HOW A NEW DRUG WOULD COME TO MARKET

The current law allows a new psychoactive to be sold anywhere and to anyone. The only exceptions are if the psychoactive is:

- A controlled or restricted substance under the Misuse of Drugs Act 1975;
- A medicine regulated by the Medicines Act 1981; or
- A herbal smoking product under the Smokefree Environments Act 1990.

But it is easy for a new product to slip between the cracks and enter the market without any regulation or control at all.

If the Government adopted the Law Commissions' proposed regulatory regime for new psychoactives, a new drug would have to go through the process below before it came to market, set out below.

APPROVAL OF NEW DRUGS

Every new psychoactive, or combination of psychoactives, intended for sale would be required to obtain approval from an independent psychoactives regulator. Approval would be required before a new psychoactive product could be imported, manufactured or distributed.

The prospective importer, manufacturer or distributor would be required to provide the psychoactives regulator with all available information, including:

- The composition of the psychoactive compounds in the products;
- The strength of the psychoactives used in the product;
- The known effects on the human body when the psychoactive is used.

This information would need to be collected by the prospective importer, manufacturer or distributor at its own cost.

The psychoactives regulator would then determine whether the product should be approved for sale, taking into account:

- the nature of the harm caused by the substance and any benefits associated with its use;
- whether that harm can be effectively managed by the imposition of regulatory controls (including considering any research into the impact of different regulatory controls on minimising harm generally and also specifically (if available) for that substance);
- the likely consequences of any proposed regulation or prohibition of the substance (including the cost of different regulatory options); and
- any possible displacement effects that might occur because of the way other substances are regulated.

If the regulator declined an approval, the regulator could then decide whether:

- further information was needed before the psychoactive product could properly be assessed; or
- the risks posed by the psychoactive product were such that the product should be submitted for classification as a controlled substance.

The psychoactives regulator will also be able impose conditions on how a particular approved psychoactive is sold, including:

- additional place of sale restrictions;
- labelling restrictions and requirements;
- packaging restrictions and requirements;
- health warning requirements;
- signage requirements;
- quantity, dosage, form and serving requirements;

- storage and display restrictions;
- record-keeping requirements; and
- any other requirements considered necessary or desirable to reduce the harm that might occur as a result of use of the substance.

HOW APPROVED PSYCHOACTIVES WOULD BE SOLD

Approved psychoactives would still be subject to a range of restrictions. The manufacturers of approved psychoactives would be required to comply with a Code of Manufacturing Practice issued by the psychoactives regulator, which would impose minimum standards for the manufacture, testing and purity of approved psychoactives.

The advertising and sale of approved psychoactives would also be subject to a range of restrictions, including:

Restrictions on Sale

- The sale or supply of approved psychoactives will be prohibited from:
    - places where alcohol is sold;
    - petrol stations;
    - pharmacies;
    - non-fixed premises such as vehicles, tents and mobile street cars; and
    - places where children gather (such as schools, recreational facilities andsports facilities).
- Approved psychoactives will only be available for sale to people aged 18 years and above;

Restrictions on Advertising

- The advertising of substances approved under the regime will be prohibited except at the point of sale;
- The promotion of new psychoactive substances, including sponsorship, should be prohibited in all media;
- Incentives to encourage people to purchase approved substances, such as promotional gifts or free-of-charge supply by retailers, will be prohibited;

Other Restrictions

- Approved substances should be packaged and stored in child-proof and tamper-proof containers; and
- Approved substances should be accurately labelled with a full list of ingredients and the phone number and address of the National Poisons Centre should be included on all labels.

Any person will be able to apply to the regulator requesting a reassessment of a substance, and the regulator should grant an application for a reassessment if:

- significant new information relating to the effects of the substance becomes available; or
- other substances with similar benefits, but less adverse effects, have become available and these could be approved in substitution.

The regulator will also have the power to recall any approved substance at any time if it considers that the substance is:

- unsound or unfit for human consumption;
- damaged, deteriorated or perished;
- contaminated with any poisonous, deleterious or injurious substance.