A.50	Triamcinolone hexacetonide – juvenile idiopathic arthritis – EML and EMLc
Draft recommendation	☒ Recommended ☐ Not recommended Justification: JIA is the most common chronic rheumatic disease of childhood, affecting approximately 1/1000 children. The application proposes the use of triamcinolone hexacetonide (TH) to be included in EML and EMLc in a box listing with triamcinolone acetetae (TA) for juvenile idiopathic arthritis (JIA) for intra-articular (IA) injection. The application is supported by several charity organisations with experience in the JIA and use of TH – including international and national organisations as well as 2 consumer organisations.
Does the proposed medicine address a relevant public health need?	☒ Yes ☐ No ☐ Not applicable Comments: Juvenile Idiopathic Arthritis (JIA) is the most common chronic rheumatic disease of childhood, affecting approximately one per 1000 children. It is characterised by joint inflammation of more than 6 weeks' duration, with onset before age sixteen years and where no other cause is found. There are estimated to be more than 2 million children with JIA around the world and most of whom are in Africa and Asia; these estimates have been derived from known prevalence rates of JIA and modelling using population data for each country. Access to 'right care' remains a major problem for many children with JIA likely with multifactorial explanation. Given the overall workforce shortages amongst paediatricians and especially in Asia and Africa, it is likely that many children with JIA have little or no access to specialist care and treatment and this is borne out with worse clinical outcomes in low resource income countries. The consequences of untreated JIA are known from historical studies that predate current approaches to treatment; essentially untreated arthritis results in pain, fatigue, joint damage, functional disability and impact on quality of life. The general effects of JIA include fatigue anaemia, poor growth and delayed puberty and many children can develop uveitis which results in blindness if not detected and treated. For untreated arthritis involving lower limb, this leads to difficulty in walking, getting up from sitting or a squat position and for upper limb joints this can result in difficulty in writing, dressing and feeding. For many children with untreated JIA, there are often absences from school with impact on peer interactions and long term studies demonstrate psychosocial impact, mental ill health issues and higher unemployment compared to healthy peers. It is therefore very likely that the burden of untreated JIA is high and especially in low resource income settings where the true burden is likely under-recognised.

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: The application provides 6 studies including 2 reviews on effectiveness. During this application review process I could not find additional evidence to contribute or refute their findings. The evidence suggests that children with inflammatory arthritis had an effective response to TH and to a lesser extent TA. Those who received TH had a statistically significant lower rate of, and time to relapse than when compared to those injected with TA.
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: however, evidence of harm/benefit is still limited.
Are there any adverse effects of concern, or that may require special monitoring?	☒ Yes ☐ No ☐ Not applicable Comments: The application has highlighted some side effects that suggest more specialized care is needed when administering TH.
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: The medication is to be injected into affected joint and there are risks of potentially debilitating side effects. Therefor medication should be administered by an expert or trained personnel.
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☒ Yes ☐ No ☐ Not applicable Comments: The medication is very expensive and there is no solid cost-effectiveness evidence yet.

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: