The selection and use of essential medicines, 2025

Report of the 25th WHO Expert Committee on Selection and Use of Essential Medicines, executive summary

World Health Organization

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WHO AWaRe (access, watch, reserve) classification of antibiotics for evaluation and monitoring of use, 2025.

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Acknowledgements

WHO gratefully acknowledges the significant contributions of the Expert Committee members and temporary advisers who participated in the meeting of the 25th WHO Expert Committee on Selection and Use of Essential Medicines, Geneva, Switzerland, from 5 to 9 May 2025.

List of participants

Expert Committee members

Loice Achieng Ombajo, Infectious disease specialist and senior lecturer, Department of Medicine and Co-director of the Center for Epidemiological Modelling and Analysis, University of Nairobi, Nairobi, Kenya.

Elie Akl, Professor of Medicine and Vice Provost for Research, American University of Beirut, Beirut, Lebanon.

Rita Banzi, Clinical pharmacologist, head of the Centre for Health Regulatory Policies, Mario Negri Institute, Milan, Italy.

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Bishal Gyawali, Medical Oncologist and associate professor in medical oncology and public health sciences, Queen's University, Kingston, Canada.

Patrick Okwen, District medical officer and health economist; Team lead at Effective Basic Services Africa (eBASE), Bali, Cameroon.

Claudia Garcia Serpa Osorio de Castro, Pharmacist, Professor and Senior Researcher in Public Health, Sergio Arouca National School of Public Health, Oswaldo Cruz Foundation, Rio de Janeiro, Brazil.

Gabriela Prutsky Lopez, Assistant Professor of Pediatrics and pediatric hospitalist, Mayo Clinic, Mankato, United States of America; co-founder of Unidad de Conocimiento y Evidencia (CONEVID), Universidad Peruana Cayetano Heredia, Lima, Peru.

Andrew Roberts, Clinical Haematologist, Royal Melbourne Hospital and Peter MacCallum Cancer Centre; Professor and deputy director, the Walter & Eliza Hall Institute; Metcalf Chair of Leukaemia Research, University of Melbourne, Melbourne, Australia.

Zoubida Tazi Mezalek, Professor of Internal Medicine and Head of the Clinical Hematology Department, Faculty of Medicine and Pharmacy, Mohammed V University of Rabat, Rabat, Morocco.

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Temporary advisers

Melissa Barber, Health economist, Yale Collaboration for Regulatory Rigor, Integrity and Transparency (CRRIT), Yale University School of Medicine, New Haven, United States of America.

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Rehab Rayan, Consultant, EML Secretariat, Department of Health Product Policy and Standards, Access to Medicines and Health Products.

Nathália Alvarez, Intern, EML Secretariat, Department of Health Product Policy and Standards, Access to Medicines and Health Products.

External invited presenters during the Open Session

Michael Muenzberg, Chief Executive Officer, Targeted Solutions AG, Zug, Switzerland.

Declaration of interests

To be effective, the work of WHO and the contributions of its experts must be, and must be perceived to be, objective and independent. In this regard, to ensure the highest integrity and public confidence in its activities, WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to a potential or reasonably perceived conflict of interest related to the subject of the activity in which they will be involved. Declarations of interest and management of any disclosures is an important process governed by the WHO Guidelines for Declaration of Interests (WHO Experts). More information on WHO's policy on declarations of interest is available on the WHO website *(1)*.

Before being invited to participate in the 25th meeting of the WHO Expert Committee on the Selection and Use of Essential Medicines, all experts submitted written declarations of interest. In reviewing and assessing these declarations, the Secretariat of the WHO Essential Medicines List sought the advice of the Office of Compliance, Risk Management and Ethics.

The declaration of interest process resulted in the participation of the Expert Committee Members, Temporary Advisers and invited external speakers during the Open Session, as reported in the list of participants.

Experts who declared having no conflicts of interest were Elie Akl, Rita Banzi, Francesco Ceppi, Patrick Okwen and Gabriela Prutsky-Lopez.

The following experts disclosed interests, which were assessed by the Secretariat for actual or potential conflicts and management strategies (if required).

Committee members

Loice Achieng Ombajo disclosed receiving honoraria from GSK to serve on a scientific advisory board for the Africa Open Lab research programme, supporting the selection of high-quality infectious diseases research proposals that have the potential to deliver significant health impact in Africa (interest ceased in 2024). She disclosed having received honoraria from Merck Sharp and Dohme for speaker engagements and conference travel on topics not related to medicines under evaluation at this meeting (interest ceased in 2024). The latter payment was below the threshold of significant financial interest. She disclosed funding to her institution (University of Nairobi) from ViiV Healthcare and Gilead Sciences for investigator-initiated clinical trials on medicines for HIV, for which she is the principal investigator. The three trials investigated switching between antiretroviral treatments (i.e. bictegravir, emtricitabine and tenofovir alafenamide to dolutegravir/lamivudine; ritonavir-boosted protease inhibitor regimen to dolutegravir; antiretroviral regimen to bictegravir, emtricitabine and tenofovir alafenamide). These trials do not include antiretroviral treatments under evaluation at this meeting. Dr Achieng Ombajo is the principal investigator of a country grant programme to improve surveillance of *Candida auris* in Kenya (funded by the US Centers for Disease Control and Prevention). She also disclosed funding to the university from the Gates Foundation for studying optimal management of dolutegravir failure, for which she is the principal investigator and for the Center for Epidemiological Modelling and Analysis. These disclosures were considered minor and did not require further management. Dr Achieng Ombajo currently serves as the Chair of the WHO Technical Advisory Group on AWaRe (TAG-AWaRe) and was involved in the TAG-AWaRe's evaluation of antibiotic applications under consideration at the Expert Committee meeting. This position is unpaid. This disclosure was considered not to represent a conflict.

Elisabeth de Vries disclosed that she served as an expert in data safety monitoring committees for an ongoing trial investigating atezolizumab in adjuvant breast cancer sponsored by a non-profit research programme (National Surgical Adjuvant Breast and Colon Project) and for a completed trial investigating trastuzumab deruxtecan in advanced breast cancer sponsored by a for-profit company (Daiichi Sankyo). She also disclosed that she provided advice to Crescendo Biologics on improving the quality of the design and conduct of preclinical and phase I clinical studies exploring biological activity of bispecific molecules for the treatment of cancers. Sponsors provide funding to

Dr de Vries' institution (University Medical Center Groningen) to cover her time commitment. She also disclosed that her institution is involved in early-phase clinical trials to explore the therapeutic and diagnostic/prognostic roles of cancer medicines and biomarkers. Her institution receives institutional funding from Amgen, Crescendo Biologics, Genentech, G1 Therapeutics, Regeneron, Roche and Servier. In two cases, the studies involved using medicines under evaluation at this meeting (atezolizumab and cemiplimab). However, these studies as well as the others, assessed radioactive tracers used in imaging tests to monitor disease progression in patients with solid tumours and did not involve assessment of medicines. Payment was made to the institution and no personal salary support was received. These disclosures were considered to be unrelated, or not directly related, to the subject matter of the Expert Committee meeting and did not require further management. Regarding public statements and positions, Professor de Vries disclosed that she is a member of the European Society of Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS) working party and of the ESMO Cancer Medicines Working Group and was a member of the Response Evaluation Criteria in Solid Tumours (RECIST) Committee. These disclosures were considered not to represent a conflict.

Claudia Garcia Serpa Osorio de Castro disclosed that she has received grant funding for consultancy work from Oswaldo Cruz Foundation Funding Agency to support a project on litigation for access to high-cost medicines sponsored by the Brazilian Ministry of Health and research grant funding from the Brazilian National Council for Scientific and Technological Development. She also disclosed being a member of the Medicines Registration Technical Committee at the Brazilian Health Regulatory Agency, Anvisa, an unpaid position. These disclosures were considered not to represent a conflict and did not require further management.

Bishal Gyawali disclosed receiving consult fees from Vivio Health, a public benefit company, to provide patient-specific advice on treatment strategies. He declared having held stock options of OneCell Diagnostics (a liquid biopsy technology company, now divested). These disclosures were considered minor, unrelated to the subject matter of the Expert Committee meeting and did not require further management.

Zoubida Tazi Mezalek disclosed receiving honoraria below the threshold for significant financial interest from pharmaceutical companies for participating in advisory boards on herpes zoster vaccine (GSK) and asciminib for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Novartis). These disclosures were considered minor, unrelated to the subject matter of the Expert Committee meeting and did not require further management.

Andrew Roberts disclosed collaboration with BeiGene and research support to his institution from BeiGene for studies evaluating zanubrutinib, a medicine under evaluation at this meeting. These collaborations date back more than 4 years (i.e. 2014), the current limit to which the WHO's conflict of interest assessment extends. Nevertheless, this disclosure was assessed in detail. The first study (NCT02343120) is a phase I study in patients with relapsed/refractory B-cell malignancies, receiving dose-escalating zanubrutinib *(2)*. The study primarily assessed safety, tolerability and pharmacokinetics/pharmacodynamics. A second study (NCT02343120) evaluated zanubrutinib in a phase I/II study in patients with Waldenström macroglobulinemia *(3)*. Subsequently, data from this trial were included in a safety analysis of zanubrutinib based on data from six pooled studies *(4)*. The long-term monitoring phase of the study, to follow up surviving enrolled participants on the trial, will cease in 2025, as per standard practice in this type of study. Given the distant timing and the fact that the studies were phase I/II or focused on the safety and toxicity of zanubrutinib, and that none of the identified studies was used to support the request of the application received, this disclosure, made verbally at the start of the meeting, was considered minor and did not require further management.

Professor Roberts disclosed that he receives financial benefit from his employer, the Walter and Eliza Hall Institute (WEHI), in the form of a share of the income the Institute has received related to the drug venetoclax. Venetoclax was created during a partnership between WEHI and the pharmaceutical companies AbbVie and Genentech. AbbVie and Genentech are responsible for the commercial development of venetoclax. WEHI has no role in its clinical trial development, commercialization or marketing. WEHI has a commercialization policy that allows distribution of a small

share of any royalties and commercial income to staff who have invented or made a major contribution to the product. The amounts received by individual staff are based on specific criteria related to their contributions and are not related to the outcome of clinical trials, nor to future drug sales. In 2017, WEHI entered a commercial agreement with CPPIB Credit Europe S.à r.l., a wholly owned subsidiary of the Canada Pension Plan Investment Board, trading future venetoclax royalties for a lump-sum payment. Professor Roberts disclosed that he was a major contributor to research that led to venetoclax, but is not a patent holder, and to early clinical trial discovery research. His contributions pre-date the 2017 commercial agreement with the Canadian pension fund. For his contribution, he has been awarded a small fraction of past commercial income to WEHI, which is diversified, independently managed and paid by his employer. Venetoclax was not under evaluation by the Expert Committee at this meeting, but it can be used as an alternative to or as a partner in combination with inhibitors of Bruton's tyrosine kinase (e.g. ibrutinib, already included in the EML, and zanubrutinib, under evaluation during the meeting). Any interest or interests that could directly influence, or could appear to influence, his professional judgement in relation to the subject matter of the Expert Committee meeting were not identified.

Professor Roberts disclosed he is the chair of the Life Saving Drugs Program Expert Panel which advises the Australian Government on the appropriateness of public subsidy for medicines to treat patients with ultra-rare conditions that are not considered cost-effective at the time of the evaluation. He also disclosed that in 2023 and 2024 he served on the Health Technology Assessment Review Reference Committee appointed by the Australian Government to provide recommendations about the conduct of Health Technology Assessment in Australia. Both positions are remunerated. These disclosures were considered not to represent a conflict and did not require further management.

Indah Widyahening disclosed that her institution received a research sponsorship from PT Sarihusada Generasi Mahardhika, a nutritional products company, for a study of growth tracker using artificial intelligence. This disclosure was considered minor and did not require further management.

Mei Zeng disclosed receiving research support for her research unit from Shanghai Roche Pharmaceuticals Ltd for a clinical trial of baloxavir marboxil in paediatric and adolescent patients with influenza. Her role in the study is lead principal investigator. This trial did not include medicines under evaluation at this meeting. This disclosure was considered minor and did not require further management.

Temporary advisers

Alfonso Iorio disclosed receiving research support for his institution, McMaster University, from F. Hoffmann-La Roche Ltd for an observational study on the long-term effectiveness and safety of emicizumab in people with haemophilia A based on the Canadian Hemophilia Bleeding Disorders Registry. Emicizumab is a medicine under evaluation at this meeting. This disclosure was considered minor. As a temporary adviser to WHO during the Expert Committee meeting, Professor Iorio participated in the discussion about medicines and blood products used in bleeding disorders but did not participate in the decision-making nor in formulating the recommendations on emicizumab.

Melissa Barber reported employment as a consultant for Médecins Sans Frontières. This disclosure was considered not to represent a conflict. As a temporary adviser to WHO during the Expert Committee meeting, Dr Barber participated in discussions about market analyses of medicines under evaluation but did not participate in the decision-making or in formulating the recommendations.

Invited external speakers during the Open session

Michael Muenzberg declared having provided consultancies to advance affordable medicines, collaborating with regulators and suppliers from low- and middle-income countries. All consultancies were unpaid. He declared that in 2024, he funded a Switzerland-based platform to support global access efforts to medicines, with a primary interest in biosimilars.

Executive summary

The meeting of the 25th WHO Expert Committee on the Selection and Use of Essential Medicines took place at WHO headquarters in Geneva, Switzerland, from 5 to 9 May 2025. The aim of the meeting was to review and evaluate applications for the 24th WHO Model List of Essential Medicines (EML) and the 10th WHO Model List of Essential Medicines for Children (EMLc) (the "Model Lists").

Essential medicines are those that satisfy the priority health care needs of a population. They are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. They are intended to always be available in functioning health systems, in appropriate dosage forms, of assured quality and at prices individuals and health systems can afford.

The WHO Model Lists are updated every two years, intended as a guide for countries or regional authorities to adopt or adapt in accordance with local priorities and treatment guidelines for the development and updating of national essential medicines lists. Selection of a limited number of medicines as essential, taking into consideration national disease burden and clinical need can lead to improved access through streamlined procurement and distribution of quality-assured medicines, support more rational or appropriate prescribing and use, and lower costs for both health care systems and for patients.

The Expert Committee considered a total of 59 applications, including 31 proposals for the addition of new medicines or medicine classes, 10 proposals for new indications for currently listed medicines, three proposals for the addition of new formulations of currently listed medicines, one proposal for the removal of a currently listed medicine, and 14 other applications relevant to the Model Lists and the WHO AWaRe classification of antibiotics. In accordance with procedures endorsed by the 109th Executive Board in the Report by the Secretariat EB109/8 in 2001, the Expert Committee reviewed and evaluated the scientific evidence for the effectiveness, safety, and comparative cost and cost-effectiveness of the medicines in question.

In summary, the Expert Committee:

- recommended the addition of 20 new medicines to the EML (16 to the core list and 4 to the complementary list);
- recommended the addition of 15 new medicines to the EMLc (12 to the core list and 3 to the complementary list);
- recommended adding additional indications for 7 currently listed medicines;
- recommended the addition of new formulations of 19 medicines on the EML and of 49 medicines on the EMLc;
- recommended the deletion of 3 medicines from the EML and 4 medicines from the EMLc and of specific formulations of a further 20 medicines from the EML and 29 medicines from the EMLc; and
- did not recommend proposals for addition of new medicines, or new indications for 24 medicines, or medicine classes.

The recommended changes bring the total number of medicines (including fixed-dose combinations) on the EML to 523 (from 502 in 2023), including 374 on the EMLc (from 361 in 2023). These totals do not include medicines recommended on the Model Lists as therapeutic alternatives.

Changes to the Model Lists are shown in Tables 1 – 3. Applications for proposed changes to the Model Lists that were not recommended are shown in Table 4. Changes to the AWaRe classification of antibiotics are shown in Table 5.

The Expert Committee's recommendations are briefly described in this document.

All applications and documents reviewed by the Expert Committee are available on the WHO website *(5)*.

Section 1: Anaesthetics, preoperative medicines, and medical gases

Section 1.1.1 Inhalational medicines

The Expert Committee recommended:

- the removal of halothane from the EML and EMLc to reinforce the importance of prioritizing alternative inhalational anaesthetic agents (e.g. sevoflurane);
- the inclusion of a note with the listing of nitrous oxide on the EML and EMLc regarding preferential supply via point-of-care cylinders instead of centrally supplied (piped) delivery systems.

The Expert Committee recognized that halothane and nitrous oxide are potent greenhouse gases and ozone depleting substances with significant environmental consequences. These recommendations support efforts to reduce the impact of essential anaesthetic gases on climate change. The Expert Committee considered that substitution of halothane with alternatives that have a lower propensity for environmental impact (e.g. sevoflurane) while delivering high-quality care is an important action for health care systems. Equally, minimizing system waste and adopting a nitrous oxide waste reduction strategy and transitioning to point-of-care cylinders from centrally piped infrastructure should be encouraged in national health care systems.

Section 5: Medicines for neurological disorders

The Expert Committee endorsed changes to the structure of Section 5 of the Model Lists, incorporating the suggestions made by Médecins Sans Frontières in the contribution received during the public consultation period. Additional changes to this section following other recommendations made during the meeting are also endorsed. The changes are summarized in Table 3.

Section 5.1 Medicines for central nervous system disorders

The Expert Committee did not recommend inclusion of risdiplam on the EML and EMLc for use in the treatment of spinal muscular atrophy at this time. As was the case when an application for risdiplam was considered by the 2023 Expert Committee, the Committee noted that greater benefits of treatment in terms of motor function were observed in younger children. In particular, the Committee noted the preliminary reporting of positive and relevant outcomes from the RAINBOWFISH trial in pre-symptomatic infants, but that the trial results have to date only been reported in a conference presentation and have not yet been evaluated by the clinical and scientific community and published in a peer-reviewed journal. As such, the internal and external validity of the results could not be fully assessed by the Expert Committee due to limited available information. The Committee requested that a further update be sought in a resubmission to the 2027 Expert Committee meeting, with the latest published RAINBOWFISH trial results. The Committee also considered that if the preliminary results of the 24-month follow-up of the RAINBOWFISH trial are confirmed for patient-important outcomes (e.g. ability to sit without support, need for respiratory support), if the risk of bias associated with the trial is low, if eligible pre-symptomatic patients can be identified, and if no evidence emerges against use of risdiplam in this population (e.g. serious safety concerns), then a positive recommendation to include risdiplam on the EMLc could be possible in the future.

Section 5.1.1 Antiseizure medicines

The Expert Committee recommended extending the listing for prednisolone on the EMLc to include the new indication of infantile epileptic spasms syndrome, based on clinical need, evidence of favourable effectiveness and safety, lower costs and better cost-effectiveness than alternative first-line treatment options.

Section 5.1.4 Medicines for cerebral palsy

The Expert Committee recommended the addition of intrathecal baclofen to the EML and EMLc in the treatment of spasticity associated with cerebral palsy based on evidence of a favourable balance of efficacy and harms. Oral baclofen was also recommended for addition in recognition of its use to assess responsiveness to intrathecal therapy

prior to surgery to install the administration pump, as a complementary therapy during the intrathecal dose titration when the pump is installed, as supportive therapy when intrathecal baclofen therapy is discontinued, and to prevent and treat baclofen withdrawal, which can be severe and life-threatening.

Section 5.1.5 Medicines for headache disorders

The Expert Committee did not recommend inclusion of carbamazepine for the new indication of trigeminal neuralgia because the available clinical evidence was of insufficient quality and therefore confidence in the reported benefits and harms was limited.

Section 5.1.5.1 Medicines for acute migraine attacks

The Expert Committee recommended the addition of eletriptan, ibuprofen and naproxen to the EML for acute treatment of migraine based on evidence of favourable benefit to harm profiles, and the possibility of increasing the choice of medicines for acute migraine for patients, while maintaining a parsimonious number of options at the pharmacological class level. Naproxen is listed as a therapeutic alternative to ibuprofen and eletriptan is listed as a therapeutic alternative to sumatriptan under square box listings.

Section 5.1.5.2 Medicines for migraine prophylaxis

The Expert Committee did not recommend inclusion of amitriptyline or bisoprolol for migraine prophylaxis due to inadequate evidence for relative benefit compared to currently listed propranolol. The Committee did not recommend inclusion of fremanezumab for prophylaxis of high-frequency or chronic migraine. The Committee considered that fremanezumab demonstrated favourable outcomes compared to placebo. However, the absence of direct comparative evidence for fremanezumab versus currently listed propranolol and resultant uncertainty regarding the relative benefit made it impossible to adequately justify the substantial cost difference between the two medicines.

Section 5.1.5.3 Medicines for cluster headache

The Expert Committee recommended inclusion of sumatriptan, prednisolone and verapamil in the EML for the acute treatment and prophylaxis of cluster headache based on a favourable balance of benefits to harms, while also noting the key role of rapid-flow oxygen for this indication.

Section 6: Anti-infective medicines

Section 6.1.2 Antifilarials

The Expert Committee recommended inclusion of moxidectin on the EML and EMLc as a therapeutic alternative to ivermectin for treatment of onchocerciasis and lymphatic filariasis based on evidence of a favourable balance of benefits to harms.

Section 6.1.3 Antischistosomals and other antitrematode medicines

The Expert Committee recommended inclusion of arpraziquantel, a dispersible or orodispersible tablet, on the EMLc for the treatment of schistosomiasis in preschool-aged children based on evidence of similar efficacy and safety when compared with praziquantel. The Committee recognized the medical need for a more palatable, easy-to-administer paediatric formulation of praziquantel and efforts to develop innovative orodispersible tablet formulations for praziquantel for paediatric use. The Committee noted that arpraziquantel is the active enantiomer of praziquantel. The Committee considered that the proposed formulation was age-appropriate for the target population, allowing precise dosing of children and infants of different body weights and with better palatability and acceptability than praziquantel for this age group. Listing is recommended for arpraziquantel as a therapeutic alternative to praziquantel (which remains the class representative) under a square box listing.

Section 6.2.3 Reserve group antibiotics

The Expert Committee did not recommended the inclusion of imipenem + cilastatin + relebactam for the treatment of infections caused by multidrug-resistant organisms for the same reasons as given by the previous Expert Committee: imipenem + cilastatin + relebactam lacks in vitro activity against the carbapenemase genotypes most commonly associated with carbapenem resistance in Enterobacterales globally, and other reserve antibiotics with a similar spectrum of activity are already included on the Model Lists. However, the Committee advised that future evaluation of an application for inclusion of imipenem + cilastatin + relebactam on the Model List could be considered following any changes to the definition of the AWaRe Reserve category arising from the planned revision (see Other matters considered by the Expert Committee).

Section 6.2.5 Antituberculosis medicines

The Expert Committee recommended inclusion of a dispersible tablet formulation of rifapentine 150 mg on the EMLc for use in tuberculosis preventive treatment regimens in children in accordance with recommendations in WHO guidelines.

The Committee recommended removal of the footnote regarding the limitation for use of rifabutin only to patients with HIV receiving protease inhibitors, and to transfer the listings of medicines used in multidrug-resistant tuberculosis from the complementary (e.g. secondary care level) to the core list (e.g. primary care level).

Section 6.4.2 Antiretrovirals

The Expert Committee recommended inclusion of a fixed-dose combination dispersible tablet formulation of abacavir + dolutegravir + lamivudine on the EMLc for the treatment of children with HIV in accordance with recommendations in WHO guidelines.

Section 6.4.3 Other antivirals

The Expert Committee recommended the removal of ribavirin from the EML and EMLc as a treatment for viral haemorrhagic fevers. The Committee noted how the interpretation of evidence supporting ribavirin for viral haemorrhagic fevers (VHFs) has shifted significantly since the 1980s. Ribavirin was recommended as a routine treatment based largely on a quasi-experimental study conducted during that time, which suggested potential benefits, particularly in Lassa fever. However, that early evidence was methodologically limited, with substantial risks of bias, including lack of randomization, small sample sizes and inadequate control groups. Over time, as standards for evaluating clinical interventions have become more rigorous, the limitations of the original evidence have become more apparent. Recent reviews have highlighted the lack of high-quality randomized controlled trials and have raised concerns about the potential for harm, such as haemolytic anaemia and other adverse effects. The Committee noted that WHO guidance for the clinical management of VHFs is currently under development in which it is expected that ribavirin treatment will be recommended only within the context of clinical trials to evaluate safety and efficacy.

Section 6.5.5 Antitrypanosomal medicines

The Expert Committee recommended extending the listing for fexinidazole on the EML and EMLc to include the new indication of treatment for first- and second-stage human African trypanosomiasis due to *Trypanosoma brucei rhodesiense* in adults and children aged 6 years and older based on evidence of effectiveness and safety compared to alternative treatments. Compared to suramin (for first stage) or melarsoprol (for second stage), fexinidazole is the preferred treatment for both stages of the disease, is administered orally and it is not associated with fatal reactive encephalopathy, a rare but severe and often deadly complication of melarsoprol.

Section 7: Medicines for cystic fibrosis

The Expert Committee recommended the inclusion of elexacaftor + tezacaftor + ivacaftor fixed-dose combination and single-agent ivacaftor on the core list of the EML and EMLc for the treatment of cystic fibrosis in people aged 2 years

and older with at least one F508del mutation or another responsive cystic fibrosis transmembrane conductance regulator (CFTR) mutation based on evidence of a favourable balance of benefits to harms. The Committee acknowledged the relevant benefits across multiple outcomes, including improvement in lung function, reduction in pulmonary exacerbations due to infections or inflammation, improvements in quality of life and potential to prevent or at least delay long-term complications, including premature death. The Committee recognized that the evidence base supporting use of elexacaftor + tezacaftor + ivacaftor is solid, originating in multiple high-quality randomized controlled trials and with post-approval observational studies confirming effectiveness and safety in more populations than those enrolled in trials. The Committee noted that elexacaftor + tezacaftor + ivacaftor therapy is effective for most patients with cystic fibrosis, significantly expanding the cohort of patients that can benefit from this therapy compared to earlier CFTR modulators, which only benefited smaller subgroups. The Committee acknowledged the high cost and limited availability of the medicines but considered that inclusion could support efforts to expand regulatory approval across countries, stimulate generic development and promote equitable access and affordability. Listing is recommended in a new section of the Model Lists for medicines for cystic fibrosis.

Section 8: Immunomodulators and antineoplastics

Section 8.2.1 Cytotoxic medicines

The Expert Committee did not recommend the inclusion of temozolomide on the EML and EMLc for the treatment of high-grade glioma (as monotherapy), relapsed or refractory high-risk neuroblastoma (in combination with irinotecan or topotecan), relapsed Ewing sarcoma (in combination with irinotecan), or as monotherapy for treatment of other relapsed or refractory paediatric solid tumours as palliative treatment. The Committee noted that temozolomide has not been demonstrated to improve survival in patients with neuroblastoma or Ewing sarcoma, and while the medicine has shown a small survival benefit in some patients with high-grade glioma, the evidence is limited. Temozolomide is also associated with an increased risk of severe haematological toxicity. Thus, the Committee considered that the balance of benefit to harm was not favourable.

Section 8.2.2 Targeted therapies

The Expert Committee did not recommend the inclusion of panitumumab, a monoclonal antibody targeting the epidermal growth factor receptor (EGFR), on the EML for the treatment of KRAS wild-type metastatic colorectal cancer based on evidence of limited survival benefit and risk of harms. The Committee noted that the overall survival benefit in the second- and third-line settings was below the established threshold for EML eligibility (i.e. a minimum overall survival benefit of 4–6 months). In the first-line setting the overall survival benefit was modest and not consistent across all patients and may be influenced by factors like tumour location and additional RAS/BRAF mutations. The Committee noted the need to exclude patients with RAS mutations, given that the addition of panitumumab to chemotherapy in this population has been shown to decrease overall survival. The Committee also noted substantial toxicities.

The Expert Committee recommended the inclusion of zanubrutinib, a Bruton's tyrosine kinase inhibitor, on the EML for the treatment of relapsed or refractory chronic lymphocytic leukaemia/small lymphocytic leukaemia (CLL/SLL) based on evidence of a survival advantage compared to chemo-immunotherapy, and similar survival benefit to that previously observed for ibrutinib, with fewer side effects (e.g., less atrial fibrillation and bleeding in some trials). Evidence in the first-line setting is promising but is not yet as well established as in the relapsed or refractory setting. An application presenting the evidence for this class of medicines in the first-line treatment of CLL/SLL is encouraged for 2027. Listing is recommended for zanubrutinib as a therapeutic alternative to ibrutinib (which remains the class representative) under a square box listing. The Committee acknowledged that ibrutinib remains highly priced in most countries. Ibrutinib may face competition from newer-generation BTK inhibitors like zanubrutinib, which is more accessible in some countries, with a better domestic cost-effectiveness profile and potentially could better align with local medicine policy priorities.

Section 8.2.3 Immunomodulators

The Expert Committee recognized that cancer is a growing societal, public health and economic problem globally, and is responsible for nearly one in three premature deaths from noncommunicable disease. The proportion of patients with advanced stage at first presentation remains substantial. Solid tumors that are amenable to effective therapy using PD-1/PD-L1 immune checkpoint inhibitors represent major causes of rising burdens with respect to lives lost and costs of management. The Committee noted the rapid pace of innovation in immuno-oncology and emphasized the importance of reducing inequities in cancer care by increasing access to immune checkpoint inhibitors, among other strategies.

In consideration of the application proposing inclusion on the EML of multiple PD-1 / PD-L1 immune checkpoint inhibitors for multiple cancer indications, the Expert Committee:

- appreciated the approach taken by the WHO Collaborating Centre on Evidence Synthesis and Evaluation of Novel Cancer Therapies at the University of Cologne, Germany, to identify the PD-1 / PD-L1 immune checkpoint inhibitor–indication pairings proposed for EML listing from among the many approved and available. The Committee considered that the approach taken was up-to-date, comprehensive, systematic, transparent and evidence based and provided a solid basis for its decision-making;
- noted that all proposed pairings are approved by the European Medicines Agency for the first-line treatment of adults for the therapeutic indications for which they are proposed, have evidence from randomized trials, and received a score of four or higher on the European Society of Medical Oncology's Magnitude of Clinical Benefit Scale in the non-curative setting;
- applied the EML principle for cancer medicines to demonstrate at least 4-6 months overall survival gain in randomized controlled trials;
- appreciated and took into consideration the review of the application undertaken by the EML Cancer Experts group and the evidence to decision frameworks following the GRADE approach prepared by the Secretariat.

The Committee favoured pairings where the evidence strongly supported a large benefit-to-risk ratio. The Committee considered monotherapy more positively than combination therapy for indications where both are approved and a trade-off between additional efficacy, toxicity and cost would typically occur.

The Expert Committee **recommended** the inclusion of the following:

- pembrolizumab, atezolizumab and cemiplimab as first-line monotherapy of metastatic non-small cell lung cancer with ≥50% PD-L1 expression. EML listing is for pembrolizumab with a square box as class representative and atezolizumab and cemiplimab as specified therapeutic alternatives;
- pembrolizumab as first-line monotherapy for deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) metastatic colorectal cancer;
- pembrolizumab, in combination with platinum-based chemotherapy, as first-line treatment of metastatic cervical cancer with ≥1% PD-L1 expression.

The Committee considered that these recommendations for inclusion provide the best chance at minimizing financial toxicity and concentrating expenditure into the areas with the most favorable incremental gain in benefit to risk ratio. The Committee noted that use of immune checkpoint inhibitors in adults with solid tumours that have predictive biomarkers (e.g., high PD-L1 expression for non-small cell lung cancer) rather than all patients is the highest priority, to enable greater access in settings where budgetary constraints may require prioritization of scenarios that offer the greatest clinical value.

With the recommendation to list pembrolizumab for the above-mentioned indications, the Committee recommended changing the current square box listing of nivolumab as the class representative and pembrolizumab as a specified therapeutic alternative for metastatic melanoma, to make pembrolizumab the class representative with nivolumab as

specified therapeutic alternative. This is intended to signal to countries the possibility of aggregating procurement of a single molecule, pembrolizumab, across multiple cancer indications, influencing price negotiations with manufacturers. Limiting procurement fragmentation by focusing on a select few immune checkpoint inhibitors is likely to facilitate central purchasing through competitive tendering and better competition from pembrolizumab biosimilars, thereby increasing access.

In addition to its recommendations on which immune checkpoint inhibitors to prioritize for inclusion on the EML, the Committee also recognized the value and recommended the use of strategies to improve access, particularly in resource-constrained settings, as presented in the report from the EML cancer experts consultation meeting. The Committee noted that these strategies were based on evaluation of available evidence and pragmatic considerations. The Committee considered the strategies to improve access to care in two components: clinical strategies and health system strategies. The Committee acknowledged that while clinical strategies (over which doctors and patients have greater control) and health system strategies (requiring government-led policy legislations and reforms) should complement each other, clinical strategies can be implemented immediately, delivering rapid benefits for access.

Clinical strategies – doctors and patients

The Committee acknowledged the importance of patients being empowered to make an informed and consensual decision about their treatment, including information on benefits, harms, accessibility, and feasibility of care. This might require comparing alternatives that may differ from each other in one or more of the aforementioned dimensions. Strategies that can be considered to improve access include: dose optimization according to patient weight (weight-based dosing); rounding down doses to the closest vial size and strength (dose banding); or hybrid dosing regimens that combine the two; and if relevant, vial sharing. Additionally, longer intervals between treatment administration or shorter durations of treatment can be also considered. The Committee also noted that ongoing studies are investigating outcomes with “ultra-low dose” immunotherapy. If the results are favourable, ultra-low dose immunotherapy could be a viable strategy to further improve access.

Health system strategies – policy makers

To enable better value procurement through tendering and competition leading to increased access for individuals and health systems, the Committee recommended that national policies should take advantage of similar clinical performance among different immune checkpoint inhibitors, regardless of their biological target (i.e. PD-1 or PD-L1). The Committee opted to recommend four immune checkpoint inhibitors for non-small cell lung cancer using the square box concept, indicating interchangeability at the health system level for this indication. The recommended medicines have different pharmacological properties but are considered therapeutic alternatives. Where there is no relevant difference in terms of efficacy and safety data, the preferred medicine at country level should be the one that is generally available at the lowest price. At the country level, the interpretation of the square box should be extensive (i.e. a class effect), potentially covering other equally effective and safe immune checkpoint inhibitors of assured quality where these are offered at an advantageous price.

The Committee also recommended that quality assured biosimilars of the listed immune checkpoint inhibitors be considered therapeutic alternatives to the corresponding reference medicine (even if not yet available), to signal to countries the importance of strategies to encourage rapid entry of biosimilars into markets.

The Committee recognized the need for companion in-vitro diagnostic tests to identify patients eligible for treatment with the recommended immune checkpoint inhibitors. The Committee noted that access to diagnostic capacity is limited in less-resourced settings and may be a barrier to appropriate and optimal use of these medicines. However, the Committee highlighted that this scenario is more variable in middle-income countries, where testing for molecular alterations is more readily available and the price associated with tests is a small fraction of the price associated with treatment. The Committee recognized that the requirement for companion diagnostics adds additional cost but offers

a pathway to limit inappropriate use of immune checkpoint inhibitors (i.e., outside of recommended indications) and serves to prevent the waste of resources with non-essential or lower-value use.

The Committee considered that countries can apply their own affordability criteria in determining which (if any) of the recommended immune checkpoint inhibitors can be reasonably incorporated into national EMLs and reimbursement schemes. In addition, the Committee considered that countries can apply their own feasibility criteria in assessing health system readiness for immune checkpoint inhibitor implementation, in terms of diagnostic infrastructure, healthcare worker training in immuno-oncology, resources for the management of immune-mediated side-effects and monitoring capabilities, to ensure their safe and effective use.

The Expert Committee **did not recommend** listing for the following:

- cemiplimab, durvalumab plus tremelimumab, nivolumab plus ipilimumab, or pembrolizumab – each in combination with chemotherapy – for the treatment of oncogenic-driver wild-type metastatic non-small cell lung cancer regardless of PD-L1 expression;
- tislelizumab in combination with chemotherapy for oncogenic-driver wild-type metastatic non-small cell lung cancer with ≥50% PD-L1 expression;
- nivolumab plus ipilimumab for the treatment of dMMR/MSI-H phenotype metastatic colorectal cancer or metastatic melanoma;
- dostarlimab in combination with chemotherapy for dMMR/MSI-H phenotype metastatic endometrial cancer;
- pembrolizumab or nivolumab, in combination with chemotherapy, for first-line treatment of metastatic ERBB2-negative gastric or gastro-esophageal junction adenocarcinoma with ≥1% or ≥5% PD-L1 expression, respectively;
- durvalumab in combination with chemotherapy for first-line treatment of biliary tract cancer regardless of PD-L1 expression;
- durvalumab monotherapy, durvalumab plus tremelimumab, or atezolizumab plus bevacizumab for first-line treatment for metastatic hepatocellular carcinoma regardless of PD-L1 expression;
- pembrolizumab in combination with chemotherapy for first-line treatment of metastatic head and neck squamous cell carcinoma;
- pembrolizumab, nivolumab, or nivolumab + ipilimumab, each in combination with chemotherapy, for first-line treatment of metastatic esophageal squamous cell cancer
- nivolumab + ipilimumab, pembrolizumab + axitinib, or pembrolizumab + lenvatinib for the first-line treatment of metastatic renal cell carcinoma regardless of PD-L1 expression;
- pembrolizumab in combination with chemotherapy for first-line treatment of triple-negative breast cancer CPS≥10 given.

Reasons not to recommend inclusion of these pairings variably included prioritization of monotherapy over combination therapy, magnitude of overall survival gains of less than 4-6 months, limited or absence of mature overall survival data, unfavourable benefit to risk profiles, uncertainty around optimal immune checkpoint inhibitor and tyrosine kinase inhibitor positioning (i.e. in sequence or in combination), and uncertainty around optimal use across different patient cohorts which may vary with the immunogenicity of tumour types.

The Expert Committee did not recommend the inclusion of tislelizumab or toripalimab on the EML for the treatment of oesophageal squamous cell carcinoma at this time. In the first-line setting, the Committee considered that the reported overall survival gains offered by these medicines were relatively consistent (suggesting that these medicines could be considered therapeutic alternatives). However, the Committee judged the overall survival gains to be moderate in size and that the benefit of these gains was offset by the unclear role of PD-L1 expression as a predictive biomarker. The Committee also noted the potential for increased harm in patients with poorer prognosis at baseline.

In the second-line setting, the Committee noted that the magnitude of benefit was smaller compared with the first-line setting and did not meet the established 4–6 months threshold.

The Expert Committee did not recommend the inclusion of toripalimab on the EML for the treatment of nasopharyngeal carcinoma. The Committee considered that toripalimab in combination with chemotherapy showed promising overall survival gains compared to chemotherapy alone in the first line setting, but noted that benefit in the second-line setting was more limited. The Committee also noted that trials of other immune checkpoint inhibitors are ongoing in nasopharyngeal carcinoma. The Committee underscored that the maturation of additional data, in the context of all immune checkpoint inhibitors approved for nasopharyngeal carcinoma, especially concerning overall survival and quality of life, will be pivotal to inform judgements on whether to include toripalimab on the EML in the future.

The Expert Committee recommended the inclusion of blinatumomab on the EML and EMLc for the treatment of CD-19-positive B-lineage acute lymphoblastic leukaemia (B-ALL) based on compelling evidence from randomized clinical trials showing superiority of blinatumomab over chemotherapy in meaningfully improving survival in: (i) children, adolescents and adults with relapsed B-ALL; (ii) survival in adults with B-ALL in the front-line setting; and (iii) disease-free survival in children with B-ALL in the front-line setting. Blinatumomab is associated with fewer grade ≥3 adverse events compared to chemotherapy but has specific adverse events that would require specialist management and may represent a barrier to implementation in most low-resource settings. Blinatumomab is available as IV formulation. It requires continuous infusion over 28 days per cycle to maintain stable plasma levels due to its very short half-life (~2 hours). This continuous exposure is crucial to maintain therapeutic efficacy and minimize cytokine release syndrome. The limited feasibility of blinatumomab should be contrasted against the limited feasibility of the comparator – standard chemotherapy – which involves highly toxic, multi-agent regimens over an extended period of time. In both paediatric and adult patients, standard chemotherapy requires frequent hospitalizations and supportive care, including long-term sequelae of prolonged myelosuppression.

Overall, the Committee considered that the balance of benefit to harm of blinatumomab was strongly favourable in a disease where clinical cure is a realistic goal. The Committee noted the current high cost of blinatumomab treatment, and that while it has been determined to be cost-effective in some high-income settings, cost-effectiveness studies in other settings have been variable, depending on patient population and line of therapy. In considering the feasibility of implementing blinatumomab, the Committee recognized that countries in resource-limited settings considering including blinatumomab on their national EMLs must consider their capacity to accommodate requirements for safe administration, management of adverse events and local prioritization of implementation with respect to age and line of treatment.

