Q&A — New pathway for smokeless tobacco products

What are smokeless tobacco and nicotine-delivery products?

These are a diverse group of products that are promoted as being potentially less harmful alternatives to tobacco smoking. They include:

- heat-not-burn tobacco products
- snus, moist snuff and dissolvables
- inhaled nicotine

What is the current law around smokeless tobacco and nicotine-delivery products?

The Smokefree Environments Act prohibits the sale of tobacco products for oral use other than smoking. Smokeless tobacco and nicotine-delivery products fall within this prohibition if the nicotine component is manufactured from tobacco.
Under the Medicines Act, it is unlawful to sell and supply a product which has not been approved by the Minister of Health (except where it has been prescribed by a doctor) if:

- it is intended for a therapeutic purpose, for example, to help smokers quit
- it contains nicotine

What has the Government decided to do?

The Government has decided to establish a pre-market approval system for smokeless tobacco and nicotine-delivery products. Manufacturers and importers will be able to apply to the Ministry of Health for approval to market a product.

What criteria will products have to meet before they can be approved?

While the detail is still to be worked out, products will need to be significantly safer than smoking, and the Ministry will take into account a range of factors related to the product's likely contribution to Smokefree 2025, including its impact on smokers, ex-smokers and non-smokers, particularly children and young people.
Product safety requirements will be put in place and products will not be able to be sold to those under the age of 18 or used in legislated smokefree areas (such as indoor workplaces and schools) if they resemble smoking or vaping.

How does this differ from pre-market approval of stop-smoking products under the Medicines Act?

The assessment process will be similar to that of medicines, although efficacy of the product for smoking cessation would not be assessed. Unlike medicines, assessment would include the likely broader impact of the product on smoking. For example, will smokers quit smoking and switch; will non-smokers, particularly children and young people, be attracted; could it be a gateway to (rather than from) tobacco smoking.

How do e-cigarettes fit into this?

The Government has already decided to legalise nicotine e-cigarettes. E-cigarettes and e-liquid will not have to be approved but will be able to be sold lawfully, once the Smokefree Environments Act is amended.

How long will it take to assess and approve a product?

This still needs to be worked out. It will depend on the detailed assessment requirements and the number of products being considered for approval. However, a medicine application takes approximately 12 months to approve (excluding time spent by the applicant responding to questions). The process could be much faster for high-quality applications where the Ministry does not have a lot of questions that need to be answered.

When will these changes happen?

The Smokefree Environments Act will need to be amended before any changes can take effect. This process will begin in early 2018.
The Health Committee is expected to consider these proposed amendments, together will proposals to regulate e-cigarettes, and is likely to call for public submissions in the middle of 2018.