

## **GUIDELINES FOR THE MOTIVATION OF A NEW MEDICINE ON THE NATIONAL ESSENTIAL MEDICINES LIST**

### **Section 1: Medication details**

- » Generic name  
A fundamental principle of the Essential Drug Programme is that of generic prescribing. Most clinical trials are conducted using the generic name.
- » Proposed indication  
There will usually be many registered indications for the medication. However, this section should be limited to the main indication which is supported by the evidence provided in section 2.
- » Prevalence of the condition in South Africa  
This information is not always readily available. However, it is an important consideration in the review of a proposed essential medicine.
- » Prescriber level  
Here the proposed prescriber level should be included. If more than one level is proposed each relevant box should be ticked.

### **Section 2: Evidence and motivation**

- » Estimated benefit
  - Effect measure: this is the clinical outcome that was reported in the clinical trial such as BP, FEV<sub>1</sub>, CD<sub>4</sub>, VL etc.
  - Risk benefit: this should be reported in the clinical trial and, in most cases, includes the 95% confidence level (95% CI). Absolute risk reduction, also termed risk difference, is the difference between the absolute risk of an event in the intervention group and the absolute risk in the control group.
  - Number Need to Treat (NNT): gives the number of patients who need to be treated for a certain period of time to prevent one event. It is the reciprocal of the absolute risk or can be calculated using the formula below.

**Calculations**

	<b>Bad outcome</b>	<b>Good outcome</b>	<b>Total patients</b>
Intervention group	<i>a</i>	<i>c</i>	<i>a + c</i>
Control group	<i>b</i>	<i>d</i>	<i>b + d</i>

<b>Measure</b>	<b>Equation</b>
Absolute risk:	$[b/(b+d)] - [a/(a+c)]$
Number needed to treat	$\frac{1}{[b/(b+d)] - [a/(a+c)]}$
Relative risk	$[a/(a+c)] \div [b/(b+d)]$
Odds ratio	$\frac{[a/(a+c)] \div [c/(a+c)]}{[b/(b+d)] \div [d/(b+d)]} = (a/c) \div (b/d)$

Reference - Aust Prescr 2008;31:12-16)

- » Motivating information (**Level of evidence based on the SORT system**)
  - The National Essential Drug List Committee has endorsed the adoption of the SORT system for categorising levels of evidence. This system<sup>1</sup> contains only three levels:

Level I	Good quality evidence	Systematic review of RCTs with consistent findings High quality individual RCT
Level II	Limited quality patient orientated evidence	Systematic review of lower quality studies or studies with inconsistent findings Low quality clinical trial Cohort studies Case-control studies
Level III	Other	Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only), or case series

1 Ebell MH, Siwek J, Weiss BD, et al. Strength of recommendation taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. Am Fam Physician. 2004;69:550-6.

A: Newer product: for most newer products, level 1 evidence such as high quality systematic reviews or peer-reviewed high quality randomised controlled trials should be identified and referenced in the space provided.

B: Older products: many of these products were developed prior to the wide use of randomised controlled trials. However, there maybe level 1 evidence where the product was used as the control arm for a newer product. If no level 1 evidence can be identified, then level II data from poorer quality controlled trials or high quality observational studies should be referenced in the space provided.

» Cost considerations

- Where a published reference supporting the review of cost is available comments should be made regarding its applicability to the South African public sector environment.
- Possible unpublished information that can be included:
  - o Cost per daily dose or course of therapy – for long term or chronic therapy such as hypertension the usual daily dose should be calculated (Dose x number of times a day) and converted into the number of dosing units e.g. tablets. This is then used to calculate the cost per day. For medications used in a course of therapy such as antibiotics this is then multiplied by the number of days in the course of therapy.
  - o Cost minimisation is used where there is evidence to support equivalence and aims to identify the least costly treatment by identifying all the relevant costs associated with the treatment.
  - o Cost-effectiveness analysis is used to compare treatment alternatives that differ in the degree of success in terms of the therapeutic or clinical outcome. By calculating a summary measurement of efficiency (a cost-effectiveness ratio), alternatives with different costs, efficacy rates, and safety rates can be fairly compared along a level playing field.

Where any of these have been performed tick the relevant block and send as an attachment with all the calculations. If possible, the spread sheet should be supplied electronically.

**Section 3: Motivator's Details**

The receipt of all submission will be acknowledged. In addition, all decisions with supporting arguments will be communicated where appropriate. This section therefore forms a vital link between the motivator and the decision making process.



