

## Feedback on Danish Proposals on Regulation of Electronic Cigarettes

Nerudia was established in 2013 to support the rapidly developing electronic cigarette industry with high quality manufacturing services and to provide scientific support to characterise our customer's products.

Nerudia is a privately owned company, which is an Anglo-German joint venture between Contraf-Nicotex-Tobacco GmbH (CNT), the worlds largest supplier of pharmaceutical grade nicotine, and two British entrepreneurs who have been involved in the electronic cigarette industry since 2008.

Nerudia expects to manufacture product for customers selling across Europe and this includes the Danish market.

Nerudia's main facility contains 15 cleanrooms to enable manufacture of e-cigarette solutions to pharmaceutical GMP standards and a laboratory containing an extensive range of analytical equipment including GC, GC-MS, HPLC etc as well as a vaping machine. This enables us to develop and run analytical methods, which use state-of-art technology and allows our analytical chemists to study e-cigarette solutions including flavours as formulations and in-use. We are developing a range of analytical tests to study nicotine e-cigarette emissions.

Nerudia has an extensive Innovations group focused on developing user friendly product improvements with a particular emphasis on safety.

Nerudia is playing an active role in the ongoing activities relating to the implementation of the Tobacco Products Directive II, and is supportive of regulation of products within Europe focused on ensuring safe use of electronic cigarettes. The use of electronic cigarettes is safer than smoking cigarettes and therefore regulation and controls for e-cigarettes should be proportional to the risks involved. This is reflected in TPDII.

Nerudia is concerned that proposals are being made to regulate nicotine electronic cigarettes in Denmark, which put nicotine electronic cigarettes on the same basis as tobacco products with the risk that this will discourage smokers from transferring to the safer vaping products. This approach is not in line with the Tobacco Products Directive II and the provisions being proposed in Denmark go beyond that agreed, further to significant work by the European institutions, at EU level. Vaping products should be easily available to 18 year olds and over and reducing all advertising and limiting where products can be used is likely to be detrimental to the use of electronic cigarettes and therefore to public health. Again, this approach is well reflected in TPDII.

Nerudia is also concerned that the proposed registration costs (initial and ongoing) are unduly high when the number of products that manufacturers have in their portfolio are considered. Ensuring data is available to meet the requirements of the TPDII and demonstrate product safety should be paramount, and manufacturers have to ensure this expensive process is carried out effectively. Given that the TPDII requires variations on each product to be registered in each country there is a risk that products and variants may not be registered in Denmark, reducing the number of products available to Danish consumers. Additionally, we believe that product variations for similar products will not require the same review load by the Danish authorities as might be required for a single product, making the high proposed costs inappropriate.

Confidential



For example, the cost of registering a typical range of 20 products over a 5 year period, with no modifications would appear to be around €180k.

Thank you for taking the time to consider the items raised herein and for agreeing to receive our submission in the English language. Please do not hesitate to contact us should you wish to discuss further.

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