A.32	Sumatriptan - migraine
Does the application adequately address the issue of the public health need for the medicine?	☒ Yes ☐ No ☐ Not applicable Comments: There is detailed data provided on both the prevalence of migraine in populations and the impact within the global burden of diseases (where it is amongst the 10 most common diseases), focussed particularly on data from the GBD.
Briefly summarize the role of the proposed medicine(s) relative to other therapeutic agents currently included in the Model List, or available in the market.	Sumatriptan is one of a family of triptans, the other members of which are not part of the application. It is a recommended first line treatment for acute migraine (with or without aura), alongside simple analgesics such aspirin and paracetamol.
Have all important studies and all relevant evidence been included in the application?	☒ Yes ☐ No ☐ Not applicable If no, please provide brief comments on any relevant studies or evidence that have not been included: There is an extensive review of the evidence for efficacy and safety of sumatriptan
Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?	☒ Yes ☐ No ☐ Not applicable Briefly summarize the reported benefits (e.g. hard clinical versus surrogate outcomes) and comment, where possible on the actual magnitude and clinical relevance of benefit associated with use of the medicine(s). Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)? Studies reported mostly compare sumatriptan to placebo or simple analgesics. There is consistent evidence presented (p27) that standard oral sumatriptan is superior to placebo. Data comparing to combinations of simple analgesics are less clear cut, with evidence for benefit in some studies. Accumulated evidence finds no evidence that sumatriptan in pregnancy poses additional risk of birth defects compared with that in the general population (Hilaire 2004)

Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	☒ Yes ☐ No ☐ Not applicable Comments: Sumatriptan was first approved in 1992 and there is extensive experience with its use.
Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☐ Not applicable Comments:
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	The treatment has a well-established place in therapy, is recommended in key guidelines . It has a favourable, if modest, beneficial to risk ratio.
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	Moderate-high quality evidence for its efficacy against placebo in resolution of symptoms. Mod-high quality evidence of some adverse effects.
Are there any special requirements for the safe, effective and appropriate use of the medicine(s)**?** (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	☐ Yes ☒ No ☐ Not applicable Comments:
Are you aware of any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	☐ Yes ☒ No ☐ Not applicable Comments:
Is the proposed medicine recommended for use in a current WHO Guideline approved by the Guidelines Review Committee? (refer to: https://www.who.int/publications/who-guidelines)	☐ Yes ☒ No ☒ Not applicable Comments: There are no WHO guidelines in relation to migraine. Sumatriptan is recommended in the RCT guidelines from International Headache Society

Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	Sumatriptan is available as oral , subcutaneous and intranasal formulations. It is now off patent and generally available
Any additional comments	Sumatriptan has been considered by the committee previously. The application lays out very clearly the evidence of efficacy and safety and the place of sumatriptan in migraine treatment. There remains little evidence that it is superior to simple analgesia, but clearly has a place in therapy. Evidence for efficacy in children and adolescents is challenged by a higher placebo response and there is no clear signal that it is beneficial in this group.
Based on your assessment of the application, and any additional evidence / relevant information identified during the review process, briefly summarize your proposed recommendation to the Expert Committee, including the supporting rationale for your conclusions, and any doubts/concerns in relation to the listing proposal.	Sumatriptan should be adopted to the EML, but not the EML/c. There should not be a black box listing for therapeutic equivalence of other oral triptans.
References (if required)	Guidelines for controlled trials of drugs in migraine: Third edition. A guide for investigators Cephalalgia 32(1) 6–38