

Antibiotic eye drops move POM to P

This week, the Medicines and Healthcare products Regulatory Agency announced the reclassification of chloramphenicol eye drops from a prescription only to a pharmacy medicine. **Harriet Adcock** examines the issues raised by this important POM-to-P switch

Sticky, red eyes need no longer be an irritation and source of frustration for pharmacists and patients. Chloramphenicol eye drops, a medicine effective against conjunctivitis, has been reclassified (some may say at last) as a pharmacy medicine. The first reclassification of a prescription only antibiotic eye treatment is a significant switch for pharmacy and is likely to be widely welcomed.

Richard Eggleston, director of research and development, Galpharm International Ltd, says pharmacists have been crying out for the switch for years. "Pharmacists probably see a couple of cases of infective conjunctivitis each week and the lack of an effective over-the-counter treatment is frustrating."

He believes pharmacists are as well placed as GPs to supply treatment. "Supply by a pharmacist will reduce delay in receiving treatment," he says.

An added benefit will be that those patients who need to be referred to a GP or ophthalmologist are more likely to be seen quickly and their condition assessed with more urgency. Having been seen by a pharmacist, patients with more serious eye problems will not have to go through the GP's differential diagnosis. "There will be an overall improvement in the management of eye conditions," says Mr Eggleston.

Safety concerns

Chloramphenicol has been associated with a number of safety concerns — specifically bone marrow toxicity and grey baby syndrome.

According to the Medicines and Healthcare products Regulatory Agency, use of the drops does not increase the risk of aplastic anaemia above that observed in the general population. However, the advice relating to the OTC product is that it should not be used by people with a personal or family history of blood abnormalities, since these are predictors of aplastic anaemia.

Grey baby syndrome was another safety concern highlighted during the reclassification process. Although life-threatening, this syndrome is associated with high systemic concentrations of chloramphenicol in newborns.

The lack of significant systemic absorption from chloramphenicol eye drops and the age restriction of two years that has been placed on the OTC product mean that the risk of grey baby syndrome is extremely low.

Marvyn Elton, a pharmacist and practising optometrist, is assured of chloramphenicol's safety. "Chloramphenicol eye drops have been in use for decades. This product is effective and very safe," he says.

Misdiagnosis needs to be considered since customers with more serious eye infections



need to be seen by a GP, optometrist or ophthalmologist. John Blenkinsopp, a consultant to the pharmaceutical industry and senior research fellow at Keele University, does not think diagnosis will be a stumbling block for pharmacists. "Pharmacists already deal with conjunctivitis and are used to asking the sorts of questions that differentiate between allergic and infective conditions," he says.

There are useful questions that can be asked. Has the infection crossed from one eye to the other? Are other family members affected? Is there a sticky, yellow discharge?

"Like doctors, pharmacists are not going to be right every time, so there needs to be safeguards built in," adds Dr Blenkinsopp. This means giving patients instructions on what to do if there is no improvement after the drops are used.

Mr Elton agrees that diagnosis is straightforward. "As a pharmacist, if one of my customers tells me they have conjunctivitis I ask whether their eye lashes were stuck together with yellowy discharge in the morning. If the answer is 'yes' then it is usually bacterial conjunctivitis."

Not everyone is as confident that the switch to pharmacy status is without any real safety concerns. The Royal College of Ophthalmologists and the College of Optometrists both believe that accurate diagnosis of bacterial conjunctivitis requires use of a slit-lamp microscope, something that only some GPs and few pharmacists are likely to have access to.

"The most obvious primary care professionals to [perform a slit-lamp assessment] are optometrists or ophthalmic medical practitioners," Bryony Pawinska, chief executive of the College of Optometrists, says.

Resistance

Any move to increase the availability of an antibiotic is bound to raise eyebrows as far as resistance is concerned. It is a political as well as a clinical issue and attempts by pharmaceutical companies to reclassify antibacterials in the past have failed. "We thought we might

never get past this issue for OTC products," says Mr Eggleston. But the climate has changed and there is now a willingness to increase access to medicines and to encourage self-care.

Resistance appears not to be a problem for chloramphenicol. Systemic absorption following ocular use is low and decades of use have not resulted in any clinically significant effect on resistance, says the MHRA.

The Royal College of Ophthalmologists has some concerns about resistance although is not opposed to the switch. "In its systemic form chloramphenicol is still effective against some life-threatening pathogens, including some strains of methicillin resistant *Staphylococcus aureus*. More indiscriminate use of the drug could lead to resistance despite the general assurances given," says Brenda Billington, vice-president of the Royal College of Ophthalmologists and chairman of its professional standards committee.

Storage

The summary of product characteristics for OTC chloramphenicol eye drops states that the drops should be stored in a refrigerator. This, says Mr Elton, applies to storage in the pharmacy and is best practice for patients who buy the product.

However, this is hardly a practical solution for a treatment that is used every two hours for the first 48 hours of the course. "During use, which would be for five days, it would not need to be stored in a fridge," he says. "Obviously, it should not be kept exposed to sunlight and while it may be good practice to store the product in the fridge, it is not necessary."

Mr Eggleston echoes this view and hopes that pharmacists will give customers pragmatic advice. "In a hospital setting, after being dispensed from the pharmacy, chloramphenicol is kept in the ward's drug trolley for up to one month," he says.

When can pharmacists expect to see OTC chloramphenicol eye drops? The first product expected to reach pharmacy shelves is Optrex Infected Eyes, launched earlier this week. It will be available from late June. A Galpharm product will be launched later this year.

CPD and practice guidance

A CPD centre pull-out in *The Journal* this week examines use of chloramphenicol for treating acute bacterial conjunctivitis. Practice guidance has been published by the Royal Pharmaceutical Society (www.rpsgb.org) and will be distributed to pharmacists with *The Journal* shortly.