Subject: TPD and Regulation of Nicotine Containing Products
Attachments: Comments on the Commission proposal for a compromise article 18 TPD.DOCX

From: Sophie Crousse [mailto:sophie.s.crousse@gsk.com]
Sent: Friday, December 06, 2013 6:00 PM
To: SCHNICHELS Dominik (SANCO)
Subject: TPD and Regulation of Nicotine Containing Products

Dear Dominik,

Further to our previous communication, the institutional debate on the TPD revision has drastically changed and we take due account of the new options on the table.

While we continue to believe in pharmaceutical legislation as the most appropriate framework to ensure highest standards of quality and safety of NCPs and to advance public health, we however acknowledge the political challenges in the on-going inter-institutional debate for the establishment of single medicinal regulatory regime for NCPs.

We acknowledge that the compromise proposed by the European Commission on article 18 although maintaining a two-tier regulatory system, however represents a step forward with regard to products safety and consumer protection as compared to the position of the European Parliament. Given that this proposal is now part of the policy debate on the way forward for NCP regulation, we would like to bring to your attention the views of our medical and regulatory industry experts on the proposed regulation.

Ahead of the next round of inter-institutional deliberations, we would ask you to consider these comments with the objective of ensuring robust regulatory standards for NCPs in the interest of public health and consumer safety.

I remain at your disposal for any questions and comments on this matter and we are looking forward to further discussing NCP regulation with you .

Kind regards,
Sophie

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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.

Regulation of electronic cigarettes in the TPD

Legend:

Opposed

Clarification needed

In favour

New provisions needed

Issue	Commission proposal	Comment/*Justification*
Article 2 Definition	Electronic cigarette means a product, or any components thereof including cartridges and the device without cartridge, that can be used for consumption of nicotine containing vapour via a mouth piece.	The current definition is too broad and goes beyond the scope of systems for electronic nicotine delivery. This could likely bring regulatory complications and overlaps in future.
	Article 18	
Scope	1. Electronic cigarettes are a tobacco related product. They can be placed on the market as a tobacco related product if they comply with the relevant provisions of this Directive and all other relevant Union legislation. Electronic cigarettes can be classified as medicinal product by presentation pursuant to first subparagraph 2a of Art. 1(2) of Directive 2001/83/EC if they are presented as having properties for treating or preventing disease in human beings. They cannot be classified as a medicinal product by function pursuant to the second subparagraph 2b	"Electronic cigarettes can be classified as medicinal product ~~by presentation~~ pursuant to ~~first subparagraph 2a of~~ Art. 1(2) of Directive 2001/83/EC if they are presented as having properties for treating or preventing disease in human beings. ~~They cannot be classified as a medicinal product by function pursuant to the second subparagraph 2b of Article 1(2) of Directive 2001/83/EC.~~" • Electronic cigarettes should be subject to classification as medicines both by presentation pursuant Art. 1(2) a)

	of Article 1(2) of Directive 2001/83/EC.	of Directive 2001/83/EC and by function pursuant to Article 1(2) b) of Directive 2001/83/EC. *This is related to the fact that electronic cigarettes can have properties for treatment of disease, i.e. permanent cessation or at a minimum a reduction of tobacco use, and their active substance nicotine have a proven pharmacological effect.* • Further specification on the application of medicinal regulatory framework to electronic cigarettes is needed. A proportionate application of medicinal products regulation needs to be ensured with licensing requirements adaptable according to the risk profiles of approved therapeutic NRT and of continuing smoking. *A proportionate approach to medicines regulation of electronic cigarettes avoids additional regulatory and administrative burden and redundancy of required data while stimulating innovation on the nicotine market.*
Notification	2. Manufacturers and importers of electronic cigarettes shall notify the products with the competent authorities of the Member States in which the product is intended to be placed on the market. The notification shall be submitted in electronic form 6 months before the intended placing on the market. For electronic cigarettes already placed on the market on the date referred to in paragraph 1 of Article 25, the notification shall be submitted within 6 months of that date. A	Keep provisions in the final text to include products already placed on the market to be covered by the scope of the Directive. *Regulating products placed on the market prior to the entry into force of the Directive is indispensible for the purpose of harmonisation of the internal market.*

	new notification shall be submitted for each substantial modification of the product. The notification shall include at least the following information: a. name and contact details of the manufacturer and, if applicable, the importer into the EU; b. list of all ingredients contained in and emissions resulting from the use of the product, by brand name and type, including quantities thereof; c. toxicological data available to the manufacturer or importer regarding these ingredients; d. information on nicotine dosing when used under reasonable and foreseeable conditions; and e. description of the components of the electronic cigarette. Proportionate fees may be charged by Member States for receiving, storing, handling and analysing the information submitted to them.	Further clarity is needed on what represents a "substantial modification" "information on nicotine dosing ***and concentration in plasma"*** *To objectively assess the product's characteristics and real impact on the human body, it is mandatory to demonstrate the level of nicotine that actually reaches the user's blood stream rather than simply the nicotine that leaves the product.*

