

NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE (NEMLC) BULLETIN FOR THE MEETING HELD ON 20 JULY 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 July 2023 Edition

**See details for launch webinar below*

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):**

Primary Healthcare (PHC), 2020 (plus updated chapters ratified by NEMLC)	https://www.knowledgehub.org.za/elibrary/primary-healthcare-phc-standard-treatment-guidelines-and-essential-medicines-list-south
Hospital Level – Paediatrics, 2023	https://knowledgehub.health.gov.za/content/standard-treatment-guidelines-and-essential-medicines-list
Hospital Level – Adults, 2019 (plus updated chapters ratified by NEMLC)	https://www.knowledgehub.org.za/elibrary/hospital-level-adults-standard-treatment-guidelines-and-essential-medicines-list-2nd
Tertiary and Quaternary, July 2023	https://www.knowledgehub.org.za/elibrary/hospital-level-tertiary-and-quaternary-essential-medicines-list

- **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 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 April to August 2023:

- WHO Guideline Adolopment_ DR-TB – 04 May 2023
- Notice: Out of Stock of Eye Drops Sodium Cromoglycate 2% – 05 June 2023

- **Notice:** Erratum to the Adult Hospital Level Standard Treatment Guidelines and Essential Medicines List, 2019, 5th edition – Erratum - Enoxaparin in Renal Failure – 14 July 2023
- **Notice for Comment:** Call for External Comment for PHC/Adult Hospital Level STGs and EML Gastrointestinal conditions and Alimentary Tract – 25 July 2023.
- **Updated Guideline:** The 5th Edition of the Paediatric STGs and EML (complete PDF) – 20 July 2023
- **Notice:** Updated Paediatric Hospital Level STGs and EML – 5th Edition – 04 August 2023
- **Notice:** Recommended Therapeutic Alternatives for Clonazepam and Lorazepam Injections – 08 August 2023
- **Notice:** Oral Morphine Extemporaneous Preparation – 08 August 2023 – **RETRACTED**
- **Notice:** Recommended Therapeutic Alternatives for Cloxacillin Injection – 14 August 2023
- **Notice:** Recommended Therapeutic Alternatives for Clonidine Tablets – 14 August 2023
- **Notice:** Accessing the Latest Chapters and Supporting Technical Documents of the Primary Healthcare STGs and EML – 14 August 2023
- **Notice:** Erratum to the Adult Hospital Level STGs and EML, 2019, 5th Edition – 21 August 2023

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 16: Mental Health Conditions** – NEMLC ratified the chapter and supporting NEMLC report for clinical editing and *publication*.
 - **Adult Hospital Chapter 15: Mental Health Conditions and substance misuse** – 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 *publication*, with amendments.
- The following chapters have been reviewed and *ratified for external comment*, with the respective NEMLC report and relevant medicine review(s):
 - **PHC Chapter 02: Gastrointestinal Conditions** – NEMLC ratified the chapter for *external comment**.
 - **Adult Hospital Chapter 01: Alimentary Tract** – NEMLC ratified the chapter for *external comment**.

**Note: The Cholera STG sections of the PHC and Adult Hospital Level chapters have been greyed out in the documents for comment, as the consultation process is still ongoing.*

Comments on the PHC and Adult Hospital Level gastrointestinal chapters are due by the 31 August 2023 and may be submitted *via* e-mail to:

Ms Maropeng Rapetsoa (E-mail: maropeng.rapetsoa@health.gov.za)

- The following were reviewed by NEMLC:
 - **Glyceryl trinitrate injection (GTN IV)** – A discontinuation notice has been issued by the supplier for GTN IV which is listed as an essential medicine for specific conditions in the Adult Hospital Level chapter 03: Cardiovascular System. It was reported anecdotally that some provinces are now using isosorbide dinitrate (ISDN) IV as an alternative to GTN IV, though not deemed therapeutically interchangeable. A proposal was presented to the Committee with short term and intermediate-long term recommendations to addressing the discontinuation of GTN IV. NEMLC recommended that GTN IV remain the preferred intravenous nitrate on the EML and that the proposed guidance on the use of ISDN be included in the EML as an alternative when GTN is not available.

