 20 mg Tablets:300mg;500 mg
7.2 For prophylaxis				
	Fd		propranolol	Tablets: 5 mg;10 mg;40 mg
	Fd		flunarizine	Tablets:5 mg;10 mg
8. ANTINEOPLASTIC; IMMUNOSUPPRESSIVES AND MEDICINES USED IN PALLIATIVE CARE				
8.1 Immunosuppressive medicines				
		Sp	azathioprine	Powder for injection:100 mg (as sodium salt) in vial Tablet:50 mg

		Sp		cyclosporin	Capsule: 25 mg Concentrate for injection: 50 mg/ml in 1-ml ampoule for organ transplantation
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8.2 Cytotoxic medicines

		Sp		cyclophosphamide	Powder for injection: 500 mg in vial Tablet: 25 mg
		Sp		methotrexate	Powder for injection: 50 mg (as sodium salt) in vial Tablet: 2.5 mg (as sodium salt)
		Sp		mycophenolate mofetil	Tablet: 500 mg

8.3 Hormones and antihormoneses

	Fd			dexamethasone	Injection: 4 mg dexamethasone phosphate (as disodium salt) in 1-ml ampoule
	Fd			hydrocortisone	Powder for injection: 100 mg (as sodium succinate) in vial
	Fd			prednisolone	Tablet: 5 mg; 20 mg, syrup 3mg/5ml
		Sp		tamoxifen	Tablet:10 mg; 20 mg (as citrate)

8.4 Medicines used in palliative care**8.4.1 Analgesics**

F				acetylsalicylic acid	Tablet: 300 mg
	Fd			codeine	Tablets: 30 mg; 20 mg (phosphate) Oral liquid: 5 mg/mL
F				ibuprofen	Oral liquid: 100mg/5ml Tablet: 200 mg; 400 mg
		Sp		morphine	Oral liquid: 10 mg (hydrochloride or sulfate)/5 ml Tablet: 10mg; 30mg modified release (sulfate)

8.4.2 Antidiarrhoeals

F				loperamide	Capsule: 2mg
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8.4.3 Antiemetics

F				domperidone	Oral liquid: 5mg /5ml Tablet: 10 mg, oral drops 0mg/ml.
F				metoclopramide	Tablet: 10 mg (hydrochloride)

	Sp			ondansetron	Tablet: 4mg; 8mg
F				promethazine	Oral liquid: 5 mg (hydrochloride)/5 ml Tablet: 10 mg; 25 mg (hydrochloride)

8.4.4 Antihistamines

F				chlorphenamine	Oral liquid: 2 mg/5 ml Tablet: 4 mg (hydrogen maleate)
	Fd			fexofenadine	Tablet: 120mg; 180mg
	Fd			Loratadine	Tablet: 10mg
	Fd			Hyroxizine	Tablets: 10mg;25mg;50mg
	Fd			Levocetirizine	Tablet: 5mg.
	Fd			Desloratadine	Tablet: 5mg.

8.4.5 Antispasmodics

F				hyoscine butyl bromide	Tablet: 10mg
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8.4.6 Antispasmodics

F				bisacodyl	Tablet: 5 mg
F				senna	Tablet: 5 mg

8.4.7 Psychotherapeutic medicines

	Fd			amitriptyline	Tablet: 25 mg (hydrochloride)
	Fd			haloperidol	Tablet: 2 mg; 5 mg
	Fd			diazepam	Tablet (scored): 2 mg; 5 mg, syrup 2mg/5ml.

9. ANTIPARKINSONISM MEDICINES

		Sp		bromocriptine	Tablet: 2.5 mg
		Sp		levodopa + carbidopa	Tablet:100 mg + 10 mg; 250 mg + 25 mg
		Sp		trihexyphenidyl	Tablet: 2 mg

10. MEDICINES AFFECTING THE BLOOD**10.1 Antianaemia medicines**

F				ferrous salt	Oral solution: equivalent to 25 mg iron (as sulfate)/ml Tablet: equivalent to 60 mg iron
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F				ferrous salt + folic acid	Tablet: equivalent to 60 mg iron + 400 micrograms folic acid (nutritional supplement for use during pregnancy.)
F				folic acid	Tablet: 1mg; 5mg
F				hydroxocobalamin	Injection: 1 mg in 1-ml ampoule

10.2 Medicines affecting coagulation

		Sp		heparin sodium	Injection: 1000 IU/ml; 5000 IU/ml; 20,000 IU/ml in 1-ml ampoule
		Sp		enoxaparin	Injection: 100 mg/ml (20mg/2000 units) (sodium)
		Sp		phytomenadione (vitamine K)	Injection: 10 mg/ml in 5-ml ampoule Tablet: 10 mg
		Sp		protamine sulfate	Injection: 10 mg/ml in 5-ml ampoule
		Sp		warfarin	Tablet: 1 mg; 2 mg and 5 mg (sodium salt)

11. BLOOD PRODUCTS AND PLASMA SUBSTITUTES

11.1 Plasma substitutes

	Fd			dextran 40	Injectable solution
		Sp		pentastarch	Intravenous: molecular weight 200,000

11.2 Plasma fractions for specific use

		Sp		human normal immunoglobulin	Human normal immunoglobulin (intramuscular) administration: 16% protein solution. Intravenous administration: 5%; 10% protein solution.
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12. CARDIOVASCULAR MEDICINES

12.1 Antianginal medicines

	Fd			atenolol	Tablet: 50 mg; 100 mg
	Fd			glyceryl trinitrate	Injection: 5 mg/ml Tablet(sublingual): 500 micrograms
	Fd			isosorbide dinitrate	Tablet (sublingual): 5 mg
	Fd			verapamil	Tablet: 40 mg; 80 mg (hydrochloride)

12.2 Antiarrhythmic medicines

	Sp	adenosine	Injection: 3mg/ml in physiological saline in 2ml ampoule
	Sp	amiodarone	Injection: 30mg/ml in 10ml Tablet: 100mg; 200mg
	Sp	digoxin	Injection: 250 micrograms/ml in 2-ml ampoule Oral solution: 50 micrograms/ml Tablet: 62.5 micrograms; 250 micrograms
	Fd	epinephrine (adrenaline)	Injection: 1 mg (as hydrochloride)/ml in ampoule
	Fd	isoprenaline	Injection: 20 micrograms (hydrochloride)/ml in ampoule
	Fd	lidocaine	Injection: 20 mg (hydrochloride)/ml in 5-ml ampoule
	Fd	metoprolol	Injection: 5mg/ml in ampoule Tablet: 25mg; 50 mg
	Fd	verapamil	Injection: 2.5 mg (hydrochloride)/ml in 2-ml ampoule Tablet: 40 mg; 80 mg (hydrochloride)

12.3 Antihypertensive medicines

	Fd	amlodipine	Tablet: 2.5mg; 10mg
	Fd	atenolol	Tablet: 25mg; 50 mg; 100 mg
	Fd	enalapril	Tablet: 2.5 mg; 5mg
	Fd	hydralazine*	Powder for injection: 20 mg (hydrochloride) in ampoule Tablet: 25 mg; 50 mg (hydrochloride) *For use in the acute management of severe pregnancy-induced hypertension only
	Fd	hydrochlorothiazide	Tablet (scored): 25 mg
	Fd	losartan potassium	Tablet: 25 mg 50mg
	Fd	methyldopa*	Tablet: 250 mg *For use in the management of pregnancy-induced hypertension only.

	Fd			nifedipine*	Capsules: 5mg; 10mg Tablet (sustained release): 10 mg; 20mg *Obstetric Use
	Fd			sodium nitroprusside	Powder for infusion: 50 mg in ampoule

12.4 Medicines used in heart failure

	Fd			digoxin	Injection: 250 micrograms/ml in 2-ml ampoule Oral solution: 50 micrograms/ml Tablet: 62.5 micrograms; 250 micrograms
	Fd			dopamine	Injection: 40 mg (hydrochloride)in 5-ml vial
	Fd			carvedilol	Tablet: 3.125mg; 6.25mg
	Fd			enalapril	Tablet: 2.5 mg; 5mg
	Fd			furosemide	Injection: 10mg/ml in 2 ml vials Tablet: 20mg; 40mg
	Fd			hydrochlorothiazide	Tablet (scored): 25 mg
	Fd			spironolactone	Tablet: 25mg

12.4.1 Vasoconstrictors

		Sp		Noradrenaline	Injection:2mg/ml in 2ml or 4ml ampoules
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12.5 Antithrombotic medicines

F				acetylsalicylic acid	Tablet: 100 mg
	Fd			clopidogrel	Tablets: 25mg; 75 mg
		Sp		streptokinase	Powder for injection:1.5 million IU in vial

12.6 Lipid-lowering agents

F				atorvastatin	Tablet: 5mg;10 mg; 20mg
F				bezafibrate	Tablet: 200mg

13. DERMATOLOGICAL MEDICINES

13.1 Antifungal medicines

F				clotrimazole	Cream / ointment: 1%
F				miconazole	Cream / ointment: 2% (nitrate)
F				clotrimazole + betamethasone	Cream: 0.025% + 1%

F				ketoconazole	Shampoo: 2%
13.2 Anti-infective medicines					
F				erythromycin	Lotion: 3%
F				povidone Iodine	Ointment and cream: 5%w/w 15gm Tube
F				neomycin sulfate + bacitracin	Ointment:5 mg + 500 IU bacitracin zinc/g
F				mupirocin	Ointment; 2% cream2%
F				potassium permanganate	Solution (aqueous): 1in10,000
13.3 Anti-inflammatory and antipruritic medicines					
F				betamethasone	Ointment / cream: 0.1% (as valerate)
F				calamine lotion	Lotion
F				hydrocortisone	Ointment or cream:1% (acetate)
	Sp			triamcinolone	Injection: 10mg; 40mg (acetonide)
13.4 Astringent medicines					
F				aluminium diacetate	Solution: 13% for dilution
13.5 Medicines affecting skin differentiation and proliferation					
F				benzoyl peroxide	Lotion and gel: 2.5% ; 5%
F				coal tar	Solution: 5%
F				dithranol	Ointment: 0.1%; 2%
F				podophyllum resin	Solution: 10; 25%
F				salicylic acid	Solution: 5%
F				tretinoin	Cream: 0.025%; 0.05%
F				urea	Ointment and cream: 10%
13.6 Scabicides and pediculicides					
F				benzyl benzoate	Lotion: 25%
F				permethrin	Cream: 5% (scabies); 1% lice Lotion: 5% (scabies); 1% lice

14. DIAGNOSTIC AGENTS

14.1 Ophthalmic diagnostics

	Fd			fluorescein	Eye drops: 1% (sodium salt)
	Fd			tropicamide	Eye drops: 0.5%

14.2 Radiocontrast media

		Sp		Amidotrizoate (urograffin)	Injection: 140-420 mg iodine (as sodium or meglumine salt)/ml in 20-ml ampoule
		Sp		barium sulfate	Aqueous suspension
		Sp		iohexol	Injection: 140 –350 mg iodine/ml in 5-ml; 10-ml and 20-ml ampoule
		Sp		iopanoic acid	Tablet: 500 mg
		Sp		propylidone	Oily suspension: 500-600 mg/ml in 20-ml ampoule (For administration only into the bronchial tree.)
		Sp		meglumine iotroxate	Solution: 5-8 g iodine in 100-250 ml

15. DISINFECTANTS AND ANTISEPTICS

15.1 Antiseptics

F				chlorhexidine	Solution: 5% (digluconate) for dilution
F				ethanol	Solution: 70% (denatured)
F				hydrogen Peroxide	Solution: strength : 20 Volume
F				polyvidone iodine	Solution: 5; 10%

15.2 Disinfectants

F				chlorine base compound	Powder: (0.1% available chlorine) for solution
F				chloroxylenol	Solution: 4.8%
F				glutaral	Solution: 2%

16. DIURETICS

		Sp		amiloride	Tablet: 5mg (hydrochloride)
F				furosemide	Injection: 10 mg/ml in 2-ml ampoule Tablet: 40 mg
	Fd			hydrochlorothiazide	Tablet: 25 mg; 50mg

	Fd			mannitol	Injectable solution:10%; 20%
		Sp		spironolactone	Tablet: 25 mg; 50mg

17. GASTROINTESTINAL MEDICINES

17.1 Antacids and other antiulcer medicines

F				aluminium-magnesium antacid	Tablet: 200mg + 200mg; 400mg + 400mg (hydroxide) Oral liquid: 40mg/ml+ 40mg/ml
F	Fd			ranitidine	Injection: 25 mg/ml in 2-ml ampoule Oral liquid: 75 mg/5-ml Tablet: 150 mg (as hydrochloride)
F				omeprazole	Capsule: 20 mg

17.2 Antiemetic medicines

F				domperidone	Oral liquid: 5mg /5ml Tablet: 10 mg
F				metoclopramide	Injection; 5 mg (hydrochloride)/ml in 2-ml ampoule Tablet: 10 mg (hydrochloride), syrup 5mg/5ml
	Fd			ondansetron	Injection; 4mg; 8mg in 2-ml ampoule Tablet: 4mg; 8mg
F				promethazine	Injection: 25 mg (hydrochloride)/ml in 2-ml ampoule Oral liquid: 5 mg (hydrochloride)/5 ml Tablet: 10 mg; 25 mg (hydrochloride)

17.3 Antiinflammatory medicines

17.4 Laxatives

F				bisacodyl	Tablet: 5 mg Suppository: 10mg
F				glycerin	Suppository: paediatric
F				lactulose	Oral suspension: 667mg/ml

17.5 Medicines used in diarrhoea

F				oral rehydration salts * (for glucose-electrolyte solution)	Glucose: 75 mEq
				Sodium: 75 mEq or mmol/l	
				Chloride: 65 mEq or mmol/l	
				Potassium: 20 mEq or mmol/l	

				Citrate: 10 mmol/l Osmolarity: 245 mOsm/l Glucose: 13.5 g/l Sodium chloride: 2.6 g/l Potassium chloride: 1.5 g/l Trisodium citrate dihydrate: 2.9 g/l * in cases of cholera a higher concentration of sodium may be required
F				neutrolin B B complex with lactobacillus
F				zinc sulphate* Oral liquid: in 10 mg per unit dosage forms. Tablet: in 10 mg per unit dosage forms. * In acute diarrhoea zinc sulfate should be used as an adjunct to oral rehydration salts.

17.6 Antispasmodic medicines

F				hyoscine butyl bromide Injection: 20 mg/ml Tablet: 10mg
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18. HORMONES; OTHER ENDOCRINE MEDICINES AND CONTRACEPTIVES

18.1 Adreno-cortical hormones

	Fd			hydrocortisone Powder for injection: 100 mg (as sodium succinate) in vial
	Fd			dexamethasone Injection: 4mg as disodium salt in 1ml ampoule Tablets: 0.5mg check tablet strength
	Fd			methylprednisolone Injection: 20/ml; 40/ml; 80mg/ml
	Fd			prednisolone Oral liquid: 5mg/5ml Tablets: 5 mg; 20 mg

