



Note To: Mr. B. Bramley
From: G. Read
Subject: Transdermal Nicotine

I have read all of the papers submitted in preparation for the TSRT paper on Transdermal Nicotine and would conclude the following:

1. Irrespective of the efficacy of nicotine patches they have three potential uses (i) as a smoking cessation strategy, (ii) in a dual use scenario with cigarettes or (iii) as a stand alone therapeutic product for alleviating neurological disorders.
2. Industry interest in these products should be conditioned by whether they will be available as prescription or non-prescription products in the short, medium and long-term.
3. It is my considered view that nicotine patches will initially only be available on prescription in Europe and the USA. This conclusion is based on past experience with other products such as nicotine gum which remained on prescription for several years. In the case of Favour, the product delivering nicotine vapour, which although never marketed was ruled to be a pharmaceutical product by the FDA.
4. For the period over which nicotine patches remain on prescription they will be considered as pharmaceutical/therapeutic products for use in smoking cessation.
5. Even though nicotine patches carry potentially high doses of nicotine, due to their design specifications a case could be made that they are reasonably safe by virtue of their slow release characteristics, and subject to satisfactory use during the prescription period, may well become freely available over time.
6. Once outside prescription control, the product would continue to be available for use in smoking cessation or in a dual use scenario. I cannot envisage that any mainstream pharmaceutical company would market the product directly on the basis of a therapeutic agent for alleviating neurological disorders without conducting long-term ethical clinical trials normally undertaken by this industry in support of product use.
7. In conclusion, I would suggest that the primary consideration should be to establish the company position on using nicotine patches in a dual use situation. Should this be the case, due to the anticipated delays in the product becoming generally available, the company would have sufficient time to conduct appropriate trials to establish their efficacy during dual use and to establish end-user response to this proposition.

Graham Read

G. Read
19th May 1992

502584581