WHO Model Lists of Essential Medicines

2021 update
(22nd EML, 8th EMLc)

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The Model Lists of Essential Medicines (EML) 1977 - 2021

1977 240 medicines

2021

New additions / changes 2021 (88 applications)
- Long-acting insulin analogues
- Medicines for smoking cessation
- Cancer medicines (enzalutamide, everolimus, ibrutinib, rasburicase; new indications for children,...)
- Sumatriptan for acute migraine
- Dental preparations (fluoride toothpaste,...)
- Reserve antibiotic (cefiderocol)
- Antifungal (echinocandins)
- ...

EML: 479 medicines
EMLc: 350 medicines

2007 first EMLc
23rd meeting of the WHO Expert Committee on Selection and Use of Essential Medicines
Virtual meeting 21 June to 2 July 2021 – 88 applications reviewed

The EC recommended:
● Addition of 20 new medicines to the EML
● Addition of 17 new medicines to the EMLc
● Additional indications for 28 already listed medicines
● Additional formulations of 23 already listed medicines
● Deletion of 2 medicines and of specific formulations of 13 medicines
● Update of 72 square box listings, removal of 7 square box listings, review of 23 square box listings recommended

The EC did not recommend:
● 25 proposals for inclusion, change or deletion for 28 medicines, medicine classes or formulations
Cancer medicines

The global cancer burden is significant and increasing

1 in 6 deaths is due to cancer

2018  18.1 mil
2040  29.4 mil

Cancer cases per year globally
Cancer medicines on the EML/EMLc
Historical review

1977
1st WHO EML published
6 cancer medicines

1984
2nd review
24 cancer medicines

1995
1st EMLc
22 cancer medicines for children

1999
2nd review
26 cancer medicines

2007
3rd review
26 cancer medicines

2015
4th review (UICC)
16 new medicines added (22 requested)
[trastuzumab, rituximab, imatinib]

2017
9 new medicines added
(16 requested)
major update of medicines recommended for childhood cancers

2019
2 new medicines added
(7 requested)
EML Cancer Medicines Working Group established

2020
3 new medicines, therapeutic alternatives and new indications for children added
EML: 62 cancer medicines

2021
9 new medicines added
(16 requested)
trastuzumab prequalified as first biosimilar medicine
EMLc: 42 cancer medicines
Recommendations for inclusion of new cancer medicines

- **Everolimus** on the complementary list of the EML and EMLc for the treatment of *subependymal giant cell astrocytoma* associated with tuberous sclerosis complex in patients, mostly children, who are not eligible for surgery.

- **Ibrutinib** on the complementary list of the EML for the treatment of *relapsed/refractory chronic lymphocytic leukaemia* (with and without chromosome 17p deletion)

- **Rasburicase** on the complementary list of the EML and EMLc for the prevention and treatment of *tumour lysis syndrome* (endorsement of single-dose treatment)

- **Enzalutamide** on the complementary list of the EML as a *therapeutic alternative* to abiraterone for treatment of metastatic *castration-resistant prostate cancer*. 
Several new highly-priced cancer medicines were not recommended

- **BRAF and MEK inhibitor combinations** for the treatment of unresectable or metastatic melanoma with BRAF V600 mutation (immune checkpoint inhibitors first choice already listed, feasibility)

- **Cyclin-dependent kinase 4/6 inhibitors** for the treatment of hormone receptor positive/HER2-negative advanced or metastatic breast cancer (immature data, high price)

- **Daratumumab** for the treatment of newly diagnosed and relapsed/refractory multiple myeloma (immature data, high price)

- **Fulvestrant** for the treatment of hormone receptor positive/HER2-negative metastatic breast cancer (immature data, high price)

- **Osimertinib** for first-line treatment of EGFR-mutated locally advanced or metastatic non-small-cell lung cancer (immature data, high price, alternatives listed)

- **PD-1/PD-L1 immune checkpoint inhibitors for** the treatment of non-oncogene addicted, locally advanced or metastatic non-small-cell lung cancer (high price, feasibility)
Essential medicines and highly priced medicines

- Essential medicines are those that satisfy the priority health care needs of the population.

- Essential medicines are selected with due regard to:
  - disease prevalence
  - public health relevance,
  - evidence of efficacy and safety
  - comparative cost-effectiveness*


The Committee recommended establishing an EML Working Group to support the Expert Committee to provide advice to WHO on policies and rules to make highly priced essential medicines more affordable and accessible.