18.2 Androgens

18.3 Contraceptives

18.3.1 Oral hormonal contraceptives

F				ethinylestradiol + levonorgestrel Tablet: 30 micrograms + 150 micrograms
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F				ethinylestradiol + norethisterone	Tablet: 35 micrograms + 1.0 mg
18.3.2 Injectable hormonal contraceptives					
F				medroxyprogesterone acetate	Depot injection: 150 mg/ml in 1-ml vial
18.3.3 Intrauterine devices					
	Sp			copper-containing device	-
18.3.4 Barrier methods					
F				condoms	-
F				diaphragms	-
18.4 Estrogens					
	Sp			ethinylestradiol	Tablet; 10 micrograms; 50 micrograms
18.4.1 Estrogen combinations for polycystic ovary syndrome					
	Sp			ethanol estradiol + cypoterone acetate	Tablet: 35 microgram + 2 mg (21 tablets packs)
18.5 Insulins and other antidiabetic agents					
	Fd			insulin injection (soluble human)	Injection: 40 IU/ml in 10-ml vial; 100 IU/ml in 10-ml vial
	Fd			intermediate-acting insulin (human)	Injection: 40 IU/ml in 10 ml vial; 100 IU/ml in 10 ml vial (as compound insulin zinc suspension or isophane insulin)
	Fd			glibenclamide	Tablet:2.5 mg; 5 mg
	Fd			gliclazide	Tablet:80 mg
	Fd			metformin	Tablet: 500 mg (hydrochloride)
18.6 Ovulation inducers					
	Sp			clomifene	Tablet: 50 mg (citrate)
18.7 Progestogens					
	Sp			dydrogesterone	Tablets: 10 mg

		Sp		medroypregesterone	Tablets: 2.5 mg; 10 mg
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18.8 Thyroid hormones and antithyroid medicines

		Sp		levothyroxine	Tablets: 50 micrograms; 100 micrograms (sodium salt)
		Sp		propylthiouracil	Tablet: 50 mg
		Sp		carbimazole	Tablet: (film coated): 5 mg

19. IMMUNOLOGICALS

19.1 Diagnostic agents

All tuberculins should comply with the WHO Requirements for Tuberculins (Revised 1985). WHO Expert Committee on Biological Standardization 36th report; (WHO Technical Report Series; No. 745; 1987; Annex 1).

		Sp		tuberculin; purified protein derivative (PPD)	Injection
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19.2 Sera and immunoglobulins

All plasma fractions should comply with the WHO Requirements for the Collection; Processing and Quality Control of Blood; Blood Components and Plasma Derivatives (Revised 1992). WHO Expert Committee on Biological Standardization Forty-third report

F				anti-D immunoglobulin (human)	Injection: 250 micrograms in single-dose vial
F				antitetanus immunoglobulin (human)	Injection: 500 IU in vial

19.3 Vaccines: All vaccines should comply with the WHO Requirements for Biological Substances.

For universal immunization

			Ph	BCG vaccine	
			Ph	hepatitis B vaccine	
			Ph	measles vaccine	
			Ph	poliomyelitis vaccine	
			Ph	tetanus vaccine	

			Ph	diphtheria; pertussis; tetanus; vaccine	
	Fd			<i>Haemophilus influenzae type b vaccine</i>	
			Ph	measles; mumps; rubella vaccine	

For specific groups of individuals

			Ph	influenza vaccine	
			Ph	meningococcal meningitis vaccine	
	Fd		Ph	mumps vaccine	
	Fd			rubella vaccine	
			Ph	typhoid vaccine	
			Ph	yellow fever vaccine	
	Fd			hepatitis A vaccine	
	Fd			varicella vaccine	

20. MUSCLE RELAXANTS AND CHOLINESTERASE INHIBITORS

		Sp		atracurium	Injection: 10 mg/ml
		Sp		neostigmine	Injection: 500 micrograms in 1-ml ampoule; 2.5 mg (metilsulfate) in 1-ml ampoule Tablet: 15 mg (bromide)
		Sp		suxamethonium	Injection: 50 mg (chloride)/ml in 2-ml ampoule
		Sp		pyridostigmine	Injection: 1 mg in 1-ml ampoule Tablet: 60 mg (bromide)

