

Reports of advisory bodies

Expert committees and study groups¹

Report by the Director-General

SELECTION AND USE OF ESSENTIAL MEDICINES

Twenty-second meeting of the Expert Committee on the Selection and Use of Essential Medicines, Geneva, 1–5 April 2019²

Main recommendations

1. The Expert Committee reviewed 65 applications proposing amendments to the WHO Model List of Essential Medicines and WHO Model List of Essential Medicines for Children (the Model Lists). The Committee recommended the addition of 28 new medicines to the WHO Model List of Essential Medicines and 23 to the WHO Model List of Essential Medicines for Children. Nine medicines or formulations were recommended for deletion. A total of 21 applications, involving 31 medicines, were rejected. Medicines listed on the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children now number 460 and 336, respectively.
2. The antibiotics included in the Model Lists represent an evidence-based selection of essential narrow-spectrum antibiotics for first- and second-choice empirical treatment of most common bacterial infections; their listing is also a tool for antibiotic stewardship. A total of 37 antibiotics are now included in the Model Lists, three of which are new antibiotics for infections due to multidrug-resistant organisms (ceftazidime + avibactam, meropenem + vaborbactam, and plazomicin). The Committee recommended that the classification of antibiotics into the Access, Watch and Reserve (AWaRe) groups should extend beyond the antibiotics included in the Model Lists to all commonly used antibiotics globally. The Committee endorsed a list of 178 commonly used antibiotics classified into the AWaRe groups, to support global stewardship and surveillance activities.
3. A total of 12 new cancer medicines demonstrating highly relevant survival benefit were added to the WHO Model List of Essential Medicines for treatment of melanoma, lung and prostate cancer, multiple myeloma and leukaemia. For the WHO Model List of Essential Medicines for Children, 10 new

¹ The Regulations for Expert Advisory Panels and Committees provide that the Director-General shall submit to the Executive Board a report on meetings of expert committees containing observations on the implications of the expert committee reports and recommendations on the follow-up action to be taken.

² WHO Technical Report Series, No. 1021 (in press).

cancer medicines were added and new indications were endorsed for 11 cancer medicines that were already listed.

4. Other new medicines added to one or both lists include biological treatments for chronic inflammatory conditions such as rheumatoid arthritis and Crohn disease, new medicines for HIV, hepatitis C and malaria, new medicines for cardiovascular diseases, new medicines used in reproductive health and perinatal care, and a new medicine for human African trypanosomiasis (sleeping sickness).

5. Medicines not recommended for listing included medicines for multiple sclerosis, immunotherapies for treatment of lung cancer, insulin analogues for diabetes and methylphenidate for attention-deficit hyperactivity disorder.

Significance for public health policies

6. The updated 2019 Model Lists provide evidence-informed guidance to Member States for developing or updating national essential medicines lists. The Model Lists represent a prioritization tool for the selection, reimbursement, procurement and use of essential medicines at country level, as part of efforts to ensure access to medicines and universal health coverage.

7. The revision of the AWaRe classification of antibiotics and its expansion to include those most commonly used worldwide provides Member States with a valuable tool for monitoring their use, in efforts to address antimicrobial resistance. This tool will support countries in meeting the target of at least 60% of overall antibiotic consumption being from the Access group, as an indicator to monitor access to essential medicines and progress towards universal health coverage specified in WHO's Thirteenth General Programme of Work, 2019–2023.

8. Several new medicines added to the Model Lists are highly priced. The Committee's recommendations to list them were based on evidence of effectiveness and safety and on public health relevance. Their inclusion signals the need for global and national strategies and interventions aimed at reducing prices and facilitating access.

Implications for the Organization's programmes

9. The continued updating of the Model Lists both informs and supports the work of WHO programmes and contributes to the delivery of consistent recommendations across the Organization through alignment of the Model Lists and WHO guidelines. The work of the Committee has been valuably facilitated by specialized expert working groups on antibiotics and cancer medicines. The ongoing activities and contributions of these working groups will continue to support the Committee and will also contribute to the broader work of WHO programmes on antimicrobial resistance and cancer.

