

## EXECUTIVE SUMMARY

The 19<sup>th</sup> Meeting of the WHO Expert Committee on the Selection and Use of Essential Medicines took place in Geneva, Switzerland from 8 to 12 April 2013. The purpose of the meeting was to review and update the 17<sup>th</sup> WHO Model List of Essential Medicines (EML) and the 3<sup>rd</sup> WHO Model List of Essential Medicines for Children (EMLc). The Expert Committee Members and Temporary Advisers who participated in the meeting will be listed in the final report, together with their declarations of interest.

In accordance with its approved procedures

([http://www.who.int/entity/selection\\_medicines/committees/subcommittee/2/eeb1098%5B1%5D.pdf](http://www.who.int/entity/selection_medicines/committees/subcommittee/2/eeb1098%5B1%5D.pdf)) the Expert Committee evaluated the scientific evidence on the comparative effectiveness, safety and cost effectiveness of medicines in order to update the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children. The Expert Committee considered 52 applications and 15 reviews and:

- ■ approved the addition of 17 new medicines (10 to the Core List and 7 to the Complementary List) to the EML;
- ■ approved the deletion of one medicine from the EML;
- ■ approved new indications for three medicines already listed on the EML;
- ■ approved the addition of a new dosage form or strength for four medicines already on the EML;
- ■ approved two medicines to be moved from the Complementary List to the Core List, and one from the Core List to the Complementary List;
- ■ rejected nine applications for the addition of a medicine to EML and deferred a decision in the case of further two application;
- ■ approved two medicines for neonatal care;

Some of the main recommendations made in order of their appearance on the Model List, were:

- ■ Section 2 (Analgesics, Antipyretics, Non-Steroidal Anti-Inflammatory Medicines (NSAIDS), Medicines used to treat Gout and Disease Modifying

Agents in Rheumatoid Disorders (DMARDs): renaming the section to Medicines for Pain and Palliative Care to emphasize the importance of the medicines used in palliative care. The Committee recognized the importance of palliative care not only in cancer but also in HIV/AIDS, MDR TB and severe congenital diseases. Therefore it moved these medicines from Section 8 (Antineoplastic, Immunosuppressives and Medicines used in Palliative Care) to Section 2 in both the EML and EMLc. Medicines needed for the treatment of other common symptoms in palliative care such as anorexia, nausea, constipation and diarrhoea were also included in Section 2. A new section, Medicines for Diseases of Joints (Section 30), was created to list the treatments for gout, disease modifying agents used in rheumatoid disorders and juvenile joint diseases that were deleted from Section 2.

■ ■ Section 6.4 (Antiviral medicines): the Expert Committee considered the applications submitted for addition, deletion and modification of antiretrovirals and noted the ongoing work on the “Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: Recommendations for a public health approach” scheduled for publication in June 2013. In consultation with the relevant departments in WHO, the Expert Committee decided to defer the applications until the guidelines were published.

■ ■ Section 6.4.3 (Other antivirals): addition of pegylated interferon alpha (2a or 2b) for the treatment of hepatitis C (in combination with ribavirin), for obtaining a sustainable virological response. Although this combination is now being used with direct-acting antivirals in some countries, the Expert Committee noted the high level of expertise and specialized facilities needed for safe and effective use of interferons, as well as its high cost and therefore included it in the Complementary List.

In the same section, the Expert Committee considered the application for deletion of oseltamivir. The Expert Committee reviewed all the evidence available to it, and decided to retain oseltamivir in the List, with the notation on the restricted indication of potentially severe or complicated illness, due to confirmed or suspected influenza virus infection, in accordance with WHO treatment guidelines.

■ ■ Section 6.5.3.1 (Antimalarial medicines - For curative treatment): addition of artesunate + mefloquine fixed-dose combination tablets for the treatment of malaria in adults and

children in line with current WHO treatment guidelines. In making its decision, the Expert Committee noted that both medicines were listed separately in the EML and EMLc, and that evaluation in clinical trials had shown similar comparative efficacy of the separate tablets and the combination. There are products containing the fixed-dose combination that are approved by the WHO-UN prequalification programme. With this addition, three of the five fixed-dose combinations recommended by the WHO for the treatment of malaria are included in the Core List.