**Motivation form for the inclusion of a new medication  
on the National Essential Medicines List**

<b>Section 1: Medication details</b>			
Generic name (or International Nonproprietary Name):			
Proposed indication:			
Prevalence of condition (based on epidemiological data, if any):			
Prescriber level			
Primary Health Care 1	Medical Officer 2	Specialist 3	Designated Specialist 4

<b>Section 2: Evidence and motivation</b>		
<b>2.1 Estimated benefit</b>		
Effect measure		
Risk difference (95% CI)		
NNT		
<b>2.2 Motivating information (Level of evidence based on the SORT system)</b>		
<b>A. Newer product:</b> High quality systematic reviews or peer-reviewed high quality randomised controlled trials (Level I)		
Author	Title	Journal ref
<b>B. Older product with weaker evidence base:</b> Poorer quality controlled trials or high quality observational studies (Level II)		
Author	Title	Journal ref
<b>2.3 Cost-considerations</b>		
Have you worked up the cost?	YES	NO
Daily cost	Cost minimisation	Cost-effectiveness analysis
Other relevant cost information if available:		
Author	Title	Journal ref
<b>2.4 Additional motivating comments.</b>		

<b>Section 3: Motivator's Details</b>	
PTC Title:	Date submitted:

## GUIDELINES FOR ADVERSE DRUG REACTION REPORTING

### **National Pharmacovigilance Programme**

The Medicines Control Council (MCC) has a responsibility to ensure the safety, efficacy and quality of all medicines used by the South African public. The National Pharmacovigilance Programme is coordinated by the MCC and has a dedicated Unit, The National Adverse Drug Event Monitoring Centre (NADEMC), in Cape Town, which monitors the safety of all registered medicines in South Africa.

### **What is Pharmacovigilance?**

Pharmacovigilance is defined as the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions to medicines (i.e. adverse drug reactions or ADRs). The ultimate goal of this activity is to improve the safe and rational use of medicines, thereby improving patient care and public health.

### **What is an Adverse Drug Reaction (ADR)?**

The Medicines Control Council (MCC) defines an Adverse Drug Reaction (ADR) reaction as a response to a medicine which is noxious and unintended, including lack of efficacy, and which occurs at any dosage and can also result from overdose, misuse or abuse of a medicine.

### **Who should report Adverse Drug Reactions?**

All health care workers, including doctors, dentists, pharmacists, nurses and other health professionals are encouraged to report all suspected adverse reactions to medicines (including vaccines, X-ray contrast media, traditional and herbal remedies), especially when the reaction is not in the package insert, potentially serious or clinically significant.

### **What happens to a report?**

All ADR reports are entered into a national ADR database. Each report is evaluated to assess the causal relationship between the event and the medicine. A well-completed adverse drug reaction/product quality form submitted could result in any of the following:

- Additional investigations into the use of the medicine in South Africa
- Educational initiatives to improve the safe use of the medicine
- Appropriate package insert changes to include the potential for the reaction
- Changes in the scheduling or manufacture of the medicine to make it safer

The purpose of ADR reporting is to reduce the risks associated with the use of medicines and to ultimately improve patient care.

**Will reporting have any negative consequences on the health worker or the patient?**

An adverse drug reaction report does not constitute an admission of liability or that the health professional contributed to the event in any way. The outcome of a report, together with any important or relevant information relating to the reaction, will be sent back to the reporter as appropriate. The details of a report are stored in a confidential database. The names of the reporter or any other health professionals named on a report and that of the patient will be removed before any details about a specific adverse drug reaction are used or communicated to others. The information is only meant to improve the understanding of the medicines used in the country.

Is the event possibly an ADR?

The following factors should be considered when an adverse drug reaction is suspected:

1. What exactly is the nature of the reaction? *(Describe the reaction as clearly as possible and where possible provide an accurate diagnosis.)*
2. Did the reaction occur within a reasonable time relationship to starting treatment with the suspected medicine? *(Some reactions occur immediately after administration of a medicine while others take time to develop.)*
3. Is the reaction known to occur with the particular medicine as stated in the package insert or other reference? *(If the reaction is not documented in the package insert, it does not mean that the reaction cannot occur with that particular medicine.)*
4. Did the patient recover when the suspected medicine was stopped? *(Some reactions can cause permanent damage, but most reactions are reversible if the medication is stopped.)*
5. Did the patient take the medicine again after the reaction abated (i.e. rechallenge). If so, did the same reaction occur again? *(In most situations it is not possible or ethical to rechallenge the patient with the same medicine. If such information is available or if such a rechallenge is necessary, recurrence of the event is a strong indicator that the medicine may be responsible.)*
6. Can this reaction be explained by other causes (e.g. underlying disease/s; other medicine/s; toxins or foods)? *(It is essential that the patient is thoroughly investigated to decide what the actual cause of any new medical problem is. A medicine-related cause should be considered, when other causes do not explain the patient's condition.)*

**What types of reactions should be reported?**

The following adverse drug reactions should be reported:

- All ADRs to newly marketed drugs or new drugs added to the EDL
- All serious reactions and interactions
- ADRs that are not clearly stated in the package insert.
- All adverse reactions or poisonings to traditional or herbal remedies

**Report even if you are not certain that the medicine caused the event.**

**What Product Quality Problems should be reported?**

The following product quality problems should be reported:

- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures

**How can ADRs be prevented from occurring?**

Some ADRs are unavoidable and cannot be prevented. However, most ADRs can be prevented by following the basic principles of rational use of medicines.

**How are adverse drug reactions reported?**

An Adverse Drug Reaction/Product Quality Report Form is enclosed in this book and should be completed in as much detail as possible before returning it by fax or post to any of the addresses provided below. Additional forms can be obtained by contacting the MCC at these addresses. Report forms may also be accessed via the following website: <http://www.mccza.com>

**1. The Registrar of Medicines**

Medicines Control Council, Department of Health, Private Bag X828  
Pretoria, 0001  
Tel: (021) 312 0295; Fax: (021) 3123106

**2. The National Adverse Drug Event Monitoring Centre (NADEMC)**

C/o Division of Pharmacology, University of Cape Town,  
Observatory, 7925  
(021) 447 1618; Fax: (021) 448 6181



**ADVERSE DRUG REACTION AND PRODUCT QUALITY  
PROBLEM REPORT FORM**

*(Identities of reporter and patient will remain strictly confidential )*

**NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE**

Medicines Control Council, Tel : (021) 447-1618  
 The Registrar of Medicines, Fax: ( 021) 448-6181  
 Department of Health In collaboration with the WHO International Drug Monitoring Programme

**PATIENT INFORMATION**

Name (or initials): \_\_\_\_\_ Age: \_\_\_\_\_ Weight (kg): \_\_\_\_\_

Sex:  M  F Date Of Birth : \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Height (cm): \_\_\_\_\_

**ADVERSE REACTION/PRODUCT QUALITY PROBLEM**

Adverse  and/or Product  Date of onset of reaction: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 reaction<sup>1</sup>  Quality problem<sup>2</sup>  Time of onset of reaction: \_\_\_\_ h \_\_\_\_ min

Description of reaction or problem (Include relevant tests/lab data, including dates):

**1. MEDICINES/VACCINES/DEVICES (include all concomitant medicines)**

Trade Name & Batch No. (Asterisk Suspected Product)	Daily Dosage	Route	Date Started	Date Stopped	Reasons for use

**ADVERSE REACTION OUTCOME (Check all that apply)**

<input type="checkbox"/> death	Event reappeared on rechallenge: <input type="checkbox"/> Y <input type="checkbox"/> N <input type="text" value="Rechallenge not done"/> Treatment (of reaction) _____ _____ _____ Recovered: _____
<input type="checkbox"/> life-threatening	
<input type="checkbox"/> disability	
<input type="checkbox"/> hospitalisation	
<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> Other _____	

<input type="checkbox"/> required intervention to _____	<input type="checkbox"/> Y <input type="checkbox"/> N
_____	
prevent permanent _____	Sequelae:
_____	<input type="checkbox"/> Y <input type="checkbox"/> N
impairment/damage _____	Describe Sequelae: _____
_____	_____

**COMMENTS:** (e.g. Relevant history, Allergies, Previous exposure, Baseline test results/lab data)

**2. PRODUCT QUALITY PROBLEM:**

Trade Name	Batch No	Reg No.	Dosage form & strength	Expiry Date	Size/ Type of container

Product available for evaluation?:  Y  N

**REPORTING DOCTOR/PHARMACIST Etc:**

NAME: \_\_\_\_\_

QUALIFICATIONS: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

TEL: \_\_\_\_\_

This report does not constitute an admission that medical personnel or the product caused or contributed to the event.

## ADVICE ABOUT VOLUNTARY REPORTING

### Report adverse experiences with:

- medications (drugs, vaccines and biologicals)
- medical devices (including in-vitro diagnostics)
- traditional and herbal remedies
- **For Adverse Events Following Immunisation (AEFI), please follow the reporting procedure recommended by the Expanded Programme in Immunisation (EPI)**

### Please report:

- adverse drug reactions to recently marketed products
- serious reactions and interactions with all products
- adverse drug reactions which are not clearly reflected in the package insert.