10. With the inclusion of additional biological medicines in the Model Lists, the Committee recognized the significant budget impact these medicines can have on health systems. It also recommended the expansion of the WHO prequalification programme to include biosimilars of listed essential biological medicines, such that biosimilars are routinely evaluated along with reference products, to improve accessibility and affordability.

11. Recognizing the ongoing challenge of access and affordability of insulin, the Committee recommended that WHO should coordinate a series of actions to identify and tackle the underlying issues contributing to the current situation of suboptimal access to insulin.

EVALUATION OF CERTAIN FOOD ADDITIVES

Eighty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives, Rome, 4–13 June 2019¹

Main recommendations

12. The report contains the Expert Committee's evaluations of technical, toxicological and epidemiological data, occurrence and dietary exposure data for six food additives: black carrot extract; brilliant black PN; carotenoids (group of five food additives); gellan gum; potassium polyaspartate; and rosemary extract.

13. Specifications for the following food additives were revised: cassia gum; citric and fatty acid esters of glycerol; metatartaric acid; mannoproteins from yeast cell walls; and steviol glycosides.

14. The Committee also provided clarification to the Codex Committee on Food Additives on two issues. First, the Committee clarified the application of group acceptable daily intakes for some food additives that were listed under the same food additive heading in the Codex General Standard for Food Additives, despite not being included in a group acceptable daily intake. Secondly, the Committee clarified its use of the term acceptable daily intake "not specified".

15. The assessments, recommendations and comments by the Committee will be discussed by the Codex Committee on Food Additives in order to generate recommendations to national authorities on the safe use of these food additives and to identify and recommend appropriate risk management and risk-mitigation measures to reduce human exposure, where necessary.

16. WHO will publish detailed monographs in the WHO Food Additives Series with the toxicological and other related information upon which the safety assessments of the compounds were based.² FAO publishes summaries of the identity and purity of food additives.

Significance for public health policies

17. The Committee identifies and, where possible, quantifies the public health significance of exposure to chemicals in food – in these cases, food additives including flavouring agents – through scientific risk assessment based on international consensus. When a health concern is identified, clear recommendations are issued for action by national governments or through the Joint FAO/WHO Food Standards Programme (the Codex Alimentarius Commission and its subsidiary bodies).

18. The Committee's recommendations are used by the Codex Alimentarius Commission in the development of international food safety standards and other guidance and recommendations. Such standards are science-based and are established only for substances that have been evaluated by the Committee. This ensures that food commodities that are traded internationally meet strict safety standards to protect the health of the consumer and ensure fair practices in food trade.

¹ WHO Technical Report Series, No. 1020 (in press).

² Safety evaluation of certain food additives. WHO Food Additives Series, No. 78. Toxicological monographs of the eighty-seventh meeting (in preparation).

19. The advice provided by the Committee is also considered by Member States directly when national or regional food safety standards are being established.

20. The Committee's work, in its complexity and in reaching an international scientific consensus on the evaluation of these compounds, is unique in its importance for and impact on global public health decisions related to food safety.

Implications for the Organization's programmes

21. The evaluation of chemicals in food by the Committee is an ongoing activity. Two meetings of the Committee were held in the biennium 2017–2018.¹ An additional meeting besides the eighty-seventh meeting is planned for the biennium 2019–2020.

22. WHO is a partner in the Joint FAO/WHO Food Standards Programme, whose principal organ is the Codex Alimentarius Commission. In its capacity to assure the sound scientific basis for international standards and recommendations on veterinary drug residues in food, the work of the Committee is crucial to the work of the Codex Alimentarius Commission.

23. The Committee's evaluations are also used by heads of WHO offices in countries, territories and areas and by regional offices when advice is provided to Member States on food safety issues.

ACTION BY THE EXECUTIVE BOARD

24. The Board is invited to note the report.

= = =

¹ For more information, see https://www.who.int/foodsafety/areas_work/chemical-risks/jecfa/en/ (accessed 1 October 2019).