

NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE (NEMLC) BULLETIN FOR THE MEETING HELD ON 12 OCTOBER 2023: 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
- **Tertiary and Quaternary:** EML October 2023 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:
Primary Healthcare (PHC) Level, 2020 <i>(plus updated chapters ratified by NEMLC, Medicine Reviews and Implementation slides)</i>	Primary Healthcare, PHC, Standard Treatment Guidelines, STGs, Essential Medicines List, EML	<i>Folder contents outlined below – constantly updated</i> 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, implementation slides, costing reports, therapeutic interchange database, EML based on 2020 edition of the STGs & EML
Hospital Level – Paediatrics, 2023 <i>(plus 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 Medicine reviews and costing reports in a separate folder, same keywords
Hospital Level – Adults, 2019 <i>(plus updated Chapters ratified by NEMLC, Errata, etc.)</i>	Hospital Level, Hospital, Adult, Standard Treatment Guidelines, STGs, Essential Medicines List, EML, Medicine Reviews, Costing Reports	Contains complete PDF of the 2019 edition, new chapters (with supporting NEMLC reports) already reviewed and 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 & EML
Tertiary and Quaternary Level, October 2023	Hospital Level, Hospital, Tertiary & Quaternary, Tertiary, Quaternary, Medicine Recommendations, Medicine Reviews, Costing Reports	2022 and 2023 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	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, National Essential, Essential Medicines, Committee	Member photos & bios, policies, terms of reference, bulletins
Affordable Medicines Circulars	Affordable Medicines Circulars, Affordable Medicines, Circulars	2022 and 2023 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 Knowledge Hub section is currently being restructured to contain all EDP related information under one URL. When the URL is live, 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 August to October 2023:

- **Notice for Comment:** Call for External Comment for Adult Hospital Level STGs and EML_Critical Care Chapter– 17 October 2023.

- **Notice:** Notice of Application for Appointment to the National Ministerial Advisory Committee on Antimicrobial Resistance – 21 September 2023. Click here to apply: [MAC-AMR Application Form \(google.com\)](#)

PRIMARY HEALTHCARE (PHC) AND ADULT HOSPITAL 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):
 - **PHC Chapter 15: Central Nervous System Conditions** – NEMLC ratified the chapter and supporting NEMLC report for clinical editing and *publication*.
 - **Adult Hospital Chapter 14: Neurological Disorders** – NEMLC ratified the chapter and supporting NEMLC report for clinical editing and *publication*.
 - **Adult Hospital Chapter 19: Poisonings** – NEMLC ratified the chapter and supporting NEMLC report for clinical editing and publication.
- The following chapters have been reviewed and *ratified for external comment*, with the respective NEMLC report and relevant medicine review(s):
 - **Adult Hospital Chapter 23: Adult Critical Care** – NEMLC ratified the chapter for *external comment*, with the respective NEMLC report and relevant medicine reviews. The commenting period however closed on 24 November 2023, and work to finalise this chapter is underway.
- The following items were reviewed by NEMLC:
 - **Tranexamic Acid injection (TXA IV) for post-partum haemorrhage (PPH) at PHC Level (PHC Chapter 06: Obstetrics & Gynaecology)** – Following publication of the PHC Chapter 6: Obstetrics & Gynaecology (2020-23), on the 22 February 2023, a provincial Pharmaceutical and Therapeutics Committee (PTC) submitted a motivation, through electronic mail, to reconsider the historical NEMLC decision not to include TXA IV at PHC level. As PPH remains a main cause of maternal death and morbidity, it was imperative to review TXA IV use at PHC level especially since late administration (after 3 hours) does not give any benefit and might be detrimental to outcomes for the patient. NEMLC reviewed the evidence and cost for TXA IV use at PHC level, following the publication of the WHO EMOTIVE Trial¹ in May 2023; overturning the October 2017 NEMLC decision not to approve TXA IV use for PHC level. TXA IV has now been added to the PHC STGs and EML for the indication of PPH. In July 2023, NEMLC recommended the use of TXA 1g IV (by slow injection or infusion in 200mls of Normal Saline over 10 minutes) for PPH, for all levels of care, which may be initiated by a nurse, but only with prior approval of a medical practitioner. The summary of evidence for TXA IV use at PHC level, updated chapter and updated NEMLC report were ratified for publication by NEMLC in July 2023 and they can be found on the Knowledge Hub eLibrary in the folder: PHC STGs and EML 7th edition - 2020. Refer to Annexure A of the bulletin for guidance on how to access documents on the Knowledge Hub.
 - **Glyceryl trinitrate injection (GTN IV)** – A discontinuation notice has been issued by the supplier of GTN IV which is listed as an essential medicine for several indications in the Adult Hospital Level Chapter 03: Cardiovascular System. As there is currently no alternative supplier available locally, the National Department of Health (NDoH) is in the process of initiating a Section 21 process for access to GTN IV. An injectable formulation of isosorbide dinitrate (ISDN) is available locally and may be considered in the interim, however, the pharmacokinetic profile of ISDN is not equivalent to GTN and

¹ Gallos I, Devall A, Martin J, Middleton L, Beeson L, Galadanci H, et al. Randomized Trial of Early Detection and Treatment of Postpartum Hemorrhage. New England Journal of Medicine. 2023 May 9;0(0): null

is therefore not considered as a therapeutic alternative. As there is currently no alternative supplier available locally, the National Department of Health (NDoH) is in the process of initiating a Section 21 process for access to GTN IV. An injectable formulation of isosorbide dinitrate (ISDN) is available locally and may be considered in the interim, however, the pharmacokinetic profile of ISDN is not equivalent to GTN and is therefore not considered as a therapeutic alternative.

- **Administration of Ethanol for Ethylene Glycol Poisoning** – In response to the previous request from the Committee to revise the guidance for the dilution and administration of ethanol for ethylene glycol poisoning, an update to the STG with clarified guidance on the dilution and administration of ethanol, was presented to the Committee for approval. The Committee approved the revised STG as included in the Adult Hospital Chapter 19: Poisonings, which is in the process of undergoing clinical editing and publication. The Committee welcomes further comment on this guidance once published. Comments can be submitted *via* e-mail to: Ms Maropeng Rapetsoa (E-mail: maropeng.rapetsoa@health.gov.za) or SAEDP@health.gov.za.
- **Aspirin for Venous Thromboembolism (VTE) Prophylaxis (AHL Chapter 2: BBFO)** – A draft evidence summary on the use of aspirin for VTE prophylaxis was undertaken and tabled in response to a previous request from the Committee. The NEMLC supported the recommendation for the use of aspirin for VTE prophylaxis in patients with operative trauma-related extremity fractures for all operative or non-operative hip and acetabular fractures, pending editorial amendments. This recommendation applies to patients identified as having a low to moderate risk of VTE. Amendments to the STG for the management of VTE are in progress and due to be presented to the Committee for approval shortly.

PAEDIATRIC HOSPITAL LEVEL STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST

- The complete Paediatric Hospital Level STGs and EML, 2023 edition is available for download on the Knowledge Hub platform on this link: <https://knowledgehub.health.gov.za/content/standard-treatment-guidelines-and-essential-medicines-list>.
- Presentations from the September Paediatric STGs and EML 2023 edition launch webinar series 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 has been reviewed and *ratified for publication*, with the respective NEMLC report:
 - **Bisphosphonates in Multiple Myeloma Associated Bone Disease** – The limited medicine review on use of bisphosphonates in multiple myeloma associated bone disease was presented for discussion. It was outlined that bisphosphonates were reviewed in 2013 and approved for multiple myeloma associated bone disease. Zoledronate was historically available on national contract, however, during the previous tender cycle, ibandronate achieved a more favourable price, and was awarded. Subsequent to this, a motivation was received from the Western Cape Province requesting that zoledronate specifically be recommended for multiple myeloma associated bone disease, rather than a class with ibandronate. The evidence while weak quality, showed that zoledronate offers a statistically significant benefit in terms of overall survival, progression free survival and skeletal related events, while data for ibandronate was limited, and it did not show an overall survival benefit. Thus, the Tertiary Hospital Level Expert Review Committee (ERC) recommended that bisphosphonates not be regarded as a class in this indication, and rather zoledronate specifically be recommended in the management of multiple myeloma associated bone disease. NEMLC supported the recommendation to approve intravenous zoledronate for this indication.
 - **Bisphosphonates in Hypercalcaemia** – The limited medicine review on use of bisphosphonates in hypercalcaemia was presented for discussion. It was outlined that pamidronate was recommended for

inclusion on the EML for hypercalcaemia in 2007. Pamidronate, however, has been discontinued in South African and thus the need arose to evaluate the other registered intravenous bisphosphonates (zoledronate and ibandronate) to establish an appropriate recommendation in the absence of pamidronate. Although the quality of evidence found was low to moderate, both zoledronate and ibandronate demonstrated the ability to achieve normocalcaemia. The Tertiary Hospital Level ERC recommended that zoledronate and ibandronate be considered a therapeutic class for hypercalcaemia. NEMLC approved this recommendation.

