



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

National Essential Medicines List Committee (NEMLC)

TERTIARY AND QUATERNARY LEVEL

ESSENTIAL MEDICINES LIST

Reviewed Items

July 2021

SUMMARY OF CHANGES TO THE NEMLC TERTIARY AND QUATERNARY LEVEL ESSENTIAL MEDICINES LIST (July 2021)

ATC CODE	MEDICINE	INDICATION	NEMLC OUTCOMES	REVIEW INDICATORS	DATE RATIFIED
A ALIMENTARY TRACT AND METABOLISM					
A04AA01/ A04AA02	Serotonin-3 (5HT3) antagonists Ondansetron, Granisetron	Highly or moderately emetogenic chemotherapy	Approved	n/a	20 September 2007 (Indication updated 29 July 2021)

TERTIARY AND QUATERNARY LEVEL ESSENTIAL MEDICINES RECOMMENDATIONS

ATC CODE	MEDICINE	INDICATION	NEMLC RECOMMENDATION	REVIEW INDICATORS	DATE RATIFIED
A ALIMENTARY TRACT AND METABOLISM					
A04AA01/ A04AA02	Serotonin-3 (5HT3) antagonists Ondansetron, Granisetron	Highly or moderately emetogenic chemotherapy	Approved	n/a	20 September 2007 (Indication updated 29 July 2021)
A05AA02	Ursodeoxycholic acid	Primary biliary cirrhosis.	Not Approved	<ul style="list-style-type: none"> The emergence of new evidence of efficacy with regard to mortality or transplantation 	13 March 2008
A07EC02	Mesalazine	Ulcerative colitis – maintenance of remission.	Approved – Special Access Special access may be granted based on recommendation by PTC for patients with sulfonamide hypersensitivity.	<ul style="list-style-type: none"> Price (to be evaluated as a therapeutic class with sulfasalazine) 	October 2015
A10BG03	Pioglitazone	Type 2 diabetes mellitus.	Not Approved	<ul style="list-style-type: none"> Robust safety data 	February 2012
A10AE05/ A10AE04	Long acting insulin analogues Insulin detemir, Insulin glargine	Diabetes mellitus.	Not Approved	<ul style="list-style-type: none"> Price decrease (similar to Neutral Protamine Hagedorn (NPH) insulin) Evidence for superior safety of analogues over NPH 	30 June 2016
A11/A12	Micronutrients	Addition to Parenteral Nutrition for long-term use.	Approved <ul style="list-style-type: none"> Approved for use where long-term parenteral nutrition is required/anticipated. 	<ul style="list-style-type: none"> New evidence 	19 March 2020

TERTIARY AND QUATERNARY LEVEL ESSENTIAL MEDICINES RECOMMENDATIONS

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			<ul style="list-style-type: none"> Short- term TPN should be done with off the shelf parenteral nutrition bags – no added micronutrients. 		
A16AA03	Glutamine	Glutamine as a component of enteral and parenteral nutrition in critically ill patients.	Not Approved	<ul style="list-style-type: none"> Robust safety data Evidence of mortality efficacy 	30 June 2016
A02BC	Proton Pump Inhibitors (PPIs), IV	For hospitalised patients requiring PPI therapy and are unable to take these orally or via nasogastric tube	Approved <ul style="list-style-type: none"> Only for hospitalised patients are unable to take PPIs orally or via nasogastric tube 	n/a	24 June 2021
B BLOOD AND BLOOD FORMING ORGANS					
B01AC04	Clopidogrel	Percutaneous coronary intervention (stenting).	Approved Clopidogrel plus aspirin recommended for a minimum of: <ul style="list-style-type: none"> 30 days in situations where a bare metal stent is inserted. 90 days in situations where a sirolimus drug-eluting stent is inserted. 180 days when a paclitaxel drug-eluting stent is inserted. Thereafter allow aspirin indefinitely. The evidence currently available to the Committee does not provide support for use beyond 6 months although there are recommendations endorsing longer term use in high risk patients.	n/a	20 September 2007
B01AC04	Clopidogrel	Ischaemic heart disease (non-myocardial infarction).	Approved for long-term use only in patients intolerant to aspirin, i.e. allergy or bleeding episodes.		20 September 2007
B01AC04	Clopidogrel	Stroke.	Approved, only for long-term therapy where patient has confirmed aspirin intolerance.	<ul style="list-style-type: none"> Decrease in clopidogrel price New safety or efficacy data for either aspirin (at doses recommended by the DoH) or clopidogrel 	24 July 2014
B01AC04	Clopidogrel	Transient ischaemic attack with/without atrial fibrillation.	Not Approved	<ul style="list-style-type: none"> Decrease in clopidogrel price 	24 July 2014

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				<ul style="list-style-type: none"> New safety or efficacy data for either aspirin or clopidogrel 	
B02BD03	Recombinant Factor VIIa (rFVIIa)	Intractable bleeding.	Not Approved	<ul style="list-style-type: none"> Robust efficacy data 	29 June 2017
B02BD03	Haemophilia bypassing agents (rFVIIa/aPCC)	Haemophilia with inhibitors (on demand, when presenting with a significant bleed).	Approved, Special Access One bypassing agent to be available on the EML (most affordable). An alternative bypassing agent can be made available as emergency stock on a special access basis as approved by the PTC for patients not responding to EML item.		14 December 2017
C CARDIAC THERAPY					
C02DC01	Minoxidil	Severe hypertension not responding to other drugs.	Approved	n/a	20 September 2007
C09CA	Angiotensin receptor blockers (ARBs)	Add on therapy in cardiac failure on patients already on standard treatment including ACE-inhibitors, β -Blockers and spironolactone.	Not Approved	<ul style="list-style-type: none"> New efficacy data from large RCT indicating larger benefit of adding ARBs to standard therapy Decrease in price of ARBs so as to be similarly priced to ACE-inhibitors 	20 September 2007
C09CA	Angiotensin receptor blockers (ARBs)	As add on therapy in proteinuric nephropathies in patients already using an ACE-inhibitor.	Not Approved Insufficient evidence to support its use.	<ul style="list-style-type: none"> New evidence indicating benefit in the form of a RCT of sufficient size with maximal doses of ACE-inhibitor used New safety concerns. Decrease in price so as to be similarly priced to ACE-inhibitors 	20 September 2007
D ANTIPRURITICS, INCLUDING ANTIHISTAMINES, ANAESTHETICS, ETC.					
D07AD	Very potent topical corticosteroid – Group IV e.g. Clobetasol 0.05% Examples: Cream/ointment:		Approved Lowest price high potency corticosteroid to be used.	n/a	20 September 2007

