Gateshead Council Public Health;

Nalmefene for reducing alcohol consumption in people with alcohol dependence.

1.0 Background

This briefing relates to the provision of Nalmefene (Selincro®) in conjunction with psychosocial support, for the reduction of alcohol consumption in people with alcohol dependence in Gateshead.

Harmful drinking has been defined by the National Institute for Health and Care Excellence (NICE) as a pattern of alcohol consumption that causes alcohol related health problems. These include psychological problems such as depression, alcohol-related accidents and physical illness such as acute pancreatitis. [1] This can progress into alcohol dependence; characterised by craving, tolerance, a preoccupation with alcohol and continued drinking in spite of harmful consequences. [1]

It is estimated that 1.6 million adults in England may have a level of alcohol dependence. A proportion of these may not need specialist treatment, but would benefit from an alcohol brief intervention. [2]

Specifically in Gateshead, the rate of alcohol related mortality in 2014 was 56.7 per 100,000 population and alcohol specific mortality in 2012-2014 was 17.7 per 100,000 population, and is significantly worse than the England average (45.5 and 11.6 respectively per 100,000 population). [3]

In 2014, NICE released a Technology Appraisal Guidance (TA325) entitled 'Nalmefene for reducing alcohol consumption in people with alcohol dependence'. [4]
NICE Technology appraisals cover the use of new and existing medicines and treatments within the NHS in England.

'Nalmefene is recommended by NICE, within its marketing authorisation, as an option for reducing alcohol consumption, for people with alcohol dependence:

- who have a high drinking risk level (defined as alcohol consumption of more than 60g per day for men and more than 40 g per day for women, according to the World Health Organization's drinking risk levels) without physical withdrawal symptoms, and
- who do not require immediate detoxification.

The marketing authorisation states that nalmefene should:

- only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption, and
- be initiated only in patients who continue to have a high drinking risk level, two weeks after initial assessment.' [4]

2.0 Nalmefene (Selincro®)

Nalmefene (Selincro®) is an opioid receptor modulator. It exhibits antagonist activity at the mu and delta opioid receptors, and also displays partial agonist activity at the kappa opioid receptors. [4]

The Summary of Product Characteristics (SPC) states that Selincro® is indicated for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. [5]

Selincro® should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Selincro® should be initiated only in patients who continue to have a high DRL two weeks after initial assessment. [5]

Dosage for Adults:

Selincro® is to be taken as-needed: on each day the patient perceives a risk of drinking alcohol, one tablet should be taken, preferably 1-2 hours prior to the anticipated time of drinking. If the patient has started drinking alcohol without taking Selincro®, the patient should take one tablet as soon as possible.

The maximum dose of Selincro® is one tablet per day. Selincro® can be taken with or without food. [5]

The most common adverse reactions were nausea, dizziness, insomnia, and headache. The majority of these reactions were mild or moderate, associated with treatment initiation, and of short duration. Confusional state and rarely, hallucinations and dissociation were reported in the clinical studies. The majority of these reactions were mild or moderate, associated with treatment initiation and of short duration (a few hours to a few days). Most of these adverse reactions resolved during continued treatment and did not recur upon repeated administration. While these events were generally short-lasting, they could represent alcoholic psychosis, alcohol withdrawal syndrome, or comorbid psychiatric disease. [5]

For full details, the SPC for Nalmefene (Selincro®) is available through the Electronic Medicines Compendium: https://www.medicines.org.uk/emc/medicine/27609. [5]