### Report even if:

- you're not certain the product caused the event
- you don't have all the details

### Report Product Quality Problems such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labelling
- therapeutic failures

### Important numbers:

#### *Investigational Products and Product Quality Problems:*

- (012) 326-4344 to fax a report
- (012) 312-0000 to report by phone

#### *Registered Medicines and Traditional and Herbal remedies:*

- (021) 448-6181 to fax a report
- (021) 447-1618 to report by phone

#### *Adverse Events Following Immunisation:*

- (012) 312 0110 to phone for information
- (012) 321 9882 to fax a report

**Confidentiality:** Identities of the reporter and patient will remain strictly confidential.

*Your support of the Medicine Control Council's adverse drug reaction monitoring programme is much appreciated. Information supplied by you will contribute to the improvement of drug safety and therapy in South Africa.*

**PLEASE USE ADDRESS PROVIDED BELOW- JUST FOLD IN THIRDS, TAPE and MAIL**

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## INDEX OF DRUGS/MEDICINES

ACE inhibitor	56,57,64,65, 66, 67,128, 161, 374
acetazolamide	305
acetic acid/alcohol	311
aciclovir	9, 87, 94, 168, 189, 190, 212, 213, 218, 219
activated charcoal	358
adrenaline	113, 114, 277, 278, 348, 350, 352, 378
albendazole	30, 91
allopurinol	236
alpha 1 and non-selective beta blocker	57
aluminium hydroxide/magnesium trisilicate	12
amitriptyline	190, 256, 324, 328
amlodipine	54, 64, 65, 67, 131, 133
amoxicillin	2, 41, 71, 77, 174, 208, 219, 275, 281, 284, 286, 287, 312, 315, 335, 363, 364
amoxicillin/clavulanic acid	136, 160, 287
amphotericin B	4
antazoline/tetrahydrozoline HCl	297
anti-D immunoglobulin	99, 109
antifungal lozenge (troche)	4
aqueous cream (UEA)	73, 86, 93
artemether/lumefantrine	170
aspirin	53, 54, 60, 156, 240
atenolol	54, 65, 66
atropine	303, 348, 359
Bacillus Calmette-Guerin vaccine (BCG)	110, 224, 225, 229, 230
beclomethasone	271, 272, 309
benzathine benzylpenicillin	69, 70, 105, 212, 213, 216, 217, 218, 219, 317
benzoyl peroxide	75
benzyl benzoate	84, 85, 221
benzylpenicillin	105, 286
betamethasone	86, 89, 106, 107
biguanide	156
biperiden	260, 261
bismuth subgallate compound	14, 15
budesonide	271, 272
calamine	73, 92,167, 337
calcium	101, 103
calcium channel blocker, long acting	54, 64, 65, 66, 67
carbamazepine	245, 246
carvedilol	57, 66
cefixime	138, 208, 210, 218, 219, 363
ceftriaxone	19, 27, 29, 42, 98, 111, 137, 207, 211,

	219, 234, 250, 251, 279, 285, 288, 300, 364, 377
cetirizine	74, 87, 297, 310
chloramphenicol	110, 175, 298, 300, 302, 303
chlorhexidine	5, 6, 7, 165, 333, 339, 345
chlorpheniramine	74, 87, 89, 91, 92, 93, 167, 191, 298, 309, 329, 337
chlorpromazine	259, 260
choline salicylate/ cetalkonium chloride	9, 187
cimetidine	12
ciprofloxacin	26, 136, 137, 138, 207, 209, 210, 211, 212, 213, 251
clotrimazole	80, 81, 82, 90, 192, 200, 208, 214, 218
codeine	327
corticosteroids	86, 106, 271, 275, 309
cotrimoxazole	186, 188, 192, 200, 286, 289
dextrose 10%	40, 111, 112, 113, 150, 352, 370
dextrose 5%	48, 60, 171, 369, 370
dextrose 5%/sodium chloride	380
dextrose 50%	40, 50, 60, 113, 150, 370
diazepam	241, 242, 243, 249, 329, 356, 380, 381
didanosine	185, 196, 197, 198
digoxin	57
diphtheria/tetanus/pertussis vaccine (DTP)	224, 226, 229, 230
doxycycline	17, 75, 105, 138, 207, 208, 210, 211, 212, 213, 217, 218, 219, 275, 363, 364
efavirenz	185, 196, 197
emulsifying ointment (UE)	73, 86
enalapril	56, 64, 65, 128, 161
ergometrine	109
erythromycin	2, 69, 70, 76, 78, 79, 88, 105, 175, 190, 208, 209, 212, 213, 217, 219, 282, 284, 286, 287, 311, 313, 315, 318, 335
ethambutol	290, 291, 293, 294
ferrous gluconate	37
ferrous lactate	37
ferrous sulphate compound (BPC)	37, 104, 117
flucloxacillin	76, 78, 79, 88, 311
fluconazole	82, 187, 191, 202
fluoxetine	257
flupenthixol decanoate	260
fluphenazine decanoate	260
folic acid	38, 104
furosemide	56, 59, 67, 129, 131, 133, 374
gentian violet	4, 165, 201
glibenclamide	157