- **Egg Allergy and Influenza Vaccine (PHC Chapter 13: Immunisation)** – A scoping review of evidence for use of inactivated influenza vaccines in egg allergy patients was conducted following a motivation to remove egg allergy as a contraindication to influenza vaccination. Severe egg allergy is no longer an absolute contraindication to the inactivated influenza vaccine. However, it is recommended that individuals reporting a history of severe egg allergy are vaccinated in a setting equipped to manage allergic reactions. NEMLC ratified the scoping review, updated chapter and updated NEMLC report for *publication*.
- **Paracetamol infusion (paracetamol IV)** – Paracetamol IV is approved for inclusion on the Paediatric Hospital Level EML. Historically, affordability of paracetamol IV was listed as the determining factor for inclusion on the Adult Hospital Level EML. During the development of Adult Critical Care chapter, it was suggested that the historical paracetamol IV review be revisited. NEMLC ratified paracetamol IV for inclusion in the Adult Hospital Level Critical Care chapter, which is still under review, for an initial treatment period of 24 hours only in adult intensive care unit (ICU)/high care ward (HCW) patients, or those who are candidates for, or awaiting admission to ICU/HCW, who cannot take oral medicines or cannot safely receive perioperative parenteral opioids and/or NSAIDs. The prescription is to be initiated by a specialist, and any extension of IV paracetamol treatment beyond 24 hours is to be authorised by a specialist. Implementation of paracetamol IV for adult hospital level will begin once the final Adult Hospital Level Critical Care chapter is approved and ratified by NEMLC in 2024 (as part of the Adult Hospital Level STGs and EML, 2024 edition).
- **Tranexamic Acid injection (TXA IV) for post-partum haemorrhage at PHC Level (PHC Chapter 06: Obstetrics & Gynaecology)** – Following publication of the updated PHC Chapter 6: Obstetrics & Gynaecology (2022-23), 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 Tranexamic Acid TXA IV at PHC level. At the 30 March 2023 NEMLC meeting, NEMLC recommended that the PHC/Adult Hospital Level Expert Review Committee (ERC) review the data available for this motivation, specifically safety and efficacy on use of TXA IV outside of hospitals. The summary of evidence for TXA IV use at PHC level, updated chapter and updated NEMLC report were tabled for discussion at NEMLC. NEMLC ratified the evidence review summary, updated chapter and supporting NEMLC report for *publication*, with amendments.

PAEDIATRIC HOSPITAL LEVEL STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST

- The complete Paediatric Hospital Level STGs and EML, 2023 edition are available for download on the Knowledge Hub platform on this link: <https://knowledgehub.health.gov.za/content/standard-treatment-guidelines-and-essential-medicines-list>

A webinar series to communicate some of the key updates in the 2023 edition of the Paediatric Hospital Level STGs and EML is planned for the following dates:

- Tuesday 29 August 2023, 13h00 to 14h00
- Tuesday 5 September 2023, 13h00 to 14h00
- Tuesday 12 September 2023, 13h00 to 14h00

To register in advance for this webinar series, click on the link below:

https://zoom.us/webinar/register/WN_Z2R5yCq4Qout9-dnsjhwUQ

TERTIARY AND QUATERNARY HOSPITAL LEVEL ESSENTIAL MEDICINES LIST

- The following has been reviewed and *ratified for publication*, with the respective NEMLC report:
 - **Mirtazapine for Major Depressive Disorder (MDD) Review** – An appeal was received on the recommendation to not include mirtazapine for major depressive disorder, which was ratified by NEMLC in December 2022. The appellant indicated that two key systematic reviews had been missed from the analysis. The two systematic reviews were reviewed by the Tertiary and Quaternary Hospital Level ERC and presented at NEMLC, with recommendations to stand by the previous decision to not include mirtazapine on the EML for this indication. Some of the studies within the systematic reviews did not meet the medicine review PICO, thus were excluded. Studies which did meet the PICO were included for completeness however this did not alter the original assessment of evidence and consequent recommendation. The updated review will be published.
 - **Tumor Necrosis Factor Inhibitors (TNF-Inhibitors) for Juvenile Idiopathic Arthritis (JIA)** – The updated TNF-Inhibitors for children and adolescents with JIA review documents (including published data on quality of life and pharmaco-economic analyses, proposed at the March 2023 NEMLC meeting, were presented for discussion. NEMLC ratified the medicine review documents for *publication* and approval of adalimumab onto the TQ EML for children and adolescents with JIA (with or without uveitis) who are refractory or intolerant to conventional therapy.
 - **Dexmedetomidine in Intensive Care Unit (ICU)** – The medicine review of dexmedetomidine for sedation of mechanically ventilated patients in intensive care compared to standard of care was presented for discussion. NEMLC ratified the recommendation against the use of dexmedetomidine for this indication and the medicine review for *publication*.
 - **Sofosbuvir/Velpatasvir in Viral Hepatitis** – It was contextualized that the direct-acting antivirals (DAAs) were previously reviewed by NEMLC in 2017, however, at the time, there were no registered products in South Africa, and thus a decision could not be taken. Recently two DAAs have been registered in South Africa, (1) sofosbuvir-velpatasvir and (2) sofosbuvir-ledipasvir. Sofosbuvir-velpatasvir was selected for review as it covers all genotypes, whereas sofosbuvir-ledipasvir is only indicated in genotypes 1, 4, 5 and 6. NEMLC recommended the sofosbuvir/velpatasvir be included in the EML for viral hepatitis, following updates on the review.
 - **Tacrolimus Extended-Release Formulation** – It was outlined that historically, the public sector had access to immediate release tacrolimus, however, during the previous oncology/immunology HP04 tendering call, a request for the extended-release preparation was received to consider opening up the specifications to include this item. NEMLC approved the Tertiary Committee recommendation to consider addition of extended-release tacrolimus if a tender price similar to that of immediate release tacrolimus can be attained.
 - **Crohn's Disease – Historically Accepted Use Agents** – It was outlined that the TNF-inhibitors are currently under review for the management of Crohn's disease. During this review it was identified that the first line treatment for Crohn's disease is not currently included in the EML for this indication. It was proposed that the inclusion of azathioprine, mercaptopurine and methotrexate be included on the EML for Crohn's disease as historically accepted use, to regularize the process for consideration of the TNF-inhibitors in this indication. NEMLC approved the inclusion of azathioprine, mercaptopurine and methotrexate for the indication of Crohn's disease.

COVID-19

- The following has been reviewed and *ratified for publication*.
 - **Nirmatrelvir and Ritonavir Review** – The initial nirmatrelvir/ritonavir review set out to review the evidence for use in vaccinated individuals. A declared price of product and availability of product in country were listed as review indicators in the 30 March 2023 medicine review version for Nirmatrelvir/ritonavir. A Single Exit Price (SEP) was recently published and the Committee recommended that the review be updated with the price, however, based on the current price and the lack of availability of the product in country, no further work will be done on this review until there is information on generic registration in the country. NEMLC ratified the updated review for *publication*.

HAEMOPHILIA SUBCOMMITTEE

- The following has been reviewed and *ratified for publication*.
 - **Factor VIII prophylaxis** – The medicine review for factor VIII prophylaxis for severe haemophilia patients without inhibitors compared to treatment of bleeds on demand was presented for discussion at NEMLC. NEMLC approved intermediate Factor VIII prophylaxis for severe haemophilia A patients without inhibitors for inclusion on the EML and ratified the medicine review for *publication*. These recommendations will be updated in the STGs and EMLs at next iterations of chapter updates for Paediatric and Adult Hospital Level STGs and EML.