■ ■ Section 8.2 (Cytotoxic and adjuvant medicines): after considering the applications for addition of imatinib and trastuzumab, the Expert Committee decided that an urgent review of the sub-section is needed, using a process and structure similar to that used for the same section in the EMLc. This process would require the identification of the treatable, public health relevant tumors in adults, and the identification of the medicines required to treat those tumors, considering a stepwise development of cancer care systems in the overall context of health system development. The Expert Committee considered the two applications in detail and noted the strong evidence in support of both imatinib and trastuzumab but deferred the final specifications of the medicines and their inclusion till the review of the section of cytotoxics is completed.

■ ■ Section 21 (Ophthalmological Preparations): addition of bevacizumab injection to the Complementary List in a new section (Section 21.6 Anti-vascular endothelial growth factor preparations) of the EML. Neovascular Age-Related Macular Degeneration is a leading cause of blindness in the persons over 50 years and bevacizumab has been shown to be effective with an acceptable risk profile. The Expert Committee recommended the addition of bevacizumab, while noting the precautions needed in intravitreal administration.

■ ■ Section 22.1 (Oxytocics): the application for deletion of misoprostol was a re-interpretation of the data presented to the previous Expert Committee. After considering the available evidence, the Expert Committee decided to retain misoprostol, restating that it was for the prevention of postpartum haemorrhage where oxytocin is not available or cannot be safely used.

■ ■ Section 24.1 (Medicines used in psychotic disorders): addition of risperidone to the Core List as an alternative to chlorpromazine and haloperidol, and clozapine to the Complementary List. The Expert Committee considered the application for risperidone and decided to list this second-generation antipsychotic based on efficacy, adverse effects, availability and cost. Clozapine was added to the Complementary List for individuals with psychosis who do not respond to other antipsychotics, provided that laboratory facilities are available for regular monitoring of white blood cells.

■ ■ Section 29 (Specific Medicines for Neonatal Care): Chlorhexidine 7.1% solution or gel delivering 4% was added to the Core List for use in umbilical cord care in community settings. A new sub-section of Medicines administered to the mother (Section 29.2) was added and dexamethasone included for accelerated foetal lung maturation in anticipated preterm birth; the efficacy of steroids for this condition has been conclusively demonstrated. While alternative steroids with similar efficacy were available, dexamethasone was considered the most appropriate product based on availability and cost.

Other medicines added were: loratidine, loperamide (for adults only in the context of palliative care), hyoscine butyl bromide, gliclazide (to replace glibenclamide), azithromycin eye drops, latanoprost eye drops and ofloxacin eye drops, which added to the Core List; and hydromorphone, oxycodone, fomepizole and prothianemide, which were added to the Complementary List.

The Expert Committee deleted dithranol which is used topically for the treatment of psoriasis. The adverse effects could be severe and when compared to other treatments, the relative efficacy was poor.

The Expert Committee did not approve the following proposals for addition of medicines: colchicine, naproxen, bedaquiline, a fixed-dose combination of isoniazid + pyridoxine + sulfamethoxazole + trimethoprim (because there is no marketed product), a new formulation of ferrous salt + folic acid, fixed-dose combination for secondary prevention of cardiovascular disease, ketorolac eye drops, ketotifen eye drops and montelukast.

The Expert Committee also noted that given the increasing number of applications, the limited time available at Expert Committee meetings and the need to coordinate with the development of WHO guidelines, more frequent meetings and alternative methods such as virtual meetings are required in order to respond in a timely manner to new clinical developments.

A summary of reasons for all changes to the List will be published in Section 1 of the final report. All applications and documents considered by the Expert Committee remain available on the web site for the meeting at: [http://www.who.int/selection\\_medicines/committees/expert/19/en/index.html](http://www.who.int/selection_medicines/committees/expert/19/en/index.html).

<http://www.who.int/medicines/publications/essentialmedicines/en/index.html>