**Reviewer No.2 checklist, section reviews**

### Section: 21. OPHTHALMOLOGICAL PREPARATIONS

<table>
<thead>
<tr>
<th>Proposed 'Green' medicines</th>
<th>Proposed 'yellow' medicines</th>
<th>Proposed 'red' medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Gentamicin* Solution (eye drops): 0.3% (sulfate).</td>
<td>Aciclovir Ointment: 3% W/W.</td>
<td></td>
</tr>
<tr>
<td>* Final selection depends on indication for use</td>
<td>Tetracycline eye ointment 1% (hydrochloride)</td>
<td></td>
</tr>
<tr>
<td>Prednisolone solution (eye drops) 0.5% (sodium phosphate)</td>
<td>Atropine Solution (eye drops): 0.1%; 0.5%, 1% (sulfate).</td>
<td></td>
</tr>
<tr>
<td>☐ Tetracaine Solution (eye drops): 0.5% (hydrochloride).</td>
<td>Epinephrine (adrenaline) Solution (eye drops): 2% (as hydrochloride). – currently listed as 'complementary'</td>
<td></td>
</tr>
</tbody>
</table>

---

**For proposed 'greens': Is there any reason not to endorse these as essential medicines for children?**

- Do these medicines meet a public health need? Yes ✓ No ☐
- Are they registered for use in (all age categories of) children? Yes ☐ No ✓
- Are there any unanswered/unexpected clinical issues with respect to effectiveness or safety? Yes ☐ No ✓
- Are there special requirements or training needed for safe/effective use? Yes ☐ No ✓

**Additional comments if any:**

While gentamicin (as an example of an antipseudomonal antibacterial) is necessary as an ophthalmic preparation, chloramphenicol (0.5% eye drops and 1% eye ointment) is required for gonococcal ophthalmia neonatorum. Chloramphenicol is also suitable for superficial eye infections in primary care settings. While the eye ointment is suitable for PHC use, the drops are needed for more frequent application in severe infections. The need for a prophylactic agent (e.g. povidone iodine 2.5% solution or erythromycin 0.5% ointment could be discussed)

Most texts would warn against the use of topical ophthalmic steroids except under expert supervision (e.g. in order to avoid inadvertent use in undiagnosed herpes simplex infections)

Tetracaine – BNF-C states that this agent, as well as lidocaine and proxymetacaine, are to be avoided in preterm neonates (due to immaturity of the metabolising enzyme system), and are not licensed for that group. This is reflected on the SPC for tetracaine 0.5% ointment in the UK.
Action proposed for the Committee to take:
List the 3 agents as above.
Add chloramphenicol 0.5% eye drops and 1% eye ointment to the Core List.

For proposed ‘yellows’: Are these essential medicines for children?

Do these medicines meet a public health need? Yes ✔ No □

Are they registered for use in (all age categories of) children? Yes □ No ✔

Are there any unanswered/unexpected clinical issues with respect to effectiveness or safety? Yes ✔ No □

Additional comments if any:

While it would appear that acyclovir ointment is needed for herpes simplex infections (the UK SPC recommends use as with adults), consideration needs to be given to the demands of neonatal herpes simplex infections where the intravenous form is more appropriate (Kesson AM. Management of neonatal HSV infection. Paediatr Drugs. 2001;3(2):81-90).

Tetracycline eye ointment is indicated for the treatment of Chlamydia, but the availability of registered products may be limited. A review (Zar HJ. Neonatal chlamydial infections: prevention and treatment. Paediatr Drugs 2005;7(2):103-10) stated that “For the treatment of chlamydial ophthalmia or pneumonia, oral erythromycin for 2 weeks is recommended; additional topical therapy is unnecessary. However, in approximately 20-30% of infants, therapy will not eradicate the organism and the infant may require a repeat oral course of antibiotics. The few published studies on the use of the new oral macrolide antibiotics, such as azithromycin, roxithromycin, or clarithromycin for chlamydial infections in neonates suggest that these agents may be effective; however, more data on their tolerability and efficacy in this patient group are warranted.”

Atropine - BNF-C lists a “risk of systemic effects with eye drops in infants under 3 months – eye ointment is preferred. In addition to the 0.5% solution, a 1% ointment would be needed. BNF-C states that the alternatives, cyclopentolate and homatropine, is not registered for use in children under 3 months. Tropicamide is an alternative, and may be available in both drops and ointment. However, SAMF 7 lists both homatropine and cyclopentolate as “inadequate cycloplegic(s) is children”. Instead, it suggests aseptic dilution of the 1% drops for use in children (< 1 yr – 0.125%, 1-5 yr and those > 5 with blue irides – 0.25%, >5 yrs – 0.5%). Despite this, both homatropine 2% and cyclopentolate 0.5-1.0% are included in the 2006 SA Paediatric STG/EDL. A recent paper would indicate that a single drop of cyclopentolate 1% is effective in children aged 1-7 years, when used to allow examination (Hug T, Olitsky S. Dilation efficacy: is 1% cyclopentolate enough? Optometry. 2007 Mar;78(3):119-21).

Epinephrine eye drops have been used as part of a topical local anesthetic regimen (ALA - adrenaline 1:1000, lignocaine (lidocaine) 4%, and amethocaine 0.5%) to reduce total treatment time for children with simple lacerations. (Priestley S, Kelly AM, Chow L, Powell C, Williams A. Application of topical local anesthetic at triage reduces treatment time for children with lacerations: a randomized controlled trial. Ann Emerg Med. 2003 Jul;42(1):34-40)

Action proposed for the Committee to take:
List acyclovir ointment.
List tetracycline ointment, but call for a review of the treatment of neonatal chlamydial infections and the need for topical treatment and prophylaxis.
List atropine as an example of the class.
Call for a proposal for the inclusion of epinephrine eye drops in children.
The draft EML-c deleted the following sub-section:

21.4 Miotics and antiglaucoma medicines

Acetazolamide Tablet: 250 mg.

- pilocarpine Solution (eye drops): 2%; 4% (hydrochloride or nitrate).
- timolol Solution (eye drops): 0.25%; 0.5% (as maleate).

Glaucoma is rare in children, but can be managed with the standard therapies available from the Model EML.