



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE (NEMLC) BULLETIN FOR THE MEETING HELD ON 14 MARCH 2024: MEETING OUTCOMES FOR PUBLIC DISSEMINATION

ACCESS TO STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST

The following are the latest editions of the Standard Treatment Guidelines (STGs) and Essential Medicines List (EML):

- **Primary Healthcare:** STGs and EML 2020 Edition (plus updated chapters ratified by NEMLC)
- **Adult Hospital Level:** STGs and EML 2019 Edition (plus updated chapters ratified by NEMLC)
- **Paediatric Hospital Level:** STGs and EML 2023 Edition (plus individual chapters)
- **Tertiary and Quaternary:** EML March 2024 Edition

The following formats of the STGs and EML are accepted by the National Department of Health (NDoH):

- **Knowledge Hub (most updated version of the STGs and EML):** eLibrary on the link: <https://knowledgehub.health.gov.za/e-library>. Refer to Annexure A on page 7 and 8 for guidance on how to access STGs and EML and related technical documents on the Knowledge Hub.

Keywords:

Resource	Keywords to use in the Search bar	Notes: <i>Folder contents outlined below – constantly updated</i>
Primary Healthcare (PHC) Level, 2020 <i>(plus updated chapters ratified by NEMLC, Medicine Reviews, Costing Reports and Implementation slides)</i>	Primary Healthcare, PHC, Standard Treatment Guidelines, STGs, Essential Medicines List, EML	Contains complete PDF of 2020 edition, new chapters already reviewed and ratified for the 2024 edition (with supporting NEMLC reports) which will be replacing chapters from the 2020 edition and form part of the 2024 edition, medicine reviews, costing reports, implementation slides, therapeutic interchange database, EML based on 2020 edition of the STGs and EML
Hospital Level – Paediatrics, 2023 <i>(plus updated Chapters ratified by NEMLC, Errata, Medicine Reviews and Costing Reports)</i>	Hospital Level, Hospital, Paediatric, Standard Treatment Guidelines, STGs, Essential Medicines List, EML, Medicine Reviews, Costing Reports	Complete PDF of the 2023 edition, updated chapters, individual chapters for the 2023 edition and errata Medicine reviews and costing reports in a separate folder
Hospital Level – Adults, 2019	Hospital Level, Hospital, Adult, Standard Treatment Guidelines, STGs,	Contains complete PDF of the 2019 edition, new chapters (with supporting NEMLC reports) already reviewed and

<i>(plus updated Chapters ratified by NEMLC, Errata, etc.)</i>	Essential Medicines List, EML, Medicine Reviews, Costing Reports	ratified for the 2024 edition replacing chapters from the 2020 edition and form part of the 2024 edition, therapeutic interchange database, notices of errata from the 2019 edition, EML based on the 2019 edition of the STGs and EML
Tertiary and Quaternary Level, March 2024	Hospital Level, Hospital, Tertiary & Quaternary, Tertiary, Quaternary, Medicine Recommendations, Medicine Reviews, Costing Reports	2022 - 2024 medicine reviews, costing reports, latest Tertiary and Quaternary EML 2017 – 2021 medicine reviews and costing documents in separate folders but same key words
Health Technology Assessment (HTA)	Health Technology Assessment, Health Technology, HTA, Essential Medicines List	HTA Methods Guide, HTA Methods Guide Templates
Medicine Reviews and Costing Reports	Medicine reviews, reviews, costing reports, costing	Different folders for Paediatrics, Adult and Tertiary/ Quaternary Contains all medicine reviews and costing reports per level of care, except PHC level
Notice for Comment	Notice for Comment, Notice Comment, PHC, Adult, Paediatric, Hospital Level, STGs, EML	Current notices for all levels of care – these notices are removed once comment period is closed
National Essential Medicines List Committee (NEMLC)	NEMLC, National Essential, Essential Medicines, Committee	Member photos and short biographies, policies, terms of reference, bulletins
Affordable Medicines Circulars	Affordable Medicines Circulars, Affordable Medicines, Circulars	2022 and 2024 circulars

- **EMGuidance mobile application:** To sign up, click on the link: <http://onelink.to/sy896k>
Please note there may be a lag time for any updated documents on Knowledge Hub to be transcribed onto the EMGuidance platform.

