Ares(2013) 3405728

Subject: TPD - Council letter
Attachments: TPD and Regulation of Nicotine Containing Products

Importance: High

From: Sophie Crousse [mailto:sophie.s.crousse@gsk.com]
Sent: Wednesday, October 30, 2013 6:05 PM
To: SCHNICHELS Dominik (SANCO)
Subject: TPD - Council letter
Importance: High

Dear Dominik,
FYI - Attached is what has been sent today to all Member States representatives in Brussels ahead of the Council meeting tomorrow. We can speak at your convenience.
Kind regards,
Sophie.

Sophie Crousse
Vice President European Public Affairs Europe
Consumer Healthcare Europe

GSK
Avenue des Arts 46/B9, 1000 Brussels, Belgium
Email sophie.s.crousse@gsk.com
Mobile +32 497 059 227
Tel +32 2 282 40 59

gsk.com | Twitter | YouTube | Facebook | Flickr

From: Dominik.Schnichels@ec.europa.eu [mailto:Dominik.Schnichels@ec.europa.eu]
Sent: mardi 15 octobre 2013 20:19
To: Sophie Crousse
Subject: Re: meeting request

Dear Sophie, thanks. Sounds good. Dominik

Schnichels Dominik

-------- Original message --------
From: Sophie Crousse <sophie.s.crousse@gsk.com>
Date:
To: "SCHNICHELS Dominik (SANCO)" <Dominik.Schnichels@ec.europa.eu>
Subject: Re: meeting request

Dear Dominik,
GSK (medical and regulatory) has done a detailed analysis on article 18. We have share it with our trade association, JnJ and Novartis and I am awaiting comments. In any event I

am keen to share it with you and will do so shortly. We can then speak if you have questions.
Thanks and kind regards,
Sophie.
Le 15 Oct 2013 à 18:36, "Dominik.Schnichels@ec.europa.eu" <Dominik.Schnichels@ec.europa.eu> a écrit :

> Dear Sophie,
>
> Many thanks for your mail. I would be very interested in a short analysis of Art. 18 as proposed by the EP by GSK, but at this stage I fear we are so pressed with time that I prefer to avoid additional meetings. On top of a meeting would require agreeing about the minutes so that they could be published on our website.
>
> Kind regards
>
> Dominik

From: Sophie Crousse [mailto:sophie.s.crousse@gsk.com]
Sent: Tuesday, October 15, 2013 4:54 PM
To: SCHNICHELS Dominik (SANCO)
Subject: meeting request

Dear Dominik,

We have met with MEP [redacted] after the ENVI vote on the TPD in July at the EP in Brussels. I had a discussion today with your admin [redacted] who said she would check with you if a face to face meeting would be possible in the near future to share with you our analysis of article 18 of the TPD and seek your advise on next steps.

I look forward to hearing from you.

Kind regards,

Sophie.

Sophie Crousse
Vice President European Public Affairs Europe
Consumer Healthcare Europe

GSK
Avenue des Arts 46/B9, 1000 Brussels, Belgium
Email sophie.s.crousse@gsk.com
Mobile +32 497 059 227
Tel +32 2 282 40 59

gsk.com | Twitter | YouTube | Facebook | Flickr

<image001.png>

From:	Sophie Crousse <sophie.s.crousse@gsk.com>
Sent:	30 October 2013 17:28
To:	Sophie Crousse
Subject:	TPD and Regulation of Nicotine Containing Products
Attachments:	TPD - Comparative analysis on NCP regulation.docx

Dear ,

As a global healthcare company committed to improving public health and consumer safety GSK welcomes the EU's efforts to strengthen the regulation of tobacco and nicotine containing products.

We welcome the approach of the Council of the European Union towards the regulation of NCPs as medicinal products and we fully support the Commission's position that the application of the General Product Safety Directive is not sufficient for marketing NCPs, and more specifically electronic cigarettes[i].

We believe in responsible and proportionate regulation for all NCPs as medicinal products (as MHRA position)[ii].

We believe in a single access system, without differentiation in clinical/regulatory and distribution advantages provided only to e-cigarettes that are not similarly provided to NCPs specifically intended to help people reduce and quit smoking.