gliclazide	157
Haemophilus influenzae type B vaccine(Hib)	224, 227, 229, 230
haloperidol	259, 260, 356
hepatitis B vaccine (HepB)	224, 225, 227, 229, 230
HMGCoA reductase inhibitors (statins)	52, 53, 55, 61, 153
hydrochlorothiazide	56, 64, 65, 66
hydrocortisone	86, 89, 191, 265, 378
hyoscine butylbromide	12
ibuprofen	117, 118, 235, 237, 321, 324, 326, 327, 328, 379
imidazole	80, 81, 82
influenza vaccine	228, 275
insulin, biphasic	148, 158
insulin, intermediate acting	147, 158
insulin, soluble short acting	147, 151
iodine tincture BP	93, 220
ipratropium bromide	265, 275
iron	37
isoniazid	186, 292, 293
isosorbide dinitrate	53, 54, 60, 374
isosorbide mononitrate	54
lactulose	14, 18, 329
lamivudine	185, 196, 197, 365, 366, 367, 368
lamotrigine	247
levonorgestrel	122, 124, 364
levonorgestrel/ethinyl oestradiol	117, 122
lignocaine	14, 15, 108, 337
loperamide	23, 188
lopinavir/ritonavir	185, 197, 198, 368
lorazepam	259, 356, 381
magnesium sulphate	102, 103
measles vaccine	224, 228, 229, 230
mebendazole	32, 37, 43
medroxyprogesterone	119, 121
metformin	156, 157, 158
methyl salicylate	232, 237
methyl dopa	63, 66, 102
metoclopramide	13, 328
metronidazole	3, 7, 24, 28, 99, 207, 208, 210, 218, 219, 336, 363, 364
misoprostol	109
morphine	11, 53, 60, 107, 142, 322, 323, 326, 328, 330, 374
multivitamin	43, 184, 200
naloxone	110, 112, 113, 322, 360
nevirapine	100, 101, 185, 196, 197

nicotinamide	47
nifedipine, short-acting	102, 106, 130, 133
nifedipine, slow release	54, 102
nitrous oxide	107
norethisterone enanthate	121
norgestrel/ethinyl oestradiol	122, 124, 364
NSAID	235, 237, 327
nystatin	4, 201
oestradiol	118, 119
oestrogen, conjugated	118, 119
oral polio vaccine (OPV)	110, 224, 227, 229, 230
oral rehydration solution (ORS)	16, 21, 23, 25, 28
orphenadrine	260, 261
oxygen	53, 59, 60, 102, 111, 130, 132, 248, 264, 265, 276, 278, 279, 284, 289, 343, 347, 358, 359, 373, 374, 380
oxymetazoline	297, 301, 316
oxytocin	98, 108, 109
paracetamol	3, 5, 7, 8, 163, 167, 170, 174, 176, 177, 189, 190, 204, 232, 237, 244, 252, 278, 281, 285, 287, 299, 301, 302, 304, 313, 316, 318, 321, 322, 324, 326, 328, 337, 345, 372, 379
permethrin	83
pethidine	107
petroleum jelly	8, 95, 96, 221
phenobarbitone	245, 246, 381
phenoxymethylpenicillin	69, 70, 317
phenytoin	245, 246, 381
pilocarpine	305
pneumococcal vaccine	224, 275
podophyllin solution	220
podophyllum resin/ salicylic acid	95, 96
polyvalent antivenom (snake)	340, 341
povidone iodine	77, 166, 333, 345
praziquantel	179
prednisone	235, 264, 265, 277, 278
procaine penicillin (depot formulation)	105
promethazine	108, 378
pyrazinamide	293
pyridoxine	47, 186, 290, 292, 293
quinine dihydrochloride	171
rabies immunoglobulin	333, 334
rabies vaccine	333, 334
rifampicin	293
rifampicin/isoniazid combination	293, 294, 295

rifampicin/isoniazid/pyrazinamide combination	293, 295
rifampicin/isoniazid/pyrazinamide/ ethambutol combination	293, 294
Ringer–Lactate	16, 21
salbutamol	108, 264, 265, 269, 271, 272, 275, 276
selenium sulphide	82, 90
sennosides A and B	18
simple linctus	318
simvastatin	52, 53, 55, 61, 153, 155, 156
sodium chloride (normal saline)	11, 16, 21, 26, 28, 41, 53, 60, 88, 98, 99, 102, 103, 106, 108, 109, 151, 159, 160, 165, 171, 276, 277, 278, 281, 300, 303, 316, 322, 341, 344, 345, 347, 348, 352, 376
spironolactone	57
β <sub>2</sub> agonist	269, 271, 272, 275
β-blocker	54, 66
stavudine	185, 196, 197
streptokinase	60
streptomycin	291, 294
sulphonylurea	157, 158
sulphur	85
tenofovir	185
tetanus toxoidvaccine (TT)	225, 228, 229, 230, 334, 340, 345, 372
tetanus/diphtheria vaccine (Td)	224, 226, 229, 230
tetracaine	8, 302, 339
theophylline	273, 275
thiamine	48, 370
tramadol	190, 321, 322, 324, 326, 327
tussi infans	318
valproate	246
vitamin A (retinol)	23, 42, 43, 45, 173
vitamin B complex	46
vitamin K	110
xylocaine with adrenaline	3
xylocaine	3
zidovudine	100, 101, 185, 196, 197, 198, 365, 366, 367, 368
zinc and castor oil	90
zinc	22, 23
zuclopenthixol acetate	259
zuclopenthixol decanoate	260

