## Economic Evaluation of Suboxone for the management of opiate addiction

prepared for the

Expert Group on a Regulatory Framework for Suboxone & Buprenorphine



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## **Executive Summary**

- Schering Plough submitted a cost effectiveness and budget impact analysis for Suboxone® (buprenorphine / naloxone combination in the ratio of 4:1) as an alternative to the standard of care i.e. methadone in the maintenance treatment of opiate addiction in the Irish setting. In August 2007, there were 8344 individuals in receipt of substitution therapy prescribed by HSE clinics (64%) and GPs (36%).
- This submission included development of a cost-effectiveness model incorporating Irish cost data as well as quality of life, opiate abstention and retention in treatment rates. The study was undertaken from the perspective of the Department of Health and Children (DoHC). The comparator used in the model was methadone.
- In the base case, opiate abstention rates were assumed equal for Suboxone and methadone based on review of literature. The company suggested an alternative base case where abstention rates were allowed to follow a single unpublished 16-week randomised control trial by Kamien et al, comparing Suboxone and methadone efficacy in a private community clinic in the US, which demonstrated superior opiate abstention associated with Suboxone measured as overall opiate negative urinalysis rates. This study did not however show a significant difference between interventions in achieving 12 consecutive opiate negative results in the context of thrice weekly urinalysis i.e. the 4-week consecutive opiate negative criteria required in the Irish setting for decreasing the level of supervision.
- In the base case, the incremental cost-effectiveness ratio (ICER) was €361,570 per quality adjusted life year (QALY) for Suboxone as compared with methadone in the clinic setting and €32,207 per QALY for Suboxone as compared to methadone in the community setting. Therefore, considering a cost-effectiveness threshold of €45,000 per QALY, Suboxone is not cost-effective in either setting under these assumptions.
- In the alternative base case using opiate abstinence rates from the single unpublished 16-week randomised control trial by Kamien et al, comparing Suboxone and methadone efficacy in a private community clinic in the US, the

ICER was cost saving for Suboxone as compared with methadone in the clinic setting (saving of 27,350 per patient per year). A threshold analysis demonstrated that Suboxone is cost-effective in the clinic setting if opiate abstinence rates are at least 10% greater than those for methadone. Suboxone was not cost-effective as compared with methadone (ICER of 317,497 per QALY) in the community setting.

- A series of univariate sensitivity analyses were conducted which provide useful information on how the cost-effectiveness of Suboxone can be improved. In the clinic setting, the total cost of Suboxone exceeds methadone by 1664 per patient treated per year (1,807 versus 30,143). Decreasing the cost of Suboxone by 10% would decrease the difference between Suboxone and methadone cost of treatment per patient per year in the clinic settings by €150. Transferring clinic patients who are opiate stable to the community at 28 weeks reduces the difference between Suboxone and methadone cost per patient of treatment by €120. Transferring patients to three times weekly dosing of Suboxone after 12 weeks stabilisation reduces the difference between Suboxone and methadone cost of treatment in the clinic setting by €590 per patient per year. It should be noted however that ICERs for Suboxone as compared to methadone remained in excess of €200,000 per QALY in all cases i.e. not cost-effective. Transferring clinic patients to three times weekly dosing of Suboxone after 8 weeks stabilisation is however costeffective and combined with transferring stable patients to the community at 28 weeks becomes cost-saving.
- In the community setting, the total cost of Suboxone exceeds methadone by €1529 per patient treated per year (€065 versus €3535). Using the same patient care fee for Suboxone as for methadone reduces the cost difference between Suboxone and methadone by €182 per patient per year. Increasing Suboxone dose from 14.1mg daily to 16mg and 24mg daily increases the difference by €203 and €1214 respectively. Allowing patients to transfer to three times weekly Suboxone after 8 weeks stabilisation reduces the cost difference by €3 per patient per year. It should be noted however that ICERs for Suboxone as compared with methadone remained in excess of €250,000 per QALY in all cases i.e. not cost-effective.

- A subsequent analysis investigated the cost-effectiveness of Subutex® (buprenorphine alone) as compared with methadone in the clinic setting. The ICER remained not cost-effective at €307,818 per QALY. The total cost of buprenorphine exceeded methadone by €1417 per patient treated per year (€31,560 versus €30,143).
- A budget impact analysis indicated the drug acquisition cost for Suboxone to the HSE including the current wholesaler mark-up to be €2.2m, €3.1m and €4.3m in 2008, 2009 and 2010 respectively. The new wholesaler margins applicable from 2008 yield estimates of €2.1m, €3.0m and €4.2m in 2008, 2009 and 2010 respectively.
- From the evidence available Suboxone and buprenorphine cannot be considered cost-effective for patients attending HSE clinics in the Irish setting unless opiate abstention rates mirror a single unpublished 16-week randomised control trial by Kamien et al, comparing Suboxone and methadone efficacy in a private community clinic in the US, or patients are switched to three times weekly dosing after 8 weeks stabilisation. The latter scenario may be a suitable option for some patients based on clinical assessment of stability and likely abstinence. Suboxone initiated in the community cannot be considered cost-effective under any scenario investigated. The cost effectiveness profile may improve as the evidence base underpinning the use of buprenorphine and Suboxone develops.