

<b>A.19</b>	<b>Hypromellose – dry eye disease – EML and EMLc</b>
<b>Draft recommendation</b>	<div data-bbox="580 275 817 353"> <input type="checkbox"/> Recommended  <input checked="" type="checkbox"/> Not recommended         </div> <p><b>Justification:</b> Dry eye disease (DED) is define as a “multifactorial disease of the ocular surface characterized by a loss of tear film homeostasis accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles”. DED is a chronic and progressive disease, and is considered the most common reasons for ophthalmic outpatient visits. Untreated dry eyes can cause vision loss, eye infections, eye inflammations, corneal abrasions, and corneal ulcers. The first-line treatment for dry eyes is artificial tears. Hypromellose is a safe and effective ocular surface lubricant in managing DED, especially for patients with low-to-moderate dry eye symptoms.</p> <p>Thus, as the complications of DED are essentially the prerogative of the severe forms, this product does not seem to us to have the necessary importance to be part of the EML/EMLc.</p>
Does the proposed medicine address a relevant public health need?	<div data-bbox="580 804 769 936"> <input type="checkbox"/> Yes  <input checked="" type="checkbox"/> No  <input type="checkbox"/> Not applicable         </div> <p><b>Comments:</b> DED is prevalent in each World Health Organization (WHO) region: the African region, the South-East Asian region, the Eastern Mediterranean region, the Western Pacific region, the European region, and the region of the Americas. The prevalence of symptomatic DED is estimated to range from 5% to 50% and the incidence reaching up to as high as 75%. Aging and female sex are significant risk factors since the prevalence of dry eye disease increases after the age of 50, with a greater occurrence in women. With the aging population and improved life expectancies, the prevalence of DED is expected to increase, resulting in significant socio-economic consequences including loss of work productivity, decreased quality of life, and increased medical care spending and financial burden of the disease on the health care systems.</p>
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)	<div data-bbox="580 1337 769 1469"> <input checked="" type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> Not applicable         </div> <p><b>Comments:</b> With the increasing prevalence of DED, a multitude of artificial tears are currently available on the market, and choosing the most appropriate artificial tear product for dry eye disease is crucial. Hypromellose (Hydroxypropyl methylcellulose), is a semisynthetic cellulose-based polysaccharide and due to its molecular size, it is less viscous than Carboxymethylcellulose. Hypromellose restores the protective nature of the mucous layer of the tear film by crosslinking upon contact with the ocular surface due to a difference in pH, resulting in decreased tear clearance. Thus, it enhances the moisturization and lubrication of the ocular surface and improve dry eye symptoms, without serious adverse effects. The evidence further suggests that hypromellose improves tear stability, optical quality, and contrast sensitivity.</p> <p>Multiple recent articles have reviewed the literature that have compared the clinical efficacy of various artificial tears with these different ingredients. Recent clinical study demonstrates that all cellulose derivatives have a similar efficacy and safety profile in reducing symptoms of dry eye. Thus, it is very challenging to make conclusive recommendation for the use of each kind of artificial tears.</p>

24<sup>th</sup> WHO Expert Committee on Selection and Use of Essential Medicines  
Expert review

<p>Does adequate evidence exist for the safety/harms associated with the proposed medicine?</p> <p>(this may be evidence included in the application, and/or additional evidence identified during the review process)</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p><b>Comments:</b> Hypromellose is regarded as a safe treatment for DED. Few patients may experience adverse effects using hypromellose like mild and transient stinging and burning sensation in the eyes. Use of hypromellose should be discontinued immediately if the stinging persists or worsens.</p>
<p>Are there any adverse effects of concern, or that may require special monitoring?</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p>
<p>Are there any special requirements for the safe, effective and appropriate use of the medicines?</p> <p>(e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p>
<p>Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p><b>Comments:</b> Hypromellose has been found to be cost-effective across several national It is relatively cheap and effective to reduce the symptoms of mild ti moderate DED.</p>
<p>Are there any issues regarding the registration of the medicine by national regulatory authorities?</p> <p>(e.g. accelerated approval, lack of regulatory approval, off-label indication)</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: The artificial tears are available all around the regions of North America, Asia Pacific, Latin America, the Middle East, and Africa.</p>
<p>Is the proposed medicine recommended for use in a current WHO guideline?</p> <p>(refer to: <a href="https://www.who.int/publications/who-guidelines">https://www.who.int/publications/who-guidelines</a>)</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p><b>Comments:</b> WHO launches the first global vision report in 2019. Some thoughts on DED emerge. For example, eye conditions that do not typically impair vision, including dry eye and conjunctivitis, should not be overlooked as they are among the top reasons people seek eye health services in all countries, the report says. Treatments are available for these conditions, often aimed at alleviating the symptoms.</p>