## INDEX OF CONDITIONS

Abdominal pain	11
Abnormal vaginal bleeding during fertile years	116
Abscess and caries, dental	2
Abscess, dental	2
Acne vulgaris	74
Acute renal failure	130
Aggressive disruptive behaviour	255
Allergic rhinitis	309
Anaemia in pregnancy	103
Anaemia	35
Anaemia, iron deficiency	36
Anaemia, macrocytic or megaloblastic	38
Anal conditions	14
Anal fissures	14
Angina pectoris, stable	54
Angina pectoris, unstable	53
Animal and human bites	332
Antenatal care	100
Antepartum haemorrhage	99
Antiretroviral therapy, adults	184
Antiretroviral therapy, children	196
Antiseptics and disinfectants	164
Anxiety and stress related disorders	255
Aphthous ulcers in HIV infection	187
Aphthous ulcers	9
Appendicitis	15
Arthralgia	232
Arthritis, rheumatoid	233
Arthritis, septic	233
Asthma, chronic	267
Athlete's foot – tinea pedis	80
Bacterial infections of the skin	75
Balanitis/balanoposthitis (BAL)	214
Benign prostatic hyperplasia	139
Bites and stings	332
Bleeding in pregnancy	98
Bleeding, post-menopausal	117
Boil, abscess	75
Bronchiolitis, acute in children	276
Bronchitis, acute in adults or adolescents	281
Bronchospasm, acute associated with asthma and chronic obstructive bronchitis	263
Bubo	213
Burns	341

Candida oesophagitis	187
Candidiasis, oesophageal	202
Candidiasis, oral (thrush)	4
Candidiasis, oral (thrush), recurrent	201
Candidiasis, skin	81
Cardiac arrest – cardiopulmonary resuscitation	346
Cardiac arrest, adults	346
Cardiac failure, congestive (CCF)	55
Cardiac failure, congestive (CCF), adults	55
Cardiac failure, congestive (CCF), children	58
Cardiopulmonary arrest, children	348
Care of HIV positive pregnant woman	100
Care of the neonate	110
Caries, dental	3
Cellulitis	78
Chickenpox	166
Childhood malnutrition, including failure to thrive (FTT)	39
Cholera	15
Chronic cancer pain	325
Chronic kidney disease	126
Chronic non-cancer pain	323
Chronic obstructive pulmonary disease (COPD)	274
Common cold and influenza	280
Common warts	95
Conditions with prominent wheeze	263
Conjunctivitis of the newborn	299
Conjunctivitis, allergic	297
Conjunctivitis, bacterial (excluding conjunctivitis of the newborn)	298
Conjunctivitis, viral (pink eye)	300
Conjunctivitis	297
Constipation	17
Contraception and HIV and AIDS	123
Contraception, barrier methods	123
Contraception, emergency	123
Contraception, hormonal	121
Contraception, intrauterine device (IUCD)	122
Contraception, missed pills	123
Contraceptive, oral	121
Contraceptives, injectable	121
Cracked nipples during breastfeeding	115
Croup (Laryngotracheobronchitis) in children	277
Delirium – acutely confused, aggressive patient	255
Delirium with acute confusion and aggression in adults	355
Dermatitis, seborrhoeic	89
Diabetes mellitus type 1, in adults	147
Diabetes mellitus type 1, in children	145
Diabetes mellitus type 2, in adolescents	146

Diabetes mellitus type 2, in adults	153
Diabetes mellitus	144
Diabetic emergencies	148
Diabetic ketoacidosis	150
Diabetic nephropathy	160
Diabeticfoot	159
Diarrhoea	19
Diarrhoea, acute in children	19
Diarrhoea, acute, without blood in adults	23
Diarrhoea, chronic in adults	24
Diarrhoea, HIV associated	188
Diarrhoea, persistent in children	22
Dosage and administration	224
Dry skin	73
Dysentery	24
Dysentery, amoebic	27
Dysentery, bacillary	25
Dysmenorrhoea	118
Dyspepsia, heartburn and indigestion	12
Eczema	85
Eczema, acute, moist or weeping	88
Eczema, atopic	85
Enuresis	140
Epilepsy	244
Exposure to poisonous substances	357
Eye injuries	302
Eye injury, (blunt or penetrating) foreign body	303
Eye injury, chemical burn	302
Failure to thrive or not growing well	43
Falciparum malaria, severe	171
Febrile convulsions	242
Feeding options for HIV positive mothers	115
Fever	163
Filiform warts	96
Fungal infections of the skin	80
Fungal nail infections	188
Genital molluscum contagiosum (MC)	220
Genital ulcer syndrome (GUS)	212
Genital warts (GW) Condylomata Accuminata	220
Gingivitis and peridontitis	5
Gingivitis, uncomplicated	5
Glaucoma, acute	304
Glomerular disease – Nephritic syndrome	132
Glomerular disease – Nephrotic syndrome	134
Glomerular disease (GN)	131
Gout	234
Gout, acute	234

Gout, chronic	236
Haematuria	139
Haemorrhoids	14
Headache, mild, non-specific	251
Helminthic infestation	30
Helminthic infestation, excluding tapeworm	31
Helminthic infestation, tapeworm	30
Herpes simplex ulcers, chronic	189
Herpes simplex	94
Herpes stomatitis	8
Herpes zoster (Shingles)	189
HIV and kidney disease	204
HIV prophylaxis, post exposure (PEP)	361
Hormone replacement therapy	118
Human immunodeficiency virus infection in adults	182
Human immunodeficiency virus infection in children	192
Hypertension in adults	61
Hypertension in children	68
Hypertension	61
Hypertensive disorders of pregnancy	101
Hypoglycaemia and hypoglycaemic coma	368
Hypoglycaemia in diabetics	149
Immunisation schedule	223
Impetigo	77
Impotence	141
Injuries	371
Insect stings and spider bites	336
Intrapartum Care	107
Irritable bowel syndrome	32
Itching (pruritus)	73
Lice (pediculosis)	83
Lower abdominal pain (LAP)	207
Malaria	169
Malaria, prophylaxis (Self provided care)	172
Male urethritis syndrome (MUS)	210
Management of suspected choking/foreign body aspiration in children	353
Measles	172
Meningitis	248
Meningitis, acute bacterial	248
Meningitis, cryptococcal	190
Meningitis, meningococcal, prophylaxis	250
Metabolic syndrome/obesity/dyslipidaemia	152
Microvascular complications of diabetes	159
Miscarriage	98
Molluscum contagiosum	93
Mood disorders	255
Mumps	176

Myocardial infarction, acute (AMI)	59
Nappy rash	90
Nausea and vomiting, non-specific	13
Necrotising peridontitis	6
Neonatal resuscitation	112
Nose bleeds (epistaxis)	373
Occupational post-exposure HIV prophylaxis for healthcare workers (HCW)	366
Opportunistic infections, prophylaxis in adults	186
Opportunistic infections, prophylaxis in children	200
Opportunistic infections, treatment in adults	187
Opportunistic infections, treatment in children	201
Osteoarthritis (osteoarthritis)	237
Otitis externa	310
Otitis media, acute	312
Otitis media, chronic, suppurative	314
Otitis	310
Pain control	320
Painful red eye	305
Papular pruritic eruption	191
Parasitic infections of the skin	83
Pellagra (nicotinic acid deficiency)	46
Penetrative sexual abuse or sexual assault	361
Peridontitis	6
Pityriasis rosea	92
Plane warts	95
Plantar warts	95
Pneumocystis pneumonia in adults	288
Pneumonia in adults with underlying medical conditions or over 65 years	287
Pneumonia in children	283
Pneumonia	282
Pneumonia, severe in adults	288
Pneumonia, uncomplicated in adults	286
Postpartum care	115
Pregnancy, ectopic	116
Preterm labour (PTL) and preterm prelabour rupture of membranes (PPROM)	106
Preterm labour (PTL)	106
Preterm prelabour rupture of membranes (PPROM)	106
Prevention of ischaemic heart disease and atherosclerosis	50
Prostate cancer	140
Prostatitis	138
Psychosis, acute	258
Pubic lice (PL)	221
Pulmonary oedema, acute	373
Pyridoxine (Vitamin B <sub>6</sub> ) deficiency	47

