Expert Committee recommendation

The Expert Committee noted that migraine is a common disabling primary headache disorder characterized by recurrent moderate to severe pain. It is a cause of disability and results in a substantial socioeconomic burden, which is greater for women than for men. The Committee noted that the available evidence supported the superior efficacy of sumatriptan compared with placebo. Evidence comparing sumatriptan with currently listed analgesics (acetylsalicylic acid, paracetamol and ibuprofen) showed mixed results, which might correlate to little or no difference between currently listed analgesics and sumatriptan. The Committee also considered that the clinical use of sumatriptan is well established and it is recommended as a first-line therapy for migraine in some national and international guidelines. The Committee considered that it was important for people with migraine to have a range of treatment options available to them, particularly for those who are at risk of specific adverse events from currently listed analgesics, those at risk of addiction and those who have little or no response to analgesics. The Committee noted that long-term use of acetylsalicylic acid, ibuprofen and paracetamol at analgesic or higher doses in patients with frequent migraine attacks poses a risk of severe adverse events (e.g. bleeding, hepatic impairment and medication-overuse headache). Sumatriptan appears to provide clinically relevant headache relief with few risks. Evidence of the safety of sumatriptan in pregnant women is still limited but, so far, accumulated data have not signalled that sumatriptan poses additional risks of birth defects compared with that in the general population. Based on a positive benefit-to-risk profile, the Committee recommended the addition of sumatriptan to the core list of the EML for the treatment of adult patients with acute migraine. Inclusion of other triptans were not part of the application. Although the Committee thought there were likely to be benefits across the pharmacological class, few data were available on efficacy, safety, price and availability of other triptans. Therefore, the Committee did not list alternative triptans at this time, but would consider requests for listing in future.