3.0 Gateshead Council Public Health Nalmefene pathway

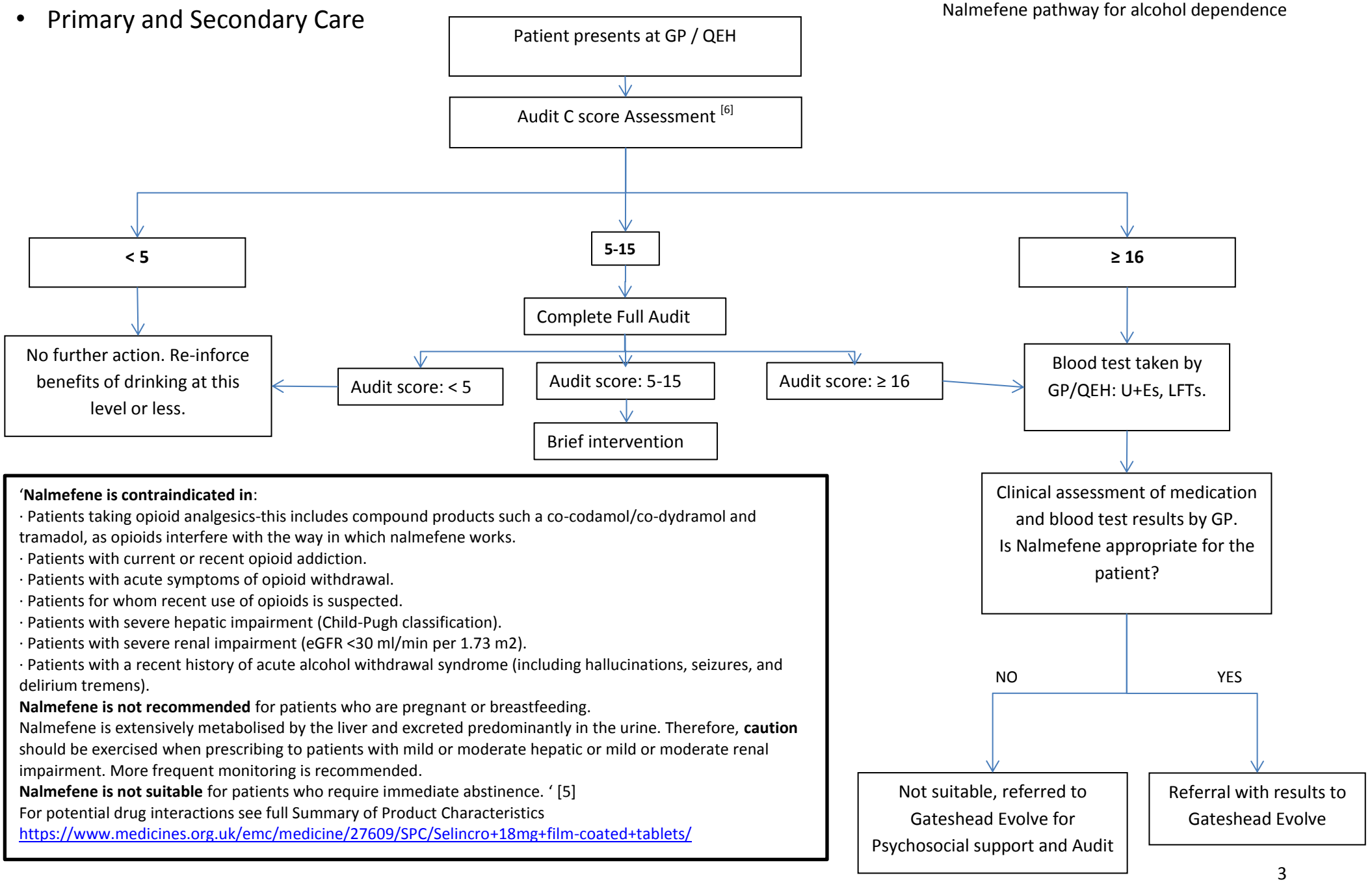
A pathway has been developed for the assessment of Alcohol dependence and provision of treatment, including Nalmefene, in Gateshead (Figure 1).

GPs and Pharmacies

Within the scope of this pathway, it is not expected that the supply of Nalmefene will take place through the provision of an FP10 prescription from the GP. The funding arrangements for the pathway **do not** include reimbursement for prescriptions issued by means other than from the Gateshead Evolve specialist substance misuse service.