Section 8.2.5 Supportive medicines

The Expert Committee did not recommend the expansion of the indications for erythropoiesis stimulating agents (e.g. epoetin alfa) on the EML and EMLc to include supportive management of chemotherapy-induced anaemia, based on evidence of a potentially unfavourable long-term benefit to harm profile. The Committee noted that judicious use of erythropoiesis-stimulating agents in patients receiving chemotherapy improves haemoglobin levels, may reduce transfusion requirements, and may be associated with improvements in quality of life. However, they have not been shown to improve overall survival, with some clinical studies reporting inferior survival and worse cancer outcomes as these medicines might stimulate tumour growth directly or affect the tumour microenvironment. The Committee also noted that guidelines from professional societies (e.g., the American Society of Clinical Oncology and the European Society of Medical Oncology) recommend careful patient selection, informed consent about risks and conservative dosing – factors which represent important limitations in terms of feasibility in the use of this class of medicines in this context.

Section 10: Medicines affecting the blood

Section 10.2 Medicines affecting coagulation

The Expert Committee recommended the inclusion of emicizumab on the EML and EMLc for prophylactic treatment of haemophilia A with and without factor VIII inhibitors based on a favourable balance of benefits to harms. The Committee also made some important remarks regarding the implementation of the recommendation depending on the level of available resources. In recognition of the current high price of emicizumab, the Committee highlighted that the value of emicizumab prophylaxis is greatest in people with haemophilia A with FVIII inhibitors, in whom factor replacement is ineffective. In people with severe haemophilia A without FVIII inhibitors, prophylaxis with plasma-derived or recombinant FVIII may represent a better value, more affordable, treatment option. In considering inclusion of emicizumab on national essential medicine lists in resource-limited settings, and in line with national needs, decision-makers may wish to prioritize/limit selection and use of emicizumab in the first instance to the population of people with haemophilia A with FVIII inhibitors, extending selection and use to people with severe haemophilia A without inhibitors when the price of emicizumab is lower and/or if resources allow.

The Expert Committee recommended the inclusion of phytomenadione mixed micelle solution formulation on the EML and EMLc for the management of haemorrhage due to severe hypoprothrombinaemia, and on the EMLc for the prophylaxis and treatment of haemorrhagic disease of the newborn. The Committee considered that the proposed formulation represents an additional effective treatment option that offers flexibility for administration, with evidence of comparable efficacy and safety to currently listed formulations.

Section 10.3 Medicines for haemoglobinopathies

The Expert Committee endorsed the proposed changes to Section 10.3 of the Model Lists made by the Secretariat, incorporating the suggestions made by the WHO Department of Maternal, Newborn, Child and Adolescent Health, and Ageing to title the section “Medicines for haemoglobinopathies” and to transfer the listing of hydroxyurea (hydroxycarbamide) from the complementary to the core list.

Section 11: Blood products, coagulation factors, and plasma substitutes

Section 11.1 Blood and blood components

The Expert Committee recommended that non-pathogen-reduced (i.e. native) cryoprecipitate and pathogen-reduced cryoprecipitate be removed from the Model Lists for use in prophylactic treatment of haemophilia A and von Willebrand disease. The Committee recognized the increased risks of transfusion-transmitted infections associated with repeated transfusions in patients with these conditions.

The Expert Committee recommended that non-pathogen-reduced (i.e., native) cryoprecipitate be retained on the EML and EMLc as a therapeutic alternative to pathogen-reduced cryoprecipitate for use in cases of life-threatening major haemorrhage and rapid loss of blood volume (e.g. severe trauma, major surgery, obstetric haemorrhage). The Committee considered that at this time and under the aforementioned clinical circumstances, native cryoprecipitate still represents a therapeutic alternative to coagulation factors or pathogen-reduced cryoprecipitate when these are not available. In such situations, the iatrogenic risks are clearly outweighed by the potential life-saving benefits of native cryoprecipitate. The Committee recognized the importance of preferential use of pathogen-reduced cryoprecipitate over native cryoprecipitate due to the reduced risk of transfusion-transmitted infections. However, the Committee noted that widespread global access to pathogen-reduced cryoprecipitate is currently limited. In settings where pathogen-reduced cryoprecipitate is not available, native cryoprecipitate represents a last resort alternative.

The Expert Committee recommended that the current listings for plasma-derived coagulation factors VIII and IX be transferred from the complementary to the core list of the EML and EMLc. For consistency across listings for other

medicines used in the treatment of haemophilia and von Willebrand disease, the Committee recommended that the listing for desmopressin also be transferred from the complementary to the core list.

The Expert Committee recommended the removal of coagulation factor IX complex as a therapeutic alternative under the square box listing of plasma-derived coagulation factor IX on the EML and EMLc given the increased risk of thrombosis associated with this product.

Section 11.3 Coagulation factors

The Expert Committee recommended the inclusion of recombinant coagulation factor VIII for prophylactic treatment and on-demand treatment of acute bleeds in people with haemophilia A, and of recombinant coagulation factor IX for prophylactic treatment and on-demand treatment of acute bleeds in people with haemophilia B to the core list of the EML and EMLc. The recommendation is made based on evidence of equal effectiveness to plasma-derived coagulation factors for outcomes including reduced bleeding rates, the percentage of patients without bleeding events, improving joint health scores and improving health-related quality of life measurement scores. Compared with plasma-derived coagulation factors, recombinant coagulation factors are not associated with an increased risk of bloodborne virus transmission. Nevertheless, the Committee recognized that plasma-derived coagulation factors continue to represent an important treatment option, may offer advantages over recombinant products in the context of inhibitor development and may be more affordable in some settings.

Section 12: Cardiovascular medicines

Section 12.3 Antihypertensive medicines

The Expert Committee recommended the inclusion of triple fixed-dose combination (FDC) antihypertensive formulations containing an angiotensin converting enzyme inhibitor or angiotensin II receptor blocker, a long-acting dihydropyridine calcium channel blocker and a thiazide or thiazide-like diuretic on the EML based on a favourable balance of benefits to harms in patients with uncontrolled blood pressure on dual therapy or in high-risk patients (e.g. with diabetes, kidney disease, cardiovascular disease). The Committee considered the benefits of triple combination therapy in terms of reductions in systolic and diastolic blood pressure and some evidence of improved adherence and persistence compared to free equivalent combination therapy. The Committee considered that the addition of the triple FDC is part of an overall strategy aimed at meeting the different needs that both patients and health systems may have in addressing hypertension, ensuring patients can choose based on preference, and standardizing supply, procurement and training. Adverse effects are generally mild and manageable, and consistent with the known adverse event profiles of the components. Cost comparisons of FDCs with the sum of the component monotherapies are variable across settings and should be considered in national selection decisions. The Committee reiterated the importance of continued availability of single-agent antihypertensives.

Section 13: Dermatological medicines

Section 13.1 Antifungal medicines

The Expert Committee did not recommend the inclusion of ciclopirox hydroxypropyl chitosan nail hydrolacquer on the EML for the treatment of onychomycosis in adults because of concerns including the lack of compelling evidence of comparative benefits and safety versus oral or combined oral and topical antifungal treatments, and unknown cost-effectiveness.

Section 13.4 Medicines affecting skin differentiation and proliferation

The Expert Committee considered that the inclusion of effective and safe biologics for psoriasis on the EML would address an important public health need and support global advocacy efforts to reduce the global burden of psoriasis, especially in low and middle-income countries. The Committee acknowledged that a large number of biologic disease-

modifying medicines for psoriasis are available and the need to prioritize the most effective, tolerable and affordable options.

The Expert Committee recommended the inclusion of adalimumab and ustekinumab on the complementary list of the EML and EMLc for the treatment of adults and children with moderate-to-severe psoriasis, based on evidence of favourable efficacy and safety, as second line treatment alternatives. Listing complements the non-biologic therapies used in first line for psoriasis currently listed on the Model Lists (e.g. topical corticosteroids, systemic methotrexate).

The Committee considered that adalimumab and other tumour necrosis factor alpha inhibitors could be considered therapeutic alternatives to each other in most clinical scenarios and that including multiple within-class alternatives on the Model Lists could support greater competition to lower prices. The Committee therefore recommended adalimumab be listed with a square box as the class representative with certolizumab pegol, etanercept and infliximab as specified therapeutic alternatives.

The Committee recommended inclusion of ustekinumab in addition to adalimumab because of some advantages ustekinumab has over adalimumab and other tumour necrosis factor alpha inhibitors. When considering the administration schedule, adalimumab is administered every two weeks while ustekinumab is administered every 12 weeks. Less frequent injections are more convenient, with reduced disruption to daily life for patients and reduced burden and costs for health systems. Ustekinumab is preferred to adalimumab in patients with heart disease and in settings where tuberculosis is endemic as it is associated with a lower risk of tuberculosis reactivation. While ustekinumab is currently more highly priced than adalimumab, biosimilars are becoming increasingly available. For ustekinumab, the Committee did not recommend listing with a square box. The Committee acknowledged the data supporting similar or better effectiveness of other monoclonal antibodies targeting IL-12 and IL-23 (e.g. guselkumab, risankizumab and tildrakizumab) but considered the alternatives to have less supportive evidence, biosimilars are not yet available, and there is no information regarding their costs in most jurisdictions which were assumed to be higher than ustekinumab.

Quality-assured biosimilars are recommended as therapeutic alternatives of both adalimumab (and therapeutic alternatives) and ustekinumab.

Section 13.6 Moisturizers

The Expert Committee recommended inclusion of urea- and glycerol-based moisturizing creams on the EML and EMLc for the treatment of atopic dermatitis based on evidence of benefit, acceptable safety and public health need. Recommended formulations are creams containing 5% urea and creams containing 15% to 20% glycerol with regulatory approval as emollients.

Section 13.7 Sunscreens, broad spectrum

The Expert Committee recommended the inclusion of therapeutic broad-spectrum topical sunscreen on the EML and EMLc for the prevention of skin cancer in people with albinism. The Committee recognized the higher susceptibility to the harmful effects of UV radiation, including (but not limited to) non-melanoma skin cancer among people with albinism and the therapeutic need for effective and safe sun protection products in this population. Therapeutic broad-spectrum sunscreens should contain proven active ingredients in appropriate amounts to absorb or filter UVA and UVB radiation and have a high sun protection factor (SPF). The Committee was not able to recommend specific formulations for listing at this time. The Committee considered that listing sunscreens, even without a preferred formulation, was important to stimulate greater investment in research to compare and identify among the various formulations available those associated with a better profile. The Committee invited the submission of proposals outlining optimal formulation specifications for future consideration by the Expert Committee.

Section 15: Antiseptics and disinfectants

The Expert Committee recommended that an explicit listing for hypochlorous acid solution as an environmental disinfectant, separate from its general inclusion as a chlorine-based compound, be included on the EML and EMLc to aid differentiation between hypochlorite and hypochlorous acid products.

The Expert Committee did not recommend inclusion of hypochlorous acid solution for topical use in antisepsis and wound care, because the application did not provide an updated comprehensive review of clinical studies to inform the decision-making, as was the request of the Expert Committee in 2021. As was the case in 2021, the evidence base in the application supporting topical use of hypochlorous acid solution in antisepsis and wound care was inconclusive.

Section 18: Medicines for endocrine disorders

Section 18.1 Adrenal hormones and synthetic substitutes

The Expert Committee recommended the inclusion of prednisolone 1 mg tablets on the core list of the EML and EMLc for treatment of adults and children with adrenal insufficiency based on evidence of an acceptable balance of benefits and harms and potential better affordability in some settings than currently listed hydrocortisone. Listing is recommended for prednisolone with a square box, specifying prednisone as a therapeutic alternative.

Section 18.5.1 Insulins

The Expert Committee recommended the inclusion of rapid-acting insulin analogues (insulin lispro, insulin aspart and insulin glulisine, and their quality-assured biosimilars as therapeutic alternatives) on the core list of the EML and EMLc for the treatment of people with type 1 and type 2 diabetes mellitus, and people with gestational diabetes. The Committee considered that the available evidence indicates generally comparable efficacy and safety between rapid-acting insulin analogues and regular human insulin. The Committee noted that some studies provide evidence of higher patient satisfaction scores with rapid-acting insulin analogues, and others suggest that rapid-acting insulin analogues may be associated with lower rates of complications, with medicine costs offset by reduced demand for high-cost treatments and health services for complications, particularly in type 1 diabetes. However, the Committee considered these arguments for including rapid-acting insulin analogues in the Model Lists to be somewhat tenuous. The Committee recognized that rapid-acting insulin analogues may be more expensive than regular human insulin and may be less affordable in some resource-limited settings. However, in other settings the prices of rapid-acting insulin analogues do not exceed the price of regular human insulin. The Committee's reason for recommending listing of rapid-acting insulin analogues is to support access, recognizing the progressive withdrawal of regular human insulin from markets, and to signal to countries the need for multi-pronged policy, pricing and procurement strategies to strengthen affordable access. The inclusion of rapid-acting insulin analogues also serves to enlarge the number of insulin products on the Model Lists and complements the listing of long-acting insulin analogues for use in basal-bolus regimens. This is also consistent with the listings for short- and intermediate-acting human insulins. Larger insulin markets could help in stabilizing prices, securing supply chains of quality-assured products, and mitigating the risks of shortages. Countries in which insulin prices are excessive should consider strengthening the regulatory framework, implementing or maintaining price control, or reference pricing mechanisms. The outcomes of price controls and reference pricing for essential medicines should be closely monitored as these policies can have several potential unintended consequences. The Committee emphasized the importance of commitment and action from WHO, Member States, insulin producers, procurement agencies and other stakeholders to address the problem of equitable and affordable access to insulin products globally.