- **Gemcitabine in Pancreatic Cancer** – The limited medicine review on use of gemcitabine in a subset of patients with unresectable pancreatic cancer was presented for discussion. Gemcitabine was previously reviewed in 2012 for advanced pancreatic cancer. At this time, it was not approved for inclusion on the EML due to the small survival benefit in relation to the cost of the agent. A review indicator of price was set. The price of gemcitabine has reduced over the past 10 years, prompting the re-evaluation of gemcitabine for this indication. NEMLC approved the inclusion of gemcitabine monotherapy for a select group of patients with unresectable or metastatic pancreatic cancer.

Final reports are published on the Knowledge Hub's eLibrary, refer to Annexure A, page 7 and 8 for a guide on how to access the documents on the Knowledge Hub.

COVID-19

- The following has been reviewed.

Molnupiravir – The initial evidence review for molnupiravir included '*registration of generic and/or innovator brands in South Africa, or access via Section 21, with declared prices*' as indicators for update of the review. South African Health Products Regulatory Authority (SAHPRA) has four molnupiravir products registered, one being the innovator product, although no Single Exit Price (SEP) is available yet. Since this review, additional data has been published warranting an update to the initial review. In parallel, nirmatrelvir/ritonavir appears to have limited stock in the country although it is still unavailable for the public sector.

OTHER

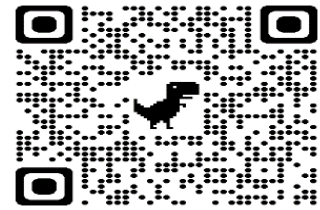
- The following have also been discussed at NEMLC.

- **Section 21 Alert List** – It was noted that there are a number of national Section 21 approvals for essential medicines. NEMLC recommended that an alert list should be made available that this is regularly updated, as items become registered or become unavailable. The alert list will be uploaded on the Knowledge Hub eLibrary on the following folder: Section 21 Alert List. Refer to Annexure A of the bulletin for guidance on how to access documents on the Knowledge Hub.
- **Access to Published STGs and EML** – NEMLC and other stakeholders raised concerns regarding difficulty in accessing the published STGs and EML and supporting documents (NEMLC reports, technical reviews and implementation slides) on the Knowledge Hub platform using the current search function; confusion between the PDF version of the STGs and EML and the individual approved chapters of the new editions; and is the fact that there is no longer a dedicated mobile application for the STGs and EML. Work has continued to consolidate documents per level of care on the Knowledge Hub's eLibrary and this allows the use of keywords like STGs, EML, PHC, etc., to access the documents (Refer to table on page 1 and Annexure A of this bulletin). The links provided in the previous circulars will no longer be active for certain documents, thus, users should use keywords on the Knowledge Hub eLibrary search box. Unfortunately, the search box does not allow users to search for specific documents within a folder on the eLibrary, e.g., for the updated PHC Chapter 6, the entire PHC STGs and EML folder to be opened to view the contents within.

The NEMLC secretariat is also currently working on the uploading of the entire PDF as chapters are updated for new versions. At the start of a new review cycle, the previous PDF will be removed and instead, all individual chapters will be loaded, clearly delineating between versions.