21. OPHTHALMOLOGICAL PREPARATIONS**21.1 Anti-infective agents**

	Fd			chloramphenicol	Solution (eye drops): 5% Ointment: 1%
	Fd			gentamicin	Solution (eye drops): 0.3% (sulfate)
	Fd			tetracycline	Ointment: 1%;

	Fd			tetramycin + dexamethasone	Solution (eye drops): 0.1%
	Fd			aciclovir	Ointment: 3%;
21.2 Anti-inflammatory agents					
		Sp		prednisolone	Solution (eye drops): 0.5% (sodium phosphate)
		Sp		hydrocortisone acetate	Solution(eye drops): 0.5%,1% Ointment:1%
21.3 Local anaesthetics					
		Sp		tetracaine	Solution (eye drops): 0.5% (hydrochloride)
21.4 Miotics and antiglaucoma medicines					
		Sp		acetazolamide	Tablet; 250 mg
		Sp		pilocarpine	Solution (eye drops); 2%; 4% (hydrochloride or nitrate)
		Sp		timolol	Solution (eye drops); 0.25%; 0.5% (as maleate)
21.5 Mydriatics					
		Sp		atropine	Solution (eye drops): 0.1%; 0.5%; 1% (sulfate)
	Fd			cyclopentolate	Solution(eye drops): 0.5%; 1%
F				phenylephrine	Solution (eye drops):0.12%
21.6 Medicines for allergic conditions					
F				cromoglycate	Solution (eye drops): 2% (sodium)
21.7 Ocular lubricant					
F				tears naturale	Solution (eye drops): dextran 70.1% hypromellose 0.3%
22. MEDICINES ACTING ON THE GENITOURINARY TRACT					
22.1 Oxytocics					
		Sp		ergometrine	Injection: 200 micrograms (hydrogen maleate) in 1-ml ampoule
		Sp		carboprost trometamine	Injection: 250micrograms/ml in 1ml amp
		Sp		dinoprostone	Gel: 400micrograms; 800micrograms per ml

		Sp		oxytocin	Injection:10 IU in 1-ml ampoule
		Sp		mifepristone	Tablet: 200 mg (Restricted use)
		Sp		misoprostol	Tablets: 100 mg ; 200 mg (Restricted use)

22.2 Antioxytocics (tocolytics)

		Sp		nifedipine	Capsule (immediate release):10mg
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22.3 Medicines for benign prostatic hyperplasia

		Sp		finasteride	Tablet:5mg
		Sp		terazosin	Tablet:2mg

22.4 Urinary antispasmodics

		Sp		oxybutinin	Tablet: 2.5mg
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23. DIALYSIS SOLUTION

		Sp		haemodialysis concentrate	Parenteral solution
		Sp		intraperitoneal dialysis solution	Solution

24. PSYCHOTHERAPEUTIC MEDICINES**24.1 Medicines used in psychotic disorders**

		Sp		chlorpromazine	Injection: 25 mg (hydrochloride)/ml in 2-ml ampoule Oral liquid: 25 mg (hydrochloride)/5ml Tablet: 100 mg (hydrochloride)
		Sp		fluphenazine	Injection: 25 mg (decanoate or enantate) in 1-ml ampoule
		Sp		haloperidol	Injection: 5 mg in 1-ml ampoule Tablet: 2 mg; 5 mg
		Sp		olanzapine	Tablet: 2.5mg; 5mg
		Sp		fentanyl	Injection: 100mcg/1ml

24.2 Medicines used in mood disorders**24.2.1 Medicines used in depressive disorders**

		Sp		amitriptyline	Tablet: 25 mg (hydrochloride)
		Sp		citalopram	Tablets: 5mg;10mg