* The absolute cost of a medicine will not be a reason to exclude it from the Model List if it meets the stated selection criteria, and cost-effectiveness comparisons be made among alternative medicines within the same therapeutic group.
Medicines for diabetes

GLOBAL DIABETES COMPACT

uniting the global health community to prevent diabetes and improve access to diagnosis and treatment.
Long-acting insulin analogues
Insulin detemir, insulin degludec and insulin glargine, and their quality-assured biosimilars, as therapeutic alternatives

- The EC recommended inclusion of long-acting insulin analogues on the core list of the EML and EMLc
  - treatment of patients with type 1 or type 2 diabetes mellitus who are at high risk of experiencing hypoglycaemia with human insulin

- Magnitude of clinical benefit of long-acting insulin analogues over human insulin small

- Objective of inclusion to make prequalified human and analogue insulins becoming available and making insulin more accessible and affordable worldwide

- Access to affordable human insulin remains a critical priority, globally
**Sodium-glucose cotransporter-2 (SGLT2) inhibitors**
Empagliflozin (with canagliflozin and dapagliflozin as therapeutic alternatives)

- Recommended addition to the core list of the EML as add-on treatment for adults with type 2 diabetes with or at high risk of cardiovascular disease and/or diabetic nephropathy

- High quality evidence of reduced risk of all-cause mortality, major cardiovascular adverse events and adverse renal outcomes, and a reasonable safety profile.
Antimicrobials

HANDLE

ANTIMICROBIALS

WITH CARE

Antibiotics
Antivirals
Antifungals
Antiparasitics
Antibiotics

• Update of the AWaRe classification

• Addition of cefiderocol on the EML for treatment of adults with multidrug resistant infections due to carbapenem-resistant Enterobacterales and carbapenem-resistant Pseudomonas aeruginosa (classification as Reserve antibiotic in the AWaRe classification)

• Recommendation of several new empiric antibiotic treatment options for infections reviewed in the context of the WHO AWARe antibiotic book

https://www.who.int/publications/i/item/2021-aware-classification
https://www.who.int/publications/m/item/the-who-essential-medicines-list-antibiotic-book-improving-antibiotic-awareness
Antituberculosis medicines - Antifungals – Antivirals - Antiparasitics

• Addition of several new formulations of **antituberculosis medicines** for treatment and prevention of **tuberculosis**
  ◦ Inclusion of rifapentine and moxifloxacin on the core list of the EML for the new indication of treatment of drug-susceptible tuberculosis

• Addition of **echinocandins** (micafungin with a square box indicating caspofungin and anidulafungin as therapeutic alternatives) on the complementary list of the EML and EMLc for the empiric treatment of suspected or proven **invasive Candida infections**

• Addition of **albendazole**, **mebendazole** and **praziquantel** on the complementary list of the EML and EMLc for the new indication of treatment of diseases caused by **taeniid cestode infections**

• Addition of new strength, **child-friendly formulation of dolutegravir** on the EMLc for the treatment of **HIV infection** in children and **deletion of several formulations / strengths**

• Addition of several **fixed-dose combinations of direct acting antivirals** to the EMLc for the treatment of children with **chronic hepatitis C virus infection**
Further additions
Medicines for smoking cessation

• Inclusion of bupropion and varenicline on the core list of the EML for use as an aid to smoking cessation
• Complements nicotine replacement therapy already listed on the EML since 2009
• The availability of different smoking cessation increases choice for patients and clinicians and may increase access and affordability through competition and reduced prices
• Integration into comprehensive approach to smoking cessation
Some further additions recommended by the EC

- **Sumatriptan** on the core list of the EML for the treatment of adult patients with acute **migraine**
- **Tacrolimus** on the complementary list of the EML and EMLc for use as maintenance immunosuppression following **organ transplantation**
- **Calcipotriol** on the core list of the EML and EMLc for the treatment of moderate forms of **psoriasis**
- **Equine rabies immunoglobulin** and **antirabies virus monoclonal antibodies** to the core list of the EML and EMLc for use as part of **rabies postexposure prophylaxis**
- **Ethinylestradiol + etonogestrel contraceptive vaginal ring** to the core list of the EML
- **Multiple micronutrient supplement tablets** on the core list of the EML for use as an **antenatal supplement** in pregnant women
- **Fluoride toothpaste** on the core list of the EML and EMLc
- **Glass ionomer cement** and **silver diamine fluoride preparations** on the core list of the EML and EMLc for the prevention and treatment of **dental caries**
Supporting country implementation

https://apps.who.int/iris/handle/10665/330898

https://global.essentialmeds.org/
Thank you for your attention!

24th Expert Committee on Selection and Use of Essential Medicines

24 – 28 April 2023 | 20 Avenue Appia - CH-1211 Geneva 27, Geneva, Switzerland

The meeting of the 24th WHO Expert Committee on the Selection and Use of Essential Medicines will take place from 24 to 28 April 2023 at WHO Headquarters in Geneva. The purpose of the meeting will be to revise and update the WHO Model List of Essential Medicines (EML) and the WHO Model List of Essential Medicines for Children (EMLc).

Special thanks to the EML team (Bernadette Cappello, Lorenzo Moja, Irina Nozdrina), consultants, WHO colleagues from other departments, experts,....
More information

Executive Summary, 23rd Expert Committee Meeting
https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.01

22nd WHO Model List of Essential Medicines (2021)
https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02

8th WHO Model List of Essential Medicines for Children (2021)
https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.03

2021 AWaRe Classification database
https://www.who.int/publications/i/item/2021-aware-classification

WHO Technical Report Series, No. 1035
https://www.who.int/publications/i/item/9789240041134

Information for applicants preparing a submission for the 2023 update
https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2022.01