- **Updates to Expanded Programme on Immunisation (EPI-SA)** – The NDoH Child, Youth and School Health Programme has made changes to the current EPI schedule with additional introduction of new vaccines. The changes are as follows:
 - Introduction of Tetanus, Diphtheria, Pertussis Vaccine (Tdap) for maternal vaccination, booster for pre-school age and switch from Td to Tdap at 6 and 12 years;
 - Introduction of Rubella-containing vaccine (RCV);
 - Pneumococcal Conjugate Vaccine Switch from PCV 13 to PCV 10; and
 - Hepatitis B vaccination of Pregnant Women and universal birth dose.
- NEMLC recommended that the PHC Chapter 13: Immunisation be updated with the latest EPI schedule which will be implemented in January 2024. For more information on the EPI schedule, please e-mail Ms Schonfeldt at marione.schonfeldt@health.gov.za.
- **Cholera Control Guidelines** – The NDoH EDP and the Communicable Diseases Programmes have been formally engaging to align the Cholera Control Guidelines with the STGs and EML. An update will be provided once available.
- **Update on Bpal-L implementation** - An update on the implementation of the Bpal-L regimen was provided by the NDoH TB Control & Management Programme. It has been noted that there is currently no reported stock-out for pretomanid 200mg tablets. The Programme reported that training has been conducted for more than 2000 healthcare workers since the implementation of the Bpal-L regimen, and a national dashboard for monitoring all patients on Drug-Resistant-TB treatment has been developed. The Programme will provide regular updates on the roll out of the 6-months BPal-L regimen to the NEMLC.

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

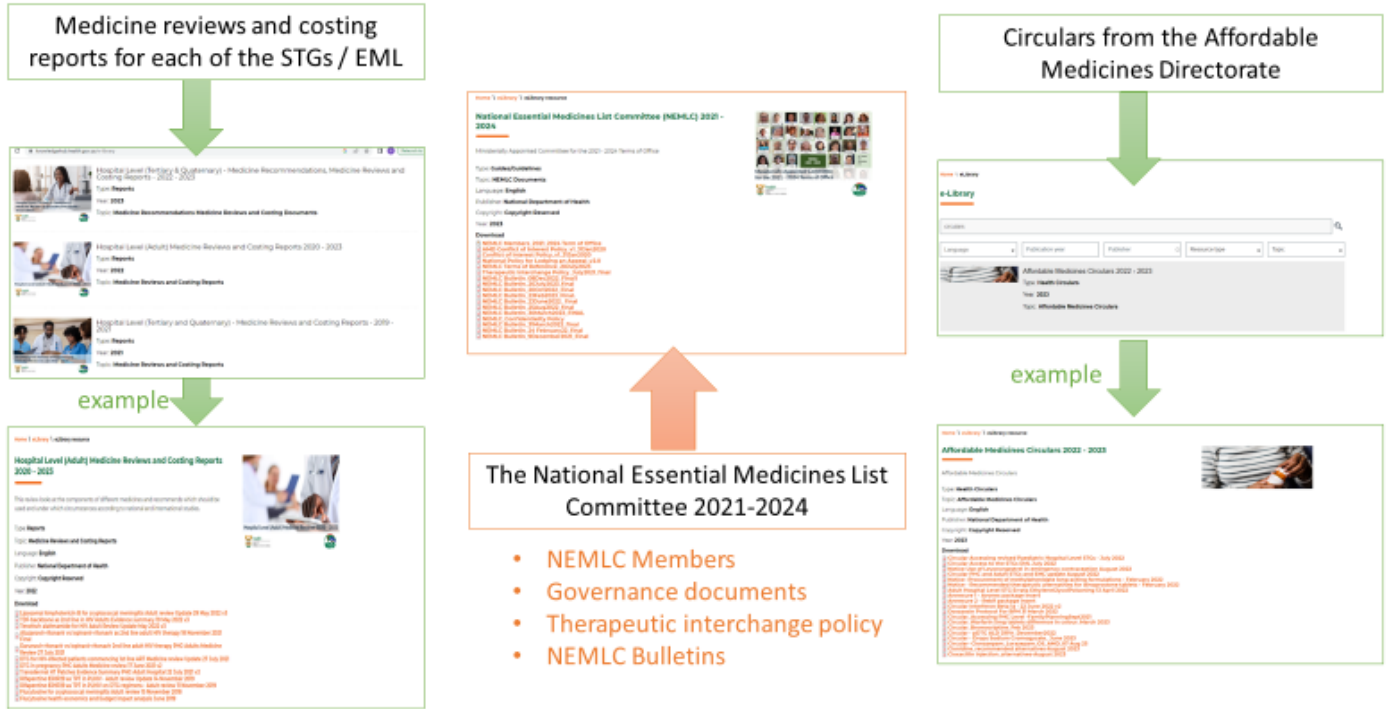


OR



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