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	<ul style="list-style-type: none"> • Clobetasol propionate 0.05%. 				
D10BA01	Isotretinoin	Moderate to severe recalcitrant nodular acne	Approved	n/a	24 June 2021 (Previously reviewed 09 February 2012)
D06BB10	Imiquimod 5% topical	Anogenital warts	Not Approved	New evidence	24 June 2021
G GENITO URINARY SYSTEM AND SEX HORMONES					
G03AC03	Levonorgestrel Intrauterine system	Abnormal Uterine Bleeding (3 rd line therapy)	Approved <ul style="list-style-type: none"> • Third line therapy where there has been treatment failure. • Prescribed and inserted by a gynaecologist. 	n/a	27 September 2018
G03CA	Estrogen	Gender Dysphoria – Feminising regimen	Approved	New evidence	5 December 2019
G03BA03	Testosterone	Gender Dysphoria – Masculinising regimen	Approved	New evidence	5 December 2019
G03DA02/ G03HA01	Medroxyprogesterone acetate OR Cyproterone acetate	Patients with hypersexual behaviour including paraphilia's	Approved <ul style="list-style-type: none"> • Most affordable agent should be procured. If price parity: cyproterone is preferred due to decreased frequency of dosing. 	<ul style="list-style-type: none"> • Evidence of harm • Price reduction 	11 April 2019
G03HB01	Cyproterone, Ethinyl estradiol	Hirsutism.	Approved	n/a	20 September 2007
G04BD10	Urinary antispasmodics Darifenacin	Over active bladder (OAB) with symptoms of urinary urgency, frequency and/or urge incontinence.	Not Approved	<ul style="list-style-type: none"> • Price • New safety/efficacy data 	13 March 2008
G04CB01	Finasteride	Benign prostatic hyperplasia.	Not Approved	<ul style="list-style-type: none"> • Price 	13 March 2008
H SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS					
H01AA01	Adrenocorticotrophic hormone (ACTH)	Infantile spasms.	Not Approved	<ul style="list-style-type: none"> • Well controlled studies of proven efficacy of ACTH 	September 2010

TERTIARY AND QUATERNARY LEVEL ESSENTIAL MEDICINES RECOMMENDATIONS

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H01AC01	Somatropin (Growth Hormone)	Turner's syndrome.	Not Approved	<ul style="list-style-type: none"> Improved cost-effectiveness. 	20 September 2007
H01AC01	Somatropin (Growth Hormone)	Prader Willi syndrome.	Not Approved	<ul style="list-style-type: none"> Price 	20 September 2007
H01AC01	Somatropin (Growth Hormone)	Intrauterine growth failure.	Not Approved	<ul style="list-style-type: none"> Price 	20 September 2007
H01AC01	Somatropin (Growth Hormone)	Idiopathic short stature.	Not Approved	<ul style="list-style-type: none"> Improved cost-effectiveness 	20 September 2007
H01AC01	Somatropin (Growth Hormone)	Chronic renal insufficiency.	Not Approved	<ul style="list-style-type: none"> Evidence of benefit 	20 September 2007
H01AC01	Somatropin (Growth Hormone)	Growth hormone deficiency.	<p>Approved</p> <p>Approved for confirmed growth hormone deficiency for use by endocrinologists only.</p> <p>Rationale:</p> <ul style="list-style-type: none"> The condition is a well-defined deficiency state that can be managed and monitored. Number of patients requiring treatment is small. 	<ul style="list-style-type: none"> New evidence on quality of life assessment in local and specific populations 	24 July 2008
H01BA05	Ornipressin	Bleeding associated with bronchoscopy and renal biopsy.	Not Approved	<ul style="list-style-type: none"> New high quality evidence of superior efficacy to adrenalin 	29 October 2012
H01CB02	Octreotide (Short-acting)	Persistent neonatal hyperinsulinism and hypoglycaemia.	<p>Approved</p> <p>The condition is rare; usage is for short term; alternative agents are limited and the consequences of not having treatment available are serious.</p>		
H01CB	<p>Somatostatin analogs</p> <p>Octreotide, Lanreotide</p>	Neuro-endocrine tumours.	Not Approved	<ul style="list-style-type: none"> Long term survival and quality of life data 	26 March 2015

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J ANTI-INFECTIVES FOR SYSTEMIC USE					
J01XC01	Fusidic acid	Treatment of staphylococcal infections, mainly involving bone and joints: <ul style="list-style-type: none"> • Methicillin-sensitive organisms, as alternative to cloxacillin or flucloxacillin. • Methicillin-sensitive organisms, in combination with cloxacillin or flucloxacillin. • Methicillin-resistant organisms, as an alternative to e.g. glycopeptides or oxazolidinones (linezolid), especially in cases where prolonged treatment is required. 	Not Approved	<ul style="list-style-type: none"> • New evidence of clinical comparative efficacy against alternatives, especially regarding long- term treatment of MRSA where the oral preparation may be of benefit in comparison to parenteral glycopeptides and infections with glycopeptide resistant organisms where the potential toxicity of oxazolidinones (linezolid) when used for prolonged periods of time, may be problematic 	13 March 2008
J01XX08	Linezolid	Resistant gram positive infections where vancomycin is contra-indicated.	<p>Approved – Special Access</p> <p>It may be available on special access basis as approved by PTC for:</p> <ul style="list-style-type: none"> • Only with a microbiology report confirming vancomycin resistance in a relative organism or confirmation of severe adverse effect to vancomycin, (i.e. vancomycin induced neutropenia or anaphylaxis, but not the “red man syndrome”). • Confirmed contra-indication to the use of vancomycin. 	<ul style="list-style-type: none"> • Clinically significant increase in vancomycin resistance in the public sector • Significant decrease in cost of linezolid 	27 November 2008
J02AB02	Ketoconazole	Cushing’s syndrome.	Approved	<ul style="list-style-type: none"> • Availability of alternate medication for this indication with superior efficacy or safety profile. New safety concerns 	10 July 2008
J02AC02	Itraconazole	Histoplasmosis.	Not Approved	<ul style="list-style-type: none"> • New evidence of clinical comparative efficacy against alternatives, especially weekly Amphotericin B • Significant increase in incidence of the condition. 	13 March 2008

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				<ul style="list-style-type: none"> • Significant change in pricing 	
J02AX04/J02AX05/J02AX06	Echinocandins (caspofungin/micafungin/anidulafungin)	Invasive candidiasis (resistant to fluconazole/amphotericin B and/or where renal dysfunction is present and amphotericin B cannot be used).	<p>Approved – Special Access</p> <ul style="list-style-type: none"> • Echinocandins approved as a class, with the most affordable agent to be procured. • The use of echinocandins should be managed through motivation/ appropriate restrictions at facilities, as part of Antimicrobial Stewardship activities. (See addendum – clinical criteria for use) 	<ul style="list-style-type: none"> • Availability of amphotericin B • Changing resistance patterns • New evidence 	12 April 2018
J02AC03	Voriconazole (VCZ)	Treatment of invasive Aspergillosis.	Not Approved	<ul style="list-style-type: none"> • High quality randomised controlled trial with amphotericin B as the comparator 	13 March 2008
J05AB04	Ribavirin	Viral haemorrhagic fever (VHF).	<p>Approved</p> <p>To be supplied on motivation from a central supply point.</p>	n/a	
J06BA02	Intravenous Immunoglobulin (IVIG)	Acute Immune thrombocytopenic Purpura (ITP)	<p>Approved</p> <ul style="list-style-type: none"> • Life-threatening bleed with platelets <50 x 10⁹/l. • Urgent surgery (any surgery urgently required within 24 hours) where rapid rise in platelets is required. • Pregnant patient prior to delivery as above. • Rapid rise in platelets required when a patient has platelet count of < 20 x 10⁹/L, with additional risk factors for bleeding (such as severe hypertension, ongoing sepsis). 	<ul style="list-style-type: none"> • Evidence of harm 	5 July 2018
J06BA02	Intravenous Immunoglobulin (IVIG)	Primary antibody immune deficiency with recurrent infections	Approved	<ul style="list-style-type: none"> • New data on dosing • Availability of more affordable subcutaneous formulations 	11 April 2019

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J06BA02	Intravenous Immunoglobulin (IVIG)	Guillain-Barré syndrome (GBS) presenting within the first 2 weeks of onset of moderate to severe weakness.	Approved The recommended regimen is 0.4 g/kg daily for 5 days.	• New evidence	5 December 2019
J06BB16	Palivizumab	Respiratory syncytial virus (RSV) infection in high-risk premature infants.	Not Approved	• Price reduction	25 April 2013
L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS					
L01	Chemotherapy Platinum coordination compounds, Taxanes, Doxorubicin, Cyclophosphamide	Uterine Cancer/ Endometrial Cancer (Advanced stage and recurrent).	Not Approved	• Better quality data	22 January 2015
L01AA01	Cyclophosphamide	Adjuvant breast cancer.	Approved (Cyclophosphamide plus Doxorubicin (AC)).	n/a	27 November 2008
L01AA01	Cyclophosphamide	Adjuvant breast cancer.	Approved (Cyclophosphamide plus methotrexate plus fluoro-uracil (CMF)).	n/a	27 November 2008
L01AA01	Cyclophosphamide	Adjuvant breast cancer.	Approved (Fluoro-uracil plus Doxorubicin plus cyclophosphamide (FAC)).	n/a	27 November 2008
L01AA02	Chlorambucil	Chronic lymphocytic leukemia, low grade non-Hodgkin's lymphoma	Approved	n/a	11 July 2019
L01AA03	Melphalan	Multiple myeloma (oral-remission induction combined with steroids in older) (IV –pre-autologous stem cell transplant in multiple myeloma and lymphomas).	Approved	n/a	11 July 2019
L01AA06	Ifosfomide	Germ cell tumours, soft tissue sarcomas, salvage therapy in lymphomas pre-autologous stem cell transplant.	Approved	n/a	11 July 2019
L01AB01	Busulfan	Pre allogeneic and autologous stem cell transplant conditioning	Approved	n/a	11 July 2019

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L01AX03	Temozolomide	Glioblastoma multiforme.	Not Approved	<ul style="list-style-type: none"> Prospective RCTs demonstrating a significant increase in effect size Significant price reduction 	25 July 2013
L03AX03	Bacille Calmette-Guerin (BCG)	Bladder Cancer (non-muscle invasive)	Approved	None	25 February 2016
L01AX04	Dacarbazine	Hodgkin's lymphoma.	Approved	n/a	11 July 2019
L01BA01	Methotrexate	Adjuvant breast cancer.	Approved (Cyclophosphamide plus methotrexate plus fluoro-uracil (CMF)).	n/a	27 November 2008
L01BA04	Pemetrexed	Lung mesothelioma.	Not Approved	<ul style="list-style-type: none"> Price changes or access programmes 	27 November 2008
L01BA04	Pemetrexed	Non-small cell lung cancer.	Not Approved	<ul style="list-style-type: none"> Evidence of superior efficacy vs. cisplatin/gemcitabine. Price reduction 	29 September 2011
L01BB02	Mercaptopurine	Acute leukaemia.	Approved	n/a	11 July 2019
L01BB03	Thioguanine	Acute leukemia.	Approved	n/a	11 July 2019
L01BB05	Fludarabine	Chronic lymphocytic leukaemia, non-Hodgkin's lymphomas, pre-conditioning regimen for allogeneic stem cell transplant, AML salvage therapy.	Approved	n/a	11 July 2019
L01BC01	Cytarabine	Acute myeloid leukaemia (AML) and acute lymphoid leukaemia (ALL).	Approved	n/a	11 July 2019
L01BC02	Topical 5 Fluorouracil	Actinic Keratosis.	Approved Approved as Historically Accepted Use.	n/a	19 March 2020
L01BC06	Capecitabine	Relapsed metastatic breast cancer failing an anthracycline and a taxane.	Not Approved	<ul style="list-style-type: none"> Price changes 	15 September 2016

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L01BC06	Capecitabine	Metastatic colorectal – first-line.	Approved (as part of the XELOX regimen).	<ul style="list-style-type: none"> • Availability of data for alternative oral fluoropyrimidines • Price increases not commensurate with approved SEP increases 	27 November 2008
L01BC06	Capecitabine	First-line therapy for advanced stomach/gastro-oesophageal junction cancer.	Approved	None	27 July 2014
L01BC06/ L01BC05	Capecitabine plus Gemcitabine	Adjuvant chemotherapy of fully resected potentially curable pancreatic adenocarcinoma).	Approved <ul style="list-style-type: none"> • Only for fully resected patients. 	<ul style="list-style-type: none"> • New adjuvant chemotherapy data in patients with R0 or R1 resected adenocarcinoma of the pancreas 	6 December 2018
L01BC52	Fluoro-uracil	Adjuvant breast cancer.	Approved (Cyclophosphamide plus methotrexate plus fluoro-uracil (CMF)).	n/a	27 November 2008
L01BC52	Fluoro-uracil	Adjuvant colorectal cancer.	Approved (Fluoro-uracil plus Doxorubicin plus cyclophosphamide (FAC)).	n/a	27 November 2008
L01CA01	Vinblastine	Relapsed metastatic breast cancer (mBC) failing an anthracycline and a taxane.	Approved	n/a	15 September 2016
L01CA02	Vincristine	General haematology and oncology	Approved	n/a	27 September 2018
L01CA04	Vinorelbine	Adjuvant non-small cell lung cancer (NSCLC) – completely resected.	Approved To be used with cisplatin for adjuvant therapy for stage IIIA NSCLC but not stage IB or stage II.	New evidence of efficacy of adjuvant therapy in NSCLC	03 December 2009
L01CA04	Vinorelbine (IV)	Relapsed metastatic breast cancer (mBC) failing an anthracycline and a taxane.	Approved	n/a	15 September 2016
L01CA04	Vinorelbine (oral)	Relapsed metastatic breast cancer (mBC) failing an anthracycline and a taxane.	Not Approved	<ul style="list-style-type: none"> • Price similar to oral • Evidence of clinical superiority 	15 September 2016

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L01CD	Taxanes Docetaxel, Paclitaxel	Adjuvant breast cancer.	Approved Approved for patients with high grade, node positive ER negative disease.	n/a	23 August 2012
L01CD01	Paclitaxel	Neoadjuvant/recurrent/ metastatic head and neck cancer.	Not Approved	n/a	27 July 2014
L01CD01	Paclitaxel	First-line chemotherapy in advanced non-small cell lung cancer (NSCLC).	Approved	None	22 January 2015
L01CD01	Paclitaxel	Metastatic cervical carcinoma.	Approved	n/a	11 July 2019
L01CD	Taxanes	Metastatic breast cancer – first- and second-line.	Approved	• Change in the price of taxanes, specifically docetaxel.	16 September 2010
L01CD02	Docetaxel	Squamous cell carcinoma of head and neck.	Approved Approved for patients with good performance status and adequate follow-up used in combination with cisplatin plus 5-fluoro-uracil.	None	25 July 2013
L01CD02	Docetaxel	Second-line therapy for advanced non-small cell lung cancer (NSCLC) in selected patients with good performance status (ECOG 0;1).	Approved	None	22 January 2015
L01CD02	Docetaxel	Castrate resistant prostate cancer.	Approved Docetaxel 75mg/m ² intravenously 3 times weekly plus prednisone 10mg orally, for 6 cycles.	• Reduction in cost and availability of 3rd generation ARBs e.g. enzalutamide and CYP17 inhibitors e.g. abiraterone	11 July 2019
L01CD02	Docetaxel	Patients with hormone sensitive prostate cancer (HSPC).	Approved For patients with high volume disease: defined as the presence of visceral metastases or ≥4 bone lesions with ≥1 beyond the vertebral bodies and pelvis	• New evidence	30 January 2020
L01DB01	Doxorubicin	Adjuvant breast cancer.	Approved (Doxorubicin plus cyclophosphamide (AC)).	None	27 November 2008
L01DB01	Doxorubicin	Adjuvant breast cancer.	Approved (Fluoro-uracil plus Doxorubicin plus cyclophosphamide (FAC)).	None	27 November 2008

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L01DB02	Daunorubicin	acute myeloid leukaemia (AML) and acute lymphoid leukaemia (ALL)	Approved	n/a	11 July 2019
L01DB06	Idarubicin	Acute Myeloid Leukemia.	Approved	n/a	10 December 2015
L01DB07	Mitoxantrone	General oncology.	Approved Indications for consideration: Advanced stage carcinomas, paediatric relapsed acute lymphoblastic leukaemia (ALL), paediatric acute myeloid leukaemia (AML).	None	30 June 2016
L01DB03	Epirubicin	Advanced stage or metastatic oesophageal junction and gastric carcinoma.	Approved	None	10 December 2015
L01DC01	Bleomycin	Hodgkin's, Kaposi, Germ cell tumours, Pleuradhesion.	Approved	None	27 September 2018
L01DC03	Mitomycin C	Bladder Cancer.	Not Approved	None	25 February 2016
L01DC03	Mitomycin C	Relapsed metastatic breast cancer (mBC) failing an anthracycline and a taxane.	Not Approved	None	15 September 2016
L01XA01	Cisplatin	Adjuvant small cell lung cancer.	Approved	None	27 November 2008
L01XA01	Cisplatin	Adjuvant lung cancer.	Approved	None	27 November 2008
L01XA01	Cisplatin	Relapsed metastatic breast cancer (mBC) failing an anthracycline and a taxane.	Approved To be used with gemcitabine	None	15 September 2016
L01XA01	Cisplatin	Radio-sensitizer in cervical cancer	Approved	None	6 December 2018
L01XA01	Cisplatin	Advanced/Metastatic: Various Cancers	Approved	n/a	11 July 2019
L01XA01	Cisplatin	Adjuvant/Neoadjuvant: various cancers.	Approved	n/a	11 July 2019
L01XA02	Carboplatin	Adjuvant lung cancer.	Approved	None	27 November 2008
L01XA02	Etoposide	Adjuvant small cell lung cancer.	Approved	None	27 November 2008
L01XA03	Oxaliplatin	Adjuvant colorectal.	Not Approved	• Mature published data	27 November 2008