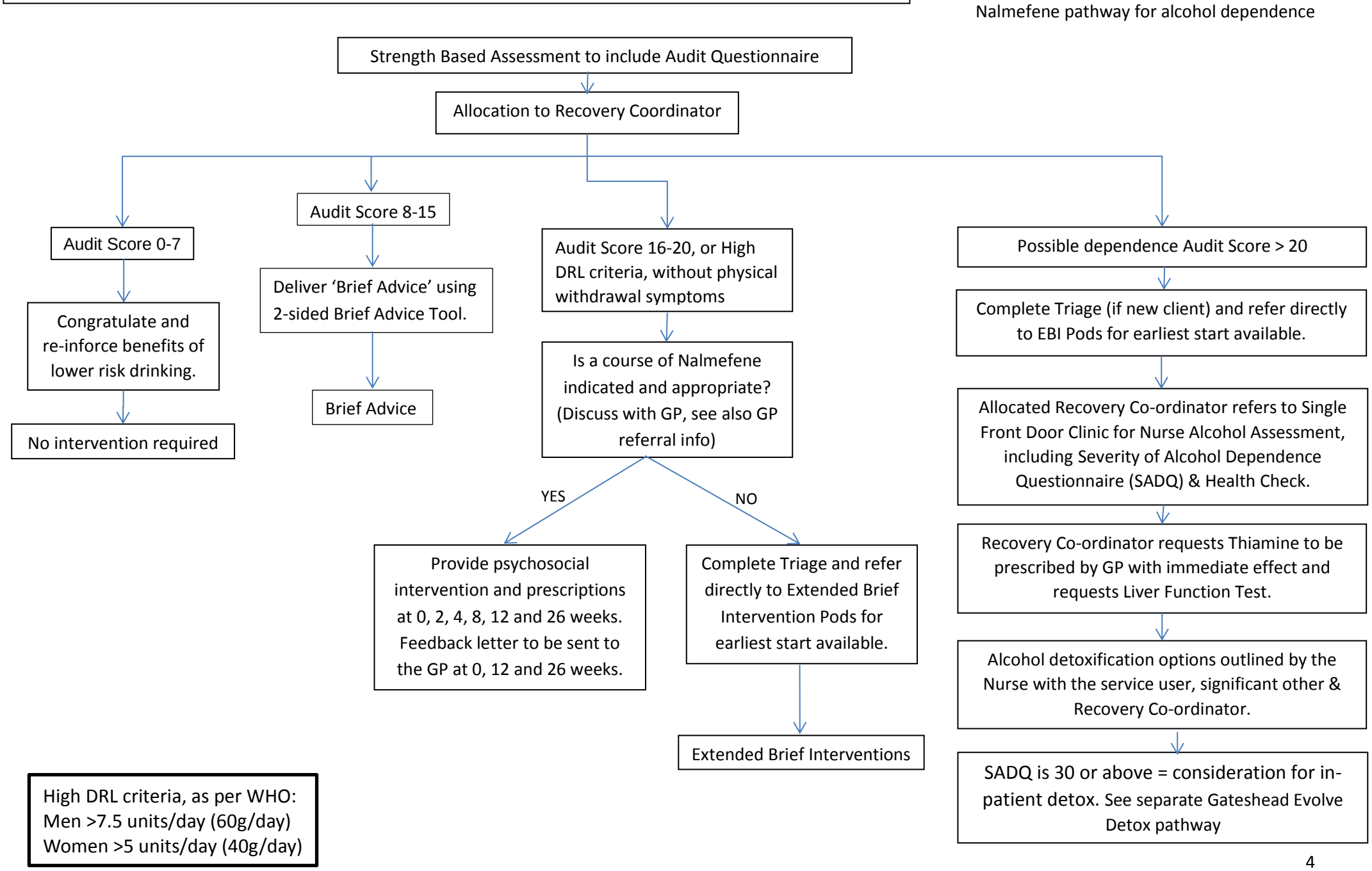
Figure 1. Alcohol intervention pathway

- Primary and Secondary Care



'**Nalmefene is contraindicated in**:
· Patients taking opioid analgesics-this includes compound products such a co-codamol/co-dydramol and tramadol, as opioids interfere with the way in which nalmefene works.
· Patients with current or recent opioid addiction.
· Patients with acute symptoms of opioid withdrawal.
· Patients for whom recent use of opioids is suspected.
· Patients with severe hepatic impairment (Child-Pugh classification).
· Patients with severe renal impairment (eGFR <30 ml/min per 1.73 m2).
· Patients with a recent history of acute alcohol withdrawal syndrome (including hallucinations, seizures, and delirium tremens).
Nalmefene is not recommended for patients who are pregnant or breastfeeding.
Nalmefene is extensively metabolised by the liver and excreted predominantly in the urine. Therefore, **caution** should be exercised when prescribing to patients with mild or moderate hepatic or mild or moderate renal impairment. More frequent monitoring is recommended.
Nalmefene is not suitable for patients who require immediate abstinence. ' [5]
For potential drug interactions see full Summary of Product Characteristics
https://www.medicines.org.uk/emc/medicine/27609/SPC/Selincro+18mg+film-coated+tablets/

Figure 1 continued. Integration of Nalmefene into Gateshead Evolve's Alcohol intervention pathway. [7]



4.0 Useful contacts

Gateshead Evolve Central Hub: 0191 594 7821

Joy Evans, Public Health Programme Lead: Risk Taking Behaviours

joyevans@gateshead.gov.uk 0191 4332421

5.0 References

[1] NICE, 2011. Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence [CG115]. https://www.nice.org.uk/guidance/cg115/chapter/introduction *Accessed 23/08/16*.

[2] PHE, 2016. Health matters: harmful drinking and alcohol dependence. https://www.gov.uk/government/publications/health-matters-harmful-drinking-and-alcohol-dependence/health-matters-harmful-drinking-and-alcohol-dependence. *Accessed 23/08/16.*

[3] PHE, 2016. Gateshead. Local Alcohol Profile. http://www.nepho.org.uk/pdfs/local-alcohol-profiles/E08000037.pdf. *Accessed 23/8/16.*

[4] NICE, 2014. Nalmefene for reducing alcohol consumption in people with alcohol dependence. NICE Technology Appraisal Guidance [TA325]. https://www.nice.org.uk/guidance/ta325/chapter/1-guidance *Accessed 22/08/16.*

[5] Lundbeck Limited, 2015. Selincro 18mg film-coated tablets. Summary of Product Characteristics. https://www.medicines.org.uk/emc/medicine/27609. *Accessed 22/08/16.*

[6] PHE, 2017. Audit-C. https://www.alcohollearningcentre.org.uk/Topics/Latest/AUDIT-C/ *Accessed 07/02/17.*

[7] CRI. Alcohol screening tool. CRI Alcohol model pathway. *Accessed 07/02/17.*

6.0 Abbreviations

Abbreviation	Definitions
DRL	Drinking Risk Level
GP	General practitioner
NICE	National Institute for Health and Care Excellence
SADQ	Severity of Alcohol Dependence Questionnaire
SPC	Summary of Product Characteristics
QEH	Queen Elizabeth Hospital