		Sp		fluoxetine	Capsules: 10mg; 20mg
		Sp		imipramine	Tablets:25mg

24.3 Medicines used in generalized anxiety and sleep disorders

		Sp		alprazolam	Tablet: 0.25 mg; 0.5mg
		Sp		diazepam	Tablet (scored): 2 mg; 5 mg

24.4 Medicines used for obsessive compulsive disorders and panic attacks

		Sp		clomipramine	Capsules: 10 mg; 25 mg (hydrochloride)
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24.5 Medicines used in substance dependence programmes

		Sp		methadone	Concentrate for oral liquid:5mg/ml; 10mg/ml (hydrochloride) Oral liquid: 5mg/5ml;10mg/5ml (used under restricted program only)	Used in NCB only
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25. MEDICINES ACTING ON THE RESPIRATORY TRACT

25.1 Antiasthmatic and medicines for chronic obstructive pulmonary disease

	Fd			aminophylline	Injection: 25mg/ml in 10ml ampoule
F				beclometasone	Inhalation (aerosol): 50 micrograms per dose (dipropionate); 250 micrograms (dipropionate) per dose
	Fd			epinephrine (adrenaline)	Injection: 1 mg (as hydrochloride or hydrogen tartrate) in 1-ml ampoule
F				ipratropium bromide	Inhalation (aerosol): 20 micrograms/metered dose
F				salbutamol	Inhalation (aerosol):100 micrograms (as sulfate) per dose Injection: 50 micrograms (as sulfate)/ml in 5-ml ampoule Respirator solution for use in nebulizers: 5 mg (as sulfate)/ml Tablet: 2 mg; 4 mg (as sulfate)
F				salmeterol/fluticasone	Inhalation (aerosol) / dry powder: 25 +25 mcg; 25 +50mcg ;25+ 250 mcg
F				terbutaline	Inhalation (aerosol): 500micograms per inhalation respirator solution for use in nebulizers:

25.2 Other medicines acting on the respiratory tract

F				codeine phosphate	Oral solution: 10mg/5ml
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26. CORRECTING WATER; ELECTROLYTE AND ACID-BASE DISTURBANCES

F				oral rehydration salts (for glucose-electrolyte solution)	See section 17.6
F				glucose	Injectable solution: 5%; 10% isotonic; 50% hypertonic
F				glucose with sodium chloride	Injectable solution: 4% glucose; 0.18% sodium chloride (equivalent to Na+ 30 mmol/l; Cl- 30 mmol/l)
	Fd			potassium chloride	Injectable solution: 11.2% in 20-ml ampoule; (equivalent to K+ 1.5 mmol/ml; Cl- 1.5 mmol/ml) Tablet: 600mg
F				sodium chloride	Injectable solution: 0.9% isotonic (equivalent to Na+ 154 mmol/l; Cl- 154 mmol/l)
	Fd			sodium hydrogen carbonate	Injectable solution: 1.4% isotonic (equivalent to Na+ 167 mmol/l; HCO3- 167 mmol/l); solution: 8.4% in 10-ml ampoule (equivalent to Na+ 1000 mmol/l; HCO3- 1000 mmol/l)
F				sodium lactate; compound solution	Injectable solution
F				water for injection	Ampoules: 2-ml; 5-ml; 10-ml

27. VITAMINS AND MINERALS

	Fd			alphacalcidol	Tablet:0.25mg
F				ascorbic acid	Tablet:500 mg
F				calcium carbonate	Tablet: 500mg
F				calcium lactate	Tablet: 300 mg
F				ergocalciferol	Capsules: 10.mg 0.25mcg
F				pyridoxine	Tablet:100 mg

F				retinol	Sugar-coated tablet; 10 000 IU (as palmitate) (5.5 mg); Capsule: 200 000 IU (as palmitate) (110 mg); Oral oily solution: 100 000 IU (as palmitate)/ml in multidose dispenser; Water-miscible injection: 100 000 IU (as palmitate) (55 mg) in 2-ml ampoule
F				vitamin B complex	Capsule: Vit B 1 mg, Vit B2 1 mg Tablet: Vit B 1 mg, Vit B2 1 mg

