

Nicotine Containing Products TPD proposals

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Article 18 – nicotine containing products

- Products above a certain amount of nicotine can only be sold if they are licensed as medicines.
- Under that level all NCPs must carry the warning ***This product contains nicotine and can damage your health***
- Warning must be at least 30% of the area and on the 2 largest surfaces of the pack

Why is this a problem?

The warning is misleading

- It's the tar in the smoke that kills, nicotine is addictive but not toxic
- Using NRT can double the chance of a smoker quitting
- However, many smokers are unwilling to use NRT, or don't use sufficient quantities because they think nicotine is harmful
- Many healthcare professionals also think nicotine is harmful
- Putting the message *'This product contains nicotine and can damage your health'* on products is misleading and risks undermining effective use of NRT

Why is this a problem?

Difficulty in measuring nicotine levels

Medicines regulation will apply for products:

- With a nicotine level above 2 mg per unit
- With a nicotine concentration above 4 mg/ml
- Whose intended use results in a max peak plasma concentration above 4 ng/ml

BUT this is difficult to measure nicotine delivery depends on how they are used

What is the solution?

- Good regulation is simple regulation
- Make all NCPs subject to medicines regulation
- Revise Article 18 to read:

Nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC

Why not just ban novel NCPs such as e-cigarettes?

- Research in the UK shows that e-cigarettes are helping smokers cut down and quit
- The medicines regulator in the UK (MHRA) decided not to ban e-cigarettes because it believed that this might lead users to revert to smoking and would therefore be bad for public health
- The MHRA is due to announce its decision on regulation in May 2013

Reasons for regulating NCPs as medicines

- NCPs such as e-cigarettes would have to have to meet quality and safety standards before they can be sold
- NCPs would have to meet medicines advertising standards before they can be sold
- Controls can be put on age of sale
- Market surveillance can be required
- BUT if they meet all these standards smokers can continue to use them to help them quit.

Conclusion

Revise Article 18 to read:

Nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC

Thank You

Background materials

- MHRA consultation documents on the regulation of nicotine containing products

<http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617>

- ASH briefing on e-cigarettes in English and French

http://www.ash.org.uk/files/documents/ASH_715.pdf

http://www.ash.org.uk/files/documents/ASH_867.pdf

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