Summary of the report of the 18th meeting of the WHO Expert Committee on the Selection and Use of Essential Medicines

The 18th meeting of the WHO Expert Committee on the Selection and Use of Essential Medicines took place in Accra, Ghana on 21-25 March 2011. The purpose of the meeting was to review and update the WHO Model List of Essential Medicines (EML) as well as the WHO Model List of Essential Medicines for Children (EMLc). Meeting participants are listed in Part 1 of the report, together with their declarations of interest.

In accordance with its approved procedures (http://apps.who.int/gb/archive/pdf_files/EB109/eeb1098.pdf), the Committee evaluated the scientific evidence on the comparative effectiveness, safety and cost effectiveness of medicines to update the WHO Model List of Essential Medicines and the Model List of Essential Medicines for Children. In so doing, it:

• approved the addition of 16 new medicines to the EML
• approved the deletion of 13 medicines from the EML
• approved new indications for 4 medicines already listed on the EML
• approved the addition of a new dosage form or strength for 4 medicines already on the EML
• rejected 9 applications for the addition of a medicine to EML
• approved the addition of 16 new medicines to the EMLc
• approved the deletion of 15 medicines from the EMLc
• rejected 3 applications for the addition of a new medicine to the EMLc

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

• Section 6: addition of a artesunate + amodiaquine combination tablet for the treatment of malaria in adults and children, in line with current WHO treatment guidelines. In making its decision, the 2011 Committee reviewed the latest clinical evidence and the information about licensing in several countries of the fixed dose combination tablet. The Committee noted, that appropriate doses of both medicines can also be achieved using combinations of the mono-component products, including as co-blistered presentations.

• Section 10: addition of tranexamic acid injection for the treatment of adult patients with trauma and significant risk of ongoing haemorrhage. On the basis of the results of a very large trial of the use of tranexamic acid specifically for trauma patients - including those who have been in road traffic accidents, the Committee concluded that there is sufficient evidence to support the proposal that listing tranexamic acid may contribute to a reduction in this cause of death.

• Section 18.5: addition of a glucagon injection, 1 mg/ml to treat acute severe hypoglycaemia in patients with diabetes, to support efforts in many countries to ensure appropriate treatment of the increasing number of patients with diabetes. The Committee also recommended that careful attention be paid to the cost of procuring glucagon and noted that based on the experience with other high cost medicines, such as antiretrovirals, inclusion in the EML may help to contribute to a reduction in prices.
• Section 22.1: addition of misoprostol tablet, 200 micrograms for the prevention of post-partum haemorrhage, where oxytocin is not available or cannot be safely used. WHO guidelines currently recommend that in situations were oxytocin is not available, misoprostol can be used to prevent and treat post partum haemorrhage due to uterine atony. Based on the evidence provided to it, the Committee considered that misoprostol can be safely administered to women to prevent post-partum haemorrhage by health workers trained in its use in the third stage of labour. The addition of misoprostol for the treatment of post-partum haemorrhage was not approved. The clinical trials that compare misoprostol to oxytocin in women who need treatment for post-partum haemorrhage show that misoprostol is not as effective as oxytocin. In addition, there is no evidence to support the safety and efficacy of the 800-microgram dose for treatment of post partum haemorrhage when given to women who have already received prophylactic misoprostol 600 micrograms orally. Countries need to work to make oxytocin available for treatment of women who are bleeding after delivery and misoprostol should only be used if there is no other option.

Other medicines that were added to the Model EML are: isoflurane, propofol, midazolam, clarithromycin, miltefosine, paclitaxel and docetaxel, bisoprolol, terbinafine cream/ointment, mupirocin cream/ointment, and atracurium.

The Expert Committee did not approve the following proposals for addition of medicines on the basis of the evidence submitted: ether, gatifloxacin, a fixed dose combination of isoniazid+ pyridoxine+ sulfamethoxazole + trimethoprim (because there is no marketed product), etravirine, darunavir, raltegravir, dihydroartemisinin + piperazine, pyronaridine+artesunate, loperamide. The Committee suggested that if the applications for some of these medicines could be updated to resolve the uncertainty about comparative effectiveness and safety, an extra session of the Committee might be convened before the next scheduled meeting to re-evaluate them.

The Expert Committee also assessed a review of the comparative effectiveness and cost-effectiveness of analogue insulins compared to recombinant human insulin. The products considered were: insulin glargine, insulin detemir, insulin aspart, insulin lispro, and insulin glulisine. The Committee noted that while many of the comparative trials find a statistically significant difference between analogue insulins and standard recombinant human insulin for some effects on blood glucose measurements, there is no evidence of a clinically significant difference in most outcomes. The Committee concluded that insulin analogues currently offer no significant clinical advantage over recombinant human insulin and there is still concern about possible long-term adverse effects.

A summary of reasons for all changes to the List is in Section 1 of the report. All applications and documents considered by the Committee will remain available on the website for the meeting at http://www.who.int/selection_medicines/committees/expert/18/en/index.html.

The next update of the WHO Model List of Essential Medicines will take place in 2013.