The most current versions of the COVID-19 rapid review reports are still available on the **NDoH website** at: <http://www.health.gov.za/covid-19-rapid-reviews/>

ACCESS TO CIRCULARS FROM THE NATIONAL DEPARTMENT OF HEALTH

Circulars that are developed by the Essential Drugs Programme (EDP) are disseminated to EDP stakeholders and uploaded on the Knowledge Hub. The EDP is currently working on uploading all EDP related information on the NHI webpage under the Affordable Medicines Directorate tab, Chief Directorate: Health Products Procurement. When the uploads are complete, a summary of what is available together with the link will be shared with all EDP stakeholders.

Please email SAEDP (SAEDP@health.gov.za) if you would like to be added to the mailing list for circulars and other EDP updates.

The following circulars/documents were disseminated from December 2023 to April 2024:

- **Notice:** Publication of Chapter 23: Adult Critical Care and Supporting Technical Documents in the Adult Hospital Level (AHL) Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) (As part of the 2024 edition of the PHC and AHL STGs and EML – 04 April 2024
- **Notice:** Publication of Chapter 16: Mental Health Conditions and Chapter 15: Mental Health Conditions & Substance Misuse in the Primary Healthcare (PHC) and the Adult Hospital Level (AHL) Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) (As part of the 2024 edition of the PHC and AHL STGs and EML – 04 April 2024
- **Notice:** Request for Comment on the Standard Treatment Guidelines and Essential Medicines List for Primary Healthcare and Adult Hospital Level of Care – 15 March 2024
- **Notice:** Vincristine Stock Challenges – 23 February 2024
- **Notice:** Recommended Therapeutic Alternative for Ranitidine Injection – 31 January 2024
- **Paediatric Hospital Level STGs and EML 2023 edition:** Paracetamol Maximum Doses and Rectal Maintenance Dose Reference – 18 January 2024
- **Notice:** Malaria Prophylaxis with Oral Doxycycline: Travel to Moderate or High-Risk Areas Outside SA – 15 January 2024
- **Alert:** Safe Use of Lidocaine Injection for Local Anaesthesia – 22 December 2023

EVOLUTION OF THE ESSENTIAL MEDICINES LIST (EML) REVIEW PROCESS AND PRIORITISATION

- The Paediatric Hospital Level Expert Review Committee's (ERC) review cycle ended in 2023, the current terms for the Primary Healthcare/Adult Hospital Level ERC, the Tertiary and Quaternary Hospital Level ERC as well as the National Essential Medicines Lists Committee (NEMLC) are due to end in 2024.
- A proposed approach on evolving the NEMLC was agreed upon:
 - It was agreed that the 2023 edition of the Paediatric Hospital Level STGs and EML will not be disseminated for widespread comment nor a new Paediatric Hospital Level ERC constituted in the short-term. Work will focus on agreed upon priority areas for 2024 and issues addressed through the currently appointed NEMLC.
 - It was recommended that an Oversight Committee be formed to coordinate priority areas across ERCs for 2024. Furthermore, the Committee will work on activities to strengthen and evolve the EML review process in the short, medium and long-term.
 - Priority chapters/disorders identified were informed by several factors including PHC/Adult Hospital Level STG chapters not prioritised in the current review cycle, items deferred from the current ERC review cycles, expected upcoming National Department of Health Programme Guidelines updates, the Affordable Medicines Directorate's Tender Project Plan for 2024-6, and external stakeholder comments received for specific chapters. Some of the disorders identified as priorities for collaborative review include Respiratory, Endocrine and Eye Chapters.
 - Stakeholders are encouraged to inform the EDP of any safety issues that may be related to any of the published STGs and EML.

