

**Subject:** Proposal for a compromise re Article 18 (NCP) /comment for trialogue negotiations on TPD

**Attachments:** Fertin Pharma\_Proposal for a Compromise on Article 18\_TPD\_19Nov2013.pdf

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**From:** Timme Bertolt Dossing [mailto:TBD@cabinetdn.com]  
**Sent:** Wednesday, November 20, 2013 1:03 PM  
**To:** SCHNICHELS Dominik (SANCO)  
**Cc:** [REDACTED]  
**Subject:** Proposal for a compromise re Article 18 (NCP) /comment for trialogue negotiations on TPD

Dear Mr Schnichels,

As a follow up on our recent "comment for trialogue negotiations" below, herewith we would like to share Fertin Pharma's additional input for the discussions on the Tobacco Products Directive.

Fertin Pharma understands that currently the EU Institutions' positions on certain aspects of the Article 18 on nicotine-containing products are very far away from each other and strongly believes that a **compromise between the EP, Council and Commission could be achieved if the threshold for nicotine concentration is limited at 12 mg/ml** instead of 4 mg/ml proposed by the Commission, 2 mg/ml as per the Council general approach or 30 mg/ml as the adopted Parliament's text suggests following the plenary vote. With regard to solid/semi-solid nicotine, Fertin Pharma would suggest a limitation of nicotine level below 1 mg/unit.

As highlighted earlier, Fertin Pharma welcomes the proposal and the public health focus underlying the text including the aim of preventing the encouragement of young people to start smoking. It is a well-recognized fact that the use of tobacco is addictive due to the content of nicotine and carries the serious risk of various cancer forms, cardiovascular problems etc.

A recent scientific study, involving e-cigarettes with a total content of 16 mg has shown that e-cigarettes reduce the desire to smoke. A content of 16 mg can be expected to be achieved with a concentration limit of 12 mg/ml. The research hence confirms, that 2 mg/ml, initially suggested by the Council, is considered to be so low a concentration that it will not give the desired effect for the smoker.

Considering that there is only very limited scientific evidence of the safety of e-cigarettes, restricting the content to 12 mg/ml concentration will ensure that the delivery of nicotine to the user does not significantly surpass the amount delivered by medicinal products, thereby reducing the risk of unexpected adverse events.

The majority of markets for e-cigarettes include products with concentrations of 0, 6 and 12 mg/ml. A concentration limit at 12mg/ml would allow companies that are active on the EU market at present to remain in the market/business.

Given the recent developments of the inter-institutional negotiations, and the further elaborated efficacy, safety and market aspects of a scientifically calculated optimal nicotine content *in the attached document*, Fertin Pharma would call upon the EU Institutions to limit the nicotine concentration at 12 mg/ml.

**We see this as a balanced compromise between the EP, Council and Commission:** NCP-products up to a reasonable and scientific-based nicotine concentration will have easy access to the market, while the quality of the *all* NCP-products, including those sold as consumer products, is ensured - taking into consideration the fact that nicotine is a highly addictive and potentially a very harmful substance (*please find a short video on this by clicking the button below*).

## Nicotine – One deadly drop

We 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,

Timme Dossing,

On behalf of [REDACTED]

*President and CEO*

*Fertin Pharma*

Timme Bertolt Dossing  
Partner

**cabinet DN**

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**From:** Timme Bertolt Dossing  
**Sent:** 30 October 2013 15:56  
**To:** 'dominik.schnichels@ec.europa.eu'  
**Cc:** [REDACTED]  
**Subject:** Fertin Pharma TPD Article 18 / NCP - comments for trialogue negotiations

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 interest shown by the EP and Council in finding an agreement on the proposal on the revision of the Tobacco Products Directive (TPD). 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 a position, which ensures the safety and quality of *all* NCP's, while maintaining liberal access to the market for NCP-products with a nicotine-content under certain thresholds.

Nicotine is a highly addictive and potentially a very harmful substance – liquid nicotine is indeed as dangerous as strychnine and arsenic. 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 **final text adopted by the European Parliament** on Article 18 leaves NCPs to be weakly regulated under the Products Safety Directive. This is not recommended, taking the potential harmfulness and addictiveness of nicotine and nicotine-containing products into account.

The **Commission** and the **Council** proposes a twin track approach for the regulation of nicotine-containing products, splitting them into two groups depending on a combination of the strength of the products and the amount of nicotine absorbed during regular use. NCP-products with a nicotine-content under the proposed thresholds can be sold as consumer products.

While we support this approach in principle, we strongly advice that the license to manufacture and import *all* nicotine-containing products should be regulated pursuant with Directive 2001/83/EC Title IV, article 40-53 'Manufacture and importation'. We also propose to set the quality standards for the manufacture of nicotine-containing products as the Good Manufacturing Practice defined in Directive 2003/94/EC.

This will ensure that the consumer can purchase products of the same assured quality irrespective of whether they choose a medicinal product approved for nicotine replacement therapy or a nicotine-containing product that is marketed without such claims.


**We see this as a balanced compromise between the EP, Council and Commission:** NCP-products will have easy access to the market, while the quality of the *all* NCP-products, including those sold as consumer products, is ensured.