We believe devices that put nicotine into the human body need to be held to a single, consistent high standard of quality.

We believe in advertising and broad distribution for products designed to improve health by helping people reduce and quit.

While we acknowledge the challenges in the inter-institutional debate for reaching a common position on the NCP regulation, we however believe that it is indispensible to take into consideration in the on-going discussions the following points:

Why medicinal regulation for NCPs:

- Only medicinal products legislation can ensure that **the most robust safety and quality standards** are applied to NCPs.
- Pharmacovigilance rules will ensure **the most robust framework for post-marketing surveillance,** taking into account the risk category of NCPs.
- Medicinal products legislation allows **NCPs to remain widely available** outside pharmacies. Member States have the competency to regulate the sale of this product in national law.
- Medicinal products legislation ensures that there is a **penalty system in place** for those manufacturers and marketing authorisation holders that do not comply with quality and safety standards of NCPs.
- Medicinal products legislation provides the most appropriate **labelling** of the risks and benefits of NCP which is the only way to fight effectively smoking cessation through **robust rules on information to consumers**.
- Medicinal products legislation is the only framework that will allow the marketing of these products to support Public Health, reduce tobacco consumption and incentivise smoking cessation.

Reasons not to regulate NCPs as General Products:

- **Consumer and product safety:**
    - Pre-marketing approval: A notification system for marketing some NCPs, such as e-cigarettes, as proposed by the European Parliament, is not sufficient to confirm the safety, quality and efficacy of these products containing substances potentially hazardous to the human health.
    - Post-marketing surveillance: General Product safety legislation doesn't provide sufficient safeguards corresponding to the health risk category of nicotine and other chemical substances contained in electronic cigarettes.
- **Product classification and information to consumer:**
    - Categorising the use of some NCPs, such as e-cigarettes, as 'lifestyle product', excludes representation of their function as a smoking cessation aid. Without proper product information and labelling requirements, consumers will not be made of aware of the benefits and risks of switching from tobacco smoking to NCPs.
    - Allowing e-cigarettes to be marketed as tobacco/consumer products without any health claims would potentially open a gateway to nicotine addiction and encourage wider nicotine usage.
- **Enforcement**
    - Tobacco and consumer products legislation does not ensure penalty system in place for manufacturers that do not comply with quality, safety and efficacy standards. Lack of sanctions may affect the enforcement of safety standards and in turn, to create potential public health threats.

Why not a two tier regulatory system for NCPs:

- A two-tiered regulatory system for NCPs may have a negative impact on the functioning of the internal market and does not take into account existing scientific evidence about product safety issues. In doing so, it goes against the TPD's statement of reasons (Recital 33) and its legal basis (Article 114).
- **Regulatory gap and inconsistency :**
    - A two-tiered approach to NCPs brings inconsistent rules and opens a regulatory gap as regards product quality, labelling, packaging, advertising, and distribution and sale of NCPs.
    - A nicotine level threshold creates a regulatory gap for products with lower dose used as adjunct to other NCPs, e.g. gums used with patches.
    - This regulatory inconsistency is further demonstrated by contradiction in the EP proposal between the call for harmonisation of all NCPs under the Tobacco Products Directive in Recital 33 and the two-tiered regulatory approach to NCPs established by Article 18.
- **Manufacturing 'race to the bottom':**
    - A two-tiered regulatory system for NCPs may encourage manufacturers to amend existing products in order to comply with the less stringent regulatory framework.
- **Market distortion:**

- A two-tiered regulatory approach will likely result in market distortion with NCPs positioned as 'lifestyle products' regardless of whether they meet health claims and given nicotine content or not.

- **Administrative burden**

  - A two-tier regulation of NCPs will place an administrative burden on competent authorities by requiring them to learn and enforce two sets of rules for medicinal and non-medicinal NCPs

- **Split of NCPs in two categories is arbitrary and misleading for consumers**

  - Defining a nominal nicotine level threshold for product classification as medicines or not is an arbitrary solution and ignores the reality that the content or nicotine concentration do not determine the level of nicotine a user can obtain from NCPs, particularly from product formulations that allow ad-libitum use.

