

To: All interested organisations

1 February 2010

Dear Sir/Madam

CONSULTATION LETTER MLX 364

THE REGULATION OF NICOTINE CONTAINING PRODUCTS

Introduction

1. We are writing to consult you on whether to

Agency calculated that in England, smoking causes an average of over 1,663 deaths per week, or 237 deaths every day, or nearly 10 deaths an hour¹⁰.

4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.
6. Ensure consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The full code of practice is available at:

CONSULTATION LIST

ActiQuit
ADFAM
Addiction Help Services
Advanced Formulations
Advisory Council on the Misuse of Drugs
Advertising Association
Advertising Standards Authority
Association of British Pharmaceutical Industry
All Party Pharmacy Group
Amazing Health
Arkopharma (UK) Limited
Arrow Generics Limited
Association of British Healthcare Industry
Association of Chief Police Officers

Carers National Association
Care Quality Commission
Cancer Research UK
Central Medical Advisory Committee
Chemist and Druggist
Child Safe Packaging Group
Cigstar
Cigtronics Limited
CN Creative Limited

Nicogel Limited
North West Medicines Information Centre
No Limited
Novartis Consumer Health UK
Nursing and Midwifery Council
Meldex International
My e cigarette
Office of Fair Trading
OTC Bulletin
OTC Business News
Paediatrics Chief Pharmacists' Group
Pati1 Tnsumeana l

Shenzhen China

Annex A

UNLICENSED NICOTINE CONTAINING PRODUCTS

100mg/patch). When measuring plasma nicotine release patches here as

! *Safety*

Summary: Intervention & Options

Department /Agency:

MHRA

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The MHRA/CHM continuously monitors the safety of

Summary: Analysis & Evidence

Evidence Base (for summary sheets)

1. Title of Proposal

Regulation of all Nicotine Containing Products (NCPs)

2. Rationale for Government Intervention

There are a number of products containing nicotine (including electronic cigarettes and topical gels), that are increasingly available but are not licensed medicine

3. Since then the indication for NRT has been extended to 'cut down to quit' and 'temporary

manufacturers will go through the proc

NCPs cannot guarantee quality; the release of nicotine from the same NCP over time can vary with reduction over time indicating instability throughout its shelf life and the amount of

Specific Impact Tests: Checklist

There will be additional benefit to the NHS as smoking reduction and quitting will see a reduction in hospital admissions for smoking related illness. This will see a release of cash spent on these treatments and a reallocation of resource to other treatments that will have