The Expert Committee also recommended the inclusion of 10 mL vial formulations of long-acting insulin analogues, in addition to the currently listed 3 mL pre-filled pen and cartridge formulations.

Section 18.5.2 Hypoglycaemic agents

The Expert Committee recommended the inclusion of glucagon-like peptide-1 (GLP-1) receptor agonists (semaglutide, dulaglutide and liraglutide) and GLP-1 and glucose-dependent insulinotropic polypeptide (GIP) dual receptor agonists (tirzepatide) on the core list of the EML as add-on glucose lowering therapy for adults with type 2 diabetes mellitus and (i) with established cardiovascular disease (CVD) or chronic kidney disease (CKD); and (ii) with obesity (body mass index (BMI) ≥ 30kg/m^2) having a significant impact on their physical health and/or quality of life. This recommendation is made based on evidence of a meaningful and favourable balance of benefits to harms in this patient population. Listing is recommended for semaglutide with a square box, with dulaglutide, liraglutide and tirzepatide as specified therapeutic alternatives.

The Expert Committee did not recommend inclusion of GLP-1 and GLP-1/GIP dual agonists on the EML for the treatment of people with obesity without the abovementioned comorbidities (type 2 diabetes mellitus and established cardiovascular disease or chronic kidney disease) because of limited and less mature evidence for benefit for cardiovascular outcomes and mortality in this population and lack of data regarding long-term safety.

The Expert Committee considered two separate applications: one for the treatment of adults with type 2 diabetes mellitus and established or at high-risk of cardiovascular disease and one for the treatment of adults with obesity.

While keeping the recommendations for the diabetes and obesity applications separate, the Expert Committee evaluated the applications together to better contrast possible differences between benefits and harms across the two conditions and appreciate implications of coverage for the two cohorts of patients at global, regional and national level. The Committee also recalled that previous applications (in 2017, 2021 and 2023) for inclusion of GLP-1 receptor agonists for use in the treatment of diabetes had been evaluated and not recommended.

The Committee recognized that diabetes and obesity currently represent two major global health challenges, with both conditions reaching epidemic proportions across diverse populations and regions. In 2022, there were over 800 million people worldwide living with diabetes, a number projected to exceed 1.3 billion by 2050, reflecting dramatic increases across all age groups, sexes and countries regardless of income level. Simultaneously, the prevalence of obesity has increased globally – more than doubling in adults since 1990 – and now affecting more than 1 billion people. Growth in the prevalence of obesity is most rapid in low- and middle-income countries. Both diabetes and obesity are major contributors to mortality and morbidity, responsible for substantial disability-adjusted life years and straining health systems worldwide. Notably, the relationship between obesity and diabetes is both causal and cyclical; excess adiposity significantly increases the risk of type 2 diabetes through mechanisms involving insulin resistance and chronic inflammation. Furthermore, diabetes and obesity together exacerbate the risk of cardiovascular diseases, forming a triad of interlinked conditions that influence each other and jointly account for a substantial proportion of preventable deaths. The Committee noted that 30% to 50% of people with type 2 diabetes have established cardiovascular disease and obesity, representing a large global cohort with this triad of comorbidities. The Committee also noted that for people with all three of these conditions, the risk of death is much higher than in people with either diabetes or obesity alone.

The Committee noted the evidence from multiple large-scale randomized controlled trials and systematic reviews demonstrating the efficacy of GLP-1 receptor agonists and GLP-1/GIP dual agonists compared to placebo in people with diabetes in improving glycemic control, reducing the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke), reducing the risk of end stage kidney disease, reducing all-cause mortality, improving health-related quality of life and promoting weight loss. The Committee noted the consistency of benefits across studies. The Committee also acknowledged that, while some degree of benefit is possible across all patients irrespective of risk of cardiovascular diseases, the cohort of patients with type 2 diabetes with known cardiovascular or chronic kidney disease represents a high-risk subgroup that is likely to experience the most relevant benefit, with a ten-fold decreased risk of premature death compared to the cohort of patients at low

risk. The large difference in benefit between those at low risk and those at high risk for premature mortality is an important factor that could be used to identify those patients to be prioritized in the introduction of these medicines at country level.

The Committee noted the evidence from the large systematic review demonstrating the efficacy GLP-1 receptor agonists and GLP-1/GIP dual agonists (particularly subcutaneous semaglutide and tirzepatide) compared to lifestyle modification alone in people with obesity for achieving clinically meaningful weight loss and improving quality of life. However, the Committee agreed that evidence for benefits in cardiovascular outcomes and mortality in people with obesity without diabetes is currently limited to a single, large, randomized controlled trial of semaglutide versus placebo. While the outcomes of this trial for cardiovascular outcomes were positive, there were more discontinuations due to adverse events among people receiving semaglutide. The Committee noted that the trial reported outcomes after almost 40 months of follow-up and considered that the available evidence with respect to mortality outcomes was still at an early stage, and limited.

Overall, the Committee considered that the magnitude of benefits and certainty of evidence were greater for people with diabetes than for people with obesity, particularly for important outcomes of cardiovascular events and mortality, upon which the Committee placed greater value compared to outcomes of glycaemic control and weight loss.

Considering the population of people with type 2 diabetes, the Committee identified those with comorbid established cardiovascular or chronic kidney disease as being the cohort for whom the net benefit of treatment was the greatest. The Committee then decided to include comorbid obesity (BMI ≥30 kg/m^2) as an additional eligibility criterion, thereby establishing a defined high-risk cohort of people for whom these medicines are listed as essential. The Committee considered the following reasons a support of a triple target population: (i) obesity is a condition that can negatively affect both the mental and physical health of people with diabetes, stalling or worsening the health status; (ii) certain molecules within the pharmacological classes of GLP-1 receptor agonists and GLP-1/GIP dual agonists have an important effect on body weight, being associated with major weight reductions, far exceeding the weight reductions associated with other hypoglycaemic agents on the EML (e.g. sodium-glucose cotransporter 2 inhibitors); and (iii) to highlight the importance of obesity as a public health priority – one that requires effective treatment and commitment at both scientific and policy levels.

The Committee noted that all proposed GLP-1 (semaglutide, liraglutide and dulaglutide) and GLP-1/GIP dual agonists (tirzepatide) were associated with important cardiovascular benefits in patients with type 2 diabetes. However, the Committee noted that there are important differences between these medicines with respect to weight loss, with semaglutide and tirzepatide being associated with more relevant body weight reductions compared to the other molecules. The Committee noted that availability and use of semaglutide and tirzepatide are constrained by a price that currently limits their use to only well-resourced health care systems.

The Committee acknowledged the current high price of these medicines and noted the reported cost-effectiveness ratios that exceed willingness-to-pay thresholds in many settings, particularly when used in low-risk patients. The Committee also noted the recent or upcoming patent expiry for liraglutide and semaglutide, which will introduce the possibility for biosimilar entry, increased competition and lower prices. The Expert Committee believed that significant price reductions could be achieved with biosimilar entry and competition, given the size and ubiquity of the market for these medicines. The Committee noted that when a large eligible patient population exists, robust biosimilar competition has consistently proven to be more reliable at sustainably reducing prices than other price-reduction mechanisms. The Committee's decision to recommend a square box listing for semaglutide, with dulaglutide, liraglutide and tirzepatide (and quality-assured biosimilars) as therapeutic alternatives aims to foster competition among available alternatives. The Committee hoped that having multiple EML-listed options would serve to facilitate the rapid introduction of prequalified biosimilar formulations and would support countries in negotiating lower medicine prices, selecting the product that represent the best value option.

The Expert Committee recommended listing of GLP-1 and GLP-1/GIP agonists in the core list to underscore the importance of these medicines being available in the primary care setting. Type 2 diabetes and its complications, including obesity, are managed primarily in primary care. Delaying access by requiring hospital referral can reduce benefits associated with early intervention, adding costs and limiting availability in rural areas or underserved communities.

In recognition of the financial implications of including GLP-1 receptor agonists and GLP-1/GIP dual agonists in national health systems at their current prices, particularly in resource-limited settings, the Committee emphasized the importance of targeting use in the first instance to those patients in whom the greatest value health benefit can be realized. The Committee also recommended that WHO continue to monitor the evolving landscape of this class of medicines, including benefits associated with use in people with obesity, potential long-term toxicities and approval of oral formulations. The Committee also recommended that WHO work on existing approaches for managing prices and evaluate alternative strategies to improve affordability and access to reduce the global burden of diabetes.

Section 19: Immunologicals

Section 19.3 Vaccines

The Expert Committee endorsed the inclusion of vaccines for Ebola and mpox on the core list of the EML and EMLc, vaccines for hepatitis E and respiratory syncytial virus on the core list of the EML, and vaccines for malaria on the core list of the EMLc, in line with recommendations of the WHO Strategic Advisory Group of Experts (SAGE) on Immunization and corresponding WHO vaccine position papers.

Section 22: Medicines for reproductive health and perinatal care

Section 22.3 Uterotonics

The Expert Committee accepted the rationale presented in the application and endorsed the proposed changes to Section 22.3 of the Model Lists, as summarized in Table 3.

The Expert Committee also noted the advice of the decision by WHO to remove the boxed text associated with the listing for mifepristone and misoprostol.

Section 24: Medicines for mental and behavioural disorders

The Expert Committee did not recommend inclusion of methylphenidate on the EML and EMLc for the treatment of children and adolescents with attention-deficit hyperactivity disorder (ADHD) because of limitations in the available evidence for benefits and safety of long-term use, which reduced confidence in the estimates of prolonged beneficial effect.

The Committee acknowledged that methylphenidate is widely recommended and used in many countries as the standard of care for children and adolescents with ADHD and has wide regulatory approval and market availability. Furthermore, it is already included in the national essential medicines lists of some countries. The Committee noted there are currently no medicines for ADHD on the Model Lists.

The Committee recalled the recommendation of the 2021 Expert Committee to not include methylphenidate on the Model Lists because of enduring uncertainty regarding the benefit-to-harm ratio for the long-term use of the medicine. The 2021 Committee also recommended that any future consideration of methylphenidate should address evidence for the effectiveness and safety of methylphenidate in the treatment of ADHD of at least 52 weeks duration; outcomes of the revision of the WHO mhGAP guidelines; and evaluation of health system capacity to provide appropriate diagnostic, non-pharmacological and pharmacological treatment and monitoring in low-resource settings.

The 2025 Expert Committee appreciated the efforts of the applicants of the current application in presenting evidence and information addressing the 2021 Committee's concerns and gaps in the evidence base previously proposed for evaluation.

In consideration of the evidence presented in the current application for longer-term efficacy and safety of methylphenidate, the Committee noted that randomized controlled trials evaluating long-term treatment (>6 months) were few and all had some methodological limitations. Selected pharmacoepidemiologic studies presented some real-world evidence for benefit in functional outcomes, reductions in all-cause mortality and unintentional injuries associated with long-term use of methylphenidate, however these studies also had intrinsic methodological limitations. In particular, the Committee noted the findings of the 1999 Multimodal Treatment Study of Children with Attention-Deficit/Hyperactivity Disorder (MTA study), in which ADHD treatment with stimulant medication (not limited only to methylphenidate) was associated with greater improvements in ADHD symptoms when compared to behavioural management over a period of 14 months, as rated by parents, teachers or independent investigators. Stimulant treatment was not associated with an increase in serious adverse events. The Committee noted evidence identified during the review process from follow-up analyses of the MTA study which showed that the magnitude of benefit of stimulant treatment compared to behavioural management seen at 14 months attenuated over time (after 2 years, 3 years, and into adulthood). The Committee noted that at longer follow up the advantage associated with methylphenidate in symptom control was not retained when compared to other strategies, including behavioral therapy alone or community care. The Committee was unable to discern if the loss in sustained benefits was due to tolerance, less adherence, crossover between different strategies, and if change in effectiveness was associated with characteristics of the children and adolescents or of the syndrome, such as baseline severity. Regarding long-term safety, the Committee noted mixed evidence of a potential association between methylphenidate use and effects on growth (height and weight) and potential for cardiovascular adverse effects.

The Committee considered the conditional recommendation in the 2023 WHO mhGAP guidelines, based on low certainty of evidence, that methylphenidate may be considered for use in children (from 6 years) and adolescents with ADHD under clearly specified circumstances. The Committee considered that the mhGAP guidelines provide an important framework for supporting and increasing health system capacity to ensure the appropriate use of methylphenidate in children and adolescents. The Committee noted that the guidelines highlight, amongst other things, the limited evidence on efficacy and tolerability of methylphenidate beyond 12 weeks of treatment, that specialist reassessment of the patient's ADHD management plan should occur at least once per year, and the need for methylphenidate treatment to be offered only in the context of a comprehensive management plan. The Committee expressed concern regarding the current capacity of some health systems to ensure appropriate diagnosis, treatment (both pharmacological and non-pharmacological) and management of ADHD, particularly in low- and middle-income settings, where reported rates of mental health workers for children and adolescents are low and among whom specialist psychiatrists are a small minority.

Section 24.1 Medicines used in psychotic disorders

The Expert Committee recommended the inclusion of aripiprazole once-monthly long-acting injection on the core list of the EML for the treatment of adults with schizophrenia based on acceptable evidence for similar efficacy and a potentially lower risk of metabolic adverse effects compared with other long-acting injectable antipsychotics currently included on the EML (i.e. paliperidone, risperidone). Listing is recommended for aripiprazole as a therapeutic alternative under the square box listing for paliperidone once-monthly long-acting injection.

Section 24.2 Medicines used in mood disorders

The Expert Committee did not recommend the inclusion of brexpiprazole on the EML for adjunctive treatment of major depressive disorder in adults based on evidence from short-term studies showing only modest incremental benefits compared to placebo, and noting other atypical antipsychotics and lithium had similar or superior gains. The Committee noted that the EML does not currently include any medicines for adjunctive treatment of major depressive disorder and advised that any future application should present a comprehensive evaluation of the evidence for all relevant treatment options for this indication, in preference to an application that focuses on a single medicine.

