Subject: Tobacco Products Directive - proposed position on NCPs
Attachments: Fertin Pharma_Position Paper_TPD.pdf

From: Petra Palfi [mailto:PP@cabinetdn.com]
Sent: Monday, September 02, 2013 6:54 PM
To: SCHNICHELS 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,

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Position paper by Fertin Pharma

27 August 2013

Comments regarding amendments proposed by the Council of the European Union and the Environment, Public Health and Food Safety Committee (ENVI) to Article 18 of

Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products.

Our position

Fertin Pharma supports the amendment adopted by the ENVI Committee to Article 18 of the Tobacco Products Directive (TPD) (Compromise Amendment 57). The ENVI Committee removes the legislative possibility to market nicotine-containing products (NCPs) as consumer products, but specifies the approach to be taken by regulatory authorities when assessing marketing authorisation applications for these products, i.e. *well-established use* (c.f. Directive 2001/83/EC, article 10a).

This approach will 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.

Amendments proposed

Amendments proposed by the Council	Amendments adopted by ENVI
1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC: (a) products with a nicotine level ***equal to or*** exceeding ***1*** ~~2~~ mg per unit, or (b) products with a nicotine concentration ***equal to or*** exceeding ***2*** 4 mg per ml. or ~~(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.~~	1. Nicotine-containing products may only be placed on the market if they ~~were~~ ***are*** authorised pursuant to Directive 2001/83/EC***, taking into account the well-established use of nicotine.*** ~~a) products with a nicotine level exceeding 2 mg per unit, or~~ ~~b) products with a nicotine concentration exceeding 4 mg per ml or~~ ~~c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.~~
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 ~~taking into account~~ ***where this is necessary based on*** scientific developments and marketing authorisations	~~2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine-~~

granted to nicotine-containing products pursuant to Directive 2001/83/EC.	~~containing products pursuant to Directive 2001/83/EC.~~
3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning: *This product contains nicotine* ***which is an addictive substance*** *and can damage your health.*	~~3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:~~ ~~This product contains nicotine and can damage your health.~~
4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10 ***8***(4). In addition, it shall: (a) be printed on the two largest surfaces of the unit packet and any outside packaging; (b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That ~~proportion~~ ***size*** shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.	~~4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:~~ ~~(a) be printed on the two largest surfaces of the unit packet and any outside packaging;~~ ~~(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.~~
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the ***wording of the health warning*** requirements in paragraphs 3 ~~and taking into account~~ ***based on*** scientific and market developments~~and to adopt and adapt the position, format, layout, design and rotation of the health warnings~~. ***5a. The provisions of paragraphs (3) to (5) of this article shall be without prejudice to the application of Directive 2001/83/EC.***	~~5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings.~~
6. Nicotine-containing products referred to in Article 18(1) and which are placed on the market before [entry into force + 24 months], may continue to be marketed until [entry into force + 36 months].	

Comments

Compromise Amendment 57 adopted by the ENVI Committee removes the legislative possibility to market NCPs as consumer products, but specifies the approach to be taken by regulatory authorities when assessing marketing authorisation applications for those products, i.e. *well-established use* (c.f. Directive 2001/83/EC, article 10a).

This approach will 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.

The requirement for the *well-established use of nicotine* to be taken into account when authorising NCPs is welcomed 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.

On the other hand, the Council has maintained legislative possibility to market NCPs as consumer products. The Council proposes to lower the allowed content of nicotine in 1a) and 1b) and delete the requirement in 1c), which will ensure that all NCPs currently authorised according to Directive 2001/83/EC would still fall under the jurisdiction of that directive.

The deletion of the requirement to document the mean maximum peak concentration of nicotine after intended use removes a requirement that would be challenging to demonstrate and control for consumer products. It is welcome that the requirements for industry and authorities to demonstrate and control the legality of NCPs are defined with easily determined objective criteria.

The lowering of allowed content of nicotine in NCPs can, however be expected to *de facto* eliminate the legal market for NCPs sold as consumer products as the likelihood for a significant market for NCPs with nicotine contents below 1 mg per unit or 2 mg per ml can be expected to be low. It may be questionable if products with such low content of nicotine as proposed by the Council will be attractive to consumers. As an illustration it can be mentioned that 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 the products marketed as nicotine-containing products, there is therefore a risk that the occurrence of NCPs on the market containing more nicotine than declared will rise above what is seen in the market at this point of time.

The Council's proposal does not effectively impose control measures to ensure the safety of NCPs and therefore does not alleviate the problems encountered in the market place today with 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.

We therefore support the amendments proposed by ENVI as we consider them to be the best approach to ensuring an effective and consistent control with 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.

It may be considered to introduce a grace period for NCPs that are currently marketed to allow for the time frame involved for approval pursuant to Directive 2001/83. A suitable grace period could be "Nicotine-containing products referred to in Article 18(1) and which are placed on the market before [entry into force + 24 months], may continue to be marketed until [entry into force + 36 months]", as proposed by the Council.

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For further information, please contact Linda Weisert, Associate Director, cabinet DN, by email (lw@cabinetdn.com) or by phone (+32 2234 61 01).