

**Key Findings Report Submitted to the ESRC, May 2015**

**Jonathan Gabe, Simon Williams, Catherine Coveney and John Abraham**

**1. Pharmaceuticalisation – the transformation of human conditions, capabilities and capacities into opportunities for pharmaceutical intervention.**

Analysis across our data sets shows an uneven pharmaceuticalisation of the sleep-wake cycle. Substantially more hypnotics are prescribed in England (remaining stable at around 10 million since 2000) than wakefulness promoting drugs.

Focus group data on the use of sleep/wakefulness medicines revealed evidence of patient/consumer resistance to pharmaceuticalisation. For example, some respondents (mainly non-users or ex-users of sleeping pills) rejected pharmaceuticals for sleep problems and preferred non-pharmacological therapies. Likewise, we found a general resistance to social uses of wakefulness promoting pharmaceuticals.

Other respondents however provided support for pharmaceuticalisation by presenting themselves as deserving of pharmaceuticals, questioning medical authority when doctors suggested coming off them and, on occasion, seeking prescription drugs outside the medical encounter. The later evidence provides a challenge to the current depharmaceuticalisation of sleep agenda.

Documented cases of depharmaceuticalisation of sleep are rare. The process is thus best seen as fluid, particularly given recent CBTi-based interventions, although doctors and other sleep experts do not necessarily see CBTi as an alternative to medication. On this basis we conclude that the degree to which sleep problems are subject to (de)pharmaceuticalisation in the future remains uncertain.

**2. Developments in sleep-promoting medications**

Drug development of hypnotics has been slow with the European Medicines Agency (EMA) approving only two, Sonata (zapelon) and Circadin (melatonin) since 1999. The pharmaceutical industry's innovation strategy has been conservative, designed primarily to limit the adverse effects of benzodiazepines through marketing more Z drugs (Zopiclone, Zolpidem and Zaleplon). However, according to the National Institute for Health and Care

## The pharmaceuticalisation of sleep and wakefulness in Britain since 2000

Excellence (NICE), Z drugs have no clinical advantages over benzodiazepines (e.g. in reducing dependence). Concurrently, there has been little attempt to address long-term insomnia, with the possible exception of Circadian, licenced for use up to 13 weeks, though chronic insomnia can last much longer.

The regulatory system also discourages innovative drug development which could meet the challenge of long-term insomnia. When innovations like Circadin are assessed for efficacy in clinical trials this is often based solely on comparisons with placebo, rather than with existing hypnotics.

### **3. The challenges for sleep promoting drugs**

A key challenge for pharmaceutical companies, given their stated aim of drug innovation, is the development of efficacious hypnotics for chronic insomnia without risk of dependence. This requires a decisive shift away from an innovation strategy based on marketing for the overuse of benzodiazepines and z-drugs. Crucial in achieving this are regulators who set the context in which the industry operates. Regulators should require new hypnotics to be compared with existing sleeping pills in clinical trials and demonstrate therapeutic advance. NICE needs to be more pro-active in encouraging cost-effective prescribing and the Government needs to take the problem of chronic insomnia more seriously by backing public health initiatives on how best to tackle this condition as part of a wider attempt to promote the sleep of the nation. Patient organisations too can lobby for access to new/existing medications and non-pharmacological alternatives.