28. MEDICINE USED FOR EAR, NOSE AND OROPHARYNX

28.1 Ear

28.1.1 Anti - infective agents and anti - infective agents with corticosteroids

		Sp		clotrimazole	Solution (ear drops)
		Sp		clotrimazole + hydrocortisone	Solution (ear drops)
		Sp		gentamicin	Solution (ear drops): 0.3%
		Sp		gentamicin + hydrocortisone	Solution (ear drops)

28.1.2 Medicines for vestibular disorders

	Fd			cinnarazine	Tablet: 25mg; 75mg
		Sp		prochlorperazine	Injection: 12.5mg/5ml ampoule Tablet: 5mg

28.1.3 Medicines for ear wax

		Sp		dichlorobenzol with chlorbutol	Solution (ear drops): 2% + 5%
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28.2 Nose

28.2.1 Corticosteroids

F				beclometasone	Solution (nasal spray)
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28.2.2 Decongestants

Fd				oxymetazoline	Solution (nose drops): 0.05%. 0.025%
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28.3 Oropharynx

28.3.1 Anti - infective agents

F				chlorohexidine gluconate	Solution (mouth wash) 0.2%, Gel: 1%
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F				clotrimazole	Solution (paint): 1% w/v / 15 ml
F				miconazole	Oral cream
28.3.2 Local anaesthetics					
		Sp		benzydamine	Solution: 0.15% (hydrochloride)
28.3.3 Wax softeners					
F				dichlorobenzene + chlorbutol	Ear drop: 2% + 5%



Maldives Food and Drug Authority

Ministry of Health and Family

Male'

Republic of Maldives

SUSPECTED ADVERSE REACTIONS REPORTING FORM

If you are suspicious that an adverse reaction may be related to a drug, combination of drugs or vaccine please complete this form and send to Maldives Food and Drug Authority. Do not be put off reporting because some details are not known.

PATIENT DETAILS

Patient Name: _____

Sex: M / F

Weight if known (kg): _____

Age (at time of reaction): _____

Identification number (Your Practice / Hospital Ref.): _____

Island: _____

Atoll: _____

Region: _____

SUSPECTED DRUG(S) / VACCINE (S)

Give brand name of drug/vaccine and

Batch number if known

Route

Dosage

Date started

Date stopped

Prescribed for

_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

SUSPECTED REACTION(S)

Please describe the reaction(s) and any treatment given:

Outcome

Recovered

Recovering

Continuing

Other

Date reaction(s) started: _____ Date reaction(s) stopped: _____

Do you consider the reactions to be serious? Yes / No

If yes, please indicate why the reaction is considered to be serious (please tick all that apply):

Patient died due to reaction

Involved or prolonged inpatient hospitalization

Life threatening

Involved persistent or significant disability or incapacity

Congenital abnormality

Medically significant; please give details:

VACCINES / OTHER DRUGS (INCLUDING HERBAL REMEDIES)

Did the patient take any other drugs/vaccines in the last 3 months prior to the reaction? Yes / No

If yes, please give the following information if known:

Drug /Vaccine	Route	Dosage	Date started	Date stopped	Prescribed for
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

Additional relevant information e.g. medical history, test results, known allergies, suspect drug interactions. For congenital abnormalities please state all other drugs taken during pregnancy and the last menstrual period.**REPORTER DETAILS**

Name: _____

Professional Address: _____

Tel No: _____

Specialty: _____

Signature: _____

Date: _____

CLINICIAN (if not the reporter)

Name: _____

Professional Address: _____

Tel No: _____ Specialty: _____

If you would like information about other adverse reactions associated with the suspected drug, please tick this box	<input type="checkbox"/>
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FOR MORE INFORMATION CONTACT:

Medicine and Therapeutic Goods Division

Phone No: 3312283, 3345721

Fax No: 3304670, 3304570