Section 24.5.2 Medicines for nicotine use disorders

The Expert Committee recommended the inclusion of cytisine (INN cytisinicline) on the core list of the EML for use as an aid to stopping smoking and tobacco use, based on a favourable balance of benefits and harms, in an area of major public health need. The Committee considered that the availability of different smoking cessation treatments serves to provide valuable options and choice for patients and clinicians, could facilitate market competition, reduce costs and improve access to effective smoking and tobacco cessation treatments for national health systems.

Section 27: Vitamins and minerals

The Expert Committee recommended deletion of iodine capsules from the EML and EMLc for prevention and treatment of iodine deficiency, noting that the formulation is no longer marketed or used in iodine supplementation programmes in countries.

Other matters considered by the Expert Committee

Age-appropriateness of formulations of essential medicines for children

In consideration of the review of the age-appropriateness of formulations of medicines on the EMLc, the Expert Committee recommended changes to the EMLc for addition of new, age-appropriate formulations and strengths of existing essential medicines, deletion of unavailable or age-inappropriate formulations and strengths and other listing modifications as proposed in the review. Corresponding changes to the EML were made for consistency, as appropriate. All changes are reported in Tables 1, 2 and 3. The Committee also noted the proposals made in the review for consideration by the Global Accelerator for Paediatric Formulations (GAP-f) network, where gaps in the availability of age-appropriate formulations of essential medicines for children exist.

Revision of AWaRe (Access, Watch, Reserve) definitions, classification and reclassification of antibiotics

The Expert Committee considered the applications proposing:

- a revision of the current AWaRe definitions for AWaRe classification and criteria for inclusion of AWaRe antibiotics on the Model Lists;
- classification of antibiotics not currently included in the WHO AWaRe classification database; and
- reclassification of cefoperazone + sulbactam from 'not recommended' to the AWaRe Watch group.

The Committee acknowledged the growing importance and adoption of AWaRe as a global tool for antibiotic selection, stewardship, surveillance and policy development, and its strong relationship with the WHO Model Lists of Essential Medicines.

The Committee noted that the definitions of AWaRe groups were developed between 2017 and 2019, reflecting the evaluation of antibiotics that were recommended for inclusion in the Model Lists. The Committee accepted that the current definition of Reserve antibiotics – intended for use as "last resort" options in life-threatening infections due to multidrug-resistant bacteria – should adapt to the needs of changing public health policies and priorities. The Committee considered that there are several aspects of the current definition that could evolve, expand, or be modified. These include expanding guidance on the level of evidence required to demonstrate "proven activity" against WHO priority pathogens, clarifying whether the relationship between the Reserve definition and the WHO Bacterial Priority Pathogens List is binding, and developing standardized definitions for multidrug resistance. The Committee also recognized the limited clinical evidence available to guide empiric use of Reserve antibiotics, particularly in low-resource settings. The Committee determined that there was also a need to consider additional dimensions in the selection of Reserve antibiotics for the Model Lists, including innovation criteria, access challenges and strategies to increase access and the role of real-world evidence.

The Committee noted a growing debate about how the definition of Reserve antibiotics should evolve. The Committee also noted the comments from the WHO Technical Advisory Group on AWaRe (TAG-AWaRe), calling for a comprehensive reassessment of all AWaRe categories, with the establishment of clear criteria for AWaRe classification groups. This reassessment should consider dimensions including efficacy, safety, impact on the emergence and spread of resistance, impact on the microbiome, and should link to other WHO products, including (but not limited to) the Bacterial Priority Pathogens Lists, the Medically Important Antimicrobial List and the report of antibacterial agents in clinical and preclinical development.

Considering the complexity of the challenges posed in refining definitions for all AWaRe categories, the Expert Committee requested the WHO Secretariat to coordinate a structured, inclusive review process, involving broad stakeholder consultation and a review of available evidence, with the aim of strengthening the AWaRe framework as a cornerstone of global antimicrobial stewardship and access policy. The recommendations of this review should be

submitted for consideration by the 2027 Expert Committee. Therefore, the Committee did not recommend any changes to the current AWaRe definitions.

Consequently, until such time as the definitions of AWaRe categories are revised, the Committee did not recommend any change to the current classification of cefoperazone + sulbactam. The Committee also noted that numerous other beta-lactam + beta-lactamase inhibitor combinations are also currently classified as 'not recommended' and considered that reclassifying only one such combination at this time would introduce inconsistency.

In consideration of the request to classify antibiotics not currently included in the AWaRe classification, the Expert Committee accepted the rationale presented in the application and recommended the antibiotics identified in the application be classified as Access, Watch, Reserve, not recommended, or remain unclassified, as proposed (Table 5).

Commemoration of the 50th anniversary of the WHO Model List of Essential Medicines in 2027

The Expert Committee noted the report of the meeting on revising the procedures for updating the Model Lists of Essential Medicines, convened by WHO at its headquarters in Geneva in November 2023 *(6)*. The Committee welcomed and endorsed all key messages that emerged during the meeting, namely:

- The importance of strengthening alignment and integration of the EML with related WHO guidelines and products to reduce redundant efforts, mitigate contradicting messages and facilitate coordinated evidence-based policymaking. This involves harmonizing procedures, identifying and then addressing situations of potential discordance.
- The importance of improving dissemination strategies related to the selection of medicines, bringing out not only information about medicines that are listed but also those that have not been recommended for listing. Rejections can be informative, as medicines rejected for addition to the EML might have drawbacks in terms of efficacy and safety, equity, feasibility, cost effectiveness, or access, with implications for national EMLs.
- The value of developing a structured process for prioritizing disease areas and medicines for EML applications to ensure an orderly, proactive approach, particularly in overlooked disease areas. Coordinated applications could be developed by leveraging partnerships with professional societies.
- The need to improve the extent and quality of information on price, cost and cost-effectiveness considered in EML selection by, among other strategies, incorporating data on pricing of medicines (including generics and biosimilars and their availability) and financial impact on patients (in terms of out-of-pocket expenditure).
- Modernizing and investigating resources that can aid the selection process. Electronic support systems such as digital submission form, artificial intelligence to increase efficiency and precision in administrative processes and increased human resources to enable to Secretariat to improve quality of the selection process were proposed.
- The need to ensure sustained progress on improving access requires addressing systemic barriers beyond medicine selection. It is crucial to study the accessibility of certain medicines once they have been listed to see if their essential medicine status can contribute to improved access, understanding the role of pricing opacity, production barriers limiting generic availability, inconsistent supply and delivery and inappropriate marketing influences.

The Committee considered that many of these recommendations relate directly to activities that address WHO's mandate to assist Member States in advising on the selection and procurement of essential medicines that offer the best value health outcomes.

The Committee highlighted that the 50th anniversary of the Essential Medicines List (EML) presents a valuable opportunity for Member States to actively participate in commemorating the WHO EML and recognizing its impact on national policies and essential medicines lists. The Committee considered that updates of national lists in 2027 should be a central activity of the commemorations. These updates should not be aimed solely at adding new medicines to national lists but should also aim to achieve greater alignment between national EMLs and national reimbursement

lists, with transparent reporting of what is made available as part of universal health coverage policies. Consideration should be given to strengthening national EMLs by developing lists that specify the indications for which medicines are considered essential.

Other important elements of the commemoration updates include:

- transparent inclusion of medicines and age-appropriate formulations for children. Disappointingly, less than 15% of countries prioritize medicines and formulations for children in their national lists *(7)*;
- clear reporting of priority formulations to guide supply and procurement, to limit fragmentation;
- optimizing interpretation and implementation of therapeutic alternative guidance (square box listings) in the WHO EML.

The 50th anniversary of the WHO Model List of Essential Medicines is a key opportunity for Member States to reaffirm the fundamental right to access essential medicines. By participating in the celebration, updating national tools, promoting public engagement and strengthening policies, countries can help ensure that essential medicines remain a living, evolving and effective instrument for health equity.

Improving the quality of EML applications

The Expert Committee noted a general improvement in the quality of applications under evaluation at the current meeting, although considerable variability remained between applications.

The Committee expressed appreciation for the open and participatory nature of the application process, where applications may be submitted by individuals, institutions, public and private sector organizations and other stakeholders. However, in many cases, applications are developed on an ad hoc and voluntary basis and sometimes lack sufficient scientific rigour (e.g. management of inherent biases), fail to present benefits across different patient subgroups and often lack comprehensive analyses of feasibility, cost-effectiveness and budget impact in different settings. The Committee considered that applications for the EML would benefit from following a process similar to that of WHO's guideline development processes, which should also facilitate alignment of the recommendations in these two WHO tools, and orient selection and appropriate use of medicines recommended by WHO.

The Committee commended two applications for exemplifying a high standard of scrutiny and comprehensive evaluation of multiple therapeutic options within specific disease areas: the 2023 application proposing essential medicines for the treatment of multiple sclerosis *(8)* and the 2025 application proposing PD-1/PD-L1 immune checkpoint inhibitors for various cancers *(9)*. These applications were the result of a coordinated effort by multiple entities including academic groups, scientific societies, methodological supporting teams and close connection with the EML Secretariat. Notable strengths were the use of a comprehensive, disease-focused strategy with clear prioritization criteria, rather than a narrower focus on individual medicines, and the systematic use of GRADE Evidence to Decision (EtD) tables to summarize the findings.

The Committee highlighted that the adoption of guiding decision-making frameworks to suit EML requirements, particularly their capacity to clarify how the magnitude of benefits varied across different therapeutic options and patient subgroups, was highly valuable in facilitating the Committee's decision-making. The Committee appreciated the efforts of the WHO Secretariat to better align the EML selection process with established guideline development tools, such as the GRADE EtD framework, to enhance transparency and evidence quality assessment.

The Committee advised that the incorporation of EtD tables in EML applications going forward was highly desirable. However, the Committee recognized that it would take time for a methodological and reporting approach to become an integral part of the application process, and that it may preclude or discourage applicants without the necessary expertise or capacity to develop EtD tables from participating in the EML process, an outcome that should be avoided. The Committee considered that a possible way to mitigate this risk would be to develop a structured process for setting priorities for EML applications where broad applicant participation can be assured.

Finally, the Committee observed that the number of applications for newer, patented, highly-priced medicines has grown considerably over time. The Committee considered that the voluntary nature of the current application process has the potential to give rise to gaps in selection and coverage for other older (but no less important) medicines for which there may be less commercial interest. The Committee recommended WHO develop a strategy guided by priority needs to complement the existing application process, to ensure applications for essential medicine candidates are submitted, regardless of their stage in the medicine life cycle.

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[1] All references in the document were last accessed on 25 June 2025.

Table 1: Recommended changes on the 2025 EML

EML – New medicines added	
Medicine	**Indication**
Baclofen	Spasticity in cerebral palsy
Blinatumomab	CD-19 positive, B-lineage acute lymphoblastic leukaemia
Coagulation factor VIII (recombinant)	Haemophilia A
Coagulation factor IX (recombinant)	Haemophilia B
Cytisine	Smoking and tobacco cessation
Ebola vaccine	Ebola virus disease
Elexacaftor + tezacaftor + ivacaftor	Cystic fibrosis
Emicizumab	Haemophilia A
Glycerol (cream, 15%-20%)	Atopic dermatitis
Hepatitis E vaccine	Hepatitis E
Insulin, analogue rapid-acting	Type 1 and type 2 diabetes
Ivacaftor	Cystic fibrosis
Mpox vaccine	Mpox
Pembrolizumab (with atezolizumab and cemiplimab as therapeutic alternatives)	Metastatic cervical cancer, metastatic colorectal cancer, metastatic non-small cell lung cancer
Perindopril + amlodipine + indapamide (with within-class medicines as therapeutic alternatives)	Hypertension
Respiratory syncytial virus vaccine	Maternal RSV vaccination
Semaglutide (with dulaglutide, liraglutide and tirzepatide as therapeutic alternatives)	Type 2 diabetes in people with established cardiovascular or chronic kidney disease, and with obesity
Sunscreen, broad-spectrum	Prevention of skin cancer in persons with albinism
Ustekinumab	Moderate to severe psoriasis
Valsartan + amlodipine + hydrochlorothiazide (with within-class medicines as therapeutic alternatives)	Hypertension
EML - New indications	
Medicine	**Indication**
Adalimumab (with certolizumab pegol, etanercept and infliximab as therapeutic alternatives)	Moderate to severe psoriasis
Fexinidazole	Human African trypanosomiasis due to Trypanosoma brucei rhodesiense infection
Ibuprofen	Acute migraine
Prednisolone	Adrenal insufficiency, cluster headache
Sumatriptan (sub-cutaneous formulation)	Cluster headache
Urea (cream 5%)	Atopic dermatitis
Verapamil	Cluster headache

