

SECRET

Note for the Tobacco Strategy Review Team

Transdermal Nicotine

A note discussing a new type of transdermal nicotine patch (TNP), developed by Stowic Resources Ltd., was circulated after the Tobacco Strategy Review Team meeting on 26th February.

Team members were asked for their reaction to this development and, more specifically,:-

- (a) Whether the Stowic product represented a significant technical advance and whether it is likely to be developed into a saleable product for mass markets.
- (b) If so, does it represent a significant threat to the tobacco industry.
- (c) What should be the reaction, if any, by B.A.T Industries.

Papers from Imasco, Brown & Williamson, BATCF and BATCo. have been circulated. Key points from these papers are:-

1. Introduction

- 1.1 The technology for the transdermal application of ethical pharmaceuticals has been in use for over 10 years. TNPs which are marketed as a major advance in smoking cessation therapy were first introduced in Europe in 1990 and in the US in late 1991. They are now available in 37 countries, sometimes on a prescription-only basis (e.g. USA) and sometimes as an over-the-counter (OTC) product (e.g. Italy and Ireland).
- 1.2 The patches work through producing an alternative source of nicotine but it is recommended that they should be used in conjunction with complementary therapy aimed at treating the requirements for the other behavioural responses and organoleptic rewards which smokers seek.
- ||| US sales of TNPs have been high since their launch in late 1991 and they do appear to be a significant development.
- 1.3 Advantages claimed over alternative sources of nicotine such as nicotine chewing gum are that the patches are more controllable, less obvious in use and avoid the possibility of very high intakes due to addictive chewing. However, the raising of the background levels of nicotine is said to be less satisfactory to the user than the peaks achieved by smokers with each cigarette.

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- 1.4 Other advantages are relatively simple manufacturing techniques and no excise. They also avoid the problems of ETS.
  - 1.5 Disadvantages include dangers associated with the discarding of patches which still contain levels of nicotine which are high enough to be toxic and possible skin irritation in use.
2. Is the Stowic Patch a Significant Technical Advance
- 2.1 If the manufacturer's claims can be confirmed, it does appear that the delivery system in the Stowic system would overcome the disadvantages of high residues in discarded patches and skin irritation in use.
3. Does the Produce Represent a Significant Threat to the Tobacco Industry
- 3.1 Assuming that the therapeutic effects of nicotine in combatting Parkinson's disease, Alzheimer's disease, etc. are accepted, TNPs could be marketed as a means for providing the 'good' components of cigarettes while avoiding the 'bad' components. This could be more effective in the long run than simply marketing the patches as a means of stopping smoking.
  - 3.2 The initial growth in demand suggests that there is immediate acceptance of the product but there must be some question as to whether this will be maintained or whether it will be a short-lived phenomenon.
  - 3.3 A view has been expressed that this is a commodity product which is not susceptible to branding. However, since it is being marketed by pharmaceutical companies who have been able to establish powerful brand images for other products, this view might be questioned.
4. What Should be the Reaction by B.A.T Industries
- 4.1 It is suggested that there should be formal arrangements to monitor further technical and marketing developments related both to the skin patch and to alternative nicotine delivery systems.
  - 4.2 BAT should also decide whether representations should be made to restrict the skin patch to prescription sales only.
  - 4.3 Basic research might be started on other nicotine delivery systems in the form of capsules or lozenges which could substitute for cigarettes. This research would include a scan of similar products developed by other companies.
  - 4.4 However, because of the possible confusion of images, TNPs which are effectively pharmaceutical products, are not thought to be suitable for promotion by a tobacco company.

RS/DJS  
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