SCOTTISH EXECUTIVE

Chief Medical Officer Directorate

From the Chief Medical Officer

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Dear Colleague

UPDATE TO HIV POST-EXPOSURE PROPHYLAXIS (PEP) GUIDANCE FROM THE EXPERT ADVISORY GROUP ON AIDS (EAGA) FOLLOWING THE RECENT RECALL OF VIRACEPT

1. The recall of the antiretroviral Viracept (nelfinavir)[1] from the European market in June 2007 has implications for PEP, since Viracept is the currently recommended protease inhibitor component of PEP starter packs[2]. EAGA has therefore recommended an update to its HIV PEP guidance, as an interim measure pending a complete update of the guidance, which is in preparation.

2. EAGA recommends that Kaletra (lopinavir/ritonavir) tablets be substituted for Viracept in PEP starter packs. In preliminary discussions regarding changes to the recommended PEP starter pack, EAGA had already concluded that Kaletra (tablet formulation) should be the preferred protease inhibitor (see below). Thus, the recommended regimen for PEP starter packs is:

   One Combivir tablet (300 mg zidovudine + 150mg lamivudine) b.d.

   plus

   Two Kaletra film-coated tablets (200mg lopinavir + 50mg ritonavir) b.d.

[1] MHRA Class 1 Drug Alert – Nelfinavir recall

[2] Uk Health Departments. HIV Post-Exposure Prophylaxis: Guidance from the UK Chief Medical Officers' Expert Advisory Group on AIDS. Revised February 2004.

3. Prescribers need to be aware of the greater potential for drug interactions between Kaletra and other prescription and non-prescription medicines and counsel patients accordingly.

4. When re-packaging Kaletra tablets from high-density polyethylene bottles, a shelf-life of 12 months can be supported provided it does not go beyond the original expiry date. As with other antiretrovirals, PEP is not a licensed indication for Kaletra. It should, therefore, be supplied under a "specials manufacturing licence" as a "special". For further information regarding stability on re-packaging, please see the EAGA website – www.advisorybodies.doh.gov.uk/eaga.

5. At the end of 2005, EAGA considered all available protease inhibitors as possible substitutes for Viracept. EAGA's primary consideration was that the PEP regimen should reflect standard of care for first-line therapy in established HIV infection and unboosted protease inhibitors were no longer recommended for first-line treatment. Kaletra has better gastrointestinal tolerability than Viracept and is effective against viral strains with protease inhibitor resistance mutations. The tablet formulation of Kaletra causes fewer side effects, does not require refrigeration and has a reduced pill burden.

Yours sincerely

DR HARRY BURNS