EML - New formulation/strength	
Medicine	**Formulation/strength**
Acetylsalicylic acid	Suppository: 300 mg Tablet (dispersible): 75 mg, 300 mg, 500 mg.
Aciclovir	Solution for infusion: 25 mg/mL (as sodium) in vial
Aripiprazole	Injection (prolonged-release): 300 mg; 400 mg as powder and solvent for suspension (as therapeutic alternative to paliperidone prolonged-release injection)
Artemether	Oily injection: 20 mg/mL, 40 mg/mL in 1 mL ampoule
Artesunate	Powder for injection: 30 mg; 60 mg, 120 mg in vial
Artesunate – sulfadoxine + pyrimethamine	Co-packaged scored tablets: artesunate 50 mg [3] and sulfadoxine + pyrimethamine 500 mg + 25 mg [1] (Section 6.5.3.1)
Budesonide	Powder for inhalation: 100 micrograms per actuation, 200 micrograms per actuation in dry powder inhaler Suspension for inhalation: 100 micrograms per actuation, 200 micrograms per actuation in pressurized metered-dose inhaler.
Charcoal, activated	Granules for oral suspension: 50 g
Dihydroartemisinin + piperaquine	Tablet: 60 mg + 480 mg (phosphate), 80 mg + 640 mg (phosphate)
Dimercaprol	Injection in oil: 100 mg/mL in 3 mL ampoule
Insulin, analogue long-acting	Injection solution: 100 IU/mL in 10 mL vial
Mesna	Injection: 100 mg/mL in 2 mL ampoule
Midazolam	Solution for oromucosal administration: 5 mg/mL in 0.5 mL, 1 mL, 1.5 mL 3 mL pre-filled syringe; 10 mg/mL in 0.25 mL, 0.5 mL, 0.75 mL, 1 mL pre-filled syringe (Section 2.3)
Omeprazole	Powder for oral liquid: 1 mg/mL, 4 mg/mL
Phytomenadione	Injection: 2 mg/0.2 mL; 10 mg/mL in ampoule (mixed micelle solution). Tablet: 5 mg
Pyridostigmine	Injection: 5 mg/mL (bromide) in ampoule or vial
Retinol	Injection (water-miscible): 50 000 IU/mL (as palmitate) in 2 mL ampoule or vial
Salbutamol	Injection 500 micrograms/mL in 1 mL, 5 mL ampoule Solution for inhalation: 100 micrograms (as sulfate) per actuation in pressurized metered dose inhaler; 2.5 mg/2.5 mL, 5 mg/2.5 mL (as sulfate) in 2.5 mL single-dose ampoules for use in nebulizers; 5 mg/mL (as sulfate) in multi-dose bottle for use in nebulizers
Warfarin	Tablet (scored): 3 mg (sodium)
EML – Medicines/formulations deleted	
Medicine	**Formulation/strength**
Acetylcysteine	Oral liquid: 10%, 20%
Acetylsalicylic acid	Suppository: 50 mg
Amodiaquine	Tablet: 153 mg or 200 mg (as hydrochloride)
Artemether	Oily injection: 80 mg/mL

Artesunate	Injection: ampoules containing 60 mg anhydrous artesunic acid with a separate ampoule of 5% sodium bicarbonate solution Rectal dosage form: 50 mg, 200 mg capsules Tablet: 50 mg
Budesonide	Inhalation (aerosol): 100 micrograms per dose, 200 micrograms per dose
Charcoal, activated	Powder
Chloroquine	Tablet: 100 mg (as phosphate or sulfate)
Coagulation factor IX complex (plasma-derived)	Removed as a therapeutic alternative to Coagulation factor IX (plasma-derived)
Cryoprecipitate (pathogen-reduced, non-pathogen reduced)	Removed for indications of haemophilia A, von Willebrand disease
Halothane	Inhalational anaesthetic
Iodine	Capsule 190 mg Iodized oil: 0.5 mL (240 mg iodine) in ampoule (oral or injectable), 0.57 mL (308 mg iodine) in dispenser bottle.
Mefloquine	Tablet: 250 mg (as hydrochloride) (Section 6.5.3.1)
Methimazole	Tablet: 20 mg
Omeprazole	Powder for oral liquid: 20 mg, 40 mg sachets
Phytomenadione	Tablet: 10 mg
Proguanil	Tablet: 100 mg (as hydrochloride)
Propranolol	Tablet: 20 mg (hydrochloride)
Pyridostigmine	Injection: 1 mg in 1 mL ampoule
Quinine	Tablet: 300 mg (sulfate) or 300 mg (bisulfate)
Retinol	Tablet (sugar-coated): 100 000 IU (as palmitate) Water-miscible injection: 100 000 IU (as palmitate) in 2 mL ampoule
Ribavirin	All listed formulations and strengths for viral haemorrhagic fevers
Salbutamol	Injection: 50 micrograms/mL (as sulfate) in 5 mL ampoule Metered dose inhaler (aerosol): 100 micrograms (as sulfate) per dose
Sulfadoxine + pyrimethamine	Tablet: 500 mg + 25 mg (Section 6.5.3.1) Tablet: 250 mg + 12.5 mg (Section 6.5.3.2)
Suxamethonium	Powder for injection: (chloride) in vial

Table 2: Recommended changes on the 2025 EMLc

EMLc – New medicines added	
Medicine	**Indication**
Abacavir + dolutegravir + lamivudine	HIV
Baclofen	Spasticity in cerebral palsy
Blinatumomab	CD-19 positive, B-lineage acute lymphoblastic leukaemia
Coagulation factor VIII (recombinant)	Haemophilia A
Coagulation factor IX (recombinant)	Haemophilia B
Ebola vaccine	Ebola virus disease
Elexacaftor + tezacaftor + ivacaftor	Cystic fibrosis
Emicizumab	Haemophilia A
Glycerol (cream, 15%-20%)	Atopic dermatitis
Insulin, analogue rapid-acting	Type 1 and type 2 diabetes
Ivacaftor	Cystic fibrosis
Malaria vaccine	Malaria
Mpox vaccine	Mpox
Sunscreen, broad-spectrum	Prevention of skin cancer in persons with albinism
Ustekinumab	Moderate to severe psoriasis
EMLc - New indications	
Medicine	**Indication**
Adalimumab (with certolizumab pegol, etanercept and infliximab as therapeutic alternatives)	Moderate to severe psoriasis
Fexinidazole	Human African trypanosomiasis due to Trypanosoma brucei rhodesiense infection
Prednisolone	Adrenal insufficiency, infantile spasm
Urea (cream 5%)	Atopic dermatitis
EMLc - New formulation/strength	
Medicine	**Formulation/strength**
Acetylsalicylic acid	Suppository: 300 mg Tablet (dispersible): 75 mg, 300 mg, 500 mg.
Aciclovir	Solution for infusion: 25 mg/mL (as sodium) in vial
Allopurinol	Powder for injection: 500 mg (as sodium)
Amitriptyline	Oral liquid: 25 mg/5 mL (Section 2.3)
Amodiaquine – sulfadoxine + pyrimethamine	Co-packaged dispersible tablets: amodiaquine 75 mg (as hydrochloride) [3] and sulfadoxine + pyrimethamine 250 mg + 12.5 mg [1]; amodiaquine 150 mg (as hydrochloride) [3] and sulfadoxine + pyrimethamine 500 mg + 25 mg [1]
Amoxicillin + clavulanic acid	Tablet (dispersible): 250 mg (as trihydrate) + 62.5 mg (as potassium salt) (Section 6.2.5)
Artemether	Oily injection: 20 mg/mL, 40 mg/mL in 1 mL ampoule

Artesunate	Powder for injection: 30 mg; 60 mg, 120 mg in vial
Artesunate – sulfadoxine + pyrimethamine	Co-packaged scored tablets: artesunate 50 mg [3] and sulfadoxine + pyrimethamine 500 mg + 25 mg [1]
Atropine	Injection: 400 micrograms/mL (sulfate) in 1 mL ampoule or vial
Budesonide	Nasal spray: 30 micrograms per actuation, 64 micrograms per actuation Powder for inhalation: 100 micrograms per actuation, 200 micrograms per actuation in dry powder inhaler Suspension for inhalation: 100 micrograms per actuation, 200 micrograms per actuation in pressurized metered-dose inhaler.
Charcoal, activated	Granules for oral suspension: 50 g
Desmopressin	Nasal spray: 150 micrograms (acetate) per actuation
Dexamethasone	Oral liquid: 0.5 mg/5 mL (as sodium phosphate) Tablet: 0.5 mg; 0.75 mg; 1.5 mg; 5 mg (as dexamethasone base) (Sections 2.3, 3, 8.2.4 and 17.2)
Diazepam	Tablet (scored): 2 mg (Section 2.3)
Dihydroartemisinin + piperaquine	Tablet: 60 mg + 480 mg (phosphate), 80 mg + 640 mg (phosphate) Tablet (dispersible): 20 mg + 160 mg (phosphate), 40 mg + 320 mg (phosphate)
Dimercaprol	Injection in oil: 100 mg/mL in 3 mL ampoule
Docusate sodium	Oral liquid: 12.5 mg/5 mL
Ferrous salts	Oral liquid: equivalent to 9 mg/mL elemental iron
Fludrocortisone	Oral liquid: 100 micrograms/mL (acetate)
Folic acid	Oral liquid: 1 mg/mL
Hydrochlorothiazide	Solid oral dosage form: 12.5 mg
Hydrocortisone	Granules: 0.5 mg, 1 mg, 2 mg, 5 mg in capsule
Insulin, analogue long-acting	Injection solution: 100 IU/mL in 10 mL vial
Ketamine	Injection: 10 mg/mL (as hydrochloride) in vial
Lidocaine	Injection: 0.5% (hydrochloride)
Loratadine	Tablet (chewable): 5 mg, 10 mg
Mesna	Injection: 100 mg/mL in 2 mL ampoule
Methylprednisolone	Powder for injection: 125 mg (as sodium succinate) in vial
Midazolam	Solution for oromucosal administration: 5 mg/mL in 0.5 mL, 1 mL, 1.5 mL 3 mL pre-filled syringe; 10 mg/mL in 0.25 mL, 0.5 mL, 0.75 mL, 1 mL pre-filled syringe (Section 2.3)
Morphine	Injection: 1 mg/mL; 2 mg/mL (morphine hydrochloride or morphine sulfate) in 1 mL vial (Section 1.3, Section 2.2) Oral liquid: 5 mg/5 mL (morphine hydrochloride or morphine sulfate) (Section 2.2) Solid oral dosage form (slow-release): 5 mg (Section 2.2)
Omeprazole	Powder for oral liquid: 1 mg/mL, 4 mg/mL
Ondansetron	Injection: 2 mg/mL in 4 mL ampoule (as hydrochloride dihydrate) (Section 2.3, Section 17.2)
Oseltamivir	Powder for oral liquid: 6 mg/mL (as phosphate)

Phytomenadione	Injection, mixed micelle solution: 2 mg/0.2 mL; 10 mg/mL in ampoule Injection: 1 mg/0.5 mL Tablet: 5 mg
Propranolol	Tablet: 10 mg (hydrochloride)
Pyridostigmine	Injection: 5 mg/mL (bromide) in ampoule or vial
Pyridoxine	Tablet: 10 mg
Quinine	Solution for infusion: 60 mg/mL (hydrochloride) in 2 mL ampoule
Retinol	Injection (water-miscible): 50 000 IU/mL (as palmitate) in 2 mL ampoule or vial
Rifapentine	Tablet (dispersible, scored): 150 mg
Salbutamol	Injection 500 micrograms/mL in 1 mL, 5 mL ampoule Solution for inhalation: 100 micrograms (as sulfate) per actuation in pressurized metered dose inhaler; 2.5 mg/2.5 mL, 5 mg/2.5 mL (as sulfate) in 2.5 mL single-dose ampoules for use in nebulizers; 5 mg/mL (as sulfate) in multi-dose bottle for use in nebulizers
Sofosbuvir	Granules: 200 mg in sachet
Sofosbuvir + velpatasvir	Granules: 150 mg + 37.5 mg; 200 mg + 50 mg in sachet
Spironolactone	Tablet 12.5 mg
Sulfadoxine + pyrimethamine	Tablet (dispersible): 250 mg + 12.5 mg
Thiamine	Injection: 50 mg/mL (hydrochloride) in ampoule or vial
Warfarin	Tablet (scored): 3 mg (sodium)
Xylometazoline	Nasal drops: 0.05%
EMLc – Medicines/formulations deleted	
Medicine	**Formulation/strength**
Acetylcysteine	Oral liquid: 10%, 20%
Acetylsalicylic acid	Suppository: 50 mg
Amodiaquine	Tablet: 153 mg or 200 mg (as hydrochloride)
Aprepitant	Capsule: 80 mg, 125 mg, 165 mg
Artemether	Oily injection: 80 mg/mL
Artesunate	Injection: ampoules containing 60 mg anhydrous artesunic acid with a separate ampoule of 5% sodium bicarbonate solution Rectal dosage form: 50 mg, 200 mg capsules Tablet: 50 mg
Budesonide	Inhalation (aerosol): 100 micrograms per dose, 200 micrograms per dose Nasal spray: 100 micrograms per dose
Charcoal, activated	Powder
Chloroquine	Tablet: 100 mg (as phosphate or sulfate)
Coagulation factor IX complex (plasma-derived)	Removed as a therapeutic alternative to Coagulation factor IX (plasma-derived)
Cryoprecipitate (pathogen-reduced, non-pathogen reduced)	Removed for indications of haemophilia A, von Willebrand disease
Desmopressin	Nasal spray: 10 micrograms (as acetate) per dose