PRIMARY HEALTHCARE (PHC) AND ADULT HOSPITAL (AH) LEVEL STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST

- The following chapters have been reviewed and *ratified for publication*, with the respective NEMLC report and relevant medicine review(s), following clinical editing:
- PHC Level
 - **PHC Chapter 2: Gastro-intestinal Conditions**
 - **PHC Chapter 8: Kidney and Urological Disorders**
 - **PHC Chapter 11: HIV and AIDS** (pending amendments recommended by NEMLC)
 - **PHC Chapter 13: Immunisation:**(Update to the published chapter) - NEMLC has adopted the amendments to the Expanded Programme on Immunisation (EPI) schedule as recommended by the National Advisory Group on Immunisation (NAGI).
 - **PHC Chapter 15: Central Nervous System Conditions**
 - **PHC Chapter 16: Mental Health Conditions***
- AH Level
 - **AH Chapter 1: Alimentary Tract**
 - **AH Chapter 2: Blood and Blood forming Organs** (pending NEMLC approval of the STG on Haemophilia management)
 - **AH Chapter 7: Nephrology/ Urological Disorders**
 - **AH Chapter 10: HIV and AIDS** (pending amendments recommended by NEMLC)
 - **AH Chapter 14: Neurological Disorders**
 - **AH Chapter 15: Mental Health Conditions and Substance Misuse***
 - **AH Chapter 23: Adult Critical Care*** (a newly developed chapter to replace previous AH CH 23 Sedation)*
**Available on the Knowledge Hub eLibrary on the following link: <https://knowledgehub.health.gov.za/e-library>*
- The following chapters have been reviewed and *ratified for external comment*, with the respective NEMLC reports and relevant medicine review(s). The commenting period closed on **03 April 2024**.
 - **AH Chapter 16: Respiratory System**
 - **PHC Chapter 17: Respiratory Conditions**
- The following items were reviewed by NEMLC:
 - **Isoniazid Preventative Therapy (IPT) safety in pregnancy** – Following a multi-stakeholder group meeting to discuss the evidence summary of IPT during pregnancy, a consensus recommendation was made that IPT should be deferred in all pregnant patients until after delivery to mitigate the risk of harm, and to simplify clinical guidance for ease of implementation. This recommendation was supported by NEMLC and will be reflected in the updated HIV chapters.
 - **Enalapril night-time dose** – In response to an external query regarding the optimal dosing frequency and timing of administration of enalapril for the management of hypertension, a rapid review was undertaken and presented to NEMLC. NEMLC supported the recommendation that once daily administration of enalapril for the management of hypertension be retained in the EML. Furthermore, this should be prescribed at a time of day that is most convenient for the individual patient and that would optimise adherence and minimise side effects. The PHC and Adult Hospital level Cardiovascular chapters will be updated accordingly.
 - **Penicillin desensitisation protocol** – A safety issue was raised post publication of the AH CH 26 Obstetrics, relating to the oral penicillin desensitisation procedure for penicillin allergic pregnant women with syphilis, as the oral desensitisation table did not include explicit instruction on the preparation of the oral penicillin doses and route of administration to be used. Therefore, the oral penicillin desensitisation table in the

syphilis STG was clarified for preparation, dosing and administration of penicillin as part of a penicillin desensitisation protocol. It was also recommended that penicillin desensitisation occur in a setting where recognition and management of anaphylaxis can be assured. The corresponding section in the “How to Use These Guidelines” for oral and parenteral penicillin desensitisation, referred to in the Obstetrics chapter, has also been updated to provide specific instruction on preparation, route and dosing of penicillin for a penicillin desensitisation protocol.

- **Haloperidol IM/IV availability** – Haloperidol IV/IM reintroduction as per historic indications in AH CH 15 and PHC CH 16 Mental Health Conditions was deliberated by the Committee due to recent availability. Haloperidol IM/IV was previously discontinued from the South African market and hence deleted from the STGs in the 2020-3 review cycle. The Committee considered the supply of Haloperidol IV/IM in the provinces, as well as the status of registration of the product by the South African Health Products Regulatory Authority (SAHPRA) in their decision-making. Due to the uncertainty of supply, at this time, NEMLC recommended that Haloperidol IV/IM not be reintroduced into the mental health chapters but be retained on the therapeutic interchange database as per historical indications.
- **Tenofovir/ Alafenamide (TAF)** – The evidence review as previously approved by NEMLC was updated to include additional data with respect to the risks of weight gain, safety data in pregnancy as well as coadministration with rifampicin. The Committee supported that a TAF-containing fixed dose combination (either emtricitabine 200mg or lamivudine 300mg together with tenofovir alafenamide 25mg and dolutegravir 50mg) be added to the EML as an alternative to the current standard of care for PLHIV with hepatitis B coinfection and renal impairment (eGFR 30-50 ml/min/1.73m²). Additionally, TAF 25mg tablets will be added to the EML (AH Chapter 1 Section 1.2.4.2 chronic hepatitis B) for the small cohort of non-HIV infected hepatitis B patients with renal impairment (eGFR 15-50mL/min/1.73m² or on haemodialysis).