Renal calculi	141
Respiratory infections	280
Rheumatic fever, acute	69
Ringworm and other tineas	81
Rubella (German measles)	177
Sandworm	91
Scabies	84
Schistosomiasis	178
Scrotal swelling (SSW)	211
Seizures (convulsions/fits)	241
Severe malnutrition	39
Sexually transmitted infections	206
Shock	375
Shock, anaphylactic	377
Sick neonate and neonatal emergencies	110
Sinusitis, acute, bacterial	314
Snakebites	338
Sprains and strains	379
Status epilepticus	380
Stroke	240
Structural abnormalities of the eye	305
Supportive care	203
Syphilis in pregnancy	104
Syphilis serology and treatment	215
TB chemoprophylaxis	186
The cold chain	228
The revised opened multi-dose vial policy	230
Thiamine deficiency (Wernicke's encephalopathy and beriberi)	48
Tonsillitis and pharyngitis	316
Toxoplasmosis	192
Treatment of more than one STI syndrome	218
Tuberculosis	289
Typhoid fever	33
Upper airways obstruction	277
Urinary tract infection	134
Urticaria	91
Vaccines for routine administration	225
Vaginal bleeding	116
Vaginal discharge syndrome (VDS)	208
Valvular heart disease and congenital structural heart disease	70
Visual problems	306
Vitamin A deficiency	44
Vitamin B deficiencies	46
Warts	95

## ABBREVIATIONS

ABCD	Airways, Breathing, Circulation, Drip/Doctor/Drugs
ACE	angiotensin-converting enzyme
AIDS	acquired immunodeficiency syndrome
AMI	acute myocardial infarction
BCG	Bacillus Calmette-Guerin vaccine
BMI	Body mass index
BP	blood pressure
BSA	Body surface area
C	Celsius
cap	capsule
CCF	congestive cardiac failure
CCMT	Comprehensive care, management and treatment
CCU	Critical Care Unit
CD4	cluster designation 4
CKD	chronic kidney disease
cm	centimetre
CNS	central nervous system
COAD	chronic obstructive airways disease
COPD	chronic obstructive pulmonary disease
CPR	cardio-pulmonary resuscitation
CrCl	creatinine clearance
CSF	cerebro-spinal fluid
CVD	cardiovascular disease
dL	decilitre
DNA	deoxyribonucleic acid
DPT	diphtheria, pertussis and tetanus vaccine
E	ethambutol
ECG	electrocardiogram
EDTA	ethylenediamine tetraacetic acid
ELISA	enzyme-linked immunosorbent assay
EPI	Expanded Programme on Immunisation
ET	Endotracheal tube
FBC	full blood count
FBG	fasting blood glucose
FEV1	forced expiratory volume in 1 second
FTA	Fluorescent Treponemal Antibody
FTT	failure to thrive
g	gram
GFR	glomerular filtration rate
GIT	gastro intestinal tract
H	isoniazid
Hb	haemoglobin
HbA <sub>1c</sub>	glycated haemoglobin
HCW	health care worker

HDL	high density lipoprotein
Hep B	hepatitis B vaccine
Hib	<i>Haemophilus influenzae</i> type B vaccine
HIV	human immunodeficiency virus
IDDM	insulin dependent diabetes mellitus
IM	intramuscular
IMCI	Integrated management of childhood illness
IU	international units
IUCD	intrauterine contraceptive device
IV	intravenous
kg	kilogram
L	litre
LAP	lower abdominal pain
LBBB	left bundle branch block
LDL	low density lipoprotein
LMP	last menstrual period
mcg	microgram
MCV	mean corpuscular volume
MDR TB	multiple drug resistant tuberculosis
mg	milligram
mL	millilitre
mmHg	millimetres mercury
mmol	millimol
MU	million units
NSAID	non-steroidal anti-inflammatory
OPV	oral polio vaccine
ORS	oral rehydration solution
PCP	<i>Pneumocystis carinii</i> pneumonia
PCR	polymerase chain reaction
PEFR	peak expiratory flow rate
PEP	post exposure prophylaxis
PHC	primary health care
PIH	pregnancy induced hypertension
PTC	Pharmacy and Therapeutics Committee
R	rifampicin
RBG	random blood glucose
Rh	Rhesus
RH	rifampicin, isoniazid, combination
RHZ	rifampicin, isoniazid, pyrazinamide combination
RHZE	rifampicin, isoniazid, pyrazinamide ethambutol, combination
RIG	human anti-rabies immunoglobulin
RPR/VDRL	rapid plasma reagent test/venereal disease research laboratory test
RTH	road to health
S	streptomycin
SC	subcutaneous
SSS	sugar and salt solution

ST	sinus tachycardia
STI	sexually transmitted infections
tab	tablet
TB	tuberculosis
Td	diphtheria and tetanus vaccine
TIA	transient ischaemic attack
TPHA	<i>Treponema pallidum</i> haemagglutination assay
TT	tetanus vaccine
UE	emulsifying ointment
UEA	aqueous cream
UTI	urinary tract infection
VVM	vaccine vial monitor
WFI	water for injection
WHO	World Health Organisation
XDR TB	extreme drug resistant tuberculosis