Diazepam (Section 2.3)	Injection: 5 mg/mL
Docusate sodium	Capsule: 100 mg
Halothane	Inhalation
Iodine	Capsule 190 mg Iodized oil: 0.5 mL (240 mg iodine) in ampoule (oral or injectable), 0.57 mL (308 mg iodine) in dispenser bottle.
Mefloquine	Tablet: 250 mg (as hydrochloride)
Methadone	Tablet: 10 mg (hydrochloride) Oral liquid: 10 mg/5 mL (hydrochloride) Concentrate for oral liquid: 10 mg/mL (hydrochloride
Methimazole	Tablet: 20 mg
Methylprednisolone	Injection: 80 mg/mL (Section 8.2.4)
Midazolam	Tablet: 7.5 mg; 15 mg
Morphine	Granules (slow release; to mix with water): 200 mg (morphine sulfate) Tablet (slow release): 200 mg (morphine hydrochloride or morphine sulfate)
Neostigmine	Tablet: 15 mg (bromide)
Omeprazole	Powder for oral liquid: 20 mg, 40 mg sachets
Phytomenadione	Tablet: 10 mg
Proguanil	Tablet: 100 mg (as hydrochloride)
Propranolol	Tablet: 20 mg (hydrochloride)
Pyridostigmine	Injection: 1 mg in 1 mL ampoule
Quinine	Tablet: 300 mg (sulfate) or 300 mg (bisulfate)
Retinol	Tablet (sugar-coated): 100 000 IU (as palmitate) Water-miscible injection: 100 000 IU (as palmitate) in 2 mL ampoule
Ribavirin	All listed formulations and strengths for viral haemorrhagic fevers
Salbutamol	Injection: 50 micrograms/mL (as sulfate) in 5 mL ampoule Metered dose inhaler (aerosol): 100 micrograms (as sulfate) per dose
Spironolactone	Oral liquid: 5 mg/5 mL, 10 mg/5 mL
Sulfadoxine + pyrimethamine	Tablet: 500 mg + 25 mg (Section 6.5.3.1) Tablet: 250 mg + 12.5 mg (Section 6.5.3.2)
Suxamethonium	Powder for injection: (chloride) in vial

Table 3: Other changes on the 2025 EML and EMLc

Other changes to listings – EML and/or EMLc		
Acetic acid	Modify formulation description to better describe available dosage forms.	EMLc
Acetylsalicylic acid	Modify formulation description to include a strength range for tablets from 75 mg to 500 mg.	EMLc
Aciclovir	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Arpraziquantel	Addition of arpraziquantel 150 mg dispersible tablets to the EMLc as a therapeutic alternative to praziquantel for treatment of schistosomiasis.	EMLc
Artemether + lumefantrine	Remove note.	EML & EMLc
Artesunate	Amend note.	EML & EMLc
Artesunate + amodiaquine	Remove note.	EML & EMLc
Artesunate + mefloquine	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Artesunate + pyronaridine	Modify formulation descriptions to better describe available dosage forms. Remove note.	EML & EMLc
Atropine	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Budesonide	Remove flunisolide as a therapeutic alternative.	EML & EMLc
Bupivacaine	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Calcium gluconate	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Charcoal, activated	Add note stating “alternative formulations of activated charcoal may be used in granules are not available”	EML & EMLc
Chloroquine	Modify formulation descriptions to better describe available dosage forms. Listing of chloroquine in malaria chemoprevention section transferred to new sub-section for malaria chemoprophylaxis in travellers.	EML & EMLc
Cyclizine	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Daclatasvir	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Daclatasvir + sofosbuvir	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Dexamethasone	Modify formulation description to reflect amount of dexamethasone in terms of salt or base.	EML & EMLc
Dihydroartemisinin + piperaquine phosphate	Modify formulation descriptions to better describe available dosage forms. Remove note.	EML & EMLc
Diloxanide	Proposed for deletion in 2027.	EML & EMLc
Doxycycline	Listings of doxycycline in malaria treatment and chemoprevention sections transferred to new sub-section for malaria chemoprophylaxis in travellers.	EML & EMLc
Eletriptan	Addition of eletriptan to the EML as a therapeutic alternative to sumatriptan for acute migraine.	EML
Ferrous salts	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Fomepizole	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Glucagon	Modify formulation description to better describe available dosage forms.	EML & EMLc
Heparin sodium	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Hydroxocobalamin	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Hypochlorous acid	Separate listing for hypochlorous acid solution as an environmental disinfectant	EML & EMLc

Insulin injection (soluble)	Modify formulation descriptions to better describe available dosage forms. Update medicine description to better differentiate between human and analogue insulins.	EML & EMLc
Intermediate-acting insulin	Modify formulation descriptions to better describe available dosage forms. Update medicine description to better differentiate between human and analogue insulins.	EML & EMLc
Intraperitoneal dialysis solution	Modify formulation description to better describe available dosage forms.	EML & EMLc
Iodine	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Isoniazid	Modify formulation descriptions to better describe available dosage forms.	EMLc
Ketamine	Remove specification of vial size.	EML & EMLc
Lactulose	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Levetiracetam	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Lidocaine	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Lidocaine + epinephrine (adrenaline)	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Linezolid	Modify formulation descriptions to better describe available dosage forms.	EMLc
Long-acting insulin analogues	Modify formulation descriptions to better describe available dosage forms. Update medicine description to better differentiate between human and analogue insulins.	EML & EMLc
Lugol's solution	Modify formulation descriptions to better describe available dosage forms. Update medicine description to reflect active ingredients.	EML & EMLc
Mannitol	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Medicines for multidrug-resistant tuberculosis	Transferred from complementary to core list	EML & EMLc
Mefloquine	Listings of mefloquine in malaria chemoprevention section transferred to new sub-section for malaria chemoprophylaxis in travellers.	EML & EMLc
Mesna	Add note to indicate injection solution may also be used for oral administration.	EML & EMLc
Methadone	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Metoclopramide	Modify formulation description to better describe available dosage forms. Remove note.	EML & EMLc
Midazolam	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Mifepristone - misoprostol	Transfer listing to the new sub-section for medicines for medical abortion.	EML
Misoprostol	Transfer listing for the indication of management of incomplete abortion to the new sub-section for medicines for medical abortion.	EML
Morphine	Modify formulation descriptions to better describe available dosage forms. Replace strength ranges for slow-release granules and solid oral dosage forms with specific strengths.	EML & EMLc
Moxidectin	Addition of moxidectin to the EML and EMLc as a therapeutic alternative to ivermectin for treatment of onchocerciasis and lymphatic filariasis	EML & EMLc
Naproxen	Addition of naproxen to the EML as a therapeutic alternative to ibuprofen for acute migraine.	EML
Nivolumab / pembrolizumab	Reverse the current listing for malignant melanoma to make pembrolizumab the representative medicine and nivolumab a therapeutic alternative.	EML
Ondansetron	Modify formulation description to better describe available dosage forms.	EML & EMLc
Oral rehydration salts	Modify formulation description to better describe available dosage forms.	EML & EMLc

Oral rehydration salts – zinc sulfate	Modify formulation description to better describe available dosage forms.	EML & EMLc
Pancreatic enzymes	Modify formulation description to better describe available dosage forms.	EML & EMLc
Phenobarbital	Replace strength range for tablet formulation with specific strengths (15 mg, 30 mg, 60 mg, 100 mg)	EML & EMLc
Potassium iodide	Modify formulation description to better describe available dosage forms.	EML & EMLc
Primaquine	Amend note.	EML & EMLc
Prostaglandin E1/ E2	Update medicine descriptions to reflect active ingredients by international non-proprietary names (alprostadil / dinoprostone).	EML & EMLc
Protamine sulfate	Modify formulation description to better describe available dosage forms.	EML & EMLc
Pyridostigmine	Modify formulation description to better describe available dosage forms.	EML & EMLc
Quinine	Modify formulation descriptions to better describe available dosage forms. Amend note.	EML & EMLc
Rasburicase	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Retinol	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Surfactant	Update medicine and formulation description to reflect active ingredients by international non-proprietary names (beractant, poractant alfa) and corresponding dosage forms.	EMLc
Valganciclovir	Modify formulation descriptions to better describe available dosage forms.	EML & EMLc
Warfarin	Modify formulation descriptions to better describe available dosage forms. Specify acenocoumarol as a therapeutic alternative.	EML & EMLc
Xylometazoline	Remove note.	EMLc
Zanubrutinib	Addition of zanubrutinib to the EML as a therapeutic alternative to ibrutinib for treatment of relapsed/refractory chronic lymphocytic leukaemia/small lymphocytic lymphoma.	EML
Zinc sulfate	Modify formulation description to better describe available dosage forms.	EML & EMLc

Changes to sections and sub-sections

	2023	**2025**
Section 5	Medicines for diseases of the nervous system	Medicines for neurological disorders
Section 5.1	Antiseizure medicines	Medicines for central nervous system disorders 5.1.1 Antiseizure medicines 5.1.2 Medicines for multiple sclerosis 5.1.3 Medicines for parkinsonism 5.1.4 Medicines for cerebral palsy 5.1.5 Medicines for headache disorders – 5.1.5.1 Medicines for acute migraine attacks – 5.1.5.2 Medicines for migraine prophylaxis – 5.1.5.3 Medicines for cluster headache 5.1.6 Medicines for central nervous system infections – 5.1.6.1 Medicines for bacterial central nervous system infections – 5.1.6.2 Medicines for viral central nervous system infections

Section 5.2	Medicines for multiple sclerosis	Medicines for peripheral nervous system disorders 5.2.1 Medicines for Guillain-Barre syndrome 5.2.2 Medicines for myasthenia gravis
Section 5.3	Medicines for parkinsonism	N/A
Section 6.5.3.3	N/A	Medicines for chemoprophylaxis in travellers
Section 7	Antimigraine medicines	Medicines for cystic fibrosis
Section 10.3	Other medicines for haemoglobinopathies	Medicines for haemoglobinopathies
Section 11	Blood products of human origin and plasma substitutes	Blood products, coagulation factors and plasma substitutes
Section 11.2	Plasma-derived medicines	Human immunoglobulins
Section 11.3	Plasma substitutes	Coagulation factors
Section 11.4	N/A	Plasma substitutes
Section 13.6	N/A	Moisturizers
Section 13.7	N/A	Sunscreens, broad-spectrum
Section 18.5.2	Oral hypoglycaemic agents	Hypoglycaemic agents
Section 22.4	Antioxytocics (tocolytics)	Medicines for medical abortion
Section 22.5	Other medicines administered to the mother	Antioxytocics (tocolytics)
Section 22.6	Medicines administered to the neonate	Other medicines administered to the mother
Section 22.7	N/A	Medicines administered to the neonate

Table 4: Applications not recommended

New medicines / indications	
Addition of brexpiprazole for adjunctive treatment of major depressive disorder	EML
Addition of temozolomide for high grade glioma, Ewing sarcoma, neuroblastoma	EMLc
Addition of erythropoiesis-stimulating agents for the new indication of chemotherapy-induced anaemia	EML & EMLc
Addition of methylphenidate for treatment of attention deficit hyperactivity disorder	EML & EMLc
Addition of pembrolizumab for treatment of metastatic: endometrial cancer, gastric or gastro-oesophageal junction adenocarcinoma, head and neck squamous cell carcinoma, oesophageal squamous cell carcinoma, renal cell carcinoma, triple-negative breast cancer.	EML
Addition of nivolumab and ipilimumab (as combination treatment) for treatment of metastatic: colorectal cancer, malignant melanoma, non-small cell lung cancer, oesophageal squamous cell carcinoma, renal cell carcinoma.	EML
Addition of nivolumab for treatment of metastatic: gastric or gastro-oesophageal junction adenocarcinoma, oesophageal squamous cell carcinoma.	EML
Addition of durvalumab for treatment of metastatic: biliary tract cancer, endometrial cancer, hepatocellular carcinoma.	EML
Addition of atezolizumab for treatment of metastatic hepatocellular carcinoma.	EML
Addition of durvalumab and tremelimumab (as combination treatment) for treatment of metastatic: hepatocellular carcinoma, non-small cell lung cancer.	EML
Addition of dostarlimab for treatment of metastatic endometrial cancer.	EML
Addition of tislelizumab for treatment of metastatic: non-small cell lung cancer, oesophageal squamous cell carcinoma.	EML
Addition of sugemalimab for treatment of metastatic non-small cell lung cancer.	EML
Addition of toripalimab for treatment of nasopharyngeal carcinoma, oesophageal squamous cell carcinoma.	EML
Addition of glucagon-like peptide 1 (GLP-1) receptor agonists for the treatment of obesity.	EML
Addition of amitriptyline for the new indication of migraine prophylaxis.	EML
Addition of bisoprolol for the new indication of migraine prophylaxis as a therapeutic alternative to propranolol	EML
Addition of fremanezumab for prophylaxis in high-frequency and chronic migraine.	EML
Addition of risdiplam for treatment of spinal muscular atrophy.	EML & EMLc
Addition of carbamazepine for the new indication of treatment of trigeminal neuralgia.	EML
Addition of imipenem + cilastatin + relebactam for treatment of multidrug-resistant infections.	EML
Addition of ciclopirox hydroxypropyl chitosan for treatment of onychomycosis.	EML
Addition of hypochlorous acid for the new indications of antisepsis and wound management.	EML & EMLc
Addition of panitumumab for the treatment of KRAS wild type metastatic colorectal cancer.	EML

Table 5: Changes to the AWaRe classification of antibiotics

Antibiotic	AWaRe classification
Azanidazole	Access
Amoxicillin + sulbactam	Access
Aztreonam + avibactam	Reserve
Benzathine phenoxymethylpenicillin	Access
Benzylpenicillin + procaine benzylpenicillin + benzathine-benzylpenicillin	Not recommended
Cefuroxime + metronidazole	Not recommended
Gepotidacin	Watch
Metronidazole + diloxanide	Not recommended
Metronidazole + furazolidone	Not recommended
Nalidixic acid (oral)	Watch
Nimorazole	Access
Norfloxacin + tinidazole	Not recommended
Ofloxacin + nitazoxanide	Not recommended
Ofloxacin + tinidazole	Not recommended
Paromomycin (oral)	Watch
Penicillins in combinations with other antibacterials	Not recommended
Pivampicillin + pivmecillinam	Not recommended
Propenidazole	Access
Satranidazole	Access
Sulfacarbamide + sulfadiazine + sulfadimidine	Not recommended
Sulfonamides in combinations with other antibacterials (excluding trimethoprim)	Not recommended
Tetracycline + chlortetracycline + demeclocycline	Not recommended
Tetracycline + nystatin	Not recommended
Ticarcillin + clavulanic acid	Watch
Tinidazole + diloxanide	Not recommended

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