We would be delighted to discuss our position with you over the phone or in person should you be available any time, and remain at your disposal should you wish to raise any questions or comments on the above. Our recommendations are elaborated in the attached position paper.

Thank you in advance for your consideration.

Kind Regards,

Timme Dossing,

On behalf of   
*President and CEO*  
*Fertin Pharma*

Timme Bertolt Dossing  
Partner



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## Proposal for a compromise re TPD / Nicotine Containing Products (Article 18)

19 November 2013

**Additional comment for triologue negotiations by the Council, the Parliament and the European Commission**

*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.*

Fertin Pharma has been developing and manufacturing Nicotine Replacement Therapy (NRT) products for more than 20 years. The products are marketed in more than 80 countries across the world including the EU, North America, Japan and Australia.

Fertin Pharma understand that currently the EU Institutional positions on certain aspects of the draft legislation including Article 18 on nicotine-containing products are very far away from each other and strongly believes that a **compromise between the EP, Council and Commission could be achieved if the threshold for nicotine concentration is limited at 12 mg/ml** instead of 4 mg/ml proposed by the Commission, 2 mg/ml as per the Council general approach or 30 mg/ml as the adopted Parliament's text suggests following the plenary vote. With regard to solid/semi-solid nicotine, Fertin Pharma would suggest a limitation of nicotine level below 1 mg/ unit.

**Fertin Pharma welcomes the proposal and the public health focus underlying the text including the aim of preventing the encouragement of young people to start smoking and hence *calls upon a scientific-based optimal nicotine concentration limit of 12 mg/ml*, which could be considered as a compromise between the positions of the EP, Council and Commission. With regard to solid/semi-solid nicotine, Fertin Pharma recommends a limitation of nicotine level below 1 mg/ unit. This could be a balanced compromise between the Institutions.**

### Efficacy aspects:

- 2 mg/ml is considered to be so low a concentration that it will not give the desired effect for the smoker
- A study involving e-cigarettes with a total content of 16 mg has shown that e-cigarettes reduce the desire to smoke. (Bullen C, McRobbie H, Thornley S, Glover M, Lin R & Laugesen M (2010): *Effect of an electronic nicotine delivery device (e cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomised crossover trial. Tob Control 19: 98-103*)  
A content of 16 mg can be expected to be achieved with a concentration limit of 12 mg/ml

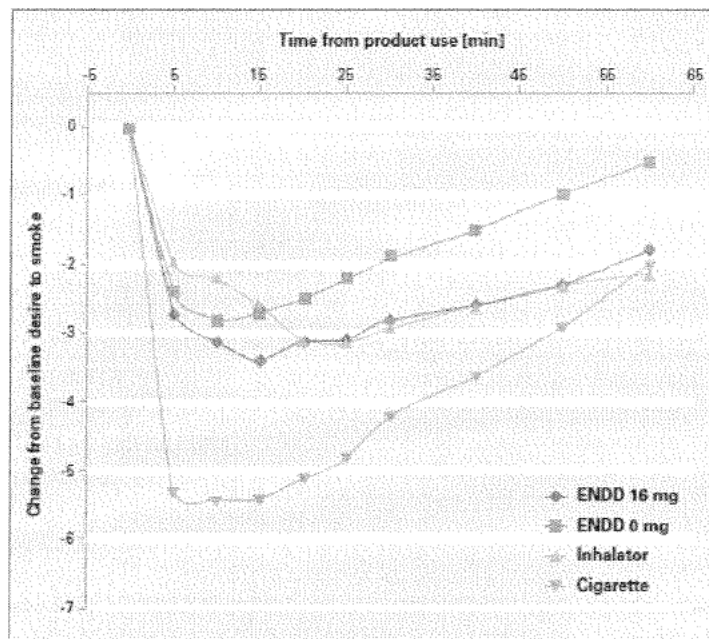


Figure 6.2  
Suppression of desire to smoke resulting from electronic cigarettes with and without nicotine, nicotine inhaler and conventional cigarettes. Participants rated their desire to smoke on a scale from zero to ten.  
Source: Bullen 2010<sup>16</sup>  
Illustration: German Cancer Research Center 2013

(Source: German Cancer Research Center. Study on Electronic Cigarettes  
<http://www.dkfz.de/en/presse/download/RS-Vol19-E-Cigarettes-EN.pdf>)

#### Safety aspects:

- Nicotine is a potentially very harmful substance and there is only very limited scientific evidence of the safety of e-cigarettes. Closed cartridges contain a limited amount of liquid and restricting the concentration to 12 mg/ml will reduce the risk of adverse event stemming from handling the product/cartridges.
- Restricting the content to this concentration will ensure that the delivery of nicotine to the user does not significantly surpass the amount delivered by medicinal products, thereby reducing the risk of unexpected adverse events.

#### Market aspects:

- The majority of markets for e-cigarettes include products with concentrations of 0, 6 and 12 mg/ml. A concentration limit at 12mg/ml would allow companies that are active on the EU market at present to remain in the market/business.

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For further information, please contact Timme Dossing, Partner, cabinet DN, [tbd@cabinetdn.com](mailto:tbd@cabinetdn.com) / +32 2234 61 12 or [REDACTED].