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L01XA03	Oxaliplatin	First or second-line metastatic colorectal cancer.	Approved	None	10 December 2015
L01XC07	Bevacizumab	Sub-retinal neovascular membranes and non-resolving macular odema.	Approved (off label indication).	None	10 December 2015
L01XE01	Imatinib	Chronic phase of chronic myeloid leukemia.	Approved	None	27 March 2014
L01XE01	Imatinib	Gastrointestinal Stromal Tumours (GIST) - adjuvant therapy.	Approved	None	25 June 2015
L01XE01	Imatinib	Gastrointestinal Stromal Tumours (GIST) - metastatic therapy.	Approved	None	25 June 2015
L01XE08	Nilotinib	Chronic Myeloid Leukemia in patients resistant or intolerant to imatinib.	Approved	<ul style="list-style-type: none"> • Longer term follow-up of nilotinib versus imatinib showing clinical benefits in the first line • Reduction in cost or availability of nilotinib generics 	22 January 2015
L01XC02	Rituximab	CD20 positive diffuse large B-cell non-Hodgkin's lymphoma: first-line.	Approved for treatment in diffuse large B-cell non-Hodgkin's lymphoma (DLBCL) patients except those with International Prognostic Index (IPI) of 0.	<ul style="list-style-type: none"> • New anti-CD20 monoclonal antibodies, more data and international consensus statements in FL patients, rituximab price changes 	23 August 2012
L01XC02	Rituximab	Rheumatoid Arthritis patients refractory to synthetic DMARDs.	Approved <ul style="list-style-type: none"> • For patients with refractory RA, who have failed ≥ 3 DMARDs taken for ≥ 6 months. (in accordance with algorithm) 	<ul style="list-style-type: none"> • Evidence of harm 	5 July 2018
L01XC02	Rituximab	Refractory lupus nephritis.	Approved – Special Access <ul style="list-style-type: none"> • Special Access may be granted on recommendation by the PTC. • Used as per NEMLC-approved treatment algorithm. Use must be monitored and managed by PTCs through a registry. Clinical outcomes to be shared with the National registry database for biological therapy.	<ul style="list-style-type: none"> • Changes in evidence of efficacy/safety • Change in cost 	11 April 2019

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L01XC02	Rituximab	CD20 positive indolent B-cell non-Hodgkin's Lymphoma	Not Approved for treatment in indolent B-Cell non-Hodgkin's lymphomas	<ul style="list-style-type: none"> • Further evidence review • Price reduction 	24 June 2021
L01XC03	Trastuzumab	Adjuvant treatment for early stage HER-2 positive breast cancer, 6 month regimen.	Approved Regimen: administered 3 weekly for a period of 6 months .	<ul style="list-style-type: none"> • New evidence 	5 December 2019 <i>(previously reviewed: 29 June 2017)</i>
L01XG01	Bortezomib	Transplant eligible multiple myeloma	Approved – Special Access Data to ensure rational use to be submitted for all patients by PTCs to the National Department of Health.	<ul style="list-style-type: none"> • New evidence Price 	25 March 2021
L01XX02	Asparaginase	Acute lymphoblastic leukemia (ALL)	Approved	n/a	11 July 2019
L01XX14	All-trans retinoic acid (tretinoin)	Acute promyelocytic leukaemia	Approved	None	27 September 2018
L01XX19	Irinotecan	Adjuvant colorectal.	Not Approved	<ul style="list-style-type: none"> • Evidence to show benefit 	27 November 2008
L01XX19	Irinotecan	First- or second-line metastatic colorectal cancer.	Approved	None	10 December 2015
L02AE03	Gonadotrophin-releasing hormone (GnRH) analogue Goserelin, Buserelin	Endometriosis.	Approved for use in the following situations: <ul style="list-style-type: none"> • For endometriosis-associated infertility prior to in vitro fertilisation (IVF). For medical management in situations in which a trial of adequate analgesia or the use of combined oral contraceptives is unsuccessful.	<ul style="list-style-type: none"> • New evidence based on Goserelin vs. Placebo • Large comparative trials with COCs for both “trial of hormone therapy” and for relief of pain • Comparisons with new agents such as aromatase inhibitor 	13 March 2008
L02AE03	Gonadotrophin-releasing hormone (GnRH) analogue	Precocious puberty.	Approved Choice of GnRH analogue will depend on best tender price.	<ul style="list-style-type: none"> • Change in price or registration of new agents which are cheaper or more efficacious, or both. New safety concerns 	13 March 2008
L02AE03	Gonadotrophin-releasing hormone (GnRH) analogue	As bridging therapy until orchiectomy.	Approved Only Approved as bridging therapy - not long-term management.	<ul style="list-style-type: none"> • Price 	25 February 2016

TERTIARY AND QUATERNARY LEVEL ESSENTIAL MEDICINES RECOMMENDATIONS

ATC CODE	MEDICINE	INDICATION	NEMLC RECOMMENDATION	REVIEW INDICATORS	DATE RATIFIED
L02AE03	Goserelin	Hormone receptor positive breast cancer in premenopausal women.	Not Approved	None	10 December 2015
L02BA01	Tamoxifen	Adjuvant breast cancer.	Approved	None	27 November 2008
L02BA01	Tamoxifen	Metastatic breast cancer.	Approved	None	27 November 2008
L02BA03	Fulvestrant	Advanced Breast Cancer (ABC) Hormone Receptor Positive (HR+) [C50] – third or fourth line therapy	Not Approved This status will be reconsidered if offered/contract price is comparable or lower than that of standard chemotherapy.	Price	25 March 2021
L02BB01/ L02BB03	Anti-androgens Flutamide, Bicalutamide	Advanced prostate cancer.	Not Approved Orchiectomy preferred.	None	29 October 2012
L01BC05	Gemcitabine	Pancreatic cancer.	Not Approved	• Reduction in cost of gemcitabine	29 October 2012
L01BC05	Gemcitabine	First-line chemotherapy in advanced non-small cell lung cancer (NSCLC) in patients intolerant to paclitaxel.	Approved Approved in patients intolerant to paclitaxel.	n/a	22 January 2015
L01BC05	Gemcitabine	Relapsed metastatic breast cancer (mBC) failing an anthracycline and a taxane.	Approved	n/a	15 September 2016
L02BG	Aromatase inhibitors Anastrozole, Letrozole, Exemestane	Adjuvant breast cancer.	Approved for use in women with confirmed intolerance to tamoxifen, i.e. thrombo-embolic disease or endometrial hyperplasia (proven on ultrasound). Choice of aromatase inhibitor will depend on best tender price.	<ul style="list-style-type: none"> • Publication of the ongoing Secondary Adjuvant Long term Study with Arimidex (SALSA) study and ATAC • Long term data BIG 1-98 • TEAM data late in 2008 • Price parity with tamoxifen 	27 November 2008
L02BG	Aromatase inhibitors	Metastatic breast cancer.	Approved for use as second-line therapy after tamoxifen in advanced breast cancer in postmenopausal women who do not have visceral metastases. Choice of aromatase inhibitor will depend on best tender price.	<ul style="list-style-type: none"> • Further developments regarding tamoxifen pharmacogenetics 	September 2010
L03AA02	Filgrastim	Febrile neutropaenia.	Approved under the following conditions: <ul style="list-style-type: none"> • Patients must have had 3 days of appropriate antimicrobial therapy without resolution of infection. 	None	27 November 2008

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			<ul style="list-style-type: none"> Filgrastim can be used up to a maximum of 5 days with a daily review of white cell count (WCC). Failure to respond must prompt further investigation of neutropenia. 		
L03AA02	Filgrastim	ARV-induced neutropenia.	Not Approved This does not preclude the use of filgrastim in the management of febrile neutropenia (see above) in HIV infected patients.	<ul style="list-style-type: none"> RCTs, with improved clinically relevant outcomes, especially mortality 	27 November 2008
L03AA02	Filgrastim	Prophylactic use in children with high-risk acute lymphoblastic leukaemia (HR-ALL).	Not Approved	<ul style="list-style-type: none"> The emergence of evidence that routine use of GCSF improves outcomes in HR-ALL. A significant reduction in the price of GCS 	3 December 2009
L03AA02	Filgrastim	Peripheral blood stem cell harvesting in autologous stem cell harvesting in haematological malignancies.	Approved	n/a	24 July 2014
L03AA02	Filgrastim	Chemotherapy-induced febrile neutropenia.	Approved for secondary prophylaxis in curable cancers requiring full dosing on-schedule, i.e. Hodgkins and germ cell tumours.	n/a	9 February 2012
L03AA02	Filgrastim	Chemotherapy-induced febrile neutropenia.	Not Approved for primary prophylaxis as no overall survival benefit and limited mortality benefit has been shown.	n/a	9 February 2012
L04AA04	ATG	Induction therapy in <u>high risk</u> renal transplantation recipients.	Approved	None	29 June 2017
L04AA10	Sirolimus	Renal transplant.	Approved for use only patients with biopsy-confirmed calcineurin inhibitor toxicity because of deteriorating kidney function (i.e. in patients at ongoing risk of acute rejection with no overt proteinuria and preserved GFR > 40mL/min) where mycophenolate mofetil is contra-indicated.	<ul style="list-style-type: none"> Reduction in cost or new efficacy data 	16 September 2010
L04AA06	Mycophenolate mofetil (MMF)	Lupus Nephritis.	Approved for both the induction and maintenance phases of treatment of lupus nephritis.	None	18 September 2014

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L04AA06	Mycophenolate mofetil (MMF)	Prevention of acute rejection post-renal transplantation.	Approved for prevention of acute rejection post-renal transplantation.	<ul style="list-style-type: none"> Reduction in cost or new efficacy data 	16 September 2010
L04AA13	Leflunomide	As add-on therapy in Rheumatoid Arthritis.	Approved – Special Access Special access be permitted on recommendation by PTC for intolerance to standard therapy.	<ul style="list-style-type: none"> New efficacy data or reduction in cost 	31 March 2016
L04AA13	Leflunomide	Rheumatoid Arthritis where patients are intolerant or have contraindications to methotrexate and sulphasalazine.	Approved Only for use in patients with intolerance to standard DMARD therapy (methotrexate or sulphasalazine)	<ul style="list-style-type: none"> New evidence Safety concerns Price change 	12 April 2018
L04AA04	Antithymocyte immunoglobulin (ATG)	Aplastic Anaemia.	Approved (in combination with ciclosporin and corticosteroids)	None	10 December 2015
L04AA31	Teriflunomide	Relapsing remitting multiple sclerosis.	Approved Provided offered price is comparable or lower than beta interferon	<ul style="list-style-type: none"> New evidence of clear benefit of efficacy of newer classes Price changes 	19 March 2020
L04AB02	Infliximab	Fistulising Crohn's Disease.	Not Approved	<ul style="list-style-type: none"> A considerable change in the price of the drug 	20 September 2007
L04AB02	Infliximab	Rheumatoid Arthritis.	Not Approved	<ul style="list-style-type: none"> Demonstration in randomized trials of reduction in clinically significant endpoints, e.g. hospitalizations, joint replacements, etc. Evidence of sustained, clinically relevant improvement upon withdrawal of infliximab A significant reduction in the price of the medicine 	13 March 2008
L03AB07/ L03AB08	Interferon beta	Relapsing remitting multiple sclerosis	Approved	<ul style="list-style-type: none"> New evidence of clear benefit of efficacy of newer classes Price 	30 January 2020
L04AC02	Basiliximab	Induction therapy in low risk patient's renal transplantation recipients.	Approved	None	29 June 2017
L04AD01	Ciclosporin	Organ transplantation.	Approved	n/a	20 September 2007

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ATC CODE	MEDICINE	INDICATION	NEMLC RECOMMENDATION	REVIEW INDICATORS	DATE RATIFIED
L04AD02	Tacrolimus	<ul style="list-style-type: none"> Primary therapy in high immunological risk renal allograft recipients. Renal allograft recipients on ciclosporin who experience steroid resistant acute allograft rejection. 	Approved	None	29 June 2017
L04AX02	Thalidomide	Multiple myeloma.	Approved	<ul style="list-style-type: none"> Price 	June 2019 (reference price met)
M MUSCULOSKELETAL SYSTEM					
M03BX01	Baclofen	Spasticity.	Not Approved	<ul style="list-style-type: none"> New evidence of clinically relevant efficacy 	25 June 2015
M03AX01	Botulinum toxin	Focal dystonias.	Approved for use in carefully selected patients. Only to be administered by suitably experienced practitioners.	<ul style="list-style-type: none"> New evidence with clinical relevant/well defined endpoints and well described dosage regimens 	30 June 2016
M03AX01	Botulinum toxin	Spastic cerebral palsy.	Not Approved	<ul style="list-style-type: none"> New evidence with clinical relevant/well defined endpoints and well described dosage regimens 	Re-review: 30 June 2016
M05BA	Bisphosphonates	Malignant bone disease in multiple myeloma.	Approved	<ul style="list-style-type: none"> New evidence of harm 	25 July 2013
	Zoledronate, Ibandronic acid				
M05BA03	Pamidronate	Hypercalcaemia of malignancy.	Approved	n/a	20 September 2007
M05BA04	Alendronate	Osteogenesis imperfect.	Not Approved	<ul style="list-style-type: none"> Evidence of efficacy and safety 	25 July 2013
M05BA04	Alendronate	Paget's.	Not Approved	<ul style="list-style-type: none"> New high quality adequately powered trials providing evidence addressing clinically important parameters New safety concerns 	September 2007
N NERVOUS SYSTEM					
N03AG04	Vigabatrin	Refractory partial epilepsy.	Not Approved	<ul style="list-style-type: none"> Good quality evidence to support the efficacy and safety in infantile spasms. 	3 December 2009

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ATC CODE	MEDICINE	INDICATION	NEMLC RECOMMENDATION	REVIEW INDICATORS	DATE RATIFIED
N03AG04	Vigabatrin	Infantile spasms.	Not Approved	<ul style="list-style-type: none"> • Good quality evidence to support the efficacy and safety in infantile spasms. 	3 December 2009
N03AX11	Topiramate	Initial therapy (epilepsy).	Not Approved	<ul style="list-style-type: none"> • New evidence, re: clinical efficacy of topiramate vs. alternatives as add-on therapy for resistant epilepsy • New evidence, re: efficacy in comparison with alternatives as initial therapy for epilepsy, where the current evidence supports using the alternative agents 	3 December 2009
N03AX11	Topiramate	Add-on therapy for resistant epilepsy.	Approved	<ul style="list-style-type: none"> • Evidence that the product is accounting for disproportionate amount of anti-epileptic spend 	26 March 2015
N03AX14	Levetiracetam	Add-on therapy for resistant epilepsy.	Not Approved	<ul style="list-style-type: none"> • Price • Data in HIV patients 	25 June 2015
N03AX12/ N03AX16	<p>α₂δ calcium channel ligands</p> <p>Gabapentin, Pregabalin</p>	Patients with peripheral neuropathy refractory or intolerant to standard of care (e.g. amitriptyline; or carbamazepine)	<p>Approve – Special Access</p> <p>Special access may be granted on recommendation by PTC in the refractory or intolerant setting.</p>	<ul style="list-style-type: none"> • New evidence in the refractory setting • Alternative indications 	30 January 2020
N04BC04/ N04BC05 G02CB01	<p>Dopamine agonist</p> <p>Ropinirole, Pramipexole, Bromocriptine</p>	Parkinson's disease.	<p>Approved for use as add-on therapy to levodopa.</p> <p>The choice of dopamine agonists and selegiline will depend on the lowest tender price.</p>	<ul style="list-style-type: none"> • Decrease in relative cost • New safety data 	27 November 2008
N05AH03	Olanzapine, IM	Emergency management of psychotic conditions.	Not Approved	<ul style="list-style-type: none"> • New evidence of superior efficacy to suitable alternatives in patients with severe adverse reactions to FGAs 	03 December 2009
N05AH04	Quetiapine	Third-line Schizophrenia.	<p>Not Approved</p> <p>Amisulpiride Approved for this indication.</p>	<ul style="list-style-type: none"> • Price 	15 September 2016

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ATC CODE	MEDICINE	INDICATION	NEMLC RECOMMENDATION	REVIEW INDICATORS	DATE RATIFIED
N05AX08	Risperidone long acting injection	Schizophrenia.	Not Approved	<ul style="list-style-type: none"> Price similar to current standard of care 	31 March 2016
N05AL05	Amisulpride	Psychosis.	Approved for use as an appropriate alternative to existing agents in patients with negative symptoms failing first and second generation antipsychotics.	<ul style="list-style-type: none"> New information suggesting adequate comparative efficacy vs. older agents such as sulpiride itself, or new safety information 	03 December 2009
N05AX12	Aripiprazole	Schizophrenia in children.	<p>Approved for use as a third-line agent in children with psychotic disorders who are intolerant to typical and atypical antipsychotic agents with:</p> <ul style="list-style-type: none"> Obesity, defined as BMI \geq 30 or age appropriate measures, or Excessive weight gain, if associated with metabolic syndrome in adherent patients on other atypical antipsychotics, not responsive to other interventions (e.g. dietary management and/or physical exercise). <p>Aripiprazole be initiated, in these cases, in consultation with or, where available, by a subspecialist (i.e. child and adolescent psychiatrist)</p>	<ul style="list-style-type: none"> New evidence of efficacy in children and adolescents 	29 November 2013
N05BA12	Alprazolam	"As required" adjunctive medication in the treatment of panic disorder.	Approved for panic disorder only. To be prescribed by a psychiatrist.	<ul style="list-style-type: none"> Any efficacy, safety or cost data 	September 2010
N05CF01/ N05CF02	Benzodiazepine related drugs Zopiclone, Zolpidem	Short-term use for insomnia associated with a primary psychiatric condition.	Not Approved	<ul style="list-style-type: none"> If the price of z-drugs were reduced to within an acceptable distance of the price of oxazepam, consideration would be given to including these on the EML 	03 December 2009
N06AX12	Bupropion	Major depressive disorder.	<p>Approved for use as a third-line treatment of major depressive disorder and anxiety associated with depression.</p> <p>To be prescribed by a psychiatrist only. The cheapest of bupropion or venlafaxine to be used.</p>	<ul style="list-style-type: none"> n/a 	27 January 2011

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ATC CODE	MEDICINE	INDICATION	NEMLC RECOMMENDATION	REVIEW INDICATORS	DATE RATIFIED
N06AX16	Venlafaxine	Major depressive disorder.	Approved for use as a third-line treatment of major depressive disorder and anxiety associated with depression. To be prescribed by a psychiatrist only. The cheapest of bupropion or venlafaxine to be used.	<ul style="list-style-type: none"> New evidence of harm, or a revision in the price of bupropion to make it more economically favourable 	27 January 2011
N06DX01	Memantine	Alzheimer's Disease.	Not Approved	<ul style="list-style-type: none"> Evidence of true clinical benefit in terms of quality of life for patients and care-givers 	10 July 2008
R RESPIRATORY SYSTEM					
R03BB04/ R03BB06	Long acting muscarinic antagonists (LAMA) <ul style="list-style-type: none"> Tiotropium Glycopyrronium 	Chronic Obstructive Pulmonary Disease (COPD).	Not Approved	Price	14 December 2017
R03DC03	Montelukast	Chronic management of severe uncontrolled asthma.	Approved for use in: <ul style="list-style-type: none"> In adults (>12 years) with difficult to control asthma despite receiving high dose inhaled steroids and long-acting β_2 agonist, a trial of low dose sustained release theophylline should be tried before use of montelukast. If there is no response to low dose theophylline, a 2-week trial of montelukast may be used. In children between 6 and 12 years of age with severe uncontrolled asthma despite being on high dose corticosteroids and long acting β_2 agonist, a 2-week trial of montelukast could be considered. In children less than 6 years with severe uncontrolled asthma on high dose inhaled corticosteroids, a 2-week trial of montelukast could be considered. If no benefit can be 	<ul style="list-style-type: none"> Properly randomized efficacy and safety comparative studies of LTRA, low dose sustained release theophyllines and long acting beta2 agonist at all ages 	13 March 2008

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ATC CODE	MEDICINE	INDICATION	NEMLC RECOMMENDATION	REVIEW INDICATORS	DATE RATIFIED
			demonstrated after this period, montelukast should be discontinued.		
S SENSORY ORGANS					
S01LA04	Ranibizumab	Sub-retinal neovascular membranes and non-resolving macular odema.	Not Approved Bevacizumab to be agent for this indication	None	10 December 2015
V VARIOUS					
V03AC03	Deferasirox	Treatment of transfusional iron overload	Approved Added as an oral alternative to deferoxamine.	n/a	15 September 2016
V03AF03	Folinic acid, intravenous	Adjuvant colorectal cancer.	Approved	n/a	27 November 2008
V03AE	Lanthanum carbonate, Sevelamer	Hyperphosphataemia in patients with chronic renal failure.	Approved – Special Access Special Access may be granted on recommendation by the PTC.	<ul style="list-style-type: none"> Evidence that the use of non-calcium-based phosphate binders significantly reduces all-cause or cardiovascular mortality and/or cardiovascular comorbidities in patients with ESRD Reduction in cost of sevelamer through price reduction or the introduction of generic equivalents 	25 June 2015
V03AF01	Mesna	Haemorrhagic cystitis post high dose cyclophosphamide/ifosfamide	Approved	n/a	11 July 2019

Abbreviations:

ACTH: Adrenocorticotrophic hormone
ARB: Angiotensin II receptor blocker
AR: Antiretroviral
ATAC: Arimidex, tamoxifen, alone or in combination
ATC: Anatomical Therapeutic Chemical Classification
BCG: Bacille Calmette-Guerin
BIG 1-98: Breast International Group 1-98
COCs: Combined oral contraceptives
COPD: Chronic Obstructive Pulmonary Disease
DLBCL: Diffuse large B-cell non-Hodgkins lymphoma
DMARD: Disease-modifying antirheumatic drugs
DoH: Department of Health
EML: Essential Medicine List
ESRD: End-stage renal disease
FGAs: First generation antipsychotics
FL: Follicular lymphoma
GCSF: Granulocyte colony stimulating factor
GFR: Glomerular filtration rate
GnRH: Gonadotrophin-releasing hormones
HIV: Human Immunodeficiency Virus
HR-ALL: High-risk Acute Lymphoblastic Leukaemia
IPI: International Prognostic Index
ITP: Immune Thrombocytopenic Purpura
IVF: In-vitro Fertilisation
IVIG: Intravenous Immunoglobulin
LTRA: Leukotriene receptor antagonists
mBC: Metastatic breast cancer
MRSA: Methicillin-resistant *Staphylococcus aureus*
NPH: Neutral Protamine Hagedorn
PTC: Pharmaceutical and Therapeutics Committee
RA: Rheumatoid arthritis
RCT: Randomised controlled trials
RSV: Respiratory syncytial virus
SEP: Single exit price
TEAM: Tamoxifen Exemestane Adjuvant Multinational
VCZ: Voriconazole
VTD: Bortezomib/thalidomide/corticosteroids
VHF: Viral haemorrhagic fever
WCC: White cell count

NOTE: General review indicators include, new evidence on efficacy, effectiveness or safety and significant price changes.

NEMLC ratified Summary and Review documents can be requested as required from: SAEDP@health.gov.za OR Janine.Jugathpal@health.gov.za