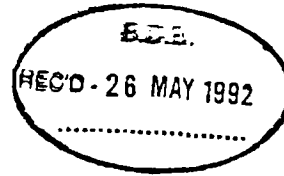


RESTRICTED



NOTE FOR MR B D BRAMLEY

TRANSDERMAL NICOTINE PATCHES

INFORMAL MEETING WITH PROFESSOR M RAWLINS  
UNIVERSITY OF NEWCASTLE - 21 MAY 1992

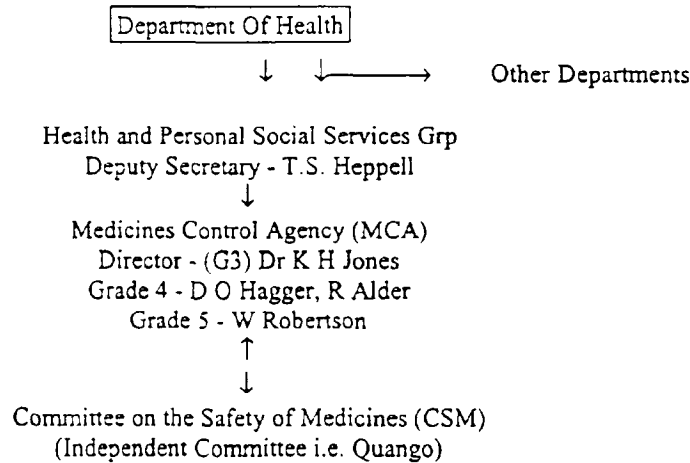
**Present:** Professor M Rawlins, Professor of Clinical Pharmacology, Newcastle  
Professor J Idle, Professor of Pharmacogenetics, Newcastle  
Dr R E Thimton, BATCo

Professor Rawlins' is a member and chairmen-elect of the Committee on the Safety of Medicines (CSM) which is consulted by the Medicines Control Agency (MCA), a sub-unit of the Department of Health. On becoming Chairman, Professor Rawlins, while remaining a Professor, will relinquish his position as Head of Department at Newcastle. This will pass to Professor Idle.

**Subject of Discussion:** Probable status of transdermal nicotine patches in the U.K.

**ORGANISATIONAL RELATIONSHIP:**

Secretary of State for Health: The Rt Hon Virginia Bottomly, MP



5025845/6

## CUSTOM AND PRACTICE:

Manufacturers must approach the MCA if any health claims are made for their products.

They can apply for three categories of product approval:-

- (a) Prescription Only
- (b) Pharmacy Sales (over the counter)
- (c) General Sales list (for widespread sales in tobacconists) - e.g. as with aspirin.

NOTE: (c) as an outlet for medicines may be unique to the U.K. in relation to other E.C. Countries and will probably disappear in the process of harmonisation.

The Manufacturer's application, and supporting evidence, is then considered by the MCA who in practice nearly always consult the independent CSM (this typically British procedure parallels the role of the Independent Scientific Committee on Smoking and Health), and the recommendations of the CSM are of critical importance.

It is also now possible to make a direct approach to the E.C. for European Registration but (a) it is more complicated and (b) almost certainly does not allow general sales to be accommodated.

## TRANSDERMAL NICOTINE PATCHES IN THE U.K.

### General

If no health claims were made, manufacturers could, in theory, market patches without reference to the MCA. However, use in smoking cessation would undoubtedly be taken as a health claim. As an alternative to cigarettes, health issues may be judged to be implicitly raised.

Because of the prevailing attitudes to smoking, and because of the acute toxicity of nicotine, Professor Rawlins felt that the MCA would almost certainly take legal advice on the status of patches if no claims were made. Professor Rawlins analogy for this was the opening of Pandora's box: In the worst scenario all new brands of cigarettes would require licensing because of their nicotine content (existing brands would automatically receive licences).

However, if patches were requested for smoking cessation, but were then used as a replacement for smoking in certain circumstances, the MCA were unlikely to be concerned. The MCA were unlikely to vary their judgement in respect of the identity of the manufacturer; they might even be more critical of a pharmaceutical

manufacturer who would be expected to be aware of the necessary procedures in some detail.

#### NATURE OF SUPPORTING DATA

##### Safety

Particularly in respect of children for articles in widespread use.

##### As an alternative to cigarettes

On-going epidemiological data would probably be requested.

##### Category of product approval

The more widespread the approval the more substantial should the supporting evidence be.

Categories of approval can be changed without product experience.

#### COMMENTS

Professor Rawlins was extremely helpful throughout our discussion but the above indicates his view that the procedures for marketing transdermal nicotine patches are substantial and likely to be expensive. He advised that if BAT were interested in proceeding further they should contact those skilled in registering compounds and lawyers.

If required a further discussion with Professor Rawlins would be possible.



Dr R E Thornton

cc: Mr G A Read  
Dr L J Rudge