Letter dated:
22 December 2010

From:
Christian Danielsson
Amabassador
Permanent Representation of Sweden to the European Union
Brussels

To:
DG SANCO
European Commission

Subject: **Sweden's response to the public consultation on Directive 2001/37/EC of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products**

Ref.: Ares(2010)996124 – 26/12/2010

Please find enclosed the above-mentioned response

Yours faithfully

[signed]

Christian Danielsson

Letter dated:
17 December 2010 Ref. S2010/6280/FH

Government Offices of Sweden
Minister for Health and Social Affairs

Sweden's response to the public consultation on Directive 2001/37/EC of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products

The European Commission has initiated a public consultation for the purposes of a forthcoming revision of Directive 2001/37/EC which closes on 17 December 2010. Sweden would like to put forward its views for the revision in this letter.

Our aim and hope for the revision is that it will result in harmonization of European legislation on tobacco products. Revision can contribute to greater consumer protection, clearer product regulation and a regulatory framework where the industry's responsibility is clearly set out and the authorities' monitoring role is tightened up and clarified. The fact that the European tobacco product legislation lays down minimum requirements is positive and something to be safeguarded in the forthcoming revision.

Sweden takes the view that it is desirable for joint European legislation to be of a high standard and lay down a clear regulatory framework. To that end, the proposal presented should be evidence-based and the legislative impact of the measures clarified.

The consultation document sets out six areas where the problem is defined and areas of possible change are to be considered. Sweden's comments on the respective areas are given below.

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1. Scope of the Directive

Sweden takes the view that the Directive should confine itself to tobacco products. Other products should be regulated by other means.

2. Smokeless tobacco products - lifting the ban on *snus* (Option 2)

Swedish *snus* should be treated like other tobacco products and should come under the Directive since, in Sweden's opinion, there are no grounds for a ban on this tobacco product. Such a prohibition is contrary to the basic idea of a free market within the Union.

Since the advent of the ban, a number of scientific studies on the contentious issue of the harmful effects of *snus* have been conducted, such as the WHO report on the Scientific Basis of Tobacco Product Regulation (2009) and the report of the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the Health Effects of Smokeless Tobacco Products (2008). Sweden was therefore surprised to see that the RAND report prepared for the European Commission

did not comment on the issue of *snus*.

It is not logical for *snus* to be the only tobacco product prohibited within the EU. Sweden would like to see this prohibition of a Swedish product, which is considerably less harmful than cigarettes and other smoking tobacco, lifted so that Swedish *snus* can be marketed in Europe like other tobacco products. Article 8 of the Directive should therefore be removed so that Swedish *snus* is treated in the same way as other tobacco products on the EU internal market

3. Consumer information

Sweden welcomes a revision and discussion of the Directive relating to information on the tar, nicotine and carbon monoxide (TNCO) content on cigarette packets. The ISO standards need to be revised and updated.

Sweden is opposed to the proposal to make pictorial warnings compulsory. This should be a matter for each Member State to decide, as is the case at present.

The Swedish constitution, in particular the section on freedom of the press, has a bearing on the question of warnings, their wording and the surface for the text and image, etc. Sweden is prepared to support the Commission in formulating these texts in order to avoid any conflict with our Constitution. In this way we can also make a constructive contribution to the process.

Sweden is very much against rules on "plain packaging" being introduced because of the damaging effects this would have on existing trademark rights. Such undermining of intellectual property rights must be handled with great care and may also have implications for international agreements on this matter. It is also doubtful whether plain packaging is compatible with the protection of property rights under the European Convention (Article 1 of the First Additional Protocol to the Convention). Sweden does not accept the claim in the report from RAND Europe on Page 133, that "plain packaging" would not violate intellectual property rights. Such rules might, on the contrary, possibly lead to trade marks lapsing. Sweden believes that there is as yet no empirical evidence to demonstrate the effect plain tobacco packaging has on public health. The studies which the RAND Europe report refers to provide no certainty because they are mainly based on assumptions rather than observations.

4. Reporting and registration of ingredients

Sweden is in favour of strengthening product monitoring but, at the same time, we would like to stress the importance of monitoring and reporting being as simple as possible. Whatever the reporting system is, it should be manageable and reporting should be handled in accordance with existing systems within the EU (see Directive 765/2008/EC).

The model should be based on clear rules, clearly defined producer liability, monitoring by the authorities and penalties when the rules are not complied with.

5. Regulation of ingredients

Sweden would like to restrict the ban on additives to dangerous additives only. The system should be based on clear producer liability. Liability and testing requirements should be laid down.

6. Access to tobacco products

Any measures taken against retail outlets should be left up to each Member State or, where applicable, be handled as part of marketing measures (Directive 2003/33/EC).

Sweden, however, sees a need to step up exchanges of experience and national cooperation on this matter

Yours sincerely
[signed]
Göran Hägglund