

# **Executive Summary**

## **The Selection and Use of Essential Medicines**

### **2019**

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**Report of the 22nd WHO Expert Committee on the  
Selection and Use of Essential Medicines**

**WHO Headquarters, Geneva  
1-5 April 2019**



**World Health  
Organization**



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## Executive summary

This Summary reports the recommendations made by the WHO Expert Committee on the Selection and Use of Essential Medicines for the 2019 Essential Medicines Lists update.

The 22<sup>nd</sup> meeting of the WHO Expert Committee on the Selection and Use of Essential Medicines took place in Geneva, Switzerland, from 1 to 5 April 2019. The aim of the meeting was to review and update the 20<sup>th</sup> WHO Model List of Essential Medicines (EML) and the 6<sup>th</sup> WHO Model List of Essential Medicines for Children (EMLc).

The Expert Committee considered **65 applications**, including proposals to add 53 new medicines and new formulations of 19 existing medicines, extend the indications for 34 listed medicines, and to remove 10 medicines or formulations from the lists. The Expert Committee also considered reports and recommendations from the EML Antibiotics and Cancer Medicines Working Groups. In accordance with applicable procedures<sup>1</sup>, the Expert Committee evaluated the scientific evidence for the comparative effectiveness, safety and cost-effectiveness of the medicines in question.

In summary, the Expert Committee:

- recommended the **addition of 28 new medicines to the EML** (12 to the core list and 16 to the complementary list);
- recommended the **addition of 23 new medicines to the EMLc** (6 to the core list and 17 to the complementary list);
- recommended the addition of **new formulations of 16 currently listed medicines**;
- recommended adding **additional indications for 26 currently listed medicines**;
- recommended the **deletion of 9 medicines** and of specific formulations of a further 4 medicines; and
- **rejected 21 applications** for inclusion, change or deletion of 31 medicines.

The recommendations are briefly described below in order of their appearance on the Model Lists according to the classification.

A full summary of changes to the Model Lists is shown in Table 1. The applications not recommended are listed in Table 2.

## Section 6: Anti-infective medicines

### Section 6.2 Antibacterials

#### AWaRe classification of antibiotics

The Expert Committee noted the adoption and utilization of the Access, Watch and Reserve (AWaRe) classification of antibiotics on the EML by several Member States including the endorsement of AWaRe by the G20 Health Ministers in Argentina in October 2018<sup>2</sup>. Furthermore, a new target indicator based on AWaRe was adopted which specifies a country level target of at least 60% of antibiotic consumption being from the Access group. This indicator is intended to monitor access to essential medicines and progress

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<sup>1</sup> [http://www.who.int/selection\\_medicines/committees/subcommittee/2/eeb1098%5b1%5d.pdf](http://www.who.int/selection_medicines/committees/subcommittee/2/eeb1098%5b1%5d.pdf)

<sup>2</sup> <http://www.g20.utoronto.ca/2018/2018-10-04-health.pdf>

towards Universal Health Coverage under the WHO 13<sup>th</sup> General Program of Work<sup>3</sup>. The Committee recognized the emerging role of the AWARe groups for stewardship and quality improvement programs.

The Expert Committee recommended that specific listing of antibiotics in the EML and the allocation of antibiotics to the different AWARe groups should be distinguished from each other, recognizing their distinct albeit complementary purposes. The Committee acknowledged that EML-listed antibiotics represent a parsimonious, evidence-based selection of essential narrow spectrum antibiotics for first- and second-choice empiric treatment of most common bacterial infections and a tool for stewardship. However, the AWARe classification should extend beyond the EML to all commonly used antibiotics globally. The Committee acknowledged the contributions of the EML Antibiotics Working Group and endorsed the Working Group's recommendations for AWARe classification of 177 commonly used antibiotics, to better support antibiotic monitoring and stewardship activities. The Expert Committee recommended the development of an AWARe classification database as a searchable resource for countries.

#### **Antibiotics not classified as Access, Watch or Reserve**

The Committee recommended, based on the advice of the EML Antibiotics Working Group, that WHO may wish to consider creating an additional group in the AWARe classification database for antibiotics whose use is not evidence-based, nor recommended in high quality international guidelines, particularly fixed-dose combinations of multiple broad-spectrum antibiotics. Antibiotics in this group are not included on the Model Lists.

The AWARe classification database will be published as an Online Appendix to the 2019 Model Lists and Technical Report of the meeting.

The Expert Committee recommended the re-structuring of Section 6.2 to better accommodate AWARe classification, and that antibiotics on the EML be listed in revised sub-sections according to AWARe groups, replacing the existing sub-sections based on chemical structure (e.g., beta-lactam and other antibacterials). The subsequent sub-sections within Section 6.2 are re-numbered accordingly:

- **6.2.1: Access group antibiotics**
- **6.2.2: Watch group antibiotics**
- **6.2.3: Reserve group antibiotics**
- **6.2.4: Antileprosy medicines**
- **6.2.5: Antituberculosis medicines**

#### **Additions, changes and deletions**

The Expert Committee recommended for inclusion three new recently registered antibiotics for treatment of multi-drug resistant infections caused by pathogens ranked as "Critical Priority" on the WHO Priority Pathogens List<sup>4</sup> and classified under AWARe as Reserve antibiotics: ceftazidime + avibactam, meropenem + vaborbactam and plazomicin. Four recently registered antibiotics were not recommended for

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<sup>3</sup> [http://apps.who.int/gb/ebwha/pdf\\_files/EB144/B144\\_7-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB144/B144_7-en.pdf)

<sup>4</sup> The WHO PPL is tool to guide the research and development (R&D) of new antibiotics, ensuring that R&D responds to public health needs. The list is divided into three tiers – critical, high and medium risk pathogens. Gram negative bacteria are shown to be the most critical priority need ([https://www.who.int/medicines/areas/rational\\_use/PPLreport\\_2017\\_09\\_19.pdf?ua=1](https://www.who.int/medicines/areas/rational_use/PPLreport_2017_09_19.pdf?ua=1)).

EML inclusion, but were classified under AWaRE for monitoring purposes (ceftolozane + tazobactam, eravacycline and omadacycline as Reserve; delafloxacin as Watch).

The Committee recommended first- and second-choice empiric antibiotic treatment options for enteric fever, surgical prophylaxis and progressive apical dental abscess on the EML and EMLc, including the addition of cefuroxime (for surgical prophylaxis), classified under AWaRE as a Watch group antibiotic.

The Committee recommended the removal of aztreonam, fourth- and fifth-generation cephalosporins (as classes), tigecycline and daptomycin from the EML and EMLc as these antibiotics did not meet the revised criteria for inclusion on the Model Lists as individual Reserve group agents (see 6.2.3 RESERVE group antibiotics, below). Furthermore, the Committee agreed that fourth-generation cephalosporins should be re-classified as Watch group as they did not meet the revised criteria for classification as Reserve. The Committee also recommended the re-classification of faropenem from Watch to Reserve due to its high potential for inappropriate use. It is an orally available formulation with a broad spectrum activity whose inappropriate use may further the spread of carbapenemase-producing *Enterobacteriaceae*.

#### Section 6.2.1 Access group antibiotics

This category includes antibiotics that have activity against a wide range of commonly encountered susceptible pathogens while showing lower resistance potential than antibiotics in Watch and Reserve groups. The following 19 Access group antibiotics are recommended as first or second choice empiric treatment options for infectious syndromes reviewed by the Expert Committee and are listed as individual medicines on the Model Lists to promote optimal use and with the goal of improving global “access to Access” antibiotics.

Access group antibiotics included on the 2019 Model Lists			
Amikacin	Benzylpenicillin	Cloxacillin	Phenoxymethylpenicillin
Amoxicillin	Cefalexin	Doxycycline	Procaine benzylpenicillin
Amoxicillin + clavulanic acid	Cefazolin	Gentamicin	Spectinomycin
Ampicillin	Chloramphenicol	Metronidazole	Sulfamethoxazole + trimethoprim
Benzathine benzylpenicillin	Clindamycin	Nitrofurantoin	-

#### Section 6.2.2 Watch group antibiotics

The Watch group includes antibiotics that have higher resistance potential and includes most of the

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