

Letter dated: 17 December 2010

From:

Austrian Federal Ministry of Health
Department II/1 Ombudsman's office for the protection of non-smokers, legal and specific tobacco and alcohol-related matters
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To: DG SANCO

sanco-tobacco-products-consultation@ec.europa.eu

Position statement on possible overhaul of the Tobacco Products Directive 2001/37/EC

Dear Sir/Madam,

The Austrian Federal Ministry of Health takes the following position regarding the possible overhaul of Directive 2001/37/EG, with reference to the DG SANCO public consultation paper:

1. Scope of the Directive

In Austria, smoking cessation products generally come under pharmaceuticals law. Under the *Arzneimittelgesetz* (Pharmaceuticals Act), two criteria are relevant in determining whether a product should be considered a pharmaceutical:

- the "objective intended use": the decisive factor is whether, according to the objective expectations of the relevant parties, the product is suitable for achieving the intended therapeutic effect; this will in particular be the case if a therapeutic effect has actually been attributed to the product;
- the "subjective intended use": the decisive factor is whether the product is clearly described by the seller as having a therapeutic effect; the key factors here are indications and therapeutic claims on the label and/or in the user information (e.g. "Helps you to quit smoking").

If either of these criteria applies, then the product is to be considered a pharmaceutical product.

Pharmaceutical products may only be placed on the market if all the relevant provisions of the *Arzneimittelgesetz* are complied with (in particular the licensing obligation for proprietary medicinal products).

No nicotine drinks or nicotine sweets have been found to date in Austria. However, any application to have such products classed as foodstuffs will be rejected by the Ministry of Health as the purpose of the product is taken into account for classification purposes, and the products in question are not really intended for nutritional or enjoyment purposes.

Electronic cigarettes, in as much as they are (supposed to be) a form of smoking prevention or contain nicotine, are subject to the rules on pharmaceuticals, as outlined above.

Regarding herbal cigarettes, which are also subject to pharmaceuticals law in Austria where they are sold as a smoking prevention product, it should be considered that these are not necessarily healthier than tobacco products as the combustion of all forms of smoking product releases all manner of chemical decomposition products and fine particulate matter of varying toxicity and carcinogenicity, whether they are made of tobacco or other plants, herbs, spices or chemical substances. Smoke is always a mixture of exhaust gases, soot and vapours, poisonous and carcinogenetic compounds, which means that inhaling it – even if there is no psychoactive effect as there would be with nicotine – is in no way 'healthier' than smoking tobacco products. Other people in a space where herbal cigarettes are being smoked feel that their rights are being at least subjectively infringed, which means that there is always a problem in Austria where herbal cigarettes are consumed in spaces subject to the ban on tobacco smoking.

Warnings on all new and alternative tobacco products and similar products would, however, help to inform consumers and are therefore welcome. We also welcome, in principle, rules going beyond that for those products which, currently, are not subject to our law on pharmaceuticals.

2. Smokeless tobacco products

The risks to health of smokeless tobacco products compared with smoking products containing tobacco and their licensing is a controversial subject among experts. The 2008 SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) report states that tobacco products for oral consumption, whilst not being less harmful, are nevertheless no more harmful than other tobacco products. Some experts such as Fagerström (Sweden) and Kunze (Austria) also take the view that oral tobacco products can reduce the risk of lung cancer for latent smokers.

It should also be pointed out that there is no risk of passive smoking where oral tobacco products are consumed. A study on the use of oral tobacco as a substitute for heavily addicted smokers, as mentioned briefly in the SCENIHR report, would be most interesting.

We do not understand why snus, which is banned, is treated differently from other oral tobacco products such as chewing tobacco.

However, if extending the ban on snus to include all oral tobacco products is to be considered, we must ensure that this measure does not drive consumers to smoking products which also affect their fellow non-smokers. That would not be desirable from a public health perspective.

In the light of the above, we should consider whether it is actually desirable to keep the ban on snus. Experts such as Professor Kunze are not in favour of unconditionally scrapping the ban, and instead recommend allowing this product subject to the simultaneous introduction of rules on dangerous substances (i.e. a regulated lifting of the ban).

3. Consumer information

There are ever more indications that warnings on tobacco product packaging are effective and

efficient, with particular emphasis on the importance of the size of such information and the use of illustrations to support the text.

The compulsory introduction of combined warnings in all Member States would be in line with Article 11 of the WHO Framework Convention on Tobacco Control, and points 14 to 17 of the associated Guidelines for Implementation. The Ministry of Health therefore has no objections.

The printing of the telephone number of the Austrian smoker hotline has led to a direct increase in the number of callers. This experience suggests that making it compulsory to indicate such a number on all packs of smoking products would be a positive step.

Information about other dangerous substances in tobacco products on packaging could, in our view, be an interesting idea, but we doubt whether it will be easy to decide which substances to warn against, given the knowledge we currently have about the toxicity of various tobacco constituents, some aspects of which are less than comprehensive.

For consumer protection reasons, we are in favour of affixing warnings to water pipes, too.

Regarding the possible introduction of plain packaging, we take the view that this would be welcome from a health perspective. However, it could lead to other problems, for example the smuggling of tobacco products, copyright and trademark law issues, etc.

4. Reporting and registration of ingredients

We agree with all the European Commission's comments in the problem definition.

In order to increase the comparability of the data and to make submitting and recording them more practical, we are in favour of the compulsory introduction of a standard electronic submission system, including a standard submission format in all the Member States of the European Union. In this context, we would point to the work of the EMTOC project under the overall charge of the Austrian Ministry of Health.

Access fees and/or penalties in the event of the tobacco industry not complying with the submission obligation could be envisaged.

5. Regulation of ingredients

We agree with all the European Commission's comments in the problem definition.

Standard criteria for the inclusion of additives/ingredients in tobacco products at EU level are necessary, in our view. However, it is important to ensure that substances are not arbitrarily allowed or certified as dangerous, because this could weaken the message sent to the public about the dangers of tobacco products or create the impression that some tobacco products are less dangerous than others.

6. Access to tobacco products

Bans on the Internet trade in tobacco products, as we have in Austria, are very difficult to enforce in cross-border trade. We would therefore welcome an EU-wide ban on Internet trade

in these products.

In any event, there is a need to check the age of purchasers of tobacco products from vending machines, for example using the chip card system as in Austria. Restricting the advertising of tobacco products at sales outlets as far as possible would also be a welcome step from a public health point of view.

We trust that our comments have clarified the views of the Austrian Federal Ministry of Health and remain,

Yours faithfully,

For the Federal Minister
Dr Franz Pietsch

Enclosures:

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