From: SCHNICHELS Dominik (SANCO)
Sent: 30 October 2013 16:17
To: 'Timme Bertolt Dossing'
Cc: [redacted]
Subject: RE: Fertin Pharma TPD Article 18 / NCP - comments for trialogue negotiations

Dear Mr Dossing,

Many thanks for your submission, which is very clear. If we have further questions we will contact you.

Kind regards

Dominik Schnichels

From: Timme Bertolt Dossing [mailto:[redacted]@cabinetdn.com]
Sent: Wednesday, October 30, 2013 3:52 PM
To: SCHNICHELS Dominik (SANCO)
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 [redacted]
President and CEO
Fertin Pharma

Timme Bertolt Dossing
Partner

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