  - Allowing e-cigarettes to be marketed as tobacco/consumer products without any health claims may encourage new or under-age nicotine users' addiction.

Please find attached for your information a comprehensive analysis of the proposals for regulatory approaches presented in the legislative debate. The document is based on input from regulatory and medical experts with proven experience in smoking cessation and nicotine containing products.

References to relevant scientific and expert positions on the issue of NCP regulation are available through the web platform A4NC, Arguments for Nicotine Control. This online database brings together statements and opinions of healthcare professionals, leading health authorities and academia supporting medicinal regulation of NCPs.

Ahead of the decisive inter-institutional debate on the regulation of NCP, we would ask you to consider the above arguments with the objective of ensuring consistent and robust regulatory standards for NCPs in the interest of the safety and health of consumers across the EU.

Should you have any questions about the points raised in this letter we would be happy to provide you with further information.

Yours sincerely,

Sophie

Sophie Crousse
Vice President European Public Affairs Europe
Consumer Healthcare Europe

GSK
Avenue des Arts 46/B9, 1000 Brussels, Belgium
Email sophie.s.crousse@gsk.com
Mobile +32 497 059 227
Tel +32 2 282 40 59

gsk.com | Twitter | YouTube | Facebook | Flickr

About GSK
GSK is a global healthcare company that is committed to helping people to do more, feel better and live longer. GSK has helped over 9 million people to quit smoking over the last 20 years with its range of Nicotine Replacement Therapy (NRT) products. GSK

believes that this is testament to the role of appropriately regulated and efficacious products in gaining consumers' confidence in Nicotine Containing Products (NCPs). GSK also produces a range of medicines to support people with respiratory conditions through its Pharmaceutical business.

[i] European Commission factsheet for information on e-cigarettes: http://ec.europa.eu/health/tobacco/docs/fs_ecigarettes_en.pdf

[ii] Licensing Procedure for Electronic Cigarettes and Other Nicotine Containing Products (NCPs) as Medicines (MHRA): http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con297583.pdf

Tobacco Products Directive - Comparative Analysis on the Regulation of Nicotine Containing Products

1. MARKETING AUTHORISATION AND PRODUCT SAFETY		
Institution	Position	Comments
European Commission (19/12/2012)	• NCPs <u>above certain nicotine level</u> should be regulated as medicines; • Divides NCPs into two categories with two regulatory regimes; • No explicit mention of how NCPs below the threshold should be regulated: *"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* ***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."*	**A two-tiered regulatory approach is applied within the same category of products** • This is disproportionate regulation because it applies double regulatory standards to the same group of products with the same functional characteristics, i.e. smoking cessation aids the purpose of which is quit tobacco smoking by delivering nicotine to the human body in alternative to tobacco combustion ways. • **As a result,** some NCPs such as light nicotine gums will fall under the general product safety rules whereas other NCPs like nasal sprays will be regulated as medicines. **The two-tiered system could create inconsistencies in products as manufacturers comply with two different sets of rules** • Manufacturers will have an incentive to amend existing products in order to comply with a preferred regulatory framework. **Two tiered regulatory framework could incentivise market distortions** • Having one system would help to assure

		that products are consistently meeting one set of quality, safety, efficacy standards. • It is likely the market place would become distorted with products positioned to sit below the threshold whether they met the threshold or not. • Potential differential availability vs. medicines in the market would further distort the market place and discourage consumers from seeking products with clearly defined safety and efficacy profiles. **A nicotine level threshold is an arbitrary cut-off point and is not evidence based.** • The cut-off point is difficult to measure as the actual level of nicotine taken in by users depend on how the product is used, the quality of the device and the delivery system rather than the nicotine content itself. Nicotine pharmacokinetic parameters should be defined rather than the proposed nicotine thresholds contained within the products. • A nicotine level threshold creates a regulatory gap for products with lower dose used as adjunct to other NCPs, e.g. gums used with patches. **Could mislead consumers by creating an erroneous impression about e-cigarettes 'characteristics**