Safety and quality	3. Member States shall require manufacturers and importers of electronic cigarettes to bear full responsibility for the quality and safety of electronic cigarettes placed on the market when used under reasonable and foreseeable conditions. Member States shall require that manufacturers and importers of electronic cigarettes to establish and comply at least with the following manufacturing requirements: a) design and manufacture in accordance with the safety requirement set out in this article; b) procedures in place for series production to remain in conformity with the safety requirement; c) a safety assessment prior to placing on the market, with information on the composition of the product, microbiological quality, impurities and traces, toxicological profiles, and adverse effects; d) a legal or natural contact person within the European Union. Member States shall require manufacturers and importers of electronic cigarettes to ensure that electronic cigarettes deliver the nicotine doses	A requirement for pre-market safety reporting including namely information on adverse effects is a step forward in ensuring safety and quality of electronic cigarettes. Clarification is needed on how safety assessment will be handled by products already placed on the market at the date of entry into force of the Directive

	uniformly and consistently. Member States shall ensure that electronic cigarettes with refillable cartridges or tanks are not placed on the market. Only single use cartridges can be placed on the market.	Ban on refillable cartridges is a necessary measure for the prevention of misuse and abuse of electronic cigarettes and accidental overdose or exposure, e.g. children.
Manufacturing requirements	4. Member States shall require manufacturers and importers to ensure that: a) Electronic cigarettes do not contain nicotine in excess of 20 mg/ml and 10 mg/unit; b) Electronic cigarettes with additives listed in paragraph 4 of Article 6 are not placed on the market; c) Only flavours which are authorized for use in nicotine replacement therapies can be used in electronic cigarettes, unless such a flavour is particularly attractive to young people and non-smokers; d) Only ingredients of high purity and free from contaminants are used in the manufacture of the liquid for electronic cigarettes; e) Unit packets of electronic cigarettes include a leaflet with	Clarification on the provision on flavouring is needed: does the text imply that flavours should be limited only to currently being used in NRT or that new flavour would need to be used first in an existing NRT format prior to be being used in electronic cigarette classified as tobacco related product. *Flavours that are suitable in oral products such as gums or lozenges may not be the optimal flavoured for electronic type of delivery.* *Flavours should be considered in terms of safety to users and attractiveness to youth.*
		Clarification is needed on what is meant by 'contra-indications' in a non-medicinal context

	information instructions for use, including a reference that the product is not recommended for use by young people and non-smokers, contra-indications, warnings for specific risk groups, information on possible adverse effects, and contact details of the manufacturer or importer; f) Unit packets and any outside packaging of electronic cigarettes: i. include a list of all ingredients contained in the product in descending order, and an indication of nicotine content and delivery per dose; ii. do not include elements or features referred to in Article 12, with the exception of paragraph 1(a) of Article 12 concerning the nicotine content; iii. do not use tobacco trademarks, brand names and symbols; iv. carry the following health warning: "This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers." g) the health warnings shall comply with the provisions in paragraph 2 of Article 11.	What packaging rules would apply to electronic cigarettes marketed as medicines?
Advertising/ Informatio	5. Member States shall ensure that: a) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited	Ban on advertising recreational use of electronic cigarettes is welcomed and should be kept in the final text.

n to consumers		in the press and other printed publications, with the exception of publications that are intended exclusively for professionals in the trade of electronic cigarettes and for publications which are printed and published in third countries, where those publications are not principally intended for the European Union market; b) Commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes which are prohibited pursuant to Art. 18 par. 5, lit. a) are prohibited in information society services as defined in Article 1(2) of Directive 98/34/EC; c) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited in the radio; d) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes is prohibited; e) any form of public or private contribution to any event, activity or individual with the aim or direct or indirect effect of promoting electronic cigarettes and involving or taking place in several Member States or otherwise having cross-border effects is prohibited; f) audiovisual commercial communications falling under Directive 2010/13/EU are prohibited for electronic cigarettes; g) cross-border distance sales of electronic cigarettes are regulated in accordance with Article 16.	*Information to consumers should target promotion of cessation rather than recreational use.* *This is in line with EU legislation applicable to tobacco products.* [redacted]

	6. Member States shall require manufacturers and importers of electronic cigarettes to submit to competent authorities on an annual basis comprehensive data on sales volumes, by brand name and type, as well as information on preferences of various consumer groups, including young people, non-smokers and main types of current users, as well as the mode of sale of the products. They shall also submit executive summaries of any market surveys carried out in respect of the above, including an English translation thereof. Member States shall monitor the development of the electronic cigarette market, including any evidence of gateway use among young people.	
	7. Member States shall ensure the dissemination of information received pursuant to paragraph 2 on a website with due regard to the protection of trade secrets. Member States shall make available, upon request, all information received pursuant to this Article to the Commission and other Member States. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.	

