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## Legal, Regulatory Affairs & Compliance Regulatory Affairs

Dr Dominik Schnichels
European Commission
DG SANCO
By e-mail: dominik.schnichels@ec.europa.eu

31 October 2013

Dear Dr. Schnichels,

In response to your request made by e-mail to Antonella Pederiva of CECCM on 25 October 2013, Japan Tobacco International (JTI) is pleased to respond as follows.

First, with regard to confidentiality, we note that your request to CECCM acknowledges concerns around confidentiality. In view of the Commission's access to documents regime, as embedded in Regulation 1049/2001, in this response JTI will not disclose any commercially sensitive information. We therefore do not object to this letter being disclosed in response to access for information requests.

Second, in relation to your request for information, JTI does not sell or market electronic cigarettes. However, we believe in the freedom of adults to choose whether they wish to use electronic cigarettes and that no one should use them unless he or she understands the risks associated with doing so.

In line with Council Recommendation 2003/54/EC, the use of tobacco brand names for non-tobacco products including e-cigarettes is regulated by many Member States.

JTI also believes that all marketed electronic cigarettes should comply with existing relevant regulations, such as those concerning general consumer product safety, electrical safety and consumer protection from misleading marketing claims.

JTI welcomes the further development of appropriate and proportionate regulations for electronic cigarettes covering product safety standards, product quality standards and product information provided to consumers.

We do not agree, however, with proposals to regulate electronic cigarettes within a medicinal framework, in the same way as pharmaceutical products that make smoking cessation claims. Many adult consumers enjoy the use of e-cigarettes, which have become increasingly popular in several markets. Unduly burdensome regulation of the sector would restrict consumers' freedom to choose these products and would set up unnecessary barriers both for existing and new entrants to the market.

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Therefore, we believe that

- any future regulation of electronic cigarettes and their individual components should reflect appropriate and proportionate requirements for product quality and safety standards;
- electronic cigarettes should not be regulated as medicinal products unless the manufacturer chooses to make a therapeutic claim, and
- · electronic cigarettes should not be subject to marketing authorisations.

JTI believes that it has a useful role to play in the consideration of appropriate and proportionate electronic cigarette regulation, and looks forward to participation in a meaningful discussion with you on this topic.

With kind regards,