		• Regulating certain smoking cessation aids like e-cigarettes, outside medicinal products legislation, can lead to consumers' confusion about the purpose of these products by shifting the focus from e-cigarettes' function as smoking cessation aid to their presentation as 'lifestyle' products. **Wrongful product classification:** • Categorising the use of some NCPs, such as e-cigarettes, as 'lifestyle product', excludes representation of their function as a smoking cessation aid. • Without proper product information and labelling requirements, consumers will not be made of aware of the benefits and risks of switching from tobacco smoking to NCPs. **Legal and regulatory uncertainty - the text creates a gap in the regulation of NCPs below the given threshold** • The text of the Commission (and Council) proposal doesn't specify the legislative framework under which NCPs below the threshold should be regulated.
Council of Ministers (21/06/2013)	• Follow the Commission text applying a twice lower nicotine level threshold: • NCPs above certain nicotine level should be regulated as medicines; • Divides NCPs into two categories with two regulatory regimes; • No explicit mention of how NCPs below the threshold should be regulated:	• See above arguments

	"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 mg per unit****, or* *(b) products with a nicotine concentration equal to or exceeding* ***2 mg per ml****.*	
European Parliament (08/10/2013)	• Divides NCPs into two categories - products with and without health claim; • Applies two regulatory regimes – Tobacco Products and Medicinal Products Directive; • NCPs with health claims shall be regulated as medicines; • **NCPs without health claims are to be marketed as novel tobacco products**: Marketing of NCPs without health claims follows the procedure for novel tobacco product: an electronic notification has to be submitted 6 months before the start of marketing and sales stating: - description of the product - labelling, - composition - instructions for use - manufacturing process - information on ingredients and emissions • Flavours allowed; • NCPs without health claims shall comply with general product safety legislation; • NCPs with nicotine level above 30 mg/ml are banned; 1. *"Nicotine-containing products may only be placed on the market in accordance with the notification procedure set out in Article 17 of this Directive. Member States shall ensure that nicotinecontaining products comply with all relevant Union legislation, and in particular with Directive 2001/95/EC on general product safety.* 2. *"Nicotine-containing products that are presented as having properties for treating or preventing disease may only be placed on the market if they were authorized pursuant to Directive 2001/83/EC."*	• General Product safety (2001/95/EC) doesn't provide sufficient safeguards corresponding to the risk category of nicotine and other chemical substances contained in electronic cigarettes. • On a pre-marketing authorization, medicinal tests are needed to guarantee the safety and quality of NCPs. A simple notification system is not sufficient to guarantee the safety and quality of this product containing substances potentially hazardous to human health. • Classifying these products as medicinal could assure that appropriate, safe levels of nicotine are in the products, and appropriate claims can be established

2. POST-MARKETING SURVEILLANCE		
Institution	Position	Comments
European Commission	• Pharmacovigilance legislation for NCPs with medicinal status; • Unclear framework for NCPs below the nicotine threshold.	• Legal unclarity; • General marketing surveillance is not proportionate to the risk category of NCPs.
Council of Ministers	• Pharmacovigilance legislation for NCPs with medicinal status; • Unclear framework for NCPs below the nicotine threshold.	• Legal unclarity; • General marketing surveillance is not proportionate to the risk category of NCPs.
European Parliament	• Pharmacovigilance legislation for NCPs with medicinal status; • General marketing surveillance rules for the rest of NCPs; • Reporting obligation for Member States to the Commission on NCPs market development; • Reporting obligation for the Commission on NCPs to the Council and the Parliament in 5 years after the entry into force.	• It is clear the current market place (due to uncertain legislation) contains a wide range of products with differing standards of safety, quality and delivery of nicotine/other substances. Whilst any and all efforts to help people stop using combustible tobacco products are encouraged, it is not acceptable to allow the current situation to continue until an issue emerges. • General marketing surveillance is not proportionate to the risk category of NCPs.

3. DISTRIBUTION AND SALE		
Institution	Position	Comments
European Commission	• Not regulated in the Proposal.	• Distribution and sale of NCPs is a competence of the Member States.
Council of Ministers	• Not regulated in the Council position.	• Distribution and sale of NCPs is a competence of the Member States
European	• NCPs with medicinal status – not regulated in the EP position;	• Breach of the subsidiary principle – Sale of

Parliament	• Electronic cigarettes and NCP without health claims should be available outside pharmacies; • Recital 33 states the need for harmonisation, in which all NCPs should be regulated under the TPD as a related tobacco product and that these should be as available as tobacco products.	NCPs including location of sale is a competence of Member States and is regulated by national law. • In 18 Member States smoking cessation aids are already available outside pharmacies. • Inconsistency in the proposal. In different approved proposals, contradictory arguments are made relating to the regulation and distribution of NCPs

4. LABELLING		
Institution	Position	Comments
European Commission	**NCPs below the threshold** – mandatory warning *"This product contains nicotine and can damage your health"* Article 10.4 and 18.4 regulate their labelling**:** • Shall be printed on the two largest surfaces of the unit packet and any outside; • cover 30 % of the package; • black border of the text warning of 3-4mm width; • printed in black Helvetica bold type on a white background. **NCP above the threshold: medicinal products legislation:**	**Misleading information to consumers** • Only points out the possible negative effects of nicotine thus associating it with tobacco and disregarding its medicinal purpose of treating tobacco smoking dependence. • Could put off smokers from having recourse to smoking cessation therapies. **Double labelling standards are applied to products of the same product category of smoking cessation aids.**
Council of Ministers	**NCPs below the threshold** – mandatory warning *"This product contains nicotine* ***which is an addictive substance*** *and can damage your health"* Same display properties as the Commission proposal	See above

European Parliament	NCPs without health claim – mandatory health warning: *"This product is intended for use by existing smokers. It contains nicotine which is a highly addictive substance"* The unit packet should include: - leaflet with instructions for use - warning that product is not recommended for use by non-smokers - contra-indications, - warnings for specific risk groups, - reporting of adverse reactions, - place of manufacture and contact details of the manufacturer or importer; NCP with health claims: medicinal products legislation	• Lack of regulatory oversight, e.g. consequential revision of the warnings or precautions, etc., resulting from periodic assessments. • The labelling could convey the message to the consumer that these are quasi medicines, regulated as medicines, when in fact they are not. • The labelling proposal is aligned to the principles of a medicine; therefore why not treat them as medicines? We have a proven, robust and reliable mechanism that can be applied in a proportionate manner.

5. ADVERTISING		
Institution	Position	Comments
European Commission	• No provision on advertising NCP below the threshold; • Advertising of NCP above the threshold under the medicinal legislation.	• Legislative gap – no provisions on advertising NCP below the threshold. • Dual standards of advertising for the same category of products.
Council of Ministers	• No provision on advertising NCP below the threshold; • Advertising of NCP above the threshold under the medicinal legislation.	
European Parliament	Electronic cigarettes - <u>prohibited advertising in printed media, information society services and radio broadcasting</u> (regulated under the TPD). Advertising of NCP classified as medicines is regulated by medicinal products legislation (Title VIII of Directive 2001/83/EC).	**Dual regulatory rules for advertising products from the same product characteristic group of smoking cessation aids:** • Ban on e-cigarettes advertising (tobacco products legislation). • Free advertising to the general public of

		NCP with health claims (medicinal products legislation). • A ban on advertising electronic cigarettes will result in an immediate 'boom' in advertising from tobacco industry during the transition period in order to establish awareness before the entry into force of the provision.

6. ENFORCEMENT		
Institution	Position	Comments
European Commission	Not regulated in the proposal	**Tobacco and consumer products legislation does not ensure penalty system in place for manufacturers that do not comply with quality, safety and efficacy standards.** • Lack of sanctions may affect the enforcement of safety standards and in turn, to create potential public health threats. **Dual product classification of NCP leads to the split of enforcement powers between different administrative bodies** leading to: • Administrative burden • Regulatory uncertainty • Overlapping of competences or gaps • Clear enforcement burden in a rapidly evolving market with many (often small) commercial operators. We will see a "whack a mole" situation where as fast as one enforcement action is taken, the

		issue will arise somewhere else.
Council of Ministers	Not regulated in the Council position	• See above
European Parliament	States a "Competent Authority"	• See above