

## 2. INTRODUCTION

In South Asia, opioid use and in particular heroin use, is on the increase. The diffusion of injecting drug use is causing concern in the region (UNODC & MSJE, 2004). Heroin and other opioid dependence cause significant morbidity and mortality; it is a chronic and enduring condition that often requires long-term treatment and care. Adequate access to a range of treatment options should be offered to respond to the varying needs of people with heroin/opioid dependence.

Substitution maintenance treatment is an efficacious, safe and cost-effective modality for the management of opioid dependence. Such treatment is a valuable and critical component of the effective management of opioid dependence and the prevention of HIV among IDUs. Scientific evidence

suggests that substitution treatment can help reduce criminality, infectious diseases and drug-related deaths as well as improve the physical, psychological and social well-being of dependent users (Gibson *et al*, 1999). Provision of substitution maintenance therapy should be integrated with other HIV preventive interventions and services, as well as with those for treatment and care of people living with HIV/AIDS (WHO, UNODC & UNAIDS, 2004). A recent review recommended that the provision of substitution treatment should be supported for opioid dependence in countries with emerging HIV and injecting drug use problems as well as in countries with established populations of injecting drug users (Gowing *et al*, 2004).

Pharmacological agents used as substitution substances in the management of opioid dependence are: methadone, buprenorphine, Levo Alpha Acetyl Methadone (LAAM), Dihydrocodeine and tincture of opium (laudanum). Methadone is the most employed agent in substitution treatment around the world. There have been increasing doubts about the safety of LAAM because of the related cardiac risk. Buprenorphine is emerging as a useful complementary or alternative option to methadone.

The partial opiate-receptor agonist profile of buprenorphine is attractive, and this drug could be used to suppress heroin craving and antagonise heroin effects, while having a limited potential for dose escalation and toxicity. Buprenorphine is efficacious in comparison with other available options as shown by individual comparative studies of buprenorphine in heroin

**Drug substitution** means replacing, under medical supervision, the drug, which the drug user is taking with a similar substance. It may also mean using the same drug but taking it in a different way, for example, sublingual buprenorphine to replace injecting of buprenorphine. Substitution treatment comes either with or without psychosocial support.

dependence (Johnson *et al*, 1992; Strain *et al*, 1994; Ling *et al*, 1996; Ling *et al*, 1998; Johnson *et al*, 2000; Pani *et al*, 2000) and meta-analyses (West *et al*, 2000; Barnett *et al*, 2001). Observational data from France where buprenorphine substitution is widely used lend support to the notion of reduced toxicity (Auriacombe *et al*, 2001). Since it is a partial agonist, buprenorphine can be especially useful for patients who need only a limited degree of agonist action. The one-year retention rate for buprenorphine substitution combined with psychosocial care was 75 per cent compared with 0 per cent for a placebo group in Sweden and the treatment was safe and efficacious for heroin dependence (Kakko *et al*, 2003).

Buprenorphine also has an important role to play in the control of HIV infection among and from injecting drug users. However, the impact of buprenorphine on HIV infection in this population has been less researched than methadone. A study at Chennai in India demonstrated the potential of buprenorphine treatment in reducing injecting drug use among heroin users (Kumar *et al*, 2003). As buprenorphine reduces the number of injecting episodes, it is likely to have an effect similar to methadone on reducing the spread of HIV.

#### **Buprenorphine Substitution**

As efficacious as other available options

Reduced toxicity

Better retention in treatment

Potential for reducing HIV among heroin injectors

Buprenorphine, in sublingual tablet form (in the doses of 0.4 mg and 2 mg), has been licensed in India for the management of opioid dependence, including maintenance and detoxification, at specified drug treatment centres approved by the Ministry of Social Justice and Empowerment, Government of India. This preparation is effective in the long-term, as a maintenance treatment programme, and in the short-term for treatment of heroin withdrawals. To assist in the safe and effective implementation of buprenorphine treatment in India and other countries of the SAARC region, a protocol was developed by the All India Institute of Medical Sciences, New Delhi. The practice of substitution maintenance therapy must be guided by clinical modules and supported by adequate training and evaluation. Possible adverse consequences need to be minimised by adhering to best clinical practices, monitoring treatment quality and outcomes, and instituting adequate control measures and regulations to avoid diversion of the medicines into illicit channels. Hence, this module on buprenorphine substitution has been developed to guide maintenance programmes using buprenorphine.