A.39	Resin-based composites
Draft recommendation	☐ Recommended ☒ Not recommended Justification: This application focusses on the addition of resin based composites (RBC's) to the EML and EMLc for both the prevention and treatment of dental caries. Mercury containing amalgam has been used for many decades but the WHO supports the Minamata Convention on reducing the use of mercury based fillings. Glass Isomer Cement was added to the EML/c for these indications in 2021, where it was noted that dental caries remains a very significant public health concern. Resin based composites have been widely used for many decades in HICs. As a prevention agent there is moderate level evidence from a Cochrane review that resin based composites applied to emerging teeth as sealants significantly reduces the development of caries over 4 years of follow up. For treatment, a recent Cochrane noted that when resin based composites were used as a dental filler in the treatment of caries compared to mercury containing amalgam there was low certainty evidence suggesting that composite resin restorations had almost double the failure rate of amalgam, with a higher rate of secondary caries. The review noted that composite resin materials had significantly improved since the trials informing the primary analysis had been conducted. Resin based composites are safe and well tolerated, with allergy the only rare contra-indication. Higher level dental care with access to electricity, is required for the use or RBCs. Very limited evidence is available on the cost effectiveness of RBCs for prevention or treatment, with higher costs noted than other prevention (fluoride) or treatment (GICs) options. It is unclear from the application that resin based composites have clear additional benefits to glass isomer cement that has recently been added to the EML/c. Although there is a clear and recognised need to reduce the use of mercury containing agents, RBCs appear to in general be associated with higher initial costs, require the availability of electricity and have no clear superiority to the alternative options on the EML for prevention and treatment of dental caries.

Does the proposed medicine address a relevant public health need?	☒ Yes ☐ No ☐ Not applicable Comments: Dental caries is a major public health concern as noted in the 2021 EML Committee TRS, with an estimated 2 billion cases in permanent teeth and over 500 million cases in primary teeth, with a high burden in MICs and deprived populations. Untreated dental caries leads to pain and infection (both local and systemic). Dental infections are common, with multiple chapters of the EML AWaRe antibiotic book providing guidance on optimal antibiotic treatment. There is a clear need to enhance the use of mercury-free options for dental fillings. Glass Isomer Cement (GIC) was added to the EML/c in 2021.
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (this may be evidence included in the application, and/or additional evidence identified during the review process)	☒ Yes ☐ No ☐ Not applicable Comments: Multiple formulations are available. Resin Based Sealants may be applied to posterior teeth as they erupt in mid to late childhood to prevent dental caries. GIC was added to the EML/c in 2021 for the indication. A 2017 Cochrane review of Pit and fissure sealants to prevent dental decay in permanent teeth included 38 trials of 7924 children. Studies were conducted over many decades, including early and late generation sealants. The review found moderate quality evidence that RBS reduced caries between 11-51% compared to no sealant at 24 months with similar benefits to 48 months. Resin based composites are also used as filling agents to restore carious lesions in both anterior and posterior teeth. A 2021 Cochrane review of Direct composite resin fillings versus amalgam fillings for permanent teeth was published in 2021. Low certainty evidence suggested that composite resin restorations may have almost double the failure rate of amalgam, with a higher rate of secondary caries. However, the review noted that composite resin materials had significantly improved since the trials informing the primary analysis had been conducted. Low levels of mercury in the urine were noted in children managed with RBC.
Does adequate evidence exist for the safety/harms associated with the proposed medicine? (this may be evidence included in the application, and/or additional evidence identified during the review process)	☒ Yes ☐ No ☐ Not applicable Comments: RBC are very well tolerated and safe, with allergy to one of the product ingredients the only rare complication.

Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☐ Not applicable Comments: No
Are there any special requirements for the safe, effective and appropriate use of the medicines? (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	☐ Yes ☒ No ☐ Not applicable Comments: No, but regular access to expert dental care and electricity is required.
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☒ Yes ☐ No ☐ Not applicable Comment For both indications limited data is available. A 2021 cost effectiveness study compared glass hybrid (GH) or Composite (CO) over 3 years of follow up, noting that survival time and effectiveness were similar and GH had lower initial costs. Generally, amalgam fillings have significant lower costs, in part related to the dentist time required for their preparation and use.
Are there 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? (refer to: https://www.who.int/publications/who-guidelines)	☐ Yes ☒ No ☐ Not applicable Comments: