

Ares (2013) 3046705

Subject:

Re: Tobacco Products Directive - proposed position on NCPs

From: SCHNICHEL Dominik (SANCO)
Sent: Monday, September 02, 2013 7:09 PM
To: 'Petra Palfi'
Cc: [REDACTED] SANCO CONSULT-D4
Subject: RE: Tobacco Products Directive - proposed position on NCPs

Dear Ms Palfi,

Many thanks for your submission, which we will read with interest. In case of questions we will revert back to you.

Kind regards

Dominik Schnichels

From: Petra Palfi [<mailto:PP@cabinetdn.com>]
Sent: Monday, September 02, 2013 6:54 PM
To: SCHNICHEL Dominik (SANCO)
Cc: [REDACTED]
Subject: Tobacco Products Directive - proposed position on NCPs

Dear Mr Schnichels,

I am contacting you on behalf of Fertin Pharma, a Danish world-market leader in developing and producing medicated chewing gums.

Fertin Pharma welcomes your proposal on the revision of the Tobacco Products Directive (TPD). However, we would like to draw your attention to the issue of how nicotine-containing products (NCPs) are regulated by the proposal (article 18) and would like to recommend supporting the amendment to the original Commission proposal proposed by the ENVI Committee, as it will ensure the quality and efficacy of NCPs marketed in the EU.

In its proposed amendments to article 18, the Council has maintained the legislative possibility to market NCPs as consumer products outlined in the original proposal, but has introduced lower thresholds. On the other hand, the ENVI Committee proposes to remove the legislative possibility to market NCPs as consumer products, but specifies the approach to be taken by the regulatory authorities when assessing marketing authorisation applications for those products, i.e. *well-established use* (c.f. Directive 2001/83/EC, article 10a).

The Council position will *de facto* eliminate the legal market for NCPs sold as consumer products, as the likelihood for a significant market for nicotine-containing products with nicotine contents below 1 mg per unit or 2 mg per ml can be expected to be low. It is questionable if products with such low content of nicotine as proposed by the Council will be attractive to consumers. The typical lowest content of nicotine in marketed electronic cigarettes is 6 mg per ml.

Unless significant efforts and resources will be dedicated to the control of products marketed as NCPs, there is a risk that the occurrence of NCPs on the market containing more nicotine than declared will increase above current levels.

The approach taken by the ENVI Committee will, on the other hand, ensure an effective and consistent control of NCPs and harmonise the market in the EU, where different rules currently apply. An efficient and consistent control of NCPs and their manufacture is important in terms of ensuring public safety and countering the problem of products being marketed for which the quality cannot be guaranteed, where the nicotine content does not comply with the declared content and where harmful substances are present in the products.

Fertin Pharma welcomes the requirement of *well-established use of nicotine* to be taken into account when authorising NCPs as a measured approach to regulate the market without imposing on the manufacturers the burden of proving clinical efficacy and safety through the conduct of clinical studies, a burden that would be a significant increase compared to the situation today both in terms of cost and time to market.

We therefore support the amendments proposed by ENVI as we consider them to be the best approach to ensuring an effective and consistent control of NCPs irrespective of the declared content of nicotine and thereby contributing to the health and safety of the citizens of the EU without imposing undue burdens on the manufacturers.

We therefore hope that you will support the ENVI position during the negotiations.

We would be delighted to further discuss our position with you over the phone or in person should you be available before the plenary vote taking place on 10 September, and remain at your disposal should you wish to raise any questions or comments on the above.

Thank you in advance for your consideration.

Kind regards,

Petra Pálfi
Junior Consultant

The logo for cabinet DN, featuring the word 'cabinet' in a lowercase serif font and 'DN' in a larger, bold, uppercase serif font.

Rue d'Arlon 25
B - 1050 Bruxelles
Tel.: +32 22 34 61 02
pp@cabinetdn.com