

### Company Guidelines on Novel Products Incorporating Nicotine

1. The invention of novel products requires additional safeguards to be met before marketing is considered, compared with conventional cigarettes, because no assumptions can be made of their inherent safety as consumer products in large scale, widespread daily use.
2. In this context, novel products are defined as those in which tobacco leaf either is not present or is a minor part of the product and would fall outside the definition of tobacco goods according to regulations in various countries.
3. A specific category of novel product is based on the use of nicotine or nicotine salts, however derived, in which these are incorporated into a non-tobacco carrier, small quantity of smoking material or aerosolising device.
4. For products of this type, the following guidelines should be followed:
  - (a) The use of the product must be demonstrated not to cause risk of acute ill-effects to the consumer or others with access to it with respect to the available dose of nicotine.
  - (b) To meet this requirement, it is recommended that:
    - (i) the nicotine delivery per unit should not exceed 1 mg under standard smoking conditions;
    - (ii) the nicotine source, as weight per volume of product and weight per weight of product, should not exceed that of conventional cigarettes;
    - (iii) evidence must be produced to show that extreme conditions of use would not result in hazard to a naive consumer, or that abuse or accident (e.g. by addition to a drink) would have minimal risk of poisoning to a child; and
    - (iv) the nicotine and its carrier should be firmly anchored to the main or other elements of the device and desirably should be totally integrated within it, in order to limit separate access to the nicotine by misuse, to prevent a mechanical accident from an individual element being detached, and to frustrate possible introduction of controlled substances.
  - (c) All elements of the device should be subject to toxicological review against the standards set for modern consumer products as well as comparison with tobacco goods. The protocol to be used, including the potential need for bioavailability studies on nicotine, should be considered and defined in response to each proposed product to ensure all aspects specific to the design are embraced.

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- (d) Each development should be examined for the implications of its content and construction, not only in comparison with existing tobacco legislation and restrictions but also with regard to the intent of other consumer product legislation, including pharmaceuticals and non-prescription drugs, poison and hazardous materials regulations.
5. In addition to these recommendations, it should be noted that less clearly defined concerns militate against the likelihood of success of products delivering nicotine and little else. These are:
- (a) Nicotine by itself would fail to be accepted as a new active ingredient for a mass consumer product when examined against current standards for defining "dangerous" or "hazardous" substances.
  - (b) Products in which the tobacco base is an insubstantial part of the whole would fall outside the special criteria defining tobacco goods in some parts of the world. Although such criteria are restrictive they are also to a degree protective.
  - (c) The delivery of nicotine, more or less by itself, renders any such product susceptible to criticism or comparison with any future findings of toxic concern attached to nicotine, allegations which might be more difficult of proof of effect when nicotine is merely one, if substantial, component of a very complex mixture.

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