MINISTRY OF HEALTH
Department
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European Commission

Directorate-General SANCO

Unit C-6

Comments on the review of Directive 2001/37/EC

Directive 2001/37/EC is a key Community document for the protection of health against tobacco products. Given the nature of tobacco products (which though legal are extremely harmful), regulation of the manufacture, presentation and sale of such products should serve above all to ensure the highest level of health protection. In relation to tobacco products, the free movement of goods and services in the internal market should be ensured whilst applying stringent health protection standards. Acceptance of such general principles should underpin the determination of the scope of the Directive and of any planned amendments to its provisions.

Subject-matter of the 'Roadmap':

1. Scope of the Directive:

1.1. The Directive should be broad in scope, covering all tobacco products. This will make it easier to establish clear provisions for effective health protection.

1.2. If the provisions cover, *inter alia*, the 'presentation and sale' of tobacco products, it would be advisable for them to also encompass advertising and promotion, which are currently regulated under separate provisions.

1.3. The emergence of imitation cigarettes (nicotine inhalers, herbal cigarettes) on the market may complicate and impede efforts to control the tobacco epidemic. Eliminating such products from the market (except where these are medicinal products) would be justified and in line with health policy aims. Consideration should be given to making the necessary legislative amendments to extend

Directive 2001/37/EC to cover such products. Other imitation tobacco products (confectionery, toys, etc.) should be subject to similar restrictions.

2. Packaging and labelling of tobacco products

2.1. We fully endorse the preparation of new health warnings, and in particular pre-testing and consultation with regard to new warnings.

2.2. Illustrations accompanying the health warnings (introduction of combined warnings with a text and illustration) should be standard in all Member States. In view of the empirical evidence that combined warnings have a greater impact on the consciousness and emotions and given the drive towards regulatory harmonisation within the EU, it makes no sense that the Member States should remain free to decide whether to use illustrated warnings.

2.3. Labels with information on tar, nicotine and carbon monoxide (TNCO) yields are unnecessary and may even be harmful to consumers. The placing on the market of cigarettes with a range of TNCO yields lower than the maximum permissible limit may mislead consumers into thinking that it is perfectly safe to smoke cigarettes with lower yields of such substances. Instead of the information on TNCOs currently provided, it would be appropriate to provide information on the presence in smoke of proven carcinogens.

2.4. We must concur that product packaging affects consumer behaviour. It is therefore important to affix to the packaging of tobacco products accurate and clear warning labels, omitting any information encouraging the use of such products or leading to erroneous preferences. However, we do not believe that it is essential to introduce simple, uniform-coloured packaging (plain packaging). We ascribe greater importance to extending the use of illustrated warnings and to reserving at least 50% of the surface area of the main package faces for such warnings, and to emphasising which indications should appear on packaging, which may appear on it and which are prohibited.

3. Reporting information on the ingredients

Although the current Directive 2001/37/EC specifies what kind of information on tobacco product ingredients the manufacturer or importer should provide to the appropriate administrative body, the content and format of such information vary to such an extent that it is of very limited use in the control of undesirable substances, for the purposes of comparison and for public information. Experience (including experience of a proven electronic system) has shown that a single electronic

system for monitoring the ingredients of tobacco products placed on the Community market should be introduced in all Member States. This would also be useful for the purposes of controlling and regulating certain tobacco additives.

4. Provisions concerning tobacco additives

4.1. The preparation of a common list of additives approved for use in tobacco products in Member States (Article 12) would jeopardise health objectives and is thus ill-advised. Legalising the additives in question would mean at the same time having to accept products resulting from the combustion of such additives, which would be a mistake. An alternative scenario of compiling a list of prohibited additives would lead to the legal use of other random additives not included in the list. It would be better to focus on establishing principles for regulating additives based on their function or effect on the body or on consumer behaviour.

4.2. Restrictions or bans should be applied to additives which:

a) lead to increased toxicity or make the product more carcinogenic;

b) accelerate addiction;

c) give tobacco an unnatural taste or smell – fruity, sugary, etc.

4.3. Additives which are required in technological processes and do not produce the above-mentioned effects (4.2) should be excluded from the provisions.

5. Availability of tobacco products

The main purpose of regulating the tobacco products market (in addition to banning the advertising and promotion of tobacco products) is restricting the availability of such products to children and young people. Pricing is a key factor in this regard, including the approximation of the pricing of ready-made cigarettes and roll-your-own cigarettes (which is the subject of separate legislation). The areas to be covered by this Directive are:

a) extending the ban on the sale of tobacco products from vending machines;

b) banning the sale of individual cigarettes and small packs;

c) banning distance sales of tobacco products, including via the internet.

Banning the display of tobacco products for sale (under-the-counter sales) is of little importance and should not be considered a priority, in particular in light of the scope for extending the use of clear health warnings. Rather, it would be preferable to ban cigarette sale displays which are arranged in such a way that they obscure warning labels.