



EUROPEAN COMMISSION

Brussels, 6th May 2013

MEETING WITH THE ASSOCIATION OF THE EUROPEAN SELF-MEDICATION INDUSTRY (AESGP)

Participants:

AESGP (including representatives of companies producing NRT products: GSK and Johnson&Johnson - in absence of Novartis but in accordance with the company's views): Christelle Anquez-Traxler, Johan Berglund, Stephen Champion, Gustavo Marañés, Noëlle Vonthron

SANCO: Dominik Schnichels, Anna-Eva Ampelas, Matus Ferech

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Summary

SANCO gave a brief summary of the revision of the Tobacco Products Directive and how it proposes to regulate nicotine containing products (NCP). The nicotine threshold set out in the proposal is based on a comparison with already authorised nicotine replacement therapies (NRTs). SANCO recalled a.o. the identity of the active pharmaceutical ingredient, the similarity of certain delivery mechanisms (devices – sprays/inhalers) and questions around establishing the "dosage".

AESGP welcomed the TPD proposal which would bring – in its view - significant benefits for public health in Europe. AESGP argued that all nicotine containing products (with the exception of tobacco) should be subjected to the regulatory framework for medicinal products (i.e. the threshold should be abolished). The main reasons are: 1) any level of nicotine has a pharmacological effect, 2) the threshold would lead to different safety, quality and efficacy standards for similar products; 3) the enforcement would be cumbersome and 4) consumers would have difficulties to distinguish between the two categories (above and below threshold).

AESGP explained that NRTs have been marketed since 1970's. Therefore companies and regulators would have significant experience with the product. According to AESGP, nicotine is a substance with long-term/well established use and a therapeutic profile which can be well-controlled.

The companies explained the marketing authorisation procedure for a new NRT. A number of national competent authorities (NCA) acknowledge the well documented history of nicotine use and accept that new formulations are in principle similar to currently marketed products. In such case, only a descriptive pharmacokinetic (PK) study

is required to demonstrate equivalent (to previously authorised NRTs) nicotine level in the blood stream. Such a study involves typically 20-25 volunteers and cost approximately 200,000 USD. Marketing authorisation can be applied for after 18 months of preparatory work. Some NCAs tend to require, in addition to PK studies, a phase III clinical trial. Such a study typically involves 300+ patients (testing cessation results after six months). The total duration of such a study is an additional 18 months and costs approximately 4-5 million USD.

AESGP confirmed that companies would – where possible – go for marketing authorisation (MA) through a decentralized or a mutual recognition procedure (or a combination thereof) or sometimes national applications (in case of line extensions of older formulation). Typically a new NRT would be first launched in Members States where no clinical phase III trials are required. In certain cases a bibliographic application in all MSs might be possible.

AESGP estimated that the procedure before the competent authorities to obtain MA would require between 12 and 18 months (including usual stop the clock interruptions) – disregarding major unforeseen developments. As the products are non-prescription medicinal products, they would not have to undergo procedures for pricing and reimbursement status. In total the time needed from first developments to marketing authorisation would thus vary between 30 months and 54 months.

AESGP estimated that the complete DCP/MRP procedure in all MSs for a new NRT would cost around 400000 € In total the costs from development to market launch for a new NRT could reach up to 10 mio USD if phase III clinical tests are needed. The costs for pharmacovigilance (required after product launch) were considered manageable (possibility to outsource, the new PhV legislation includes lighter requirements for well-established substances).

AESGP explained that the pharma legislation would oblige companies to respect good manufacturing practices (GMPs). They assumed that certain producers of e-cigarettes would respect GMP already. In a recent report "Global Tobacco Findings 2012" Euromonitor estimates that "e-cigarette sales are now of the same value as Nicotine Replacement Therapy (NRT)" (e-cigarette sales were 2.0 bn USD in 2011, in a separate report NRT sales in 2012 were estimated to amount to 1.6bn USD). AESGP undertook to provide SANCO with NRT market data for the EU.

According to AESGP, most if not all NRTs are non-prescription medicinal products, i.e. do not require prescription in any MS. In 18 MSs, NRTs can be sold in general sales stores, i.e. outside pharmacies. The mode of distribution is regulated at national level and is separate from the legal status of NRTs as medicines. AESGP undertook to provide SANCO with a table with a country by country overview.

According to one company, in the year 2012, 71% of the market value share in the EU countries (excluding Portugal) came from products with a dosage of 2mg or less, if one considers the solid nicotine formats (lozenges, gums and microtabs). Accordingly a significant number of current NRT's could be relaunched as consumer products. It was also confirmed that the lowest nicotine content of an authorised medicinal product is 1 mg per dosage. AESGP stressed that the products below the threshold would likely be ineffective for smoking cessation purposes and would not present the same guaranty of quality, safety and efficacy as products of the higher-tier. In addition, according to AESGP, a threshold would not have the desired objective to control the market but it

would rather shape the market of the future and by that lead to unfair competition between new consumer products with low nicotine content and existing NRTs.