Single Technology Appraisal (STA)

[Alcohol dependence –nalmefene ID660}

Comments on behalf of the National Substance Misuse Non-Medical Prescribers Forum

---

The Forum recognises the significant change that the licensing of nalmefene may open up in the treatment of individuals drinking at hazardous/harmful levels. It brings a pharmaceutical arm to a harm reduction approach for alcohol in respect of the treatment of patients who are not physically dependant and this is welcome indeed.

- Along with our comments we have attached two papers which we think the Appraisal Committee should consider- firstly "**Nalmefene for Alcohol Dependency"** in the *Drugs & Therapeutic Bulletin of the British Medical Journal* Vol 52 | No 5| May 2014. This concludes that "Based on the limitations of the evidence, the relatively modest reductions in drinking compared with placebo, lack of evidence on health related outcomes and concerns over the generalisabilty of the data, we cannot recommend the use of nalmefene." The paper also contrasts the cost of nalmefene versus naltrexone – in effect double the cost of naltrexone. It also goes on to highlight the inconsistency of psychosocial interventions in the treatment of alcohol misuse in England notably within Primary Care [The marketing authorisation for nalmefene specifies that it should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption] — which is the setting where the use of nalmefene would appear to be most relevant. These inconsistencies point to a lack of suitably trained staff across the country and this is linked to the different health infrastructures in place as well as differing health resource allocation between areas. The Forum is aware of examples of nalmefene being prescribed by specialist alcohol agencies [secondary care] – so as to be able to ensure the correct level of psychosocial support to patients.
- Secondly **"Evidence about the use of naltrexone and for different ways of using it in the treatment of alcoholism"** *John David Sinclair – Alcohol & Alcoholism Vol 36 No1, pp2-10 2001.* His paper details 8 double-blind placebo controlled studies using naltrexone in patients who were still drinking. Various psychosocial approaches were utilised in the studies. We would direct you to his "General Conclusions and Comments" on pp8.

The Forum makes the following comments

- There appear to be no head to head trials of nalmefene v naltrexone to compare and contrast. This is something that we would like to see carried out.
- Previous contributors to this STA have made comment of nalmefene having less side effects and possibly less liver toxic than naltrexone. Given that they are almost identical agents the evidence

for those differences appears limited. Nalmefene is licensed for use on an as needed basis: patients should take one tablet on days on which they perceive a risk of drinking – naltrexone could be given in the same way and therefore the risk of liver damage would appear in both cases to be very low. It is also worth noting that the hepatoxic effect of heavy drinking is much worse than either naltrexone or nalmefene.

- The Forum would like to ask is there a role for naltrexone being prescribed to patients currently drinking [off-licence indication] in combination with psychosocial support? Would the Appraisal Committee be willing to comment on this?
- Cost effectiveness – it is clear that naltrexone which can be prescribed as a generic pharmaceutical product in the United Kingdom has significant savings over nalmefene. This is another consideration that the committee may wish to comment on

[redacted] on behalf of the National Substance Misuse Non-Medical Prescribers Forum – [redacted] [redacted]
25/07/14