PAEDIATRIC HOSPITAL LEVEL STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST

- The updated complete Paediatric Hospital Level STGs and EML, 2023 edition, updated December 2023 (plus individual chapters updated and ratified by NEMLC in December 2023) is available for download on the Knowledge Hub platform’s eLibrary on this link: <https://knowledgehub.health.gov.za/elibrary/hospital-level-paediatric-standard-treatment-guidelines-stgs-and-essential-medicines-list> and the NHI webpage on the following link: <https://www.health.gov.za/nhi-edp-stgs-eml/>
- Presentations from the Paediatric Hospital Level STGs and EML 2023 edition launch webinar series (held in September 2023) can be found on the Knowledge Hub Webinars tab or on the following link: <https://knowledgehub.health.gov.za/webinars>.

TERTIARY AND QUATERNARY HOSPITAL LEVEL ESSENTIAL MEDICINES LIST

- The following items were reviewed by NEMLC:

- **TNF Inhibitors fistulising Crohn's Disease** – NEMLC recommended that both infliximab and adalimumab be recommended for the management of fistulizing Crohn's disease. Adalimumab will be the preferred agent based on the cost; however infliximab will be available if an alternative is needed (e.g. in cases of antibody development). Guidance on therapeutic drug monitoring will be added as an annexure to the review document.
- **IV Bisphosphonates in secondary osteoporosis** – The Adult Hospital Level STGs and EML currently recommend oral bisphosphonates for the secondary prevention of osteoporotic fractures. There is however a subset of patients where oral therapy may be contraindicated, and thus IV bisphosphonates are required. NEMLC approved the inclusion of IV bisphosphonates for this indication. IV bisphosphonates, zoledronate and ibandronate will be considered a class for this indication with the most affordable option procured. Currently IV zoledronate is the most affordable option.

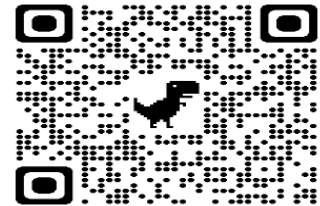
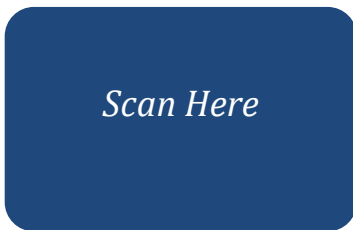
Final reports are published on the Knowledge Hub's eLibrary on the following link: <https://knowledgehub.health.gov.za/elibrary/hospital-level-tertiary-quaternary-medicine-recommendations-medicine-reviews-and-costing> or refer to Annexure A below for a guide on how to access the documents on the Knowledge Hub platform.

HAEMOPHILIA SUBCOMMITTEE OF NEMLC

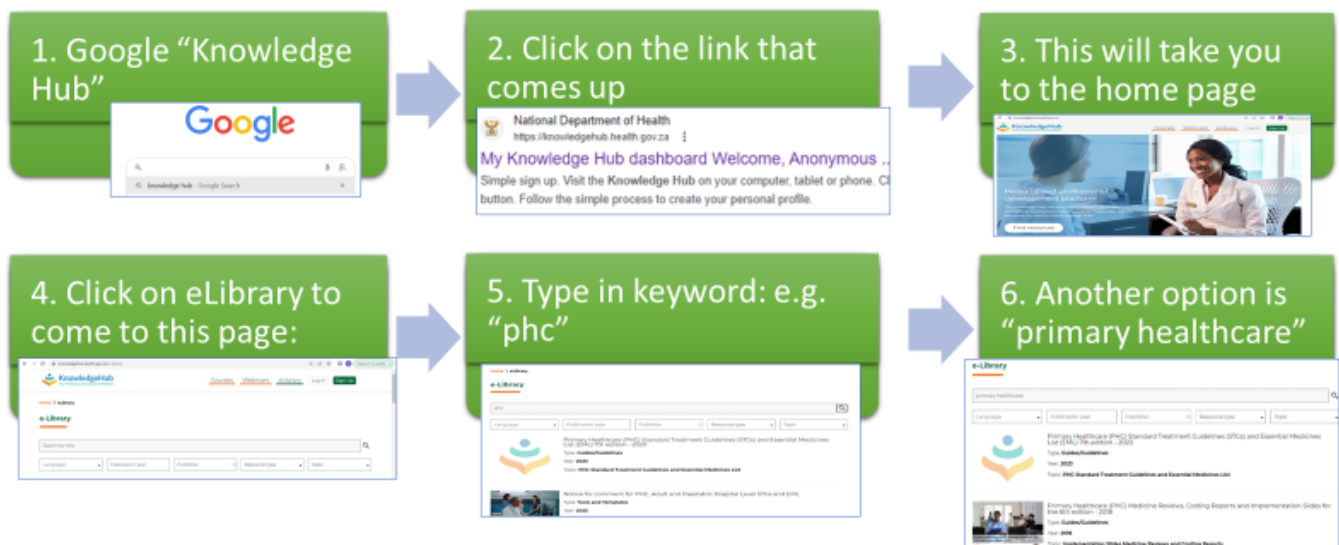
The following documents were presented for consideration by NEMLC:

- **Emicizumab for prophylaxis in haemophilia A with inhibitors** – NEMLC recommended that this agent not be approved at this time based on the price, affordability and availability of higher quality evidence with a bigger effect size. Although this product will not be listed on the EML, it can still be considered for use by Pharmaceutical and Therapeutics Committees on an individual patient basis.

Guide on how to access the Standard Treatment Guidelines and Essential Medicines List and related technical documents on Knowledge Hub

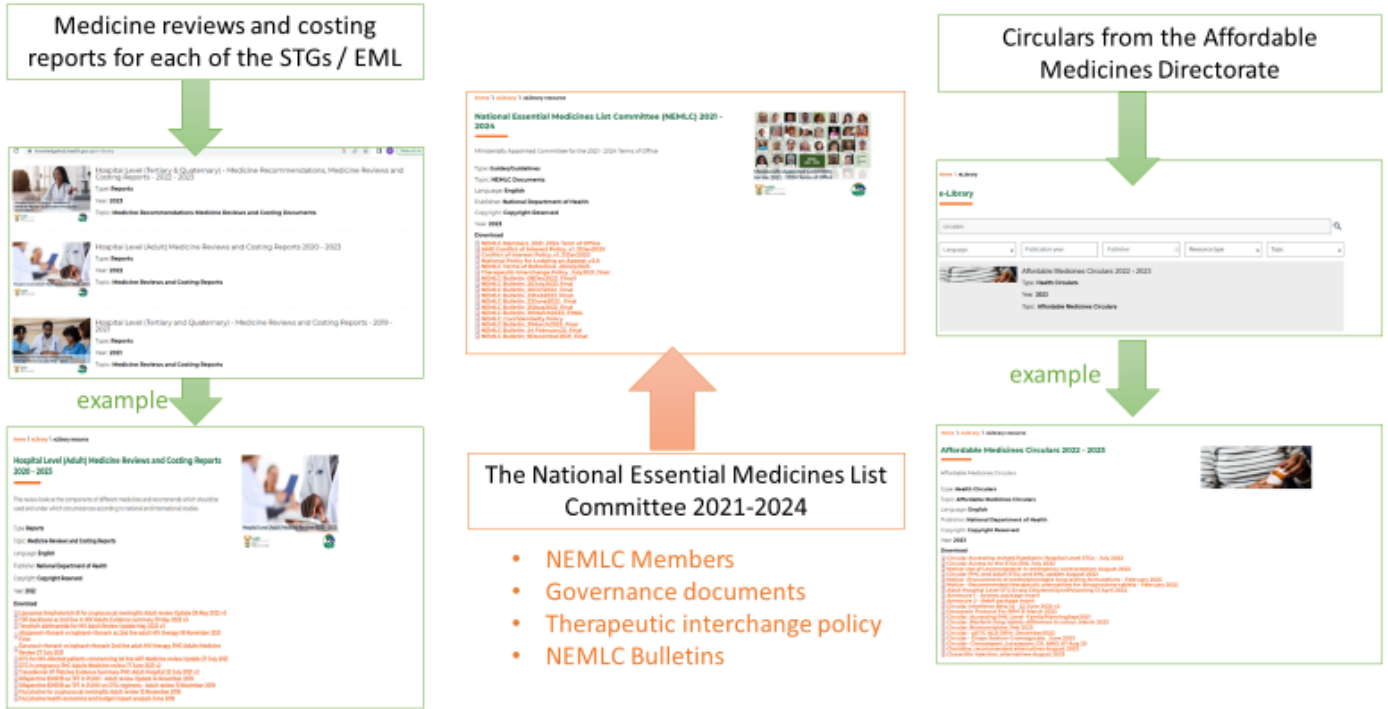


OR



Other keywords that you can use:
'hospital level'; 'paediatric'; 'adult'; 'tertiary';
'notice for comment'

What else is available on KnowledgeHub?



How the STGs/EML are presented on KnowledgeHub