	8. Member States shall require that manufacturers, importers or distributers establish and maintain a system to collect information about all suspected adverse effects. If an operator considers or has reason to believe that electronic cigarettes, which are in its possession and are intended to be placed on the market, are not of good safety or quality or is otherwise not in conformity with this Directive, the operator shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, as appropriate. In such a case the operators shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available, giving details, in particular, of the risk to health and safety and of any corrective action taken, and of the results of such corrective action. Member States may also request additional information from the operators, for example on safety and quality aspects or any adverse effects.	
Delegated acts	9. The Commission shall also be empowered to adopt delegated acts to adapt the wording of the health warning in paragraph 4 (f) iv. The Commission shall adopt by means of implementing acts a common notification format pursuant to paragraph 2.	
Article 20 Cooperation of competent authorities	The competent authorities of the Member States shall cooperate with each other and with the Commission to ensure the proper application and due enforcement of this Directive and shall transmit to each other all information necessary with a view to applying this Directive uniformly.	
Article 21 Designation of	Member States shall designate the competent authorities within the period of 3 months after the transposition pursuant to Article 25. Member States shall, without delay, inform the Commission about the	One single competent authority should be in charge of the marketing of electronic cigarettes regardless of their classification.

competent authorities	identity of the competent authorities responsible for enforcement of obligations provided for in this Directive. The Commission shall publish that information in the Official Journal of the European Communities.	*This is needed to avoid enforcement complexity and unnecessary administrative burden.*
Recital a)	a) Electronic cigarettes are a tobacco related product and should be regulated within this Directive. They simulate smoking behaviour and are increasingly used and marketed to young people and non-smokers. Diverging legislation exists in Member States to regulate these products requiring action at Union level to improve the functioning of the internal market. Other nicotine containing products are not covered by the provisions of this Directive. Electronic cigarettes which are presented as having properties for treating or preventing disease in human beings should not fall under this Directive. They can only be placed on the market if duly authorised under Directive 2001/83/EC. For electronic cigarettes that fall under this Directive, the definition of medicinal products according to Article 1.2.b of Directive 2001/83/EC does not apply. This clarifies the legal situation of this product in the light of Article 2.2 of Directive2001/83/EC.	The exclusion of the product category of NCP creates a regulatory gap and legal uncertainty on how future nicotine containing products other than electronic cigarettes and NRT will be regulated. This brings the risk of fragmenting the nicotine containing products market into a three-tier system and of affecting future innovation in this sector. "Electronic cigarettes which are presented as having properties for treating or preventing disease in human beings should not fall under this Directive. They can only be placed on the market if duly authorised under Directive 2001/83/EC. [redacted]
	b) Refillable cartridges or electronic cigarettes with refillable tanks are considered to pose a risk to public health. Such products would for example allow for a circumvention of the flavour regulation, they would increase the risk of contamination and they would lead to the wider availability of larger quantities of nicotine containing liquids, which can be a risk to inexperienced users or children.	
	c) Given the risk that electronic cigarettes can develop into a gateway to normal cigarettes, and considering that they mimic and normalise the action of smoking, Member States should lay down age limits for	

	their sale to consumers and their use, and shall ensure that their labelling displays sufficient and appropriate information on safe use, in order to protect human health and safety.	
	d) Responsibility for ensuring that electronic cigarettes comply with the essential safety requirements should rest with manufacturers. If manufacturers are not established in the European Union, the natural or legal person who imports electronic cigarettes into the European Union should bear the responsibility.	
	e) Disparities existing between national practices on electronic cigarettes advertising and sponsorship impede the free movement of goods and the freedom to provide services and create an appreciable risk of distortions to competition. Without further action at Union level, the existing disparities are likely to increase in the coming years, considering also the growing market for electronic cigarettes. European legislature should therefore approximate national legislation on the advertising and sponsoring of electronic cigarettes. Article 114(3) of the Treaty on the Functioning of the European Union requires the Commission, in its proposals for the establishment and functioning of the internal market concerning health, to take as a base a high level of protection. In this light, restrictions on the advertising of electronic cigarettes is intended to protect public health by regulating the promotion of these products, which can develop into a gateway to normal cigarettes, and which mimic and normalise the action of smoking. This Directive does not harmonise rules on domestic sales arrangements or advertising, nor does it introduce an age limit for electronic cigarettes. Member States are free to regulate such matters in their own domain.	
	f) Brand names have the potential to attract consumers and maintain	

	their brand loyalty. The strength of tobacco brands names could lead to attracting people – especially young people – to buy and use electronic cigarettes marketed under the same brand. Moreover the use of tobacco trademarks, brand names and symbols for electronic cigarettes could indirectly promote smoking, facilitate the shift of users from one category to the other. It could also undermine national legislation limiting the advertising for tobacco products. Therefore the use of tobacco trademarks, brand names and symbols for electronic cigarettes is prohibited under this Directive.	